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EFFECTIVENESS OF TWO VIRTUAL PROGRAMS ON PERCEIVED STRESS, STRESS COPING, AND LIFE SATISFACTION AMONG WOMEN WITH BREAST CANCER: PROTOCOL FOR A RANDOMIZED CONTROLLED TRIAL

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Abstract

Introduction: *Breast cancer is a frequent cancer among women worldwide. In addition to the physical hardships, Breast cancer survivors often experience traumatic psychological pains. The effectiveness of educational and supportive interventions in this regard has been under-researched. The present study aims at evaluating and comparing two supportive programs with regard to their effectiveness in reducing stress, improving stress coping and increasing life satisfaction in women with Breast cancer.*

Material and Method: *The study includes a three-arm randomized controlled trial study protocol that assesses the effectiveness of two virtual programs (family-based and peer support) launched at the Cancer Institute, in Tehran, Iran, in 2021. 315 patients, were randomly assigned to one of the interventions or control groups.The participants completed portfolios of self-reported Demographic and Disease Characteristics, Perceived Stress Scale (PSS-14), and Coping Inventory for Stressful Situations Scale (CISS-21) before and three months after the intervention. The Satisfaction With Life Scale (SWLS) was also completed before the intervention, and after a six-month interval. Data was analyzed using SPSS 18.*

Results: *This study is ongoing. Recruitment was done in March 2021 to August 2021. A total of 315 participants have been recruited. The intervention was done in December 2021 to January 2022. Data collection and analysis are expected to be finalized early in 2023, and the study will be published in December 2023.*

Conclusions: *Consistent with the findings of the study, it is concluded that social media prove quite helpful as supportive interventions for women with Breast cancer in diminishing psychological pains.*

Keywords: *breast neoplasms, randomized controlled trials, perceived stress, stress coping, Methods, peer support, social media*

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INTRODUCTION

Breast cancer (BC) is the world's second most common cancer [*Vignes et al. 2020*]. It is a leading public health issue in certain countries [*Aissami and Guido 2021*]. The incidence rate of Breast cancer in young adults (15-49 years) is more in developing countries than in developed ones (23% vs. 10%). It is 28% and 39% in post-menopausal women (over 50 years) in the two countries, respectively [*Nafissi et al. 2018*]. Breast cancer diagnosis and treatment are stressful events for women [*Kim and Jang 2020; Samami et al. 2020*]. Breast cancer is associated with physical, psychological, and cognitive symptoms such as stress, anxiety, sadness, pain, sleep problems, fatigue, limitations of body function, and relapse risk [*Zhou et al. 2016; Gosain et al. 2020*]. Furthermore, after surgery, chemotherapy or radiotherapy, some of the women experience negative sexual health issues due to premature menopause, diminished sextual desire, negative body image, and a diminished sense of femininity [*Kim and Jang 2020*]. Approximately one-third of cancer patients endure significant emotional and psychological distress during treatment. Approximately 30% of them experience anxiety and hopelessness in the first year after diagnosis [*Sajadian et al. 2017*].

Even though cancer incidence rates are increasing and survival rates are steadily improving, access to supportive interventions is still important due to the high prevalence of distress [*Giese-Davis et al. 2016*]. In this vein, patients with breast cancer need the different coping skills more than other patients do [*Moghaddam Tabrizi and Alizadeh 2018*]. Sadly, the supportive systems for cancer patients are insufficient in developing countries [*Pourfallahi et al. 2020*]. Social support is an important aspect of the quality of life and the ability of patients in responding to stress [*Akbari et al, 2015*]. In this way, the supportive role of spouses and relatives is crucial for women's coping [*Moghaddam Tabrizi and Alizadeh 2018*]. It is suggested that a peer who has been through a similar ordeal could provide helpful assistance [*Toija et al. 2019*]. Patients can benefit from peer support throughout their fight against cancer [*Giese-Davis et al. 2016*]. Sajadian et al. highlight the role of social support as one of the most commonly used coping strategies immediately after the diagnosis and six months later [*Sajadian et al. 2017*].

So far, many programs have been used to improve the health-related quality of life for breast cancer patients, such as art therapy, exercise therapy, and psychological and educational support. However, they have neither assessed nor anticipated the existing health problems in physical, psychological, or social domains sufficiently [*Zhou et al. 2016*]. Cancer patients often receive information about treatment- such as possible symptoms and side effects - which can help them gain a sense of control and adapt to the unwelcome physical and psychological complications that arise in the wake of the treatment [*Lehmann et al. 2020*]. Social support has proven blissfully helpful in increasing adaptation to the disease condition [*Akbari et al. 2019*]. In this vein, an increasing number of electronic health (e-Health) interventions for patients have been developed in recent years, and it is a preferred method in improving healthcare [*Latulippe et al, 2017; Grapp et al., 2022*]. More specifically, this method can be useful for patients with cancer primarily because of the accessibility of the training. The current study zeroes in meticulously on applying the mentioned protocol to investigatie the effectiveness of two programs (family-based and peer support) in reducing stress, improving stress coping, and life satisfaction among women with breast cancer.

Study Objectives: This randomized–controlled trial study investigates the effectiveness of two virtual supportive programs (family-based and peer support) on perceived stress, stress coping, and life satisfaction among women with breast cancer. The study builds on the hypothesis that the changes in mean scores of perceived stress and task-oriented, emotion-oriented, and avoidance-oriented stress coping before and three months after the intervention are not the same in family-based, peer support, and control groups.

Moreover, the changes in mean scores of life satisfaction before and six months after the intervention are not the same in family-based, peer support, and control groups. Outcomes of the study will be viewed in light of the perceived stress and stress coping) primary (and life satisfaction) secondary. The study builds on the hypotheses that the intervention would decrease perceived stress,

emotion-oriented ,and avoidance-oriented and improve task-oriented and life satisfaction in the intervention groups.

Materials and methods

Trial design: This is a parallel group, three-armed, non-blinded, randomized–controlled trial. There are the same number of participants in both intervention and control groups that an allocation proportion of 1:1:1 was performed for randomization. Each patient was given a unique code that was written on a separate piece of paper and put in a box. The sequence in which the patients are placed is as follows: 1-family-based, 2-peer support, and 3-control group. This intervention will obviously not affect the control group in the course of the study.

Study Setting: The study is conducted in the Cancer Institute (CI) of Tehran. The CI is the leading specialized educational, research, and cancer treatment institute running under direct supervision of the Tehran University of Medical Sciences. Hospital and outpatient clinics from across the country refer patients with diverse socioeconomic backgrounds to the CI.

Ethical considerations: The study was approved by the Research Ethics Committee at Tehran University of Medical Sciences (IR. TUMS. SPH. REC.1399.251). The researchers confirm that all procedures comply with the ethical standards of the Helsinki Declaration of 1975, as revised in 2013. On the outset, participants were properly briefed on the study objectives and design, and then asked to submit written consentsby by the first author. They were assured that their personal information would remain confidential. Finally, they were informed that they could withdraw from the study any time they wished to. Each questionnaire in this study was assigned a code, and the obtained data was analyzed anonymously.

Eligibility criteria: The inclusion criteria were set to involve women aged 18-85 who have been diagnosed with a minimum of six months of stage 1 to 4 breast cancer, were literate and able to listen and see, had access to a smartphone, and were willing to participate in the study. (Patients' breast cancer stage corresponds the TNM classification: T= Tumor, N= Node(s), and M= Metastasis) [*Rosen and Sapra 2021*]

Patients who suffered from mental illnesses such as delusions and hallucinations, were under the supervision of a psychologist or psychiatrist, participated in similar training classes (virtual or non-virtual), and/or missed half of the training sessions were excluded from the study.

Interventions

The choice of comparators: A random assignment of participants has been made to two intervention or control groups following baseline measurements. The intervention, as the name implies, is not given to a control group but routine hospital care during the study. Nevertheless, at the end of the study group members will have access to the content of this intervention for potential benefits.

Intervention description: The study consists of two phases: 1) development of virtual supportive programs, and 2) implementation and evaluation of the programs. This randomized trial study protocol follows the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) guidelines. The authors confirm that all procedures contributing to this study conformed to the ethical standards of the relevant national and institutional committees on human experimentation and the Helsinki Declaration of 1975, as revised in 2013.

Developing virtual supportive programs: The supportive programs were designed based on evidence and information obtained from cross sectional study. It included completing questionnaires (demographic and disease characteristics, perceived stress, stress coping, and life satisfaction) and evaluating the 372 women with breast cancer to determine participants' perceived stress, stress coping, and life satisfaction. Furthermore, content of the virtual intervention is provided for cancer patients based on factors and beliefs from research team surveys and useful information about breast cancer disease, its treatments, and side effects. Stress management consists of communication strategies, problem-solving, and the role of physical activity (Tai Chi).

The supportive program consists of an eight-week virtual program presented to women with breast cancer via WhatsApp, a popular application in Iran used by people to share messages, videos, and discussions [*Hamzavi Zarghani et al. 2021*]. As some patients were not properly educated or suffered from poor eyesight, the programs were

presented through motion graphics, shows, and voice messages. The programs were prepared by Canva software and analysed by health education and promotion professionals.

The intervention is an eight-week systematic educational program delivered to women with breast cancer through WhatsApp providing personalized electronic textual advice, motion visuals, and podcasts which aim to reduce stress and improve life satisfaction. The intervention is presented twice a week. Each session lasts for one hour. Discussion and question and answer sessions are held throughout the week (Table 1).

Implementation and evaluation

Intervention groups: Patients with high perceived stress levels and low stress coping levels were assigned to two intervention and a control groups with random numbers in the ratio of.1:1:1 The intervention groups received an eight-week intervention program based on social networking software, video guidance on stress management and muscle relaxation training twice a week. The researcher (S.Sh.O.) participated in the groups in the event a problem arises.

Family-based group: Patients in this group were trained with a recently designed and evaluated virtual education package for eight weeks alongside routine hospital care. The researcher instructed each patient and a family member approved by the patient. The family member should have met the following criteria-1: being responsible for the patient‘s needs-2. Being approved by the patient to participate in the study-3, aged 18 or older-4, consenting to participate in the study, and-5 being able to hear, see and communicate verbally. Exclusion criteria included-1 history of mental illnesses-2 - refusal to continue the study, and-3 patient dissatisfaction with their participation in the study.

Peers support group: The patients in this group were trained with a recently designed and evaluated virtual training package for eight weeks along with regular hospital care. Upon agreement of the center‘s administration and using the patients' medical information the researcher (S.SH.O) trained the peer support group.

Some of the peers were then chosen as trainers based on the inclusion criteria and were instructed to give training to the group. Inclusion criteria for coaches in the peer support group were :breast cancer with at least two years of diagnosis history, no signs of recurrence or metastasis, ability to communicate verbally, literacy ,access to a smartphone, and consent to participate. It follows that refusal to cooperate at any stage was considered as exclusion criterion.

Table 1.

Session modalities, domain and activities modalities of family-based and peers support group

Session modalities	Domain	Activities
• Presentation of Agenda • Introduce participants • An explanation of the group of goals and attending group of benefits	Knowledge	MG, VS, V
• Orientation with BC	Knowledge	MG, VS, V
• An orientation with chemotherapy and its side effects	Knowledge; Self-efficacy	MG, VS, V
• Presentation of stress and stressors	Knowledge	MG, VS, V
• Orientation with stress assessments • Overcoming stress skills	Knowledge; Self-efficacy	MG, VS, V
• Orientation with character types • Self-efficacy • A successful coping • An unsuccessful coping	Knowledge	MG, VS, V
• Description of stress management • Prevention of stress	Knowledge; Practice	MG, VS, V
• Orientation with muscles relaxation	Knowledge; Practice	MG, VS, V
• Orientation with visual imagery • Tai Chi exercise	Knowledge; Practice	MG, VS, V
• Doing Tai Chi (1)	Practice	MG, VS, Ve
• Doing Tai Chi (2)	Practice	MG, VS, V
• Orientation with spiritual methods • Different support	Knowledge; Practice	MG, VS, V
• Orientation with different solutions • Conflicts ways	Knowledge; Practice	MG, VS, V
• Orientation with the cognitive-emotional way in stress management	Knowledge; Practice	MG, VS, V
• Orientation with self-control ways	Knowledge; Practice	MG, VS, V
• Humor, Wellness	Knowledge; Practice	MG, VS, V

***Notions**:MG - Motion graphic; VS - Voice show;, V - Voice.*

Individuals with low perceived stress and high stress coping scores were chosen as coaches and trained to use the virtual training package. They were expressly informed and advised against providing medical advice, critiquing the treatment procedures, or suggesting personal alternatives to patients.

Control group: Participants in the control group received the routine hospital care such as treatment procedures, follow-up clinic visits, and regular information from doctors and nurses. The control group was tightly insulated against any intervention during the study. However, upon completion of the study, the group received the intervention package. Participants in the three groups completed the perceived stress and stress coping questionnaires in three months and the life satisfaction questionnaire in six months, respectively, after the end of the program. Consort Consolidated Standards of Reportingt Trials (diagram for patients (Figure 1)

Intervention procedure: The intervention for the support group was given through WhatsApp. The program includes the skills needed by women with breast cancer to manage the stress as well as side effects of the treatment.

Criteria for discontinuing or modifying allocated interventions: Upon death, personal request,

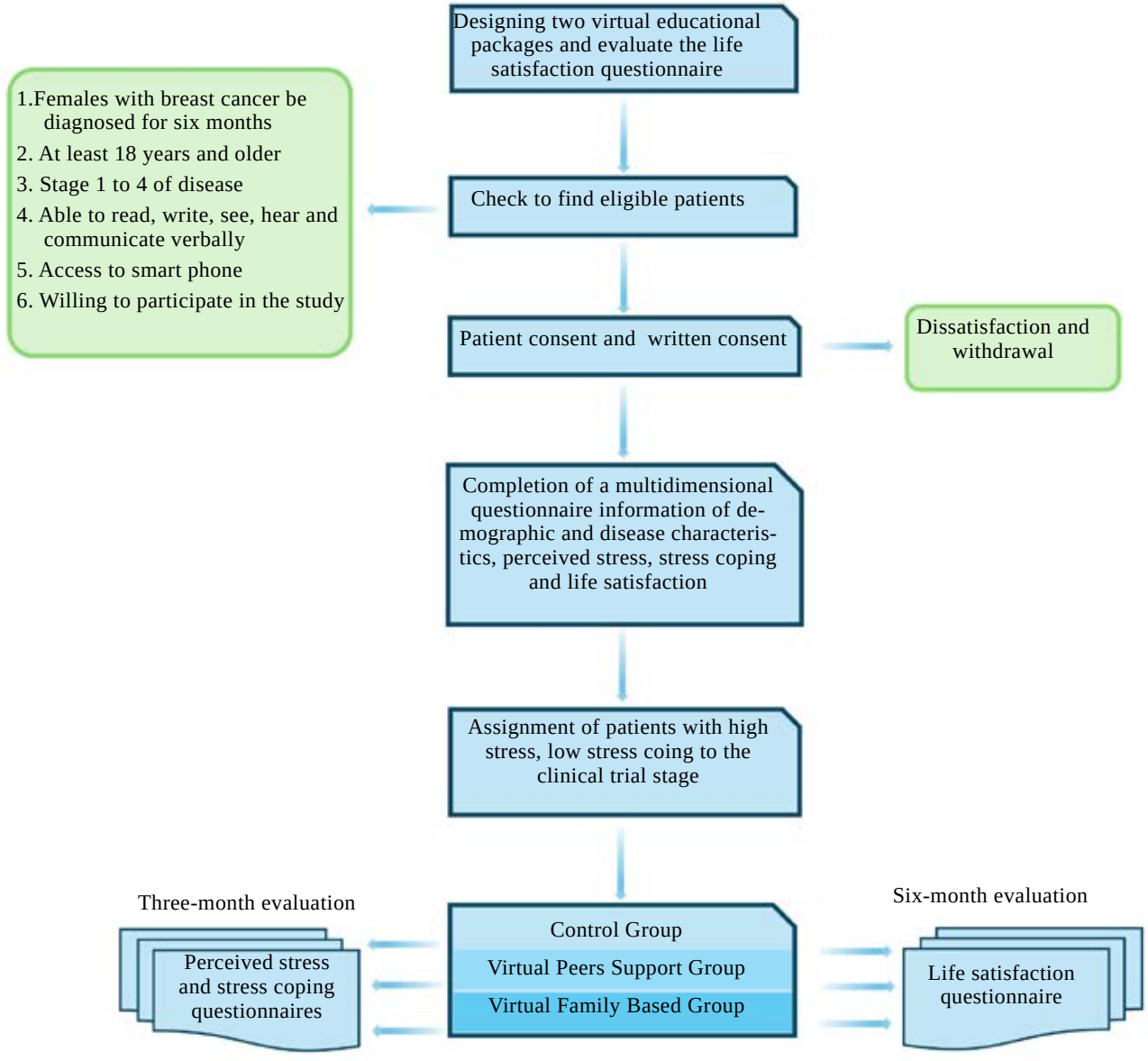

***FIGURE 1**. Schematic overview of program course.*

dissatisfaction with the procedure, reluctance to use the WhatsApp platform, or even feeling adverse during the study, partcipants would be excluded from the study.

Strategies to improve adherence to intervention: Participants were assigned to one of the three groups (family-based, peer support, and control). Participants in the intervention groups learned how to use the programs. They were reminded to use the programs twice a week through phone messages (SMS). In addition, messages were sent to peers as coaches to remind them to send programs to their groups. Participants were continually encouraged to use the programs. Also, the researcher (S.Sh.O) participated in peer support group so that they could increase their common sense and monitor the process.

Relevant concomitant care permitted or prohibited during the trial: In order to receive the virtual educational supportive programs, participants had to accept the inclusion of a family member in the group. Furthermore, participants with mental illnesses such as delusions and hallucinations, under the supervision of a psychologist or psychiatrist, participants to similar training classes (virtual or non-virtual), and missing half of the training sessions were excluded.

Provision for post-trial care: The researchers (S.Sh.O) will remain accessible to answer the participants' questions about breast cancer, stress, stress coping strategies, and stress management ex post trial. Although the subject of this study is educational and favourable, it doesn't seem to be harmful, researchers are responsible for a follow up during the time when any negative effect is reported, pending resolution of the problem or compensation.

Outcomes: The study was intent on investigating two primary outcomes variables: the perceived stress and stress coping. Use was made of the Perceived Stress Scale-14 (PSS-14) and coping inventory for stressful situations scale (CISS-21) two times during the study, namely before (T0), and by the end of the three months after the intervention (T1). Furthermore, the study investigated a secondary outcome variable, i.e. life satisfaction, which was measured by Satisfaction With life Scale (SWLS), before (T0), and by the end of the six months after the intervention (T2). The effectiveness of this program on perceived stress, stress coping, and life satisfaction in the intervention groups and the control group have been assessed and compared prior to and following an intervention. Also, a difference in mean scores between outcomes has been assessed.

Participant timeline: Participants to the study were invloved from March 2021 to August 2021. The intervention was done in December 2021 to January 2022. Data analysis, and final report takes place up to early in 2023, and the study will be published in December 2023. According to the guidelines of SPIRIT, this manuscript was designed [*Chan et al. 2013*]. Based on the SPIRIT guideline, a time schedule of enrollment, intervention and evaluation is shown in table 2.

Sample size: A simple random sampling method was used in this study. Participants were identified in the surgical and medical oncology wards and outpatient clinics. In the presence of the oncologist and with his consultation, eligible patients were selected based on inclusion and exclusion criteria. The scores of the three variables of perceived stress, stress coping, and life satisfaction were calculated based on 100 bases for comparability. A standard deviation (SD) of 16.7 was yield-

Table 2.

Participant's timeline in the study

Timepoint	Study period: Enrolement -t1	Allocation t0	Post-allocation t1	Post-allocation t2
Eligibility screen	√			
Informed consent	√			
Allocation and randomization	√			
Interventions:				
Intervention (3 months after intervention)			√	
Intervention (6 months after intervention)				√
Assessments:				
Baseline assessment: Demographic questionnaire And disease characteristics+ PSS+ CISS		√		
Assessment (T1 PSS+ CISS)			√	
Assessment (T2 SWLS)				√

Notes: PSS - Perceived Stress Scale, CISS - Stressful Situations Scale, SWLS - Satisfaction With Life Scale

ed for the scores. The average difference between the two intervention groups and the control group was 7 points or more which is statistically significant with a confidence interval of 95% and a test power of .80% Since the study is a trial type with a three-month follow-up and there is a 15% chance of attrition ,the number of subjects in each group was adjusted accordingly. Finally 105, people were included in each group (315subjects in total).

Recruitment

The researcher (S.Sh.O) attended in the CI and started screening patients in surgical and medical oncology wards and clinics using the inclusion and exclusion criteria. In case a patient was identified to meet the inclusion criteria, she was verbally asked to participate and sign a written informed consent form. The recruitment process continued until a total of 315 patients with high perceived stress and low stress coping scores were recruited.

Assignment of interventions: allocation

Sequence generation: After submitting informed written consents and completing the questionnaires, patients with high perceived stress and low stress coping scores were randomly assigned to three groups, including family-based, peer support, and control groups, with an allocation proportion of 1:1:1. Each patient was given a unique code that was written on a paper and put in a box. The sequence in which the patients were placed is as follows: 1-family-based, 2-peer support, and 3-control groups.

Concealment mechanism: For every person in each of the groups, anonymous codes were generated by the concealment code. Hidden codes were given to the researchers in the field and randomization was blinded during random assignment rather than a sequence of intervention groups as A, B or C.

Implementation: Participants were then formally invited to the study by the researcher (S.Sh.O), joined online groups, and received the programs.

Assignment of interventions: blinding

Who will be blinded: It was impossible to keep the participants in the intervention and control groups blinded in this study since the researcher had direct interaction with patients and taught the intervention groups either directly (family-based) or indirectly (peer support).

Table 3.

Assessment outcomes

Variable	Baseline	Time after the intervention	
		3 months	6 months
Perceived stress (PSS)	×	×	
Stress coping	×	×	
Life satisfaction	×		×

Data collection and management

Plans for assessment and collection of outcomes: Data was collected in three stages: before (T0), three months after (T1), and six months after intervention (T2). Patients completed the perceived stress and stress coping questionnaires at the outset and three months later, and the life satisfaction questionnaire at the outset and six months after the intervention. The Perceived stress scale (PSS-14) [*Safaei and Shokri 2014*], coping inventory for stressful situations scale (CISS-21) [*Shokri et al, 2008*], satisfaction With life scale (SWLS) [*Taheri A et al. 2012*], as well as researcher-made demographic and disease characteristics of patients were used (Table 3). The demographic and disease characteristics questionnaire includes (1) personal data including age, marital status ,number of children, ethnicity, education level, occupation, economic status, source of information, someone who supports them and insurance coverage and (2) disease data: breast cancer stage, duration of breast cancer, lymph node)s (involvement ,surgery type, and treatment type.

Perceived stress: Cohen et al developed a Perceived Stress Scale (PSS) to measure stress levels [*Cohen et al., 1983*]. This tool has 14 items on a five-point Likert scale. The questionnaire has two subscales of perceived self-efficacy and perceived helplessness .Cronbach's α for perceived self-efficacy, perceived helplessness, and total score of perceived stress are, 0.6, 0.80 and ,0.76 respectively [*Safaei and Shokri 2014*]. The full range of scores is from 0 to 56 with a cut-off point of 2.18. A higher score represents more perceived stress level [*Hasan Zadeh et al, 2013*]

Stress coping: Stress coping was measured using the Coping Inventory for Stressful Situations scale (CISS-21). This questionnaire was developed by Endler and Parker and includes 21 items on a -5point Likert scale [*Endler & Parker, 1994*]. It was designed to evaluate three coping strategies,

namely task-oriented coping, emotion-oriented coping, and avoidance-oriented coping. Each type that received a higher score is considered the person's coping method .Cronbach's α of the questionnaire has been calculated as 0.70-0.86 [*Shokri et al., 2008*]

Life satisfaction: Life satisfaction was measured by the Satisfaction With Life Scale (SWLS). This questionnaire was developed by Diener et al. and includes five questions on a-5 point Likert scale [*Diener et al., 1985*]. A higher score indicates greater life satisfaction. Cronbach's α was calculated as 0.70-0.86 [*Bayani A. et al, 2007*]. A score of 5-10 indicates poor life satisfaction 10-15 moderate, and 10-15 good [*Delavar A and Shokouhi Amirabadi L. 2020*].

Plans to promote participant retention and complete follow-up: Before obtaining written informed consent, patients who met all inclusion criteria were informed about the methodology and objectives of the study. During the study, the researcher (S.Sh.O.) was available to the participants; she contacted participants, answered their questions, monitored the peer support group through the patients as coaches, and sent reminder messages to participants in family - based group and peers to use programs. The follow up questionnaires were sent to the groups and participants were asked to read them and get ready a week earlier. In a week, the researcher called them and filled the questionnaires by phone.

Data management: At the outset ,raw data including written informed consent ,demographic characteristics, PSS, CISS, and SWLS was collected by the researcher in person. However, in the follow-up, the PSS, CISS, and SWLS were filled and their data was collected through phone calls.

Confidentiality. Each participant has a code on each questionnaire. This way, her right to privacy wouldn't be compromised. Data for each participant shall be stored on the basis of a study identification code. The identification code list is only available to the research team and is documented and protected by the researchers (S.Sh.O). The related publications do not indicate any information concerning the identification of participants.

Plans for collection, laboratory evaluation, and storage of biological specimens for generic or molecular analysis in the trial/future use: This does not apply. According to the researchers, this study did not have a laboratory evaluation of or storage of biological specimens for general and molecular analysis.

Statistical methods: Data was collected anonymously (by researcher S.Sh.O) and statistical analysis was done using SPSS 18. In the wake of withdrawal of informed written consent, inability to attend sessions or death, the patients were excluded from the study. Demographic and disease characteristics, perceived stress, stress coping, and life satisfaction were analyzed using descriptive statistics (frequency, mean, standard deviation). A one-sample Kolmogorov-Smirnov test was applied to determine normal distribution of the quantitative data. For dependent variables between two groups that have normal distribution scores, an independent t-test is used to compare two groups and ANOVA is used to compare three groups. For the dependent variables that have not follow a normal distribution, Mann-Whitney is used to compare two groups, and Kruskal-Wallis is used for comparison among three groups. $P \leq 0.05$ is considered significant.

Interim analysis: It is not applicable. Interim analyses are not planned.

Methods for additional analysis

This does not apply. A subgroup analysis is not planned.

Methods in analysis to handle protocol nonadherence and any statistical methods to handle missing data

If the study doesn't have any data on a randomly selected basis, Imputation of it will be used.

Plans to give access to the full protocol, participant-level data, and statistical code

The full protocol details, as well as appropriate data analyses carried out during the study, shall be provided upon request by the corresponding author.

Oversight and monitoring: During the entire implementation procedure, which was open to possible recommendations for protocol amendment, the study was monitored by the vice chancellor of research at Tehran Medical University.

The composition of the coordination centre and the trial steering committee: This study is undertaken as a PhD, with the main responsibility for preparation of protocols, implementation of in-

tervention and publication of studies reports being student S.Sh.O. The duty to be observed by students shall be that they perform their duties in terms of health education and healthcare promotion. The research team consists of a supervisor and advisors, two professors of health education and health promotion, one epidemiologist and one surgeon, in addition to a PhD student. The protocol review, monitoring of the implementation of the study, project development, consent to amendments if necessary and approval of accuracy for publication shall be carried out by the Project Supervisor and his advisors. If there is any adverse effect, R.S and S.Sh.O shall continue to report it to the Ethics Committee. This study was carried out by the financial support of the Vice Chancellor for Research of Tehran University of Medical Sciences.

Composition of the data monitoring committee, its role, and reporting structure: The researcher will follow monitoring plan to ensure that the clinical trial is carried out and that data is generated, documented, and reported in accordance with the protocol.

Adverse event reporting and harms: The participants' health will not be at risk, and no adverse consequences have been foreseen in view of the nature of these training and support interventions. In a written informed consent, it was agreed that the members of the research team would have responsibility for treating complications and their costs if any unexpected adverse effects occurred to participants while or after participating in this study. The followup team would collect all adverse events related to or unrelated to the intervention according to the time schedule during the study. For all the collected negative effects, a causal assessment would be carried out.

Frequency and plans for auditing trial conduct: The quality of data or the progress of trials will be subject to unforeseen checks. If necessary, an audit shall be undertaken by analysing a data set and setting up the program. Auditors are independent from those who investigate the case.

Plans to communicate important protocol amendments to interested parties, such as trial participants, ethical committees: Any major change in the project implementation method, which might have an appreciable effect on participants' benefits, safety or health conditions shall be agreed and notified by the authors to the Ethics Committee. Changes will be made to the participants and new consents are required in addition to registration.

Dissemination plans: The findings of the study shall be reported to interested parties at seminars, and they shall be made public in peer reviewed journals. Requests for data sets from the appropriate author shall be granted. A complete summary of the study's results will be provided to participants at their request.

Results

This study recruitment was done in March 2021 to August 2021. A total of 315 participants have been recruited to the trial. The intervention was done in December 2021 to January 2022. Data collection and analysis are expected to be finalized early in 2023, and the study will be published in December 2023.

Discussion

The study aims to gain a deeper understanding of some ways we can decrease perceived stress and improve stress coping and life satisfaction among women with breast cancer .The researchers are aware that this study will have various operational limitations .If this psychosocial intervention ,the results of which will be analyzed upon completion, are effective ,this detailed description allows for generalization in similar contexts .Psychosocial interventions ,including education and teaching coping strategies are useful for patients with cancer [*Denti et al., 2020*]

It has been found that Tai Chi and aerobic exercise can improve cancer-related health outcomes ,for example ,mood disorders and health-related quality of life [*Denti et al., 2020; Babaei Bonab 2020*]. Much in the same way ,this study provides data on the effectiveness of a non-pharmacological intervention to address the needs of women with breast cancer. Cancer can affect patients and their families in many physical, mental, and emotional conditions, Several studies have shown that stress can promote breast cancer growth [*Gosain et al, 2020*]. Overall determining the effectiveness of this intervention on women with breast cancer can help health care providers and policymakers design interventions to help these patients manage their stress and improve stress coping and life satisfaction.

Potential Strengths of the study: This study compares the effectiveness of two approaches: direct education (by the researcher) in a family-based group and indirect teaching (by peers) in a peer support group. The design of two appropriate educational packages for family-based and peer support groups, including the active involvement of family members in helping patients in the family-based group and inviting patients previously diagnosed with breast cancer and whose disease is now under control to help patients in the peer support group are both included in the study as an innovation.

Potential limitations of the study: The study has several operational limitations. As mentioned above, there is no possibility of sealed blindness. Also, according to the condition of patients and the risk of disease recurrence within six months after the follow-up and the possibility of patients' non-cooperation, dropping out may occur any time during the study. Considering the time limit caused by the physical and mental conditions of these patients, the researchers shall provide them with comprehensive instructional resources without wasting time and clarify any ambiguities. The patients might not answer at all or give incorrect answers to some of the questions which might be a result of a lack of access to a smartphone, or an outage on the internet, or the patient's inability to participate in virtual training sessions, etc. Some patients may lose consciousness, or death may happen during the study. It is possible that they do not actively participate in training sessions.

Conclusion

This paper offers detailed insights into the design and evaluation of two virtual training programs. If the study is effective in reducing perceived stress and improving stress coping and life satisfaction of women with breast cancer in the CI, adapting the intervention for other patients with breast cancer disease, other cancers, and chronic diseases may be effective and useful.

Acknowledgments: *This study is based on the Ph.D. thesis in the Health Education and Health Promotion field, approved by the Tehran University of Medical Sciences, and is conducted in collaboration with the CI of Imam Khomeini hospital. The researchers are grateful to the Deputy of Education and Research and the many participants of the study for their generous cooperation .This study has been approved as a Tehran University of Medical Sciences research project with code No .55423-300-2-1400 .Ethics code :IR.TUMS.SPH.REC.1400.255.*

Trial registration: The study has been approved by the Research Ethics Committee at Tehran University of Medical Sciences (IR.TUMS.SPH.REC.1399.251/2021/01/13) and registered in the Iranian Registry of Clinical Trials (IRCT20210118050070N1/2021/06/28).

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