The Effectiveness of a Multicomponent Program for Nutrition and Physical Activity Change in Clinical Setting: Short-term Effects of PACE+ Japan


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The purpose of this study was to verify the effectiveness of a multi-component program (PACE+ Japan) for nutritional improvement and changes in physical activity in a clinical setting. PACE+ Japan consists of lifestyle assessment and making an action plan using a computer, in combination with counseling from a physician. Outpatients with lifestyle related diseases were allocated randomly to two groups; a PACE+ Japan only group (n=26) and a PACE+ Japan & follow-up counseling group (n=25) and an age- and sex-matched control group (n=16) was also selected. The patients in all intervention groups completed a computerized assessment and created action plans to aid in physical activity and nutritional behavior. PACE+ Japan & follow-up counseling group received approximately 20 minutes counseling two weeks after PACE+ Japan. The control group received no intervention. The analysis of results one month after intervention showed an improvement in physical activity and a reduction in the total energy intake for the intervention group in comparison with that of the control group. There was no observable difference in other indices for the three groups. PACE+ Japan has a high usability and physician counseling was highly evaluated. In the future, effective follow-up in maintaining the effect will be pursued.

Keywords: clinical setting, interactive health communication, behavior modification, physical activity, nutrition

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1. Introduction

Physical inactivity and poor nutritional practices are closely linked to the causes of disease and death. Previous studies showed that improvement in eating habits and increased physical activity are very effective in preventing lifestyle related diseases such as hypertension, type 2 diabetes mellitus, and obesity [U.S. Department of Health and Human Services (1991), Sallis and Owen (1999)]. Generally it is not easy for an individual to modify their life style and even if they succeeded in modifying it, maintaining the new regime can be difficult. With regard to this problem, behavior modification approaches have been applied to life style interventions and it is reported that they are more effective than conventional health education and health
These approaches are based on behavioral theory and social cognitive theory, including stimulus control, self-monitoring, goal setting, goal attainment, behavioral contracting, and so on. Also, [Prochaska et al. (1983)] proposed the importance of stages of behavior change. This concept has been widely recognized and the effectiveness of many lifestyle interventions based on this concept has been verified [Marcus et al. (1992, 97); Dunn et al. (1999)]. In spite of these research trials, the chance for the health care professionals to learn the effective methods of behavior change is very limited and behavioral intervention in the clinical setting is not yet popular. The clinics and university hospitals may be an important setting in which to begin changing the population’s physical activity levels and poor nutritional practices, because the subjects include every type of social group with lifestyle related diseases and potential patients who can be contacted and found. In order to diffuse effective behavioral intervention, not only the continuous education of medical workers, but also the developments of a program which can be applied at ease to the patients by simple education are highly demanded. In order to solve these problems, Patrick, K., Sallis, J.F., et al., developed the program with a medium of printout based on the social cognitive theory [Bandura (1977)] and stage theory [Prochaska and DiClemente (1983)] so that the patients themselves can self determine the target of lifestyle improvement. They have verified its effectiveness [Calfas et al. (1996, 97); Norris et al. (2000)]. This program is under development in combination with computer program and physician counseling, so-called PACE+ (Patient-centered Assessment and Counseling for Exercise plus nutrition). They are intended to increase the levels of physical activity and modify eating habits, therefore, after an evaluation of lifestyle on computer, a plan is designed to prepare for the change of lifestyle. It is discussed face to face with a physician. With regard to PACE+, its effectiveness has been verified using patients and junior high school students. It is reported that PACE+ is effective in promoting physical activity and modifying eating habit [Prochaska (2000); Patrick (2001); Calfas (2002)]. However, until now the effectiveness of this program in comparison with normal medical examinations by physician has never been investigated. This study was intended to investigate the possibility of lifestyle intervention by using above-mentioned computer program into Japanese clinic setting. In general, the process of behavior change is divided into two stages. The adoption of a target behavior and the maintenance of target behavior. Health behaviors in both stages are influenced by various socio-psychological factors [Sallis (1986)]. Therefore, in this study, by taking into account adoption and maintenance, 6 month behavioral intervention was planned. Consequently, in order to investigate the influence of PACE+ Japan on the adoption stage of behavior, we paid an attention to the short term effect of one month after intervention and the following points were investigated in this report; 1) Investigated the effectiveness from the viewpoint of behavior aspect and physiological aspect in comparison with the conventional medical treatment. 2) Investigated the usability of program using computer.

2. Methods

2.1. Subjects

Outpatients of cardiovascular department at university hospital qualified to have the following conditions were screened; they are suffering from either of essential hypertension, hyperlipidemia, type 2 diabetes mellitus, they never received any periodical diet/exercise instruction or health education, they have eating habit to be improved in vegetable eating, fat taking, salt taking or over eating, they take no habitual exercise or vigorous exercise less than three times per week for more than 20 min or moderate exercise of more than 30 min or less than 2 hours per week. Five physicians in charge of outpatients were involved in the recruitment of the subjects. It took them about one year to recruit them. The final participants are 67 subjects (35 males and 32
females) and mean age are 61.2 ± 9.9 years old (Tab. 1). The study program was approved by the ethics committee of the medical department of Fukuoka University.

2.2. Program content and modified points in Japanese version.

In our study, we used [PACE+ Japan] developed by OMRON Healthcare Co., Ltd based on [PACE+] developed by Patrick, K., Sallis, J.F. et al.. This program consists of an evaluation of lifestyle and determination of behavior plan (using computer) and physician counseling (face to face). It takes about 40-50 minutes. Health behaviors to be checked are 2 items of physical activities (vigorous and moderate exercise) and 4 items of nutrition (fat taking, vegetable taking, overeating and salt taking) in total 6 items. First priority was given to self determination of the subject in this program and the subject chose 1 item of physical activity and 1 item of nutrition as target behavior. Then, action plan sheet including benefits of self determined behaviors, tips on dealing with barriers to practicing targeted behavior is printed out. Based on the output result, physician made a counseling of about 5 minutes. The content of counseling includes; confirmation of target behavior, confirmation of patient confidence in goal attainment, encouraging the patient, making a signature on the action plan sheet and hand it over to the patient in a sense of agreement of action plan and support to the patient. Modified points in Japanese version includes; by taking into account of Japanese specialty, increase of fruit eating was deleted. Instead, salt taking is added, the document summarizing the points of counseling according to the characteristics of the patient is prepared to facilitate the counseling of the physician.

The physician received only one lesson of about 40 minutes comprising of outline of PACE+ Japan and counseling procedure guided by printed action plan sheet by behavior scientist.

2.3. Procedures and intervention

The recruited patient signed a paper of consent agreeing with the protocol and then received an accelerometer to measure physical activity before the intervention. All patients received medical advice once every month. At the time of medical examination after one month of patients consent, baseline measurement for example eating, lifestyle, blood pressure, body fat rate, spot urine test and blood test was made (one month before intervention).

In this study, three groups, PACE+ Japan only group, PACE+ Japan & follow-up counseling group and control group were formed. Two groups with intervention were asked to come to the hospital one hour before their appointment time one month after the baseline measurement were taken they received computer program. All the data inputs were made by the assistant of the hospital. Thereafter, based on printed action plan sheet, they received the counseling of the physician. This is the only one intervention for PACE+ Japan only group. PACE+ Japan & follow-up counseling group were

| Tab. 1. Patient Demographic and Clinical Characteristics at Baseline |
|-----------------|-----------------|-----------------|-----------------|
|                  | Pace+ Japan  | Pace+ Japan & follow up | Control |
|                  | (n=26)        | (n=25)           | (n=16)         | Analysis of variance |
| Male : Female    | 14:12         | 13:12            | 8:8            |                         |
| Age              | 60±9.7        | 60±7.2           | 63±13.4        | n.s.                      |
| Weight (kg)      | 68.9±9.2*     | 65.3±11.0        | 58.6±10.8      | p <.05                    |
| BMI (kg/m²)      | 26.3±3.7*     | 25.7±3.6*        | 22.9±2.7       | p <.01                    |
| % Body Fat       | 30.4±6.1      | 30.8±6.3         | 26.6±6.6       | n.s.                      |
| Exercise energy expenditure (kcal/day) | 166.7±83.0 | 161.9±78.9 | 173.8±76.8 | n.s. |
| Total energy expenditure (kcal/day) | 1876.3±207.1 | 1804.8±261.2 | 1751.9±266.4 | n.s. |
| Total energy intake (kcal) | 1967.8±203.6 | 1895.0±196.9 | 1879.1±150.7 | n.s. |
| SBP (mmHg)       | 136.8±18.1    | 134.4±14.3       | 136.6±17.3     | n.s.                      |
| DBP (mmHg)       | 80.3±9.8      | 83.2±8.8         | 81.7±13.3      | n.s.                      |
| Total cholesterol (mg/dl) | 206.6±36.5 | 208.4±35.0 | 196.1±27.6 | n.s. |
| Triglyceride (mg/dl) | 234.5±177.8 | 141.0±67.5 | 183.9±179.7 | n.s. |
| HDL cholesterol (mg/dl) | 53.6±21.4 | 61.0±14.9 | 55.3±17.7 | n.s. |
| Glucose (mg/dl)  | 104.3±26.5    | 111.6±26.1       | 109.0±19.7     | n.s.                      |

Chi-square test

Essential hypertension n=24 (92%) n=19 (76%) n=16 (100%) n.s.  
Hyperlipidemia n=17 (65%) n=20 (80%) n=4 (25%) p <.01  
Diabetes mellitus n= 7 (27%) n= 8 (32%) n= 2 (13%) p <.01

BMI: body mass index * vs. Control

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asked to come to the hospital again 2 weeks after PACE+ Japan and received one counseling for about 20 minutes. The content of counseling includes confirmation of the goal, confirmation of factors hindering achievement of the goal and how to deal with them. The counselor at this time was a female assistant engaged in data input at PACE+ Japan, who was fresh from graduation of the university and received 5 hours training in counseling techniques based on behavioral therapy. The patients of this group, thereafter, received a total of 5 counseling sessions at a rate of one every month. At each counseling session they received 20 minutes of counseling prior to medical advice from the physician. But as the intervention is not yet finished, the effect of its intervention will not be dealt in this study. The patients of control group received normal medical advice and put on accelerometer periodically. They were handed over a general health promotion booklet. No other intervention is given to them (Fig. 1).

2.4. Measures

All the patients were basically required to put on an accelerometer (Lifecorder, Suzuken Inc.) attached at the waist, from waking-up until going-to bed in order to investigate the effect of intervention on daily physical activity. As a representative value of each measuring period, a mean value of one month was used. Then total energy expenditure and energy expenditure due to exercise were analyzed. The accelerometer used in this study is reported to be adequate as it correlates closely with metabolic chamber which is regarded as a standard, i.e., the correlation in terms of total energy expenditure and energy exercise expenditure are 0.89 and 0.66 respectively [Tanaka (2000)]. Semi-quantitative food frequency questionnaire (FFQW65) comprising of 65 items was used to measure total energy intake. FFQW65 is a questionnaire for responding frequency and quantity of food eaten for a recent month. FFQW65 is correlated with the most accurate weighed dietary record (r=0.64) and its validity is examined [Yamaoka (2000)]. Although original format is based on self-administered method, we applied the interview method for reasons of enhancing accuracy in our study. Other measured items are height, weight, percent body fat, systolic blood pressure (SBP), diastolic blood pressure (DBP). Measurement of body weight was made once by using a scale to be measured by 50g unit. The weight was calculated from the indicated figure minus 1kg (weight of cloth). The measurement of percent body fat was made by body fat scale (HBF-302, Omron, Inc.) using BI method at both arms. The measured value by HBF-302 is reported to be appropriate as the correlation with the under water method is relatively high (r = 0.70-0.76) [Okuno (2000)]. Measurement of percentage body fat was made once and the indicated value was used. Measurement of blood pressure was made by using an automatic blood pressure meter (HEM-906, Omron, Inc.) using the oscillometric method. After taking five deep breaths, blood pressure was measured three times and the mean of three measurements was used. At the same time, lipid and glucose metabolism indices was
measured, but as no measurement was made after one month of intervention for the control group, this is not discussed in this article. Acceptability ratings from patients indicating the level of satisfaction with the computer were collected after PACE+ Japan implementation. Furthermore, a satisfaction rating of physician counseling by the patients was also made one month after intervention. Most satisfaction questions were scored on a 5-point Likert-type scale from 1 ("Not at all helpful") to 5 ("Very helpful").

2.5. Analysis

Three sets of primary analyses were conducted. First, in order to check whether there was any difference in basic property, physical activity and energy intake at baseline among three groups, one-way ANOVA and chi-square analyses (condition) was conducted. Second, to confirm the effect of intervention, the quantity of change before and after intervention was calculated and then a one-way ANOVA (condition) was made on each of the dependent variables. The third set of analyses determined the differential effect of targeting a behavior for change [Target (chosen for action plan vs. not chosen) × Time repeated-measures ANOVAs] on the three nutrition variables. LSD was used as multiple comparisons. All analyses were conducted using STATISTICA for Windows and statistical significance was set at an alpha level of 0.05.

3. Results

3.1. Patient background

Out of 67 patients, 64 patients took medicine in some way during intervention period. There were 2 patients in PACE+ Japan only group for whom it was not necessary to take medicine. The percentage of patients who modified the medicine 23% (3 increase / 3 reduction), 16% (3 increase / 1 reduction) and 19% (2 increase / 1 reduction) for PACE+ Japan only group, PACE+ Japan & follow-up counseling group and control group respectively. As there is no significant difference between the groups, no special attention was paid to this aspect in our analysis. Random assignment was made between PACE+ Japan only and PACE+ Japan & follow-up counseling in our study. Control group consisted of the outpatients with the same life style related disease. Consequently, the weight of the control group was significantly lower than that of PACE+ Japan only group (p < 0.05) and BMI of control group was significantly lower than that of PACE+ Japan only and PACE+ Japan & follow-up counseling (p < 0.01). Although the rate of essential hypertension was not different among three groups, the rates of hyperlipidemia ($\chi^2 = 10.4$, p < 0.01) and diabetes mellitus ($\chi^2 = 31.2$, p < 0.01) were different. With regard to the number of patients, the number of hyperlipidemia and diabetes mellitus of control group was lower than that of intervention group as shown in Tab. 1. Although the difference in the patient background before the intervention was partly observed among three groups, we proceeded our study without paying further attention of this aspect for the following reason; there were no differences in physical activity, intake energy and the lipid and glucose metabolism indices and all patients never received any periodical diet/exercise instruction or health education. All of the patients chose moderate exercise as a target of physical activity at the initial PACE+ Japan execution. The target behavior of nutrition was fat intake (29.4%), vegetable intake (27.5%), over eating (7.8%) and salt reduction (35.3%).

3.2. The change of physical activity

In order to investigate the influence of PACE+ Japan intervention on daily life physical activity, we calculated the change of exercise energy expenditure (EEE) measured by an accelerometer before and one month after intervention. As a result, 35.1 ± 62.1kcal/day and 22.5 ± 41.3 kcal/day of the improvement were observed for PACE+ Japan only group and PACE+ Japan & follow-up counseling group respectively. No change was observed for control group with the change of -8.9 ± 41.4 kcal/day. One-way ANOVA (condition) revealed a significant main effect in the change of EEE [F (2, 64) = 3.82, p < 0.05]. LSD showed the result that EEE of PACE+ Japan only was significantly improved over that of the control group. Similarly, with regard
to total energy expenditure (TEE), 34.1 ± 89.7 kcal/day and 38.5 ± 74.3 kcal/day improvement were observed for PACE+ Japan only group and PACE+ Japan & follow-up counseling group respectively. Degradation was observed for the control group with the change of -36.5 ± 67.6 kcal/day. One-way ANOVA (condition) revealed a significant main effect in the change of TEE [F (2, 64) = 5.15, p < 0.01]. LSD showed the result that change of TEE of the both intervention group were significantly higher than that of control group as shown in Fig. 2.

### 3.3. Change of energy intake

The change of total energy intake (TEI) before and one month after intervention was calculated based on TEI measured by FFQW65 to investigate the influence of PACE+ Japan intervention. As a result, a reduction of -160.2 ± 177.1 kcal/day and -87.3 ± 157.6 kcal/day were observed for PACE+ Japan only and PACE+ Japan & follow up respectively. No change was observed for control group with the change of 1.9 ± 163.9 kcal/day. One-way ANOVA (condition) revealed significant main effect in the change of TEI [F (2, 64) = 4.71, p < 0.05]. LSD showed the result that change of TEI of PACE+ Japan only was significantly higher than that of control group as shown in Fig. 2. Furthermore, in order to investigate whether PACE+ Japan intervention gave specific influence on the improvement of eating habits as a target, the change of energy intake in separating targeted behavior and non-targeted behavior was calculated by using only the data of intervention groups. From FFQW65, fat intake was obtained from item of [meat] and [oil/fat], vegetable intake was calculated from item of [vegetable], salt intake was calculated from the total of the foods containing salt such as bread, ham, sausage, noodle and miso soup etc. Only 4 patients proposed improvement of [over eating] as target behavior, therefore, this item was neglected in our analysis. As a result of ANOVA with two factors (time, target/non-targeted), there were significant main effects of time for fat intake [F (1, 49) = 21.16, p < 0.01], reduction of salt [F (1, 49) = 5.93, p < 0.05] and vegetable intake [F (1, 49) = 8.11, p <0.01]. But no difference was observed between target behavior / non-targeted behavior.

### 3.4. Change of clinical characteristics
No differences were observed among three groups in the change of other items such as weight, body fat rate, SBP, and DBP as shown in Tab. 2.

### 3.5. Ratings of PACE+ Japan components and physician counseling

With regard to satisfaction with the computer program, 80% of patients responded [very satisfied] or [satisfied]. 88% of patients responded [very appropriate] or [appropriate] concerning the appropriateness of the advice. 95% of patients replied that time required for the test was [acceptable]. Regarding form of data input, the current method, interview method, touch panel, and questionnaire paper were agreeable to 59% of patients, 26%, 9%, and 3% respectively. From the above result, it is shown that the computer program in our study had a good usability. According to the report of the patients (n=40), the time spent by the physician for the PACE+ Japan counseling excluding normal medical examination was 3.8 minutes (mean) for exercise and 3.4 minutes (mean) for eating. The helpfulness of printed materials was 4.3±1.3 points out of 5 and the helpfulness of counseling by the physician was 4.2±1.0. The degree of improvement in medical examination was 3.7±1.0. Other ratings are shown in Tab. 3.

### 4. Discussion

In this study, we investigated the effectiveness of computer program and physician counseling for the purpose of modification of physical activity and eating habits of outpatients with lifestyle-related diseases. Although intervention plan included a periodical 6-month follow-up counseling, the effect of intervention on the initiation of target behavior was assessed one month after intervention. As a result, the patients who made an action plan in line with the computer program before medical examination and received the counseling from the physician based on the action plan showed an improvement in physical activity and reduction of intake energy compared to the patient who received conventional medical advice. That means, PACE+ Japan is superior to the normal medical advice as a support system for the outpatients requiring a modification of lifestyle. PACE+ Japan has the following characteristics: 1) The decision of improvement target behavior was left to the patient. 2) A target behavior was set by the patient after recognizing their own problems. 3) The progress of the program and the output information depended on the content of individual input, they are very interactive. 4) There is a final confirmation and encouragement by the physician on the action plan. These compositions may have accelerated the initiation of target behavior. The characteristics of this program is not only the making of a computer program but also face to face counseling with a physician. As many patients believe that physician advice is reliable, this procedure is supposed to be effective. However, we did not set up the intervention group without physician counseling in our study.

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<th>Tab. 2. Change of clinical characteristics</th>
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<th>Tab. 3. Ratings of PACE+ Components and Physician Counseling</th>
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<td>PACE+ Japan Components</td>
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<td>Impression of assistant</td>
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therefore, it is difficult to make a final decision. There are many studies reported that face to face counseling is effective in life style modification programmes in a clinical setting [Harris (1989)]. But expert counselors are not always available in the clinical setting. The application of a computer program is considered to be a useful approach in spreading effective intervention in the clinical setting.

In general, it is said that the time spent on the patient by the physician is very limited and less than 10 minutes at 66% of hospitals [Department of statistics and information, Japan Ministry of Health and Welfare (1999)]. In PACE+ Japan, the assessment of life style was made beforehand and action plan was prepared before medical advice was given. This supporting system may reduce the burden on the physician and enable them to give effective advice within the limited time. No difference was observed in intervention effects between PACE+ Japan only and PACE+ Japan & follow-up group. The difference of intervention is the existence of one follow-up counseling two weeks after PACE+ execution. If PACE+ Japan intervention is already received, one follow-up counseling after two weeks is considered to be not influential in promotion of target behavior in short term. In other studies using same program, the effectiveness of follow-up by telephone and letter were investigated, but the result was not superior to that of PACE+ Japan only. Continuous follow-up is thought to be effective in maintaining target behavior. But not so many points are unknown as to what kind of follow-up is more effective. At present, total of five counseling sessions at a rate of one per month is under way for the patients of PACE+ Japan & follow-up counseling group. The results will be followed up by future investigations. We found no difference in the change in calorie intake between targeted eating behavior and non-targeted eating behavior, which was different from the previous study [Calfas et al. (2002)]. Since the intervention effect of our study was something out of ordinary, it may have worked as a good opportunity to start life style modification, rather than being due to program structure and content. However, in our study, all of the patients had life style related diseases and the mean of body fat rate was 30%. 37% of the patients had plural diseases. Therefore, patient background is different from the previous study. Hence, there is a possibility that the patient setting a target [reduction of salt] in program procedure (only one target), may intend to improve also in problems in over eating and decrease of fat taking. Furthermore, FFQW65 used in the analysis is high in the appropriateness of total energy intake but the appropriateness of each food classification is scattered [Yamaoka et al. (2000)]. Especially, regarding [vegetable], the correlation with weighed dietary record was 0.15-0.18 and regarding [oil and fat], it was 0.36-0.38. These correlations were relatively low. If evaluating intervention effect by each food classification, reanalysis is necessary by using more sensitive index. With regard to weight, body fat and blood pressure, no intervention effect in the short term was realized. In the short term such as one month, physical activity change may not soon influence the assessment value. But when watching the quantity of change among three groups (Tab. 2.), the intervention group showed a decreased tendency. With regard to intervention effects in a physiological aspect, it is necessary to review the data 6 months after intervention together with blood test results in the future.

A major limitation of current study was that random assignment was not performed between interventions group and control group. In fact, there is a difference in weight and BMI before intervention among the groups. The difference in clinical characteristics may have influenced the result. But there are no differences in activity aspects such as life style between the groups. In addition, analysis was based on the quantity of change, therefore, its influence was thought to be not so significant. Regarding usability (ease-of-use) of computer program, most of the items received high evaluation points. Hence, minor modifications may make it possible to apply it to the clinical setting. The only point at issue is keyboard input. Although 60% of the patients agreed with the current system concerning the form of input, it is desirable to modify the interface so that it can be used by more patients with ease, allowing more widespread use. On obtaining all data for a 6 month period, not only will the effect of follow-up counseling and physical activity aspects but also the physiological aspects
including the blood test data will be investigated.

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