CHAPTER III

METHODOLOGY

Research methodology can be thought of as the structure of research - a "glue" that holds all of the elements in a research work together. This chapter deals with the steps taken by the investigator to determine the effectiveness of Educative Supportive Nursing Interventions on clinical indicators and behavioural adherence among women with abnormal cervical smears.

3.1 Research Design

The research design adopted was Randomized Control Trial with the components of manipulation, randomization and control. The aim of this study was to determine the effectiveness of Educative Supportive Nursing Interventions on clinical indicators and behavioural adherence among women with abnormal cervical smears.

Table 3. Schematic representation of research design

<table>
<thead>
<tr>
<th>Group</th>
<th>Baseline</th>
<th>Intervention 1st week</th>
<th>Reinforcement 4th week</th>
<th>Post test 8th week</th>
<th>Reinforcement 8th week</th>
<th>Post test 12th week</th>
</tr>
</thead>
<tbody>
<tr>
<td>SG</td>
<td>O₁</td>
<td>* X</td>
<td>* X₁</td>
<td>O₂</td>
<td>* X₂</td>
<td>O₃</td>
</tr>
<tr>
<td>CG</td>
<td>O₁</td>
<td>*</td>
<td>*₁</td>
<td>O₂</td>
<td>*₂</td>
<td>O₃</td>
</tr>
</tbody>
</table>

S – Screening of women through visual inspection of cervix followed by cytological and microbiological cervical smear analysis.

R – Randomization of women with abnormal cervical smears

SG – Study Group

CG – Control Group
O_1 – Baseline symptoms and behavioural adherence variables
X – Educative Supportive Nursing Interventions.
* – Tips for healthy living
*X_1 – 1st reinforcement for study group
*1 – 1st reinforcement for control group
*X_2 – 2nd reinforcement for study group
*2 – 2nd reinforcement for control group
O_2 – Post assessment of knowledge.
O_3 – Post assessment of clinical indicators and behavioral adherence

**Manipulation**

Manipulation refers to the Educative Supportive Nursing Interventions that was provided by the investigator to the women with abnormal cervical smears in the study group apart from the routine care. The investigator educated the women with abnormal cervical smears on one to one basis for 20 - 30 minutes, using a structured information booklet (Appendix K) with information on cervical dysplasia: risk factors, causes, prevention, screening and management and also information on risk factors, causes, prevention, screening and management of cervicovaginal infections. Tips for healthy living (Appendix L) were also incorporated. The booklets were handed over to them for their future reference. The treatment modalities that the patient had to undergo were clearly explained to her. Queries related to the treatment and behavior changes were clarified. These messages were tailored according to the need of the individual. Using a male penis model, demonstration followed by re-demonstration by women on insertion of male condoms was organized. Packed and
sealed condoms were distributed. Women were given adequate support to choose their treatment modalities and were empowered to make their decision choices. Follow up visits were encouraged by timely telephonic reminders. In case of missed follow-up visit on the scheduled dates, maximum three more telephonic reminders were given for encouraging follow-up prior to each proposed visit. Reinforcements were given during every hospital visit for 10 minutes.

**Table 4. Activities of Manipulation**

<table>
<thead>
<tr>
<th>Step I</th>
<th>Step II</th>
<th>Step III</th>
<th>Step IV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Telephonic reminder for follow-up after 1 week (1st follow-up visit)</td>
<td>a. Educating women about cervical dysplasia and cervicovaginal infections: risk factors, causes, prevention, screening, clinical features, management and complications. Also tips for healthy living were added. b. Distribution of male condoms and demonstration of its insertion.</td>
<td>Telephonic reminders prior to follow up visits on 4th, 8th and 12th week.</td>
<td>a. Reinforcement and clarification of queries during 2nd and 3rd follow up visits. b. Distribution of male condoms</td>
</tr>
</tbody>
</table>

**Control Group**

The patients in the control group received the routine care given by the doctors, nurses and other paramedical personnel in the health care facility. The investigator also gave 10 tips for healthy living that included importance of diet, rest,
hygiene, exercise, adoption of small family norm and avoidance of over the counter drugs using an information booklet (Appendix L) for 10-15 minutes on one to one basis. The booklet was handed over for future reference. Follow-up visits were encouraged by timely telephonic reminders similar to that of study group. The investigator initiated measures to hold the attention of control group women as the subjects for study and control group were from the same setting. At the completion of the study, women in the control group were offered education received by other women in the study group.

Randomization

The women who had cervicovaginal discharge were detected for abnormalities through visual inspection of the cervix, microbiological and cytological smear analysis. Women with abnormal cervical smears became samples. They were divided into two strata: the first strata had women with cervical dysplasia who were randomly assigned to two groups by pick of a chit from a box throughout the period of study. The second strata had women with cervicovaginal infection. Randomized block design was utilized to assign samples to respective groups in this stratum. The previous records indicated that at least 20 - 40 samples may be detected with cervical dysplasia in a year. Considering this factor, out of the estimated sample size of 300, 280 women with cervicovaginal infections were divided into 5 blocks with 56 samples in the each block. A box with 56 chits, 28 marked as SG (Study group) and 28 marked as CG (Control group) was prepared by the investigator. As the patients became samples for second stratum, the investigator requested the nursing assistants to pick a chit from the box. As per the letters indicated in the selected chit, women
were randomly assigned to the study or control group. When the assignment of samples to the first block was completed, the second block was considered.

### 3.2 Setting

The study was conducted in the Gynaecological Outpatient Department of Sri Ramachandra Hospital, located in the 1st floor of outpatient wing. An average daily census ranged from 50 – 60 women. Everyday about 10 - 12 samples were sent for microbiological and cytological examination. There were eight units under the Department of Obstetrics and Gynaecology. Each day, one unit took up the functioning of the outpatient department. The seventh and the eighth unit functioned on alternate Sundays. Patients who received care on a particular day were requested to follow-up only on the same day except in case of emergency. Once the patient entered the Gynaecological block, the name of the patient was registered by the nursing assistant. The new and the old patients were segregated for entry in the register. There were totally 4 private rooms in that area apart from the patient’s waiting area and registration counter. Consultation was given by medical experts in the two of the rooms. Visual examination and sample collection for investigations were carried out in the medical consultation room. One room was utilized by the investigator to provide individual education, support and appropriate reinforcements for patients of both the groups. The 4th room was used as a utility room.

### 3.3 Population

The accessible population included the women who had cervicovaginal discharge and sought medical help at the out patient department of Sri Ramachandra
hospital. The target population included the women with abnormal cervical smears, who were detected cytologically and microbiologically for cervical infections and cervical dysplasia at Gynaecology outpatient department of Sri Ramachandra Hospital.

3.4 Sample

Women diagnosed with abnormal cervical smears and those who fulfilled the inclusion criteria during the period of study at Gynaecological Outpatient Department of Sri Ramachandra Hospital, Chennai, were selected as samples.

3.5 Sample Size

Sample size was calculated using the formula.

\[ m = \frac{2 \left[ Z_{(1-a/2)} + Z_{(1-\beta)} \right]^2}{\Delta^2} \]

The required sample size was based on \( \alpha = 5\% \), power =80\% and an effect size 0.35. The estimated sample size was about 128 subjects in each group. Considering the attrition factor, the total sample was further increased by 15\%. Hence, the sample constituted of 147 subjects in each group. Rounding up to the nearest whole number, the estimated sample size was 300 with 150 subjects in study group and 150 subjects in control group.

3.6 Sampling Criteria

Inclusion Criteria

It includes:

- women with the following abnormalities in the cytological smear:
a. Women with epithelial cell abnormality namely Atypical Squamous Cell of Undetermined Significance (ASC-US), Atypical Squamous Cell – cannot exclude high grade lesion (ASC-H), Low grade Squamous Intraepithelial Lesion (LSIL), and High grade Squamous Intraepithelial Lesion (HSIL)

b. Women with glandular cell abnormality namely Atypical Endometrial/Endocervical / Glandular Cells.

- women with infections such as Trichomonas vaginalis, Bacterial vaginosis and Candidiasis as detected by microscopic smear.
- women willing to participate in the study
- women in the age group of 21 – 60 years.
- sexually active women.
- women who had telephone facilities/ postal address for future contact.
- women who can understand and speak Tamil or English.

**Exclusion Criteria**

It excludes:

- pregnant or lactating women
- women with co morbid conditions such as heart disease and renal disease.
- women already on treatment for cervical dysplasia or cervicovaginal infections
- women diagnosed with upper genital tract infections
- women with HIV / AIDS
- women with atrophic vaginitis
- women diagnosed with cervical cancer
3.7 Sampling Technique

Subjects who fulfilled the inclusion criteria, during the period of study were considered as samples. They were randomly assigned to study or control group.

3.8 Instrument

Development of the Instrument

Lack of appropriate standardized tools to assess the symptoms of cervical abnormalities, knowledge, healthy behavioural practice and barriers for follow-up adherence created a need for preparing appropriate instruments. The tool development phase that preceded the study was based on related literature searches and expert’s
guidance and suggestion. Blueprints of the tools were prepared. The language, feasibility and practicability of the tool were considered during preparation.

A blueprint of the structured booklet on abnormal cervical smears with information on cervical dysplasia and cervicovaginal infections and also the booklet on tips for healthy living was prepared by the investigator based on the literature search, previous experiences, interactions with women who had cervical abnormalities and suggestions from experts in the area. The factors considered during preparation of these booklets included: the literacy level of subjects, language, time limit for imparting education, content clarity and simplicity.

Followed by the development of the booklet, criteria checklist was prepared to seek content validity from experts. The criteria included: objective based relevance of the content, accuracy, feasibility and clarity. The final draft was prepared based on the suggestions given by experts.

**Translation of the Instrument**

Instruments and the booklet were translated in local language by four experts – two nurses with M.Sc Nursing qualification with fluency in the chosen bilinguals and two experts with M.A., M.Ed. qualification in Tamil. Using combined translation technique, two experts translated the tools to local language and then the remaining two other experts translated the local language tool to English. Consensus was obtained from four experts and final version was prepared.
Description, Scoring and Administration of the Instruments

The Instrument used for data collection had 3 parts.

3.8.1 Part – I Background variables

It includes Demographic variables, Obstetric and gynaecological related variables and record data (Appendix C)

Demographic variables

It had the details of the subjects on the following aspects: age, education, occupation, family income, religion, place of residence and distance from residence to hospital.

Obstetric and Gynaecological Variables

This part included data on gravida, parity, abortion, menstrual cycle, age of intercourse initiation, years of active sexual life, use and type of contraception, history of any RTI/ STIs in the past 2 years, frequency of treatment, history of extramarital contact for self and spouse, menstrual protective device used and history of previous pap test.

Data from Medical Records

It included the type of cervical abnormality, type of management: medical or surgical, type of surgical management, investigations and diabetic status.

Administration

The demographic, obstetric and gynaecological variables had open or closed questions that were answered by women during their second follow up visit, on selection of subjects as samples through cytological and microbiological analysis. The record data were collected by the investigator from the patient’s medical record.
3.8.2 Part - II Clinical Indicators

Clinical indicators were assessed using the following instruments: cervical visual examination checklist, symptom inventory checklist and data on cervical smear analysis. (Appendix D)

Section A: Cervical Visual Examination Checklist

This standardized form was adapted from the training module prepared by Dr. Saloney Nazeer for Geneva Foundation of Medical Education and Research, World Health Organization Collaborating Center in Human Reproduction. It is a standardized form utilized worldwide by health care personnel with 4 subdivisions

- Discharge from cervix: Normal, bloody, dirty, greenish, white or cheesy
- Appearance of the cervix: Normal or Abnormal
- If abnormal, signs of low threshold: hypertrophy, redness/congestion, irregular surface, distortion, erosion (No bleeding on touch), edematous cervix, polyp/growth (with smooth surface), nabothian follicles and prolapsed uterus
- Signs of high threshold: erosion (bleeds on touch) and growth: friable, fungating, irregular or non specific appearance

Scoring and Interpretation

Each item under the subdivision had to be marked yes or no based on the presence or absence of the clinical feature on observation of the cervix through a per vaginal speculum examination.
Administration

The investigator assisted the gynaecologist during the cervical speculum examination and in consensus with the consultant, the abnormalities in the reporting form were recorded. This instrument was utilized twice: baseline data was observed during the subject’s first visit to the hospital. The post intervention visual examination was carried out during the 12th week.

Section B: Symptom Inventory Checklist

This checklist had 13 items with symptoms commonly expressed by women with cervical dysplasia or infection like abdominal pain, vaginal discharge, abnormal / unpleasant odor, soreness around the vagina / vulva, vulvovaginal irritation, vulval itching, dyspareunia, frequency of micturition, burning micturition, dysuria, urethral discharge for husband, abnormal vaginal bleeding and other symptom if any. The checklist was prepared by the investigator after literature search on the symptoms among women. The first aspect abdominal pain included the Numerical pain scale that had rating from 0 to 10, with 0 as no pain and 10 as the most intense pain experienced by the woman.

Scoring and Interpretation

The first item, abdominal pain had a score range from 0 to 10. The remaining 12 items had dichotomous yes or no responses based on the presence or absence of the particular symptom. A score of 1 was given for yes and 0 for no. The total score of this tool was 22.
Administration

This tool was administered twice, baseline and during the 12th week post intervention. Subjects were asked to report the presence of absence of these symptoms, based on their past three week’s experience. The investigator showed the numerical scale to the subject and thoroughly explained the instructions. Then, the subject was given a pen to circle her pain score. Same tool was used pre and post for comparison. The remaining symptoms were read out by the investigator and the subject answered whether it was present or not.

Section C: Cervical Smear Analysis

This included the cytological, microbiological smear analysis results and also the results of other investigations such as colposcopy / biopsy.

Cytological smear analysis

Cytological smear analysis was based on 2001 Bethesda system. This reporting system had following components

- Specimen adequacy
- Categorization and interpretation of results:
  - Negative for intraepithelial lesion or malignancy: organisms or other non neoplastic findings was mentioned
  - Epithelial cell abnormality: squamous or glandular cell abnormality.

Administration

The first smear for cytological examination was sent during the screening process, when the first per vaginal speculum examination was performed. A sample of cervical discharge collected by the investigator using a wooden spatula was smeared
on the named and numbered glass slide and fixed immediately using a fixative. Nursing assistants sent the samples to the pathology department. Within 4-5 days, the analysis given by clinical pathologist was released by the department that can be accessed from the register placed in the department or from the report collecting center at the outpatient department. The baseline results helped in diagnosis of cervical dysplasia. The posttest cytology samples were collected during the 12\textsuperscript{th} week only for those women who had their initial diagnosis as cervical dysplasia.

Scoring and Interpretation

The cytological smear result was noted as reported by clinical pathologists. The presence or absence of epithelial cell abnormality, the type of abnormality was recorded. As the report was qualitative, no scores were assigned to them.

**Microbiological Smear Analysis**

Microbiologists reported the presence of normal vaginal flora / inflammatory cells/ clue cells/ yeast cells/ gram positive or negative cocci or bacilli or any squamous cell abnormality through gram stain test. The presence of *Trichomonas vaginalis* was identified through wet mount microscopy. The report given by the microbiologist was recorded in the form.

Administration

The examination was done in the screening period and again the smear was taken during the 12\textsuperscript{th} week post intervention to check the status of infecting organism. The presence or absence of the organism or emergence of any new organism was noted, based on the report given by the microbiologist. The sample was taken during
the pervaginal speculum examination along with the cytological smear sample, and the contents were smeared on two slides. One slide was air dried, heat fixed and sent to microbiologist for analysis using Gram stain technique. A drop of saline was added to the second slide and a cover slip was fixed. It was observed under the microscope. Trichomoniasis was diagnosed when flagellated, moving and pear shaped organisms were found on saline mount.

Scoring and Interpretation

The microbiological smear result was noted in the form as reported by microbiologists. The report had either normal vaginal flora or presence of microorganisms such as yeast, clue cells, trichomonads or gram positive or negative bacilli or cocci. Only the name of the presenting organism or normal flora was written and no scores were assigned.

3.8.3 Part – III Behavioural Adherence

Behavioural adherence (Appendix E) was determined using the following instruments: Questionnaire to assess knowledge on cervical abnormalities, Healthy behavioural practice rating scale, Follow-up adherence details and Barriers for adherence checklist

Section A: Questionnaire to assess knowledge on cervical abnormalities

It consisted of a structured questionnaire prepared by the investigator to assess the knowledge of women on cervical abnormalities, namely cervical dysplasia and cervicovaginal infections. It had 50 multiple choice questions, with four options, of
which, one was the correct option. The items were grouped under the following headings:

- Risk factors and causes of cervical dysplasia (7)
- Prevention of cervical dysplasia(6)
- Screening of cervical dysplasia (9)
- Signs, symptoms and management of cervical dysplasia (5)
- Causes of cervicovaginal infections (4)
- Symptoms and investigations of cervicovaginal infections (3)
- Prevention and treatment of cervicovaginal infections (16)

Scoring and Interpretation

Each correct answer was scored as 1 and the wrong answer as 0.

Total score was 50. The score was interpreted as follows:

- >75 % Highly adequate knowledge
- 50% – 75 % Moderately adequate knowledge
- <50% Inadequate knowledge

Administration

The questionnaire was read to the participants, by the investigator during their visit to the hospital, after being selected as samples through cytology and microbiology analysis confirmation. Answers given for each question was marked in front of the subject. Post knowledge was assessed during the 8th week, using a fresh sheet of questionnaire. The period between the reinforcement and posttest assessment was one month. The posttest assessment of knowledge was conducted by the research assistant
appointed by the investigator to enforce a blinding approach. The research assistant
was not aware of the group the subject belonged to.

Section B: Healthy Behavioural Practice Rating Scale

The rating scale had 20 items to assess the practice of healthy behaviours
among women with abnormal cervical smears. Each item had four options. The
healthy behaviours were grouped under the following headings:

- Perineal hygiene (6)
- Menstrual hygiene (3)
- Sexual hygiene (4)
- Glycemic control (1)
- Repeat smear examination awareness (1)
- Adherence with follow-up, medication, investigations and treatment (5)

The first four components were assessed during baseline and posttest, whereas
the remaining two components were assessed only during posttest.

Scoring and Interpretation

Each item had 4 options categorized on a 1 – 4 rating scale with scores:

1 – Unsatisfactory
2 – Least satisfactory
3 – Satisfactory
4 – Most satisfactory

Pre total score was 56. The post total score was 80. The level of healthy behavioural
practice was grouped as follows:

>75 % High level of healthy behavioural practice
50% – 75 % Moderate level of behavioural practice
<50% Poor level of behavioural practice
Administration

This rating scale was administered twice: baseline data was collected during the visit of the subject to the hospital, once they were selected as samples, on confirmation of cytology and microbiology analysis. The items under perineal, menstrual sexual hygiene, repeat smear awareness were elicited by questioning the subject. The answer given by the subject for each item was marked in front of her. The glycemic control was recorded using the investigations reports in the medical record of the patient. The second assessment was carried out during the 12th week after the intervention. The contents under the treatment adherence aspect were recorded using the patient’s medical records. The pill count was elicited orally and counter checked by counting the remaining pills the woman had with her. Apart from these record details, the oral answers for certain mentioned items were collected by the research assistant in a fresh sheet of rating scale.

Section C: Details of Follow-up Adherence

Follow-up adherence was identified based on numbers of reminders given prior to each follow up visit, lapse days between visits and missed visits for each subject in both the groups.

Scoring and Interpretation

Actual numbers of reminders given during each visit, the number of lapsed days between visits were quantified in numerals. If the subject did not turn up for the proposed visit in spite of the four reminders, it was considered as a missed visit. The missed visit was also noted down as whole number for each subject.
Section D: Barriers for Adherence Checklist

The 16 item barriers checklist list had dichotomous yes or no answers, under these headings:

- Knowledge related barriers: 3
- Attitude related barriers: 5
- Practice related barriers: 8

Scoring

A score of 1 was given for yes and 0 for No. Total score was 16.

Administration

This checklist was administered by the investigator during the 12th week post intervention visit by the subject.

3.8.6 Cervical Abnormalities teaching module

The module prepared by the investigator had content on cervical dysplasia and cervicovaginal infections grouped under the headings: risk factors and causes, preventive aspects, screening and investigations, management and complications. It also included the demonstration on insertion and use of a male condom. (Appendix F).

3.8.7 Tips for healthy living teaching module

The teaching module had 10 tips for healthy living that was imparted to the women in both the groups. (Appendix G)
3.8.8 Information booklet on Cervical Abnormalities

The booklet (Appendix L & N - English and Tamil version) prepared by the investigator was based on the content imparted to women during the educative session on cervical abnormalities. The structured information booklet was used as a visual aid during the one to one teaching session for women with abnormal smears in the study group. This aid had pictorial representation also, for easy perception of content. This booklet was handed over to the women after the first teaching session.

3.8.9 Information booklet on tips for healthy living

This booklet prepared by the investigator was based on the content imparted to women during the educative session on tips for healthy living. (Appendix M & O - English and Tamil version). It was used for teaching women in the both the groups. This aid had pictorial representation also, for easy perception of content. It was handed over to the women after the first teaching session.

3.9 Validity and Reliability

All the instruments were reviewed and validated by experts of the review committee as well other medical and nursing experts (Appendix H). They were also pilot tested to assess the usability and ease of administration

3.9.1 Cervical Visual Examination Checklist

It was a standardized tool. The interrater reliability of this visual reporting form was established. Two experts used this form for documentation. They independently assessed the same 10 patients. The reliability correlation coefficient was 0.9 (p=0.008).
3.9.2 Symptom Inventory Checklist

The content validity index was calculated by counting the number of agreements as judged by five experts, which were then divided by the total number of agreements + disagreements. The content validity index was 0.82. The calculated interrater reliability coefficient of this form was 0.83 (p=0.005).

3.9.3 Behavioural Adherence Instruments

Questionnaire to assess knowledge on cervical abnormalities, Healthy Behavioural Practice rating scale and Barriers for adherence checklist:

The content validity index for the behavioural adherence instruments were calculated by counting the number of very relevant agreements and then dividing by the total number of very relevant + not relevant agreements, as judged by five experts. The content validity index was 0.78, 0.81 and 0.89 respectively for the three tools. The reliability of the tools was established by test – retest method for 10 samples and the calculated correlation coefficient was 0.82, 0.88 and 0.91 respectively.

3.9.4 Information Booklet

The criteria for content validity of the booklets included objective based relevance of the content, language, accuracy, feasibility and clarity on a five point rating scale (1= strongly disagree, 2= disagree, 3= neither agree nor disagree, 4= agree and 5= strongly agree). Five experts rated the cervical abnormalities and tips for healthy living booklets. Mean expert ratings given for the information booklet on cervical abnormalities and tips for healthy living were: relevance of content 4.53 and 4.19, accuracy 4.31 and 4.25, clarity 4.64 and 4.43 and feasibility 4.28 and 4.16.
respectively. The average overall rating for cervical abnormalities booklet and tips for healthy living were 4.44 and 4.25 respectively.

3.10 Pilot Study

The pilot study was conducted in the Gynecology Outpatient Department of Sri Ramachandra hospital from 28.8.2007 to 16.1.2008. The pilot study helped to assess the reliability and feasibility of the study. 15% of the proposed sample size was considered for the pilot study. Out of 75 samples screened, 40 subjects who satisfied the inclusion criteria were equally distributed to both the groups. One sample in the control group was lost to follow up. The modifications that were brought after pilot study were:

- Assessment of barriers for follow up adherence was added
- Some information in the gynecological and personal variables such as frequency and duration of contraception use, chewing habits and details of the subject’s spouse regarding smoking and history of circumcision were excluded.

3.11 Data Collection Procedure

Data collection was conducted from 3.2.2008 to 27.1.2009.

Ethical approval was obtained prior to the commencement of study. Women who visited the gynaecology OPD with cervicovaginal discharge were screened for cervical smears abnormalities through three stage screening. Prior to screening, permission and willingness to consider them as study samples was obtained from subjects through a written consent after an explanation about the study. Telephone
number and the address for contact were noted. A visual inspection of the cervix was
done followed by extraction of three smears— one for cytological analysis and two for
microbiological analysis. The specimen for cytological examination was fixed and
sent to the pathology lab. One specimen for microbiological examination was air
dried, heat fixed for gram stain test. The results were obtained within a 4 – 5 days. In
the third smear, a drop of normal saline was added; a cover slip was placed and
examined under the microscope for Trichomonads. Women were asked to report after
a week. Women who satisfied the inclusion criteria were given reminders for next
visit. Willingness for participation was again confirmed.

Background variables were collected. Women with cervical dysplasia were
randomly assigned to either study or control group and those with cervicovaginal
infections were assigned by block randomization. Knowledge, symptoms and healthy
behavioural practice were assessed using structured questionnaire.

Women in the study group were given Educative Supportive Nursing
Interventions by the investigator using the structured booklet in the outpatient
department itself. The investigator gave a detailed education on risk factors, causes,
preventive measures, screening methods, signs, symptoms and management of
cervical dysplasia and cervicovaginal infections. It also included the tips for healthy
living. Teaching was given on one to one basis. The time for teaching, discussion and
clarification took approximately 20 to 30 minutes. Other information on
investigations, management and behavioural changes required were tailored according
to the need of the patient. Male condoms were distributed and the method of insertion
was demonstrated. The number of condoms given was based on the woman’s need
and decision until her next visit. Booklet was handed over for further reference. Women in the control group were also taken to the same room and they were educated only on tips for healthy living for 10 -15 minutes on one to one basis.

The subjects in both the groups were given a reminder two days prior to their date of visit. If in case, they did not turn up on the due date; they were given additional reminders two days prior to the due day of visit, the following week. A maximum of 4 reminders were given for each due visit. If the subject did not turn up with four remainders, it was accounted as “missed visit”.

During the follow up visit, reinforcement was given using the booklet for 10 minutes for subjects in both the groups. The 3rd follow up visit was after 4 weeks from their first day of visit. Reinforcement was given during this visit. During the 4th visit, 8 weeks from the first visit, their knowledge on cervical abnormalities was assessed through the structured questionnaire (blinding approach) by a research assistant. After the assessment, 2nd reinforcement was given. During the 5th visit, 12 weeks after the first visit, the subject’s behavioural adherence was assessed using the rating scale, symptoms were also assessed, using blinding approach. A visual per vaginal speculum examination was carried out and a smear specimen was taken according to their diagnosis. Microbiological smear was taken for all the subjects. If the smear showed the organism, it was considered as persistence of infection. Post cytological smear was taken only for those women with cervical dysplasia. Post hysterectomy, a vault smear was sent and results recorded. The barriers for the follow up were also collected during this visit using the checklist.
Table 5. Schematic representation of data collection procedure

<table>
<thead>
<tr>
<th>S.No</th>
<th>Activities</th>
<th>1st day of visit</th>
<th>2nd visit After 1 week</th>
<th>3rd visit 4th week</th>
<th>4th Visit 8th week</th>
<th>5th visit 12th week</th>
</tr>
</thead>
</table>
| 1.   | a. Informed consent  
b. Cervical visual examination  
c. Microbiological & cytological smear | O # | | | | |
| 2.   | Reminder (2 days prior to visit) | O # | O # | O # | O # |
| 3.   | a. Background variables  
b. **Baseline**: Symptoms, knowledge & healthy behavioural practice | O # | | | | |
| 4    | **Interventions** | O(X*) # (*) | O(X1*) # (*1) | O(X2*) # (*2) | |
| 5.   | **Posttest**: Knowledge | O # | | | | |
| 6.   | **Posttest**:  
a. Cervical visual examination  
b. Microscopic & cytological smear analysis (if required)  
c. Symptoms, Healthy behavioural practice,  
  Barriers for adherence  
d. Follow-up adherence | O # | | | | |

O - Study group  
# - Control group  
X* - Educative Supportive Nursing Interventions.  
* - Tips for healthy living  
* X1 & *X2 - 1st and 2nd reinforcement for study group  
*1 & *2 - 1st and 2nd reinforcement for control group
3.12 Plan for Data Analysis

Descriptive statistics was used to arrange the data in scientific way. Inferential statistics was used to test the hypothesis. The Statistical Package for the Social Science (SPSS) version 10.0 was used for data analysis. In all the tests, p values less than .05 were interpreted as statistically significant.

Table 6. Plan for data analysis

<table>
<thead>
<tr>
<th>Methods</th>
<th>Type of statistic</th>
<th>Purpose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Descriptive</td>
<td>Frequency,</td>
<td>Assess the sample characteristics and study variables.</td>
</tr>
<tr>
<td>Statistics</td>
<td>Percentage,</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Mean, SD</td>
<td></td>
</tr>
<tr>
<td>Inferential</td>
<td>Paired ‘t’ test</td>
<td>Compare the behavioural adherence variables before and after intervention within the groups.</td>
</tr>
<tr>
<td>Statistics</td>
<td>Student ‘t’ test</td>
<td>Compare the behavioural adherence variables before and after intervention between the groups.</td>
</tr>
<tr>
<td></td>
<td>Chi square</td>
<td>Assess the homogeneity of samples between the groups.</td>
</tr>
<tr>
<td></td>
<td>Pearson’s</td>
<td>Compare the clinical indicators within the groups before and after intervention</td>
</tr>
<tr>
<td></td>
<td>correlation</td>
<td>Compare the clinical indicators between the groups before and after intervention</td>
</tr>
<tr>
<td></td>
<td>ANOVA</td>
<td>Identify the relationship within the behavioural adherence variables.</td>
</tr>
<tr>
<td></td>
<td>Regression</td>
<td>Identify the relationship between symptom and behavioural adherence variables.</td>
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<td></td>
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<td>Identify the relationship between clinical indicators and behavioural adherence variables.</td>
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<tr>
<td></td>
<td></td>
<td>Associate selected background variables with selected outcome variables.</td>
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<tr>
<td></td>
<td></td>
<td>Identify the relationship between selected background variables with selected outcome variables.</td>
</tr>
</tbody>
</table>