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Research Protocol

Oncology Section

Efficacy of Structured Teaching Programme on Knowledge Regarding Endometrial Cancer and its Prevention among Middle Adulthood Women: A Research Protocol

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ABSTRACT

Introduction: Globally, the incidence of Endometrial Cancer (EC) is increasing, making it one of the most prevalent gynaecological cancers in high-income countries. Organising EC prevention and awareness programs in a timely manner is crucial, particularly in developing nations where awareness is urgently needed. Early detection is a key factor in reducing cancer mortality. Healthcare professionals have a duty to educate the public about EC and how to prevent it.

Need of the study: There is currently no established method for preventing EC. However, several studies indicate that overweight and obesity pose substantial risk factors for EC. Other risk factors include weight fluctuations and weight gain in middle age. It is critical to reduce weight and maintain a healthy weight. Raising awareness among community members is therefore crucial.

Aim: To evaluate the impact of a structured education program on middle-aged women's understanding of EC and how to prevent it.

Materials and Methods: The study will use a one-group, quasi-experimental pretest-post-test design and will take place at the AVBR Hospital's OPD in the Gynaecology department, Sawangi (Meghe), Wardha, Maharashtra, India. The duration of the study will be April 2025 to September 2025. Women who visit the OPD between the ages of 40 and 65 years will be invited to participate. Informed consent will be obtained from each participant. A quantitative method will be used to assess how well the structured teaching program affects women's knowledge of EC and its prevention. Fifty women will participate, and a structured questionnaire will be used to collect data. Section I (demographic data) will include: age, marital status, weight, height, age at menarche, age at menopause and family history of cancer. Section II will comprise an organised survey regarding EC and its prevention. Data will be organised and analysed using descriptive and inferential statistics. For statistical analysis, data will be coded and entered into an Excel spreadsheet. Descriptive statistics will summarise demographic variables using frequency, mean, standard deviation and percentages. To assess the significance of the difference in knowledge scores between the pre- and post-tests, a paired t-test will be used. To investigate the association between knowledge levels and demographic factors, the Chi-square test will be applied.

Keywords: Crucial, Gynaecological, Malignancy, Obesity

INTRODUCTION

Endometrial cancer is the most common gynaecological cancer in high-income nations, with incidence rising worldwide. This trend is driven by factors such as an ageing population and, to some extent, a decline in benign hysterectomies; however, the most significant contributing factor is the increasing prevalence of obesity [1]. Numerous epidemiological studies have linked modifiable lifestyle risk factors, particularly obesity, to EC. Despite its rising prevalence, there has been limited media coverage on preventing EC. Recent studies have highlighted obesity as a major risk factor for the disease. Middle-aged weight gain and weight fluctuations are associated with an increased risk of developing EC. However, bariatric surgery can reduce this risk by up to 81% in overweight women by helping them maintain a healthy weight. Additionally, the combination of oral contraceptives with the levonorgestrel intrauterine system and inert intrauterine devices can lower the risk of EC [2]. The most widely accepted explanation for the biology of type 1 endometrial carcinogenesis is that progesterone fails to counteract adipose-derived oestrogen in obese postmenopausal women [3].

Globally, there is a steady increase in research on EC. However, the great majority of original articles are published by authors based in wealthy countries [4]. Recent studies suggest that coffee and tea consumption may lower the risk of EC, while alcohol consumption may increase it. Case-control and prospective studies have shown that tobacco use is associated with significantly lower risks of EC, although it is rarely advised [5]. Reducing risk with effective interventions targeted toward those at highest risk may influence EC diagnoses by addressing the main processes underlying endometrial carcinogenesis. To develop such preventive measures, it is imperative to understand the primary risk factors and how they contribute to cancer development [6]. When EC is detected in a woman without symptoms, her chances of survival are not higher than those of a woman with symptoms [7].

EC is the most common gynaecological cancer. It has historically been divided into groups based on its sensitivity to hormones. Vaginal bleeding is the most common symptom of EC. It is advisable to investigate unusual bleeding in premenopausal women over 35 years who also have other risk factors, such as overweight, nulliparity, or any postmenopausal bleeding [8].

Primary objectives: To assess the efficacy of a structured educational intervention in raising middle-aged women's knowledge.

Secondary objectives: To determine whether knowledge level and demographic factors are related.

REVIEW OF LITERATURE

According to Ball HG's study "EC: Current Concepts and Management," EC is the most prevalent pelvic gynaecologic cancer

in women. Its incidence is linked to unopposed oestrogen therapy, endometrial hyperplasia, and, more recently, tamoxifen. The staging procedure relies on information obtained during surgery. For patients with prognostic factors beyond low risk, postoperative radiotherapy is administered, while hysterectomy remains the primary treatment for most individuals with EC [9].

According to a review by Trojano G et al., EC has become the most prevalent gynaecological cancer, with incidence rising. Diagnosing EC in young, fertile women is rare, as only about 4% of patients are under 40 years. The majority of cases are diagnosed in postmenopausal women [10]. Corzo C et al., conducted a survey and noted that EC is typically diagnosed in postmenopausal women [11]. Beavis AL et al., found that modifiable lifestyle factors such as obesity, smoking and physical inactivity have a major effect on global morbidity and mortality from chronic diseases, including cancer. This review examines recent research on how lifestyle factors can impact the prevention of EC and ovarian cancer and offers new perspectives on lifestyle management for survivors of these cancers. Although exercise, oral contraceptives and bariatric surgery may offer some protection, obesity remains the primary risk factor for EC. Current interventional studies are investigating whether other medications, like metformin and non steroidal anti-inflammatory drugs, could also offer protective benefits [12].

Elit L, conducted a study on EC: prevention, detection, management, and follow-up. The main finding was that uterine cancer is linked to extrinsic and intrinsic risk factors. To prevent disease, family physicians should ensure that progesterone therapy is included in Hormone Replacement Therapy (HRT) regimens for all women with a uterus in situ using HRT. Finding abnormal uterine bleeding or undetected postmenopausal bleeding requires endometrial biopsy investigation; detection is key. In addition to removing the uterus and ovaries, surgery aims to address risk factors for high recurrence. Adjuvant radiotherapy modifies the pattern of disease recurrence but does not increase survival. Following primary therapy, the aim of follow-up is to detect recurrent disease while it is still treatable [13].

The study revealed that elderly women have inadequate knowledge, beliefs and practices, heightening their susceptibility to EC. However, those who participated in an EC prevention program showed significantly improved awareness and Quality of Life (QoL) scores compared to those who did not participate, as well as compared to their pretest scores. A highly significant difference was observed in the study group's beliefs, practices, knowledge and QOL across pre-, post-, and follow-up tests (p-value=0.001). Within the control group, a noteworthy distinction was observed only in beliefs (p-value=0.002), with no significant changes in practices, knowledge, or QOL (p-value=0.240, 0.085, 0.250). These results underscore the importance of integrating EC prevention programs into healthcare priorities for elderly women [14].

MATERIALS AND METHODS

The study will use a one group, quasi-experimental pretest post-test design and will take place at the AVBR Hospital OPD in the Gynaecology Department, Sawangi (Meghe), Wardha, Maharashtra, India. The duration of the study will be April 2025 to September 2025. Women who visit the OPD and are aged 40-65 years will be invited to participate. Fifty participants meeting the inclusion criteria will be recruited and informed consent will be obtained from each participant. The Institutional Ethical Clearance (IEC) was obtained from DHIMER (DU)/IEC/2024/210 prior to the study.

Inclusion criteria:

- Middle adulthood who are willing to participate.
- Middle adulthood who are in a specified age range 40 to 65 years.
- Middle adulthood who are available during data collection.
- An adult in their middle years who is literate in Marathi.

Exclusion criteria:

- Middle adulthood who had attend similar programme before six months.
- Woman who are not in age group 40 to 65-year-old.

Sample size: By using Cochran formula for sample size estimation:

$$n = \frac{(Z^2\ P\ (1\text{-}P)}{d^2}$$

- If population more than10.000

  Where,

- Z: statistic for a level of confidence (For the level of confidence of 95%, which is conventional, Z value is 1.96)
- P: expected prevalence or proportion. (P is considered 0.5) [15]
- d: precision (d is considered 0.05 to produce good precision and smaller error of estimate)

  Z=1.96

  P=Incidence of EC

  =14.7%

  =0.147

  d=Desired error of margin=10%=0.10

  n=1.962 *0.147*(1-0.147)

  0.10*0.10

  =48.17

  =50 participants needed in study.

{Cochran WG et al., (1977) [16]}

Study Procedure

Each participant will be asked to provide consent. There will be 50 participating women, and data will be collected using a structured questionnaire. Section I of the tools will include demographic information such as age, marital status, weight, height, age at menarche, age at menopause and family history of cancer. Section II consists of a structured knowledge questionnaire about EC and its prevention. The pretest questionnaire will be administered to the women who agree to participate. After responses are recorded, data collection will proceed. EC prevention will be taught for approximately 30 minutes using a poster and flash cards. Following the instruction, a post-test questionnaire will be administered. The time gap between the pretest and post-test will be one hour. A total of 27 questions are included, divided into two sections. Section I comprises seven questions on demographic data, while Section II consists of 20 structured knowledge questions.

Primary outcomes: Pre- and postintervention knowledge assessment via a self-structured questionnaire.

Scoring Guide for the questionnaire used:

- **Correct answer:** 1 point
- **Incorrect answer:** 0 point

Total Scoring:

- Section I (demographics) is not scored.
- Section II (knowledge) has a maximum score of 20 points.
- The knowledge levels will be categorised as follows:
  - 0-5 points: Poor
  - 6-10 points: Fair
  - 11-15 points: Good
  - 16-20 points: Very good

Secondary outcomes: The association between knowledge level and demographic variables.

Outcome measures: The structured knowledge questionnaire consists of 20 questions, each carrying 1 point. The maximum possible score is 20, and the minimum is 0.

STATISTICAL ANALYSIS

The data will be analysed using both descriptive and inferential statistics. Data will be coded and entered into an Excel spreadsheet. Demographic variables will be described using descriptive statistics (frequency, mean, standard deviation, percentages). To assess the significance of differences in knowledge scores between pre- and post-tests, a paired t-test will be used. Statistical Package for the Social Sciences (SPSS) version 17.0 will be used for analysis. To investigate the relationship between knowledge levels and demographic factors, a Chi-square test will be employed.

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