BMJ Open

Effectiveness of a low-intensity telephone counselling intervention on an untreated metabolic syndrome detected by national population screening in Korea: a non-randomised study using regression discontinuity design

Sang-Wook Yi,[1] Soon-Ae Shin,[2] Youn-Jung Lee[2]

To cite: Yi S-W, Shin S-A, Lee Y-J. Effectiveness of a low-intensity telephone counselling intervention on an untreated metabolic syndrome detected by national population screening in Korea: a non-randomised study using regression discontinuity design. *BMJ Open* 2015;**5**: e007603. doi:10.1136/bmjopen-2015-007603

► Prepublication history and additional material is available. To view please visit the journal (http://dx.doi.org/10.1136/bmjopen-2015-007603).

Received 7 January 2015
Revised 4 June 2015
Accepted 25 June 2015

[1]Department of Preventive Medicine and Public Health, Catholic Kwandong University College of Medicine, Gangneung, Gangwon-do, Republic of Korea
[2]Big Data Steering Department, National Health Insurance Service, Seoul, Republic of Korea

Correspondence to
Professor Sang-Wook Yi;
flyhigh@cku.ac.kr

ABSTRACT

Objective: Whether low-intensity telephone-counselling interventions can improve cardiometabolic risk factors in screen-detected people with metabolic syndrome (MetS) is unclear. The aim of this study was to evaluate the effectiveness of a low-intensity, telephone-counselling programme on MetS implemented by the National Health Insurance Service (NHIS) of Korea using regression discontinuity design.

Design: A nationwide non-randomised intervention study with a regression discontinuity design. A retrospective analysis using data from NHIS.

Setting: NHIS, Korea from January 2011 to June 2013.

Participants: 5 378 558 beneficiaries with one or more MetS components by NHIS criteria detected by population screening were enrolled in the NHIS MetS Management Programme in 2012. Of these, 1 147 695 underwent annual follow-up examinations until June 2013 ('control group' which received control intervention, n=855 870; 'eligible group' which was eligible for counselling, n=291 825; 'intervention group' which participated in telephone counselling among eligible groups, n=23 968).

Main outcome measures: Absolute changes in MetS components, weight and body mass index (BMI) were analysed. Multiple regression analyses were applied using the analysis of covariance model (baseline measurements as covariates).

Results: Low-intensity telephone counselling was associated with decreased systolic BP (−0.85 mm Hg, 95% CI −1.02 to −0.68), decreased diastolic BP (−0.63 mm Hg, −95% CI −0.75 to −0.50), decreased triglyceride (−1.57 mg/dL, 95% CI −2.89 to −0.25), reduced waist circumference (−0.09 cm, 95% CI −0.16 to −0.02), reduced weight (−0.19 kg, 95% CI −0.24 to −0.15) and reduced BMI (−0.07 kg/m^2, 95% CI −0.09 to −0.05), when comparing the intervention and control groups. When individuals with low high-density lipoprotein cholesterol were analysed, the intervention was also associated with increased HDL cholesterol (0.90 mg/dL, 95% CI 0.51 to 1.29).

Conclusions: Low-intensity telephone counselling programmes could yield improvements in the following year on blood pressure, lipid profiles, weight and body mass index in untreated patients detected at the population screening. However, the improvements may be very modest and the clinical relevance of these small improvements may be limited.

Strengths and limitations of this study

- The effectiveness of low-intensity interventions, which can be easily implemented in various healthcare settings, has rarely been evaluated.
- The effectiveness of intervention programmes for metabolic syndrome based on population screening has seldom been examined.
- The intervention effects were retrospectively assessed by regression discontinuity design (a quasi-experimental design) using analysis of covariance models and the stabilised inverse probability of the treatment weighting method using the propensity score.
- Small improvements by the intervention programme could be detected due to the large number of participants.
- Since the interval between the intervention and the follow-up examination was less than 1 year, the effects after one or more years of low-intensity counselling should be investigated through further research.

INTRODUCTION

The concept of metabolic syndrome (MetS) was proposed to identify populations at high risk for vascular diseases and diabetes.[1–3] MetS is prevalent worldwide,[1 4–6] and its prevalence is increasing.[1 6 7] Evidence linking

BMJ Open: first published as 10.1136/bmjopen-2015-007603 on 10 July 2015. Downloaded from http://bmjopen.bmj.com/ on April 20, 2024 by guest. Protected by copyright.

MetS with cardiovascular diseases,[8 9] diabetes[8] and cancers[10] has continued to grow. Screening people with MetS, and intervening with lifestyle or pharmacological interventions could be a cost-effective health policy for reducing the burden of diabetes and vascular diseases.[11] However, the effectiveness of intervention programmes after population screening for MetS has rarely been evaluated. Intensive interventions could be effective in clinically diagnosed patients,[12–14] yet intensive programmes are generally too demanding to implement in people with diseases detected at screening.[15 16] Low-intensity interventions (≤30 min of provider contact) could be easy to implement in various settings; therefore, low-intensity interventions should be further evaluated.[16]

The National Health Insurance Service (NHIS) in Korea provides mandatory universal health insurance that covers 97% of the population; low-income households are further supported by Medical Aid.[17] The NHIS has provided regular health screening examinations for beneficiaries since 1980. Pending the development and implementation of an evidence-based, cost-effective intervention programme for people with disease detected at health examinations, the NHIS initiated the MetS Management Programme in 2012, which provides a maximum of three counselling sessions within 6 months mainly on lifestyle modification.

The purpose of this study was to evaluate the effectiveness of this low-intensity telephone-counselling programme implemented by the NHIS. A regression discontinuity design was applied to examine the intervention effects on intermediate outcomes such as cardiometabolic parameters and weight loss in screen-detected individuals with MetS components. When randomisation is impossible and interventions should be given to those in need, the regression discontinuity design, if properly conducted, can provide a valuable evidence base for intervention effects.[18–23]

METHODS

Participant enrolment for the MetS Management Programme managed by the NHIS

All those insured through employment and those insured as self-employed or contractors of all ages, and their dependants aged 40 years or older may be enrolled for regular annual (mainly for blue-collar workers) or biennial health screening examinations at a local hospital. The NHIS has been selecting participants for the MetS Management Programme who have at least one of the components of MetS every month since January 2012 based on recent health examinations reported the previous month by local hospitals (figure 1). MetS was defined by the NHIS criteria, which adopted the criteria published by the National Cholesterol Education Programme (NCEP)[1] using the recommended cut-off for waist circumference in Koreans[24] and additional body mass index (BMI) criteria as follows:

1. Abdominal obesity, a waist circumference ≥90 cm in men and ≥85 cm in women or a BMI ≥25 kg/m^2
2. Elevated triglycerides ≥150 mg/dL
3. Low high-density lipoprotein (HDL) cholesterol of <40 mg/dL in men and <50 mg/dL in women
4. Elevated blood pressure (BP), a systolic BP ≥130 mm Hg or a diastolic BP ≥85 mm Hg
5. Elevated fasting plasma glucose ≥100 mg/dL.

Individuals with three or more components of MetS were defined as having MetS. People with the following criteria would not be eligible for the programme:

1. If they had been treated for hypertension (I10–I15 of the International Classification of Diseases, 10th Edition) or diabetes (E10–E14) at least once during the past 12 months as reported in the NHIS claims data at enrolment.
2. If they had been enrolled in the NHIS Hypertension and Diabetes Management Programme.
3. If they agreed to participate in a different health management programme being operated by a public health centre.
4. If they were deceased, had emigrated, entered the military or were admitted into a special facility as reported in the NHIS beneficiary data at enrolment.

Low-intensity interventions in the NHIS MetS Management Programme

All enrollees received a leaflet explaining MetS and a letter notifying them of any elevated components of MetS. Additionally, a contact telephone number for participant support services was included (figure 1). Screened participants with MetS were labelled as the high-risk group and were referred for additional services; people without MetS were labelled as the low-risk group and were invited to contact their local NHIS office to request additional services.

Approximately 300 trained personnel at the NHIS office contacted the high-risk group directly. Contacted individuals who agreed to participate in telephone counselling received a maximum of three personalised counselling sessions within 6 months. In the counselling session, goals for reducing elevated components of MetS were discussed by suggesting lifestyle modification, informing them of available resources, and advising them to contact their physician, when appropriate. Additionally, a booklet explaining self-management guidelines and a short message were sent by mobile phone twice per month for 6 months with the participants' consent. Participants were counselled during the day at regular business hours. The first telephone counselling session took an average of 7.8 min, while the second and third counselling sessions took an average of 5.8 min and 5.5 min, respectively, according to a self-reported survey of all counselling personnel recorded in September 2013.

43% of all health counsellors in September 2013 were administrative staff, while 57% were health/medical staff (57%) who were nationally licensed or certified as a registered nurse, social worker, dietitian or health educator. Before counselling participants, they received

BMJ Open: first published as 10.1136/bmjopen-2015-007603 on 10 July 2015. Downloaded from http://bmjopen.bmj.com/ on April 20, 2024 by guest. Protected by copyright.

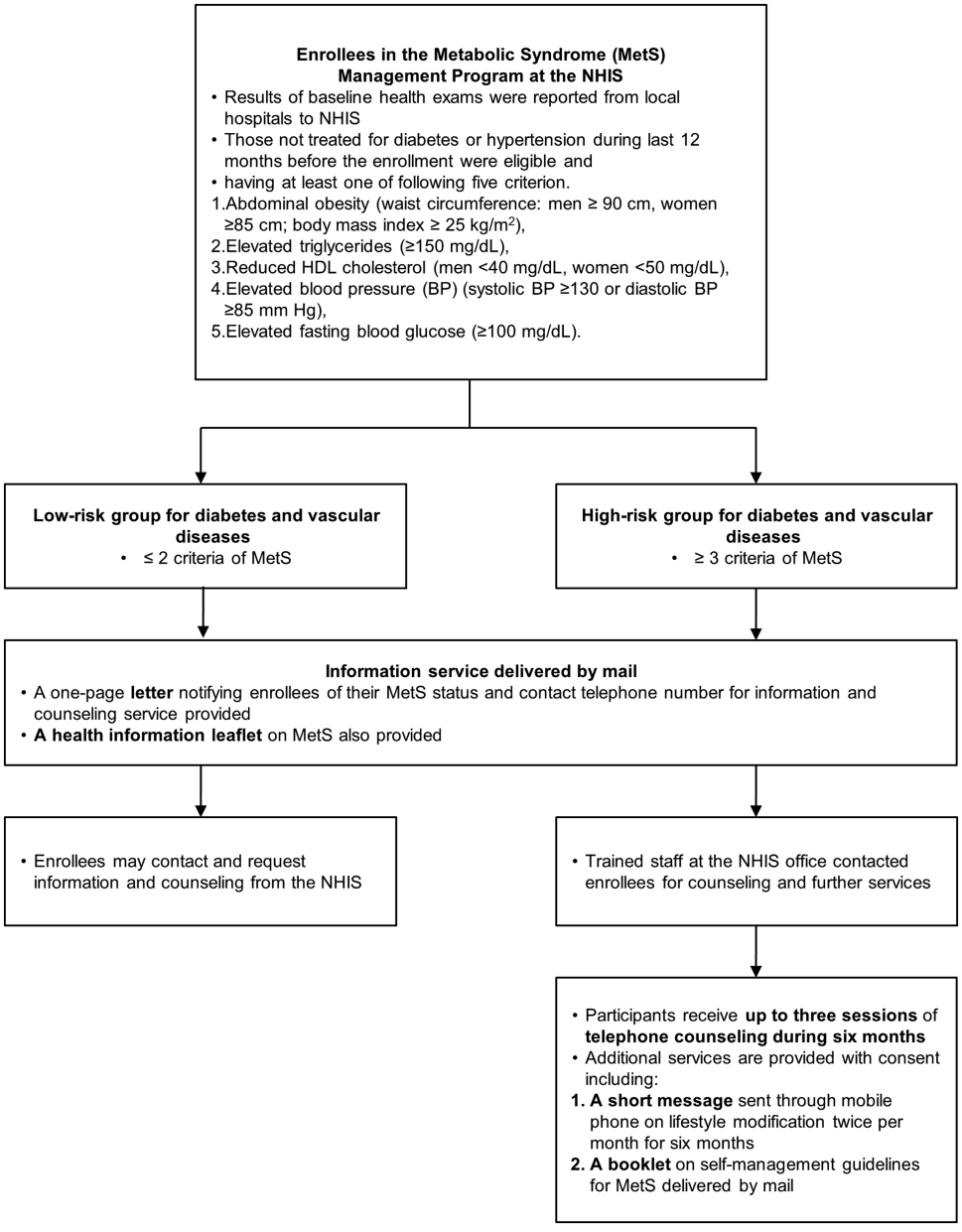


Figure 1 Flow of Metabolic Syndrome Management Programme at the National Health Insurance Service (NHIS) in Korea.

training on counselling methods such as communication skills, how to interpret the health examination results, the management of MetS, methods of weight reduction and diet modification, and physical activity guidelines through a minimum of a 24 h face-to-face group session and twenty 20 min online modules (400 total minutes). Counsellors also received refresher trainings lasting approximately 16 h/year.

Study participants

In 2012, 5 378 558 beneficiaries who had at least one component of MetS detected at health screening and had not been treated for diabetes or hypertension in the past 12 months were enrolled in the NHIS MetS Management Programme. Of these, 3 958 652 and 1 419 906 participants were categorised as low risk and high risk, respectively (figure 2). In the high-risk group, 206 437 enrollees (14.5%) participated in the counselling programme several months after the baseline examinations.

Among all those who underwent follow-up examinations the year after their baseline examination until June 2013, 855 870 enrollees and 291 825 enrollees in the low-risk and high-risk groups, respectively, were recruited for this study. Those in the low-risk group were considered the control group, and those in the high-risk group were considered eligible for counselling (eligible group). Of the eligible group, 23 968 participated in counselling at least once before follow-up examinations, and they were classified as the intervention group. Although the participation rate for follow-up examinations in individuals who received telephone counselling (n=206 437, 'counselling participants') was low, the

BMJ Open: first published as 10.1136/bmjopen-2015-007603 on 10 July 2015. Downloaded from http://bmjopen.bmj.com/ on April 20, 2024 by guest. Protected by copyright.

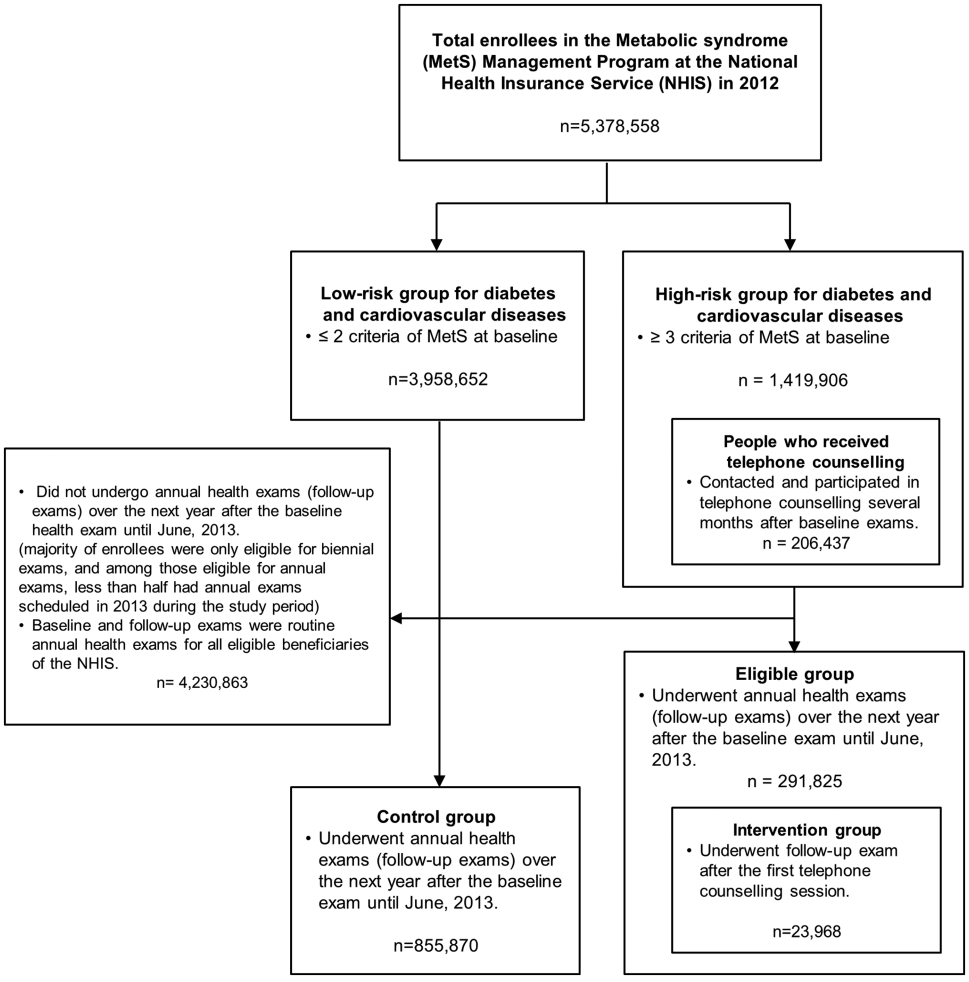


Figure 2 Flow of the study population.

participation rate for follow-up examinations was not different for counselling participants versus non-participants, after adjustment for the beneficiary status.

Ethics statement

This study is a retrospective analysis using data from two public health services, the Health Examination and Metabolic Syndrome Management Programme, implemented by a government agency (NHIS) of Korea. These public health services are planned and operated in compliance with the Framework Act on Health Examination, the Framework Act on Health Promotion and the National Health Insurance Act of Korea. Services for the high-risk group in the Metabolic Syndrome Management Programme are provided with verbal consent, which is obtained when they are contacted by a health counsellor by phone. All data with personally identifiable information are collected and maintained by the NHIS according to several Korean laws. Data were anonymised for the analysis and provided to the authors by the NHIS. Data were only available through a specific computer within the NHIS headquarters. Ethics approval was sought for analysis of the anonymised data and was approved by the Institutional Review Board of Kwandong University.

Data collection of health screening examinations

Annual health examinations were administered at local hospitals for all eligible beneficiaries of the NHIS. Weight and height were measured to the nearest 1 kg or 1 cm, respectively, while examinees wore light clothing without shoes. Waist circumference was measured at the midpoint between the lowest rib margin and iliac crest at the mid-axillary line to the nearest 1 cm. BMI (kg/m^2) was calculated as weight (kg) divided by height (m) squared. Blood pressure was measured after at least a 5 min rest while examinees were seated. If the first collected blood pressure reading was ≥120/80 mm Hg, a second measurement was taken after at least two additional minutes of rest and only this measurement was recorded. Blood samples were obtained after at least an 8 h fast for biochemical analyses including triglyceride (mg/dL), fasting glucose (mg/dL) and HDL cholesterol (mg/dL) levels.

In addition, participants self-reported health behaviours such as smoking, drinking and physical activity through a questionnaire. Physicians also assessed the enrollees' health status and health behaviours at the

BMJ Open: first published as 10.1136/bmjopen-2015-007603 on 10 July 2015. Downloaded from http://bmjopen.bmj.com/ on April 20, 2024 by guest. Protected by copyright.

health screening. Further details about this health screening are available elsewhere.[25]

Outcome measures

The outcomes in this study were the absolute value of change for each component of MetS, for body weight, and for BMI from baseline. In addition, the data were analysed for changes in the number of MetS components and the prevalence of MetS from baseline. The prevalence of MetS was defined by the NHIS criteria as well as the modified NCEP criteria,[1] which applied the Korean waist circumference cut-off.[24]

Covariates

Sociodemographic covariates were collected from the beneficiary database and included age at baseline, gender, the beneficiary status (employee, self-employed, dependant of an employee, dependant of a self-employed person) and health insurance premium (vigintile; 5th or below, 6th–10th, 11th–15th, 16th or above). The beneficiary status and health insurance premium were included as indicators of socioeconomic status. The health behaviors of smoking, drinking and physical inactivity of enrollees were assessed by the attending physician who interviewed them at health examinations, and included as covariates. These data were collected as 'yes' or 'no' according to whether there was a need for improvement. Since the interval between baseline and follow-up measures was not the same for each participant, it was included as another covariate.[19] In addition, the baseline measurements of the number of prevalent components of MetS, the value of each component, body weight and BMI were considered covariates in our analysis. For all of the variables, 0.02% or below of the values were missing except for beneficiary status (795, 0.07%) and those with missing values were excluded from the relevant analyses.

Statistical analysis

χ^2 Tests and one-way analysis of variance (ANOVA) were performed to compare differences between groups. The McNemar and paired t tests were performed to analyse within-group changes in values from baseline.

Participants were assigned to the eligible group based on the number of MetS components (the assignment variable) independently of covariates; therefore, multiple regression analyses were applied using baseline measurements (that were related to the assignment variable) and other variables as covariates (analysis of covariance (ANCOVA) models).[23 26–28] The model in this analysis is as follows:

$$Y_{ij} = \beta_0 + \beta_1 G_{ij} + \beta_{c1} X_{ij}^{C1} + \ldots + \beta_{ck} X_{ij}^{Ck} + e_{ij}$$

where Y_{ij} is the follow-up examination value of the outcome variable of person i in group j (eg, j=1 for the control group, j=2 for the intervention group); G_{ij} is an intervention indicator (G_{i1}=0 for the control group, G_{i2}=1for the intervention group); X_{ij}^{C1},…, and X_{ij}^{Ck} are the covariates including the assignment variable (the number of MetS components) and initial examination values of the outcome variable; and e_{ij} is normally distributed with a zero mean and constant variance. Difference in the mean value of outcome variables at the cut-off point (the number of MetS components=3) between intervention groups, namely β_1, is the effect of the intervention. More details about regression discontinuity designs, including their basic concept and applications, can be found elsewhere.[18 20–23 29]

In this study, the control group was compared with both the eligible and intervention groups. Comparison between the eligible and control groups may be considered an intention-to-treat analysis, or rather an observational study without intervention since only 8.2% of the eligible group received counselling. When analysing changes in the value of each component of MetS, analyses in people having certain MetS components were additionally performed (for instance, analysis of systolic BP was performed in those with a BP component (n=552 988), namely, BP ≥130/85 mm Hg). Furthermore, interaction between intervention and severity of MetS was assessed using the linear interaction term between the assignment variable and the intervention as a covariate.

For sensitivity analysis, the effects of the NHIS low-intensity intervention was estimated using propensity score weighting methods with a robust variance estimator[30] among participants with MetS (the intervention group (n=23 968) versus 'the propensity control group' (n=267 857)) and with three components of MetS (the intervention group (n=12 796) versus the propensity control group (n=187 433)). The stabilised inverse probability of treatment weighting (stabilised IPTW)[31] and standardised mortality ratio weighting (SMRW)[32] using the propensity score were used. A propensity score was estimated using a logistic regression model in which the intervention status was regressed on all variables in the main analysis. Each continuous variable was modelled using restricted cubic splines with five knots.[30 33]

Two-sided p values were calculated and the statistical significance level was set at 0.05. All statistical analyses were performed using SAS V.9.2 (SAS Institute, Cary, North Carolina, USA).

RESULTS

General characteristics

The eligible group tended to be older, male, current smokers, current drinkers and physically inactive as well as having a higher insurance premium (higher income) than the control group (table 1). The intervention group was 7.7 years older than the control group and had more males, fewer employees and a lower premium (less income) than the control group. All differences between variables were statistically significant (p<0.001 for all) for the eligible group versus the control group and the intervention group versus the control group.

BMJ Open: first published as 10.1136/bmjopen-2015-007603 on 10 July 2015. Downloaded from http://bmjopen.bmj.com/ on April 20, 2024 by guest. Protected by copyright.

Table 1 Sociodemographic and behavioural characteristics by group

Characteristics	Classification	Total enrollees* (n=1 147 695)		Eligible group* (n=291 825)		Intervention group* (n=23 968)		Control group* (n=855 870)		p Value†	p Value‡
		n	(%)	n	(%)	n	(%)	n	(%)		
Age at baseline examination (years)	Mean (SD)			42.7	(10.3)	48.7	(10.9)	41.0	(11.0)	<0.001§	<0.001¶
Gender	Female	270 964	(23.6)	42 547	(14.6)	5641	(23.5)	228 417	(26.7)	<0.001	<0.001
	Male	876 731	(76.4)	249 278	(85.4)	18 327	(76.5)	627 453	(73.3)		
Beneficiary status	Self-employed	16 274	(1.4)	4822	(1.7)	1006	(4.2)	11 452	(1.3)	<0.001	<0.001
	Dependant of a self-employed	7963	(0.7)	1968	(0.7)	452	(1.9)	5995	(0.7)		
	Employee	1 098 562	(95.7)	278 418	(95.5)	20 990	(87.6)	820 144	(95.9)		
	Dependant of an employee	24 101	(2.1)	6410	(2.2)	1515	(6.3)	17 691	(2.1)		
Premium vigintile**	5th or below	258 342	(22.5)	62 702	(21.5)	7220	(30.1)	195 640	(22.9)	<0.001	<0.001
	6th-10th	211 831	(18.5)	46 917	(16.1)	4557	(19.0)	164 914	(19.3)		
	11th-15th	337 455	(29.4)	86 828	(29.8)	6163	(25.7)	250 627	(29.3)		
	16th or above	340 067	(29.6)	95 378	(32.7)	6028	(25.2)	244 689	(28.6)		
Smoking††	Yes	414 357	(36.1)	123 449	(42.3)	8380	(35.0)	290 908	(34.0)	<0.001	<0.001
Drinking††	Yes	453 142	(39.5)	130 367	(44.7)	9492	(39.6)	322 775	(37.7)	<0.001	<0.001
Physical Inactivity††	Yes	392 419	(34.2)	104 026	(35.6)	8421	(35.1)	288 393	(33.7)	<0.001	<0.001

*Total enrollees consisted of the control and eligible groups. The intervention group was a subset of the eligible group which participated in the counselling programme several months after baseline examinations.
†χ^2 Test between the eligible and control groups.
‡χ^2 Test between the intervention and control groups.
§One-way analysis of variance between the eligible and control groups.
¶One-way analysis of variance between the intervention and control groups.
**Premium vigintile of a dependant of a self-employed (or an employee) was based on that of their insured (a self-employed or an employee). Premium vigintile was calculated based on data from all citizens insured by the National Health Insurance Service in Korea, but not from the study participants.
††These variables are not smoking, drinking, and physical inactivity status per se answered by each enrollee, rather than an assessment by the attending physicians on the need for improvement of each variable for an enrollee. The attending physicians at health examination made an assessment whether there is a need for improvement in smoking, drinking, and physical inactivity status in each enrollee, based on examinees' answers to the questionnaire and personal interview.

BMJ Open: first published as 10.1136/bmjopen-2015-007603 on 10 July 2015. Downloaded from http://bmjopen.bmj.com/ on April 20, 2024 by guest. Protected by copyright.

Absolute changes in the values and the number of MetS components from baseline

The value of each component and the total number of components of MetS at baseline were significantly higher in the eligible group and intervention group than those in the control group (table 2). Within-group changes from baseline in all variables were statistically significant. Changes in the eligible and intervention groups seemed to be more clinically meaningful than changes observed in the control group (table 2). Waist circumference, weight and BMI changed less than 1% from baseline in the eligible and intervention groups.

Change in the prevalence of MetS and MetS components

The eligible and intervention groups had a higher prevalence of MetS than did the control group at both baseline and follow-up (see online supplementary table S1). However, using the NHIS criteria, MetS was newly detected in 15.3% of those in the control group at follow-up examinations and reductions of 42.4% and 36.9% of MetS were observed in the eligible and intervention groups, respectively. When individuals with MetS by the modified NCEP criteria were analysed, a 49.1% (105 522/214 833) and 44.1% (8805/19 969) reduction in the prevalence of MetS was observed in the eligible and intervention groups, respectively. The prevalence of MetS was significantly increased from baseline in the control group. However, the prevalence of MetS was significantly decreased in the eligible and intervention groups (see online supplementary table S1).

Multiple regression analysis using ANCOVA models

All of the values of each MetS component, except fasting glucose and HDL cholesterol and the number of prevalent MetS components modestly but statistically significantly improved from baseline in the intervention group compared to the control group (table 3). However, in the eligible group, only systolic BP was modestly improved.

In a comparison of the intervention and control groups, when the analysis was restricted to only those with a given component of MetS at baseline, systolic BP, diastolic BP, triglyceride and HDL cholesterol levels improved the most, while waist circumference, weight and BMI did not change as much as when the analysis included all enrollees (table 3). The additive treatment effects at the cut-off point of three MetS components were similar with or without a linear interaction term (the assignment variable and the intervention; see online supplementary figure S1, table 3) in the eligible and intervention groups compared to the control group. The linear interaction effects of counselling and the assignment variable were not significant for HDL cholesterol, weight and BMI in the intervention group (see online supplementary figure S1).

Sensitivity analysis using a propensity score method

Among all participants with MetS, all of the values of each MetS component, except HDL cholesterol, modestly but statistically significantly improved from baseline in the intervention group compared to the propensity control group, in the results from the stabilised IPTW method. Among participants with three MetS components, intervention effects estimated from both stabilised IPTW and SMRW methods were also generally similar to the main analysis (see online supplementary table S2).

DISCUSSION

Participants in this low-intensity intervention programme showed modest improvements 1 year after baseline examinations for blood pressure, triglyceride, weight, BMI and the number of MetS components in patients with untreated MetS detected by population screening.

Potential mechanism of improvement

Changes to participants' lifestyle could partly account for the observed improvements.[3 34] Participating in the counselling intervention was associated with a decreased prevalence of self-reported current smoking (OR=0.91, 95% CI 0.86 to 0.95), current drinking (at least once per week; OR=0.92, 95% CI 0.88 to 0.96) and physical inactivity (not walking at least 30 min per day at least 1 day a week for at least 10 min each time; OR=0.91, 95% CI 0.88 to 0.94) at follow-up examinations. However, counselling assignment per se was not associated with a reduction in the prevalence of current smoking (OR 1.0043), current drinking (OR 1.0039) or physical inactivity (OR 0.9951) when the eligible group was compared with the control group..

In addition to lifestyle changes, increased use of medical services could also explain the observed improvements to blood pressure and lipid profiles after participating in the low-intensity programme.[34 35] In another NHIS telephone counselling programme for diabetes and hypertension, participants (n=42 356) had visited a medical clinic (including ambulatory visits and hospital stays) 1.4 days more throughout 1 year after their first telephone consultation than the control group (n=178 543). The mixed results on fasting glucose (in the main analysis and the sensitivity analysis) might be due to the relative ineffectiveness of pharmacological management for this condition. For example, evidence on the effectiveness of hypoglycaemic agents has been less than compelling;[36 37] on the other hand, drugs for lowering blood pressure[38] and triglyceride[39] levels have been shown to be more effective.

Methodological considerations

Although the non-randomised design of this study could be viewed as a significant limitation, when properly implemented, the regression discontinuity design can provide an unbiased estimation of the intervention effects with a slightly lower statistical power than that of a randomised design.[18 21–23 29] However, the chance of a low statistical power was not a concern in our study because of the large study population. The basic

BMJ Open: first published as 10.1136/bmjopen-2015-007603 on 10 July 2015. Downloaded from http://bmjopen.bmj.com/ on April 20, 2024 by guest. Protected by copyright.

Table 2 Changes in the value of each component of the metabolic syndrome, the number of metabolic syndrome components, body weight and BMI from baseline by group

Outcome variables	Classification	Eligible group (n=291 825) Mean	(SD)	Intervention group* (n=23 968) Mean	(SD)	Control group (n=855 870) Mean	(SD)
Age (years)	Baseline	42.7	(10.3)	48.7	(10.9)	41.0	(11.0)
Interval between baseline and follow-up examinations (days)	Baseline	333.7	(65.5)	335.9	(64.6)	334.2	(64.9)
The number of MetS components by NHIS criteria†	Baseline	3.36	(0.56)	3.55	(0.64)	1.41	(0.50)
	Follow-up	2.68	(1.14)	2.83	(1.13)	1.40	(1.06)
	Change	−0.68	(1.12)	−0.72	(1.10)	−0.01	(1.02)
	p value‡	<0.001		<0.001		<0.001	
The number of MetS components by modified NCEP criteria§	Baseline	2.96	(0.74)	3.20	(0.77)	1.20	(0.58)
	Follow-up	2.33	(1.18)	2.53	(1.17)	1.20	(1.01)
	Change	−0.63	(1.17)	−0.68	(1.16)	−0.003	(1.04)
	p value‡	<0.001		<0.001		0.003	
Systolic blood pressure (mm Hg)	Baseline	131.2	(12.7)	135.7	(14.9)	122.3	(12.6)
	Follow-up	128.0	(13.4)	130.2	(14.8)	121.7	(12.7)
	Change	−3.1	(13.9)	−5.5	(15.6)	−0.7	(13.1)
	p value‡	<0.001		<0.001		<0.001	
Diastolic blood pressure (mm Hg)	Baseline	82.6	(9.4)	84.9	(10.7)	76.8	(8.9)
	Follow-up	80.9	(9.7)	81.9	(10.4)	76.6	(9.0)
	Change	−1.7	(10.4)	−3.0	(11.3)	−0.2	(9.6)
	p value‡	<0.001		<0.001		<0.001	
Triglyceride (mg/dL)	Baseline	230.9	(152.6)	252.7	(179.2)	125.3	(82.0)
	Follow-up	206.4	(154.2)	211.7	(161.0)	128.6	(93.8)
	Change	−24.5	(159.6)	−41.0	(170.3)	3.3	(91.6)
	p value‡	<0.001		<0.001		<0.001	
Fasting plasma glucose (mg/dL)	Baseline	105.7	(26.3)	115.2	(37.2)	94.0	(15.3)
	Follow-up	103.9	(26.7)	110.7	(34.0)	94.6	(15.6)
	Change	−1.8	(23.6)	−4.5	(30.8)	0.6	(15.8)
	p value‡	<0.001		<0.001		<0.001	
Waist circumference (cm)	Baseline	87.8	(7.5)	87.9	(7.7)	80.6	(8.0)
	Follow-up	87.7	(7.8)	87.5	(7.9)	80.9	(8.2)
	Change	−0.1	(5.2)	−0.4	(5.3)	0.3	(5.1)
	p value‡	<0.001		<0.001		<0.001	
HDL cholesterol (mg/dL)	Baseline	47.1	(19.1)	47.2	(17.6)	55.4	(20.0)
	Follow-up	47.9	(14.9)	48.4	(15.3)	55.2	(17.1)
	Change	0.8	(20.3)	1.2	(19.2)	−0.1	(21.1)
	p value‡	<0.001		<0.001		<0.001	
Weight (kg)	Baseline	77.1	(11.6)	74.6	(12.0)	67.7	(11.3)
	Follow-up	77.0	(11.9)	74.2	(12.1)	68.1	(11.6)
	Change	−0.1	(3.3)	−0.4	(3.2)	0.4	(3.0)
	p value‡	<0.001		<0.001		<0.001	
Body mass index (kg/m^2)	Baseline	26.7	(2.9)	26.7	(3.0)	23.9	(2.9)
	Follow-up	26.7	(3.1)	26.5	(3.1)	24.0	(3.0)
	Change	−0.05	(1.1)	−0.2	(1.1)	0.1	(1.1)
	p value‡	<0.001		<0.001		<0.001	

p Values, which were calculated by one-way analysis of variance between the eligible and control groups, and between the intervention and control groups, were all <0.001 for all outcome variables.
*The intervention group was a subset of the eligible group which participated in the counselling programme.
†NHIS criteria applied the NCEP criteria[1] with the Korean waist circumference cut-off and BMI. (Abdominal obesity as a waist circumference of ≥90 cm in men and ≥85 cm in women or a BMI ≥25 kg/m^2).
‡Paired t test of within-group change from baseline.
§NCEP criteria[1] with the Korean waist circumference cut-off (abdominal obesity as a waist circumference of ≥90 cm in men and ≥85 cm in women).
BMI, body mass index; HDL, high-density lipoprotein; MetS, metabolic syndrome; NCEP, National Cholesterol Education Programme of the USA; NHIS, the National Health Insurance Service of Korea.

assumption that participants were assigned to the intervention group according to the MetS status was rarely violated; only 0.2% of the control group requested counselling, and regardless of participation in the counselling, all participants with two or less MetS components were placed in the control group. Choice of the

BMJ Open: first published as 10.1136/bmjopen-2015-007603 on 10 July 2015. Downloaded from http://bmjopen.bmj.com/ on April 20, 2024 by guest. Protected by copyright.

Table 3 Intervention effects on the metabolic syndrome-related risk factors by multiple regression analysis (ANCOVA models*)

Outcome variables	Eligible group vs control group			Intervention group vs control group†		
	Intervention effect‡	95% CI	p Value	Intervention effect‡	95% CI	p Value
All participants						
The number of MetS components by NHIS criteria§	0.03	(0.02 to 0.03)	<0.001	−0.02	(−0.04 to −0.01)	0.001
The number of MetS components by modified NCEP criteria¶	0.01	(0.00 to 0.02)	0.006	−0.05	(−0.06 to −0.03)	<0.001
Systolic BP (mm Hg)	−0.16	(−0.25 to −0.07)	0.001	−0.85	(−1.02 to −0.68)	<0.001
Diastolic BP (mm Hg)	−0.06	(−0.12 to 0.01)	0.086	−0.63	(−0.75 to −0.50	<0.001
Triglyceride (mg/dL)	2.52	(1.72 to 3.32)	<0.001	−1.57	(−2.89 to −0.25)	0.020
Fasting plasma glucose (mg/dL)	0.29	(0.16 to 0.42)	<0.001	2.03	(1.81 to 2.25)	<0.001
Waist circumference (cm)	0.0004	(−0.04 to 0.04)	0.983	−0.09	(−0.16 to −0.02)	0.017
HDL cholesterol (mg/dL)	0.12	(0.00 to 0.25)	0.052	0.17	(−0.07 to 0.42)	0.172
Weight (kg)	−0.02	(−0.04 to 0.01)	0.143	−0.19	(−0.24 to −0.15)	<0.001
Body mass index (kg/m^2)	−0.004	(−0.01 to 0.00)	0.395	−0.07	(−0.09 to −0.05)	<0.001
Participants with a relevant MetS component**						
Systolic BP (mm Hg)	−0.06	(−0.18 to 0.07)	0.377	−1.29	(−1.53 to−1.05)	<0.001
Diastolic BP (mm Hg)	0.04	(−0.05 to 0.13)	0.399	−0.81	(−0.98 to−0.63)	<0.001
Triglyceride (mg/dL)	−1.87	(−3.37 to −0.36)	0.015	−7.58	(−10.3 to −4.89)	<0.001
Fasting plasma glucose (mg/dL)	−0.05	(−0.32 to 0.21)	0.691	0.52	(0.08 to 0.96)	0.020
Waist circumference (cm)	0.08	(0.03 to 0.13)	0.002	0.05	(−0.05 to 0.15)	0.328
HDL cholesterol (mg/dL)	−0.12	(−0.31 to 0.08)	0.243	0.90	(0.51 to 1.29)	<0.001
Weight (kg)	0.01	(−0.03 to 0.05)	0.618	−0.08	(−0.15 to 0.00)	0.044
Body mass index (kg/m^2)	0.01	(−0.01 to 0.02)	0.356	−0.03	(−0.05 to 0.00)	0.044

*Baseline measurements (the number of MetS components by NHIS criteria, systolic BP, diastolic BP, triglyceride, fasting glucose, HDL cholesterol, waist circumference, weight, body mass index), age at baseline, gender, health insurance beneficiary status, health insurance premium vigintile, smoking, drinking, physical inactivity and interval between baseline and follow-up examinations (days) were included in the model as covariates.
†The intervention group was a subset of the eligible group which participated in the counselling programme.
‡Negative values mean that the outcome variable is decreased more from the baseline in the intervention group (or eligible group) than in the control group.
§NHIS criteria applied the NCEP criteria[1] with the Korean waist circumference cut-off and BMI (abdominal obesity as a waist circumference of ≥90 cm in men and ≥85 cm in women or a BMI ≥25 kg/m^2 in both sexes).
¶NCEP criteria[1] with the Korean waist circumference cut-off (abdominal obesity as a waist circumference of ≥90 cm in men and ≥85 cm in women).
**For example, analysis of systolic BP was restricted to those having elevated BP components at baseline, namely those having systolic BP ≥130 or diastolic BP ≥85 mm Hg.
ANCOVA, analysis of covariance; BMI, body mass index; BP, blood pressure; HDL, high-density lipoprotein; MetS, metabolic syndrome; NCEP, National Cholesterol Education Programme of USA; NHIS, the National Health Insurance Service of Korea.

correct functional form between the assignment variable and the outcome is crucial to maintain validity in a regression discontinuity design.[22 23 29] In this study, the functional form was modelled as a linear function because of its simplicity in interpreting the results, and the adjusted R^2 value did not increase when polynomial terms of the assignment variable were added to the model.[18 23] The estimated function between the eligible and control groups could serve as a reference when evaluating the discontinuity of the function estimated between the intervention and control groups.[23] For example, intervention effects in the eligible group compared to the control group were close to 0 (in case of OR, 1.0), and were mostly insignificant when participants with a relevant MetS component for outcome were analysed. Therefore, we could assume that the estimated intervention effects from the selected functional form in this study did not substantially deviate from the true effects.

The overall participation rate for follow-up examinations was low (21.3% of 5 378 558) because the majority of participants were not eligible for an annual examination and should not have been included in the study population in the first place, if beneficiary data could have identified them. Therefore, low participation in the follow-up examination is unlikely to introduce a bias. Furthermore, the participation rates for follow-up examinations were the same between groups after adjustment for the beneficiary status using the Cochran-Mantel-Hanzel test. For example, the participation rate for follow-up examinations were not different for counselling participants versus non-participants with ≥3 MetS components (n=1 213 469) (p=0.50) or for counselling participants versus all non-participants (n=5 172 121) (p=0.34).

BMJ Open: first published as 10.1136/bmjopen-2015-007603 on 10 July 2015. Downloaded from http://bmjopen.bmj.com/ on April 20, 2024 by guest. Protected by copyright.

Participant bias may have affected this study. For example, the intervention group tended to have a more severe value of MetS components than did the eligible group at baseline. However, intervention effects would have been underestimated rather than overstated in this study, if people with truly more severe MetS had participated in the counselling.[20 21]

Strengths and limitations

To the best of our knowledge, this is the first study to evaluate the effectiveness of a national-level low-intensity counselling programme in patients with previously untreated MetS detected at population screening. Additionally, low-intensity interventions have rarely been conducted in a selected group of individuals with cardiovascular disease risk.[16] The modest improvements of this counselling programme on blood pressure and lipid profiles may have been observed partly because counselling was provided in patients with untreated MetS, not in a general or low-risk population. Our large study population was a clear strength because small improvements by the low-intensity counselling intervention programme were detected.

The interval between the first counselling session and the follow-up examination was less than 1 year (mean (SD), 234 (72) days). Since the intervention effects may change over time,[40] the effects after more than 1 year of low-intensity counselling should be investigated through further research. Our results may have limited generalisability to healthy people or people with MetS who already have been clinically treated for diabetes or hypertension, because this study examined people with MetS who had been untreated for diabetes or hypertension over the past 12 months before enrolment.

Implications of the study

Some high-intensity interventions have been relatively established as improving intermediate health outcomes such as blood pressure, lipid profiles and fasting glucose as well as reducing body weight. However, restricted resources cause difficulties in efforts to implement even a medium-intensity intervention in community or primary care settings.[16 41] Evidence regarding the effectiveness of low-intensity programmes on intermediate outcomes has been lacking.[16 40 42] This study shows that low-intensity interventions may be effective on some intermediate health outcomes. However, the effects of this low-intensity telephone counselling were modest, and the clinical relevance of these small improvements needs to be further clarified.

In this study, 42.4% and 49.1% of screen-detected MetS by the NHIS criteria and modified NCEP criteria, respectively, was resolved 1 year after baseline in the eligible group. Previous studies reported that, in a group with minimal or no intervention, study participants who were enrolled based on one screening examination showed more resolution of MetS than those enrolled based on two or more examinations or clinical diagnosis.[12 41 43–45] These results could largely be due to the regression to the mean phenomenon.[28 46] When screening-based programmes for early detection and intervention of MetS are considered, the regression to the mean effect should be taken into account to explain anticipated changes between measurements and to evaluate the cost-effectiveness of these programmes.

When face-to-face programmes have limited reach due to distance, transportation and time constraints, telephone-delivered programmes may be useful to overcome those obstacles.[47 48] This study may provide evidence that counselling could be effectively delivered by telephone. Moreover, since around 40% of the telephone counsellors were administrative staff, and even the health staff performing telephone counselling at the NHIS lacked real-world clinical experience compared to their counterparts at clinics, this study may suggest that counselling could be effectively delivered by educators without clinical training.[49] Further research is required to confirm these findings.

CONCLUSION

The present study provides evidence that low-intensity telephone counselling could yield improvements on blood pressure, lipid profiles, weight and BMI as well as decrease the prevalence of the MetS in the following year in patients with untreated MetS detected by population screening. However, improvements may be modest, and the clinical relevance of these small improvements may be limited. Moreover, the regression to the mean phenomenon could have caused a large proportion of MetS detected at the general population screening to be spontaneously resolved. These findings suggest that, even if low-intensity interventions modestly improve intermediate health outcomes, the cost-effectiveness of systematic screening and intervention programmes among general populations for MetS needs to be further evaluated.

Acknowledgements The authors thank the staff at the Big Data Steering Department at the National Health Insurance Service (NHIS) for providing the data and support.

Contributors S-WY, S-AS and Y-JL conceived the study concept and design. S-AS and YJL acquired the data. S-WY analysed and interpreted the data, and wrote the first draft. S-WY, S-AS and Y-JL contributed to the critical revision of the manuscript. All authors have read and approved of the final submitted version of the manuscript. S-WY is the study guarantor.

Funding Metabolic Syndrome Management Programme and health examinations were funded and managed by the NHIS. All data were collected and maintained by the NHIS.

Competing interests S-WY had been a part-time consultant to the NHIS during the conduct of the study. S-AS and Y-JL have been working at the department that is responsible for the Metabolic Syndrome Management Programme by the NHIS during the conduct of the study. The authors have no other individual competing interests to declare.

Ethics approval Kwandong University.

Provenance and peer review Not commissioned; externally peer reviewed.

Data sharing statement All relevant raw data are collected and stored by the NHIS in accordance with the several Korean laws. Data are available from the NHIS for the researcher if his/her proposal for collaborative study is approved by the data sharing committee at the NHIS.

BMJ Open: first published as 10.1136/bmjopen-2015-007603 on 10 July 2015. Downloaded from http://bmjopen.bmj.com/ on April 20, 2024 by guest. Protected by copyright.

Open Access This is an Open Access article distributed in accordance with the Creative Commons Attribution Non Commercial (CC BY-NC 4.0) license, which permits others to distribute, remix, adapt, build upon this work non-commercially, and license their derivative works on different terms, provided the original work is properly cited and the use is non-commercial. See: http://creativecommons.org/licenses/by-nc/4.0/

REFERENCES

1. Alberti KG, Eckel RH, Grundy SM, *et al*. Harmonizing the metabolic syndrome: a joint interim statement of the International Diabetes Federation Task Force on Epidemiology and Prevention; National Heart, Lung, and Blood Institute; American Heart Association; World Heart Federation; International Atherosclerosis Society; and International Association for the Study of Obesity. *Circulation* 2009;120:1640–5.
2. Després JP, Lemieux I, Bergeron J, *et al*. Abdominal obesity and the metabolic syndrome: contribution to global cardiometabolic risk. *Arterioscler Thromb Vasc Biol* 2008;28:1039–49.
3. Grundy SM, Cleeman JI, Daniels SR, *et al*. Diagnosis and management of the metabolic syndrome: an American Heart Association/National Heart, Lung, and Blood Institute Scientific Statement. *Circulation* 2005;112:2735–52.
4. de Carvalho Vidigal F, Bressan J, Babio N, *et al*. Prevalence of metabolic syndrome in Brazilian adults: a systematic review. *BMC Public Health* 2013;13:1198.
5. Delavari A, Forouzanfar MH, Alikhani S, *et al*. First nationwide study of the prevalence of the metabolic syndrome and optimal cutoff points of waist circumference in the Middle East: the national survey of risk factors for noncommunicable diseases of Iran. *Diabetes Care* 2009;32:1092–7.
6. Lim S, Shin H, Song JH, *et al*. Increasing prevalence of metabolic syndrome in Korea: the Korean National Health and Nutrition Examination Survey for 1998–2007. *Diabetes Care* 2011;34:1323–8.
7. Liu M, Wang J, Jiang B, *et al*. Increasing prevalence of metabolic syndrome in a Chinese elderly population: 2001–2010. *PLoS ONE* 2013;8:e66233.
8. Ford ES. Risks for all-cause mortality, cardiovascular disease, and diabetes associated with the metabolic syndrome: a summary of the evidence. *Diabetes Care* 2005;28:1769–78.
9. Mottillo S, Filion KB, Genest J, *et al*. The metabolic syndrome and cardiovascular risk a systematic review and meta-analysis. *J Am Coll Cardiol* 2010;56:1113–32.
10. Esposito K, Chiodini P, Colao A, *et al*. Metabolic syndrome and risk of cancer: a systematic review and meta-analysis. *Diabetes Care* 2012;35:2402–11.
11. Gillies CL, Lambert PC, Abrams KR, *et al*. Different strategies for screening and prevention of type 2 diabetes in adults: cost effectiveness analysis. *BMJ* 2008;336:1180–5.
12. Orchard TJ, Temprosa M, Goldberg R, *et al*. The effect of metformin and intensive lifestyle intervention on the metabolic syndrome: the Diabetes Prevention Program randomized trial. *Ann Intern Med* 2005;142:611–19.
13. Ilanne-Parikka P, Laaksonen DE, Eriksson JG, *et al*. Leisure-time physical activity and the metabolic syndrome in the Finnish diabetes prevention study. *Diabetes Care* 2010;33:1610–17.
14. Wareham NJ, Griffin SJ. Should we screen for type 2 diabetes? Evaluation against National Screening Committee criteria. *BMJ* 2001;322:986–8.
15. Eddy DM, Schlessinger L, Kahn R. Clinical outcomes and cost-effectiveness of strategies for managing people at high risk for diabetes. *Ann Intern Med* 2005;143:251–64.
16. Lin JS, O'Connor E, Whitlock EP, *et al*. Behavioral counseling to promote physical activity and a healthful diet to prevent cardiovascular disease in adults: a systematic review for the US Preventive Services Task Force. *Ann Intern Med* 2010;153:736–50.
17. Jeong HS. Korea's National Health Insurance—lessons from the past three decades. *Health Aff (Millwood)* 2011;30:136–44.
18. Bor J, Moscoe E, Mutevedzi P, *et al*. Regression discontinuity designs in epidemiology: causal inference without randomized trials. *Epidemiology* 2014;25:729–37.
19. Locascio JJ, Atri A. An overview of longitudinal data analysis methods for neurological research. *Dement Geriatr Cogn Dis Extra* 2011;1:330–57.
20. Kenny D. A quasi-experimental approach to assessing treatment effects in the nonequivalent control group design. *Psychol Bull* 1975;82:345–62.
21. Goldberger AS. *Selection bias in evaluating treatment effects: the case of intervention*. Technical Report 129. Madison, WI: Institute for Research on Poverty, University of Wisconsin-Madison, 1972:1–19.
22. Cappelleri JC, Trochim WM, Stanley T, *et al*. Random measurement error does not bias the treatment effect estimate in the regression discontinuity design: I. The case of no interaction. *Eval Rev* 1991;15:395–419.
23. Pennell ML, Hade EM, Murray DM, *et al*. Cutoff designs for community-based intervention studies. *Stat Med* 2011;30:1865–82.
24. Lee S, Park HS, Kim SM, *et al*. Cut-off points of waist circumference for defining abdominal obesity in the Korean population. *Korean J Obes* 2006;15:1–9.
25. The Ministry of Health and Welfare. Health Examination Practice Guide (Korean). Public Notification 2011–166. 2011. http://www.law.go.kr/admRulLsInfoP.do?chrClsCd=&admRulSeq=2000000017810
26. Van Breukelen GJ. ANCOVA versus change from baseline: more power in randomized studies, more bias in nonrandomized studies [corrected]. *J Clin Epidemiol* 2006;59:920–5.
27. Senn S. Change from baseline and analysis of covariance revisited. *Stat Med* 2006;25:4334–44.
28. Barnett AG, van der Pols JC, Dobson AJ. Regression to the mean: what it is and how to deal with it. *Int J Epidemiol* 2005;34:215–20.
29. Lee DS, Lemieux T. Regression discontinuity designs in economics. *J Econ Lit* 2010;48:301–55.
30. Austin PC. The use of propensity score methods with survival or time-to-event outcomes: reporting measures of effect similar to those used in randomized experiments. *Stat Med* 2014;33:1242–58.
31. Cole SR, Hernan MA. Adjusted survival curves with inverse probability weights. *Comput Methods Programs Biomed* 2004;75:45–9.
32. Sato T, Matsuyama Y. Marginal structural models as a tool for standardization. *Epidemiology* 2003;14:680–6.
33. Harrell FE. *Regression modeling strategies: with applications to linear models, logistic regression, and survival analysis*. New York: Springer, 2001.
34. Gillies CL, Abrams KR, Lambert PC, *et al*. Pharmacological and lifestyle interventions to prevent or delay type 2 diabetes in people with impaired glucose tolerance: systematic review and meta-analysis. *BMJ* 2007;334:299.
35. Wong ND. Metabolic syndrome: cardiovascular risk assessment and management. *Am J Cardiovasc Drugs* 2007;7:259–72.
36. Boussageon R, Supper I, Erpeldinger S, *et al*. Are concomitant treatments confounding factors in randomized controlled trials on intensive blood-glucose control in type 2 diabetes? A systematic review. *BMC Med Res Methodol* 2013;13:107.
37. Norris SL, Lau J, Smith SJ, *et al*. Self-management education for adults with type 2 diabetes: a meta-analysis of the effect on glycemic control. *Diabetes Care* 2002;25:1159–71.
38. Lewington S, Clarke R, Qizilbash N, *et al*. Age-specific relevance of usual blood pressure to vascular mortality: a meta-analysis of individual data for one million adults in 61 prospective studies. *Lancet* 2002;360:1903–13.
39. Berglund L, Brunzell JD, Goldberg AC, *et al*. Evaluation and treatment of hypertriglyceridemia: an Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab* 2012;97:2969–89.
40. Heshka S, Anderson JW, Atkinson RL, *et al*. Weight loss with self-help compared with a structured commercial program: a randomized trial. *JAMA* 2003;289:1792–8.
41. Bo S, Ciccone G, Baldi C, *et al*. Effectiveness of a lifestyle intervention on metabolic syndrome. A randomized controlled trial. *J Gen Intern Med* 2007;22:1695–703.
42. Braeckman L, De Bacquer D, Maes L, *et al*. Effects of a low-intensity worksite-based nutrition intervention. *Occup Med (Lond)* 1999;49:549–55.
43. Esposito K, Marfella R, Ciotola M, *et al*. Effect of a mediterranean-style diet on endothelial dysfunction and markers of vascular inflammation in the metabolic syndrome: a randomized trial. *JAMA* 2004;292:1440–6.
44. den Engelsen C, Gorter KJ, Salomé PL, *et al*. One year follow-up of patients with screen-detected metabolic syndrome in primary care: an observational study. *Fam Pract* 2013;30:40–7.
45. Yoo S, Kim H, Cho HI. Improvements in the metabolic syndrome and stages of change for lifestyle behaviors in Korean older adults. *Osong Public Health Res Perspect* 2012;3:85–93.
46. Yudkin PL, Stratton IM. How to deal with regression to the mean in intervention studies. *Lancet* 1996;347:241–3.
47. Fappa E, Yannakoulia M, Ioannidou M, *et al*. Telephone counseling intervention improves dietary habits and metabolic parameters of patients with the metabolic syndrome: a randomized controlled trial. *Rev Diabet Stud* 2012;9:36–45.
48. Weinstock RS, Trief PM, Cibula D, *et al*. Weight loss success in metabolic syndrome by telephone interventions: results from the SHINE Study. *J Gen Intern Med* 2013;28:1620–8.
49. Ali MK, Echouffo-Tcheugui J, Williamson DF. How effective were lifestyle interventions in real-world settings that were modeled on the Diabetes Prevention Program? *Health Aff (Millwood)* 2012;31:67–75.

BMJ Open: first published as 10.1136/bmjopen-2015-007603 on 10 July 2015. Downloaded from http://bmjopen.bmj.com/ on April 20, 2024 by guest. Protected by copyright.

Table S1. Changes of the prevalence of Metabolic syndrome and its components from baseline by group.

Outcome variables	Classification	Total enrollees[a] (n = 1,147,695)		Eligible group[a] (n = 291,825)		Intervention group[a] (n = 23,968)		Control group[a] (n = 855,870)			
		n	(%)	n	(%)	n	(%)	n	(%)	p-value[b]	p-value[c]
MetS prevalence	Baseline	291,825	(25.4)	291,825	(100.0)	23,968	(100.0)	0	(0.0)	<0.001	<0.001
by NHIS criteria[d]	Follow-up	299 445	(26.1)	168,220	(57.6)	15 130	(63.1)	131,225	(15.3)	<0.001	<0.001
	Difference		(0.7)		(-42.4)		(-36.9)		(15.3)		
	p-value[e]		<0.001		<0.001		<0.001		<0.001		
MetS prevalence	Baseline	214,833	(18.7)	214,833	(73.6)	19,969	(83.3)	0	(0.0)	<0.001	<0.001
by modified NCEP	Follow-up	222,989	(19.4)	130,975	(44.9)	12,380	(51.7)	92,014	(10.8)		
criteria[f]	Difference		(0.7)		(-28.7)		(-31.7)		(10.8)		
	p-value[e]		<0.001		<0.001		<0.001		<0.001		

BMI, body mass index; HDL, high density lipoprotein; MetS, metabolic syndrome; NCEP, National Cholesterol Education Program of United States; NHIS, the National Health Insurance Service of Korea;

[a]Total enrollees consisted of the control and eligible group. The intervention group was a subset of the eligible group who participated in the counseling program.

[b]Chi-squared test between the eligible and control group.

[c]Chi-squared test between the intervention and control group.

[d]NHIS criteria applied the NCEP criteria with the Korean waist circumference cut-off and BMI (abdominal obesity as a waist circumference of ≥90 cm in men and ≥85 cm in women)

[e]McNemar test of within-group change of prevalence

[f]NCEP criteria with the Korean waist circumference cut-off (abdominal obesity as a waist circumference of ≥90 cm in men and ≥85 cm in women)

Table S2. Intervention effects estimated by propensity score weighting methods (sensitivity analysis)

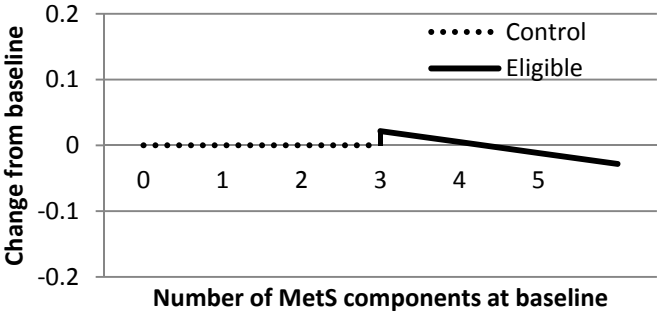
Variables	Stabilized IPTW method			SMRW method		
	Intervention effect[a]	95% CI	p-value	Intervention effect[a]	95% CI	p-value
Participants with MetS[b]						
The number of MetS component by NHIS criteria[c]	-0.02	(-0.04, 0.00)	0.059	-0.02	(-0.04, -0.01)	0.002
The number of MetS component by modified NCEP criteria[d]	-0.02	(-0.04, 0.00)	0.038	-0.02	(-0.04, 0.00)	0.020
Systolic blood pressure (mmHg)	-0.54	(-0.77, -0.31)	<0.001	-0.04	(-0.28, 0.19)	0.711
Diastolic blood pressure (mmHg)	-0.27	(-0.44, -0.10)	0.002	0.03	(-0.14, 0.19)	0.766
Triglyceride (mg/dL)	-5.99	(-8.51, -3.48)	<0.001	-1.71	(-4.3, 0.88)	0.196
Fasting plasma glucose (mg/dL)	-0.42	(-0.77, -0.07)	0.018	0.08	(-0.45, 0.60)	0.774
Waist circumference (cm)	-0.12	(-0.21, -0.03)	0.007	-0.05	(-0.13, 0.02)	0.177
HDL cholesterol (mg/dL)	0.16	(-0.20, 0.51)	0.389	0.05	(-0.22, 0.32)	0.719
Weight (kg)	-0.17	(-0.23, -0.11)	<0.001	-0.10	(-0.15, -0.05)	<0.001
Body mass index (kg/m^2)	-0.06	(-0.08, -0.04)	<0.001	-0.04	(-0.05, -0.02)	<0.001
Participants with 3 components of MetS[e]						
The number of MetS component by NHIS criteria	0.002	(-0.02, 0.03)	0.897	-0.02	(-0.04, 0.00)	0.031
The number of MetS component by modified NCEP criteria	-0.004	(-0.03, 0.02)	0.744	-0.02	(-0.04, 0.00)	0.063
Systolic blood pressure (mmHg)	-0.69	(-1.00, -0.38)	<0.001	-0.46	(-0.77, -0.15)	0.003
Diastolic blood pressure (mmHg)	-0.33	(-0.55, -0.10)	0.004	-0.19	(-0.41, 0.02)	0.079
Triglyceride (mg/dL)	-5.94	(-9.14, -2.74)	<0.001	-4.97	(-7.82, -2.13)	0.001

Fasting plasma glucose (mg/dL)	-0.51	(-0.95, -0.08)	0.021	-0.44	(-1.02, 0.14)	0.134
Waist circumference (cm)	-0.15	(-0.27, -0.04)	0.011	-0.10	(-0.20, 0.00)	0.044
HDL cholesterol (mg/dL)	0.13	(-0.37, 0.62)	0.618	0.27	(-0.10, 0.65)	0.156
Weight (kg)	-0.19	(-0.27, -0.11)	<0.001	-0.13	(-0.19, -0.07)	<0.001
Body mass index (kg/m^2)	-0.07	(-0.09, -0.04)	<0.001	-0.05	(-0.07, -0.03)	<0.001

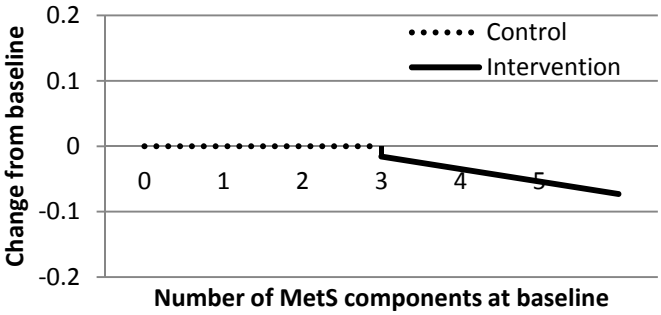
BMI, body mass index; BP, blood pressure; CI, confidence interval; HDL, high density lipoprotein; IPTW, inverse probability of treatment weighting; MetS, metabolic syndrome; NCEP, National Cholesterol Education Program of United States; NHIS, the National Health Insurance Service of Korea; SMRW, standardized mortality ratio weighting

[a]Negative values mean that the outcome variable is more decreased from baseline in the intervention group than in the control group.
[b]Number of weighted intervention group and control group were 22,954 and 268,005 in stabilized IPTW method, respectively, and 23,964 and 24,310 in SMRW method, respectively.
[c]NHIS criteria applied the NCEP criteria with a Korean waist circumference cut-off and BMI (abdominal obesity as a waist circumference of ≥90 cm in men and ≥85 cm in women or BMI ≥25 kg/m^2)
[d]NCEP criteria with Korean waist circumference cut-off (abdominal obesity as a waist circumference of ≥90 cm in men and ≥85 cm in women)
[e]Number of weighted intervention group and control group were 14,787 and 184,019 in stabilized IPTW method, respectively, and 12,793 and 13,150 in SMRW method, respectively.

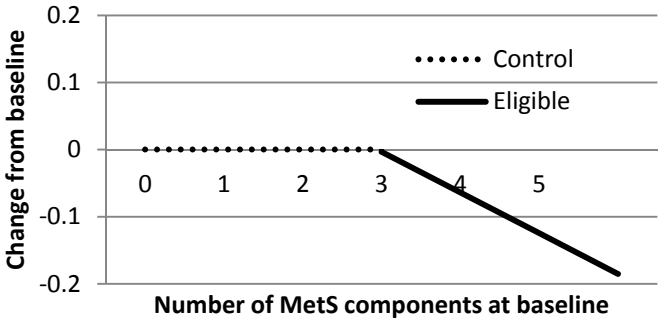
1) Number of Mets components by NHIC criteria*



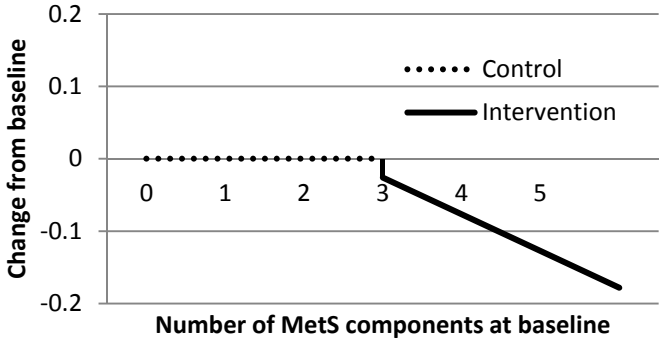
a) Number of Mets components by NHIC criteria†



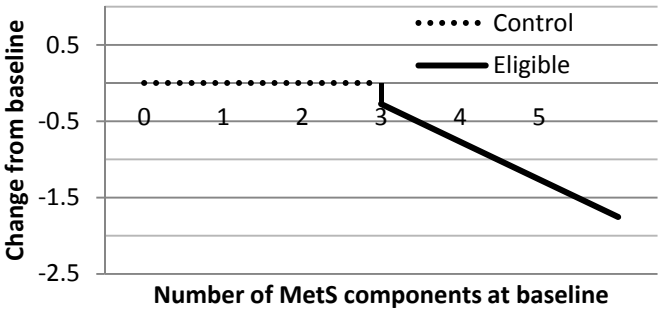
2) Number of Mets components by NCEP criteria*



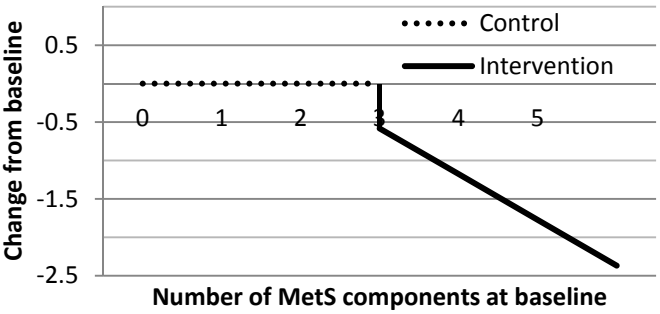
b) Number of Mets components by NCEP criteria*



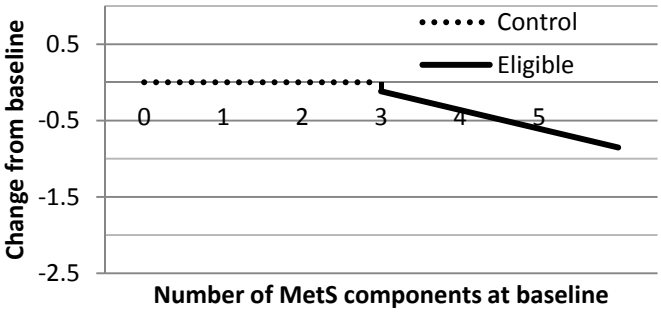
3) Systolic blood pressure (mmHg)*



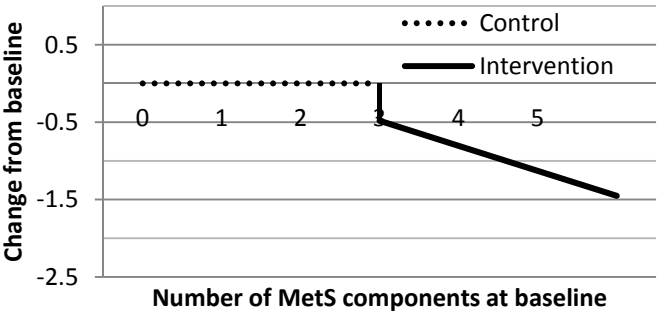
c) Systolic blood pressure (mmHg)*



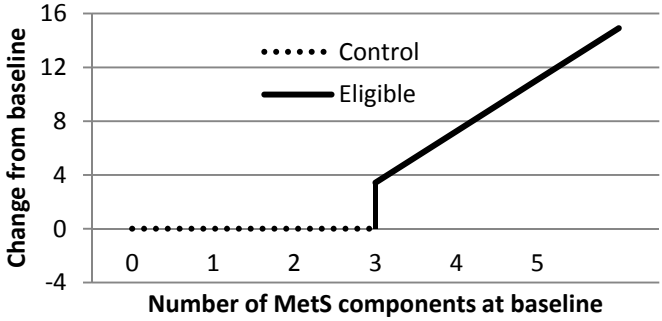
4) Diastolic blood pressure (mmHg)*



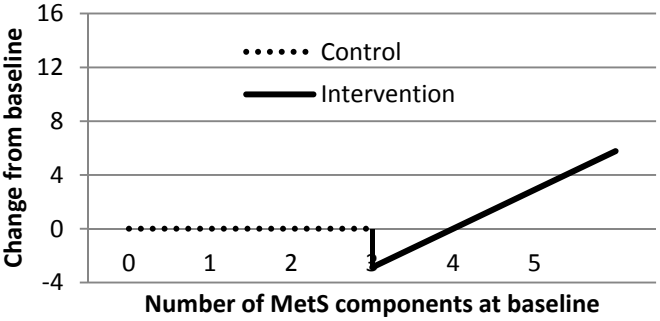
d) Diastolic blood pressure (mmHg)*

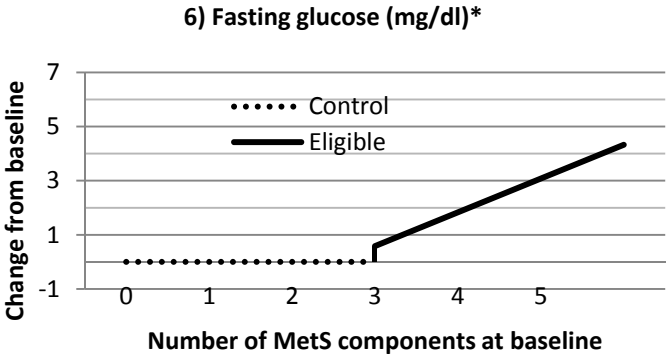


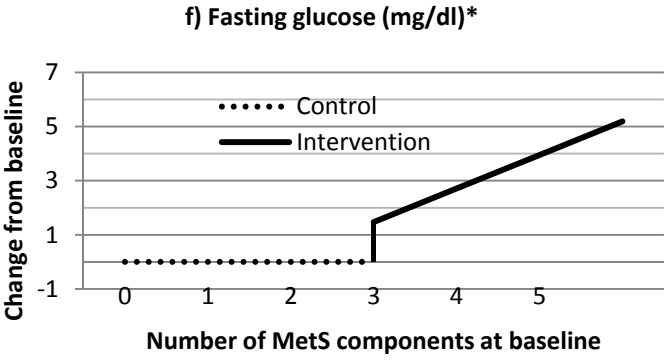
5) Triglyceride (mg/dl)*

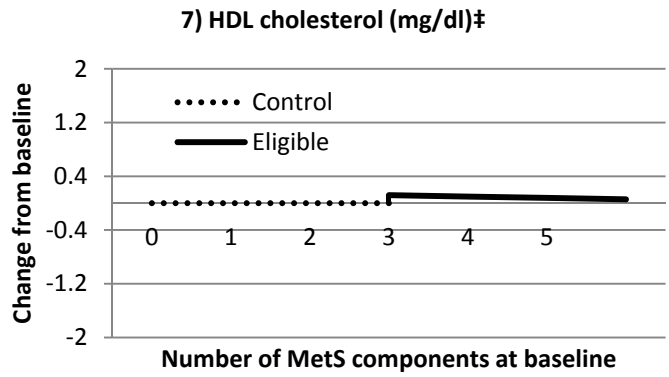


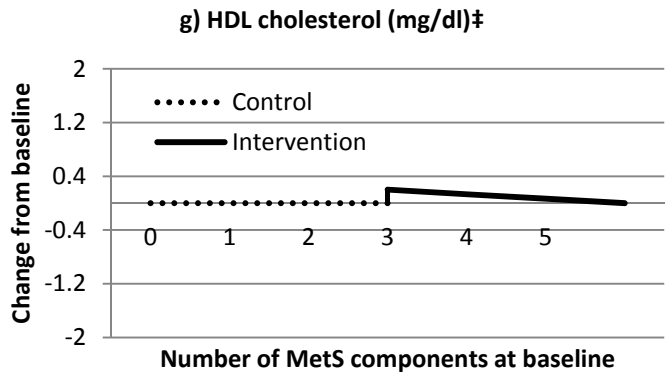
e) Triglyceride (mg/dl)*

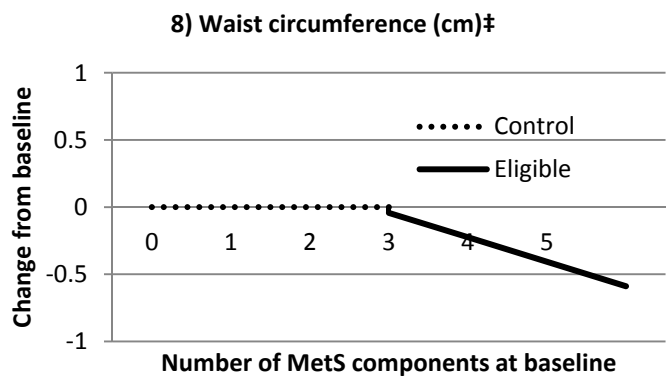


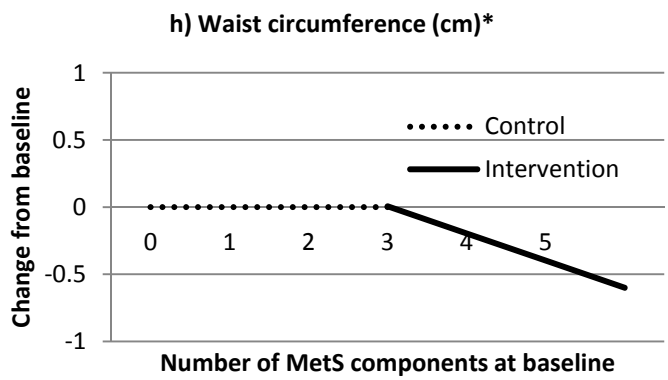

6) Fasting glucose (mg/dl)*
Change from baseline
7
5
3
1
-1
0 1 2 3 4 5
Control
Eligible
Number of MetS components at baseline

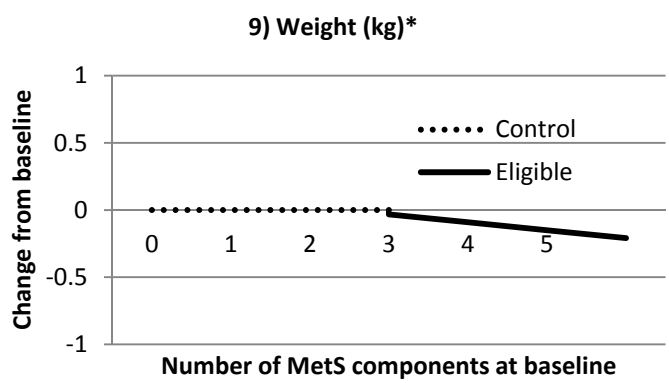

f) Fasting glucose (mg/dl)*
Change from baseline
7
5
3
1
-1
0 1 2 3 4 5
Control
Intervention
Number of MetS components at baseline

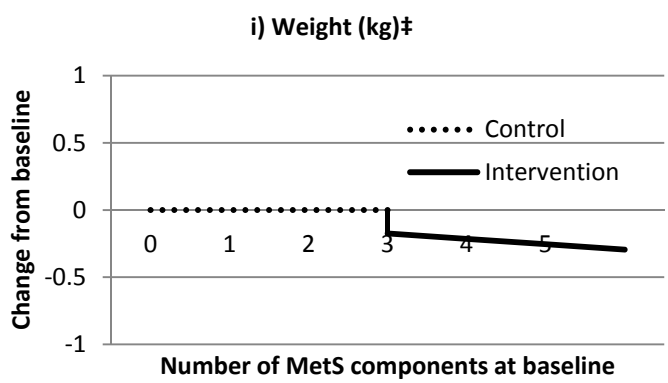

7) HDL cholesterol (mg/dl)‡
Change from baseline
2
1.2
0.4
-0.4
-1.2
-2
0 1 2 3 4 5
Control
Eligible
Number of MetS components at baseline

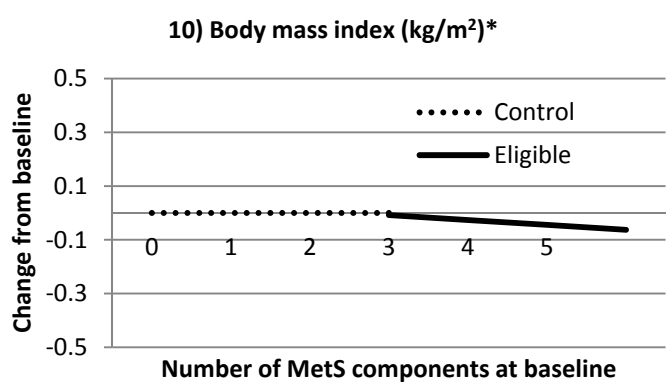

g) HDL cholesterol (mg/dl)‡
Change from baseline
2
1.2
0.4
-0.4
-1.2
-2
0 1 2 3 4 5
Control
Intervention
Number of MetS components at baseline


8) Waist circumference (cm)‡
Change from baseline
1
0.5
0
-0.5
-1
0 1 2 3 4 5
Control
Eligible
Number of MetS components at baseline


h) Waist circumference (cm)*
Change from baseline
1
0.5
0
-0.5
-1
0 1 2 3 4 5
Control
Intervention
Number of MetS components at baseline


9) Weight (kg)*
Change from baseline
1
0.5
0
-0.5
-1
0 1 2 3 4 5
Control
Eligible
Number of MetS components at baseline


i) Weight (kg)‡
Change from baseline
1
0.5
0
-0.5
-1
0 1 2 3 4 5
Control
Intervention
Number of MetS components at baseline


10) Body mass index (kg/m²)*
Change from baseline
0.5
0.3
0.1
-0.1
-0.3
-0.5
0 1 2 3 4 5
Control
Eligible
Number of MetS components at baseline

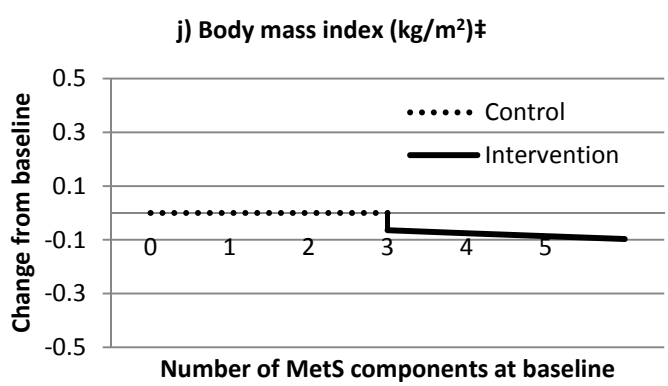

j) Body mass index (kg/m²)‡
Change from baseline
0.5
0.3
0.1
-0.1
-0.3
-0.5
0 1 2 3 4 5
Control
Intervention
Number of MetS components at baseline

Figure S1 Predictive follow-up measurements according to the number of the MetS components when the estimated slope of the number of the MetS components at baseline (assignment variable) was considered to be zero. Additive and linear interaction effects of the intervention were estimated from multiple regression analysis via an ANCOVA model that was adjusted for all baseline measurements (the number of the MetS components by the NHIS criteria, systolic BP, diastolic BP, triglyceride, fasting glucose, HDL cholesterol, waist circumference, weight, and BMI), age at baseline, gender, beneficiary status, health insurance premium, smoking status, drinking status, physical inactivity, and the interval between baseline and follow-up exams. a)–j) were based on an analysis between the intervention and control group, while 1)–10) were based on an analysis between the eligible and control group. **Values at the number of MetS components = 3 are intervention effects. Negative values mean that the outcome variable is more decreased from baseline in the intervention group (or eligible group) than in the control group.** The p-value for the linear interaction effect of the intervention and the assignment variable was indicated as *P<0.001, †P<0.05, ‡P≥0.05.