Women's Knowledge on Cesarean Section and Vaginal Delivery in the Kanyakumari District of Tamil Nadu, India

Master of Public Health Integrating Experience Project

Community Service Grant Proposal

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LIST OF ABBREVATIONS

ACOG	-	The American college of Obstetricians & Gynecologists
CDC	-	Centers for Disease Control and Prevention
C-Section	-	Cesarean Section
DHS	-	Demographic Health Survey
HBM	-	Health Belief Model
ICMR	-	Indian Council of Medical Research
KAP	-	Knowledge Attitude and Practice
NFHS	-	National Family Health Survey
NGO	-	Non-Governmental Organization
SMFM	-	The Society of Maternal - Fetal Medicine
SPSS	-	Statistical Package for the Social sciences
USD	-	United States Dollars
VD	-	Vaginal Delivery
WHO	-	World Health Organization

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EXECUTIVE SUMMARY

In the modern era, Cesarean section (C-section) is one of the major and most common surgeries performed worldwide. Its rate is tremendously increasing across the globe. Around the world, China tops the first place in C-section rate at 42%. In India, C-section rates fluctuate across its states. India is the second most populated country in the world, where two-third of its population (which is mostly under middle-income category) faces tremendous expenditure on health care. Among these, birth delivery charges are climbing high especially in private hospitals. Out-of-pocket expenses increase even more for deliveries done through C-section which is a big public health issue in terms of Indian Economy. According to the 2015-16, National Family Health Survey (NFHS-4), Telengana, a newly formed former state of Andhra Pradesh had a high rate of C-section at 58%, followed by Andhra Pradesh, Kerala and Tamil Nadu at 40.1%, 35.8%, 34.1%, respectively in the South.

In India, the C-section rate is higher among South Indian women, as compared to North Indian women. At South, Kanyakumari district of Tamil Nadu tops first place in C-section at a rate of over 50%. Of these, 54.6% were conducted among private hospitals.

A lack of proper knowledge on use of healthcare resources could increase avoidable financial burden in the families. There should be official mandates on maintaining a complete transparency between the patients and health care providers on every resource spent and utilized. Thus, improving health care quality and reducing the overuse of resources.

An educational decision aid support and counseling services to the pregnant women, during their period of gestation, could improve their knowledge on strengths and weakness of modes of delivery. In addition, this will also decrease the anxiety of pregnant women toward natural mode of delivery. Thus, the aim of this proposal is to focus on increasing the pregnant women's (13-28 weeks) knowledge on C-section and vaginal delivery.

The specific objectives of the proposed program used for evaluation are:

1. At the end of the two month educational program, there will be 22% absolute increase in the average knowledge percent score from the baseline in the intervention group.
2. By the end of six-months after the implementation of the educational training program, the rate of caesarean section in the intervention group will be 14% (relative) lower compared to the control group.

The study sample population estimates to around 705. This study incorporates the knowledge, attitude and socio-demographic instruments that were used in previous similar studies. SPSS software will be used for data entry and descriptive analysis will be used for analytical purposes. The study received approval from the Institutional Review Board of the American University of Armenia. The budget of the proposed study is USD26,843 (INR1, 900,990). This study will carve evidence for future research and development in this particular arena of public health.

AIM AND OBJECTIVE OF THE STUDY

The proposed study aims to 1) increase maternal knowledge on Cesarean Section (C-section), its cost and future burden on the health of the mother and child; 2) decrease maternal psychological anxiety on Vaginal Delivery (VD); and 3) increase women's decision-making power regarding delivery, through an educational intervention.

The specific objectives of the program are:

3. By the end of six-months after the implementation of the educational training program, the rate of caesarean section in the intervention group will be 14% (relative) lower compared to the control group.[1]
4. At the end of the two month educational program, there will be 22% absolute increase in the average knowledge percent score from the baseline in the intervention group.[2]
5. At the end of the two month educational program, there will be 50% (relative) increase in the attitude percent score towards vaginal mode of delivery from the baseline in the intervention group.[2]

The target population for the study includes pregnant women in their 2nd trimester (13-28 weeks)[3] of pregnancy, irrespective of their parity status, appearing for their antenatal checkup in the selected hospitals of Kanyakumari district of Tamil Nadu, India.

INTRODUCTION

According to the World health Organization (WHO), normal birth is "Spontaneous in onset, low-risk at the start of labor and remaining so throughout labor and delivery. The infant is born spontaneously in the vertex position between 37 and 42 completed weeks of pregnancy. After birth, mother and infant are in good condition."[4(p.4)]

A clear universal definition for normal birth is still controversial, that is yet to be established and practiced in all clinical settings. In 1997, World Health Organization (WHO) had proposed their version of normal birth in accordance with the normal labor physiology, risks and quality of both mother and baby.[4] However, the British and Canadian statements on defining normal birth also include electronic fetal monitoring and epidural anesthesia to mothers during labor, respectively.[5] Different countries define normal birth differently; hence can follow different standards and practices for care and delivery management.

In general, normal birth is attained through vaginal delivery (VD) (which follows the natural birth canal route) without any medical intervention such as pharmacological induction of labor process, instrumental delivery (forceps and vacuum methods), and surgical caesarean section (C-section) (abdominal incision for delivery of baby). The above mentioned methods are indicated in cases of obstetric necessities to prevent maternal and fetal adverse outcomes.[6] Both VD and surgical modes of delivery have their own advantages and disadvantages.[7] However, VD outweighs in benefits, when compared to C-section. According to a population study conducted in Canadian hospitals, VD resulted in fewer maternal re-admissions, as compared to deliveries via C-section.[8] In addition, VD has a shorter hospital stay and recovery time when compared to C-section.[8] However, the length of hospital stay is influenced by various factors, including the presence of skilled birth attendants, country, mother's age (the higher the age, the longer her stay), presence or absence of complication

during the entire pregnancy period, and the facility in which the delivery took place(private or public hospitals).[9]

VD has a stimulating effect in initiating breastfeeding.[10] Moreover, it provides direct contact to maternal vaginal micro biome (which contains lactobacillus), which facilitates baby's early intestinal micro flora colonization. The former together with bifidobacterium, produce lactic acid, which enhances the defense system in newborn.[11] The microbial colonization could be delayed up to six months in case of C-section.[12] Thus, babies delivered through VD possess better immune protection against diseases as they gain immunity faster.[11] However, despite its advantages, VD may result in anal sphincter injury, genital lacerations, and pain.[13,14]

C-section is a surgical manipulation which is necessary for complicated pregnancies, such as repeat C-section,[15] high maternal age (>40),[16] fetal distress, prolonged labor, placental bleeding, pre-term birth of the baby, preeclampsia, breech presentation, dystocia, cephalic-pelvic disproportion and other illnesses observed during history of previous pregnancies and antenatal visits.[8,17,18] Thus, it is a life-saving procedure for both the mother and the fetus in medically necessary situations, whereas unnecessary indications and overuse of C-section may negatively affect the quality of life of both mother and newborn, and put their family under financial constraint.[19]

Postpartum complications of C-section for both the mother (infections, blood transfusion, deep vein thrombosis, hysterectomy)[20] and child (respiratory distress)[21] are described in various studies. In addition, the 2013 US National Institute for Child Health and Human Development study reported a positive association between C-section and childhood obesity.[22] Moreover, several studies suggest that children delivered through C-section are more likely to develop childhood asthma, juvenile diabetes mellitus and childhood obesity, as well as have an increased risk of cancer later in their life.[23–25]

According to the World Health Organization (WHO), the rates of medically necessary C-section should be between 10% to 15%.[26] However, for the past two-decades CS rates have dramatically increased from 5% to 20% worldwide.[17] The WHO 2005-2008 global survey placed China in the first place with C-section deliveries at 46%, compared to 24% in other Asian countries.[7] A 2011 cross-sectional study from 39 diverse hospitals in 14 provinces of three regions in China indicated a high C-section delivery rate at 54.5%, of which 38.4% were non-medically indicated C-sections.[27] Likewise, in a European country like the UK, the C-section rate was 26.2% in 2014.[28] Moreover, the US Centers for Disease Control and Prevention (CDC) has reported a high rate of C-section delivery in the United States: approximately 32% of all births in 2017.[29]

Pregnancy related anxiety among women has been reported as one of the major cofactors in raising the demand for C-section.[30] Fear of pregnancy in women is linked to various factors that make women more anxious about getting pregnant.[31] Young girls might receive misleading information from friends and family regarding individual birth experiences.[31,32] It could increase psychological negative perceptions regarding pregnancy and pain during VD. Anxiety may greatly interfere with the process of VD, increasing the physiological labor time.[33] Thereby, increasing the chances to opt for a C-section during the next pregnancy, or avoiding a second pregnancy altogether. Moreover, some studies suggest that fear of VD could make women postpone pregnancy and even have abortions.[34] In a study conducted among a cohort of Australian women, about 48% experienced high and 26% moderate levels of child birth fear during pregnancy;[35] those with higher level of fear were more likely to get a C-section as compared to the lower fear group.[35]

Some authors emphasize the ethical issues faced by physicians in the 'physician-patient relationship', which respects the patient's autonomy to select their preferred choice of delivery.[36] However, obstetricians and gynecologists could at least inform patients

requesting elective C-section about the health risks and benefits of medically unnecessary C-section.[37]

There is controversial evidence in the association between socio-demographic and educational status and the choice of delivery across different countries. A study conducted in Norway states that lower educational status leads to higher rates of C-section.[38] However, the trend is the opposite in most other countries. According to a 2010 retrospective cohort study from the Royal medical hospital in Canada, higher levels of maternal education resulted in higher rates of C-section.[39] A study from Pakistan showed that women's socio-demographic status was strongly associated with their choice of delivery, where high social class women tended to opt for C-section at the rate of 35.3%, as compared to low social class women at 5.5%.[40] In addition, in this same study, educated women chose C-section at a higher rate of 40.3%, as compared to uneducated women at 7.3%. Thus, there is a knowledge gap among women about choice of delivery irrespective of their education level. Various training programs have been conducted to improve women's decision making capacity, by reducing their fear during delivery and by helping them understand their autonomy of choice on the mode of delivery.[41–45]

Situation in India

According to the 2005-2006 National Family Health Survey (NFHS), C-section accounted for 8.5% of all deliveries in India.[46] In 2015-2016, the proportion increased two-fold, reaching 17.2%.[46] There was also an increase in the proportion of C-section in the private sector from 27.7% (2005) to 40.9% (2016).[46] India also faces inter-state variations in the rates of C-section between 5.9% in the state of Nagaland to 58% in the state of Telangana.[47] Some of these differences could be explained by socio-economic status, demographic variations, and accessibility to healthcare.[48]

People in India are still influenced by superstitious beliefs, compelling them to choose the time and date of their child's birth, thus favoring private health care facilities which allow delivery through elective C-section.[49] Young girls and pregnant women believe that vaginal delivery is painful and are scared ofit.[2,50] There is varying degree of ignorance among patients to choose C-section over VD.[50,51] Physicians do not explain the options available for delivery and their consequences for women and newborns. Due to lack of proper awareness among women and their families, as well as a paternalistic approach to physicians decision making for C-section (doctors make the decisions for the mother and her family), there is an overuse of C-section intervention without any medical indication.[36]

Consequently there is over consumption of hospital amenities for obstetric services (for example, unnecessary hospital stay, medicines, nursing care).[19] It poses extra-burden on the family to cover the additional delivery related charges, eventually leading to financial constraints.[52] In 2012, a study using data from DLHS-3 (2005-2006) demonstrated the mean out-of-pocket expenses across India, which reported that the average cost for vaginal delivery was 1,624 rupees in public and 4,458 rupees in private institutions.[52] The cost was nearly triple for C-section, at 5,935 rupees and 14,276 rupees in public and private institutions, respectively.[52]

There is a huge knowledge gap among people, which tends to increase medicalization in their choice of delivery. Education training programs have proved to improve the decision making process and combat the fear among women regarding the process of childbirth.[53–55] Therefore, it is important as a public health professional to support evidence based decision making and empower women to make informed decisions regarding the mode of delivery.

Appraisal of different strategies: Measures for controlling C-section rates

The alarming raise in C-section rates prompted many countries across the world to start implementing various measures to control it, such as setting up administrative controls to set back C-section rate, legal acts, physician guidelines, and antenatal quality improvements. However, their success in reduction of C-section remains dependent on each country's healthcare setting, its legislations and social norms. The US government took various policy interventions, such as the 'Hard-stop' policy intervention, to control elective deliveries (induction of delivery without any medical indication and C-sections) in 14 states of the US, which helped reduce the elective deliveries from 9.6% in 2007 to 4.3% in 2009.[56] In Ohio state in the US, the use of strict guidelines by physicians, patient education on effects of CS, and follow-up after delivery have decreased the rate of elective CS from 13% in January 2006 to 8% in August 2009.[57]

In a Chinese randomized study, an emotional management intervention based on a cognitive behavioral therapy including obstetrician and psychological therapy as well as counseling services to pregnant women, resulted in improved control of C-section rate.[41] In Canada, QUARISMA (Quality of Care, Obstetrics Risk Management, and Mode of Delivery) trials conducted regular audit checkups on C-section indications, with evidence based practice routines for the physicians and nurses in the intervention hospitals.[58] This showed small but significant reduction in C-section rates as compared to the control hospitals. In Australia, a psycho-social intervention by midwives via telephone to combat prenatal fear among pregnant women showed clinically significant results in reducing C-section.[44] Many face-to-face group and individual educational training programs during the prenatal period have resulted in a notable reduction in C-section rates and improved VD rates.[53,54,59] Educational training programs are needed in addition to policy interventions; the training programs have improved maternal knowledge and strengthened their decision making capacity on delivery modes.[59,60] There are many suggestions by literature in delivering effective and appropriate

educational content to mothers in different formats including brochures, videos, lectures or counseling sessions, in order to raise their knowledge on the pros and cons of each mode of delivery.[60–63]

Recommendations for a course of action

Health education is the core solution to control the unnecessary use of medical resources and safeguard people from financial and adverse health outcomes.[64] In this context, many countries have tried to educate pregnant women, their husbands, and physicians in an effort to control C-section rates.[56,65,66] An Iranian trial study reported significant results in reducing elective C-section among residents of Isfahan by educating husbands of pregnant women.[65] A 2016 prospective study from Punjab, India, postulated that empowering pregnant women and their husbands could aid in their positive decision making power towards the choice of delivery.[67] A Knowledge Attitude and Practice (KAP) study from Nagpur, India, reported a lack of knowledge on different modes of delivery among women.[51] Though many women were aware of the C-section option, they failed to understand the risks and benefits associated with it.

The population for the proposed study includes pregnant women without previous history and current risk for C-section, currently in their second trimester (13-28weeks) irrespective of their parity status, coming for their antenatal visit in the selected 12 hospitals of Kanyakumari district. The grounds for selecting this district is the high rate of institutional births (91.3%) and high rate of C-section (51.3%), as compared to other districts of the same state[47], or the statewide C-section rate of 34% in Tamil Nadu.[47] In Kanyakumari district, the percent of women contacting for their antenatal care at first trimester is only 52.4% and those having at least four or more antenatal visits is 81.5%.[68]

There is no standardized delivery pricing in the country. It is different between the public and private sectors.[52] The Government is yet to establish a regulation to control and mandate the physician's role in avoiding elective C-sections and encouraging VDs.[69]

METHODOLOGY

Conceptual framework:

The conceptual framework for the proposed study is the Health Belief Model (HBM)[70]

(Appendix 1). There are different factors affecting a mother's decision on choice of delivery mode. Social, psychological and clinical factors and her desire for labor have an influence on women's decision regarding the mode of delivery.[71,72] Other factors include previous birth experience, potential complications, and worries over the wellbeing and security of the mother and child.[73] Therefore, the implementation of the project will focus on the behavioral aspect of pregnant women, knowledge, attitudes and factors controlling their preference of mode of delivery.

The HBM can determine the connection between wellbeing related convictions and maternal practices, which can help in foreseeing the likelihood of picking a specific method of delivery. It constitutes the below mentioned five constructs.

Perceived susceptibility and severity (perceived threat) is related to pregnant women's belief that they would face difficulties during delivery. For example, a negative involvement in a past delivery experience or misleading information from close community could influence her inclination for a specific mode of delivery, because of the conviction that the negative involvement could happen to her.[62]

A *perceived benefit* of a specific mode of delivery by pregnant women could motivate women to change their behavior. For example, if women consider VD safer and cheaper than

C-section they might want to opt for VD; if they think C-section is safer and can prevent adverse health events, then they might request for an elective C-section.[49]

Perceived barriers allude to a women's view of the troubles preventing her from having a particular mode of delivery.

Cues to action focuses on role of health care professionals to build positive attitude and beliefs among women. Thus, conveying the women towards informed decision making in their choice of delivery.

Implementation Plan

The aim of the proposal is to provide pregnant women with a concise knowledge on delivery types (C-section and VD) and the advantages and disadvantages associated with each delivery method, through structured educational sessions. The educational training program will last two months in the intervention hospitals. The preliminary procedures for implementation will begin in January and last till end of February. This will include the planning and recruitment process of workers, obtaining hospital permissions and training program for nurses. In March, the selection process of study participants will start, along with baseline data collection. In April and May, the training of pregnant women will take place. By the end of May, immediately after the training, the post-test measurements will take place.

For the intervention, 12 hospitals, which provide obstetrical services in the administrative district of Kanyakumari and are willing to participate in the study will be selected during January and February, 2020. A random sampling of those hospitals into intervention (six) and control (six) groups will take place.

Then, the project team will select pregnant women who are eligible and willing to participate in the study from these selected hospitals in March, 2020. During the physician's consultation waiting hours, all pregnant women in their 2nd trimester of pregnancy appearing

for their antenatal visit in selected hospitals will be invited for refreshments. The nurses will navigate the interested participants to the respective hall. Women will be provided with a consent form and those interested in the study will be recruited. In addition, a journal form (attached as *Appendix 2*) will be maintained for calculating the refusal rate of participation in the study population. In case of agreement to participate, they will be requested to fill in the baseline questionnaire for data on demographics, knowledge, attitude, and planned behavior (self-efficacy) on modes of delivery. Their unique identification number will be noted for the post-test evaluation. Also, they will be requested to have a flexible accompanier during their next visits, who may stay in a separate room during the training days. The accompanying person will be led by the peons to a separate room with refreshments and pamphlet containing the summary of day-events and learning materials. Pregnant women will be requested to appear for the training program twice a month (starting from their next antenatal visit) until they complete the four sessions. Each participating woman will be specifically informed to visit during the allotted time and date prepared in accordance with their schedule of antenatal visits. A maximum of 12 participants will be included in one session. The same session will be repeated for all participants.

Third, the educational program will be provided in the intervention hospitals only in April and May 2020. There will be two educational sessions per month; overall, four sessions during the months of April and May. Each session will last approximately two hours. This type of weekly educational sessions strategy has been proved in a previous study to show significant results in raising knowledge of pregnant women during their antenatal period.[42] Each session contains a combination of different modes of educational formats (recommended for pregnant women from a previous study for effective antenatal training) such as face to face counseling, group lectures, role plays, videos, and brochure distribution by the end of the session.[62] These formats will incorporate fear management skills, yoga and

breathing practices, delivery ward visit by pregnant women, physician - patient relationships, self-efficacy building skills for women, and having positive attitude towards pregnancy.[41,42,44,74,75] Midwives and nurses will lead the session with interactive learning methods. In between the sessions, the participants will receive breaks and refreshments.[76] These strategies make the audience more attentive and allow them to grasp all the information provided.[55,66] Educational health counselors will provide individual counseling sessions to those participants who request. The participants will be informed about the availability of counseling services at the hospitals until the end of their pregnancy. Those participants who are perceived to be in a state of anxiety with low self-efficacy will be encouraged to contact the counseling team. Each training session will last around two hours. By the end of the session, the participant will be given an approximately fourteen page brochure.[77] This will contain a summary of the entire session's materials. This will aid them to effectively review the information until the next session. All selected participants will be informed about their succeeding ante-natal visits and the training sessions in April and May. Following their last educational session in May, immediate post-test assessment will commence on the same day.

The inclusion criteria for the study include: women currently in their second trimester (13-28 weeks) of pregnancy, irrespective of parity status, appearing for their antenatal checkup in the selected hospitals of Kanyakumari district of Tamil Nadu, India in March, 2020.

The exclusion criteria include: having pre-existing medical conditions such as contracted pelvis, diabetes, genetic conditions, history of hypertension and present or past medical condition indicating C-section will not be considered eligible for the study.[78]

The preliminary setup procedures are as follows, the program begins by obtaining permission letters from the hospitals and partnering with the local Non-Governmental Organization (NGO) named 'Swadhina'.[79] As they are aware of the local context and population, it will be

helpful in hiring health experts (gynecologist, obstetricians), nurses and midwives. They will also provide them with background information on the program. The NGO will also assist the student researcher in printing educational materials, transport services, providing places for meetings and in arranging refreshments. The student researcher, along with the health experts will start the training of trainers (TOT) program. The trainers' include both midwives and nurses with at least one year of professional experience. This will last for one month before the participant recruitment. These trained nurses will also perform role-plays (for example, how to facilitate and lead a lecture) during their training session. This will be done to make sure that they have learned the concepts taught during their training process and are able to share their experiences and give suggestions to achieve good communication with the participants of the program.

The midwives and nurses will also be trained to strengthen their patient communication and counseling skills, so that they could convey the educational materials to pregnant women without any flaws or difficulties. Their training will be based on recommendation of the American College of Obstetrics & Gynecology (ACOG) and Society of Maternal & Fetal Medicine(SMFM).[80] The WHO recommendations on antenatal care on 'positive pregnancy experience' will also be followed during the training program to improve the pregnant women's decision making process.[78]

There will be videos, lectures, decision aid booklets, and interactive counseling sessions on reducing the anxiety surrounding labor pain and emotional management. Each session will include a video session, a lecture, and a role-play performance; in addition those with perceived higher fear and low self-efficacy will have individual counseling. Women will be informed about the availability of free counseling services any time until the end of pregnancy. Each activity will be limited to 20 minutes, which is considered to be the 'attention span limit' for any audience.[81] This will build effective listening and attentive

capacity of the audience. The whole session will accumulate information about the benefits of VD, dieting and exercise practices (as per WHO recommendation: nutrition and physical activity intervention for positive pregnancy experience)[74], indications for C-section, risks and benefits of VD and C-section, differences in hospital expenses, and emotional fear management.[41,74,80] At the end of each session, the participants will be given a brochure that will summarize the topics covered during the entire session. The control group will receive usual antenatal care and by end of post-test both groups will receive breast feeding promotion brochures. The existing literature suggests that the proposed training sessions can empower women's decision making ability in deciding mode of delivery[62,63,74,82] and improve their knowledge on different modes of delivery.[50,54,62]

The health experts and researcher will create educational training materials such as pamphlets, video and lecture sessions, and decision-making booklets, adapted to local customs, for the intervention group. In addition, a separate brochure containing only breastfeeding benefits will also be created for the participants in the control group.

Evaluation Plan

The study evaluation will include all the intervention (six) and control (six) hospitals. For selecting the hospitals, random sampling will be used from the list provided at Kanyakumari district hospitals directory.[83] The study population for evaluation will include the same participants who have successfully completed pre-test and educational program in the intervention hospitals and all the eligible pregnant women from those selected control hospitals. The timeline for the evaluation phase begins from March 2020 and will last till October 2020. It includes baseline data collection (March), follow-up data collection after the educational intervention (May), and collection of data regarding type of delivery by the participants (October). Both the pre and post-test assessments will use the same questionnaires. The questionnaire is adopted from a previous study.[2] It includes questions

about knowledge and attitude on the mode of delivery by pregnant women. The data collection about socio-demographic characteristics of participants will be done through questions that were utilized in a previous similar study.[62,67] The questionnaire will be adapted to the study settings via forward and backward translations by two bilingual (English and Tamil) translators. The backward translated version will be compared with the original in English for corrections. In addition, the translated instrument will be pilot tested in a small group of participants from different hospitals. The interviewer will provide and collect the self-administered questionnaire to the participants and it will take around 25-30 minutes to complete it.

Evaluation questions:

1. After the implementation of the educational program in May 2020, will there be a 22% absolute higher knowledge score among the intervention group women as compared to the control group?[2]
2. By the end of October 2020, will the rate of CS be 14% relatively lower in the intervention group as compared to the control group?[1]

A quazi-experimental, non-equivalent control group design, pre-test and post-test, panel will be utilized for the evaluation. The Campbell and Stanley nomenclature for the study design is as follows:

GROUPS	PRETEST	INTERVENTION	POST TEST
Intervention	O	X	O
Control	O		O

This study design reduces time and resources compared to experimental designs. In addition, it would not be ethical to randomize pregnant women into the intervention and control groups.[84]

Variables:

Table 1 presents all the variables of the study. The main independent variable of interest is the presence or absence of the educational program. The primary dependent variable the delivery type (VD or C-section) for each woman.

The intervening variables are: knowledge score of the participants, attitude score of the participants, age, parity status, maternal occupation, economic status, maternal literacy, previous mode of delivery, health care providers current recommendation on the mode of delivery (a measure of cues to action) and obstetric complications during delivery.[61,85]

Baseline preference in mode of delivery by pregnant women will be compared with the post-test questionnaire. This will take place in both intervention and control groups. Also, their post-test preference of mode of delivery will be compared with the actual type of delivery from the hospitals obstetric records to be collected in October 2020 from both the intervention and control groups.

Sampling method

The sampling frame will include the names of all pregnant women meeting the eligibility criteria from the selected 12 hospitals. We will choose the sample for the project evaluation through simple random sampling.

Sample Size

The sample size for the proposed study is calculated using the standard deviation and mean knowledge score for comparison of two sample means.[2]

$N= (Z_{\alpha/2} + Z_{\beta})^2 * 2 * \sigma^2 / d^2$

Where, $Z_{\alpha/2} = 1.96$; $Z_{\beta} = 0.84$

$\sigma^2 = 1.84$ and $d = 0.22$

Therefore, the sample size after calculation is 597 (rounded to the nearest value) in each group. From the previous similar study, the response rate will be assumed to be 90%.[86] The final sample size = 597/0.9 = 663 (rounded to the nearest value). After considering the 6% attrition rate from a previous study,[42] the sample size is calculated to be 663/0.94= 705. Therefore, equal numbers will be selected from six intervention and six control hospitals.

Threats to Internal validity[84]

History may occur as a threat if during the course of the program the participants get exposed to other interventions. However, it is minimized with the presence of a control group. *Maturation* is a threat as with time the pregnant participants might learn more about delivery or change their opinion due to natural changes during the pregnancy. Having a comparison group helps to minimize this threat.

Testing is a threat as the data collection utilizes the same questionnaire at baseline and follow-up in a panel design. However, it is minimized with the presence of a comparison group.

Instrumentation will not be a significant threat because of utilization of the same questionnaire at baseline and follow-up and in the intervention and control groups. It is a self-administered questionnaire. However, the interviewers will be trained in order to answer any questions raised by the participants consistently.

Statistical regression is not a threat as the participants will not be selected because of their outlying characteristics related to the outcome variables.

Selection is a threat to internal validity as the intervention and control groups are not equivalent.

Experimental Mortality is a threat as at any time during the study program the participants may drop out of the study. The study team will compare the characteristics of those who drop out with those who remain in the study to understand the magnitude of this threat.

Compensatory rivalry is not a threat as the control and intervention groups will be selected from different hospitals from different geographical areas and will not be informed about the alternative group.

Selection-history is a threat as the participants in one group might react to other interventions differently because of their different characteristics.

Selection-maturation is a threat as the groups might mature differently during the evaluation.
Selection-testing might be a threat due to differential effects of the baseline measurement on the participants, which might alter the post test results in two groups differently.

Threats to External Validity[84]

Testing Treatment Interaction is a threat to external validity as the outcome variables might be influenced not only by the intervention but also by the baseline measurement. Hence, the intervention effects might not be generalizable to other settings where there are no baseline measurements.

Selection Treatment Interaction is a threat as the evaluated results might not be generalizable to other settings as pregnant women from other hospitals or settings might have different characteristics and the intervention might not lead to the same effects.

Reactive Effect might be a threat to external validity as the participants may change the way they answer the questions or their behavior because of participating in an evaluation; hence,

the results might not be generalizable to settings where the intervention is not being evaluated.

Multiple Treatment effects is a threat to external validity as the intervention group might be exposed to other interventions that might not be present in other settings making the findings from this evaluation less generalizable to other settings.

Questionnaire

The questionnaire for measuring the socio demographic characteristics and childbirth knowledge and attitude will be adopted from previous studies.[2,62,67,73,87] The socioeconomic status and education level will be assessed using validated Kuppuswamy scale.[88] Permission from the questionnaire source authors will be obtained before adaption. Field experts like health educators, obstetricians and midwifes will cross verify the questionnaire and their opinion will be obtained before and after translations. Forward (English to Tamil) and backward translation (Tamil to English) will be performed by two bilingual translators. The back-translated questionnaire will be compared with the original questionnaire in English for making corrections. The translated questionnaire will be pilot tested among a small group of 20 pregnant women from non-interventional hospitals. The study team will make improvements based on the pilot testing of the questionnaire. The socio-demographic characteristics will include questions on age, maternal occupation and education status, and monthly income status. In addition, questions regarding mother's parity status and previous mode of delivery are also included. It will be a self-administered questionnaire. It may take around 25-30 minutes to complete. The whole questionnaire contains 39 questions that are divided into four parts. The questionnaire is provided in *Appendix 3*.

Data entry and Analysis

Data entry and analysis are planned to take place in March to June, and October, 2020. Immediately after the collection of baseline and follow-up assessments, the data enterers will enter the data. The data on the mode of delivery, presence of any complications during pregnancy and delivery will be obtained from the hospital records (from the intervention and control hospitals). The research team will hire two data entry officers. The project team will train the data entry officers. Double data entry will be done using the SPSS (Statistical Package for the Social Sciences) software, after which the databases will be merged for cleaning.

Descriptive statistics will be performed to obtain the socio-demographic characteristics of the study population and the main variables of interest. Paired t-test will assess the significant difference in the attitude score in the intervention group before and after the educational program, set at a significance level of less than 0.05. Means and standard deviations will be summarized for all the continuous variables. Chi-square test for dichotomous outcome variable will be used in order to compare between baseline and follow-up or between the intervention and control groups. For the purpose of analysis, dummy variables will be created and coded as 0 and 1 for the VD and C-section respectively. A multi-variable logistic regression will be performed for assessing the association between the dependent and independent variables after adjusting for the intervening variables. As this kind of analysis helps in identification of various risk factors associated with dichotomous outcome variables of the study.

Timeline

The duration of the program is eleven months. In 2020, January and February, planning, setup procedures, obtaining hospital permissions, recruitment of personnel and assignment of schedules for TOT will take place. During March, selection of study participants and baseline data collection will take place. The training process will be organized in April and

May in the selected intervention hospitals. The date and timing for the training sessions will correspond to the hospitals' average appointments for obstetric care. By the end of May 2020, follow-up measurements will take place, immediately after the completion of the educational program. The actual type of delivery by the study participants will be assessed in October 2020. The data analysis and report writing will be finalized in November, 2020. In May, immediately after collecting follow-up data, the data entry process will start. The evaluation of the objective concerning the rate of C-section in the intervention and control groups is time dependent (as the delivery dates of the participants may vary with time). Therefore, it will be performed five months after the implementation of the educational program, in October 2020 as by this time all the participants will deliver the babies.

Thus, their preference of choice could be compared to the actual obstetric delivery type. The final data analysis and report preparation will be completed in November, 2020. The project timeline is summarized in *Appendix 4*.

BUDGET

The budget for the proposed study during the study period of January - November 2020, is formulated considering the personnel and other direct costs. The budget items for "personnel costs" include salaries of research team members such as project investigator, health experts, nurses, midwives and consultants. The "other direct cost" item includes the cost of printing, papers, transport allowances, office room rentals and other supplies. The guidelines from the Indian Council of Medical Research (ICMR) were used for estimating the short term research projects' staff salaries and allowances.[89] The budget estimate is included in *Appendix 5*.

ETHICAL CONSIDERATION

The proposal will receive approval from the Institutional Review Board of the American University of Armenia. The study team will obtain approval from the Kanyakumari district

health and family welfare department'sdirector. The participants will be provided with a written informed consent forms. The consent forms will include the details about the evaluation of the intervention, its setting, the voluntary basis of participation and the participant's rights to withdraw from the study at any time (*Appendix 6*). The participants will be assured about confidentiality of the data collected for the study purpose and secured maintenance of their personal and medical information within the research team. All the data's are secured separately in password allotted systems. It is authorized only by the research team. Local support will be obtained through the NGO called Swadhina and trust will be built with the participants through opinion leaders.

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Table 1: Variables

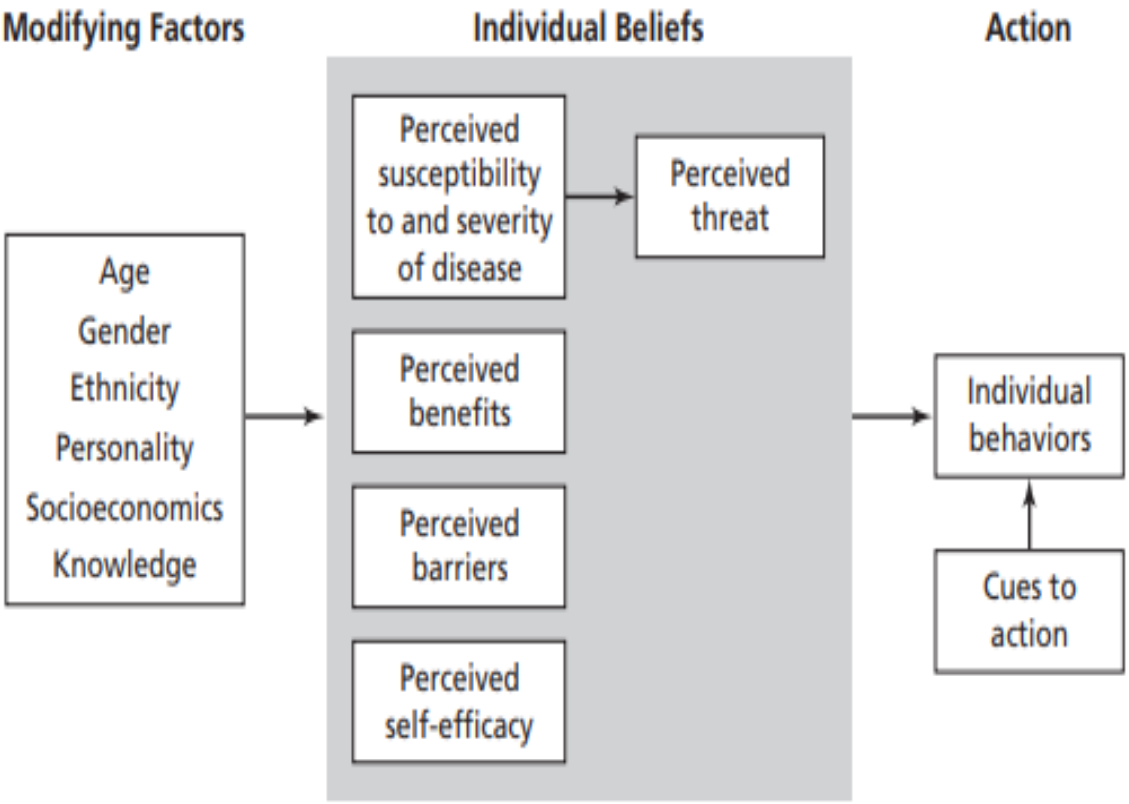
Variables	**Type of the variable**	**Measurement of the variables**	**Sources for the variables**
Dependent: Delivery type	Dichotomous	VD or CS	Hospitals obstetrics records
Independent Presence or absence of the program	Dichotomous	Presence or absence of the educational program	Group assignments
Intervening: Attitude score about modes of delivery	Numeric	Attitude scores	Questionnaire
Knowledge score about modes of delivery	Numeric	Knowledge scores	Questionnaire
Women's current preference on modes of delivery	Dichotomous	VD vs. C-section	Questionnaire
Cues to action: Health care providers current recommendation on modes of delivery	Dichotomous	VD Vs. C-section	Questionnaire

Maternal education	Ordinal	-Profession or Honors -Graduate -Intermediate or diploma -High school certificate -Middle school certificate -Primary school certificate -Illiterate	Questionnaire
Maternal age	Numeric	in years	Questionnaire
Maternal occupation	Dichotomous	Employed vs. Unemployed	Questionnaire
Parity status	Numeric	number of …	Questionnaire
Previous mode of delivery	Dichotomous	VD vs. CS	Questionnaire
Medical complications developed during the delivery	Dichotomous	Yes Vs. No	Hospitals obstetric record

Socio-economic status	Ordinal	-Upper -Upper middle -Lower middle -Upper lower -Lower	Questionnaire

APPENDIX

Appendix 1*: Conceptual model* - Health Belief Model: constructs and their links.[70]



Appendix 2: Journal form

#	Eligible Participant's Name	Age	Obstetric Id no	Hospital Type - I/C (Intervention/Control)	Baseline		Follow-up	
					Date	Result code**	Date	Result code**
001								
002								
003								
004								
005								

****Result Code:**

1 - Successfully completed the survey

2 - Refusal to participate from beginning

3 - Not eligible

4 - Refusal to participate in the follow-up

5 - Incomplete interview

6 – Lost to follow-up

Appendix 3*: Questionnaire*

(99 for 'refusal' to answer any question, 0 for missing values)

Participant ID number: [ ]

Day/month/year: [____ / ____ /_____]

Part-1: Questions related to maternal knowledge about the mode of delivery

Instructions: From your knowledge, please select the most appropriate answer with a (✓) mark:

1. Cesarean delivery is less painful
    a) True
    b) False
2. Cesarean delivery results in more maternal complication
    a) True
    b) False
3. Cesarean delivery has higher infection risk than vaginal delivery
    a) True
    b) False
4. Emotional relationship between mother and baby after vaginal delivery is better
    a) True
    b) False
5. Infants born by cesarean section are smarter compared with those born by vaginal delivery
    a) True
    b) False

6. Infants bone fractures is impossible in cesarean section

    a) True

    b) False

7. It is reasonable to request Cesarean section again for the next delivery after the first cesarean section

    a) True

    b) False

8. Respiratory disorders in infants born by Cesarean section is less than vaginal delivery

    a) True

    b) False

9. Hemorrhage after cesarean delivery is less likely than vaginal delivery

    a) True

    b) False

10. Cesarean delivery is reasonable when the baby is in breech presentation

    a) True

    b) False

Part-2: Statements related with the attitude towards vaginal delivery and cesarean section

Instructions: Please rate the following statements in regard to your degree of agreement from 1 to 5 with a (✓) mark:

Statements:	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
11. Vaginal delivery is a natural and acceptable method	1	2	3	4	5
12. It is pleasant for a mother to see her baby immediately after the birth	1	2	3	4	5
13. The mother recovers sooner after vaginal delivery	1	2	3	4	5
14. Emotional relationship between mother and the infant is better after vaginal delivery	1	2	3	4	5
15. Because of anesthesia, vaginal delivery is much better	1	2	3	4	5
16. Vaginal delivery is much better in long term	1	2	3	4	5
17. I prefer vaginal delivery because I don't like the scars of surgery on my abdomen	1	2	3	4	5
18. Vaginal delivery is less risky for the mother	1	2	3	4	5
19. If there is no financial problem, CS is much better	1	2	3	4	5
20. I prefer CS because I don't like mother's position on the gynecology bed	1	2	3	4	5
21. I prefer CS because it is less painful than vaginal delivery	1	2	3	4	5

22. Infants born by CS are healthier than those born by vaginal delivery	1	2	3	4	5
23. If there is an intention for tubal ligation, CS is much better	1	2	3	4	5
24. CS prevents uterine and bladder prolapsed	1	2	3	4	5
25. CS prevents deformation and malformation of female genital tract	1	2	3	4	5
26. Vaginal delivery has lower risk for the mother	1	2	3	4	5
27. If I knew CS complications, I would never request CS	1	2	3	4	5
28. If I knew CS complications, I would request CS again	1	2	3	4	5
29. I believe that a mother should have her own right to request CS	1	2	3	4	5
30. I believe that CS should be done when vaginal delivery is risky	1	2	3	4	5

Part-3: Questions related to participants socio-demographic status

Instructions: Please choose the most appropriate answer with a (✓) mark:

31. What is your present Age (in Years) at this point of Interview? Please mention it in below given blank.

    _____

32. What is your present level of education?

    a) Profession or Honors

    b) Graduate

    c) Intermediate or diploma

d) High school certificate

e) Middle school certificate

f) Primary school certificate

g) Illiterate

33. What is your employment status?

a) Employed

b) Unemployed

c) Student

34. What is your known parity status?

a) First pregnancy

b) One live birth

c) More than 2 live births

35. What is your choice of mode of delivery?

a) Vaginal delivery

b) Cesarean section

36. Did you receive any suggestion on modes of delivery (Cesarean section or vaginal delivery) by your healthcare provider? If yes, please specify it by giving a tick.

c) Yes, 1. Vaginal 2. Cesarean section

d) No

Part-4: Questions related to participants socioeconomic status.

Instructions: Please choose the most appropriate answer with a (✓) mark:

37. Please select the occupation of the head of the family from the below mentioned options.

	Occupation name	**Tick here(✓)**
a)	Legislators, Senior Officials & Managers	
b)	Professionals	
c)	Technicians and Associate Professionals	
d)	Clerks	
e)	Skilled Workers and Shop & Market Sales Workers	
f)	Skilled Agricultural & Fishery Workers	
g)	Craft & Related Trade Workers	
h)	Plant & Machine Operators and Assemblers	
i)	Elementary Occupation	
j)	Unemployed	

38. Please select the education of head of the family from the below mentioned options.

	Education of Head of family	**Tick here(✓)**
a)	Profession or Honors	
b)	Graduate	
c)	Intermediate or diploma	
d)	High school certificate	

e)	Middle school certificate	
f)	Primary school certificate	
g)	Illiterate	

39. Please select approximate total monthly income of your family from below mentioned options.

	Monthly Family Income in Rupees	**Tick here(✓)**
a)	≥ 78,063 INR	
b)	39,033–78,062 INR	
c)	29,200 –39,032 INR	
d)	19,516–29,199 INR	
e)	11,708–19,515 INR	
f)	3,908–11,707 INR	
g)	≤ 3,907 INR	

Thank you for your participating.

Appendix 4*: Timeline for the Proposed Study*

Year2018	**Jan**	**Feb**	**Mar**	**Apr**	**May**	**Jun**	**Jul**	**Aug**	**Sep**	**Oct**	**Nov**
Activities	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**
Planning	X										
Setups and Recruitments	X										
Permissions from hospitals	X	X									
TOT implementation		X									
Baseline selection of participants			X								
Pretest assessment			X								
Educational program – Videos + lectures+ counseling+ pamphlets				X							
Educational program- Videos+ role plays+ counseling+ pamphlets					X						

Post-test assessment					X	X					
Audits at end of every month	X										
Analysis & data entry			X	X	X	X			X	X	
Final report preparation & submission									X	X	X

Appendix 5: Budget Estimate

Personal Costs:

Budget item	Type of appointments	Number of units	Amount (INR)	Total(INR)/ (Approximately USD)
Project Investigator	Fixed monthly	For 10 months	INR31,000 per month	INR310,000/ USD4,338.09
Health experts	Fixed for developing each educational material	2 (Total number of expert) -2 Videos -2 brochure -2 lectures Total: 6 items	INR5,300 per item - INR(5,300*6 items)	INR31,800/ USD445
Trainers (nurses & midwives)	Fixed for whole implementation educational sessions	6 (nurses and midwives) - 4 session * 6 intervention hospitals only	INR9,300 per person/session - INR(9,300* 4 sessions* 6)	INR 223,200/ USD3,172.90
Health Counselors	Fixed monthly	3 counselors - 2 months * 6 intervention hospitals only	INR60,000 per counselor - INR(60,000*3 * 2 months)	INR 360,000/ USD5,037.78

Supporting staff - Data entry, cleaning and analyst	a) Fixed per questionnaire entry b) Fixed monthly	a) Entry -2 b) Analyst – 1 (486 questionnaire for both baseline and follow-up)	a) INR140 per questionnaire b) INR17,000 per month	a) INR486*140 = INR 68,040 b) 2*17,000= INR34,000 Total = INR 102,040/ USD1,427.93
Supporting Staff - Interviewers	Fixed for every complete questionnaire during baseline and follow-up	6 (Total number of staffs) (3- intervention hospital and 3control hospital)	INR125 per questionnaire	INR125*243= INR30,375 Total= 2*30,375 = INR60,750/ USD850.13
				Total personal cost= INR1,087,790/ USD15,463.48

Administrative and other cost:

Budget item	**Type of appointments**	**Number of units**	**Amount (INR)**	**Total(INR), (USD)**
General support staff -Peons, office assistance	Fixed monthly	a)3 nos. for intervention b) 1 nos. for control hospital	INR15,800	a) INR15,800*3= INR47,400 b) INR15,800*1= INR 15,800 Total= INR 63,200/ USD884.41
Transports compensation along with driver allowance	Fixed per day	10 months	INR1500 per day - INR (1500*10*30days)	Approximately INR 450,000/ USD6,297.23
Office room rent	Fixed monthly	10 months - 1 room	INR10,000 per room - INR (10,000 * 1 room*10 months)	INR 100,000/ USD1,399.3
Water, internet, telephone, electricity and other supplies	Fixed monthly	10 months	NA	Approximately INR 200,000/ USD2,798.77
Printing cost and paper bundles	As per requirements	INR 350 per bundle INR 10 per print	NA	Approximately INR35,000/ USD489.78
				Total cost: INR 813,200/ USD11,379.79

Appendix 6*:* Informed Consent Forms

(For the intervention group)

American University of Armenia

Institutional Review Board#1

Women's knowledge on cesarean section and vaginal delivery in the Kanyakumari district of Tamil Nadu, India

Hello! I am _____. We are implementing an educational program on cesarean section and vaginal delivery in the Kanyakumari district of Tamil Nadu, India. Our aim is to improve knowledge levels and positive attitudes towards the natural mode of delivery. I will try my best to explain the program to you. If anything is unclear, please let me know and I will clarify it for you.

You have been approached because you are in your second trimester of pregnancy, do not have any medical ailments in your history, and reside in Kanyakumari. Approximately 250 pregnant women will be approached and included in this program. Allow me to explain the details to you.

We are going to implement an educational program in 12 hospitals of the Kanyakumari district. These hospitals have been randomly equally divided into intervention and control group hospital. As your hospital is already included in the ***intervention*** group you too will be selected into this group. Your participation is purely voluntary and refusal to participate or withdrawing during implementation will not have any consequences to you. However, we strongly encourage you to take part, as both you and your child will benefit from the information provided to you. If you agree to participate, I will be asking you certain questions regarding your knowledge and attitude towards modes of delivery, as well as a few questions regarding your socio-demographics. It will take only around 25-30 minutes for you

to fill these questions. I would then like to invite you to attend 4 training programs during your next 2 antenatal visits and after two weeks following each visit, where you will learn about the modes of delivery, their pros and cons, how to manage yourself efficiently during your pregnancy period, and to combat your fear about pregnancy and delivery. By the end of training program, once again you will be asked to fill a questionnaire which will take around 15 -20 minutes (as a follow-up measure). All the personal information (your name, obstetric Id and details) is treated very confidential and private. The results of the interviews and trainings will be summarized in a single report. Not only will you gain knowledge about pregnancy, but your participation in our study is also very valuable as it will help other women who want to have a cost efficient and best delivery experience.

The training will take place in your respected hospitals in a separate room. We will be obliged to give you as much information via videos, lectures and individual sessions. Each session will last an hour. Note that your participation will not affect your delivery process or the services provided to you by any means. This study is only intended to raise your knowledge on cesarean section and vaginal delivery, help your efficient decision making process, and relieve you of your pregnancy-related fears.

For any further questions regarding the study, you could contact the project's principal investigator Dr. Varduhi Petrosyan (vpetrosi@aua.am). If you think you have not been treated fairly or feel troubled by any means, you could contact Varduhi Hayrumyan, the Human Participants Protections Administrator of the American University of Armenia (auairb@aua.am).

Do you agree to participate? If yes, can we continue?

Thank you for your valuable time.

(For the control group)

American University of Armenia

Institutional Review Board#1

Women's knowledge on cesarean section and vaginal delivery in the Kanyakumari district of Tamil Nadu, India

Hello! I am _____. We are implementing an educational program on cesarean section and vaginal delivery in the Kanyakumari district of Tamil Nadu, India. Our aim is to improve knowledge levels and positive attitudes towards the natural mode of delivery. I will try my best to explain the program to you. If anything is unclear, please let me know and I will clarify it for you.

You have been approached because you are in your second trimester of pregnancy, do not have any medical ailments in your history, and reside in Kanyakumari. Approximately 250 pregnant women will be approached and included in this program. Allow me to explain the details to you.

We are going to implement an educational program in 12 hospitals of the Kanyakumari district. These hospitals have been randomly equally divided into intervention and control group hospital. As your hospital is already included in the ***control*** group you too will be selected into this group. Your valuable time in filling our survey questionnaire is purely voluntary and refusal to participate or withdrawing during implementation will not have any consequences to you. However, we strongly encourage you to take part in this survey, as both you and your child will benefit from the information provided to you. If you agree to participate, I will be asking you certain questions regarding your knowledge and attitude towards modes of delivery, as well as a few questions regarding your socio-demographics. It will take only around 25-30 minutes for you to fill these questions. After 2 months from

now, you will be again contacted by our research team for a follow-up survey questionnaire filling. This will take only 15- 20 minutes. All the personal information (your name, obstetric Id and details) is treated very confidential and private. The results of the interviews and trainings will be summarized in a single report. Not only will you gain knowledge about breastfeeding, but your participation in our study is also very valuable as it will help other women who want to have a cost efficient and best delivery experience.

For any further questions regarding the study, you could contact the project's principal investigator Dr. Varduhi Petrosyan (vpetrosi@aua.am). If you think you have not been treated fairly or feel troubled by any means, you could contact Varduhi Hayrumyan, the Human Participants Protections Administrator of the American University of Armenia (auairb@aua.am).

Do you agree to participate? If yes, can we continue?

Thank you for your valuable time.