

# Effectiveness of a Self-Determination Theory (SDT) Based Intervention on Physical Activity, Quality of Life, and Happiness: A Protocol for a Randomized Clinical Trial

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## Abstract

Background of the study: Despite the important role of physical activity in maximizing health during the life span, impaired mobility is the main cause of diseases such as breast cancer, diabetes and a significant proportion of the burden of ischemic heart diseases. This paper will describe the protocol for a randomized clinical trial of an SDT-based (self-determination theory) physical activity motivational intervention for women aged 30-45 years. To this end, an SDT-based intervention aims at promoting physical activity, quality of life and happiness of women. Methodology: A randomized controlled trial parallel design will be used to evaluate the effectiveness of SDT-based intervention on physical activity, quality of life, and happiness. Ninety two women aged 30-45 years (non-pregnant, Body Mass Index  $\leq 35$  (kg/m<sup>2</sup>) and without a medical ban to do physical activity) will be randomly allocated into the self-determination (intervention) and control group. The primary outcome will be the physical activity and motivation for physical activity and secondary outcomes will be the quality of life and happiness. Physical activity will be evaluated using 7-day accelerometer. Moreover, participants will complete MPAM-r, BREQ-2, EQ-5D-5L, SF-36 and OHI questionnaires. The change in the mean score of the determinants at baseline, 1 and 3 months after intervention will be compared between the two groups (5% alpha error and 80% power). Discussion: This study will be conducted to assess the effectiveness of an SDT-based intervention developed for 30-45 years old women. If successful, the intervention would help women with the necessary knowledge and skills to enable them to make healthier choices for themselves. Moreover, women living in urban areas with similar economic and social conditions would be able to benefit from the current research's experiences.

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**Key words:** SDT-based intervention, Happiness, Quality of life, Physical activity, RCT.

## Introduction

Physical activity (PA) plays a very important role in maximizing the individual mental and physical health during childhood, adolescence and throughout adult life (Cadogan, Keane and Kearney, 2014; Parker, Strath and Swartz, 2008; Mortazavi, et al., 2013). PA, especially at the beginning of life, is associated with better health outcomes (Dik et al., 2003; Piqueras et al., 2011) and has a significant relationship with low body mass index (BMI) (Lyubomirsky, King and Diener, 2005; Fararouei et al., 2013). Physical activity refers to any activity caused by the skeletal muscle that results in energy consumption (Caspersen, Powell and Christenson, 1985). To maintain and improve health, all healthy adults between ages of 18 and 65 require moderate intensity aerobic PA for at least 30 minutes

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and 5 days a week or 20 minutes of intense aerobic exercise 3 times a week (Cardiology, A.C.o. and A.H, 2006). Physical inactivity has been identified as the fourth most common cause of global mortality (6% of all deaths) and low mobility is estimated to be the main cause of 21-25% of breast and colon cancers, 27% of diabetes and it accounts for approximately 30% of the burden of ischemic heart diseases (Organization, W.H, 2009). Obesity and overweight are some of the cases where the association with a sedentary lifestyle is inevitable (Warburton, 2006; Organization, 2000). Parents' physical condition is predictive of childhood obesity (Charney et al., 1976) since both low-birth-weight and overweight infants are at increased risk of obesity in the future (Oken and Gillman, 2003). Parenthood obesity directly correlates with the birth weight of the offspring and there is a stronger relationship between the mother and infant than the father (Okun et al., 1997). The prevalence of obesity is developing rapidly in many countries and especially women's obesity is of particular importance and can be linked to the lack of mobility of women (Organization, 2000). About 75% of health care costs are related to chronic illnesses caused by unsafe behaviors such as physical inactivity, smoking and exposure to it and poor nutrition (Patrick and Williams, 2012). In 2004, obesity-related disability and its consequences were estimated at more than 36 million disability-adjusted life-years (DALYs) (Ezzati et al., 2004).

Despite the numerous evidence about the role and importance of participation in regular programs of PA in promoting health (Cadogan, Keane and Kearney, 2014; Organization, 2010), 23% of adults and 81% of adolescents in the world (aged 11 to 17) do not meet the global recommendations for physical activity (regular participation in PA for 60 minutes a day for children and 150 minutes spread throughout the week for adults) (Organization, 2018). In the United States, the results of the study indicated that 5.27% of adults aged - 50 years and older - did not have proper PA outside the workplace during the past month and inactivity rate was significantly higher in women than men (Watson et al., 2016). In Iran, physical inactivity is common, especially in women and elderly groups such that 40% of Iranian adults (31.6% of men and 48.6% of women) are on the floor with low PA and approximately 15% of adults (7.4 Million people) do not participate in a particular PA (Esteghamati et al., 2011). Recent studies have shown that the mobility of women has diminished such that more than 63% of them were inactive and only 22% of women had proper PA (Ghaneapur MR, 2017). The current inactivity situation depends on a large extent of insufficient participation in leisure activities and increased inactivity in the occupational field and other areas. Due to the expansion of urbanization, the increase of inactive methods of transport, traffic and many environmental factors such as violence, heavy traffic, bad weather, pollution, lack of parks, lack of leisure facilities and sports, the amount of PA and walking, has decreased (Organization, 2013).

#### *Physical activity, happiness and quality of life*

Recent studies have indicated that total PA performed by an individual associated with a higher level of happiness (De Souto Barreto, 2014) increased positive emotions that may turn depressed status into a happy mood, increased the satisfaction of one's life (Schutz et al., 2013) and was positively related to mental health (Chai, et al., 2010). Research findings suggested that health costs were negatively related to happiness levels and even health messages based on healthy lifestyles had less effect on depressed people (Graham, 2008). Happiness is a mental or emotional state characterized by contentment, love, satisfaction, pleasure or joy (Cook and Chater, 2010) that can be attributed to the general assessment of people's lives that may lead to a sense of momentum of pleasure (Subramanian and Kim, and Kawachi, 2005). Happiness can be considered as an important component of the quality of life; hence, the WHO has recognized happiness as a part of the concept of health (Oliveira Pinto, 2013) and on the one hand, quality of life is closely related to many factors such as self-perception of health, life satisfaction, and happiness (Brown and Bowling and Flynn, 2004). On the other hand, PA can improve satisfaction and quality of life (Feicht et al., 2013). High levels of happiness are associated with better health outcomes (Dolan, 2006), a higher level of life satisfaction (Bourne, Morris and Eldemire-Shearer, 2010) and simultaneously more suitable physical activity (Levasseur, Desrosiers and St-Cyr Tribble, 2008; Wang et al., 2012). Hence, some researchers believe that increasing happiness can increase the health of individuals (Veenhoven, 2008). Despite the reasons for the importance of happiness, according to a global ranking of happiness in 2013, Iran was ranked 115<sup>th</sup> country in the world (with a score of 643.4), and Denmark (with a score of 7,963) was the happiest country in the world. However, Togo (with a score of 2,936) was ranked 156<sup>th</sup> in the world (Helliwell, 2013).

#### *Physical activity intervention*

At the sixty-sixth World Health assembly (June 2013), members of WHO agreed upon reducing 10 percent of inactivity by 2025 (Organization, 2013) and 15% by 2030 (Organization, 2018). Regarding the important role of "self-awareness" in the health of individual, for many years, individual education has been emphasized as the main solution for increasing physical activity (Friedman and Kern, 2014). Several studies have also suggested the provision of environmental information, especially in adults and the elderly at risk as an effective intervention strategy to increase PA (van Stralen et al., 2010). Certainly, sports interventions cannot always be maintained and even those who fit into sports programs may be able to reduce their lifestyles. This fact reflects that current efforts to change lifestyles through such programs may lead to success in short-term adaptation of active lifestyles but they would fail to develop continuous sports behaviors (Kaminski, 2010). Hence, the results of the studies indicated that 50% of the participants in the physical activity plans abandoned the physical activity program within 3 to 6 months (Westen and Morrison, 2001). It is clear that changing the behavior is difficult but returning to a former behavior is simple (DeLong, 2006). The results of the research indicated the superiority of

motivational interventions over traditional approaches toward behavior change (Burke, Arkowitz, and Menchola, 2003). In spite of the rapid growth and development of motivational interventions and its expansion in various areas of health, there is not enough comprehensive information on this approach in Iran (Navidian, et al., 2010).

#### *SDT, A new approach to change physical activity*

Different models and methods for changing behavior have been proposed, but Self-Determination Theory (SDT) is the only theory of motivation and behavior change that emphasizes the importance of individual autonomy and its evaluation methods. The SDT was introduced in the 70s of the twentieth century as a result of studying the internal and external motivations. The SDT evolved through developing the perception of the dominant role of internal motivation in people's behavior. The SDT has a multidimensional framework, advantages and complexity and assumes that due to rewards and self-satisfaction - based on their vast nature - people are eager to learn, active, motivated and interested in success (Deci and Ryan, 2002). SDT emphasizes the need for a psychological basis including self-sufficiency (autonomy), competence, and communication. The degree of community facilitation to achieve the highest motivation to persuade depends on physiological needs including the need for a "sense of competence", "independence" and "dependence on others", which is explicitly emphasized in the SDT (Muller and Khoo, 2014). Based on SDT, the highest level of self-determination is "intrinsic motivation". To motivate a person, the intended behavior is interesting and enjoyable for the individual. In the cases of the community support from autonomy, individuals are motivated to "internalize" their important activities, thus when the community is being controlled, their self-dependent motivation would be weakened (Deci and Ryan, 2002). Therefore, SDT can even be considered for the prediction of behaviors such as fitness and a person's desire to exercise in the future (Carron, 2003). The SDT specialists claim that by protecting individual autonomy, choices are provided through recognizing individual views. Moreover, the onset of behavior is supported through providing related information, thus the motive for independent performance increases during the time. The process of increasing autonomy and competence is called "internalization" (Williams et al., 2006). One of the most important activities that can lead to permanent physiological and psychological outcomes - when it is internalized - is exercise (Kaminski, 2010). Internalization of PA would have a positive effect on has been made effort, encouraging to perform independent PA, implementation and long-term survival of the behavior. Therefore, setting goals for interventional sessions will be somehow that the selected goals are internal and focus on health and fitness of the individual than to be emphasized on external goals and focused on weight loss and physical appearance (Kaminski, 2010).

#### *Rationale*

The importance of maternal health in family and community health is not overlooked, but maternal health in some societies continues to face major challenges. Therefore, the health of mothers, children and adolescents has been supported and emphasized in the targets and global strategies of "Sustainable Development Goals (SDGs) by 2030" (Brizuela and Tunçalp, 2017). Numerous studies have been carried out on happiness, physical activity and quality of life on the health of specific groups (Maturi, Afshary, and Abedi, 2011) and patients, but few studies have been carried out simultaneously on happiness, physical activity and quality of life and their effects on healthy people. Moreover, several studies have been conducted on the SDT and its measurement tools related to its different domains and so many different tools have been provided. However, there is still a major problem with developed tools, which is able to evaluate all defined SDT domains. Even though there is a claim that SDT can even be used to predict fitness and intention of a person to exercise in the future (Carron, 2003), there is not enough information on how to motivate individuals to change their multiple health risks and in many cases, the effects of interventions are abstract. In countless cases, self-reports and some scholars even have stated that "interventions based on the theory have limited success in explaining and changing physical activity" (Adams, 2009). Although some studies suggest that increasing the level of self-efficacy, in general, would increase the chance of being happy, more specific self-efficacy measurements have not shown any independent effects (Natvig, Albrektsen, and Qvarnstrom, 2003). Since no comprehensive study has been conducted for this purpose in Iran, it was intended to investigate the effect of SDT-based interventions on physical activity, happiness, and quality of life of healthy women aged 30 to 45 years. Moreover, it was aimed at examining other related factors and comparing them with other methods having the same purpose, objectively and subjectively.

#### *Research objectives*

This study was conducted to evaluate the effectiveness of an SDT-based intervention on physical activity, quality of life and happiness.

## **Methods**

#### *Study design*

In a comprehensive health service center, a randomized controlled trial parallel design will be conducted to evaluate the effectiveness of SDT-based intervention on physical activity. The project and its appendixes (informed consent form) were approved by the ethics

committee of vice-chancellor of technology research in Tehran University of Medical Sciences (Code of ethics: IR.TUMS.REC.1394.1020). This protocol has been approved by the Iranian Registry of Clinical Trials (IRCT2016020223072N1).

### *Study population*

The eligibility of all women invited to participate in this project will be assessed via a letter and phone. After enrollment, a presentation will be held to all women to inform them about the trial including details about the intervention, controlling conditions and the chance of being in either conditions. All willing women to participate in the study will be involved in the research. The eligibility criteria for participants include women aged 30-45 years; BMI  $\leq 35$ ; not pregnant, no history of regular physical activity and lack of serious illness (or being on medicine) leading to any movement prohibition recommendation. Participants can withdraw from the study at any time without any consequences. Comprehensive health services center, Semnan province, in the northern regions of Iran, is the unit of randomization.

### *Study interventions*

In the first meeting, participants in each group will receive educational materials and related equipment (pedometer, brochures guide and instructions on how to use and protect a pedometer, and training exercise instructions in accordance with the ministry of health of Iran). SDT based group (intervention) will participate in 8-hour SDT based interviewing designed sessions about physical activity and will have access to SDT-based messages that include a mix of face-to-face meetings, texts and at the same time communicate with other related educational materials (Muller and Khoo, 2014).

This study will be based on the "motivational interview" and includes the following objectives:

1. Evaluating the perception, especially through listening reflection.
2. Declaration of acceptance and approval.
3. Extracting and selecting self-motivating expressions of the references about the diagnosis of the problem, the concerns, intentions of people to change and the ability to change.
4. Monitoring the level of readiness for change and ensuring that progress before the authorities does not lead to resistance.
5. Finally, emphasizing freedom of choice and self-referencing of the client (Rollnick and Miller, 1995) A summary of the SDT-based intervention is provided in Appendix1.

The control group will participate in 8-hour routine training sessions on physical activity.

Physical activity, body composition (body fat percentage, visceral fat level, subcutaneous fat, skeletal muscle and resting metabolism) and BMI as the primary outcome and secondary outcomes will be the quality of life and happiness. The outcomes of 1<sup>st</sup> and 3 months after the intervention will be measured and compared with baseline, 1<sup>st</sup> and 3 months after the intervention.

### *Target behavior / measuring physical activity*

Walking, which is a common, free, easy and safe form of physical activity with well-known therapeutic properties and a safe type of activity with well-known health benefits - 10,000 steps per day (that approximately equal to 5 miles or about 8 kilometers) for 5 days or more per week, will be considered as the ultimate goal for both groups. Of course, it was not expected that all participants can achieve this level of activity, but this goal is considered as a long-term goal (Organization, 2010; Adams, 2009). Determining 10,000 steps per day indicated an active lifestyle in adults. People with inactivity may never achieve this level of physical activity. Therefore, it is important to get information about their activities and strengthening their efforts to achieve their goals of behavior (Tudor-Locke, C. and D.R, 2004). As such, all women are encouraged to increase their step counts gradually, as they feel to do so.

A pedometer is a simple and relatively inexpensive device that uses different mechanical and electronic motion sensors to measure the amount of physical activity by calculating the number of steps. The accuracy of the pedometer may have a significant impact on the number of steps taken during a day. Therefore, it is essential that the pedometer shows the exact results (Schneider et al., 2003). The investigated findings proved that the HJ series of Omron pedometers (151 or 720 ITC) could be used as a precise and reliable instrument for measuring physical activity in self-walking and prescribed walking (very slowly to very fast). Moreover, validity and reliability of these two types of pedometer have been proven (Holbrook, Barreira and Kang, 2009). Among the features of the Style Pro pedometers (in particular the HJ-720ITC), it is possible to unload data via USB that is unique and can store data for more than a week, but due to lack of access to it and lack of production of HJ-720 in recent years, the research team intend to use the most similar brand of pedometer as the Style Pro 2.0 (HJ-322U-E) - the only difference is that the HJ-720ITC pedometer stores the measured data for 42 days than for 22 days by HJ-322U-E and these are the same in all technical and functional features.

All participants will complete motives for Physical Activities Measure-Revised (MPAM-R) (Sawatzky, et al., 2007), Behavioral Regulation In Exercise Questionnaire and its subsequent modification (BREQ-2) (Markland and Tobin, 2004), Oxford Happiness

Inventory (OHI) (Hills and Argyle, 2002), SF-36 (Montazeri et al., 2005), EQ-5D-5L (Herdman et al., 2011; Goudarzi et al., 2016) questionnaires. The mean score of the determinants at baseline, 1<sup>st</sup> and 3 months after intervention will be measured and compared.

In order to measure BMI and body component, the body fat meter BF-511 is used.

#### *Sample size and statistical analysis*

As the investigation will be a randomized trial, a formal sample size calculation based on detecting evidence for effectiveness has been conducted. The sample size was calculated for all parameters in this study. Among all these variables, the two parameters - SDT and the number of steps - yielded the largest sample size. To have 80% power to detect 4 scores difference between two groups when the standard deviation of the scores in the two groups were assumed 5.96 and 7.15 (Silva et al., 2010), a sample size of 43 in each group was required. The type 1 error was assumed 0.05 in this calculation. Descriptive comparisons of these data will be made between the intervention and control groups. The loss to follow-up in intervention and control groups will be reported. The mean, standard deviation, median, range, frequency, and the percentage are used to describe and interpret the data. To assess the changes within groups, a linear mixed model with sidak method will be used to correct the multiple corrections. To evaluate the difference between two groups when considering the effects of the clusters multilevel linear and logistic regression will be used. Additionally, the simultaneous effect of variables will be assessed in this model. Structural Equation Modeling (SEM) will be used to model structures as SDTs. All analyses will be performed by SPSS, version 22.0, software, as well as AMOS .

#### *Randomization*

Initial enrollment of individuals - willing to participate in the study – will be conducted. Participants will be assessed based on the inclusion and exclusion criteria and enter the study. Participants will be allocated to the intervention and the control group via permuted block randomized design (computer generated allocation) by an independent member of the RCT collaboration, who will be blinded to the women identity. However, due to the nature of the study, it will be difficult for researchers to be blinded in collecting outcome data and allocation of the participants completely. Women will be asked to study the assumptions and goals of the research carefully. They will be asked any questions and uncertainties to provide written informed consent to the trial and post-intervention evaluation interview. They are also asked to consent the confidential use of data to extract and analyze them ( Figure 1 shows the study flow diagram ).

#### *Limitations / Protecting against bias*

It is difficult for researchers to be blinded in collecting outcome data and allocation of the participants. However, none of the staff and other health workers participated in providing the intervention, collecting outcome data or follow up. To minimize the risk of contamination of control participants, two potential mechanisms will be used: Firstly, The health service provider has to be unaware of how the participants will be allocated and the content they received. Secondly, each of the two groups (intervention and control) will be invited to the meetings independently and the interventions will be presented to them in a different timeframe. Outcome data will be collected by skilled and trained researchers allied to the project. Since the findings of some studies on specific groups such as elderly, diabetic patients, cardiovascular and cancer patients have shown that using a pedometer and setting goals in terms of number of steps per day has increased the participant's physical activity in comparison with the control group, a pedometer is given to both intervention and control groups in the present study.

## **Discussion**

Due to the importance of physical activity in developing health (Organization, 2010), low level of physical activity (Organization, 2018), low-mobility complications especially in women of reproductive age (Watson et al., 2016; Esteghamati et al., 2011), and inadequate educational success in increasing physical activity (Friedman and Kern, 2014), new intervention approaches are needed. SDT-based physical activity trial aimed at using a motivational intervention to increase the physical activity thus, promoting happiness and quality of life of women aged 30-45 years. If successful, the SDT-based intervention would help women with the necessary knowledge and skills to enable them to make healthier choices for themselves. Moreover, women living in urban areas with similar economic and social conditions would be able to benefit from the current research experiences.

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### *Abbreviations*

BMI: Body mass index; SDT: Self - determination theory; ICC: Intra-cluster correlation; PA: Physical activity; QALY: Quality-adjusted life years; RCT: Randomized controlled trial; MPAM-R: Motives for physical activities measure-Revised questionnaire; BREEQ-2: Behavioral regulation in exercise questionnaire-2; ICC: Intra cluster correlation coefficient.

## Appendix 1

### *SDT-based intervention sessions*

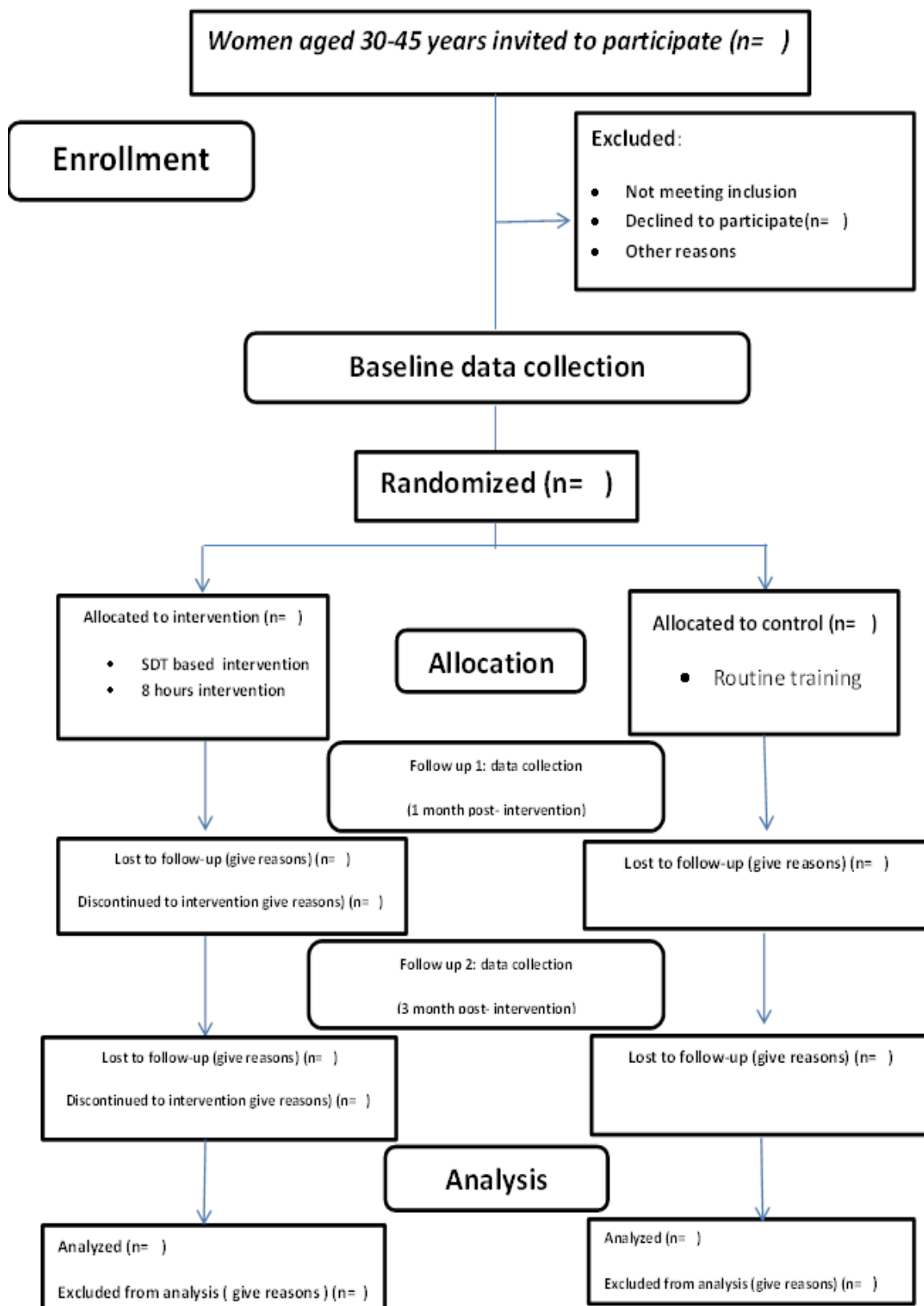
SDT-based intervention focused on incorporating physical activity into life values. Educational counselors were advocates to support participants in making explicit and independent decisions about whether they want to improve, modify or improve their physical activity. Participants were informed that increased physical activity and its continuity could enhance the health and quality of life of the individual. Then the consequences of the lack of mobility and its benefits to the health and quality of life of the participants were noted. The consultants were asked about the challenges of the individual's life and how he or she was doing current physical activity and its patterns, whether they were controversial or helpful. Objectives must be specific, measurable, achievable, realistic and have timeliness to be effective and focus on the aims and should be on real behaviors rather than on results (Donnelly et al., 2004). In these meetings, the counselor utilized and facilitated participation and acceptance of the goals and supported their favorable behavioral changes, through empathy and co-operation with the participants. By setting the real goals, matching individuals with real and transparent expectations about the aspects of their behavior, they became able to change, encourage themselves to believe that they were capable of changing their behavior and they had the ability to change behavior they wanted. These were followed by giving positive feedback, based on individual progress in their goals and behaviors (Kaminski, 2010).

At the first session, by conducting an assessment and understanding of the participants' viewpoints about physical activity, counselors provided information about benefits and barriers to physical activity and disadvantages and provided a list of effective choices for those who wanted to change. They discussed about the field of sports history and the benefits and risks of increasing physical activity (individual opinions of participants about the consequences of regular physical activity and health hazards for each person). Members of the team consulted and helped by other contributors for a specific target to participate in physical activities in the coming weeks. In addition to educational programs, a self-reading booklet was provided for monitoring and maintaining physical activity. Duration of the consultant meeting at the initial meeting was 50 to 70 minutes and was lessened to 30 minutes in the next meetings.

At the second session, the participants' viewpoints on the benefits and disadvantages of changing the level of physical activity, perceived barriers and resources for change were reviewed. Also, according to the protocol, participants were encouraged to see how their intentions could be more proactive and implemented and where and how they could benefit from community support for engaging in physical activity. These sessions had a high level of training, so that the counselor provided information to enable participants to make their choices about the current situation or adopt their own behavior based on their own.

In the subsequent sessions, the intervention involved more interaction between the collaborators and the research team (by phone and face to face), focusing on maintaining any positive changes, reformulation of problem-solving, attempts to the elimination of fail and will be focused on barriers and setting new individual goals in physical activity.

Further follow-up visits for those who do not want to change their physical activity that will force the counselors to re-examine the determination of such contributors. Advisors empowered those who wanted to change or increase their physical activity to identify and review plans or attempts to change and consider failures as "small successes".



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