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RESEARCH ARTICLE

IMPACT OF THEORY BASED EDUCATIONAL INTERVENTION ON KNOWLEDGE, BELIEF AND SELF-EFFICACY REGARDINGOSTEOPOROSIS AMONG THE FEMALE STAFF IN SELANGOR, MALAYSIA: RESEARCH CONCEPT, FRAMEWORK AND METHODOLOGY

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ABSTRACT

Background: Osteoporosis is a global health problem along with heart disease, stroke, diabetes and cancer which not only causes increase economic burden, it also leads to physical ,mental and social sufferings. It is considered as woman's chronic health problem which is characterized by decreased bone mass density, micro architectural deterioration of bone tissue and fragility fractures, particularly to the hip, spine, wrist and shoulder. It is a silent undiagnosed disease until a fracture occurs due to an accidental fall. Even though it could affect both gender, 80% of those affected are women. Worldwide, 1 in 3 women over age 50 will affected by osteoporotic fractures, as will 1 in 5 men aged over 50.

Objective: To develop, implement and evaluate effectiveness of an educational intervention program on prevention of Osteoporosis based Health Belief Model among the female staff in Universiti Putra Malaysia.

Methodology: Single blinded, Cluster Randomized Control Trial will be conducted among female staff in Universiti Putra Malaysia as full time. After cluster sampling, total 240 samples will be allocated in intervention and control group who will expose to educational module and follow up for three months to measure the outcomes. The intervention group will give prevention of osteoporosis knowledge based on Health Belief Model and the control group will in wait list. The data will analyse by computer software SPSS version 22 and the descriptive statistics, paired t test, repeated measure ANOVA, chi square, general linear model will do to measures the outcome. Results from this study about knowledge, belief and self-efficacy regarding osteoporosis among the female staff will help to identify areas that need focus and enforcement.

Key words: Osteoporosis, Health belief model, Intervention study, Female.

INTRODUCTION

WHO has defined osteoporosis as a systemic skeletal disease characterized by low bone mass and micro architectural deterioration of bone tissue with a consequent increase in bone fragility and susceptibility to fracture, which generally entails the wrist, backbone, hip, ribs, pelvis or humerus (Elizabeth, 2011). It is a foremost public health problem affecting millions of people globally, with huge physical, psychosocial and economic consequences for the affected person and the health care system Chang, 2007). Women are at high risk of getting osteoporosis because of attainment of decrease peak bone mass early in life and hormonal changes that arise at the menopause (Yeap *et al*., 2013).Osteoporosis is a crippling condition that not only causes economic burden but additionally results in social, physical and mental effects which expected to affect globally by2050 (Yusra *et al*., 2013).Osteoporosis can start as early as age twenty-five, yet majority of those affected by osteoporosis are postmenopausal women (Yosria *et al*., 2014). Since the bone density decreases with age, acquisition of peak bone mass during the first three decades and the following retention of bone through middle age are essential determinants for reducing the risk of osteoporosis (Valerie and Bollenbacher, 2014). Osteoporosis is not limited to the developing older population but has implications for all age groups. Although osteoporosis can have an effect on either gender, 80% of these affected are women (Vytrisalova *et al*., 2008). Worldwide, 1 in 3 women over age 50 will revel in osteoporotic fractures, as will 1 in 5 men aged over 50 (Yusra *et al*., 2013). Furthermore, each year, 1.5 million fractures are attributed to osteoporosis, such as 350,000 hip fractures (Cooper *et al*., 1992). Seventy percentage of those struggling fractures from osteoporosis don't return to their pre injury status. The National Osteoporosis Foundation USA estimates that approximately 24% of the approximately 300,000 people who fracture a hip every year die within one year (Pizzorno and Lara, 2011). Many others suffer extreme depression and withdraw from society because they are so frightened of breaking bones. The intense and long-term hospital treatment charges related to these fractures cost the nation an estimated $17 billion (RM 52 billion) in 2005. The cumulative cost over the subsequent two decades is estimated to be $474 billion (RM 1500 billion) worldwide. In addition to a financial burden, osteoporosis-associated fractures deliver a burden of pain and disability, ensuing in lost time or incapability to perform daily dwelling activities(Cooper *et al*., 1992).In

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Malaysia, the most comprehensive survey in hip fracture incidence was done in 1996–1997 which was a retrospective study, whereby it was stated that the rate was 218/100,000 for women and 88/100,000 for men (Lee and Khir, 2007) and the prevalence of osteoporosis in Malaysia was reported as 24.1% in 2005, predominantly affecting the hip among the elderly(Lim *et al*., 2005). Currently there are no intensive curative treatment measures for osteoporosis similar to other chronic diseases; diabetics and hypertension; however, there are many preventative measures that can be taken to dissuade the development of the disorder. One of the method to prevent osteoporosis is to apply population based interventional approaches to decrease the risk of osteoporosis. Previous research shows that health education or health promoting interventions have the capacity to persuade selected health behaviors that affect bone health (Laslett, 2004).

Study Aim

In Malaysia, there is scarcity of local studies which discuss the level of awareness toward osteoporosis in both females and males members, therefore the present study will be conducted with the purpose of assessing the effect of osteoporosis preventive health education program based on Health Belief Model (HBM) on knowledge, beliefs and behavior towards osteoporosis among the female staff in Universiti Putra Malaysia in Serdang. In addition, it will examine the constructs of the HBM, perceived susceptibility, severity, benefits, barriers, and health motivation, related to osteoporosis prevention. So it could be as a basis for health care providers to plan and develop effective osteoporosis prevention education programs based on HBM. The use of an evidence based approach when setting the intervention outcomes will be a potential to affect the burden of osteoporosis. The result would indicate the degree to which the intervention design improves on current practice.

Significance for public health

Osteoporosis, the utmost common bone disorder, generally does not manifest until late life, when bone loss begins due to bone breakdown and decreased levels of bone formation. Loss of bone mass leads to the development of structural abnormalities that make the skeleton extra fragile causes fracture which is very expensive to treat. It not only causes increase financial burden but also leads to social (loss of job), physical (unable to walk) and psychological (depression) consequences which expected to affect more people globally. Worldwide, 1 in 3 women over age 50 will experience osteoporotic fractures, as will 1 in 5 men elderly over 50. Osteoporosis is preventable. Health education on osteoporosis is crucial for higher aware of the etiology and symptoms of osteoporosis and how proper nutrition with regular exercise can help to achieve optimal peak bone mass. So, the public health impact of osteoporosis consists of important and sustained effect on mortality, substantial upsurge in functional impairments and improves quality of life and cause diminution of financial burden on our health care structures.

Theoretical implication: The Health Belief Model and osteoporosis

Health Belief Model is described as an individual level theory. It theorizes whether or not people are susceptible to a disease, and if their perceptions of the benefits of trying to avoid a disease influence their readiness to act. Six constructs are used to explain behavior. Perceived susceptibility is defined as the belief about the chances of getting a condition. Perceived severity is defined as the belief about the seriousness of a condition and its consequences. Perceived benefits are the beliefs about the effectiveness of taking action to reduce risk or seriousness. Perceived barriers are the individual's about the material and psychological costs of taking action. Cues to action are the factors that activate their readiness to change. Self-efficacy is the confidence in one's ability to take action (Glanz, 2002).

This was added to allow better accounting of habitual behavior (Hazavehei, 2007). By utilizing the HBM, an understanding of health behaviors and reasons for non-compliance are possible. Osteoporosis programs utilize this model to plan and intervene with at risk populations. For example, a reason typically cited for non-compliance to osteoporosis programs is the belief that osteoporosis is not severe. Fifty percent women believed osteoporosis is a minor health problem, and 53% think it is a curable disease (Drozdzowska, 2004). Through the HBM, researchers can increase the likelihood of healthy behaviors if people perceive a disease as severe.

Conceptual framework

According to the HBM, certain variables may influence preventive actions. Healthy behaviors are likely to occur if an individual feels susceptible to osteoporosis and feels that osteoporosis is serious. Perceived benefits of osteoporosis preventive actions with few barriers to the action add to the likelihood of osteoporosis preventive behaviors.

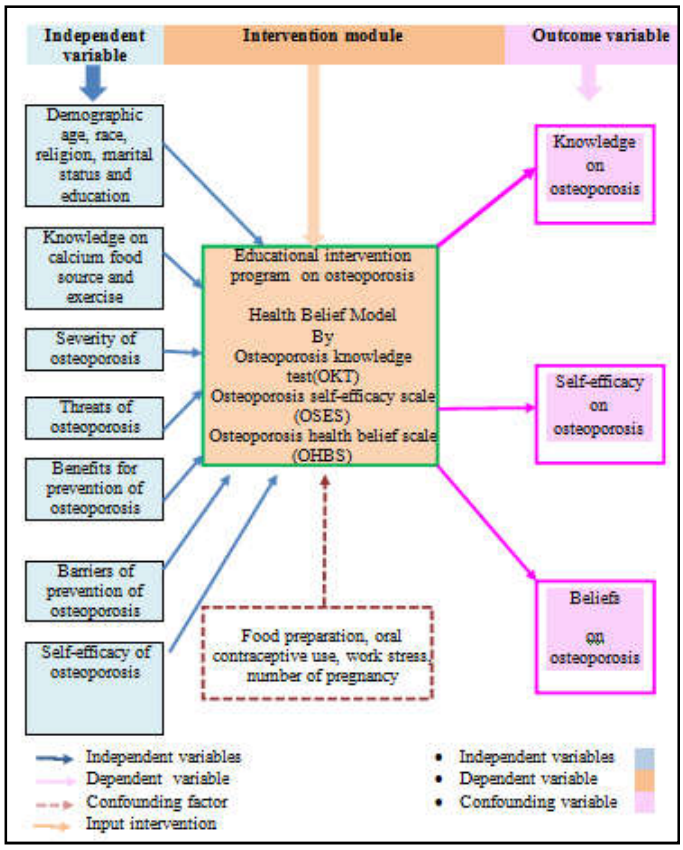

Figure 1. Conceptual framework for effectiveness of educational intervention on knowledge, belief and self-efficacy regarding osteoporosis among the female staff in Universiti Putra Malaysia

Health motivation is a very important variable in health promotion and resulting behavior change concerning osteoporosis. Knowledge about osteoporosis influences health beliefs and self-efficacy which in turn may lead to osteoporosis preventive behaviors. The last variable to be included in the HBM is the concept of self-efficacy which refers to a person's belief about the ability to perform a desired behavior concerning osteoporosis healthy lifestyles. Individuals must feel competent to make the necessary changes in behavior. The conceptual framework is emphasized in Figure: 1

Design and method

Study Location

The study will be conducted among the female academic staff in Universiti Putra Malaysia, Serdang.

and control groups (Figure 2). To assess the effectiveness of the educational intervention on osteoporosis among the female staff in Universiti Putra Malaysia participants; the intervention group will receives the intervention and control group will not receive any information's related to osteoporosis; will be in waitlist. In this study single blinding will be done to reduce bias. Participants in both groups (intervention and control group) will be single blinded; not aware of the procedure. Only the researcher is able to differentiate which groups are under intervention or control group. The respondent will not be informed whether they are categorized under intervention or control group.

Sampling technique

All the female academic staff who meet the inclusion criteria will be taken as respondent by multi stage random sampling.

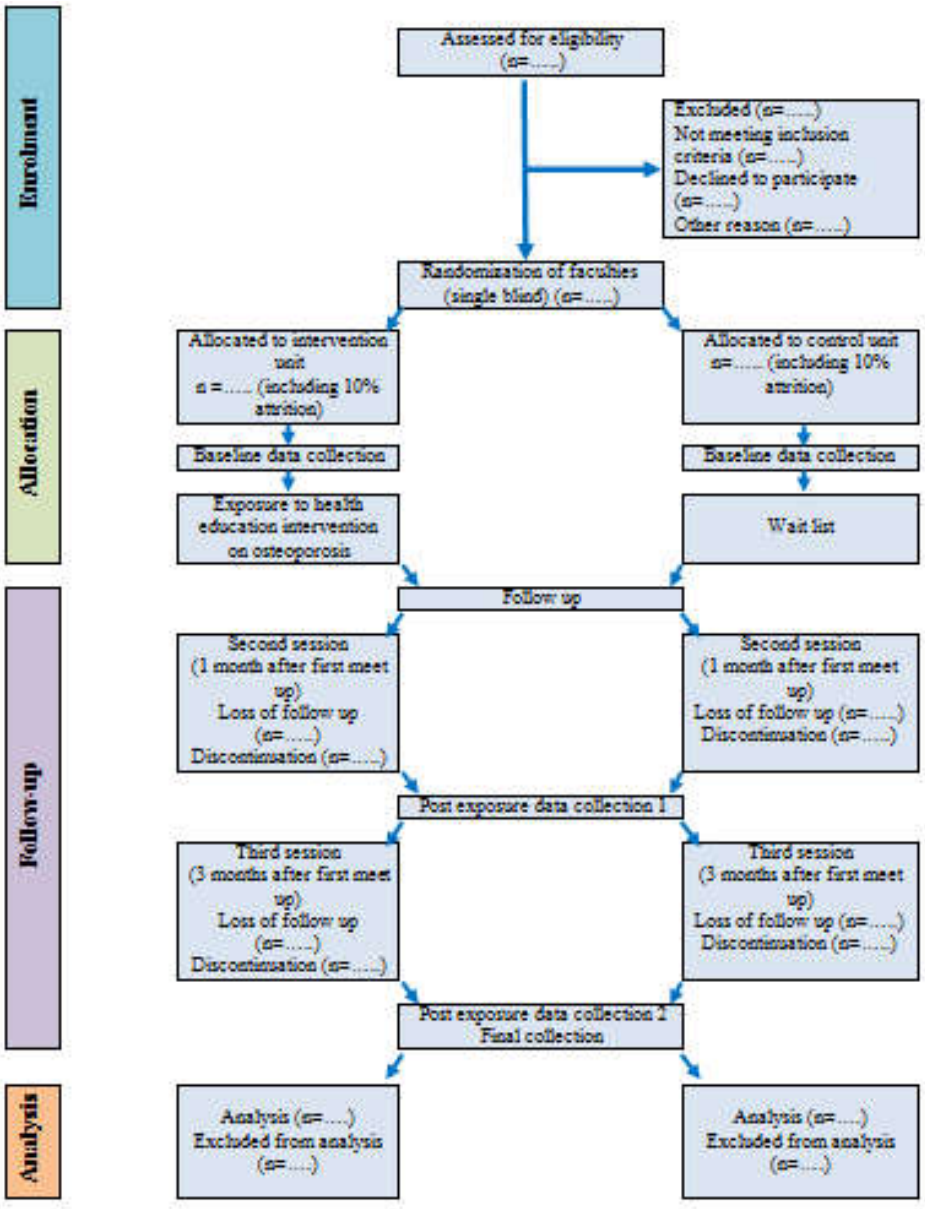

Figure 2. Design timeframe and flow of the participants through all stages of the study (according to CONSORT 2010 Flow Diagram

Study design

The design used for this research is a Cluster Randomized Control Trial in which groups of subjects will be randomized. Cluster of respondents will be allocated into the intervention

There are sixteen different faculties in Universiti Putra Malaysia which are located in 1108,103 hectares area in Serdang, Selangor, Malaysia; therefore different faculty is located in different location which is named as main campus and extended campus. All non-health science faculties are

situated in main campus and Health Science, Agriculture and Veterinary faculties are located in extended campus. Therefore, in order to get estimated sample, The UPM area will be divided into two groups and each group will randomly assign to one of the study group, named as Group A and Group B. Each faculty will be assign with a number. Once UPM area will separate into two groups, there will be seven (7) faculties in each group. The name of all the faculties will be written in piece of paper separately and drawn lottery to assign individual Group A and Group B. The name of first lottery drawing will be Group A and second drawing will be Group B. Once randomly selected name of each zone, they will be randomly assigned to study groups; control and intervention group.

Sampling criteria

Inclusion criteria: Female academic participants

- Are full time staff
- Age in between 25-55 years.
- Speak and understand english language
- Will give written consent.
- Not going for leave in coming three months.
- Using smart mobile phone with internet subscription.

Exclusion criteria: Female academic participants

diagnosed as osteoporosis doing short time training are pregnant has chronic disease with medication (e.g. Hypertension/ Diabetics) active participant in another study from Faculty of Medicine and Faculty of veterinarian those who are not available during verbal screening in consecutive three visits in different dates. Those who did not replied email with three consecutive email reminder.

Sample size

The sample size was calculated by using group comparison of two means (Stanley *et al*., 1990). The average knowledge scores about osteoporosis in both groups were M=19.08, SD= 5.00 for the control group and M= 33.22, SD= 1.08 for intervention group (Malakeh & Malak, 2015).

Estimated mean of knowledge in post intervention program in intervention group ($\mu 1$) = 33.22

Estimated mean of knowledge in post intervention program in control group ($\mu 2$) = 19.08

Estimated standard deviation (σ) =3.61

Z1-$\alpha/2$=Z statistic for level of confidence of 95%=1.96

Z1-β= Z statistic for 80% of power=0.842

N=56 (After calculation from the above equation). Attrition rate of 10% will used, to take care of non-compliance N=56+10%=62

A sample size of N = 45 in each study group would have 80% power for a chi square test (α=5%, 2sided) in order to detect the differences based on a calculation using G power.

As participants are nested within in department, a potential design effect needed to be considered. The intra-cluster coefficient (ICC) needs to incorporate into the sample size calculations. The formula is as follows: Design effect = 1 + (m – 1) X ICC. Design effect is the size the sample needs to be inflated by and "m" is the number of people in the cluster. Assumed number of participants per faculty is 20 (m) and intra-cluster coefficient (ICC) of 0.05 could be expected. This would result in a design effect = 1+ (m-1) x ICC=1+ (20-1) x 0.05=1.95, multiplying this design effect by the required size for an unnested sample (N=62), result in a required sample size of N = 120 in each study group. Total sample size = 120 x 2 = 240 (intervention + control group).

Research instruments

Structured questionnaire will use for data collection and the education program module on osteoporosis prevention intervention will be developed through a process of consultations with a group of expert from various fields such as public health promotion experts and educators.

Study variables

Independent variables: The independent variables studied in this study included demographic factors as age, sex, education, ethnicity, occupation, religion, income and the components of intervention modules(susceptibility, severity, benefits, barriers and self-efficacy of osteoporosis) to assess the outcome at 1 and 3 months.

Dependent /outcome variables: The outcome variable for this study is osteoporosis knowledge, health beliefs and self-efficacy. Outcome variables will compare at baseline and the effects of intervention on immediately and after three months follow-up.

Data collection procedure: A formal introduction will be made verbally and by email; addressing researcher identity and explaining the aim of the research to screen the participants. The participants will be allocated a code number which will be used to identify them on the questionnaire in order to maintain confidentiality. Data will collected by structured intervention module and questionnaire by Google form by internet through email. There will be a baseline survey (pre-assessment) and end survey (post-assessment).After fulfill the exclusion and inclusion criteria; the participants group will be randomized into treatment and control group and base line data will be collected. Then the educational intervention will be proceeding on and after one month (from the date of delivery of intervention) of follow up the posttest 1 will be proceed on and data will be collected. And final posttest 2 will be taken three months (from the date of delivery of intervention) following up.

Quality control: The validity and reliability will be measure to maintain the accuracy and consistency of the questionnaire and intervention module by content and concurrent validity, Cronbach's alpha, test-retest reliability and factor analysis.

Data analysis

Data will analyze by using SPSS, version 22 and the significance level will be set at $P<0.05$. Intention to treat (ITT) analysis concept will be employed for final analysis. By this concept, all respondents in intervention are analyzed by randomized treatment assignment. This will be regardless of

the noncompliance status, deviation from protocol, attrition and or any other occurrences after randomization. Descriptive analysis including calculations of means, 95% confidence intervals (CI) of means and frequencies of categorical variables will be presented at the baseline socio-demographic and behavioral characteristics for osteoporosis prevention among the female staff in Universiti Putra Malaysia. It will be also used to qualify the level of knowledge before and after the intervention. Paired T test and repeated measure ANOVA test will be used to determine the effectiveness of the intervention program by comparing the pre and posttest of knowledge on osteoporosis. Chi-square will determine the prevalence of osteoporosis by the intervention program and the outcome variable. Intra-class correlation will be computed to test for any design effect on outcome variables. If there are any designs effect revealed in this result, General Linear Modeling (GLM) will be used to assess the impact of condition (intervention, control) across baseline and 3 months intervention. Multivariate Repeated Measures Analyses will be conducted to allow examination of whether the group means changed statistically significantly over the different time periods.

Ethical approval

This research project has been granted ethical approval from the Ethical Review Board of Universiti Putra Malaysia with the reference number UPM/TNCPI/RMC/1.4.18.2 (JKEUPM).

Trial registration

This intervention study register under Australia New Zealand clinical trial (ANZCTR) registry under WHO registry network on 9th December, 2016 and trial registration number is ACTRN12616001699459

Expected outcome

The health promotion intervention program is predicted to produce a considerable difference in prevention of osteoporosis in female among the intervention and the control group. Consequences from this study may be used to increase awareness about the preventive factors of osteoporosis which will help to identify the focus areas that need awareness and enforcement in order to reduce and eliminate the risk of osteoporosis among female.

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