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A Pragmatic, Multicenter, Randomized Controlled Trial of a Hospital-Community-Home Tiered Transitional Care (HCH-TTC) Program for Individuals with Type 2 Diabetes: A Study protocol

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Keywords： Diabetes Mellitus, Clinical Trial Protocol, Randomized Controlled Trial, Transitional Care, HCH-TTC

Abstract

Introduction: Effective transitional care has been shown to improve patient health outcomes. However, in China, transitional care for T2DM faces challenges including service discontinuity, communication breakdowns, and a lack of personalized design, leading to potential issues of under-treatment and overtreatment, increasing the risk of improper blood sugar management. This directly results in higher unplanned readmission rates and decreased satisfaction with nursing services. There is an urgent need for innovative and more effective transitional care strategies to meet the immediate and pressing needs.

Method and analysis: The multicenter, practical, double-blind randomized controlled trial (RCT) will select 180 T2DM patients within the Jinqiao Medical Union in Pudong New Area, Shanghai, China as participants. This program aims to leverage the synergistic benefits of hospitals, communities, and homes by working together to monitor and assess shifts in patients' health statuses and their needs for services. The assessment, grounded in 'biopsychosocial' dimensions, will stratify patients by diabetes risk to tailor differentiated transitional care strategies, varying in intensity, frequency, and type of follow-up, educational support, personalized advice, and health monitoring, adapting to each patient's stage. The control group will receive transitional care program with routine follow-up and health education during the same period. The primary outcome measure will be glycated hemoglobin (HbA1c) and Blood Sugar, Secondary outcomes will include diabetes knowledge level, self-management ability, treatment adherence, nursing satisfaction, diabetes complications rates and unplanned readmission rates. Data collection will be conducted at baseline, 1 months post-intervention, 3 and 6 months. The statistical evaluations will involve independent *t*-tests and repeated measures analysis of variance.

Ethics and dissemination : The protocol was approved by the Ethics Committee

of Pudong Gongli Hospital, Shanghai, China in November 2021(GLYY1s2021-010), and is being conducted in accordance with the Declaration of Helsinki and Good Clinical Practice. Results will be published in journals.

Strengths and limitations of this study

(1) The first study to explore the integration of hospital, community, and home care within a tiered transitional care framework for diabetes.

(2) This study is designed as a multicenter, practical, double-blind randomized controlled trial (RCT).

(3) Hospital-community-home cooperation can effectively reduce the interruption of transitional care services and information flow.

(4) Based on tiered management and supported by multidisciplinary teams, transitional care strategies can be tailored according to diabetes risk and individual patient needs, with variations in frequency, intensity, type, and content focus.

(5) The study only intervened for 6 months and did not investigate the long-term effects and cost-effectiveness. Therefore, future research could further explore the effectiveness of the HCH-TTC program from these two points.

Trial registration： Chinese Clinical Trial Registry ChiCTR2200063322

1 INTRODUCTION

China, as the world's largest developing country, is experiencing a surge in diabetes cases due to rapid urbanization, increased migration, an aging population, and lifestyle changes[1]. The diabetic population is projected to reach 130 million by 2030, with prevalence rates expected to soar to 19.8%. This escalation poses significant health risks, as Type 2 Diabetes Mellitus (T2DM) can lead to critical complications like neurological, kidney, and retinal disorders, greatly elevating the risk of premature mortality and disability[2-3]. These health consequences, alongside the economic pressure (diabetes-related costs in China reached $141.58 billion in

2015, equivalent to 1.3% of GDP), emphasize the critical need to tackle this escalating epidemic [4] . Diabetes now stands as a formidable challenge to China's public health and economic stability, highlighting the need for effective management and prevention strategies to combat this prevalent chronic non-communicable disease.

1.1 Background

The key to managing diabetes is glycemic control. Effective glycemic control can prevent complications and reduce the burden of diabetes. In China, the prevalence of adequate glycemic control among diabetes patients in 2018 was 50.1%[5]. However, there remains a gap from the target set by the China Chronic Disease Prevention and Control Plan (2012-2015), which aimed for a 60% rate of glycemic control among diabetes patients in China by 2015[6]. Reasons for this gap include poor self-management ability in T2DM patients, limited awareness of the disease, and a low treatment rate[5]. Public health institutions must intensify efforts to enhance glycemic control in T2DM patients by improving self-management abilities, increasing disease knowledge, and ensuring adherence to comprehensive treatment plans.

Transitional care extends professional care beyond hospital settings and incorporates various care models, including the Guided Care Model, the Geriatric Resources for Assessment and Care of Elders model (GRACE) [7-15]. Its goal is to provide discharged patients with continuous, professional care over the long term. This includes follow-up services such as health education, disease monitoring, and additional support, delivered through a variety of methods including phone calls, text messages, and home visits. In China, the independently operated medical models often result in poor coordination and linkage between healthcare institutions, leading to prolonged care services and disruptions in information flow. This leads to T2DM patients experiencing a lack of sustained professional guidance and consistent care support outside the hospital, thereby increasing the likelihood of poor glycemic control and unplanned rehospitalizations. Moreover, transitional care models have

limitations in their personalized design[16]. They often overlook changes in patients' conditions and service needs, which can lead to significant problems. These include "under-treatment", where high-risk diabetes patients with glycated hemoglobin (HbA1c) ≥ 8.5%, severe complications, and multiple unplanned rehospitalizations do not receive adequate attention and care. Conversely, "overtreatment" occurs when low-risk patients with stable conditions and no risk factors for HbA1c < 7% receive excessive medication and nursing interventions. Such issues can diminish patient satisfaction with transitional care services and increase the rates of loss to follow-up [17]. Given these critical issues, it is critical to recognize the limitations of the conventional transitional care model for T2DM. There is an urgent need to develop and implement a more efficient transitional care management strategy to meet the pressing demands.

In recent years, despite improvements in China's medical resource allocation, challenges persist due to resource shortages and regional imbalances [18]. Consequently, there's a growing exploration into utilizing the synergy of hospital-community-home collaboration, aiming to achieve complementary advantages and develop sustainable care models for the future of China's healthcare system. In response to this challenge, our research team developed the Hospital-Community-Home Tiered Transitional Care Program (HCH-TTC) through rigorous literature reviews and expert consultations [19]. The program aims to integrate

the diagnostic and treatment capabilities of hospitals with the community's geographical accessibility and follow-up support, alongside the benefits of long-term familial care. By adopting a stratified management model, we deliver individualized transitional care services that are tailored to the changing conditions and specific requirements of T2DM patients. HCH-TTC is expected to improve collaboration between the medical system, healthcare professionals, T2DM patients, and their families. It seeks to integrate valuable nursing resources, ensure seamless transitions for patients from hospitals to post-acute care settings, improve health outcomes, increase satisfaction with nursing services, and reduce the rates of diabetes complications and unplanned readmissions.

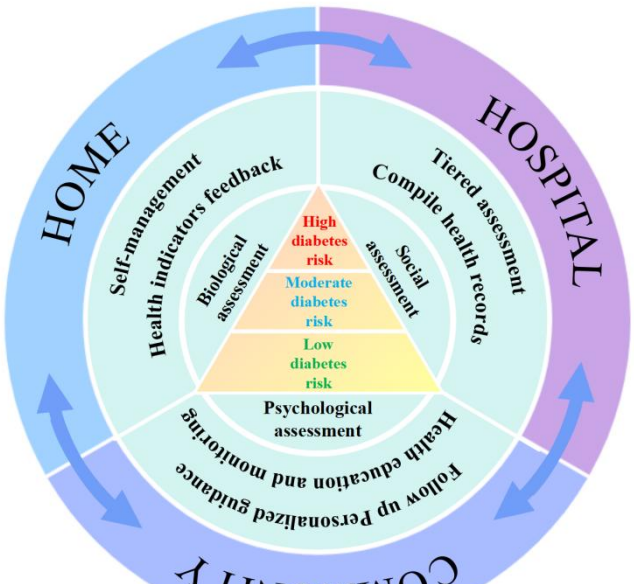

FIGURE 1 The HCH-TTC conceptual framework

1.2 Conceptual Framework

The HCH-TTC conceptual framework, as shown in Figure 1 [19], incorporates the Bio-psycho-social Medical Model [20] and the Triangle Chronic Disease Stratified Management Model [21] during the framework design process, clarifying the internal hierarchical relationships of the variable system and the dynamic intervention process. It can be used to guide the practical application of the HCH-TTC Program. The

practice will be carried out through the collaboration of hospitals communities, and families. We will use the Triangle Chronic Disease Stratified Management Model to guide the strategy and techniques for implementation, while the Bio-psycho-social Medical Model will be utilized to assess the diabetes risk levels systematically. Building on the foundation of collaboration among hospitals, communities, and families, our goal is to form a multidisciplinary team spearheaded by the hospital. This team will tailor guidance and support based on patient needs and diabetes risk levels, ensuring the project's comprehensive implementation. Additionally, we will conduct standardized training to ensure consistency in interventions. This will enable us to provide patients with continuous and tiered follow-up, health education, health monitoring, and other transitional care services, facilitating the smooth transition from the hospital to non-acute environments. We will engage family members in the management process, supporting patients through feedback on their conditions, promoting consistent follow-ups and medication adherence, as well as ensuring punctual participation in health education sessions.

2 THE STUDY

2.1 Aims

Our overarching aim is to evaluate the effectiveness of the HCH-TTC for T2DM patients, comparing it to the usual transitional care approaches in terms of enhancing patient health outcomes, nursing service satisfaction, reducing the rates of diabetes complications and unplanned readmissions within the constraints of limited healthcare resources. The specific aims included:

(1) To determine the program's impact on glycemic control by measuring changes in HbA1c levels;

(2) To evaluate the program’s effect on on glycemic control by measuring changes in fasting plasma glucose (FPG) and postprandial blood glucose (PBG) levels;

(3) To measure the impact on patients' diabetes self-management abilities, treatment adherence, and knowledge levels;

(4) To explore the program's effect on patient satisfaction with nursing services, diabetes complications and unplanned readmissions during a 6-month follow-up.

2.2 Methodology

2.2.1 Design

The research is a multicenter, practical, double-blind randomized controlled trial (RCT), with blinding applied to the study subjects, data collectors, and data analysts. The intervention will be known to the providers who are administering it; however, they will be unaware of the outcomes being studied. Upon completing the study, participants will receive a debriefing letter describing the two groups and their group allocation. The Participants will be randomly allocated into two groups: the experimental group will receive a 6-month HCH-TTC program, while the control group will receive routine transitional care services.

2.2.2 Study setting and recruitment plan

The implementation period of this study is from April 2021 to December 2024. From November 2023, participants will be recruited through large-scale diabetes health education activities within the JinQiao Medical Consortium in Pudong New Area, Shanghai, China. The JinQiao Medical Union, under the leadership of the Pudong New Area Gongli Hospital in Shanghai, comprises four community health service centers in JinQiao, Yangjing, Jinyang, and Hudong. Participants will be screened for eligibility based on existing electronic medical records or paper-based records. By December 2023, 180 participants had been recruited.

The inclusion criteria are as follows: (1) a diagnosis of type 2 diabetes; (2) aged 18 years or older; (3) an HbA1c level of 7.0% (53 mmol/mol) or higher in the past month; (4) Being able to accept a transitional care from community health service Center; (5) possession of self-monitoring blood glucose instruments or the ability to measure at community health service centers; (6) stable internet conditions for long-term use of smartphones and applications; (7) voluntary participation and

signing of an informed consent form after receiving a thorough explanation. The multicenter, practical, double-blind randomized controlled trial (RCT) study will select 180 T2DM patients seeking treatment within the Jinqiao Medical Union in Pudong New Area, Shanghai, China, as participants.

The exclusion criteria are as follows: (1) Pregnant or lactating women; (2) individuals with serious complications or comorbidities; (3) those experiencing cognitive impairments, communication and reading difficulties, or mental illness; (4) slated for long-term interventions at other medical care facilities post-discharge; (5) participants who are excluded for reasons such as withdrawal, loss to follow-up, lack of cooperation, or death during the study period. Clinical nurses or researchers will inform the patients about the study's purpose, procedures, and importance, and provide them with informed consent forms. Participants who express interest and sign the consent form will then be officially enrolled in the study.

We conducted a power analysis using two-sample *t-tests* for sample size calculation. The primary outcome is the difference in HbA1c levels between the intervention and control groups after 6 months. Based on our previous research on the effectiveness of HbA1c interventions in transitional care for T2DM [5], with α=0.05 (u_α=1.96) and β=0.10 (u_β=1.282), and assuming a standardized effect size (δ/σ) of 0.47, we performed an effectiveness analysis assuming equal sizes for both groups. Using Power Analysis and Sample Size software (PASS2008, NCSSCorporation) we calculated that n_1=n_2=72, with a total of 144 participants. Considering a potential 20% dropout rate, we determined that at least 180 participants are needed for the study, with 90 in each group.

2.2.3 Randomization

After fulfilling the inclusion and exclusion criteria, study participants, sequentially numbered from 001 to 180 based on the order of enrollment, will be randomized following the completion of baseline data collection (Figure 2).

Independent researchers utilized SPSS 26.0 software to generate random numbers (with the random number generator set seed at 180) and allocated study participants randomly into intervention and control groups in a 1:1 ratio.

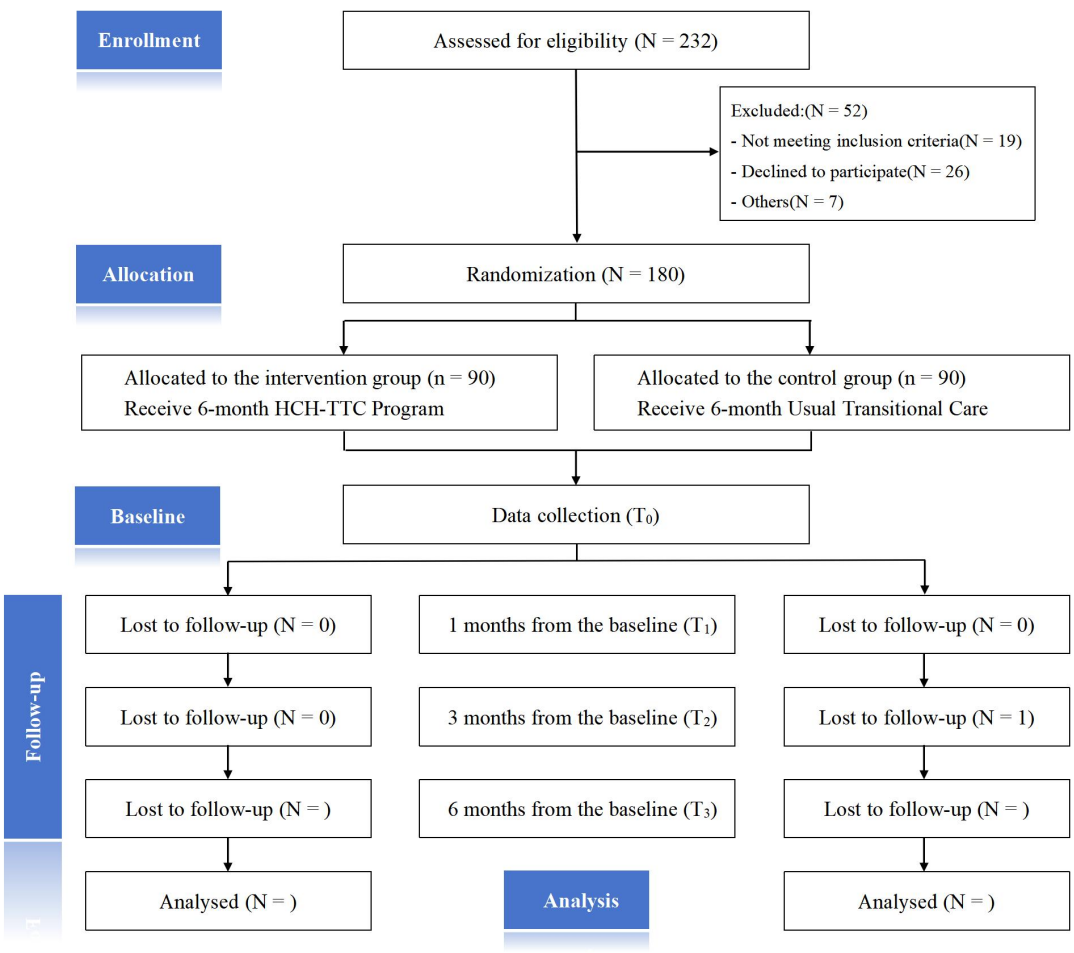

FIGURE 2 CONSORT flowchart describing progress of participants through the trial

2.2.4 Study intervention

2.2.4.1 Routine Transitional Care Program for the control group

Ninety T2DM patients in the control group will receive routine transition care services for a period of six months. After discharge, patients are required to participate in telephonic follow-ups every three months, attend health education lectures, and undergo hospital follow-ups every six months to assess their health status and revise their diabetes management plans accordingly.

2.2.4.2 HCH-TTC Program for the experimental group

The experimental group, comprising 90 participants, will be enrolled in a comprehensive six-month HCH-TTC service program structured into three distinct stages, each with specific objectives and processes:

Tiered Assessment Process:

Step 1 Evaluation: The initial phase will involve a comprehensive assessment of participants' health status and service needs across bio-psycho-social dimensions. This includes evaluating self-management abilities, daily activity capacity, blood sugar control, diabetes knowledge, treatment adherence, social support, and level of depression. This evaluation is conducted via questionnaire.

Step 2 Stratification: Based on the collected data, diabetes specialists will categorize participants into three risk categories—high, moderate, and low risk for diabetes—according to predefined criteria outlined in Table 1. This stratification is crucial for tailoring the subsequent care and intervention strategies to individual needs.

Step 3 Connection: Following stratification, diabetes specialist nurses will compile comprehensive health records for each participant, including essential data like diagnosis, treatment history, and risk category. These records will serve as the basis for establishing a connection with local community health service centers, ensuring continuity of care.

Tiered Transition Care: This phase will be delivered through a collaborative effort between general practitioners and diabetes specialist nurses and is divided into four key components:

(1) Follow-up: Participants will receive regular follow-ups, which may include outpatient visits and telephone check-ins. The frequency and specifics of these

follow-ups will be varied based on the patient's risk level, as detailed in Table 2, ensuring a personalized approach to care.

(2) Health education: This multifaceted component will comprise large group lectures, small group sessions, and individual case management, each targeting different educational needs based on risk levels. Topics will range from basic diabetes management for low-risk individuals to comprehensive disease management and quality of life improvement for those at high risk. Special focus will be given to practical skills and coping strategies for managing complications and adapting to life with diabetes.

(3) Personalized guidance: Tailored to each participant's unique circumstances, this personalized plan will address seven critical areas of diabetes management, from blood sugar monitoring to emergency response strategies. Developed by a multidisciplinary team, this guidance will be integrated into both follow-ups and educational activities, ensuring participants receive coherent and customized support.

(5) **Health monitoring:** Leveraging digital platforms like WeChat and traditional methods like telephone feedback, this component will encourage active participation from both patients and their families in monitoring key health indicators. Regular check-ins will help track progress and maintain engagement, while also providing a mechanism for timely intervention if necessary.

Table 1 Tiered assessment criteria for T2DM patients

	Tiered criteria
High Diabetes Risk	1. Diabetes duration: >20 years. 2. Average blood sugar levels in the past week (FPG, 2HPG): FPG ≥10mmol/L and 2hPG >13.9mmol/L. 3. Glycated hemoglobin (HbA1c) levels in the past 3 months: (1) <60 years old: HbA1c >8.0%; (2) ≥60 years old: HbA1c >9.0%. 4. Incidence of hypoglycemia in the past month (meeting any of the following criteria): (1) Incidence of level 1 hypoglycemia or clear reason for level 2 hypoglycemia occurs ≥ 3 times; (2) Significant daily blood sugar fluctuations are present; (3) Incidence of severe level 3 hypoglycemia occurs ≥1 time; (4) Incidence of unexplained level 2 hypoglycemia is ≥1 time. 5. Incidence of acute diabetes complications in the previous year (DKA/HHS/diabetic lactic acidosis): ≥ 2 occurrences. 6. Chronic complications of diabetes (meeting any of the following criteria): (1) Diabetic foot: Wagner classification falls within levels 3-5; (2) Diabetic nephropathy: CKD is at stage ≥G3b; (3) Diabetic retinopathy: severe NPDR or DR present; (4) Diabetic neuropathy (DPN): symptomatic DPN observed; (5) Lower extremity arterial disease in diabetes (LEAD): Fontaine stage falls within stages Ⅱb-Ⅳ. 7. Complications: ≥2 or history of cardiovascular and cerebrovascular diseases. 8. Diabetes self-management ability: SDSCA <46.2 points. 9. Activities of daily living: ADL ≤40 points. 10. Diabetes knowledge: DKT ≤20 points. 11. Treatment adherence: Treatment compliance scale score ≤20 points. 12. Social support status: SSRS <20 points. 13. Mental health: GDS-5 >2 points, without relief after self-regulation or moderate to severe depression.
Moderate Diabetes Risk	1. Diabetes duration: 10-20 years. 2. Average blood sugar levels in the past week (FPG, 2HPG): (1) <60 years old: 7mmol/L ≤ FPG <10 mmol/L, 2hPG arbitrary value or fasting blood sugar ≥ 10mmol/L, 2hPG ≤ 13.9mmol/L; (2) ≥ 60 years old: FPG <10mmol/L, 2hPG ≥12mmol/L or FPG ≥10mmol/L, 2hPG ≤13.9mmol/L. 3. Glycated hemoglobin (HbA1c) levels in the past 3 months: For non-pregnant adults: (1) <60 years old: 7.0% ≤ HbA1c <8.0%; (2) ≥60 years old: 8.0% ≤ HbA1c ≤9.0%. 4. Incidence of hypoglycemia in the past month (meeting any of the following criteria): Incidence of grade 1 or definite cause of grade 2 low blood sugar 2 times. 5. Incidence of acute complications of diabetes in the past year (DKA/HHS/Diabetic lactic acidosis): 1 time. 6. Chronic complications of diabetes (meeting any of the following criteria): (1) Diabetic foot: Wagner classification falls within levels 0-2; (2) Diabetic nephropathy: CKD is at stage G1-G3a; (3) Diabetic retinopathy: No obvious retinopathy or mild NPDR or moderate NPDR; (4) Diabetic neuropathy (DPN): Asymptomatic DPN; (5) Lower extremity arterial disease in diabetes (LEAD): Fontaine stage falls within stages I-IIa. 7. Complications: 1 and no history of cardiovascular and cerebrovascular disease. 8. Self-management ability of diabetes: 46.2 points ≤ SDSCA <61.6 points. 9. Daily activity ability: 40 points < ADL ≤60 points. 10. Diabetes knowledge: 21 points. ≤ DKT <59 points. 11. Treatment adherence: Treatment compliance score <40 points, >20 points. 12. Social support status: 20 points ≤ SSRS <30 points. 13. Mental health: 1 points ≤ GDS-5 ≤2 points, partial relief after self-regulation or mild depression.

Low Diabetes Risk	1. Diabetes duration: <10 years. 2. Average blood sugar levels in the past week (FPG, 2HPG): (1) <60 years old: 4.4mmol/L ≤ FPG ＜7 mmol/L and 2hPG ≤10mmol/L; (2) ≥60 years old: 8mmol/L ≤ FPG ＜10mmol/L and 8mmol/L≤ 2hPG ＜12 mmol/L). 3. Glycated hemoglobin (HbA1c) levels in the past 3 months: (1) <60 years old: HbA1c ＜7.0%; (2) ≥60 years old: HbA1c ＜8.0%). 4. Incidence of hypoglycemia in the past month (meeting any of the following criteria): Grade 1 or definite reason for Grade 2 hypoglycemia ≤1 time. 5. Incidence of acute complications of diabetes in the past year (DKA/HHS/Diabetic lactic acidosis): 0 times. 6. Chronic complications of diabetes: None. 7. Complications: None. 8. Diabetes self-management ability: SDSCA ≥61.6 points. 9. Daily activity ability: ADL >60 points. 10. Diabetes knowledge: DKT ≥60 points. 11. Treatment adherence: Treatment compliance scale score 40～60 points. 12. Social support status: SSRS ≥30 points. 13. Mental health: GDS-5 score of 0, no depression.

Footnote： Fasting Plasma Glucose (FPG); 2-hour Postprandial Glucose (2hPG); HbA1c: Glycated Hemoglobin; DKA: Diabetic Ketoacidosis; HHS: Hyperosmolar Hyperglycemic State; SDSCA: Summary of Diabetes Self-Care Activities; DKT: Diabetes Knowledge Test; ADL: Activities of Daily Living; SSRS: Social Support Rating Scale; GDS-5: Geriatric Depression Scale-5; Level 1 Hypoglycemia: Blood glucose <3.9 mmol/L and ≥3.0 mmol/L; Level 2 Hypoglycemia: Blood glucose <3.0 mmol/L; Level 3 Hypoglycemia: Severe event requiring assistance from another person, with changes in consciousness and/or physical status, but without specific blood glucose limits.

Table 2 Tiered transitional care（TTC）for patients with T2DM

	Tiered transitional care	
High Diabetes Risk	**Follow-up**	**1.Outpatient clinic follow-up：** (1) Frequency: When the condition changes. (2) Content: Evaluate the comprehensive disease control, the severity of acute events, and the adaptability of ongoing nursing plans. Conduct a hierarchical reassessment every 6 months or upon changes in the condition and promptly adjust management measures. **2.Telephone calls follow-up：** (1) Frequency: Once every 1 months. (2) Content: Primarily inquire about the patient’ s recent blood sugar control, oversee the implementation of the patient’ s ongoing nursing plan, enhance personalized guidance, address questions online, and notify patients of the schedule and location of large-group educational sessions.
	Health education	**1.Large class education：** (1) Frequency: Once every 3 months. (2) Duration: 1 hour per session. (3) Number of people: 50-80 people. (4) Method: Lecture, peer education, experiential patient education, live webcast. (5) Content: Focus on pain and comprehensive disease management based on Moderate-Diabetes Risk, emphasizing the improvement of patients' quality of life and social and psychological adaptation. **2.Groups education：** (1) Frequency: Once every 1 months. (2) Duration: 1 hour per session. (3) Number of people: 10-15 people. (4) Method: Face-to-face teaching and teaching methods for counter-teaching. (5) Content: Mainly educate patients with common professional nursing problems and demonstrate education and invasive operation skills for complications nursing. **3.Case Study:** Carry out for the seriously ill who cannot go out, and suggest hospitalization or home visits by the team when necessary.
	Personalized guidance	**1.Time:** Initial evaluation/re-evaluation/changes in condition. **2.Form:** Face-to-face communication or questionnaire survey, personalized guidance programs are tailored by a multidisciplinary team based on assessment results, individual conditions, and patient needs. **3.Content:** **(1) Blood glucose monitoring guidance:** ① Determine the FPG, 2hPG monitoring frequency according to the patient's medication and blood sugar fluctuations (HbA1c should be monitored every 3 months in the absence of special circumstances); ② Teach patients the correct use of the blood glucose meter. **(2) Exercise guidance:** ① Exercise therapy should be approached cautiously in the presence of acute or severe chronic complications; ② The treatment of patients with severe cognitive impairment should consider their social support situation. **(3) Dietary guidance:** The personalized diet plan for one month is developed by the nutritionist from the diabetes multidisciplinary team based on the patient’ s nutritional assessment results. **(4) Medication guidance:** ① Patients with comorbidities should consider whether the medications exhibit antagonistic or synergistic effects; ② Patients with chronic complications should receive emphasis on medication dosage and usage instructions; ③ Patients requiring invasive or aseptic procedures are recommended to seek treatment at a specialized outpatient clinic. **(5) Complication guidance:** To reduce the incidence and progression of patient-related complications, primarily aiming to decrease disability and mortality rates. **(6) Psychological guidance:** ① Implement individual peer education to enhance the patient’ s psychological resilience. ② Patients with severe mental health issues should be referred to a

		mental health center for specialized treatment. **(7) Other guidance:** Recommend smoking and alcohol cessation. Hypoglycemia guidance: ① Guide patients/main caregivers to identify the symptoms of hypoglycemia and master emergency measures for hypoglycemia; ② Assess whether patients have factors that induce hypoglycemia, and guide them to avoid triggers or self-monitor their blood sugar when the above-mentioned triggers occur.
	Health monitoring	**1.Frequency:** Community nurses review information twice a month. **2.Form:** Patients under observation can offer timely feedback on blood glucose control, medication, diet, and exercise over the previous two weeks via WeChat, telephone, and other channels, assisted by family members. If a patient fails to provide feedback for a month or the quality of feedback is inadequate, the patient should follow up with a call to investigate the reasons and find solutions. Throughout this process, we advocate for the active involvement of the patient's family members in collaborative monitoring and management to enhance and optimize the patient's health outcomes.
Moderate Diabetes Risk	**Follow-up**	**1.Outpatient clinic follow-up:** (1) Frequency: Once every 2 months. (2) Content: Evaluate the comprehensive disease control, the severity of acute events, and the adaptability of ongoing nursing plans. Conduct a hierarchical reassessment every 6 months or upon changes in the condition and promptly adjust management measures. **2.Telephone calls follow-up:** (1) Frequency: Once every 2 months. (2) Content: Primarily inquire about the patient's recent blood sugar control, oversee the implementation of the patient's ongoing nursing plan, enhance personalized guidance, address questions online, and notify patients of the schedule and location of large-group educational sessions.
	Health education	**1.Large class education:** (1) Frequency: Once every 2 months. (2) Duration: 1 hour per session. (3) Number of people: 50-80 people. (4) Method: Lecture, peer education, experiential patient education, live webcast. (5) Content: Based on Low Diabetes Risk, focus on the prevention and treatment of acute and chronic complications of diabetes and medication guidance. **2.Groups education:** (1) Frequency: Once every 1 months. (2) Duration: 1 hour per session. (3) Number of people: 10-15 people. (4) Method: Face-to-face teaching and teaching methods for counter-teaching. (5) Content: Mainly educate patients with common professional nursing problems and demonstrate education and invasive operation skills for complications nursing.
	Personalized guidance	**1.Time:** Initial evaluation/re-evaluation/changes in condition. **2.Form:** Face-to-face communication or questionnaire survey, personalized guidance programs are tailored by a multidisciplinary team based on assessment results, individual conditions, and patient needs. **3.Content:** **(1) Blood glucose monitoring guidance:** ① Determine the FPG, 2hPG monitoring frequency according to the patient's medication and blood sugar fluctuations (HbA1c should be monitored every 3 months in the absence of special circumstances); ② Teach patients the correct use of the blood glucose meter. **(2) Exercise guidance:** ① Assess if the patient has any contraindications to exercise. If so, discontinue exercise until the condition stabilizes, then gradually reintroduce exercise. ② Evaluate the patient's exercise capacity and, based on the assessment results, identify the suitable exercise intensity, type, and duration for the patient.

		(3) Dietary guidance: ① Assess the patient's nutritional status and dietary habits, and analyse the existing problems in the patient's current dietary situation; ② Fully consider the nutritional needs of patients with comorbidities and chronic complications; ③ Calculate the patient's total daily energy requirement and food exchange portions, and develop a personalized weekly menu for the patient, and teach the patient how to change the menu content on their own. **(4) Medication guidance:** ① Patients with comorbidities should consider whether the medications exhibit antagonistic or synergistic effects; ② Patients with chronic complications should receive emphasis on medication dosage and usage instructions; ③ Patients requiring invasive or aseptic procedures are recommended to seek treatment at a specialized outpatient clinic. **(5) Complication guidance:** ① Inform the patient/main caregiver about the frequency and specific timing for monitoring chronic complications; ② Assess the risk factors for chronic complications of diabetes and implement appropriate interventions; ③ Highlight the preventive measures and care strategies for managing chronic complications of diabetes. **(6) Psychological guidance:** ① Evaluate and analyze the reasons behind the patient's anxiety or depression, provide encouragement, comfort, and assistance; ② Encourage the patient to actively engage in social activities; ③ Understand the patient's social background, engage with family members in communication, and manage conflicting factors; ④ Teach the patient techniques for emotional relaxation and, if needed, guide the patient through mindfulness-based stress reduction therapy conducted by a psychotherapist. **(7) Other guidance:** Recommend smoking and alcohol cessation. Hypoglycemia guidance: ① Guide patients/main caregivers to identify the symptoms of hypoglycemia and master emergency measures for hypoglycemia; ② Assess whether patients have factors that induce hypoglycemia, and guide them to avoid triggers or self-monitor their blood sugar when the above-mentioned triggers occur.
	Health monitoring	**1.Frequency:** Community nurses review information twice a month. **2.Form:** Patients under observation can offer timely feedback on blood glucose control, medication, diet, and exercise over the previous two weeks via WeChat, telephone, and other channels, assisted by family members. If a patient fails to provide feedback for a month or the quality of feedback is inadequate, the patient should follow up with a call to investigate the reasons and find solutions. Throughout this process, we advocate for the active involvement of the patient's family members in collaborative monitoring and management to enhance and optimize the patient's health outcomes.
Low Diabetes Risk	**Follow-up**	**1.Outpatient clinic follow-up:** (1) Frequency: Once every 3 months. (2) Content: Evaluate the comprehensive disease control, the severity of acute events, and the adaptability of ongoing nursing plans. Conduct a hierarchical reassessment every 6 months or upon changes in the condition and promptly adjust management measures. **2.Telephone calls follow-up:** (1) Frequency: Once every 3 months. (2) Content: Primarily inquire about the patient's recent blood sugar control, oversee the implementation of the patient's ongoing nursing plan, enhance personalized guidance, address questions online, and notify patients of the schedule and location of large-group educational sessions.
	Health education	**1.Large class education:** (1) Frequency: Once every 1 months. (2) Duration: 1 hour per session. (3) Number of people: 50-80 people. (4) Method: Lecture, peer education, experiential patient education, live webcast. (5) Content: Focus on diabetes basic knowledge education and lifestyle guidance, helping patients establish healthy beliefs and disease management awareness, and establish a healthy lifestyle.

Personalized guidance	**1.Time:** Initial evaluation/re-evaluation/changes in condition. **2.Form:** Face-to-face communication or questionnaire survey, personalized guidance programs are tailored by a multidisciplinary team based on assessment results, individual conditions, and patient needs. **3.Content:** **(1) Blood glucose monitoring guidance:** ① Determine the FPG, 2hPG monitoring frequency according to the patient's medication and blood sugar fluctuations (HbA1c should be monitored every 6 months in the absence of special circumstances); ② Teach patients the correct use of the blood glucose meter. **(2) Exercise guidance:** Furnish diabetic patients with exercise guidelines, elucidating exercise choices, intensity levels, guiding principles, precautions, and emergency measures for adverse events. **(3) Dietary guidance:** Issuing diabetes dietary guidance manuals and disseminating knowledge on diabetes nutrition; specifying principles, classifications, and glycemic index of common foods; teaching patients/main caregivers to assess total caloric intake and food exchange portions. **(4) Medication guidance:** ① Oral Medication Guidance: Emphasize the importance of adhering to the prescribed medication regimen and do not stop or change the type and dosage of medication without authorization; Educate patients or primary caregivers to understand the names, dosages, administration instructions, potential side effects, mitigation strategies, and precautionary measures associated with hypoglycemic drugs; ② Injection Guidance for Hypoglycemic Drugs: Provide patients with insulin injection guidance manuals and demonstrate the injection method. **(5) Complication guidance:** ① Notify patients/caregivers to undergo regular screenings for the retina, kidneys, heart, lower limb arteries, and foot examinations; ② Provide patients with education on preventive measures and care for complications; ③ Evaluate patients' potential risk factors and actively address, correct, and improve health outcomes. **(6) Psychological guidance:** ① Inform the patient about the impact of emotional changes on blood sugar fluctuations; ② Encourage the patient to express their inner feelings and thoughts, actively listen to the patient's concerns, share successful cases of blood sugar control, assist the patient in building the confidence to overcome the disease, promote participation in community activities, and seek support from family members; ③ Inform the patient to seek medical attention or contact the 24-hour psychological counseling hotline if psychological issues significantly impact their enthusiasm for life or sleep. **(7) Other guidance:** Recommend smoking and alcohol cessation. Hypoglycemia guidance: ① Guide patients/main caregivers to identify the symptoms of hypoglycemia and master emergency measures for hypoglycemia; ② Assess whether patients have factors that induce hypoglycemia, and guide them to avoid triggers or self-monitor their blood sugar when the above-mentioned triggers occur.
Health monitoring	**1.Frequency:** Community nurses review information twice a month. **2.Form:** Patients under observation can offer timely feedback on blood glucose control, medication, diet, and exercise over the previous two weeks via WeChat, telephone, and other channels, assisted by family members. If a patient fails to provide feedback for a month or the quality of feedback is inadequate, the patient should follow up with a call to investigate the reasons and find solutions. Throughout this process, we advocate for the active involvement of the patient's family members in collaborative monitoring and management to enhance and optimize the patient's health outcomes.

Footnote: FPG: Fasting Plasma Glucose; PBG: postprandial blood glucose; HbA1c: Glycated Hemoglobin.

2.2.5 Outcome measures

2.2.5.1 Primary outcomes

HbA1c, endorsed by the National Diabetes Association as a reliable indicator for monitoring blood sugar control in individuals with diabetes and widely utilized as a key outcome measure in diabetes research [22], will be assessed using the MQ-6000 glycated hemoglobin analyzer by Medconn Diagnotics, Shanghai, China. Venous whole blood samples, each with a blood volume of 5ml, will be collected at four key times: baseline, 3-month and 6-month post-intervention. Skilled community diabetes specialist nurses will supervise these blood sample collections. The samples will be promptly dispatched to the researchers for analysis. The preparation of the blood collection tube reagent kit and the sample analysis will be carried out in the laboratory department of Pudong Gongli Hospital, Shanghai, China, aiming for a standardized value of 6.5% (48 mmol/mol) [23].

Fasting plasma glucose (FPG) and postprandial blood glucose (PBG) levels. will be measured using the rapid blood glucose monitor from SINOMEDISITE in Beijing, China. This device will assess peripheral blood glucose levels at baseline, as well as at the 1-month, 3-month and 6-month post-baseline, with results recorded in mmol/L. During these procedures, the second droplet of blood will be selected for testing to ensure accurac, and values will be recorded immediately. The target benchmarks for FPG and PBG have been set at 7.0mmol/L and 11.1mmol/L, respectively [24].

2.2.5.2 Secondary outcomes

Self-management ability is evaluated using the Summary of Diabetes Self-Care Activities (SDSCA) questionnaire [25], which has been translated into Chinese by Li and colleagues. Building on Toobert's original work, the SDSCA includes 11 items across 6 dimensions, designed to assess patients' self-management behaviors over the previous week, yielding a maximum total score of 77. With a Cronbach's α value of 0.918, it is the most widely used instrument for assessing the self-management abilities of individuals with diabetes.

Disease knowledge is assessed with the Diabetes Knowledge Test (DKT) questionnaire [26], which has been translated into Chinese by Sun and colleagues, building upon the work of Fitzgerald. The DKT contains 23 items; the first 14 items are relevant for all patients, while the latter nine are tailored for those receiving insulin therapy. It has a Cronbach's α of 0.76 and a Content Validity Index (CVI) of 1, indicating good internal consistency and content validity.

Diabetes treatment adherence is assessed using the Diabetes Patient Treatment Adherence Scale designed by Chen[27]. The scale includes 20 items across five domains: medication, diet, exercise, self-monitoring, and regular reexamination. The overall Cronbach's α is 0.86 and the CVI is 0.83, indicating good internal consistency and content validity.

The rate of diabetes complications: Diabetes complications refer to those that are newly developed during the study period such as diabetic ketoacidosis, hyperosmolar hyperglycemic state, as well as those diagnosed during the study period including diabetic nephropathy, diabetic retinopathy, diabetic neuropathy, diabetic peripheral arterial disease, and diabetic foot disease, making a total of 7 types of acute and chronic diabetes complications. The incidence rate of diabetes complications is calculated as the number of new acute or chronic complications divided by the total number of individuals multiplied by 100%.

Satisfaction with nursing services: Evaluated using a self-designed Patient Satisfaction Survey, crafted by our research team, comprising 10 items. These items cover aspects such as overall satisfaction with nursing services, the ease of access to these services, the attitude of the nursing staff, and satisfaction with the provided health guidance and education. The pre-experimental exhibited a content validity of 0.73, and Cronbach's α coefficient stood at 0.85.

The rate of unplanned readmissions: This metric captures the proportion of

patients who unexpectedly return to the hospital due to diabetes or its complications, which could stem from subpar medical care or the worsening or lack of control over the disease. It is determined by dividing the number of unplanned readmissions by the total number of patients and then multiplying by 100%.

TABLE 3 Timeline and overview of patient engagement and assessments in this study

	Enrolment	Allocation	Follow-up		Close-out
TIMEPOINT	**$-T_0$**	**Baseline (T_0)**	**1 months post-baseline (T_1)**	**3 months post-baseline (T_2)**	**6 months post-baseline (T_3)**
ENROLMENT					
Eligibility screen	x				
Informed consent	x				
Allocation		x			
INTERVENTIONS					
HCH-TTC					
ASSESSMENTS					
Demographics		x			
Primary outcomes					
HbA1c		x		x	x
FPG and PBG		x	x	x	x
Secondary outcomes					
Self management ability: SDSCA		x			x
Disease knowledge level: DKT		x			x
Diabetes treatment adherence		x			x
Diabetes complication rate		x			x
Nursing service satisfaction		x			x
Unplanned readmission rate		x			x

Footnote: HCH-TTC: Hospital-Community-Home Tiered Transitional Care Program; FPG: Fasting Plasma Glucose; PBG: postprandial blood glucose; HbA1c: Glycated Hemoglobin; SDSCA: Summary of Diabetes Self-Care Activities; DKT: Diabetes Knowledge Test.

2.2.6 Data collection and safety monitoring

This study will collect data at four time points: baseline, 1 months, 3 and 6 months post-intervention. Two nurses from the hospital will be selected as data collectors and will receive comprehensive training covering patient recruitment discussions, informed consent procedures, and the collection of assessment data at Gongli Hospital. This training will last for two weeks. A key evaluation criterion for this training is the consistency of standardized patient assessment outcomes. Subsequently, the data collectors will conduct on-site surveys, providing participants with a brief overview of the project background and survey instructions. Assistance will be given to participants who are unable to complete the survey on their own, with care taken to avoid the use of suggestive or directive language. Table 3 presents a detailed schedule and overview of the patient participation and assessment procedures.

All research data will be encrypted and stored by the data management officer of the Nursing Department of the Gongli Hospital in Pudong New Area, Shanghai. The data will not be disclosed to the public, only accessible to internal research members for study, application, and paper writing. No one is authorized to modify or delete the data to prevent incidents such as information leakage, loss, or falsification. In addition, the data management officer must promptly report adverse events to the Pudong New Area Health Commission in Shanghai and provide regular reports. The Pudong New Area Health Commission in Shanghai will serve as the independent Data and Safety Monitoring Board (DSMB) for this research, reviewing the data security and providing appropriate recommendations.

2.2.7 Data analysis

After thorough verification, all collected data will be entered into an Excel spreadsheet for the creation of a comprehensive database. Independent statistical analysts will be engaged to perform data analysis utilizing SPSS version 26.0 for Windows (SPSS Inc., Chicago, Illinois, USA). Baseline data, including demographic

and clinical characteristics, will be made through *chi-square* tests or independent *t*-tests to confirm the equivalence of samples. Assuming a normal distribution for outcome variables, parametric testing methods will be applied. To evaluate the intervention's temporal effects on primary outcomes, the study will analyze differences in outcomes over time—baseline, 1 months, 3 and 6 months post-intervention—using repeated-measures ANOVA, focusing on the interaction effect (group × time). Intention-to-treat (ITT) analysis will address missing data, employing strategies like the use of group means for weighting missing values. All statistical tests will be two-tailed, with a significance threshold set at a p-value of $\leqslant$.05.

2.3 Patient and public involvement

Patients or the public were not involved in the design, or conduct, or reporting, or dissemination plans of our research.

2.4 Ethics and dissemination

This research protocol received approval from the Ethics Committee of Gongli Hospital, Pudong, Shanghai, China in November 2021 (GLYY1s2021-010) and is subjected to regular review. The study will provide participants with free testing for glycated hemoglobin, fasting blood sugar, and postprandial blood sugar on three occasions, as well as cover essential transportation expenses for participation in the study. Prior to enrollment, all participants will be thoroughly informed about the purpose, significance, procedures, potential risks, benefits, and the work they are expected to cooperate with in face-to-face sessions and will be required to provide written informed consent. After enrollment, we ensure the confidentiality of participants' personal information, and blood samples used for laboratory tests will be promptly destroyed after testing. All research data and laboratory test results will be used strictly for project research and paper writing purposes.

Furthermore, due to the impact of the COVID-19 pandemic, the overall

implementation of this research plan has been postponed by a year. Following consultation with experts and ethical committee review, specific indicators have been modified, clarified, and strengthened, and these revisions have been promptly updated in the Chinese Clinical Trial Registry. After the trial concludes, the four participating communities can choose whether to continue using the project for ongoing care for Type 2 diabetes. Patients also have the right to decide whether to continue receiving transition care services in their communities. If harm is caused to patients as a result of this study, compensation will be determined by a third-party assessment agency.

Additionally, research results will be disseminated in the following manner: laboratory test results will be emailed to community intervention personnel in Excel format, and the results will be communicated to the patients. Survey scores will serve as the basis for adjusting intervention measures, will be published in paper form after the study, and the process of changes in outcome indicators will be verbally reported to patients and intervention implementers.

3 DISCUSSION

This study is, to the best of our knowledge, the first study to explore the integration of hospital, community, and home care within a tiered transitional care framework for diabetes, with the objective of evaluating its impact on health-related outcomes in individuals with T2DM. The outcomes assessed include HbA1c, FPG, and PBG, alongside diabetes knowledge, self-management abiliy, treatment adherence, patient satisfaction with nursing services, rate of unplanned readmissions and diabetes complications.

Building upon the premise of our investigation, it is worth noting that existing literature on the tiered collaborative management of diabetes is scarce[28-31] . This gap highlights the innovative nature of our study within the broader context of diabetes care. Notably, the work of Jia and colleagues[30] emerges as a foundational effort in this field within China's healthcare settings. This study spearheaded a stratified

diabetes management plan specifically tailored for primary care settings in China. This ambitious project involved the recruitment of 19,546 participants across 864 communities and executed a comprehensive cluster randomized controlled trial spanning two years. The intervention at the heart of this study leveraged mobile health services to provide patient-centered diabetes management within a tri-level framework. The results demonstrated significant enhancements in diabetes control within primary care settings, thus presenting valuable insights into the management of chronic diseases and underscoring the potential efficacy of tiered, integrated care models like the one our current study seeks to evaluate.

While the study[31] conducted by Jia and colleagues covered various primary care institutions and engaged in collaboration with doctors in community primary care clinics and county-level hospitals to form a hierarchical structure of regional nursing teams, it did not implement a stratified management approach for diabetes patients. The stratification of management remained purely at an organizational level, without addressing the need for differentiated management based on patients' varying diabetes risk levels. Moreover, the study primarily harnessed synergistic benefits within the primary healthcare sector, overlooking the pivotal role of tertiary comprehensive hospitals in diabetes care, including diagnosis, treatment, and patient education. It also overlooked the critical role of patient self-management and the potential for disease monitoring within the home environment.

In contrast, our HCH-TTC program is designed to encompass the entire continuum of care, from inpatient treatment to post-discharge home care. It aims to stratify patients by their risk of diabetes and to customize transitional care strategies—varying in frequency, intensity, type, and content focus—to meet the specific needs and disease statuses of T2DM patients at different stages. This approach seeks to minimize disruptions in transitional care services and information flow, thereby addressing potential over-treatment or under-treatment. Our goal is to enhance patient health outcomes, increase satisfaction with nursing services, reduce

rates of unplanned readmissions and diabetes complications.

4 Conclusions

This study protocol is designed to direct a multicenter RCT to assess the potential effectiveness of the HCH-TTC program for T2DM patients within a specified medical consortium in Pudong New Area, Shanghai. The study will employ a detailed conceptual framework, tailored to fit the diabetes risk levels and specific service needs of patients, to deliver integrated and coordinated Tiered Transitional Care through a collaborative effort among hospitals, community health services, and home care. Planned intervention include routine follow-ups (outpatient visits and telephone consultations), health education (ranging from large group lectures to small group discussions and individual case management), personalized guidance, and ongoing health monitoring. The anticipated outcomes of this intervention aim to determine its effect on patients' glycemic control, diabetes knowledge, self-management skills, adherence to treatment and complications. Moreover, the study intends to explore the HCH-TTC program's impact on nursing satisfaction and the rate of unplanned readmissions. The expected findings seek to provide critical insights for improving the efficacy of T2DM care continuity programs and for developing comprehensive national diabetes management strategies.

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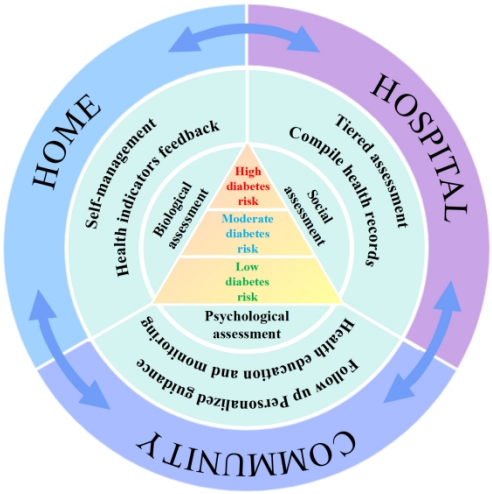

FIGURE 1 The HCH-TTC conceptual framework

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1140x641mm (57 x 57 DPI)

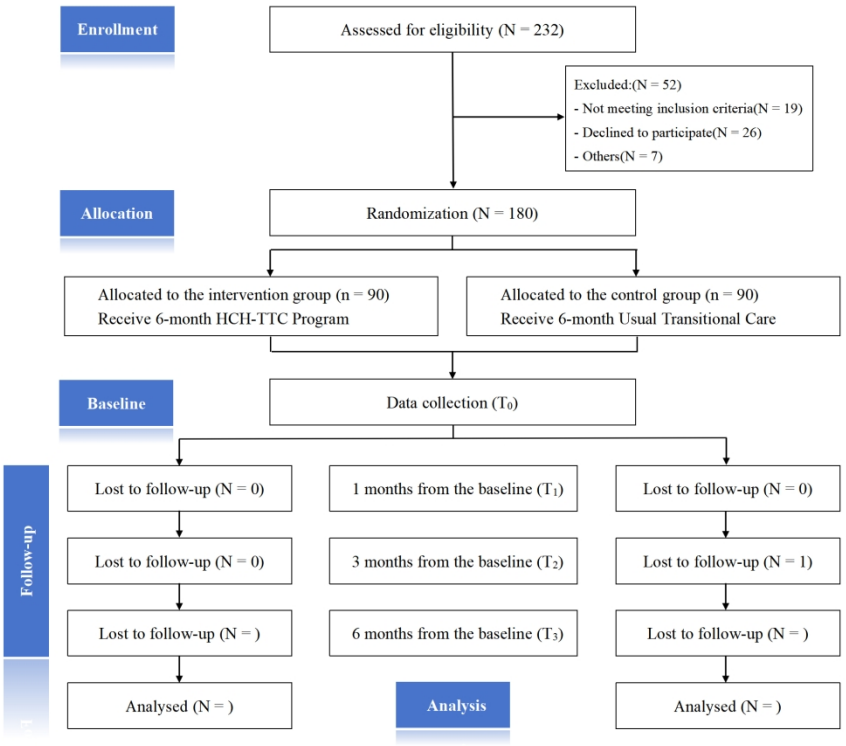

FIGURE 2 CONSORT flowchart describing progress of participants through the trial

FIGURE 2 CONSORT flowchart describing progress of participants through the trial

1000x958mm (57 x 57 DPI)

Table 1 Tiered assessment criteria for T2DM patients

	Tiered criteria
High Diabetes Risk	1. Diabetes duration: >20 years. 2. Average blood sugar levels in the past week (FPG, 2HPG): FPG ⩾10mmol/L and 2hPG >13.9mmol/L. 3. Glycated hemoglobin (HbA1c) levels in the past 3 months: (1) <60 years old: HbA1c >8.0%; (2) ⩾60 years old: HbA1c >9.0%. 4. Incidence of hypoglycemia in the past month (meeting any of the following criteria): (1) Incidence of level 1 hypoglycemia or clear reason for level 2 hypoglycemia occurs ⩾3 times; (2) Significant daily blood sugar fluctuations are present; (3) Incidence of severe level 3 hypoglycemia occurs ⩾1 time; (4) Incidence of unexplained level 2 hypoglycemia is ⩾1 time. 5. Incidence of acute diabetes complications in the previous year (DKA/HHS/diabetic lactic acidosis): ⩾2 occurrences. 6. Chronic complications of diabetes (meeting any of the following criteria): (1) Diabetic foot: Wagner classification falls within levels 3-5; (2) Diabetic nephropathy: CKD is at stage ⩾G3b; (3) Diabetic retinopathy: severe NPDR or DR present; (4) Diabetic neuropathy (DPN): symptomatic DPN observed; (5) Lower extremity arterial disease in diabetes (LEAD): Fontaine stage falls within stages ⅡⅠb-Ⅳ. 7. Complications: ⩾2 or history of cardiovascular and cerebrovascular diseases. 8. Diabetes self-management ability: SDSCA <46.2 points. 9. Activities of daily living: ADL ⩽40 points. 10. Diabetes knowledge: DKT ⩽20 points. 11. Treatment adherence: Treatment compliance scale score ⩽20 points. 12. Social support status: SSRS <20 points. 13. Mental health: GDS-5 >2 points, without relief after self-regulation or moderate to severe depression.
Moderate Diabetes Risk	1. Diabetes duration: 10-20 years. 2. Average blood sugar levels in the past week (FPG, 2HPG): (1) <60 years old: 7mmol/L ⩽ FPG <10 mmol/L, 2hPG arbitrary value or fasting blood sugar ⩾10mmol/L, 2hPG ⩽13.9mmol/L; (2) ⩾60 years old: FPG <10mmol/L, 2hPG ⩾12mmol/L or FPG ⩾10mmol/L, 2hPG ⩽13.9mmol/L. 3. Glycated hemoglobin (HbA1c) levels in the past 3 months: For non-pregnant adults: (1) <60 years old: 7.0% ⩽ HbA1c <8.0%; (2) ⩾60 years old: 8.0% ⩽ HbA1c ⩽9.0%. 4. Incidence of hypoglycemia in the past month (meeting any of the following criteria): Incidence of grade 1 or definite cause of grade 2 low blood sugar 2 times. 5. Incidence of acute complications of diabetes in the past year (DKA/HHS/Diabetic lactic acidosis): 1 time. 6. Chronic complications of diabetes (meeting any of the following criteria): (1) Diabetic foot: Wagner classification falls within levels 0-2; (2) Diabetic nephropathy: CKD is at stage G1-G3a; (3) Diabetic retinopathy: No obvious retinopathy or mild NPDR or moderate NPDR; (4) Diabetic neuropathy (DPN): Asymptomatic DPN; (5) Lower extremity arterial disease in diabetes (LEAD): Fontaine stage falls within stages I-IIa. 7. Complications: 1 and no history of cardiovascular and cerebrovascular disease. 8. Self-management ability of diabetes: 46.2 points ⩽ SDSCA <61.6 points. 9. Daily activity ability: 40 points < ADL ⩽60 points. 10. Diabetes knowledge: 21 points. ⩽ DKT <59 points. 11. Treatment adherence: Treatment compliance score <40 points, >20 points. 12. Social support status: 20 points ⩽ SSRS <30 points. 13. Mental health: 1 points ⩽ GDS-5 ⩽2 points, partial relief after self-regulation or mild depression.

Low Diabetes Risk	1. Diabetes duration: <10 years. 2. Average blood sugar levels in the past week (FPG, 2HPG): (1) <60 years old: 4.4mmol/L ≤ FPG ＜7 mmol/L and 2hPG ≤10mmol/L; (2) ≥60 years old: 8mmol/L ≤ FPG ＜10mmol/L and 8mmol/L≤ 2hPG ＜12 mmol/L). 3. Glycated hemoglobin (HbA1c) levels in the past 3 months: (1) <60 years old: HbA1c ＜7.0%; (2) ≥60 years old: HbA1c ＜8.0%). 4. Incidence of hypoglycemia in the past month (meeting any of the following criteria): Grade 1 or definite reason for Grade 2 hypoglycemia ≤1 time. 5. Incidence of acute complications of diabetes in the past year (DKA/HHS/Diabetic lactic acidosis): 0 times. 6. Chronic complications of diabetes: None. 7. Complications: None. 8. Diabetes self-management ability: SDSCA ≥61.6 points. 9. Daily activity ability: ADL >60 points. 10. Diabetes knowledge: DKT ≥60 points. 11. Treatment adherence: Treatment compliance scale score 40～60 points. 12. Social support status: SSRS ≥30 points. 13. Mental health: GDS-5 score of 0, no depression.

Footnote： Fasting Plasma Glucose (FPG); 2-hour Postprandial Glucose (2hPG); HbA1c: Glycated Hemoglobin; DKA: Diabetic Ketoacidosis; HHS: Hyperosmolar Hyperglycemic State; SDSCA: Summary of Diabetes Self-Care Activities; DKT: Diabetes Knowledge Test; ADL: Activities of Daily Living; SSRS: Social Support Rating Scale; GDS-5: Geriatric Depression Scale-5; Level 1 Hypoglycemia: Blood glucose <3.9 mmol/L and ≥3.0 mmol/L; Level 2 Hypoglycemia: Blood glucose <3.0 mmol/L; Level 3 Hypoglycemia: Severe event requiring assistance from another person, with changes in consciousness and/or physical status, but without specific blood glucose limits.

Table 2 Tiered transitional care（TTC）for patients with T2DM

	Tiered transitional care	
High Diabetes Risk	**Follow-up**	**1.Outpatient clinic follow-up：** (1) Frequency: When the condition changes. (2) Content: Evaluate the comprehensive disease control, the severity of acute events, and the adaptability of ongoing nursing plans. Conduct a hierarchical reassessment every 6 months or upon changes in the condition and promptly adjust management measures. **2.Telephone calls follow-up：** (1) Frequency: Once every 1 months. (2) Content: Primarily inquire about the patient’ s recent blood sugar control, oversee the implementation of the patient’ s ongoing nursing plan, enhance personalized guidance, address questions online, and notify patients of the schedule and location of large-group educational sessions.
	Health education	**1.Large class education：** (1) Frequency: Once every 3 months. (2) Duration: 1 hour per session. (3) Number of people: 50-80 people. (4) Method: Lecture, peer education, experiential patient education, live webcast. (5) Content: Focus on pain and comprehensive disease management based on Moderate-Diabetes Risk, emphasizing the improvement of patients' quality of life and social and psychological adaptation. **2.Groups education：** (1) Frequency: Once every 1 months. (2) Duration: 1 hour per session. (3) Number of people: 10-15 people. (4) Method: Face-to-face teaching and teaching methods for counter-teaching. (5) Content: Mainly educate patients with common professional nursing problems and demonstrate education and invasive operation skills for complications nursing. **3.Case Study:** Carry out for the seriously ill who cannot go out, and suggest hospitalization or home visits by the team when necessary.
	Personalized guidance	**1.Time:** Initial evaluation/re-evaluation/changes in condition. **2.Form:** Face-to-face communication or questionnaire survey, personalized guidance programs are tailored by a multidisciplinary team based on assessment results, individual conditions, and patient needs. **3.Content:** **(1) Blood glucose monitoring guidance:** ① Determine the FPG, 2hPG monitoring frequency according to the patient's medication and blood sugar fluctuations (HbA1c should be monitored every 3 months in the absence of special circumstances); ② Teach patients the correct use of the blood glucose meter. **(2) Exercise guidance:** ① Exercise therapy should be approached cautiously in the presence of acute or severe chronic complications; ② The treatment of patients with severe cognitive impairment should consider their social support situation. **(3) Dietary guidance:** The personalized diet plan for one month is developed by the nutritionist from the diabetes multidisciplinary team based on the patient’ s nutritional assessment results. **(4) Medication guidance:** ① Patients with comorbidities should consider whether the medications exhibit antagonistic or synergistic effects; ② Patients with chronic complications should receive emphasis on medication dosage and usage instructions; ③ Patients requiring invasive or aseptic procedures are recommended to seek treatment at a specialized outpatient clinic. **(5) Complication guidance:** To reduce the incidence and progression of patient-related complications, primarily aiming to decrease disability and mortality rates. **(6) Psychological guidance:** ① Implement individual peer education to enhance the patient’ s psychological resilience. ② Patients with severe mental health issues should be referred to a

		mental health center for specialized treatment. **(7) Other guidance:** Recommend smoking and alcohol cessation. Hypoglycemia guidance: ① Guide patients/main caregivers to identify the symptoms of hypoglycemia and master emergency measures for hypoglycemia; ② Assess whether patients have factors that induce hypoglycemia, and guide them to avoid triggers or self-monitor their blood sugar when the above-mentioned triggers occur.
	Health monitoring	**1.Frequency:** Community nurses review information twice a month. **2.Form:** Patients under observation can offer timely feedback on blood glucose control, medication, diet, and exercise over the previous two weeks via WeChat, telephone, and other channels, assisted by family members. If a patient fails to provide feedback for a month or the quality of feedback is inadequate, the patient should follow up with a call to investigate the reasons and find solutions. Throughout this process, we advocate for the active involvement of the patient's family members in collaborative monitoring and management to enhance and optimize the patient's health outcomes.
Moderate Diabetes Risk	**Follow-up**	**1.Outpatient clinic follow-up:** (1) Frequency: Once every 2 months. (2) Content: Evaluate the comprehensive disease control, the severity of acute events, and the adaptability of ongoing nursing plans. Conduct a hierarchical reassessment every 6 months or upon changes in the condition and promptly adjust management measures. **2.Telephone calls follow-up:** (1) Frequency: Once every 2 months. (2) Content: Primarily inquire about the patient's recent blood sugar control, oversee the implementation of the patient's ongoing nursing plan, enhance personalized guidance, address questions online, and notify patients of the schedule and location of large-group educational sessions.
	Health education	**1.Large class education:** (1) Frequency: Once every 2 months. (2) Duration: 1 hour per session. (3) Number of people: 50-80 people. (4) Method: Lecture, peer education, experiential patient education, live webcast. (5) Content: Based on Low Diabetes Risk, focus on the prevention and treatment of acute and chronic complications of diabetes and medication guidance. **2.Groups education:** (1) Frequency: Once every 1 months. (2) Duration: 1 hour per session. (3) Number of people: 10-15 people. (4) Method: Face-to-face teaching and teaching methods for counter-teaching. (5) Content: Mainly educate patients with common professional nursing problems and demonstrate education and invasive operation skills for complications nursing.
	Personalized guidance	**1.Time:** Initial evaluation/re-evaluation/changes in condition. **2.Form:** Face-to-face communication or questionnaire survey, personalized guidance programs are tailored by a multidisciplinary team based on assessment results, individual conditions, and patient needs. **3.Content:** **(1) Blood glucose monitoring guidance:** ① Determine the FPG, 2hPG monitoring frequency according to the patient's medication and blood sugar fluctuations (HbA1c should be monitored every 3 months in the absence of special circumstances); ② Teach patients the correct use of the blood glucose meter. **(2) Exercise guidance:** ① Assess if the patient has any contraindications to exercise. If so, discontinue exercise until the condition stabilizes, then gradually reintroduce exercise. ② Evaluate the patient's exercise capacity and, based on the assessment results, identify the suitable exercise intensity, type, and duration for the patient.

		(3) Dietary guidance: ① Assess the patient's nutritional status and dietary habits, and analyse the existing problems in the patient's current dietary situation; ② Fully consider the nutritional needs of patients with comorbidities and chronic complications; ③ Calculate the patient's total daily energy requirement and food exchange portions, and develop a personalized weekly menu for the patient, and teach the patient how to change the menu content on their own. **(4) Medication guidance:** ① Patients with comorbidities should consider whether the medications exhibit antagonistic or synergistic effects; ② Patients with chronic complications should receive emphasis on medication dosage and usage instructions; ③ Patients requiring invasive or aseptic procedures are recommended to seek treatment at a specialized outpatient clinic. **(5) Complication guidance:** ① Inform the patient/main caregiver about the frequency and specific timing for monitoring chronic complications; ② Assess the risk factors for chronic complications of diabetes and implement appropriate interventions; ③ Highlight the preventive measures and care strategies for managing chronic complications of diabetes. **(6) Psychological guidance:** ① Evaluate and analyze the reasons behind the patient's anxiety or depression, provide encouragement, comfort, and assistance; ② Encourage the patient to actively engage in social activities; ③ Understand the patient's social background, engage with family members in communication, and manage conflicting factors; ④ Teach the patient techniques for emotional relaxation and, if needed, guide the patient through mindfulness-based stress reduction therapy conducted by a psychotherapist. **(7) Other guidance:** Recommend smoking and alcohol cessation. Hypoglycemia guidance: ① Guide patients/main caregivers to identify the symptoms of hypoglycemia and master emergency measures for hypoglycemia; ② Assess whether patients have factors that induce hypoglycemia, and guide them to avoid triggers or self-monitor their blood sugar when the above-mentioned triggers occur.
	Health monitoring	**1.Frequency:** Community nurses review information twice a month. **2.Form:** Patients under observation can offer timely feedback on blood glucose control, medication, diet, and exercise over the previous two weeks via WeChat, telephone, and other channels, assisted by family members. If a patient fails to provide feedback for a month or the quality of feedback is inadequate, the patient should follow up with a call to investigate the reasons and find solutions. Throughout this process, we advocate for the active involvement of the patient's family members in collaborative monitoring and management to enhance and optimize the patient s health outcomes.
Low Diabetes Risk	**Follow-up**	**1.Outpatient clinic follow-up:** (1) Frequency: Once every 3 months. (2) Content: Evaluate the comprehensive disease control, the severity of acute events, and the adaptability of ongoing nursing plans. Conduct a hierarchical reassessment every 6 months or upon changes in the condition and promptly adjust management measures. **2.Telephone calls follow-up:** (1) Frequency: Once every 3 months. (2) Content: Primarily inquire about the patient's recent blood sugar control, oversee the implementation of the patient's ongoing nursing plan, enhance personalized guidance, address questions online, and notify patients of the schedule and location of large-group educational sessions.
	Health education	**1.Large class education:** (1) Frequency: Once every 1 months. (2) Duration: 1 hour per session. (3) Number of people: 50-80 people. (4) Method: Lecture, peer education, experiential patient education, live webcast. (5) Content: Focus on diabetes basic knowledge education and lifestyle guidance, helping patients establish healthy beliefs and disease management awareness, and establish a healthy lifestyle.

	Personalized guidance	**1.Time:** Initial evaluation/re-evaluation/changes in condition. **2.Form:** Face-to-face communication or questionnaire survey, personalized guidance programs are tailored by a multidisciplinary team based on assessment results, individual conditions, and patient needs. **3.Content:** **(1) Blood glucose monitoring guidance:** ① Determine the FPG, 2hPG monitoring frequency according to the patient's medication and blood sugar fluctuations (HbA1c should be monitored every 6 months in the absence of special circumstances); ② Teach patients the correct use of the blood glucose meter. **(2) Exercise guidance:** Furnish diabetic patients with exercise guidelines, elucidating exercise choices, intensity levels, guiding principles, precautions, and emergency measures for adverse events. **(3) Dietary guidance:** Issuing diabetes dietary guidance manuals and disseminating knowledge on diabetes nutrition; specifying principles, classifications, and glycemic index of common foods; teaching patients/main caregivers to assess total caloric intake and food exchange portions. **(4) Medication guidance:** ① Oral Medication Guidance: Emphasize the importance of adhering to the prescribed medication regimen and do not stop or change the type and dosage of medication without authorization; Educate patients or primary caregivers to understand the names, dosages, administration instructions, potential side effects, mitigation strategies, and precautionary measures associated with hypoglycemic drugs; ② Injection Guidance for Hypoglycemic Drugs: Provide patients with insulin injection guidance manuals and demonstrate the injection method. **(5) Complication guidance:** ① Notify patients/caregivers to undergo regular screenings for the retina, kidneys, heart, lower limb arteries, and foot examinations; ② Provide patients with education on preventive measures and care for complications; ③ Evaluate patients' potential risk factors and actively address, correct, and improve health outcomes. **(6) Psychological guidance:** ① Inform the patient about the impact of emotional changes on blood sugar fluctuations; ② Encourage the patient to express their inner feelings and thoughts, actively listen to the patient's concerns, share successful cases of blood sugar control, assist the patient in building the confidence to overcome the disease, promote participation in community activities, and seek support from family members; ③ Inform the patient to seek medical attention or contact the 24-hour psychological counseling hotline if psychological issues significantly impact their enthusiasm for life or sleep. **(7) Other guidance:** Recommend smoking and alcohol cessation. Hypoglycemia guidance: ① Guide patients/main caregivers to identify the symptoms of hypoglycemia and master emergency measures for hypoglycemia; ② Assess whether patients have factors that induce hypoglycemia, and guide them to avoid triggers or self-monitor their blood sugar when the above-mentioned triggers occur.
	Health monitoring	**1.Frequency:** Community nurses review information twice a month. **2.Form:** Patients under observation can offer timely feedback on blood glucose control, medication, diet, and exercise over the previous two weeks via WeChat, telephone, and other channels, assisted by family members. If a patient fails to provide feedback for a month or the quality of feedback is inadequate, the patient should follow up with a call to investigate the reasons and find solutions. Throughout this process, we advocate for the active involvement of the patient's family members in collaborative monitoring and management to enhance and optimize the patient's health outcomes.

Footnote: FPG: Fasting Plasma Glucose; PBG: postprandial blood glucose; HbA1c: Glycated Hemoglobin.

TABLE 3 Timeline and overview of patient engagement and assessments in this study

	Enrolment	Allocation	Follow-up		Close-out
TIMEPOINT	**$-T_0$**	**Baseline (T_0)**	**1 months post-baseline (T_1)**	**3 months post-baseline (T_2)**	**6 months post-baseline (T_3)**
ENROLMENT					
Eligibility screen	x				
Informed consent	x				
Allocation		x			
INTERVENTIONS					
HCH-TTC					
ASSESSMENTS					
Demographics		x			
Primary outcomes					
HbA1c		x		x	x
FPG and PBG		x	x	x	x
Secondary outcomes					
Self management ability: SDSCA		x			x
Disease knowledge level: DKT		x			x
Diabetes treatment adherence		x			x
Diabetes complication rate		x			x
Nursing service satisfaction		x			x
Unplanned readmission rate		x			x

Footnote: HCH-TTC: Hospital-Community-Home Tiered Transitional Care Program; FPG: Fasting Plasma Glucose; PBG: postprandial blood glucose; HbA1c: Glycated Hemoglobin; SDSCA: Summary of Diabetes Self-Care Activities; DKT: Diabetes Knowledge Test.

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The authors RJM, YMW, ZZ made significant contributions to the concept and design of this article, participated in drafting the manuscript, and critically revised its important intellectual content. ML and HYW undertook overall coordination, whereas BYZ and MYS were responsible for data collection, organization, analysis, and interpretation. All authors have given their final approval for the submitted version. YMW has agreed to be accountable for all aspects of the work, ensuring that questions related to the accuracy or integrity of any part of the work are appropriately addressed and resolved.

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A Pragmatic, Multicenter, Randomized Controlled Trial of a Hospital-Community-Home Tiered Transitional Care (HCH-TTC) Program for Individuals with Type 2 Diabetes: A Study protocol

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A Pragmatic, Multicenter, Randomized Controlled Trial of a Hospital-Community-Home Tiered Transitional Care (HCH-TTC) Program for Individuals with Type 2 Diabetes: A Study protocol

Abstract

Introduction: Type 2 Diabetes Mellitus (T2DM) and its complications significantly increase the risk of premature mortality and disability among patients, placing a considerable burden on socio-economic development. Evidence shows that effective transitional care can improve health outcomes for patients with T2DM. However, T2DM transitional care faces challenges including service discontinuity, communication breakdowns, and a lack of personalized design, leading to potential issues of under-treatment and overtreatment, increasing the risk of improper blood sugar management. To address these challenges, our research team developed the HCH-TTC program for patients with T2DM, aiming to evaluate its effectiveness and feasibility through a randomized controlled trial (RCT).

Method and analysis: The multicenter, pragmatic, double-blind RCT will enroll 180 patients with T2DM from the Jinqiao Medical Union in Pudong New Area, Shanghai, China. Participants will be randomly assigned to either the experimental group or the control group. The experimental group will participant in a 6-month HCH-TTC program, which provides personalized transitional care strategies tailored to patients' evolving health conditions and nursing needs. This tiered management approach includes follow-up, health education, personalized guidance, and health monitoring, with variations in intensity, frequency, and type based on individual requirements. The control group will receive Hospital-Community-Home Routine Transitional Care (HCH-RTC) program, consisting of routine follow-up, health education, and health monitoring during the same period. Data collection will be conducted at baseline, 1 month post-intervention, 3 months, and 6 months. The primary outcomes being glycated hemoglobin (HbA1c), fasting plasma glucose

(FPG), and 2-hour postprandial blood glucose (2hPPG). Secondary outcomes include diabetes knowledge level, diabetes self-management ability, diabetes treatment adherence, nursing service satisfaction, diabetes complications rate and unplanned readmission rate. Statistical analysis will employ independent sample *t*-tests and repeated measures analysis of variance (ANOVA).

Ethics and dissemination: The Gongli Hospital Ethics Committee (GLYY1s2021-010) approved the study. Results will be disseminated through publication in a peer-reviewed journal.

Trial registration： Chinese Clinical Trial Registry ChiCTR2200063322

Keywords： Diabetes Mellitus, Clinical Trial Protocol, Randomized Controlled Trial, Transitional Care, HCH-TTC

Strengths and limitations of this study

(1) This is the first study to explore the integration of multidisciplinary collaboration and hospital-community-home care within a tiered transitional care framework for diabetes management..

(2) The study is designed as a multicenter, pragmatic, double-blind RCT, minimizing selection bias and enhancing the credibility of its findings, including community and public involvement to increase the practicality and applicability of the study results.

(3) The intervention introduces an innovative way based on tiered management and supported by multidisciplinary teams, allowing transitional care strategies to be tailored to diabetes risk and individual patient needs.

(4) A limitation is the short duration of the intervention, which spans only six months, without assessing long-term effects or cost-effectiveness.

(5) As the study is conducted in China, its findings may have limited generalizability to other countries with differing healthcare systems and approaches.

1 INTRODUCTION

China, as the world' s largest developing country, is experiencing a surge in diabetes cases due to rapid urbanization, increased migration, an aging population,

and lifestyle changes.[dataset] [1] The diabetic population is projected to reach 130 million by 2030, with prevalence rates expected to soar to 19.8%. This escalation poses significant health risks, as Type 2 Diabetes Mellitus (T2DM) can lead to critical complications like neurological, kidney, and retinal disorders, greatly elevating the risk of premature mortality and disability.[dataset] [2,3] These health consequences, alongside the economic pressure (diabetes-related costs in China reached $141.58 billion in 2015, equivalent to 1.3% of GDP), emphasize the critical need to tackle this escalating epidemic.[dataset] [4] Diabetes poses a significant threat to China's public health and economic stability, underscoring the necessity for effective management and prevention strategies against this widespread chronic disease.

1.1 Background

The key to managing diabetes is glycemic control. Effective glycemic control can prevent complications and reduce the burden of diabetes. In China, the prevalence of adequate glycemic control among patients with diabetes in 2018 was 50.1%.[dataset] [5] However, there remains a gap from the target set by the China Chronic Disease Prevention and Control Plan (2012-2015), which aimed for a 60% rate of glycemic control among patients with diabetes in China by 2015.[dataset] [6] Reasons for this gap include poor self-management ability in patients with T2DM, limited awareness of the disease, and a low treatment rate.[dataset] [5] Public health institutions must intensify efforts to enhance glycemic control in patients with T2DM by improving self-management abilities, increasing disease knowledge, and ensuring adherence to comprehensive treatment plans.

Transitional care extends professional care beyond hospital settings and incorporates various care models, including the Guided Care Model, and the Geriatric Resources for Assessment and Care of Elders model (GRACE).[dataset] [7-15] Its goal is to provide discharged patients with continuous, professional care over the long term. This includes follow-up services such as health education, disease monitoring, and additional support, delivered through a variety of methods including phone calls, text messages, and home visits. In China, the independently operated medical models

often result in poor coordination and linkage between healthcare institutions, leading to prolonged care services and disruptions in information flow. This leads to patients with T2DM experiencing a lack of sustained professional guidance and consistent care support outside the hospital, thereby increasing the likelihood of poor glycemic control and unplanned rehospitalizations. Moreover, transitional care models have limitations in their personalized design.[dataset] [16] They often overlook changes in patients' conditions and service needs, which can lead to significant problems. These include "under-treatment", where high-risk patients with diabetes with glycated hemoglobin (HbA1c) ≥ 8.5%, severe complications, and multiple unplanned rehospitalizations do not receive adequate attention and care. Conversely, "overtreatment" occurs when low-risk patients with stable conditions and no risk factors for HbA1c < 7% receive excessive medication and nursing interventions. Such issues can diminish patient satisfaction with transitional care services and increase the rates of loss to follow-up.[dataset] [17] Given these critical issues, it is critical to recognize the limitations of the conventional transitional care model for T2DM. There is an urgent need to develop and implement a more efficient transitional care management strategy to meet the pressing demands.

In recent years, despite improvements in China's medical resource allocation, challenges persist due to resource shortages and regional imbalances.[dataset] [18] Consequently, there's a growing exploration into utilizing the synergy of hospital-community-home collaboration, aiming to achieve complementary advantages and develop sustainable care models for the future of China's healthcare system. In addressing this challenge, our research team developed the Hospital-Community-Home Tiered Transitional Care Program (HCH-TTC).[dataset] [19] The program was based on comprehensive literature reviews, rigorous quality evaluations, and qualitative studies involving patients and healthcare professionals, and was further enhanced through expert consultations. It is specifically tailored to China's healthcare system. The program is designed to integrate the diagnostic and treatment capabilities of hospitals with the community's geographical accessibility and follow-up support, while also leveraging the benefits of long-term familial care.

By adopting a stratified management model, we offer individualized transitional care services that are specifically tailored to the dynamic conditions and particular requirements of patients with T2DM. HCH-TTC is expected to further enhance collaboration among the medical system, healthcare professionals, patients with T2DM, and their families. This initiative seeks to integrate and optimize valuable nursing resources, thereby ensuring smooth transitions for patients from hospitals to post-acute care settings, enhancing health outcomes, increasing satisfaction with nursing services, and decreasing the rates of diabetes complications and unplanned readmissions. Given that the program was developed based on China's healthcare context, future research could potentially involve feasibility and pilot studies to evaluate the its generalizability and effectiveness in different healthcare settings. Such studies would be crucial in determining the program's generalizability beyond China's healthcare context.

1.2 Conceptual Framework

The HCH-TTC conceptual framework, as shown in Figure 1,[dataset] [19] incorporates the Bio-psycho-social Medical Model [dataset] [20] and the Triangle Chronic Disease Stratified Management Model (Triangle model) [dataset] [21,22] during the framework design process, clarifying the internal hierarchical relationships of the variable system and the dynamic intervention process. It can be used to guide the pragmatic application of the HCH-TTC Program. The practice will be carried out through the collaboration of hospitals communities, and families. We will use the Triangle Model to guide the strategy and techniques for implementation, while the Bio-psycho-social Medical Model will be utilized to assess the diabetes risk levels systematically. In the context of collaboration among hospitals, communities, and families, our aim is to establish a multidisciplinary team spearheaded by the hospital. The multidisciplinary team, led by the hospital, comprises experts in diabetes healthcare and nursing, clinical staff, sports rehabilitation specialists, dietitians, pharmacists, psychotherapists, and specialized medical personnel addressing diabetic complications. These professionals are drawn from a tertiary comprehensive hospital

and a community health service center. All team members have more than five years of relevant experience, with expert-level members possessing over fifteen years of expertise. The team will provide customized guidance and support tailored to patients' needs and diabetes risk levels. In addition, family members will be invited to participate throughout the intervention process, aiding healthcare professionals in comprehending relevant information regarding the patient's illness, supervising and encouraging patients in their home self-management. This aims to promote the comprehensive implementation of the project and ensure timely feedback of information. This approach will furnish patients with ongoing graded follow-up, health education, health monitoring, and additional transitional care services, facilitating a seamless transition from the hospital to non-acute settings and ensuring the effective progress of the study. It is noteworthy that the Hospital-Community-Hamily cooperation transitional care program has demonstrated favorable outcomes in the management of patients with T2DM in China and represents a relatively mature approach.[dataset] [23]

2 THE STUDY

2.1 Aims

Our overarching aim is to evaluate the effectiveness of the HCH-TTC for patients with T2DM, comparing it to the HCH-RTC approaches in terms of enhancing patient health outcomes, nursing service satisfaction, reducing the rates of diabetes complications and unplanned readmissions within the constraints of limited healthcare resources. The specific aims included:

(1) To evaluate the HCH-TTC intervention's effectiveness on HbA1c control in patients with T2DM by measuring HbA1c changes at baseline, 3 and 6 months post-intervention, and comparing with HCH-RTC;

(2) To assess the HCH-TTC intervention's impact on FPG and 2hPPG control in patients with T2DM by measuring changes at baseline, 1 months, 3 months and 6 months post-intervention, and comparing with HCH-RTC;

(3) To measure changes in diabetes knowledge, self-management, and treatment

adherence due to the HCH-TTC intervention at baseline, 3 and 6 months post-intervention, and comparing with HCH-RTC;

(4) To compare changes in diabetes complications rate, unplanned readmissions rate, and nursing service satisfaction due to the HCH-TTC intervention at baseline and 6 months post-intervention, and comparing with HCH-RTC.

2.2 Methodology

2.2.1 Design

The research is a multicenter, pragmatic, double-blind randomized controlled trial (RCT), with blinding applied to the study participants, data collectors, and data analysts. The intervention will be known to the providers who are administering it; however, they will be unaware of the outcomes being studied. The participants were informed that they would be randomly allocated into two groups: the experimental group will receive a 6-month HCH-TTC program, while the control group will receive an HCH-RTC program during the same period. It is noteworthy that the intervention protocols for the experimental and control groups are comparable. Both groups receive continuous, coordinated, comprehensive, and efficient care services provided by multidisciplinary teams within a hospital-community-home linkage model, with the primary distinction being the different management strategies employed. To achieve participant blinding, the intervention sites will be located in four independent community health service centers, thereby avoiding potential unblinding due to participant interaction. The specific details of each intervention were not disclosed until the intervention period began. Upon completion of the trial, participants will receive a letter disclosing their group assignment, detailed intervention information, and outcome changes. Through these strategies, we aim to minimize the likelihood of participants identifying their intervention type, thereby ensuring their benefits without knowledge of specific group allocation. This approach maintains the integrity of blinding and the randomization process, protecting the rights and welfare of the patients.

2.2.2 Study setting and recruitment plan

The implementation period of this study is from April 2021 to December 2024. From November 2023, the trial will select 180 participants through large-scale diabetes health education activities within the Jinqiao Medical Consortium in Pudong New Area, Shanghai. The JinQiao Medical Union, under the leadership of the Pudong New Area Gongli Hospital in Shanghai, comprises four community health service centers in JinQiao, Yangjing, Jinyang, and Hudong. The research team members will identify potential participants meeting the inclusion criteria from the clinical database of Jinqiao Medical Alliance. A written medical certificate provided by the responsible physician or nurse of each participant will serve as a prerequisite for inclusion in the study. Subsequently, the research team members will conduct face-to-face interviews with eligible patients, providing them with a participant information booklet outlining the study's purpose and specific protocol, displaying study promotional posters, and assessing their interest in participation to determine their willingness to join. Those expressing interest will undergo screening assessments. Upon passing these assessments, the research team members will provide written informed consent forms, invite participants to sign after obtaining their consent, and complete baseline data collection by trained data collectors. As of December 2023, a total of 232 participants have undergone eligibility assessments for this study. Following a rigorous screening process, 180 participants have been successfully recruited.

The inclusion criteria are as follows: (1) A diagnosis of type 2 diabetes; (2) Aged 18 years or older; (3) Inadequately glycemic control, with HbA1c levels at or above 7.0% (53 mmol/mol) in the past month;[dataset] [24] (4) Participants capable of adhering to the intervention protocol's specified timing and frequency are regularly attending follow-up consultations, health education sessions, health monitoring activities, and other transitional care services; (5) Possession of self-monitoring blood glucose instruments or the ability to measure at community health service centers; (6) Stable internet conditions for long-term use of smartphones and applications; (7) Voluntary participation and signing of an informed consent form after receiving a thorough explanation. The exclusion criteria are as follows: (1) Pregnant or lactating women;

(2) Individuals with serious complications or comorbidities; (3) Those experiencing cognitive impairments, communication and reading difficulties, or mental illness; (4) Patients participating in long-term interventions at other medical care facilities after discharge.

We conducted a power analysis using two-sample *t-tests* for sample size calculation. The primary outcome is the difference in HbA1c levels between the intervention and control groups after 6 months. Based on our previous research on the effectiveness of HbA1c interventions in transitional care for T2DM,[dataset] [5] with α=0.05 (u_α=1.96) and β=0.10 (u_β=1.282), and assuming a standardized effect size (δ/σ) of 0.47, we performed an effectiveness analysis assuming equal sizes for both groups. Using Power Analysis and Sample Size software (PASS 2008, NCSS Corporation) we calculated that n_1=n_2=72, with a total of 144 participants. Considering a potential 20% dropout rate, we determined that at least 180 participants are needed for the study, with 90 in each group.

2.2.3 Randomization

After the completion of participant recruitment, study participants will be sequentially numbered from 001 to 180 based on the order of enrollment, and they will be randomized following the completion of baseline data collection (Figure 2). Independent researchers utilized SPSS 26.0 software to generate random numbers (with the random number generator set seed at 180) and allocated study participants randomly into intervention and control groups in a 1:1 ratio.

2.2.4 Study intervention

2.2.4.1 HCH-RTC Program for the control group

Ninety patients with T2DM in the control group will receive routine transitional care services provided by a multidisciplinary team within a hospital-community-home linkage model, referred to as the HCH-RTC service program. During their hospital stay, patients will undergo diabetes risk assessments and health strategy development by a multidisciplinary team. After discharge, they will receive uniform follow-up

care. At the beginning of each subsequent month, they will receive telephone follow-ups from healthcare providers and participate in face-to-face health education lectures. Upon reaching the sixth month of intervention, patients will undergo a hospital follow-up to re-evaluate their health status and make necessary adjustments to their diabetes management plan accordingly.

2.2.4.2 HCH-TTC Program for the experimental group

The experimental group, comprising 90 participants, will be enrolled in a comprehensive six-month HCH-TTC service program structured into three distinct stages, each with specific objectives and processes:

Tiered Assessment Process:

Step 1 Evaluation: The initial phase will involve a comprehensive assessment of participants' health status and service needs across bio-psycho-social dimensions. This evaluation, performed by trained clinical nurses or researchers, assesses the patient' s disease duration, blood sugar control, and complications based on self-reported information, medical records, and in conjunction with glucose metabolism index testing and complication screening. Subsequently, the patient' s self-management ability, daily activity capacity, diabetes knowledge, treatment adherence, social support, and level of depressionis are evaluated through face-to-face questionnaire surveys. The references and psychometric properties of the questionnaire used can be found in Table 1 and the outcome measures.

Step 2 Stratification: Based on the collected data, a diabetes expert team, composed of four doctors with over 15 years of experience from the endocrine department of the tertiary general hospital within the Jinqiao Medical Union, will categorize participants into three risk categories—high, moderate, and low risk of diabetes—according to the tiered assessment criteria outlined in Table 1. Within the tiered assessment criteria, a total of 13 indicators serve as the basis for evaluating diabetes risk levels, it is plausible for a single patient to meet the criteria for multiple categories. Given the "irreversible" nature of certain indicators (e.g., "diabetes duration" and complications) and the "dynamic" nature of others (e.g., "average blood

glucose over the past week" and "HbA1c within the last three months"), adherence to the principles of dynamic evaluation and tiered transitions of diabetes risk levels is paramount. This approach aims to prevent patients with lengthy disease histories but who exhibit effective blood glucose control and high self-management scores from being erroneously classified into the "high-risk" stratum. Post expert consultations and group discussions, we have established the median count of criteria in the tiered assessment as the cutoff point to define the following hierarchical classification criteria: (1) Participants meeting two or more criteria for the high-risk level will be classified as "high-risk"; (2) Participants meeting one high-risk criterion and six or more moderate-risk criteria will be classified as "moderate-risk"; (3) Participants meeting no high-risk criteria but six or more low-risk criteria will be classified as "low-risk". These hierarchical classification criteria were developed based on expert consultations and group discussions.

Step 3 Connection: Following stratification, diabetes specialist nurses will compile comprehensive health records for each participant, including essential data like diagnosis, treatment history, and risk category. These records will serve as the basis for establishing a connection with local community health service centers, ensuring continuity of care.

Tiered Transition Care: This phase will be delivered through a collaborative effort between general practitioners and diabetes specialist nurses, as shown in Table 2, and is divided into four key components:

(1) Follow-up: Participants will receive regular follow-ups, which may include outpatient visits and telephone check-ins. The frequency and specifics of these follow-ups will be varied based on the patient's risk level, ensuring a personalized approach to care.

(2) Health education: Aims to assess the health education needs of participants at different stages, observe their behavior change processes, and facilitate stratified education to help patients at various risk levels maximize their self-care skills, improve glycemic control, enhance health outcomes, and elevate quality of life. This multifaceted component will comprise large group lectures, small group sessions, and

individual case management, each targeting different educational needs based on risk levels. Methods will include lectures, peer education, and experiential patient education. Topics will range from basic diabetes management for low-risk individuals to comprehensive disease management and quality of life improvement for those at high risk. Special focus will be given to practical skills and coping strategies for managing complications and adapting to life with diabetes. All health education personnel are specialized, certified, and have undergone uniform training and assessment. Standardized educational materials and teaching processes will be employed, accompanied by printed summaries of key health education knowledge. After the health education sessions, tiered knowledge will be disseminated through WeChat groups online for review and preservation. Additionally, participant feedback and suggestions will be considered to further optimize the program.

(3) Personalized guidance: This guidance plan aims to tailor interventions to the unique circumstances of each participant, emphasizing seven critical areas of diabetes management, including blood glucose monitoring, physical activity, dietary management, medication therapy, prevention of complications, mental health, and emergency response strategies for hypoglycemia. The plan is developed by a multidisciplinary team that will integrate these guidelines into follow-up consultations and educational activities, thereby ensuring that participants receive consistent and personalized support. The multidisciplinary team will leverage their expertise to provide detailed, pragmatic, and personalized guidance. This includes tailoring exercise programs by considering patient preferences, health conditions, and specifying appropriate intensity, frequency, and duration; calculating energy requirements; developing dietary plans with balanced nutrient ratios; and providing essential precautions and recommendations.

(4) Health monitoring: Leveraging digital platforms like WeChat and traditional methods like telephone feedback, this component will encourage active participation from both patients and their families in monitoring key health indicators. Regular check-ins will help track progress and maintain engagement, while also providing a mechanism for timely intervention if necessary.

Table 1 Tiered assessment criteria for patients with T2DM

	Tiered criteria
High Diabetes Risk	1. Diabetes duration: >20 years. 2. Average blood sugar levels in the past week (FPG, 2HPG): FPG ⩾10mmol/L and 2hPG >13.9mmol/L. 3. Glycated hemoglobin (HbA1c) levels in the past 3 months: (1) <60 years old: HbA1c >8.0%; (2) ⩾60 years old: HbA1c >9.0%. 4. Incidence of hypoglycemia in the past month (meeting any of the following criteria): (1) Incidence of level 1 hypoglycemia or clear reason for level 2 hypoglycemia occurs ⩾3 times; (2) Significant daily blood sugar fluctuations are present; (3) Incidence of severe level 3 hypoglycemia occurs ⩾1 time; (4) Incidence of unexplained level 2 hypoglycemia is ⩾1 time. 5. Incidence of acute diabetes complications in the previous year (DKA/HHS/diabetic lactic acidosis): ⩾2 occurrences. 6. Chronic complications of diabetes (meeting any of the following criteria): (1) Diabetic foot: Wagner classification falls within levels 3-5; (2) Diabetic nephropathy: CKD is at stage ⩾G3b; (3) Diabetic retinopathy: severe NPDR or DR present; (4) Diabetic neuropathy (DPN): symptomatic DPN observed; (5) Lower extremity arterial disease in diabetes (LEAD): Fontaine stage falls within stages ⅡⅠb-Ⅳ. 7. Complications: ⩾2 or history of cardiovascular and cerebrovascular diseases. 8. Diabetes self-management ability: SDSCA <46.2 points. 9. Activities of daily living: ADL ⩽40 points. 10. Diabetes knowledge: DKT ⩽20 points. 11. Treatment adherence: Treatment compliance scale score ⩽20 points. 12. Social support status: SSRS <20 points. 13. Mental health: GDS-5 >2 points, without relief after self-regulation or moderate to severe depression.
Moderate Diabetes Risk	1. Diabetes duration: 10-20 years. 2. Average blood sugar levels in the past week (FPG, 2HPG): (1) <60 years old: 7mmol/L ⩽ FPG <10 mmol/L, 2hPG arbitrary value or fasting blood sugar ⩾10mmol/L, 2hPG ⩽13.9mmol/L; (2) ⩾60 years old: FPG <10mmol/L, 2hPG ⩾12mmol/L or FPG ⩾10mmol/L, 2hPG ⩽13.9mmol/L. 3. Glycated hemoglobin (HbA1c) levels in the past 3 months: For non-pregnant adults: (1) <60 years old: 7.0% ⩽ HbA1c <8.0%; (2) ⩾60 years old: 8.0% ⩽ HbA1c ⩽9.0%. 4. Incidence of hypoglycemia in the past month (meeting any of the following criteria): Incidence of grade 1 or definite cause of grade 2 low blood sugar 2 times. 5. Incidence of acute complications of diabetes in the past year (DKA/HHS/Diabetic lactic acidosis): 1 time. 6. Chronic complications of diabetes (meeting any of the following criteria): (1) Diabetic foot: Wagner classification falls within levels 0-2; (2) Diabetic nephropathy: CKD is at stage G1-G3a; (3) Diabetic retinopathy: No obvious retinopathy or mild NPDR or moderate NPDR; (4) Diabetic neuropathy (DPN): Asymptomatic DPN; (5) Lower extremity arterial disease in diabetes (LEAD): Fontaine stage falls within stages I-IIa. 7. Complications: 1 and no history of cardiovascular and cerebrovascular disease. 8. Self-management ability of diabetes: 46.2 points ⩽ SDSCA <61.6 points. 9. Daily activity ability: 40 points < ADL ⩽60 points. 10. Diabetes knowledge: 21 points. ⩽ DKT <59 points. 11. Treatment adherence: Treatment compliance score <40 points, >20 points. 12. Social support status: 20 points ⩽ SSRS <30 points. 13. Mental health: 1 points ⩽ GDS-5 ⩽2 points, partial relief after self-regulation or mild depression.

Low Diabetes Risk	1. Diabetes duration: <10 years. 2. Average blood sugar levels in the past week (FPG, 2HPG): (1) <60 years old: 4.4mmol/L ≤ FPG ＜7 mmol/L and 2hPG ≤10mmol/L; (2) ≥60 years old: 8mmol/L ≤ FPG ＜10mmol/L and 8mmol/L≤ 2hPG ＜12 mmol/L). 3. Glycated hemoglobin (HbA1c) levels in the past 3 months: (1) <60 years old: HbA1c ＜7.0%; (2) ≥60 years old: HbA1c ＜8.0%). 4. Incidence of hypoglycemia in the past month (meeting any of the following criteria): Grade 1 or definite reason for Grade 2 hypoglycemia ≤1 time. 5. Incidence of acute complications of diabetes in the past year (DKA/HHS/Diabetic lactic acidosis): 0 times. 6. Chronic complications of diabetes: None. 7. Complications: None. 8. Diabetes self-management ability: SDSCA ≥61.6 points. 9. Daily activity ability: ADL >60 points. 10. Diabetes knowledge: DKT ≥60 points. 11. Treatment adherence: Treatment compliance scale score 40～60 points. 12. Social support status: SSRS ≥30 points. 13. Mental health: GDS-5 score of 0, no depression.

Footnote: DKA: Diabetic Ketoacidosis; HHS: Hyperosmolar Hyperglycemic State; SDSCA: Summary of Diabetes Self-Care Activities scale (Cronbach's alpha = 0.918),[dataset] [25] using a Likert 8-point scale, each item is scored from 0 to 7, with a total of 11 items, higher total scores (maximum 77) reflect better self-management behaviors; DKT: Diabetes Knowledge Test questionnaire (Cronbach's alpha = 0.760),[dataset] [26] with a total of 23 items, the questionnaire score = (number of correct answers / total number of questions) × 100, higher total scores (maximum 100) indicate better mastery of diabetes knowledge by the patient; ADL: Activities of Daily Living questionnaire (Cronbach's alpha = 0.850),[dataset] [27] each item is scored as 5, 10 or 15 point for independent performance and 0 points for needing assistance, with a total of 10 items, higher total scores (maximum 100) reflect better overall functional independence; SSRS: Social Support Rating Scale (Cronbach's alpha = 0.796),[dataset] [28] with a total of 10 items, higher total scores (maximum 66) reflect better social support; GDS-5: Geriatric Depression Scale-5 (Cronbach's alpha = 0.810),[dataset] [29] using a Likert 2-point scale, affirmative answers are worth 1 point, while negative answers are worth 0 points, with a total of 5 items, higher total scores (maximum 5) reflect more severe the depression; Level 1 Hypoglycemia: Blood glucose <3.9 mmol/L and ≥3.0 mmol/L; Level 2 Hypoglycemia: Blood glucose <3.0 mmol/L; Level 3 Hypoglycemia: Severe event requiring assistance from another person, with changes in consciousness and/or physical status, but without specific blood glucose limits.

Table 2 Tiered transitional care（TTC）for patients with T2DM

	Tiered transitional care	
High Diabetes Risk	**Follow-up**	**1.Outpatient clinic follow-up:** When the condition changes. **2.Telephone calls follow-up:** Once every 1 months.
	Health education	**1.Large class education:** Once every 3 months; 1 hour per session; 50-80 people. Method: Lecture, peer education, experiential patient education, live webcast. Content: Based on Moderate Diabetes Risk, focus on pain and comprehensive disease management, emphasizing the improvement of life quality and social psychological adaptation. **2.Groups education:** Once every 1 months; 1 hour per session; 10-15 people. Method: Face-to-face teaching and teaching methods for counter-teaching. Content: Focus on common professional nursing problems and demonstrate invasive operation skills for complications in nursing. **3.Case Study:** Carry out for the seriously ill who cannot go out, and suggest hospitalization or home visits by the team when necessary.
	Personalized guidance	**1.Frequency:** Initial evaluation/re-evaluation/changes in condition. **2.Method:** Face-to-face or online communication. **3.Content: (1) Blood glucose monitoring guidance:** Determine monitoring frequency based on patients' medication and glucose fluctuation patterns, and guide on proper blood glucose meter usage. **(2) Exercise guidance:** Exercise therapy should be approached cautiously in the presence of acute or severe chronic complications. **(3) Dietary guidance:** The personalized diet plan for one month is developed by the nutritionist from the diabetes multidisciplinary team based on the patient' s nutritional assessment results. **(4) Medication guidance:** Ealuate the interactions of medications, focusing on dosage and usage. Invasive or aseptic procedures should be performed at specialized outpatient clinics. **(5) Complication guidance:** To reduce the incidence and progression of patient-related complications, primarily aiming to decrease disability and mortality rates. **(6) Psychological guidance:** Utilize peer education to boost patients' psychological resilience, and refer patients with severe mental health issues to specialized treatment centers. **(7) Other guidance:** Recommend smoking and alcohol cessation, evaluate hypoglycemia triggers and instruct patients/caregivers on symptom recognition and emergency response.
	Health monitoring	**1.Frequency:** Community nurses review information thrice a month. **2.Form:** Patients under observation should provide timely feedback on blood glucose management, medication adherence, diet, and exercise through WeChat, phone, and other channels, with family support. If feedback is not received for a month or is of poor quality, a follow-up call should be made to explore the reasons and identify solutions.
Moderate Diabetes Risk	**Follow-up**	**1.Outpatient clinic follow-up:** Once every 2 months. **2.Telephone calls follow-up:** Once every 2 months.
	Health education	**1.Large class education:** Once every 2 months; 1 hour per session; 50-80 people. Method: Lecture, peer education, experiential patient education, live webcast. Content: Based on Low Diabetes Risk, focus on the prevention and treatment of acu te and chronic complications of diabetes and medication guidance. **2.Groups education:** Once every 1 months; 1 hour per session; 10-15 people. Method: Face-to-face teaching and teaching methods for counter-teaching. Content: Focus on common professional nursing problems and demonstrate invasive o peration skills for complications in nursing.
	Personalized guidance	**1.Frequency:** Initial evaluation/re-evaluation/changes in condition. **2.Form:** Face-to-face or online communication. **3.Content: (1) Blood glucose monitoring guidance:** Determine monitoring frequency based on patients' medication and glucose fluctuation patterns, and guide on proper bl ood glucose meter usage. **(2) Exercise guidance:** Assess exercise contraindications, paus e until stabilization, then gradually resume while evaluating capacity to establish suitabl e intensity, type, and duration. **(3) Dietary guidance:** Evaluate the patient's nutrition, di

		etary patterns, and requirements, calculate daily energy needs, and create a weekly menu with instructions for self-modifications. **(4) Medication guidance:** Ealuate the interactions of medications, focusing on dosage and usage. Invasive or aseptic procedures should be performed at specialized outpatient clinics. **(5) Complication guidance:** Notify the monitoring schedule for chronic complications, evaluate risk factors, apply suitable interventions, and emphasize preventive measures and care strategies. **(6) Psychological guidance:** Assess the causes of the patient's anxiety or depression, offer support and encouragement, instruct on emotional relaxation techniques, and guide the patient through mindfulness-based stress reduction therapy with a psychotherapist if necessary. **(7) Other guidance:** Recommend smoking and alcohol cessation, evaluate hypoglycemia triggers and instruct patients/caregivers on symptom recognition and emergency response.
	Health monitoring	**1.Frequency:** Community nurses review information twice a month. **2.Form:** Patients under observation should provide timely feedback on blood glucose management, medication adherence, diet, and exercise through WeChat, phone, and other channels, with family support. If feedback is not received for a month or is of poor quality, a follow-up call should be made to explore the reasons and identify solutions.
Low Diabetes Risk	**Follow-up**	**1.Outpatient clinic follow-up:** Once every 3 months. **2.Telephone calls follow-up:** Once every 3 months.
	Health education	**Large class education：** Once every 1 months; 1 hour per session; 50-80 people. Method: Lecture, peer education, experiential patient education, live webcast. Content: Focus on diabetes basic knowledge education and lifestyle guidance, helping patients establish healthy beliefs and disease management awareness, and establish a healthy lifestyle.
	Personalized guidance	**1.Frequency:** Initial evaluation/re-evaluation/changes in condition. **2.Form:** Face-to-face or online communication. **3.Content: (1) Blood glucose monitoring guidance:** Determine monitoring frequency based on patients' medication and glucose fluctuation patterns, and guide on proper blood glucose meter usage. **(2) Exercise guidance:** Elucidating exercise choices, intensity levels, guiding principles, precautions, and emergency measures for adverse events. **(3) Dietary guidance:** Issuing diabetes dietary guidelines, detailing food classifications and glycemic indices, and educating patients/caregivers on caloric intake and food exchanges. **(4) Medication guidance:** Emphasize medication adherence; specify drug names, dosages, administration routes, side effects, mitigation strategies, and precautions for hypoglycemic agents. Provide manuals and demonstrate injection techniques. **(5) Complication guidance:** Guide patients/caregivers to routinely have retinal, renal, cardiac, lower limb arterial, and foot exams; educate on prevention and complication management; and evaluate risk factors to enhance health outcomes. **(6) Psychological guidance:** Educate the patient on how emotional fluctuations affect blood sugar, promote emotional expression and community involvement, actively listen to concerns, share success stories, enhance confidence, encourage family support, and recommend medical assistance or a 24-hour psychological counseling hotline if psychological issues severely impact quality of life or sleep. **(7) Other guidance:** Recommend smoking and alcohol cessation, evaluate hypoglycemia triggers and instruct patients/caregivers on symptom recognition and emergency response.
	Health monitoring	**1.Frequency:** Community nurses review information once a month. **2.Form:** Patients under observation should provide timely feedback on blood glucose management, medication adherence, diet, and exercise through WeChat, phone, and other channels, with family support. If feedback is not received for a month or is of poor quality, a follow-up call should be made to explore the reasons and identify solutions.

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2.2.5 Outcome measures

A summary of the timeline and an overview of patient engagement and assessments in this trial are presented in Table 3.

2.2.5.1 Primary outcomes

HbA1c, endorsed by the National Diabetes Association as a reliable indicator for monitoring blood sugar control in individuals with diabetes and widely utilized as a key outcome measure in diabetes research,[dataset] [30] will be the primary efficacy endpoint of this study. The assessment of the change in HbA1c levels will be conducted at three key time points from baseline (defined as the value obtained on the day of enrollment) to the efficacy evaluation period (defined as the values measured during outpatient follow-up from months 3 and 6 post-intervention), using venous whole blood samples (approximately 5 mL each) analyzed with the MQ-6000 glycated hemoglobin analyzer (Medconn Diagnostics, Shanghai, China). Skilled community diabetes specialist nurses will supervise these blood sample collections. The samples will be promptly dispatched to the researchers for analysis. The preparation of the blood collection tube reagent kit and the sample analysis will be carried out in the laboratory department of Pudong Gongli Hospital, Shanghai, China. The therapeutic target benchmarks for participants' HbA1c are set at value of $\leqslant$6.5% ($\leqslant$48 mmol/mol).[dataset] [31]

FPG and 2hPPG levels, will be the primary outcomes of this study. The change in FPG and 2hPPG levels will be assessed from baseline (defined as the value obtained on the day of enrollment) to the efficacy evaluation period (defined as the values measured during outpatient follow-up from months 1-month, 3-month and 6-month post-intervention). The assessment will be measured using the rapid blood glucose monitor from SINOMEDISITE in Beijing, China, with results recorded in mmol/L. During these procedures, the second droplet of blood will be selected for testing to ensure accurac, and values will be recorded immediately. The therapeutic target benchmarks for participants' FPG and 2hPPG are set at value of $\leqslant$7.0mmol/L and 11.1mmol/L, respectively.[dataset] [32]

2.2.5.2 Secondary outcomes

Diabetes self-management ability, diabetes knowledge level, diabetes treatment adherence, nursing service satisfaction, diabetes complication rate, and unplanned readmission rate will be the secondary outcomes of this study. The change in diabetes self-management ability, diabetes knowledge level, and diabetes treatment adherence will be assessed from baseline (defined as the value obtained on the day of enrollment) to the efficacy evaluation period (defined as the values measured during outpatient follow-up from months 3 and 6 post-intervention). The change in nursing service satisfaction, diabetes complications rate and unplanned readmissions rate will be assessed from baseline (defined as the value obtained on the day of enrollment) to the efficacy evaluation period (defined as the values measured in outpatient follow-up from month 6 post-intervention). The specific measurement methods for the secondary outcomes indicators are as follows:

Diabetes self-management ability is evaluated using the Summary of Diabetes Self-Care Activities (SDSCA) questionnaire,[dataset] [25] which has been translated into Chinese by Li and colleagues. Building on Toobert's original work, the SDSCA includes 11 items across 6 dimensions, designed to assess patients' self-management behaviors over the previous week, using a Likert 8-point scale, yielding a maximum total score of 77. With a Cronbach's α value of 0.918, it is the most widely used instrument for assessing the self-management abilities of individuals with diabetes.

Diabetes knowledge level is assessed with the Diabetes Knowledge Test (DKT) questionnaire,[dataset] [26] which has been translated into Chinese by Sun and colleagues, building upon the work of Fitzgerald. The DKT contains 23 items; the first 14 items are relevant for all patients, while the latter nine are tailored for those receiving insulin therapy. It has a Cronbach's α of 0.76 and a Content Validity Index (CVI) of 1, indicating good internal consistency and content validity.

Diabetes treatment adherence is assessed using the Diabetes Patient Treatment Adherence Scale designed by Chen.[dataset] [33] The scale includes 20 items across five domains: medication, diet, exercise, self-monitoring, and regular reexamination. The overall Cronbach's α is 0.86 and the CVI is 0.83, indicating good internal consistency

and content validity.

Diabetes complications rate: Diabetes complications refer to those that are newly developed during the study period such as diabetic ketoacidosis, hyperosmolar hyperglycemic state, as well as those diagnosed during the study period including diabetic nephropathy, diabetic retinopathy, diabetic neuropathy, diabetic peripheral arterial disease, and diabetic foot disease, making a total of 7 types of acute and chronic diabetes complications. The incidence rate of diabetes complications is calculated as the number of new acute or chronic complications divided by the total number of individuals multiplied by 100%.

Nursing service satisfaction: Evaluated using a self-designed Patient Satisfaction Survey, crafted by our research team, comprising 10 items. These items cover aspects such as overall satisfaction with nursing services, the ease of access to these services, the attitude of the nursing staff, and satisfaction with the provided health guidance and education. The pre-experimental exhibited a content validity of 0.73, and Cronbach's α coefficient stood at 0.85.

Unplanned readmissions rate: This metric is defined as the proportion of patients who unexpectedly return to the hospital due to diabetes or its complications It is calculated by dividing the number of unplanned readmissions by the total number of patients and then multiplying by 100%. The assessment timeframe spans from baseline to the outpatient follow-up at the 6th month post-intervention. Data collection will be carried out through patient self-reporting and verified by querying health records. Frequency analysis of the readmission rate data will be performed using SPSS statistical software to evaluate the intervention’ s effect.

463 **TABLE 3** Timeline and overview of patient engagement and assessments in this study

	Enrolment	Allocation	Follow-up		Close-out
TIMEPOINT	**$-T_0$**	**Baseline (T_0)**	**1 months post-baseline (T_1)**	**3 months post-baseline (T_2)**	**6 months post-baseline (T_3)**
ENROLMENT					
Eligibility screen	x				
Informed consent	x				
Allocation		x			
INTERVENTIONS					
HCH-TTC					
ASSESSMENTS					
Demographics		x			
Primary outcomes					
HbA1c		x		x	x
FPG and 2hPPG		x	x	x	x
Secondary outcomes					
Diabetes self-management ability: SDSCA		x		x	x
Diabetes knowledge level: DKT		x		x	x
Diabetes treatment adherence		x		x	x
Diabetes complication rate		x			x
Nursing service satisfaction		x			x
Unplanned readmission rate		x			x

464 **Footnote:** HCH-TTC: Hospital-Community-Home Tiered Transitional Care Program; FPG:
465 Fasting Plasma Glucose; 2hPPG: 2-Hour Postprandial Blood Glucose; HbA1c: Glycated
466 Hemoglobin; SDSCA: Summary of Diabetes Self-Care Activities; DKT: Diabetes Knowledge
467 Test.

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2.2.6 Data collection and safety monitoring

This study will collect data at four time points: baseline, 1 months, 3 and 6 months post-intervention. Two nurses from the hospital will be selected as data collectors and will receive comprehensive training covering patient recruitment discussions, informed consent procedures, and the collection of assessment data at Gongli Hospital. This training will last for two weeks. A key evaluation criterion for this training is the consistency of standardized patient assessment outcomes. Subsequently, the data collectors will conduct on-site surveys, providing participants with a brief overview of the project background and survey instructions. Assistance will be given to participants who are unable to complete the survey on their own, with care taken to avoid the use of suggestive or directive language. Table 3 presents a detailed schedule and overview of the patient participation and assessment procedures.

All research data will be encrypted and stored by the data management officer of the Nursing Department of the Gongli Hospital in Pudong New Area, Shanghai. The data will not be disclosed to the public, only accessible to internal research members for study, application, and paper writing. No one is authorized to modify or delete the data to prevent incidents such as information leakage, loss, or falsification. In addition, the data management officer must promptly report adverse events to the Pudong New Area Health Commission in Shanghai and provide regular reports. The Pudong New Area Health Commission in Shanghai will serve as the independent Data and Safety Monitoring Board (DSMB) for this research, reviewing the data security and providing appropriate recommendations.

2.2.7 Data analysis

After thorough verification, all collected data will be entered into an Excel spreadsheet for the creation of a comprehensive database. Independent statistical analysts will be engaged to perform data analysis utilizing SPSS version 26.0 for Windows (SPSS Inc., Chicago, Illinois, USA). Baseline data, including demographic and clinical characteristics, will be made through *chi-square* tests or independent

t-tests to confirm the equivalence of samples. Assuming a normal distribution for outcome variables, parametric testing methods will be applied. To evaluate the intervention's temporal effects on primary outcomes, the study will analyze differences in outcomes over time—baseline, 1 months, 3 and 6 months post-intervention—using repeated-measures ANOVA, focusing on the interaction effect (group × time). The analysis will follow the intention-to-treat (ITT) principles, and all data from every participant will be analysed. Missing data will be handled based on established guidelines for each measure or CONSORT-SPI statement. No interim analysis will occur. All statistical tests will be two-tailed, with a significance threshold set at a p-value of $\leqslant$.05.

2.3 Ethics and dissemination

This research protocol received approval from the Ethics Committee of Gongli Hospital, Pudong, Shanghai, China in November 2021 (GLYY1s2021-010) and is subjected to regular review. The study will provide participants with free testing for glycated hemoglobin, fasting blood sugar, and postprandial blood sugar on three occasions, as well as cover essential transportation expenses for participation in the study. Prior to enrollment, all participants will be thoroughly informed about the purpose, significance, procedures, potential risks, benefits, and the work they will be informed regarding what the trial will invite them to do. What' s more, they will be required to provide written informed consent. After enrollment, we ensure the confidentiality of participants' personal information, and blood samples used for laboratory tests will be promptly destroyed after testing. All research data and laboratory test results will be used strictly for project research and paper writing purposes.

Furthermore, due to the impact of the COVID-19 pandemic, the overall implementation of this research plan has been postponed by a year. Following consultation with experts and ethical committee review, specific indicators have been modified, clarified, and strengthened, and these revisions have been promptly updated in the Chinese Clinical Trial Registry. After the trial concludes, the four participating

communities can choose whether to continue using the project for ongoing care for Type 2 diabetes. Patients also have the right to decide whether to continue receiving transition care services in their communities. If harm is caused to patients as a result of this study, compensation will be determined by a third-party assessment agency.

Additionally, research results will be disseminated in the following manner: laboratory test results will be emailed to community intervention personnel in Excel format, and the results will be communicated to the patients. Survey scores will serve as the basis for adjusting intervention measures, will be published in paper form after the study, and the process of changes in outcome indicators will be verbally reported to patients and intervention implementers.

3 DISCUSSION

This study is, to the best of our knowledge, the first study to explore the integration of hospital, community, and home care within a tiered transitional care framework for diabetes, with the objective of evaluating its impact on health-related outcomes in individuals with T2DM. The outcomes assessed include HbA1c, FPG, and 2hPPG, alongside diabetes knowledge, self-management abiliy, treatment adherence, patient satisfaction with nursing services, rate of unplanned readmissions and diabetes complications.

Building upon the premise of our investigation, it is worth noting that existing literature on the tiered collaborative management of diabetes is scarce.[dataset] [34-37] This gap highlights the innovative nature of our study within the broader context of diabetes care. Notably, the work of Jia and colleagues emerges as a foundational effort in this field within China's healthcare settings.[dataset] [36] This study spearheaded a stratified diabetes management plan specifically tailored for primary care settings in China. This ambitious project involved the recruitment of 19,546 participants across 864 communities and executed a comprehensive cluster randomized controlled trial spanning two years. The intervention at the heart of this study leveraged mobile health services to provide patient-centered diabetes management within a tri-level framework. The results demonstrated significant enhancements in diabetes control

within primary care settings, thus presenting valuable insights into the management of chronic diseases and underscoring the potential efficacy of tiered, integrated care models like the one our current study seeks to evaluate. While the study [dataset] [37] conducted by Jia and colleagues covered various primary care institutions and engaged in collaboration with doctors in community primary care clinics and county-level hospitals to form a hierarchical structure of regional nursing teams, it did not implement a stratified management approach for patients with T2DM. The stratification of management remained purely at an organizational level, without addressing the need for differentiated management based on patients' varying diabetes risk levels. Moreover, the study primarily harnessed synergistic benefits within the primary healthcare sector, overlooking the pivotal role of tertiary comprehensive hospitals in diabetes care, including diagnosis, treatment, and patient education. It also overlooked the critical role of patient self-management and the potential for disease monitoring within the home environment.

In contrast, our HCH-TTC project aims to encompass the full spectrum of care from hospital treatment to home care post-discharge. To enhance pragmatic, the research team employed qualitative research methods in the early stages of project development, conducting face-to-face interviews with patients diagnosed with T2DM and specialized medical care personnel within the Jinqiao Medical Alliance. These interviews probed deeply into their needs and suggestions regarding tiered transitional care. The purpose of this project is to assemble a multidisciplinary expert team within the Jinqiao Medical Alliance, where team members will stratify patients according to their diabetes risk levels and customize transitional care strategies—varying in frequency, intensity, type, and content focus—to meet the specific needs and disease states of patients with T2DM at different stages. This approach aims to minimize disruptions in transitional care services and information flow, thereby addressing potential issues of overtreatment or undertreatment. Our goal is to improve patients' health outcomes, enhance satisfaction with care services, and reduce unplanned readmission rates and diabetes-related complications. The anticipated research outcomes aim to provide crucial insights into enhancing the effectiveness of

continuity of care plans for T2DM and formulating comprehensive national diabetes management strategies.

Furthermore, this research may have two limitations. First, due to time and budget constraints, the study will implement only a six-month intervention without including long-term follow-up or evaluating the intervention's effectiveness and cost-effectiveness beyond the trial period. Future research could address these limitations by examining the long-term efficacy and cost-effectiveness of the HCH-TTC program. Secondly, the HCH-TTC program developed in this study is specifically tailored to China's healthcare context. The generalizability and effectiveness may vary across difference countries, healthcare systems, and other contextual conditions. Future research should broaden its scope, adhering to the principle of maximum variation, to enhance the representativeness of research subjects and validate the feasibility and effectiveness of the HCH-TTC program for international application and dissemination.

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Contributors:

The authors RJM, YMW, ZZ made significant contributions to the concept and design of this article, participated in drafting the manuscript, and critically revised its important intellectual content. ML and HYW undertook overall coordination, whereas BYZ and MYS were responsible for data collection, organization, analysis, and interpretation. All authors have given their final approval for the submitted version. YMW has agreed to be accountable for all aspects of the work, ensuring that questions related to the accuracy or integrity of any part of the work are appropriately addressed and resolved. YMW is the guarantor. The corresponding author attests that all listed authors meet authorship criteria and that no others meeting the criteria have been omitted.

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Competing interests: No competing interests.

Community and public involvement:

In the initial phase of the study, patients with T2DM, through qualitative research methods, articulated their needs and recommendations for hierarchical and

graded continuing care, and were actively involved in the development of the intervention protocol for the experimental group. Four communities—Yangjing, Jinqiao, Jinyang, and Hudong—played a pivotal role in the research design, participant recruitment, data collection and interpretation, dissemination of the study protocol, and its subsequent implementation.

Patient consent for publication: Not applicable.

Provenance and peer review: Not commissioned; externally peer reviewed.

Data confidentiality and availability:

The study has been reviewed by the Ethics Committee of the Chinese Clinical Trial Registry, and the relevant ethical consent documents, funding documents, and trial data are available for review by the Editorial Office. Due to the data protection policies of the national government and relevant institutions regarding patient information, we will share the research data, subject to the approval of the Ethics Committee of Gongli Hospital in the Pudong New Area of Shanghai and the Data Safety Monitoring Committee, with units or individuals that meet the following sharing conditions one year after the publication of the main findings:

(1) Data Use Agreement: Data users are required to sign a data use agreement, committing to comply with specific conditions of use. These conditions include, but are not limited to, data protection, privacy security, and data purposes.

(2) Anonymization: To protect participant privacy, all shared metadata will be anonymized. Any information that could potentially identify individuals will be removed or modified.

(3) Non-Commercial Use: The data is intended for non-commercial use only, such as academic research, education, and other nonprofit activities. The data must not be used for any commercial purposes.

(4) Ethical Approval: Data users must provide proof of ethical approval to confirm that their data use behavior complies with relevant ethical and legal

requirements.

The data-sharing platform is ResMan.

The URL for the platform is: http://www.medresman.org.cn/login.aspx.

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Reference:

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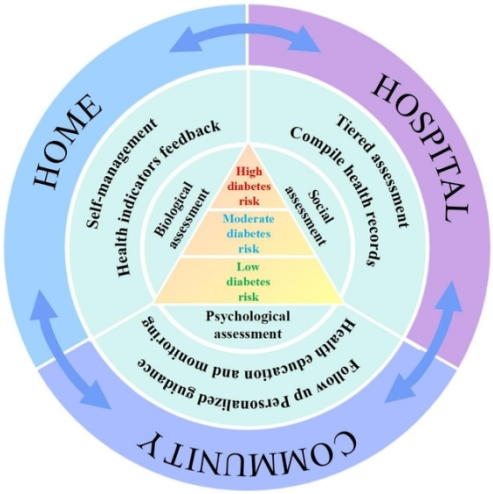
FIGURE 1 The HCH-TTC conceptual framework. HCH-TTC, Hospital-Community-Home Tiered Transitional Care.

FIGURE 2 CONSORT flowchart describing progress of participants through the trial. HCH-TTC, Hospital-Community-Home Tiered Transitional Care. HCH-RTC, Hospital-Community-Home Routine Transitional Care.



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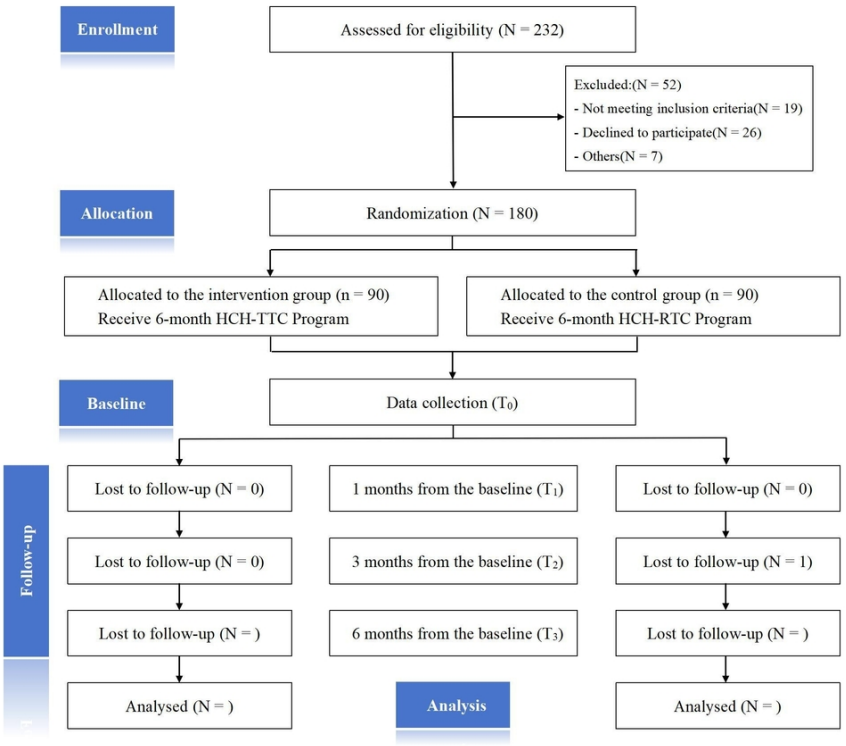

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A Pragmatic, Multicenter, Randomized Controlled Trial of a Hospital-Community-Home Tiered Transitional Care (HCH-TTC) Program for Individuals with Type 2 Diabetes: A Study protocol

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A Pragmatic, Multicenter, Randomized Controlled Trial of a Hospital-Community-Home Tiered Transitional Care (HCH-TTC) Program for Individuals with Type 2 Diabetes: A Study protocol

Abstract

Introduction: Type 2 Diabetes Mellitus (T2DM) and its complications significantly increase the risk of premature mortality and disability among patients, placing a considerable burden on socio-economic development. Evidence shows that effective transitional care can improve health outcomes for patients with T2DM. However, T2DM transitional care faces challenges including service discontinuity, communication breakdowns, and a lack of personalized design, leading to potential issues of under-treatment and overtreatment, increasing the risk of improper blood sugar management. To address these challenges, our research team developed the HCH-TTC program for patients with T2DM, aiming to evaluate its effectiveness and feasibility through a randomized controlled trial (RCT).

Method and analysis: The multicenter, pragmatic, double-blind RCT will enroll 180 patients with T2DM from the Jinqiao Medical Union in Pudong New Area, Shanghai, China. Participants will be randomly assigned to either the experimental group or the control group. The experimental group will participant in a 6-month HCH-TTC program, which provides personalized transitional care strategies tailored to patients' evolving health conditions and nursing needs. This tiered management approach includes follow-up, health education, personalized guidance, and health monitoring, with variations in intensity, frequency, and type based on individual requirements. The control group will receive Hospital-Community-Home Routine Transitional Care (HCH-RTC) program, consisting of routine follow-up, health education, and health monitoring during the same period. Data collection will be conducted at baseline, 1 month post-intervention, 3 months, and 6 months. The primary outcomes being glycated hemoglobin (HbA1c). Secondary outcomes

include , fasting plasma glucose (FPG), 2-hour postprandial blood glucose (2hPPG), diabetes knowledge level, diabetes self-management ability, diabetes treatment adherence, nursing service satisfaction, diabetes complications rate and unplanned readmission rate. Statistical analysis will employ independent sample *t*-tests and repeated measures analysis of variance (ANOVA).

Ethics and dissemination: The Gongli Hospital Ethics Committee (GLYY1s2021-010) approved the study. Results will be disseminated through publication in a peer-reviewed journal.

Trial registration： Chinese Clinical Trial Registry ChiCTR2200063322

Keywords： Diabetes Mellitus, Clinical Trial Protocol, Randomized Controlled Trial, Transitional Care, HCH-TTC

Strengths and limitations of this study

(1) This is the first study to explore the integration of multidisciplinary collaboration and hospital-community-home care within a tiered transitional care framework for diabetes management..

(2) The study is designed as a multicenter, pragmatic, double-blind RCT, minimizing selection bias and enhancing the credibility of its findings, including community and public involvement to increase the practicality and applicability of the study results.

(3) The intervention introduces an innovative way based on tiered management and supported by multidisciplinary teams, allowing transitional care strategies to be tailored to diabetes risk and individual patient needs.

(4) A limitation is the short duration of the intervention, which spans only six months, without assessing long-term effects or cost-effectiveness.

(5) As the study is conducted in China, its findings may have limited generalizability to other countries with differing healthcare systems and approaches.

1 INTRODUCTION

China, as the world's largest developing country, is experiencing a surge in diabetes cases due to rapid urbanization, increased migration, an aging population,

and lifestyle changes.[dataset] [1] The diabetic population is projected to reach 130 million by 2030, with prevalence rates expected to soar to 19.8%. This escalation poses significant health risks, as Type 2 Diabetes Mellitus (T2DM) can lead to critical complications like neurological, kidney, and retinal disorders, greatly elevating the risk of premature mortality and disability.[dataset] [2,3] These health consequences, alongside the economic pressure (diabetes-related costs in China reached $141.58 billion in 2015, equivalent to 1.3% of GDP), emphasize the critical need to tackle this escalating epidemic.[dataset] [4] Diabetes poses a significant threat to China's public health and economic stability, underscoring the necessity for effective management and prevention strategies against this widespread chronic disease.

1.1 Background

The key to managing diabetes is glycemic control. Effective glycemic control can prevent complications and reduce the burden of diabetes. In China, the prevalence of adequate glycemic control among patients with diabetes in 2018 was 50.1%.[dataset] [5] However, there remains a gap from the target set by the China Chronic Disease Prevention and Control Plan (2012-2015), which aimed for a 60% rate of glycemic control among patients with diabetes in China by 2015.[dataset] [6] Reasons for this gap include poor self-management ability in patients with T2DM, limited awareness of the disease, and a low treatment rate.[dataset] [5] Public health institutions must intensify efforts to enhance glycemic control in patients with T2DM by improving self-management abilities, increasing disease knowledge, and ensuring adherence to comprehensive treatment plans.

Transitional care extends professional care beyond hospital settings and incorporates various care models, including the Guided Care Model, and the Geriatric Resources for Assessment and Care of Elders model (GRACE).[dataset] [7-15] Its goal is to provide discharged patients with continuous, professional care over the long term. This includes follow-up services such as health education, disease monitoring, and additional support, delivered through a variety of methods including phone calls, text messages, and home visits. In China, the independently operated medical models

often result in poor coordination and linkage between healthcare institutions, leading to prolonged care services and disruptions in information flow. This leads to patients with T2DM experiencing a lack of sustained professional guidance and consistent care support outside the hospital, thereby increasing the likelihood of poor glycemic control and unplanned rehospitalizations. Moreover, transitional care models have limitations in their personalized design.[dataset] [16] They often overlook changes in patients' conditions and service needs, which can lead to significant problems. These include "under-treatment", where high-risk patients with diabetes with glycated hemoglobin (HbA1c) ≥ 8.5%, severe complications, and multiple unplanned rehospitalizations do not receive adequate attention and care. Conversely, "overtreatment" occurs when low-risk patients with stable conditions and no risk factors for HbA1c < 7% receive excessive medication and nursing interventions. Such issues can diminish patient satisfaction with transitional care services and increase the rates of loss to follow-up.[dataset] [17] Given these critical issues, it is critical to recognize the limitations of the conventional transitional care model for T2DM. There is an urgent need to develop and implement a more efficient transitional care management strategy to meet the pressing demands.

In recent years, despite improvements in China's medical resource allocation, challenges persist due to resource shortages and regional imbalances.[dataset] [18] Consequently, there's a growing exploration into utilizing the synergy of hospital-community-home collaboration, aiming to achieve complementary advantages and develop sustainable care models for the future of China's healthcare system. In addressing this challenge, our research team developed the Hospital-Community-Home Tiered Transitional Care Program (HCH-TTC).[dataset] [19] The program was based on comprehensive literature reviews, rigorous quality evaluations, and qualitative studies involving patients and healthcare professionals, and was further enhanced through expert consultations. It is specifically tailored to China's healthcare system. The program is designed to integrate the diagnostic and treatment capabilities of hospitals with the community's geographical accessibility and follow-up support, while also leveraging the benefits of long-term familial care.

By adopting a stratified management model, we offer individualized transitional care services that are specifically tailored to the dynamic conditions and particular requirements of patients with T2DM. HCH-TTC is expected to further enhance collaboration among the medical system, healthcare professionals, patients with T2DM, and their families. This initiative seeks to integrate and optimize valuable nursing resources, thereby ensuring smooth transitions for patients from hospitals to post-acute care settings, enhancing health outcomes, increasing satisfaction with nursing services, and decreasing the rates of diabetes complications and unplanned readmissions. Given that the program was developed based on China's healthcare context, future research could potentially involve feasibility and pilot studies to evaluate the its generalizability and effectiveness in different healthcare settings. Such studies would be crucial in determining the program's generalizability beyond China's healthcare context.

1.2 Conceptual Framework

The HCH-TTC conceptual framework, as shown in Figure 1,[dataset] [19] incorporates the Bio-psycho-social Medical Model [dataset] [20] and the Triangle Chronic Disease Stratified Management Model (Triangle model) [dataset] [21,22] during the framework design process, clarifying the internal hierarchical relationships of the variable system and the dynamic intervention process. It can be used to guide the pragmatic application of the HCH-TTC Program. The practice will be carried out through the collaboration of hospitals communities, and families. We will use the Triangle Model to guide the strategy and techniques for implementation, while the Bio-psycho-social Medical Model will be utilized to assess the diabetes risk levels systematically. In the context of collaboration among hospitals, communities, and families, our aim is to establish a multidisciplinary team spearheaded by the hospital. The multidisciplinary team, led by the hospital, comprises experts in diabetes healthcare and nursing, clinical staff, sports rehabilitation specialists, dietitians, pharmacists, psychotherapists, and specialized medical personnel addressing diabetic complications. These professionals are drawn from a tertiary comprehensive hospital

and a community health service center. All team members have more than five years of relevant experience, with expert-level members possessing over fifteen years of expertise. The team will provide customized guidance and support tailored to patients' needs and diabetes risk levels. In addition, family members will be invited to participate throughout the intervention process, aiding healthcare professionals in comprehending relevant information regarding the patient's illness, supervising and encouraging patients in their home self-management. This aims to promote the comprehensive implementation of the project and ensure timely feedback of information. This approach will furnish patients with ongoing graded follow-up, health education, health monitoring, and additional transitional care services, facilitating a seamless transition from the hospital to non-acute settings and ensuring the effective progress of the study. It is noteworthy that the Hospital-Community-Hamily cooperation transitional care program has demonstrated favorable outcomes in the management of patients with T2DM in China and represents a relatively mature approach.[dataset] [23]

2 THE STUDY

2.1 Aims

Our overarching aim is to evaluate the effectiveness of the HCH-TTC for patients with T2DM, comparing it to the HCH-RTC approaches in terms of enhancing patient health outcomes, nursing service satisfaction, reducing the rates of diabetes complications and unplanned readmissions within the constraints of limited healthcare resources. The specific aims included:

(1) To evaluate the HCH-TTC intervention's effectiveness on HbA1c control in patients with T2DM by measuring HbA1c changes at baseline, 3 and 6 months post-intervention, and comparing with HCH-RTC;

(2) To assess the HCH-TTC intervention's impact on FPG and 2hPPG control in patients with T2DM by measuring changes at baseline, 1 months, 3 months and 6 months post-intervention, and comparing with HCH-RTC;

(3) To measure changes in diabetes knowledge, self-management, and treatment

adherence due to the HCH-TTC intervention at baseline, 3 and 6 months post-intervention, and comparing with HCH-RTC;

(4) To compare changes in diabetes complications rate, unplanned readmissions rate, and nursing service satisfaction due to the HCH-TTC intervention at baseline and 6 months post-intervention, and comparing with HCH-RTC.

2.2 Methodology

2.2.1 Design

The study employs a multicenter, pragmatic, double-blind randomized controlled trial (RCT) design, with blinding applied to the study participants, data collectors, and data analysts. The intervention will be known to the providers who are administering it; however, they will be unaware of the outcomes being studied. The participants were informed that they would be randomly allocated into two groups: the experimental group will receive a 6-month HCH-TTC program, while the control group will receive an HCH-RTC program during the same period. It is noteworthy that the intervention protocols for the experimental and control groups are comparable. Both groups receive continuous, coordinated, comprehensive, and efficient care services provided by multidisciplinary teams within a hospital-community-home linkage model, with the primary distinction being the different management strategies employed. To achieve participant blinding, the intervention sites will be located in four independent community health service centers, thereby avoiding potential unblinding due to participant interaction. The specific details of each intervention were not disclosed until the intervention period began. Upon completion of the trial, participants will receive a letter disclosing their group assignment, detailed intervention information, and outcome changes. Through these strategies, we aim to minimize the likelihood of participants identifying their intervention type, thereby ensuring their benefits without knowledge of specific group allocation. This approach maintains the integrity of blinding and the randomization process, protecting the rights and welfare of the patients.

We conducted a feasibility study to assess the practical aspects of implementing

the protocol for this systematic review. However, the results of this study have not yet been published, as data analysis is still in progress. We plan to publish the findings of the feasibility study once the analysis is complete.

2.2.2 Study setting and recruitment plan

The implementation period of this study is from April 2021 to December 2024. From November 2023, the trial will select 180 participants through large-scale diabetes health education activities within the Jinqiao Medical Consortium in Pudong New Area, Shanghai. The JinQiao Medical Union, under the leadership of the Pudong New Area Gongli Hospital in Shanghai, comprises four community health service centers in JinQiao, Yangjing, Jinyang, and Hudong. The research team members will identify potential participants meeting the inclusion criteria from the clinical database of Jinqiao Medical Alliance. A written medical certificate provided by the responsible physician or nurse of each participant will serve as a prerequisite for inclusion in the study. Subsequently, the research team members will conduct face-to-face interviews with eligible patients, providing them with a participant information booklet outlining the study's purpose and specific protocol, displaying study promotional posters, and assessing their interest in participation to determine their willingness to join. Those expressing interest will undergo screening assessments. Upon passing these assessments, the research team members will provide written informed consent forms, invite participants to sign after obtaining their consent, and complete baseline data collection by trained data collectors. As of December 2023, a total of 232 participants have undergone eligibility assessments for this study. Following a rigorous screening process, 180 participants have been successfully recruited.

The inclusion criteria are as follows: (1) A diagnosis of type 2 diabetes; (2) Aged 18 years or older; (3) Inadequately glycemic control, with HbA1c levels at or above 7.0% (53 mmol/mol) in the past month;[dataset] [24] (4) Participants capable of adhering to the intervention protocol's specified timing and frequency are regularly attending follow-up consultations, health education sessions, health monitoring activities, and other transitional care services; (5) Possession of self-monitoring blood glucose

instruments or the ability to measure at community health service centers; (6) Stable internet conditions for long-term use of smartphones and applications; (7) Voluntary participation and signing of an informed consent form after receiving a thorough explanation. The exclusion criteria are as follows: (1) Pregnant or lactating women; (2) Individuals with serious complications or comorbidities; (3) Those experiencing cognitive impairments, communication and reading difficulties, or mental illness; (4) Patients participating in long-term interventions at other medical care facilities after discharge.

We conducted a power analysis using two-sample *t-tests* for sample size calculation. The primary outcome is the difference in HbA1c levels between the intervention and control groups after 6 months. Based on our previous research on the effectiveness of HbA1c interventions in transitional care for T2DM,[dataset] [5] with α=0.05 (u_α=1.96) and β=0.10 (u_β=1.282), and assuming a standardized effect size (δ/σ) of 0.47, we performed an effectiveness analysis assuming equal sizes for both groups. Using Power Analysis and Sample Size software (PASS 2008, NCSS Corporation) we calculated that n_1=n_2=72, with a total of 144 participants. Considering a potential 20% dropout rate, we determined that at least 180 participants are needed for the study, with 90 in each group.

2.2.3 Randomization

After the completion of participant recruitment, study participants will be sequentially numbered from 001 to 180 based on the order of enrollment, and they will be randomized following the completion of baseline data collection (Figure 2). Independent researchers utilized SPSS 26.0 software to generate random numbers (with the random number generator set seed at 180) and allocated study participants randomly into intervention and control groups in a 1:1 ratio.

2.2.4 Study intervention

2.2.4.1 HCH-RTC Program for the control group

Ninety patients with T2DM in the control group will receive routine transitional

care services provided by a multidisciplinary team within a hospital-community-home linkage model, referred to as the HCH-RTC service program. During their hospital stay, patients will undergo diabetes risk assessments and health strategy development by a multidisciplinary team. After discharge, they will receive uniform follow-up care. At the beginning of each subsequent month, they will receive telephone follow-ups from healthcare providers and participate in face-to-face health education lectures. Upon reaching the sixth month of intervention, patients will undergo a hospital follow-up to re-evaluate their health status and make necessary adjustments to their diabetes management plan accordingly.

2.2.4.2 HCH-TTC Program for the experimental group

The experimental group, comprising 90 participants, will be enrolled in a comprehensive six-month HCH-TTC service program structured into three distinct stages, each with specific objectives and processes:

Tiered Assessment Process:

Step 1 Evaluation: The initial phase will involve a comprehensive assessment of participants' health status and service needs across bio-psycho-social dimensions. This evaluation, performed by trained clinical nurses or researchers, assesses the patient's disease duration, blood sugar control, and complications based on self-reported information, medical records, and in conjunction with glucose metabolism index testing and complication screening. Subsequently, the patient's self-management ability, daily activity capacity, diabetes knowledge, treatment adherence, social support, and level of depressionis are evaluated through face-to-face questionnaire surveys. The references and psychometric properties of the questionnaire used can be found in Table 1 and the outcome measures.

Step 2 Stratification: Based on the collected data, a diabetes expert team, composed of four doctors with over 15 years of experience from the endocrine department of the tertiary general hospital within the Jinqiao Medical Union, will categorize participants into three risk categories—high, moderate, and low risk of

diabetes—according to the tiered assessment criteria outlined in Table 1. Within the tiered assessment criteria, a total of 13 indicators serve as the basis for evaluating diabetes risk levels, it is plausible for a single patient to meet the criteria for multiple categories. Given the "irreversible" nature of certain indicators (e.g., "diabetes duration" and complications) and the "dynamic" nature of others (e.g., "average blood glucose over the past week" and "HbA1c within the last three months"), adherence to the principles of dynamic evaluation and tiered transitions of diabetes risk levels is paramount. This approach aims to prevent patients with lengthy disease histories but who exhibit effective blood glucose control and high self-management scores from being erroneously classified into the "high-risk" stratum. Post expert consultations and group discussions, we have established the median count of criteria in the tiered assessment as the cutoff point to define the following hierarchical classification criteria: (1) Participants meeting two or more criteria for the high-risk level will be classified as "high-risk"; (2) Participants meeting one high-risk criterion and six or more moderate-risk criteria will be classified as "moderate-risk"; (3) Participants meeting no high-risk criteria but six or more low-risk criteria will be classified as "low-risk". These hierarchical classification criteria were developed based on expert consultations and group discussions.

Step 3 Connection: Following stratification, diabetes specialist nurses will compile comprehensive health records for each participant, including essential data like diagnosis, treatment history, and risk category. These records will serve as the basis for establishing a connection with local community health service centers, ensuring continuity of care.

Tiered Transition Care: This phase will be delivered through a collaborative effort between general practitioners and diabetes specialist nurses, as shown in Table 2, and is divided into four key components:

(1) Follow-up: Participants will receive regular follow-ups, which may include outpatient visits and telephone check-ins. The frequency and specifics of these follow-ups will be varied based on the patient's risk level, ensuring a personalized approach to care.

(2) Health education: This section follows the PRECEDE-PROCEED health education framework,[dataset] [25] aiming to assess the health education needs of participants at different stages of diabetes risk, observe their behavior change processes, and evaluate the effectiveness of stratified education in maximizing patient knowledge levels through the measurement of the secondary outcome, diabetes knowledge levels. In the PRECEDE phase, a pre-assessment identifies health issues, behavior influences, and educational needs to design tailored strategies. Based on these assessments, patients will be grouped into low, medium, and high-risk categories. For low-risk patients, large group lectures will focus on basic diabetes management and prevention. Medium-risk patients will engage in small group sessions, learning about complication care and self-management skills. High-risk patients will receive individualized case management through a multidisciplinary team, offering personalized, continuous support. Special focus will be given to practical skills and coping strategies for managing complications and adapting to life with diabetes.

In the PROCEED phase, certified, specialized health educators will use standardized materials and teaching processes. Printed summaries of key health knowledge will be distributed, and knowledge will also be disseminated through WeChat groups for continued learning. Methods include lectures, peer education, and experiential learning, with content ranging from fundamental diabetes management for low-risk patients to comprehensive disease management and quality of life improvement for high-risk individuals.

(3) Personalized guidance: This guidance plan aims to tailor interventions to the unique circumstances of each participant, emphasizing seven critical areas of diabetes management, including blood glucose monitoring, physical activity, dietary management, medication therapy, prevention of complications, mental health, and emergency response strategies for hypoglycemia. The plan is developed by a multidisciplinary team that will integrate these guidelines into follow-up consultations and educational activities, thereby ensuring that participants receive consistent and personalized support. The multidisciplinary team will leverage their expertise to

provide detailed, pragmatic, and personalized guidance. This includes tailoring exercise programs by considering patient preferences, health conditions, and specifying appropriate intensity, frequency, and duration; calculating energy requirements; developing dietary plans with balanced nutrient ratios; and providing essential precautions and recommendations.

(4) Health monitoring: Leveraging digital platforms like WeChat and traditional methods like telephone feedback, this component will encourage active participation from both patients and their families in monitoring key health indicators. Regular check-ins will help track progress and maintain engagement, while also providing a mechanism for timely intervention if necessary.

Table 1 Tiered assessment criteria for patients with T2DM

	Tiered criteria
High Diabetes Risk	1. Diabetes duration: >20 years. 2. Average blood sugar levels in the past week (FPG, 2HPG): FPG ⩾10mmol/L and 2hPG >13.9mmol/L. 3. Glycated hemoglobin (HbA1c) levels in the past 3 months: (1) <60 years old: HbA1c >8.0%; (2) ⩾60 years old: HbA1c >9.0%. 4. Incidence of hypoglycemia in the past month (meeting any of the following criteria): (1) Incidence of level 1 hypoglycemia or clear reason for level 2 hypoglycemia occurs ⩾3 times; (2) Significant daily blood sugar fluctuations are present; (3) Incidence of severe level 3 hypoglycemia occurs ⩾1 time; (4) Incidence of unexplained level 2 hypoglycemia is ⩾1 time. 5. Incidence of acute diabetes complications in the previous year (DKA/HHS/diabetic lactic acidosis): ⩾2 occurrences. 6. Chronic complications of diabetes (meeting any of the following criteria): (1) Diabetic foot: Wagner classification falls within levels 3-5; (2) Diabetic nephropathy: CKD is at stage ⩾G3b; (3) Diabetic retinopathy: severe NPDR or DR present; (4) Diabetic neuropathy (DPN): symptomatic DPN observed; (5) Lower extremity arterial disease in diabetes (LEAD): Fontaine stage falls within stages ⅡⅠb-Ⅳ. 7. Complications: ⩾2 or history of cardiovascular and cerebrovascular diseases. 8. Diabetes self-management ability: SDSCA <46.2 points. 9. Activities of daily living: ADL ⩽40 points. 10. Diabetes knowledge: DKT ⩽20 points. 11. Treatment adherence: Treatment compliance scale score ⩽20 points. 12. Social support status: SSRS <20 points. 13. Mental health: GDS-5 >2 points, without relief after self-regulation or moderate to severe depression.
Moderate Diabetes Risk	1. Diabetes duration: 10-20 years. 2. Average blood sugar levels in the past week (FPG, 2HPG): (1) <60 years old: 7mmol/L ⩽ FPG <10 mmol/L, 2hPG arbitrary value or fasting blood sugar ⩾10mmol/L, 2hPG ⩽13.9mmol/L; (2) ⩾60 years old: FPG <10mmol/L, 2hPG ⩾12mmol/L or FPG ⩾10mmol/L, 2hPG ⩽13.9mmol/L. 3. Glycated hemoglobin (HbA1c) levels in the past 3 months: For non-pregnant adults: (1) <60 years old: 7.0% ⩽ HbA1c <8.0%; (2) ⩾60 years old: 8.0% ⩽ HbA1c ⩽9.0%. 4. Incidence of hypoglycemia in the past month (meeting any of the following criteria): Incidence of grade 1 or definite cause of grade 2 low blood sugar 2 times. 5. Incidence of acute complications of diabetes in the past year (DKA/HHS/Diabetic lactic acidosis): 1 time. 6. Chronic complications of diabetes (meeting any of the following criteria): (1) Diabetic foot: Wagner classification falls within levels 0-2; (2) Diabetic nephropathy: CKD is at stage G1-G3a; (3) Diabetic retinopathy: No obvious retinopathy or mild NPDR or moderate NPDR; (4) Diabetic neuropathy (DPN): Asymptomatic DPN; (5) Lower extremity arterial disease in diabetes (LEAD): Fontaine stage falls within stages I-IIa. 7. Complications: 1 and no history of cardiovascular and cerebrovascular disease. 8. Self-management ability of diabetes: 46.2 points ⩽ SDSCA <61.6 points. 9. Daily activity ability: 40 points < ADL ⩽60 points. 10. Diabetes knowledge: 21 points. ⩽ DKT <59 points. 11. Treatment adherence: Treatment compliance score <40 points, >20 points. 12. Social support status: 20 points ⩽ SSRS <30 points. 13. Mental health: 1 points ⩽ GDS-5 ⩽2 points, partial relief after self-regulation or mild depression.

Low Diabetes Risk	1. Diabetes duration: <10 years. 2. Average blood sugar levels in the past week (FPG, 2HPG): (1) <60 years old: 4.4mmol/L ≤ FPG ＜7 mmol/L and 2hPG ≤10mmol/L; (2) ≥60 years old: 8mmol/L ≤ FPG ＜10mmol/L and 8mmol/L≤ 2hPG ＜12 mmol/L). 3. Glycated hemoglobin (HbA1c) levels in the past 3 months: (1) <60 years old: HbA1c ＜7.0%; (2) ≥60 years old: HbA1c ＜8.0%). 4. Incidence of hypoglycemia in the past month (meeting any of the following criteria): Grade 1 or definite reason for Grade 2 hypoglycemia ≤1 time. 5. Incidence of acute complications of diabetes in the past year (DKA/HHS/Diabetic lactic acidosis): 0 times. 6. Chronic complications of diabetes: None. 7. Complications: None. 8. Diabetes self-management ability: SDSCA ≥61.6 points. 9. Daily activity ability: ADL >60 points. 10. Diabetes knowledge: DKT ≥60 points. 11. Treatment adherence: Treatment compliance scale score 40～60 points. 12. Social support status: SSRS ≥30 points. 13. Mental health: GDS-5 score of 0, no depression.

Footnote: DKA: Diabetic Ketoacidosis; HHS: Hyperosmolar Hyperglycemic State; SDSCA: Summary of Diabetes Self-Care Activities scale (Cronbach's alpha = 0.918),[dataset] [26] using a Likert 8-point scale, each item is scored from 0 to 7, with a total of 11 items, higher total scores (maximum 77) reflect better self-management behaviors; DKT: Diabetes Knowledge Test questionnaire (Cronbach's alpha = 0.760),[dataset] [27] with a total of 23 items, the questionnaire score = (number of correct answers / total number of questions) × 100, higher total scores (maximum 100) indicate better mastery of diabetes knowledge by the patient; ADL: Activities of Daily Living questionnaire (Cronbach's alpha = 0.850),[dataset] [28] each item is scored as 5, 10 or 15 point for independent performance and 0 points for needing assistance, with a total of 10 items, higher total scores (maximum 100) reflect better overall functional independence; SSRS: Social Support Rating Scale (Cronbach's alpha = 0.796),[dataset] [29] with a total of 10 items, higher total scores (maximum 66) reflect better social support; GDS-5: Geriatric Depression Scale-5 (Cronbach's alpha = 0.810),[dataset] [30] using a Likert 2-point scale, affirmative answers are worth 1 point, while negative answers are worth 0 points, with a total of 5 items, higher total scores (maximum 5) reflect more severe the depression; Level 1 Hypoglycemia: Blood glucose <3.9 mmol/L and ≥3.0 mmol/L; Level 2 Hypoglycemia: Blood glucose <3.0 mmol/L; Level 3 Hypoglycemia: Severe event requiring assistance from another person, with changes in consciousness and/or physical status, but without specific blood glucose limits.

Table 2 Tiered transitional care（TTC）for patients with T2DM

		Tiered transitional care
High Diabetes Risk	Follow-up	**1.Outpatient clinic follow-up:** When the condition changes. **2.Telephone calls follow-up:** Once every 1 months.
	Health education	**1.Large class education:** Once every 3 months; 1 hour per session; 50-80 people. Method: Lecture, peer education, experiential patient education, live webcast. Content: Based on Moderate Diabetes Risk, focus on pain and comprehensive disease management, emphasizing the improvement of life quality and social psychological adaptation. **2.Groups education:** Once every 1 months; 1 hour per session; 10-15 people. Method: Face-to-face teaching and teaching methods for counter-teaching. Content: Focus on common professional nursing problems and demonstrate invasive operation skills for complications in nursing. **3.Case Study:** Carry out for the seriously ill who cannot go out, and suggest hospitalization or home visits by the team when necessary.
	Personalized guidance	**1.Frequency:** Initial evaluation/re-evaluation/changes in condition. **2.Method:** Face-to-face or online communication. **3.Content: (1) Blood glucose monitoring guidance:** Determine monitoring frequency based on patients' medication and glucose fluctuation patterns, and guide on proper blood glucose meter usage. **(2) Exercise guidance:** Exercise therapy should be approached cautiously in the presence of acute or severe chronic complications. **(3) Dietary guidance:** The personalized diet plan for one month is developed by the nutritionist from the diabetes multidisciplinary team based on the patient's nutritional assessment results. **(4) Medication guidance:** Ealuate the interactions of medications, focusing on dosage and usage. Invasive or aseptic procedures should be performed at specialized outpatient clinics. **(5) Complication guidance:** To reduce the incidence and progression of patient-related complications, primarily aiming to decrease disability and mortality rates. **(6) Psychological guidance:** Utilize peer education to boost patients' psychological resilience, and refer patients with severe mental health issues to specialized treatment centers. **(7) Other guidance:** Recommend smoking and alcohol cessation, evaluate hypoglycemia triggers and instruct patients/caregivers on symptom recognition and emergency response.
	Health monitoring	**1.Frequency:** Community nurses review information thrice a month. **2.Form:** Patients under observation should provide timely feedback on blood glucose management, medication adherence, diet, and exercise through WeChat, phone, and other channels, with family support. If feedback is not received for a month or is of poor quality, a follow-up call should be made to explore the reasons and identify solutions.
Moderate Diabetes Risk	Follow-up	**1.Outpatient clinic follow-up:** Once every 2 months. **2.Telephone calls follow-up:** Once every 2 months.
	Health education	**1.Large class education:** Once every 2 months; 1 hour per session; 50-80 people. Method: Lecture, peer education, experiential patient education, live webcast. Content: Based on Low Diabetes Risk, focus on the prevention and treatment of acute and chronic complications of diabetes and medication guidance. **2.Groups education:** Once every 1 months; 1 hour per session; 10-15 people. Method: Face-to-face teaching and teaching methods for counter-teaching. Content: Focus on common professional nursing problems and demonstrate invasive operation skills for complications in nursing.
	Personalized guidance	**1.Frequency:** Initial evaluation/re-evaluation/changes in condition. **2.Form:** Face-to-face or online communication. **3.Content: (1) Blood glucose monitoring guidance:** Determine monitoring frequency based on patients' medication and glucose fluctuation patterns, and guide on proper blood glucose meter usage. **(2) Exercise guidance:** Assess exercise contraindications, pause until stabilization, then gradually resume while evaluating capacity to establish suitable intensity, type, and duration. **(3) Dietary guidance:** Evaluate the patient's nutrition, di

		etary patterns, and requirements, calculate daily energy needs, and create a weekly menu with instructions for self-modifications. **(4) Medication guidance:** Ealuate the interactions of medications, focusing on dosage and usage. Invasive or aseptic procedures should be performed at specialized outpatient clinics. **(5) Complication guidance:** Notify the monitoring schedule for chronic complications, evaluate risk factors, apply suitable interventions, and emphasize preventive measures and care strategies. **(6) Psychological guidance:** Assess the causes of the patient's anxiety or depression, offer support and encouragement, instruct on emotional relaxation techniques, and guide the patient through mindfulness-based stress reduction therapy with a psychotherapist if necessary. **(7) Other guidance:** Recommend smoking and alcohol cessation, evaluate hypoglycemia triggers and instruct patients/caregivers on symptom recognition and emergency response.
	Health monitoring	**1.Frequency:** Community nurses review information twice a month. **2.Form:** Patients under observation should provide timely feedback on blood glucose management, medication adherence, diet, and exercise through WeChat, phone, and other channels, with family support. If feedback is not received for a month or is of poor quality, a follow-up call should be made to explore the reasons and identify solutions.
Low Diabetes Risk	**Follow-up**	**1.Outpatient clinic follow-up:** Once every 3 months. **2.Telephone calls follow-up:** Once every 3 months.
	Health education	**Large class education：** Once every 1 months; 1 hour per session; 50-80 people. Method: Lecture, peer education, experiential patient education, live webcast. Content: Focus on diabetes basic knowledge education and lifestyle guidance, helping patients establish healthy beliefs and disease management awareness, and establish a healthy lifestyle.
	Personalized guidance	**1.Frequency:** Initial evaluation/re-evaluation/changes in condition. **2.Form:** Face-to-face or online communication. **3.Content: (1) Blood glucose monitoring guidance:** Determine monitoring frequency based on patients' medication and glucose fluctuation patterns, and guide on proper blood glucose meter usage. **(2) Exercise guidance:** Elucidating exercise choices, intensity levels, guiding principles, precautions, and emergency measures for adverse events. **(3) Dietary guidance:** Issuing diabetes dietary guidelines, detailing food classifications and glycemic indices, and educating patients/caregivers on caloric intake and food exchanges. **(4) Medication guidance:** Emphasize medication adherence; specify drug names, dosages, administration routes, side effects, mitigation strategies, and precautions for hypoglycemic agents. Provide manuals and demonstrate injection techniques. **(5) Complication guidance:** Guide patients/caregivers to routinely have retinal, renal, cardiac, lower limb arterial, and foot exams; educate on prevention and complication management; and evaluate risk factors to enhance health outcomes. **(6) Psychological guidance:** Educate the patient on how emotional fluctuations affect blood sugar, promote emotional expression and community involvement, actively listen to concerns, share success stories, enhance confidence, encourage family support, and recommend medical assistance or a 24-hour psychological counseling hotline if psychological issues severely impact quality of life or sleep. **(7) Other guidance:** Recommend smoking and alcohol cessation, evaluate hypoglycemia triggers and instruct patients/caregivers on symptom recognition and emergency response.
	Health monitoring	**1.Frequency:** Community nurses review information once a month. **2.Form:** Patients under observation should provide timely feedback on blood glucose management, medication adherence, diet, and exercise through WeChat, phone, and other channels, with family support. If feedback is not received for a month or is of poor quality, a follow-up call should be made to explore the reasons and identify solutions.

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2.2.5 Outcome measures

A summary of the timeline and an overview of patient engagement and assessments in this trial are presented in Table 3.

2.2.5.1 Primary outcomes

HbA1c, endorsed by the National Diabetes Association as a reliable indicator for monitoring blood sugar control in individuals with diabetes and widely utilized as a key outcome measure in diabetes research,[dataset] [31] will be the primary efficacy endpoint of this study. The assessment of the change in HbA1c levels will be conducted at three key time points from baseline (defined as the value obtained on the day of enrollment) to the efficacy evaluation period (defined as the values measured during outpatient follow-up from months 3 and 6 post-intervention), using venous whole blood samples (approximately 5 mL each) analyzed with the MQ-6000 glycated hemoglobin analyzer (Medconn Diagnostics, Shanghai, China). Skilled community diabetes specialist nurses will supervise these blood sample collections. The samples will be promptly dispatched to the researchers for analysis. The preparation of the blood collection tube reagent kit and the sample analysis will be carried out in the laboratory department of Pudong Gongli Hospital, Shanghai, China. The therapeutic target benchmarks for participants' HbA1c are set at value of $\leqslant$6.5% ($\leqslant$48 mmol/mol).[dataset] [32]

2.2.5.2 Secondary outcomes

FPG and 2hPPG levels, diabetes self-management ability, diabetes knowledge level, diabetes treatment adherence, nursing service satisfaction, diabetes complication rate, and unplanned readmission rate will be the secondary outcomes of this study. The change in FPG and 2hPPG levels will be assessed from baseline (defined as the value obtained on the day of enrollment) to the efficacy evaluation period (defined as the values measured during outpatient follow-up from months 1-month, 3-month and 6-month post-intervention). The change in diabetes self-management ability, diabetes knowledge level, and diabetes treatment adherence will be assessed from baseline (defined as the value obtained on the day of enrollment) to the efficacy evaluation period (defined as the values measured during

outpatient follow-up from months 3 and 6 post-intervention). The change in nursing service satisfaction, diabetes complications rate and unplanned readmissions rate will be assessed from baseline (defined as the value obtained on the day of enrollment) to the efficacy evaluation period (defined as the values measured in outpatient follow-up from month 6 post-intervention). The specific measurement methods for the secondary outcomes indicators are as follows:

FPG and 2hPPG levels is assessed using the rapid blood glucose monitor from SINOMEDISITE in Beijing, China, with results recorded in mmol/L. During these procedures, the second droplet of blood will be selected for testing to ensure accurac, and values will be recorded immediately. The therapeutic target benchmarks for participants' FPG and 2hPPG are set at value of $\leqslant$7.0mmol/L and 11.1mmol/L, respectively.[dataset] [33]

Diabetes self-management ability is evaluated using the Summary of Diabetes Self-Care Activities (SDSCA) questionnaire,[dataset] [26] which has been translated into Chinese by Li and colleagues. Building on Toobert's original work, the SDSCA includes 11 items across 6 dimensions, designed to assess patients' self-management behaviors over the previous week, using a Likert 8-point scale, yielding a maximum total score of 77. With a Cronbach's α value of 0.918, it is the most widely used instrument for assessing the self-management abilities of individuals with diabetes.

Diabetes knowledge level is assessed with the Diabetes Knowledge Test (DKT) questionnaire,[dataset] [27] which has been translated into Chinese by Sun and colleagues, building upon the work of Fitzgerald. The DKT contains 23 items; the first 14 items are relevant for all patients, while the latter nine are tailored for those receiving insulin therapy. It has a Cronbach's α of 0.76 and a Content Validity Index (CVI) of 1, indicating good internal consistency and content validity.

Diabetes treatment adherence is assessed using the Diabetes Patient Treatment Adherence Scale designed by Chen.[dataset] [34] The scale includes 20 items across five domains: medication, diet, exercise, self-monitoring, and regular reexamination. The overall Cronbach's α is 0.86 and the CVI is 0.83, indicating good internal consistency and content validity.

Diabetes complications rate: Diabetes complications refer to those that are newly developed during the study period such as diabetic ketoacidosis, hyperosmolar hyperglycemic state, as well as those diagnosed during the study period including diabetic nephropathy, diabetic retinopathy, diabetic neuropathy, diabetic peripheral arterial disease, and diabetic foot disease, making a total of 7 types of acute and chronic diabetes complications. The incidence rate of diabetes complications is calculated as the number of new acute or chronic complications divided by the total number of individuals multiplied by 100%.

Nursing service satisfaction: Evaluated using a self-designed Patient Satisfaction Survey, crafted by our research team, comprising 10 items. These items cover aspects such as overall satisfaction with nursing services, the ease of access to these services, the attitude of the nursing staff, and satisfaction with the provided health guidance and education. The pre-experimental exhibited a content validity of 0.73, and Cronbach's α coefficient stood at 0.85.

Unplanned readmissions rate: This metric is defined as the proportion of patients who unexpectedly return to the hospital due to diabetes or its complications It is calculated by dividing the number of unplanned readmissions by the total number of patients and then multiplying by 100%. The assessment timeframe spans from baseline to the outpatient follow-up at the 6th month post-intervention. Data collection will be carried out through patient self-reporting and verified by querying health records. Frequency analysis of the readmission rate data will be performed using SPSS statistical software to evaluate the intervention's effect.

471 **TABLE 3** Timeline and overview of patient engagement and assessments in this study

	Enrolment	Allocation	Follow-up		Close-out
TIMEPOINT	**$-T_0$**	**Baseline (T_0)**	**1 months post-baseline (T_1)**	**3 months post-baseline (T_2)**	**6 months post-baseline (T_3)**
ENROLMENT					
Eligibility screen	x				
Informed consent	x				
Allocation		x			
INTERVENTIONS					
HCH-TTC					
ASSESSMENTS					
Demographics		x			
Primary outcomes					
HbA1c		x		x	x
Secondary outcomes					
FPG and 2hPPG		x	x	x	x
Diabetes self-management ability: SDSCA		x		x	x
Diabetes knowledge level: DKT		x		x	x
Diabetes treatment adherence		x		x	x
Diabetes complication rate		x			x
Nursing service satisfaction		x			x
Unplanned readmission rate		x			x

472 **Footnote:** HCH-TTC: Hospital-Community-Home Tiered Transitional Care Program; FPG:
473 Fasting Plasma Glucose; 2hPPG: 2-Hour Postprandial Blood Glucose; HbA1c: Glycated
474 Hemoglobin; SDSCA: Summary of Diabetes Self-Care Activities; DKT: Diabetes Knowledge
475 Test.

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2.2.6 Data collection and safety monitoring

This study will collect data at four time points: baseline, 1 months, 3 and 6 months post-intervention. Two nurses from the hospital will be selected as data collectors and will receive comprehensive training covering patient recruitment discussions, informed consent procedures, and the collection of assessment data at Gongli Hospital. This training will last for two weeks. A key evaluation criterion for this training is the consistency of standardized patient assessment outcomes. Subsequently, the data collectors will conduct on-site surveys, providing participants with a brief overview of the project background and survey instructions. Assistance will be given to participants who are unable to complete the survey on their own, with care taken to avoid the use of suggestive or directive language. Table 3 presents a detailed schedule and overview of the patient participation and assessment procedures.

All research data will be encrypted and stored by the data management officer of the Nursing Department of the Gongli Hospital in Pudong New Area, Shanghai. The data will not be disclosed to the public, only accessible to internal research members for study, application, and paper writing. No one is authorized to modify or delete the data to prevent incidents such as information leakage, loss, or falsification. In addition, the data management officer must promptly report adverse events to the Pudong New Area Health Commission in Shanghai and provide regular reports. The Pudong New Area Health Commission in Shanghai will serve as the independent Data and Safety Monitoring Board (DSMB) for this research, reviewing the data security and providing appropriate recommendations.

2.2.7 Data analysis

After thorough verification, all collected data will be entered into an Excel spreadsheet for the creation of a comprehensive database. Independent statistical analysts will be engaged to perform data analysis utilizing SPSS version 26.0 for Windows (SPSS Inc., Chicago, Illinois, USA). Baseline data, including demographic and clinical characteristics, will be made through *chi-square* tests or independent

t-tests to confirm the equivalence of samples. Assuming a normal distribution for outcome variables, parametric testing methods will be applied. To evaluate the intervention's temporal effects on primary outcomes, the study will analyze differences in outcomes over time—baseline, 3 and 6 months post-intervention—using repeated-measures ANOVA, focusing on the interaction effect (group × time). The analysis will follow the intention-to-treat (ITT) principles, and all data from every participant will be analysed. Missing data will be handled based on established guidelines for each measure or CONSORT-SPI statement. No interim analysis will occur. All statistical tests will be two-tailed, with a significance threshold set at a p-value of $\leqslant$.05.

2.3 Ethics and dissemination

This research protocol received approval from the Ethics Committee of Gongli Hospital, Pudong, Shanghai, China in November 2021 (GLYY1s2021-010) and is subjected to regular review. The study will provide participants with free testing for glycated hemoglobin, fasting blood sugar, and postprandial blood sugar on three occasions, as well as cover essential transportation expenses for participation in the study. Prior to enrollment, all participants will be thoroughly informed about the purpose, significance, procedures, potential risks, benefits, and the work they will be informed regarding what the trial will invite them to do. What's more, they will be required to provide written informed consent. After enrollment, we ensure the confidentiality of participants' personal information, and blood samples used for laboratory tests will be promptly destroyed after testing. All research data and laboratory test results will be used strictly for project research and paper writing purposes.

Furthermore, due to the impact of the COVID-19 pandemic, the overall implementation of this research plan has been postponed by a year. Following consultation with experts and ethical committee review, specific indicators have been modified, clarified, and strengthened, and these revisions have been promptly updated in the Chinese Clinical Trial Registry. After the trial concludes, the four participating

communities can choose whether to continue using the project for ongoing care for Type 2 diabetes. Patients also have the right to decide whether to continue receiving transition care services in their communities. If harm is caused to patients as a result of this study, compensation will be determined by a third-party assessment agency.

Additionally, research results will be disseminated in the following manner: laboratory test results will be emailed to community intervention personnel in Excel format, and the results will be communicated to the patients. Survey scores will serve as the basis for adjusting intervention measures, will be published in paper form after the study, and the process of changes in outcome indicators will be verbally reported to patients and intervention implementers.

3 DISCUSSION

This study is, to the best of our knowledge, the first study to explore the integration of hospital, community, and home care within a tiered transitional care framework for diabetes, with the objective of evaluating its impact on health-related outcomes in individuals with T2DM. The outcomes assessed include HbA1c, FPG, and 2hPPG, alongside diabetes knowledge, self-management abiliy, treatment adherence, patient satisfaction with nursing services, rate of unplanned readmissions and diabetes complications.

Building upon the premise of our investigation, it is worth noting that existing literature on the tiered collaborative management of diabetes is scarce.[dataset] [35-38] This gap highlights the innovative nature of our study within the broader context of diabetes care. Notably, the work of Jia and colleagues emerges as a foundational effort in this field within China's healthcare settings.[dataset] [37] This study spearheaded a stratified diabetes management plan specifically tailored for primary care settings in China. This ambitious project involved the recruitment of 19,546 participants across 864 communities and executed a comprehensive cluster randomized controlled trial spanning two years. The intervention at the heart of this study leveraged mobile health services to provide patient-centered diabetes management within a tri-level framework. The results demonstrated significant enhancements in diabetes control

within primary care settings, thus presenting valuable insights into the management of chronic diseases and underscoring the potential efficacy of tiered, integrated care models like the one our current study seeks to evaluate. While the study [dataset] [37] conducted by Jia and colleagues covered various primary care institutions and engaged in collaboration with doctors in community primary care clinics and county-level hospitals to form a hierarchical structure of regional nursing teams, it did not implement a stratified management approach for patients with T2DM. The stratification of management remained purely at an organizational level, without addressing the need for differentiated management based on patients' varying diabetes risk levels. Moreover, the study primarily harnessed synergistic benefits within the primary healthcare sector, overlooking the pivotal role of tertiary comprehensive hospitals in diabetes care, including diagnosis, treatment, and patient education. It also overlooked the critical role of patient self-management and the potential for disease monitoring within the home environment.

In contrast, our HCH-TTC project aims to encompass the full spectrum of care from hospital treatment to home care post-discharge. To ensure pragmatic implementation of the study, the research team employed qualitative research methods in the early stages of project development, conducting face-to-face interviews with patients diagnosed with T2DM and specialized medical care personnel within the Jinqiao Medical Alliance. These interviews probed deeply into their needs and suggestions regarding tiered transitional care. The purpose of this project is to assemble a multidisciplinary expert team within the Jinqiao Medical Alliance, where team members will stratify patients according to their diabetes risk levels and customize transitional care strategies—varying in frequency, intensity, type, and content focus—to meet the specific needs and disease states of patients with T2DM at different stages. This approach aims to minimize disruptions in transitional care services and information flow, thereby addressing potential issues of overtreatment or undertreatment. Our goal is to improve patients' health outcomes, enhance satisfaction with care services, and reduce unplanned readmission rates and diabetes-related complications. The anticipated research outcomes aim to provide

crucial insights into enhancing the effectiveness of continuity of care plans for T2DM and formulating comprehensive national diabetes management strategies.

Furthermore, this research may have two limitations. First, due to time and budget constraints, the study will implement only a six-month intervention without including long-term follow-up or evaluating the intervention's effectiveness and cost-effectiveness beyond the trial period. Future research could address these limitations by examining the long-term efficacy and cost-effectiveness of the HCH-TTC program. Secondly, the HCH-TTC program developed in this study is specifically tailored to China's healthcare context. The generalizability and effectiveness may vary across difference countries, healthcare systems, and other contextual conditions. Future research should broaden its scope, adhering to the principle of maximum variation, to enhance the representativeness of research subjects and validate the feasibility and effectiveness of the HCH-TTC program for international application and dissemination.

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Contributors:

The authors RJM, YMW, ZZ made significant contributions to the concept and design of this article, participated in drafting the manuscript, and critically revised its important intellectual content. ML and HYW undertook overall coordination, whereas BYZ and MYS were responsible for data collection, organization, analysis, and interpretation. All authors have given their final approval for the submitted version. YMW has agreed to be accountable for all aspects of the work, ensuring that questions related to the accuracy or integrity of any part of the work are appropriately addressed and resolved. YMW is the guarantor. The corresponding author attests that all listed authors meet authorship criteria and that no others meeting the criteria have been omitted.

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Competing interests: No competing interests.

Community and public involvement:

In the initial phase of the study, patients with T2DM, through qualitative research methods, articulated their needs and recommendations for hierarchical and

graded continuing care, and were actively involved in the development of the intervention protocol for the experimental group. Four communities—Yangjing, Jinqiao, Jinyang, and Hudong—played a pivotal role in the research design, participant recruitment, data collection and interpretation, dissemination of the study protocol, and its subsequent implementation.

Patient consent for publication: Not applicable.

Provenance and peer review: Not commissioned; externally peer reviewed.

Data confidentiality and availability:

The study has been reviewed by the Ethics Committee of the Chinese Clinical Trial Registry, and the relevant ethical consent documents, funding documents, and trial data are available for review by the Editorial Office. Due to the data protection policies of the national government and relevant institutions regarding patient information, we will share the research data, subject to the approval of the Ethics Committee of Gongli Hospital in the Pudong New Area of Shanghai and the Data Safety Monitoring Committee, with units or individuals that meet the following sharing conditions one year after the publication of the main findings:

(1) Data Use Agreement: Data users are required to sign a data use agreement, committing to comply with specific conditions of use. These conditions include, but are not limited to, data protection, privacy security, and data purposes.

(2) Anonymization: To protect participant privacy, all shared metadata will be anonymized. Any information that could potentially identify individuals will be removed or modified.

(3) Non-Commercial Use: The data is intended for non-commercial use only, such as academic research, education, and other nonprofit activities. The data must not be used for any commercial purposes.

(4) Ethical Approval: Data users must provide proof of ethical approval to confirm that their data use behavior complies with relevant ethical and legal

requirements.

The data-sharing platform is ResMan.

The URL for the platform is: http://www.medresman.org.cn/login.aspx.

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FIGURE 1 The HCH-TTC conceptual framework. HCH-TTC, Hospital-Community-Home Tiered Transitional Care.

FIGURE 2 CONSORT flowchart describing progress of participants through the trial. HCH-TTC, Hospital-Community-Home Tiered Transitional Care. HCH-RTC, Hospital-Community-Home Routine Transitional Care.

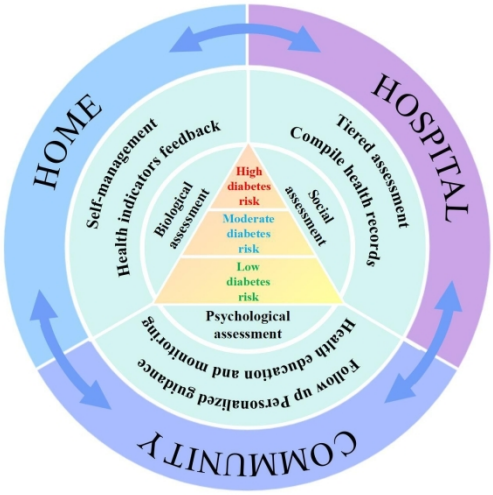

FIGURE 1 The HCH-TTC conceptual framework

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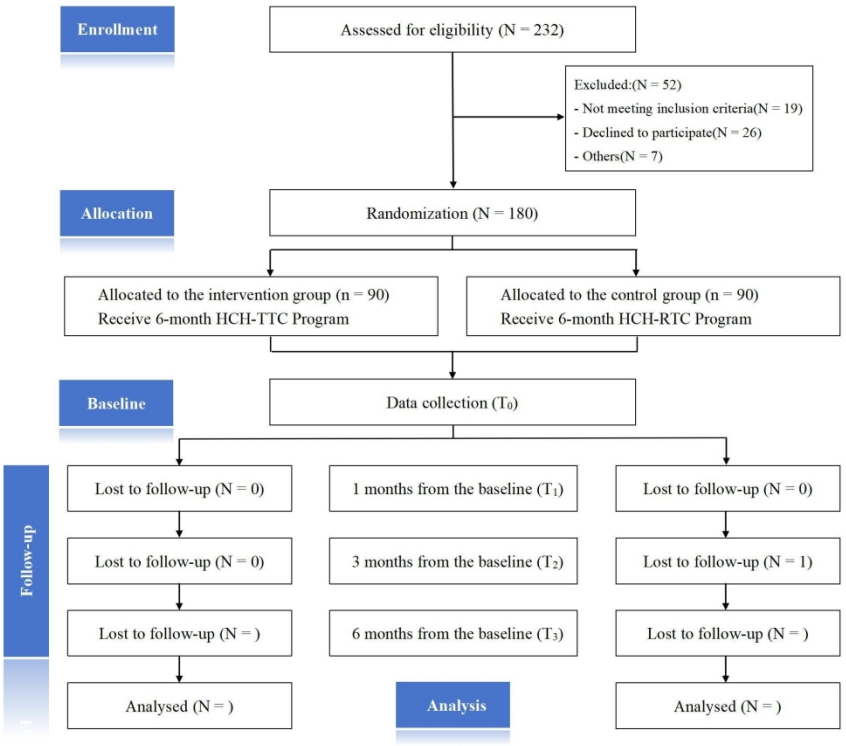
108x60mm (600 x 600 DPI)



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