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Development and Verification of an Alzheimer's disease Risk Reduction Program for Korean Middle-aged adults with low-educated

-based on Behavior Change Wheel Model-

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Abstract

The purpose of this study is to develop an Alzheimer's disease(AD) Risk Reduction Program. also examined the effects of the program on the Middle-aged adults at risk of AD

This is a Randomized Controlled Trial repeated measurements experimental study attempted to determine the effectiveness of the program. In consideration of securing the normality of the sample, the number of samples was calculated with a total of 52 people. Each group was assigned 26 people (ramdomization). For the analysis of the study, the intent-to-treat (ITT) presented in the CONSORT list was followed.

Repeated measures of variance analysis to investigate the impact of the Alzheimer's risk reduction program on Alzheimer's knowledge, health-related self-efficacy, interpersonal relationships, depression, and health-promoting behaviors, confirming group interactions before, 3, and 6 weeks. A measurement ANOVA was performed. As a result, it was found that knowledge of Alzheimer's disease, health-related self-efficacy, and health-promoting behavior showed significant differences in the timing of measurement and the interaction between groups, and the effects were proven. However, interpersonal relationships were found to be effective in terms of time and between groups, but were not significant in interactions. In addition, there was a significant change in depression between groups, but it was not effective in terms of time. Therefore, it was confirmed that the Alzheimer's risk reduction program was effective in improving Alzheimer's disease knowledge, health-related self-efficacy, and health promotion behavior.However, it has been confirmed that a program of 6 weeks or longer is required to improve interpersonal relationships, reduce depression, and promote healthy behavior.

It is presented as an intervention method that can be used in public health centers or nursing sites for middle-aged adults in local communities.

***Keywords*:**Alzheimer's disease Risk Reduction Program; Middle-age adult, Randomized Controlled Trial(RCT); Behavior Change Wheel Model;Knowledge of Alzheimer's disease; Health related self-efficacy; Health promoting lifestyle

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Introduction

Recently, with the development of science and medical technology, the life expectancy of humans has increased, and the elderly population continues to increase. In particular, the increase rate of Alzheimer's diseaseis very fast and occurs one patient every 4 seconds worldwide(Alzheimer's Disease International Data., 2014). The factors of Alzheimer's disease are pluralistic, which are the result of complex interactions between aging, heredity, lifestyle and environmental factors(Han, J. Y., & Han, S. H., 2014)., and similar to those of the origin of vascular and other dementia. In the past, it was considered impossible to prevent Alzheimer's disease. In recent studies, more than 50% of cases of Alzheimer's disease were found to be caused by lifestyle factors and physical disease-related factors, which are modifiable risk factors(Barnes, D. E., & Yaffe, K., 2011). The practice of health life behavior was recognized as an important preventive act, and the necessity of mediation was also highlighted. As preventive intervention studies to reduce risk factors, active physical activity(Hardeman, W *et al.*,2009), Mediterranean diet(Scarmeas, N*et al.*,2006), alcohol consumption(Anstey, K. J*et al.*, 2009), regular leisure activities (Akbaraly, T. N*et al.*,2009), social and cognitive stimulation(Kim, S*et al.*,2014) can reduce the risk of Alzheimer's disease. Recently, physical activity as a lifestyle factor(Anstey, K. J*et al.*, 2013; Rovio, S*et al.*, 2005)and dietary intervention(Otaegui-Arrazola, A*et al.*, 2014) Research is being conducted focusing on the other hand, in Korea, several intervention studies focusing on physical activity are reported(Lee, J. W., & Han, S. I. 2015). To date, foreign studies based on the behavior change (BCW) model include Anstey et al(2013). and Clare et al(2015). self-reported the increase in fish consumption and cognitive activity as a result of developing and applying a 12-week Alzheimer's risk factor reduction program for middle-aged adults. Through this, it was reported that Alzheimer's disease risk factors can be reduced. Clare L.et al.(2015)reported that the risk factors were reduced by increasing memory, cholesterol, aerobic ability, flexibility, balance, grip strength, agility and physical activity as a result of conducting behavior change intervention for adults for 12 months. Alzheimer's disease based on a behavioral change (BCW) model has not been reported in Korea.

Looking at the study that applied the behavioral change (BCW) model, the study mainly used for

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COM-B and intervention was the study of Anstey et al. A study that mediated physical activity in adults(Hardeman, W et al., 2009)and a study on learning and behavioral change by supporting computer-aided customized feedback messages(Landis-Lewis, Z et al., 2015)have.In the UK, policy and intervention functions were used in national health projects for smoking cessation and weight management Adults reported that they had low knowledge related to Alzheimer's disease and dementia, but showed high demand for education and anxiety about outbreaks. It suggested that development is urgent. Therefore, this study was conducted to verify the effectiveness of the Alzheimer's disease risk reduction program based on the behavior change (BCW) model and applied to middle-aged adults. Attempted to provide basic data for this.

Materials and Methods

Selection of research subjects

Among the middle-aged adults aged 45 years or older and under 65 years of age who attend an academically recognized high school in J City, those who have 3 or more of Alzheimer's risk factors were selected. The selection criteria are as follows.

1. Middle-aged adults aged 45 to 65 years old
2. Those who can communicate in general
3. Those who understand the purpose and voluntarily agree to participate in the study
4. Those who have 3 or more of the following risk factors for Alzheimer's disease

• Low-educated (high school graduates and below).
• Overweight or obese as calculated by BMI.
• Those who have been diagnosed with diabetes or high blood pressure.
• Those who have been diagnosed with hypercholesterolemia or hyperlipidemia.
• People who have experienced smoking or depression.
• People who have experienced brain trauma to the point of losing consciousness.
• Those with low physical activity, that is, those who exercise for 30 minutes or more and less than twice a week.

Those who consume meat more often than fish

• People with a family history of dementia or Alzheimer's disease.
• Those with sleep disorders.

Sample size and analysis method

To calculate the effect size for this study, a pilot study was conducted, and the result was obtained using the website www.uccs.edu/~faculty/lbecker/ to obtain the effect size value, and the number of samples was calculated with a large effect size. For repeated measurement variance analysis, it was calculated using the G*Power 3.1 Program. In this study, significance level (α) .05, Repeated

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Measure between factors effect size (Effect size) 0.61 , Power (1-β) of .80, the number of groups was 2, and the number of subjects required for the study was calculated as a total of 20 subjects. However, in this study, the number of samples was calculated with a total of 52 in consideration of dropout of the study subjects and securing the normality of the sample.A research assistant downloaded a randomly assigned number table from http://www.random.org using a computer wireless assignment program, and based on the list and random assignment number, 26 people were assigned to each group (ramdomization). For the analysis of this study, the intent-to-treat (ITT) analysis presented in the CONSORT list was followed.The flow chart of the progress of this study is according to the2010 Consort -Flow Chart list as shown in Figure 1

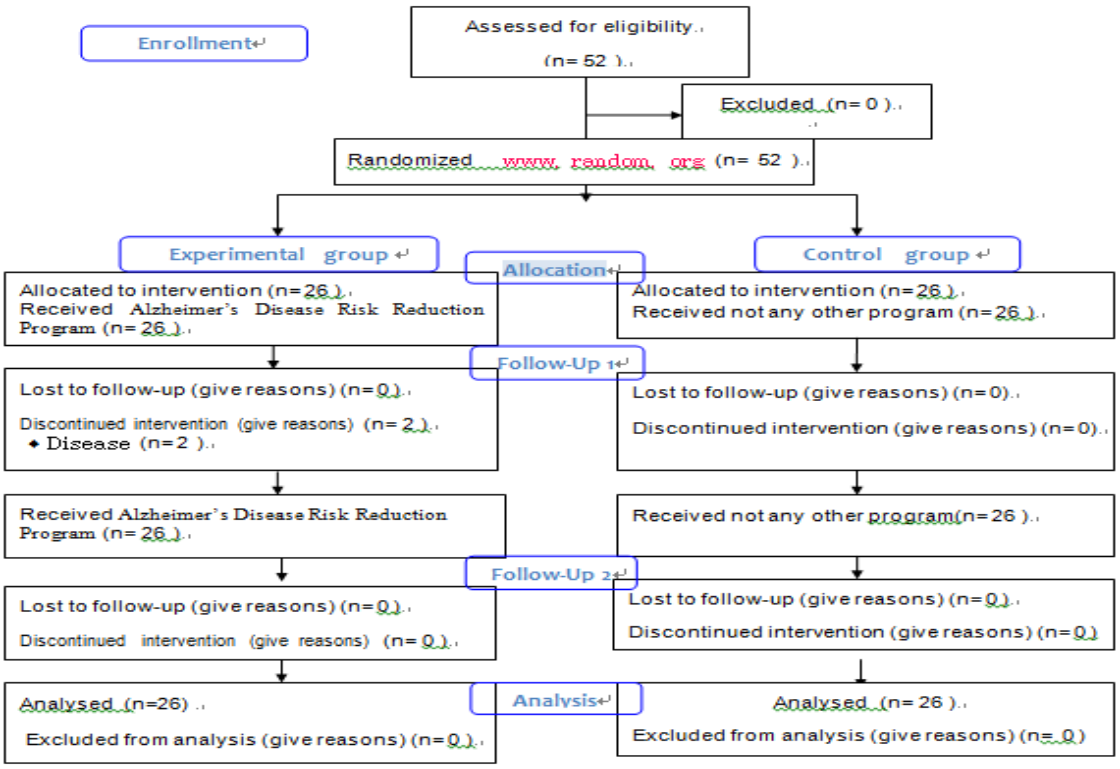

Figure 1:The Consort –Flow Diagram of subject selection method

The allocation was concealed until the start of the intervention. The program was applied to the experimental group from March 14th through April 19th, 2016, specifically two times a week for six weeks, 60 minutes each time, a total of 12 times.Data were collected using structured questionnaires; As measurement tools, Alzheimer's disease knowledge scale, health-related self-efficacy, and health promotion lifestyle profile II (HPLP-II) were used and are shown in Table 1.

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Table 1:Research Design

Group	Pre-test	Intervention1	Post-test 1 (after 3weeks)	Intervention2	Post-test 2 (after 6weeks)
Experimental Group [Exp.]	**Ye1**	**X1**:	**Ye2**	**X2**	**Ye3**
Control Group [Cont.]	**Yc1**	-	**Yc2**	-	**Yc3**

Ye1, Yc1: General Characteristics, Knowledge for Alzheimer's Disease, Health related Self-efficacy, Health Promoting Lifestyle
X1: Program for the Alzheimer's Disease Risk Reduction, 60min/session, twice a week for 3weeks
Ye2, Yc2: Knowledge for Alzheimer's Disease, Health related Self-efficacy, Health Promoting Lifestyle,
X2: Program for the Alzheimer's Disease Risk Reduction, 60min/session, twice a week for 3weeks
Ye3, Yc3: Knowledge for Alzheimer's Disease, Health related Self-efficacy, Health Promoting Lifestyle

Ethical consideration

The researcher has completed research ethics education for researchers, and after obtaining approval from the Institutional Review Board (IRB) (approval number 1040647–201601-HR-002-03), the researcher is informed of the purpose and method of the research to the head of the institution.

After explaining and obtaining permission, I proceeded.After explaining the purpose of the study and the procedure for conducting the study, consent was obtained. All information that could identify the subject through the study was coded and processed anonymously, and confidentiality was promised.

The experimental group was provided with an Alzheimer's disease risk reduction program for 6 weeks, and the control group was not provided with a program and a booklet related to the Alzheimer's disease risk reduction program was provided after the intervention of the experimental group was completed. I provid a gift certificate.

Theoretical conceptual framework

The theoretical conceptual framework of this study was developed based on domestic and international prior studies based on intervention, COM-B system and theoretical domain structure (TDF), which are components of the behavior change (BCW) model. In this study, interventions suggested according to behavioral factors included education, training, permission, persuasion, restructuring of the environment, incentives, modeling, coercion, and restrictions.

Statistics method

Data was analyzed by SPSS WIN 12.0 program, and The principle of ITT (Intent-to-Treat) was applied. Frequency, percentage, mean, and standard deviation were calculated in order to

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understand the general characteristics of the subjects. X^2-test, t-test were used to evaluate homogeneity of two groups. Repeated measures ANOVA were conducted in order to verify the Alzheimer's disease risk reduction program.

Results and Discussion

As a result of the homogeneity test for the selection criteria and study variables of the experimental group and the control group, there was no significant difference between the experimental group and the control group at the significance level of 0.05 for all items, confirming that the two groups were homogeneous

The Kolmogorov-Smirnov test was performed to test the normal distribution of the study variable, and it was found to be normally distributed**.** The results of confirming the effect of the Alzheimer's disease risk reduction program on Alzheimer's disease knowledge, self-efficacy, and health promotion behavior are as follows.

Knowledge of Alzheimer's disease

Table 2 shows the effects of Alzheimer's risk reduction program on Knowledge of Alzheimer's disease. As a result of measuring the subject's knowledge of Alzheimer's disease before (T1), 3 weeks of intervention (T2), 6 weeks of intervention (T3), there was a significant difference in the change according to the measurement period (F=37.75 p<.001) , There were also significant differences in the changes between groups (F=17.06, p<.001), and there were also significant differences in the timing of measurement and interactions between groups (F=21.75, p<.001, partial η^2= .303) appeared to be effective.

Table 2: Effects of Alzheimer's Disease Risk Reduction Program on Alzheimer's Disease Knowledge (N=52)

Group	Pre-test	Post-test 1 (after 3weeks)	Post-test 2 (after 6weeks)	Source	F	*p*
	Mean±SD	Mean±SD	Mean±SD			
Exp.(n=26)	16.53±2.50	22.26±3.04	21.23±3.31	Time	37.75	<.001
				Group	17.06	<.001
Cont.(n=26)	17.03±2.70	18.15±2.47	17.11±2.71			
				T×G	21.75	<.001

Exp.=experimental group; Cont.=control group

T1=pre-test; T2=post-test 1(after 3weeks); T3=post-test 2(after 6weeks)

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Health related Self-efficacy

Table 3 shows the effects of Alzheimer's risk reduction program on Health related Self-efficacy. In terms of self-efficacy for health, there was a significant difference in the change according to the measurement period (F=4.03, p=.030), and there was also a significant difference in the change between groups (F=10.39, p=.002). There was also a significant difference in the timing of measurement and the interaction between groups (F=3.80, p=.036, partial η^2=.071), demonstrating the effectiveness of the program[Table 3].

Table 3: Effects of Alzheimer's Disease Risk Reduction Program on Health related Self-efficacy (N=52)

Group	Pre-test	Post-test 1 (after 3weeks)	Post-test 2 (after 6weeks)	Source	F	*p*
	Mean±SD	Mean±SD	Mean±SD			
Exp. (n=26)	78.46±7.59	85.00±7.94	88.46±10.56	Time	4.03	.030
				Group	10.39	.002
Cont.(n=26)	78.23±9.92	78.11±8.45	78.42±13.63	T×G	3.80	.036

Exp.=experimental group; Cont.=control group

T1=pre-test; T2=post-test 1(after 3weeks); T3=post-test 2(after 6weeks)

Health promotion behavior

Table 4 shows the effects of Alzheimer's risk reduction program on Health promotion behavior. As a result of measuring the health promotion behavior of the subject at prior (T1), 3 weeks of intervention (T2), and 6 weeks of intervention (T3), there was a significant difference in the change according to the measurement period (F=14.21, p=.032).), there were also significant differences in the changes between groups (F=14.21, p<.001), but there were also significant differences in the timing of measurement and interactions between groups (F=2.98, p=.040, partial η^2). =.056) The effect was proven.

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Table 4: Effects of Alzheimer's Disease Risk Reduction Program on Health Promoting Lifestyle (N=52)

Group	Pre-test	Post-test 1 (after 3weeks)	Post-test 2 (after 6weeks)	Source	F	*p*
	Mean±SD	Mean±SD	Mean±SD			
Exp.(n=26)	121.42±22.48	131.96±16.28	136.46±8.52	Time	3.69	.032

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				Group	14.21	<.001
Cont.(n=26)	117.30±23.53	117.96±14.43	118.07±11.75			
				T×G	2.98	.040

Exp.=experimental group; Cont.=control group

T1=pre-test; T2=post-test 1(after 3weeks); T3=post-test 2(after 6weeks)

Conclusion

As dementia and Alzheimer's disease prevention programs are focused on old age, it can be seen that middle-aged people are in blind spots, so it is necessary to develop and apply Alzheimer's risk reduction programs for middle-aged people. In this study, it was found that the Alzheimer's disease knowledge, health-related self-efficacy, and health promotion behavior were improved by applying the Alzheimer's risk reduction program based on the BCW theory for 6 weeks to middle-aged adults with low education at risk of Alzheimer's disease.

The Alzheimer's disease risk reduction program was applied by using interventions, which are components of the behavioral change wheel model, and interventions based on the COM-B system and the theoretical domain (TDF). Intervention, which is a component of the behavior change (BCW) model, is that when the subject's knowledge of Alzheimer's disease improves, or when interpersonal relationships as an opportunity, or health-related self-efficacy as a motivator, improves, the behavioral health promotion behavior is improved. (intervention) and the results in support of the COM-B system theory are presented.

Based on this, it is meaningful to propose a new theoretical conceptual framework for the Alzheimer's risk reduction program that promotes the behavior change of the subject in nursing, and it can be used as a theoretical framework for the nursing intervention program that promotes the behavior change of the subject.In addition, the Alzheimer's risk reduction program is suggested as a way to expect positive and active Alzheimer's risk reduction behavior changes of middle-aged adults through physical, mental, and psychological health management. In addition, it is meaningful to propose an intervention method that can be used in public health centers or nursing fields for middle-aged adults in the community.

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