

Two-year results of a community-based randomized controlled lifestyle intervention trial to control prehypertension and/or prediabetes in Thailand: a brief report

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Abstract: The aim of the study was to assess the 2-year effect of a community-based randomized controlled lifestyle intervention on glucose and blood pressure levels in Thailand. Participants (N=443, with prediabetes and/or prehypertension) received a six 2-hr group sessions lifestyle intervention (physical activity and nutrition) over 6 months. Measurements were at baseline, 12 months (89%) and at 24 months (84.7%). Statistically significant interaction effects on fasting plasma glucose and DBP at 12 months were not maintained at 24 months, while significant interaction effects were found on high-density lipoprotein and low-density lipoprotein cholesterol at 24 months. Improvements were found for fasting plasma glucose, SBP, DBP and total cholesterol, but no significant interaction effect was detected. The development of type 2 diabetes was higher in the control than in the intervention group, but it was not reaching significance ($P=0.181$), while 3.0% in the intervention group and 2.6% in the control group developed hypertension at 24 months. No significant group differences were found in psycho-behavioral variables. The lifestyle intervention did not provide additional benefits compared to the control group at 24-month follow-up.

Trial registration number: TCTR20170721001

Keywords: community-based intervention, lifestyle intervention, prediabetes, prehypertension, Thailand

Introduction

Lifestyle interventions have been found to be effective to prevent the progression of prehypertension to hypertension and prediabetes to diabetes.¹⁻⁵ In a 12-month follow-up study, partial effectiveness of a community (Buddhist temple)-based lifestyle intervention program to control prehypertension and/or prediabetes in temple members was found in Thailand,⁶ showing the potential effectiveness of such a community intervention. In order to assess longer term effects of this intervention trial, we report findings on the results of this study at 24-month follow-up.

Materials and methods

The study is a cluster randomized controlled evaluation of a group-based program in community settings (12 Buddhist temples) in Nakhon Pathom

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province; more detail.⁶ The study protocol was approved by the “Committee for Research Ethics (Social Sciences), Mahidol University (MU-SSIRB: 2016/053-B1).” Written informed consent was obtained from all participants. This study was in compliance with the ethical principles of the Declaration of Helsinki.

The intervention consisted of six group lifestyle (diet and physical activity) counseling sessions (on average 60–90 mins) over a period of 6 months conducted by trained study nurses in the temple premises and/or the adjacent health facility.

Participants were followed-up at 12 and 24 months following baseline assessment. A detailed study description, including intervention content, study flow chart, sample characteristics and assessment measures, has been published previously.⁶ The study sample consisted of 443 participants (220 in intervention and 223 in the control group) aged 35–65 years with prediabetes and/or prehypertension, of which 394 participants (89%) were retained at 12 months and 375 (84.7%) (179 in the intervention and 196 in the control group) at 24 months.

All clinical and psycho-behavioral questionnaire data at baseline, 12 months and 24 months were collected by study nurses. Outcomes included changes in SBP and blood glucose levels from baseline to year 2.

The analyses conducted used intention-to-treat, participants and clusters (temples) were analyzed according to the group they were allocated to. The intervention effects on continuous 24-month outcomes (ie, fasting plasma glucose, SBP and DBP, triglyceride, low-density lipoprotein=LDL, high-density lipoprotein=HDL, BMI and waist circumference) and diabetes and hypertension incidence outcomes and psycho-behavioral outcomes were analyzed using linear, gamma and logistic mixed-effect models adjusted for clustering (ie, a random effect of temple community), and baseline covariates, namely age, gender, education, smoking, alcohol use and depression. Fixed effects in these analyses consisted of time, condition, a time-by-condition interaction (ie, between-group changes) and baseline covariates. The data were analyzed using IBM-SPSS for Windows, version 24 (Chicago, IL, USA).

Results

Table 1 presents the physical study outcomes at each data assessed and results of multilevel mixed

modeling. At 24-month follow-up, mixed modeling found significant interaction effects on HDL cholesterol ($P=0.037$) and LDL cholesterol ($P<0.011$). Improvements were found for fasting plasma glucose, SBP, DBP and total cholesterol, but no significant interaction effect was detected. Further, there were no significant changes in terms of BMI, waist circumference, body fat and muscle mass (Table 1).

Finally, Table 2 shows the development of diabetes and hypertension at 24 months. The development of type 2 diabetes was higher in the control than in the intervention group, but it was not reaching significance ($P=0.181$), while 3.0% in the intervention group and 2.6% in the control group developed hypertension at 24 months (Table 2).

Table 3 shows the changes in psycho-behavioral variables by study group at 24 months. Compared with the control group participants, intervention group participants were less likely to have a general anxiety disorder and were less likely to engage in hazardous or harmful drinking, but this did not reach significance. No group differences were found for fruit and vegetable consumption, smoking, physical activity and major depressive disorder (Table 3).

Conclusion

The aim of this community (Buddhist temple)-based lifestyle intervention programme was to control prehypertension and/or prediabetes in temple members. Previously, we showed that the intervention model was partially effective at 12-month follow-up.⁶

In this longer term follow-up, however, the lifestyle intervention did not provide additional benefits compared to the control group at 24-month follow-up. This finding seems to confirm that although the target was six intervention sessions only 3.8 sessions were on average attended,⁶ more intervention sessions are needed to make this lifestyle programme effective. Even in a 15 session lifestyle intervention for prediabetics in India non-significant reduction in diabetes incidence was found at 24-month follow-up.⁷ The original PREMIER lifestyle intervention to control blood pressure included 18 sessions,⁸ and in a lifestyle intervention to prevent type 2 diabetes (DE-PLAN) in primary care included eleven counselling sessions, “six motivational phone calls and two letters followed by organized physical activity sessions.”⁹

Table 1 Clinical study outcomes of the intervention and control groups at baseline and 24 months

Variables	Intervention group	Control group	Group effects ^c		Time effects ^c		Group × time effects ^c	
			COE (SE)	P-value	COE (SE)	P-value	COE (SE)	P-value
Fasting plasma glucose (mg/dL), mean (SD) ^a								
Baseline	97.5 (9.9)	96.3 (10.3)	-0.98 (1.93)	0.611	-0.13 (1.01)	0.892	-0.94 (2.34)	0.690
24 months	96.5 (11.6)	97.1 (19.3)						
SBP, mmHg, mean (SD) ^a								
Baseline	126.7 (7.1)	126.6 (7.1)	-0.52 (1.31)	0.693	-3.60 (0.67)	<0.001	-2.35 (1.44)	0.104
24 months	124.4 (13.9)	122.3 (7.9)						
DBP, mmHg, mean (SD) ^a								
Baseline	79.8 (6.5)	79.0 (6.5)	-0.89 (0.78)	0.253	-1.38 (0.49)	0.005	-1.06 (0.75)	0.156
24 months	77.0 (7.6)	78.5 (6.0)						
Total cholesterol (mg/dL), mean (SD) ^a								
Baseline	206.1 (35.4)	211.8 (37.6)	4.32 (6.59)	0.512	-12.23 (2.73)	<0.001	-5.17 (6.48)	0.426
24 months	202.0 (33.9)	196.2 (39.9)						
Triglyceride (mg/dL), median (IQR) ^b								
Baseline	110.5 (50.5)	121 (64.1)	-0.06 (0.06)	0.301	-0.003 (0.03)	0.918	-0.04 (0.05)	0.363
24 months	114.0 (57.0)	114.0 (59.0)						
HDL cholesterol (mg/dL), median (IQR) ^b								
Baseline	55.4 (17.3)	48.4 (6.8)	0.06 (0.03)	0.048	0.02 (0.01)	0.039	-0.07 (0.03)	0.037
24 months	53.0 (5.0)	53.0 (3.0)						
LDL cholesterol (mg/dL), mean (SD) ^b								
Baseline	124.7 (36.8)	133.3 (32.6)	3.03 (6.21)	0.626	-13.82 (2.49)	<0.001	9.07 (3.58)	0.011
24 months	116.0 (46.0)	112.5 (51.0)						
BMI, kg/m ² , mean (SD) ^a								
Baseline	25.0 (3.9)	25.3 (4.1)	-0.42 (0.42)	0.315	0.58 (0.29)	0.043	0.08 (0.59)	0.894
24 months	25.5 (3.9)	25.6 (4.5)						
Waist circumference: male, cm, mean (SD) ^a								
Baseline	87.6 (10.2)	87.6 (10.2)	-0.08 (2.18)	0.971	2.37 (1.44)	0.100	0.06 (2.58)	0.981
24 months	88.9 (9.2)	89.0 (9.7)						
Waist circumference: female, cm, mean (SD) ^a								
Baseline	84.2 (9.8)	86.4 (8.7)	-2.88 (0.77)	<0.001	0.40 (0.81)	0.620	1.72 (1.23)	0.161
24 months	84.8 (11.1)	86.8 (8.9)						
Body fat (%), median (IQR) ^b								
Baseline	28.9 (11.2)	30.2 (10.6)	-0.13 (0.04)	0.002	-0.03 (0.30)	0.935	1.85 (1.83)	0.314
24 months	32.5 (12.7)	33.7 (11.9)						
Muscle mass (kg), median (IQR) ^b								
Baseline	40.4 (7.9)	41.7 (9.4)	-0.03 (0.02)	0.178	-0.19 (0.48)	0.697	-0.16 (0.47)	0.729
24 months	38.0 (8.2)	38.8 (7.7)						

Notes: ^aLinear mixed regression model; ^bgamma mixed regression model; ^cadjusted for cluster effects and baseline characteristics (demographic and lifestyle variables)
Abbreviations: BMI, body mass index; COE, coefficient; LDL, low-density lipoprotein; HDL, high-density lipoprotein; SE, standard error.

Table 2 Changes to type 2 diabetes and/or hypertension

Variables	Intervention group	Control group	Group effects ^b		Time effects ^b		Group × time effects ^b	
			n (%)	n (%)	COE (SE)	P-value	COE (SE)	P-value
Type 2 diabetes ^a								
Baseline	0	0	0.09 (0.31)	0.784	0.61 (0.38)	0.107	-0.69 (0.52)	0.181
24 month follow-up	5 (2.8)	9 (4.6)						
Hypertension ^a								
Baseline	0	0	-0.15 (0.27)	0.586	0.49 (0.39)	0.206	0.06 (0.52)	0.906
24 month follow-up	5 (3.0)	5 (2.6)						

Notes: ^aLogistic mixed regression model; ^bAdjusted for cluster effects and baseline characteristics (demographic and lifestyle variables).

Abbreviations: COE, coefficient; SE, standard error.

Table 3 Psycho-behavioral study outcomes of the intervention and control groups at baseline and 24 months

Variables	Intervention group	Control group	Group effects ^b		Time effects ^b		Group × time effects ^{2b}	
			N (%)	N (%)	COE (SE)	P-value	COE (SE)	P-value
Fruit and vegetable consumption (≥5 serves/day) ^a								
Baseline	21 (9.6)	3 (1.4)	0.50 (0.24)	0.040	0.66 (0.28)	0.019	0.29 (0.36)	0.420
24 months	19 (11.8)	16 (8.8)						
Current smoking ^a								
Baseline	25 (11.4)	21 (9.5)	0.25 (0.32)	0.428	-0.27 (0.29)	0.344	-0.031 (0.34)	0.940
24 months	17 (10.6)	9 (5.0)						
Hazardous or harmful alcohol use ^a								
Baseline	23 (10.5)	25 (11.4)	-0.43 (0.51)	0.403	0.13 (0.25)	0.594	-0.11 (0.48)	0.818
24 months	16 (9.9)	22 (12.2)						
Physically active ^{a,c}								
Baseline	166 (75.8)	154 (70.0)	0.14 (0.13)	0.286	0.04 (0.17)	0.835	-0.08 (0.26)	0.751
24 months	116 (72.5)	135 (75.0)						
Major depressive disorder ^a								
Baseline	33 (15.1)	24 (10.9)	0.26 (0.27)	0.328	-0.10 (0.21)	0.640	0.38 (0.33)	0.116
24 months	24 (14.9)	24 (13.3)						
Generalized anxiety disorder ^a								
Baseline	13 (5.9)	9 (4.1)	0.52 (0.64)	0.414	0.40 (0.34)	0.240	-0.60 (0.49)	0.226
24 months	3 (1.9)	5 (2.8)						

Notes: ^aLogistic mixed regression model; ^bAdjusted for cluster effects and baseline characteristics (demographic and clinical variables) ^cMeeting physical activity recommendations assessed with the Global Physical Activity Questionnaire.

Abbreviations: COE, coefficient; SE, standard error.

Data sharing statement

The dataset used in the current study are available from the corresponding author on reasonable request.

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Author contributions

All authors contributed to data analysis, drafting and revising the article, gave final approval of the version to be published and agree to be accountable for all aspects of the work.

Disclosure

The authors report no conflicts of interest in this work.

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