Original Article

A Randomized Clinical Trial of a Self-Determination Theory-Based Intervention on Physical Activity of Women Aged 30-45 Years

Mohammadreza Ghaneapur [1]*, Hassan Eftekhar [2], Ali Montazeri [3], Elahe Saleh [4], Mohamad Ezati Asar [1]

[1] Department of Health Education & Health Promotion, School of Public Health, Semnan University of Medical Sciences, Semnan, Iran. [2] Department of Health Education and Health Promotion, School of Public Health, Tehran University of Medical Sciences, Tehran, Iran. [3] Population Health Research Group, Health Metrics Research Centre, Iranian Institute for Health Sciences Research, ACECR. Tehran, Iran. [4] Department of Epidemiology and Biostatistics, School of Public Health, Tehran University of Medical Sciences, Tehran, Iran.

Abstract

Background: Despite the existence of much evidence about the importance and impact of physical activity in maximizing the various dimensions of health, steps have been taken to increase physical activity in the continuation of regular physical activity in women who have not been very successful. **Materials and Methods:** To investigate the effect of SDT-based intervention on physical activity and motivation drivers, this Randomized Clinical Trial parallel design was conducted in a comprehensive health center of Damghan at the northeast IRAN, 2017-2018. In this research, 114 women (age 30-45 years, non-pregnant, physical activity without medical prohibition, body mass index less than 35 (kg / m2) were randomly allocated in two groups: intervention and control. Physical activity and motivation drivers were studied as a study outcome. The MPAM-R questionnaire was completed via interviews with all participants. The mean scores of the intragroup and intergroup components at the beginning, one and three months later (5% alpha error and 80% power) were assessed. **Results:** Among the drivers of physical activity through the MPAM-R questionnaire, the effect of the "pleasure and interest" component in increasing physical activity of women in the SDT group, and "fitness" in the control group were statistically significant. Also, between the number of aerobic steps a person took while walking, the mean distance walked, and finally, the average calorie consumed by a person through daily physical activity each day after the study increased in SDT-based intervention group compared to the onset of the study and this increase continued for three months after the intervention. **Discussion and Conclusion**: Although SDT-based interventions can be effective in stabilizing and maintaining physical activity and similar health behaviors, lack of providing autonomy-supporting environments and lack of implementing SDT-based RCT and quasi-experimental interventions in the cultural and social context, etc. given the demographic and contextual variables and other social and cultural components related to health make it difficult to judge on the results and generalize them into other populations.

Keywords: SDT-based intervention, Happiness, Quality of life, Physical activity, RCT

Introduction

Changes in the pattern of diseases have led to a shift in the focus of health care from "disease and care" to "behavior and health" and, as a result, a change in the welfare policies of some countries toward individual responsibility of citizens and self-management [1]. Several factors, such as background, lifestyle, and social and economic conditions, known as "social determinants of health (SDH) also affect a person's health status. Social determinants of health are defined as situations in which people are born, continue to live, and work, and these conditions affect their ability to enjoy a healthy life [2]. Recent health promotion models have adopted SDH as a key component of the socioeconomic and political environment that affects their lifestyle and selective health behavior and quality of life [3]. Other important components related to people's health include "physical activity", which is effective in promoting physical and mental health throughout a person's life [4]. It is associated with promoting mental health [5, 6], better body mass index (BMI) [7, 8], health-related behaviors [7], and satisfaction and quality of life [9] and one's general physical activity is accompanied by more happiness [10]. In some studies, lower body fat percentage, weight, and BMI have been reported as better markers of quality of life

Address for correspondence: Mohammadreza Ghaneapur, Department of Health Education & Health Promotion, School of Public Health, Semnan University of Medical Sciences, Semnan, Iran.
Email: mrghaneapur@semums.ac.ir

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[11]. In this regard, paying particular attention to the maternal and women's health as half of the society will lead to improving the health of other family members and ultimately the society and will reduce costs, improve efficiency and effectiveness in the health system [12]. Inactivity or immobility is among the threats to women health and despite the Importance and benefits of physical activity in providing, maintaining and promoting the health and quality of life of individuals, many women in developed and developing countries are physically inactive [13-15], So a small percentage of US citizens (15%) follow proper physical activity. [16] and unfortunately between the years 2013 and 2017, people inactivity in European countries has generally increased. The rate of inactivity varied from 23% in Sweden to 62.4% in Italy [17] and in Iran, 31% of men and 48.6% of women do not have proper physical activity [18].

Many studies have emphasized "individual education" as an important strategy to promote physical activity [19] and some studies suggest that "providing environmental awareness" is an effective intervention to increment the physical activity of adults who are the risk [20]. The results of some investigate illustrate that although 79.5% of respondents of the study believe that inactive people are exposed to serious health problems, 94% of their believed in the impact of physical activity on their lives, merely 46.1% of these individuals reported adequate physical activity [21] and many of the efforts made in recent years to increase and improve physical activity and exercise have not been very successful in creating continuous physical activity [22, 23]. Moreover, it has been proven that a set of intrinsic and extrinsic motivations is effective on behavior and continuity of behavior, including Individuals' physical activity and several theories such as self-determination theory (SDT) have examined it [24]. SDT was first introduced in the 1970s. It focuses on basic psychological needs, including autonomy, competence, and relatedness with others [25]. SDT is a macro and essential theory of human motivation, personality development, and well-being that focuses on voluntary and autonomous behaviors and the social and cultural conditions that promote it. The fulfillment of these needs, Regardless of the structure of culture or evolutionary stage, is considered essential for human vital and healthy functioning [26]. SDT researchers believe that as one’s motivation is more autonomous, his or her insistence in continuity and peace of mind in a particular activity or domain will increase [27]. To determine the type of motivation and drivers related to physical activity and its continuity, various scales, and questionnaires such as Breq, Breq-2 [28], and MPAM-R [29, 30] have been designed and used in recent years in some countries. So far, few studies in Iran have been designed and implemented in this regard; the present study was conducted to investigate the effect of a Self-Determination Theory-based physical activity intervention on the quality of life of women.

Methods and Materials

Aim:

The present study was conducted to explain the impact of SDT-based intervention on physical activity and related components among women aged 30-45 years as a Randomized Clinical Trial. The protocol of this study has been published [31] and here we will briefly review.

Setting/participants:

This study was conducted in a comprehensive center of urban health services in Damghan, Semnan province, in the northeastern region of Iran. The statistical population of the study included women aged 30 to 45 years covered by the selected center, and all of them were invited to participate in the study via phone call. Voluntary presence in the research and providing equal opportunities for all participants were always considered by researchers. Women who wished to participate in the study were enrolled. (n = 149). Due to spouse dissatisfaction and evaluation of them in terms of inclusion criteria, 35 people were excluded and 57 people were included in each of the two groups. We used the term "SDT group" instead of the "SDT-based or intervention group" because of its ease of use throughout the text.

Random allocation of participants:

After obtaining written consent, participants were allocated to SDT and control groups via the "Permuted Randomized Block Design" method and the Block Stratified Randomization Ver.6 program. The tests on the homogeneity of the variables were performed in two groups and the results were evaluated.

Inclusion criteria:

The criteria for entering the study were: women aged 30 to 45 years, lack of regular participation in physical activity, lack of medical problems leading to inhibition of physical activity, BMI (body mass index) less than 35, and no pregnancy. The right to leave the study was considered for all participants and at each stage of the study.

Intervention:

All participants, including the SDT-based intervention group and the control group, received education materials, pedometer, and guidelines for using and protecting them, and underwent the designed interventions following the prescribed protocol for 8 hours at the same location. The strength of the present study is providing SDT-based intervention in the intervention group and providing routine educational interventions in the control group and that participants in both groups were given a pedometer.

Evaluation of intervention/data collection:

All participants in the SDT and control groups were assessed, evaluated, and compared at the beginning, one and three months after the intervention.

The questionnaire and research tools include:

1. **Demographic and contextual questions** (17 questions).
2. **Motivations for Physical Activity Measure – Revised** (*MPAM-R*) (30 questions): The participants' physical activity drivers were evaluated by the MPAM-R, which included 30 questions. This questionnaire was first developed in 1993 by Frederick and Ryan and revised in 1997 by Ryan, Frederick, Lepes, Rubio, and Sheldon [29, 30]. The MPAM-R assesses the following five motivations: **A**. **Pleasure/interest**, being physically active just because it is fun and makes the person happy, favored, mobile, and enjoyable. **B**. **Competence**, being physically active just because it is a desire to improve activity, face problems, and acquire new skills. **C**. **Appearance**, the person is physically active and thus is more physically attractive and has better muscles, looks better, achieves, or maintains the desired weight. **D**. **Fitness**: Being physically active, regardless of whether the person is physically healthy, strong, or energetic. **E**. **Social**, being physically active due to being with friends and meeting new people. The two motivations of "**pleasure/interest**" and "**competence**" are referred to as "**intrinsic motivation**" and other factors such as "appearance", "fitness" and "social motivations" are referred to as "**extrinsic motivation**". This questionnaire includes 30 questions scored on a 7-point Likert scale and lists of the reasons that people engage in physical activities. Based on this questionnaire, people determine their physical condition in each case in a range of 1 "not always true" and to 7 "always true" depending on the level of physical activity. Finally, the person state is determined based on the score obtained.
3. **Measurement of participants' physical activity:** Omron walking style Pro 2.0 Hj-322U-E pedometer was selected to be used in this study by reviewing the similar studies [32, 33] on the measurement of physical activity by the pedometer, disadvantages, and advantages of each of the existing pedometers/accelerometers, including services, easy to use, storage and duration of memory, the possibility of data extraction, error rate and accuracy of the pedometer, vulnerability, cost and way of protecting them by participants as well as the possibility of connecting to a computer via USB and data discharge with the help of Bi-Link Gateway2.2.0.0 software, which largely prevents human errors during data transfer. This pedometer is simply placed in a pocket, on a belt or as a necklace on one's body, and measures the number of steps, distances traveled, the calories consumed by walking, and especially the number of aerobic steps taken by the person. There is always the possibility that having a pedometer alone may lead to increased physical activity, so it is considered as confounding factor that by reviewing the studies conducted Studies to investigate the consequence of pedometer on physical activity, it was found that there was no ideal relationship between the intervention and the hypothesis of change in level and slope of the line or variance of the number of steps (per day) due to the pedometer in any of the participants [34]. However, in the present study, pedometers were given to both groups to avoid any possible errors.

Statistics and Sample size:

According to similar studies (s =5.96) [35], the sample size was set at 86 people, but due to the possibility of dropout in samples during the implementation and follow-up stages, the number of designated samples increased to 114 (57 in each group). The collected data was entered into SPSS.22 software. After examining the normality of the data, to determine the homogeneity of the SDT and control groups in terms of quantitative demographic data, Mann-Whitney or independent t and Chi-square or Fisher's exact tests were used to check the homogeneity of qualitative data. Mean, Standard error of the mean was used to describe the data. The changes in each group were evaluated using pair t-test and Wilcoxon and repeated measure tests. Analysis of covariance and logistic regression was also used to remove the possible effect of initial values.

Ethical considerations:

After examining the individuals' eagerness to participate in the research in terms of inclusion and exclusion criteria, to enter the research and conduct further follow-ups, all participants completed the conscious consent form. The code of ethics of IR.TUMS.REC.1394.1020) was received from the Ethics Committee of the Research Deputy of Tehran University of Medical Sciences and the code of IRCT IRCT201602020223072N1 was also obtained for the implementation of the research.

Results

The statistical population of the study included urban women aged 30 to 45 years referred to one of the comprehensive centers of urban health services in Damghan and out of 114 eligible participants, only 92 women were present at all stages of the study. During the study, SDT group number decreased to 38 people for reasons such as having a young child (n = 3), spouse dissatisfaction (n = 4), lack of personal desire to continue participating in the study (n = 11) and pregnancy (n = 1), and for reasons such as unwillingness to continue participating in the study (n = 2) and pregnancy (n = 1), 3 people were excluded from the control group and the number of participants decreased to 54. Respectively the mean age of the subjects in the SDT and control groups was 36.25 and 36.54 years (P-V = 0.708), and 91.7% and 82.7% of the women in the SDT and control groups, were married (P-V = 0.345), 44.4% and 51.9% of the participants in the SDT and control groups, had a university education (P-V=0.490) and 19.4% and 28.8% of the women in intervention and control

groups, were employed in the administrative organizations (P-V = 0.317). No significant statistical differences were observed between the two groups. Data on individual motivation to perform physical activity in two groups of intervention and control (before and three months after the intervention) were collected by MPAM-R and compared and analyzed by Paired t-test and analysis of covariance. Accordingly, in the SDT group, the component of "pleasure and interest" (P-V = 0.037) and the control group "fitness" (P-V = 0.038) were statistically significant, but in other components, no significant statistical difference was observed within and between the groups (Table 1).

Repeated measure test was used to measure physical activity and related components, including the number of steps, took while walking (per day), the mean distance walked (meters), the energy consumed (kilocalories), and the number of aerobic steps a person took while walking. In the SDT group, the number of steps taken one and three months after the intervention had a significant increase compared to the beginning of the study (P-V = 0.011) but compared to mean some steps in the control group, an increasing trend in the number of steps were observed one month later, but the number of steps decreased significantly three months later (P-V = 0.001) (Table 2). Also, based on the results obtained in the intervention group (after implementing the intervention), the number of aerobic steps a person took while walking per day increased compared to the beginning of the study and this increase continued for three months after the intervention (P-V = 0.445). The mean distance traveled each day increased compared to the baseline of the study, and this increase continued three months after the intervention (P-V = 0.154), and finally, the amount of calorie used by a person during physical activity increased compared to the onset of the study, and this increase continued for three months later (P-V = 0.098).

In above-mentioned periods, a statistically significant difference was observed in the number of individuals in the aerobic steps (P-V = 0.038), distance traveled (P-V = 0.003) and calorie consumption (P-V = 0.001) in the control group, but an increasing and constant trend was not found over time. However, in the number of steps taken while walking (per day) (P-V = 0.451), the distance traveled (P-V = 0.466), the average calorie consumed by a person due to walking (P-V = 0.558) and the number of aerobic steps taken (P-V = 0.090) was not found a significant difference between the two groups.

To investigate the distribution of physical activity data, including the number of steps taken while walking per day, distance traveled, energy consumed and aerobic steps measured by a pedometer, repeated measure analysis was used. According to Mauchly's Test, the sphericity hypothesis is rejected. Based on the results of the Greenhouse-Geisser test on the number of steps, the sphericity hypothesis was rejected according to the Mauchly's Test ($p = 0.05$). It was also found that the number of steps of the participants at different times in the control group (P_VALUE = 0.001) and in the intervention group (P_VALUE = 0.011) differs, but the number of steps between the two groups is not significantly different (P_VALUE = 0.45). Concerning the distance traveled in meters, according to Mauchly's Test ($p = 0.069$), the sphericity hypothesis is accepted. According to the Sphericity test, the values of the distance traveled in two or three different times were different only in the control group (P_VALUE = 0.003), but no difference was observed between the two groups (P_VALUE = 0.47). Concerning calorie consumption (Kcal), according to Mauchly's Test ($p \leq 0.01$), the sphericity hypothesis was rejected. According to the Greenhouse-Geisser test, there was a difference between the amounts of energy consumed at times only in the control group (P_VALUE = 0.001) and there was no difference between the two groups (P_VALUE = 0.56). Based on the results of the Greenhouse-Geisser test on the number of steps, the Sphericity hypothesis was rejected according to Mauchly's Test ($p \leq 0.01$). Also, the number of aerobic steps at different times was different only in the control group (P_VALUE = 0.038) and no difference was observed between the two groups (P_VALUE = 0.09) (Table 2).

Discussion and Conclusion

A total of 114 women were eligible in this study but only 92 women were present at the end of the research (the percentage of dropout in participants was 19.7%). The present study aims to achieve more realistic results by eliminating or replacing the defects and ambiguities of similar studies and in the context of society. Thus, the present study can be considered as a leading study on women's health in the context of real life. Accordingly, we simultaneously examine the impact of SDT-based intervention on physical activity and each of the relevant components and analyze predictions to examine the possibility of using it in future health promotion programs Introduce SDT-based intervention on physical activity and motivation drivers. Concerning the change in motivation levels after SDT interventions, despite the significant difference between the results before and after the intervention in the intervention group, no significant difference was found between the two groups of intervention and control. Researchers believe that given the duration of the study compared to similar cases, lack of providing an autonomy-supporting environment at conditions of comprehensive urban health service centers makes it difficult to make the judgment in this regard. Based on Self-Determination Theory (SDT), the environment supporting the essential psychological needs (autonomy, competence, and communication with others) is a prerequisite for autonomy-based motivations [36] that should be considered in future studies. Based on the present study findings, among the five drivers of physical activity, only "interest and pleasure" had a significant relationship with motivation to perform physical activity among study participants, which confirms

the results of the study conducted by Luong, Amy et al [37] who showed "interest and pleasure" were significantly more effective than other motivations in physical behavior. The results of this study also consistent with the findings of the study conducted by Do Nascimento Júnior [38] which confirmed "pleasure and happiness" as a determinant of a healthy lifestyle among students, and the difference between the two groups was significant after SDT interventions. Hence, in motivational interventions aimed at improving physical activity, it will be very important to pay attention to the "pleasure and interest" component.

In the present study, in addition to the distance traveled and the calories consumed, the number of aerobic steps were measured and compared for the first time in an SDT-based RCT. The findings showed that within one month of the intervention, the distance traveled, calorie consumed, and the number of aerobic steps increased in both groups, although it was not statistically significant. This increasing trend continued only in the SDT-based group in a 3-month evaluation. In other words, in the control group, a return to the previous state (relapse) of physical activity occurred. Based on the above evidence, the use of SDT-based interventions can be more effective in stabilizing and maintaining physical activity behavior and even similar health behaviors and these results confirm the results of a study implemented by Kaminski et al [22]. Although the findings of a study conducted by Mahmoud Abad [39] indicated a significant increase in physical activity in the SDT-based intervention group, as physical activity was not measured by appropriate tools in his study, so it is not possible to make a clear and definite judgment about reducing or maintaining behavior after the study period.

In another randomized trial conducted by Duda et al, a significant improvement in physical activity (except for walking), a sense of vitality, indicators of anxiety and depression, changes in overall health and well-being in 3-month follow-up was observed and a significant improvement in the quality of life was observed in 6-month follow-up compared to baseline (based on the Dartmouth quality of life domains) [40]. Due to the use of different questionnaires and the differences in the methodology used, it will be difficult to judge in this regard. Although the results of some cross-sectional studies have shown a positive correlation between physical activity level and health-related quality of life, there are limited longitudinal studies on implementing RCT to prevent a definite statement on the nature of this correlation [41].

Results of some cross-sectional studies suggest that even people who exercise insufficiently have a better quality of life compared to inactive people, but they do not have a better quality of life than those who have physical activity based on the recommended level. It has also been shown that performing "too much physical activity" can reduce the benefits of quality of life. Thus, individuals should be divided into two groups of actions based on the amount of physical activity [42]. As mean physical activity (number of steps) recorded for individuals (in both SDT and control groups, at the onset of the study, one and three months after the intervention is classified at the moderate level based on recommendations of the World Health Organization [43], it was not possible to investigate this possible difference. Researchers of the present study believe that inability to observe blindness in this study and the possibility of contamination, unequal conditions of the participants due to physiological reasons and due to women conditions during menstruation, adhering to previously-learned methods, lack of providing autonomy-supporting environments in comprehensive health service centers, a short period of the study period and the impossibility of holding sessions with short intervals due to the limitation of transferable tools (pedometers) can largely justify these results.

Self-Determination Theory (SDT) is a macro and essential theory of motivation, personality development, and human welfare. This theory focuses specifically on the behavior of kinship or self-regulation and the social and cultural conditions that improve it. SDT also includes a set of basic universal and psychological needs, the needs that are necessary for autonomy, competence, and relatedness, and to achieve them is essential for healthy human performance regardless of culture or level of development [26]. Although SDT claims that independence is a key factor in changing motivation and maintaining behavior, a significant number of investigates have shown that changes in motivational structure do not lead to actual behavior [44].

Various studies have been implemented so far on SDT and measurement tools related to its various fields in many countries, including Iran, and several scales and tools have been introduced, but there has always been a major gap that these tools will be developed when they can measure all defined SDT domains and components. There are still some ambiguities about the ways of motivating people to change multiple health risks, such as the impact of interventions on a limited number of factors affecting the physical activity and quality of life and SDT components have been considered selectively and measurement tools have been used in conditions where they do not cover all aspects of the intervention. Also, in some studies, the control group has not been predicted and considered, good and appropriate financial incentives have been provided at the time of data collection, a standard and specific intervention have not been provided and inadequate routine interventions have been proposed. In some cases, erroneously, motivational interventions (MI) have been considered equal to SDT, and self-report methods have been used to collect data, and in several cases, a method to eliminate the confounding effect has not been considered.

Limitations of the study

Due to unpredictable reasons such as unwillingness to continue participating in the study, spouse dissatisfaction, pregnancy, some samples were excluded from the study, which considering a higher volume of samples could be considered necessary in similar studies. Also, "educational", "behavioral" and "medical" approaches have been selected as the dominant approaches to health education to implement awareness or attitude change interventions to change the health behavior of the people in the health system of countries such as Iran, making it difficult to implement innovative and incentive programs. Also, due to the implementation of research in the comprehensive urban health services center and the impossibility of separating the participants and the possibility of the impact of the knowledge and awareness received from the environment, it was not possible to fully provide autonomy-supporting environments based on the designed protocol.

Recommendations

Recent studies have investigated the complexity of the relationship between physical activity, one's health status, and social functioning for quality of life and related components. Results of the studies on gender differences in physiological responses to physical activity have shown that models and predictions about physical activity vary under the infiltration of gender. Therefore, further studies on the benefits, barriers, and personality outcomes of physical activity for women, especially in cases such as urinary incontinence, depression, and mood and obesity disorders that lead to an inability to communicate [45] should be performed. To investigate the causes and inactivity, low motivation of people to participate in physical activity increasing programs, conducting qualitative studies, especially exploratory, in both genders and age groups is recommended. Although growth-dependent tendencies in which internalization motivation plays a role and they evolve and seem natural, it does not mean that motivational factors operate strongly in all situations [26]. Hence, other studies are needed according to each of the demographic groups and based on special needs and in the social and cultural context of different communities.

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Table 1. Frequency distribution of data related to Motives for Physical Activities Measure – Revised (MPAM-R) of the participants in the intervention group (baseline and one month after the intervention

MPAM-R Components / Study groups	Social		Fitness		Competence		Appearance		Interest_ Enjoyment	
	Before Mean (SD)	After Mean (SD)	Before Mean (SD)	After Mean (SD)	Before Mean (SD)	After Mean (SD)	Before Mean (SD)	After Mean (SD)	Before Mean (SD)	After Mean (SD)
SDT Group	21.3 (1.6)	21.3 (1.5)	28 (1.5)	30.6 (1)	32.1 (2.2)	35.4 (1.8)	28.6 (2.2)	31 (1.8)	34.3 (2.1)	37.8 (1.6)
P-Value (Within)	0.968		0.100		0.578		0.053		0.037*	
Control group	20.8 (1.3)	21.2 (1.3)	27.3 (1.3)	28.8 (1.2)	33.5 (1.8)	34.7 (1.6)	29.1 (1.6)	29.3 (1.5)	33.8 (1.4)	35.8 (1.2)
P-Value (Within)	0.769		0.038*		0.175		0.564		0.917	
P- value (Between)	0.778		0.282		0.452		0.305		0.075	

*significant at the 0.05 level

Table 2. Comparison between and within groups of participants components of physical activity (baseline, one and three months after the intervention)

Study groups / variables		SDT group			Control group			P-value
		Baseline	1 month later	3 month Later	baseline	1 month later	3 month later	
NST	Mean(SE)	4601.51(376.2)	5642.74(427.9)	5650.87(418.9)	4465.73(240.5)	5573.07(432.9)	4779.01(356.6)	0.45
	P- Value		0.011*			0.001*		
ADT	Mean(SE)	2998.20(288.3)	3339.23(266.9)	3353.61(264.9)	2803.03(174.4)	3320.00(253.8)	2879.26(219.6)	0.47
	P- value		0.154			0.003*		
ACCW	Mean(SE)	91.38(16.03)	121.02(16.03)	111.61(15.2)	71.56(7.1)	102.02(11.4)	83.46(10.2)	0.56
	P value		0.098			0.001*		
ANAS	Mean(SE)	1449.51(363.4)	1695.2(351.17)	1700.12(340.1)	737.86(151.9)	1358.05(267.8)	970.59(220.5)	0.09
	P value		0.445			0.038*		

Number of steps taken per day(NST), Average distance traveled per day (ADT), Average calories consumed while walking(ACCW), Average number of aerobic steps(ANAS)
*significant at the 0.05 level