Effects of the National Health Guidance Intervention for Obesity and Cardiovascular Risks on Healthcare Utilization and Healthcare Spending in Japan: Regression Discontinuity Design

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Effects of the National Health Guidance Intervention for Obesity and Cardiovascular Risks on Healthcare Utilization and Healthcare Spending in Japan: Regression Discontinuity Design

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ABSTRACT

Objectives: Increases in obesity and cardiovascular diseases contribute to rapidly growing healthcare expenditures in many countries. However, little is known about whether the population-level health guidance intervention for obesity and cardiovascular risk factors is associated with reduced healthcare utilization and spending. The aim of this study was to investigate the effect of population-level health guidance intervention introduced nationally in Japan on healthcare utilization and spending.

Design: Retrospective cohort study, using a quasi-experimental regression discontinuity design.

Setting: Japan's nationwide employment-based health insurers.

Participants: Participants in the national health screening program (from January 2014 to December 2014) aged 39 to 74 years.

Predictors: Assignment to health guidance intervention (counseling on healthy lifestyles, and referral to physicians as needed) determined primarily on whether the individual's waist circumference was above or below the cut-off value in addition to having at least one cardiovascular risk factor.

Primary and secondary outcome measures: Healthcare utilization (the number of outpatient visits days, any medication use, and any hospitalization use) and spending (total medical expenditure, outpatient medical expenditure, and inpatient medical expenditure) within three years of the intervention.

Results: A total of 51,213 individuals within the bandwidth (±6 cm of waist circumference from the cut-off) out of 113,302 screening participants (median age 50.0 years, 11.9% female) were analyzed. We found that the assignment to the national health guidance intervention was associated with fewer outpatient visit days

(-1.6 days; 95%CI, -11.9 to -0.7 days; $P = .03$). We found no evidence that the assignment to the health guidance intervention was associated with changes in medication or hospitalization use, or healthcare spending.

Conclusion: The national health guidance intervention was associated with a decline in outpatient visits, with no impact on medication/hospitalization use or healthcare spending.

Strengths and limitations of this study

- First study to investigate the effect of a national health guidance intervention on healthcare spending and utilization of care, using a robust quasi-experimental causal design.
- Nationwide health screening data and medical claims data in Japan.
- Some variations in the national health guidance intervention.
- Secondary outcome of any hospitalization including hospitalizations due to non-cardiovascular diseases.

Introduction

Obesity and obesity-related diseases, such as diabetes and hypertension, are the major causes of disease burdens and increasing health expenditures in many countries. In the United States, annual health expenditures relating to obesity, diabetes, and hypertension are US$ 147 billion,[1] US$ 237 billion,[2] and US$ 131 billion,[3] respectively. In addition, individuals with obesity have a higher risk of coronary heart disease, stroke, and cancer, further contributing to higher disease burdens and health expenditures. At the global level, the prevalence of obesity has been increasing in most countries, regardless of their sociodemographic indices,[4] causing 4 million deaths annually, two-thirds of which are due to cardiovascular diseases. Despite the magnitude of this public health problem and major efforts to address this issue, no policies or interventions that effectively reduce the rate of obesity at the population level have been discovered.

Policymakers in many countries are turning to preventive care as a promising intervention for curbing the rapidly growing disease burdens of obesity and related health expenditures. Among existing interventions, population-level health screening programs for obesity and cardiovascular risk factors have attracted attention and have been implemented in many countries, including China,[5] Denmark,[6] and Japan.[7] The underlying assumption is that the identification of high-risk populations and the provision of interventions to improve their lifestyles or referring them to a physician for medical treatment may reduce future healthcare spending on the treatment of cardiovascular diseases. However, evidence showing the effectiveness of such programs on healthcare utilization and spending is weak and mixed. Existing research is limited to studies conducted in a single district in Denmark[8 9] (therefore, of limited generalizability) or observational studies lacking sufficient consideration of unmeasured confounding[10 11] (e.g., studies that compared individuals who self-selected to receive interventions versus those who did not). Therefore, it remains unclear whether lifestyle interventions targeted at high-risk populations identified through population-level health screening are effective for lowering healthcare spending in the long term.

The purpose of this study is to examine the effects of population-level health guidance intervention on healthcare utilization and spending. In doing so, we compared individuals whose waist circumference values were just above and below the eligibility cut-off level using the quasi-experimental regression discontinuity (RD) design. The RD design allows us to examine the causal impact of the national health guidance intervention, because individuals just above and below the cut-off value were very similar in many characteristics, and the only major difference among them was whether or not they received the intervention.

Method

Data source

Data was obtained from one of Japan's largest employment-based health insurers (a national sample of employees of a civil engineering and construction company) collected between January 2014 and December 2019 , and developed by linking three databases: annual health screening data, enrollment data, and medical claims data. The health screening data included information on demographics (age and gender), weight, body mass index [BMI], waist circumference, systolic and diastolic blood pressure, hemoglobin A1c [HbA1c], triglyceride, high-density lipoprotein [HDL] cholesterol, medication use, and smoking status. Baseline variables were measured using the results of the first screening in 2014. Visit days for outpatient care, medical expenditure (including medications), and any hospitalization were measured by medical claims data in subsequent years (2015-2019). Medication use was measured by a self-reported questionnaire at a health screening in subsequent years (2015-2019).

National health guidance intervention

If a participant had one or more cardiovascular risk factors (hypertension, hyperglycemia, and dyslipidemia), and a waist circumference larger than the cut-off value (85 cm for males and 90 cm for females) or a BMI higher than or equal to 25, he/she was assigned to the health guidance intervention. Those who were assigned to the health guidance intervention were notified by the health insurer and received health guidance from trained instructors (many of whom were qualified dietitians or public health nurses). Participants with medication use (antihypertensives, antidiabetics, or antihyperlipidemic drugs) were not assigned to health guidance. All subjects who underwent the health screening received a summary report of their screening results in the mail, regardless of whether they were assigned to the health guidance.

The national health guidance intervention in Japan consists of an initial interview (at least 20 minutes of individual support or 80 minutes of group support), followed by continuous support for 3-6 months. The instructor provides explanations about lifestyle improvements (mainly exercise and diet) and recommends medical treatment if it is needed. The health guidance intervention assignment process is shown in eFigure 1. Detailed information about the national health guidance intervention is described in the previous study.[12]

Participants

A total of 113,418 individuals, between 39 and 74 years old, received baseline health screening during the period from January 2014 to December 2014. After excluding those whose waist circumference measurements were missing from the data (n=116), we analyzed 113,302 participants.

Healthcare utilization and healthcare spending

Healthcare utilization and spending were defined as visit for outpatient care (days), medication use (hypertension, diabetes, and dyslipidemia), hospitalization, total medical expenditure (dollars), medical expenditure for outpatient care (dollars), and medical expenditure for inpatient care (dollars), using medical claims data and follow-up screening results from January 2015 to December 2019. To convert the Japanese yen to US dollars, we used the rate on January 8, 2021 (1 US dollar = 103.92 Japanese yen). Our main outcomes were the sum of those outcomes for three years (from January 2015 to December 2017). We also examined those outcomes from year 1 (2015) to year 5 (2019). Note that lifestyle consultations provided by health insurers are not medical treatments and thus not covered by public health insurance. Therefore, they are not included in our utilization and spending measures.

Statistical analysis

To estimate the effect of health guidance intervention on healthcare utilization and spending, we used a regression discontinuity (RD) design, which utilizes a clinical or policy decision rule that participants are differentially assigned to the intervention or control group according to an arbitrarily defined cut-off value for a continuous variable. In our RD analysis, waist circumference was used as the assignment variable. In the national health guidance intervention, participants with a waist circumference above the cut-off value (85 cm in males and 90 cm in females) were more likely to receive the health guidance intervention than those below it. The RD analysis compares individuals whose values of the assignment variable (waist circumference) are just above and below the cut-off level. The RD analysis allows us to estimate causal effects because individuals just above or below the cut-off value were very similar in most characteristics, except whether or not they received the intervention. We selected 6 cm as the bandwidths from the cut-off value of waist circumference, according to the previous study.[13] We used a fuzzy RD analysis, which allows for situations in which the assignment variable does not completely determine the intervention but is determined probabilistically.

Our RD analysis estimated causal effects of the intervention on healthcare utilization and spending for three years (from 2015 to 2017), using a local polynomial (cubic function) regression-discontinuity estimation with robust bias-corrected confidence intervals to avoid overfitting of the data and misinterpretation of the effect. To further control for potential confounders, we included age, gender, current smoking status (yes/no), and baseline medication use as covariates in the model. We used a triangular kernel function that gives more weight to subjects near the threshold. We estimated both the effect of assignment to the intervention (i.e., intention-to-treat [ITT] effects) and the effect of receipt of the intervention (i.e., the treatment [ToT] effect on the treated).

Secondary analysis

We conducted several secondary analyses. First, we described a histogram of waist circumference and tested whether waist circumference changed smoothly at the cut-off value by McCrary's density test.[19] Second, we described a bar graph of the proportion of participants assigned to the health guidance intervention based on the values of their waist circumferences to show how the probability of the assignment changed discontinuously around the cut-off value of the waist circumferences. Third, to test the smooth continuity of observed covariates at the cut-off of waist circumference, we described the RD plots using covariates as the outcome variable and waist circumference as the running variable. Fourth, we examined the effect of health guidance intervention on healthcare utilization and hospitalization spending in each year from 2015 (year 1) to 2019 (year 5). Fifth, we conducted subgroup analysis according to gender.

Patient involvement

No patients were involved in setting the research question or the outcome measures, nor were they involved in developing plans for the design or implementation of the study. No patients were asked to advise on interpretation or writing up of results. There are no plans to disseminate the results of the research to study participants or the relevant patient community. Patient consent was not required for the study.

Results

Participant characteristics

We analyzed 51,213 individuals within the bandwidth of waist circumference (±6 cm from the cut-off) out of 113,302 health screening participants. The median age was 50 years, and 11.9% were female. Table 1 shows participant characteristics within the bandwidth.

Effect of the health guidance intervention on healthcare utilization and hospitalization

Figure 1 shows RD plots of healthcare utilization and spending. According to those RD plots, we did not find significant discontinuity of outcomes at the cut-off of waist circumference. Table 2 shows that assignment to the health guidance intervention(ITT effect) was associated with fewer visit days for outpatient care (-1.6 days, 95% CI: -11.9 to -0.7, *P*-value = 0.03). We found no evidence that assignment to health guidance intervention was associated with medication use, hospitalization, total medical expenditure, medical expenditure for outpatient care, or medical expenditure for inpatient care.

Table 3 shows that the effect of receipt of the health guidance intervention(ToT effect) was greater on visit days for outpatient care (-10.6 days, 95% CI: -78.2 to -4.9, P-value = 0.03), compared to that of assignment to the intervention (ITT effect). We found no evidence that the receipt of health guidance intervention was associated with medication use, hospitalization, or total medical expenditure.

Secondary analyses

We found no evidence of discontinuity of waist circumference at the cut-off (eFigure 2). Around the cut-off of waist circumference, the proportion of participants assigned to the health guidance intervention dramatically increased from 19.6% (-1 to 0 cm from the cut-off) to 80.2% (0 to 1 cm from the cut-off). The proportion of those who received the intervention increased from 4.2% (-1 to 0 cm from the cut-off) to 12.7% (0 to 1 cm from the cut-off) (eFigure 3). We found no evidence of discontinuity of observed covariates at the cut-off of waist circumference (eFigure 4). These results support the validity of our RD analysis. Except for visit days for outpatient care in year 2 (-1.0 days, 95% CI: -4.7 to -0.5, P-value = 0.01), we did not find significant associations of the assignment to the national health guidance intervention with healthcare utilization and spending in each year from 2015 (year 1) to 2019 (year 5) (eTable 1). According to the subgroup by gender, the point estimates of the effect of assignment to the intervention were larger in females than those in males, with larger confidence intervals (eTable 2).

Discussion

Using nationwide claims data linked with information from the national screening program, we found that Japan's national health guidance intervention was associated with fewer outpatient visit days. On the other hand, we found no evidence that the health guidance intervention was associated with medication use, hospitalizations, or healthcare spending. These findings indicate that the current structure of Japan's national health guidance intervention has a limited impact on growing health expenditures and highlights the importance of improving the design of the national health guidance intervention based on robust evidence to make it more effective.

There are several potential reasons why we found that the national health guidance intervention was associated with fewer outpatient visit days. First, participants who are under the health guidance intervention have opportunities to interact with an instructor, who may be able to solve minor health issues, thereby replacing physician visits. This hypothesis is supported by the Patient's Behavior Survey by the Japanese Ministry of Health, Labour, and Welfare, which found that 25.8% of patients visited an outpatient clinic despite the lack of any symptoms because of concern, recommendations by family and friends, and referrals after undergoing a health screening program.[14] Second, a previous study[12] found a small reduction in participants' weight due to the lifestyle intervention, which may have clinical benefits among those individuals near the cut-off value of waist circumference, possibly leading to fewer outpatient visit days. Lastly, the participants of the national health guidance intervention may have the chance to reflect on their lifestyles, which in turn may improve their health status and reduce outpatient visits.[10]

We found no evidence that the national health guidance intervention changed healthcare spending, and there are several mechanisms that may explain this finding. First, the implicit assumption behind promoting preventive care is that early interventions for individuals with a high risk of diseases could reduce future healthcare spending due to treatments of those conditions. However, the national health guidance intervention introduced in Japan may not be effective in preventing future incidences of cardiovascular diseases, and thereby leading to its lack of association with healthcare spending. This hypothesis is supported by a previous work showing that the national health guidance intervention had no impact on cardiovascular risk factors, such as blood pressure, hemoglobin A1c level, and low-density lipoprotein (LDL) cholesterol level.[12] Second, the cut-off value of waist circumference used to determine the population who received the health guidance intervention may be relatively low. Our data show that the current waist circumference cut-off values are close to the median waist circumferences for men (Supplement eFigure 2), indicating that a large number of healthy individuals received the intervention. It is possible that focusing the intervention on a population at higher risk may be more effective in lowering healthcare utilization and spending. Lastly, the current intervention may not effectively incentivize payers to improve health outcomes or reduce health expenditures. The current intervention incentivizes payers based on the quantity of support provided, such as initial interviews and telephone follow-ups, while being agnostic about changes in individual health outcomes. Incentivizing the performance achieved (e.g., improvements in cardiovascular risk factors) may be more effective than incentivizing the quantities of inputs used.

Our findings provide valuable evidence regarding the impact of health guidance interventions. A randomized control study conducted in one region in Denmark found that regular preventive health checks did not have any effects on primary and secondary healthcare utilization,[8 9] but rate ratios for daytime outpatient visits initially increased and gradually decreased. Another quasi-experimental study in Austria used regional variations in the exposure to screening recommendations as an instrumental variable and concluded that no association between health screening and health expenditure existed in the long run.[15] However, prior studies were limited in that they evaluated regional programs (as opposed to the evaluation of a national program in our study), and used observational designs that could not account for unmeasured confounders.[11 16] To our knowledge, no study to date has investigated the effect of a national health guidance intervention on healthcare spending and utilization of care using a robust quasi-experimental causal design.

Our study has limitations. First, we did not evaluate how different types of interventions affect health expenditure and utilization. For example, an eligible participant begins the national health guidance intervention with an interview, either as part of a group or as an individual. Participants are designated to receive either active or motivational support, and there is a difference in the frequency of interventions between those types of support. The association between the intervention and outcomes might vary by the type of intervention that participants receive. Second, we defined secondary hospitalization utilization as any hospitalization, which included hospitalizations due to non-cardiovascular diseases such as pneumonia and pyelonephritis. This might have led to an overestimation of the secondary hospitalization utilization. Finally, our findings are based on a relatively intensive health guidance intervention in Japan, whose participants are aged 40-74 years. Our findings may not be generalizable to the population in other contexts.

Conclusions

In summary, we found that the national health guidance intervention in Japan was associated with fewer outpatient visit days, but was not associated with changes in healthcare spending, medication use, or hospitalizations. Ultimately, the effectiveness of these interventions hinges on the actual designs and structures of the interventions, and these findings suggest that the current design of the program is not effective in reducing future healthcare spending. These findings, coupled with the high implementation cost and limited effects on population health outcomes, suggest that the national health guidance intervention needs to be reevaluated to improve its efficiency and effectiveness.

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Contributors: Fukuma, Mukaigawara, and Tsugawa conceived and designed the study, interpreted the data, and drafted the initial manuscript. Fukuma analyzed the data. All authors critically revised the manuscript for important intellectual content and approved the final manuscript. Fukuma is the guarantor. The corresponding author attests that all listed authors meet authorship criteria and that no others meeting the criteria have been omitted.

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Competing interests: All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf and declare: no support from any organization for the submitted work; no financial relationships with any organizations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work.

Ethical approval: The institutional review board (IRB) of Kyoto University approved this study (R0817).

Data sharing: No additional data available.

Transparency: The lead author (S.F.) affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned have been explained.

Table 1. Characteristics of Participants in the National Health Screening Program

Characteristics	Total N=113,302	Within bandwidth N=51,213
Age, y	49.4 (44.4-57.4)	50.0 (44.8-58.4)
Female, No. (%)	30,263 (26.7%)	6,111 (11.9%)
Waist circumference, cm	83.5 (77.3-90)	85.1 (82.5-88)
Above the cutoff, No. (%)	46,701 (41.2%)	24,214 (47.3%)
Body mass index[a]	23.5 (21.3-25.8)	24 (22.8-25.3)
Systolic Blood Pressure (SBP), mmHg	124 (113-134)	125 (115-135)
Diastolic Blood Pressure (DBP), mmHg	77 (69-85)	78 (71-86)
Triglyceride, mg/dL	98 (68-149)	109 (78-159)
HDL cholesterol, mg/dL	60 (50-72)	57 (49-67)
HbA1c, %	5.5 (5.3-5.7)	5.5 (5.3-5.7)
Fasting blood glucose (FBG), mg/dL	94 (87-102)	95 (88-103)
Current smoking, No. (%)	34,186 (30.2%)	17,233 (33.7%)
Anti-hypertensive drug, No. (%)	18,414 (16.3%)	8,860 (17.3%)
Anti-diabetic drug, No. (%)	5,241 (4.6%)	2,325 (4.5%)
Anti-hyperlipidemic drug, No. (%)	10,556 (9.3%)	4,987 (9.7%)
SBP ≥130 mmHg, DBP ≥85 mmHg, or anti-hypertensive drug	50,963 (45.0%)	24,934 (48.7%)
FBG ≥100 mg/dL, HbA1c ≥5.6%, or anti-diabetic drug	52,559 (46.4%)	24,651 (48.1%)
Triglyceride ≥150 mg/dL, HDL cholesterol <40mg/dL, or anti-hyperlipidemic drug	36,613 (32.3%)	18,842 (36.8%)

[a] Calculated as weight in kilograms divided by height in meters squared.

Table 2. Association of Assignment to the national health guidance intervention with Healthcare Utilization and Healthcare Spending (3 years cumulative) using Fuzzy Regression Discontinuity Design[a] (ITT effect)

	Adjusted effects n = 42,050	95% CI	P-value
Healthcare utilization			
Visit days for outpatient care, days[c]	-1.6 days	(-11.9 to -0.7)	0.03
Medication use,[b] percentage points (pp)[c]	-3.9 pp	(-9.3 to +2.0)	0.21
Hospitalization, percentage points (pp)[c]	-0.9 pp	(-9.1 to +3.2)	0.35
Healthcare spending			
Total medical expenditure, dollars[c]	-$1132	(-4447 to +953)	0.21
Medical expenditure for outpatient care, dollars[c]	+$77	(-2000 to +1595)	0.83
Medical expenditure for inpatient care, dollars[c]	-$1210	(-3127 to +38)	0.06

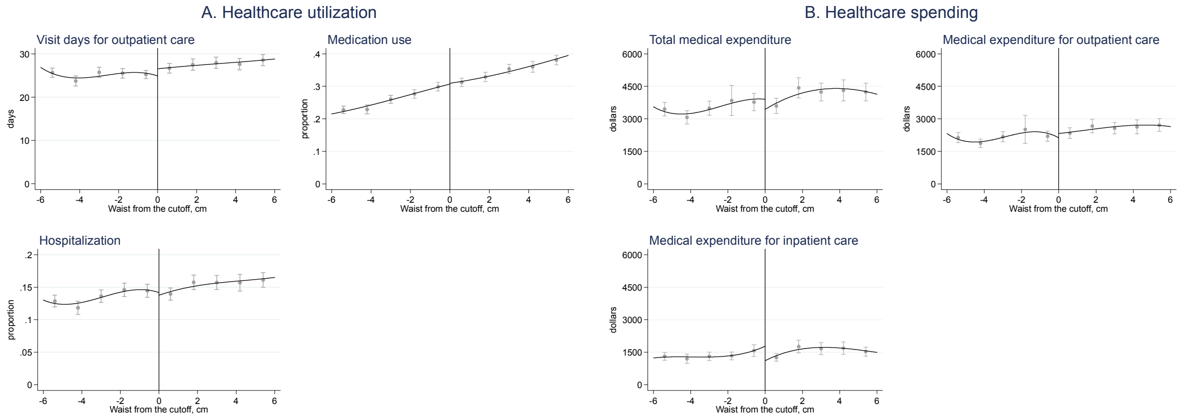
[a] We used the bandwidth of ±6 cm for fuzzy type regression discontinuity design.
[b] Any medication includes drugs for hypertension, hyperglycemia, and hyperlipidemia.
[c] We adjusted for age, gender, current smoking, and baseline medication use.

Table 3. Association of Receipt of the national health guidance intervention with Healthcare Utilization and Healthcare Spending (3 years cumulative) using Fuzzy Regression Discontinuity Design[a] (TOT effect)

	Adjusted effects n = 42,050	95% CI	P-value
Healthcare utilization			
Visit days for outpatient care, days[c]	-10.6 days	(-78.2 to -4.9)	0.03
Medication use,[b] percentage points (pp)[c]	-26.5 pp	(-64.7 to +13.9)	0.21
Hospitalization, percentage points (pp)[c]	-5.8 pp	(-59.5 to +21.1)	0.35
Healthcare spending			
Total medical expenditure, dollars[c]	-$7418	(-29399 to +6137)	0.20
Medical expenditure for outpatient care, dollars[c]	+$510	(-13091 to +10468)	0.83
Medical expenditure for inpatient care, dollars[c]	-$7928	(-20873 to +234)	0.06

[a] We used the bandwidth of ±6 cm for fuzzy type regression discontinuity design.
[b] Any medication includes drugs for hypertension, hyperglycemia, and hyperlipidemia.
[c] We adjusted for age, gender, current smoking, and baseline medication use.

Figure 1. Healthcare Utilization and Spending for 3 Years According to Assignment to Health guidance intervention: Regression Discontinuity Plots



The dots and error bars indicate sample means and 95% CIs, respectively. The vertical solid line indicates the cut-off of waist circumference, which is an assignment variable for health guidance intervention.

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Appendix file

Effects of the National Health Guidance Intervention for Obesity and Cardiovascular Risk on Healthcare Utilization and Healthcare Spending in Japan: Regression Discontinuity Design

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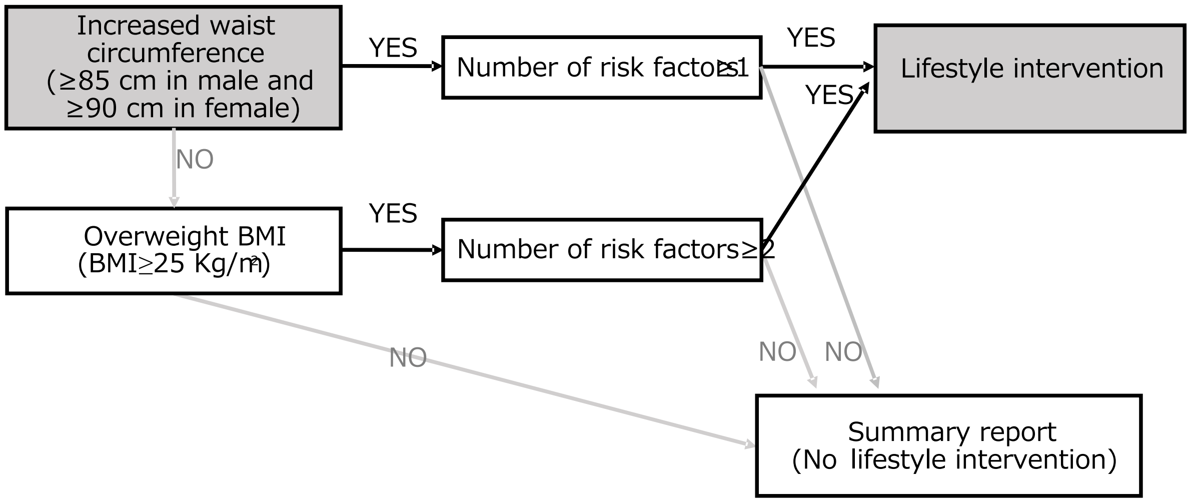
eFigure 1. Process of assignment to the health guidance intervention



Number of risk factors

The number of risk factors is counted from the following three items.

A) Hypertension: systolic blood pressure ≥130 mmHg, diastolic blood pressure ≥85 mmHg, or antihypertensive drugs

B) Hyperglycemia: hemoglobin A1c ≥5.6%, fasting blood glucose ≥100 mg/dL, or anti-diabetic drugs

C) Hyperlipidemia: triglyceride ≥150 mg/dL, high density lipoprotein cholesterol <40 mg/dL, or anti-hyperlipidemic drugs

Summary report

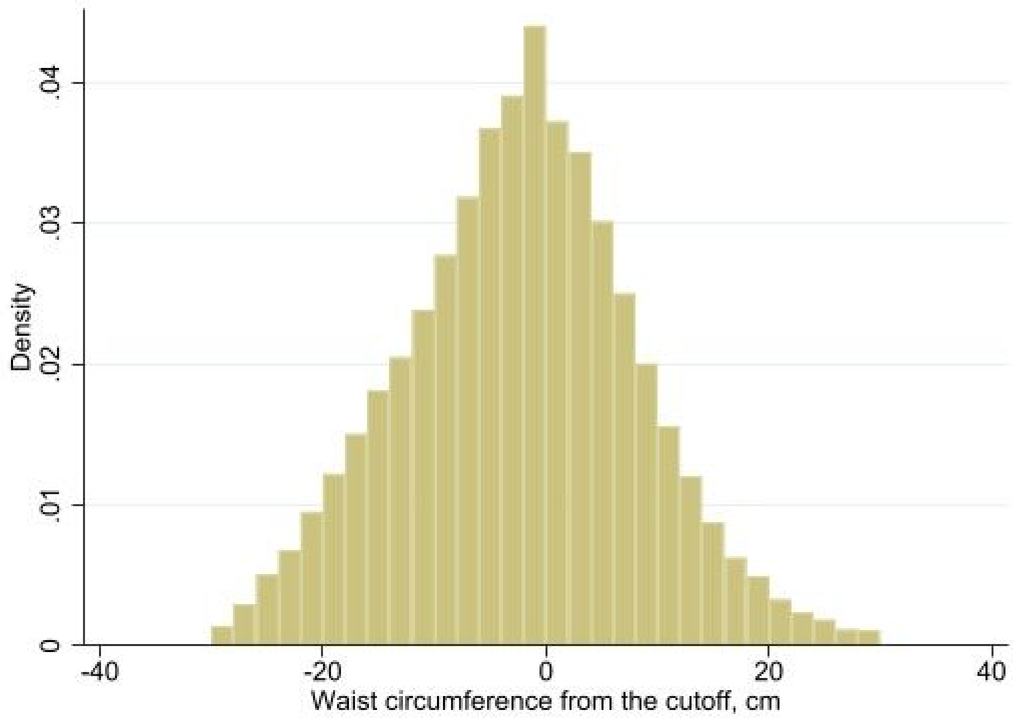
All participants who joined the health screening program receive the results of the health screenings (Summary report). Payers (or "instructors" hired by payers or by outsourced companies to provide the health guidance intervention to participants) are required to provide written feedback on summary reports to help increase participants' awareness of their health conditions and consider reviewing their lifestyle choices.

Health guidance intervention

Support is provided through an initial interview, followed by continuous support for three months or more. Provide support based on participants' current lifestyle and progress on action plans. The health guidance intervention includes the following:

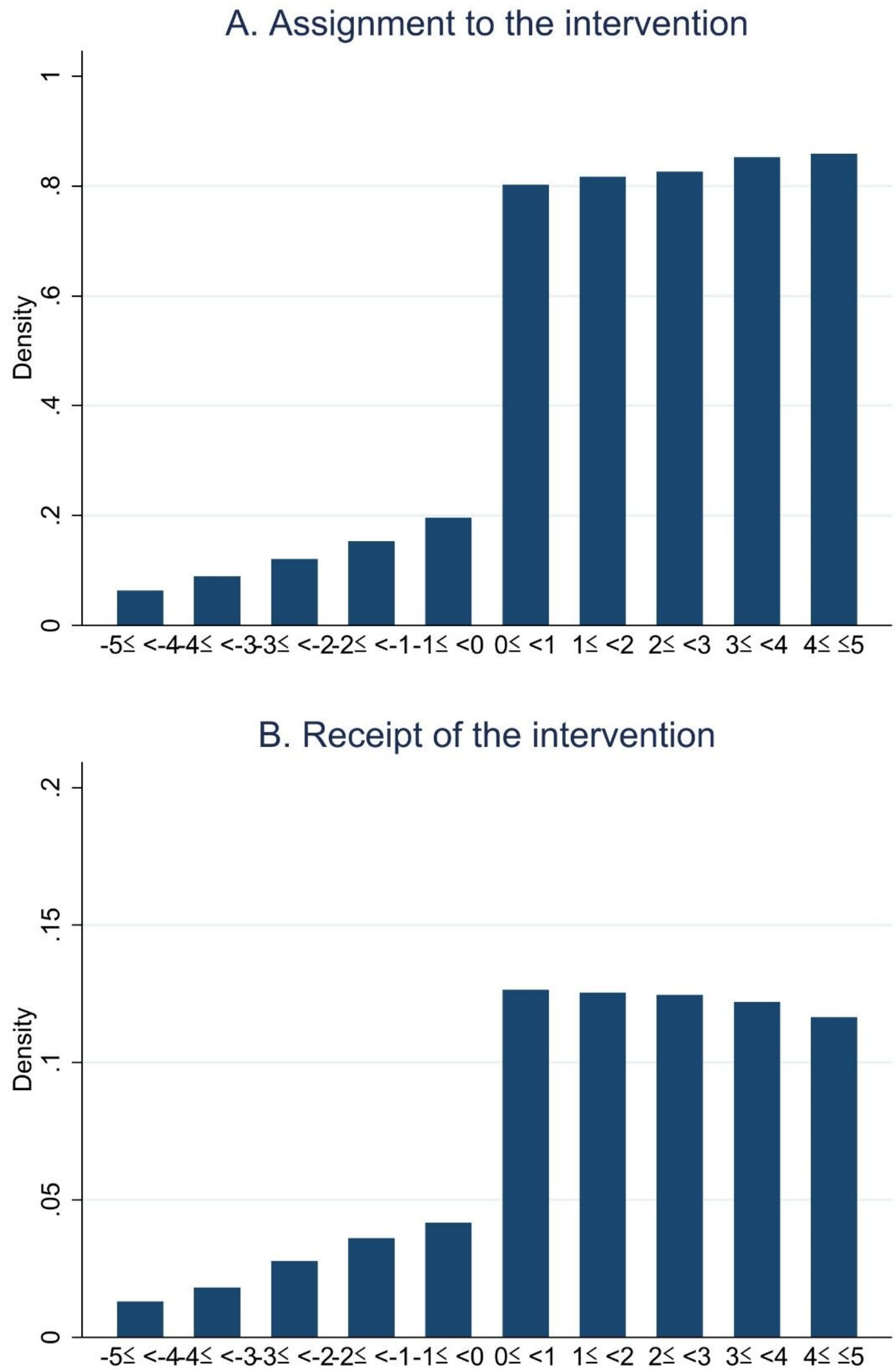
A) Provide practical guidance on lifestyle factors, such as diet and physical activity.
B) Evaluate and revise progress on action plans in a timely manner based on evaluation results.
C) Request that participants submit detailed descriptions of their achievements among the items included in their action plans; provide feedback based on that information.

eFigure 2. Distribution of waist circumference of participants

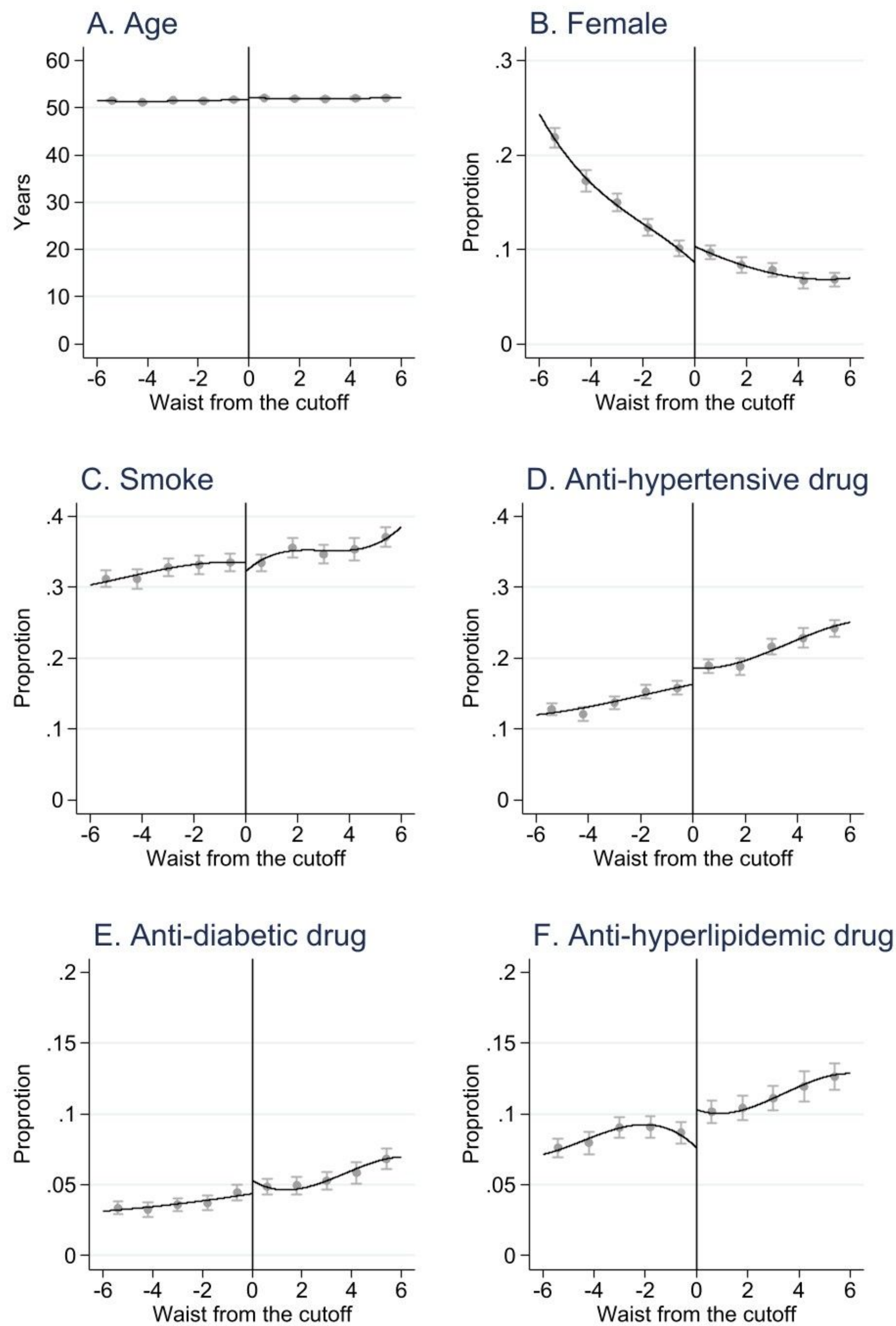


We failed to reject the null hypothesis of a smooth density of waist circumference at the threshold (p=0.20 by McCrary's density test), indicating that there is no evidence that waist circumference was manipulated by participants during the screening program.

eFigure 3. Proportion of participants who were (A) assigned to the health guidance intervention and (B) received the intervention based on their value of waist circumference.



eFigure 4. Continuity of observed covariates at the cutoff of waist circumference



The vertical solid line indicates the cutoff of waist circumference, which is an assignment variable for the health guidance intervention.

eTable 1. Association of Assignment to the Health guidance intervention with Healthcare Utilization and Spending from Year 1 to Year 5 using Fuzzy Regression Discontinuity Design[a]

	Year 1 n = 47,725	Year 2 n = 44,695	Year 3 n = 42,058	Year 4 n = 39,812	Year 5 n = 37,885
Healthcare utilization					
Visit days for outpatient care, days[c]	-0.04 days (-2.9 to +0.8) P = 0.25	-1.0 days (-4.7 to -0.5) P = 0.01	+0.2 days (-3.9 to +0. 9) P = 0.21	+0.2 days (-2.8 to +1.6) P = 0.61	+0.8 days (-3.09 to +1.33) P = 0.43
Medication use,[b] percentage points (pp)[c]	-2.6 pp (-9.7 to -0.01) P = 0.049	-2.2 pp (-7.8 to +2.9) P = 0.38	-3.5 pp (-9.1 to +3.2) P = 0.34	-0.9 pp (-8.1 to +5.5) P = 0.70	-0.4 pp (-7.6 to +6.3) P = 0.86
Hospitalization, percentage points (pp)[c]	-1.0 pp (-5.1 to +2.9) P = 0.60	-0.8 pp (-5.5 to +2.6) P = 0.48	+0.03 pp (-5.1 to +3.1) P = 0.64	-0.3 pp (-5.0 to +4.2) P = 0.87	+0.3 pp (-3.3 to +5.8) P = 0.60
Healthcare spending					
Total medical expenditure, dollars[c]	-$178 (-1195 to +526) P = 0.45	-$539 (-2073 to +413) P = 0.19	-$212 (-1604 to +906) P = 0.59	-$49 (-1803 to +768) P = 0.43	+$532 (-361 to +1642) P = 0.21
Medical expenditure for outpatient care, dollars[c]	$221 (-319 to +636) P = 0.52	$93 (-645 to +600) P = 0.94	-$145 (-1068 to +575) P = 0.56	+$96 (-890 to +813) P = 0.93	+$205 (-489 to +900) P = 0.56
Medical expenditure for inpatient care, dollars[c]	-$399 (-1171 to +186) P = 0.16	-$632 (-1764 to +154) P = 0.10	-$67 (-774 to +570) P = 0.77	-$145 (-1233 to +276) P = 0.21	+$328 (-198 to +1068) P = 0.18

[a] We used the bandwidth of ±6 cm for fuzzy type regression discontinuity design.
[b] Any medication includes drugs for hypertension, hyperglycemia, and hyperlipidemia.
[c] We adjusted for age, gender, current smoking, and baseline medication use.

eTable 2. Association of Assignment to the Health guidance intervention with Healthcare Utilization and Spending for 3 Years using Fuzzy Regression Discontinuity Design[a] by Gender

A. Female

	Adjusted effects n = 4,499	95% CI	P-value
Healthcare utilization			
Visit days for outpatient care, days[c]	-23.4 days	(-102.3 to +3.4)	0.07
Medication use,[b] percentage points (pp)[c]	-3.3 pp	(-47.2 to +46.1)	0.98
Hospitalization, percentage points (pp)[c]	-17.0 pp	(-75.5 to +25.6)	0.33
Healthcare spending			
Total medical expenditure, dollars[c]	-$5145	(-17309 to +5238)	0.29
Medical expenditure for outpatient care, dollars[c]	-$788	(-5622 to +4409)	0.81
Medical expenditure for inpatient care, dollars[c]	-$4357	(-14472 to +3614)	0.24

B. Male

	Adjusted effects n = 37,551	95% CI	P-value
Healthcare utilization			
Visit days for outpatient care, days[c]	-0.6 days	(-9.8 to +1.0)	0.11
Medication use,[b] percentage points (pp)[c]	-3.9 pp	(-9.2 to +1.9)	0.20
Hospitalization, percentage points (pp)[c]	-0.2 pp	(-8.2 to +3.9)	0.48
Healthcare spending			
Total medical expenditure, dollars[c]	-$954	(-4385 to +1182)	0.26
Medical expenditure for outpatient care, dollars[c]	+$114	(-2074 to +1658)	0.83
Medical expenditure for inpatient care, dollars[c]	-$1068	(-3007 to +219)	0.09

[a] We used the bandwidth of ±6 cm for fuzzy type regression discontinuity design.
[b] Any medication includes drugs for hypertension, hyperglycemia, and hyperlipidemia.
[c] We adjusted for age, gender, current smoking, and baseline medication use.

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Impact of the National Health Guidance Intervention for Obesity and Cardiovascular Risks on Healthcare Utilization and Healthcare Spending in Working-age Japanese Cohort: Regression Discontinuity Design

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Impact of the National Health Guidance Intervention for Obesity and Cardiovascular Risks on Healthcare Utilization and Healthcare Spending in Working-age Japanese Cohort: Regression Discontinuity Design

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ABSTRACT

Objectives: Increases in obesity and cardiovascular diseases contribute to rapidly growing healthcare expenditures in many countries. However, little is known about whether the population-level health guidance intervention for obesity and cardiovascular risk factors is associated with reduced healthcare utilization and spending. The aim of this study was to investigate the effect of population-level health guidance intervention introduced nationally in Japan on healthcare utilization and spending.

Design: Retrospective cohort study, using a quasi-experimental regression discontinuity design.

Setting: Japan's nationwide employment-based health insurers.

Participants: Participants in the national health screening program (from January 2014 to December 2014) aged 40 to 74 years.

Predictors: Assignment to health guidance intervention (counseling on healthy lifestyles, and referral to physicians as needed) determined primarily on whether the individual's waist circumference was above or below the cut-off value in addition to having at least one cardiovascular risk factor.

Primary and secondary outcome measures: Healthcare utilization (the number of outpatient visits days, any medication use, and any hospitalization use) and spending (total medical expenditure, outpatient medical expenditure, and inpatient medical expenditure) within three years of the intervention.

Results: A total of 51,213 individuals within the bandwidth (±6 cm of waist circumference from the cut-off) out of 113,302 screening participants (median age 50.0 years, 11.9% female) were analyzed. We found that the assignment to the national health guidance intervention was associated with fewer outpatient visit days (-1.6 days; 95%CI, -11.9 to -0.7 days; $P = .03$). We found no evidence that the assignment to the health guidance intervention was associated with changes in medication or hospitalization use, or healthcare spending.

Conclusion: Among working-age, male-focused Japanese from a health insurer of companies of civil engineering and construction, the national health guidance intervention might be associated with a decline in outpatient visits, with no change in medication/hospitalization use or healthcare spending.

Strengths and limitations of this study

- First study to investigate the effect of a national health guidance intervention on healthcare spending and utilization of care, using a robust quasi-experimental causal design.
- Nationwide health screening data and medical claims data in Japan.
- Some variations in the national health guidance intervention.
- Secondary outcome of any hospitalization including hospitalizations due to non-cardiovascular diseases.

Introduction

Obesity and obesity-related diseases, such as diabetes and hypertension, are the major causes of disease burdens and increasing health expenditures in many countries. In the United States, annual health expenditures relating to obesity, diabetes, and hypertension are US$ 147 billion,[1] US$ 237 billion,[2] and US$ 131 billion,[3] respectively. In addition, individuals with obesity have a higher risk of coronary heart disease, stroke, and cancer, further contributing to higher disease burdens and health expenditures. At the global level, the prevalence of obesity has been increasing in most countries, regardless of their sociodemographic indices,[4] causing 4 million deaths annually, two-thirds of which are due to cardiovascular diseases. Despite the magnitude of this public health problem and major efforts to address this issue, no policies or interventions that effectively reduce the rate of obesity at the population level have been discovered.

Policymakers in many countries are turning to preventive care as a promising intervention for curbing the rapidly growing disease burdens of obesity and related health expenditures. Among existing interventions, population-level health screening programs for obesity and cardiovascular risk factors have attracted attention and have been implemented in many countries, including China,[5] Denmark,[6] and Japan.[7] The underlying assumption is that the identification of high-risk populations and the provision of interventions to improve their lifestyles or referring them to a physician for medical treatment may reduce future healthcare spending on the treatment of cardiovascular diseases. However, evidence showing the effectiveness of such programs on healthcare utilization and spending is weak and mixed. Existing research is limited to studies conducted in a single district in Denmark[8 9] (therefore, of limited generalizability) or observational studies lacking sufficient consideration of unmeasured confounding[10 11] (e.g., studies that compared individuals who self-selected to receive interventions versus those who did not). Therefore, it remains unclear whether lifestyle interventions targeted at high-risk populations identified through population-level health screening are effective for lowering healthcare spending in the long term.

The purpose of this study is to examine the effects of population-level health guidance intervention on healthcare utilization and spending. In doing so, we compared individuals whose waist circumference values were just above and below the eligibility cut-off level using the quasi-experimental regression discontinuity (RD) design. The RD design allows us to examine the causal impact of the national health guidance intervention, because individuals just above and below the cut-off value were very similar in many characteristics, and the only major difference among them was whether or not they received the intervention.

Method

Data source

Data was obtained from one of Japan's largest employment-based health insurers (a national sample of employees of a civil engineering and construction company) collected between January 2014 and December 2019, and developed by linking three databases: annual health screening data, enrollment data, and medical claims data. The health screening data included information on demographics (age [continuous] and gender [binary]), weight (continuous), body mass index [BMI] (continuous), waist circumference (continuous), systolic and diastolic blood pressure (continuous), hemoglobin A1c [HbA1c] (continuous), triglyceride (continuous), high-density lipoprotein [HDL] cholesterol (continuous), medication use (binary), and smoking status (binary). Baseline variables were measured using the results of the first screening in 2014. Visit days for outpatient care, medical expenditure (including medications), and any hospitalization were measured by medical claims data in subsequent years (2015-2019). Medication use was measured by a self-reported questionnaire at a health screening in subsequent years (2015-2019).

National health guidance intervention

If a participant had one or more cardiovascular risk factors (hypertension, hyperglycemia, and dyslipidemia), and a waist circumference larger than the cut-off value (85 cm for males and 90 cm for females) or a BMI higher than or equal to 25, he/she was assigned to the health guidance intervention. Those who were assigned to the health guidance intervention were notified by the health insurer and received health guidance from trained instructors (many of whom were qualified dietitians or public health nurses). Participants with medication use (antihypertensives, antidiabetics, or antihyperlipidemic drugs) were not assigned to health guidance. All subjects who underwent the health screening received a summary report of their screening results in the mail, regardless of whether they were assigned to the health guidance.

The national health guidance intervention in Japan consists of an initial interview (at least 20 minutes of individual support or 80 minutes of group support), followed by continuous support for 3-6 months. The instructor provides explanations about lifestyle improvements (mainly exercise and diet) and recommends medical treatment if it is needed. The health guidance intervention assignment process is shown in eFigure 1. Detailed information about the national health guidance intervention is described in the previous study.[12]

Participants

A total of 113,418 individuals, between 40 and 74 years old, received baseline health screening during the period from January 2014 to December 2014. After excluding those whose waist circumference measurements were missing from the data (n=116), we analyzed 113,302 participants.

Healthcare utilization and healthcare spending

Healthcare utilization and spending were defined as visit for outpatient care (days), medication use (hypertension, diabetes, and dyslipidemia), hospitalization, total medical expenditure (dollars), medical expenditure for outpatient care (dollars), and medical expenditure for inpatient care (dollars), using medical claims data and follow-up screening results from January 2015 to December 2019. To convert the Japanese yen to US dollars, we used the rate on January 8, 2021 (1 US dollar = 103.92 Japanese yen). Our main outcomes were the sum of those outcomes for three years (from January 2015 to December 2017). We also examined those outcomes from year 1 (2015) to year 5 (2019). Note that lifestyle consultations provided by health insurers are not medical treatments and thus not covered by public health insurance. Therefore, they are not included in our utilization and spending measures.

Statistical analysis

To estimate the effect of health guidance intervention on healthcare utilization and spending, we used a regression discontinuity (RD) design, which utilizes a clinical or policy decision rule that participants are differentially assigned to the intervention or control group according to an arbitrarily defined cut-off value for a continuous variable.[13] In our RD analysis, waist circumference was used as the assignment variable. In the national health guidance intervention, participants with a waist circumference above the cut-off value (85 cm in males and 90 cm in females) were more likely to receive the health guidance intervention than those below it. The RD analysis compares individuals whose values of the assignment variable (waist circumference) are just above and below the cut-off level. The RD analysis allows us to estimate causal effects because individuals just above or below the cut-off value were very similar in most characteristics, except whether or not they received the intervention. In our main analyses, we used the data-driven approach to determine the optimal bandwidths for each outcome variable in the RD analyses.[14] We used a fuzzy RD analysis, which allows for situations in which the assignment variable does not completely determine the intervention but is determined probabilistically.

Our RD analysis estimated causal effects of the intervention on healthcare utilization and spending for three years (from 2015 to 2017), using a local polynomial (cubic function) regression-discontinuity estimation with robust bias-corrected confidence intervals to avoid overfitting of the data and misinterpretation of the effect. To further control for potential confounders, we included age, gender, current smoking status (yes/no), and baseline medication use as covariates in the model. We used a triangular kernel function that gives more weight to subjects near the threshold. Because only 0.05% (25 individuals) have missing data with covariates of smoking status and baseline medication use, we conducted complete case analysis. We estimated both the effect of assignment to the intervention (i.e., intention-to-treat [ITT] effects) and the effect of receipt of the intervention (i.e., the treatment [ToT] effect on the treated). For all analysis, we used Stata version 17.0 (StataCorp, College Station, TX, USA). To conduct RD analysis, we used the rdrobust command in Stata.

Secondary analysis

We conducted several secondary analyses. First, we described a histogram of waist circumference and tested whether waist circumference changed smoothly at the cut-off value by McCrary's density test.[15] Second, we described the proportion of participants assigned to the health guidance intervention based on the values of their waist circumferences to show how the probability of the assignment changed discontinuously around the cut-off value of the waist circumferences. Third, to test the smooth continuity of observed covariates at the cut-off of waist circumference, we described the RD plots using covariates as the outcome variable and waist circumference as the running variable. Fourth, we examined the effect of health guidance intervention on healthcare utilization and hospitalization spending in each year from 2015 (year 1) to 2019 (year 5). Fifth, we conducted subgroup analysis according to gender. Finally, to examine whether the estimated effects were sensitive to the selection of bandwidths, we conducted RD analyses using different bandwidths.

Patient and public involvement

This research was performed without patient involvement.

Results

Participant characteristics

We analyzed 51,213 individuals within the bandwidth of waist circumference (±6 cm from the cut-off) out of 113,302 health screening participants. The median age was 50 years, and 11.9% were female. Table 1 shows participant characteristics within the bandwidth.

Effect of the health guidance intervention on healthcare utilization and hospitalization

Figure 1 shows RD plots of healthcare utilization and spending. According to those RD plots, we did not find significant discontinuity of outcomes at the cut-off of waist circumference. Table 2 shows that assignment to the health guidance intervention(ITT effect) was associated with fewer visit days for outpatient care (-1.6 days, 95% CI: -11.9 to -0.7, *P*-value = 0.03). We found no evidence that assignment to health guidance intervention was associated with medication use, hospitalization, total medical expenditure, medical expenditure for outpatient care, or medical expenditure for inpatient care.

Table 3 shows that the effect of receipt of the health guidance intervention(ToT effect) was greater on visit days for outpatient care (-10.6 days, 95% CI: -78.2 to -4.9, P-value = 0.03), compared to that of assignment to the intervention (ITT effect). We found no evidence that the receipt of health guidance intervention was associated with medication use, hospitalization, or total medical expenditure.

Secondary analysis

We found no evidence of discontinuity of waist circumference at the cut-off (eFigure 2). Around the cut-off of waist circumference, the proportion of participants assigned to the health guidance intervention dramatically increased from 19.6% (-1 to 0 cm from the cut-off) to 80.2% (0 to 1 cm from the cut-off). The proportion of those who received the intervention increased from 4.2% (-1 to 0 cm from the cut-off) to 12.7% (0 to 1 cm from the cut-off) (eFigure 3). We found no evidence of discontinuity of observed covariates at the cut-off of waist circumference (eFigure 4). These results support the validity of our RD analysis. Except for visit days for outpatient care in year 2 (-1.0 days, 95% CI: -4.7 to -0.5, P-value = 0.01), we did not find significant associations of the assignment to the national health guidance intervention with healthcare utilization and spending in each year from 2015 (year 1) to 2019 (year 5) (eTable 1). According to the subgroup by gender, the point estimates of the effect of assignment to the intervention were larger in females than those in males, with larger confidence intervals (eTable 2). The estimated effects were qualitatively unaffected when we used different bandwidths (eTable 3).

Discussion

Using nationwide claims data linked with information from the national screening program, we found that Japan's national health guidance intervention was associated with fewer outpatient visit days. On the other hand, we found no evidence that the health guidance intervention was associated with medication use, hospitalizations, or healthcare spending. These findings indicate that the current structure of Japan's national health guidance intervention has a limited impact on growing health expenditures and highlights the importance of improving the design of the national health guidance intervention based on robust evidence to make it more effective.

There are several potential reasons why we found that the national health guidance intervention was associated with fewer outpatient visit days. First, participants who are under the health guidance intervention have opportunities to interact with an instructor, who may be able to solve minor health issues, thereby replacing physician visits. This hypothesis is supported by the Patient's Behavior Survey by the Japanese Ministry of Health, Labour, and Welfare, which found that 25.8% of patients visited an outpatient clinic despite the lack of any symptoms because of concern, recommendations by family and friends, and referrals after undergoing a health screening program.[16] Second, a previous study[12] found a small reduction in participants' weight due to the lifestyle intervention, which may have clinical benefits among those individuals near the cut-off value of waist circumference, possibly leading to fewer outpatient visit days. Lastly, the participants of the national health guidance intervention may have the chance to reflect on their lifestyles, which in turn may improve their health status and reduce outpatient visits.[10]

We found no evidence that the national health guidance intervention changed healthcare spending, and there are several mechanisms that may explain this finding. First, the implicit assumption behind promoting preventive care is that early interventions for individuals with a high risk of diseases could reduce future healthcare spending due to treatments of those conditions. However, the national health guidance intervention introduced in Japan may not be effective in preventing future incidences of cardiovascular diseases, and thereby leading to its lack of association with healthcare spending. This hypothesis is supported by a previous work showing that the national health guidance intervention had no impact on cardiovascular risk factors, such as blood pressure, hemoglobin A1c level, and low-density lipoprotein (LDL) cholesterol level.[12] Second, the cut-off value of waist circumference used to determine the population who received the health guidance intervention may be relatively low. Our data show that the current waist circumference cut-off values are close to the median waist circumferences for men

(Supplement eFigure 2), indicating that a large number of healthy individuals received the intervention. It is possible that focusing the intervention on a population at higher risk may be more effective in lowering healthcare utilization and spending. Lastly, the current intervention may not effectively incentivize payers to improve health outcomes or reduce health expenditures. The current intervention incentivizes payers based on the quantity of support provided, such as initial interviews and telephone follow-ups, while being agnostic about changes in individual health outcomes. Incentivizing the performance achieved (e.g., improvements in cardiovascular risk factors) may be more effective than incentivizing the quantities of inputs used.

Our findings provide valuable evidence regarding the impact of health guidance interventions. A randomized control study conducted in one region in Denmark found that regular preventive health checks did not have any effects on primary and secondary healthcare utilization,[8 9] but rate ratios for daytime outpatient visits initially increased and gradually decreased. Another quasi-experimental study in Austria used regional variations in the exposure to screening recommendations as an instrumental variable and concluded that no association between health screening and health expenditure existed in the long run.[17] However, prior studies were limited in that they evaluated regional programs (as opposed to the evaluation of a national program in our study), and used observational designs that could not account for unmeasured confounders.[11 18] To our knowledge, no study to date has investigated the effect of a national health guidance intervention on healthcare spending and utilization of care using a robust quasi-experimental causal design.

Our study has limitations. First, we did not evaluate how different types of interventions affect health expenditure and utilization. For example, an eligible participant begins the national health guidance intervention with an interview, either as part of a group or as an individual. Participants are designated to receive either active or motivational support, and there is a difference in the frequency of interventions between those types of support. The association between the intervention and outcomes might vary by the type of intervention that participants receive. Second, we defined secondary hospitalization utilization as any hospitalization, which included hospitalizations due to non-cardiovascular diseases such as pneumonia and pyelonephritis. This might have led to an overestimation of the secondary hospitalization utilization. Third, as is the case with any studies using the RD analysis, the estimates calculated in our analyses are only interpretable as causal effects for those individuals near the cut-off values we used ("local average treatment effect"). Therefore, our findings may not be generalizable to individuals whose waist circumference are far away from our cut-off values. In particular, it is possible that the intervention may be more effective among those who are more obese (partially due to the regression to the mean), but the causal effect of the intervention is challenging to evaluate in this population using the quasi-experimental design. Fourth, we should be careful about the generalizability of the results, because we analyzed male-focused, working-age population from specific industry area (civil engineering and construction) in Japan. Only 11.9% were female in the bandwidth. There may be differences of the estimated effects between gender because of different cutoff value of waist circumference between them. Future studies will need to further examine this in populations that include more females. We analyzed employees and their family members from more than 1700 civil engineering and construction companies. These companies consist of various sizes (small construction companies and large general constructors), and the occupations are expected to be diverse (white-collar workers, blue-collar workers, etc.). Although the healthcare spending per enrollee is very close to the national average for employment-based health insurance when adjusted for age, gender, and employee or family, the associations may differ based on some factors such as socio-economic status, education, and work type. The limitation of our study includes the lack of those variables in our data. Finally, our findings are based on a relatively intensive health guidance intervention in Japan. Our findings may not be generalizable to the population in other contexts.

Conclusions

In summary, we found that the national health guidance intervention in Japan was associated with fewer outpatient visit days, but was not associated with changes in healthcare spending, medication use, or hospitalizations. Ultimately, the effectiveness of these interventions hinges on the actual designs and structures of the interventions, and these findings suggest that the national health guidance intervention needs to be reevaluated to improve its efficiency and effectiveness.

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Contributors: Fukuma, Mukaigawara, Iizuka, and Tsugawa conceived and designed the study, interpreted the data, and drafted the initial manuscript. Fukuma analyzed the data. All authors critically revised the manuscript for important intellectual content and approved the final manuscript. Fukuma is the guarantor. The corresponding author attests that all listed authors meet authorship criteria and that no others meeting the criteria have been omitted.

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Ethical approval: The institutional review board (IRB) of Kyoto University approved this study (R0817).

Data sharing: No additional data available.

Transparency: The lead author (S.F.) affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned have been explained.

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Table 1. Characteristics of Participants in the National Health Screening Program

Characteristics	Total N=113,302	Within bandwidth of 6cm N=51,213
Age, y	49.4 (44.4-57.4)	50.0 (44.8-58.4)
Female, No. (%)	30,263 (26.7%)	6,111 (11.9%)
Waist circumference, cm	83.5 (77.3-90)	85.1 (82.5-88)
Above the cutoff, No. (%)	46,701 (41.2%)	24,214 (47.3%)
Body mass index[a]	23.5 (21.3-25.8)	24 (22.8-25.3)
Systolic Blood Pressure (SBP), mmHg	124 (113-134)	125 (115-135)
Diastolic Blood Pressure (DBP), mmHg	77 (69-85)	78 (71-86)
Triglyceride, mg/dL	98 (68-149)	109 (78-159)
HDL cholesterol, mg/dL	60 (50-72)	57 (49-67)
HbA1c, %	5.5 (5.3-5.7)	5.5 (5.3-5.7)
Fasting blood glucose (FBG), mg/dL	94 (87-102)	95 (88-103)
Current smoking, No. (%)	34,186 (30.2%)	17,233 (33.7%)
Anti-hypertensive drug, No. (%)	18,414 (16.3%)	8,860 (17.3%)
Anti-diabetic drug, No. (%)	5,241 (4.6%)	2,325 (4.5%)
Anti-hyperlipidemic drug, No. (%)	10,556 (9.3%)	4,987 (9.7%)
SBP ≥130 mmHg, DBP ≥85 mmHg, or anti-hypertensive drug	50,963 (45.0%)	24,934 (48.7%)
FBG ≥100 mg/dL, HbA1c ≥5.6%, or anti-diabetic drug	52,559 (46.4%)	24,651 (48.1%)
Triglyceride ≥150 mg/dL, HDL cholesterol <40mg/dL, or anti-hyperlipidemic drug	36,613 (32.3%)	18,842 (36.8%)

[a] Calculated as weight in kilograms divided by height in meters squared.

Table 2. Association of Assignment to the national health guidance intervention with Healthcare Utilization and Healthcare Spending (3 years cumulative) using Fuzzy Regression Discontinuity Design[a] (ITT effect)

	Bandwidth,[d] cm (number)	Average within bandwidth	Adjusted effects n = 42,050	95% CI	P-value
Healthcare utilization					
Visit days for outpatient care, days[c]	6.1 (44,333)	26.4 days	-1.3 days	(-11.4 to -0.5)	0.03
Medication use,[b] percentage points (pp)[c]	6.8 (47,016)	30.0 %	-3.8 pp	(-9.0 to +1.4)	0.15
Hospitalization, percentage points (pp)[c]	6.9 (47,726)	14.4 %	-1.2 pp	(-7.2 to +4.1)	0.59
Healthcare spending					
Total medical expenditure, dollars[c]	5.9 (42,050)	$3816	-$1138	(-4506 to +932)	0.20
Medical expenditure for outpatient care, dollars[c]	5.7 (41,081)	$2366	+$46	(-2063 to +1572)	0.79
Medical expenditure for inpatient care, dollars[c]	6.3 (44,986)	$1450	-$1214	(-2932 to +68)	0.06

[a] We used the data-driven approach to determine the optimal bandwidths for each outcome variables we have investigated.

[b] Any medication includes drugs for hypertension, hyperglycemia, and hyperlipidemia.

[c] We adjusted for age, gender, current smoking, and baseline medication use.

[d] We selected optimal bandwidths for each outcome by data-driven approach.

Table 3. Association of Receipt of the national health guidance intervention with Healthcare Utilization and Healthcare Spending (3 years cumulative) using Fuzzy Regression Discontinuity Design[a] (ToT effect)

	Bandwidth,[d] cm (number)	Adjusted effects n = 42,050	95% CI	P-value
Healthcare utilization				
Visit days for outpatient care, days[c]	8.2 (55,458)	-10.6 days	(-42.7 to +18.7)	0.45
Medication use,[b] percentage points (pp)[c]	8.8 (57,815)	-28.0 pp	(-56.7 to +6.5)	0.12
Hospitalization, percentage points (pp)[c]	9.1 (60,250)	-14.7 pp	(-38.2 to +25.8)	0.70
Healthcare spending				
Total medical expenditure, dollars[c]	7.2 (50,273)	-$7638	(-23672 to +7351)	0.30
Medical expenditure for outpatient care, dollars[c]	7.3 (50,940)	-$4	(-9549 to +11022)	0.89
Medical expenditure for inpatient care, dollars[c]	6.7 (46,974)	-$7818	(-18900 to +368)	0.06

[a] We used the data-driven approach to determine the optimal bandwidths for each outcome variables we have investigated.

[b] Any medication includes drugs for hypertension, hyperglycemia, and hyperlipidemia.

[c] We adjusted for age, gender, current smoking, and baseline medication use.

[d] We selected optimal bandwidths for each outcome by data-driven approach.

Figure 1. Healthcare Utilization and Spending for 3 Years According to Assignment to Health guidance intervention: Regression Discontinuity Plots

The dots and error bars indicate sample means and 95% CIs, respectively. The vertical solid line indicates the cut-off of waist circumference, which is an assignment variable for health guidance intervention.

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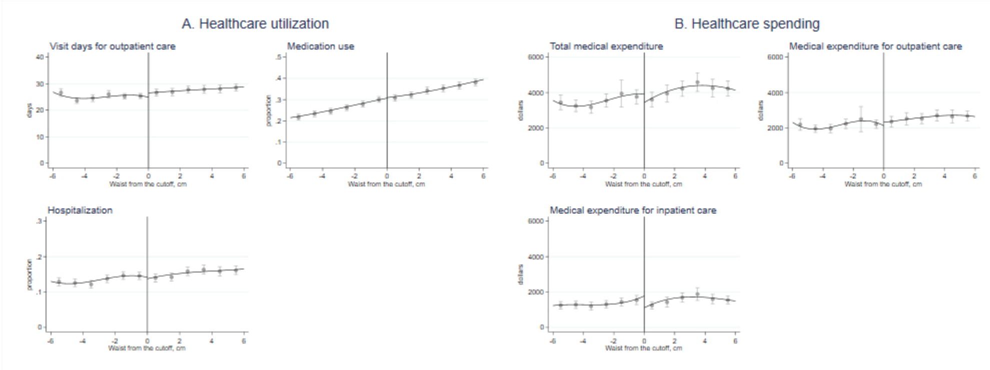

Figure 1

352x132mm (72 x 72 DPI)

Appendix file

Effects of the National Health Guidance Intervention for Obesity and Cardiovascular Risk on Healthcare Utilization and Healthcare Spending in Japan: Regression Discontinuity Design

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Toshiaki Iizuka, PhD [3]

Yusuke Tsugawa, MD, PhD [4,5]

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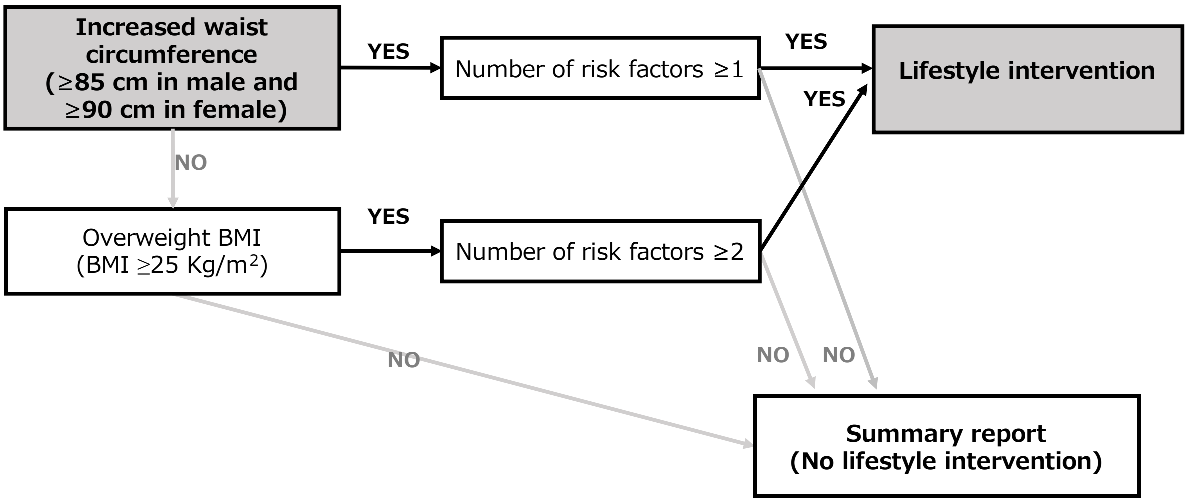
eFigure 1. Process of assignment to the health guidance intervention



Number of risk factors

The number of risk factors is counted from the following three items.

A) Hypertension: systolic blood pressure ≥130 mmHg, diastolic blood pressure ≥85 mmHg, or antihypertensive drugs

B) Hyperglycemia: hemoglobin A1c ≥5.6%, fasting blood glucose ≥100 mg/dL, or anti-diabetic drugs

C) Hyperlipidemia: triglyceride ≥150 mg/dL, high density lipoprotein cholesterol <40 mg/dL, or anti-hyperlipidemic drugs

Summary report

All participants who joined the health screening program receive the results of the health screenings (Summary report). Payers (or "instructors" hired by payers or by outsourced companies to provide the health guidance intervention to participants) are required to provide written feedback on summary reports to help increase participants' awareness of their health conditions and consider reviewing their lifestyle choices.

Health guidance intervention

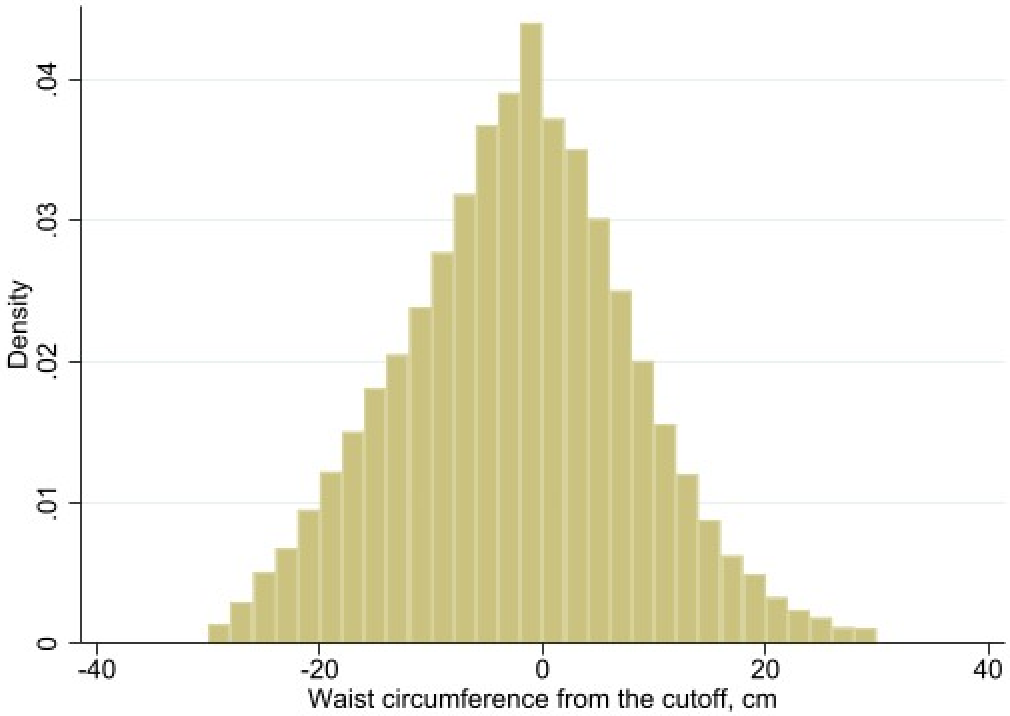
Support is provided through an initial interview, followed by continuous support for three months or more. Provide support based on participants' current lifestyle and progress on action plans. The health guidance intervention includes the following:

A) Provide practical guidance on lifestyle factors, such as diet and physical activity.

B) Evaluate and revise progress on action plans in a timely manner based on evaluation results.

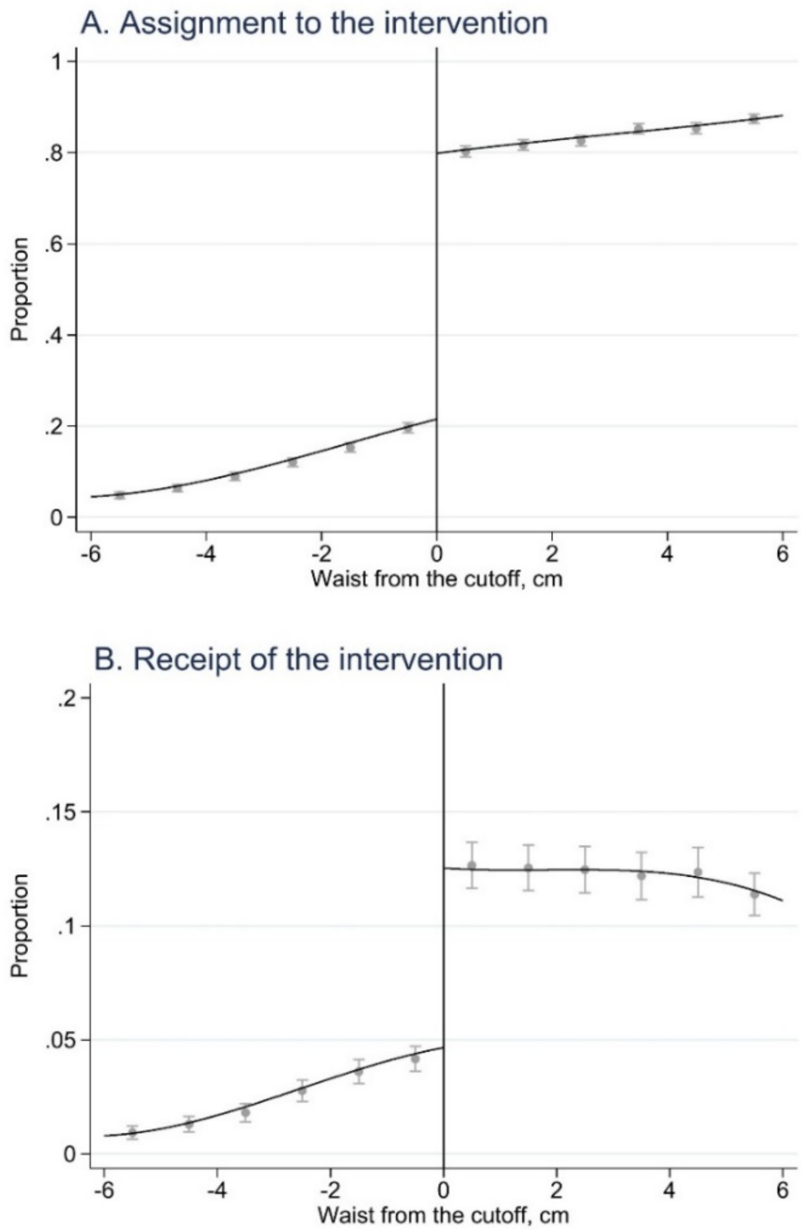
C) Request that participants submit detailed descriptions of their achievements among the items included in their action plans; provide feedback based on that information.

eFigure 2. Distribution of waist circumference of participants

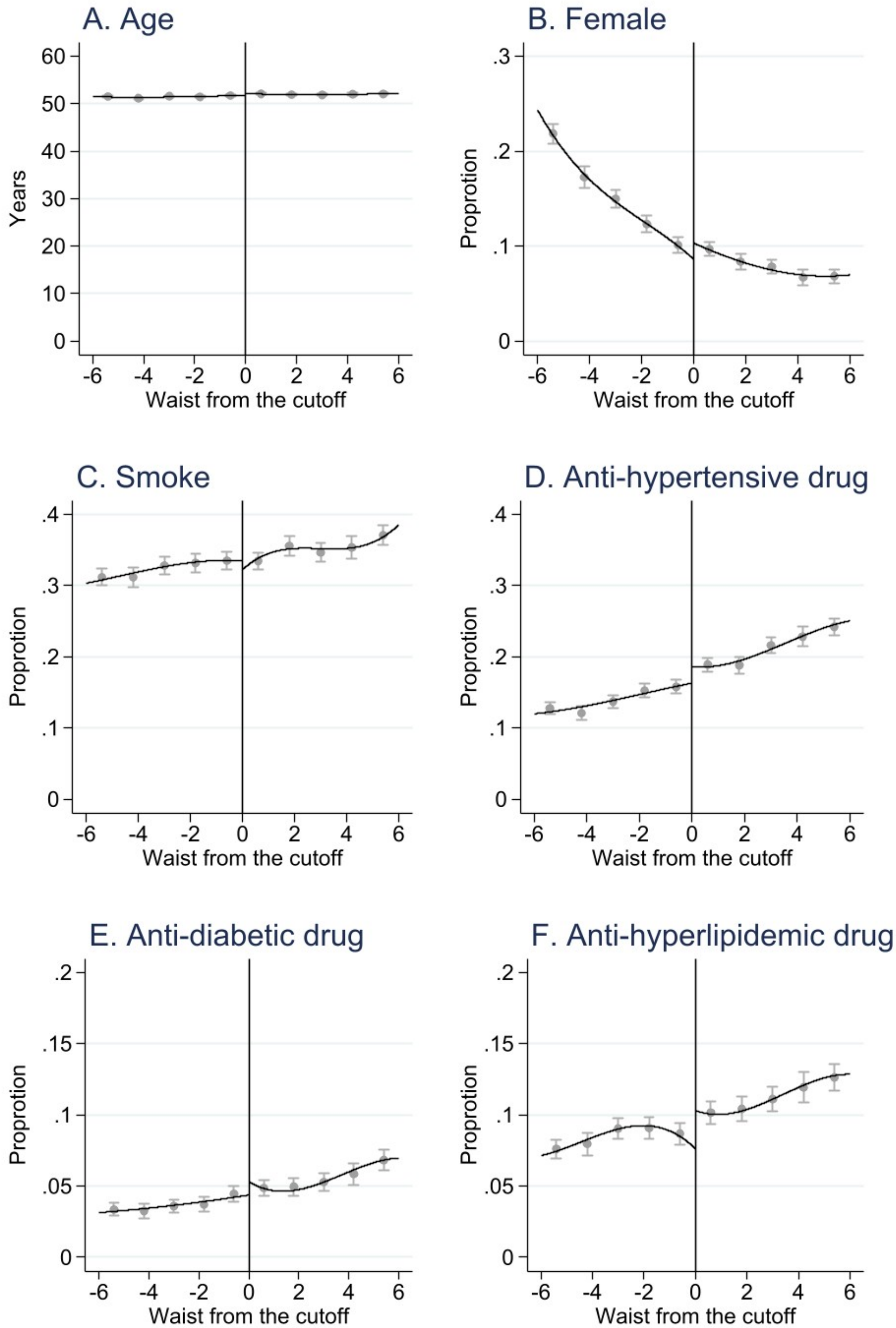


We failed to reject the null hypothesis of a smooth density of waist circumference at the threshold (p=0.20 by McCrary's density test), indicating that there is no evidence that waist circumference was manipulated by participants during the screening program.

eFigure 3. Proportion of participants who were (A) assigned to the health guidance intervention and (B) received the intervention based on their value of waist circumference.



eFigure 4. Continuity of observed covariates at the cutoff of waist circumference



The vertical solid line indicates the cutoff of waist circumference, which is an assignment variable for the health guidance intervention.

eTable 1. Association of Assignment to the Health guidance intervention with Healthcare Utilization and Spending from Year 1 to Year 5 using Fuzzy Regression Discontinuity Design[a]

	Year 1	Year 2	Year 3	Year 4	Year 5
Healthcare utilization					
Visit days for outpatient care, days[c]	+0.1 (-2.8 to +0.8) P = 0.25	-1.4 (-4.7 to -0.4) P = 0.02	-1.3 (-3.9 to +0. 9) P = 0.21	-0.8 (-13.3 to +1.2) P = 0.10	+0.7 (-2.0 to +2.7) P = 0.79
Medication use,[b] percentage points (pp)[c]	-2.3 pp (-9.3 to +0.1) P = 0.06	-3.9 pp (-9.9 to -0.03) P = 0.048	-3.8 pp (-9.0 to +1.4) P = 0.15	-4.3 pp (-10.0 to +2.2) P = 0.21	-4.7 pp (-10.2 to +2.1) P = 0.20
Hospitalization, percentage points (pp)[c]	-1.1 pp (-4.8 to +2.9) P = 0.62	-1.3 pp (-7.0 to +3.3) P = 0.49	-1.2 pp (-7.2 to +4.1) P = 0.59	-0.1 pp (-9.2 to +5.4) P = 0.61	+0.3 pp (-9.8 to +6.7) P = 0.71
Healthcare spending					
Total medical expenditure, dollars[c]	-$181 (-1212 to +525) P = 0.44	-$724 (-2935 to +612) P = 0.20	-$1138 (-4506 to +932) P = 0.20	-$621 (-2997 to +2285) P = 0.43	+$91 (-2796 to +3655) P = 0.79
Medical expenditure for outpatient care, dollars[c]	$209 (-373 to +507) P = 0.77	+$244 (-1073 to +948) P = 0.90	+$46 (-2063 to +1572) P = 0.79	+$411 (-1485 to +2684) P = 0.57	+$725 (-1507 to +3814) P = 0.40
Medical expenditure for inpatient care, dollars[c]	-$365 (-1094 to +136) P = 0.13	-$1024 (-2500 to -42) P = 0.04	-$1214 (-2932 to +68) P = 0.06	-$874 (-2552 to +210) P = 0.10	-$587 (-1970 to +716) P = 0.36

[a] We used the data-driven approach to determine the optimal bandwidths for each outcome variables we have investigated.

[b] Any medication includes drugs for hypertension, hyperglycemia, and hyperlipidemia.

[c] We adjusted for age, gender, current smoking, and baseline medication use.

eTable 2. Association of Assignment to the Health guidance intervention with Healthcare Utilization and Spending for 3 Years using Fuzzy Regression Discontinuity Design[a] by Gender

A. Female

	Bandwidths	Number	Adjusted effects	95% CI	P-value
Healthcare utilization					
Visit days for outpatient care, days[c]	6.9	5398	-18.5	(-77.4 to +9.0)	0.12
Medication use,[b] percentage points (pp)[c]	8.1	6592	-6.4 pp	(-32.3 to +31.7)	0.99
Hospitalization, percentage points (pp)[c]	7.9	6320	-7.6 pp	(-55.9 to +16.1)	0.28
Healthcare spending					
Total medical expenditure, dollars[c]	7.1	5774	-$4427	(-14553 to +3462)	0.23
Medical expenditure for outpatient care, dollars[c]	6.7	5270	-$876	(-5267 to +3771)	0.75
Medical expenditure for inpatient care, dollars[c]	6.9	5431	-$3403	(-12396 to +2089)	0.16

B. Male

	Bandwidths	Number	Adjusted effects	95% CI	P-value
Healthcare utilization					
Visit days for outpatient care, days[c]	5.0	34348	-2.4	(-10.9 to +1.0)	0.11
Medication use,[b] percentage points (pp)[c]	3.9	25785	-3.5 pp	(-10.4 to +4.1)	0.40
Hospitalization, percentage points (pp)[c]	5.9	37393	-0.2 pp	(-8.4 to +3.8)	0.47
Healthcare spending					
Total medical expenditure, dollars[c]	3.9	25868	-$1623	(-6010 to +446)	0.09
Medical expenditure for outpatient care, dollars[c]	3.8	25429	-$196	(-2750 to +532)	0.19
Medical expenditure for inpatient care, dollars[c]	4.4	29363	-$1275	(-3797 to +326)	0.10

[a] We used the data-driven approach to determine the optimal bandwidths for each outcome variables we have investigated.
[b] Any medication includes drugs for hypertension, hyperglycemia, and hyperlipidemia.
[c] We adjusted for age, gender, current smoking, and baseline medication use.

eTable 3. Association of the national health guidance intervention with healthcare utilization and healthcare spending by different bandwidths

	Adjusted ITT effects[a]			Adjusted ToT effects[a]		
	5 cm	6 cm	7 cm	5 cm	6 cm	7 cm
Healthcare utilization						
Visit days, days	-3.8 (-11.8 to -0.6) P = 0.03	-1.6 (-11.9 to -0.7) P = 0.03	-0.7 (-15.7 to -2.5) P = 0.01	-25.5 (-79.5 to -3.7) P = 0.03	-10.6 (-78.2 to -4.9) P = 0.03	-4.4 (-103.8 to -17.0) P = 0.01
Medication use,[b] percentage points	-3.9 (-9.4 to +1.8) P = 0.18	-3.9 (-9.3 to +2.0) P = 0.21	-3.8 (-9.8 to +3.4) P = 0.34	-27.2 (-66.7 to +12.8) P = 0.18	-26.5 (-64.7 to +13.9) P = 0.21	-26.4 (-69.4 to +22.8) P = 0.32
Hospitalization, percentage points	-1.8 (-8.9 to +3.3) P = 0.37	-0.9 (-9.1 to +3.2) P = 0.35	-1.2 (-11.9 to +2.4) P = 0.19	-11.9 (-59.9 to +22.0) P = 0.37	-5.8 (-59.5 to +21.1) P = 0.35	-7.7 (-78.9 to +15.4) P 0.19
Healthcare spending						
Total medical expenditure, dollars	-$1420 (-4443 to +986) P = 0.21	-$1132 (-4447 to +953) P = 0.21	-$1110 (-5326 to +881) P = 0.16	-$9462 (-29869 to +6603) P = 0.21	-$7418 (-29399 to +6137) P = 0.20	-$7315 (-35561 to +5527) P = 0.15
Medical expenditure for outpatient care, dollars	-$43 (-2030 to +1667) P = 0.85	+$78 (-2000 to +1595) P = 0.83	+$61 (-2481 to +1573) P = 0.66	-$287 (-13537 to +11107) P = 0.85	+$510 (-13091 to +10468) P = 0.83	+$404 (-16332 to +10391) P = 0.66
Medical expenditure for inpatient care, dollars	-$1377 (-3107 to +14) P =0.052	-$1210 (-3127 to +38) P = 0.056	-$1171 (-3632 to +95) P = 0.06	-$1377 (-3107 to +14) P = 0.052	-$1210 (-3127 to +38) P = 0.056	-$1171 (-3632 to +95) P = 0.06

[a] We adjusted for age, gender, current smoking, and baseline medication use.

[b] Any medication includes drugs for hypertension, hyperglycemia, and hyperlipidemia.

Impact of the National Health Guidance Intervention for Obesity and Cardiovascular Risks on Healthcare Utilization and Healthcare Spending in Working-age Japanese Cohort: Regression Discontinuity Design

STROBE Statement—Checklist of items that should be included in reports of ***cohort studies***

	Item No	Recommendation	Part
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	**Title & Abstract**
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	Abstract
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	1st, 2nd paragraph (Introduction)
Objectives	3	State specific objectives, including any prespecified hypotheses	3rd paragraph (Introduction)
Methods			
Study design	4	Present key elements of study design early in the paper	Statistical analysis (Methods) & 3rd paragraph (Introduction)
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Data source (Methods)
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	Participants (Methods)
		(*b*) For matched studies, give matching criteria and number of exposed and unexposed	Not applicable
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	Healthcare utilization and healthcare spending (Methods)
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	Data source (Methods)
Bias	9	Describe any efforts to address potential sources of bias	Statistical analysis (Methods)
Study size	10	Explain how the study size was arrived at	Participants (Methods)
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	Data source (Methods)
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	Statistical analysis (Methods)
		(*b*) Describe any methods used to examine subgroups and interactions	Secondary analysis (Methods)

		(*c*) Explain how missing data were addressed	Statistical analysis (Methods)
		(*d*) If applicable, explain how loss to follow-up was addressed	Not applicable
		(*e*) Describe any sensitivity analyses	Secondary analysis (Methods)
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	Participant characteristics (Results) & Participants (Methods)
		(b) Give reasons for non-participation at each stage	Participants (Methods)
		(c) Consider use of a flow diagram	Not applicable
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	Participant characteristics (Results) & Table 1
		(b) Indicate number of participants with missing data for each variable of interest	Statistical analysis (Methods)
		(c) Summarise follow-up time (eg, average and total amount)	Not applicable
Outcome data	15*	Report numbers of outcome events or summary measures over time	Table 2
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	Effect of the health guidance intervention on healthcare utilization and hospitalization (Results)
		(*b*) Report category boundaries when continuous variables were categorized	Table 2 & Table 3
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	Not applicable
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	Secondary analyses (Results)
Discussion			
Key results	18	Summarise key results with reference to study objectives	1st paragraph (Discussion)
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	5th paragraph (Discussion)
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	2-4th paragraph (Discussion)
Generalisability	21	Discuss the generalisability (external validity) of the study results	5th paragraph (Discussion)
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the	Funding

original study on which the present article is based

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at http://www.strobe-statement.org.