

The Investigation of the Relationship between Physical Activity and Depressive Symptom Levels among Women during Senility

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Abstract

Background: The purpose of the present research is evaluating the effects of some individual and environmental factors (body composition, education status, residential centre, number of children) on depressive symptoms and the relationship between physical activity and depressive symptom levels during senility. **Method:** The sample of the present research consisted of 164 women who applied to an official health centre in the province of Kırıkkale due to various health problems. The physical activity levels of the sample women were measured using the International Physical Activity Questionnaire (IPAQ); depressive symptoms among women were identified using the Geriatric Depression Scale (GDS). **Findings:** According to the findings of the present research there is a low level of negative correlation between physical activity and depressive symptom level. It was also found that personal and environmental factors such as body composition, residential location, number of children, and educational status did not affect the level of physical activity and depressive symptoms of older women, who participated in the present research. **Conclusion:** Findings of the present research showed that even low, physical activity had effects on the reduction of depressive symptoms among women during senility.

Keywords: Physical activity, depressive symptom, senility

Introduction

Aging, which has chronological, biological, social and psychological dimensions, is an inevitable process in physiological sense. In this process, physiological and physical changes that occur in the elderly restrict the ability of the elderly to act, cause them to feel unhappy and affect their quality of life negatively (Tajvar, Arab, Montazeri, 2008).

Depression is a common health problem that causes mental disorders among the elderly (Anderson, Freedland, Clouse, Lustman, 2001; Rudisch & Nemeroff 2003; Roseman, Backenstrass, Joest, Rosemann, Szecsenyi, Laux, 2007). The World Health Organization (WHO) predicts that in 2020, depression will be the most common health problem following ischemic heart disease (Mammen & Faulkner, 2014). Depression reduces quality of life and causes social isolation (Moore, Babyak, Wood, Napolitano, Khatri, Craighead, 1999).

The positive effects of physical activity on physical and mental health are well-known (Biddle, 2000; Lin, Halgin, Well, Ockene, 2008). Experts have emphasized the role of physical activity in protecting the heart, preventing diabetes and ensuring low blood pressure for years (Oefinger, 2012). It is reported that regular physical activity contributes to a reduction in cardiovascular risk factors, leads to positive improvements in insulin sensitivity, and results in lowering blood pressure among hypertensive individuals (Lim & Taylor, 2005; Chrysohoou et al. 2015; Conraads et al. 2015). Today, many experts focus on the relationship of physical activity to mental health. Regular physical activity is an important factor that reduces the symptoms of depression and makes individuals feel better (Oefinger, 2012). Archer, Josefsson, Lindwall, (2014) reported that physical activity and exercise contributed to mental development and reduced stress.

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For this reason, the present research studies the effects of some individual and environmental factors (body composition, educational status, residential centre, number of children) on depressive symptoms during the senility period when the likelihood of mental health problems increases. In addition, the relationship between physical activity and depressive symptom level in senility was also investigated. Thus, it is aimed to reveal the effectiveness of some individual and environmental factors, primarily physical activity, which may affect the emergence of depressive symptoms during senility.

Method

The sample of the present research consisted of 164 women who applied to an official health centre in the province of Kırıkkale due to various health problems.

Data Collection Tools

The physical activity levels of the sample of the research were measured using the International Physical Activity Questionnaire (IPAQ); and the depressive symptoms seen among women were measured using the Geriatric Depression Scale (GDS). Considering that the sample had a high average age (71.25 ± 6.4), the questionnaire was read to the individuals who formed the sample by the researcher. Questionnaires were filled in accordance with the answers given.

International Physical Activity Questionnaire

The International Physical Activity Questionnaire (IPAQ) was developed in 1998 by the International Physical Activity Assessment Group in short and long forms. IPAQ is designed to determine adult physical activity levels and inactivity states. Craig et al. (2003) who conducted a study to define validity and reliability of IPAQ reported that criterion validity of the questionnaire was 0.33 for the long form and 0.30 for the short form.

Validity and reliability studies of the questionnaire in Turkey were conducted by Öztürk, (2005) with the voluntary participation of 1097 university students between the ages of 18-32. The construct validity, criterion validity and test retest reliability of the short and long forms of the questionnaire were assessed. The study reported that short and long forms of the questionnaire can provide repeatable ($r=0.69$ for the short form and $r=0.64$ for the long form) and comparable data ($r=0.66$). The criterion validity was found as $r=0.30$ for the short form and $r=0.29$ for the long form. The short form of the questionnaire was used for the present research.

IPAQ provides information about sitting, walking, moderately intense activities and time spent in intense activities. The criterion for all activities is that each activity should be done for at least 10 min. at one time (Craig et al. 2003).

MET (metabolic equivalent) values of individuals can be calculated with the data obtained from IPAQ. Frequency, duration and intensity variables are used to calculate MET values. Frequency refers to the number of days a week the activity is performed; duration refers to how long (in hours or minutes) the activity is performed each time; intensity refers to the amount of MET value spent per hour during the activity. MET is a measure of the amount of oxygen consumed per kilogram in the defined unit of time. A MET refers to the amount of oxygen consumed during rest (about 3.5 ml/kg/min) (Craig et al. 2003).

The following formula is used to calculate the MET min / week values:

MET / week: Frequency of activity X Activity duration X Intensity of activity (Karaca & Turnagöl, 2007).

Calculated MET values are collected in 3 categories:

- 1- High level of physical activity > 3000 MET-min/week
- 2- Physical activity level sufficient for health > 600 - 3000 MET-min/week
- 3- Inactive < 600 MET-min/week (Craig et al. 2003).

Geriatric Depression Scale (GDS)

Geriatric Depression Scale (GDS) developed by Brink, Yesavage, Lum, Heersema, Adey, Rose, (1982) measures the level and severity of depressive symptoms among elderly people over 60 years of age with no significant hearing impairment and moderate to severe dementia.

However, it excludes such items as somatic complaints and sexual function related to depression and future expectations. It can be filled in by the individuals themselves. However, it is also possible that the researcher reads the question and to marks the answer if necessary. The scale consists of 30 items. Items 1, 5, 7, 9, 15, 19, 21, 28, 29 and 30 are scores 0 for YES responses and 1 for NO responses. The total score ranges between 0-30. For the Turkish version of the scale, sensitivity and specificity cut-off scores were taken as 13/14. It is considered that likelihood of depression among individuals who score above this cut-off score is high (Sağduyu, 1997).

Height and Body Weight Measurements

Prior to measurements of body length and body weight, women who participated in the present research were asked to remove their shoes, socks, and wear clothes that would not weigh as little as possible. During height measurement, women were asked to assemble their heels, keep the body straight, keep the head in the frankfort plane, and protect their position after a deep inspiration. The height of the sample was measured with a height scale of 0.01 cm sensitivity and the body weight was measured with an electronic scale of 0.1 kg sensitivity (Tamer, 2000).

Statistical Analysis of Data

The Kolmogorov-Smirnov test was used to test whether the data obtained from the measurements fit the normal distribution. One-way ANOVA was used for parametric tests when multiple groups were compared independently, since the data normally distributed. Pearson's correlation coefficient (r) was used to determine whether there was a relationship between two different variables. Relation coefficients used in the research were taken according to the coefficients indicated as absolute values below:

- 0.00-0.19 No relationship or low level of significance
- 0.20-0.39 Weak (low) relationship
- 0.40-0.69 Intermediate level relationship
- 0.70-0.89 Strong (high) relationship
- 0.90-1.00 Very strong relationship (Alpar, 2006).

The data obtained in the present research were analysed at 0.05 error margin in the 95% confidence interval in the SPSS 22.0 package program.

Findings

Table 1. Descriptive Statistics Related to Participants

Variables		N	%
Depressive symptom level	Low risk	77	47
	High risk	87	53
	Total	164	100
Physical activity level	Inactive	78	47.6
	Healthy enough	73	44.5
	Active	13	7.9
	Total	164	100
Body composition	Thin	7	4.3
	Normal	39	23.8
	Fat	51	31.1
	Obese	67	40.9
	Total	164	100

Table 1. presents descriptive statistics for the individuals participated in the present research. Accordingly, high-level depressive symptoms were observed in 53% of the sample (n=87). A significant proportion of the sample was fat (31.1%; n=51) and obese (40.9%; n=67) and 47.6% (n=78) had an inactive lifestyle.

Table 2. Comparison of Depressive Symptom Levels of Participants in terms of Body Composition

Variables	Body Composition	N	X	Sd	S _{error}	F	p
Depression risk	Thin	7	15.14	5.61	2.12	0.191	0.902
	Normal	39	14.41	4.55	0.73		
	Fat	51	13.90	4.88	0.68		
	Obese	67	14.31	4.69	0.57		
	Total	164	14.24	4.72	0.36		

As presented in Table 2. there is no significant difference between participants according to body composition in terms of depressive symptom level ($p>0.05$).

Table 3. Comparison of Depressive Symptoms and Physical Activity Level of Participants by Resident Centres

Variables	Resident Centre	N	X	Sd	S _{error}	F	p
Depressivesymptomlevel	Village or town	32	14.78	4.77	0.84	0.310	0.734
	District centre	14	13.71	3.89	1.04		
	Provincial centre	118	14.16	4.82	0.44		
	Total	164	14.24	4.72	0.36		
MET values	Village or town	32	1153.41	2142.4	378.7	0.890	0.413
	District centre	14	465.79	763.1	203.9		
	Provincial centre	118	914.81	1516.9	139.6		
	Total	164	923.03	1612.3	125.9		

As presented in Table 3. there is no significant difference between the participants according to the resident centre in terms of the depressive symptom and physical activity level ($p>0.05$).

Table 4. Comparison of Depressive Symptoms and Physical Activity Level of Participants According to the Number of Children

Variables	Number of children	N	X	Sd	S _{error}	F	p
Depressivesymptomlevel	1-3 children	61	13.74	4.61	0.59	0.612	0.544
	4-6 children	82	14.46	4.93	0.54		
	7 and more	21	16.86	4.26	0.93		
	Total	164	14.24	4.72	0.36		
MET values	1-3 children	61	705.36	873.9	111.9	0.889	0.413
	4-6 children	82	1044.08	1982.4	218.9		
	7 and more	21	1082.67	1657.2	361.6		
	Total	164	923.03	1612.3	125.9		

As presented in in Table 4. there is no significant difference between the participants according to number of children in terms of the depressive symptom and physical activity level ($p>0.05$).

Table 5. Comparison of Depressive Symptoms and Physical Activity Levels of Participants in Terms of Educational Background

Variables	Educational Background	N	X	Sd	S _{error}	F	p
Depressivesymptomlevel	Uneducated	71	15.54	4.87	0.57	4.124	0.072
	Primary S.	71	13.68	4.35	0.51		
	Secondary S.	10	11.80	3.91	1.23		
	High S. and University	12	12.00	4.78	1.38		
	Total	164	14.24	4.72	0.36		
MET values	Uneducated	71	1068.55	2110.2	250.43	0.459	0.711
	Primary S.	71	831.74	1154.7	136.96		
	Secondary S.	10	533.10	765.9	242.22		
	High S. and University	12	927.17	948.4	273.79		
	Total	164	923.03	1612.3	125.90		

As presented in in Table 5.there is no significant difference between the participants according to educational background in terms of the depressive symptom and physical activity level ($p>0.05$).

Table 6. The Relationship between Physical Activity and Depressive Symptom Level of Participants

Variables	Depressive symptom level		
	n	r	p
MET values	164	-0.232*	0.014

* *significant relationship at 0.05 level (2-way)*

As presented in Table 6. there is a low negative correlation between physical activity and depressive symptom level of the participants.

Discussion and Conclusion

In recent years, the importance of physical activity has been emphasized more and more in order to remind people that they are a productive part of society in old age, to minimize the incompetence, disability, discomforts that occur with aging, and to maintain the lives of the elderly independently (Soyuer, Şenol, Elmalı, 2012).However, although physical activity is known to reduce the risk of chronic illnesses, the relationship between physical activity and secondary diseases (complications) has not been identified (Yardley et al. 2015).For this reason, many experts now focus on the relationship between physical activity and mental health (Oefinger, 2012).Physicians recommend physical activity programs for individuals with threshold or moderate depression and indicate that exercise is effective in preventing depression (Chalder et al. 2012).As well as being active, the type, duration and intensity of activity are also important. For example; whether activities such as home or garden work reduce depression is not known (Tawashy, Eng, Lin, Tang, Hung, 2009).However, Jonsdottir, Rödger, Hadjibajramovic, Börjesson, Ahlborg, (2010) reported in their study that activities such as gardening and walking for 120 minutes a week prevented the risk of depression. Similar studies have reported that low-intensity activities of less than 20 minutes may prevent depression (Brown, Yore, Ham, Macera, 2005; Lucas, Mekary, Pan, Mirzaei, O'Reilly, Willett, 2011).Mammen & Faulkner, (2014) who reviewed 30 different activities, reported in their study that the activities performed for 150 minutes per-week prevented depression. Lindwall et al. (2011) stated that moderate to intense physical activity may be effective in reducing depressive symptoms among adults. The findings obtained in these studies indicate that the duration and intensity of exercise and activity are important in the prevention of depression.

The findings of the present research revealed that there was a low negative correlation between physical activity and depressive symptom level. This finding suggests that, although at a low level, depressive symptoms decrease as the level of physical activity increases; the lower the level of physical activity is, the more the depressive symptoms are observed. In a similar study, Almagro Valverde, Guzman, Tercoder Sanchez, (2014) reported an inverse relationship between physical activity and depressive symptoms or alleviation of these symptoms.Azar, Ball, Salmon, Cleland, (2011)who found a negative relationship between physical activity and depression risk in their study, reported that risk of depression increased as physical activity decreased.Sund, Larsson, Wichstrøm, (2011)stated that physical activity was an important determinant of depressive symptoms.

Suh, Weikert, Dlugonski, Sandroff, Motl, (2012) reported that physical activity programs and social support resulted in decrease in depressive symptoms. Review of the related literature will provide many similar studies with findings that are in agreement with the present research (O'Neal,Dunn, Martinsen, 2000; Brosse, Sheets, Lett, 2002; Paluska & Schwenk 2000; Craft & Perna 2004; Teychenne, Ball, Salmon, 2008a;Teychenne, Ball, Salmon, 2008b)

The findings of the present research showed that personal and environmental factors such as body composition, residential centre, number of children, and educational status had no effect on the level of physical activity and depressive symptoms among older women, who participated in the research. All these personal and environmental factors can be important for many young and adult individuals and affect their mental health. Since the individuals who made up the sample of this research were older, factors such as body composition, education status and number of children may not be very important for these individuals, so the expected effect could not be obtained. In addition, the fact that Kırıkkale province, villages and towns are small, and the living conditions that can lead to the stress are not available, may cause the residential centre to have no effect on the depression depressive symptoms.

Of the old women participating in the present research, 53% (n=87) presented high levels of depressive symptoms. These individuals are at high risk for health. 47.6% (n=78) of the sample had an inactive lifestyle. In a similar study Brown, Ford, Burton, Marshall, Dobson, (2005) reported that less than 40% of individuals aged 65 years and older regularly exercised and a large proportion of older population were sedentary.

Findings of the present research showed that even low, physical activity had effects on the reduction of depressive symptoms among women during senility. For this reason, exercise and physical activity programs may be preferred among individuals, who are depressed or present depressive symptoms besides relaxation techniques, meditation, yoga, music therapy and drug therapy. While organizing these programs, the determinants of physical activity such as frequency, duration and type of intensity should be taken into consideration. Elderly women should be given aerobic activities, muscle strengthening activities and balance activities against falling risk for no less than 30 minutes, at least three times a week to prevent depressive symptoms.

References

- Almagro Valverde, S., Guzman, D., & Tercedor Sanchez, P. (2014). Physical activity and depression: A systematic review. *Revista Internacional de Medicina y Ciencias de la Actividad Física y del Deporte*, 14,377-92.
- Alpar, R. (2006). *Spor bilimlerinde uygulamalı istatistik*. (3. baskı). Ankara: Nobel.
- Anderson, R.J., Freedland, K.E., Clouse, R.E., & Lustman, P.J. (2001). The prevalence of comorbid depression in adults with diabetes: A meta-analysis. *Diabetes Care*, 24(6), 1069-78.
- Archer, T., Josefsson, T., & Lindwall, M. (2014). Effects of physical exercise on depressive symptoms and biomarkers in depression. *CNS & Neurological Disorders-Drug Targets (Formerly Current Drug Targets-CNS & Neurological Disorders)*, 13(10), 1640-1653.
- Azar, D., Ball, K., Salmon, J., & Cleland, V. (2011). Individual, social, and physical environmental correlates of physical activity among young women at risk of depression. *Journal of Physical Activity and Health*, 8(1), 133-140.
- Biddle, S. (2000). Exercise, emotions, and mental health. In: L.H. Yuri (Eds.), *Emotions in sport* (pp.267-291). USA: Human Kinetics.
- Brink, T.L., Yesavage, J.A., Lum, O., Heersema, P.H., Adey, M., & Rose, T.L. (1982). Screening tests for geriatric depression. *Clinical Gerontologist*, 1,37-43.
- Brosse, A.L., Sheets, E.S., Lett, H.S., & Blumenthal, J.A. (2002). Exercise and the treatment of clinical depression in adults. *Sports Medicine*, 32(12),741-760.
- Brown, D.R., Yore, M.M., Ham, S.A., & Macera, C.A. (2005). Physical activity among adults > or=50 yr with and without disabilities, BRFSS 2001. *Medicine and Science in Sports and Exercise*, 37(4), 620-629.
- Brown, W.J., Ford, J.H., Burton, N.W., Marshall, A.L., & Dobson, A.J. (2005). Prospective study of physical activity and depressive symptoms in middle-aged women. *American Journal of Preventive Medicine*, 29(4), 265-272.
- Chalder, M., Wiles, N.J., Campbell, J., Hollinghurst, S.P., Searle, A., Haase, A., ... & Thorp, H. (2012). A pragmatic randomised controlled trial to evaluate the cost-effectiveness of a physical activity intervention as a treatment for depression: The treating depression with physical activity (TREAD) Trial,16(1),164.
- Chrysohoou, C., Angelis, A., Tsitsinakis, G., Spetsioti, S., Nasis, I., Tsiachris, D., ... & Dimitris, T. (2015). Cardiovascular effects of high-intensity interval aerobic training combined with strength exercise in patients with chronic heart failure. A randomized phase III clinical trial. *International Journal of Cardiology*, 179, 269-274.
- Conraads V.M., Pattyn, N., De Maeyer, C., Beckers, P.J., Coeckelberghs, E., Cornelissen, V.A. ... & Vanhees, L. (2015). Aerobic interval training and continuous training equally improve aerobic exercise capacity in patients with coronary artery disease: The SAINTEX-CAD study. *International Journal of Cardiology*, 179, 203-210.
- Craft, L.L., & Perna, F.M. (2004). The benefits of exercise for the clinically depressed. *Primary Care Companion to The Journal of Clinical Psychiatry*, 6(3), 104.
- Craig, C.L., Marshall, A.L., Sjoström, M., Bauman, A.E., Booth, M.L., Ainsworth, B.E., ... & Oja, P. (2003). International physical activity questionnaire: 12-country reliability and validity. *Medicine and Science in Sports and Exercise*, 35(8), 1381-1395.

- Jonsdottir, I.H., Rödger, L., Hadzibajramovic, E., Börjesson, M., & Ahlberg Jr, G. (2010). A prospective study of leisure-time physical activity and mental health in Swedish health care workers and social insurance officers. *Preventive Medicine*, 51(5), 373-377.
- Karaca, A., & Turnagöl, H.H. (2007). Çalışan bireylerde üç farklı fiziksel aktivite anketinin güvenilirliği ve geçerliği. *Spor Bilimleri Dergisi*, 18(2), 68-84.
- Lim, K., & Taylor, L. (2005). Factors associated with physical activity among older people - a population-based study. *Preventive Medicine*, 40, 33-40.
- Lin, L., Halgin, R.P., Well, A.D., & Ockene, I. (2008). The relationship between depression and occupational, household, and leisure-time physical activity. *Journal of Clinical Sport Psychology*, 2(2), 95-107.
- Lindwall, M., Larsman, P., & Hagger, M.S. (2011). The reciprocal relationship between physical activity and depression in older European adults: A prospective cross-lagged panel design using SHARE data. *Health Psychology*, 30(4), 453.
- Lucas, M., Mekary, R., Pan, A., Mirzaei, F., O'Reilly, É.J., Willett, W.C., ... & Ascherio, A. (2011). Relation between clinical depression risk and physical activity and time spent watching television in older women: A 10-year prospective follow-up study. *American Journal of Epidemiology*, 174(9), 1017-1027.
- Mammen, G., & Faulkner, G. (2014). Can Physical Activity Prevent Depression?. *Research Update*, 21, 1-2.
- Moore, K.A., Babyak, M.A., Wood, C.E., Napolitano, M.A., Khatri, P., Craighead, W.E., ... & Blumenthal, J.A. (1999). The association between physical activity and depression in older depressed adults. *Journal of Aging and Physical Activity*, 7(1), 55-61.
- Oefinger, M. (2012). Basic strategies for managing depression with physical activity. *ACSM Fit Society*, 5.
- O'Neal, H.A., Dunn, A.L., & Martinsen, E.W. (2000). Depression and exercise. *International Journal of Sport Psychology*, 31, 110-35.
- Öztürk, M. (2005). Üniversitede eğitim-öğretim gören öğrencilerde uluslararası fiziksel aktivite anketinin geçerliliği ve güvenilirliği ve fiziksel aktivite düzeylerinin belirlenmesi (Yüksek Lisans Tezi). Hacettepe Üniversitesi Sağlık Bilimleri Enstitüsü, Ankara.
- Paluska, S.A., & Schwenk, T.L. (2000). Physical activity and mental health. *Sports Medicine*, 29(3), 167-180.
- Rosemann, T., Backenstrass, M., Joest, K., Rosemann, A., Szecsenyi, J., & Laux, G. (2007). Predictors of depression in a sample of 1,021 primary care patients with osteoarthritis. *Arthritis Care & Research*, 57(3), 415-422.
- Rudisch, B., & Nemeroff, C.B. (2003). Epidemiology of comorbid coronary artery disease and depression. *Biological Psychiatry*, 54(3), 227-240.
- Sağduyu, A. (1997). Yaşlılar için depresyon ölçeği: Hamilton depresyon ölçeği ile karşılaştırmalı güvenilirlik ve geçerlilik çalışması. *Türk Psikiyatri Dergisi*, 8(1), 3-8.
- Soyuer, F., Şenol, V., & Elmalı, F. (2012). Huzurevinde kalan 65 yaş ve üstündeki bireylerin, fiziksel aktivite, denge ve mobilite fonksiyonları. *Van Tıp Dergisi*, 19 (3), 116-121.
- Suh, Y., Weikert, M., Dlugonski, D., Sandroff, B., & Motl, R.W. (2012). Physical activity, social support, and depression: Possible independent and indirect associations in persons with multiple sclerosis. *Psychology, Health & Medicine*, 17(2), 196-206.
- Sund, A.M., Larsson, B., & Wichstrøm, L. (2011). Role of physical and sedentary activities in the development of depressive symptoms in early adolescence. *Social Psychiatry and Psychiatric Epidemiology*, 46(5), 431-441.
- Tajvar, M., Arab, M., & Montazeri, A. (2008). Determinants of health-related quality of life in elderly in Tehran, Iran. *BMC Public Health*, 8(1), 323-40.
- Tamer, K. (2000). Sporda fiziksel-fizyolojik performansın ölçülmesi ve değerlendirilmesi. (2. baskı). Ankara: Bağırğan Yayınevi.
- Tawashy, A.E., Eng, J.J., Lin, K.H., Tang, P.F., & Hung, C. (2009). Physical activity is related to lower levels of pain, fatigue and depression in individuals with spinal-cord injury: A correlational study. *Spinal Cord*, 47(4), 301-42.
- Teychenne, M., Ball, K., & Salmon, J. (2008a). Associations between physical activity and depressive symptoms in women. *International Journal of Behavioral Nutrition and Physical Activity*, 5, 27-38.
- Teychenne, M., Ball, K., & Salmon, J. (2008). Physical activity and likelihood of depression in adults: A review. *Preventive Medicine*, 46(5), 397-411.
- Yardley, J.E., Kenny, G.P., Perkins, B.A., Riddell, M.C., Goldfield, G.S., Donovan, L., ... & Sigal, R.J. (2015). Resistance Exercise in Already-Active Diabetic Individuals (READI): study rationale, design and methods for a randomized controlled trial of resistance and aerobic exercise in type 1 diabetes. *Contemporary Clinical Trials*, 41, 129-138.