Effectiveness of an integrative program on reducing hypertension incidence among population at risk for hypertension

1 Introduction

The population at risk for hypertension has a doubling risk of developing hypertension, and higher morbidity and mortality attributable to cardiovascular and cerebrovascular diseases compared to individuals who are not at risk. Several studies have evaluated the effects of community-based integrative interventions to manage the population at risk for hypertension, including self-monitoring of blood pressure (BP), dietary adjustments, and regular exercises. In China, high-quality evidence is lacking regarding the effects of community-based integrative interventions on the population at risk for hypertension. This study aimed to evaluate the effectiveness of a community-based integrative program in reducing hypertension incidence among the population at high risk for hypertension in Shanghai, Eastern China.

2 Methods

2.1 Study design

We conducted a community-based randomized intervention trial among the population at risk for hypertension from October 2019-October 2020, with measurements obtained at baseline and after a one-year follow-up to evaluate the effect of the integrative intervention. We selected a community in Changning District of Shanghai, located in the Eastern Region of China, as the study setting. In 2019, its Gross Domestic Product per capita was 237,800 RMB ($34,481), with 17 neighborhood blocks and more than 80,000 residents. Six neighborhood blocks were randomly selected for inclusion in the study, in which three blocks were randomized as the intervention group and the other three were treated as the control group.

2.2 Sample size calculation

A multi-stage, cluster sampling was conducted to select the participants at risk for hypertension, based on the screening tool designed by our research team. The awareness rate of hypertension-related knowledge was considered as the key indicator

for determining the sample size, assuming that the average awareness rate of the intervention group and the control group were 70% and 50%, respectively. A sample size of 280 for both the intervention and control groups was determined based on the confidence level (1-α=0.95), power (β=0.9), design effect (Deff=2), and response rate of the survey (90%). Thus, around 1,000 residents were needed to screen the required high-risk individuals, assuming that the prevalence of prehypertension was about 30%.

2.3 Study participants and eligibility criteria

The sampling in the intervention group was performed as follows: one lane was randomly selected from each sampled neighborhood block by using a computer-generated random number, with approximately 300 to 400 residents in each lane. All adult residents in the three sampled lanes were invited to participate in our study. Excluding those who were absent during screening or not willing to participate in the screening, 1089 residents were screened by our screening tool to reach the required sample size. Similarly, we recruited the participants in the control group after screening 1,109 residents.

The inclusion criteria were: (i) permanent residents aged 18-80 years of the sampled lane (excluding those who have left this lane for more than half a year); (ii) having been identified as individuals at risk for hypertension, with the total risk score more than 20 based on our screening tool; (iii) informed consent and willingness to participate in this study; (iv) no previous history of hypertension diagnosis or use of anti-hypertensive medication; (v) with good cognitive function and physical condition.

A total of 303 and 304 individuals at risk for hypertension were included in the intervention and control group at baseline, respectively.

2.4 Intervention methods

The intervention group was managed through the integrative program, and the control group received usual care (i.e., the general practitioners followed up with patients and queried their BP levels, and lifestyles via phone every 6 months). The integrative program consisted of three sections: health education, physician

follow-ups, and self-management (Table 1). The training was provided to all general practitioners (GPs) and staff involved in the intervention group, including the intervention measures for high-risk individuals, the intervention contents, the implementation procedures, and rules for filling out the tables regarding the intervention process. Before the intervention, health education lecture schedules, self-management cards, and health education leaflets were allocated to individuals in the intervention group, and an online group chat using social media (WeChat, Tencent Co. Ltd, China) was also created.

Table 1 Intervention measures and frequency in the intervention group

Session	Interventions	Major intervention content	Method	Frequency
1	Health education	◆ Diagnostic criteria, causes, and characteristics of hypertension in adults ◆ Hazards and complications of hypertension ◆ Measurement method of BP ◆ Monitoring for the risk factors of hypertension and lifestyle intervention methods	Holding health education lectures	once per quarter (i.e. at the end of 3, 6, 9, 12 months after enrollment)
			Distributing health education leaflets	once per month
			Releasing health-related knowledge using social media	once per month
2	Physician follow-ups	◆ Basic information of the participant (height, weight, systolic BP, diastolic BP, etc) ◆ Progress of risk factors of hypertension ◆ Changes in healthy behaviors	Group visits, online visits, telephone visits, and home visits	once per quarter
3	Self-management	Changes in physical activity, diets, smoking, alcohol consumption, weight control, etc	Filling out self-management cards by the participants and getting feedback from the GPs	once per month

Notes: BP: blood pressure; GPs: general practitioners.

3 Intervention process

Before the implementation of the integrative intervention program for population at risk for hypertension, we conducted a pilot study to improve our questionnaires. The community service center was responsible for the site preparation and the arrangement of screening objects and intervention objects.

Questionnaire surveys and physical examinations were conducted by trained GPs for participants in the two groups at baseline and one-year follow-up. All investigators

were trained based on the contents of the questionnaire and interview techniques before the survey. The completed questionnaire and records were checked by the research team. In case of any error or missing, the investigators would contact the subject by telephone to correct or add the information.

The operation process of the intervention was as follows:

Table 2 Operation process of the intervention

Group	Period	Step	Content
Intervention group	Baseline period	Step 1	Inclusion performed with informed consent
		Step 2	Investigation of the high-risk-related factors of hypertension and physical examinations
		Step 3	Investigation of hypertension-related knowledge, attitudes, and behaviors
		Step 4	1.Issuing health education lecture courses arrangement 2.Self-management cards were issued to high-risk individuals
		Step 5	An online group chat using social media (WeChat) was created
	Intervening period	Step 1	Holding health education lectures at the end of 3, 6, 9, 12 months after enrollment
		Step 2	Releasing health-related knowledge using social media (WeChat) once per quarter
		Step 3	Participate in the Physician follow-ups once per quarter
		Step 4	Self-management cards were released every month
	End of the one-year follow-up	Step 1	Investigation of the high-risk-related factors of hypertension and physical examinations
		Step 2	Investigation of hypertension-related knowledge, attitudes, and behaviors
Control group	Baseline period	Step 1	Inclusion performed with informed consent
		Step 2	Investigation of the high-risk-related factors of hypertension and physical examinations
		Step 3	Investigation of hypertension-related knowledge, attitudes, and behaviors
	Intervening period	-	Receive usual care (the general practitioners followed up with patients and queried their BP levels, and lifestyles via phone every 6 months)
	End of the one-year follow-up	Step 1	Investigation of the high-risk-related factors of hypertension and physical examinations
		Step 2	Investigation of hypertension-related knowledge, attitudes, and behaviors

4 Quality control

All recordings and documents of the management process were employed to ensure that assessment and intervention procedures were standardized across the study

sites and all participants. The activities of the interviews, physical assessment procedures, and program implementation were routinely supervised and monitored by senior researchers.