IMPACT OF THE INNOVATIVE CARE FOR CHRONIC CONDITIONS PROGRAM ON BLOOD SUGAR, BLOOD PRESSURE, LIPID LEVELS, MEDICATION COMPLIANCE AND MENTAL HEALTH AMONG ELDERLY CHINESE WITH HYPERTENSION AND TYPE 2 DIABETES MELLITUS

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Abstract. Hypertension (HT) and type 2 diabetes mellitus (DM) affect the morbidity and mortality of elderly Chinese. In this study, we aimed to determine the efficacy of the Innovative Care for Chronic Conditions (ICCC) program for improving blood sugar levels, blood pressure levels, lipid levels, medication compliance and mental health among elderly Chinese with HT and DM in order to inform efforts to reduce morbidity and mortality caused by these conditions in the study population. The ICCC program, administered along with standard pharmacotherapy in the study population (valsartan and metformin), consists of a 6-month program of a supervised low-salt/fat diet, a regular exercise program, daily self-monitoring of blood pressure and blood sugar and psychological support. The minimum number of subjects calculated to be needed for the study was 322. Study subjects were recruited from patients with HT and DM admitted to Nanjing First Hospital, China during April 2021-January 2025. Inclusion criteria for study subjects were: 1) being aged ≥65 years, 2) having diagnoses of HT and DM, 3) living in the study area for at least 6 months, and 4) giving written informed consent to participate in the study. Exclusion criteria for study subjects were: 1) having severe cardiac, hepatic or renal disease, 2) having a malignant neoplasm, a mental health condition or an active peptic ulcer, 3) being allergic to or intolerant of valsartan and/or metformin, 4) having undergone major surgery in the previous 3 months or 5) having had a serious infection in the previous 3 months. All patients received standardized pharmacotherapy (valsartan 80-160 mg/day and metformin 1500 mg/day), which is standard pharmacological treatment

in this study population. Subjects were randomly assigned to either the usual treatment (control) group (n = 161) or the ICCC group (n = 161). The following were conducted both prior to and after the intervention: blood tests consisting of a fasting blood glucose (FBG) level and lipid profile (consisting of a total cholesterol (TC) level, triglyceride (TG) level, a low density lipoprotein cholesterol (LDL-C) level and a high density lipoprotein cholesterol (HDL-C) level), a blood pressure (BP), a medication compliance assessment (using the Medication Adherence Report Scale (MARS-5) where good compliance was given a score of 5, moderate compliance a score of 3-4 and poor compliance a score of ≤2), a mental health assessment (using the Self-related Anxiety Scale (SAS) and the Self-related Depression Scale (SDS), where the higher the SAS/SDS score the more severe the anxiety/depression) and being asked about treatment adverse reactions with each adverse reaction being counted separately when more than one was present). A total of 322 subjects were included in the study: 161 in the ICCC (n = 104, 64.6% males) and 161 in the control (n = 97, 60.2% males) group. The mean (\pm standard deviation (SD)) ages of study subjects in the ICCC and Control groups were 69 (±3) (range: 65-76) and 69 (±3) (range: 65-74) years, respectively. Among the ICCC and Control groups after the intervention, the mean (\pm SD) FPG results were 7.0 (\pm 0.8) and 7.6 (\pm 0.96) mmol/l (p<0.05), the mean (\pm SD) HbA1c results were 7.1 (\pm 0.6%) and 7.5 (\pm 0.9%) (p<0.05), the mean (\pm SD) TC levels were 4.6 (\pm 0.6) and 5.0 (\pm 0.7) mmol/l (p<0.05), the mean (\pm SD) TG levels were 1.5 (\pm 0.4) and 1.6 (\pm 0.3) mmol/l (p<0.05), the mean (\pm SD) LDL-C levels were 3.0 (\pm 0.7) and 3.6 (\pm 0.8) mmol/l (p<0.05), the mean (±SD) HDL-C levels were 1.3 (±0.2) and 1.1 (±0.2) mmol/l (p<0.05), the mean (±SD) SBP levels were 125.1 (±14.7) and 137.1 (±10.9) mmHg (p<0.001), the mean (\pm SD) DBP levels were 77 (\pm 9) and 81 (\pm 7) mmHg (p<0.001), the mean (\pm SD) SAS scores were 25.8 (\pm 4.2) and 30.9 (± 5.2) (p<0.001), the mean $(\pm SD)$ SDS scores were 24.8 (± 4.9) and 28.3 (± 4.4) (p<0.001), the incidence of adverse reactions were 9.3% and 17.4% (*p*=0.033), the proportions of subjects with good blood pressure control were 78.9% and 50.3% (p<0.001) and the proportions of subjects with good treatment compliance were 88.2% and 79.5% (*p*<0.05), respectively. In summary, the ICCC program was significantly more effective than the usual treatment for lowering blood sugar, lowering blood lipids, lowering blood pressure, improving SAS and SDS scores, improving medication compliance and reducing adverse reactions. We conclude the ICCC program should be considered for use in the study population to improve outcomes. Further studies are needed to determine if the results of this study can be applied to other populations in China and if the financial benefits of the ICCC program outweigh the additional costs of the program.

Keywords: blood glucose, blood pressure, innovative care, elderly, community

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INTRODUCTION

Hypertension (HT) and diabetes mellitus (DM) are common diseases among older adults (Jia and Sowers, 2021). 51.2% of people aged ≥65 years worldwide are estimated to have HT, 21.8% are estimated to have DM and 30.5% are estimated to have both (Peng *et al*, 2022). Both HT and DM usually require lifelong medical treatment. These patients need blood glucose, lipid, and blood pressure (BP) control and their mental health and treatment adherence need to be monitored.

Following the development of the Innovative Care for Chronic Conditions (ICCC) framework by World Health organization (WHO, 2002), the Pan American Health Organization (PAHO) proposed a model of health care that could deliver integrated management of NCDs within the context of primary health care (PHC), and provides practical guidance for health care program managers, policy-makers, and stakeholders on how to plan and deliver high-quality services for people with chronic non communicable diseases (CNCDs) or CNCD risk factors (PAHO, 2013). The ICCC program prioritizes patient needs and promotes interdepartmental collaboration in order to deliver holistic care (Evans et al, 2021; Ghiyasvandian et al, 2021). It has been applied to the management of

DM and HT (Fernández et al, 2022; Wangpitipanit et al, 2024) but has not been implemented widely in China. There are three reasons for this:

1) most studies from China focus on a single condition, not holistic care (Zhu et al, 2025b), 2) there are few randomized control trials from China that assess the efficacy of the ICCC to manage HT and DM among elderly Chinese patients, 3) there are few studies showing the ICCC program can improve multiple health condition outcomes.

In this study, we aimed to evaluate the efficacy of the ICCC program to improve blood glucose, blood lipid, blood pressure, medication compliance and mental health levels and reduce adverse reaction levels among elderly Chinese with HT and DM in order to inform efforts to reduce the morbidity and mortality caused by these conditions in the study population.

MATERIALS AND METHODS

Study subjects were recruited from elderly patients with HT

and DM admitted to Nanjing First Hospital, China during April 2021-January 2025.

The minimum number of study subjects calculated to be needed for the study was determined using an α of 0.05, an effect size of 0.3 (consistent with a medium-sized trial), adding an additional 20% to compensate for subject dropouts and using a power of 0.95 (by G-Power v3.1 software which was available at URL: https://www.psychologie.https://www.psychologie/gpower). The minimum number of study subjects calculated to be needed for the study was 322.

Inclusion criteria for study subjects were being aged ≥65 years, having been diagnosed with HT and DM (American Diabetes Association Professional Practice Committee, 2025), living in the study area for ≥6 months and giving written informed consent to participate in the study. Exclusion criteria for study subjects were having severe cardiac, hepatic or renal disease, having a malignant neoplasm,

mental health condition or an active peptic ulcer, being allergic to or intolerant of valsartan and/or metformin, having undergone major surgery during the previous 3 months or having had a serious infection in the previous 3 months.

All subjects were divided equally into control (usual treatment) or treatment (ICCC) groups.

All subjects received identical drug therapy. Their HT was treated with valsartan (Batch No.: H20010824, Changzhou Siyuan Pharmaceutical Co Ltd, Changzhou, PR China) 80-160 mg once daily before breakfast to keep the systolic blood pressure (SBP) ≤140 mmHg and the diastolic blood pressure (DBP) ≤90 mmHg and their DM was treated with metformin (Drug Batch No.: H20213448, Hangzhou Zhongmei Huadong Pharmaceutical Co Ltd, Hangzhou, PR China): 500 mg 3 times daily after meals.

Subjects in the Control group were followed up quarterly, their BP and fasting blood glucose (FBG) levels were checked, they were asked about any abnormal symptoms or drug-related side effects and given a handout about HT and DM giving advice about diet and exercise.

Subjects in the ICCC group received the above and were given additional interventions consisting of the followings. Firstly, individualized medication guidance was given by community nurses during biweekly home visits and lasted 30 minutes each. During these visits, a patient-completed medication log was reviewed and advice was given about what to do if a medication dose was missed. Treatment adverse reactions were also asked. Besides, medication reminder alerts were also sent to their phones. Secondly, subjects were educated about a low salt, low fat diet (≤5 gm sodium and ≤25 gm fat per day) and about the use of carbohydrates (50-60% of calories per day), protein (15-20% of calories per day) and fiber (≥25 gm per day). Patients received food scales and measuring cups and were asked to complete a

daily food diary. Nutritionists contacted subjects by telephone once every two weeks to monitor progress and give advice. Thirdly, a personalized exercise regimen was created for each subject, consisting of moderate-intensity physical activity for ≥150 minutes per week divided into five 30-minute sessions per week. A community nurse called the subject weekly to ask about exercise and visited the subject monthly and reviewed the subject's pedometer step counts. Fourthly, each subject received an electronic sphygmomanometer and was asked to record their blood pressure twice daily after resting for at least 5 minutes before each blood pressure reading. These were recorded in a BP log. The log was reviewed monthly during the community health nurse visit. Fifthly, each subject was given a glucose meter and asked to check their glucose levels twice daily and record them in a glucose log book. The log was reviewed monthly during the community health nurse visit. Sixthly, each subject was asked to complete a Zung Self-rated Anxiety Scale (SAS) and a Zung Self-rated Depression Scale (SDS) evaluation (Zhu *et al*, 2025a) and those with a SAS >50 and/or a SDS >52 (the higher the number the more likely they were to have anxiety or depression, respectively) were referred to a psychological counselor where they received cognitive-behavioral therapy.

The study adopted an openlabel design with assessor blinding. Random allocation details were concealed in sequentially numbered, opaque, sealed envelopes. Independent statisticians opened the envelopes only after all outcome assessments were completed to ensure allocation concealment during data analysis. Outcome assessors (eg, personnel conducting blood tests, psychological evaluations, and medication adherence assessments) were blinded to group assignments throughout the study to minimize measurement bias. Subjects and intervention providers (eg, community nurses) were not

blinded due to the nature of the ICCC program interventions.

In both the Control and ICCC groups, blood pressures were recorded before and after the intervention 6 months later and subjects with a SBP of 90-139 mmHg and a DBP of 60-89 mmHg were considered to have a normal blood pressure. The blood pressure control rate was calculated as the number of subjects with a normal blood pressure/the total number of subjects × 100%. This rate was compared between the Control group and the ICCC group. Fasting blood glucose (FBG), glycated hemoglobin A1c (HbA1c), total cholesterol (TC), triglyceride (TG), low-density lipoprotein-cholesterol (LDL-C) and high-density lipoprotein-cholesterol (HDL-C) levels were obtained before and after the intervention in all subjects. Post-intervention adherence was measured using the Medication Adherence Report Scale (MARS-5) (Spetz et al, 2024); with a total score ranging from 0 to 5, where good adherence was a score of 5, moderate adherence a score of 3-4 and poor adherence a score of ≤2. The total adherence rate was determined by the formula: (subjects with good adherence + moderate adherence)/ the total number of subjects × 100%. All adverse reactions occurring during the intervention, such as hypotension, renal dysfunction or gastrointestinal complaints, were recorded. Each adverse reaction was counted separately when a subject had multiple adverse reactions.

The data were entered in duplicate by 2 different persons into EpiData, version 3.1 (data processing software developed by EpiData Association, Copenhagen, Denmark). For subjects with ≤5% missing values, the mean was imputed and for subjects with missing data >5%, the subject and data were removed from the study.

Data analysis was conducted using the Statistical Package for the Social Sciences (SPSS) version 24.0 (International Business Machines Corporation, Armonk, NY). Quantitative data

were recorded as numbers and percentages with comparative analyses carried out using the Chisquare test. Measured data with normal distribution were expressed as means ± standard deviation, with inter-group comparisons conducted using independent t-tests and intra-group comparisons made with paired t-tests. Data with non-normal distribution were documented as medians with 25th and 75th percentiles, with intergroup comparisons made with the Mann-Whitney U test and intragroup comparisons made with the Wilcoxon test. Significance was set at a p-value ≤ 0.05 .

This study was approved by the Ethics Committee of Nanjing First Hospital (approval No. KY20250120-KS-03). All subjects gave written informed consent prior to participation in the study.

RESULTS

A total of 322 subjects were included in the study: 161 in the ICCC (n = 104, 64.6% males) and

161 in the control (n = 97, 60.2% males) group. The mean (±standard deviation (SD)) ages of study subjects in the ICCC and control groups were 69 (±3) (range: 65-76) and 69 (±3) (range: 65-74) years, respectively (Table 1). There were no significant differences in age and gender characteristics between the two study groups.

In the ICCC and Control groups after the intervention, the mean (\pm SD) FPG results were 7.0 (\pm 0.8) and 7.6 (\pm 0.96) mmol/l (p<0.05) and the mean (\pm SD) HbA1c results were 7.1 (\pm 0.6%) and 7.5 (\pm 0.9%) (p<0.05), respectively (Fig 1).

In the ICCC and Control Groups after the intervention, the mean (\pm SD) TC levels were 4.6 (\pm 0.6) and 5.0 (\pm 0.7) mmol/l (p<0.05), the mean (\pm SD) TG levels were 1.5 (\pm 0.4) and 1.6 (\pm 0.3) mmol/l (p<0.05), the mean (\pm SD) LDL-C levels were 3.0 (\pm 0.7) and 3.6 (\pm 0.8) mmol/l (p<0.05) and the mean (\pm SD) HDL-C levels were 1.3 (\pm 0.2) and 1.1 (\pm 0.2) mmol/l (p<0.05), respectively (Fig1).

In the ICCC and Control groups

Table 1

	Characteristics of study subjects	subjects		
Characteristics	Control group $(N = 161)$	ICCC group $(N = 161)$	Statistics	p-value
Mean (±SD) age in years	69 (±3)	69 (±3)	t = 0.162	0.872
Sex, n (%)			$\chi^2 = 0.649$	0.421
Male	60) 26	104 (65)		
Female	64 (40)	57 (35)		
Mean (±SD) duration of DM in years	$8.1 (\pm 3.4)$	$8.2 (\pm 4.4)$	t = 0.271	0.787
Mean (±SD) duration of HT in years	$8.8 (\pm 3.8)$	$9.2 (\pm 4.1)$	t = 0.835	0.404
Mean (±SD) BMI in kg/m²	$25.1 (\pm 3.4)$	$24.8 (\pm 2.9)$	t = 0.855	0.393
Smoking history, n (%)			$\chi^{^2} = 0.311$	0.577
Yes	80 (50)	75 (47)		
No	81 (50)	86 (53)		
Alcohol use history, n (%)			$\chi^{2} = 0.645$	0.422
Yes	58 (36)	65 (40)		
No	103 (64)	(09) 96		

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Characteristics	Control group $(N = 161)$	ICCC group $(N = 161)$	Statistics	<i>p</i> -value
Education level, n (%)			$\chi^2 = 0.320$	0.572
Junior high school and lower	132 (82)	128 (80)		
Higher than Junior high school	29 (18)	33 (20)		
Living status, n (%)			$\chi^{^2} = 0.719$	0.396
Living alone	34 (21)	28 (17)		
Not living alone	127 (79)	133 (83)		

BMI: body mass index; DM: diabetes mellitus; HT: hypertension; ICCC: innovative care for chronic conditions; kg/m²: kilogram per square meter; SD: standard deviation

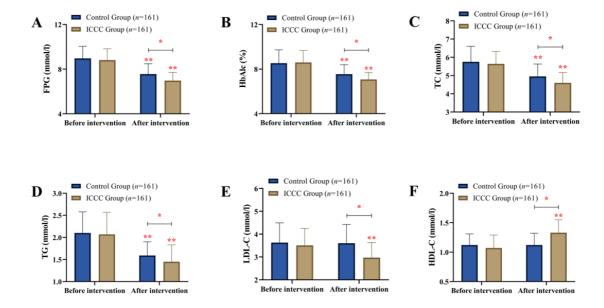


Fig 1 - Glucose and lipid changes before and after intervention by study group A: comparison of FPG; B: comparison of HbA1c; C: comparison of TC; D: comparison of TG; E: comparison of LDL-C; F: comparison of HDL-C ** indicates *p*-value <0.05 compared with before intervention; and * indicates *p*-value <0.05 comparison between Control group and ICCC group.

FPG: fasting plasma glucose; HbA1c: glycated hemoglobin A1c; HDL-C: high-density lipoprotein cholesterol; ICCC: innovative care for chronic conditions; LDL-C: low-density lipoprotein cholesterol; mmol/l: millimoles per liter; TC: total cholesterol; TG: triglycerides

after the intervention, the mean (\pm SD) SBP levels were 125.1 (\pm 14.7) and 137.1 (\pm 10.9) mmHg (p<0.001), the mean (\pm SD) DBP levels were 77 (\pm 9) and 81 (\pm 7) mmHg (p<0.001) and the proportions of subjects

with good blood pressure control were 78.9% and 50.3% (p<0.001), respectively (Table 2).

In the ICCC and Control groups after the intervention, the mean (±SD) SAS scores were 25.8 (±4.2)

Comparison of BP changes between conventional group and ICCC group Table 2

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Variables	Control group $(N = 161)$	ICCC group $(N = 161)$	Statistics	<i>p</i> -value
SBP in mmHg				
Mean (±SD) SBP before intervention	151.63 ± 12.67	153.98 ± 12.57	t = 1.674	0.095
Mean (±SD) SBP after intervention	137.12 ± 10.90	125.11 ± 14.68	t = 8.337	<0.001
Statistics	t = 11.024	t = 18.962		
<i>p</i> -value	<0.001	<0.001		
DBP in mmHg				
Mean (±SD) DBP before intervention	88.09 ± 8.53	89.08 ± 8.70	t = 1.029	0.304
Mean (±SD) DBP after intervention	80.96 ± 7.27	77.30 ± 9.21	t = 3.963	<0.001
Statistics	t = 8.072	t = 11.810		
<i>p</i> -value	<0.001	<0.001		
BP control rate, n (%)	81 (50.3)	127 (78.9)	$\chi^2 = 28.734$	<0.001

BP: blood pressure; DBP: diastolic blood pressure; ICCC: innovative care for chronic conditions; mmHg: millimeter of mercury; SBP: systolic blood pressure

and 30.9 (\pm 5.2) (p<0.001) and the mean (\pm SD) SDS scores were 24.8 (\pm 4.9) and 28.3 (\pm 4.4) (p<0.001), respectively (Table 3).

In the ICCC and Control groups after intervention, the proportions of subjects with good treatment adherence were 88.2% and 79.5% (p<0.05), respectively (Table 3).

In the ICCC and Control groups after the intervention, the incidences of adverse reactions were 9.3% and 17.4% (p=0.033) (Table 4).

DISCUSSION

In our study, subjects in the ICCC group had better outcomes than subjects in the Control group.

In our study, the FPG and HbA1c results in the ICCC group were significantly lower than those in the control group after intervention, which is consistent with a previous study on community management of pregnant women with gestational diabetes mellitus (Igwesi-Chidobe et al, 2022). A similarity between that study and ours was subjects monitored their

glucose levels daily and they had access to telephone support from a dietitian. A difference between our study and that study was, in our study, we checked the blood sugar of subjects twice daily but in their study, they checked it once daily. A study in an elderly population in Thailand found monitoring blood glucose levels three times a week helped improve glycemic control (Wangpitipanit et al, 2024) similar to the findings in our study. The American Diabetes Association Guidelines state monitoring blood glucose levels in uncomplicated patients with type 2 diabetes provides no significant benefit (Samson et al, 2023). However, our study results did show benefit, suggesting in our study there was a benefit to monitoring glucose levels twice daily among type 2 diabetics.

In our study, subjects in the ICCC group had significantly better blood lipids than those in the control group, similar to the findings of a previous study (Nowak and Jeziorek, 2023) but subjects in their study in the intervention

Table 3

Mental state and treatment adherence characteristics among study subjects

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Variables	Control group $(N = 161)$	ICCC group $(N = 161)$	Statistics	p-value
SAS				
Mean (±SD) SAS before intervention	30.45 ± 5.72	30.86 ± 4.29	t = 0.727	0.468
Mean (±SD) SAS after intervention	30.85 ± 5.20	25.76 ± 4.16	t = 9.710	<0.001
Statistics	t = 0.653	t = 10.841		
<i>p</i> -value	0.515	<0.001		
SDS				
Mean (±SD) SDS before intervention	28.16 ± 4.40	28.20 ± 3.97	t = 0.093	0.926
Mean (±SD) SDS after intervention	28.30 ± 4.43	24.78 ± 4.85	t = 6.819	<0.001
Statistics	t = 0.290	t = 6.948		
<i>p</i> -value	0.772	<0.001		
MARS-5, n (%)				
Good	42 (26.09)	64 (39.75)		
Moderate	86 (53.42)	78 (48.45)		
Poor	33 (20.50)	19 (11.80)		
Adherence rate	128 (79.50)	142 (88.20)	$\chi^2 = 4.495$	0.034

ICCC: innovative care for chronic conditions; MARS-5: Medication Adherence Report Scale; SAS: Zung MARS-5 score: score 5 = good adherence; scores 3-4 = moderate adherence; scores ≤2 = poor adherence

Self-rating Anxiety Scale; SDS: Zung Self-Rating Depression Scale; SD: standard deviation

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Table 4
Adverse reactions by study group

Groups	Hypotension, n (%)	Hypotension, Gastrointestinal Abnormal renal Insomnia, Arrhythmias Total, n (%) reactions, n (%) function, n (%) n (%) n (%) n (%)	Gastrointestinal Abnormal renal Insomnia, μ reactions, n (%) μ (%) μ (%)	Insomnia, n (%)	Arrhythmias n (%)	Total, n (%)
Control Group (N=161)	6 (3.7)	11 (6.8)	3 (1.9)	5 (3.1)	3 (1.9)	28 (17.4)
ICCC Group (N=161)	3 (1.9)	5 (3.1)	3 (1.9)	2 (1.2)	2 (1.2)	15 (9.3)
χ^2						4.536
<i>p</i> -value						0.033

p-value <0.05 was considered statistically significant.

group had greater reductions in lipid levels that was seen in our study. A similarity between our study and their study was that both our subjects and their subjects were put on a low-fat diet and food diaries were obtained. A difference between our study and their study was that in our study food diaries were reviewed remotely by telephone but in their study the food diaries were reviewed during face-to-face visits. This suggests face-to-face visits may be superior than phone visit to improve lipid levels.

In our study, the proportion of subjects in the ICCC group with good blood pressure control was significantly greater than the proportion of subjects in the control group, similar to the findings of a previous study of family doctor services in China (Jing *et al*, 2023). We believe this is due to daily subject blood pressure measurement and regular follow-up by nurses. A previous study (Bludorn and Railey, 2024) reported without daily home monitoring to give immediate

feedback regarding blood pressure control, there is less blood pressure control, showing the importance of home blood pressure monitoring.

In our study, subjects in the ICCC group were sent to receive cognitive behavioral therapy and this resulted in a decrease in their SAS/SDS scores, showing the efficacy of cognitive behavioral therapy in the study population, similar to the findings of a previous study that showed cognitive behavioral therapy can improve depression scores among patients with chronic diseases (Mansor et al, 2023). Another component of the ICCC to improve SAS/SDS scores is the use of exercise in the program. Exercise has been previously reported to improve depression (Basiri et al, 2023). This may be due to the release of endorphins during exercise and a feeling of improved self-efficacy.

The compliance rate of subjects in the ICCC group was significantly higher than that of the control group. A previous study reported frequent nursing contact and medication reminders are significantly associated with higher compliance rates (Geerlings et al, 2023). A similar finding was also reported in a previous study where they found providing only medication guidelines is less effective than follow up contacts (Zhang et al, 2021).

In our study, the adverse reaction rate in the ICCC group was lower than in the Control group, similar to the findings of a previous study (Zhang et al, 2024) that also had medication guidance. Our hypotension adverse even rate of 4.3% is lower than that reported in a previous study of 15% who also had monthly home visits (Wang et al, 2022). This difference may be due to our subjects monitoring their blood pressures daily, enabling them to earlier detect any problems with the blood pressure, or for that matter, for glucose either.

Our study had several weaknesses: study subjects were selected from previously hospitalized patients had had both DM and HT. The previous

hospitalization may select for more frail patients in whom intensive lifestyle might have a greater benefit, making the results show more benefit with the program than would be observed among subjects who were not previously hospitalized. Study subjects were all urban dwellers, which could also select for more frail individuals which might make the benefits of the program appear greater than they would be in the general population. The 6-month duration of the intervention prevents evaluation of the longterm impact of the ICCC program, underestimating its potential benefits. Another weakness was that the socioeconomic factors were not evaluated in our study which could have a potential impact on our results. Because this study did not include a blank control group who did not receive any management intervention, it is possible that there is a Hawthorne effect (the observer's behavior is influenced by his or her attention and expectations, leading to behavior

change). For example, treatment adherence might be higher than it normally would be. To assess the real-world benefit of the program, future studies need to be conducted in a variety of populations and longer-term prospective studies are needed to determine the long-term benefits. Another weakness of the study is we did not conduct a cost-benefit analysis, evaluating the higher cost of the program compared to standard treatment to determine if the cost of the program is outweighed by the financial benefits of reduced morbidity and mortality of those who participate in the program. Finally, we did not separate the benefits of each component of the ICCC and evaluate them individually to determine if there were components that did not provide benefit.

In summary, the ICCC program was significantly more effective than the usual treatment for lowering blood sugar, lowering blood lipids, lowering blood pressure, improving SAS and SDS scores, improving medication compliance

and reducing adverse reactions. We conclude the ICCC program should be considered for use in the study population to improve outcomes. Further studies are needed to determine if the results of this study can be applied to other populations in China and if the financial benefits of the ICCC program outweigh the additional costs of the program.

CONFLICT OF INTEREST DISCLOSURE

The authors declare no conflict of interest.

AVAILABILITY OF DATA AND MATERIALS

The datasets analyzed in the current study are available from the corresponding author upon reasonable request.

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