



## Effect of a worksite-based intervention program on metabolic parameters in middle-aged male white-collar workers: A randomized controlled trial

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### ABSTRACT

**Objective.** An effective program for preventing metabolic diseases through lifestyle modification is urgently needed. We investigated the effects of the Life Style Modification Program for Physical Activity and Nutrition program (LiSM10!<sup>®</sup>) on metabolic parameters in middle-aged male Japanese white-collar workers.

**Methods.** One hundred and one male office workers, 30 to 59 years of age, with metabolic syndrome risk factors, were randomly allocated into no-treatment control ( $n = 49$ ) and LiSM intervention ( $n = 52$ ) groups. The LiSM group attended individualized assessment and collaborative goal setting sessions based on food group intake and physical activity, followed by two individual counseling sessions with a registered dietitian and physical trainer, and received monthly website advice during the 4-month period from December 2006 to May 2007, in Tokyo, Japan. They were encouraged to enter current targeted food intakes and pedometer data on self-monitoring websites during the entire study period.

**Results.** Habitual food group intakes changed significantly in the LiSM group, showing improvements in 14 anthropometric and biochemical parameters contributing to inter-group differences in body weight, body mass index, fasting plasma glucose, insulin and homeostasis model assessment of insulin resistance changes ( $p < 0.01$ ).

**Conclusion.** The LiSM10!<sup>®</sup> program effectively improved insulin resistance-related metabolic parameters in middle-aged male white-collar workers.

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### Introduction

Improvements in lifestyle habits focusing on physical activity and nutrient intake can reportedly normalize disorders of energy metabolism (Yamaoka and Tango, 2005; Lichtenstein et al., 2006; Teramoto et al., 2007). Metabolic syndrome (MetS) is widely regarded as targets for preventing the early stages of coronary artery disease (Lakka et al., 2002; Zimmet et al., 2005).

Development of a simple yet effective program to prevent MetS through continuous lifestyle modification is urgently needed. People should be encouraged to maintain desirable lifestyle habits and become self-reliant over the long-term (Wing and Phelan, 2005). Intervention programs that include health behavior theories (Prochaska et al., 1992; Johnson et al., 2008), social cognitive theory (Bandura, 2001), and other theories based on behavioral sciences (Kaplan et al., 1977), have been suggested to be effective (Fujii and Muto, 2009). However, few studies have examined the results of

health promotion programs in Japanese white-collar workers, prompting us to design this randomized controlled trial.

We previously reported the effectiveness of a worksite health promotion program, the Life Style Modification Program for Physical Activity and Nutrition (LiSM10!<sup>®</sup>), on metabolic parameters in factory employees (Arai et al., 2007). The LiSM10!<sup>®</sup> is composed of individual structured counseling sessions, as well as social and environmental approaches. Looking back on comprehensive evaluation of the program, there are problems requiring resolution before this program can be effectively applied to white-collar workers. White-collar workers, whose lifestyles are more irregular because of their long commutes, long working hours, skipping meals, and dining with colleagues than those of subjects in other professions, reportedly have more physical symptoms (Kawada and Suzuki, 2008). Particularly with white-collar workers who eat out more frequently and are rather sedentary as compared to factory employees (The National Health and Nutrition Survey in Japan, 2005), opportunities to benefit from environmental support in the company cafeteria may be lacking. In terms of the counseling sessions, the subjects often find visits inconvenient due to their irregular job schedules. In the last decade, web/computer-based health education programs, tailored to individuals, have been developed and their effectiveness in modifying

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habitual dietary intake and physical activity has been reported (Brug et al., 2003; Portnoy et al., 2008). As personal computers are popular among white-collar workers in Japan, it was anticipated that using a personal computer might facilitate supporting ongoing lifestyle improvements.

This study was designed to investigate the effectiveness of a worksite-based LiSM101<sup>®</sup> program on metabolic parameters in middle-aged male Japanese white-collar workers requiring health guidance based on regular health check-up results. We report herein the results of the first period of a randomized, cross-over study.

## Methods

### Study design and subjects

The study period was the first 4 months of study with a randomized cross-over design. Sample size was calculated to detect the intervention effect of a 10% change within the group and between groups, using 0.05 for the alpha and 0.20 for the beta error. The necessary sample size was 45 subjects in each group. The protocol was approved by the Health Science Research Ethics Committee of Showa Women's University. Among office workers belonging to the health insurance association of the Nichirei Group Corporation in Tokyo and its surrounding area, aged from 30 to 59 years, those with MetS risk factors based on the results of regular health check-ups were enrolled in this study. Eight hundred male employees were informed about the study, 319 individuals agreed using their health check-up data and interested in participating in the study. After a detailed explanation of the program, 115 subjects agreed to participate.

A subject was considered to be at risk of developing MetS if one or more abnormalities involving serum lipids, glucose levels and blood pressure were present, with visceral obesity (umbilical circumference: 85 cm or more) and/or BMI  $\geq 25$ . The following were considered to be abnormal: triglyceride (TG)  $\geq 150$  mg/dL and/or HDL-cholesterol (HDL-C)  $< 40$  mg/dL, systolic blood pressure  $\geq 130$  mmHg and/or diastolic blood pressure  $\geq 85$  mmHg, fasting glucose  $\geq 110$  mg/dL and/or HbA1c  $\geq 5.5\%$ .

### Data collection

The medical check-ups were conducted by the Tokyo Health Service Association (Shinjuku-ku, Tokyo), not involved in the study. The data from regular health check-ups conducted in December 2006 and May 2007 were used as baseline and post-completion data, respectively.

A randomization code with equal numbers of alternative groups was generated from a list of all participants, using software SPSS (ver.15) at Waseda University. The Nichirei Inc staff members managing the study and contacting participants were not involved in this randomization process. However, as the participants received detailed explanations of the objectives and other aspects of this study, blinding to group assignments was not possible.

Lifestyle data were collected at baseline in January and at completion in May 2007. All subjects were asked to answer a questionnaire on lifestyle, habitual food intake (Supplement 1), the stages and self-efficacies of changes in their habitual food intakes and efforts to increase physical activity. Subjects were given a pedometer (Walking style HJ-7101T Omron Health Care Co., Ltd. Japan) to count the number of steps in a week.

Primary outcome measures were changes in food group intake and increased number of steps. Secondary outcome measures were anthropometric and biochemical parameters.

### Intervention program

The LiSM101<sup>®</sup> program was designed to promote healthy dietary habits and physical activity. Participants had monthly individual contact with a well trained dietitian and a physical trainer, both certified health counselors for this program. Just after the baseline data collection, participants attended an individual goal and action planning session, and at 1 and 2 months, they reviewed their plans with counselors. The fourth counseling session, at the end of the third month, was conducted through the website. The subjects were encouraged to use the website personal page of the LiSM101<sup>®</sup> (Nichirei Foods Inc, Tokyo), and were required to enter their current weight, record their practices as regards targeted food intake and physical activity, upload

data from the computer-linkable pedometer and discuss awareness of their lifestyles for self-monitoring throughout the intervention period. The data obtained were automatically presented in figures on their individual website pages. To support their efforts, the subject's family members and the counselor could make comments and/or note their impressions of the data on the self-monitoring page.

### First goal setting session

For the intervention group, individual counseling sessions were provided by a registered dietitian and physical trainer for 20 and 10 min, respectively. First, the dietitian encouraged assessment of the subjects' health check-up results and setting clinical goals to be met by the end of the 4 months. Then, participants assessed their own habitual food group intakes using the food frequency questionnaire, i.e. the "Check your dietary habits" sheet (Supplement 1). The sheet consisted of two major food groups and subgroups (group A: foods recommended to be increased: 5 subgroups: fish, soybeans/soybean-products, green/deep-yellow vegetables, white-vegetables, and mushrooms/seaweed/konnyaku) (group B: foods recommended to be decreased: 11 subgroups: large servings of grains such as rice/bread/noodles, confectionaries, sweet-drinks, fatty-meats, meat-products, butter/margarine/dressing/mayonnaise, eggs/liver, fried-dishes, pickles, soup, and alcoholic-drinks). The dietitian explained the significance and effects expected from consuming each A group food and avoidance or reduction of each B group food.

Then, the subjects were encouraged to set their action plans to change dietary behaviors by increasing the consumption of 1 or 2 foods in the A group, and decreasing the consumption of 1 or 2 foods in the B group. The numbers of target food subgroups, which they wanted to change consumption of, were recommended by the dietitian according to their stages of change and self-efficacy. If the stage of change for food intake was pre-contemplation, they were advised to count the number of Japanese dishes consumed in a day, as low fat traditional Japanese dishes could be regarded as healthy food models. Each subject was required to record his personal goals and action plan on a commitment sheet. Next, with advice from the physical trainer, subjects assessed their recorded steps for seven days, and decided on an action plan based on how many steps had been taken, or on lifestyle changes aimed at increasing physical activity. Each subject was also required to record his personal action plan concerning physical activity on a commitment sheet.

### Follow-up counseling

The participants were encouraged to enter their current targeted food intake and pedometer data on a website for self-monitoring during the entire study period. At the end of the first and then the second month, the counselors supported the participant in reviewing the month's achievements, to evaluate the level of achievement of his action plan based on the subject's own self-monitoring records, then encouraged him to consider the reason for the results and possible ways to more effectively implement or revise the plan. These face-to-face sessions each lasted 10 min. The participants received website advice after the personal counseling. At the end of the third month, the participants reported their conditions on their website pages, and the counselors both entered comments and advice, for example: answer his questions, acknowledge and praise what he was able to change, or advise him to lower the level and/or change the target if he was not able to change, remind him of behaviors he could do with his family, let him think over the plan to change without effort if he felt stressed, and so on.

### Anthropometric measurements

Body mass index (BMI) was calculated as weight(kg)/height(m)<sup>2</sup>. Umbilical circumference was measured during the late exhalation phase in the standing position. Blood pressure was measured using an automatic blood pressure manometer with the subject in the seated position.

### Blood sampling and analysis

Fasting blood samples were obtained and blinded measurements were conducted in the laboratory of the Tokyo Health Service Association as follows (total cholesterol (TC) and TG, enzymatic method; HDL-C, direct method; LDL-cholesterol (LDL-C), Friedewald equation; Aspartate aminotransferase (AST), alanine aminotransferase (ALT) and gamma-glutamyl

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