The Effect of Educational and Counseling Support on Stress, Adjustment and Health-Related Quality of Life in Women with Breast Cancer in Yemen: non-randomized clinical trial protocol

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Abstract:

Background: The diagnosis of cancer is one of the most distressing and devastating events that may befall women. It is considered a major stressful event that threats all aspects of womans' life, and can regarded as a challenge to women's basic values, beliefs and goals, life functions and threatening their sense of identity. At the time of diagnosis, the patients face unmet information needs and they express the greatest need to speak with someone who has experienced the same disease and already exceeded this crisis. In this study, related information and counseling will be provided to the breast cancer patients with aim of reduce the stress, and promote adjustment and health-related quality of life.

Methods: A quasi-experimental, pre-test/post-test design with a comparison group will be used in this study. The participants will be 120 from separate locations; the intervention group from the National Oncology Center in Sana'a and the control group will be chosen from the National Oncology Center Aden and Cancer Centre Hadramout. The participants include all women in aged ≥ 18 years and have newly diagnosed with breast cancer (stage I, II and III). The participants who met the eligibility criteria will be selected randomly through sample random sample method (SRS). The intervention consists of six sessions that include providing medical information and counseling and a booklet containes seven messages.

The outcomes will be measured at baseline, then 2 months and 6 months post-intervention., by using EORTC QLQ-C30 and QLQ-BR23 questionnaires to assess the quality of life, the Perceived Stress Scale to assess the stress degree, and Mini-MAC scale to assess mental adjustment to cancer. The magnitude of the dependent and independent variables will be determined, and repeated measurement will be used to assess the effectiveness of time and intervention over time. Additionally, the

Significant predictive will be determined and mediating effect and the effect of of covariate in the changes in outcomes over time will be tested.

Keywords: Breast cancer, counseling, education, coping, intervention, stress, adjustment and quality of life

Background:

Breast cancer is the most common type of cancer in women worldwide, including Yemen, accounting for 32.3 % of all female cancers (Cancer, 2015; Ferlay et al., 2015), it mainly affects young women (El-Zaemey et al., 2012; Harhra & Basaleem, 2012). It attacks the most valuable thing in woman's life, where the breast constitutes a part of her esthetic appearance, identity and a symbol of her femininity, motherhood and love in her life (Galjchen, 1999; Kunkel et al., 2002; Lewis et al., 2012; Ohaeri et al., 2012). Thus, the breast cancer is one of the life-limiting and threatening (Jimmie C. Holland et al., 2010; Stevenson et al., 2004), as well as, it is a symbol of the end the life (J. C. Holland & Gooen-Piels, 2000).

As soon as woman has known that she has a cancer, she becomes absolutely terrified, scared and might feel of shock, worry, sadness, unity, and anxiety (Al-Azri et al., 2014; J. Holland et al., 2004), she experiences a feeling of fear of dying, and hopelessness (Fu et al., 2008). Furthermore, the treatment side effects lead to a myriad of physical disturbance (Jassim & Whitford, 2014; Miller et al., 2009), such as, the chemotherapy-induced menopause and weight gain, beside a variety of severe side effects including nausea, vomiting, weakness, and loss of appetite (Reich et al., 2008). Moreover, the most important aspect is the change in body structure through loss of hair and remove or disfigurement of one or both breasts, which equivalent to the loss of femininity and shapes the sense of inferiority (Enache, 2012).

Therefore, cancer diagnosis has a negative influences on the emotional and psychological condition (Parle et al., 1996; Vos et al., 2004), as well, has a major impact on the quality of life in woman (Nissen et al., 2001). On the other hand, socio-demographic, lifestyle and clinical characteristics influence and react

with the patient's ability to cope with the disease (Ashing-Giwa & Lim, 2009; Jimmie C. Holland et al., 2010; Kobayashi et al., 2008; Ogce et al., 2007).

At this juncture, the patients desire more detailed information about their disease, treatment options and survival opportunity (Raupach & Hiller, 2002). As well, they express the greatest need to speak with someone who has experienced the same disease and already exceeded this crisis and now is leading an ordinary Life (Giese-Davis et al., 2006). Fortunately, the communication with the patints in this phase is more significant and effective (Epstein & Street JR, 2007; Henselmans et al., 2010; J. Holland et al., 2004), the patients in this period able to do positive reappraisal (Li et al., 2015), and the response and benefit from any support and able to adjust with their cancer (Council, 2004; Drageset et al., 2012; Jimmie C. Holland et al., 2010; Lally et al., 2012).

Unfortunately, almost of healthcare professionals are unaware to the patients' concerns (Farrell et al., 2005; Parker et al., 2009). Also, unbalanced of doctors-patients ratios (MOHP., 2013) may lead to insufficient of the counselition time (Claramita et al., 2011). As well, the information provided to patients, frequently, does not meet the individual patients' needs within the disease's trajectory (Au et al., 2013; Harrison et al., 2009; Park & Hwang, 2012). In addition, the cancer centers in Yemen lack supportive services such as the mental health services (Ba-Khubaira & Al-Kahiry, 2012; MopHP, 2010).

Based on the systematic review, the majority of studies have been focused on stress management during the treatment period or survival life, few of these studies have focused on the patients at the time of diagnosis, where the patients in this period become more stressful (Jimmie C. Holland et al., 2010), and the health professional unware to their needs (Farrell et al., 2005; Parker et al., 2009). Moreover, the

majority of studies have been utilised the cognitive, and behavioral approaches, psychotherapeutic (group and individual), psychopharmacologic, and complementary therapies. While, there is few interventions that have been utilised the educational and counseling support.

In addition, based on the systematic review, most studies have assessied the effectiveness of the interventions and time on the stress, adjustment and quality of life, but, there is a few studies that concerned to study the effect of the significant predictors on the changes in stress, adjustment and quality of life over time. In addition, there are few studies have examined the mediating effect of intervention model on the relationship between the stress and quality of life. Additionally, there is no study determined the significant predictors and developed a predictive modeling for the stress, adjustment and quality of life in breast cancer patients in Arabic countries. Furthermore, Arabic researchers encounter to lack of valid and reliable Arabic version of scales and questionnaires. The available scales with English version that need to localization and modified to be valid and reliable for using with Arabic audiance. Last but not least, based on the systematic review, the studies identified through database searching were 5,076 intervention studies worldwide, only three studies of them, that have been conducted in Arabic countries; one in Saudi Arabia, one in Jordan and one in Egypt, while, there was not found any study has been conducted in this field in Yemen.

Therefore, in this study, intervention program was developed and will be implemented among women who are newly diagnosed with non-metastatic breast cancer. The program consists of two main axis, are; the educational and counseling axis; the cancer-related educational themes will be provided by an oncologist physician, and the counseling support will be offered by breast cancer survivor.

Choose a survivor of cancer to provide the counseling axise, because she experienced the cancer and overwhelmed and overcome it. The effectiveness of the intervention will be assessed. The factors interaction with the intervention and related predictors will be determined.

Objectives:

General objective:

The purpose of this study is:

To reduce the stress and enhance the adjustment to breast cancer and health-related quality of life (HRQoL), among women who are newly diagnosed with breast cancer (stage I, II and III).

Specific Objectives:

1. To identify the participant's socio-demographic, lifestyle and clinical characteristics in the women with breast cancer patients.
2. To determine the level of stress, adjustment and HRQoL levels in the women newly diagnosed with breast cancer patients.
3. To develop and implement a brief health education and counseling intervention, based on stress and appraisal coping theory, through; individual sessions and printed booklet.
4. To assess the effectiveness of the intervention program and time on the stress, adjustment and HRQoL in breast cancer women overtime.
5. To determine the significant predictors for the stress, adjustment and HRQOL among Yemeni women who have non-metastatic breast cancer.

6. To develop the predictive statistical model for the significant predictors that effect on the stress, adjustment and HRQOL among Yemeni women who have non-metastatic breast cancer.
7. To determine the relationship between the significant predictors and the changes in the stress, adjustment and HRQOL over time.
8. To examine the mediating effect of intervention model on the relationship between the stress and HRQoL among women with breast cancer over time.

Methods

Study design/participants:

A quasi-experimental, pre-test/post-test design with a comparison group will be used in this study. The participants (120) will be chosen from separate locations; the intervention group from the National Oncology Center in Sana'a and the control group will be chosen from the National Oncology Center Aden and Cancer Centre Hadramout. The participants include all women in aged ≥ 18 years and have newly diagnosed with breast cancer (stage I, II and III) and they will visit the selected public cancer centers to receive the treatments during the period of August 2017 to Feb 2018.

Eligibility Criteria:

Inclusion Criteria: 1. Yemeni citizens. 2. Be diagnosed with breast cancer for the first time. 3. Women who are 18 years or older. 4. Women Diagnosed with Stage I, II or III Breast cancer. 5. Women who undergo chemotherapy for breast cancer after surgery. 6. Score of 13 or less on the Perceived Stress Scale (PSS) 10 scale, would be considered low stress (Sheldon Cohen, 1988; S Cohen et al., 1983).

Exclusion criteria: 1. Pregnant woman. 2. Patient has any obstacles to communication. 3. Patients who are planning to receive the treatments out of the

targeted cancer facilities. 4. A history of schizophrenia or schizo-affective disorder (Huang & Shi, 2016), use of antipsychotics, anxiolytics, or antidepressants or use of a stress management technique.

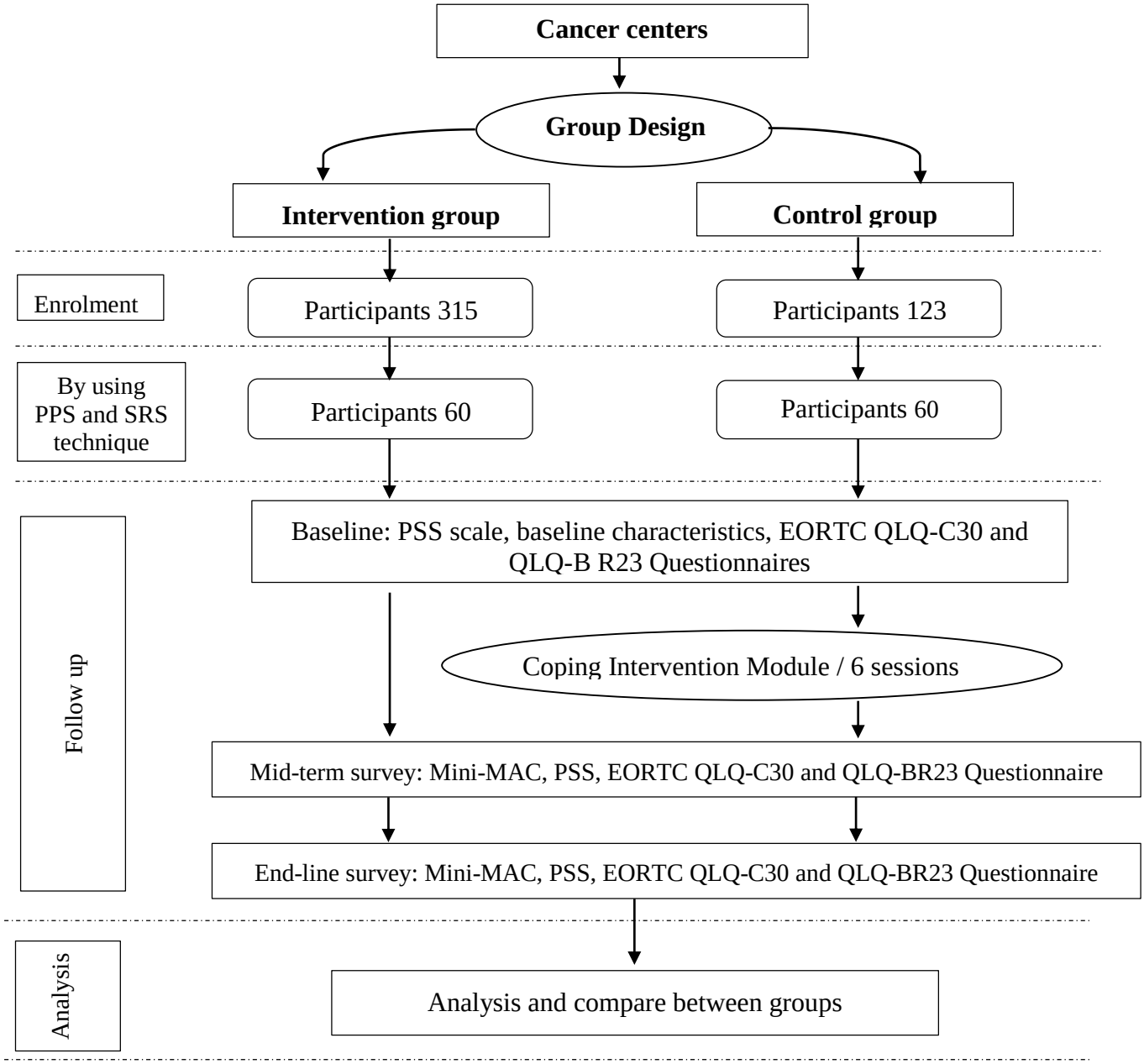

Figure 1: Flow of participants through each stage of the study (CONSORT flowchart)

Sample Size Estimation:

To detect significant differences between control and intervention group, 60 participants per group (120 participants in total) are needed in order to achieve a

statistical power of 80%, based on alpha of 0.05 and expected mean effect size difference between the groups. The sample size was calculated according to the formula (25) two-sample problem to test Hypothesis for two population means, which developed by Lemeshow et al. (1990), World Health Organization (Lemeshow et al., 1990). According to past experimental studies, Banerjee et al. (2007) and Antoni et al. (2006)) the mean (μ) and standard deviation (SD) for the variables were selected from (see the sample size matrix table), the largest sample size was selected.

Table 1: the sample size matrix table that was calculated by using two previous studies

Author	Variables		Baseline test					
			Intervention Mean/(SD)	Control Mean/SD	Power (1-β)	Error (α)	Sample size/ arm	Sample size/ two arms
(Antoni et al., 2006)	Quality of life	Social interaction	877.61 (16.53)	891.17 (14.71)	80%	0.5	35	70
		Recreation and pastimes	330.61 (7.08)	318.53 (6.43)	80%	0.5	8	16
		Positive states of mind	21.31 (0.41)	22.07 (0.38)	80%	0.5	7	14
		Benefit finding	3.16 (0.10)	3.32 (0.09)	80%	0.5	9	18
		Lifestyle change	2.60 (0.18)	2.77 (0.18)	80%	0.5	29	58
	Stress	MOCS Relaxation	2.12 (0.11)	2.26 (0.09)	80%	0.5	14	28
		MOCS Coping	3.16 (0.08)	3.31 (0.08)	80%	0.5	7	15
		MOCS Getting Needs Met	3.41 (0.10)	3.51 (0.09)	80%	0.5	24	48
		MOCS Awareness of Tension	3.27 (0.09)	3.20 (0.08)	80%	0.5	38	76
Banerjee et al. (2007)	Perceived Stress	PSS scale	20.4 (2.8)	19.0 (2.1)	80%	0.5	49	98

S_p^2 = $[S_1^2 + S_2^2]$ /2 = $(20.4)^2$ + $(19.0)^2$ /2 = 12.25 / 2 = 6.125

$$n = \frac{2\sigma^2\left[Z_{1-\alpha} + Z_{1-\beta}\right]^2}{\left[\mu_1 - \mu_2\right]^2}$$

n = 2 (6.125) $[1.960+ 0.84]^2$/ $(20.4 – 19)^2$ = 49 subjects

Adding of 20 % to the number of subjects ≈ 10

Hence, the sample will be 59 participants, we will select 60 participants for intervention group and 60 participants for control group.

Outcome measures:

Five data collection instruments will be used in this study; 1. Baseline characteristics questionnaire. 2. Perceived Stress Scale (PSS). 3. The EORTC QLQ C30. 4. The EORTC QLQ-BR23 questionnaires. And 5. Mini-MAC scale. The questionnaires are an Arabic version and administered face-to-face interview.

Perceived Stress Scale (PSS):

Perceived Stress Scale (PSS) developed by Cohen (1983), it measures the degree to which one appraises a situation as stressful. The PSS is used to determine the extent to which a person perceives her or his life to be unpredictable, uncontrollable, and overloading. It is a 10-item five-point Likert scale survey that asks respondents about their feelings and thoughts during the last month. (S Cohen et al., 1983). The scale is an easy-to-use questionnaire with established acceptable psychometric properties. Many studies confirmed the validity and reliability of the scale. It was translated to more than 25 languages other than English included Arabic language (Chaaya et al., 2010; Eskin & Parr, 1996; Lee, 2012; Leung et al., 2010; Mimura & Griffiths, 2004; Örücü & Demir, 2009; Remor, 2006).

Mini-Mental Adjustment to Cancer scale:

Mini-Mental Adjustment to Cancer (Mini-MAC) scale is one of the most widely used self-rating questionnaire for cancer patients (M Watson et al., 1988). It is developed to measure coping responses in individuals with cancer. The Mini-MAC scale consists of 29 items on a four-point Likert Scale and grouped into same five dimensions; helplessness/hopelessness, anxious preoccupation, fighting spirit, avoidance and fatalism. (Maggie Watson et al., 1994). The instrument proved to be a reliable, valid and sensitive measure in the study of mental adjustment of patients with cancer receiving palliative care (Pereira & de Brito Santos, 2014). It has also been translated into a number of other languages (Sinclair, 2014). According to our best knowledge, there is no Arabic version for the Mini-MAC scale, therefore, translation and back translation will be carried in this study.

European Quality of Life Questionnaires:

The European Organization for the Research and Treatment of Cancer (EORTC) created the Quality of Life Group, which in 1986 initiated a research programme to develop an integrated, modular approach for evaluating the QoL of patients participating in cancer clinical trials. The questionnaires are the most acceptable instruments to patients and health professionals (Ali Montazeri, 2008; Rahou et al., 2016). EORTC created a core questionnaire for cancer patients QLQ-C30 and QLQ-BR 23 that design to be a supplement for the EORTC core measure QLQ-C30 (Shi et al., 2011). EORTC QLQ-C30 is an integrated system for assessing the health related quality of life (QoL) of cancer patients participating in clinical trials. It incorporates five functional scales: Physical (PF), role (RF), cognitive (CF), emotional (EF) and social (SF) (Fayers et al., 2001). EORTC QLQ-BR23 questionnaire was designed to supplement the EORTC core measure QLQ-C30

(Spangers et al., 1996). The questionnaire contains 23 items to measure functional aspects; body image, sexual functioning, sexual enjoyment, and future perspective and symptom aspects; systemic therapy side effects, breast symptoms, arm symptoms, and upset by hair loss (Fayers et al., 2001). The questionnaires were translated into the most languages, including Arabic language, and have been used in Arabic countries; in Egypt, UAE, and Jordan. Globally, the questionnaires are revised, reliable and valid instruments (A Montazeri, 2010; Tan et al., 2014).

Follow-up phases:

Baseline survey/pre-intervention:

Baseline questionnaire, PSS scale, EORTC QLQ C30 and BR23 questionnaires will be used in this phase,

Mid-term survey: After Two Months:

PSS scale, EORTC QLQ C30 and BR23 questionnaires, and Mini-MAC scale will be used in this phase.

End-line Survey; post intervention:

PSS scale, EORTC QLQ C30 and BR23 questionnaires, and Mini-MAC scale will be used in this phase.

Table 2: Instruments used at baseline and follow-up assessments:

Measurement point		The Instruments
Pilot study	Pre-test	Baseline Characteristics Questionnaire, PSS, Mini-MAC, EORTC QLQ-C30 and EORTC QLQ-BR23
First phase	Baseline survey/pre-intervention	Baseline Characteristics Questionnaire, PSS, EORTC QLQ-C30 and QLQ-BR23
Second phase	Mid-term survey/2 months post-intervention	Mini-MAC, PSS, EORTC QLQ-C30 and QLQ-BR23
Third phase	End-line survey/6 months post-	Mini-MAC, PSS, EORTC QLQ-C30 and QLQ-BR23

The Coping Intervention Model:

According to the transactional model of stress and coping theory, the stress arise as a result of an imbalance between demands and resources, and the patient become stressful when demands (pressure) exceeds her resources "her ability" (Lazarus & Folkman, 1984). The patient appreciates the stress event, and according to her ability have to use internal resources and external support to cope with stressful events (Friedman. S, 2002).

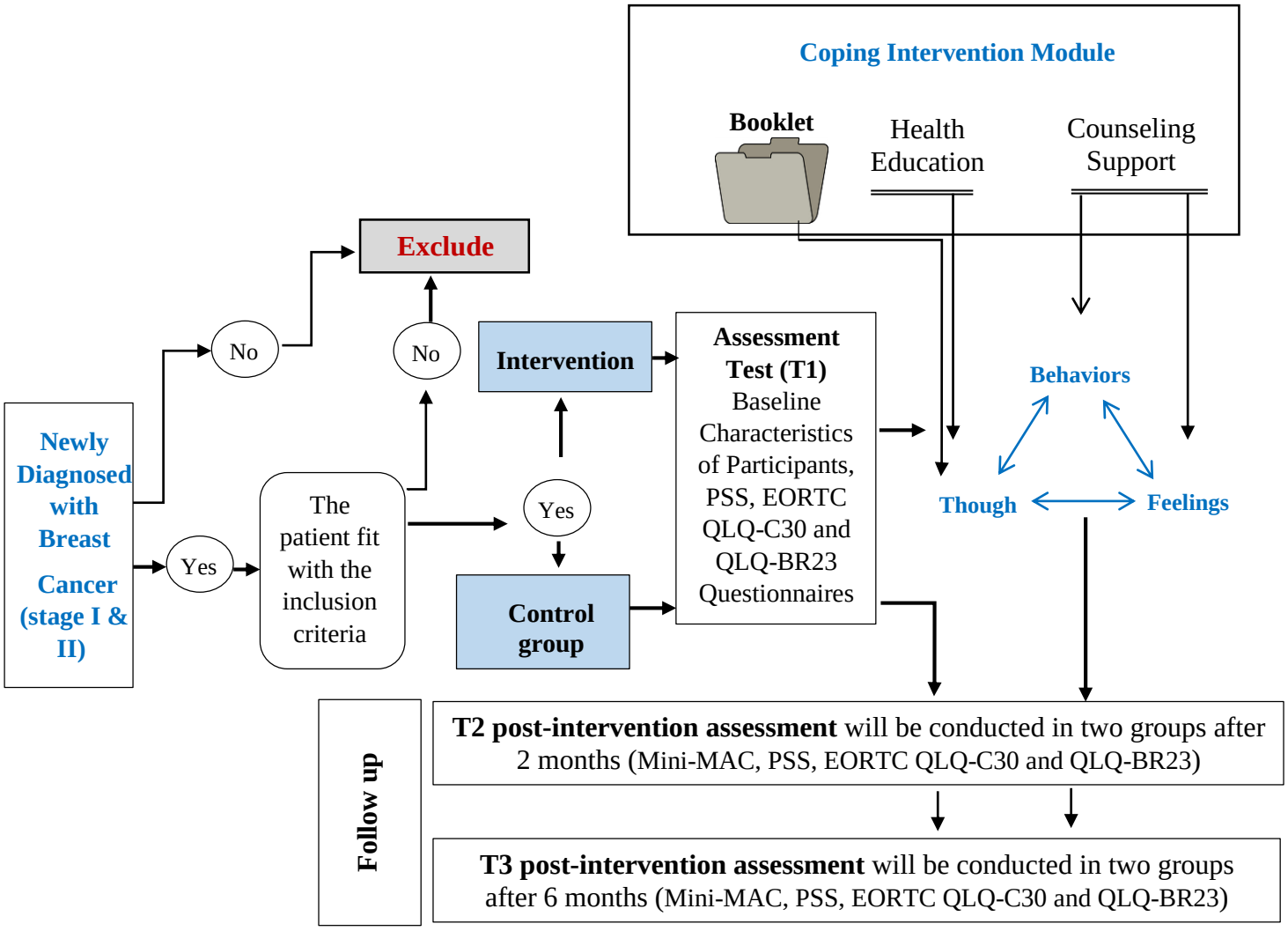

Figure 2: intervention coping pathway for reducing stress and improving quality of life in breast cancer women

Providing patients with information and counseling support, can improve the sense of control and his resources (Lyons & Chamberlain, 2006). As well, understanding

stressful events can improve not only patient health statue, but the quality of her life. (Coon & Mitterer, 2014). Moreover, the patients express the greatest need to speak with someone who has experienced the same disease and already exceeded this crisis and now is leading an ordinary Life (Giese-Davis et al., 2006).

The Content of the Coping Intervention Model:

This model includes two major themes are 1) Medical education. And 2) counseling support. The education axis will be performed through six sessions and given the patients a booklet, as well, the counseling axis will be given by a breast cancer survivor.

The Health Education: The education axis aims to give the patients a related information about cancer, its treatment, adverse effects of treatment, suitable nutrition and important of the physical activity for the breast cancer patients. The education axis will be implemented through 6 learning sessions face to face with the patients and given a booklet for each patient. **The Booklet:** The booklet was designed as a supplement to the sessions, where it addresses seven health messages. The messages were designed according to the breast cancer journey and will be given in parallel with the awareness sessions. In each session, the patient will be given a health message, which will be suitable with the session topic.

Table 3: the contents of psychoeducation sessions:

Date	Time	Session	Contents content	Health Massage (booklet)
1st week	1 Hrs	Assessment	Assessment (1), Baseline survey.	The will is the secret of life.
	2 Hrs	Basic Information	- Provision of simple information about breast cancer and its treatment, side effects and discussion of this information. - Common myths about cancer and cancer survivorship.	

2nd week	2 Hrs	Basic Information	- Hospital regulations and policies regarding to breast cancer. Explain the hospital procedures; treatments (type, length of, procedures), place of diagnosis, physician visits appointment, treatments sessions appointment. - Discussing prognosis and survival chances with breast cancer, recurrence and fear of recurrence. - Physician's personal experience with breast cancer.	Be contented with what Allah ordains
3rd week	2 Hrs	Nutrition Life style	- Proper nutrition and nutrition foods to be avoided. - Exercise and activities. - Habits and Hobbies.	- Food safety a key pillar for the prevention and control of cancer. - Physical activity is an important part of preventive health care
4th week	2 Hrs	Problem solving	- Problem definition, definition of problem solving, effective problem solving process and problem solving techniques. - Body image and sexuality after breast cancer. - Pain, fatigue and trouble sleeping.	The cancer is not a death sentence.
5th week	2 Hrs	Interpersonal relationships	- Importance of human relations, body language for a good impression, important points in human relations, behaviors that hinder our relationships with people, importance of self-knowledge, cancer and communication with family, basic skills for an effective communication.	Letter to my dear husband
6th week	2 Hrs	Emotional and social support	- Coping up with emotions. - Social support and partner/ family support. - A survivor's personal experience with breast cancer.	New life.

Counseling support: This axis will be performed by a breast cancer survivor, because the women at the diagnosis time need to speak with someone who has experienced the same disease and already exceeded this crisis and now is leading an ordinary Life (Giese-Davis et al., 2006).

Data Analysis:

The data will be analysed by using the IBM-SPSS statistics version 22, for the univariate analysis, determining the significant predictors, and test the effectiveness

of the intervention over time. Also, IBM.AMOS software will be used for analysing the relationships; assessment of the mediating effect of the intervention, regression and data panel modeling. The statistically significant results will be tested by calculating p-value at alpha value 0.05 ($P \leq 0.05$), or by using confidence intervals (I.C). The data will be tested for meets the assumptions, which must be met if the test can be used. The questionnaires will be scored according to their scoring manuals; EORTC QLQ-C30 and QLQ-BR 23, PSS scale and Mini-Mac scale.

First of all, the data will be screened and reviewed (data entry, case screening, and variables screening), as well, missing date will be treated or replaced. The data will be organized, summarized, and presented in a convenient and informative way (the frequency distribution, draw the table and graphs). The frequency and percent will be used to describe the qualitative data and the MCT and MD will be used to describe the quantitative data for the participants' characteristics, clinical characteristics and dependent variables. The significance differences will be tested for the participants' characteristics and clinical characteristics to prove the similarities between them in the intervention and control group.

Secondly, the repeated measurement ANOVA will be used to assess the effectiveness of the intervention modal over time. The main effects and interaction effect between trails and intervention will be estimated too. If the assumption not meet, Friedman's test will be used. In case the result is significant, Wilcoxon Signed Rank test will be applied as a post-hoc test.

Thirdly, the multiple regression will be used to determine the relevant candidate predictor variables to the stress, adjustment and quality of life among women with breast cancer in Yemen. Then, the predictive model for this study will be developed after determining the significant predictor variables. Thereafter, the Panel analysis

will be used to determine the effect of the relevant candidate predictor variables in the changes in the stress, adjustment and HRQOL over time. The Cross-Lagged Panel analysis will be used to determine the effect of the relevant candidate predictor variables in the changes of the stress, adjustment and HRQOL over time. Las but not least, Multi-Model Analysis (MMA) will be used to clarify the nature of the relationship between the stress and quality of life.

Ethical Consideration:

The Ethical approval was obtained from Ethics committee for research involving human subjects, University of UPM, JKEUPM Ref No. FPSK(EXP16)P161 date 07 July 2017. Moreover, the approval Ethical Letter was obtained from the National Health and Medical Research Committee (NHRMC), Ministry of Public Health and Population in Yemen as an official approval letter Ref No. G7/85 date 30 July 2016.

The Participants will sign the participation voluntarily before participation in this study. This consent will give the participants the right to withdraw from this study at any time without giving any reason whatsoever. As well, based on the consent form the participants will inform that the study is confidential, and all information that will be provided will be remained private and confidential, and no unauthorized person will have access to this information. In data processing, name and personal identity number will be replaced by a code so that no individual can be identified. Only the principal investigator of the study will have ability to access to the code key. Moreover, the participants will be informed about the nature and benefits of the research. All research team will be females except the investigator. Health Messages and questionnaires will be used the Arabic language.

All procedures will be performed in this study involving human participants are in accordance with the ethical standards of the national research committee and with the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards. There is no conflict of interest linked to any of the authors associated with this study. The research has been conducted to benefit the breast cancer patients, without any financial benefit to the authors.

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