Abstract of thesis entitled

“An Evidence-based Educational Protocol for Adult Patients Awaiting Colposcopy”

Submitted by

Cheung, Wing Yee

for the degree of Master of Nursing
at The University of Hong Kong
in July 2013

Introduction: Colposcopy is a gynaecological invasive day procedure involving visualization of cervix for diagnostic and therapeutic purpose. Women who are waiting for this procedure often experience high anxiety. Several studies have demonstrated that adopting pre-colposcopy patient education strategy can relieve such psychological distress. In this translational research, a relevant evidence-based education guideline is formulated for a colposcopy clinic in a local public hospital.

Objectives: The objectives of this translational research proposal include (1) extracting the current empirical evidence on the education intervention for minimizing the psychological distress among women waiting for their first colposcopy examination; (2) developing an educational protocol; (3) and developing a plan of intervention and evaluation for the proposed protocol.

Methods: A literature search for studies dealing with patient education of women at risk of cervical cancer was performed in PubMed and PsycINFO. After data extraction from the identified studies, the methodology quality of the studies was
appraised by the methodology checklist of Scottish Intercollegiate Guidelines Network (SIGN) (2011). Then, an evidence-based protocol was formulated according to the recommendations drawn from the evidence. Before putting the protocol into practice, a systematic implementation potential assessment was done by evaluating the transferability of the findings, and the feasibility and cost-benefit ratio of the protocol. Both communication and evaluation plan were developed for a smooth implementation of the protocol.

**Results:** 10 studies fulfilled the inclusion criteria of the literature search and were used for developing an evidence-based protocol of pre-colposcopy patient education. After the assessment, distributing written and audio-visual education materials at patients’ first colposcopy appointment is concluded to be a feasible innovation in the target setting.

**Conclusion:** Based on the extracted evidence from the systematical review, patient education strategy can potentially benefit the first-time colposcopy patient in the target setting to alleviate their anxiety during their wait for the examination.
An evidence-based Educational Protocol for Adult Patients
Awaiting Colposcopy

by

Cheung, Wing Yee

B. Nursing. C.U.H.K.

A thesis submitted in partial fulfilment of the requirements for
the Degree of Master of Nursing
at The University of Hong Kong.
July 2013
Declaration

I declare that this thesis represents my own work, except where due acknowledgement is made, and that it has not been previously included in a thesis, dissertation or report submitted to this University or to any other institution for a degree, diploma or other qualifications.

Signed .................................................................................................

Cheung, Wing Yee
Acknowledgements

It is my great honour to gain support by many people throughout the strenuous journey to the production of this dissertation. First and foremost I would like to offer my sincere thanks to my dissertation supervision, Dr. William Li, for his high degree of patience and insightful guidance that helped me greatly in turning the manuscript into this final work. I also extend my thanks to Dr. Daniel Fong for his systematic guidance in his tutorials.

Besides, I cannot forget my dear classmates who accompanied me with great support in the process.

To complete this acknowledgement, I have to express my heartfelt thanks to my family, particularly my younger sister, for their selfless love that assist me a lot to pass through all the difficult moments over the past two years.
# Contents

*Declaration* ........................................................................................................... i  
*Acknowledgements* ............................................................................................. ii  
*Table of Contents* ............................................................................................... iii  
*Lists of Illustrations (Tables /Appendices)* ......................................................... v

## CHAPTER 1: INTRODUCTION

1.1 Background ........................................................................................................ 1  
1.2 Affirming the Need ....................................................................................... 3  
  1.2.1 Local Setting ....................................................................................... 3  
  1.2.2 Current Practice ............................................................................... 3  
  1.2.3 Description on Clinical Issue ............................................................... 3  
  1.2.4 Potential Innovation ....................................................................... 4  
1.3 Objectives and Significance ....................................................................... 4  
  1.3.1 Significance of the Potential Innovation ........................................ 4  
  1.3.2 Objective, Question and Hypothesis of the Research .................... 5

## CHAPTER 2: CRITICAL APPRAISAL

2.1 Search and Appraisal Strategies .................................................................. 6  
  2.1.1 Identification of Studies ................................................................. 6  
  2.1.2 Data Extraction .............................................................................. 7  
  2.1.3 Appraisal Strategies ..................................................................... 7  
2.2 Result ............................................................................................................. 8  
  2.2.1 Search Results .............................................................................. 8  
  2.2.2 Table of Evidence .......................................................................... 9  
  2.2.3 Study Characteristics ................................................................. 9  
  2.2.4 Subject Characteristics .............................................................. 10  
  2.2.5 Methodological Issues .............................................................. 10  
2.3 Summary and Synthesis .......................................................................... 15  
  2.3.1 Summary of Data ........................................................................ 15  
  2.3.2 Data Synthesis .......................................................................... 19

## CHAPTER 3: TRANSLATION AND APPLICATION

3.1 Implementation Potential Assessment ..................................................... 25  
  3.1.1 Target Audience ....................................................................... 25  
  3.1.2 Target Setting ........................................................................... 26  
  3.1.3 Transferability of the Findings ...................................................... 26  
  3.1.4 Feasibility ............................................................................... 28  
  3.1.5 Cost-benefit Ratio of the Innovation ........................................... 31  
3.2 Evidence-Based Practice Guideline / Protocol ....................................... 35
CHAPTER 4: IMPLEMENTATION PLAN
4.1 Communication Plan................................................................. 44
  4.1.1 Identification of Stakeholders.............................................. 44
  4.1.2 Concerns of Stakeholders.................................................. 44
  4.1.3 Communication Process.................................................... 45
4.2 Pilot Study Plan........................................................................ 47

CHAPTER 5: EVALUATION PLAN
5.1 Identification and Measurement of Outcomes............................ 49
  5.1.1 Patient Outcome................................................................. 49
  5.1.2 System Outcome............................................................... 51
5.2 Nature of Clients Involved.......................................................... 51
5.3 Size of Evaluation...................................................................... 52
5.4 Timing and Frequency of Outcome Measurement....................... 52
5.5 Data Analysis............................................................................. 53
5.6 Effectiveness of the Innovation.................................................. 54

CHAPTER 6: SUMMARY
6.1 Summary.................................................................................... 56

Appendices......................................................................................... 57
References.......................................................................................... 100
Illustrations

Tables

Table 1
Summary of the internal validity and level of evidence for the selected studies................................................................. 14

Table 2
Estimated man-hours needed for the innovation......................... 33

Table 3
Estimated cost of the 14-month EBP project.............................. 34

Table 4
Estimated annual operation cost............................................. 35

Appendices

Appendix A
Literature Search History..................................................... 57

Appendix B
Table of Evidence.................................................................. 58

Appendix C
Methodology Quality Assessment of Selected Studies............... 73

Appendix D
Key to evidence statements from Scottish Intercollegiate Guidelines Network (2011)......................................................... 83

Appendix E
Criteria for Referral for Colposcopy....................................... 84

Appendix F
Key to Grades of Recommendations from Scottish Intercollegiate Guidelines Network (2011)............................................. 85
Appendix G
Criteria for Evaluating the Implementation Potential of an Innovation under Scrutiny……………………………………………………………………… 86

Appendix H
The Timeline for Innovation Implementation and Evaluation……………… 88

Appendix I
Summary on the Information for the Intervention Groups of Pre-colposcopy Patients in the Selected Studies…………………………………… 89

Appendix J
Details of the Intervention Investigated in the Selected Studies…………… 90

Appendix K
Flow chart of Communication Process……………………………………….. 94

Appendix L
Survey Questionnaire of Patient’s Opinion on Pre-colposcopy Education Materials…………………………………………………………………… 95

Appendix M
Outline for the Semi-Structured Evaluation Meeting among Project Operators……………………………………………………………………… 99
CHAPTER 1
INTRODUCTION

1.1 Background

Public awareness of cervical cancer prevention in Hong Kong has been increasing. In recent years, the ever cervical screening coverage rate has increased dramatically in Hong Kong (Department of Health, 2011). As recommended by the Hong Kong College of Obstetricians and Gynaecologists (HKCOG) in 2008, referral for colposcopy after abnormal cervical cytology is necessary for detection of more advanced cervical disease (Appendix E). Due to these increased demands, the sequel of the examination and treatment has been lengthened substantially. Nurses thus are experiencing huge demand from the expanding population of women requiring colposcopy. Particularly, nurses have a strong need to attend to women’s psychological needs since awaiting colposcopy is an afflicting experience to patients (Freeman-Wang et al., 2001; Kola & Walsh, 2011).

The heightened pre-colposcopy anxiety is resulted from a combination of variables. In a local qualitative investigation, Twinn and Lo (2007) demonstrated that Hong Kong Chinese women experienced fear, uncertainty, confusion, and lack of control when referred for colposcopy. The contributing factors include being notified of abnormal cytology, lack of tailor-made information, relationship with sexuality, and waiting time (Twinn & Lo, 2007). For abnormal cytology, many women react with shock because of their misconception of the abnormality as cancer, despite the reassurance from healthcare provider (Twinn & Lo, 2007). Their fear of cancer to certain extent
reflects their inadequate knowledge of cervical cancer. Apart from fear, feeling of uncertainty is also common. It is because women have limited knowledge on what will come next after referral. They may worry about procedural pain, disease progression, and future management (Kola & Walsh, 2012; Twinn & Lo, 2007; Mortensen & Adeler, 2010). These worries risk the women’s sense of control. It is especially true for women who have fertility-related or family-related concern (Kola & Walsh, 2011).

Some women are confused by their positive smear result due to sexuality issue. While it is known that human papillomavirurs (HPV) is the root of cancer, many Hong Kong Chinese women especially those in monogamous relationship do not accept the fact that it is a sexually transmitted disease (STD) (Kwan et al., 2010). There is a stereotypical belief that STD is an indicator of amorality, even though HPV infection is not limited to people not in monogamous relationship (Kwan et al., 2010). Therefore, a positive infection status can cause confusion or anger in pre-colposcopy patients. Such stigmatization to HPV infection implies the need of high quality patient education.

Pre-colposcopy anxiety is closely related to waiting time for colposcopy as well. Unfortunately, waiting time is prolonged because of the long waiting list due to understaff. Those with smear result showing mild cervical dysplasia need to wait longer than those with moderate or severe dysplasia. However, even though they are at lower risk of malignancy, it is not necessary that their pre-colposcopy anxiety is less since anxiety level is not associated with severity of dysplasia (Mortensen and Adeler, 2010).
1.2 Affirming the Need

1.2.1 Local Setting

Generally, colposcopy is a day procedure which can be undergone in outpatient setting. Some clinics such as Family Planning Association’s (FPA) cervical disease clinic and private clinics in the community can provide colposcopy service with expensive charges. Therefore, public hospital is still the common choice.

1.2.2 Current Practice

In public hospital setting, all patients requesting colposcopy service have to make an appointment with referral letter. The appointment is determined by the cytology result. On colposcopy day, patient will be given pre-colposcopy introduction session with content including examination procedure and disease management before examination. Sometimes, treatment can be completed at once and hospitalization in general is not necessary.

1.2.3 Description on Clinical Issue

In many occasion, patients have received various information on colposcopy, depending on their sources. As public hospitals receive referrals from different sources, patients in public hospital may have various expectations. A study assessing leaflets from 128 colposcopy clinics generated a surprising result in which the suggested time for resuming intercourse after local cervical treatment was ranged from 0 to 8 weeks (Byrom et al., 2003). This result highlights the possible inconsistent knowledge among patients upon referral for colposcopy. As opinioned by Byrom et al. (2003), such inconsistence of information may
induce confusion and anxiety.

Additionally, Byrom et al. (2003) indicated that patients may have very little information from their cervical smear providers. Therefore, nurses should not assume that all the referred patients have been well informed about the referral. As recommended by Byrom et al. (2003), colposcopy clinic should bear partial responsibility for timely pre-colposcopy patient education so as to reduce patient anxiety due to lack of knowledge.

As mentioned above, waiting time is a determinant of pre-colposcopy anxiety. While patients with severe dysplasia on their cervical smear can receive colposcopy service in a few weeks, those having a mild one may need to wait for months even a year due to their lower risk level (Appendix E). Hence, addressing patient’s pre-colposcopy anxiety is especially important.

1.2.4 Potential Innovation

Conventionally, nurses provide patient care upon patient’s attendance for examination. Actually, the waiting period before the actual colposcopy day may be a good opportunity for nurses to address patient’s anxiety.

1.3 Objectives and Significance

1.3.1 Significance of the Potential Innovation

Using educational strategy to reduce pre-colposcopy anxiety may greatly benefit patients. Firstly, using appropriate patient education, patient’s fear of cancer may be reduced. According to Khanna and Phillips (2001), patient’s adherence
to care plan is associated with their fear of cancer. Patient’s risk of cancer will increase if they fail to comply with medical management. Secondly, education may help to increase patient’s perceived control over their condition and in turn can minimize cancer-specific distress (Audrain et al., 1997). This may prevent future psychiatric and psychological morbidity. Finally, it may increase patients’ satisfaction and in turn improves nurse-and-patient relationship.

Therefore, this translational research aims to set up an evidence-based patient education strategy to minimize the anxiety level of patients awaiting colposcopy.

1.3.2 Objective, Research Question, and Hypothesis of the Research

The objectives, research question, and hypothesis of the translational nursing research are listed as follows:

Objectives:

• To extract the current empirical evidence on the education intervention for reducing patients’ psychological distress among women indicated for colposcopy
• To develop an educational protocol based on the identified evidence
• To develop a plan of intervention and evaluation for the proposed protocol

Research Question:

Does an evidence-based education intervention provided before the colposcopy examination reduce the anxiety level among patients awaiting first-time colposcopy?

Hypothesis:
An evidence-based education intervention will help patients who are waiting for their first colposcopy reduce their anxiety arising from the abnormal Pap smear result and the need of colposcopy.

CHAPTER 2

CRITICAL APPRAISAL

2.1 Search and Appraisal Strategies

2.1.1 Identification of Studies

The inclusion and exclusion criteria of the search were listed as follows:

Inclusion criteria

- The target group of the study is women who are at risk of cervical cancer;
- The primary outcome measure is psychological distress;
- Interventions in the study is related to patient education;
- Controlled trial studies;
- Full text of the studies can be accessed via the library of the University of Hong Kong

Exclusion criteria:

- The full text of the studies cannot be retrieved
- Studies that do not have a quantitative design.

2.1.2 Data Extraction

Information related to the study design, country of study, subjects’ characteristics, treatments (both intervention- and control-group), length of follow-up, relevant outcome measure, effect size, and source of funding were extracted from the eligible studies and are summarized in appendix B.

2.1.3 Appraisal Strategies

The methodology checklist of Scottish Intercollegiate Guidelines Network (SIGN) (2011) was used as the tool to assess the methodological quality of the selected studies. The checklist encompasses ten questions addressing the
following methodological aspects of the studies:

1. Appropriateness and clearness of study question

2. Randomization of subject allocation

3. Concealment method

4. Blinding to treatment allocation

5. Similarity of subject characteristics

6. Contamination of treatments

7. Standard, validity and reliability of outcome measurement

8. Drop-out rate

9. Use of intention-to-treat analysis

10. Comparability of results from multi-site

After assessing the methodological quality, the evidences were graded based on the Scottish Intercollegiate Guidelines Network (2011) grading system (Appendix F).

2.2 Result

2.2.1 Search Results

The literature search was performed between 5th September, 2012 and 12th
September, 2012. The search history was tabulated in Appendix A. In accordance to the aforementioned search strategy, 10 intervention studies were selected for appraisal.

2.2.2 Table of Evidence

For overview, relevant data of the selected studies were extracted and summarized in the table of evidence (Appendix B).

2.2.3 Study Characteristics

All the selected studies are randomized controlled trials (RCT). Two studies were conducted in Hong Kong (Kwan et al., 2010; Chan, Lee, Ng, & Ngan, 2004) and the remaining eight were from the Western countries, including Australia (Byrom et al., 2002), Canada (Stewart, Lickrish, Sierra, & Parkin, 1993), Netherlands (de Bie et al., 2011), the United States (Tomaino-Brunner, Freda, & Damus, 1998), and the United Kingdom (Freeman-Wang, 2004; Howells, 1999; Marteau, Kidd, & Cuddeford, 1996; Wilkinson, Jones, & McBride, 1990). Most of the studies conducted in hospitals but one was carried out in a community-based setting (Kwan et al., 2010).

The timing of the post-intervention outcome measure varies across studies. In Kwan et al.’s study (2010), the measure was performed immediately after the intervention. For other studies, their timing of measure ranged from 1- to 16-week (Byrom et al., 2002; Chan et al., 2004; Howells et al., 1999; Marteau et al., 1996; Stewart et al., 1993; Tomaino-Brunner et al., 1998). Three studies did not give the exact time interval of follow-up (de Bie et al., 2001; Freeman-Wang et al., 2001; Wilkinson et al., 1990).
Concerning the funding, 5 studies were financially supported by external sources (Byrom et al., 2002; Freeman-Wang et al., 2001; Kwan et al., 2010; Marteau et al., 1996; Wilkinson et al., 1990). The other studies did not mention the sources (Chan et al., 2004; de Bie et al., 2011; Howells et al., 1999; Stewart et al., 1993; Tomaino-Brunner et al., 1998).

2.2.4 Subject Characteristics

All subjects in these studies were women who were at risk, in various degree, of cervical cancer. Subjects were patients who were being referred for their first time colposcopy (Byrom et al., 2002; de Bie et al., 2011; Chan et al., 2004; Freeman-Wang et al., 2001; Howells et al., 1999; Marteau et al., 1996; Stewart et al., 1993; Tomaino-Brunner et al., 1998; Wilkinson et al., 1990), or patients who accepted the services of cervical surveillance or birth control (Kwan et al., 2010). Despite having an increased cancer risk, all subjects were healthy and had no significant medical history. The mean age of the subjects in these studies ranged from 28.3 years to 43.9 years; two included studies did not provide relevant information (Freeman-Wang et al., 2001; Wilkinson et al., 1990).

2.2.5 Methodological Issues

The methodological quality assessment of the selected studies was done with aid of the SIGN (2011) as shown in Appendix D. The results of the assessment are demonstrated in Appendix C. The summary of the internal validity of these selected studies and their level of evidence was shown in Table 1.

Firstly, all of the studies well addressed their research questions. With appropriate and clearly focused questions provided, it allows adequate assessment
of whether the studies have made relevant conclusion within the scope.

With regard to the randomization method, 4 studies adopted computer-generated method (Byrom et al., 2002; Chan et al., 2004; Howells et al., 1999; Kwan et al., 2010) and 1 study randomized the subjects blindly using sealed envelopes (de Bie et al., 2011). On the other hand, the randomization of 3 studies was poor as they used an alternate subject assignment (Marteau et al., 1996; Stewart et al., 1993; Tomaino-Brunner et al., 1998). Due to insufficient information, assessment of the randomization method of 2 studies was not plausible (Freeman-Wang et al., 2001; Wilkinson et al., 1990).

For concealment method, 5 studies addressed this aspect well (de Bie et al., 2011; Chan et al., 2004; Howells et al., 1999; Kwan et al., 2010; Byrom et al., 2002). In Marteau et al.’s study (1996), randomization was completed by means of strict rotation. As the subject allocation could be predictable, it imposed a potential bias affecting the validity of the study. Stewart et al.’s study (1993) and Tomaino-Brunner et al.’s study (1998) did not include concealment. Another two studies did not report sufficient relevant information (Freeman-Wang et al., 2001; Wilkinson et al., 1990).

Patient education is the target of these intervention studies. Due to the nature of the intervention, keeping both subjects and investigators blind about the treatment allocation was not feasible. Hence, it was not applicable to do methodological quality assessment of blinding about treatment allocation in these studies.

Regarding the similarity of the subjects’ characteristics across study groups, 7 studies reported that their participants were comparable at the start of the trial.
(Byrom et al., 2002; Chan et al., 2004; de Bie et al., 2001; Howells et al., 1999; Kwan et al., 2010; Marteau et al., 1996; Tomaino-Brunner et al., 1998). Two studies did not provide sufficient data for relevant assessment (Stewart et al., 1993; Wilkinson et al., 1990). Freeman-Wang et al. (2001) even did not mention this aspect.

For avoidance of contamination bias in both groups, all studies had addressed it satisfactorily.

Most of the studies well discussed the outcome instrument. Spielberger’s State-Trait Anxiety Inventory (STAI; Spielberger et al., 1983), a widely used reliable tool assessing state anxiety, was adopted in 7 studies (Byrom et al., 2002; de Bie et al., 2011; Freeman-Wang et al., 2001; Howells et al., 1999; Marteau et al., 1996; Tomaino-Brunner et al., 1998; Wilkinson et al., 1990). Some studies selected other well-validated tools for measuring subjects’ psychological distress (i.e. General Health Questionnaire, Abnormal Smear Questionnaire and Cervical Screening Questionnaire in Byrom et al.’s study and the Brief Symptom Inventory in Stewart et al.’s study). In Kwan et al.’s study (2010), a pilot study was conducted to affirm the reliability of their measurements of the high-risk HPV-related sexual stigma so this study addressed the aspect adequately.

In studies with secondary outcome measurement (Byrom et al., 2002; Chan et al., 2004; de Bie et al., 2011; Kwan et al., 2010; Marteau et al., 1996; Stewart et al., 1993; Tomaino-Brunner et al., 1998), instruments for measuring the effect of the trials on subjects’ knowledge were mostly self-designed.

All selected studies stated their drop-out rate, except the Wilkinson et al.’s study (1990). Two studies had zero attrition and they did not need to utilize the
intention-to-treat approach (Chan et al., 2004; Kwan et al., 2010). Three studies had the attrition rates (in both treatment and control arms) less than 20%, which is within the acceptance level recommended by the SIGN (Byrom et al., 2002; Freeman-Wang et al., 2001; Marteau et al., 1996). However, among these three studies, only one used the intention-to-treat approach in their analysis (Byrom et al., 2002).

Finally, assessment of inter-site result comparison within the selected study is not applicable, as they all carried out their interventions in a single site.

Based on the above assessment, 4 studies were qualified as methodologically strong since they had fulfilled most of the SIGN’s criteria on internal validity (Chan et al., 2004; de Bie et al., 2011; Howells et al., 1999; Kwan et al., 2010). One study was ranked with a medium quality due to its high drop-out rate, although intention-to-treat analysis was applied (Byrom et al., 2002). 5 studies were of low quality (Freeman-Wang et al., 2001; Marteau et al., 1996; Stewart et al., 1993; Tomaino-Brunner et al., 1998; Wilkinson et al., 1990). They showed flaws in their randomization, allocation concealment, degree of attrition, and data analysis.
<table>
<thead>
<tr>
<th>Citation</th>
<th>1.1</th>
<th>1.2</th>
<th>1.3</th>
<th>1.4</th>
<th>1.5</th>
<th>1.6</th>
<th>1.7</th>
<th>1.8</th>
<th>1.9</th>
<th>1.10</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chan et al., 2004</td>
<td>Well covered</td>
<td>Well covered</td>
<td>Not applicable</td>
<td>Well covered</td>
<td>Well covered</td>
<td>Well covered</td>
<td>No drop-out</td>
<td>Not applicable</td>
<td>Not applicable</td>
<td>I++</td>
</tr>
<tr>
<td>de Bie et al., 2011</td>
<td>Well covered</td>
<td>Well covered</td>
<td>Not applicable</td>
<td>Well covered</td>
<td>Adequately addressed</td>
<td>Well covered</td>
<td>I: 10.7%</td>
<td>C: 12.9%</td>
<td>Not addressed</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Howells et al., 1999</td>
<td>Well covered</td>
<td>Well covered</td>
<td>Well covered</td>
<td>Well covered</td>
<td>Well covered</td>
<td>Well covered</td>
<td>I: 6.5%</td>
<td>C: 2.9%</td>
<td>Well covered</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Kwan et al., 2010</td>
<td>Well covered</td>
<td>Well covered</td>
<td>Not applicable</td>
<td>Well covered</td>
<td>Adequately addressed</td>
<td>No drop-out</td>
<td>Not applicable</td>
<td>Not applicable</td>
<td>Not applicable</td>
<td>I++</td>
</tr>
<tr>
<td>Byrom et al., 2002</td>
<td>Well covered</td>
<td>Well covered</td>
<td>Not applicable</td>
<td>Well covered</td>
<td>Adequately addressed</td>
<td>Well covered</td>
<td>I: 39.8%</td>
<td>C: 32.7%</td>
<td>Well covered</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Marteau et al., 1996</td>
<td>Well covered</td>
<td>Poorly addressed</td>
<td>Poorly addressed</td>
<td>Not applicable</td>
<td>Well covered</td>
<td>Well covered</td>
<td>I: 49.0%</td>
<td>C: 53.1%</td>
<td>Not addressed</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Stewart et al., 1993</td>
<td>Well covered</td>
<td>Poorly addressed</td>
<td>Not addressed</td>
<td>Adequately addressed</td>
<td>Well covered</td>
<td>I: 4.8%</td>
<td>C: 11.1%</td>
<td>Not addressed</td>
<td>Not applicable</td>
<td>1-</td>
</tr>
<tr>
<td>Tomaino-Brunner et al.,</td>
<td>Poorly addressed</td>
<td>Not addressed</td>
<td>Not applicable</td>
<td>Well covered</td>
<td>Well covered</td>
<td>I: 1.7%</td>
<td>C: 0%</td>
<td>Not addressed</td>
<td>Not applicable</td>
<td>1-</td>
</tr>
<tr>
<td>Wilkinson et al., 1990</td>
<td>Not reported</td>
<td>Not reported</td>
<td>Not applicable</td>
<td>Adequately addressed</td>
<td>Well covered</td>
<td>Not reported</td>
<td>Not reported</td>
<td>Not applicable</td>
<td>Not applicable</td>
<td>1-</td>
</tr>
</tbody>
</table>

Table 1: Summary of the internal validity and level of evidence for the selected studies
2.3 Summary and Synthesis

2.3.1 Summary of Data

Among the selected studies, provision of printed materials was commonly used as an educational strategy for trial of anxiety alleviation. Five studies solely tested the effect of the printed materials (Byrom et al., 2002; Howells et al., 1999; Stewart et al., 1993; Tomaino-Brunner et al., 1998; Wilkinson et al., 1990). Two other studies compared the printed materials (Kwan et al., 2010; Marteau et al., 1996). For Kwan et al.’s study (2010), comparison of leaflets with different writing styles was performed. The focus of the comparison was on leaflets with information on high risk human papillomavirus (hrHPV) presented in a destigmatized manner or in a neutral clinical manner. In Marteau et al.’s study (1996), both booklet types (brief and simple booklet and detailed booklet) were assayed. The effect of combined use of both booklets was also considered.

Other educational strategies in combination with printed materials were also tested in some trials. In de Bie et al.’s study (2011), an extensive individual phone discussion with nurses was offered to the intervention group before the colposcopy appointment. In Freeman-Wang et al.’s study (2001), information video was mailed to the participants as an additional education tool. In Chan et al.’s study (2004), all participants were provided with information leaflet and video in pre-colposcopy session held 1-to-2 weeks before the actual colposcopy. The intervention group received additional patient-nurse discussion session along with a role play of colposcopic consultation and examination. Byrom et al. (2002) also delivered video information in combination with group session in the intervention group while the control group only received usual care.
Although all the selected studies concomitantly used printed materials as the main mode of educational intervention, differences existed across their format, readability and the content of the printed materials.

Printed materials in leaflet form were used by Howells et al. (1999), Wilkinson et al. (1990) and Tomaino-Brunner et al.’s study (1998). In the studies conducted by de Bie et al. (2011) and Marteau et al. (1996), leaflet was used as a baseline intervention in both intervention and control groups.

Compared to leaflet, booklet has a greater capacity to cover more content. Its usefulness was tested by Marteau et al. (1996) and Stewart et al. (1993). The booklet in Freeman-Wang et al.’s study (2001) was given as a baseline treatment.

Regarding readability, the leaflet used by Howells et al. (1999) in the intervention group scored 80 in the Flesh readability index, indicating 80% of the participants understand the leaflet. Marteau et al. (1996) also utilized the same index in their study (3 levels of readability: fairly easy, fairly difficult, and difficult). In Stewart et al.’s study (1993), the booklet used as the intervention treatment was easy to comprehend; its reading level is at grade 6. Although Kwan et al. (2010) had not used any scale to measure the readability of their printed material, they collected comments about the readability, overall impression, and language usage from their participants. Other studies did not provide any information about the readability of their printed materials (Chan et al., 2004; de Bie et al., 2011; Tomaino-Brunner et al., 1998).

In most of the selected studies providing education materials, implication of an abnormal cervical smear result on cervical cancer was one of the components of the printed materials (de Bie et al., 2011; Howells et al., 1999; Marteau et al.,
Among the studies, only Wilkinson et al. (1990) emphasized that they delivered the information in reassuring approach. In de Bie et al.’s study (2011), such information was included in the extensive phone discussion for the intervention group. In Freeman-Wang et al.’s study (2001), the information was delivered in video format instead of in printed version. In addition to the above information, Howells et al. (1999) provided message about the high incidence and aetiology of abnormal smear to the intervention group.

Determination of the effect of information about HPV was performed in both de Bie et al.’s (2011) and Kwan et al.’s study (2010). While de Bie et al. (2011) provide additional information about HPV vaccination in the extensive phone discussion for the intervention group, Kwan et al. (2010) developed a relatively detailed HPV written message including prevalence, transmission, signs and symptoms and the natural infection history for testing.

For colposcopy-related information, Chan et al. (2004) showed the nature and reason of colposcopy by video; Howells et al. (1999) and Tomaino-Brunner et al. (1998) provided similar information by printed materials. Howells et al. (1999) also described colposcopy procedure by written format, similar to what Tomaino-Brunner et al. (1998) did. While the control group in de Bie et al.’s study (2011) received brief descriptive leaflet on colposcopy procedure, the intervention group received relevant information in details from nurse via phone communication. In Chan et al.’s study (2004), similar descriptive message was conveyed by video. For reassurance, information about the common body sensation during colposcopy, which is a mild pain, was also stated in the studies of Howells et al.’s (1999) and Tomaino-Brunner et al.’s (1998).
Howells et al. (1999) and Tomaino-Brunner et al. (1998) also stated the after-effect of colposcopy in their leaflets. In Howells et al.’s study (1999), advice on post-colposcopy patient care was given in the leaflet. In Freeman-Wang et al.’s study (2001), similar information was included in the mailed video material.

In 3 studies, message on disease management (e.g. possible treatments) was delivered to the intervention group in written format (Howells et al., 1999; Marteau et al., 1996; Stewart et al., 1993). In Marteau et al.’s study (1996), the message was delivered in a booklet. However, their booklet had a fair-to-poor readability. In Freeman-Wang et al.’s study (2001), similar message was provided for both study arms in booklet but, for the intervention group, the information was repeated in video. Likewise, while both study arms in de Bie et al.’s study (2011) received relevant written information, the subjects of the intervention group could discuss it with nurse on phone.

Some other content was included in the education materials in several individual studies. For example, the videos used in 3 studies contained introductory information of colposcopy clinic (Chan et al., 2004; Byrom et al., 2002; Freeman-Wang et al., 2001). The leaflets for the intervention groups in 2 studies conveyed message of the availability of help (Howells et al., 1999; Tomaino-Brunner et al., 1998). In 2 studies, the intervention group could request extra information in pre-colposcopy session (Byrom et al., 2002; Chan et al., 2004).

Finally, regarding the timing of the intervention, 3 studies provided the treatment to the intervention groups when making the colposcopy appointment
(Howells et al., 1999; Stewart et al., 1993; Wilkinson et al., 1990). In 4 studies, the treatment was offered at some time after colposcopy appointment (Byrom et al., 2002; Freeman-Wang et al., 2001; Marteau et al., 1996; de Bie et al., 2011). Another 2 studies gave the treatment 1 to 2 weeks before colposcopy (Chan et al., 2004; Tomaino-Brunner et al., 1998). In Kwan et al.’s study (2010), the HPV information leaflet was distributed when the subjects attended the clinics for cervical screening or birth control.

2.3.2 Data Synthesis

In order to develop an evidence-based education intervention for minimizing patients’ pre-colposcopy anxiety level, conclusions were drawn from studies with high- (Chan et al., 2004; de Bie et al., 2011; Howells et al., 1999; Kwan et al., 2010) and medium-methodological quality (Byrom et al., 2002) and this information will be translated into practice. Meanwhile, data from the poor-quality studies will also be used but only as reference information (Freeman-Wang et al., 2001; Marteau et al., 1996; Stewart et al., 1993; Tomaino-Brunner et al., 1998; Wilkinson et al., 1990).

All the studies regarded p-value smaller than 0.05 as statistically significant. Among the 5 studies of medium-to-high methodological quality, 4 studies adopted STAI to measure subjects’ state anxiety level but there was no significant decrease in the state anxiety level in the intervention groups (Byrom et al., 2002; Chan et al., 2004; de Bie et al., 2011; Howells et al., 1999). On the other hand, those low-quality studies using the same instrument in measuring state anxiety reported a significant reduction among the intervention group (Freeman-Wang et al., 2001; Marteau et al., 1996; Wilkinson et al., 1990). However, it is important to note
that the studies from Freeman-Wan et al. (2001) and Wilkinson et al. (1990), which were regarded as weak in methodology, did not provide sufficient details for thorough assessment of their internal validity. But, despite the potential issue with these studies, the positive result of the state anxiety reduction from these 2 studies should not be ignored. Furthermore, Wilkinson et al’s study (1990) noted that there were fewer subjects having cancer thought and perception of health deterioration on the receipt of Pap smear. This encouraging result should not be neglected.

de Bie et al.’s study (2011), a high-quality study, did not find a significant reduction of anxiety level in the intervention group. They used other instruments rather than STAI. Similar result was demonstrated in Byrom et al.’s study (2002) (a study of medium quality) when other validated tools were used.

In Stewart et al.’s study (1993), the post-treatment alleviation of pre-colposcopy psychological distress (e.g. diagnosis-related distress, fear of cancer, worries about future health) was significant. In Tomaino-Brunner et al.’s study (1998), significantly fewer subjects in the intervention group felt scared and nervous to have colposcopy. In Marteau et al.’s study (1996), a brief and simple booklet was shown to be able to significantly reduce state anxiety and anxiety relating to possible abnormalities of colposcopy. Also, the detailed booklet significantly reduced patients’ perceived seriousness of their health problem.

With regard to the content of the educational information provided to the intervention groups, Appendix I and Appendix J show the variety among the studies. Nevertheless, some common content are noted. For example, information about the implication of an abnormal smear result to cervical cancer
was provided in the education materials in the 5 studies with satisfactory effect of psychological distress alleviation (Freeman-Wang et al., 2001; Kwan et al., 2010; Marteau et al., 1996; Stewart et al., 1993; Wilkinson et al., 1990). These studies delivered the information by different means. Among the 5 studies, 2 studies took consideration of the readability of the written education materials (Marteau et al., 1996; Stewart et al., 1993). They demonstrated that readable education materials should be used. In Freeman-Wang et al.’s study (2001), video was used. Video in general is an easy-comprehended communication tool for educational information delivery. Personalized information presented in reassuring approach also showed satisfactorily effect on anxiety reduction (Wilkinson et al., 1990).

Concerning HPV related information, the de-stigmatized hrHPV information used in Kwan et al.’s study (2010) was found to be more useful than either the neutrally presented cervical cancer-focused or the genital HPV-focused information in reducing the subjects’ sexual stigma to hrHPV.

Aside from the primary outcome measure (pre-colposcopy anxiety level), the secondary outcome measure, which is the post-treatment knowledge level, was included in 6 studies with varied methodological quality (Byrom et al., 2002; de Bie et al., 2011; Kwan et al., 2010; Marteau et al., 1996; Stewart et al., 1993; Tomaino-Brunner et al., 1998). All the studies reported positive effect on it.

In conclusion, from the above evidence, the following education intervention was recommended for minimizing the anxiety level of patients waiting for colposcopy. The strength of the recommendations was graded on the basis of the recommendations from SIGN (2011) as showed in Appendix F. The grades,
which are in descending order, will provide information to nurses about how desirable the recommendations are. The recommendations are as follows:

A. Timing of intervention

Patient education materials for reducing pre-colposcopy anxiety level should be delivered to patient immediately after the colposcopy appointment. [B]

Education materials that successfully minimized the anxiety level of the intervention groups were distributed either on the same day or in a few days after the appointment. (Freeman-Wang et al., 2001; Marteau et al., 1996; Stewart et al., 1993; Wilkinson et al., 1990) (1-)

B. Mode of intervention delivery

Prior to the colposcopy appointment, information video should be distributed to patients’ as a supplementary of the information booklet. [B]

When supplementing with the information video, the effect of colposcopy explanatory booklet on reducing pre-colposcopy state anxiety among colposcopy clinic attendees is much greater. The video should present images of the clinical setting and instrument, and outlined the nature of abnormal Pap smear (PS), consultation workflow and post-colposcopy management. (Freeman-Wang et al., 2001) (1-)

There is no strong evidence demonstrating the provision of patient counseling
before colposcopy appointment can ameliorate the pre-colposcopy anxiety. [A]

- Adjunct to individually targeted information, nurse-patient extensive discussion via phone before the colposcopy appointment had no obvious effect on patients’ pre-colposcopy anxiety level (de Bie et al., 2011). (1++)
- An extra nurse-patient discussion session did not allay patients’ anxiety level better than information from leaflet and video alone. (Chan et al., 2004) (1++)
- Patients attending nurse-led pre-appointment counseling did not significantly allay pre-colposcopy anxiety. (Byrom et al., 2002) (1+)

C. Content of education

De-stigmatizing content should be included in Human papillomavirus (HPV) message delivery and genital HPV-focused message should be avoided. [A]

HPV is a sexually transmitted disease. Emphasizing the high prevalence of HPV (hrHPV) infection could not conceal the stereotypical thinking relating to the sexual stigma. De-stigmatizing content stressing hrHPV can affect everyone could minimize the stigma and the psychosocial impact of a positive HPV PS result. (Kwan et al., 2010) (1++)

Information about colposcopy procedure and the correlation between abnormal PS result and cervical cancer should be the basic components of
the patient education. [B]

- All the 5 studies with positive psychological outcomes explained the meaning of abnormal PS result to the intervention group. (Freeman-Wang et al., 2001; Marteau et al., 1996; Stewart et al., 1993; Tomaino-Brunner et al., 1998; Wilkinson et al., 1990) (1-)
- Except Wilkinson et al.’s study (1990), studies with positive psychological outcomes provided information about colposcopy procedure. (Freeman-Wang et al., 2001; Marteau et al., 1996; Stewart et al., 1993; Tomaino-Brunner et al., 1998) (1-)

D. Presentation skill

The information about risk of cervical cancer should be written in a personal and reassuring style. [B]

Informing patients by written materials about the need of follow-up after their abnormal PS was inadequate. If patients with abnormal PS result can receive written material that reassure her not to be anxious, their pre-colposcopy state anxiety, cancer thought, and perception of deteriorating health may significantly reduce. (Wilkinson et al., 1990) (1-)

Written education material should be readable for general population. [B]

Patients receiving a brief and simple information booklet had significantly less pre-colposcopy state anxiety and worry than who did not receive it. The content of
the booklet should be comprehensible by general population. Compared to a simple booklet, a detailed and fairly difficult booklet at the college level did not provide greater effect on decreasing patients’ anxiety level. (Marteau et al., 1996) (1-)

CHAPTER 3

TRANSLATION AND APPLICATION

3.1 Implementation Potential Assessment

Nursing practice that serves to solve clinical problems should be built on solid evidence (Polit & Beck, 2012). Also, feasibility of the actual practice should also be stressed. Therefore, the implementation potential of the proposed education intervention innovation is analyzed as follows. The analysis focuses on the transferability, feasibility and the cost-benefit ratio of the innovation (Appendix G).

3.1.1 Target Audience

As investigated in Chapter 1, awaiting colposcopy is a process that can significantly disturb patients’ psychological health. It is especially true for those who have a long waiting time and those who have never experienced it before. In order to meet the patients’ need, the innovation will target on women who have just referred to make their first colposcopy appointment. These women are required to able to understand written Chinese and spoken Cantonese.
3.1.2 Target Setting

The target setting is a gynaecological day procedure center in an acute public hospital in Hong Kong. Colposcopy is one of the procedures provided by the centre. In the centre, there are both doctor-led and nurse-led colposcopy clinics. The nurse-led colposcopy clinic in the centre has been accredited to be one of the nurse clinics by Hospital Authority (HA) in Hong Kong since 2005. Four nurse-led sessions and 1-3 doctor-led sessions are run in a weekly basis. One of the nurse-led sessions provides service to clients without a history of colposcopy. On doctors’ clinical decision, the new colposcopy cases are arranged to receive service in either one of the clinic.

For manpower, there are 1 advance practice nurse (APN), 4 full-time registered nurses (RN), 2 part-time RNs, 3 health care assistants (HCA), and 2 clerical staff working in the centre. All the full-time nursing staffs have been trained for colposcopy.

3.1.3 Transferability of the Findings

Transferability refers to the degree of the evidence-based innovation adequate for the proposed practice setting (Polit & Beck, 2012). The findings to be transferred into practice should be congruent with some elements of the proposed setting, including clients’ characteristics and philosophy of care. When utilizing the findings, number of clients being benefited should be sufficiently large. As well, duration of the implementation and evaluation should be reasonable. Accordingly, the following will explain how the proposed education intervention fits in the setting.
(I) Similarity of target population

The target audiences in this setting are women who aged 25 to 50 awaiting their first time in-office colposcopy. They have similar characteristics with the subjects from the identified studies. In particular, their sex is female. The age range of the subjects in most of the identified studies was also within the 25-to-50. Subjects in eight of the identified studies were women awaiting their first time in-office colposcopy as well (Chan et al., 2004; Byrom et al., 2002; de Bie, 2011; Freemen-Wang et al., 2001; Howells et al., 1999; Marteau et al., 1996; Stewart et al., 1993; Tomaino-Brunner et al., 1998). Their waiting time ranged from 1 to 16 weeks while the target audience in the proposed setting would have more or less the same waiting time.

(II) Philosophy of care

To be accredited as a HA nurse clinic, the colposcopy clinic has committed to provide high quality nursing care. The care includes providing patient education that can optimize client’s health and promoting continuity of care and also the service is autonomously managed by nurse (Task Force on Evaluation of Nurse Clinics, Hospital Authority, 2010). The proposed education intervention exactly fulfills the prevailing philosophy of care of the colposcopy clinic. Aiming at promoting client’s psychological health, it can satisfy the conditions of HA nurse clinic since its quality is supported by research evidence and an implementation plan is also in place for the intervention.

(III) Number of potential clients being benefited

The number of clients being benefited should be sufficiently large.
According to the 2011 annual statistics of the target setting, about 960 new colposcopy appointments were arranged. On average, there were 72 cases per month. Inferentially, the proposed intervention in each month can potentially help 72 patients alleviate their anxiety while waiting for the examination.

(IV) Length of time for implementation and evaluation

The innovation implementation and evaluation of anxiety level will last for 10 months, a reasonable length of time. As showed in Appendix H, the whole process will comprise a 2-month preparation; a 4-month pilot testing; and a 4-month post-pilot evaluation. A full implementation will be followed. A final evaluation will be performed simultaneously with the full implementation. It will last for 4 months.

3.1.4 Feasibility

According to Polit and Beck (2010), feasibility of an innovation is related to availability of staff and resources, organization climate, availability of necessary external assistance, and potential for clinical evaluation. It is also affected by nurses’ perceived control of the innovation (Polit & Beck, 2010). As demonstrated in below, the feasibility of the proposed education intervention is high.

(I) Nurse’s control over the innovation

Since the nature of the proposed patient education intervention is an independent nursing practice, involved nurses have full control of the innovation. The control is exhibited by the freedom of termination.
(II) Availability of staff

Annually, the centre provides over 10,000 various gynaecological day procedures. Although the patient load is large, there are part-time RNs who can share the workload. Therefore, there is room for allowing the core staff to prepare, implement and evaluate the innovation. One of the clerical staff can be released to assist the preparation of the education materials.

The availability of staff is not only related to the quantity but also affected by staff’s competence and attitude. These qualities determine the smoothness of the implementation.

Regarding staffs’ competence, the core nursing staff have already equipped with adequate knowledge for the content of the patient education (including the written- and audio-visual-materials).

Generally, staffs have positive attitude towards the innovation. First, they voluntarily take cervical disease-associated courses on a regular basis so their knowledge on patient education is up-to-date. Besides, in accordance to the accreditation criteria of HA nurse clinics (Task Force on Evaluation of Nurse Clinics, Hospital Authority, 2010), nurses should have commitment in employing their advanced nursing competence to deliver quality holistic client care. By experience, nurses also realize that handling an anxious patient who undergoes colposcopy can be very time-consuming, adding extra burden on top of the high nurse-to-patient ratio and limited patient consultation time. For above reasons, consensus is clear among staffs that the innovation is worth testing.

While the staff’s attitude is positive in general, their possible worry on the
increased workload may be a resistance to the process of innovation. This problem can be overcome by adequate communication with the staffs. A communication plan is in place for this purpose (Appendix K).

**(III) Availability of resources**

The target setting has equipped with the needed resources for the innovation (i.e. computers and printer for preparing the written education materials). For preparing the audio-visual materials, funding from the hospital chief executive (HCE) that supports departmental service improvement is available.

**(IV) Organization climate**

The HA cluster which the centre belongs to upholds a culture that is conducive to research utilization for service outcome improvement. In addition, because of the encouragement of innovation and high quality patient-oriented healthcare services, the cluster is likely to support the innovation. Therefore, the nurses of the centre are well prepared to implement the proposed evidence based innovation.

**(V) The availability of necessary external assistance**

As the target audiences’ first contact point, the specialty outpatient department (SOPD) is an ideal place for education material distribution. Since the distribution can be carried out during the process of appointment making, inter-departmental friction resulting from the innovation is not expected.

**(VI) The potential for clinical evaluation**

State-Trait Anxiety Inventory (STAI), a well-established and validated
measuring tool for anxiety level, was widely used in the majority of the identified studies (Chan, 2004; Byrom, 2002; de Bie, 2011; Freeman-Wang, 2001; Howells, 1999; Marteau, 1996; Tomaino-Brunner, 1996; Wilkinson, 1990). Since the proposed innovation share similar purpose with the identified studies and its primary outcome is pre-colposcopy anxiety level, the Chinese version of STAI should be an appropriate selection.

3.1.5 Cost-benefit Ratio of the Innovation

Examining the cost-benefit ratio of an EBP project is critical for the implementation. Costs and benefits should be viewed from the perspective of the 3 affected parties, which are clients, nurses, and the organization. The costs and benefits of this innovation is identified in below:

(I) Benefits and costs to clients

Relieving clients’ pre-colposcopy anxiety is the upmost benefit of the innovation. The innovation can satisfy clients’ need for colposcopy-associated information before their appointment. Since clients receiving non-standardized information from usual healthcare providers or other sources may create confusion, the innovation can help provide clarification. Negative impact on physical health to client is unlikely in this innovation.

Conversely, if the status quo is maintained, the clients will not be able to enjoy the above advantages of the innovation. They may suffer psychologically and avoid follow-up if their pre-colposcopy anxiety is not addressed (Khanna & Phillips, 2001).

(II) Benefits and costs to nurses
The prospective involving nurses will be rewarded for their efforts to the innovation. Firstly, their knowledge on the psychological need of this specific patient group will be increased. Such increase in the knowledge can strengthen their confidence in nurse-patient communication and in turn facilitates patient rapport building. Therefore, smoother patient care is possible.

Secondly, requirement of on-site management of patients’ anxiety can be reduced. Then, nurses can spare more time for post-colposcopy patient care and their workload-associated stress can be relieved.

Lastly, the project provides them an opportunity to bring their potential into full play. If the project can be successfully implemented with satisfactory patient outcome, their job satisfaction and morale can be boosted.

However, translating research evidence into practice can impose burden on the manpower of the full-time nurses. Therefore, the nursing staff has to make adjustment in their usual practice such as job duty reassignment. This is to relieve the full-time nurses to develop and run the project.

(III) Benefits and costs to the organization

Increase in staff’s job satisfaction and morale resulting from the innovation can benefit the organization since it may reduce staff turnover and subsequently reduce investment in new staff training.

Also, the image of the organization may be improved due to the enhancement of patient care. Consequently, the ground for re-accrediting the centre as a HA’s nurse clinic will become strong and the funding to the centre can be secured.
According to the existing evidence, information booklet and video will be used as the tools for patient education intervention in the innovation. The labour cost and the direct cost for the innovation development are estimated to be HK$164,322 and HK$20,957 respectively. Totally, the developmental will cost HK$185,279. For annual operation, the cost is estimated to be HK$6,728. The cost calculation is detailed as follows:

**Table 2: Estimated man-hours needed for the innovation**

<table>
<thead>
<tr>
<th>Item description</th>
<th>Man-hour used (hours)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Project coordinator (APN) (n = 1)</td>
</tr>
<tr>
<td></td>
<td>10</td>
</tr>
<tr>
<td><strong>1. Project meeting (2 hours / meeting)</strong></td>
<td>6</td>
</tr>
<tr>
<td>• Preparation</td>
<td>5 meetings</td>
</tr>
<tr>
<td>• Post-pilot evaluation</td>
<td>3 meetings</td>
</tr>
<tr>
<td>• Final evaluation</td>
<td>2 meetings</td>
</tr>
<tr>
<td><strong>2. Education material preparation</strong></td>
<td>21</td>
</tr>
<tr>
<td>• Information booklet</td>
<td>35</td>
</tr>
<tr>
<td>• VCD design</td>
<td>14</td>
</tr>
<tr>
<td><strong>3. Data entry</strong></td>
<td>--</td>
</tr>
<tr>
<td>• Post-pilot evaluation</td>
<td>--</td>
</tr>
<tr>
<td>• Final evaluation</td>
<td>--</td>
</tr>
<tr>
<td><strong>4. Data analysis</strong></td>
<td>--</td>
</tr>
<tr>
<td>• Post-pilot evaluation</td>
<td>10</td>
</tr>
<tr>
<td>• Final evaluation</td>
<td>20</td>
</tr>
<tr>
<td><strong>5. Evaluation report writing</strong></td>
<td>--</td>
</tr>
<tr>
<td>• Post-pilot evaluation</td>
<td>7</td>
</tr>
<tr>
<td>• Final evaluation</td>
<td>21</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>148</td>
</tr>
</tbody>
</table>
Table 3: Estimated cost of the 13-month EBP project

<table>
<thead>
<tr>
<th>Item</th>
<th>Item description</th>
<th>Cost (HK$)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Labour cost <em>(Indirect cost in terms of money)</em></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Project coordinator (APN) (n=1)</td>
<td>$279 per hour</td>
</tr>
<tr>
<td></td>
<td>• Project facilitator (RN) (n=4)</td>
<td>$232 per hour</td>
</tr>
<tr>
<td></td>
<td>• Part-time RN (n=2)</td>
<td>$189 per hour</td>
</tr>
<tr>
<td></td>
<td>• Clerical staff (n = 1)</td>
<td>$61 per hour</td>
</tr>
<tr>
<td></td>
<td>Total indirect cost</td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td>Education materials cost *(80 cases / month) <em>(Direct cost)</em></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Printing and photocopying (e.g. Pamphlets, evaluation form)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Video production</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• VCD production *</td>
<td>$2,000 / 100 pieces</td>
</tr>
<tr>
<td></td>
<td>• VCD duplication *</td>
<td>$1,300 / 100 pieces</td>
</tr>
<tr>
<td>3.</td>
<td>Evaluation materials cost *(30 cases for post-pilot evaluation; 238 cases for final evaluation) <em>(Direct cost)</em></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• C-STAT Form Y</td>
<td>$7.8 / copy</td>
</tr>
<tr>
<td></td>
<td>• Other questionnaire form</td>
<td>$0.2 / copy</td>
</tr>
<tr>
<td></td>
<td>Total direct cost</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td>Other cost</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Venue for holding meetings</td>
<td>Hospital premises</td>
</tr>
<tr>
<td></td>
<td>• Computer accessories</td>
<td>Departmental property</td>
</tr>
<tr>
<td></td>
<td>• Photocopying machine</td>
<td>Departmental property</td>
</tr>
</tbody>
</table>

* - The target audiences can receive VCD when making colposcopy appointment.
- They will be required to return the VCD on the appointment day.
- Average waiting time for colposcopy is about 14 weeks
Table 4: Estimated annual operation cost

<table>
<thead>
<tr>
<th>Item Description</th>
<th>Cost (HK$)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Education materials cost (80 cases / month)</td>
<td></td>
</tr>
<tr>
<td>• Printing and photocopying</td>
<td>1,200</td>
</tr>
<tr>
<td>• VCD duplication #</td>
<td>2,600</td>
</tr>
<tr>
<td>• 4 hours / month</td>
<td></td>
</tr>
<tr>
<td>• $61 / hour</td>
<td></td>
</tr>
<tr>
<td>• Checking for wear of VCD by clerical staff</td>
<td>2,928</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Total annual operation cost</td>
<td>6,728</td>
</tr>
<tr>
<td>2. Other cost</td>
<td></td>
</tr>
<tr>
<td>• Computer accessories</td>
<td>Departmental property</td>
</tr>
<tr>
<td>• Photocopying machine</td>
<td>Departmental property</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td># For compensating the depreciation of VCD</td>
<td></td>
</tr>
</tbody>
</table>

3.2 Evidence-Based Practice Guideline / Protocol

Title

An evidence-based patient education intervention for minimizing the anxiety level of patients awaiting first-time colposcopy

Objectives of the guideline

To compile a standardized guideline for an education intervention to relief anxiety among women awaiting their first time colposcopy

Target users

This guideline is intended to be used by nurses in the gynaecological day
procedure center who are trained to perform colposcopy.

**Target patient population**

The target patient population is all new cases from doctor- or nurse-led colposcopy clinic. Being able to communicate with Cantonese is necessary.

**Description of the proposed education intervention**

This guideline encourages an evidence-based education intervention that should include written materials and educational video. The details of these two educational materials are tabulated as follows:
1. Written materials

<table>
<thead>
<tr>
<th>Details</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Readability</td>
<td>Brief and simple</td>
</tr>
<tr>
<td>Information style</td>
<td>Reassuring</td>
</tr>
<tr>
<td>Information content</td>
<td></td>
</tr>
<tr>
<td>• Purpose of cervical screening by Pap smear</td>
<td>Emphasize that most abnormal Pap smear do not indicate cervical cancer</td>
</tr>
<tr>
<td>• Purpose of colposcopy</td>
<td>Provide reassuring message such as ‘to rule out severe illness’</td>
</tr>
<tr>
<td>• Procedure to be undergone during colposcopy clinic visit</td>
<td></td>
</tr>
<tr>
<td>• Suggestions for coping with the colposcopy procedure</td>
<td>For example, relaxation and distraction</td>
</tr>
<tr>
<td>• The likely outcome</td>
<td>Emphasize the low probability of life-threatening condition</td>
</tr>
<tr>
<td>• De-stigmatized information of high-risk human papillomavirus</td>
<td>Emphasize that every woman, regardless of the social class and sexual behavior, may be infected</td>
</tr>
<tr>
<td>Time of distribution</td>
<td>The time when the target patients receive their colposcopy appointment</td>
</tr>
</tbody>
</table>
2. Educational video

<table>
<thead>
<tr>
<th>Details</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Length</strong></td>
<td>7 minutes</td>
</tr>
</tbody>
</table>
| **Information content**               | · Image of the colposcopy clinic and instrument seen in the clinic  
· Explanation on the nature of abnormal Pap smears  
· Outline of consultation and treatment  
· Treatment options  
· Post-colposcopy self-care  
· Interview of women with experience of see-and-treat colposcopy |
| **Time of distribution**              | The time when the target patients receive their colposcopy appointment |

*Recommendation and evidence support*

This guideline consists of 7 recommendations which are based on the evidence drawn from the 10 selected studies. The strength of each recommendation is defined by the grading system of SIGN (SIGN, 2011). The grades, which are in descending order of strength (from A to D), will provide nurses information about how desirable the recommendations are. The recommendations are as follows:

*A. Timing of intervention*

*Patient education materials for reducing pre-colposcopy anxiety level should*
be delivered to patient immediately after the colposcopy appointment. [B]

Education materials that successfully minimized the anxiety level of the intervention groups were distributed either on the same day or in a few days after the appointment. (Freeman-Wang et al., 2001; Marteau et al., 1996; Stewart et al., 1993; Wilkinson et al., 1990) (1-)

B. Mode of intervention delivery

Prior to the colposcopy appointment, information video should be distributed to patients’ as a supplementary of the information booklet. [B]

When supplementing with the information video, the effect of colposcopy explanatory booklet on reducing pre-colposcopy state anxiety among colposcopy clinic attendees is much greater. The video should present images of the clinical setting and instrument, and outlined the nature of abnormal Pap smear (PS), consultation workflow and post-colposcopy management. (Freeman-Wang et al., 2001) (1-)

There is no strong evidence demonstrating the provision of patient counseling before colposcopy appointment can ameliorate the pre-colposcopy anxiety. [A]

- Adjunct to individually targeted information, nurse-patient extensive discussion via phone before the colposcopy appointment had no obvious effect on patients’ pre-colposcopy anxiety level (de Bie et al., 2011). (1++)
• An extra nurse-patient discussion session did not allay patients’ anxiety level better than information from leaflet and video alone. (Chan et al., 2004) (1++)

• Patients attending nurse-led pre-appointment counseling did not significantly allay pre-colposcopy anxiety. (Byrom et al., 2002) (1+)

C. Content of education

De-stigmatizing content should be included in Human papillomavirus (HPV) message delivery and genital HPV-focused message should be avoided. [A]

HPV is a sexually transmitted disease. Emphasizing the high prevalence of HPV (hrHPV) infection could not conceal the stereotypical thinking relating to the sexual stigma. De-stigmatizing content stressing hrHPV can affect everyone could minimize the stigma and the psychosocial impact of a positive HPV PS result. (Kwan et al., 2010) (1++)

Information about colposcopy procedure and the correlation between abnormal PS result and cervical cancer should be the basic components of a patient education. [B]

• All 5 studies with positive psychological outcomes explained the meaning of abnormal PS result. (Freeman-Wang et al., 2001; Marteau et al., 1996; Stewart et al., 1993; Tomaino-Brunner et al., 1998; Wilkinson et al., 1990) (1-)
• Except Wilkinson et al.’s study (1990), studies with positive psychological outcomes provided information about colposcopy procedure. (Freeman-Wang et al., 2001; Marteau et al., 1996; Stewart et al., 1993; Tomaino-Brunner et al., 1998) (1-)

D. Presentation skill

The mentioning of the risk of cervical cancer should be written in a personal and reassuring style. [B]

Informing patients by written materials about the need of follow-up after their abnormal PS was inadequate. Pre-colposcopy state anxiety, cancer thought and perception of deteriorating health could be reduced significantly when patient with abnormal PS result received written material reassuring her not to be too anxious for the usual low risk of cervical cancer. (Wilkinson et al., 1990) (1-)

Written education material should be comprehensible by general population. [B]

Patients receiving a brief and simple information booklet had significantly less pre-colposcopy state anxiety and worry than those receiving no information. Higher education should not be needed for understanding the booklet content. Compared to the simple booklet, detailed and fairly difficult booklet could not further decrease the anxiety level. (Marteau et al., 1996) (1-)
Bibliography


CHAPTER 4

IMPLEMENTATION PLAN
4.1 Communication Plan

Stakeholder, who will be affected by the innovation, may have different opinions towards the innovation. Convincing them to support the innovation is essential for a smooth innovation implementation. To do so, building relationship with the stakeholders using a good communication plan is necessary.

4.1.1 Identification of Stakeholders

Before the actual communication, stakeholders should first be identified. Those who will use the proposed EBP guideline are one of the stakeholders. They include the APN, the 4 full-time RNs, the 2 part-time RNs, and the staff of SOPD responsible for making colposcopy appointment for patients. The ward manager (WM) and the department operations manager (DOM) of the gynaecology day procedure center, the DOM of SOPD, and the chief of service of obstetrics and gynaecology department (COS / O&G) will be the administrators of the innovation project and thus they are the stakeholders. Since the preparation of the patient education materials and the evaluation of the project will involve participation of the clerical staff in the centre, these staff are also stakeholders. Certainly, the patients awaiting their first colposcopy are stakeholders as well.

4.1.2 Concerns of Stakeholders

Understanding stakeholders’ concerns can smooth the communication. For patients, the proposed education intervention is expected to benefit them since it aims to allay their pre-colposcopy anxiety. If outcome is satisfactory, patients may have a higher perceived control over their condition (Audrain et al., 1997) and their adherence to medical management may increase (Khanna & Phillips,
2001). As a result, the innovation should gain support from them.

The development of the guideline will increase the workload of the APN and the 4 full-time nurses. However, as the increase of workload is within a short period, they are still likely to support the project. In long run, their workload may be reduced if the colposcopy patients attending the colposcopy clinic have less anxiety. The part-time RNs will also be benefited by the long-term relief of workload, although they are required to take over some routine duties of the full-time RNs temporarily. Their opposing voice should be not strong.

The WM, the DOM of the gynaecology day procedure centre, the DOM of SOPD and the COS / O&G are likely to welcome the innovation. It is because putting an EBP guideline into practice with the necessary funding conforms to their commitment of quality holistic client care delivery.

Among the stakeholders, some may oppose the innovation because of the increase in workload. One of the potential opponents is the clerical staff since their involvement in education material preparation and data entry for project evaluation is inevitable. Another probable opponent is the staff of SOPD as they will be assigned with extra work of distributing the patient education materials.

4.1.3 Communication Process

After considering the stakeholders’ concerns, communication strategy with timeline has been formulated (shown in Appendix K). The communication process is summarized in below:

At the beginning, the APN will discuss with the 4 full-time RNs and the 2 part-time RNs about the observed high pre-colposcopy anxiety among the
first-time colposcopy patients. The APN will convince all the staffs to tackle this problem.

After affirming the need of allaying patient’s pre-colposcopy anxiety level, the APN and the 4 full-time RNs did literature search for identifying the potentially useful evidence-based strategy. After patient education intervention is designed, they will start to develop a new EBP guideline and write an innovation proposal.

Then, the WM will first be approached. If the WM show interest in the proposal, the chance of getting support from the DOM of the gynaecology day procedure centre will increase. After gaining support from the WM, the APN will introduce the proposed innovation to the DOM.

Once the DOM approves the innovation, she can act as an appropriate bridge to communicate with other staffs in similar rank, such as the DOM of SOPD and the COS / O&G. Through the DOM’s arrangement, the APN will give a presentation in a quarterly inter-departmental meeting of O&G to seek consensus from the DOM of SOPD and the COS / O&G on the need of the proposed guideline. The content of the innovation will also be displayed. The agreed guideline will then emailed to the WM, both DOMs, and COS for them to disseminate to their relevant subordinates.

To instruct the staffs of SOPD (who are responsible for making colposcopy appointment) to distribute the education materials and instruct patients to use the VCD, a half-hour briefing-session will be held before the launch of the proposed intervention. Approval of the briefing session will be obtained from the DOMs.
When the proposed guideline is in effect, sustaining its use is necessary. Therefore, audit of distribution rate of the education materials will be done by interviewing the target colposcopy clinic attendants. In addition, patient’s outcome including their anxiety level and attendance rate will be monitored. If the evaluation and audit show satisfactory result, the stakeholders will be motivated. If not, revision of the innovation will be performed.

Throughout the entire communication process, stakeholders may have concerns or enquiry on the proposed innovation. To ensure all these concerns and enquiry can be addressed, the APN will be the contact person so that the stakeholders can approach her for whatever issues about the innovation.

4.2 Pilot Study Plan

Despite the aforementioned literature review and implementation potential assessment, the proposed intervention still cannot be guaranteed to work well in the targeted setting unless it has been evaluated. Thus, a pilot test, which is a small-scale trial, is necessary. It can test the feasibility of the EBP in turn preventing a costly but flawed large-scale practice, as noted by Polit and Beck (2012).

On the basis of the Iowa Model (Titler et al., 2001), 5 key activities will be included in the pilot test. The first activity is to develop an evaluation plan that encompasses determination of what outcomes to be achieved, how many patients to involve, and when and how often to collect data of the outcomes. In line with the objective of this innovation, alleviation of pre-colposcopy anxiety among the
first-time patients will be the outcome to be achieved. This pilot test will recruit this patient type for 2 weeks, involving about 15 patients. When scheduling appointment, these patients will be instructed to use the education materials as an information source. Because of the time gap between the appointment and the procedure day, after patient recruitment, the outcome measurement will be withheld until the patients do attend the colposcopy clinic. In this clinical setting, the time gap is about 14 weeks at most.

Information on the condition before the innovation is essential for preliminarily appraisal of the effect of the proposed intervention. Thus, the pilot test will include establishing baseline pre-colposcopy anxiety level by doing measurement on another 15 new cases with similar dates of appointment making.

Aside from outcome measurement, pilot test involves staff training as well. For example, the staff for making appointment will be trained by an assigned full-time RN on education material distribution. The training will focus on giving instructions of the information video to patients.

Testing the appropriateness of the guideline is a core activity of the pilot test. Due to this reason, 15 new pre-colposcopy patients, as stated previously, will be recruited for this purpose.

Evaluating both process and outcomes of pilot test is the final activity. Regarding the process, every implementation problem such as difficulties in education material distribution will be attended. In the outcome evaluation, questions such as how patient’s anxiety level is altered and what feedbacks patients may have will be prompted. Therefore, a post-trial meeting will be held for feedback collection from the involved staffs. Patient’s opinion will be
collected as well via interviews on the procedure day.

Based on the results of the pilot test, refinement on the proposed guideline will be done accordingly before the full implementation.

CHAPTER 5

EVALUATION PLAN

Evaluation is crucial for drawing conclusions on the effectiveness of the project. To ensure reliable conclusions, the following evaluation plan will be implemented.

5.1 Identification and Measurement of Outcomes

Identifying the project outcomes to be measured and choosing appropriate measurement tools will first be performed in the plan. To start with, the outcomes are classified into 2 types (i.e. patient and system).

5.1.1 Patient Outcome

Reducing patient’s pre-colposcopy anxiety level is the ultimate goal of the innovation and thus it is the primary indicator of the patient outcome measurement. Guided by the 8 selected studies in chapter 2, the STAI, a widely employed anxiety measure developed by Spielberger et al. (1983), will be used in
this primary outcome evaluation. The Chinese version of the STAI (C-STAI) will be adopted since all target patients will be Chinese. The C-STAI (C-STAI Form Y) is a self-administered questionnaire addressing subject’s anxiety proneness (also known as trait anxiety) and state or acute anxiety (also known as state anxiety), measuring by A-Trait scale and A-State scale respectively. Each scale is constructed from 20 four-point Likert items to give a total score ranging from 20 to 80. A higher score denotes a higher anxiety level and vice versa. In this evaluation, the A-State scale will be adopted.

Utilizing the C-STAI is appropriate because of the following reasons. As proven by Shek (1988), the C-STAI has a high reliability with Cronbach’s alpha of 0.90 for A-State scale. For validity, the correlation between C-STAI and other measures of psychological well-being was significantly high (Shek, 1993). In addition, concerning practicality, the price of each single assessment is affordable, which is less than US$1 (Mind Garden, Inc., 2013). For patients, completing the assessment is not too time-consuming as it only requires 12-to-20 minutes only (Spielberger et al., 1983).

Anxiety related to cancer fear may reduce patients’ follow-up compliance (Khanna & Phillips, 2001). According to a local qualitative study, women who were referred for colposcopy were likely to experience fear if they misperceived that all abnormal cervical cytology leading to colposcopy meant cancer (Twinn & Lo, 2007). Accordingly, patient’s non-compliance to follow up due to anxiety will be taken seriously and is regarded as the secondary patient outcome in the evaluation. Patient’s anxiety causing non-compliance will be identified by patient phone interview that is already practicing routinely.
5.1.2 System Outcome

System effectiveness, which determines the success of the innovation, is measured by system outcome evaluation. One of the system outcomes to be measured is the utilization of the education materials. It will be reviewed by using a self-developed questionnaire written in Chinese (Appendix L). The questionnaire will evaluate the contents of the materials in terms of its usefulness in anxiety relief, suitability, understandability and coverage. Distribution and utilization of the materials will be assessed as well.

Another system outcome is the cost of material distribution. It will be measured to avoid over-budget. Especially, as each VCD is designed for repeated use by subsequent patients, the actual cost for replacement due to loss and fault will be calculated.

Finally, attitudes of personnel who operate the project will be measured as their attitudes, such as perceiving difficulties in the project implementation, can influence the effectiveness of the project. The nursing staff from the clinic and the staffs from the SOPD who are responsible for education material distribution will be invited for a semi-structured evaluation meeting as outlined in Appendix M.

5.2 Nature of Clients Involved

Clients are first-time patients who can read and write Chinese as both the C-STAI and the questionnaire to elicit patient’s opinions are written in Chinese and are self-administered. In order to avoid outlier, pregnant women will not be
included. Also, those with existing mental illness, suspicious cervical carcinoma, or history of other malignancies will be excluded.

5.3 Size of Evaluation

Estimation of an appropriate sample size by power analysis is necessary for reducing the risk of Type II error (false negative result). For this project, the conventional power of 0.8 will be used to limit the risk of committing a Type II error to 20%. With reference to Polit and Beck’s (2012) suggestion, a modest effect size of 0.4 is taken here. As a result, to achieve a power of 0.8 with significance level of 0.05, at least 198 subjects will be necessary for the evaluation of the anxiety outcome. In fact, more than 198 subjects will be recruited due to possible attrition. As attribute rate of 20% at most is regarded as acceptable (SIGN, 2011), 238 subjects who will be divided evenly into the intervention group and the control group are necessary.

5.4 Timing and Frequency of Outcome Measurement

Resembling the pilot study, the timing of anxiety level measurement in the evaluation phase is determined by the waiting time for colposcopy. For patient convenience, the measurement will be done on the appointment day. All eligible patients will be identified in advance from the patient list. When they do attendance registration, they will receive the C-STA1 Form Y. Sufficient time will be allocated for them to complete the form before the routine pre-colposcopy patient interview.
Recruiting patients with or without education materials given is needed for comparison. As mentioned above, 119 subjects will be necessary for each study group. In order to reach this target, 2 months will be spent on distributing the C-STAI form to the control group. The distribution will start at the first month of the implementation since the colposcopy patients at that time should not have received the education materials yet. Similarly, the distribution will last for 2 months for the intervention group. However, it will commence at the third month after the start of the education materials distribution. It is to cover patients with all range of waiting time.

As for patient’s compliance rate, the measurement will be done for a year to minimize any possible seasonal factor affecting the result.

With regard to the system outcome measurement, the patient survey on education material utilization will last for a month. For the same reason, the survey will be conducted throughout the third month. Meanwhile, the aforementioned evaluation meeting for staff opinion collection is withheld until the fourth month so as to avoid over-packed evaluation schedule at the third month.

Different from other outcome measurements, cost evaluation of education material distribution is relatively long-term. It will be done annually for the sake of annual departmental budget reservation.

### 5.5 Data Analysis

Data analysis involves ample data. Thus, Statistical Package for the Social
Sciences (SPSS) will be used.

Basically, the analysis of anxiety will be done by the \( t \)-test for independent group. Data from the experimental- and control- group including their respective mean A-State score will be compared based on \( t \) value (\( t_{crit} \)). Simultaneously, the normative data from Spielberger et al. (1983) will be used as reference for the data analysis.

In data analysis of patient’s compliance, the 1 year post-implementation data will be compared with the pre-implementation by Chi-square test (\( \chi^2 \)).

Referring to the survey questionnaire in Appendix L, patients are requested to rank attributes about the education materials. The frequency counts and percentages of the relative ranks for each attribute will be calculated and displayed in form of histograms. Besides, the data from the open-ended questions will be summed up by the APN.

Finally, for the staff evaluation meeting, staff’s feedback will be summed up with their approval at the meeting.

5.6 Effectiveness of the Innovation

To discuss the patient outcomes, there should be a standard for a successful EBP project. Since the anxiety level and the compliance rate are going to be analyzed by inferential statistics, the null hypothesis will be rejected if the \( p \)-value is less than 0.05, indicating statistical significance.

In assessing the effectiveness of anxiety reduction, the obtained C-STAI
score from the two study groups will be compared based on t test at the significance level (α) of 0.05. If the obtained $t$ value is greater than the $t_{crit}$, the null hypothesis is rejected. In other words, making a false positive conclusion (Type I error) is unlikely.

Additionally, the normative data of A-State will be used. In the studies of Freeman-Wang et al. (2001) and Wilkinson et al. (1990), the post-treatment mean A-State score for the intervention group was 43.2 and 39.0 respectively. Therefore, if the obtained mean A-State score closes to this score range, the project will be regarded as effective in anxiety reduction.

For the compliance rate, $\chi^2$ of 3.84 or above is necessary for establishing significant results at the 5 percent level.

Proceeding to the system outcomes, the project is considered effective if the education material utilization is high. For instance, if over two third of patients deem that the materials are understandable with suitable contents and coverage, the project is considered satisfactory. In addition, there should be a high utilization rate of the materials and the actual cost of the material production and replacement is affordable for the organization.

In the aspect of staff evaluation meeting, the project is deemed as worthy if staffs agree that they have sufficient perceived control on the project; there are adequate manpower and resources; and their difficulties can be overcome with minimal barriers.

The above defines what a successful project should be. If there is unsatisfactory finding for some evaluated parameters, appropriate modification of
the project will be done accordingly.

CHAPTER 6

SUMMARY

6.1 Summary

As the recent demand of colposcopy is increasing, waiting time for cervical diagnostic examination is getting longer. Because of the lengthened waiting time, more patients may be emotionally afflicted. This translational research proposal details an innovation project using patient education to alleviate pre-colposcopy anxiety level for the first-time patients. By introducing this innovation, it becomes possible to address patient's psychological need during their wait for the examination. As a result, unfavourable outcomes such as non-adherence to care plan due to anxiety can be prevented. After a systematic literature review, evidence of using written material and information video for anxiety reduction was translated into a guideline for practice in the proposed setting. The proposed guideline is expected to benefit patients who are awaiting their first colposcopy examination in terms of anxiety reduction.
Appendix A

Literature Search History

<table>
<thead>
<tr>
<th>Keywords used for searching</th>
<th>Database / Date of searching</th>
<th>Number of literatures found</th>
<th>PubMed</th>
<th>PsycINFO</th>
</tr>
</thead>
<tbody>
<tr>
<td>(2) Abnormal Pap / Abnormal smear / Abnormal cervical cytology / Positive Pap / Positive smear</td>
<td></td>
<td></td>
<td>14184</td>
<td>307</td>
</tr>
<tr>
<td>(3) HPV / HPV infection / Human papillomavirus / Human papillomaviral infection</td>
<td></td>
<td></td>
<td>31584</td>
<td>715</td>
</tr>
<tr>
<td>(4) Anxiety / Burden / Distress / Fear / Worry / Psycho / Psychological / Psychology</td>
<td></td>
<td></td>
<td>1235690</td>
<td>1885084</td>
</tr>
<tr>
<td>(5) Education / Information / Intervention / Program / Programme</td>
<td></td>
<td></td>
<td>2066852</td>
<td>1282179</td>
</tr>
<tr>
<td>(6) Precolposcopy / Pre-colposcopy</td>
<td></td>
<td></td>
<td>14</td>
<td>1</td>
</tr>
<tr>
<td>(1) AND (4)</td>
<td></td>
<td></td>
<td>286</td>
<td>47</td>
</tr>
<tr>
<td>Limit to: Clinical Trial, Randomized Controlled Trial, Meta-Analysis</td>
<td></td>
<td></td>
<td>51</td>
<td>--</td>
</tr>
<tr>
<td>(2) AND (4)</td>
<td></td>
<td></td>
<td>718</td>
<td>134</td>
</tr>
<tr>
<td>Limit to: Clinical Trial, Randomized Controlled Trial, Meta-Analysis</td>
<td></td>
<td></td>
<td>56</td>
<td>--</td>
</tr>
<tr>
<td>(3) AND (4)</td>
<td></td>
<td></td>
<td>1307</td>
<td>226</td>
</tr>
<tr>
<td>Limit to: Clinical Trial, Randomized Controlled Trial, Meta-Analysis</td>
<td></td>
<td></td>
<td>85</td>
<td>--</td>
</tr>
<tr>
<td>(1) AND (5)</td>
<td></td>
<td></td>
<td>1015</td>
<td>39</td>
</tr>
<tr>
<td>Limit to: Clinical Trial, Randomized Controlled Trial, Meta-Analysis</td>
<td></td>
<td></td>
<td>121</td>
<td>--</td>
</tr>
<tr>
<td>(2) AND (5)</td>
<td></td>
<td></td>
<td>2579</td>
<td>187</td>
</tr>
<tr>
<td>Limit to: Clinical Trial, Randomized Controlled Trial</td>
<td></td>
<td></td>
<td>226</td>
<td>--</td>
</tr>
<tr>
<td>(3) AND (5)</td>
<td></td>
<td></td>
<td>2101</td>
<td>484</td>
</tr>
<tr>
<td>Limit to: Clinical Trial, Randomized Controlled Trial</td>
<td></td>
<td></td>
<td>107</td>
<td>--</td>
</tr>
<tr>
<td>Limit to: Quantitative Study, Journal Article, Adulthood (18 Yrs or Older) / Outpatient</td>
<td></td>
<td></td>
<td>--</td>
<td>8</td>
</tr>
</tbody>
</table>

After
1. title, abstracts, full papers, and reference list of the searched literature were reviewed and
2. duplicated literatures were eliminated

10
Appendix B

Table of Evidence


<table>
<thead>
<tr>
<th>Study Design / Country of Study</th>
<th>Evidence Level</th>
<th>Subject Characteristics</th>
<th>Intervention (I)</th>
<th>Control (C)</th>
<th>Length of Follow Up</th>
<th>Outcome Measures</th>
<th>Effect Size</th>
<th>Interpretation</th>
</tr>
</thead>
</table>
| RCT • Australia               | 1 (+)          | - Mean age (years): I: 35.4, C: 35.9
- Being referred to colposcopy for 1st time
- Non-severe dyskaryosis on Pap smear
- Non-pregnant (n=98)          | 60-90 minute nurse-led pre-colposcopy session before appointment - short video - group session - individual session (on request from individual subject) (n=98) | Conventional management (n=98) | Time interval between 4th week after appointment being made and 6th week after colposcopy (9-11 weeks) | Immediate before colposcopy (1) State anxiety (measured by STAI) 1 (score: 20-80)
(2) General psychological distress (measured by General Health Questionnaire 28: GQH-28) 2
(3) Smear result distress & procedural distress (measured by Abnormal smears questionnaire: ASQ) 3
(4) Psychological responses to abnormal smear result (measured by devised Cervical Screening questionnaire: CSQ) 4
(5) Knowledge about smear result & colposcopy procedure | (1) 46.36 vs 45.94 [t=0.179, df=120, 95%CI (-4.2671–5.1162), p=0.858]
(2) 19.86 vs 22.48 (p>0.05)
(3) p>0.05
(4) 11.61 vs 11.84 (p > 0.05)
(5) 3.82 vs 3.56 [t=2.097, df=85, 95%CI (3.7122–1.3938), p=0.039*] | No difference between groups in
- state anxiety
- general psychological distress
- smear result distress & procedural distress
- psychological responses to abnormal smear result
Intervention group generated significantly greater knowledge about smear result & colposcopy | NHS Cervical Screening Programme funding |
**Keys:**
*: Statistically significant

1. **STAI: State-Trait Anxiety Inventory**

2. General Health questionnaire 28 (GHQ-28):
   - With subscales representing 4 dimensions of symptomatology:
     - (a) anxiety and insomnia; (b) somatic symptoms; (c) social dysfunction; (d) severe depression
     - The 28 items were rated on a 4-point scale. Score 0 = ‘not at all’; score 3 = ‘much more than usual’
     - A higher score indicated greater distress.

3. Abnormal smears questionnaire (ASQ)
   - A factor-analytically derived questionnaire
   - Target groups: (a) women with an abnormal smear test result; (b) women requiring a colposcopy examination.
   - Scoring on 2 subscales: smear result distress & procedural distress
   - Items were rated on 4-point scale
   - A higher score indicated greater distress

4. Devised Cervical Screening questionnaire (CSQ)
   - For assessing the following psychological responses related to an abnormal smear result
     - State of general & gynaecological health,
     - Body image,
     - Concern about fertility
     - Sexual interest
     - Fears of cancer or serious illness
     - Pessimism about future health.
   - Scores on 4-point scales. Score 0 = ‘better than usual’; score 3 = ‘much worse than usual’.

5. **Knowledge questionnaire.**
   - A 4-item questionnaire
   - For measuring women’s understanding of (a) their smear results, (b) colposcopy procedure
   - Questions asked
     - ‘what do you think your smear result means?’
     - ‘what do you understand about colposcopy’?
     - information source
     - knowledge about relevant female anatomy

<table>
<thead>
<tr>
<th>Study Design / Country of Study</th>
<th>Evidence Level</th>
<th>Subject Characteristics</th>
<th>Intervention (I)</th>
<th>Control (C)</th>
<th>Length of Follow Up</th>
<th>Outcome Measures</th>
<th>Effect Size</th>
<th>Source of Funding</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. RCT Hong Kong</td>
<td>1 (+++)</td>
<td>· Mean age (year): 40</td>
<td>The following were offered during a precolposcopy session (1-2 weeks before colposcopy): · A locally produced information leaflet · Information video · Discussion session with nurse (with role play on colposcopy consultation &amp; procedure) (n=112)</td>
<td>Same as intervention group except no discussion session (n=108)</td>
<td>The 1-2 week time before colposcopy</td>
<td><strong>Primary</strong> (1) Pre-colposcopy anxiety on the appointment day (measured by C-STAI)¹ (score: 20-80)</td>
<td>With power = 0.85 (1) 45.21 vs 45.81 (p&gt; 0.05) (2) · Immediately after pre-colposcopy session (11.02 vs 9.64, p = 0.003*) · Before colposcopy on the appointment day (10.90 vs 10.04, p=0.015*)</td>
<td>Not stated</td>
<td>No significant between-group difference in anxiety before colposcopy on the appointment day. Significant increase in knowledge about smear test, colposcopy procedure, &amp; usual post-colposcopy management immediately after intervention &amp; on colposcopy appointment day.</td>
</tr>
</tbody>
</table>

**Keys:**

*: Statistically significant

1. C-STAI: the Chinese version of State-Trait Anxiety Inventory
2. Score 1 = ‘correct’; score 0 = ‘incorrect’

<table>
<thead>
<tr>
<th>Study Design / Country of Study</th>
<th>Evidence Level</th>
<th>Subject Characteristics</th>
<th>Intervention (I)</th>
<th>Control (C)</th>
<th>Length of Follow Up</th>
<th>Outcome Measures</th>
<th>Effect Size</th>
<th>Source of Funding</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>• RCT · Netherlands</td>
<td>1 (++)</td>
<td>· Mean age (years): 34   · Dutch-speaking   · Being referred to colposcopy for 1st time · Low-/ high-grade Pap smear result</td>
<td>Some days after 1st colposcopy appointment being made: · Individually targeted discussion(^1) with nurses by phone as extensive as the subjects required (by phone) · 16-page illustrated and detailed document(^2) (by mail) ((n=84))</td>
<td>Standard 2-page colposcopy information leaflet(^3) ((n=85))</td>
<td>Time interval between some days after appointment being made &amp; the day of appointment</td>
<td>Before colposcopy exam on the appointment day: <strong>Primary</strong> (1) State anxiety (measured by the Dutch version of STAI)(^4) (score: 20-80) (2) Anxiety &amp; depression (measured by HADS)(^5) (score: 0-42)</td>
<td>With · Power = 0.8 · Significant level = 5% (1) 48 vs 50 ((p=0.92)) (2) · HADS anxiety [5 vs 6 ((p=0.26)]] · HADS depression [1 vs 1 ((p=0.73)]] (3) 4 vs 3 ((p=0.004*))</td>
<td>No funding</td>
<td>Intervention group showed a significant increase in knowledge about HPV &amp; colposcopy</td>
</tr>
</tbody>
</table>

\(^1\) Individualized by the participants themselves

\(^2\) Included a written description of the procedure

\(^3\) Included a written description of the procedure

\(^4\) STAI = State-Trait Anxiety Inventory

\(^5\) HADS = Hospital Anxiety and Depression Scale
Keys:
*: Statistically significant

1. Structured into 7 topics:
   · Explanation about smear result
   · Precancer instead of cancer
   · Colposcopy procedure
   · Possible invasive treatment
   · HPV
   · HPV vaccination
   · Fertility

2. Containing detailed content of:
   · the aim of the screening programme
   · the procedure of taking a cervical smear
   · the meaning of an abnormal smear result
   · all possible diagnostic & treatment options following an abnormal smear

3. Included a brief description about
   · colposcopy
   · the possibility of immediate treatment by excisional procedure

4. STAI: State-Trait Anxiety Inventory

5. HADS: Consisting 14 items (7 items for both anxiety & depression) which are scored on a 4-point scale from 0 to 3.

<table>
<thead>
<tr>
<th>Study Design / Country of Study</th>
<th>Evidence Level</th>
<th>Subject Characteristics</th>
<th>Intervention (I)</th>
<th>Control (C)</th>
<th>Length of Follow Up</th>
<th>Outcome Measures</th>
<th>Effect Size</th>
<th>Source of Funding</th>
<th>Interpretation</th>
</tr>
</thead>
</table>
| · RCT UK                      | 1 (-)          | · Being referred to see-and-treat colposcopy\(^1\) for 1\(^{st}\) time  
· Moderate or severely dyskaryotic smear | Prior to appointment day, the followings were provided:  
· Explanatory booklet on colposcopy procedure  
· Treatment information leaflet  
· 7-minute information video (n= 64) | Prior to appointment day, the followings were provided:  
· Explanatory booklet on colposcopy procedure  
· Treatment information leaflet  
· 7-minute information video given prior to appointment day (n=68) | No data | (1) Anxiety (measured by STAI)\(^2\)  
(score: 20-80) | (1) 43.2 vs 54.7  
(p = 0.000041*) | The BMA TP Gunton Award 1998 | Intervention group showed a significant decrease in pre-colposcopy state anxiety on appointment day |

**Keys:**

* : Statistically significant

1. See-and-treat colposcopy: Colposcopist provided treatment straight out if indicated by colposcopy result without confirmed by results of cervical biopsy in advance.

2. STAI: State-Trait Anxiety Inventory

<table>
<thead>
<tr>
<th>Study Design / Country of Study</th>
<th>Evidence Level</th>
<th>Subject Characteristics</th>
<th>Intervention (I)</th>
<th>Control (C)</th>
<th>Length of Follow Up</th>
<th>Outcome Measures</th>
<th>Effect Size</th>
<th>Source of Funding</th>
<th>Interpretation</th>
</tr>
</thead>
</table>
| RCT                           | 1 (++)         | - Mean age (years): 28.3  
- Age not over 45 years  
- Being referred to colposcopy for 1st time  
- Cervical cytology abnormality not more severe than moderate dyskaryosis | Received an information leaflet with colposcopy appointment letter (n = 107) | Received colposcopy appointment letter only (n = 103) | 37.2 days (i.e. Mean colposcopy waiting time) | Pre-colposcopy state anxiety: (measured by STAI) (Score: 20-80) | 50.36 vs 48.82 (p=0.47) | Not stated | Provision of sending an information leaflet prior colposcopy showed no significant difference in state anxiety between groups |

**Keys:**
1. STAI: State-Trait Anxiety Inventory

<table>
<thead>
<tr>
<th>Study Design / Country of Study</th>
<th>Evidence Level</th>
<th>Subject Characteristics</th>
<th>Intervention (I)</th>
<th>Control (C)</th>
<th>Length of Follow Up</th>
<th>Outcome Measures</th>
<th>Effect Size</th>
<th>Source of Funding</th>
<th>Interpretation</th>
</tr>
</thead>
</table>
| • RCT                          | 1 (+)          | • Mean age (years): 38.3 • Ethnic Chinese • Women who attended for cervical screening or birth control service • Non-pregnant • Not obtain abnormal Pap smear result | Group *ds+hrHPV* 1  
• Cervical cancer-focused information  
• high-risk HPVs presented in a neutral clinical manner  
(n = 99)  
• The information was de-stigmatized by dissociating it from the prevailing sexual-transmitted infection related stereotype, maximizing its content simplicity and adding motivational component to it. | Group *lr+hrHPV* 2  
• Genital HPV-focused information on both low-risk and high-risk HPVs presented in a neutral clinical manner (n = 95)  
• The information was de-stigmatized by dissociating it from the prevailing sexual-transmitted infection related stereotype, maximizing its content simplicity and adding motivational component to it. | Period of time required by subjected for reading the information provided | Primary  
(1) Post-reading level of high-risk HPV-related sexual stigma (measured by a 7-point Likert scale)  
(2) Post-reading attitude towards message  
(3) Knowledge about high-risk HPV and cervical cancer (score: 0-6) | (1)  
• Genital HPV-focused message (i.e. group *lr+hrHPV*) vs Cervical cancer-focused message (i.e. group *hrHPV* and *ds+hrHPV*)  
(t = -4.192, mean difference = -0.117, 95% CI -0.172 to -0.062, p < 0.001*)  
• Group *hrHPV* vs *ds+hrHPV*  
(t = 2.153, mean difference = 0.067, 95% CI 0.006 to 0.129, p = 0.033*) | Stated  
(Jointly funded by University research fund, a charitable foundation, and a grant by a vaccine manufacturer) | Genital HPV-focused message significantly increases high-risk HPV-related sexual stigma  
De-stigmatized high-risk HPV message generated significant lower stigma than those without de-stigmatization  
No significant change in attitude toward message  
Knowledge increased significantly after reading for all groups but no difference in post-reading knowledge between groups |
| • Hong Kong                    |                |                         |                  |             |                     |                |            |                  |                |

65
**Keys:**

*: Statistically significant

1. $ds+hr$HPV denotes de-stigmatization of high-risk HPV

2. $lr+hr$HPV denotes low-risk HPV and high-risk HPV in combination

3. $hr$HPV denoted high-risk HPV

4. 1 = ‘Highly disagree’ to 7 = ‘Highly agree’

5. Multivariate analysis of covariance was used to detect the overall effects on all the continuous outcomes with message allocation and education entered as factors and age and pre-reading knowledge as covariates.

6. The 6 items included positivity, discomfort helpfulness, fear, relevance and understandability.

7. 6 items on knowledge related to high-risk HPV and cervical cancer were used to assess before and after reading effect.

   - The 6 items are: - High-risk HPV can be transmitted by sexual contact. (True)
   - Persistent high-risk HPV infection may cause cervical cancer. (True)
   - Bodily symptoms will appear in case of a high-risk HPV infection. (False)
   - Cervical lesions will turn cancerous shortly after their occurrence. (False)
   - For most people, the chance of being infected by high-risk HPV is very low. (False)
   - 90% of high-risk HPV infection will be cleared by the body automatically. (True)

   - Answer choices: ‘true’, ‘false’ or ‘don’t know’

   - Score 1 = Correct answer. Score 0 = Incorrect or ‘don’t know’ response

<table>
<thead>
<tr>
<th>Study Design / Country of Study</th>
<th>Evidence Level</th>
<th>Subject Characteristics</th>
<th>Intervention (I)</th>
<th>Control (C)</th>
<th>Length of Follow Up</th>
<th>Outcome Measures</th>
<th>Effect Size</th>
<th>Source of Funding</th>
<th>Interpretation</th>
</tr>
</thead>
</table>
| RCT UK                          | 1 (-)          | • Mean age (years): 32.4 • Being referred for 1st time colposcopy • Cervical cytology indicated mild to severe dyskaryosis | Received the following booklet(s) days after receipt of both colposcopy appointment letter & clinical information sheet²:  
Group 1  
Brief, simple booklet [Booklet A]³ (n = 32)  
Group 2  
Detailed booklet written at college level [Booklet B]³ (n = 32)  
Group 3  
Both Booklet A & B (n = 32) | Group 4  
Received clinical information sheet together with colposcopy appointment letter (n = 32) | 8-16 weeks (i.e. Colposcopy waiting time) | On appointment day:  
Primary  
(1) Pre-colposcopy state anxiety:  
(measured by STAI)³  
(Score: 20-80)  
(2) Specific anxieties  
(measured on a 7-point rating scale) in areas about  
a) colposcopy  
b) what doctor might find wrong  
c) perceived seriousness of problem  
Secondary  
(3) Knowledge about colposcopy & cervical abnormalities:  
(measured by an 11-item multiple choice questionnaire) | (1) Receipt of Booklet A (i.e. group 1 & 3) vs No Booklet A received (i.e. group 2 & 4)  
[F(1, 52) = 6.2, p < 0.025*]  
(2) a) Receipt of Booklet A (i.e. group 1 & 3) vs No Booklet A received (i.e. group 2 & 4)  
[F(1, 58) = 3.2, p < 0.76]  
b) Receipt of Booklet A (i.e. group 1 & 3) vs No Booklet A received (i.e. group 2 & 4)  
[F(1, 60) = 5.3, p < 0.025*]  
c) Receipt of Booklet B (i.e. group 2 & 4) vs No Booklet B received (i.e. Group 1 & 3)  
[F(1, 58) + 6.7, p < 0.025*]  
(3) Receipt of booklet(s) (i.e. group 2, 3 & 4) vs No booklet (i.e. group 1)  
(p < 0.025*) | (The Wellcome trust) |
|                                 |                |                          |                  |             |                    |                  |             | Compared to detailed booklet or absence of booklet, brief & simple booklet generated significantly … 1. less state anxiety 2. less anxiety about what the doctor might find wrong |
Keys:
*: Statistically significant

1. Colposcopy appointment letter: Indicated the date & time of colposcopy

2. Clinical information sheet:
   • Comprised 4 paragraphs on one side of an A4 sheet describing the procedure of colposcopy

3. Booklet A:
   • Included information about the procedure, behavioural instructions on dealing with it, and likely outcome of a colposcopy examination
   • No information was provided about the hospital itself

4. Booklet B:
   • A 6-page booklet describing the aetiology of cervical abnormalities, procedural details of their treatment and details about the likely outcome.
   • No sensory information or behavioural instructions on coping with colposcopy were included.

5. STAI: State-Trait Anxiety Inventory

<table>
<thead>
<tr>
<th>Study Design / Country of Study</th>
<th>Evidence Level</th>
<th>Subject Characteristics</th>
<th>Intervention (I)</th>
<th>Control (C)</th>
<th>Length of Follow Up</th>
<th>Outcome Measures</th>
<th>Effect Size</th>
<th>Source of Funding</th>
<th>Interpretation</th>
</tr>
</thead>
</table>
| - RCT                          | 1 (-)          | - Mean age (years): 30.7  | - A grade 6 reading level of 6-page brochure with illustration together with appointment reminder. Being sent by mail on the same day the colposcopy appointment was made, along with a reminder of the appointment (n=62) | - A standard hospital letter about the clinic & appointment time. Being sent by mail on the same day the colposcopy appointment was made (n=63) | Time interval between the time of appointment being made & the day of appointment (Mean interval = 2 weeks; range 1-4 weeks) | The following outcomes were measured on the colposcopy appointment day:  
**Primary**  
1. Psychological distress (measured by the Brief Symptom Inventory)  
2. Psychological distress (measured by 6 additional questions)  
**Secondary**  
3. Knowledge about - meaning of dysplasia - definition of colposcopy - the usual follow-up examination required for dysplasia after treatment | - Psychoticism subscale: Less distress score in the intervention group (Mean difference = 3.73, 95% CI 0.28-7.18; p=0.03*)  
- Depression subscale: No significant difference between group (t = -1.77, p = 0.07)  
- Diagnosis-related distress: Lower in Intervention group (Mean difference = 0.49, 95% CI 0.11-0.87; p=0.01*)  
- Fear of cancer: Less in Intervention group (Mean difference = 0.61, 95% CI 0.19-1.03; p=0.01*)  
- Worries concerning future health: Less in Intervention group (Mean difference = 1.13, 95% CI 0.65-1.61; p=0.001*)  
- Future sexual functioning, relationship with partner, & future fertility: No significant difference between groups  
3. Intervention group gave more correct answers on the 3 knowledge aspects (p = 0.001*) | Not stated | An easy brochure which was given with the colposcopy appointment reminder could generate less psychoticism distress, depression, diagnosis-related distress, fear of cancer, worries about future health and increase patient knowledge. |
Keys:
*: Statistically significant

1. Brief Symptom Inventory of Derogatis and Melisaratos:
   · A 53-item self-report psychometric instrument
   · It yielded 9 subscales & 3 indices of psychological distress
   · Scored on a 5-point scale

2. The 6 additional questions (scored on a 5-point scale) included
   - pertaining to distress about having an abnormal Pap smear
   - future fertility
   - future sexual function
   - cancer
   - future health
   - relationship with the partner

3. The psychoticism subscale included questions related to loneliness, self-consciousness, inferiority, and the idea of punishment for own sins
Citation: Tomaino-Brunner, C., Freda, M. C., & Damus, K. (1998). Can precolposcopy education increase knowledge and decrease anxiety? 

<table>
<thead>
<tr>
<th>Study Design / Country of Study</th>
<th>Evidence Level</th>
<th>Subject Characteristics</th>
<th>Intervention (I)</th>
<th>Control (C)</th>
<th>Length of Follow Up</th>
<th>Outcome Measures</th>
<th>Effect Size</th>
<th>Source of Funding</th>
<th>Interpretation</th>
</tr>
</thead>
</table>
| RCT USA                         | 1 (-)          | - Mean age (years): 34  
- Referred to colposcopy for 1st time  
- Pap smear result showed normal to severe dysplasia | - 1-page handout about colposcopy by mailed to the subjects 1 week before the appointment  
- 6-grade reading level (n=55) | No education material (n=58) | The 1-week time before colposcopy appointment | \*Primary\*  
(1) State anxiety (measured by STAI) \(^1\)  
(score: 20-80)  
(2) Feeling about having colposcopy (“Scared & nervous”) (measured by asking open-ended question in pre-colposcopy interview) | (1) 47.9 vs 50.8 (p>0.05)  
(2) 59% vs 91% (p < 0.0001*) | Not stated | The intervention did not lessen precolposcopy state anxiety but caused less feeling of scare and nervousness.  
The intervention increased patients’ concepts about the indication, nature, and purpose of colposcopy. |
|                                 |                |                          |                 |             |                     | \*Secondary\*  
(3) Knowledge about  
indication of colposcopy, meaning of an abnormal Pap smear, nature of colposcopy, & what colposcopy looking for (measured by comparing number of “I don’t know” answer in response to open-ended questions in pre-colposcopy interview) | (3) Knowledge about  
indication of colposcopy  
[14% vs 38% (p =0.003*)]  
meaning of an abnormal Pap smear  
[52% vs 60% (p > 0.05)]  
nature of colposcopy  
[28% vs 58% (p = 0.0001*)]  
what colposcopy looking for  
[21% vs 40% (p = 0.025*)] |                |                                    |              |

*Keys:*

*: Statistically significant

1. STAI: State-Trait Anxiety Inventory

<table>
<thead>
<tr>
<th>Study Design / Country of Study</th>
<th>Evidence Level</th>
<th>Subject Characteristics</th>
<th>Intervention (I)</th>
<th>Control (C)</th>
<th>Length of Follow Up</th>
<th>Outcome Measures</th>
<th>Effect Size</th>
<th>Source of Funding</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>· RCT · UK</td>
<td>1 (-)</td>
<td>· Women with recent Pap smear showing dyskaryosis · A repeat test and consultation by doctor were necessary</td>
<td>Reassuring leaflet &amp; a more personalized letter notifying the subjects of Pap smear results and the need to follow up without giving reassuring content (n=29)</td>
<td>A standard computerized letter notifying the subjects of Pap smear results and the need to follow appointment without giving reassuring content (n=31)</td>
<td>Time interval between the time of appointment making and the day of appointment</td>
<td>(1) State anxiety before consultation (measured by STAI) (^1) (score 20-80) (2) Cancer thought (number of subjects) (3) Perceived having deteriorated health on receipt of the smear result (number of subjects)</td>
<td>(1) 39.00 vs 49.59 [Mean difference =10.59, 95%CI 5.8-14.8] (p&lt;0.001*) (2) 1 vs 19 ([x^2=22.56, df=1, p&lt;0.001*]) (3) 2 vs 12 (p&lt;0.01*)</td>
<td>Pfizer</td>
<td>Intervention group showed significantly lower pre-consultation state anxiety level on the appointment day Significantly fewer subjects in intervention group thought that - they had cancer - their health had deteriorated on receipt of the result</td>
</tr>
</tbody>
</table>

**Keys:**
*: Statistically significant

1. STAI: State-Trait Anxiety Inventory
Appendix C

Methodology Quality Assessment of Selected Studies


<table>
<thead>
<tr>
<th>SECTION 1: INTERNAL VALIDITY</th>
<th>In a well conducted RCT study…</th>
<th>In this study this criterion is:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1</td>
<td>The study addresses an appropriate and clearly focused question.</td>
<td>Well covered</td>
</tr>
<tr>
<td>1.2</td>
<td>The assignment of subjects to treatment groups is randomized.</td>
<td>Well covered</td>
</tr>
<tr>
<td></td>
<td>A computer-generated random numbers series was used.</td>
<td></td>
</tr>
<tr>
<td>1.3</td>
<td>An adequate concealment method is used.</td>
<td>Well covered</td>
</tr>
<tr>
<td></td>
<td>The assigned random numbers were concealed by close opaque envelops.</td>
<td></td>
</tr>
<tr>
<td>1.4</td>
<td>Subjects and investigators are kept “blind” about treatment allocation.</td>
<td>Not applicable</td>
</tr>
<tr>
<td>1.5</td>
<td>The treatment and control groups are similar at the start of the trial.</td>
<td>Well covered</td>
</tr>
<tr>
<td></td>
<td>There was no difference in demographic characteristics and trait anxiety level.</td>
<td></td>
</tr>
<tr>
<td>1.6</td>
<td>The only difference between groups is the treatment under investigation.</td>
<td>Well covered</td>
</tr>
<tr>
<td>1.7</td>
<td>All relevant outcomes are measured in a standard, valid and reliable way.</td>
<td>Well covered</td>
</tr>
<tr>
<td></td>
<td>The State-Trait Anxiety Inventory (STAI), General Health Questionnaire-28 (GHQ-28), Abnormal smears questionnaire (ASQ), and Cervical Screening questionnaire (CSQ) were used to measure outcomes.</td>
<td></td>
</tr>
<tr>
<td>1.8</td>
<td>What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed?</td>
<td>Intervention group: 39.8% (39/98)</td>
</tr>
<tr>
<td></td>
<td>Control group: 32.7% (32/98)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Reason of drop-out was not mentioned.</td>
<td></td>
</tr>
<tr>
<td>1.9</td>
<td>All the subjects are analyzed in the groups to which they were randomly allocated (often referred to as intention to treat analysis)</td>
<td>Well covered</td>
</tr>
<tr>
<td></td>
<td>Intention to treat analysis was used.</td>
<td></td>
</tr>
<tr>
<td>1.10</td>
<td>Where the study is carried out at more than one site, results are comparable for all sites.</td>
<td>Not applicable</td>
</tr>
<tr>
<td></td>
<td>The study was carried out at one site.</td>
<td></td>
</tr>
</tbody>
</table>

SECTION 2: OVERALL ASSESSMENT OF THE STUDY

| 2.1                         | How well was the study done to minimize bias? | 1+ |

**SECTION 1: INTERNAL VALIDITY**

<table>
<thead>
<tr>
<th>In a well conducted RCT study…</th>
<th>In this study this criterion is:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1 The study addresses an appropriate and clearly focused question.</td>
<td>Well covered</td>
</tr>
<tr>
<td>1.2 The assignment of subjects to treatment groups is randomized.</td>
<td>Well covered A computer-generated random number series, which was contained within closed opaque envelops, was used in randomization.</td>
</tr>
<tr>
<td>1.3 An adequate concealment method is used.</td>
<td>Well covered A computer-generated random number series, which was contained within closed opaque envelops, was used in randomization.</td>
</tr>
<tr>
<td>1.4 Subjects and investigators are kept “blind” about treatment allocation.</td>
<td>Not applicable</td>
</tr>
<tr>
<td>1.5 The treatment and control groups are similar at the start of the trial.</td>
<td>Well covered Both groups had similar sociodemographic characteristics, distribution of the referring smears, waiting time for colposcopy, concerns about smears findings and colposcopy, and baseline score of anxiety and knowledge.</td>
</tr>
<tr>
<td>1.6 The only difference between groups is the treatment under investigation.</td>
<td>Well covered Measures were taken to avoid contact between the subjects in the treatment and the control groups after the precolposcopy session.</td>
</tr>
<tr>
<td>1.7 All relevant outcomes are measured in a standard, valid and reliable way.</td>
<td>Well covered Spielberger's State-Trait Anxiety Inventory (STAI), a well validated instrument for anxiety assessment, was used.</td>
</tr>
<tr>
<td>1.8 What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed?</td>
<td>No drop-out</td>
</tr>
<tr>
<td>1.9 All the subjects are analyzed in the groups to which they were randomly allocated (often referred to as intention to treat analysis)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>1.10 Where the study is carried out at more than one site, results are comparable for all sites.</td>
<td>Not applicable The study was carried out at one site.</td>
</tr>
</tbody>
</table>

**SECTION 2: OVERALL ASSESSMENT OF THE STUDY**

| 2.1 How well was the study done to minimize bias? | 1++ |

### SECTION 1: INTERNAL VALIDITY

<table>
<thead>
<tr>
<th>In a well conducted RCT study…</th>
<th>In this study this criterion is:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1</td>
<td>The study addresses an appropriate and clearly focused question.</td>
</tr>
<tr>
<td>1.2</td>
<td>The assignment of subjects to treatment groups is randomized.</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>1.3</td>
<td>An adequate concealment method is used.</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>1.4</td>
<td>Subjects and investigators are kept “blind” about treatment allocation.</td>
</tr>
<tr>
<td>1.5</td>
<td>The treatment and control groups are similar at the start of the trial.</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>1.6</td>
<td>The only difference between groups is the treatment under investigation.</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>1.7</td>
<td>All relevant outcomes are measured in a standard, valid and reliable way.</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>1.8</td>
<td>What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed?</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>1.9</td>
<td>All the subjects are analyzed in the groups to which they were randomly allocated (often referred to as intention to treat analysis)</td>
</tr>
<tr>
<td>1.10</td>
<td>Where the study is carried out at more than one site, results are comparable for all sites.</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### SECTION 2: OVERALL ASSESSMENT OF THE STUDY

| 2.1  | How well was the study done to minimize bias? | 1++ |
SECTION 1: INTERNAL VALIDITY

<table>
<thead>
<tr>
<th>In a well conducted RCT study…</th>
<th>In this study this criterion is:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1 The study addresses an appropriate and clearly focused question.</td>
<td>Well covered</td>
</tr>
<tr>
<td>1.2 The assignment of subjects to treatment groups is randomized.</td>
<td>Not reported</td>
</tr>
<tr>
<td>1.3 An adequate concealment method is used.</td>
<td>Not reported</td>
</tr>
<tr>
<td>1.4 Subjects and investigators are kept “blind” about treatment allocation.</td>
<td>Not applicable</td>
</tr>
<tr>
<td>1.5 The treatment and control groups are similar at the start of the trial.</td>
<td>Not addressed</td>
</tr>
<tr>
<td>1.6 The only difference between groups is the treatment under investigation.</td>
<td>Well covered</td>
</tr>
<tr>
<td>1.7 All relevant outcomes are measured in a standard, valid and reliable way.</td>
<td>Well covered</td>
</tr>
<tr>
<td>1.8 What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed?</td>
<td>Treatment group: 25% (16/64) Control group: 33.8% (23/68)</td>
</tr>
<tr>
<td>Reasons:</td>
<td></td>
</tr>
<tr>
<td>1.9 All the subjects are analyzed in the groups to which they were randomly allocated (often referred to as intention to treat analysis)</td>
<td>Not addressed</td>
</tr>
<tr>
<td>1.10 Where the study is carried out at more than one site, results are comparable for all sites.</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

SECTION 2: OVERALL ASSESSMENT OF THE STUDY

| 2.1 How well was the study done to minimize bias? | 1- |
SECTION 1: INTERNAL VALIDITY

<table>
<thead>
<tr>
<th>In a well conducted RCT study…</th>
<th>In this study this criterion is:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1 The study addresses an appropriate and clearly focused question.</td>
<td>Well covered</td>
</tr>
<tr>
<td>1.2 The assignment of subjects to treatment groups is randomized.</td>
<td>A computer-generated random number series, which was contained within closed opaque envelops, was used in randomization.</td>
</tr>
<tr>
<td>1.3 An adequate concealment method is used.</td>
<td>Well covered</td>
</tr>
</tbody>
</table>
| 1.4 Subjects and investigators are kept “blind” about treatment allocation. | - The full nature of the study was not revealed to subjects in order to avoid patient bias.  
- The investigators were blinded to the treatment allocation. |
| 1.5 The treatment and control groups are similar at the start of the trial. | Both groups had similar trait anxiety, age, colposcopy waiting time, marital status, parity, and referral smear result. |
| 1.6 The only difference between groups is the treatment under investigation. | No other intervention was provided prior to colposcopy in addition to the treatment. |
| 1.7 All relevant outcomes are measured in a standard, valid and reliable way. | Well covered  
Speilberger’s State-Trait Anxiety Inventory (STAI), a well validated instrument for anxiety assessment, was used. |
| 1.8 What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed? | Intervention group: 6.5% (7/107)  
Control group: 2.9% (3/103)  
Reason of drop-out was not mentioned. |
| 1.9 All the subjects are analyzed in the groups to which they were randomly allocated (often referred to as intention to treat analysis) | Well covered |
| 1.10 Where the study is carried out at more than one site, results are comparable for all sites. | Not applicable  
The study was carried out at one site. |

SECTION 2: OVERALL ASSESSMENT OF THE STUDY

| 2.1 How well was the study done to minimize bias? | 1++ |

### SECTION 1: INTERNAL VALIDITY

<table>
<thead>
<tr>
<th>In a well conducted RCT study…</th>
<th>In this study this criterion is:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1 The study addresses an appropriate and clearly focused question.</td>
<td>Well covered</td>
</tr>
<tr>
<td>1.2 The assignment of subjects to treatment groups is randomized.</td>
<td>Well covered Computer-generated randomization was used on consecutive subjects.</td>
</tr>
<tr>
<td>1.3 An adequate concealment method is used.</td>
<td>Well covered The core investigator was blind to the allocation sequence upon recruitment of subjects.</td>
</tr>
<tr>
<td>1.4 Subjects and investigators are kept “blind” about treatment allocation.</td>
<td>Not applicable</td>
</tr>
<tr>
<td>1.5 The treatment and control groups are similar at the start of the trial.</td>
<td>Well covered There was no significant difference between groups in age, education level, economical status, marital status, history of cervical screening, and previous hearing of HPV.</td>
</tr>
<tr>
<td>1.6 The only difference between groups is the treatment under investigation.</td>
<td>Well covered Same clinical facts about high-risk HPV were given to both intervention and control group.</td>
</tr>
<tr>
<td>1.7 All relevant outcomes are measured in a standard, valid and reliable way.</td>
<td>Adequately addressed The scale used to measure high-risk HPV-related sexual stigma was pilot tested with good reliability yielded. (Cronbach’s Alpha = 0.789-0.896)</td>
</tr>
<tr>
<td>1.8 What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed?</td>
<td>No drop-out</td>
</tr>
<tr>
<td>1.9 All the subjects are analyzed in the groups to which they were randomly allocated (often referred to as intention to treat analysis)</td>
<td>Not applicable Due to no drop-out</td>
</tr>
<tr>
<td>1.10 Where the study is carried out at more than one site, results are comparable for all sites.</td>
<td>Not applicable The study was carried out at one site.</td>
</tr>
</tbody>
</table>

### SECTION 2: OVERALL ASSESSMENT OF THE STUDY

| 2.1 How well was the study done to minimize bias? | 1++ |
SECTION 1: INTERNAL VALIDITY

<table>
<thead>
<tr>
<th>In a well conducted RCT study…</th>
<th>In this study this criterion is:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1 The study addresses an appropriate and clearly focused question.</td>
<td>Well covered</td>
</tr>
</tbody>
</table>
| 1.2 The assignment of subjects to treatment groups is randomized. | Poorly addressed  
Strict rotation was used in the assignment of subjects. |
| 1.3 An adequate concealment method is used. | Poorly addressed |
| 1.4 Subjects and investigators are kept “blind” about treatment allocation. | Not applicable |
| 1.5 The treatment and control groups are similar at the start of the trial. | Well covered  
There were no differences between groups in age, parity, or severity of referred abnormality. |
| 1.6 The only difference between groups is the treatment under investigation. | Well covered |
| 1.7 All relevant outcomes are measured in a standard, valid and reliable way. | Well covered  
- Spielberger’s State-Trait Anxiety Inventory (STAI), a well validated instrument for anxiety assessment, was used.  
- The 11-item multiple choice questionnaire for knowledge measurement was proved valid |
| 1.8 What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed? | Group 1: 59.4% (19/32)  
Group 2: 34.4% (11/32)  
Group 3: 53.1% (17/32)  
Group 4 (Control group): 53.1% (17/32)  
Reasons:  
1. No return of questionnaire by mail  
2. High default rate |
| 1.9 All the subjects are analyzed in the groups to which they were randomly allocated (often referred to as intention to treat analysis) | Not addressed  
The collection of data was done upon receipt of colposcopy appointment and immediately before and after colposcopy. Only subjects for whom there were complete data were analyzed. |
| 1.10 Where the study is carried out at more than one site, results are comparable for all sites. | Not applicable  
The study was carried out at one site. |

SECTION 2: OVERALL ASSESSMENT OF THE STUDY

| 2.1 How well was the study done to minimize bias? | 1- |

**SECTION 1: INTERNAL VALIDITY**

<table>
<thead>
<tr>
<th>In a well conducted RCT study…</th>
<th>In this study this criterion is:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1 The study addresses an appropriate and clearly focused question.</td>
<td>Well covered</td>
</tr>
<tr>
<td>1.2 The assignment of subjects to treatment groups is randomized.</td>
<td>Poorly addressed Alternate assignment of consecutive subjects was used as the randomization method.</td>
</tr>
<tr>
<td>1.3 An adequate concealment method is used.</td>
<td>Not addressed No concealment was adopted.</td>
</tr>
<tr>
<td>1.4 Subjects and investigators are kept “blind” about treatment allocation.</td>
<td>Adequately addressed Single blinding to the subject was used.</td>
</tr>
<tr>
<td>1.5 The treatment and control groups are similar at the start of the trial.</td>
<td>Not reported Only comparison on education level (significantly better educated in the control group with p = 0.04) and marital status (no significant difference) were reported.</td>
</tr>
<tr>
<td>1.6 The only difference between groups is the treatment under investigation.</td>
<td>Well covered Nearly all subjects (98.4%) in intervention group (n = 62) did read the brochure that was distributed as the treatment under the investigation.</td>
</tr>
<tr>
<td>1.7 All relevant outcomes are measured in a standard, valid and reliable way.</td>
<td>Well covered The Brief Symptom Inventory used was reliable and validated psychometric instrument.</td>
</tr>
<tr>
<td>1.8 What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed?</td>
<td>Intervention group: 4.8% (3/62) Control group: 11.1% (7/63) The drop-out rate is acceptable. Reasons of drop-out: 1. Refusal of participation 2. Missing data on the questionnaire</td>
</tr>
<tr>
<td>1.9 All the subjects are analyzed in the groups to which they were randomly allocated (often referred to as intention to treat analysis)</td>
<td>Not addressed Not mentioned</td>
</tr>
<tr>
<td>1.10 Where the study is carried out at more than one site, results are comparable for all sites.</td>
<td>Not applicable The study was carried out at one site.</td>
</tr>
</tbody>
</table>

**SECTION 2: OVERALL ASSESSMENT OF THE STUDY**

| 2.1 How well was the study done to minimize bias? | 1- |

<table>
<thead>
<tr>
<th>SECTION 1: INTERNAL VALIDITY</th>
<th>In this study this criterion is:</th>
</tr>
</thead>
<tbody>
<tr>
<td>In a well conducted RCT study…</td>
<td>Well covered</td>
</tr>
<tr>
<td>1.1 The study addresses an appropriate and clearly focused question.</td>
<td>Poorly addressed</td>
</tr>
<tr>
<td>1.2 The assignment of subjects to treatment groups is randomized.</td>
<td>Not addressed</td>
</tr>
<tr>
<td>1.3 An adequate concealment method is used.</td>
<td>Not applicable</td>
</tr>
<tr>
<td>1.4 Subjects and investigators are kept “blind” about treatment allocation.</td>
<td>Not applicable</td>
</tr>
<tr>
<td>1.5 The treatment and control groups are similar at the start of the trial.</td>
<td>Well covered</td>
</tr>
<tr>
<td>1.6 The only difference between groups is the treatment under investigation.</td>
<td>Well covered</td>
</tr>
<tr>
<td>1.7 All relevant outcomes are measured in a standard, valid and reliable way.</td>
<td>Well covered</td>
</tr>
<tr>
<td>1.8 What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed?</td>
<td>Intervention group: 1.7% (1/58) Control group: 0%</td>
</tr>
<tr>
<td>1.9 All the subjects are analyzed in the groups to which they were randomly allocated (often referred to as intention to treat analysis)</td>
<td>Not addressed</td>
</tr>
<tr>
<td>1.10 Where the study is carried out at more than one site, results are comparable for all sites.</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

| SECTION 2: OVERALL ASSESSMENT OF THE STUDY | |
| 2.1 How well was the study done to minimize bias? | 1- |

<table>
<thead>
<tr>
<th>SECTION 1: INTERNAL VALIDITY</th>
<th>In a well conducted RCT study…</th>
<th>In this study this criterion is:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1</td>
<td>The study addresses an appropriate and clearly focused question.</td>
<td>Well covered</td>
</tr>
<tr>
<td>1.2</td>
<td>The assignment of subjects to treatment groups is randomized.</td>
<td>Not reported Insufficient details were provided for doing the assessment</td>
</tr>
<tr>
<td>1.3</td>
<td>An adequate concealment method is used.</td>
<td>Not reported Insufficient details were provided for doing the assessment</td>
</tr>
<tr>
<td>1.4</td>
<td>Subjects and investigators are kept “blind” about treatment allocation.</td>
<td>Not applicable</td>
</tr>
<tr>
<td>1.5</td>
<td>The treatment and control groups are similar at the start of the trial.</td>
<td>Not reported Only trait anxiety that was comparable between groups was mentioned.</td>
</tr>
<tr>
<td>1.6</td>
<td>The only difference between groups is the treatment under investigation.</td>
<td>Adequately addressed</td>
</tr>
<tr>
<td>1.7</td>
<td>All relevant outcomes are measured in a standard, valid and reliable way.</td>
<td>Well covered Speilberger’s State-Trait Anxiety Inventory (STAI), a well validated instrument for anxiety assessment, was used.</td>
</tr>
<tr>
<td>1.8</td>
<td>What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed?</td>
<td>Not reported Insufficient details were provided for doing the assessment</td>
</tr>
<tr>
<td>1.9</td>
<td>All the subjects are analyzed in the groups to which they were randomly allocated (often referred to as intention to treat analysis)</td>
<td>Not reported Insufficient details were provided for doing the assessment</td>
</tr>
<tr>
<td>1.10</td>
<td>Where the study is carried out at more than one site, results are comparable for all sites.</td>
<td>Not applicable The study was carried out at one site.</td>
</tr>
</tbody>
</table>

SECTION 2: OVERALL ASSESSMENT OF THE STUDY

| 2.1                           | How well was the study done to minimize bias? | 1- |


Appendix D

Key to evidence statements
from Scottish Intercollegiate Guidelines Network (2011)

Levels of evidence

<table>
<thead>
<tr>
<th>Code</th>
<th>Evidence Statements</th>
</tr>
</thead>
<tbody>
<tr>
<td>1++</td>
<td>High quality meta-analyses, systematic reviews of RCTs, or RCTs with a very low risk of bias</td>
</tr>
<tr>
<td>1+</td>
<td>Well-conducted meta-analyses, systematic reviews, or RCTs with a low risk of bias</td>
</tr>
<tr>
<td>1-</td>
<td>Meta-analyses, systematic reviews, or RCTs with a high risk of bias</td>
</tr>
<tr>
<td>2++</td>
<td>High quality systematic reviews of case control or cohort or studies</td>
</tr>
<tr>
<td></td>
<td>High quality case control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is causal</td>
</tr>
<tr>
<td>2+</td>
<td>Well-conducted case control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal</td>
</tr>
<tr>
<td>2-</td>
<td>Case control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal</td>
</tr>
<tr>
<td>3</td>
<td>Non-analytic studies, e.g. case reports, case series</td>
</tr>
<tr>
<td>4</td>
<td>Expert opinion</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Code</th>
<th>Evidence Statements</th>
</tr>
</thead>
<tbody>
<tr>
<td>++</td>
<td><strong>All or most</strong> of the criteria have been fulfilled. Where they have not been fulfilled the conclusions of the study or review are thought very unlikely to alter.</td>
</tr>
<tr>
<td>+</td>
<td><strong>Some</strong> of the criteria have been fulfilled. Those criteria that have not been fulfilled or not adequately described are thought unlikely to alter the conclusions.</td>
</tr>
<tr>
<td>-</td>
<td><strong>Few or no</strong> criteria fulfilled. The conclusions of the study are thought likely or very likely to alter.</td>
</tr>
</tbody>
</table>

Source:
Appendix E

Criteria for Referral for Colposcopy

The decision to refer for colposcopy depends on the likelihood that a patient has CIN II/III or more advanced disease. The following table is a guide to this decision.

<table>
<thead>
<tr>
<th>Cervical Cytology</th>
<th>Significance</th>
<th>Suggested actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal (+ inflammation)</td>
<td>0.1% CIN II-III</td>
<td>• Normal screening program (Once every 3 years after 2 normal annual cytology tests)</td>
</tr>
</tbody>
</table>
| ASC-US (1) | 5-17% CIN II-III 0.1-0.2% invasive | • Reflex HPV testing is preferred especially in postmenopausal women if cervical cells were collected with liquid based cytology.  
• The alternative is to repeat cytology in 6 months. Refer for colposcopy if abnormality persists. |
| ASC-H (2) | 24-94% CIN II-III | • Refer for colposcopy and biopsy |
| Low grade squamous intraepithelial lesion (LSIL) | 15-30% CIN II-III 0.1% invasive | • Refer for colposcopy and biopsy |
| High grade Squamous Intraepithelial lesion (HSIL) | 70-75% CIN II-III 1-2% invasive | • Refer for colposcopy and biopsy  
• Immediate LEEP can be offered if frank high-grade lesion can be seen (Adolescent is an exception).  
• Review of cytology slides is recommended if no high grade lesion could be found. |
| HSIL—cannot exclude invasion | | • Early referral for colposcopy and biopsy |
| Invasive cancer | 53.8% invasive | • Biopsy if frank growth, otherwise early referral for colposcopy and biopsy |
| Abnormal glandular cells | | • Refer for colposcopy and biopsy, endocervical sampling.  
• Cone biopsy and endometrial sampling may be required (Exception: endometrial sampling first for AGC-NOS, endometrial cells).  
• For AGC-favor neoplasia and AIS, if there is no significant pathology explaining the source of the abnormal cells, a diagnostic cold knife cone is recommended to obtain an intact specimen with interpretable margins without thermal artifacts. Ablative procedure is unacceptable. |
| AGC-NOS (3) | 9-41% CIN2-3, AIS, Ca (6) | |
| AGC-favor neoplasia | 27-96% CIN2-3, AIS, Ca | |
| AIS (5) | 48-69% AIS(11) 38% Adenocarcinoma | |
| Benign looking endometrial cells | | |
| (a) women after menopause | 28% benign pathology, 12% significant pathology (hyperplasia, endometrial carcinoma, sarcoma) | • Investigation recommended |
| (b) women greater or equal to 40 years of age | | • For asymptomatic women with benign endometrial cells, no further evaluation is recommended |
| (c) women < 40 years of age | | • Treat as normal |

**Keys:**
1. CIN  Cervical interstitial neoplasia  
2. ASC-US  Atypical squamous cells, undetermined significance  
3. ASC-H  Atypical squamous cells, high grade cannot be excluded  
4. AGC-NOS  Atypical glandular cells, not otherwise specified  
5. AIS  Adenocarcinoma in situ  
6. CA  Carcinoma

**Source:**
## Appendix F

### Key to Grades of Recommendations from Scottish Intercollegiate Guidelines Network (2011)

#### Grades of Recommendations

<table>
<thead>
<tr>
<th>Grade</th>
<th>Statements</th>
</tr>
</thead>
</table>
| **A** | At least one meta-analysis, systematic review, or RCT rated as 1++, and directly applicable to the target population; *or*  
A body of evidence consisting principally of studies rated as 1+, directly applicable to the target population, and demonstrating overall consistency of results |
| **B** | A body of evidence including studies rated as 2++, directly applicable to the target population, and demonstrating overall consistency of results; *or*  
Extrapolated evidence from studies rated as 1++ or 1+ |
| **C** | A body of evidence including studies rated as 2+, directly applicable to the target population and demonstrating overall consistency of results; *or*  
Extrapolated evidence from studies rated as 2++ |
| **D** | Evidence level 3 or 4; *or*  
Extrapolated evidence from studies rated as 2+ |

Source:  
Appendix G

Criteria for Evaluating the Implementation Potential of an Innovation under Scrutiny

Transferability of the Findings
1. Will the innovation “fit” in the proposed setting?
2. How similar are the target population in the research and that in the new setting?
3. Is the philosophy of care underlying the innovation fundamentally different from the philosophy prevailing in the practice setting? How entrenched is the prevailing philosophy?
4. Is there a sufficiently large number of clients in the practice setting who could benefit from the innovation?
5. Will the innovation take too long to implement and evaluate?

Feasibility
1. Will nurses have the freedom to carry out the innovation? Will they have the freedom to terminate the innovation if it is considered undesirable?
2. Will the implementation of the innovation interfere inordinately with current staff functions?
3. Does the administration support the innovation? Is the organizational climate conducive to research utilization?
4. Is there a fair degree of consensus among the staff and among the administrators that the innovation could be beneficial and should be tested? Are there major pockets of resistance or uncooperativeness that could undermine efforts to implement and evaluate the innovation?
5. To what extent will the implementation of the innovation cause friction within the organization? Does the utilization project have the support and cooperation of departments outside the nursing department?
6. Are the skills needed to carry out the utilization project (both the implementation and the clinical evaluation) available in the nursing staff? If not, how difficult will it be to collaborate with or to secure the assistance of others with the necessary skills?
7. Does the organization have the equipment and facilities necessary for the innovation? If not, is there a way to obtain the needed resources?
8. If nursing staff need to be released from other practice activities to learn about and implement the innovation, what is the likelihood that this will happen?
9. Are appropriate measuring tools available for a clinical evaluation of the innovation?

Cost/Benefit Ratio of the Innovation
1. What are the risks to which clients would be exposed during the implementation of the innovation?
2. What are the potential benefits that could result from the implementation of the innovation?
3. What are the risks of maintaining current practices (i.e., the risks of not trying the innovation)?

4. What are the material costs of implementing the innovation? What are the costs in the short term during utilization, and what are the costs in the long run, if the change is to be institutionalized?

5. What are the material costs of not implementing the innovation (i.e., could the new procedure result in some efficiencies that could lower the cost of providing service)?

6. What are the potential nonmaterial costs of implementing the innovation to the organization (e.g., lower staff morale, staff turnover, absenteeism)?

7. What are the potential nonmaterial benefits of implementing the innovation (e.g., improved staff morale, improved staff recruitment)?

Source:
## Appendix H

### The Timeline for Innovation Implementation and Evaluation of Anxiety Level

<table>
<thead>
<tr>
<th></th>
<th>Month 1</th>
<th>Month 2</th>
<th>Month 3</th>
<th>Month 4</th>
<th>Month 5</th>
<th>Month 6</th>
<th>Month 7</th>
<th>Month 8</th>
<th>Month 9</th>
<th>Month 10</th>
<th>Onward</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preparation</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pilot testing*</td>
<td></td>
<td></td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Post-pilot evaluation*</td>
<td></td>
<td></td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Full implementation</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>……..</td>
</tr>
<tr>
<td>Final evaluation#</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
</tbody>
</table>

* A 2-week patient recruitment for the pilot testing will be performed during scheduling colposcopy appointment. The post-pilot evaluation will be done by using C-STA1 and the evaluation form will be distributed on the procedure day, which is about 14 weeks at most after appointment scheduling.

# 2 months will be spent on distributing the C-STA1 form to the control group. The distribution will start at the first month of the full implementation since the colposcopy patient at that time should not have received the education materials yet. Similarly, the distribution will last for 2 months for the intervention group. However, it will commence at the third month after the start of the education materials distribution. It is to cover patients with all range of waiting time.
# Appendix I

## Summary on the Information of the Education Materials for the Intervention Groups in the Selected Studies

<table>
<thead>
<tr>
<th>Citation</th>
<th>de Bie et al., 2011</th>
<th>Howells et al., 1999</th>
<th>Byrom et al., 2002</th>
<th>Freeman-Wang et al., 2001</th>
<th>Marteau et al., 1996</th>
<th>Stewart et al., 1993</th>
<th>Tomano-Brunner et al., 1998</th>
<th>Wilkinson et al., 1990</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Level of evidence</strong></td>
<td>++</td>
<td>++</td>
<td>+</td>
<td>-</td>
<td>-</td>
<td>1-</td>
<td>1-</td>
<td>1-</td>
</tr>
<tr>
<td><strong>Other positive outcome</strong></td>
<td>Knowledge</td>
<td>--</td>
<td>Knowledge</td>
<td>--</td>
<td>Knowledge</td>
<td>Knowledge</td>
<td>Knowledge</td>
<td>--</td>
</tr>
<tr>
<td><strong>Mode of intervention</strong></td>
<td>P + L</td>
<td>L</td>
<td>F + V</td>
<td>B + V</td>
<td>B</td>
<td>B</td>
<td>B</td>
<td>L</td>
</tr>
<tr>
<td>Colposcopy</td>
<td>Indicator</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pap smear</td>
<td>Indication</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(PS)</td>
<td>Nature of procedure</td>
<td>(\checkmark)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Abnormal PS</td>
<td>Incidence</td>
<td>(\checkmark)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Implication to cancer</td>
<td>(\checkmark)</td>
<td>(\checkmark)</td>
<td>(\checkmark)</td>
<td>(\checkmark) (V)</td>
<td>(\checkmark)</td>
<td>(\checkmark)</td>
<td>(\checkmark)</td>
<td>(\checkmark)</td>
</tr>
<tr>
<td>Aetiology</td>
<td>(\checkmark)</td>
<td>(\checkmark)</td>
<td>(\checkmark)</td>
<td>(\checkmark) (V)</td>
<td>(\checkmark)</td>
<td>(\checkmark)</td>
<td>(\checkmark)</td>
<td>(\checkmark)</td>
</tr>
<tr>
<td>Clinical setting</td>
<td>(\checkmark)</td>
<td>(\checkmark) V</td>
<td>(\checkmark)</td>
<td>(\checkmark)</td>
<td>(\checkmark)</td>
<td>(\checkmark)</td>
<td>(\checkmark)</td>
<td>(\checkmark)</td>
</tr>
<tr>
<td>The Condition on colposcopy appointment day</td>
<td>Before procedure</td>
<td>(\checkmark)</td>
<td>(\checkmark)</td>
<td>(\checkmark)</td>
<td>(\checkmark)</td>
<td>(\checkmark)</td>
<td>(\checkmark)</td>
<td>(\checkmark)</td>
</tr>
<tr>
<td>Description on procedure</td>
<td>(\checkmark)</td>
<td>(\checkmark)</td>
<td>(\checkmark)</td>
<td>(\checkmark) (B + V)</td>
<td>(\checkmark)</td>
<td>(\checkmark)</td>
<td>(\checkmark)</td>
<td>(\checkmark)</td>
</tr>
<tr>
<td>Sense perception</td>
<td>(\checkmark)</td>
<td>(\checkmark)</td>
<td>(\checkmark)</td>
<td>(\checkmark) (B + V)</td>
<td>(\checkmark)</td>
<td>(\checkmark)</td>
<td>(\checkmark)</td>
<td>(\checkmark)</td>
</tr>
<tr>
<td>After colposcopy</td>
<td>(\checkmark)</td>
<td>(\checkmark)</td>
<td>(\checkmark)</td>
<td>(\checkmark) (B + V)</td>
<td>(\checkmark)</td>
<td>(\checkmark)</td>
<td>(\checkmark)</td>
<td>(\checkmark)</td>
</tr>
<tr>
<td>Further management</td>
<td>Treatment</td>
<td>(\checkmark)</td>
<td>(\checkmark)</td>
<td>(\checkmark) (B + V)</td>
<td>(\checkmark)</td>
<td>(\checkmark)</td>
<td>(\checkmark)</td>
<td>(\checkmark)</td>
</tr>
<tr>
<td>Post-colposcopy advice</td>
<td>(\checkmark)</td>
<td>(\checkmark)</td>
<td>(\checkmark)</td>
<td>(\checkmark) (B + V)</td>
<td>(\checkmark)</td>
<td>(\checkmark)</td>
<td>(\checkmark)</td>
<td>(\checkmark)</td>
</tr>
<tr>
<td>Source of assistance</td>
<td>(\checkmark)</td>
<td>(\checkmark) (F)</td>
<td>(\checkmark)</td>
<td>(\checkmark) (V)</td>
<td>(\checkmark)</td>
<td>(\checkmark)</td>
<td>(\checkmark)</td>
<td>(\checkmark)</td>
</tr>
<tr>
<td>Miscellaneous</td>
<td>(\checkmark)</td>
<td>(\checkmark) (P)</td>
<td>(\checkmark)</td>
<td>(\checkmark) (V)</td>
<td>(\checkmark)</td>
<td>(\checkmark)</td>
<td>(\checkmark)</td>
<td>(\checkmark)</td>
</tr>
</tbody>
</table>

**Keys:**
1. B = Booklet
2. F = Face-to-face counseling
3. L = Leaflet
4. P = Phone counseling
5. V = Video
## Appendix J

### Details of the Intervention Investigated in the Selected Studies

<table>
<thead>
<tr>
<th>Citation</th>
<th>Education Strategy</th>
<th>Desired Outcomes</th>
<th>Evidence Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chan et al., 2004</td>
<td><strong>Leaflet</strong>&lt;br&gt; <em>A locally produced information leaflet</em>&lt;br&gt; (1) The nature and purpose of colposcopy&lt;br&gt; (2) The setting of the colposcopy room&lt;br&gt; (3) The procedure of colposcopic examination&lt;br&gt; (4) The subsequent treatment options&lt;br&gt; (5) A role-play of a normal colposcopic consultation and examination</td>
<td>The addition of Q&amp;A session improved the subjects’ knowledge of colposcopy</td>
<td>1++</td>
</tr>
<tr>
<td></td>
<td><strong>Counseling</strong>&lt;br&gt; <em>Question and answer (Q&amp;A) session conducted by the colposcopic nurse</em></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Byrom et al., 2002</td>
<td>60-90 minute evening counseling session before colposcopy appointment:&lt;br&gt; • Patients were encouraged to discuss any issues that concerned them.&lt;br&gt; • Individual counseling was offered to patients who required more privacy or information.</td>
<td>Increased in knowledge</td>
<td>1+</td>
</tr>
<tr>
<td>de Bie et al., 2011</td>
<td><strong>Leaflet</strong>&lt;br&gt; <em>16-page illustrated document with details of:</em>&lt;br&gt; (1) the aim of the screening programme&lt;br&gt; (2) the procedure of taking a cervical smear&lt;br&gt; (3) the meaning of an abnormal smear result&lt;br&gt; (4) all possible diagnostic and treatment option that follow an abnormal smear result</td>
<td>Phone counseling that covered 7 topics:&lt;br&gt; (1) Explanation about smear result&lt;br&gt; (2) Pre-cancer instead of cancer&lt;br&gt; (3) Colposcopic procedure&lt;br&gt; (4) Possible invasive treatment&lt;br&gt; (5) HPV&lt;br&gt; (6) HPV vaccination&lt;br&gt; (7) Fertility</td>
<td>1++</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Increased in knowledge</td>
<td></td>
</tr>
<tr>
<td>Citation</td>
<td>Leaflet</td>
<td>Video</td>
<td>Counseling</td>
</tr>
<tr>
<td>---------------------------</td>
<td>----------------------------------------------</td>
<td>-----------------------------------------------</td>
<td>------------</td>
</tr>
</tbody>
</table>
| Freeman-Wang et al., 2001 | *Booklet:* (1) Procedure of colposcopy  
(2) Information of treatment | *Information video:*  
• 7-minute video  
• Contents:  
(1) Image of reception area, nursing and medical staff who worked in the colposcopy clinic  
(2) Pictures of the clinic and the instrument seen in the clinic  
(3) Explanation on the nature of abnormal Pap smears  
(4) Outline of consultation and treatment  
(5) Nature of cervical intraepithelial neoplasia and its treatment  
(6) The care required following treatment  
(7) Treatment complications  
(8) Interview of a women immediately following her see-and-treat attendance |            | Less state anxiety | 1-              |
| Howells et al., 1999      | *Information leaflet with contents of:*  
(1) Abnormal smear not identical to cancer  
(2) Indication of colposcopy  
(3) Procedure of colposcopy  
(4) Possible treatment  
(5) Patient flow in the colposcopy clinic  
(6) Post-colposcopy self-care  
(7) Contact method for appointment rearrangement  
  • The Flesch readability index = 80 | | | Nil | 1++ |
<table>
<thead>
<tr>
<th>Citation</th>
<th>Education Strategy</th>
<th>Desired Outcomes</th>
<th>Evidence Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kwan et al., 2010</td>
<td><em>Information of high-risk HPV facts with de-stigmatizing components.</em>&lt;br&gt;<em>(ds+hrHPV)</em> was constructed as followed:&lt;br&gt;<strong>(1)</strong> <em>Specific anti-stereotypic component:</em>&lt;br&gt;• 2 lay beliefs common among Chinese were targeted:&lt;br&gt;  (i) Only individuals like sex workers or people who fool around will have STIs. These individuals tend to be seen as being younger in age, unmarried or belonging to the lower social class.&lt;br&gt;  (ii) Monogamy and practicing 'proper' sex, i.e. sex within a heterosexual marital relationship protect a person from all potential STIs.&lt;br&gt;• Incompatible information was explicated with following fictitious examples given:&lt;br&gt;  (i) Women such as housewife and medical doctor, whose occupations were traditionally associated with positive attributes such as trustworthiness and respectability and the least risk for STIs, could be high-risk HPV infected.&lt;br&gt;  (ii) Women with only one sexual partner might also be infected.&lt;br&gt;• The first person pronoun 'we' or 'our' was used in the message to stress that all women belonged to the same at-risk group.&lt;br&gt;<strong>(2)</strong> <em>Low complexity component:</em> Information on low-risk HPV and genital warts were excluded in accordance with the focus and to achieve maximal content simplicity.&lt;br&gt;<strong>(3)</strong> <em>Motivational component:</em> Cervical cancer prevention was explicitly stated as the goal in the title of ds+hrHPV.</td>
<td>Less high-risk HPV-related sexual stigma&lt;br&gt;Increased in knowledge</td>
<td>1++</td>
</tr>
<tr>
<td>Marteau et al., 1996</td>
<td><em>Brief, simple booklet:</em>&lt;br&gt;<strong>(1)</strong> Colposcopy procedure&lt;br&gt;<strong>(2)</strong> behavioural instructions on dealing with it, and&lt;br&gt;<strong>(3)</strong> The likely outcome of a colposcopy examination&lt;br&gt;<em>Clinical information sheet:</em>&lt;br&gt;• 4 paragraphs on one side of an A4 sheet&lt;br&gt;• describing the procedure of colposcopy</td>
<td>Less state anxiety&lt;br&gt;Less anxiety about what the doctor might find wrong&lt;br&gt;Increased in knowledge</td>
<td>1-</td>
</tr>
<tr>
<td>Citation</td>
<td>Education Strategy</td>
<td>Desired Outcomes</td>
<td>Evidence Level</td>
</tr>
<tr>
<td>----------</td>
<td>--------------------</td>
<td>------------------</td>
<td>----------------</td>
</tr>
<tr>
<td>Stewart et al., 1993</td>
<td><strong>Leaflet</strong>&lt;br&gt;A 6-page illustrated brochure:&lt;br&gt;• Mailed to patients on the same day the colposcopy appointment was made, along with a reminder of the appointment&lt;br&gt;• At a grade 6 reading level&lt;br&gt;• With contents of the following&lt;br&gt;  (1) the screening purpose of Pap smear&lt;br&gt;  (2) the important of dysplasia as an early warning signal requiring further tests, and sometimes treatment, to prevent a more serious problem&lt;br&gt;  (3) emphasizing that most Pap smears with dysplasia do not indicate cervical cancer&lt;br&gt;  (4) description of the usual examinations and treatments&lt;br&gt;  (5) advice on what to expect during colposcopic examination&lt;br&gt;  (6) general advice about post-treatment follow-up&lt;br&gt;  (7) indicating that specific follow-up plans may vary&lt;br&gt;  (8) availability of doctor for discussion of follow-up plan</td>
<td>Less psychological distress&lt;br&gt;Less fear of cancer&lt;br&gt;Less worries concerning future health&lt;br&gt;Increased in knowledge</td>
<td>1-</td>
</tr>
<tr>
<td>Tomaino-Brunner et al., 1998</td>
<td><strong>1-page handout:</strong>&lt;br&gt;• Mailed to patients approximately 1 week before the appointment&lt;br&gt;• At a grade 6 reading level&lt;br&gt;• With contents of the following&lt;br&gt;  (1) the reason for the upcoming scheduled office visit&lt;br&gt;  (2) the definition of a colposcopy, including the length of time for the examination&lt;br&gt;  (3) the usual reasons for referral for colposcopy (stating that a scheduled colposcopy does not necessarily mean that one has cancer)&lt;br&gt;  (4) an acknowledgement that even if the thought of the test is frightening, it is essential to rule out any illness&lt;br&gt;  (5) a description of what will happen after the colposcopy&lt;br&gt;  (6) an assurance that questions will be answered at the appointment&lt;br&gt;  (7) the importance of keeping the appointment</td>
<td>Less scare and nervousness feeling about having colposcopy&lt;br&gt;Increased in knowledge</td>
<td>1-</td>
</tr>
<tr>
<td>Wilkinson et al., 1990</td>
<td><strong>Leaflet &amp; personalized letter:</strong>&lt;br&gt;“Your recent smear test showed slight abnormality which need cause you no anxiety. Please read the enclosed leaflet carefully, you will find it helpful and reassuring. Please could you attend the cytology clinic at … on …”&lt;br&gt;The main message in the leaflet was that most smears showing dyskaryosis do not indicate cervical cancer.</td>
<td>Standard computerized letter: “Your recent smear test showed slight abnormality. Please could you attend the cytology clinic at … for a repeat test and further advice”</td>
<td>Less state anxiety</td>
</tr>
</tbody>
</table>

Key: (1) HPV: Human papillomavirus (2) STI: Sexually-transmitted infection
Appendix K

Flow Chart of Communication Process

1. During counseling immediate before colposcopy, the first-time colposcopy patients expressed that they felt very anxious when they were informed of the need of the examination.
2. The APN, together with the 4 full-time RNs and the 2 part-time RNs, held a discussion to affirm a clinical need to allay the patient’s pre-colposcopy anxiety.

The APN and the 4 full-time RNs
1. searched high quality evidence of allaying pre-colposcopy anxiety strategy from electronic databases
2. identified from the evidence that patient education strategy was potentially applicable to the setting of the colposcopy clinic
3. developed a new EBP guideline on pre-colposcopy education and wrote a proposal on this innovation

WM will be given a presentation of the proposal for gaining her support to the innovation.

1. For the support from the DOM of the gynaecology day procedure centre, the APN will assist the WM to introduce the proposed guideline to the DOM.
2. Meanwhile, a written proposal is submitted to the DOM for her reference.

1. The DOM will preliminarily inform the DOM of SOPD (the department responsible for making colposcopy appointment) and the COS / O&G about the proposed guideline.
2. With the DOM’s arrangement, the APN will give a formal presentation to the DOM of SOPD and the COS during a quarterly inter-departmental meeting of O&G department.
3. Consensus on the need and the content of the proposed guideline are expected to be obtained after the presentation.

1. The agreed guideline will be emailed to the WM, both of the DOMs and the COS for further distribution to other relevant frontline staff.
2. The guideline will be given to both full-time and part-time RNs for their reference.

1. The APN, the 4 full-time RNs and the clerical staff start to prepared patient education materials
2. When the patient education materials are ready, the staff responsible for making colposcopy appointment at SOPD will be invited to attend a half-hour briefing session about the guideline. Both of the DOMs will be informed of the invitation in advance.

Get the proposed change

* The APN is the contact person throughout the whole communication process
Appendix L

Survey Questionnaire of Patient’s Opinion on Pre-colposcopy Education Materials

問卷編號：________

有關病人對子宮頸窺鏡檢查資料素材之意見調查

此問卷旨在收集有關病人對使用子宮頸窺鏡檢查資料素材意見後之意見。閣下之寶貴意見將有助本診所優化向病人提供資料素材的措施，從而提升服務質素，故敬希閣下花大約 5 分鐘時間填寫此問卷。此問卷是不記名的，而閣下所提供的一切資料均絕對保密，並只會用作整體分析，不會影響本診所日後為閣下所提供之護理及治療方案。完成分析後，所有資料均予以銷毀。

以下部分由病人填寫
請於適當的方格內填上「√」號。

甲：個人資料

<table>
<thead>
<tr>
<th></th>
<th>16-19 歲</th>
<th>20-29 歲</th>
<th>30-39 歲</th>
<th>40-49 歲</th>
<th>50-59 歲</th>
<th>60 歲或以上</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. 年齡:</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>2. 教育程度:</td>
<td>小學以下</td>
<td>小學</td>
<td>中學</td>
<td>大專</td>
<td>大學或以上</td>
<td></td>
</tr>
<tr>
<td></td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td></td>
</tr>
<tr>
<td>3. 婚姻狀況:</td>
<td>單身</td>
<td>同居</td>
<td>已婚</td>
<td>離婚</td>
<td>喪偶</td>
<td></td>
</tr>
<tr>
<td></td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td></td>
</tr>
<tr>
<td>4. 子女數目:</td>
<td>無</td>
<td>1 個</td>
<td>2 個</td>
<td>3 個</td>
<td>4 個或以上</td>
<td></td>
</tr>
<tr>
<td></td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td></td>
</tr>
</tbody>
</table>
乙: 意見調查
一、資料單張

<table>
<thead>
<tr>
<th>1.</th>
<th>應診前你有否閱讀有關本診所子宮頸窺鏡檢查的資料單張？</th>
</tr>
</thead>
<tbody>
<tr>
<td>□</td>
<td>無 (請往第 2 題)</td>
</tr>
<tr>
<td>□</td>
<td>有 (請往第 3 題)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2.</th>
<th>未能閱讀之原因：</th>
</tr>
</thead>
<tbody>
<tr>
<td>□</td>
<td>預約時職員並未派發 (請往第二部分)</td>
</tr>
<tr>
<td>□</td>
<td>遺失單張</td>
</tr>
<tr>
<td>□</td>
<td>無暇閱讀</td>
</tr>
<tr>
<td>□</td>
<td>認為無需要</td>
</tr>
<tr>
<td>□</td>
<td>其他</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>3.</th>
<th>單張的內容大致容易明白。</th>
</tr>
</thead>
<tbody>
<tr>
<td>□</td>
<td>極同意</td>
</tr>
<tr>
<td>□</td>
<td>同意</td>
</tr>
<tr>
<td>□</td>
<td>不同意</td>
</tr>
<tr>
<td>□</td>
<td>極不同意</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>4.</th>
<th>單張已包含我所需的資料。</th>
</tr>
</thead>
<tbody>
<tr>
<td>□</td>
<td>極同意</td>
</tr>
<tr>
<td>□</td>
<td>同意</td>
</tr>
<tr>
<td>□</td>
<td>不同意</td>
</tr>
<tr>
<td>□</td>
<td>極不同意</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>5.</th>
<th>單張有部分內容深奧難明。</th>
</tr>
</thead>
<tbody>
<tr>
<td>□</td>
<td>極同意</td>
</tr>
<tr>
<td>□</td>
<td>同意</td>
</tr>
<tr>
<td>□</td>
<td>不同意</td>
</tr>
<tr>
<td>□</td>
<td>極不同意</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>6.</th>
<th>單張的篇幅適中。</th>
</tr>
</thead>
<tbody>
<tr>
<td>□</td>
<td>極同意</td>
</tr>
<tr>
<td>□</td>
<td>同意</td>
</tr>
<tr>
<td>□</td>
<td>不同意</td>
</tr>
<tr>
<td>□</td>
<td>極不同意</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>7.</th>
<th>單張的字體清晰。</th>
</tr>
</thead>
<tbody>
<tr>
<td>□</td>
<td>極同意</td>
</tr>
<tr>
<td>□</td>
<td>同意</td>
</tr>
<tr>
<td>□</td>
<td>不同意</td>
</tr>
<tr>
<td>□</td>
<td>極不同意</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>8.</th>
<th>單張的內容有助減低我對子宮頸檢查的憂慮。</th>
</tr>
</thead>
<tbody>
<tr>
<td>□</td>
<td>極同意</td>
</tr>
<tr>
<td>□</td>
<td>同意</td>
</tr>
<tr>
<td>□</td>
<td>不同意</td>
</tr>
<tr>
<td>□</td>
<td>極不同意</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>9.</th>
<th>單張中最難明白的部分：</th>
</tr>
</thead>
<tbody>
<tr>
<td>____</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>10.</th>
<th>我希望單張能加插的內容：</th>
</tr>
</thead>
<tbody>
<tr>
<td>____</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>11.</th>
<th>我希望單張能删減的內容：</th>
</tr>
</thead>
<tbody>
<tr>
<td>____</td>
<td>(請註明原因)</td>
</tr>
<tr>
<td>____</td>
<td></td>
</tr>
</tbody>
</table>
二、資料光碟

1. 應診前你有否觀看有關本診所子宮頸鏡檢查的資料光碟？
   - □ 無（只需填寫第 2 題）
   - □ 有（請往第 3 題）

2. 未能觀看之原因：
   - □ 預約時職員並未派發
   - □ 遺失光碟
   - □ 無暇觀看
   - □ 忘記觀看
   - □ 認為無需要
   - □ 沒有播放設備
   - □ 光碟損壞
   - □ 其他

<table>
<thead>
<tr>
<th></th>
<th>極同意</th>
<th>同意</th>
<th>不同意</th>
<th>極不同意</th>
</tr>
</thead>
</table>

3. 光碟的內容大致容易明白。

4. 光碟已包含我所需的資料。

5. 光碟有部分內容深奧難明。

6. 光碟的篇幅適中。

7. 光碟操作容易。

8. 光碟的內容有助減低我對子宮頸鏡檢查的憂慮。

9. 光碟中最難明白的部分是：
   ____________________________

10. 我希望光碟能加插的內容是：
    ____________________________
11. 我希望光碟能刪除的內容是：

______________________________________
(請註明原因)
______________________________________

～問卷完～

以下部分由職員填寫

1. Indication:
   □ ASCUS, NOS
   □ ASC-H
   □ LGSIL
   □ HGSIL
   □ AGC
   □ CA
   □ Others (Please specify:________________)

2. Referral Source:
   □ Family Planning Association
   □ Maternal Care Health Centre
   □ Women Health Centre, Department of Health
   □ Social Hygiene Clinic
   □ Private Practitioner (Local)
   □ Private Practitioner (Outside Hong Kong)
   □ A&E
   □ Own Department
   □ Public Hospital (Except own department)
   □ Others

3. Waiting Time
   □ < 1 month
   □ ≥ 1 to < 2 months
   □ ≥ 2 to < 3 months
   □ ≥ 3 to < 4 months
   □ ≥ 4 months
## Appendix M

### Outline for the Semi-Structured Evaluation Meeting among Project Operators

<table>
<thead>
<tr>
<th><strong>Aim:</strong></th>
<th>To provide channel for frontline staff to express feelings towards implementation of the EBP project</th>
</tr>
</thead>
</table>
| **Participant:** | 1. Nursing staff of colposcopy clinic  
2. SOPD’s staff who are responsible for education materials distribution |
| **Duration:** | 60 minutes |
| **Venue:** | Gynaecology Day Procedure Center |
| **Discussion Points:** | 1. Positive impact of the project implementation on daily job *  
2. Difficulties encountered during implementation *  
3. Suggestion for improvement  
4. Any other opinion |

* Discussion points encompasses…  
  a) Feasibility (Nurse’s control over the project, availability of staff, resources and external assistance, and organization climate)  
  b) The exact cost-benefit ratio for clients, staff and the organization |
References


Evidence for Nursing Practice (9th ed.). Philadelphia: Wolters Kluwer Health / Lippincott Williams & Wilkins.


