Improving the management of type 2 diabetes in China using a multifaceted digital health intervention in primary health care: the SMARTDiabetes cluster randomised controlled trial

Puhong Zhang,[a] Xuanchen Tao,[a] Yuxia Ma,[b] Yaosen Zhang,[c] Xinyan Ma,[d] Hongyi Song,[e] Yu Liu,[f] Anushka Patel,[g] Stephen Jan,[g] and David Peiris[g,*]

[a]The George Institute for Global Health China, UNSW, Sydney, Australia
[b]Hebei Medical University, Shijiazhuang, Hebei Province, China
[c]Luquan Center for Disease Control and Prevention, Shijiazhuang, Hebei Province, China
[d]Shijiazhuang Center for Disease Control and Prevention, Shijiazhuang, Hebei, China
[e]The George Institute for Global Health China, China
[f]Beihang University, Beijing, China
[g]The George Institute for Global Health, UNSW Sydney, Australia

The Lancet Regional Health - Western Pacific 2024;49: 101130

Published Online xxx
https://doi.org/10.1016/j.lanwpc.2024.101130

Summary

Background There is limited evidence, mainly from high-income countries, that digital health interventions improve type 2 diabetes (T2DM) care. Large-scale implementation studies are lacking.

Methods A multifaceted digital health intervention comprising: (1) a self-management application ('app') for patients and lay 'family health promotors' (FHPs); and (2) clinical decision support for primary care doctors was evaluated in an open-label, parallel, cluster randomized controlled trial in 80 communities (serviced by a primary care facility for >1000 residents) in Hebei Province, China. People >40 years with T2DM and a glycated haemoglobin (HbA1c) ≥7% were recruited (~25/community). After baseline assessment, community clusters were randomly assigned to intervention or control groups (1:1) via a web-based system, stratified by locality (rural/urban). Control arm clusters received usual care without access to the digital health application or family health promoters. The primary outcome was at the participant level defined as the proportion with ≥2 "ABC" risk factor targets achieved (HbA1c < 7.0%, blood pressure < 140/80 mmHg and LDL-cholesterol < 2.6 mmol/L) at 24 months.

Findings A total of 2072 people were recruited from the 80 community clusters (40 urban and 40 rural), with 1872 (90.3%) assessed at 24 months. In the intervention arm, patients used FHPs for support more in rural than urban communities (252 (48.6%) rural vs 92 (21.5%) urban, p < 0.0001). The mean monthly proportion of active app users was 46.4% (SD 7.8%) with no significant difference between urban and rural usage rates. The intervention was associated with improved ABC control rates (339 [35.9%] intervention vs 276 [29.9%] usual care; RR 1.20, 95% CI 1.02–1.40; p = 0.025), with significant heterogeneity by geography (rural 220 [42.6%] vs 158 [31.0%]; urban 119 [27.9%] vs 118 [28.6%]; p = 0.022 for interaction). Risk factor reductions were mainly driven by improved glycaemic control (mean HbA1C difference –0.33%, 95% CI –0.48 to –0.17; p = 0.00025 and mean fasting plasma glucose difference –0.58 mmol, 95% CI –0.89 to –0.27; p = 0.00013). There were no changes in blood pressure and LDL-cholesterol levels.

Interpretation A multifaceted digital health intervention improved T2DM risk factor control rates, particularly in rural communities where there may be stronger relationships between patients and doctors and greater family member support.

Funding National Health and Medical Research Council Global Alliance for Chronic Diseases (ID 1094712).

Keywords: Type 2 diabetes; Capacity strengthening; mHealth; China; Implementation

*Corresponding author. The George Institute for Global Health, Level 18, International Towers 3, 300 Barangaroo Ave, NSW 2000, PO Box M201, Missenden Rd, Barangaroo, NSW 2050, Australia.
E-mail address: dpeiris@georgeinstitute.org (D. Peiris).
Trial registration: Clinicaltrials.gov NCT02726100.

Research in context

Evidence before this study

A systematic search was conducted in MEDLINE and PubMed databases to find studies on diabetes management using digital health technologies in the past 10 years. The search strategy included keywords related to digital health technologies and diabetes. Studies focussing on specific populations such as gestational diabetes and type 1 diabetes, and protocol, pilot, qualitative findings were excluded. A total of 47 randomized clinical trials and 46 systematic reviews were selected for review. While most studies supported the use of digital technologies in improving health outcomes for diabetes management, some had null findings, and many had small sample sizes and short follow-up periods. There were limited studies in low-income and middle-income countries, and the variability in digital interventions made comparisons challenging. Large-scale evaluations are needed to explore the effectiveness and implementation of mHealth interventions for diabetes management.

Added value of this study

In this large cluster randomized controlled trial covering urban and rural areas in Hebei province, China, we found that a multifaceted digital health intervention focussed on self-management and incentives to engage in care, peer support through family health members, and decision support for clinicians led to improved risk factor control (defined as achieving 2 or more ABC targets [HbA1c, blood pressure and LDL-cholesterol]). There was marked heterogeneity of effect by geography with greater engagement in rural areas (higher use of lay family health promoters and more frequent use of the SMARTDiabetes app) when compared with urban areas.

Implications of all the available evidence

Digital health interventions to improve diabetes control are complex strategies and outcomes tend to vary according to local health system context. Close engagement of patients, family members and care providers, particularly in rural areas, has potential to improve quality of care and diabetes outcomes. Replication and scale-up studies in other health system contexts are needed to build the evidence base on effective implementation strategies to improve diabetes care.

Introduction

The disease burden from type 2 diabetes mellitus (T2DM) is rapidly rising worldwide with the largest rises occurring in low- and middle-income countries (LMICs). China has the largest number of people with T2DM of any nation worldwide and this places considerable strain on its healthcare system. The China central government introduced a national Basic Public Health Service programme in 2009, which includes uniform T2DM and hypertension management in primary health care (PHC).[1] Before-after studies have found this programme is associated with increased rates of diabetes awareness (30.1% in 2010 and 43.3% in 2017) and anti-diabetic treatment (25.8% in 2010 and 49.0% in 2017).[2] However, glycaemic control rates remained unchanged at 49.4% in the 2013–2017 period,[2] and only 5.6% of patients achieved optimal control of combined 'ABC' risk factor targets (HbA1c < 7.0% [53 mmol/mol], blood pressure [BP] < 130/80 mmHg and low-density lipoprotein cholesterol [LDL-c] < 2.6 mmol/L).[3]

PHC workforce capacity is a major challenge to improving T2DM management and outcomes in China. Despite a 60% increase in the number of public health service providers, the workload measured by standardized output of public health services per primary care facility disproportionately increased by 233% from 2009 to 2017.[4] Innovative and scalable strategies are therefore urgently needed to increase the quality and efficiency of services delivered while ensuring PHC providers have sufficient support.

Mobile health (mHealth) technologies have the potential to improve health system efficiency and health outcomes. In the past two decades, many randomized controlled trials (RCTs) and systematic reviews have been conducted to evaluate the effect of mHealth in diabetes management focussing on improving knowledge and behaviour change,[5] self-management skills,[6,7] adherence to medication,[8] and clinical outcomes.[9–12] However most of the literature is from hospital-based studies in high income countries,[12] with small sample sizes and short follow-up periods.[9–13] Clinical effects are highly variable and may relate to the diversity of the mHealth interventions studied. Large scale evaluations based on real-world practice are needed to explore clinical effectiveness and implementation.

In addition to knowledge gaps on effectiveness of mHealth interventions, there is a scarcity of implementation research to better understand factors that support adoption and sustained use of mHealth interventions.[9,10] Family-supported mHealth interventions have shown promise in improving healthy lifestyle and blood glucose control for older patients in USA, Thailand and India.[14–16] In China, a family engagement model has been trialled in which a voluntary family member (named a family health promotor (FHP)) receives training in chronic disease management and takes responsibility for maintaining the health of their family members.[17,18] however, there have been no studies supporting FHPs with mHealth tools.

In this study, we hypothesized that a multifaceted digital health intervention (SMARTDiabetes) can support patients, FHPs and health care staff to improve T2DM management in urban and rural communities in

China. The primary aim was to assess whether the intervention improved attainment of combined glycaemic, BP and cholesterol targets. Secondary aims included an assessment of implementation adoption and fidelity, and clinical effectiveness in improving individual risk factors.

Methods

Design

SMARTDiabetes was evaluated in an open-label parallel cluster randomized controlled trial involving 80 community clusters from Hebei province, China (40 urban communities and 40 rural villages) and 2000 people with established T2DM (around 25 patients per site). The study protocol has been published elsewhere.[19] The fieldwork took place between August 2017, and October 2019, prior to the emergence of COVID-19.

Study setting and cluster inclusion/exclusion criteria

The study communities (clusters) were selected from an urban district and a rural county in Hebei Province, central China. Hebei is China's sixth most populous province with over 75 million people (~60% residing in urban areas). Eligible communities were those with a minimum of 1000 residents, a PHC station or clinic, and staff willing to participate who are not engaged in other studies. Two government agencies (PHC Management Centre in urban areas and Centre for Disease Control and Prevention in rural areas) supervised provision of PHC services including training, quality control and performance evaluation. These governors were also responsible for site selection and recruitment.

Randomisation and masking

After baseline recruitment and assessment, study sites were allocated to intervention or control groups in a 1:1 ratio using a central web-based randomization, stratified by locality (urban/rural). The control arm received usual care while the intervention arm received healthcare facilitated by the SMARTDiabetes platform. Participants were followed up for 24 months. Data for evaluation were collected at baseline, mid-term (12 months) and end of study (24 months). This was an open-label trial in which the PHC providers and participants were aware of their group assignment, but the staff responsible for data collection, the scientists conducting laboratory tests, and the statistician conducting the analysis were blinded to group allocation.

Participants

The participating patients were screened by the PHC providers from the patient list of routine registration system and formally recruited by trained investigators at baseline. The inclusion and exclusion criteria were as below.

Inclusion criteria

(1) Established T2DM, (2) age $\geq$ 40 years, (3) HbA1c $\geq$ 7% (53 mmol/mol), (4) accessible to internet through a smartphone by himself/herself or by a nominated FHP, and (5) able to provide informed consent.

Exclusion criteria

(1) Severe physical or psychological injury or illness, (2) unable to attend the site visit or consciously answer questions, (3) women in the process of or planning for pregnancy or breastfeeding, or (4) participated in any other clinical trial within the previous 6 months.

Intervention and implementation

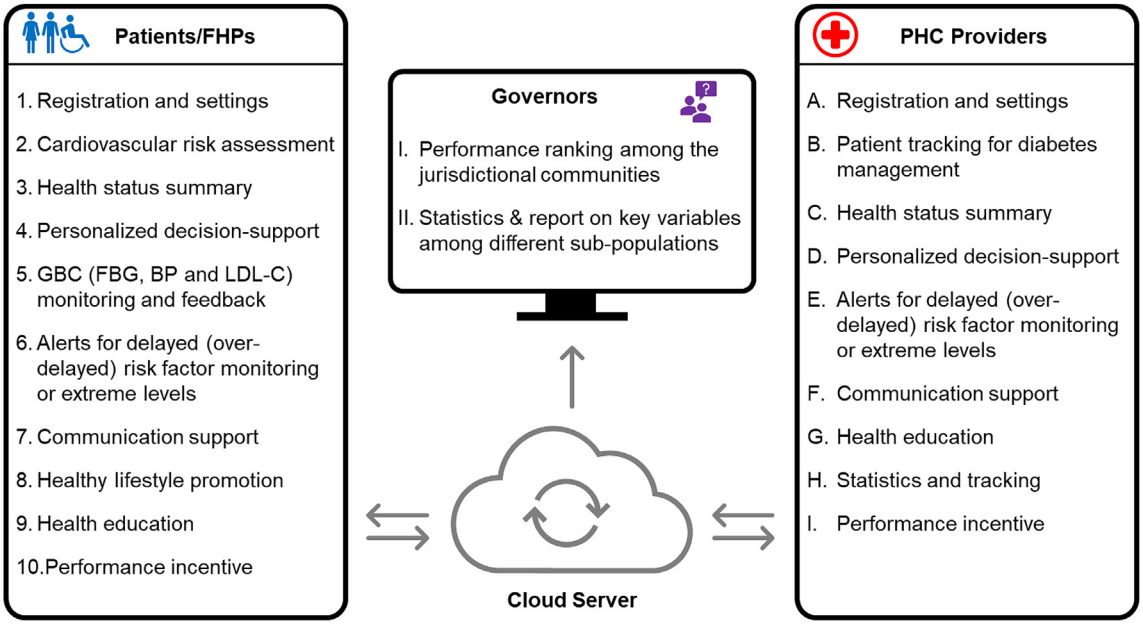
The SMARTDiabetes intervention components were developed from the following activities:

(1) a theory-driven needs analysis using Michie's behaviour change theories to (1) understand the capabilities, opportunities and motivation of medical staff, families and patients to obtain improved outcomes related to diabetes; and (2) to determine whether mHealth interventions could mitigate provider and patient barriers to improving diabetes care.[20]
(2) a review and synthesis of Chinese guideline recommendations for prevention and treatment of type 2 diabetes.[21]
(3) a user-centred design process in which platform users (FHPs, patients, doctors, health service government officials) were engaged in the design and development of prototype applications over several iterative cycles.

The key components of the intervention are outlined in Fig. 1. Detailed features of the app for different users as well as the adopted intervention functions/categories using Michie's Behaviour Change Wheel framework are illustrated in Appendix Document S1.

The intervention was made freely available to patients (and their nominated FHP where requested) via their PHC provider. Face-to-face training on the installation and use of the applications was provided for doctors. The doctors would then schedule an initial medical consultation for all their enrolled patients/FHPs. Personal health information was entered into the application during the consultation. The local governors supported intervention development, trial coordination, and organization of quarterly intervention reviews by the care providers. They had no other role in the implementation of the intervention.

Strategies to optimise engagement with the intervention included personalised goals on the app home screen, in-app reminders for self-monitoring of blood glucose and BP, prompts for scheduling doctor visits. A score was generated based on app usage and patients could obtain small gift incentives (e.g. toiletries, hygiene products) from their treating doctor for maintaining



Note: PHC: primary health care; FBG: fasting blood glucose; BP: blood pressure; LDL-C: Low density lipoprotein cholesterol; GBC: FBG, BP and LDL-C; FHP: family health promotor

Fig. 1: **Intervention components of SMARTDiabetes.**

high levels of usage. FHPs were also instructed to assist patients with self-management actions including healthy diet, engaging in exercise, monitoring blood glucose and BP, managing medication, and accessing medical care. The use of FHPs was at the discretion of the patient. The doctors in the intervention group met every 4 months with local investigators as part of a quality improvement activity to assess performance and implementation barriers for their patients.

The application was built with Java and SpringBoot frameworks for iOS and Android operating systems. To avoid contamination with the control group, the platform was not publicly available during the trial and could only be accessed for free by participants in the intervention arm via a secure password-protected registration process. Data collected from the patient's mobile device, was encrypted and saved on a cloud-based server which was secured from unauthorised access using industry standard firewalls and anti-virus software.

Control group

Participants in the control arm received usual care provided by PHC facilities which are called community health centres and stations in urban areas, and township hospitals and village clinics in rural areas. Apart from routine clinical diagnosis and treatment, the key services recommended to be provided to patients with T2DM include (1) at least four fasting blood glucose tests per year; (2) at least four BP measurements per year for patients comorbid with hypertension; (3) diet, physical exercise, medication instruction at every face to face visit; (4) patient referral if necessary for specialist advice; and (5) an annual review.[1]

Data collection

Fidelity data were collected from the intervention arm based on log-in frequency and app pages visited, and medical data entered into the app by patients, FHPs and doctors. For outcome evaluation, participants in both arms had a comprehensive survey, anthropometric measurements and blood sample collection at baseline, mid-term (12 months) and end of study (24 months) at their local PHC facility by independent trained data collectors.

Except for on-site measurement of body weight and height, all other data, including medical history and incidence of diabetes complications, were conducted by trained and qualified investigators through face-to-face inquiry. For BP measurement, three consecutive seated measurements were performed at 1-min intervals on the right arm of each participant utilizing an OMRON HBP-1300 after a 10-min rest; the average of the last two readings was used for subsequent analysis. For HbA1c and lipid measurement, two accredited central laboratories were used for participants in both study arms. All laboratory tests were performed on the Hitachi High-Tech Corporation's 7180 Clinical Analyzer. For quality control, these laboratories conduct daily testing and must meet a minimum accuracy standard for all blood samples.

A validated electronic data collection system (mEDC) mobile app was used.[22] This allowed for realtime queries

on missing, non-logical and outlier data. The mEDC app also supported data collection activities in accordance with standard operating procedures. For example, for BP measurement accuracy a 60-s timer was available on the app for consistent time intervals between measurements.

Outcomes

The primary outcome was the difference in proportion of patients achieving at least two "ABC" goals defined as any two of the following: HbA1c < 7.0%, both systolic/diastolic blood pressure (SBP/DBP) < 140/80 mmHg and LDL-c < 100 mg/dl or 2.6 mmol/L)[21] at 24 months. The pre-specified secondary outcomes were the proportion of patients achieving each individual "ABC" goal at 24 months, the proportion of patients achieving laboratory fasting plasma glucose (FPG) < 7.0 mmol/L at 24 months, mean change in ABC variables (HbA1c, SBP and DBP and LDL-c) and FPG from baseline to 24 months.

Pre-specified subgroups included locality (urban vs rural), age, sex, duration of diabetes, baseline HbA1c and diabetic complication at baseline.

Exploratory outcomes included the following:

- Summary of Diabetes Self-Care Activities (SDSCA) score
- renal function (albumin to creatinine ratio—ACR, and estimated glomerular filtration rate–eGFR)
- body mass index (BMI)
- quality of life (EQ5D score and EQ5D VAS score)
- self-reported use of BP, lipid and glycaemic medication
- health care utilization (inpatient and outpatient times and costs)
- hypoglycaemia (defined as a plasma glucose ≤ 3.9 mmol/L or self-reported symptomatic episodes)
- doctor diagnosed diabetic nephropathy, retinopathy, peripheral neuropathy, peripheral artery disease, diabetic foot damage
- doctor diagnosed cardiovascular disease (including coronary stenosis, myocardial infarction, coronary revascularization, cerebral infarction, or cerebral haemorrhage)
- death from any cause.

Statistical considerations

Sample size estimation

Assuming 20% of people in the control arm would achieve ≥2 "ABC" goals (primary outcome) at the end of the study, an intra-class correlation coefficient of 0.05, a 20% loss to follow-up and a two-sided significance level of 0.05, 80 community clusters and a mean community cluster size of 25 participants (2000 total) provided 90% power to detect an absolute improvement of 10% in the primary outcome in the intervention arm. Sample size assumptions and effect sizes were based on risk factor prevalence studies and the previous family health promoter trial and assessed using PASS software (NCSS LLC).[3,15]

Fidelity data analysis

App utilisation for intervention arm participants was assessed as: (1) the mean/median app click rate per month assessed during months 9–24 of follow-up to allow time for initial training and support with installing and using the app; (2) the monthly proportion of participants or FHPs who accessed the app at least once in that month; and (3) the proportion of participants or FHPs who accessed the app at least once per month for 12 months or more during the follow-up period. Other measures of fidelity included use of the reward incentives and mean monthly blood glucose and BP measurements. Frequencies were reported overall and by rural vs urban region.

Outcome analysis

Appendix Document S2 shows the pre-specified outcome statistical analysis plan (SAP). In summary, all outcomes were analysed according to intention-to-treatment (ITT). All analyses were at patient level. The primary analysis for categorical outcomes was conducted using log-binomial regression with generalized estimation equation (GEE) to account for clustering at the health service level, and the effect of intervention was presented as the relative risk (RR) with its 95% confidence intervals (CIs). For continuous variables, the primary analysis was conducted using linear regression with GEE accounting for clustering at the health service level.

The primary analysis included complete cases with missing values excluded. In a sensitivity analysis, imputed data analyses were conducted for variables with over 5% missingness. Sensitivity analyses were also conducted with adjustment for locality (rural/urban) and baseline demographic and clinical characteristics of the participants. The subgroup analyses were performed by adding the subgroup variable as well as its interaction with the intervention as fixed effects to the primary model, with the results displayed on a forest plot including the p value for interaction between the intervention and the subgroup variable.

In a post-hoc analysis, an inverse propensity score weighted analysis was also conducted to compare the outcomes between FHPs engaged or not and app-active or not subgroups within the intervention group. Propensity scores were developed to control for the differences in baseline demographics, medical history and lab characteristics between participants with an FHP engaged or not in the intervention group. Propensity scores were generated by a logit regression model with covariates of age, sex, locality, HBA1c, FBG, SBP, DBP, LDL-c, education levels, duration of diabetes category, and diabetic complications. A log-binomial regression

model with GEE and adjustment for community clustering and the weighted inverse propensity score was then developed.

All tests were two-sided with a nominal level of α set at 5% without multiplicity adjustment. All analyses were performed with SAS software, version 9.4 or above (SAS Institute).

Ethical considerations

The study was approved by the Peking University Health Sciences Institutional Review Board (IRB00001052-15062) and the University of Sydney Human Research Ethics Committee (HREC 2016/105), NSW, Sydney. It was registered in the Australian and New Zealand Clinical Trials Registry. All data collection and reporting are compliant with national privacy law, and no report is allowed identification of individual participants. Data were securely stored at the George Institute China.

Trial registration

Clinicaltrials.gov NCT02726100.

Protocol amendments

At study commencement, the inclusion criterion was meeting no more than one of 2013 ADA and CDS (Chinese Diabetes Society) management targets. After enrolment in an initial village, it was found that screening for all three parameters (HBA1C, BP and serum cholesterol) was not logistically feasible. Therefore, the biochemical inclusion criteria were simplified to only an HbA1c ≥ 7%. Two patients were recruited based on the original inclusion criteria prior to this change.

Role of funding source

The funders did not participate in the study design, data collection, data analysis, interpretation, or writing of the report.

Results

In 2017, from July to November, 2072 eligible patients were recruited from 80 clusters (half rural and half urban). All the participants were randomized into intervention group (1038 patients from 40 clusters) and control group (1034 patients from 40 clusters) after baseline assessment and used for analysis. By October 2019, 1872 patients (947 from intervention and 925 from control group) completed the 24 months follow-up (Fig. 2). Compared to those followed up, patients lost to follow up predominantly came from urban areas (72.5% vs 45.0%), were slightly older [average age 63.6 (SD 7.4) vs 61.3 (SD 7.0)] and had higher baseline SBP [140.0 (SD 21.3) vs 135.9 (SD 19.0) mmHg]. No significant differences were found in other demographic, physical, medical history, lab tests, and quality of life measures.

Baseline characteristics

Community cluster characteristics by urban and rural location show reasonable balance between randomised groups. Similarly, the baseline participant demographic and clinical characteristics were well balanced between the randomised groups (Table 1).

Primary and secondary outcomes

The proportion of participants with any 2 of 'ABC' goals achieved was significantly higher in the intervention group compared to usual care (339 [35.9%] vs 276 [29.9%]; RR 1.20, 95% CI 1.02–1.40; p = 0.025). The intervention was associated with lower HbA1c (mean difference –0.33%, 95% CI –0.48% to –0.17%; p < 0.0001) and FPG (mean difference –0.58 mmol/L, 95% CI –0.89 to –0.27; p = 0.00025) levels and increased FPG control rate (RR 1.21, 95% CI 1.03–1.41; p = 0.019). There was no significant difference in BP and lipid outcomes between the two groups (Table 2).

Sensitivity analyses using the covariate-adjusted analysis (including adjustment for locality), and imputed analysis regarding the primary and secondary outcomes did not show major significant differences when compared to the primary models. The only exception was that the LDL-c control rate and mean LDL-c levels were improved in the intervention group vs control in the adjusted model (Appendix Table S1).

Subgroup analysis for the primary outcome between groups

There was significant heterogeneity in the primary outcome between urban and rural areas (rural 220 [42.6%] vs 158 [31.0%]; urban 119 [27.9%] vs 118 [28.6%]; p = 0.022 for heterogeneity) (Fig. 3), There was no significant heterogeneity for any of the other pre-specified sub-groups.

Exploratory outcomes

The intervention was associated with small improvements in quality of life (mean difference in EQ-5D score 0.02, 95% CI 0.00–0.03; p = 0.0067). Although the absolute numbers of events were small, the intervention was associated with a reduced incidence of peripheral arterial disease (4 [0.4%] vs 20 [2.2%]; RR 0.20, 95% CI 0.07–0.54; p = 0.0017) and ischaemic heart disease events (44 [4.6%] vs 69 [7.5%]; RR 0.62, 95% CI 0.45–0.86; p = 0.0039) when compared with control. Compared with control, the intervention was associated with increased oral glucose-lowering (RR 1.06, 95% CI 1.01–1.12; p = 0.014) and lipid-lowering medications (RR 1.72, 95% CI 1.41–2.09; p < 0.0001) but not insulin or BP-lowering medication (Appendix Table S2). No statistically significant differences were found for other

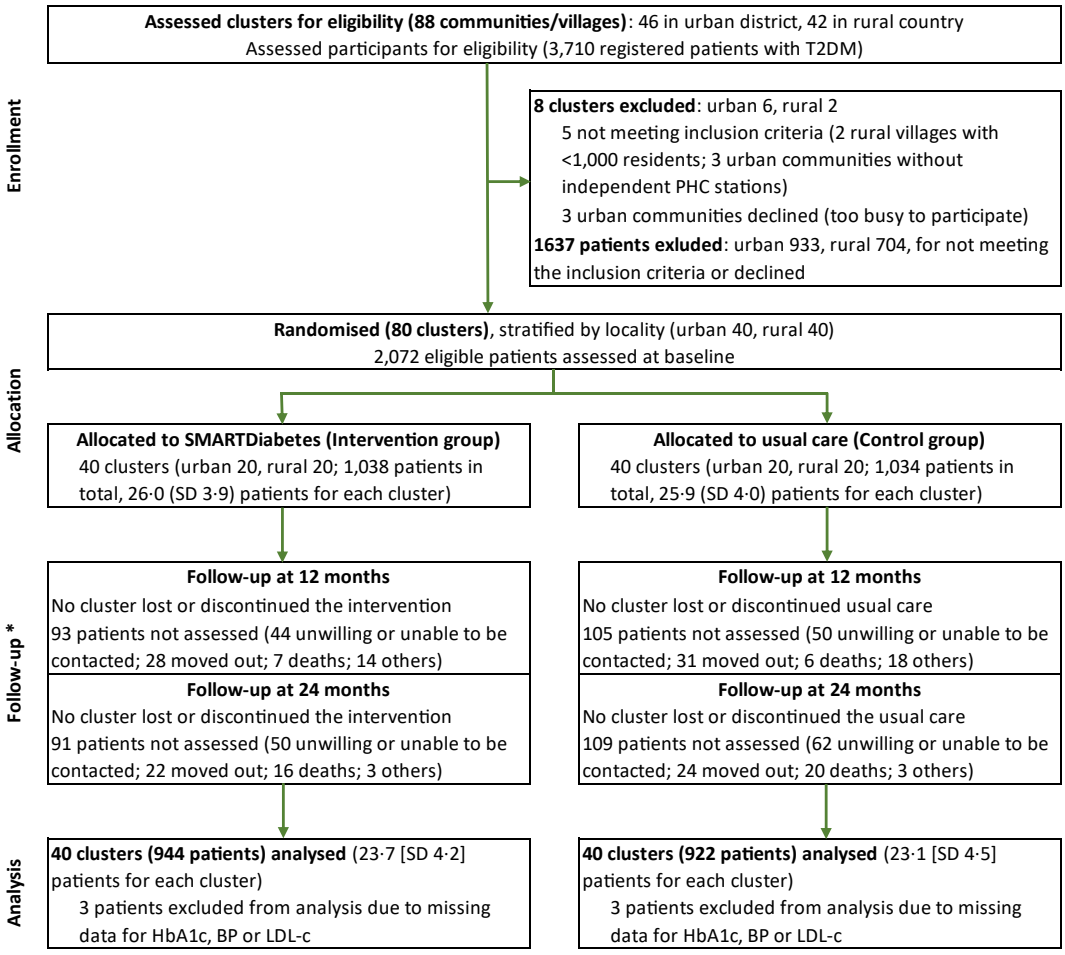


Fig. 2: **Flowchart of patient enrolment, randomization and follow-up.** Note: ITT: intention-to-treatment; BP: blood pressure; LDL-c: low-density lipoprotein cholesterol. *Some people not contacted at 12 months attended the 24-month follow-up visit. This is particularly due to some older people temporarily relocating to warmer cities during winter months and/or to live with their children before returning home.

risk factors (BMI, waist circumference, renal function, hypoglycemics episodes), other comorbidities and total deaths (Appendix Tables S3–S5).

The annual medical cost at 24 months increased in both trial arms but the mean difference from baseline was non-significant (mean difference 1069 CNY ($149 USD), 95% CI –838 to 2976; p = 0.27). Mean annual clinic visits increased in the intervention group compared to usual care (mean difference 2.93 visits/year, 95% CI 1.43–4.43; p = 0.00013) (Appendix Table S6).

The inverse propensity score weighted primary model showed that the engagement of FHP was associated with higher ABC control (40.5% vs 33.4%; RR 1.30, 95% CI 1.17–1.44; p < 0.0001), improved control for HbA1c, BP and LDL-c, and lowered HbA1c, FPG and LDL-c levels (Appendix Table S7 and S8). People who were active users of the app had significantly higher ABC control rates when compared to inactive users (43.5% vs 32.4%; RR 1.29, 95% CI 1.06–1.57; p = 0.010) (Appendix Table S9).

Implementation adoption

App usage

Among the 1038 intervention participants (541 rural and 497 urban), the mean monthly app click rate was 13.2 (SD 20.2) times per person with no significant difference in rural vs urban areas (Appendix Table S10). The mean monthly proportion of active app users (accessed at least once during months 9–24 of follow-up) was 46.4% (SD 7.8%), with non-significantly greater uptake in rural vs urban communities (rural 49.2% [SD 8.2%] vs urban 43.3% [SD 8.9%]; p = 0.062). There was a moderate decline in usage between month 9 and month 24 of the follow-up period (56.3% vs 42.2%). The overall dropout rate (the % with no recorded usage over months 9–24 of the intervention period) was 16.4%. The proportion of continuously active users (being monthly-active for at

Characteristics	Control	Intervention
Cluster level		
Number of participating facilities	40	40
Government owned facilities[a], n (%)	33 (83%)	33 (83%)
Size of the community served, median (IQR)	4276 (1976, 7488)	4250 (2466, 6491)
Distance to the nearest tertiary hospital (km), mean (SD)	9.6 (9.52)	7.6 (7.44)
Staff per facility, median (IQR)	5.5 (2.0, 11.0)	4.0 (2.0, 6.8)
Doctors	2.0 (1.0, 5.8)	2.0 (1.0, 3.0)
Nurse	0.0 (0.0, 3.0)	0.5 (0.0, 3.0)
Staff providing routine NCD management services	2.0 (1.0, 2.0)	2.0 (1.0, 3.0)
Patient level		
Total number	1034	1038
Locality-rural, n (%)	543 (52.5%)	541 (52.1%)
Age (years), mean (SD)	61.6 (6.9)	61.4 (7.1)
Male, n (%)	481 (46.5%)	449 (43.3%)
BMI (kg/m^2), mean (SD)	26.7 (3.3)	26.6 (3.6)
Education level, n (%)		
Primary school or lower	117 (11.3%)	119 (11.5%)
Junior high school	336 (32.5%)	364 (35.1%)
Senior high school	261 (25.2%)	236 (22.7%)
Junior college	27 (2.6%)	29 (2.8%)
Bachelor degree or higher	293 (28.3%)	290 (27.9%)
Current smoker, n (%)	181 (17.5%)	193 (18.6%)
Duration of diabetes (years), mean (SD)	9.0 (6.68)	9.1 (7.04)
Any 2 of 'ABC' goals achieved[b], n (%)	103 (10.0%)	94 (9.1%)
HbA1c < 7%, n (%)	0 (0.0%)	2 (0.2%)
SBP/DBP < 140/80 mmHg, n (%)	421 (40.7%)	475 (45.8%)
LDL-c < 2.6 mmol/L, n (%)	226 (21.9%)	215 (20.7%)
HbA1c (%), mean (SD)	8.66 (1.48)	8.59 (1.40)
SBP (mmHg), mean (SD)	137.4 (19.5)	135.3 (19.1)
DBP (mmHg), mean (SD)	79.2 (10.4)	78.3 (10.8)
LDL-c (mmol/L), mean (SD)	3.29 (0.84)	3.33 (0.87)
FPG < 7.0 mmol/L, n (%)	157 (15.2%)	127 (12.2%)
FPG (mmol/L), mean (SD)	9.74 (3.14)	9.83 (3.06)
SDSCA total score, mean (SD)	31.99 (8.57)	31.64 (8.97)
Hypertension[c], n (%)	764 (73.9%)	717 (69.1%)
Diabetic nephropathy, n (%)	48 (4.6%)	43 (4.1%)
Diabetic retinopathy, n (%)	189 (18.3%)	183 (17.6%)
Peripheral neuropathy, n (%)	63 (6.1%)	51 (4.9%)
Peripheral arterial disease, n (%)	94 (9.1%)	87 (8.4%)
Known macrovascular disease, n (%)	181 (17.5%)	163 (15.7%)
Cardiac disease, n (%)	91 (8.8%)	80 (7.7%)
Cerebral disease, n (%)	112 (10.8%)	98 (9.4%)
Diabetic complications[d], n (%)	375 (36.3%)	363 (35.0%)

Notes: IQR: interquartile range; SD: standard deviation; BMI: body mass index; FPG: laboratory fasting plasma glucose; SBP: systolic blood pressure; DBP: diastolic BP; LDL-c: low-density lipoprotein cholesterol; SDSCA: the summary of diabetes self-care activities. [a]The facilities are classified as government owned and non-government owned (including enterprise owned or private facilities). [b]ABC goals are HbA1c < 7.0%, SBP/DBP < 140/80 mmHg and LDL-c < 2.6 mmol/L. [c]Including previous diagnosed hypertension, taking antihypertensive medicines, or with measured SBP ≥ 140 mmHg or DBP ≥ 80 mmHg. [d]Diabetic complication was defined as presence of any diagnosed diabetic nephropathy, diabetic retinopathy, peripheral neuropathy, carotid artery disease, lower extremity artery disease, diabetic foot damage, coronary stenosis, myocardial infarction, coronary revascularization, cerebral infarction, or cerebral haemorrhage.

Table 1: **Baseline characteristics at cluster and patient levels by treatment arms.**

least 12 months during the follow-up) was greater in rural than urban areas (207 [38.3%] vs 135 [27.2%]; p = 0.00014) (Appendix Table S11).

Fig. 4 shows that the most frequently clicked sections by patients and/or FHPs was healthy diet and exercise reminders (≥40,000 clicks overall), followed by blood

Outcomes	Control	Intervention	Difference (95% CI)[a]	RRs (95% CI)[a]	p value	ICC[b]
Primary outcome at 24-months, n (%)						
Any 2 of 'ABC' goals achieved	276 (29.9%)	339 (35.9%)	5.9% (0.7%, 11.1%)	1.20 (1.02, 1.40)	0.025	0.021
Secondary binary outcomes at 24-months, n (%)						
HbA1c < 7.0%	141 (15.2%)	172 (18.2%)	2.7% (−1.6%, 7.0%)	1.18 (0.91, 1.52)	0.218	0.026
FPG < 7.0 mmol/L	239 (25.9%)	295 (31.3%)	5.4% (0.7%, 10.0%)	1.21 (1.03, 1.41)	0.019	0.012
BP < 140/80 mmHg	486 (52.6%)	525 (55.4%)	2.8% (−2.7%, 8.3%)	1.05 (0.95, 1.17)	0.320	0.021
LDL-c < 2.6 mmol/L	373 (40.5%)	438 (46.4%)	5.8% (−0.6%, 12.3%)	1.15 (0.99, 1.33)	0.074	0.047
Secondary continuous outcomes (change from baseline to 24-months), mean (SD)						
HbA1c level, %	−0.06 (1.58)	−0.35 (1.53)	−0.33 (−0.48, −0.17)	–	<0.0001	0.025
FPG level, mmol/L	−0.53 (3.38)	−1.13 (3.53)	−0.58 (−0.89, −0.27)	–	0.00025	0.033
SBP, mmHg	−3.7 (17.8)	−3.6 (16.7)	−0.72 (−2.52, 1.09)	–	0.436	0.062
DBP, mmHg	−3.2 (8.8)	−3.0 (8.6)	−0.13 (−1.12, 0.87)	–	0.804	0.057
LDL-c level, mmol/L	−0.47 (0.80)	−0.58 (0.87)	−0.10 (−0.24, 0.04)	–	0.179	0.229

Notes: 'ABC' goals consist of HbA1c level < 7.0%, BP(SBP/DBP) < 140/80 mmHg and LDL-c < 2.6 mmol/L; SBP: systolic blood pressure; DBP: diastolic blood pressure; FPG: laboratory fasting plasma glucose; LDL-c: low-density lipoprotein cholesterol. SD: standard deviation. [a]Primary model: for the primary outcome and secondary binary outcomes, log-binomial model with GEE was adopted with adjustment of clusters (villages/communities); for secondary continuous outcomes, linear regression with GEE was adopted with adjustment for baseline values of the analysed outcome. [b]Intraclass Correlation Coefficient for endpoints; mixed-effect models were applied (logit regression for binary outcomes, linear regression for continuous outcomes), with clusters (villages/communities) adopted as random effect.

Table 2: **Primary and secondary outcomes.**

For any two of 'ABC' goals at 24-month	Usual care	Intervention	RRs (95% CI)	P values
Locality				
Urban	118 (28·6%)	119 (27·9%)	0·974 (0·794, 1·195)	
Rural	158 (31·0%)	220 (42·6%)	1·377 (1·133, 1·674)	
P for interaction				0·022
Sex				
Male	133 (30·5%)	148 (36·5%)	1·206 (0·978, 1·487)	
Female	143 (29·4%)	191 (35·4%)	1·193 (0·975, 1·460)	
P for interaction				0·940
Age group (years)				
<60 years	101 (29·5%)	120 (33·1%)	1·106 (0·873, 1·401)	
≥60 years	175 (30·2%)	219 (37·7%)	1·254 (1·040, 1·512)	
P for interaction				0·373
Diabetes Duration				
<6 years	98 (26·6%)	118 (32·7%)	1·220 (0·987, 1·509)	
≥6 years	178 (32·2%)	221 (37·9%)	1·181 (0·980, 1·422)	
P for interaction				0·790
HbA1c level (%)				
<8%	120 (32·3%)	160 (40·5%)	1·269 (1·038, 1·553)	
≥8%	156 (28·4%)	179 (32·6%)	1·134 (0·917, 1·402)	
P for interaction				0·407
Diabetic complication				
Yes	101 (30·4%)	120 (36·4%)	1·197 (0·930, 1·539)	
No	175 (29·7%)	219 (35·7%)	1·198 (1·008, 1·425)	
P for interaction				0·991
OAD or insulin				
Yes	232 (30·1%)	295 (36·0%)	1·192 (1·008, 1·409)	
No	44 (29·3%)	44 (35·5%)	1·228 (0·873, 1·729)	
P for interaction				0·870
Blood pressure medication				
Yes	76 (23·4%)	119 (33·1%)	1·391 (1·075, 1·799)	
No	200 (33·5%)	220 (37·7%)	1·132 (0·936, 1·370)	
P for interaction				0·196
Lipid-lowering medication				
Yes	23 (39·7%)	27 (34·6%)	0·912 (0·593, 1·403)	
No	253 (29·3%)	312 (36·0%)	1·224 (1·041, 1·438)	
P for interaction				0·219

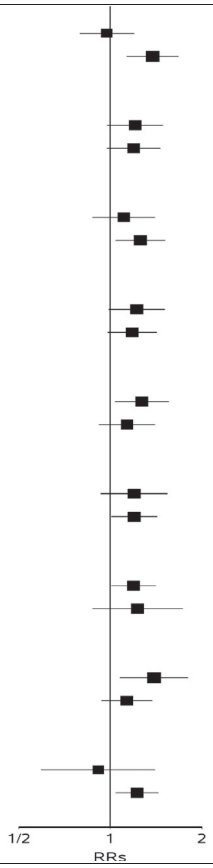


Fig. 3: **Subgroup analysis for the primary outcome.**

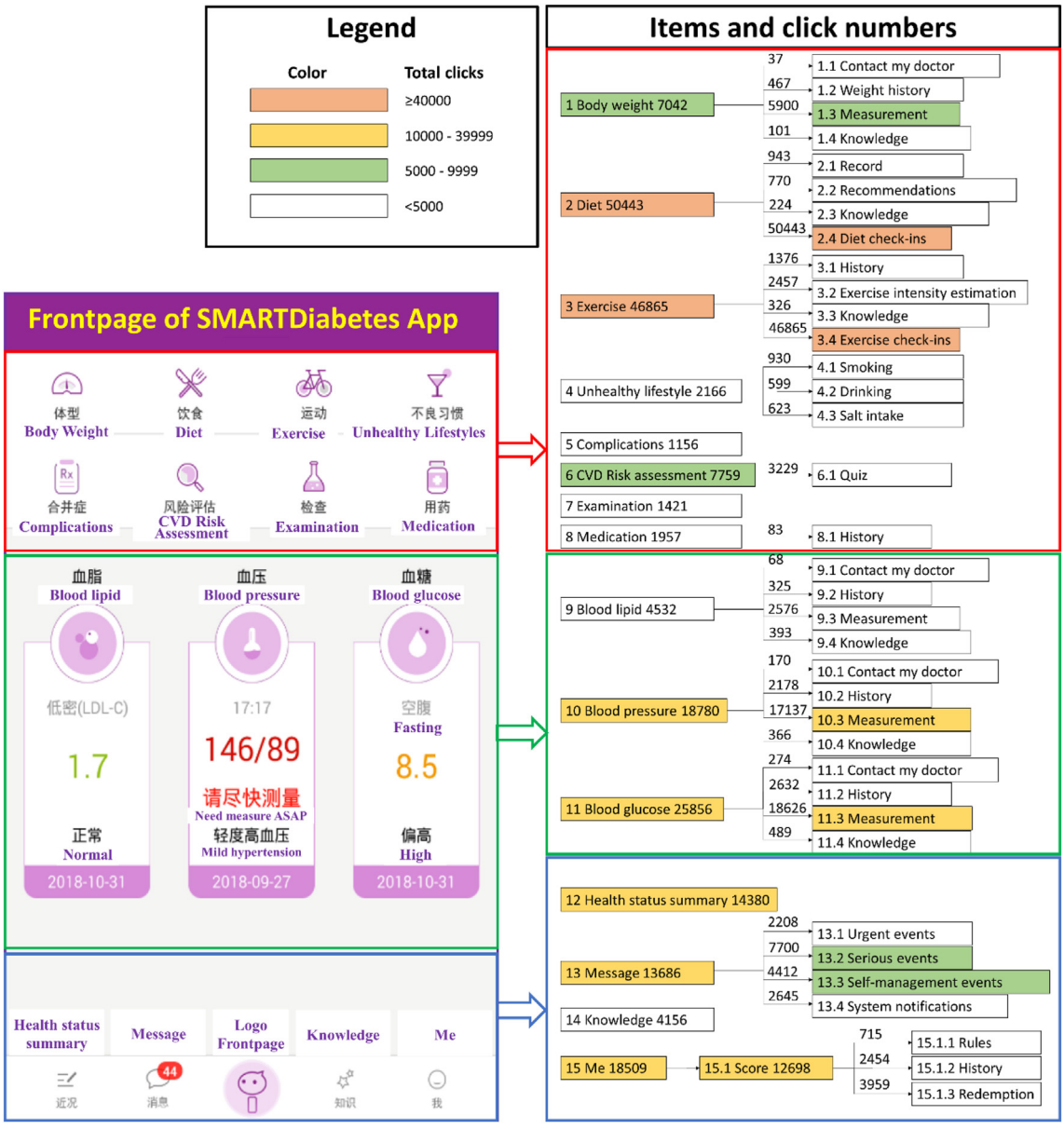


Fig. 4: **Features of SMARTDiabetes and clicking behaviours among 1038 participants.**

glucose and BP measurement entries, health status summary, and 'Me' which showed performance scores and supported gift redemption (10,000–39999 clicks each). Body weight measurement and CVD risk assessment were moderately used (5000–9999 clicks each).

Aside from message notifications, the most accessed sections (>5000 clicks) were directly related to the incentive gift scheme (Appendix Document S1). The total average gift costs for each patient during the two-year follow-up was 134.9 (SD: 66.8) CNY (USD$18.80) with no difference between rural and urban participants. The knowledge section, unhealthy habits (smoking and drinking) assessment, and clinical information (lipid test, other examinations, complications, and medications) were among the least used features and these features were not related to the incentive scheme.

The mean monthly frequency of recording risk factor measurements was 1.50 (SD 0.39) for fasting blood glucose and 1.45 (SD 0.39) for BP with no significant difference in rural vs urban communities. In urban communities, most blood glucose (76.1%) and BP (76.3%) measurements were conducted by patients/FHPs themselves, while in rural areas most of the blood

glucose (59.3%) and BP (59.5%) measurements were conducted by village doctors (Appendix Table S12).

FHP engagement

There were 344 (36.4%) FHPs engaged in diabetes management at 24 months in the intervention group. FHPs were engaged at a greater rate in rural vs urban areas (252 [48.6%] vs 92 [21.5%], $p < 0.0001$) (Appendix Table S13). Most FHPs (80.4% in urban and 78.2% in rural) were the patients' adult children, and the majority were male (62 [67.4%] in urban and 144 [57.1%] in rural) and lived together with the patients (58.7% in urban and 76.2% in rural). The main activities undertaken by FHPs included reminders about healthy diets and exercise, taking medicines and attending hospital visits (Appendix Table S14).

Discussion

This multifaceted digital health intervention implemented in one Chinese province was associated with a relative 20% improvement in attainment of combined glycaemic, BP and cholesterol targets over a 24-month period. In pre-specified subgroup analyses the intervention was more effective in rural compared to urban communities. Implementation fidelity compared favourably with the literature with around 50% of intervention participants engaging in the intervention at least monthly throughout the intervention period.[23] FHPs supported one-third of the intervention arm participants. In exploratory analyses to better understand the trial outcomes, use of FHPs and active use of the app was better in rural than urban communities, and significantly associated with improved ABC control rates. The intervention was not associated with improvements in BP levels, control rates or use of BP-lowering medications. There was an improvement in use of lipid-lowering medications but no improvement in LDL-c levels or control rates.

A 2021 meta-analysis of mobile app-based interventions (21 RCTs/1920 patients) found a 0.38% reduction in HbA1c levels, a similar effect size to that observed in our study.[24] The studies included in this meta-analysis were small scale (largest sample 229 participants) and short follow-up periods (≤6 months for 15 studies). Another systematic review (11 RCTs/961 total participants) in low-income and-middle income countries found HbA1c reductions of <0.3%.[11] The ROADMAP study which was conducted by our research team was a large cluster RCT enrolling 19,601 participants from 864 communities in 25 provinces in China. It focussed on an integrated care intervention involving primary care clinics and county hospitals and found similar HbA1c reductions (−0.30%) to those observed in SMARTDiabetes.[25] Together with SMARTDiabetes and its complementary focus on community based care not involving hospitals, these are the two largest trials of digital health interventions conducted to date.

A reduction of 0.3% in HbA1c is considered by the European Medicines Agency as a clinically meaningful improvement.[26] Although this absolute effect size may be considered modest, there is potential for substantial population health level benefits if such interventions can be implemented at scale. Diabetes control rates have been stagnant (remaining unchanged at around 50% in the 2013–2017 period) in China.[2] Therefore a 20% relative increase in effectiveness of a low cost intervention scaled to a large population could be highly impactful, particularly in rural areas. An economic evaluation modelling such effects is being conducted and will be reported separately. However, it is important to note that SMARTDiabetes did not significantly impact other CVD risk factors, especially blood pressure, LDL-cholesterol and body weight compared with usual care. This is consistent with the findings of a recent meta-analysis on the clinical effects of T2DM patient management using digital healthcare technology.[12] It is likely that additional strategies are needed to generate clinically meaningful improvements in these risk factors. In addition, we found the intervention was associated with an increase of almost three clinic visits per year. This suggests greater engagement with care providers may result in increased primary health care service utilisation.

SMARTDiabetes is a multifaceted mHealth platform with personalized monitoring and decision support targeting four user groups: patients and their nominated FHPs, doctors and local governors. Its core features drew on existing evidence from almost exclusively high-income country settings and included tailored feedback from PHC providers through app or interactive communication, reminder functions, self-monitoring of outcomes, and other multifaceted functions.[13,24,27–29] We provided free access to the digital intervention and aligned it with the requirements of the national BPHS package. The novelty of SMARTDiabetes is that it tested an implementation strategy which strengthened existing elements of the primary health care system. The importance of such a strategy is its potential scalability. However, to achieve sustained implementation on a larger scale, the intervention would require government support including policies and guidelines on usage, integration with existing information systems such as the "Doctor Working Station" and/or "BPHS Registration and Reporting System", and consideration of performance incentives for care providers. With such system level supports, interventions such as SMARTDiabetes would have greater potential to be sustained and scaled to a larger number of people across China. Further, in this study, local government officials supported the intervention by facilitating quarterly quality improvement reviews with care providers. These officials are expected to conduct these reviews as part of the

Basic Public Health Service package. Their contribution should therefore be considered as one key enabling component of the implementation strategy.

A key feature of the intervention was the use of FHPs to assist patients with self-management and use of the SMARTDiabetes app. Similar approaches involving lay family member or friends have been found to be effective.[14–16] However, in our study FHPs were only engaged by around one-third of intervention arm participants with greater uptake in rural compared to urban areas. This suggests that where they were deployed, this part of the intervention strategy was effective, however, it is not likely to be an acceptable solution for all people with T2DM, particularly those in urban areas.

The use of small gift incentives is a commonly used mechanism for engaging, empowering and retaining patients in primary care.[30,31] We observed higher use of app components that were associated with incentives such as blood glucose and BP measurement and conversely less use of app components that did not directly attract incentives such as messaging between doctors and patients. More research is needed to understand the effective design of such incentives but given the monetary value of such incentives was small, it does suggest that this may be an effective and scalable ancillary measure to support engagement with interventions. Unintended consequences such as excessive or inappropriate use of certain functions, and reduced use of other important functions such as communication between doctors and patients should also be considered in incentive design.

Comparing app engagement levels across studies is challenging due to the heterogeneity in adopted technologies, the targeted health conditions, the chosen evaluation metrics, and the health system context.[32] A systematic review of app-based chronic disease interventions (17 studies) reported a pooled dropout rate of 43% compared to 16% observed in our study.[33] While another systematic review of "real world usage" of mental health apps (10 studies) reported sustained usage rates of 0.5%–28.6%.[34] The rate of continuously active users in SMARTDiabetes was 38% and 27% in rural and urban areas respectively. However, with a minority of participants (46%) being active monthly app users, there is a need to improve engagement and outcomes further. Possible solutions include: (1) increasing patient health literacy on the importance of blood glucose and blood pressure control, (2) targeted reminders to upload information for key health indicators, (3) "social contagion" interventions to increase peer/family/social support; and (4) increasing provider engagement by integrating the digital app with routinely used health information systems. Further, given clinical improvements were observed despite modest usage rates of the app, this suggests that there is not a simple dose response relationship with app usage. Rather such apps need to be embedded in a broader care package to effectively support a person with T2DM.

There was substantial heterogeneity in intervention effects between urban and rural community clusters. This aligns with previous evaluation research we have conducted in India in which we found such interventions are influenced by four overarching narratives within the individual's micro-level and meso-level environments: illness experiences; receptiveness to risk and prevention information; history of the doctor-patient relationship; and relationship with technology.[35,36] Frequency of feedback to patients from PHC providers was identified to be an influential factor in one systematic review.[29] Possible drivers of the rural-urban disparity observed in our study include: (1) rural village doctors are paid by the local government and had high engagement with the intervention, while more than one-third of urban facilities are operated by private entities and have less direct incentives to provide public health services; (2) rural village doctors reside in their villages, have longstanding ties to the residents and have more regular communication with their patients, while most PHC providers and residents in urban communities are less familiar with one another–this may also explain the higher loss to follow-up rate among urban patients compared with rural patients; (3) the population served by an urban community health station exceeds that of rural villages by threefold on average, and therefore the workload of urban doctors may be considerably greater and they may have had less time to engage with the intervention; (4) urban patients can more easily visit higher-level hospitals, bypassing primary care; and (5) extended families in rural areas tend to live together or in neighbouring houses which makes FHP engagement easier when compared with urban areas. Rural patients also tended to be younger, with shorter diabetes history, higher LDL-c, and lower diabetes self-care scores, which may contribute to the varied outcomes.

Strength and limitations

The size of the SMARTDiabetes trial is a major strength. The rural/urban stratified design allowed us to identify important differences in use and effectiveness of the strategy. There were technical challenges in ensuring access on diverse mobile phone types and operating systems. This could be addressed by deploying the SMARTDiabetes platform on an existing widely used application platform such as WeChat, which is the most popular communication application and works on any operation system and device brand in China. The lack of integration of the SMARTDiabetes app with local information systems (which were at a rudimentary stage during this study) is an important consideration to support sustainability and scalability outside of a trial setting. Although SMARTDiabetes focused on enhancing care under the uniformly implemented

national BPHS program, regional differences especially in economic development, elderly care culture, access to PHC facilities and hospitals, workforce capacity, and PHC supervision should be considered for scalability. The observed effects in this study may be influenced by its unblinded design. This reflects the need for a balance between pragmatism (where observed effects approximate what might be achieved in real world practice) and experimental rigour (where major biases are minimised).[37] The risk of observer induced behaviour change is reduced somewhat with a 2-year follow up duration. Further, the behaviour change due to unblinding ought to be uniformly distributed, however we observed significant heterogeneity between urban and rural areas. Despite a high follow-up rate (91%), there were some differences in those lost to follow-up compared to those in the trial (older, more urban residents, and higher baseline BP). These differences were evenly distributed between intervention and control arms and therefore the risk of differential bias is low. It may, however, impact generalisability. The study design focussed on a single complex intervention which makes it challenging to identify the relative effects of particular intervention components. The time lag between study completion and reporting of this study was influenced by COVID-19 and the procedure of fulfilling China's new genetic resource management policy. However, current policies for diabetes management have been unchanged since 2018, with the exception of increased funding for PHC facilities. Consequently, the findings of SMARTDiabetes remain relevant now despite the time lag in reporting.

Conclusion

This multi-faceted digital diabetes management platform was effective in improving diabetes risk factor control rates, particularly in rural areas where there are more intimate links between patients and their doctors and support from family members may be stronger. The findings support replication, spread and scale-up of such intervention strategies, however tailoring to local contextual requirements is needed.

Contributors

PZ and DP spearheaded the study's conceptualization, funding acquisition, and intervention development, while also managing the project. They were instrumental in drafting and revising the manuscript, and had final responsibility for the decision to submit for publication. XT, YM, YZ, and XM were pivotal in conducting research and supervising fieldwork, as well as interpreting data. AP and SJ significantly refined the methodology and contributed to the manuscript's editing process. XT, HS, and PZ were responsible for directly accessing and verifying the underlying data, with HS conducting the formal analysis. YL was in charge of software development. All authors played a role in reviewing the results and refining the final manuscript for publication.

Data sharing statement

Anonymised individual-level data and datasets generated or analysed during the current study, together with the data dictionary and study protocol, are available for researchers who provide a methodologically sound proposal. Proposals should be directed to Dr Puhong Zhang (zpuhong@georgeinstitute.org.cn) and Dr David Peiris (dpeiris@georgeinstitute.org).

The data will be available beginning 3 months after publication of this Article, with no end date. Any cross-border transfer of individual data must obtain official approval following legal procedures, in accordance with relevant regulations.

Declaration of interests

AP received fellowship and grant support from the Australian NHMRC, UK National Institute for Health and Care Research, and Australian Medical Research Future Fund for the present manuscript. She also sits in the DSMB of an international trial on coronary artery disease screening in end-stage kidney disease patients and chairs the DSMB of a heart failure rehabilitation trial. She is the Executive Director of The George Institute for Global Health and George Institute Ventures, Non-Executive Director of George Health Enterprises, Chair of George Medicines, Director and Trustee of the Pulmonary Vascular Research Institute, and a Member of Council and Chair of the Research Committee of the Australian National Health & Medical Research Council. The other authors declare that they have no competing interests.

Acknowledgements

This work was funded by the Australian National Health and Medical Research Council (NHMRC) through a Global Alliance for Chronic Diseases grant (ID 1094712). We are grateful to Professors Linong Ji and Junfeng Xu for their contributions to the development of our mHealth intervention. We thank Xian Li, Fengzhuo Chen, Qiang Li, and Laurent Billot for their assistance in developing the statistical analysis plan and for checking the SAS program. We also extend our thanks to the patients, their relatives, and the doctors who participated in this study.

Appendix A. Supplementary data

Supplementary data related to this article can be found at https://doi.org/10.1016/j.lanwpc.2024.101130.

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