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Pragmatic, multicentre, randomised controlled trial of a Hospital-Community-Home Tiered Transitional Care (HCH-TTC) programme for individuals with type 2 diabetes: a study protocol

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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 socioeconomic development. Evidence has 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 personalised design, leading to potential issues of undertreatment and overtreatment, increasing the risk of improper blood sugar management. To address these challenges, our research team developed the Hospital-Community-Home Tiered Transitional Care (HCH-TTC) programme for patients with T2DM, aiming to evaluate its effectiveness and feasibility through a randomised controlled trial (RCT).

Method and analysis The multicentre, pragmatic, double-blind RCT will enrol 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 participate in a 6-month HCH-TTC programme, which provides personalised transitional care strategies tailored to patients' evolving health conditions and nursing needs. This tiered management approach includes follow-up, health education, personalised 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 programme, consisting of routine follow-up, health education and health monitoring during the same period. Data collection will be conducted at baseline, 1 month postintervention, 3 months and 6 months. The primary outcomes are glycated haemoglobin (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.

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 number Chinese Clinical Trial Registry ChiCTR2200063322.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ 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.
⇒ The study is designed as a multicentre, pragmatic, double-blind randomised controlled trial, minimising selection bias and enhancing the credibility of its findings, including community and public involvement to increase the practicality and applicability of the study results.
⇒ 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.
⇒ A limitation is the short duration of the intervention, which spans only 6 months, without assessing long-term effects or cost-effectiveness.
⇒ As the study is conducted in China, its findings may have limited generalisability to other countries with differing healthcare systems and approaches.

INTRODUCTION

China, as the world's largest developing country, is experiencing a surge in diabetes cases due to rapid urbanisation, increased migration, an ageing 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 gross domestic product), emphasise the critical need to tackle this escalating epidemic. [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.

Background

The key to managing diabetes is glycaemic control. Effective glycaemic control can prevent complications and reduce the burden of diabetes. In China, the prevalence of adequate glycaemic control among patients with diabetes 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 glycaemic control among patients with diabetes in China by 2015.[6] Reasons for this gap include poor self-management ability in patients with T2DM, limited awareness of the disease and a low treatment rate.[5] Public health institutions must intensify efforts to enhance glycaemic 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.[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 glycaemic control and unplanned rehospitalisations. Moreover, transitional care models have limitations in their personalised 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 patients with diabetes with glycated haemoglobin (HbA1c) ≥ 8.5%, severe complications and multiple unplanned rehospitalisations 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 recognise 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 using 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 (HCH-TTC) Programme.[19] The programme 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 programme 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 individualised 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 optimise valuable nursing resources, thereby ensuring smooth transitions for patients from hospitals to postacute care settings, enhancing health outcomes, increasing satisfaction with nursing services and decreasing the rates of diabetes complications and unplanned readmissions. Given that the programme was developed based on China's healthcare context, future research could potentially involve feasibility and pilot studies to evaluate its generalisability and effectiveness in different healthcare settings. Such studies would be crucial in determining the programme's generalisability beyond China's healthcare context.

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 (Triangle Model) [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 Programme. The practice will be carried out through the collaboration of hospitals, communities and families. We will use

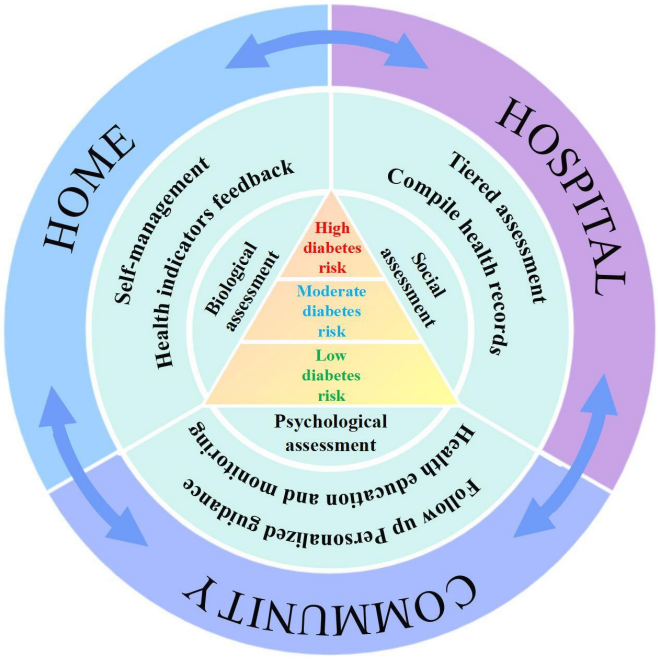

Figure 1 The HCH-TTC conceptual framework. HCH-TTC, Hospital-Community-Home Tiered Transitional Care.

the Triangle Model to guide the strategy and techniques for implementation, while the Bio-psycho-social Medical Model will be used 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, dieticians, pharmacists, psychotherapists and specialised medical personnel addressing diabetic complications. These professionals are drawn from a tertiary comprehensive hospital and a community health service centre. All team members have more than 5 years of relevant experience, with expert-level members possessing over 15 years of expertise. The team will provide customised 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-family cooperation transitional care programme has demonstrated favourable outcomes in the management of patients with T2DM in China and represents a relatively mature approach.[23]

THE STUDY

Aims

Our overarching aim is to evaluate the effectiveness of the HCH-TTC for patients with T2DM, comparing it to the Hospital-Community-Home Routine Transitional Care (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:

- 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 postintervention and comparing with HCH-RTC.
- To assess the HCH-TTC intervention's impact on FPG and 2hPPG control in patients with T2DM by measuring changes at baseline, 1 month, 3 months and 6 months postintervention and comparing with HCH-RTC.
- To measure changes in diabetes knowledge, self-management and treatment adherence due to the HCH-TTC intervention at baseline, 3 and 6 months postintervention and comparing with HCH-RTC.
- 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 postintervention and comparing with HCH-RTC.

Methodology

Design

The study employs a multicentre, pragmatic, double-blind randomised 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 programme, while the control group will receive an HCH-RTC programme 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 centres, thereby avoiding potential unblinding due to participant interaction. The specific details of each intervention were not disclosed until the intervention period began. On 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 minimise 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 randomisation 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.

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 centres 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. On 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 glycaemic control, with HbA1c levels at or above 7.0% (53 mmol/mol) in the past month;[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 centres; (6) stable internet conditions for long-term use of smartphones and applications; and (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; and (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,[5] with α=0.05 (u_α=1.96) and β=0.10 (u_β=1.282), and assuming a standardised 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.

Randomisation

After the completion of participant recruitment, study participants will be sequentially numbered from 001 to 180 based on the order of enrolment, and they will be randomised following the completion of baseline data collection (figure 2). Independent researchers used 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.

Study intervention

Hospital-Community-Home Routine Transitional Care (HCH-RTC) programme 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 programme. 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. On 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.

Hospital-Community-Home Tiered Transitional Care (HCH-TTC) programme for the experimental group

The experimental group, comprising 90 participants, will be enrolled in a comprehensive 6-month HCH-TTC service programme 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

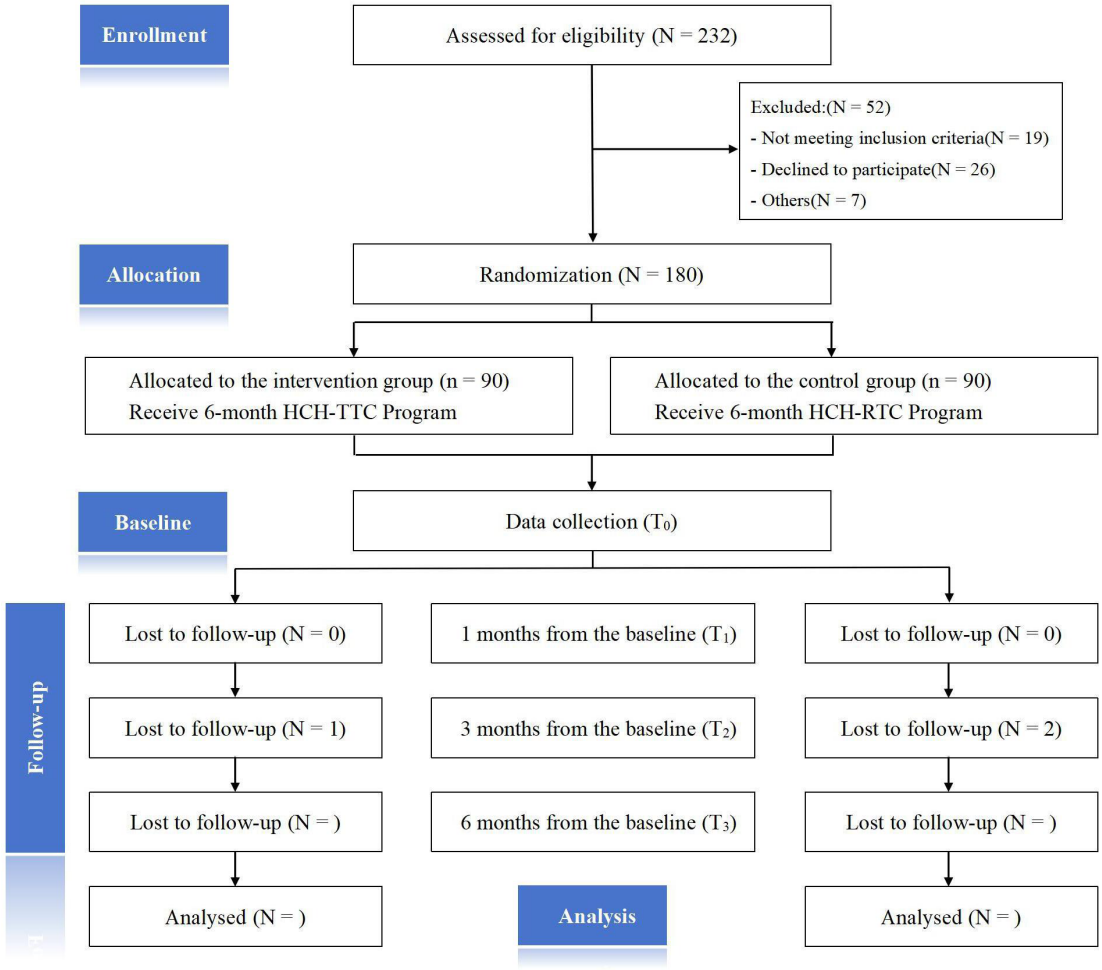

Figure 2 Consolidated Standards of Reporting Trials flowchart describing progress of participants through the trial. HCH-RTC, Hospital-Community-Home Routine Transitional Care; HCH-TTC, Hospital-Community-Home Tiered Transitional Care.

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 depression 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 categorise 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 (eg, 'diabetes duration' and complications) and the 'dynamic' nature of others (eg, 'average blood glucose over the past week' and 'HbA1c within the last 3 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 cut-off 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] and 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

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, 2hPPG): FPG ≥10 mmol/L and 2hPPG >13.9 mmol/L. 3. Glycated haemoglobin (HbA1c) levels in the past 3 months: (1) <60 years old, HbA1c >8.0%. (2) ≥60 years old, HbA1c>9.0%. 4. Incidence of hypoglycaemia in the past month (meeting any of the following criteria): (1) incidence of level 1 hypoglycaemia or clear reason for level 2 hypoglycaemia occurs ≥3 times; (2) significant daily blood sugar fluctuations are present; (3) incidence of severe level 3 hypoglycaemia occurs ≥1 time; (4) incidence of unexplained level 2 hypoglycaemia 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, 2hPPG): (1) <60 years old: 7 mmol/L≤FPG <10 mmol/L, 2hPPG arbitrary value or fasting blood sugar ≥10 mmol/L, 2hPPG≤13.9 mmol/L. (2) ≥60 years old: FPG <10 mmol/L, 2hPPG ≥12 mmol/L or FPG ≥10 mmol/L, 2hPPG ≤13.9 mmol/L. 3. HbA1c levels in the past 3 months: for non-pregnant adults. (1) <60 years old: 7.0%≤HbA1 c <8.0%. (2) ≥60 years old: 8.0% ≤HbA1c ≤9.0%. 4. Incidence of hypoglycaemia in the past month (meeting any of the following criteria): incidence of grade 1 or definite cause of grade 2 low blood sugar two times. 5. Incidence of acute complications of diabetes in the past year (DKA/HHS/diabetic lactic acidosis): one 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) DPN, asymptomatic DPN; 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 point ≤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, 2hPPG): (1) <60 years old: 4.4 mmol/L≤FPG < 7 mmol/L and 2hPPG≤10 mmol/L. (2) ≥60 years old: 8 mmol/L≤FPG < 10 mmol/L and 8 mmol/L≤2hPPG < 12 mmol/L. 3. HbA1c levels in the past 3 months: (1) <60 years old, HbA1c < 7.0%; (2) ≥60 years old, HbA1c < 8.0%. 4. Incidence of hypoglycaemia in the past month (meeting any of the following criteria): grade 1 or definite reason for grade 2 hypoglycaemia ≤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.

Summary of Diabetes Self-Care Activities (SDSCA) scale (Cronbach's alpha = 0.918),[29] 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;
Diabetes Knowledge Test (DKT) questionnaire (Cronbach's alpha = 0.760),[30] 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;
Activities of Daily Living (ADL) questionnaire (Cronbach's alpha = 0.850),[36] each item is scored as 5, 10 or 15 points 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;
Social Support Rating Scale (SSRS) (Cronbach's alpha = 0.796),[37] 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),[38] 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 hypoglycaemia: blood glucose <3.9 mmol/L and ≥3.0 mmol/L;
Level 2 hypoglycaemia: blood glucose <3.0 mmol/L; Level 3 hypoglycaemia: severe event requiring assistance from another person, with changes in consciousness and/or physical status, but without specific blood glucose limits.
The colored entries in Table represent different tiers of diabetes risk for patients with Type 2 Diabetes Mellitus (T2DM). Red - colored sections denote high diabetes risk, yellow - colored sections indicate moderate diabetes risk, and green - colored sections signify low diabetes risk. Each risk tier is defined by specific criteria related to diabetes duration, blood sugar levels, glycated hemoglobin (HbA1c) levels, incidence of hypoglycemia, diabetes complications, self - management ability, daily activity levels, knowledge, treatment adherence, social support, and mental health status.
DKA, diabetic ketoacidosis; FPG, fasting plasma glucose; HHS, hyperosmolar hyperglycaemic state; 2hPPG, 2-hour postprandial blood glucose; T2DM, type 2 diabetes mellitus.

like diagnosis, treatment history and risk category. These records will serve as the basis for establishing a connection with local community health service centres, 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:

- 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 personalised approach to care.
- Health education: this section follows the PRECEDE-PROCEED health education framework,[25] aiming to assess the health education needs of participants at different stages of diabetes risk, observe their behaviour change processes and evaluate the effectiveness of stratified education in maximising patient knowledge levels through the measurement of the secondary outcome, diabetes knowledge levels. In the PRECEDE phase, a pre-assessment identifies health issues, behaviour 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 individualised case management through a multidisciplinary team, offering personalised, 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, specialised health educators will use standardised 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.

- Personalised guidance: this guidance plan aims to tailor interventions to the unique circumstances of each participant, emphasising 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 hypoglycaemia. 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 personalised support. The multidisciplinary team will leverage their expertise to provide detailed, pragmatic and personalised guidance. This includes tailoring exercise programmes 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.
- 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.

Outcome measures

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

Primary outcomes

HbA1c, endorsed by the National Diabetes Association as a reliable indicator for monitoring blood sugar control in individuals with diabetes and widely used as a key outcome measure in diabetes research,[26] 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 enrolment) to the efficacy evaluation period (defined as the values measured during outpatient follow-up from months 3 and 6 postintervention), using venous whole blood samples (approximately 5 mL each) analysed with the MQ-6000 glycated haemoglobin analyser (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 a value of ≤6.5% (≤48 mmol/moL).[27]

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 enrolment) to the efficacy evaluation period (defined as the values measured during outpatient follow-up from 1 month, 3 months and 6 months postintervention). The change in diabetes self-management ability, diabetes knowledge level and

Table 2 Tiered transitional care 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 month.
	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, emphasising the improvement of life quality and social psychological adaptation. *2. Group education:* once every 1 month; 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 hospitalisation or home visits by the team when necessary.
	Personalised 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 metre usage. *(2) Exercise guidance:* exercise therapy should be approached cautiously in the presence of acute or severe chronic complications. *(3) Dietary guidance:* the personalised diet plan for 1 month is developed by the nutritionist from the diabetes multidisciplinary team based on the patient's nutritional assessment results. *(4) Medication guidance:* evaluate the interactions of medications, focusing on dosage and usage. Invasive or aseptic procedures should be performed at specialised 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:* use peer education to boost patients' psychological resilience, and refer patients with severe mental health issues to specialised treatment centres. *(7) Other guidance:* recommend smoking and alcohol cessation, evaluate hypoglycaemia triggers and instruct patients/caregivers on symptom recognition and emergency response.
	Health monitoring	*1. Frequency:* community nurses review information three times per 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 month; 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.
	Personalised 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 metre usage. *(2) Exercise guidance:* assess exercise contraindications, pause until stabilisation and then gradually resume while evaluating capacity to establish suitable intensity, type and duration. *(3) Dietary guidance:* evaluate the patient's nutrition, dietary patterns and requirements; calculate daily energy needs; and create a weekly menu with instructions for self-modifications. *(4) Medication guidance:* evaluate the interactions of medications, focusing on dosage and usage. Invasive or aseptic procedures should be performed at specialised outpatient clinics. *(5) Complication guidance:* notify the monitoring schedule for chronic complications, evaluate risk factors, apply suitable interventions and emphasise 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 hypoglycaemia triggers and instruct patients/caregivers on symptom recognition and emergency response.
	Health monitoring	*1. Frequency:* community nurses review information two times per 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 month; 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.
	Personalised 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 metre 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 glycaemic indices, and educating patients/caregivers on caloric intake and food exchanges. *(4) Medication guidance:* emphasise medication adherence; specify drug names, dosages, administration routes, side effects, mitigation strategies and precautions for hypoglycaemic 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 counselling hotline if psychological issues severely impact quality of life or sleep. *(7) Other guidance:* recommend smoking and alcohol cessation, evaluate hypoglycaemia 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.

T2DM, type 2 diabetes mellitus.

diabetes treatment adherence will be assessed from baseline (defined as the value obtained on the day of enrolment) to the efficacy evaluation period (defined as the values measured during outpatient follow-up from months 3 and 6 postintervention). 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

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 month postbaseline (T_1)**	**3 months postbaseline (T_2)**	**6 months postbaseline (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-managementability: 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

DKT, Diabetes Knowledge Test; FPG, fasting plasma glucose; HbA1c, glycated haemoglobin; HCH-TTC, Hospital-Community-Home Tiered Transitional Care; 2hPPG, 2-hour postprandial blood glucose; SDSCA, Summary of Diabetes Self-Care Activities.

enrolment) to the efficacy evaluation period (defined as the values measured in outpatient follow-up from month 6 postintervention). The specific measurement methods for the secondary outcomes indicators are as follows:

FPG and 2hPPG levels are 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 accuracy, and values will be recorded immediately. The therapeutic target benchmarks for participants' FPG and 2hPPG are set at value of ≤7.0 mmol/L and 11.1 mmol/L, respectively.[28]

Diabetes self-management ability is evaluated using the Summary of Diabetes Self-Care Activities (SDSCA) questionnaire,[29] which has been translated into Chinese by Li and colleagues. Building on Toobert's original work, the SDSCA includes 11 items across six dimensions, designed to assess patients' self-management behaviours 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,[30] which has been translated into Chinese by Sun and colleagues, building on 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 and Huang.[31] The scale includes 20 items across five domains: medication, diet, exercise, self-monitoring and regular re-examination. 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 hyperglycaemic 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 seven 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 re-admissions by the total number of patients and then multiplying by 100%. The assessment timeframe spans from baseline to the outpatient follow-up at the sixth month postintervention. 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.

Data collection and safety monitoring

This study will collect data at four time points: baseline, 1 month, 3 months and 6 months postintervention. 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 2 weeks. A key evaluation criterion for this training is the consistency of standardised 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 authorised 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 for this research, reviewing the data security and providing appropriate recommendations.

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 using SPSS V.26.0 for Windows (SPSS Inc., Chicago, Illinois, USA). Baseline data, including demographic and clinical characteristics, will be made through χ^2 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 analyse differences in outcomes over time—baseline and 3 and 6 months postintervention—using repeated-measures analysis of variance, focusing on the interaction effect (group×time). The analysis will follow the intention-to-treat principles, and all data from every participant will be analysed. Missing data will be handled based on established guidelines for each measure or Consolidated Standards of Reporting Trials Statement for Social and Psychological Interventions. No interim analysis will occur. All statistical tests will be two-tailed, with a significance threshold set at a p-value of≤0.05.

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 haemoglobin, fasting blood sugar and postprandial blood sugar on three occasions, as well as cover essential transportation expenses for participation in the study. Prior to enrolment, 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 enrolment, 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.

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 on the premise of our investigation, it is worth noting that existing literature on the tiered collaborative management of diabetes is scarce.[32–35] 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.[34] This study spearheaded a stratified diabetes management plan specifically tailored for primary care settings in China. This ambitious project involved the recruitment of 19546 participants across 864 communities and executed a comprehensive cluster RCT spanning 2 years. The intervention at the heart of this study leveraged mobile health services to provide patient-centred 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 [34] 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 organisational 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 postdischarge. 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 specialised 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 customise 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 minimise 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 6-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 programme. Second, the HCH-TTC programme developed in this study is specifically tailored to China's healthcare context. The generalisability and effectiveness may vary across different 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 programme for international application and dissemination.

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