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EFFECTIVENESS OF LIFESTYLE MODIFICATION STRATEGIES ON KNOWLEDGE, LIFESTYLE PRACTICES, AND MODIFIABLE RISK FACTORS OF STRESS INDUCED CARDIOMYOPATHY AMONG MIDDLE-AGED WOMEN IN SELECTED COMMUNITY AREAS OF GUJARAT: A STUDY PROTOCOL

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BACKGROUND OF THE STUDY

The mind has great influence over the body, and maladies often have their origin.

-Moliere

Cardiovascular diseases (CVDs) are a group of disorders of the heart and blood vessels, including coronary heart disease, cerebrovascular disease, peripheral arterial disease, rheumatic heart disease, congenital heart disease, deep vein thrombosis and pulmonary embolism. An estimated 17.9 million people died from CVDs in 2016, representing 31% of all global deaths. Of these deaths, 85% were due to heart attack and stroke. Over 75% of CVD deaths take place in low- and middle-income countries where raised blood pressure happens to be amongst the most important risk factors for CVDs. In 2016 India reported 63% of total deaths due to NCDs, of which 27% were attributed to CVDs. CVDs also account for 45% of deaths in the 40-69 years age group.

According to ***Longitudinal Ageing Study in India*** (LASI), 2020, the number of self-reported prevalence of diagnosed CVDs in India are **21.9%**. Out of which 20.1% are males and ***23% are females***. In Gujarat, the number of self-reported prevalence of diagnosed CVDs are **20.1%**, out of which ***29.1 % are females*** and 22.7% are males.

One of the cardiovascular disease, *Takotsubo* cardiomyopathy (TTC), also known as stress-induced cardiomyopathy or apical ballooning syndrome (ABS), is a condition most frequently characterized by dysfunction of the apical and mid-portions of the myocardium, with a relatively preserved or hyperkinetic base. The clinical significance
of this entity is that the clinical presentation of TTC can be similar to a myocardial infarction, although there is an absence of or only mild coronary artery disease.

The word *takotsubo* is Japanese for "octopus trap", a jar-like shape that is the resulting configuration that can be demonstrated on left ventriculography when the base segment contracts with a relatively hypokinetic apical segment. Literature reviews report a mean patient age of 67 years, although cases of takotsubo cardiomyopathy have occurred in children and young adults. Nearly 90% of reported cases involved postmenopausal women. Often, the condition is triggered by a physical or emotional stressor.

Stress is a feeling of emotional or physical tension. It can come from any event or thought that makes a person feel frustrated, angry, or nervous. Body reacts to stress by releasing hormones. These hormones make brain more alert, cause muscles to tense, and increase the pulse. Chronic stress can put an individual at risk for health problems, including heart disease, hypertension, diabetes, obesity, depression and anxiety. Stress can be managed with help of regular exercise, healthy diet, adequate sleep and use of complementary alternative therapies like yoga asanas, meditation, foot reflexology and guided imagery.

NEED FOR THE STUDY (RATIONALE)

Prevention is better than cure.
Takotsubo Cardiomyopathy, also called as a Broken heart syndrome, is caused by sudden emotional and physical stressors. Emotional stressors that can bring on broken heart syndrome include: Grief from the death of a loved

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one and other large or meaningful loss (eg, divorce/relationship, job, home, money, beloved pet), Bad news, Intense fear (e.g., public speaking, armed robbery, car accident), Extreme anger. Sudden physical stressors that can bring on broken heart syndrome include: Severe pain, an exhausting physical event, Health issues, including Asthma attack, seizure, stroke, high fever, low blood sugar, large blood loss, surgery.

TTC is a preventable disease. The preventive measures are healthy lifestyle practices and learning to manage stress. Healthy Lifestyle practices include stop
smoking, choosing health diet (low salt and low sugar), being physically active (at least 150 minutes per week moderate-intensity physical activity), maintaining healthy weight, limiting alcohol intake, lowering Blood pressure, and reduction of stress. Stress can be reduced by meditation, gratitude habit, yoga, sleeping better, opting nutritious well-balanced meal, regular physical activity, pursuing healthy hobbies, and seeking support from family, friends and social groups.

Yoga is a mind-body practice that combines physical poses, controlled breathing, and meditation or relaxation. Yoga may help reduce stress, lower blood pressure and lower the heart rate. Yoga can enhance the mood and overall sense of well-being. Practicing yoga may lead to improved balance, flexibility, range of motion and strength. Yoga can also help reduce risk factors for chronic diseases, such as heart disease and high blood pressure. Deep breathing is a form of meditation, which is called as breath- focused breathing. Research shows that meditation can reduce anxiety, sharpen memory, treat symptoms of depression, promote more restful sleep, and even improve heart health. A new paper published in the journal *Frontiers in Human Neuroscience* now shows that yoga and meditation appear to have a positive effect on the central nervous system as well as the immune system, and that it may improve the individuals' overall sense of well-being.

The backbone of the nursing profession has always been recognized as that of a caring profession and one that excels in disease prevention and health promotion. One of the most critical roles that nurses have in health promotion and disease preventions is that of an educator. Nurses are consistently working to prevent illnesses such as heart disease, stroke, diabetes, and obstructive pulmonary disease; they do this through a variation of tactics that include education, risk factor prevention, and the monitoring of safety hazards either in the workplace, community, or home.

Nurses are best qualified to take on the job of health promoter due to their expertise. Here, the researcher felt the need to reduce the risk of Takotsubo Cardiomyopathy among women at risk for developing TTC by using nurse-led intervention like video- assisted teaching, practice of yoga asanas and meditation.

REVIEW OF LITERATURE

The literature review has been organised and presented under following headings.
SECTION A: Review related to Stress Induced Cardiomyopathy

TITLE	AUTHOR	METHOD & RESULT
Assess the psychological characteristics of patients with Takotsubo Syndrome (TTS) and patients with Acute Coronary Syndrome (ACS) with a aim to provide better personalized care.	**Gorini A. Galli F. Giuliani M. Pierobon A. Werba J. Adriano EP. et al (2022)**	**Method:** An exploratory study was conducted with sample size 40, out of which 20 were TTS patients and 20 ACS patients. **Result:** They reported that both the disease shared similar clinical characteristics. The result reported that only TTS patients reported the presence of a significant emotional trigger preceding the acute cardiac event: Six patients reported the death of a relative, a friend or a significant one; Three patients reported a serious quarrel with a relative or a friend; Six patients reported an assault suffered or witnessed (e.g., snatch or domestic violence); Three patients reported an acute stress related to specific work or family issues.

SECTION B: Review related to Lifestyle modification strategies in reducing risk factors of cardiovascular disease

TITLE	AUTHOR	METHOD & RESULT

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Effectiveness of Lifestyle modification programme on knowledge, lifestyle practices and modifiable	**Dr. Reena V.I. (2021)**	**Method:** A pre-test post-test control group design was used. 102 middle aged women were randomly divided in experimental group and in control
risk factors of coronary artery disease among middle aged women in selected community in Kerala.		group. The tools used for the study were socio-personal and clinical data sheet to assess the risk factors, rating scale to assess lifestyle practices and perceived stress scale (PSS-10) to assess stress and questionnaire to assess knowledge. **Result:** Post test was conducted after 90 days of interventions. The intervention was effective in modifying knowledge (p=0.01) and lifestyle practice scores, SBP, DBP, FBS, physical activity scores and dietary practice scores between control and experimental groups after the intervention.

SECTION C: Review related to effect of yoga on stress

TITLE	AUTHOR	METHOD & RESULT
Effect of Hatha Yoga on Stress in Middle-Aged Women	H. Fu-Jung; C. Ding-Kuo; C. Ue-Lin. (2013)	Method: Quasi-experimental study was conducted and participants were randomly divided into an experimental group (n = 30) and a control group (n = 33). The experimental group received the 8-week Hatha yoga course, 90-minute-class-per-week course. The Perceived Stress Scale (PSS) and heart rate variability (HRV) assessed stress reduction effectiveness. Chi-square, independent t test, and paired t test, were used for data analysis. Result: The post-intervention result showed that HRV and PSS of the experimental group decreased significantly (p < .001) more than the control group.

SECTION D: Review related to effect of Motivational Interviewing intervention

TITLE	AUTHOR	METHOD & RESULT
Motivational Interviewing Intervention to Improve Whole- Person Lifestyle and reduce cardiovascular disease risk profile.	**Sawyer, A. T., Wheeler, J., Jennelle, P., Pepe, J., & Robinson, P. S. (2020)**	**Method:** Randomized Controlled Trial was conducted on sample of 111 adults with type 2 diabetes and/or hypertension, recruited from a primary care physician practice. The intervention was facilitated by a program specialist trained in motivational interviewing. Outcomes included body mass index, cholesterol, hemoglobin A1c, blood pressure, waist circumference, wellness scores, and substance use. **Result:** Differences in the changes in body mass index, blood pressure and waist circumference existed between the intervention and control groups after 6 months. In the intervention group, the proportion of high wellness scores increased after the program. A whole-person lifestyle intervention with motivational interviewing for patients with metabolic syndrome can improve one's health in terms of components in the cardiovascular disease risk profile, as well as overall wellness.

AIM OF THE STUDY

The aim of study is to assess the effectiveness of lifestyle modification strategies in reducing modifiable risk factors of Stress-induced Cardiomyopathy among middle- aged women in selected community areas of Gujarat.

OBJECTIVES

1) To assess the pre-test and post-test level of knowledge, lifestyle practices, and modifiable risk factors of Stress-induced Cardiomyopathy among middle-aged women in selected community areas of Gujarat in

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experimental and control group.

2) To evaluate the effectiveness of Lifestyle modification strategies on knowledge, lifestyle practices, and modifiable risk factors of Stress-induced Cardiomyopathy among middle-aged women in selected community areas of Gujarat in experimental group.

3) To identify correlation between lifestyle practices, knowledge and modifiable risk factors of Stress-induced Cardiomyopathy among middle-aged women in selected community areas of Gujarat in experimental group.

4) To find out the association between pre-test level of knowledge, lifestyle practices, and modifiable risk factors of Stress-induced Cardiomyopathy with the selected demographic variables of middle-aged women in selected community areas of Gujarat in experimental and control group.

HYPOTHESES

Hypotheses will be tested at 0.05 level of significance

H1: There will be significant change in knowledge, lifestyle practices, and modifiable risk factors of Stress-induced Cardiomyopathy among middle-aged women in experimental group after administration of lifestyle modification strategies.

H2: There will be significant correlation between lifestyle practices, knowledge and modifiable risk factors of Stress-induced Cardiomyopathy among middle-aged women in experimental group.

H3: There will be significant association between pre-test level of knowledge, lifestyle practices, and modifiable risk factors of Stress-induced Cardiomyopathy with the selected demographic variables of middle-aged women in selected community areas of Gujarat in experimental and control group

DELIMITATIONS

Delimitations: The study is delimited to:

1) Middle-aged women at risk for Stress-induced Cardiomyopathy residing in selected community areas
2) 250 Sample size
3) 6 months of study duration

RESEARCH METHODOLOGY

Research Approach & Design

Research approach of this study will be Quantitative Research Approach.

Research Design will be True Experimental design: Pre-test Post-test Control Group Design

Groups	Pre-test	Intervention (12 weeks) 84 days	Post-test at 13 weeks (90 days)
Experimental group (R)	EGO1	X	EGO2
Control group (R)	CGO1	------	CGO2
Where R = Randomization, EGO = Experimental group outcome, X=Lifestyle Modification Strategies, CGO = Control Group Outcome.			

Variables

Independent Variables: Lifestyle modification strategies

Dependent Variables: Knowledge, Lifestyle practices and Modifiable risk factors of Stress-induced Cardiomyopathy

Demographic Variables: Age, Qualification, Marital status, Type of family, Working status, Menses record, Presence of Chronic illness, Medication record

Population:

Target Population: Middle-aged women residing in selected community areas of Gujarat.

Accessible Population: Middle-aged Women residing in selected community areas of Ahmedabad district of Gujarat and available during the time of data collection.

Sample: Middle-aged women residing in selected community areas of Gujarat. **Sample size:** Using power analysis, the calculated sample size is 250 at the power of 0.8.

Sampling technique: Stratified Random Sampling Technique

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Settings: The researcher will carry out the research in selected community areas.

Participant's eligibility criteria
Inclusion Criteria: Middle-aged women who are:

1) Between 35-55 years of age.
2) Presenting with moderate or high-risk factor assessment score for Stress induced Cardiomyopathy
3) Willing to participate during the study.
4) Available to understand instructions in Hindi/English.

Exclusion Criteria

1) Women who are undergoing any complementary and alternative therapies like Yoga, Meditation, Foot reflexology etc.
2) Women who are having any medical conditions like herniated disk, Eye conditions including glaucoma, Severe balance problem and Severe osteoporosis.

ETHICAL CONSIDERATIONS

- The study objectives, interventions and data collection procedure would be approved by the Ethical committee of the Institution.
- The eligible middle-aged women would be involved in studies after obtaining Informed Consent.
- Detailed explanation of the procedure, its benefits would be explained and their doubts would be clarified.
- Confidentiality and anonymity will be maintained during the collection and storage of data.
- The 3 basic ethical principles, as per Belmont ethical principles justice, respect of individuals and benefits will be maintained.

DESCRIPTION OF A TOOL
The data collection tool consists of following sections:

Section A: Demographic information and characteristics of the middle-aged women will be recorded in separate data sheet which includes Age, Qualification, Marital status, Type of family, Working status, Menses record, Presence of Chronic illness.

Section B: Tools for measurement of knowledge, lifestyle practices & Modifiable risk factors of Stress induced Cardiomyopathy.
Knowledge will be assessed using Structured Knowledge Questionnaires regarding Stress-induced Cardiomyopathy & its preventive measures, lifestyle practices will be assessed using modified lifestyle assessment tool, and Modifiable risk factors by Risk Factors Assessment tool for Stress induced Cardiomyopathy and Perceived Stress Scale.

PLAN OF DATA COLLECTION

- Formal permission will be obtained from the concerned authorities for conducting research in selected community areas.
- Then according to the inclusion and exclusion criteria, the samples will be selected using Probability Sampling technique.
- Middle aged women with moderate to high risk factor assessment score for Stress induced cardiomyopathy will be selected and randomly allotted in experimental and control group.
- Pre-test level of Knowledge will be assessed using Structured Knowledge Questionnaires regarding Stress-induced Cardiomyopathy & its preventive measures, pre-test level of lifestyle practices will be assessed using modified lifestyle assessment tool, and pre-test level of Modifiable risk factors by Risk Factors Assessment tool for Stress induced Cardiomyopathy and Perceived Stress Scale.
- Lifestyle modification strategies will be implemented for 12 weeks.
- Post-test will be collected at 13th week.

INTERVENTIONS

1) Educational intervention will be administered regarding Stress-induced Cardiomyopathy and its preventive measures among middle-aged women.

2) Motivational Interviewing (MI) will be implemented for stimulating behaviour change. With researcher's support and participants' motivations to change, self- nominated goals/priority areas will be planned and obstacles or catalysts to achieve them will be identified.
Attainable targets includes: Regular moderate-intensity physical activity for at least 30 mins; Maintaining a Sleeping habit of at least 7 hours; Adapting healthy dietary habits by understanding how to read food labels; managing portion serving sizes and comprehension. MI will be provided once a week for 3 months.

3) Hatha Yoga will be implemented for 3 days a week for a period of 3 months. The session will be of total duration of 45 minutes. It mainly consists of pranayama, yoga asanas and meditation.

OUTCOMES

1) Expected outcome related to Knowledge is increase in the post-test level of knowledge among middle-aged women.

2) Expected outcome related to lifestyle practices are regular physical activity, improved sleeping and dietary habits.

3) Expected outcome related to modifiable risk factors are low stress level and lower risk factor assessment score for Stress induced Cardiomyopathy.

PLAN OF DATA ANALYSIS

1) Demographic variables will be analysed using frequency and percentage and presented in the form of graphs and tables.

2) Effectiveness of lifestyle modification strategies will be analysed using z-test.

3) The correlation between knowledge, lifestyle practices and modifiable risk factors of Stress-induced Cardiomyopathy will be estimated using Karl Pearson Formula.

4) The association between the pre-test level of knowledge, lifestyle practices and modifiable risk factors of Stress-induced Cardiomyopathy with the selected demographic variables will be analysed using Chi-square test.

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