

Comparison of Education-Only versus Group-Based Intervention in Promoting Weight Loss: A Randomised Controlled Trial

| | |
|------------------------------|---|
| 著者別名 | 中田 由夫, 岡田 昌史, 橋本 幸一, 原田 義則, 曾根 博仁, 田中 喜代次 |
| journal or publication title | Obesity facts : the European journal of obesity |
| volume | 4 |
| number | 3 |
| page range | 222-228 |
| year | 2011-06 |
| 権利 | (C) 2011 S. Karger AG, Basel |
| URL | http://hdl.handle.net/2241/113563 |

doi: 10.1159/000329619

1 **Title Page**

2 **Title**

3 Comparison of education-only versus group-based intervention in promoting weight loss: a
4 randomised controlled trial

5

6 **Running head**

7 Education-only versus group-based intervention

8

9 **Authors**

10 Yoshio Nakata^{a,b}, Masafumi Okada^{a,b}, Koichi Hashimoto^{a,b}, Yoshinori Harada^{a,b}, Hirohito
11 Sone^a, Kiyoji Tanaka^a

12

13 ^aGraduate School of Comprehensive Human Sciences, University of Tsukuba

14 1-1-1 Tennodai, Tsukuba 305-8575, Japan

15 ^bTsukuba Critical Path Research and Education Integrated Leading Center (CREIL),

16 University of Tsukuba, 1-1-1 Tennodai, Tsukuba 305-8575, Japan

17

18 **Correspondence**

19 Yoshio Nakata, PhD

20 Graduate School of Comprehensive Human Sciences, University of Tsukuba

21 1-1-1 Tennodai, Tsukuba 305-8575, Japan

22 PHONE & FAX: +81-29-853-3076

23 E-mail: nakata@md.tsukuba.ac.jp

24

25 **Key words**

26 Behavioral interventions; Diet; Metabolic syndrome; Obesity; Physical activity

27

1 **Summary**

2 **Aim:** To compare the effectiveness of education-only versus group-based intervention in
3 promoting weight loss.

4 **Methods:** Between April and October 2009, a 6-month randomised controlled trial was
5 conducted at Mito Kyodo General Hospital in Japan (UMIN000001259). The participants
6 were 188 overweight adults (145 women, 43 men) aged 40–65 years. They were randomly
7 assigned to one of three groups: control, moderate or intensive intervention. A single
8 motivational lecture was provided to all three groups, educational materials (textbooks,
9 notebooks, and a pedometer) to the moderate and intensive intervention groups, and
10 group-based support to the intensive intervention group. Amount of weight loss was the
11 primary outcome measure. Secondary outcome measures were components of metabolic
12 syndrome.

13 **Results:** Mean \pm SD weight loss of participants in the control, moderate and intensive
14 intervention groups was 2.9 ± 4.1 , 4.7 ± 4.0 and 7.7 ± 4.1 kg, respectively. Bonferroni
15 post-hoc comparisons revealed all between-group differences to be significant ($p < 0.05$).
16 Waist circumference decreased in the intensive intervention group more than in the other
17 groups, whereas no significant differences were observed in the other secondary outcome
18 measures.

19 **Conclusion:** Education-only intervention is a cost-effective method to promote weight
20 loss. Adding group-based intervention further promotes weight loss.

1 **Introduction**

2 Prevention and treatment of obesity are still a challenge. A typical weight loss
3 treatment entails multiple face-to-face counselling sessions on a wide range of lifestyle
4 recommendations [1–4]. The core behavioural programme includes detailed and frequent
5 monitoring of diet, exercise, and weight, with specific and quantified goals for energy
6 intake and expenditure. In two well-controlled studies that included a lifestyle intervention
7 arm diabetes could be delayed or prevented with only modest changes in weight, but
8 considerable effort from well-trained staff was needed to achieve these behavioural changes
9 [1–4]. A recent meta-analysis of the effectiveness of dietary counselling for weight loss
10 reported its effectiveness but emphasized the importance of determining the factors that
11 will afford more effective weight loss [5]. In most clinical and public health settings, costs
12 in terms of time and physical effort are limited [3, 4]. With detailed evidence of the relative
13 contributions of individual components in weight loss programmes, cost-effective
14 approaches could be selectively used to promote weight loss.

15 We focused on providing educational materials (textbooks, notebooks, and a
16 pedometer) and implementing group-based support as effective individual components of a
17 weight loss programme. Providing a pedometer or informative materials has been shown to
18 promote physical activity [6–8]. If education-only intervention is effective to promote
19 weight loss, it could be a cost-effective approach. Implementing group-based intervention
20 could be a reliable method with apparent effectiveness by comparison with the
21 education-only intervention. In weight loss intervention trials, there is a possibility that
22 characteristics of participants who are willing and motivated may have influenced the trial
23 results [3, 9, 10]. Therefore, we set a control intervention group that was only given a single
24 motivational lecture on weight loss.

25 Thus, we planned to implement a 6-month randomised controlled trial with three
26 groups: control, moderate or intensive intervention. The control intervention group was
27 given a single motivational lecture on weight loss, the moderate intervention group was
28 additionally provided educational materials, and the intensive intervention group was

- 1 additionally provided group-based support during the 6-month trial. We determined the
- 2 effectiveness of each component in the weight loss programme and clarified their relative
- 3 contributions in promoting weight loss.

1 **Participants and Methods**

2 **Study design**

3 The trial methods have been described in detail elsewhere [11]; the protocol has
4 been registered with the UMIN Clinical Trials Registry (UMIN000001259). This study was
5 a 6-month randomised controlled trial conducted at Mito Kyodo General Hospital in Japan
6 between April and October 2009. Assuming a 2.5 ± 4.0 kg intervention-related difference in
7 the amount of weight loss at the end of 6 months between the three groups, a two-sided
8 alpha value of 0.0167 (with Bonferroni adjustment for post-hoc tests), power of 80%, and
9 an average attrition rate of 10%, the required sample size was estimated to be more than 60
10 participants in each group (180 participants in total). Participants received no financial
11 compensation or gifts. The protocol was approved by the ethical committee of Mito Kyodo
12 General Hospital and by the Industrial Review Board of the University of Tsukuba.

13

14 **Participants**

15 Participants were recruited through newspaper advertisements and attended a
16 2-hour explanatory session. In this session, they were informed about the aim and design of
17 the study, including random assignment and the importance of minimising dropout rate for
18 maintaining the study quality. Their written informed consent was obtained, and the time
19 for their baseline measurements was scheduled.

20 Within 4 weeks before the beginning of weight-loss intervention, participants were
21 assessed for eligibility at the baseline measurement. The eligibility criteria for the
22 participants included age between 40 and 65 years, BMI between 25 and 40 kg/m^2 (BMI is
23 calculated as weight in kilograms divided by the square of height in meters), and the
24 presence of at least one of the following components involved in the diagnosis of metabolic
25 syndrome according to the Japanese criteria [12]: i) waist circumference ≥ 85 cm in males
26 and ≥ 90 cm in females, ii) systolic blood pressure ≥ 130 mm Hg, iii) diastolic blood
27 pressure ≥ 85 mm Hg, iv) triglyceride level ≥ 150 mg/dl (1.70 mmol/l), v) high-density
28 lipoprotein (HDL) cholesterol level < 40 mg/dl (1.04 mmol/l), or vi) fasting plasma glucose

1 level \geq 110 mg/dl (6.11 mmol/l). The criteria for ineligibility included drug treatment for
2 diabetes (to avoid a potential influence on weight change [5]), past history of coronary
3 disease or stroke, or current or planned pregnancy. Participants whose cohabiting family
4 member had participated in this study were also ineligible (to avoid contamination from the
5 ripple effect on weight loss [13]).

6

7 **Motivational lecture**

8 At week 0, all participants attended a 2-hour group-based single motivational
9 lecture (approximately 40–50 participants per subgroup, with four subgroups). They
10 received typical behavioural weight control instructions on diet, exercise, and behavioural
11 changes. Recommendations included a calorie-restricted diet of 1,200 and 1,600 kcal/day
12 for women and men, respectively, and a minimum of 1,000 kcal/week of increased physical
13 activity. All participants were encouraged to self-monitor their body weight. The same
14 investigator gave the lecture using a standard slide presentation to ensure overall
15 comparability of the different subgroups.

16

17 **Randomisation**

18 After the motivational lecture, the participants were randomly assigned to one of
19 the following three groups by using simple randomisation procedures involving
20 computerised random numbers: control, moderate, or intensive intervention group.
21 Allocation data were generated by an investigator who had no contact with the participants
22 or the other staff members and was maintained at a central secure location until completion
23 of the motivational lecture.

24

25 **Interventions**

26 At week 1, following the announcement of the allocated groups through mail, the
27 participants in the moderate and intensive intervention groups attended a group-based
28 2-hour session (approximately 20–30 participants per subgroup, with four subgroups) in

1 which they were provided educational materials such as textbooks and notebooks
2 containing information on daily diet and other lifestyle-related topics as well as a
3 pedometer (FB-720; Tanita, Tokyo, Japan). The content of the textbooks and notebooks was
4 based on prior work of the investigators [14, 15]. The goals of energy intake (1,200 and
5 1,600 kcal/day for women and men, respectively) and increased energy expenditure (1,000
6 kcal/week) were the same in all three groups and remained the same throughout the 6
7 months. The participants in the moderate and intensive intervention groups were
8 recommended to modify their diet along with the provided educational materials. The
9 dietary programme is based on the Four-Food-Group Point Method [16]. According to this
10 method food is organized into four food groups (FG) based on their nutrient contents: FG 1
11 (eggs and dairy products), FG 2 (meat, fish, and soybean products), FG 3 (vegetables and
12 fruits), and FG 4 (carbohydrates and oil). To calculate energy intakes and nutrient balances
13 easily, a cluster of 80-kcal foods was translated into one point in the method. For
14 consuming a well-balanced daily diet, each person chose 3-point foods from FGs 1 to 3 (9
15 points in total) to take in the necessary nutrients. Then, depending on a participant's gender,
16 the rest of the energy (6 and 11 in women and men, respectively) was obtained from FG 4.
17 They were instructed to record their body weight, content of meals, and step counts on a
18 daily basis in the notebook provided. They were also instructed to calculate their daily
19 energy intake and check nutritional balance themselves using the textbooks provided. The
20 same investigator gave the instructions on how to use the educational materials to ensure
21 overall comparability of the different subgroups.

22 Furthermore, the participants in the intensive intervention group attended a
23 group-based 2-hour weight loss support programme at weeks 2, 4, 6, 10, 14, 18, and 22
24 (approximately 15–20 participants per subgroup, with four subgroups), during which a
25 trained staff member gave lectures to explain the content of the textbooks and two other
26 staff members reviewed participants' notebooks and advised them on their diet and other
27 lifestyle factors. The same staff member gave each lecture to ensure overall comparability
28 of the different subgroups.

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

Study outcomes

Data were collected at baseline and at months 3 and 6 in the hospital by trained hospital staff members who were masked to treatment assignment.

The primary outcome measure was an amount of weight loss from baseline to 6 months. Weight was measured in light clothes, without shoes, to the nearest 0.05 kg using a calibrated digital scale (WB-150; Tanita). Height was measured to the nearest 0.1 cm on a wall-mounted stadiometer at baseline for determination of BMI. The secondary outcome measures were waist circumference, systolic and diastolic blood pressure, levels of triglycerides, HDL cholesterol, and fasting plasma glucose. Waist circumference was measured to the nearest 0.1 cm at the umbilicus level, with the participants in the standing position, using a flexible plastic tape. Blood pressure was measured using a manual sphygmomanometer with the participants in the seated position after a 20-min rest period. Two readings of systolic and diastolic blood pressure were recorded, and the average was used for data analysis. Approximately 10 ml of blood was drawn from each participant between 10:30 and 11:30 a.m. after fasting for more than 12 h. Fresh samples were used for enzymatic analysis of triglycerides, and fasting plasma glucose was assayed using glucose oxidase. Serum HDL cholesterol was measured using heparin-manganese precipitation. Venous blood was analysed by an independent laboratory (Kotobiken Medical Laboratories, Ibaraki, Japan).

We also measured dietary intake by 3-day food records and physical activity with a three-axis accelerometer (HJA-350IT; Omron Healthcare, Kyoto, Japan) [17]. Participants were asked to record everything that they ate and drank for 3 days—2 weekdays and 1 weekend day. Foods were measured using standard measuring cups, spoons, and digital scales. To ensure overall comparability, one skilled nutritionist who was masked to treatment assignment analysed all food records. Participants were also asked to wear the accelerometer which additionally includes a step-counting function for 14 consecutive days on their waist throughout the day except when sleeping, when engaged in a water-based

1 activity (e.g., taking a bath or swimming), or when engaged in certain activities, such as
2 contact sports for safety reasons. Records obtained when wearing the device for at least 10
3 h a day were defined as valid records [18]. If no acceleration signal was obtained over a
4 10-s time interval for 20 min or more continuously, it was defined as “non-wear” [19]. If
5 there are valid records for more than 2 weekdays and 1 weekend day, we estimated daily
6 step counts and total daily minutes of moderate to vigorous (≥ 3 metabolic equivalents)
7 physical activity.

8

9 **Statistical analysis**

10 An intention-to-treat analysis, with missing data replaced by last observation
11 carried forward (data at baseline or month 3), was applied to the measures of body weight
12 and related outcome variables. One-way analysis of variance and Bonferroni’s post-hoc test
13 was used to examine statistical significance of between-group differences. The chi-square
14 test was used to compare proportions. Data were analysed using IBM SPSS Statistics 18
15 (SPSS Inc., Chicago, IL, USA), with the level of statistical significance set at 5%.

1 Results

2 Figure 1 shows the flow of participants through the study. We recruited 222
3 participants between November 2008 and March 2009 and assessed 213 participants for
4 eligibility (9 did not attend). After excluding 25 ineligible participants, 188 adults (145
5 women and 43 men) were enrolled in the study and were assigned to one of three groups.

6 Table 1 provides baseline characteristics of the participants. The numbers of those
7 with abdominal obesity, hypertension, lipidaemia and hyperglycaemia were 179 (95%), 102
8 (54%), 59 (31%) and 22 (12%), respectively. The attrition rate was 3.7% (7/188) and 8.5%
9 (16/188) at months 3 and 6, respectively (fig. 1). The numbers of those lost to follow-up at
10 6 months were similar in the three groups ($p = 0.63$). The medical reasons for which
11 participants were lost to follow-up included influenza, hepatic disease, menopause
12 syndrome, and hysteromyoma. No clinically significant adverse events occurred that were
13 judged by the investigators to be related to participation in the trial. The attendance rate at
14 the group-based support in the intensive intervention group ranged from 57.1% (36/63 at
15 week 22) to 96.8% (61/63 at week 1), and the mean attendance rate was 80.8%.

16 The pattern of weight change is shown in figure 2. The mean \pm SD body weights
17 of participants in the control, moderate, and intensive intervention groups declined by 2.4
18 ± 2.9 kg, 3.9 ± 3.1 kg, and 6.0 ± 3.0 kg at 3 months, and by 2.9 ± 4.1 kg, 4.7 ± 4.0 kg, and
19 7.7 ± 4.1 kg at 6 months, respectively, as determined by intention-to-treat analysis.
20 Bonferroni post-hoc comparisons revealed all between-group differences to be significant.
21 Mean weight loss at 6 months in the intensive intervention group was by 4.8 kg (95%
22 confidence interval (95% CI) 3.1–6.6 kg; $p < 0.01$) and 3.0 kg (95% CI 1.3–4.8 kg; $p <$
23 0.01) greater than those in the control and moderate intervention groups, respectively. Mean
24 weight loss in the moderate intervention group was also 1.8 kg (95% CI 0.0–3.5 kg; $p =$
25 0.04) greater than that in the control group.

26 The mean percentages of initial body weight lost at 6 months were 4.1% (95% CI
27 2.7–5.5%), 6.4% (95% CI 5.1–7.7%) and 10.5% (95% CI 9.2–11.8%) in the control,
28 moderate and intensive intervention groups, respectively. The numbers of participants who

1 lost 5% or more of initial body weight were 18 (29%), 35 (56%), or 56 (89%), and the
2 numbers who lost 10% or more were 10 (16%), 17 (27%), or 34 (54%) in the control,
3 moderate, or intensive intervention groups.

4 Table 2 shows changes in the secondary outcome measures, dietary energy intake,
5 and physical activity. The mean decrease in waist circumference in the intensive
6 intervention group was by 5.2 cm (95% CI 3.2–7.1 cm; $p < 0.01$) and 3.4 cm (95% CI
7 1.5–5.4 cm; $p < 0.01$) greater than those in the control and moderate intervention groups,
8 respectively. No significant between-group differences were observed with regard to the
9 other secondary outcome measures. The participants in the intensive intervention group
10 decreased their dietary intake by 412 kcal/day (95% CI 241–583 kcal/day; $p < 0.01$) and
11 264 kcal/day (95% CI 92–436 kcal/day; $p < 0.01$) more than the participants in the control
12 and moderate intervention groups, respectively. Step counts and moderate to vigorous
13 physical activity increased, while no significant between-group differences were observed.

1 **Discussion**

2 The 6-month randomised controlled trial provides evidence that using educational
3 materials and group-based support are effective components of weight-loss programmes.
4 Education-only intervention produced an additional weight loss of 1.8 kg compared with
5 the single motivational lecture. Group-based intervention further increased weight loss by
6 3.0 kg compared with the education-only intervention.

7 In weight loss intervention trials, well-designed randomised controlled trials are
8 needed to avoid potential influences on the trial results by the characteristics of participants
9 who are willing and motivated [3, 9, 10]. In this study, the participants in the control
10 intervention group tried to lose weight only with self-help after a single motivational
11 lecture. Indeed, they had a mean loss of 2.9 kg after 6 months. These changes may
12 represent the effect of the single lecture and/or the characteristics of highly motivated
13 individuals. In either case, we could clearly show the effectiveness of providing educational
14 materials and group-based support compared with the control intervention.

15 Providing a pedometer has been shown to promote physical activity and decrease
16 BMI [6, 7]. Providing informative materials seems to also promote physical activity levels
17 among inactive patients [8]. In the present study, education-only intervention as well as
18 group-based intervention could not significantly increase physical activity compared with
19 the control intervention, but could decrease body weight and dietary intake. Therefore, the
20 significant differences in weight loss could be attributed to a greater reduction in dietary
21 intake, and not to an increase in physical activity. This is probably the influence of the
22 behavioural changes stimulated by our emphasising the importance of recording diet and
23 checking nutritional balance themselves for achieving short-term weight loss using the
24 textbook provided to the moderate and intensive intervention groups. Another strategy is
25 needed to promote physical activity in addition to providing a pedometer for participants of
26 the weight loss programme.

27 A need for effective behavioural interventions requiring less face-to-face contact
28 has been created because of preferred alternatives to face-to-face treatment [20] as well as

1 limited costs [3, 4]. Recent studies have reported the effectiveness of an alternative method
2 for promoting weight loss using the internet and e-mail [21–23], text messages via mobile
3 phones [24], or diet counselling via the telephone [25]. In this regard, education-only
4 intervention can be a cost-effective weight loss method that requires less face-to-face
5 contact.

6 Group-based intervention has a greater extent of effectiveness in achieving weight
7 loss than the education-only intervention. A recent randomised controlled trial showed the
8 effectiveness of high-frequent (18 times in 6 months) face-to-face counselling (8.9% loss of
9 initial body weight) compared with self-help (5.2%) or low-frequent (6 times in 6 months)
10 face-to-face counselling (6.4%) along with sibutramine use; in contrast, the effectiveness of
11 low-frequent face-to-face counselling was not statistically significant compared with
12 self-help [25]. In the present study, the group-based intervention was not highly frequent (8
13 times in 6 months including the instruction at week 1); however, the effectiveness (10.5%
14 loss of initial body weight) was clearly shown compared with the control (4.1%) or
15 education-only intervention (6.4%). The results may be attributed to different approaches:
16 group versus individual. Group treatment appears to allow participants to interact with each
17 other and bring short-term benefits in achieving weight loss [26]. From a cost-effective
18 perspective as well, a group-based support appears to have some advantages [27], whereas
19 further studies are needed to demonstrate the effectiveness of a group approach compared
20 with an individual approach.

21 The major strength of this study is that it was a one-phase randomised trial in
22 which all participants started simultaneously in a population at risk of metabolic syndrome.
23 A low attrition rate as in the present study provides a more accurate estimate of the actual
24 treatment effect because it reduces the potential effect of selection bias.

25 The present study includes some limitations. First, despite significant differences
26 in weight loss between the three groups, the improvement in most secondary outcome
27 measures was not statistically different. In part, this is a statistical issue because the study
28 was powered to detect differences in the amount of weight loss, not in the secondary

1 outcome measures. Furthermore, the secondary outcome measures of most participants
2 were in the normal range at baseline. Therefore, not much improvement could be obtained.
3 Second, the study length of 6 months is short because the maintenance of weight loss is
4 necessary for enduring health benefits. We have designed a 2-year follow-up
5 no-intervention observation period and planned to implement annual follow-up
6 measurements for participants in the moderate and intensive intervention groups; however,
7 due to ethical concerns, we provided the group-based support to the control intervention
8 group after the 6-month study period. Therefore, after the 2-year follow-up, we will report
9 the long-term residual effectiveness in achieving weight maintenance of the intensive
10 intervention group compared with the moderate intervention group. Another limitation is
11 that the study population included only Japanese participants who are willing and motivated,
12 which limits the generalisation of the results. Further studies are required to confirm the
13 generalisation to other populations.

14 In summary, education-only intervention can be a cost-effective method for
15 promoting weight loss that requires less face-to-face contact. This approach is potentially
16 appropriate if costs in terms of time and physical effort are limited to implement intensive
17 weight-loss intervention, or if participants prefer treatments requiring less face-to-face
18 contact in clinical and public health settings. Group-based intervention further promotes
19 weight loss, although it needs considerable effort from well-trained staff.

1 **Acknowledgments**

2 This study was supported by the Japan Agriculture Ibaraki Public Welfare
3 Federation and partly funded by the Meiji Yasuda Life Foundation of Health and Welfare,
4 2008. We wish to thank members of Mito Kyodo General Hospital for their cooperation in
5 data acquisition and members of the Tsukuba Critical Path Research and Education
6 Integrated Leading Center (CREIL) at the University of Tsukuba for their critical advice in
7 conducting the study and data management during the study period. We owe special thanks
8 to the participants of this study and are also grateful to Yuriko Sakairi for her excellent
9 cooperation to implement the present study.

10

11 **Disclosure**

12 The authors declare no conflict of interest.

1 **References**

- 2 1. Knowler WC, Barrett-Connor E, Fowler SE, Hamman RF, Lachin JM, Walker EA,
3 Nathan DM; Diabetes Prevention Program Research Group: Reduction in the incidence
4 of type 2 diabetes with lifestyle intervention or metformin. *N Engl J Med*
5 2002;346:393–403.
- 6 2. Tuomilehto J, Lindström J, Eriksson JG, Valle TT, Hämäläinen H, Ilanne-Parikka P,
7 Keinänen-Kiukaanniemi S, Laakso M, Louheranta A, Rastas M, Salminen V, Uusitupa
8 M; Finnish Diabetes Prevention Study Group: Prevention of type 2 diabetes mellitus by
9 changes in lifestyle among subjects with impaired glucose tolerance. *N Engl J Med*
10 2001;344:1343–1350.
- 11 3. American Diabetes Association and National Institute of Diabetes, Digestive and
12 Kidney Diseases: The prevention or delay of type 2 diabetes. *Diabetes Care*
13 2002;25:742–749.
- 14 4. Wing RR: Behavioral interventions for obesity: recognizing our progress and future
15 challenges. *Obes Res* 2003;11(suppl):3–6.
- 16 5. Dansinger ML, Tatsioni A, Wong JB, Chung M, Balk EM: Meta-analysis: the effect of
17 dietary counseling for weight loss. *Ann Intern Med* 2007;147:41–50.
- 18 6. Bravata DM, Smith-Spangler C, Sundaram V, Gienger AL, Lin N, Lewis R, Stave CD,
19 Olkin I, Sirard JR: Using pedometers to increase physical activity and improve health: a
20 systematic review. *JAMA* 2007;298:2296–2304.
- 21 7. Richardson CR, Newton TL, Abraham JJ, Sen A, Jimbo M, Swartz AM: A
22 meta-analysis of pedometer-based walking interventions and weight loss. *Ann Fam*

- 1 Med 2008;6:69–77.
- 2 8. Smith BJ, Bauman AE, Bull FC, Booth ML, Harris MF: Promoting physical activity in
3 general practice: a controlled trial of written advice and information materials. *Br J*
4 *Sports Med* 2000;34:262–267.
- 5 9. Heshka S, Anderson JW, Atkinson RL, Greenway FL, Hill JO, Phinney SD, Kolotkin
6 RL, Miller-Kovach K, Pi-Sunyer FX: Weight loss with self-help compared with a
7 structured commercial program: a randomized trial. *JAMA* 2003;289:1792–1798.
- 8 10. Glasgow RE, Lichtenstein E, Marcus AC: Why don't we see more translation of health
9 promotion research to practice? Rethinking the efficacy-to-effectiveness transition. *Am*
10 *J Public Health* 2003;93:1261–1267.
- 11 11. Nakata Y, Okada M: Effects of weight-loss tools and a group-based weight-loss support
12 program: Rationale and study design of a randomized controlled trial (in Japanese).
13 *Nippon Kosshu Eisei Zasshi* 2010;57:835–842.
- 14 12. The Examination Committee of Criteria for 'Metabolic Syndrome' in Japan: Criteria for
15 'metabolic syndrome' in Japan (in Japanese). *Nippon Naika Gakkai Zasshi*
16 2005;94:188–203.
- 17 13. Gorin AA, Wing RR, Fava JL, Jakicic JM, Jeffery R, West DS, Brelje K, Dilillo VG;
18 Look AHEAD Home Environment Research Group: Weight loss treatment influences
19 untreated spouses and the home environment: evidence of a ripple effect. *Int J Obes*
20 2008;32:1678–1684.
- 21 14. Tanaka K, Okura T, Shigematsu R, Nakata Y, Lee DJ, Wee SW, Yamabuki K: Target

- 1 value of intraabdominal fat area for improving coronary heart disease risk factors. *Obes*
2 *Res* 2004;12:695–703.
- 3 15. Nakata Y, Okura T, Matsuo T, Tanaka K: Factors alleviating metabolic syndrome via
4 diet-induced weight loss with or without exercise in overweight Japanese women. *Prev*
5 *Med* 2009;48:351–356.
- 6 16. Kagawa A: The “four-food-group-point-method” (in Japanese). *J Kagawa Nutr Univ*
7 1983;14:5-12.
- 8 17. Oshima Y, Kawaguchi K, Tanaka S, Ohkawara K, Hikihara Y, Ishikawa-Takata K,
9 Tabata I: Classifying household and locomotive activities using a triaxial accelerometer.
10 *Gait Posture* 2010;31:370–374.
- 11 18. Troiano RP, Berrigan D, Dodd KW, Mâsse LC, Tilert T, McDowell M: Physical activity
12 in the United States measured by accelerometer. *Med Sci Sports Exerc*
13 2008;40:181–188.
- 14 19. Mâsse LC, Fuemmeler BF, Anderson CB, Matthews CE, Trost SG, Catellier DJ, Treuth
15 M: Accelerometer data reduction: a comparison of four reduction algorithms on select
16 outcome variables. *Med Sci Sports Exerc* 2005;37(suppl):544–554.
- 17 20. Sherwood NE, Morton N, Jeffery RW, French SA, Neumark-Sztainer D, Falkner NH:
18 Consumer preferences in format and type of community-based weight control programs.
19 *Am J Health Promot* 1998;13:12–18.
- 20 21. Tate DF, Wing RR, Winett RA: Using Internet technology to deliver a behavioral
21 weight loss program. *JAMA* 2001;285:1172–1177.

- 1 22. Tate DF, Jackvony EH, Wing RR: Effects of Internet behavioral counseling on weight
2 loss in adults at risk for type 2 diabetes: a randomized trial. *JAMA*
3 2003;289:1833–1836.
- 4 23. Tate DF, Jackvony EH, Wing RR: A randomized trial comparing human e-mail
5 counseling, computer-automated tailored counseling, and no counseling in an Internet
6 weight loss program. *Arch Intern Med* 2006;166:1620–1625.
- 7 24. Patrick K, Raab F, Adams MA, Dillon L, Zabinski M, Rock CL, Griswold WG, Norman
8 GJ: A text message-based intervention for weight loss: randomized controlled trial. *J*
9 *Med Internet Res* 2009;11:e1.
- 10 25. Digenio AG, Mancuso JP, Gerber RA, Dvorak RV: Comparison of methods for
11 delivering a lifestyle modification program for obese patients: a randomized trial. *Ann*
12 *Intern Med* 2009;150:255–262.
- 13 26. Befort CA, Donnelly JE, Sullivan DK, Ellerbeck EF, Perri MG: Group versus
14 individual phone-based obesity treatment for rural women. *Eat Behav* 2010;11:11–17.
- 15 27. Renjilian DA, Perri MG, Nezu AM, McKelvey WF, Shermer RL, Anton SD: Individual
16 versus group therapy for obesity: effects of matching participants to their treatment
17 preferences. *J Consult Clin Psychol* 2001;69:717–721.
- 18

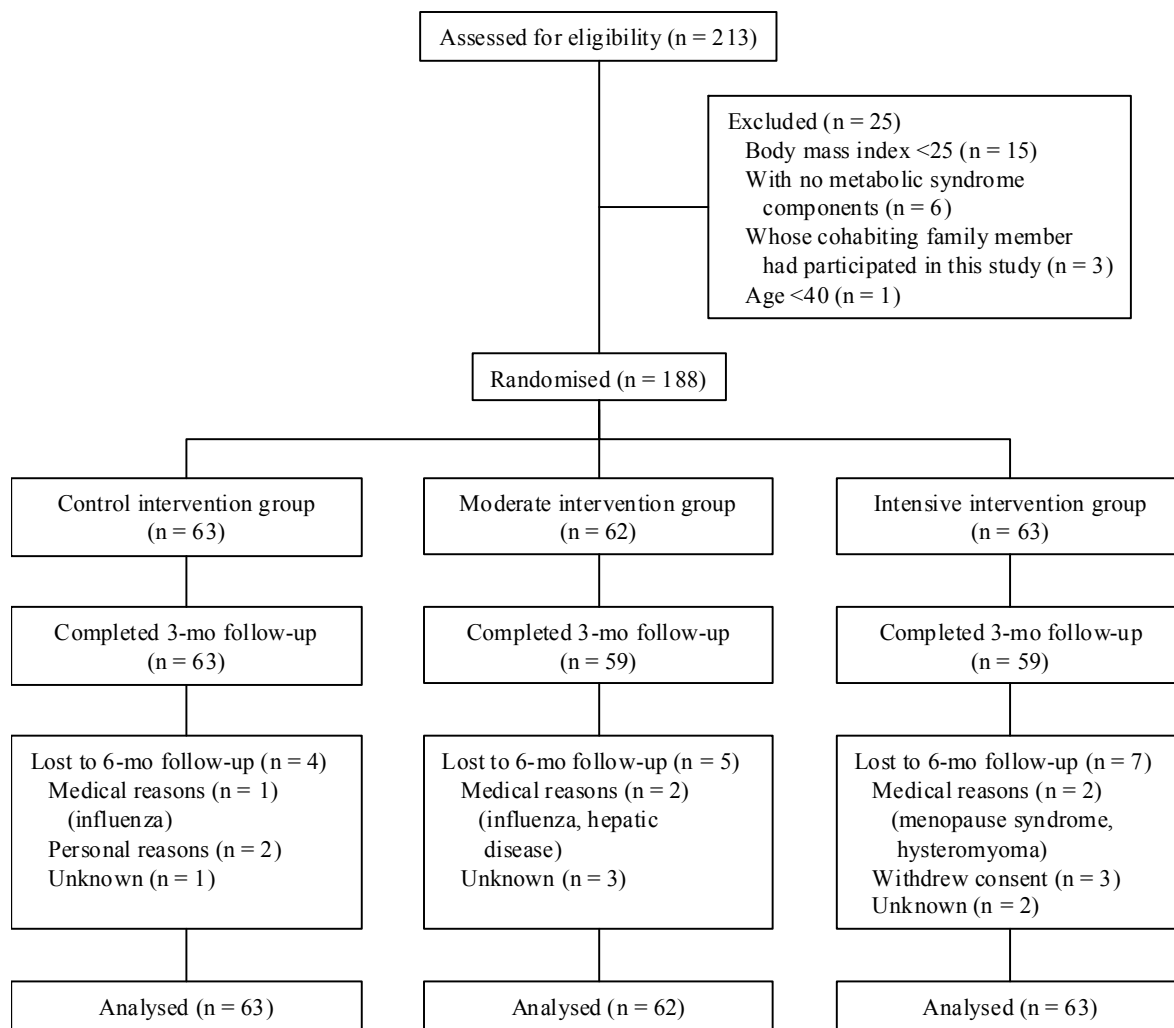
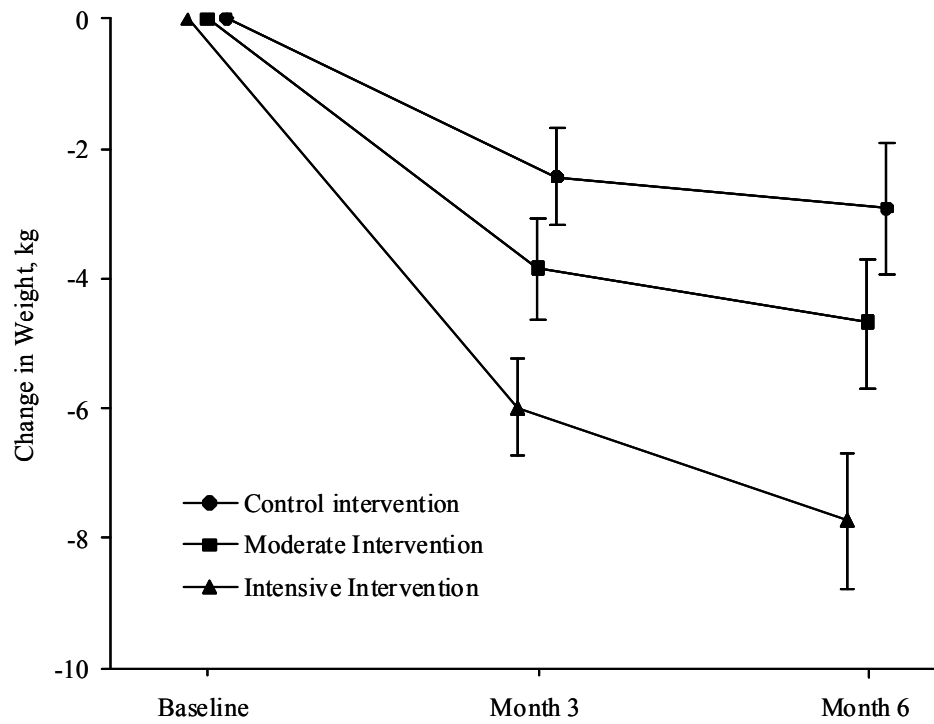


Fig. 1. Flow diagram of participant progress through the phases of the 6-month randomised trial.



1

2

3 **Fig. 2.** Pattern of change in body weight during 6-month intervention by treatment
4 assignment. Each data point represents the mean value for all randomised participants with
5 missing data replaced by the last observation carried forward. Error bars indicate 95%
6 confidence intervals. Points and error bars are jittered horizontally to improve visibility.

Table 1. Baseline characteristics of eligible overweight adults by treatment assignment^a

| | Control intervention (n = 63) | Moderate intervention (n = 62) | Intensive intervention (n = 63) | Total (n = 188) |
|--|-------------------------------------|--------------------------------------|---------------------------------------|--------------------|
| Age, years | 51.6 (6.2) | 51.7 (6.8) | 50.7 (6.7) | 51.3 (6.6) |
| Number of women (%) | 53 (84) | 41 (66) | 51 (81) | 145 (77) |
| Number of current smokers (%) | 4 (6) | 3 (5) | 3 (5) | 10 (5) |
| Number of lipid-lowering therapies (%) | 8 (13) | 9 (15) | 7 (11) | 24 (13) |
| Number of antihypertensive therapies (%) | 15 (24) | 18 (29) | 11 (17) | 44 (23) |
| Height, cm | 157.2 (7.6) | 160.0 (9.0) | 159.1 (7.2) | 158.8 (8.0) |
| Weight, kg | 71.0 (10.1) | 74.9 (12.1) | 73.5 (9.9) | 73.1 (10.8) |
| BMI, kg/m ² | 28.6 (2.8) | 29.2 (3.8) | 29.0 (3.0) | 28.9 (3.2) |
| Waist circumference, cm | 98.7 (7.3) | 100.7 (7.9) | 99.2 (7.3) | 99.5 (7.5) |
| Systolic blood pressure, mm Hg | 131.5 (19.5) | 131.2 (14.5) | 131.9 (16.4) | 131.6 (16.8) |
| Diastolic blood pressure, mm Hg | 78.4 (10.6) | 80.2 (7.4) | 79.9 (10.2) | 79.5 (9.5) |
| Triglycerides, mmol/l | 1.67 (0.91) | 1.80 (0.81) | 1.45 (0.68) | 1.64 (0.82) |
| HDL cholesterol, mmol/l | 1.49 (0.37) | 1.39 (0.34) | 1.49 (0.31) | 1.46 (0.35) |
| Fasting plasma glucose, mmol/l | 5.35 (0.61) | 5.50 (0.96) | 5.25 (0.59) | 5.37 (0.74) |
| Dietary intake, kcal/day | 2050 (397) | 2181 (417) | 2169 (414) | 2133 (411) |
| Step counts, step/day [†] | 5677 (2565) | 6198 (2740) | 6435 (3016) | 6100 (2782) |
| MVPA, min/day [†] | 94 (34) | 86 (30) | 93 (35) | 91 (33) |

HDL = high-density lipoprotein; MVPA = moderate to vigorous physical activity.

^aData are presented as mean (SD) unless otherwise specified.

[†]Eligible data were available for 186 participants (63, 61, and 62 in the control, moderate, and intensive intervention groups, respectively).

Table 2. Changes in primary and secondary outcome measures, dietary intake, and physical activity during 6-month intervention*

| | Control intervention (n = 63) | | | Moderate intervention (n = 62) | | | Intensive intervention (n = 63) | | |
|--------------------------|-------------------------------|--------------|---------------------------|--------------------------------|--------------|---------------------------|---------------------------------|--------------|---------------------------|
| | baseline | month 6 | change | baseline | month 6 | change | baseline | month 6 | change |
| Weight, kg | 71.0 (10.1) | 68.1 (10.5) | -2.9 (-3.9 to -1.9) | 74.9 (12.1) | 70.2 (12.6) | -4.7 (-5.7 to -3.7) | 73.5 (9.9) | 65.7 (9.5) | -7.7 (-8.8 to -6.7) |
| BMI, kg/m ² | 28.6 (2.8) | 27.5 (3.2) | -1.2 (-1.6 to -0.8) | 29.2 (3.8) | 27.4 (4.0) | -1.8 (-2.2 to -1.5) | 29.0 (3.0) | 25.9 (3.0) | -3.0 (-3.4 to -2.6) |
| WC, cm | 98.7 (7.3) | 95.8 (8.1) | -3.0 (-4.1 to -1.8) | 100.7 (7.9) | 96.0 (9.1) | -4.7 (-5.9 to -3.6) | 99.2 (7.3) | 91.1 (8.4) | -8.1 (-9.2 to -7.0) |
| SBP, mm Hg | 131.5 (19.5) | 122.9 (19.1) | -8.7 (-12.4 to -4.9) | 131.2 (14.5) | 120.5 (13.3) | -10.7 (-13.8 to -7.6) | 131.9 (16.4) | 119.6 (18.1) | -12.3 (-15.8 to -8.8) |
| DBP, mm Hg | 78.4 (10.6) | 72.9 (10.5) | -5.5 (-7.6 to -3.3) | 80.2 (7.4) | 73.2 (9.1) | -7.0 (-8.7 to -5.3) | 79.9 (10.2) | 71.3 (9.7) | -8.6 (-10.6 to -6.6) |
| TG, mmol/l | 1.67 (0.91) | 1.52 (0.93) | -0.15 (-0.34 to 0.04) | 1.80 (0.81) | 1.41 (0.79) | -0.39 (-0.56 to -0.23) | 1.45 (0.68) | 1.10 (0.50) | -0.35 (-0.51 to -0.19) |
| HDL-C, mol/l | 1.49 (0.37) | 1.52 (0.40) | 0.03 (-0.03 to 0.09) | 1.39 (0.34) | 1.44 (0.35) | 0.05 (-0.01 to 0.11) | 1.49 (0.31) | 1.56 (0.35) | 0.07 (0.02 to 0.13) |
| FPG, mmol/l | 5.35 (0.61) | 5.03 (0.62) | -0.32 (-0.41 to -0.24) | 5.50 (0.96) | 5.16 (0.82) | -0.34 (-0.47 to -0.20) | 5.25 (0.59) | 4.91 (0.38) | -0.34 (-0.44 to -0.23) |
| Dietary intake, kcal/day | 2050 (397) | 1816 (361) | -234 (-340 to -128) | 2181 (417) | 1799 (440) | -382 (-470 to -294) | 2169 (414) | 1524 (354) | -646 (-751 to -540) |
| Step counts, step/day‡ | 5677 (2565) | 6912 (3177) | 1235 (706 to 1765) | 6198 (2740) | 7468 (3676) | 1270 (682 to 1859) | 6435 (3016) | 7525 (3326) | 1090 (590 to 1590) |
| MVPA, min/day‡ | 94 (34) | 102 (41) | 8 (2 to 15) | 86 (30) | 95 (37) | 10 (4 to 16) | 93 (35) | 98 (36) | 5 (0 to 11) |

DBP = diastolic blood pressure; FPG = fasting plasma glucose; HDL-C = high-density lipoprotein cholesterol; MVPA = moderate to vigorous physical activity; SBP = systolic blood pressure; TG = triglycerides; WC = waist circumference.

*Data at baseline and 6 months are presented as mean (SD). Changes from baseline are presented as mean (95% confidence interval). The numbers of completers are 59, 57, and 56 in the control, moderate, and intensive intervention groups, respectively. For intention-to-treat analysis, the missing data are replaced by the last observation carried forward.

‡Eligible data were available for 186 participants (63, 61, and 62 in the control, moderate, and intensive intervention groups, respectively).