“AWARENESS AND ACCEPTABILITY OF SCREENING FOR DOWN SYNDROME IN WOMEN ATTENDING THE ANTENATAL CLINIC AT KLE’S DR. PRABHAKAR KORE HOSPITAL & MRC, BELGAUM”

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ABBREVIATIONS

ACOG - American College of Obstetricians and Gynaecologists

AFP – α-fetoprotein

APL – Above Poverty Line

BPL – Below Poverty Line

cfDNA – Cell Free Deoxyribonucleic Acid

CG – Chorionic Gonadotropin

CVS – Chorionic Villus Sampling

DNA – Deoxyribonucleic Acid

DR – Detection Rate

DS – Down Syndrome

DV – Ductus Venosus

uE3 – Unconjugated Oestriol

hCg – Human Chorionic Gonadotropin

ISPD – International Society for Prenatal Diagnosis

PAPP-A – Pregnancy associated plasma protein A

POG – Period of Gestation

PPV – Positive predictive value

NB – Nasal Bone

NBL – Nasal Bone Length

NF – Nuchal Fold Thickness

NIPT – Non Invasive Prenatal Testing

NT – Nuchal Translucency

MoM – Multiple of Median

MR – Mental Retardation

PT – Prenasal Thickness

SD – Standard Deviation

ABSTRACT

BACKGROUND AND OBJECTIVES

Down syndrome is the leading genetic cause of intellectual disability. Prenatal screening is now an established part of routine antenatal care in developed countries. It not only gives the parents the chance to prepare psychologically, socially, financially and medically for a baby with a disability but also gives the couple the chance to abort a foetus with the diagnosed condition. In India, unlike the western world, prenatal diagnosis had not yet gained the level of awareness and acceptance that it should have and this study was designed to evaluate the awareness in women regarding prenatal screening for Down Syndrome and to promote its acceptance in them.

METHODOLOGY

This one year prospective descriptional study was conducted in the Antenatal Clinic at KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum during the period of September 2014 to August 2015. A total of 502 pregnant women under 23 weeks period of gestation were recruited for the study and data was obtained through a questionnaire regarding their knowledge about the screening techniques for Down Syndrome. The women were then extensively counselled regarding the different methods and timings of screening for Down syndrome, and were offered a screening test according to their period of gestation. The acceptance and attitude of the women towards the offered test was analyzed.

RESULTS

Majority of the study population (93%) had no prior knowledge about the screening methods for down syndrome. Acceptance was maximum for NT scan (99%), and lesser for biochemical markers (94% for dual markers and 63% for quadruple markers). Over all acceptance was 76% and the acceptability rate was 76.09%. Majority of the study population (43%) cited non affordability as the reason for declining the offered test. Majority of the pregnant women (88%) had a positive attitude towards prenatal screening.

CONCLUSION

There is a lack of awareness regarding Down syndrome screening among women especially regarding various tests and their availability. There is a need for a systematic informing, counseling and guiding pregnant women about the availability, implications and limitations of the screening tests. Implementation of a standardized and comprehensive policy which makes prenatal screening a routine part of antenatal care can play a key role in easing the substantial economic burden incurred by families as a result of caring for a child with disabilities.

KEYWORDS

Down syndrome, Prenatal screening, Awareness, Acceptability, Attitude

TABLE OF CONTENTS

LIST OF TABLES

LIST OF GRAPHS

LIST OF PHOTOGRAPHS

INTRODUCTION

Down syndrome (DS) is the leading genetic cause of intellectual disability, with an estimated prevalence rate of 8.27 per 1,000. [1] There are various features occurring in all DS population, including learning disabilities, craniofacial abnormality and hypotonia in early infancy.[2] They have a variety of physical characteristics like a small chin, slanted eye, poor muscle tone, a flat nasal bridge, a single crease of the palm and a protruding tongue due to small mouth and large tongue.[3]

Evidence in literature indicates that the financial burden incurred by the families parenting a child diagnosed with DS can be substantial, especially among families who care for a child with a severe disability.[4–12] Timely diagnosis not only gives the parents the chance to prepare psychologically, socially, financially and medically for a baby with DS but also gives the couple the chance to abort an affected foetus. Termination of an affected pregnancy can not only drastically reduce the economic burden but also the social and emotional stress incurred by the couple as a result of caring for a child with DS.

Keeping this in mind, in 2007, the American College of Obstetricians and Gynaecologists (ACOG) recommended that all pregnant women, regardless of their age, should be offered screening for DS. Those with high risk should be confirmed by an invasive diagnostic procedure like amniocentesis or chorionic villus sampling. [13]

Extensive review of literature indicates that Indian women continue to remain either oblivious to the existence of prenatal screening tests, or hesitant and apprehensive about undergoing the offered screening test despite being counseled extensively about the risks and the benefits.[14] Similar findings were observed in the women attending the antenatal clinic at our hospital. A lack of awareness among majority of the women was noted. There was also a deficiency of data available on the attitude of these women towards prenatal screening tests for DS.

Despite increased recognition of the importance of involving patients in medical decisions, consideration of patient attitudes and preferences is not currently employed to determine prenatal genetic screening policies, an area that is particularly value-laden and where such considerations are arguably the most important. [15]

Another assumption underlying much of the discussion surrounding prenatal genetic testing is that screening tests should focus on disorders for which women would elect to terminate their pregnancy or which are severe enough that termination of pregnancy is considered a reasonable option by the medical profession.[16] Whether the target population shares this assumption is unknown. While previous studies have retrospectively evaluated differences in the rate of termination of pregnancy for disorders of increased severity or those that include intellectual disability, few to no data exist on how women compare or value testing for different categories of conditions and whether they associate a desire for testing with an inclination toward termination for a given condition. [16]

There is a paramount need to study the women’s attitudes regarding prenatal genetic testing for DS, to assess their awareness and promote acceptability towards the same. Keeping these in mind, this study was designed not just to highlight the perspective of the pregnant women towards prenatal screening and their readiness to undergo the offered test, but also to analyze the reason for their declination. The data obtained would not only be valuable in streamlining the provision of screening tests as a part of basic antenatal care, but also help in the formulation of prenatal genetic screening policies at KLE'S Dr. Prabhakar Kore Charitable Hospital and Medical Research Centre, Belgaum.

OBJECTIVE

To evaluate the awareness in women regarding prenatal screening for Down syndrome and to promote its acceptance in them.

REVIEW OF LITERATURE

Every pregnant woman deserves to receive the best possible estimate of her risk for fetal chromosomal abnormalities. Keeping this in mind, prenatal screening has now become an established part of routine antenatal care in developed countries. Prenatal screening and diagnosis may have medical benefits but may also cause sustained parental psychological distress and elevated anxiety levels. Exploring the pregnant women's and their partner's, experiences of counselling and need for support during either termination or continued pregnancy following a prenatal diagnosis remains a major objective for obstetricians.

All approaches to risk assessment not just re-assure the pregnant women that their fetus is unlikely to be affected by a chromosomal disorder but also reduce the number of invasive procedures performed. It also helps in identifying those women at highest risk for an affected pregnancy. The women who are identified as being at elevated risk based on any of these screening options can further be subjected to counselling, additional testing and appropriate follow-up obstetric care.

Children with disabilities often require exceptional levels of care and related costs. Majority of children with disabilities are being cared for at their home, leaving families as the most important source of long-term care and assistance. [4–12] Literature reports troubling findings that uncover an association between low income and children with special needs such as those suffering from DS. [5] Timely prenatal screening can help in substantially easing this burden.

In 2011, a study done in Amsterdam, Netherlands aimed to determine the content of decision-relevant knowledge needed for informed decision-making about (non-) participation in prenatal screening for Down syndrome, in order to develop a knowledge questionnaire for routine application in large-scale programme evaluations. A generic list of content domains for knowledge about screening was extracted from the literature. Items reflecting specific knowledge domains were constructed. An expert group of professionals and pregnant women expressed whether domains and items represented decision-relevant information. All presented domains were scored as (very) important. Options when receiving an ‘increased probability for DS’ test result, the meaning of this result, the aim of the screening, and voluntary nature of the test were scored as most important. The condition being screened for, prevalence, and the screening procedure were scored as relatively less important. [17]

A prospective study done from 2004 to 2006 in Indore, Madhya Pradesh, aimed to summarize the experience of women regarding the decision making to undergo triple test for Down's syndrome screening and how many of them make use of the triple test and to evaluate its outcome. Of the 745 women included in the study, 106 (14.2%) were aware about triple test. Acceptability rate was 16.6% and most of them were those who were either aware of triple test or who had past or family history of congenital or chromosomal disorder. Those who accepted had an attitude of undergoing triple test in future pregnancy.[14]

A similar questionnaire based study done in Australia concluded that pregnant women need clearer information about prenatal testing, including the conditions that might be detected.[18] The majority of women preferred to have as much information available as possible so that an informed decision regarding further investigations could be made . [19]

Another prospective qualitative study done in 2014 in a tertiary foetal cardiology unit in Sweden on Six pregnant women and their partners, consecutively recruited after a prenatal diagnosis of an isolated and significant cardiac defect, aimed at assessing their experience of counseling and their need for support. It was concluded that the women and their partners valued a short waiting time from the first suspicion of fetal heart disease to final diagnosis and counseling, information in their native language, support from parents with similar experiences and continued contact with a specialist or a nurse.[20]

In the Indian obstetric population, most patients who pursue a prenatal diagnosis of chromosomal abnormalities choose to terminate pregnancies that are affected by autosomal trisomy. This is consistent with published data in other populations.[21] Over the past decade, the gestational ages at prenatal diagnosis and abortion for Down syndrome have declined significantly. Earlier abortion has lower rates of complications compared with abortion later in the second trimester. [22] Thus, changes in timing and methods of screening that lead to earlier prenatal diagnosis can have a significant impact.

A retrospective review done from 2005 to 2014 at Weill Medical College of Cornell University, New York of 213 cases that included 142 cases of Down syndrome (66.7%), 47 cases of Trisomy 18 (22.1%), and 24 cases of Trisomy 13 (11.3%) aimed at evaluating the changes in the timing of prenatal diagnosis and abortion for chromosomal abnormalities over the past 10 years. Two hundred one women (94.4%) chose to undergo abortion. The median gestational ages at prenatal diagnosis and abortion for Trisomy 18 or 13 were 12 weeks (interquartile range, 12–13 weeks) and 13 weeks (interquartile range, 12–15.5 weeks) and did not change over the study period. In contrast, in pregnancies with Down syndrome, the median gestational age at prenatal diagnosis (16, 13, and 12 weeks; $P < .001$) and abortion (17, 14, and 13 weeks; $P < .001$) both decreased significantly over the study intervals. In Down syndrome pregnancies, the proportion of women who underwent chorionic villus sampling significantly increased over the 3 study intervals (36%, 63%, and 86%; $P < .001$). It was concluded that since 2005, the gestational ages at prenatal diagnosis and abortion for Down syndrome have declined significantly. These changes are likely attributable to improvements in early screening that leads to higher rates of chorionic villus sampling. [23]

A review from the Swedish council on Technology Assessment in Health Care in 2006 concluded that women's knowledge often is insufficient to make informed decisions about prenatal diagnosis.[24] The main sources of information about DS were midwives or general practitioners. [25] A few studies have shown that many midwives and specialists in obstetrics have insufficient competence to inform expectant parents about DS screening [26] and desire more education in this area.[27] It is important to ensure that midwives in antenatal care have sufficient knowledge to inform expectant parents about the conditions screened for.

A cross-sectional, prospective study with a questionnaire was completed by 64 out of 70 midwives working in the outpatient antenatal care in Uppsala County, Sweden. The study aimed to investigate midwives' knowledge of prenatal diagnosis especially Down syndrome, information given by midwives to parents, expectant parents' requests for information and how midwives perceive their own competence to give information. It was concluded that the majority (83-89%) had insufficient or no education regarding different prenatal tests. Only 2 midwives (3%) had received education about Down syndrome and 10% felt they had sufficient knowledge to inform about the syndrome. More education about prenatal tests and Down syndrome was desired by 94%. [28]

The Royal College of Physicians proposed that prenatal testing services should be equally available to the whole community,[29] yet the provision of serum and ultrasound screening for Down syndrome is still dependent on individual health district policy. The result is an inconsistent service, and ‘public and professional confusion’.[30] In an attempt to address this, the UK National Screening Committee of the Department of Health has made recommendations to the Government, advising that prenatal screening for Down syndrome should be offered to all pregnant women regardless of their age.

While an equitable and consistent service is desirable, in practice, a ‘screening for all’ policy may have some psychosocial consequences worthy of consideration. When Down’s syndrome is detected, termination is the only available ‘treatment’, and over 90% of couples take this option. [31] It is now recognized that the psychological sequelae of abortion for fetal abnormality are frequently severe in the short-term and can extend for a number of years. [32] These sequelae include the grief which accompanies loss of all kinds, but in addition, many couples experience reduced biological and moral self-esteem, a perception of social isolation, and fear of censure by others.[32] There has been little systematic investigation of the factors predisposing some women to greater distress than others in this situation. However, the literature relating to abortion for non-medical reasons suggests that negative sequelae are more likely in women who are single; have no experience of bereavement; have no other children; experience ambivalence about their decision; perceive they are coerced into termination by significant others (partner, parents, health professionals); have unstable relationships with partner and parents; lack social and moral support from family and peers. [33] Very young women are most likely to fall into one or more of these categories, and youth itself consistently appears as a risk factor in predicting psychiatric morbidity following abortion. Some evidence suggests that following such therapeutic abortions, very young women experience coping difficulties more frequently than do older women. [34]

One such study reported that 100% of the women under 21 years felt unsure about their decision to abort in comparison to 30% of the women over 30. [34] White-van Mourik has suggested that that for very young couples, moral convictions are frequently more ‘black and white’, their self-esteem is often lower and their peers have less experience or interest in bereavement processes. [35] Young women also tend to lack assertiveness in their dealings with health professionals. They may be less likely to seek information than older women, and they may also be treated differently during antenatal care. White-van Mourik reported that the 16 to 20 year olds terminating for abnormality ‘complained of indifference and insensitivity’ in their treatment. [34]

A Finnish study investigating attitudes of pregnant women towards testing reported that those in the youngest age group (under 24 years) were most likely to say they would not terminate for abnormality: in practice however, younger women are not less likely to terminate once an abnormality is detected.[36]

Although the association between older mothers and risk of Down’s syndrome is well established, one-fifth of babies with the condition are actually born to women less than 25 years old. One almost inevitable result of a screening for all policy would be a greater number of therapeutic terminations being carried out in this younger age group. Women considering testing report that they have little real knowledge of Down's syndrome on which to base their decision. [37] The younger the woman, the less likely she is to have experience of individuals with the condition and their families. In addition, the limited time available once the screening result is received may be a compounding factor. Very young women often have a poor knowledge of prenatal screening, and may be more likely to accept tests presented as routine without considering what the outcome might be.[38] A longer, less fraught period for preparation and decision-making is available to women of advanced maternal age who are usually aware of their increased risk prior to pregnancy. Young women also tend to lack assertiveness in their dealings with health professionals. They may be less likely to seek information than older women, and they may also be treated differently during antenatal care.[34]

It is evident from the above observations that there is a deficit of awareness regarding DS screening among the general population, especially regarding the various methods and their availability. A systematic approach is needed, which aims at better informing and counseling the pregnant woman and her spouse about the implications and the limitations of DS screening.

Screening for fetal aneuploidy in pregnancy

The range of maternal serum biochemical and fetal ultrasound markers used for screening have well-documented efficacy in distinguishing between affected and unaffected pregnancies.[39] Each has validity within a specified time interval in pregnancy and should not be offered at an earlier or later gestational ages.[39]

Combination of markers is valid, provided the correlation between them has been taken into consideration in the risk calculation. [39]

First trimester screening

When multi-marker Down syndrome screening began, the focus was in the second trimester using: hCG or free β-hCG and AFP ("**Double**" test); plus uE_3 ("**Triple**" test); or both uE_3 and inhibin A ("**Quad**" test).[40] In recent years many developed countries have moved screening from the second to the first trimester using PAPP-A and either hCG or free β-hCG, together with NT ("**Combined**" test).[40] The advantages of the latter include earlier diagnosis, less traumatic and safer termination of pregnancy if requested, earlier reassurance, and better screening performance.[40]

NT is considered to be a particularly important marker because of the additional associations of large NT with cardiac defects and other serious fetal defects.[41] NT is performed between 11 to 13 weeks 6 days to facilitate optimal patient scheduling, because fetal anatomy is more clearly visualized and the screening performance is superior.[39] Increasingly, additional markers of Down syndrome assessed at the NT scan are being incorporated into the Combined test. Three are dichotomous: Absence of the fetal nasal bone (NB); tricuspid regurgitation; and absent or reversed ductus venosus (DV) blood flow.[40] The detection rate (DR) of NT Scan alone is 64-70% where as the detection rate of the combined test is 80 percent and the positive predictive value (PPV) is 29.[39]

Second trimester screening

In 1988, **triple test** was introduced as a screening test for DS. The triple test is usually performed at 15 to 18 weeks of gestation. In this test, three maternal serum markers [α-fetoprotein (AFP), chorionic gonadotropin (CG) and unconjugated oestriol (uE3)] are measured and used to modify the women's prior risk (based on her age) to yield a patient specific Down Syndrome risk. [42] The triple test can detect 60 percent of trisomy 21 pregnancies; it has a false positive rate of 5 percent. [43]

The **quadruple test** can be provided from 14 to 23 weeks gestation but 15-19 weeks is preferred because it is optimal for open neural tube screening.[39] Additional second trimester ultrasound markers can also improve aneuploidy screening. One approach is to measure three facial profile markers concurrently with the quadruple test. These facial profile markers are nuchal fold thickness (NF), nasal bone length (NBL) and prenasal thickness (PT).[39] The DR of the quadruple test is 64 percent and the PPV is 36.[39]

Sequential first and second trimester screening

Many women who receive a first trimester risk estimate that is intermediate between very high or moderately low risk may benefit from the provision of additional serum and ultrasound screening tests in the second trimester ('Contingent' screening) and this can be associated with highly effective screening.[39] The DR of the contingent screening is as high as 90 percent and the PPV is 26.[39] Protocols that include first and second trimester tests but only provide a risk figure after all screening tests are complete ('integrated' screening) are also associated with a high detection rate and low false-positive rate but it delays reassurance and/or restrict women's options in the first trimester.[39] The DR of the integrated screening is as high as 91 percent and the PPV is 26.[39]

METHODOLOGY

The study was conducted in the Antenatal Clinic at KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum during the period of September 2014 to August 2015

STUDY DESIGN – A prospective descriptional study

STUDY PERIOD – One year (1ST September 2014 to 31st August 2015)

SOURCE OF DATA – Pregnant women along with their spouse who attended the Antenatal Clinic at KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum

SELECTION CRITERIA

INCLUSION CRITERIA – All women who were less than 23 weeks period of gestation

EXCLUSION CRITERIA – Women who were not willing to participate in the study

ETHICAL CLEARANCE – Prior to the commencement, the study was approved by the Ethical and Research Committee, Jawaharlal Nehru Medical College, Belgaum (Annexure 3 - Letter number MDC/DOME/75 dated 06/12/2013)

INFORMED CONSENT – All the participants fulfilling the selection criteria were explained about the purpose of the study and a written informed consent in their own vernacular language was obtained from all the participants before enrolment

METHOD OF COLLECTION OF DATA

A questionnaire was developed consisting of 4 sections-

1) Participants demographic data
2) Knowledge about prenatal screening for Down syndrome
3) Readiness to undergo the offered screening test
4) Attitude regarding prenatal screening

After the enrolment in the study, the pregnant woman with their spouse were asked to answer questions in the first two sections of the questionnaire verbally, while the investigator noted down their answers in the proforma. All the interviews were conducted by the same investigator (the author).

The first section consisted of the participants' demographic data like the age, education status, socio economic status, obstetric score and past or family history of any congenital or chromosomal disorder.

The second section consisted of the participants' knowledge about prenatal screening of DS. **Knowledge was defined as the awareness of the patient regarding one or more screening test for DS.** The couple was questioned extensively about whether they were hearing about prenatal screening for DS for the first time or whether they knew about it from before, and if they knew, what was their knowledge regarding it and the source of the information.

The couple was then counseled extensively about DS, its social aspects, the modes of prenatal screening for DS and the gestational age at which they have to be done. The couple was offered a screening method according to their period of gestation.

- The women who were less than 11 weeks period of gestation were offered an **NT Scan** followed by a **Dual Marker Test**, however they were explained that the offered test would be done only when there were between 11 weeks to 13 weeks 6 days period of gestation.
- The women between 11 weeks to 13 weeks 6 days period of gestation were offered an **NT Scan** followed by **Dual Marker Test**.
- The women between 14 weeks to 15 weeks period of gestation were offered a **Quadruple Marker Test** after being explained that the test would only be done when they were between 15 to 23 weeks
- The women between 15 to 23 weeks period of gestation were offered **Quadruple Marker Test**.

The counseling session was conducted in a non directive way and the women were allowed to make a voluntary choice to either accept the offered screening test, or to decline it. The women were assured that their decision would in no way affect the present or future health care services offered to them at KLE Hospital.

The readiness of the woman to undergo the offered screening test for DS was documented by the investigator in the third section of the questionnaire and the in case the woman was not willing to undergo the offered test, the reason for declining the test was documented. **Acceptability was defined as the readiness of the pregnant woman to undergo the offered screening test, regardless of whether she actually undergoes the said test or not.**

The women were also asked about their attitude towards prenatal screening, and their answer was documented in the fourth section of their questionnaire.

STATISTICAL ANALYSIS

The data obtained was coded and entered into Microsoft Excel Worksheet. The categorical data was expressed in terms of percentage and continuous data was expressed as mean ± standard deviation (SD)

PHOTO 1: The investigator conducting a group counseling session were the women were offered a screening test according to their period of gestation

RESULTS

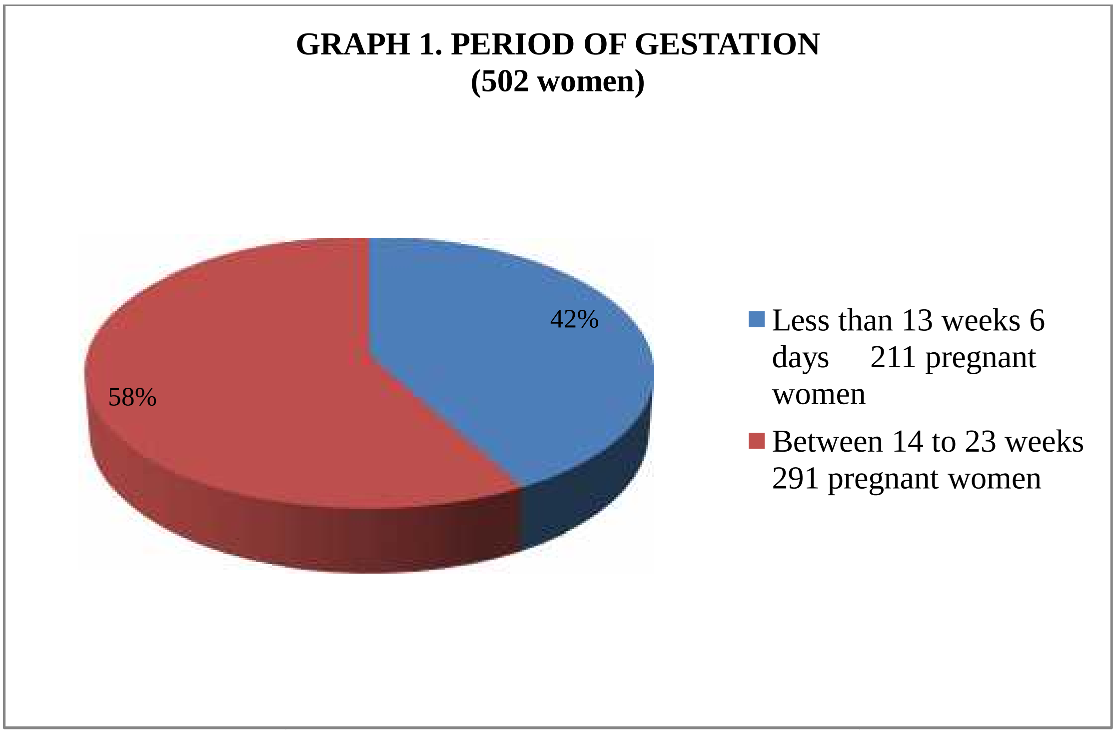
The present one year prospective descriptional study was conducted in the Antenatal Clinic of KLE'S Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum during the period of September 2014 to August 2015.

A total of 502 pregnant women (along with spouse, in cases where the spouse was accompanying the patient) who were less than 23 weeks period of gestation, who attended the Antenatal Clinic were included in the study.

The data obtained was coded and entered into the Microsoft Excel spreadsheet. The data was analysed and the final results and observations were interpreted as follows.

Table 1. Period of gestation

Period of gestation	Number of women
Less than 13 weeks 6 days	211
Between 14 to 23 weeks	291

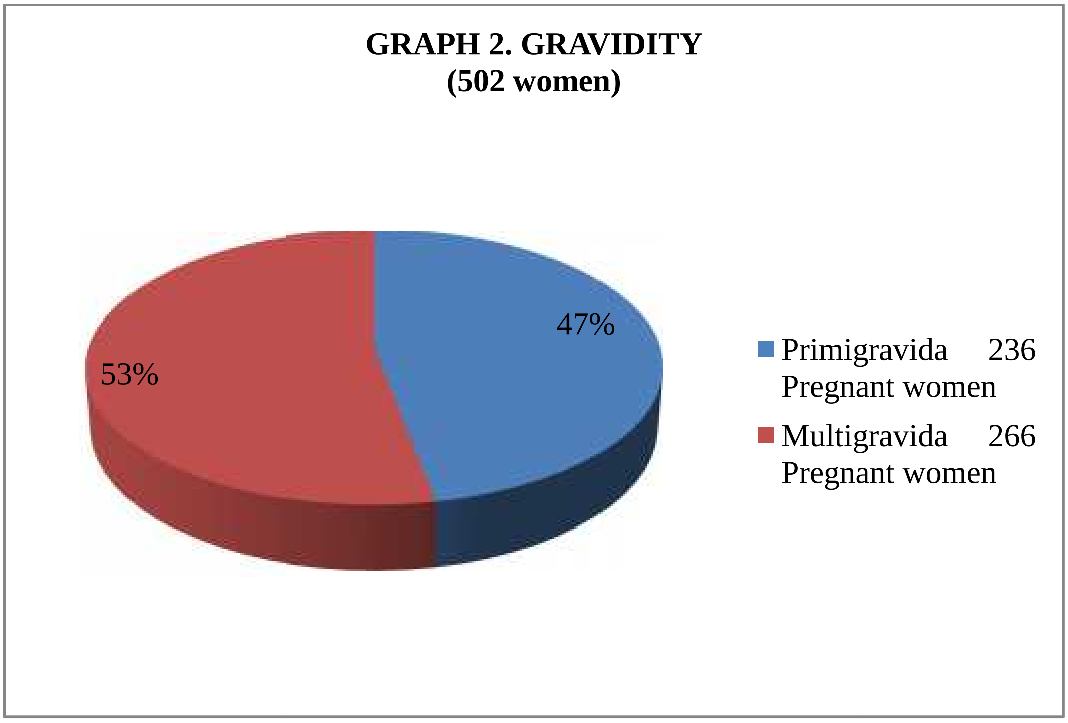


GRAPH 1. PERIOD OF GESTATION
(502 women)

In the present study, 211 pregnant women (42%) were less than 13 weeks 6 days period of gestation. The remaining 291 (58%) were between 14 to 23 weeks period of gestation.

Table 2. Gravidity

Gravidity	Number of women
Primigravida	236
Multigravida	266

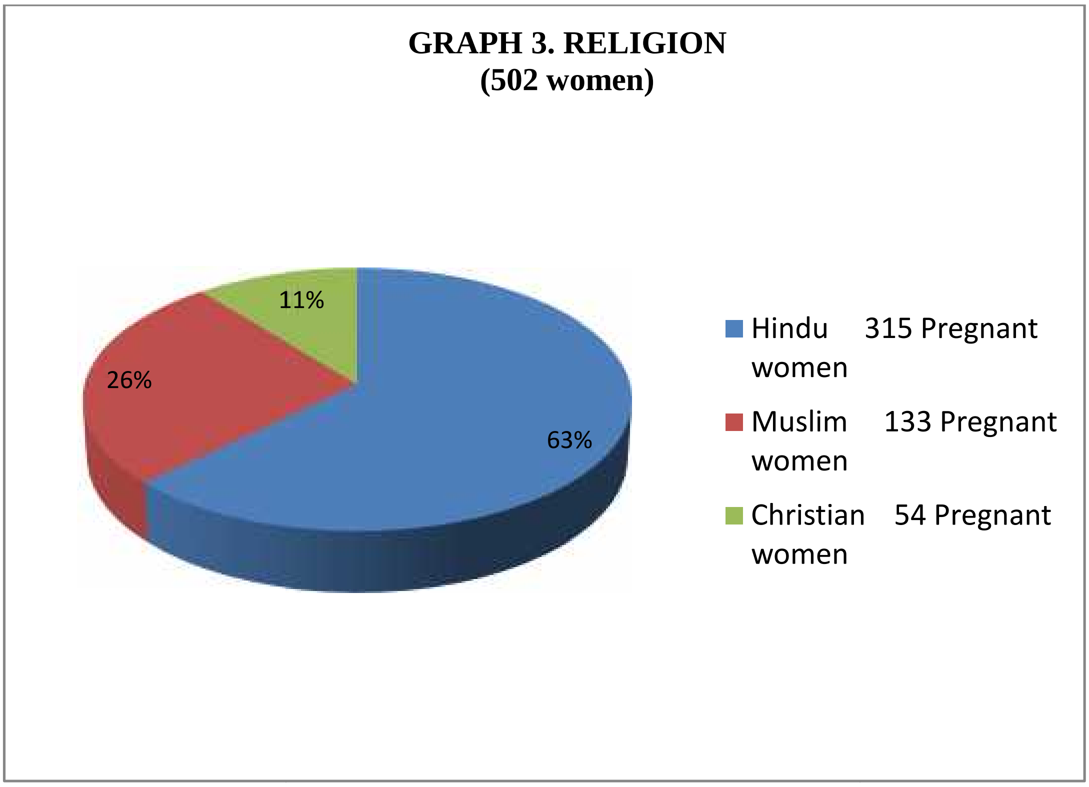


GRAPH 2. GRAVIDITY
(502 women)

In the present study, 236 pregnant women (47%) were primigravida. The remaining 266 (53%) were multigravida.

Table 3. Religion

Religion	Number of women
Hindu	315
Muslim	133
Christian	54

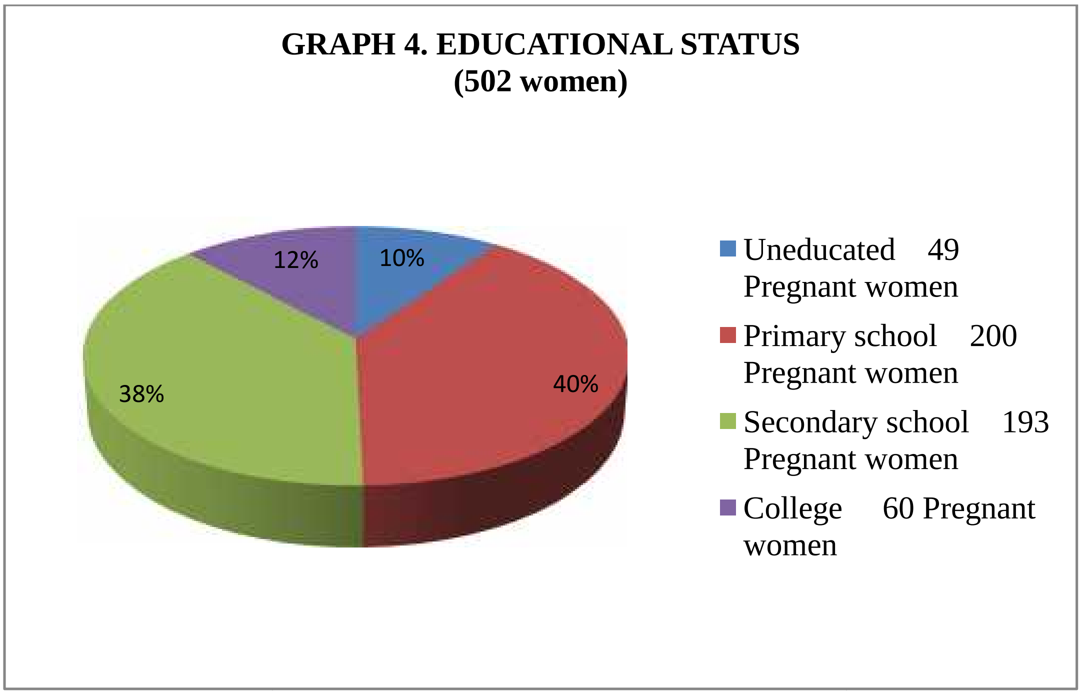


GRAPH 3. RELIGION (502 women)

In the present study, majority of the pregnant women were hindus (63% or 315 women). Out of the remaining women, 26% (133 women) were muslim, and the rest of the 54 women were christian (11%).

Table 4. Educational Status

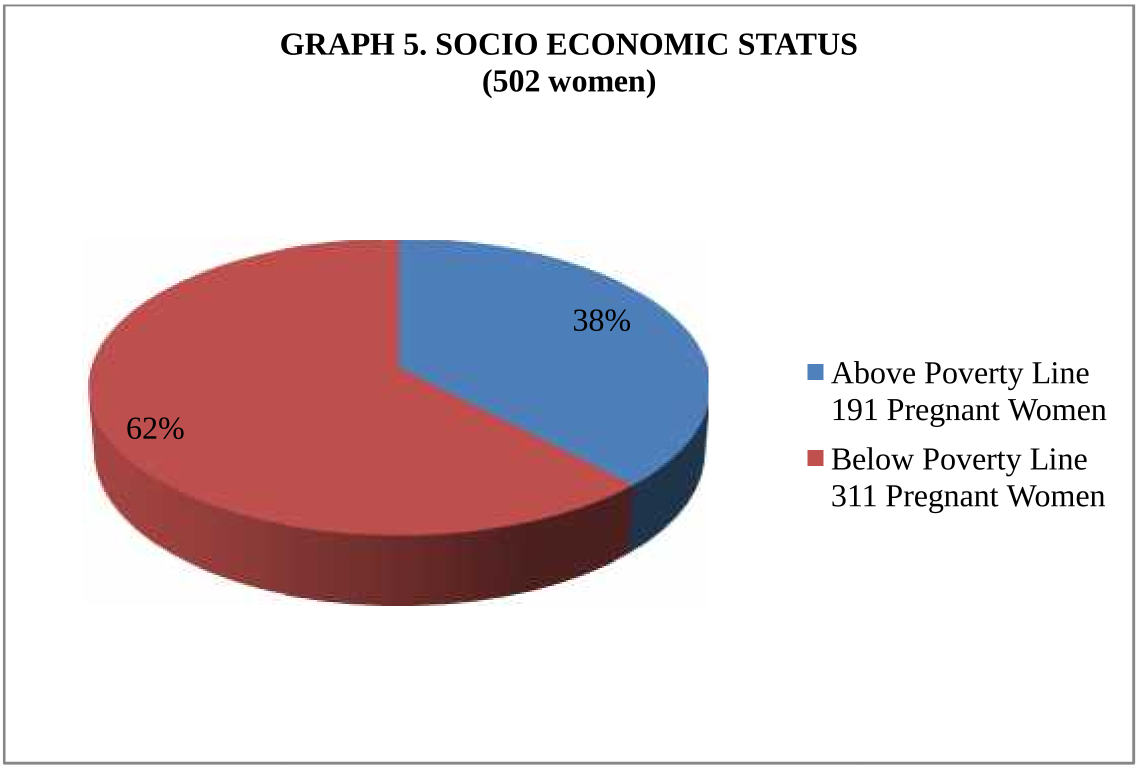
Educational status	Number of women
Uneducated	49
Primary school	200
Secondary school	193
College	60



In the present study, majority of the pregnant women (40% or 200 women) had attended primary school, followed closely by 38% of the pregnant women who had attended secondary school (193 women). 60 women had attended college (12%), while the remaining 49 women (10%) were uneducated.

Table 5. Socio economic status

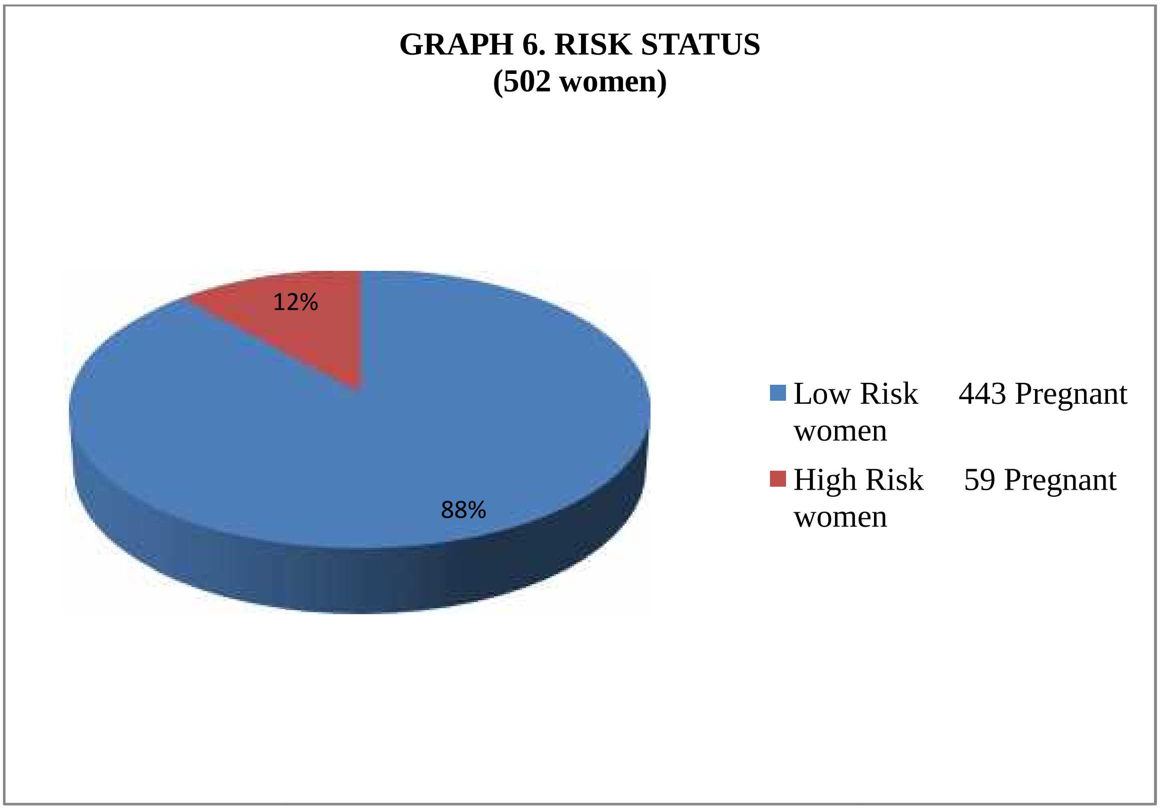
Socio economic status	Number of women
Above poverty line (APL)	191
Below poverty line (BPL)	311



In the present study, 191 pregnant women were Above Poverty line (APL) (38%). The majority of the patients (311 pregnant women or 62%) were Below Poverty Line (BPL).

Table 6. Risk status

Risk status	Number of women
High Risk	443
Low Risk	59

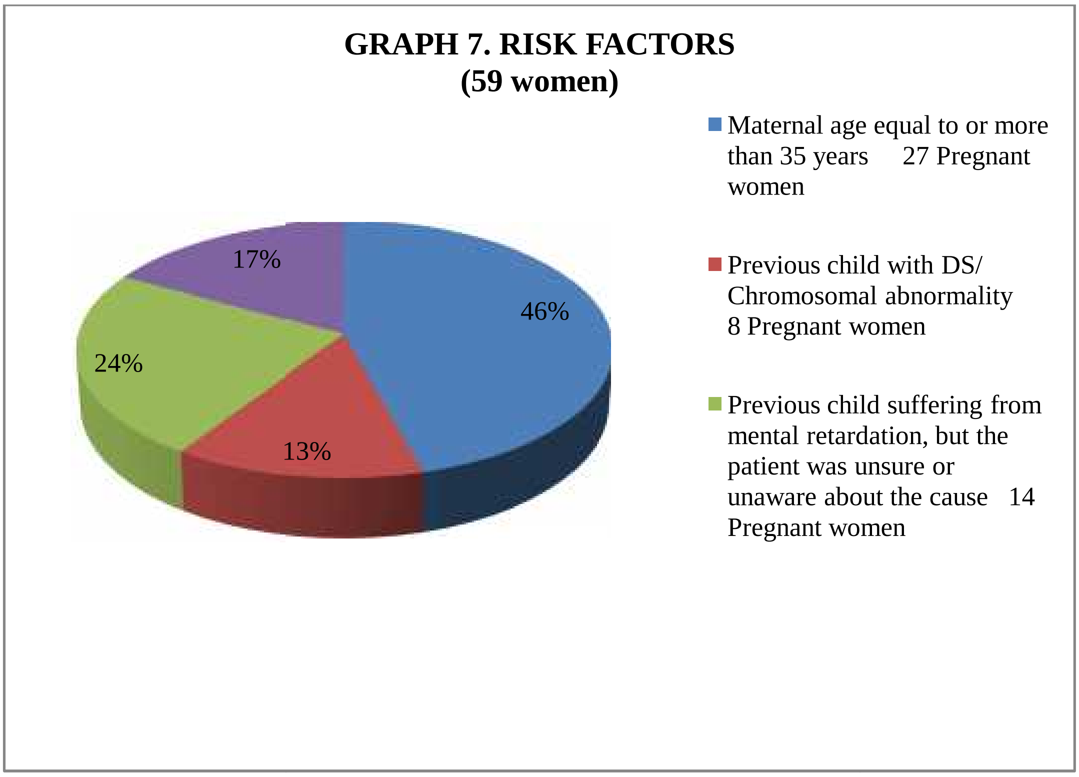


GRAPH 6. RISK STATUS (502 women)

In the present study, majority of the pregnant women were low risk (443 women or 88%). The remaining 59 pregnant women were classified as high risk (12%).

Table 7. Risk factors

Risk factors	Number of women
Increased maternal age (equal to or more than 35 years)	27
Previous child with DS or a chromosomal abnormality	8
Previous child (or children) suffering from Mental retardation (MR) but the patient was either unsure or unaware about the cause of the mental retardation	14
Others	10



In the present study, out of 59 women classified as High Risk cases, majority of the pregnant women (27 women or 46%) had increased maternal age (equal to or more than 35 years) as the risk factor. 8 women (13%) had a previous child with DS or a chromosomal abnormality. 14 women (24%) had a previous child (or children) suffering from Mental retardation (MR) but the patient was either unsure or unaware about the cause of the mental retardation. 10 women (17%) were classified as others, and this included the women who had a history of chromosomal abnormality in the family or had family members who were suffering from MR or other signs and symptoms similar to DS, the cause of which the patient was unsure of.

Table 8.

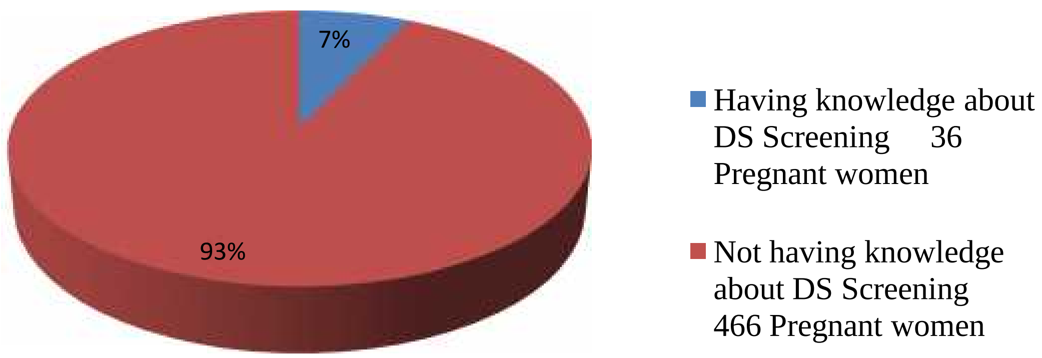
Mean Age (in years)	23.90
Mean period of gestation	16 weeks

In the present study, the mean age of the pregnant women included in the study was 23.90 years, and the mean period of gestation of the women included in the study was 16 weeks.

Table 9. Knowledge about screening for DS

Knowledge about screening for DS	Number of women
No knowledge of DS Screening methods and their availability	466
Knowledge about DS Screening	36

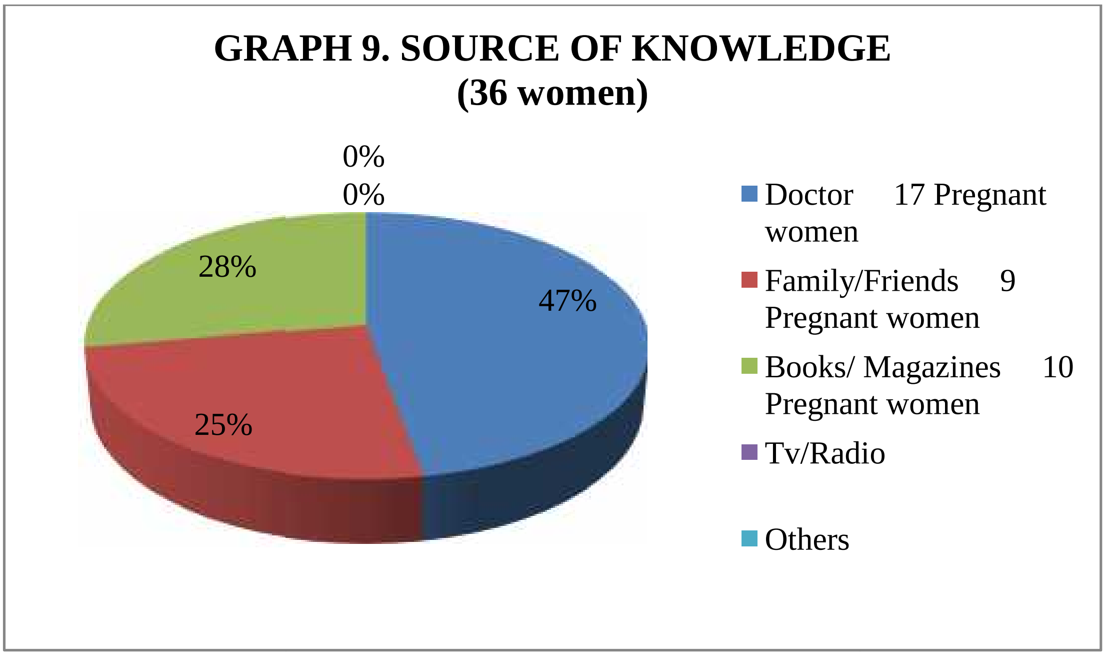
GRAPH 8. KNOWLEDGE ABOUT SCREENING FOR DS (502 women)



In the present study, majority of the pregnant women (466 women or 93%) had no knowledge of DS Screening methods and their availability, while only 36 women (7%) had knowledge about DS Screening.

Table 10. Source of knowledge

Source of knowledge	Number of women
Doctor	17
Family/Friends	9
Books/Magazines	10
TV/Radio	0
Others	0

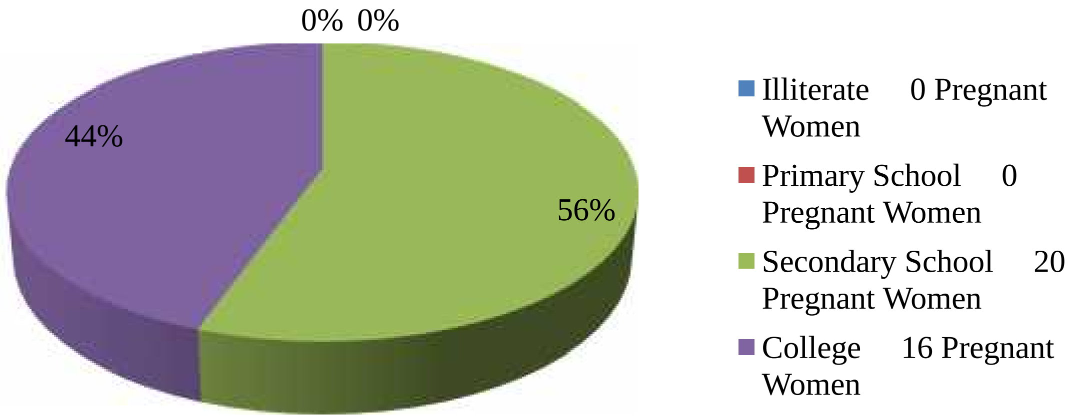


In the present study, out of the 36 women who had knowledge about DS Screening, 17 women (47%) said that their source of their knowledge was their Local Doctor, while 10 women (28%) said the source of their knowledge was Books or Magazines and 9 women (25%) said the source of their knowledge was from Family or Friends.

Table 11. Educational status of women having knowledge about DS screening

Educational status of women having knowledge about DS screening	Number of women
Illiterate	0
Primary school	0
Secondary school	20
College	16

GRAPH 10. CORRELATION BETWEEN KNOWLEDGE ABOUT SCREENING FOR DS AND THE EDUCATIONAL STATUS (36 women)

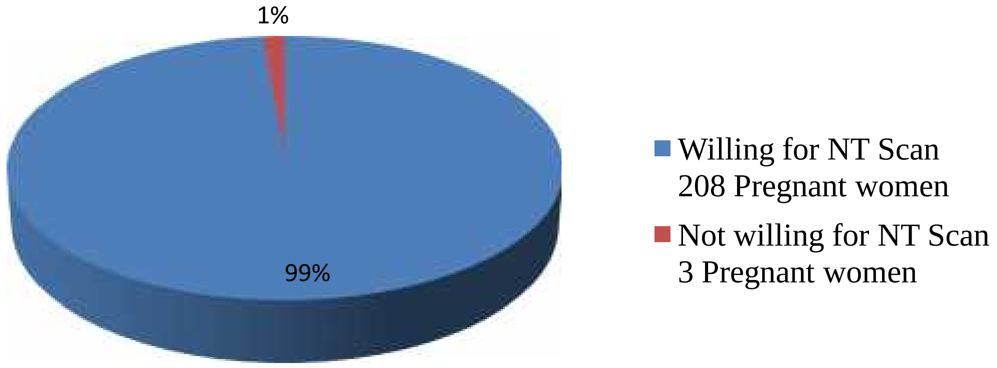


In the present study, out of the 36 women who had knowledge about the screening for DS, 20 pregnant women (56%) had attended High School, and 16 pregnant women (44%) had attended College. None of the women who were illiterate or who had attended Primary School had prior knowledge about DS Screening.

Table 12. Acceptance of NT Scan in women less than 13 weeks 6 days POG

Acceptance of NT Scan	Number of women
Willing to undergo an NT Scan	208
Not willing to undergo NT Scan	3

GRAPH 11. ACCEPTANCE OF NT SCAN IN WOMEN LESS THAN 13 WEEKS 6 DAYS POG (211 Patients)

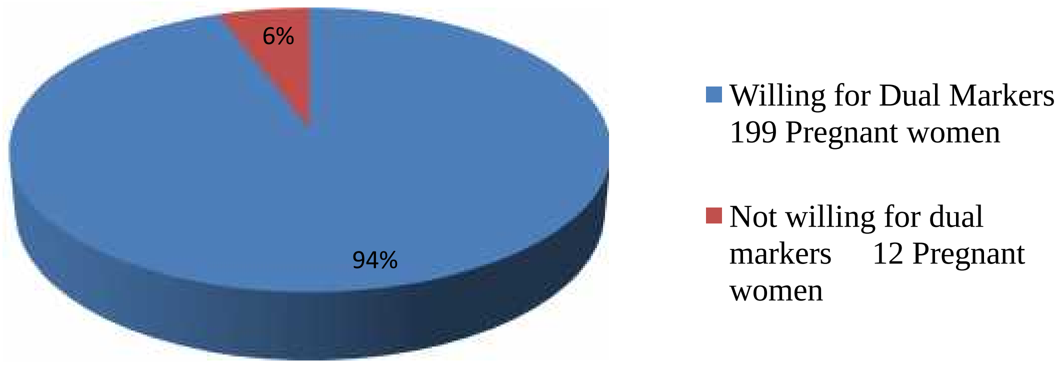


In the present study, 211 patients were offered NT Scan as the mode of screening for DS according to their period of gestation. Majority or the women (208 women, or 99%) were willing to undergo an NT Scan, while only 3 women (1%) refused the NT Scan.

Table 13. Acceptance of dual makers in women less than 13 weeks 6 days POG

Acceptance of dual makers in women less than 13 weeks 6 days POG	Number of women
Willing for dual marker test	199
Not willing for dual marker test	12

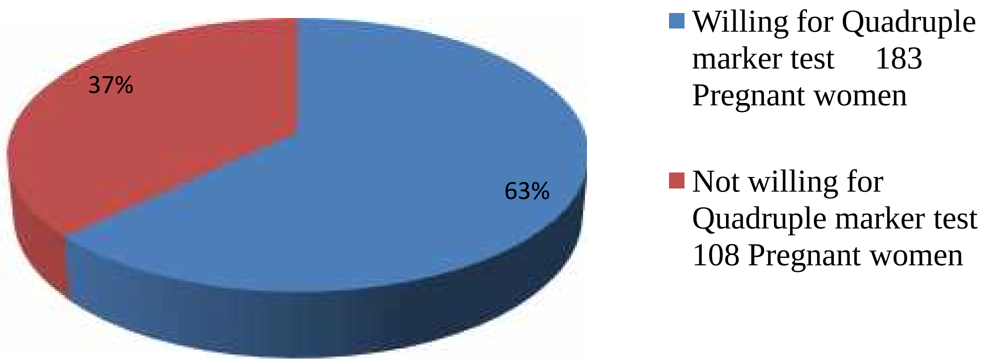
GRAPH 12. ACCEPTANCE OF DUAL MARKERS IN WOMEN LESS THAN 13 WEEKS 6 DAYS POG
(211 Patients)



In the present study, 211 pregnant women were offered a Dual Marker test. Majority of the women (199 women, or 94%) were willing to undergo the offered Dual Marker test, while 12 women (6%) declined to undergo the Dual Marker Test.

Table 14. Acceptance of Quadruple marker test in women between 14 to 23 weeks POG

Acceptance of Quadruple marker test	Number of women
Willing for quadruple marker test	183
Not willing for quadruple marker test	108



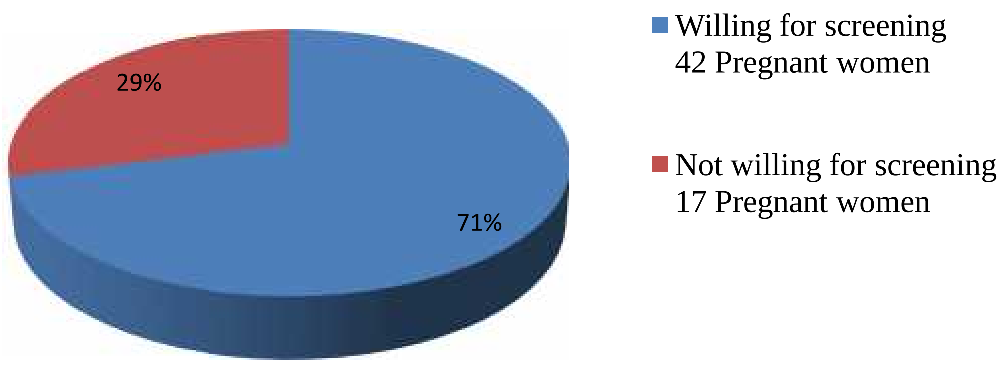
GRAPH 13. ACCEPTANCE OF QUADRUPLE MARKERS IN WOMEN BETWEEN 14 to 23 WEEKS POG (291 women)

In the present study, 291 pregnant women were offered a Quadruple marker test according to their period of gestation. Out of these, 183 women (63%) were willing to undergo the offered test, while 108 women (37%) declined to undergo the Quadruple marker test.

Table 15. Acceptance in high risk patients

Acceptance in high risk patients	Number of women
Willing for screening tests	42
Not willing for screening tests	17

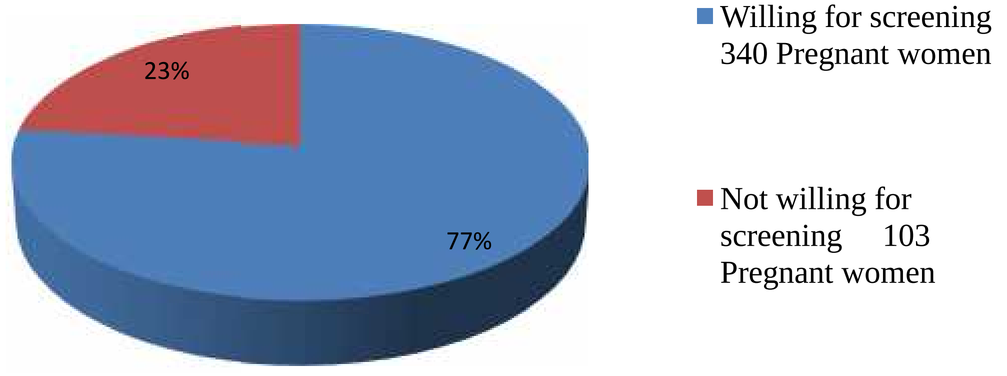
**GRAPH 14. ACCEPTANCE IN HIGH RISK PATIENTS
(59 women)**



In the present study, out of the 59 women classified as high risk, 42 women (71%) were willing to undergo the offered screening test for DS according to their period of gestation, while 17 women (29%) declined the offered test.

Table 16. Acceptance in low risk patients

Acceptance in low risk patients	Number of women
Willing for screening	340
Not willing for screening	103



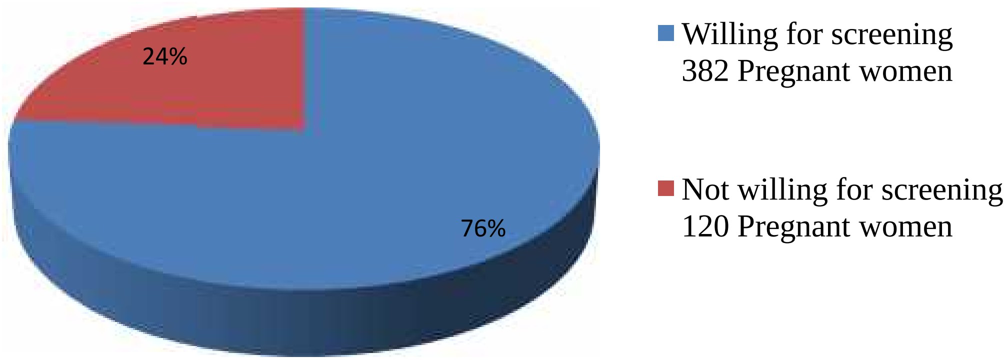
GRAPH 15. ACCEPTANCE IN LOW RISK PATIENTS (443 women)

In the present study, out of the 443 women classified as low risk, 340 women (77%) were willing to undergo the offered screening test for DS according to their period of gestation, while 103 women (23%) declined to undergo the offered screening test.

Table 17. Overall acceptance

Overall acceptance	Number of women
Willing for screening	382
Not willing for screening	120

GRAPH 16. OVERALL ACCEPTANCE
(502 women)

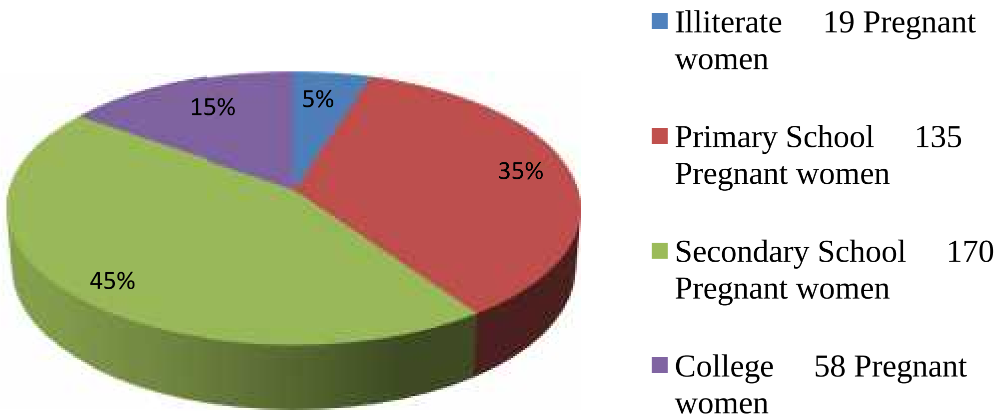


In the present study, out of the 502 women recruited, 382 women (76%) were willing to undergo the offered screening test for DS according to their period of gestation, while 120 women (24%) declined to undergo the offered screening test.

Table 18. Educational status of women accepting the offered screening test

Educational status of women accepting the offered screening test	Number of women
Illiterate	19
Primary school	135
Secondary school	170
College	58

GRAPH 17. CORRELATION BETWEEN ACCEPTABILITY OF SCREENING FOR DS AND EDUCATIONAL STATUS (382 women)

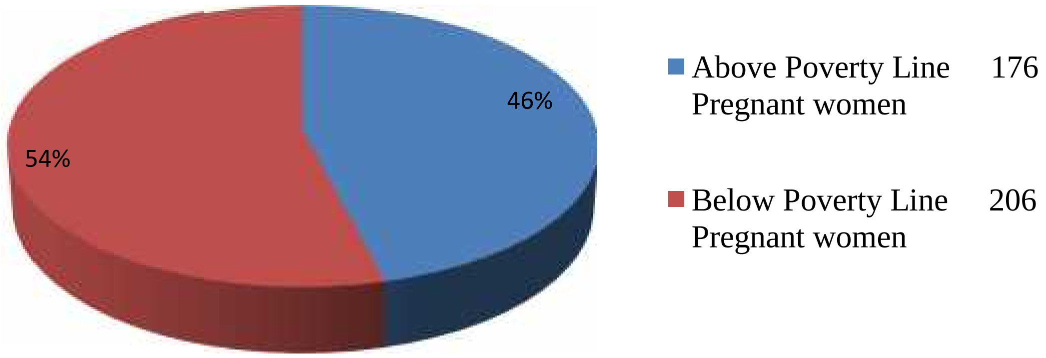


In the present study, out of the 382 patients who accepted the screening test for DS offered to them according to their period of gestation, majority of the patient (170 pregnant women or 45%) had attended Secondary school, 135 pregnant women (35%) had attended Primary school, 58 pregnant women (15%) had attended College and 19 pregnant women (5%) were illiterate.

Table 19. Socio economic status of women accepting the offered screening tests

Socio economic status of women accepting the offered screening tests	Number of women
Above poverty line	176
Below poverty line	206

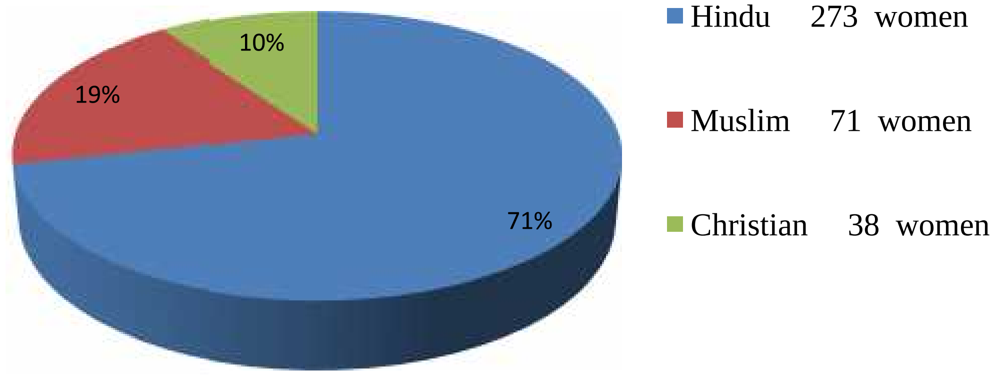
GRAPH 18. CORRELATION BETWEEN ACCEPTABILITY OF SCREENING FOR DS AND THE SOCIO ECONOMIC STATUS (382 women)



In the present study, out of the 382 patients who accepted the screening test for DS offered to them according to their period of gestation, 206 pregnant women were Below poverty line (54%), and the remaining 176 pregnant women were Above poverty line (46%).

Table 20. Religion of women accepting the offered screening tests

Religion of women accepting the offered screening tests	Number of women
Hindu	273
Muslim	71
Christian	38



GRAPH 19. CORRELATION BETWEEN ACCEPTABILITY OF SCREENING FOR DS AND RELIGION (382 women)

In the present study, out of the 382 patients who accepted the screening test for DS offered to them according to their period of gestation, majority of the pregnant women (273 women or 71%) were Hindu, 71 pregnant women (19%) were Muslim, and the remaining 38 pregnant women (10%) were Christian.

Acceptability rate was calculated as :

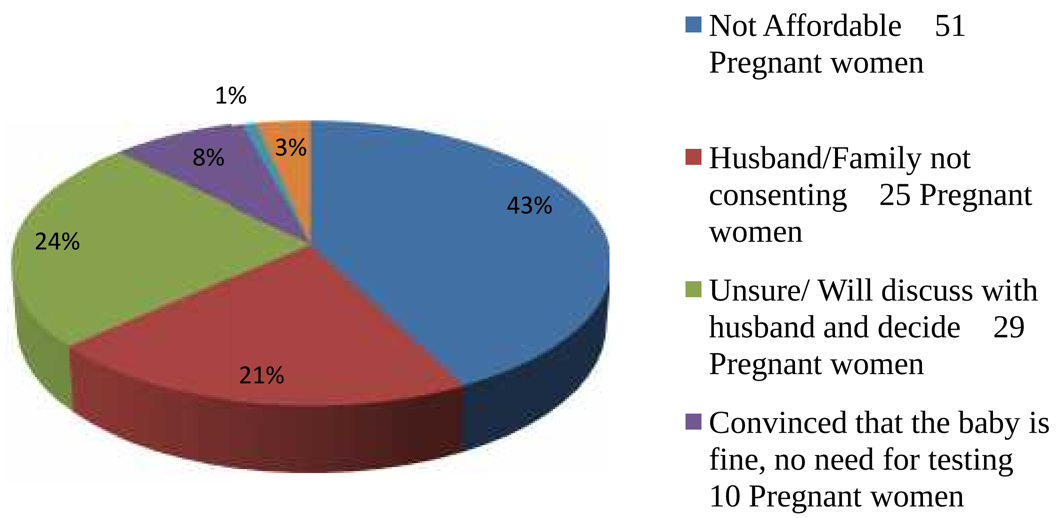
$$\frac{\textit{Total number of women accepting the test}}{\textit{Total number of women to whom the test was offered}} \times 100$$

Table 21. Acceptability Rate

Over all acceptability rate of the offered screening test for DS according to the period of gestation	76.09%
Acceptability rate in low risk patients	76.74%
Acceptability rate in high risk patients	71.18%

Table 22. Reason for non acceptance

Reason for non acceptance	Number of women
Lack of affordability	51
Will discuss with their husband/family members	29
Husband/family members were not consenting	25
Convinced that their baby was fine and that testing for DS was not required	10
Pregnancy was too precious for the couple	1
Others	4



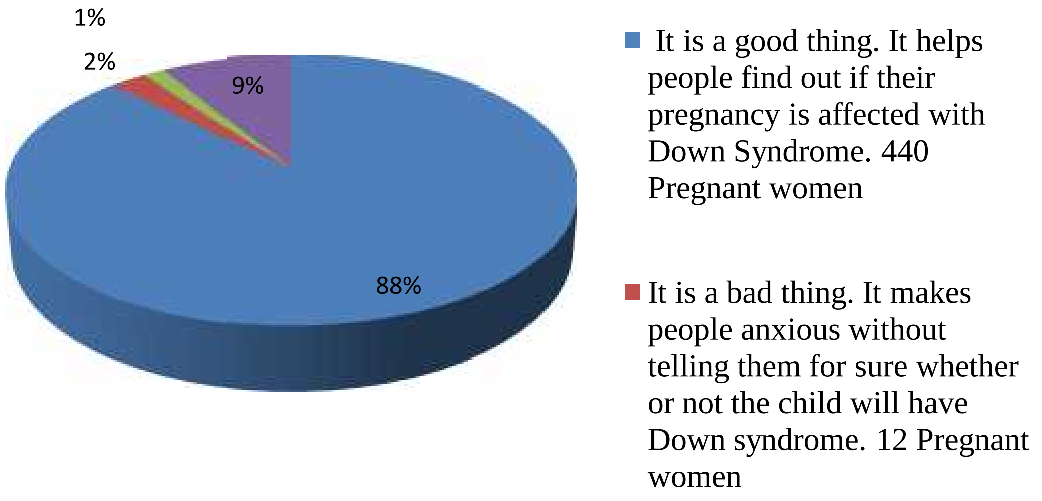
GRAPH 20. REASON FOR NON ACCEPTANCE (120 women)

In the present study, out of the 120 women declining the offered screening test for DS according to their period of gestation, majority of them (51 women or 43%) said lack of affordability of the test was the reason for non acceptance. 29 women (24%) were unsure about undergoing the offered test, and wanted to discuss with their husband/family members and then decide. 25 women (21%) declined the offered test because their husband/family members were not consenting, and 10 women (8%) were convinced that their baby was fine and that testing for DS was not required. 1 patient (1%) said that she had conceived after an assisted reproductive technique and as the pregnancy was too precious for the couple, they did not want to know the fate of the child. 4 patients (3%) gave other reasons for declining the test such as inability of the test to predict for sure if the baby was affected with DS, and that the test will lead to undue anxiety levels in the couple.

Table 23. Attitude towards prenatal screening test

Attitude towards prenatal screening test	Number of women
It is a good thing and that it helps people find out if their pregnancy is affected with DS or not	440
It is a bad thing as it makes people anxious without telling them for sure whether or not the child will have DS	12
It is a bad thing as its only purpose is to allow people to terminate pregnancies affected with DS	7
Unsure about how they felt about prenatal screening for DS.	43

GRAPH 21. ATTITUDE OF WOMEN TOWARDS THE SCREENING TEST
(502 women)



In the present study, out of the 502 pregnant women recruited, majority of the women (440 women, 88%) felt that prenatal screening for DS is a good thing and that it helps people find out if their pregnancy is affected with DS or not. 12 women (2%) felt that prenatal screening is a bad thing as it makes people anxious without telling them for sure whether or not the child will have DS. 7 women (1%) felt that prenatal screening was a bad thing as its only purpose is to allow people to terminate pregnancies affected with DS, while 43 women (9%) were unsure about how they felt about prenatal screening for DS.

DISCUSSION

The present study sought to highlight the women's awareness, attitude and acceptability towards the offered prenatal screening test for DS. The one year prospective descriptional study was conducted during the period of 1st September 2014 to 31st August 2015 in the antenatal clinic of KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum and a total of 502 pregnant women fulfilling the inclusion criteria were recruited for the study.

Demographic characteristics

In the present study, 211 pregnant women (42%) were less than 13 weeks 6 days period of gestation. The remaining 291 (58%) were between 14 to 23 weeks period of gestation. In the total sample population, 236 pregnant women (47%) were Primigravida. The remaining 266 (53%) were Multigravida. Majority of the pregnant women were Hindus (63% or 315 women). Out of the remaining women, 26% (133 women) were Muslim, and the rest of the 54 women were Christian. (11%) . In the present study, majority of the pregnant women (40% or 200 women) had attended primary school, followed closely by 38% of the pregnant women who had attended secondary school (193 women). 60 women had attended college (12%), while the remaining 49 women (10%) were uneducated. It was noted that 191 pregnant women were Above Poverty line (38%). The majority of the patients (311 pregnant women or 62%) were Below Poverty Line.

Majority of the pregnant women were low risk (443 women or 88%). The remaining 59 pregnant women were classified as high risk (12%). Out of 59 women classified as High Risk cases, majority of the pregnant women (27 women or 46%) had increased maternal age (equal to or more than 35 years) as the risk factor. 8

women (13%) had a previous child with DS or a chromosomal abnormality. 14 women (24%) had a previous child (or children) suffering from Mental retardation (MR) but the patient was either unsure or unaware about the cause of the mental retardation. 10 women (17%) were classified as others, and this included the women who had a history of chromosomal abnormality in the family or had family members who were suffering from MR or other signs and symptoms similar to DS, the cause of which the patient was unsure of.

In the present study, the mean age of the pregnant women included in the study was 23.90 years, and the mean period of gestation of the women included in the study was 16 weeks.

Prior knowledge about Screening tests for DS

In the present study, majority of the pregnant women (466 women or 93%) had no knowledge of DS Screening methods and their availability, while only 36 women (7%) had knowledge about DS Screening. Knowledge was defined as the awareness of the patient regarding one or more screening test for DS. Similar observations were made in a study conducted in Indore from October 2004 to September 2006. It was found that only 14.2% of the patients were aware about the screening tests for DS. [17]

Out of the 36 women who had knowledge about DS screening, 17 women (47%) said that their source of their knowledge was their local doctor, while 10 women (28%) said the source of their knowledge was books or magazines and 9 women (25%) said the source of their knowledge was from family or friends. Similar observations were made by Baxi who noted that source of information was newspapers and magazines in 31% of the women, Internet in 39.6% of the women and medical personal in 29.4% of the women.[17]

Similar results were noted in the Swedish council on Technology Assessment in Health Care in 2006 which concluded that the main sources of information about DS were midwives or general practitioners. [24]

A similar study done in Hong Kong in 2014 concluded that the women received information on NIPT largely from their private doctors (47.4 %) and web (41.5 %). [44]

In the present study, in a correlation between the educational status of the women and their knowledge about screening test for DS, it was found that out of the 36 women who had knowledge about the screening for DS, 20 pregnant women (56%) had attended high school, and 16 pregnant women (44%) had attended college. None of the women who were illiterate or who had attended primary school had prior knowledge about DS Screening. These findings underline the importance of education and its correlation with awareness and good health care among the women attending the antenatal clinics.

Similar findings were reported in a study done in 2014 in Ibadan were it was concluded that there was a direct correlation between acceptance and educational attainment: 41.5%, 31.50%, 19%, 19% of women who agreed to have prenatal diagnosis had tertiary, secondary school, primary school and no formal education respectively. [45]

Acceptability towards the offered screening test

In the present study, acceptability was defined as the readiness of the pregnant woman to undergo the offered screening test, regardless of whether she actually undergoes the said test or not.

Out of the 502 pregnant women recruited for the study, 211 pregnant women (42%) were offered an NT Scan along with Dual Marker test according to their period of gestation. The remaining 291 (58%) were offered a Quadruple Marker test according to their period of gestation. It was noted that the acceptability was highest towards the NT Scan as compared to the biochemical tests. Out of the 211 patients who were offered NT Scan as the mode of screening for DS according to their period of gestation, majority or the women (208 women, or 99%) were willing to undergo an NT Scan, while only 3 women (1%) refused the NT Scan. In the same group, among the 211 pregnant women who were offered a Dual Marker test, majority of the women (199 women, or 94%) were willing to undergo the offered Dual Marker test, while 12 women (6%) declined to undergo the Dual Marker Test.

In the present study, out of the 291 pregnant women who were offered a Quadruple marker test according to their period of gestation, 183 women (63%) were willing to undergo the offered test, while 108 women (37%) declined to undergo the Quadruple marker test.

Out of the 59 women classified as high risk, 42 women (71%) were willing to undergo the offered screening test for DS according to their period of gestation, while 17 women (29%) declined to undergo the offered screening test.

Out of the 413 women classified as low risk, 340 women (77%) were willing to undergo the offered screening test for DS according to their period of gestation, while 103 women (23%) declined to undergo the offered screening test.

The acceptability rate was low for patients categorized as high risk (71.18%) while it was higher for patients categorized as low risk (76.74%). It was noted that even though majority of the patients categorized as high risk were educated and the socio economic class was that of above poverty line, the acceptance in them was lower.

Over all, out of the 502 women recruited, 382 women (76%) were willing to undergo the offered screening test for DS according to their period of gestation, while 120 women (24%) declined to undergo the offered screening test. The overall acceptability rate was found to be 76.09%.

A similar study done in 2014 in four antenatal clinics in England reported similar findings. 88.2% of the women indicated that they would use the offered test. [46]

In the present study, a correlation between the acceptance of the offered test and the socio economic status of the patient concluded that out of the 382 patients who accepted the screening test for DS offered to them according to their period of gestation, 206 pregnant women were Below poverty line (54%), and the remaining 176 pregnant women were Above poverty line (46%). It was noted that even though the women belonged to the BPL category, the motivation to undergo the test was more in them as compared to the women belonging to the APL category.

In the present study, a correlation between the acceptance of the offered test and the religion of the sample population concluded that out of the 382 patients who accepted the screening test for DS offered to them according to their period of gestation, majority of the pregnant women (273 women or 71%) were Hindu, 71 pregnant women (19%) were Muslim, and the remaining 38 pregnant women (10%) were Christian.

In the present study, out of the 120 women declining the offered screening test for DS according to their period of gestation, majority of them (51 women or 43%) said lack of affordability of the test was the reason for non acceptance. 29 women (24%) were unsure about undergoing the offered test, and wanted to discuss with their husband/family members and then decide. 25 women (21%) declined the offered test because their husband/family members were not consenting, and 10 women (8%) were convinced that their baby was fine and that testing for DS was not required. 1 patient (1%) said that she had conceived after an assisted reproductive technique and as the pregnancy was too precious for the couple, they did not want to know the fate of the child. 4 patients (3%) gave other reasons for declining the test such as inability of the test to predict for sure if the baby was affected with DS, and that the test will lead to undue anxiety levels in the couple.

Similar results were noted in the study conducted by Baxi A, were it was concluded that the most common cause of refusal was that the couple does not want to know the fate of the child, as the pregnancy is precious to them.[17] Other reasons included non acceptance for medical termination of pregnancy, further invasive test if the test reports high risk and a gut feeling about their pregnancy outcome that everything was fine.[17]

Attitude towards prenatal testing

In the present study, out of the 502 pregnant women recruited, majority of the women (440 women, 88%) felt that prenatal screening for DS is a good thing and that it helps people find out if their pregnancy is affected with DS or not. 12 women (2%) felt that prenatal screening is a bad thing as it makes people anxious without telling them for sure whether or not the child will have DS. 7 women (1%) felt that prenatal screening was a bad thing as its only purpose is to allow people to terminate pregnancies affected with DS, while 43 women (9%) were unsure about how they felt about prenatal screening for DS.

Similar results were noted by other observers. Lewis et al reported that respondents were overwhelmingly positive towards the uptake of NIPT and that the vast majority (95.7%) thought that NIPT was a positive development in prenatal case. [46] A study done in the antenatal clinic of Songklanagarind Hospital in 2007 noted similar results. It was reported that even though most pregnant women had inadequate knowledge of DS and the screening tests, they did have a positive attitude and were willing to accept the test.[47]

A similar study conducted in Netherlands in 2014 concluded that some participants felt that current prenatal screening has great disadvantages such as uncertain results and risk of miscarriage from follow-up diagnostics. [48]

The findings in the present study indicate that steps should be taken to make the women more aware about the various screening tests for DS and their availability, so that the morbidity due to DS can be prevented. Sources of information like Television and Radio can be used to impart relevant knowledge, which currently have been underutilized. Further, there is a need for better methods of giving the woman and her partner appropriate information in a comprehensible manner.

The medical personnel should also take it upon themselves to maintain equal access to prenatal testing, as to any other health service. An important finding of the present study was the cost of the tests and the non affordability of the study population towards the offered test. The cost-effectiveness of the test should be weighed against the economic burden of rearing a child with DS, and steps should be taken to establish a standardized policy making prenatal testing a part of routine antenatal care.

CONCLUSION

Despite the overwhelming positive attitude of the women towards prenatal screening, there is a lack of awareness regarding Down syndrome screening among women especially regarding various tests and their availability. There is a need for systematic informing, counseling and guiding pregnant women about the availability, implications and limitations of the screening tests.

Implementation of a standardized and comprehensive policy which makes prenatal screening a routine part of antenatal care can play a key role in easing the substantial economic burden incurred by families as a result of caring for a child with disabilities.

SUMMARY

The present one year descriptional study was conducted from 1st September 2014 to 31st August 2015 in the Antenatal clinic of KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum.

The study sought to highlight the awareness and the acceptability towards screening for DS among the women attending the antenatal clinic. The attitude of the women towards prenatal testing was also assessed.

A total of 502 women fulfilling the inclusion criteria were recruited for the study, and data was obtained through a questionnaire which consisted of demographic data, knowledge about screening tests for DS, acceptability towards the offered test and attitude of the woman towards prenatal testing.

211 pregnant women (42%) were less than 13 weeks 6 days period of gestation. The remaining 291 (58%) were between 14 to 23 weeks period of gestation.

In the total sample population, 236 pregnant women (47%) were primigravida. The remaining 266 (53%) were multigravida.

Majority of the pregnant women were hindus (63% or 315 women). Out of the remaining women, 26% (133 women) were muslim, and the rest of the 54 women were christian. (11%).

Majority of the pregnant women (40% or 200 women) had attended primary school, 38% of the pregnant women had attended secondary school (193 women), 60 women had attended college (12%) and 49 women (10%) were uneducated. 191

pregnant women were Above Poverty line (38%). The majority of the patients (311 pregnant women or 62%) were Below Poverty Line.

Majority of the pregnant women were low risk (443 women or 88%). The remaining 59 pregnant women were classified as high risk (12%).

Out of 59 women classified as High Risk cases, majority of the pregnant women (27 women or 46%) had increased maternal age (equal to or more than 35 years) as the risk factor. 8 women (13%) had a previous child with DS or a chromosomal abnormality. 14 women (24%) had a previous child (or children) suffering from Mental retardation (MR) but the patient was either unsure or unaware about the cause of the mental retardation. 10 women (17%) were classified as others, and this included the women who had a history of chromosomal abnormality in the family or had family members who were suffering from MR or other signs and symptoms similar to DS, the cause of which the patient was unsure of.

The mean age of the pregnant women included in the study was 23.90 years, and the mean period of gestation of the women included in the study was 16 weeks.

211 pregnant women (42%) were offered an NT Scan along with Dual Marker test according to their period of gestation. The remaining 291 (58%) were offered a Quadruple Marker test according to their period of gestation.

Out of the 211 patients who were offered NT Scan as the mode of screening for DS according to their period of gestation, majority of the women (208 women, or 99%) were willing to undergo an NT Scan, while only 3 women (1%) refused the NT Scan. In the same group, among the 211 pregnant women who were offered a dual marker test, majority of the women (199 women, or 94%) were willing to undergo the offered Dual Marker test, while 12 women (6%) declined to undergo the Dual Marker Test.

Out of the 291 pregnant women who were offered a quadruple marker test according to their period of gestation, 183 women (63%) were willing to undergo the offered test, while 108 women (37%) declined to undergo the quadruple marker test.

Out of the 59 women classified as high risk, 42 women (71%) were willing to undergo the offered screening test for DS according to their period of gestation, while 17 women (29%) declined to undergo the offered screening test.

Out of the 443 women classified as low risk, 340 women (77%) were willing to undergo the offered screening test for DS according to their period of gestation, while 103 women (23%) declined to undergo the offered screening test.

The acceptability rate was low for patients categorized as high risk (71.18%) while it was higher for patients categorized as low risk (76.74%).

Over all, out of the 502 women recruited, 382 women (76%) were willing to undergo the offered screening test for DS according to their period of gestation, while 120 women (24%) declined to undergo the offered screening test. The overall acceptability rate was found to be 76.09%.

A correlation between the acceptance of the offered test and the educational status of the patient concluded that acceptance was highest in the women who were educated and the least in women who were illiterate.

A correlation between the acceptance of the offered test and the socio economic status of the patient concluded that out of the 382 patients who accepted the screening test for DS offered to them according to their period of gestation, 206 pregnant women were below poverty line (54%), and the remaining 176 pregnant women were above poverty line (46%).

A correlation between the acceptance of the offered test and the religion of the sample population concluded that out of the 382 patients who accepted the screening test for DS offered to them according to their period of gestation, majority of the pregnant women (273 women or 71%) were hindu, 71 pregnant women (19%) were muslim, and the remaining 38 pregnant women (10%) were christian.

Out of the 120 women declining the offered screening test for DS according to their period of gestation, majority of them (51 women or 43%) said lack of affordability of the test was the reason for non acceptance. 29 women (24%) were unsure about undergoing the offered test, and wanted to discuss with their husband/family members and then decide. 25 women (21%) declined the offered test because their husband/family members were not consenting, and 10 women (8%) were convinced that their baby was fine and that testing for DS was not required. 1 patient (1%) said that she had conceived after an assisted reproductive technique and as the pregnancy was too precious for the couple, they did not want to know the fate of the child. 4 patients (3%) gave other reasons for declining the test such as inability of the test to predict for sure if the baby was affected with DS, and that the test will lead to undue anxiety levels in the couple.

Out of the 502 pregnant women recruited, majority of the women (440 women, 88%) felt that prenatal screening for DS is a good thing and that it helps people find out if their pregnancy is affected with DS or not. 12 women (2%) felt that prenatal screening is a bad thing as it makes people anxious without telling them for sure whether or not the child will have DS. 7 women (1%) felt that prenatal screening was a bad thing as its only purpose is to allow people to terminate pregnancies affected with DS, while 43 women (9%) were unsure about how they felt about prenatal screening for DS.

It was concluded that despite the overwhelming positive attitude of the women towards prenatal screening, there was a lack of awareness regarding Down syndrome screening among women especially regarding various tests and their availability. Implementation of a standardized and comprehensive policy which makes prenatal screening a routine part of antenatal care can play a key role in easing the substantial economic burden incurred by families as a result of caring for a child with disabilities.

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ANNEXURE – I – CONSENT FORM

CONSENT FOR PARTICIPATION IN RESEARCH STUDY

Mr./Mrs./Ms. _____________________________ we are requesting you to enroll yourself in a study titled “AWARENESS AND ACCEPTABILITY OF SCREENING FOR DOWN SYNDROME IN WOMEN ATTENDING THE ANTENATAL CLINIC AT KLE’S DR. PRABHAKAR KORE HOSPITAL & MRC, BELGAUM”, Conducted By Dr. _______________, Post Graduate M.S. in Obstetrics And Gynaecology Under The Guidance Of Dr. ________________, Professor, Department Of Obstetrics And Gynaecology, J.N. Medical College, Belgaum.

Respected Sir/Madam, We request you to enroll yourself to participate in our study, as you are eligible for participating in the study. During the study you and your spouse will be asked some questions regarding your current knowledge about Down syndrome and its screening, and past history of Chromosomal disorders in the family and Genetic screening, and you are supposed to answer to the best of your knowledge.

Your participation in this research is voluntary. Your decision whether or not to participate in the study will not affect your relationship with J. N. Medical College. If you decide to participate, you are free to withdraw at any time.

Need for the Study

Down syndrome is the most commonly recognized genetic cause of mental retardation and many other developmental defects. In India, women are still unaware and apprehensive about the Prenatal Diagnostic Techniques, and this study is needed to evaluate the awareness and promote its acceptance in the women.

Purpose of the study:

The purpose of the research is evaluating the awareness and promoting the acceptance of the screening tests for Down syndrome in the women attending the Antenatal Clinic.

Procedure Involved:

If you agree to enroll yourself in my study, you will be asked to fill out a questionnaire regarding your current knowledge about Down syndrome screening, past history of chromosomal disorders in the family and Genetic screening, and you and your spouse will be counseled regarding the various screening tests available to you, according to your period of gestation. Your attitude towards the tests, and your readiness to accept the test will be documented.

Risks:

No risks will be involved, during the process of filling out the Questionnaire, or during the counseling session.

Benefits:

It will help to formulate local evidence based guideline regarding the awareness and acceptance of women for Down's syndrome and its screening, and it will offer the couple a choice to continue or terminate an effected pregnancy.

Voluntary Participation/Withdrawal:

Taking part in the study is voluntary. You may choose not to enroll yourself in this study. Your decision will not change present or future health care services offered to you at K.L.E. hospital.

Alternatives:

Even if you decline the participation in the study, you will get the routine line of management.

Privacy and Confidentiality:

The only people to know that you are a research subject are members of the research team. No information about you or information provided by you during the research will be disclosed to other without your written permission except:

1. In emergency to protect your rights and welfare.
2. If required by law.

Authorization to Publish Results:

When the results of the research are published or discussed, in a conference, no information will be displayed that would disclose your identity. Any information that is obtained in connection with this study and that can be identified with your identity remaining confidential.

Financial Incentives for participation:

No financial incentives are being offered to enrolled patients. It is purely being done with the idea of research and all the cost of the study will be borne by the investigator.

Compensation:

In the event of any untoward complication related to the study, treatment will be made available through KLE'S Hospital & MRC, Belgaum. There is no compensation or payment for such medical treatment by law. If untoward complications occur, you may contact Dr. ________________, at Department of Obstetrics and Gynaecology, KLE’S Hospital & MRC.

Questions:

If you have any queries about your rights as a study subject, you may call Dr. Ganga Pilli, Professor, Department of Pathology and Chairman, J.N. Medical College Institutional Ethical Committee for Human Subjects Research, Phone number-9448863866, or extension 4052 at J.N. Medical College, Belgaum.

Consent for participation in research trial

AWARENESS AND ACCEPTABILITY OF SCREENING FOR DOWN SYNDROME IN WOMEN ATTENDING THE ANTENATAL CLINIC AT KLE'S PRABHAKAR KORE HOSPITAL & MRC, BELGAUM

I, Mrs. _______________________________ voluntarily agree for the participation as a subject of study. By signing this consent form I am not giving up any of my legal rights, I may withdraw from the study anytime. I am signing the consent form after having read or been read for me in vernacular language, including the risks and the benefits and having all my questions answered.

Subject Name: _________________________

Signature or the Left Thumb Print of Subject : ______________________

Date:

Witness Name: ________________________ Signature: ______________

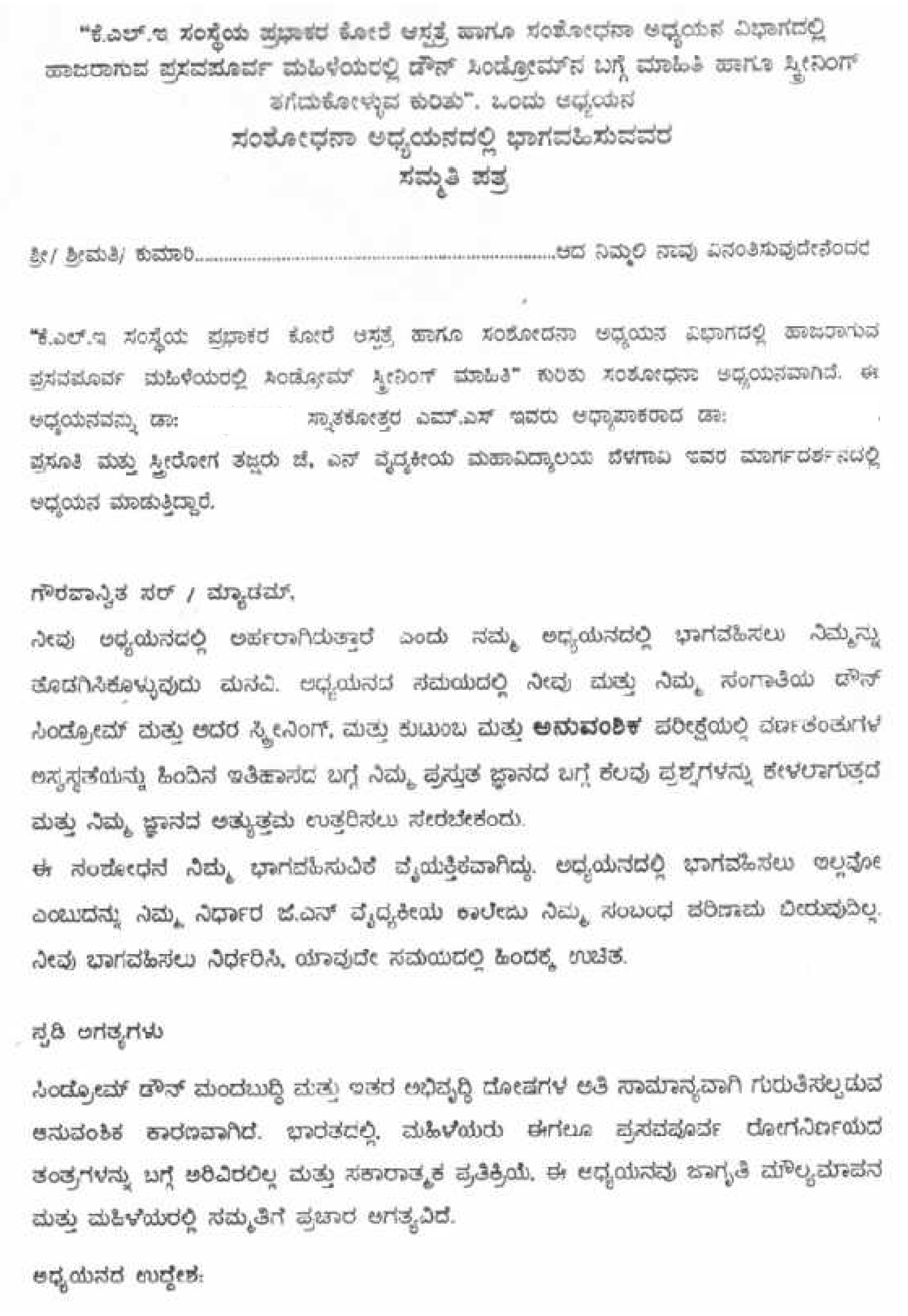
Date:

Investigators Name: ________________________ Signature: ______________

Date:

Place : _______________

KANNADA CONSENT FORM



"ಕೆ.ಎಲ್.ಇ ಸಂಸ್ಥೆಯ ಪ್ರಭಾಕರ ಕೋರೆ ಆಸ್ಪತ್ರೆ ಹಾಗೂ ಸಂಶೋಧನಾ ಅಧ್ಯಯನ ವಿಭಾಗದಲ್ಲಿ
ಹಾಜರಾಗುವ ಪ್ರಸವಪೂರ್ವ ಮಹಿಳೆಯರಲ್ಲಿ ಡೌನ್ ಸಿಂಡ್ರೋಮ್‌ನ ಬಗ್ಗೆ ಮಾಹಿತಿ ಹಾಗೂ ಸ್ಕ್ರೀನಿಂಗ್
ತಗೆದುಕೊಳ್ಳುವ ಕುರಿತು". ಒಂದು ಅಧ್ಯಯನ

ಸಂಶೋಧನಾ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸುವವರ
ಸಮ್ಮತಿ ಪತ್ರ

ಶ್ರೀ/ ಶ್ರೀಮತಿ/ ಕುಮಾರಿ...ಆದ ನಿಮ್ಮಲ್ಲಿ ನಾವು ವಿನಂತಿಸುವುದೇನೆಂದರೆ

"ಕೆ.ಎಲ್.ಇ ಸಂಸ್ಥೆಯ ಪ್ರಭಾಕರ ಕೋರೆ ಆಸ್ಪತ್ರೆ ಹಾಗೂ ಸಂಶೋದನಾ ಅಧ್ಯಯನ ವಿಭಾಗದಲ್ಲಿ ಹಾಜರಾಗುವ ಪ್ರಸವಪೂರ್ವ ಮಹಿಳೆಯರಲ್ಲಿ ಸಿಂಡ್ರೋಮ್ ಸ್ಕ್ರೀನಿಂಗ್ ಮಾಹಿತಿ" ಕುರಿತು ಸಂಶೋಧನಾ ಅಧ್ಯಯನವಾಗಿದೆ. ಈ ಅಧ್ಯಯನವನ್ನು ಡಾ: ಸ್ನಾತಕೋತ್ತರ ಎಮ್.ಎಸ್ ಇವರು ಅಧ್ಯಾಪಾಕರಾದ ಡಾ:
ಪ್ರಸೂತಿ ಮತ್ತು ಸ್ತ್ರೀರೋಗ ತಜ್ಞರು ಜೆ. ಎನ್ ವೈದ್ಯಕೀಯ ಮಹಾವಿದ್ಯಾಲಯ ಬೆಳಗಾವಿ ಇವರ ಮಾರ್ಗದರ್ಶನದಲ್ಲಿ ಅಧ್ಯಯನ ಮಾಡುತ್ತಿದ್ದಾರೆ.

ಗೌರವಾನ್ವಿತ ಸರ್ / ಮ್ಯಾಡಮ್,
ನೀವು ಅಧ್ಯಯನದಲ್ಲಿ ಅರ್ಹರಾಗಿರುತ್ತಾರೆ ಎಂದು ನಮ್ಮ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಲು ನಿಮ್ಮನ್ನು ತೊಡಗಿಸಿಕೊಳ್ಳುವುದು ಮನವಿ. ಅಧ್ಯಯನದ ಸಮಯದಲ್ಲಿ ನೀವು ಮತ್ತು ನಿಮ್ಮ ಸಂಗಾತಿಯ ಡೌನ್ ಸಿಂಡ್ರೋಮ್ ಮತ್ತು ಅದರ ಸ್ಕ್ರೀನಿಂಗ್, ಮತ್ತು ಕುಟುಂಬ ಮತ್ತು **ಅನುವಂಶಿಕ** ಪರೀಕ್ಷೆಯಲ್ಲಿ ವರ್ಣತಂತುಗಳ ಅಸ್ವಸ್ಥತೆಯನ್ನು ಹಿಂದಿನ ಇತಿಹಾಸದ ಬಗ್ಗೆ ನಿಮ್ಮ ಪ್ರಸ್ತುತ ಜ್ಞಾನದ ಬಗ್ಗೆ ಕೆಲವು ಪ್ರಶ್ನೆಗಳನ್ನು ಕೇಳಲಾಗುತ್ತದೆ ಮತ್ತು ನಿಮ್ಮ ಜ್ಞಾನದ ಅತ್ಯುತ್ತಮ ಉತ್ತರಿಸಲು ಸೇರಬೇಕೆಂದು.
ಈ ಸಂಶೋಧನೆ ನಿಮ್ಮ ಭಾಗವಹಿಸುವಿಕೆ ವೈಯಕ್ತಿಕವಾಗಿದ್ದು. ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಲು ಅಲ್ಲವೋ ಎಂಬುದನ್ನು ನಿಮ್ಮ ನಿರ್ಧಾರ ಜೆ.ಎನ್ ವೈದ್ಯಕೀಯ ಕಾಲೇಜು ನಿಮ್ಮ ಸಂಬಂಧ ಪರಿಣಾಮ ಬೀರುವುದಿಲ್ಲ. ನೀವು ಭಾಗವಹಿಸಲು ನಿರ್ಧರಿಸಿ, ಯಾವುದೇ ಸಮಯದಲ್ಲಿ ಹಿಂದಕ್ಕೆ ಉಚಿತ.

ಪ್ರಡಿ ಅಗತ್ಯಗಳು

ಸಿಂಡ್ರೋಮ್ ಡೌನ್ ಮಂದಬುದ್ಧಿ ಮತ್ತು ಇತರ ಅಭಿವೃದ್ಧಿ ದೋಷಗಳ ಅತಿ ಸಾಮಾನ್ಯವಾಗಿ ಗುರುತಿಸಲ್ಪಡುವ ಆನುವಂಶಿಕ ಕಾರಣವಾಗಿದೆ. ಭಾರತದಲ್ಲಿ, ಮಹಿಳೆಯರು ಈಗಲೂ ಪ್ರಸವಪೂರ್ವ ರೋಗನಿರ್ಣಯದ ತಂತ್ರಗಳನ್ನು ಬಗ್ಗೆ ಅರಿವಿರಲಿಲ್ಲ ಮತ್ತು ಸಕಾರಾತ್ಮಕ ಪ್ರತಿಕ್ರಿಯೆ. ಈ ಅಧ್ಯಯನವು ಜಾಗೃತಿ ಮೌಲ್ಯಮಾಪನ ಮತ್ತು ಮಹಿಳೆಯರಲ್ಲಿ ಸಮ್ಮತಿಗೆ ಪ್ರಚಾರ ಅಗತ್ಯವಿದೆ.

ಅಧ್ಯಯನದ ಉದ್ದೇಶ:

ಸಂಶೋಧನಾ ಉದ್ದೇಶ ಜಾಗೃತಿ ಮೌಲ್ಯಮಾಪನ ಮತ್ತು ಪ್ರಸವಪೂರ್ವ ಕ್ಲಿನಿಕ್ ಹಾಜರಾಗುವ ಮಹಿಳೆಯರಲ್ಲಿ ಡೌನ್ ಸಿಂಡ್ರೋಮ್ ಪರೀಕ್ಷಾ ಸ್ವೀಕಾರ ಪ್ರಚಾರ.

ವಿಧಾನ ಒಳಗೊಂಡ:

ನೀವು ನನ್ನ ಅಧ್ಯಯನದ ನಿಮ್ಮನ್ನು ತೊಡಗಿಸಿಕೊಳ್ಳುವುದು ಒಪ್ಪುತ್ತೀರಿ ವೇಳೆ, ನೀವು ಗರ್ಭಾವಸ್ಥೆಯ ನಿಮ್ಮ ಅವಧಿಯಲ್ಲಿ (– 11 ರಿಂದ 13 ವಾರಗಳ ಜೊತೆಗೆ 6 ದಿನಗಳ. ಗುಂಪು 2 – 15 ರಿಂದ 23 ವಾರಗಳ ಗ್ರೂಪ್ 1) ಪ್ರಕಾರ, ಎರಡು ಗುಂಪುಗಳಲ್ಲಿ ಒಂದರಲ್ಲಿ ಇಡಲಾಗುತ್ತದೆ. ಪ್ರಕಾರ. ನೀವು ಲಭ್ಯವಿರುವ ವಿವಿಧ ಪರೀಕ್ಷಾ ಬಗ್ಗೆ ನೀವು ಡೌನ್ ಸಿಂಡ್ರೋಮ್ ಸ್ಕ್ರೀನಿಂಗ್, ಕುಟುಂಬ ಮತ್ತು ಜೀನ್ಗಳ ಪರೀಕ್ಷೆಯಲ್ಲಿ ರಲ್ಲಿ ವರ್ಣತಂತುಗಳ ಅಸ್ವಸ್ಥತೆಯನ್ನು ಹಿಂದಿನ ಇತಿಹಾಸವನ್ನು ಬಗ್ಗೆ ನಿಮ್ಮ ಪ್ರಸ್ತುತ ಜ್ಞಾನದ ಬಗ್ಗೆ ಒಂದು ಪ್ರಶ್ನಾವಳಿಯನ್ನು ತುಂಬಲು ಕೇಳಲಾಗುತ್ತದೆ, ಮತ್ತು ನೀವು ಮತ್ತು ನಿಮ್ಮ ಸಂಗಾತಿಯ ಸಲಹೆ ಮಾಡಲಾಗುತ್ತದೆ ನಿಮ್ಮ ಗರ್ಭಾವಸ್ಥೆಯ ಅವಧಿ. ಪರೀಕ್ಷೆಗಳು ಕಡೆಗೆ ನಿಮ್ಮ ವರ್ತನೆ ಮತ್ತು ಪರೀಕ್ಷಾ ಸ್ವೀಕರಿಸಲು ನಿಮ್ಮ ಸಿದ್ಧತೆ ದಾಖಲಿಸಲಾಗಿದೆ ಮಾಡಲಾಗುತ್ತದೆ.

ಅಪಾಯಗಳು:

ಯಾವುದೇ ಅಪಾಯಗಳನ್ನು ಪ್ರಶ್ನಾವಳಿಗಳ ಭರ್ತಿ ಪ್ರಕ್ರಿಯೆಯಲ್ಲಿ, ಅಥವಾ ಸಮಾಲೋಚನೆ ಸಮಯದಲ್ಲಿ, ಭಾಗಿಯಾಗಬಹುದು.

ಪ್ರಯೋಜನಗಳು:

ಇದು ಡೌನ್ ಸಿಂಡ್ರೋಮ್ ಮತ್ತು ಅದರ ಸ್ಕ್ರೀನಿಂಗ್ ಅರಿವು ಮತ್ತು ಮಹಿಳೆಯರ ಸ್ವೀಕಾರ ಬಗ್ಗೆ ಸ್ಥಳೀಯ ಸಾಕ್ಷಿ ಆಧಾರಿತ ಮಾರ್ಗದರ್ಶಿ ರೂಪಿಸಲು ಸಹಾಯ ಮಾಡುತ್ತದೆ. ಮತ್ತು ಇದು ಒಂದೆರಡು ಮುಂದುವರಿಸಲು ಅಥವಾ ಕಬಳಿಸಿದ ಗರ್ಭಧಾರಣೆಯ ಅಂತ್ಯಗೊಳಿಸಲು ಆಯ್ಕೆ ನೀಡುತ್ತದೆ.

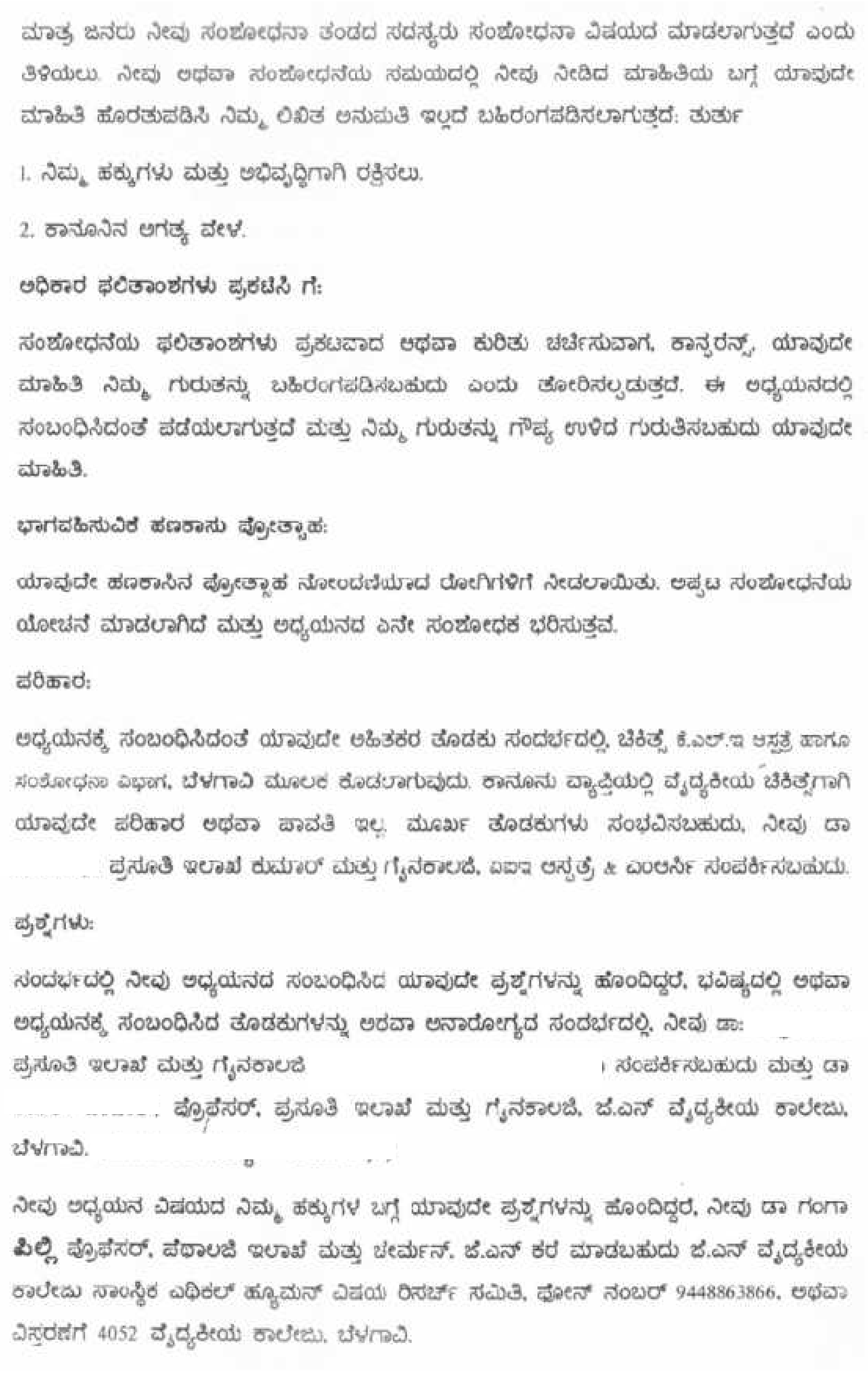
ವಾಲಂಟರಿ ಭಾಗವಹಿಸುವಿಕೆ / ವಾಪಸಾತಿ:

ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಿದ ವೈಯಕ್ತಿಕವಾಗಿದ್ದು. ಈ ಅಧ್ಯಯನದಲ್ಲಿ ನಿಮ್ಮನ್ನು ತೊಡಗಿಸಿಕೊಳ್ಳುವುದು ಅಲ್ಲ ಆಯ್ಕೆ ಮಾಡಬಹುದು. ನಿಮಗೆ ಪ್ರಸ್ತುತ ಅಥವಾ ಭವಿಷ್ಯದ ಆರೋಗ್ಯ ಸೇವೆಗಳ ಬದಲಾಗುವುದಿಲ್ಲ ನಿಮ್ಮ ನಿರ್ಧಾರ ಆಸ್ಪತ್ರೆಯಲ್ಲಿ.

ಪರ್ಯಾಯಗಳು:

ನೀವು ಅಧ್ಯಯನದಲ್ಲಿ ಪಾಲ್ಗೊಳ್ಳುವಿಕೆಯನ್ನು ಇಳಿಕೆ, ನೀವು ನಿರ್ವಹಣೆಯ ದಿನನಿತ್ಯದ ಲೈನ್ ಪಡೆಯುತ್ತಾನೆ.

ಗೌಪ್ಯತೆ ಮತ್ತು ರಹಸ್ಯವಾದ.



ಮಾತ್ರ ಜನರು ನೀವು ಸಂಶೋಧನಾ ತಂಡದ ಸದಸ್ಯರು ಸಂಶೋಧನಾ ವಿಷಯದ ಮಾಡಲಾಗುತ್ತದೆ ಎಂದು ತಿಳಿಯಲು. ನೀವು ಅಥವಾ ಸಂಶೋಧನೆಯ ಸಮಯದಲ್ಲಿ ನೀವು ನೀಡಿದ ಮಾಹಿತಿಯ ಬಗ್ಗೆ ಯಾವುದೇ ಮಾಹಿತಿ ಹೊರತುಪಡಿಸಿ ನಿಮ್ಮ ಲಿಖಿತ ಅನುಮತಿ ಇಲ್ಲದೆ ಬಹಿರಂಗಪಡಿಸಲಾಗುತ್ತದೆ: ತುರ್ತು

1. ನಿಮ್ಮ ಹಕ್ಕುಗಳು ಮತ್ತು ಅಭಿವೃದ್ಧಿಗಾಗಿ ರಕ್ಷಿಸಲು.

2. ಕಾನೂನಿನ ಅಗತ್ಯ ವೇಳೆ.

ಅಧಿಕಾರ ಫಲಿತಾಂಶಗಳು ಪ್ರಕಟಿಸಿ ಗೆ:

ಸಂಶೋಧನೆಯ ಫಲಿತಾಂಶಗಳು ಪ್ರಕಟವಾದ ಅಥವಾ ಕುರಿತು ಚರ್ಚಿಸುವಾಗ, ಕಾನ್ಫರೆನ್ಸ್, ಯಾವುದೇ ಮಾಹಿತಿ ನಿಮ್ಮ ಗುರುತನ್ನು ಬಹಿರಂಗಪಡಿಸಬಹುದು ಎಂದು ತೋರಿಸಲ್ಪಡುತ್ತದೆ. ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಸಂಬಂಧಿಸಿದಂತೆ ಪಡೆಯಲಾಗುತ್ತದೆ ಮತ್ತು ನಿಮ್ಮ ಗುರುತನ್ನು ಗೌಪ್ಯ ಉಳಿದ ಗುರುತಿಸಬಹುದು ಯಾವುದೇ ಮಾಹಿತಿ.

ಭಾಗವಹಿಸುವಿಕೆ ಹಣಕಾಸು ಪ್ರೋತ್ಸಾಹ:

ಯಾವುದೇ ಹಣಕಾಸಿನ ಪ್ರೋತ್ಸಾಹ ನೋಂದಣಿಯಾದ ರೋಗಿಗಳಿಗೆ ನೀಡಲಾಯಿತು. ಅಪ್ಪಟ ಸಂಶೋಧನೆಯ ಯೋಚನೆ ಮಾಡಲಾಗಿದೆ ಮತ್ತು ಅಧ್ಯಯನದ ಏನೇ ಸಂಶೋಧಕ ಭರಿಸುತ್ತವೆ.

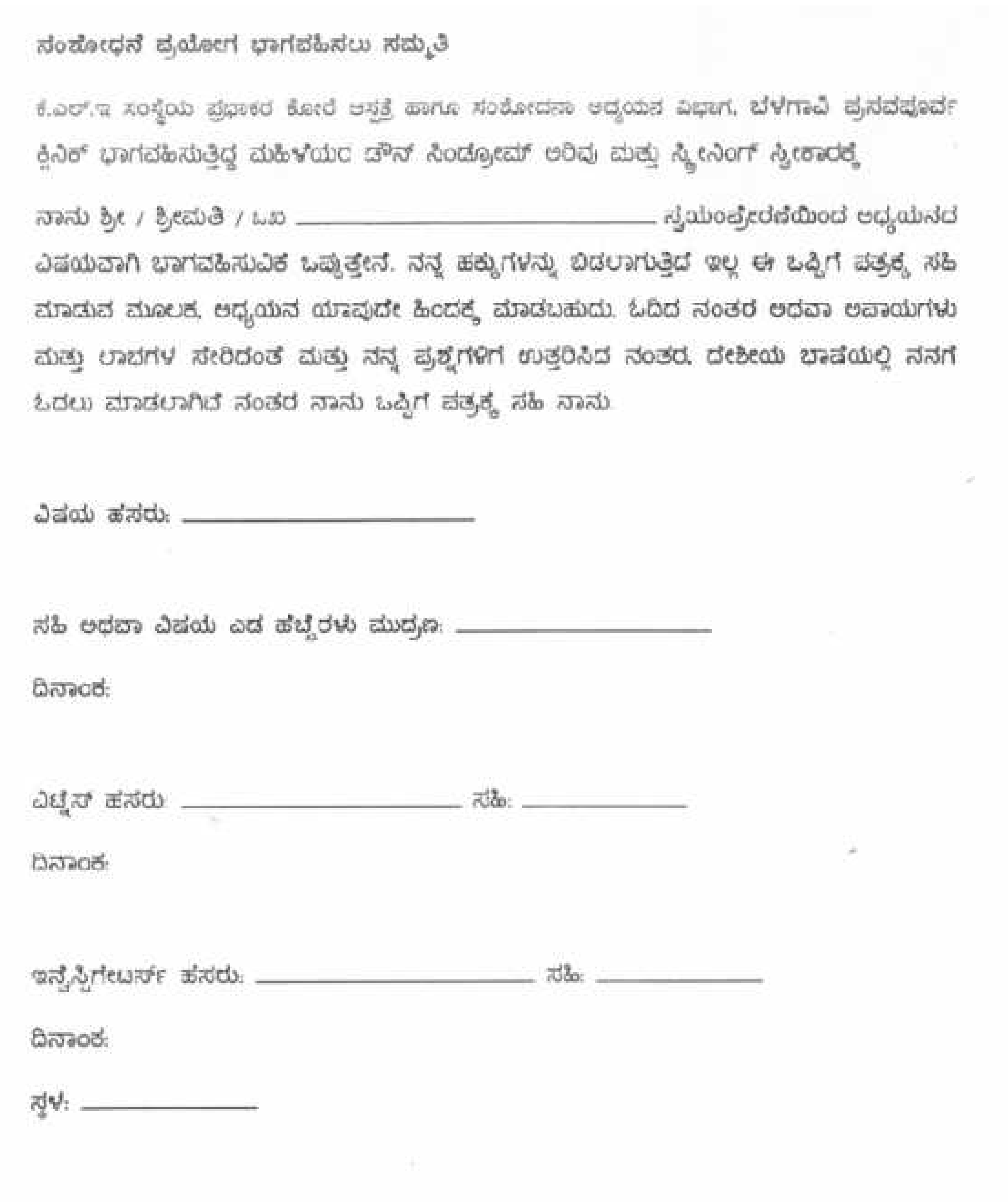
ಪರಿಹಾರ:

ಅಧ್ಯಯನಕ್ಕೆ ಸಂಬಂಧಿಸಿದಂತೆ ಯಾವುದೇ ಅಹಿತಕರ ತೊಡಕು ಸಂದರ್ಭದಲ್ಲಿ, ಚಿಕಿತ್ಸೆ ಕೆ.ಎಲ್.ಇ ಆಸ್ಪತ್ರೆ ಹಾಗೂ ಸಂಶೋಧನಾ ವಿಭಾಗ, ಬೆಳಗಾವಿ ಮೂಲಕ ಕೊಡಲಾಗುವುದು. ಕಾನೂನು ವ್ಯಾಪ್ತಿಯಲ್ಲಿ ವೈದ್ಯಕೀಯ ಚಿಕಿತ್ಸೆಗಾಗಿ ಯಾವುದೇ ಪರಿಹಾರ ಅಥವಾ ಪಾವತಿ ಇಲ್ಲ. ಮೂರ್ಖ ತೊಡಕುಗಳು ಸಂಭವಿಸಬಹುದು, ನೀವು ಡಾ ಪ್ರಸೂತಿ ಇಲಾಖೆ ಕುಮಾರ್ ಮತ್ತು ಗೈನಕಾಲಜಿ, ಎವಾಇ ಆಸ್ಪತ್ರೆ & ಎಂಆರ್ಸಿ ಸಂಪರ್ಕಿಸಬಹುದು.

ಪ್ರಶ್ನೆಗಳು:

ಸಂದರ್ಭದಲ್ಲಿ ನೀವು ಅಧ್ಯಯನದ ಸಂಬಂಧಿಸಿದ ಯಾವುದೇ ಪ್ರಶ್ನೆಗಳನ್ನು ಹೊಂದಿದ್ದರೆ, ಭವಿಷ್ಯದಲ್ಲಿ ಅಥವಾ ಅಧ್ಯಯನಕ್ಕೆ ಸಂಬಂಧಿಸಿದ ತೊಡಕುಗಳನ್ನು ಅರವಾ ಅನಾರೋಗ್ಯದ ಸಂದರ್ಭದಲ್ಲಿ, ನೀವು ಡಾ: ಪ್ರಸೂತಿ ಇಲಾಖೆ ಮತ್ತು ಗೈನಕಾಲಜಿ । ಸಂಪರ್ಕಿಸಬಹುದು ಮತ್ತು ಡಾ ಪ್ರೊಫೆಸರ್, ಪ್ರಸೂತಿ ಇಲಾಖೆ ಮತ್ತು ಗೈನಕಾಲಜಿ, ಜೆ.ಎನ್ ವೈದ್ಯಕೀಯ ಕಾಲೇಜು, ಬೆಳಗಾವಿ.

ನೀವು ಅಧ್ಯಯನ ವಿಷಯದ ನಿಮ್ಮ ಹಕ್ಕುಗಳ ಬಗ್ಗೆ ಯಾವುದೇ ಪ್ರಶ್ನೆಗಳನ್ನು ಹೊಂದಿದ್ದರೆ, ನೀವು ಡಾ ಗಂಗಾ ಪಿಲ್ಲೈ ಪ್ರೊಫೆಸರ್, ಪೆಥಾಲಜಿ ಇಲಾಖೆ ಮತ್ತು ಚೇರ್ಮನ್, ಜೆ.ಎನ್ ಕರೆ ಮಾಡಬಹುದು ಜೆ.ಎನ್ ವೈದ್ಯಕೀಯ ಕಾಲೇಜು ಸಾಂಸ್ಥಿಕ ಎಥಿಕಲ್ ಹ್ಯೂಮನ್ ವಿಷಯ ರಿಸರ್ಚ್ ಸಮಿತಿ, ಫೋನ್ ನಂಬರ್ 9448863866, ಅಥವಾ ವಿಸ್ತರಣೆಗೆ 4052 ವೈದ್ಯಕೀಯ ಕಾಲೇಜು, ಬೆಳಗಾವಿ.



ಸಂಶೋಧನೆ ಪ್ರಯೋಗ ಭಾಗವಹಿಸಲು ಸಮ್ಮತಿ

ಕೆ.ಎಲ್.ಇ ಸಂಸ್ಥೆಯ ಪ್ರಭಾಕರ ಕೋರೆ ಆಸ್ಪತ್ರೆ ಹಾಗೂ ಸಂಶೋದನಾ ಅಧ್ಯಯನ ವಿಭಾಗ, ಬೆಳಗಾವಿ ಪ್ರಸವಪೂರ್ವ ಕ್ಲಿನಿಕ್ ಭಾಗವಹಿಸುತ್ತಿದ್ದ ಮಹಿಳೆಯರ ಡೌನ್ ಸಿಂಡ್ರೋಮ್ ಅರಿವು ಮತ್ತು ಸ್ಕ್ರೀನಿಂಗ್ ಸ್ವೀಕಾರಕ್ಕೆ

ನಾನು ಶ್ರೀ / ಶ್ರೀಮತಿ / ಒ.ಖ ______________________ ಸ್ವಯಂಪ್ರೇರಣೆಯಿಂದ ಅಧ್ಯಯನದ ವಿಷಯವಾಗಿ ಭಾಗವಹಿಸುವಿಕೆ ಒಪ್ಪುತ್ತೇನೆ. ನನ್ನ ಹಕ್ಕುಗಳನ್ನು ಬಿಡಲಾಗುತ್ತಿದೆ ಇಲ್ಲ ಈ ಒಪ್ಪಿಗೆ ಪತ್ರಕ್ಕೆ ಸಹಿ ಮಾಡುವ ಮೂಲಕ, ಅಧ್ಯಯನ ಯಾವುದೇ ಹಿಂದಕ್ಕೆ ಮಾಡಬಹುದು. ಓದಿದ ನಂತರ ಅಥವಾ ಅಪಾಯಗಳು ಮತ್ತು ಲಾಭಗಳ ಸೇರಿದಂತೆ ಮತ್ತು ನನ್ನ ಪ್ರಶ್ನೆಗಳಿಗೆ ಉತ್ತರಿಸಿದ ನಂತರ, ದೇಶೀಯ ಭಾಷೆಯಲ್ಲಿ ನನಗೆ ಓದಲು ಮಾಡಲಾಗಿದೆ ನಂತರ ನಾನು ಒಪ್ಪಿಗೆ ಪತ್ರಕ್ಕೆ ಸಹಿ ನಾನು.

ವಿಷಯ ಹೆಸರು: ______________________

ಸಹಿ ಅಥವಾ ವಿಷಯ ಎಡ ಹೆಬ್ಬೆರಳು ಮುದ್ರಣ: ______________________

ದಿನಾಂಕ:

ವಿಟ್ನೆಸ್ ಹೆಸರು ______________________ ಸಹಿ: ______________

ದಿನಾಂಕ:

ಇನ್ವೆಸ್ಟಿಗೇಟರ್ ಹೆಸರು: ______________________ ಸಹಿ: ______________

ದಿನಾಂಕ:

ಸ್ಥಳ: ______________

ANNEXURE – II - PROFORMA

Awareness and Acceptability of Screening for Down Syndrome in the women attending Antenatal Clinic at KLE'S Dr. Prabhakar Kore Charitable Hospital & MRC, Belgaum

Serial Number -

Date of Interview - IP No.

SECTION ONE

Name of Patient Age

Husband's Name Age

Address – Urban/Rural

Phone Number -

Education (Patient) – Illiterate/ Primary school/ High school/ Pre University/ Diploma/ Graduation/ Post graduation

Education (Husband) - lliterate/ Primary school/ High school/ Pre University/ Diploma/ Graduation/ Post graduation

Socio-economic Class –

Obstetric History Married life & Consanguinity -

Gravida Para Living Abortion Death

Did any child have a birth defect or was diagnosed with a chromosomal abnormality? Yes/No

If yes, what was the diagnosis?

Menstrual History

LMP EDD POG

SECTION TWO

Have you heard of Down's Syndrome?

Patient : Yes/No

Husband : Yes/No

If yes, then what was the source of your information?

TV/ Radio/ Newspaper/ Textbook/ From a friend or family member

Others-

What is your knowledge regarding it?

Have you heard about Prenatal SCREENING techniques for DS?

(NT Scan/Dual/Triple/Quadruple markers) Yes/No

If Yes, What is your knowledge regarding it?

SECTION THREE

Screening test offered to the patient according to the period of gestation-

NT Scan, PAPP-A, hcG

Alpha-fetoprotein, Unconjugated estrioL, Beta hcG, Inhibin A

Would you be willing to undergo the screening test advised to you? Yes/No

If no, then what is the reason?

1. Not affordable
2. Unsure, Will discuss with Husband/Family members and then decide
3. Do not think the tests are necessary, Have a ‘feeling’ that the child will be allright
4. Do not want to know the fate of the child as this pregnancy is precious to them
5. Others –

SECTION FOUR

What do you think about prenatal screening tests?

1. It is a good thing. It helps people find out if their pregnancy is affected with Down Syndrome.
2. It is a bad thing. It makes people anxious without telling them for sure whether or not the child will have Down syndrome.
3. It is a bad thing. Its purpose is only to allow people to terminate pregnancies that are affected with Down syndrome.
4. I am not sure what I think about prenatal screening tests for Down syndrome.

I, Mrs. ______________________________, have answered the above questions to the best of my knowledge.

Subject name :

Signature or the Left thumb print of subject :

Date:

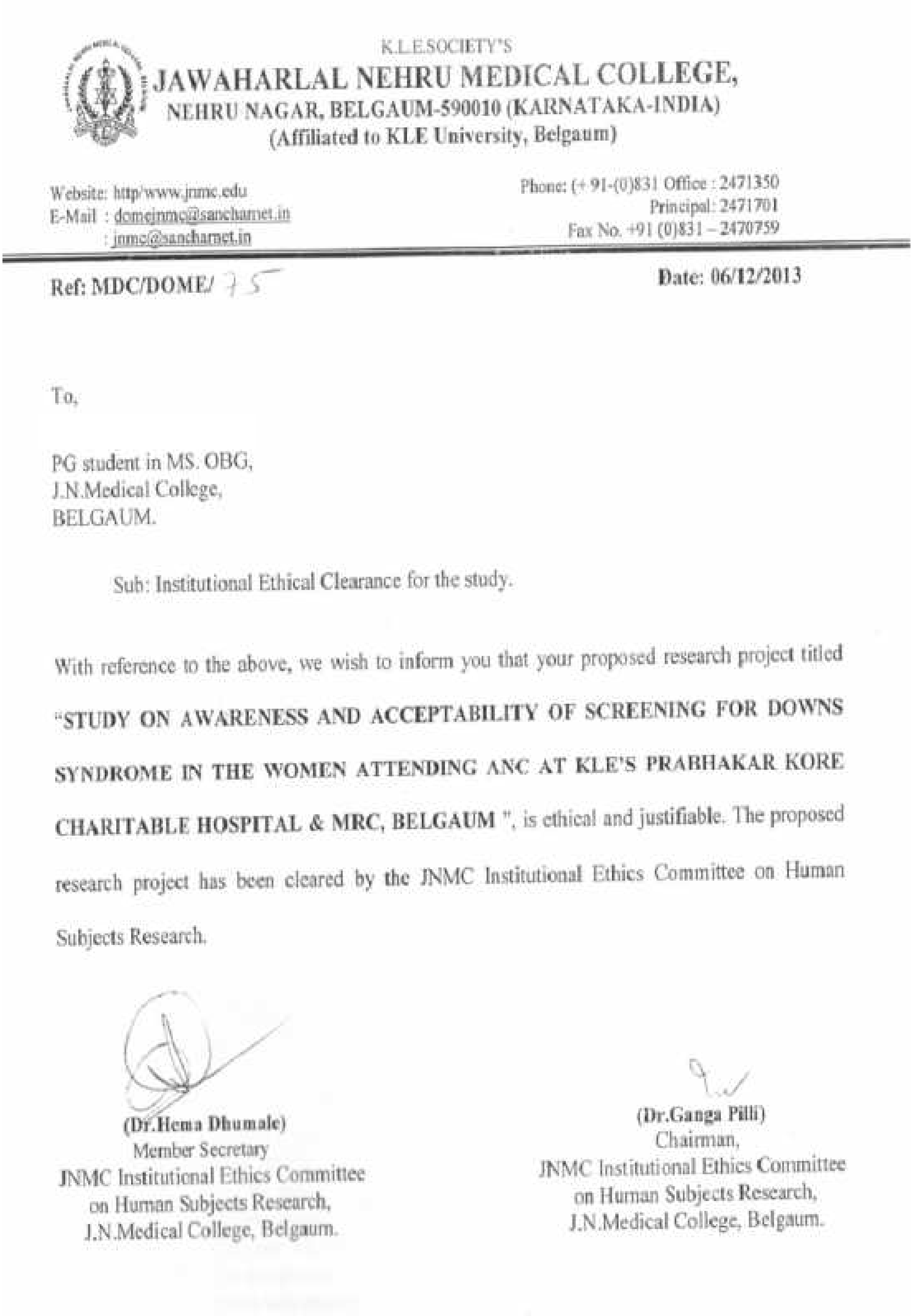
Investigators Name:

Signature:

Date:

Place:

ANNEXURE – III – ETHICAL CLEARANCE LETTER



K.L.E.SOCIETY'S
JAWAHARLAL NEHRU MEDICAL COLLEGE,
NEHRU NAGAR, BELGAUM-590010 (KARNATAKA-INDIA)
(Affiliated to KLE University, Belgaum)

Website: http/www.jnmc.edu
E-Mail : domejnmc@sancharnet.in
: jnmc@sancharnet.in

Phone: (+91-(0)831 Office : 2471350
Principal: 2471701
Fax No. +91 (0)831 – 2470759

Ref: MDC/DOME/ 75

Date: 06/12/2013

To,

PG student in MS. OBG,
J.N.Medical College,
BELGAUM.

Sub: Institutional Ethical Clearance for the study.

With reference to the above, we wish to inform you that your proposed research project titled "**STUDY ON AWARENESS AND ACCEPTABILITY OF SCREENING FOR DOWNS SYNDROME IN THE WOMEN ATTENDING ANC AT KLE'S PRABHAKAR KORE CHARITABLE HOSPITAL & MRC, BELGAUM** ", is ethical and justifiable. The proposed research project has been cleared by the JNMC Institutional Ethics Committee on Human Subjects Research.

(Dr.Hema Dhumale)
Member Secretary
JNMC Institutional Ethics Committee
on Human Subjects Research,
J.N.Medical College, Belgaum.

(Dr.Ganga Pilli)
Chairman,
JNMC Institutional Ethics Committee
on Human Subjects Research,
J.N.Medical College, Belgaum.

ANNEXURE – IV - KEY TO MASTERCHART

Education

I – Illiterate

PS – Primary School

SS – Secondary School

C – College

Socio economic Status

APL – Above Poverty Line

BPL – Below Poverty Line

Religion

H – Hindu

M – Muslim

C – Christian

Obstetric Score

G – Gravida

P – Para

L – Living

A – Abortion

Risk Status

H – High Risk

L – Low Risk

Risk Factor

1. Increased maternal age (equal to or more than 35 years)
2. Previous child/ children having DS/other chromosomal abnormality
3. Previous child (or children) suffering from Mental retardation (MR) but the patient was either unsure or unaware about the cause of the mental retardation
4. History of chromosomal abnormality in the family or had family members who were suffering from MR or other signs and symptoms similar to DS, the cause of which the patient was unsure of.

NA – Not Applicable

Screening test offered

NT and DM – NT Scan and Dual Marker test

QM – Quadruple Marker Test

Knowledge about screening for DS

Y – Yes

N – No

Source of knowledge

1 – Doctor

2 – Family / Friends

3 – Books / Magazines

Acceptability for NT Scan

Y – Yes

N – No

NA – Not Applicable

Acceptability for DM

Y – Yes

N – No

NA – Not Applicable

Acceptability for QM

Y – Yes

N – No

NA – Not Applicable

Reason for Non Acceptance

1 – Non affordability

2 – Husband/ Family not consenting for the test

3 – Unsure, Will decide later

4 – Convinced that the baby is fine, No need for testing

5 – Pregnancy is precious to them, do not want to know the fate of the baby

6 – Others

NA – Not Applicable

Attitude towards prenatal testing

1. Is a good thing and that it helps people find out if their pregnancy is affected with DS or not
2. Is a bad thing as it makes people anxious without telling them for sure whether or not the child will have DS
3. Is a bad thing as its only purpose is to allow people to terminate pregnancies affected with DS
4. Unsure how they feel about prenatal testing