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Effects of behavioral counseling on cardiometabolic biomarkers: A longitudinal analysis of the Japanese national database

Nayu Ikeda[a], Nobuo Nishi[a,*], Motohiko Miyachi[b]

[a] International Center for Nutrition and Information, National Institute of Health and Nutrition, National Institutes of Biomedical Innovation, Health and Nutrition, 1-23-1 Toyama, Shinjuku, Tokyo 162-8636, Japan

[b] Department of Physical Activity Research, National Institute of Health and Nutrition, National Institutes of Biomedical Innovation, Health and Nutrition, 1-23-1 Toyama, Shinjuku, Tokyo 162-8636, Japan

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ABSTRACT

In Japan, health insurers are obliged to conduct Specific Health Checkup (SHC) for middle-aged and elderly persons. High-risk persons are referred to Specific Health Guidance (SHG) to receive behavioral counseling based on individual action plans including targets for modification of daily energy balance through diet and physical activity. Using individual-level observational data, we examined the effects of diet and physical activity counseling on cardiometabolic biomarkers across the country. Subjects were 363,440 high-risk persons aged 40–64 who participated in intensive support in SHG for ≥3 months between April 2008 and March 2012. We considered participants as receiving counseling on diet alone, physical activity alone, combined, or neither if they had targets for diet only, physical activity only, both, or neither, respectively. Biomarkers included body mass index, waist circumference, systolic and diastolic blood pressure, high-density lipoprotein cholesterol, and hemoglobin A1c. Under the difference-in-differences approach, we used multivariable linear regression on repeated measures of biomarkers at SHCs before and after SHG and estimated the effects of each counseling type as an interaction with time of SHC. Compared with neither counseling, diet and physical activity counseling, alone or combined, were significantly associated with additional improvements in biomarkers after SHG, for example, body mass index (men: 0.03–0.06 kg/m^2, women: 0.10–0.15 kg/m^2) and waist circumference (men: 0.16–0.29 cm, women: 0.43–0.47 cm) in both sexes and high-density lipoprotein cholesterol in men (0.13–0.29 mg/dL). Modest improvements in biomarkers were associated with diet and physical activity counseling, although effect sizes were small.

1. Introduction

Effective control of cardiometabolic risk factors is of growing importance for healthy aging of populations worldwide. Metabolic abnormalities such as hypertension, glucose intolerance, dyslipidemia, and obesity rank among the major contributors to death and functional health loss associated with cardiovascular diseases and diabetes (GBD 2015 Risk Factors Collaborators, 2016). These diseases are the leading causes of global disability-adjusted life years, particularly in the middle-aged and older populations (GBD 2015 DALYs and HALE Collaborators, 2016). It is therefore necessary to design and implement effective strategies for cardiometabolic risk factor reduction at the population level.

In Japan, nearly 50% of men and 20% of women aged 40–74 years are either strongly suspected of having or likely to get metabolic syndrome, (Ministry of Health, Labour and Welfare, 2017a) while cardiovascular diseases and diabetes account for approximately a quarter of all deaths and national health expenditure (Ministry of Health, Labour and Welfare, 2014; Ministry of Health, Labour and Welfare, 2017b). To strengthen disease prevention, the Japanese government launched a nationwide program in April 2008 titled Specific Health Checkups (SHC) and Specific Health Guidance (SHG) as part of the health care reform (Health Service Bureau, and Ministry of Health, Labour and Welfare, 2017). In this program, health insurers are obliged to conduct annual health checkups and provide guidance focused on metabolic syndrome for their insured persons aged 40–74 years under universal health coverage. The participation rate in SHC has been gradually increasing from 39% in 2008 to 50% in 2015 (Ministry of Health, Labour and Welfare, 2017c).

Beneficial effects of lifestyle modification on cardiovascular risks

* Corresponding author at: International Center for Nutrition and Information, National Institute of Health and Nutrition, National Institutes of Biomedical Innovation, Health and Nutrition, 1-23-1 Toyama, Shinjuku, Tokyo 162-8636, Japan.
E-mail address: nnishi@nibiohn.go.jp (N. Nishi).

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have been reported from previous randomized controlled trials (Eckel et al., 2013). Intensive behavioral counseling on diet and physical activity in persons with cardiovascular risk factors modestly improved physiological biomarkers such as serum cholesterol and blood pressure (Lin et al., 2014). Interventions for lifestyle modification were also effective for persons with metabolic syndrome in decreasing its prevalence and abnormalities of its components (Yamaoka and Tango, 2012).

Previous studies analyzed the data of persons enrolled in National Health Insurance, one of the major social health insurance programs in Japan, to examine the effects of SHG on cardiometabolic risks in a prefecture (Fukuda, 2011; Suzuki et al., 2015) and a municipality (Haruyama et al., 2012). However, no previous study has specifically examined the effects of behavioral counseling on diet and physical activity provided in intensive support of SHG across all insurance programs in the country. In this study, we used a national database for SHC and SHG to evaluate the longitudinal effects of these lifestyle modification interventions on cardiometabolic risks among high-risk individuals in Japan.

2. Methods

2.1. Behavioral counseling in intensive support of SHG

Participants in SHG were stratified according to multiple cardiometabolic risk factors measured at SHC. Moderate- and high-risk persons aged 40–64 years not taking medications were referred to motivational and intensive support, respectively, for lifestyle modification in SHG. Both moderate- and high-risk persons firstly developed an individual action plan under face-to-face communication with health professionals such as medical doctors, public health nurses, registered dietitians, and other qualified experts in dietary modification and exercise guidance. Action plans included targets for modification of daily energy balance through diet and physical activity. In addition, high-risk persons assigned to intensive support participated in continuous care including counseling and practical advice from health professionals in person, by phone or e-mail at least once a month for > 3 months. Health professionals used materials such as a detailed questionnaire, a pedometer, and official guides on food and exercise (Yoshiike et al., 2007; Ministry of Health, Labour and Welfare, 2006) to check the state of implementation of action plans and behavioral changes, provide practical guidance for improvement of diet and physical activity, and give praise and encouragement to continue efforts. A final assessment was performed 6 months after the initiation of support.

2.2. Data

We obtained all records of SHC (n = 88,043,712) and SHG (n = 2,304,883) conducted across the country between April 2008 and March 2012 (fiscal years 2008–2011) from the National Database of Health Insurance Claims and Specific Health Checkups of Japan. This was an observational longitudinal database of administrative claims developed by the Ministry of Health, Labour and Welfare for conducting research on formulation, implementation and evaluation of programs for the moderation of healthcare costs (Ministry of Health, Labour and Welfare, n.d.). We selected 2008–2011 because data were available for scientific research only for these years when we obtained approval of access to data from the Ministry of Health, Labour and Welfare. All personal identifiers such as name, birthday and a health insurance card number were substituted with a hash value and removed from datasets. The SHC and SHG datasets contained multiple checkup and guidance records per participant. These multiple records were linked for each participant by a hash value that was common within and between the two datasets.

The subjects of our analysis were participants assigned to intensive support in SHG. To prepare an analytical dataset, we excluded 4748 checkup records of participants having ≥ 5 checkups during the 4 years from the SHC dataset. We converted the remaining 88,038,964 checkup records to obtain participant-level SHC data (n = 45,710,579). For the SHG dataset, we excluded a total of 12,326 guidance records: 60 for missing hash values, and 12,266 for having duplicated records. Of the remaining 2,292,557 SHG records, we kept only those records of the first guidance phase that each participant had during the study period (n = 1,918,722). We then joined corresponding observations from this dataset of 1,918,722 SHG participants with those from the dataset of 45,710,579 SHC participants by deidentified hash values and successfully merged the records of 1,903,442 participants (99.2%). We obtained the final analytical dataset of 363,440 participants assigned to intensive support in SHG (332,476 men and 30,964 women) after excluding 1,090,350 participants assigned to motivational support, 38,088 participants assigned to intensive support for the first time after the fourth checkup, 1457 participants aged < 40 or ≥ 65 years, 316,865 participants having < 10 or ≥16months between checkups before and after guidance, 92,121 participants having outliers of changes in biologically plausible values between checkups before and after guidance falling in < 2.5th or ≥97.5th percentiles in any of body mass index (BMI), waist circumference, systolic blood pressure (SBP), diastolic blood pressure (DBP), or HDL cholesterol, and 1121 participants having missing data on current smoking status at a checkup before or after guidance. We used a subset of 261,831 participants (237,745 men and 24,086 women) for the analysis of hemoglobin A1c (HbA1c) because participants had either fasting plasma glucose or HbA1c measured in a blood glucose test.

2.3. Measures

For analysis, we considered participants to have received dietary counseling if they had a valid numerical target for reducing daily energy intake by diet for modification of daily energy balance in individual action plans developed at the initial SHG interview. We also considered participants to have received physical activity counseling if they had a valid numerical target for increasing daily energy expenditure by physical activity. Combining these definitions, we considered participants to have received counseling on diet alone, physical activity alone, both or neither. Participants who had a missing value or zero for both targets on diet and physical activity were considered to have received neither counseling for an unknown reason.

Our outcome variables were physiological biomarkers of cardiometabolic risk factors measured at SHCs before and after SHG. Agencies implementing health checkups were required to ensure sufficient internal and external quality control of measurements in their laboratories by the notification of the Ministry of Health, Labour and Welfare (Health Service Bureau, and Ministry of Health, Labour and Welfare, 2017). Body height was measured with a stadiometer to the nearest millimeter, and body weight was measured in light clothing with a scale to the nearest 0.1 kg. BMI was calculated as weight in kilograms divided by the square of height in meters. Waist circumference was measured by health professionals to the nearest millimeter at the umbilicus level in the upright position after light exhalation (Health Service Bureau, and Ministry of Health, Labour and Welfare, 2017). SBP and DBP were recorded once or twice at each SHC, but a majority of participants had only one measurement. To ensure consistency of measurements across subjects, we used the first measurement of blood pressures, or the second measurement if the first was invalid. HDL cholesterol was measured by visible or ultraviolet spectrophotometric methods. HbA1c was measured by high-performance liquid chromatography, immunoassay, or enzymatic techniques. Levels of HbA1c were standardized using calibrators certified by the Japan Diabetes Society. In this analysis, we multiplied them by 1.02 and added 0.25 to obtain HbA1c values equivalent to the National Glycohemoglobin Standardization Program values (Kashiwagi et al., 2012).