



Lifestyle intervention to improve cardiovascular risk factors in middle-aged adults with metabolic syndrome

Norma P. Rodriguez-Rocha*, 김수경*, 김혜경**†

*이화여자대학교 일반대학원 융합보건학과 대학원생, **이화여자대학교 융합보건학과 부교수

Lifestyle intervention to improve cardiovascular risk factors in middle-aged adults with metabolic syndrome

Norma P. Rodriguez-Rocha*, Soo Kyoung Kim*, Hyekyeong Kim**†

* Graduate student, Department of Health Convergence, Graduate School of Ewha Womans University

** Associate professor, Department of Health Convergence, Ewha Womans University

Objectives: Metabolic syndrome prevalence among Korean adults is high and even though efforts have been made to reduce it, the numbers have remained steady for the past 9 years. This study aimed to develop a lifestyle intervention for the management and prevention of metabolic syndrome using a theoretical approach. **Methods:** Intervention contents were developed in a 2-phased process, the initial phase consisted in the review of theory and evidence, and in the second phase the intervention content was developed, including the creation of an intervention matrix. The development of the content was informed by the Transtheoretical Model. **Results:** The lifestyle intervention included two components, a 12-week counseling program, including strategies to target specific constructs (e.g. decisional balance, self-efficacy, stimulus control) and the distribution of twelve-monthly newsletters including information such as healthy recipes and other healthy lifestyle behaviors (e.g. stress management, exercising). **Conclusions:** To be able to develop an intervention that can be further tested for its effectiveness is paramount to create an intervention matrix and to systematically report the process through which the intervention contents were developed. This study can be useful to inform the development of new interventions for health behavior modification.

Key words: metabolic syndrome, intervention development, theory matrix, transtheoretical model, lifestyle modification

I. Introduction

Metabolic syndrome (MS) refers to a cluster of conditions which occur simultaneously, represented by abdominal obesity, high blood pressure, high blood glucose levels, and abnormal lipid levels. According to the Korea National Health and Nutrition Examination Survey (KNHANES), the estimated prevalence of MS

among Korean adults in 2015 was 22.4%, and the overall prevalence has remained stable for the past nine years. MS increases the risk to develop cardiovascular diseases and type 2 diabetes (T2DM) (Galassi, Reynolds, & He, 2006; Gami et al., 2007; Mottillo et al., 2010; Wilson, D'Agostino, Parise, Sullivan, & Meigs, 2005). Due to the high prevalence of MS among Korean adult population, urgent

Corresponding author: Hyekyeong Kim

Department of Health Convergence, Ewha Womans University, 52, Ewhayeodae-gil, Seodaemun-gu, Seoul, 03760, Republic of Korea

주소: (03760) 서울시 서대문구 이화여대길 52 이화여자대학교 융합보건학과

Tel: +82-2-3277-4646, Fax: +82-2-3277-2867, E-mail: hkim@ewha.ac.kr

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measures to reduce the social problems caused by the increase in medical expenses and reduced productivity are required. To prevent and manage metabolic syndrome, it is essential to modify lifestyle habits such as: having a healthy diet, increasing physical activity levels, smoking cessation, reduce alcohol consumption, and manage stress levels (Cornier et al., 2008; Haffner, 2006). Nonetheless, to the best of our knowledge, there are no multi-component lifestyle programs that target all of these behaviors. In fact, in a systematic review conducted by Lin et al. (2014), only five randomized controlled trial (RCT) studies were identified that used multi-component interventions for MS and other quality of life indicators, and these interventions only included diet and exercise as target behaviors. Therefore, developing an intervention that includes all the behaviors related to MS indicators is paramount to enhance effectiveness.

The Transtheoretical Model (TTM) is considered an integrative model of behavior change which combines various kinds of process oriented variables to explain and predict how and when individuals change their own behaviors (Johnson et al., 2008). These variables include decisional balance, self-efficacy, and processes of change. Each of these constructs have a main role or work better at particular stages of change, helping to reduce resistance to change (precontemplation), facilitate progress to a further stage (contemplation, preparation), and prevent relapse (action, maintenance) (Prochaska, Redding, & Evers, 2015). According to previous studies, interventions based on TTM had significant effects on the improvement of self-monitoring on healthy eating (Jones et al., 2003), better quality diet, and increased levels of physical activity (Johnson et al., 2006; Prochaska et al., 2005). Particularly, the TTM is one of the very few behavior change theories that include in its model the time factor, which is represented by the five stages of change: precontemplation, contemplation, preparation,

action, and maintenance. This categorization allows the practitioners to tailor their interventions according to the individual's stage of change and to apply the constructs that the theory postulates that better work for each stage, allowing for transition to further stages. Nonetheless, little is known about the effectiveness of the use of the TTM for lifestyle interventions targeting MS. Thus, for the development of this intervention program, a 2-phased process was chosen. The first phase consisted of a literature review to support the selection of the behavior modification theory to be used, while the second phase was the development of the intervention.

The purpose of this study was to develop a theory-based, multi-component program, targeting lifestyle modification for the management of metabolic syndrome. Intervention development was carried out following a systematic process and obtaining an intervention matrix that might serve as a basis for a further intervention effectiveness evaluation through an experimental study design.

II. Methods

A 2-phased process was used for the development of the intervention. This method has been previously suggested as an approach to develop interventions that will subsequently be tested in a randomized controlled trial (Hardeman et al., 2005). The research team used an intervention matrix approach to define the methods, strategies, contents, and outcomes. This method has been used previously for the development of other health behavior modification interventions (Byrd et al., 2012; McEachan, Lawton, Jackson, Conner, & Lunt, 2008).

1. Phase 1: literature review

The research team conducted a literature review of

evidence on metabolic syndrome prevalence among Korean adults and examined the results of a mixed-methods study on the patterns of MS among Korean population. Additionally, a review of health behavior theories used for MS interventions was conducted to inform the decision of the behavioral theory to be used and the type of intervention that would be developed. Because the main objective of the review was to identify the most effective interventions and their characteristics, studies using RCT designs to evaluate behavioral interventions for adults with MS were searched first. In a second and less strict search, studies evaluating interventions for MS (regardless of the study design), were identified. Lastly, studies evaluating interventions aiming at least two health behaviors related to MS, applying experimental designs were searched. Because this is not a systematic review but a common review of the literature, detailed eligibility criteria were not defined. Instead it was decided to go from a stricter to a less strict search method in order to identify interventions effectiveness, and the gaps in the literature related to the implementation of multi-component lifestyle interventions for MS. Moreover, given that there are few studies using RCTs to test effectiveness of interventions for MS among Korean population, it was decided to include in the review studies among non-Korean population as well. After reviewing the literature and discussing the findings, the research team decided to develop a multi-component intervention to change health behaviors based on components of the TTM to improve health indicators related to MS, such as waist circumference, fasting blood glucose and blood pressure levels.

A group of experts for the intervention development was formed: clinical nutritionists, medical doctors and nurses, and experts in health behavior modification, health education and health promotion. Once the group of experts was formed,

the second phase consisted in the modelling of the intervention.

2. Phase 2: Intervention matrix & logic model development

To create the “map” of the intervention content and the theory constructs targeted in each session, the research team created a theory matrix. The intervention matrix included: session focus, the theoretical construct targeted; the program contents to be delivered to the participants (inputs); the cognitive elements targeted (short-term outcomes); the behavioral elements to be improved through the short-term outcomes targeted (mid-term outcomes); the health indicators to be improved by targeting the previous outcomes (long-term outcomes); and, the behavior stage of change that is targeted accordingly. To determine the contents of the matrix, a method used previously was applied (French et al., 2012). The research team answered the following questions: What is needed to do differently? Which health behaviors need to be addressed? Which barriers and facilitators need to be addressed? Which TTM constructs and strategies could help individuals to overcome these barriers and enhance the facilitators? And what is the path through which the modification of these behaviors could ultimately improve MS indicators?

Once the intervention matrix was elaborated, a logic model was created which included not only the intervention outcomes and activities for the intervention, but also other outputs that are complementary to the intervention matrix (Figure 1).

The intervention program was divided into two main components: face-to-face counseling sessions, and distribution of newsletters.

a) Face-to-face counseling sessions:

The content of the counseling sessions was defined

and developed based on the three core principles of the TTM: decisional balance (pros and cons), self-efficacy, and processes of change. Among the 10 processes of change presented in the TTM, five constructs were chosen to be included, because of the feasibility of the implementation. Constructs selected were those that are effective in at least one of the stages of change: consciousness raising, self-liberation, counter conditioning, reinforcement management, and stimulus control. Other behavioral strategies included were: outcome expectation, skill-building, goal-setting, and self-monitoring. Additionally, personalized feedback according to the stage of change of each individual was defined for each of the main health behaviors related to MS management: 1) healthy diet, 2) physical activity, 3) moderate alcohol drinking, and 4) smoking cessation.

The group of experts worked together to determine the focus of each session and to define the number of sessions needed. Subsequently, the theoretical constructs to be targeted in each session were determined.

b) Newsletters:

The content was defined in collaboration with the group of clinical nutritionists. To help participants to reinforce their management of MS, health behaviors that could be addressed through newsletters were selected. Eligible behaviors were those that a) could be targeted with brief information; b) could be addressed using information easily understandable to the individuals; c) did not require the provider to explain the contents to the individuals (i.e. the individual could understand the information just by reading it). For this purpose, some of the key elements of plain language defined by Kandula (2009) were used, such as: a) delivering important information first b) breaking complex information into understandable chunks c) using simple language and d) defining technical terms. For the graphic design of the newsletters, a design team was in charge of

working on a couple of prototypes, following the indications of the research team. The designers were instructed to work on newsletter designs that: used attractive colors, used a clean and easy to read font style and size, and to include images that complemented the information presented without taking off the attention from the text.

Healthy diet recipes. The nutritionists determined the recipes to be included in each newsletter. They considered the food items which are low in sodium and rich in nutrients that help to lower blood lipid, blood pressure, and blood glucose levels, as well as to improve digestion, which in turn can help with the management of other indicators of MS.

Healthy lifestyle. Information related to improving health behaviors through lifestyle behaviors was developed based on small behavioral changes that individuals could apply in their everyday life, providing simple information that the average person could understand and would not require much effort or structural change to be adopted.

Additionally, to ensure that the intervention facilitators would consistently deliver the components of the program, a health counseling guideline and health education manual were developed. Likewise, a self-management booklet was created to reinforce the information provided during the counseling sessions.

III. Results

1. Literature review summary

Among the studies using RCT designs to test the effectiveness of behavioral interventions for all the MS indicators, only a small proportion reported the use of a health behavior theory for the development of the interventions. Nonetheless, we found common behavioral strategies used among studies that showed to be effective, such as self-monitoring, goal-setting, and

skill training. Additionally, evidence showing that multi-component lifestyle modification interventions for MS are more effective compared to minimal interventions (e.g. health education counseling only or providing printed health-related information) was found. Most of these multi-component lifestyle interventions target two health behaviors: diet and physical activity. Most importantly, evidence suggests that while pharmacological and lifestyle interventions are effective to reverse MS compared to comparison groups, lifestyle interventions have a higher probability (87%) of being most clinically effective (Dunkley et al., 2012). As mentioned previously, while there is a lack of lifestyle interventions for MS reporting the use of behavior change theories, when reviewing interventions targeting eating behavior modification and physical activity, there is clearer reporting of the use of specific theories for intervention development. In this matter, TTM has been widely used showing positive results to improve dietary habits and increase physical activity.

2. Intervention matrix and logic model

a) Face-to-face counseling sessions

After several months of iteratively working on the development of the intervention contents and structure of the intervention program, a 12-week face-to-face health counseling program was defined, including one counseling session per week, for a total of 12 topics delivered, and each session targeting at least two theoretical constructs (Table 1). Sessions were planned in a way that the content could be tailored to the individual's stage of change for each of the four health behaviors targeted. The provider is instructed to evaluate the stage of change of the patient at the beginning of the session.

A summary of the focus of each session and the reasoning for its decision is presented as follows:

Session 1. Managing MS and health behavior change.

Targeting the constructs consciousness raising, outcome expectation, and self-liberation. This focus was defined for the first session because participants firstly need to be aware of the health problems and implications of MS and have general information about the lifestyle modifications they could make to control MS.

Session 2. Weight control. This session targets the constructs knowledge acquisition, skill-building, goal setting, and self-monitoring. To help participants to lose weight in a healthy manner and reduce waist circumference to decrease other cardiovascular risk factors, this session aims to improve participants' knowledge related to abdominal fat and obesity.

Session 3. Balanced diet and fruits & vegetables consumption increase. This session focuses on knowledge acquisition, decisional balance training, self-efficacy building, goal-setting, skill-building, and self-monitoring. The aim is to provide a more specific dietary counseling, explaining the importance of balanced meals, the food guide and dietary guidelines for Korean adults, and the benefits of eating the recommended daily amount of vegetables and fruits. Focusing on this food group is important because fruits and vegetables provide dietary fiber and other nutrients that are helpful to control MS related health problems, such as blood glucose levels and high blood pressure.

Session 4. Reduction of total caloric intake and low fat diet. This session targets skill-building, self-efficacy building, counterconditioning and stimulus control. The focus is in the regulation of the individual's diet, particularly to reduce the total caloric intake by reducing fat intake.

Session 5. Special diet for risk factor management. This session aims to improve knowledge about dietary fiber, dietary sodium, and low fat dairy products, and building skills to make the eating habit changes necessary to regulate the consumption of these nutrients in the diet.

〈Table 1〉 Intervention matrix

Week	Session focus	Theory based methods & strategies	Program contents (inputs)	Short-term outcomes	Mid-term outcomes	Long-term outcomes
1	Managing MS and health behavior change	<ul style="list-style-type: none"> • Consciousness raising • Outcome expectation raising • Self-liberation 	<ul style="list-style-type: none"> • Overview of the program rationale • Knowledge on the diagnostic criteria and consequences of MS • Participant's MS status and related health behavior problems • Perceived benefits and barriers to change health behaviors • Benefits of healthy lifestyles for managing MS • Personalized lifestyle modification guideline and sign a commitment contract 	<p>Improve:</p> <p>Knowledge, Attitudes, and Outcome expectations related to MS</p>		
2	Weight control	<ul style="list-style-type: none"> • Knowledge acquisition • Skill-building • Goal-setting • Self-monitoring 	<ul style="list-style-type: none"> • Knowledge on health consequences of abdominal fat obesity • Goal setting skills for losing weight • Self-monitoring skills for the body weight and waist circumference • Principle of energy balance • Nutritional assessment and prescription • Setting daily physical activity goals over the next 6 month 	<p>Improve:</p> <p>Knowledge, Attitudes, and Self-efficacy, and Self-control skills related to obesity, weight control, diet, and physical activity</p>	<p>Increase:</p> <p>Weight control behavior</p>	<p>Improve:</p> <p>MS prevalence</p> <p>Waist circumference</p> <p>Weight</p> <p>BMI</p> <p>MS score</p>
3	Balanced diet & Fruits and vegetable intake	<ul style="list-style-type: none"> • Knowledge acquisition • Decisional balance training • Self-efficacy building • Goal-setting • Skill-building • Self-monitoring 	<ul style="list-style-type: none"> • Importance of balanced meal • Food Guide Pyramid and Dietary Guidelines for Korean adults • How to eat a variety of foods from each of the food groups • Benefits of fruits and vegetables intake • Personalized goals for fruits and vegetables intake • Self-monitoring skill for food intake 	<p>Improve:</p> <p>Knowledge, Self-efficacy, and Self-control skills related to diet and healthy eating</p>	<p>Increase:</p> <p>Balanced diet</p> <p>Portion size control</p> <p>Fruits and vegetable intake</p> <p>Low-sodium diet</p>	<p>Improve:</p> <p>MS prevalence</p> <p>Waist circumference</p> <p>Weight</p> <p>BMI</p> <p>MS score</p>

Week	Session focus	Theory based methods & strategies	Program contents (inputs)	Short-term outcomes	Mid-term outcomes	Long-term outcomes
		<ul style="list-style-type: none"> • Skill-building • Self-efficacy building • Stimulus control 	<ul style="list-style-type: none"> • Physical activity guidelines to manage MS: Types, frequency and duration of exercise • Cardio-respiratory endurance activity • Benefits of brisk walking and guides on safe/healthy walking • Resistance exercises • Age-appropriate balance and flexibility exercise 	Self-control skills related to physical activity	Physical activity Managing stress	Waist circumference Weight BMI MS score Stress level Fasting blood glucose
7	Physically active lifestyle	<ul style="list-style-type: none"> • Knowledge acquisition • Skill-building • Self-efficacy building • Stimulus control 	<ul style="list-style-type: none"> • Incorporating physical activity into one's daily lives based on personal preference and life circumstances • Physical activity as a regular and sustainable part of their lives • Strategies to overcome the barriers to physical activity 	Improve: Knowledge, Self-efficacy, and Self-control skills related to maintenance of regular physical activity.	Increase: Weight control behavior Physical activity Managing stress	Improve: MS prevalence Waist circumference Weight BMI MS score Stress level
8	Moderate alcohol drinking & Smoking cessation	<ul style="list-style-type: none"> • Knowledge acquisition • Skill-building • Self-efficacy building • Stimulus control 	<ul style="list-style-type: none"> • Benefits of non-smoking and moderation of alcohol drinking • Smoking cessation techniques • Coping skills for withdrawal symptoms • Coping strategies for high risk situation of smoking and excessive alcohol drinking 	Improve: Knowledge, Attitudes, Outcome expectations, Self-efficacy, and Self-control skills related to smoking cessation and moderate alcohol consumption	Increase: Smoking cessation Moderate alcohol drinking	Improve: MS prevalence Blood pressure MS score

Week	Session focus	Theory based methods & strategies	Program contents (inputs)	Short-term outcomes	Mid-term outcomes	Long-term outcomes
9	Managing stress and depressive mood	<ul style="list-style-type: none"> • Knowledge acquisition • Skill-building 	<ul style="list-style-type: none"> • Definition and consequences of stress Psychological stress and unhealthy behaviors • Evaluating one's stress level and identifying stressors • Coping skills to manage stress • Coping strategies to overcome depressive mood 	<p>Improve:</p> <p>Knowledge, Self-efficacy, and Self-control skills related to stress management and overcoming depressive mood</p>	<p>Increase:</p> <p>Managing stress</p>	<p>Improve:</p> <p>MS prevalence</p> <p>Stress level</p> <p>MS score</p>
10	Regular health check-ups	<ul style="list-style-type: none"> • Knowledge acquisition 	<ul style="list-style-type: none"> • Importance of regular medical check-ups • Personalized information on the kinds and interval of medical check-ups 	<p>Improve:</p> <p>Knowledge and Attitudes related to taking regular medical check-ups</p>		
11-12	Maintaining healthy lifestyle	<ul style="list-style-type: none"> • Personalized feedback • Self-efficacy building • Reinforcement management 	<ul style="list-style-type: none"> • Modifying undesirable attribution • Reassessing one's current status of MS and related health behaviors • Providing personalized feedback on the effects of the program on the MS status and lifestyle behaviors • Providing rewards for the completion of the study 	<p>Improve:</p> <p>Knowledge, Attitudes, Self-efficacy, and Self-control skills related to the management of MS</p>	<p>Increase:</p> <p>Weight control behavior</p> <p>Physical activity</p> <p>Smoking Cessation</p> <p>Moderate alcohol drinking</p> <p>Managing stress</p>	<p>Improve:</p> <p>MS prevalence</p> <p>Waist circumference</p> <p>Weight</p> <p>BMI</p> <p>Blood pressure</p> <p>MS score</p> <p>Stress level</p>

Session 6. Physical activity guideline to manage MS.

The individuals are presented a guideline to increase their physical activity (PA), including motivational factors such as benefits of an active lifestyle. Individuals also receive guidance to evaluate their personal PA history, helping them to do a self-reevaluation of their behavior, motivating them to increase their PA.

Session 7. Physically active lifestyle. The sessions focuses on increasing the knowledge about how to incorporate PA into one's daily life, and this information is targeted to each individuals' preferences and lifestyle. Additionally, individuals learn strategies to overcome perceived barriers to include PA in their routine.

Session 8. Moderate alcohol drinking and smoking cessation. This session aims the constructs knowledge acquisition, skill-building, self-efficacy, and stimulus control in relation to the benefits of non-smoking and moderate alcohol drinking. Smokers learn cessation techniques along with coping skills for withdrawal symptoms, and skills to avoid or deal with high risk situations. Participants learn how smoking and alcohol also affect their MS status, and the importance of modifying these behaviors to be able to manage other indicators related to MS.

Session 9. Managing stress and depressive mood. As this intervention program is a comprehensive multi-component lifestyle intervention, other important health factors had to be included in the sessions. Understanding the effects of stress in our body, and identifying personal stressors is important to build skills that help manage one's stress. Additionally, this session aims to provide coping strategies to overcome depressive mood, either as a

consequence of smoke quitting or simply as a result of the individuals' daily life.

Session 10. Regular health check-ups. This session focuses on knowledge acquisition related to the importance of getting regular medical check-ups. Individuals receive personalized information about the types of medical check-ups they need, and how often they must get checked. This is important for MS patients to constantly monitor their health indicators and be able to identify the aspects that need more attention to better manage their health.

Sessions 11 & 12. Maintaining healthy lifestyle. The last two sessions are aimed to reassess the individual's current MS status, to provide personalized feedback related to the areas the individual has improved thanks to the program, and the areas with improvement opportunity. Self-efficacy is reinforced, and rewards are provided to the participants for completing the program.

b) Newsletters

A total of 12 newsletters were developed, each one to be delivered to the participants once a month. Each newsletter addresses one different topic. Similarly, a total of 12 different healthy recipes were developed, specifying the nutrients provided by the dish and the health benefits. The newsletters contain information about recipes of healthy foods which can be made by using seasonal ingredients. Some of the nutrients provided by the recipes in the newsletters are: vitamin C, vitamin A, dietary fiber, iron, folate, potassium, and magnesium. Accordingly, tips to adopt twelve healthy lifestyles, such as, stress management, physical activity, and healthy sleep were included (Table 2).

〈Table 2〉 Newsletters content and description of targeted indicators

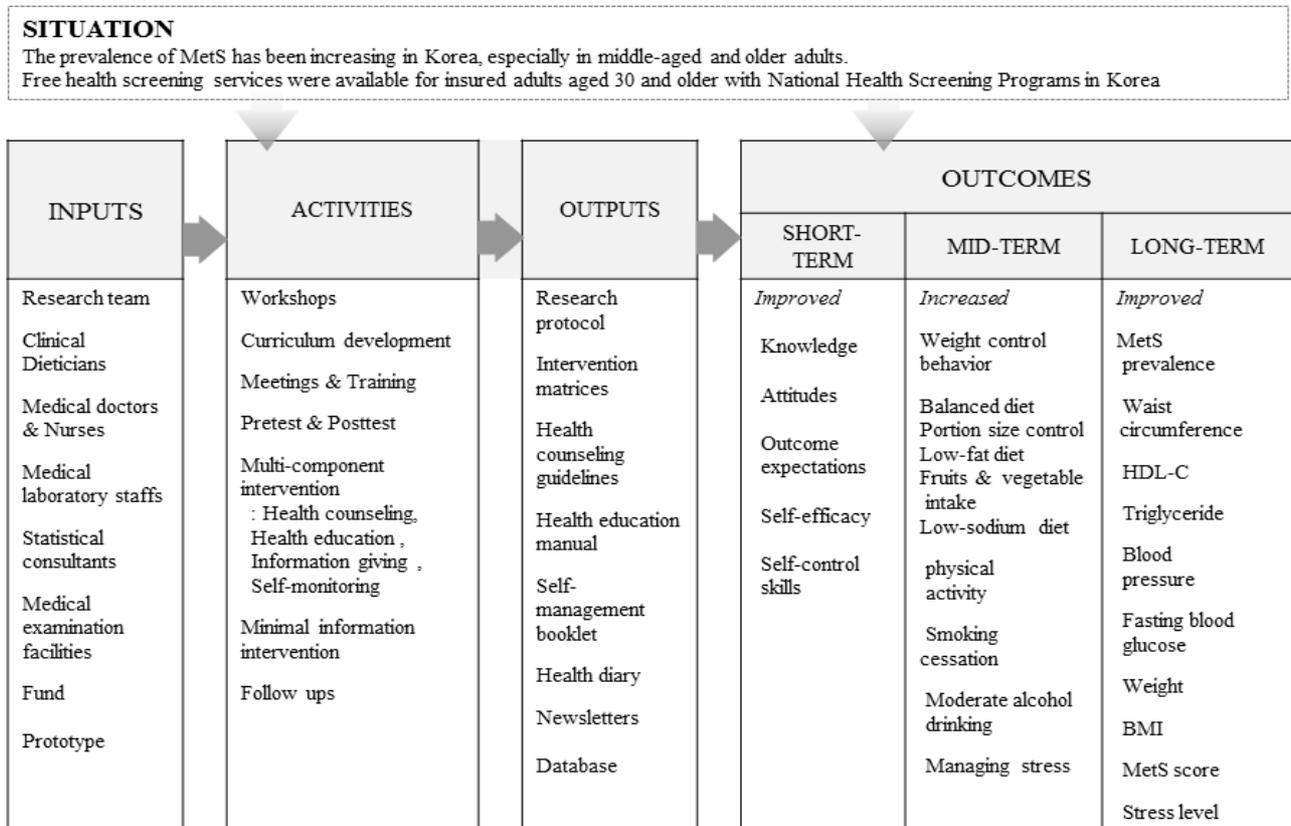
	Management of MS	Healthy diet recipes		Healthy lifestyle
		Nutrients	Health benefits	
Jan.	Obesity and MS	<u>Tangerine peel tea</u> Vitamin C and P, dietary fiber, etc	<ul style="list-style-type: none"> ■ Lower blood lipids, blood pressure & blood sugar ■ Increase bowel movement 	Stress management
Feb.	Blood glucose and MS	<u>Spinach & Tofu salad</u> Folate, iron, dietary fiber, etc	<ul style="list-style-type: none"> ■ Lower blood lipids, blood pressure & blood sugar ■ Increase bowel movement ■ Prevent overeating 	How to quit smoking
Mar.	Plasma triglyceride level and MS	<u>Mugwort & soybean soup</u> Chlorophyll, vitamins, iron & Potassium, etc.	<ul style="list-style-type: none"> ■ Improve blood circulation ■ Regulate sodium excretion ■ Stimulate lipid metabolism 	Moderate alcohol drinking
April	High blood pressure and MS	<u>Strawberry & wild chive salad</u> Vitamin C, folate, potassium, dietary fiber, etc	<ul style="list-style-type: none"> ■ Protect against the cell damage by oxygen-free radicals ■ Regulate sodium excretion 	Exercising in the spring
May	Low HDL-C and MS	<u>Paprika and mushroom salad</u> Dietary fiber, vitamin, iron, potassium, etc	<ul style="list-style-type: none"> ■ Regulate sodium excretion ■ Stimulate lipid metabolism 	Diet to reduce saturated and trans fat
Jun.	Risk factors for MS	<u>Tomato & bean-soup noodle</u> Lycopene, potassium, vitamin A and C, protein, complex carbohydrate, dietary fiber, etc	<ul style="list-style-type: none"> ■ Lower blood lipids and blood sugar ■ Lower the risk of lipid peroxidation in the bloodstream ■ Regulate sodium excretion 	Healthy sleep
Jul.	Effect of health related behavior change to improve MS	<u>Steamed Korean zucchini & tofu</u> Potassium, folate, vitamin C & E, protein, unsaturated fatty acids, isoflavone, etc	<ul style="list-style-type: none"> ■ Lower blood lipids ■ Regulate sodium excretion ■ Make the blood (Hematogenesis) ■ Reduce post menopause hot flashes in women 	Aquarobic exercise
Aug.	Role model story 1	<u>Chives and potato pancake</u> vitamins A, C and K., calcium, potassium, dietary fiber, etc	<ul style="list-style-type: none"> ■ Lower blood lipids, blood pressure & blood sugar ■ Increase bowel movement ■ Protect against colon cancer 	Stretching exercise
Sep.	Best practices in health counseling 1	<u>Baked sweet potato</u> Complex carbohydrates, dietary fiber, vitamin A&B6, Potassium	<ul style="list-style-type: none"> ■ Lower blood lipids and blood pressure ■ Prevent macular degeneration ■ Maintain normal function of the brain and central nervous system 	Office, Car or Airplane Stretches
Oct.	Role model story 2	<u>Steamed chicken breast with chestnut & jujube</u> Protein, niacin, selenium, unsaturated fatty acids, potassium, magnesium, dietary fiber, etc	<ul style="list-style-type: none"> ■ Lower blood lipids, blood pressure and blood sugar ■ Promote muscle-building & bone health ■ Increase bowel movement 	Brisk walking
Nov.	Best practices in health counseling 2	<u>Steamed white radish rice</u> Dietary fiber, vitamin C, folate, potassium, etc	<ul style="list-style-type: none"> ■ Lower blood lipids, blood pressure and blood sugar ■ Regulate sodium excretion ■ Increase bowel movement 	Stretching exercise
Dec.	Role model story 3	<u>Vegetable mix</u> Dietary fiber, vitamins, etc	<ul style="list-style-type: none"> ■ Lower blood lipids and blood pressure ■ Increase bowel movement ■ Prevent macular degeneration 	Keep exercising in the winter

c) Logic Model

This model was developed having in mind that to evaluate the effectiveness of the intervention in the future, a RCT design would be ideal. Thus, the logic model [Figure 1] included not only the inputs, outputs, and outcomes of the program itself, but also the activities needed to develop the program, and specifies the type of interventions to be used in a RCT. The intervention group would receive the multi-component intervention, which consists of the health counseling, health education, information giving, and self-monitoring. The control group would

receive minimal information intervention, including only the distribution of newsletters.

Besides the main components of this intervention (counseling sessions and newsletters), other outcomes include health counseling guidelines used to inform the facilitators about the proper delivery of the intervention; a health education manual, including the informative contents related to the health behaviors targeted in the intervention; a self-management booklet for the individuals receiving the intervention; and a health diary to help individuals to monitor their behaviors.



[Figure 1] Logic model of the intervention program

IV. Discussion

In the process of the development of the intervention contents, it is highly useful to form a

team of experts in the different areas that the intervention is expected to aim. In this way, back and forth discussions as well as feedback about each area of expertise can be achieved, enriching the

development of the intervention contents, such as it has been previously suggested by Helitzer and colleagues (Helitzer, Bobo Peterson, Thompson, & Fluder, 2008). Even though the process of forming the experts team can be time consuming, and we are aware that depending on the human and financial resources available, forming a multidisciplinary team might not be possible, we found that the constant feedback from each expert was fruitful for the development of the intervention contents.

Furthermore, using a health behavior theory as a basis to tailor the contents of the intervention helps not only to potentially enhance the effectiveness of the intervention, but also to more efficiently define the strategies to be used according to the theoretical construct that the facilitator intends to target. The importance of the use of theory to inform the development of intervention content has been well exemplified by Lytle and colleagues in their 10 steps for the development of health change programs (Lytle & Perry, 2001).

Additionally, developing an intervention matrix serves as a great tool for the facilitators to better understand the objectives of each session, and for the entire team to have a common understanding of the contents and their role in the intervention program. Also, this can help the developers to systematically identify the content and strategies to be used, and visually show the specific constructs and outcomes targeted. Having this visual representation or “map” of the intervention can also help to efficiently evaluate the effects of the intervention in terms of short-term, mid-term, and long-term outcomes, and be able to distinguish constructs that are related to the achievement of these outcomes.

Developing this matrix also helped as a basis to decide on the contents for the newsletters, matching them to the contents of the counseling sessions, in order to enhance the outcomes.

It is also important to point out that specific intervention strategies included, such as goal setting for behavior change, self-monitoring of progress toward goals, and providing reward to reinforce healthy lifestyle, help to set realistic short-term goals for each individual to be achieved easily (Pearson, 2012), such as increasing the minutes of walking during the day rather than losing 10% of baseline weight, for example.

Even though this document only presents the process of the development of the intervention program, and its effectiveness is yet to be evaluated through an experimental design, we consider this intervention to have strengths that make it potentially successful. For instance, this intervention is based on the stages of change of the TTM and it is designed to allow tailoring of the contents to each individual, rather than being a “one-size-fits-all” type of program. While we could not identify through the literature review a multi-component lifestyle intervention for MS applying stages of change, interventions targeting single behaviors, such as weight loss (Johnson et al., 2008), physical activity (Prochaska et al., 2008) and smoking cessation (Prochaska et al., 2001) that use stages of change tailoring, have shown to be effective for the modification of these behaviors. Additionally, most of the behavioral interventions for MS target only two behaviors (diet and physical activity), while the presented intervention program targets four MS related health behaviors: diet, physical activity, alcohol drinking, and smoking cessation, complementing it with strategies to manage stress levels.

This intervention development study presents a few limitations. Firstly, it would have been ideal to present results about the implementation and effectiveness of the intervention along with the development process. However, the authors were only assigned the task to develop the intervention and did not take part in the

later implementation of the program. Therefore, the information about the effectiveness of the intervention could not be included in this paper. Secondly, due to time constraints a full systematic review could not be conducted as part of the initial phase of the study, instead it was opted for a simple literature review. Nonetheless, we considered that the use of an interdisciplinary team and the use of an intervention theory matrix strengthens this study. Lastly, it has been suggested in previous studies that to allow for comparison of interventions effectiveness, the strategies used in health behavior modification programs should be reported using a uniform classification (Seo, 2015) regardless of the health behavior theory used to develop the intervention. For this purpose, the Behavior Change Techniques (BCT) CALO-RE taxonomy developed by Michie and colleagues (2011) is a helpful tool. In the work presented in this paper, intervention components are not described in terms of the CALO-RE taxonomy, nonetheless this should be specified in later reports, such as results of an RCT where the intervention's effectiveness is tested.

V. Conclusions

Intervention developers often face the difficulties of finding previously validated tools to inform the development of new intervention contents. Taking this vision into consideration, we consider pertinent to develop future interventions using a theory matrix and subsequently test the intervention through a RCT, evaluating each of the outcomes specified in the matrix.

When developing behavioral interventions based on behavior change theory, the decision of the theoretical constructs to be targeted and the content and strategies to be developed, tailored according to the constructs, should be taken after a comprehensive process of iterative discussions of an interdisciplinary team.

It is also paramount for intervention developers to systematically report the process through which they built their intervention contents, in order to contribute to the better understanding of theory-based intervention development and contribute to the effectiveness of such interventions.

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