IMPACT OF MORINGA LEAVES TABLETS ON PROLACTIN LEVELS OF LACTATING WOMEN AND WEIGHT GAIN PATTERN OF INFANTS

APRIL 2023

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Foods and Nutrition

IMPACT OF MORINGA LEAVES TABLETS ON PROLACTIN LEVELS OF LACTATING WOMEN AND WEIGHT GAIN PATTERN OF INFANTS

A DISSERTATION SUBMITTED IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE DEGREE OF

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(PUBLIC HEALTH NUTRITION)

BY

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Certificate

This is to certify that the research work presented in this thesis has been carried out independently by

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DEDICATION

I dedicated my humble effort of M.Sc. dissertation work,

to my back bones,

Father (Mr. Rakesh Arora), Mother (Mrs. Manju Arora)

And

Grandmother (Mrs. Ishwaridevi Arora)

For their endless Love, Support and Prayers.

Without the inspiration, drive and support, that you have given me, I might not be the person I am today. Nothing I say could ever convey my gratitude and appreciation for you.

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A special thanks goes to all the women who enrolled themselves for the study. Without their cooperation the research wouldn't have been possible.

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I so want to take the opportunity to thank my parents from the bottom of my heart for all the selfless love, care, blessings, for always been my back. I would be nothing without their support. Special thanks to Mom for giving me strength and making me a courageous, ethical and confident person; for teaching me to take confident decision; And dad for all the endless love and care despite being an inexpressive humour. No words could ever explain my feelings, gratitude and love for them. Also, thank you for making my life prosperous. I hope I get ample chances in my life to make your chest filled with pride and give you a fulfilling life ahead.

I special thanks to my co-researcher and friend Palak Nilesh Bhagat. This journey couldn’t be full of laughter, craziness and smiles without you.

Above all, I am indebted to the Almighty, who has immensely blessed me with all the things a have. Just want him to continue shower his blessings on me and I can’t be moregrateful and fulfilled from my life. Will always be trusting his plans before mine.

Dhwani Arora

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INTRODUCTION

BACKGROUND

Breastfeeding is one of sustainable and effective method considered for a child's survival, growth and development. Breast milk is considered as an ideal food for infant, provides all the essential nutrients in sufficient amounts needed in first new months of life. It is sterile, safe and contains antibodies which helps as an immunity factor providing defense against infections. About 1/2 & 1/3 of child's nutritional requirements are fulfilled by breastmilk in second half of first year and second year of life respectively.

Breastfeeding helps in combating malnutrition (undernutrition & overnutrition), helps in giving healthy start to the life, helps in developing appropriate IQ. (WHO)

Malnutrition continues to afflict millions of women and children, particularly in low-income and middle-income countries. Malnutrition refers to undernutrition resulting from inadequate consumption, poor absorption or excessive loss of nutrients but the term also includes overnutrition, resulting from excessive intake of specific nutrients and diet related non-communicable diseases.

Around 45% of deaths among children under 5 years of age are linked to undernutrition. These mostly occur in low- and middle-income countries. At the same time, in these same countries, rates of childhood overweight and obesity are rising. Women, infants, children, and adolescents are at particular risk of malnutrition.

Breastfeeding plays a vital role in conquering childhood Malnutrition including wasting, stunting, underweight and overweight. It helps in protection of infectious and non-infectious disease prevention. The unique composition of breastmilk, helps in maintaining iron status of the infant and acts as immunity factor. (Veronika Scherbaum and M Leila Srour, 2019)

Importance of breastmilk

- Human milk is sterile, and the most cost-effective strategy to promote adequate growth and wellbeing.
- It is known that breastmilk is the most digestible food for an infant for improving child survival and reducing the burden of childhood disease.
- The bioactive components found in breast milk:

✓ promote gastrointestinal development,

✓ provide substrate for brain development and

✓ reduce the incidence of sepsis and necrotizing enterocolitis, both of which are linked in part to a negative impact on neurodevelopment. (Asztelos, 2018)

✓ **Advantages of breastfeeding:**

- Perfect nutrition

Best food containing all important nutrients in sufficient amount needed for the development and growth of an infant.

- Protection

Breastfeeding contains colostrum and antibodies like IgA which helps in providing immunity to the infants against infectious disease, SIDS, overweight or obesity.

- Brain power

Children who were breastfed have higher IQ than who were not breastfed.

- Ready, portable and free of cost.

Breastmilk is fresh and always available at right temperature and consistency. It is also available free of cost.

- Size do not matter

Breast size has nothing to do with the amount of milk produced. All sizes of breasts produce enough milk required for their infant.

- Beneficial for mothers too

Breastfeeding helps to protect mothers from diseases like ovarian cancer, breast cancer, diabetes, hypertension, heart disease.

- Builds a special bond.

Breastfeeding helps in strengthening mother- child relation by feeling the closeness and warmth between both of them.

- Good for the planet

Gets delivered right to baby without any processing, preservation, chemicals involvement. (https://www.canada.ca/en/public-health/services/health-promotion/childhood-adolescence/stages-childhood/infancy-birth-two-years/breastfeeding-infant-nutrition/10-great-reasons-breastfeed-your-baby.html)

Benefits of breastmilk for infants and mechanism of action

- Aids in iron binding and transport. Therefore, increase in iron absorption.

- Transportation of antibodies and WBCs from mother's milk to the child. Disease specific antibodies to which mother was exposed to is easily transmitted through breast milk to the child.
  Therefore, provides immunity and protection to the child.

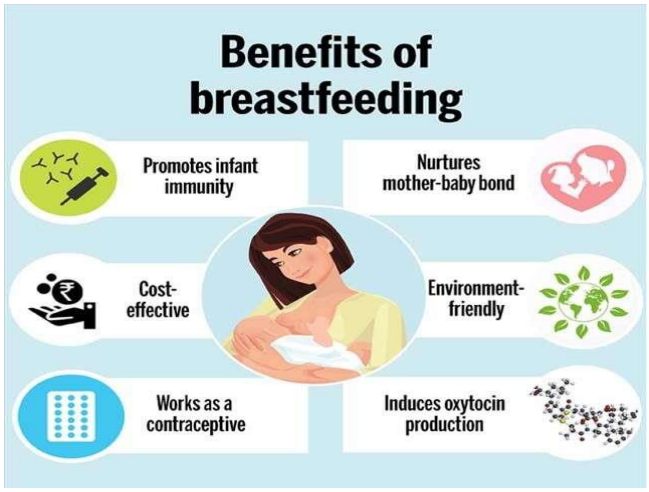
- Breastmilk acts as Bifidus factor. It promotes the growth of lactobacillus bacteria in the gut of the child.

- Certain pancreatic enzymes like amylase and lipase are transported through breastmilk to the infant for its immature pancreatic function. Therefore, aids in perfect digestion for the child

- Breast feeding induces skin-to-skin contact. Therefore, helps in the body temperature and blood pressure of the child; also boosts bonding and pain relief.

Source: (https://calgaryguide.ucalgary.ca/benefits-of-breast-milk-to-infants-mechanism-of-action/)

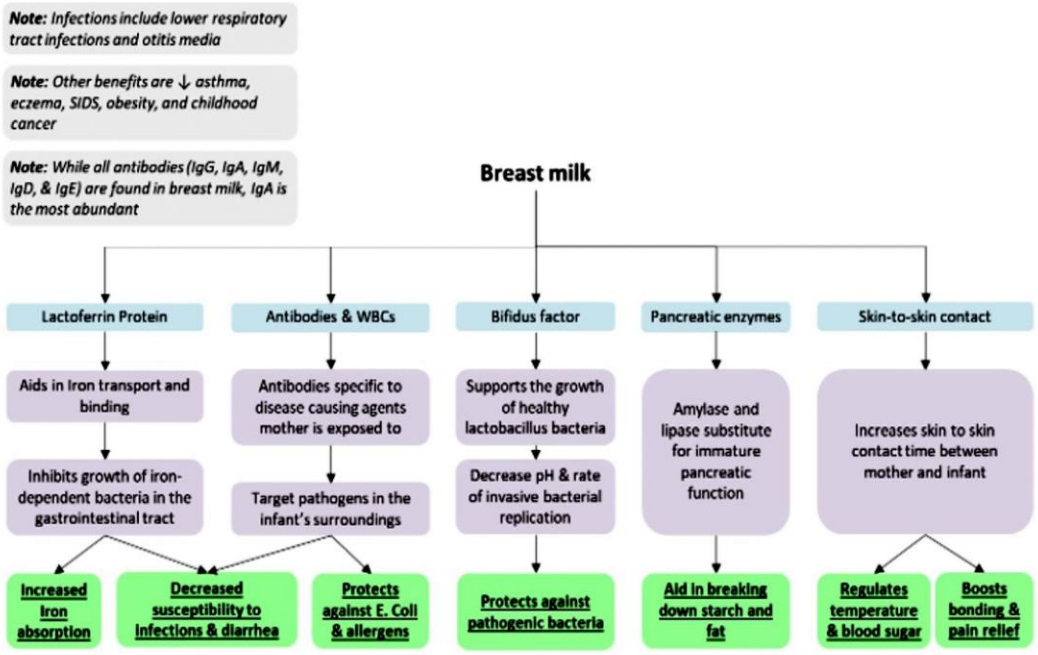
General Advantage of Breastfeeding is presented in **Fig 1.1**



Source:(https://femina.wwmindia.com/content/2018/aug/info1533210087.jpg

Benefits of breast milk for infants and its mechanism of action is presented in Fig-1.2

Fig 1.2 – Mechanism of Breastmilk and its advantages in infant.



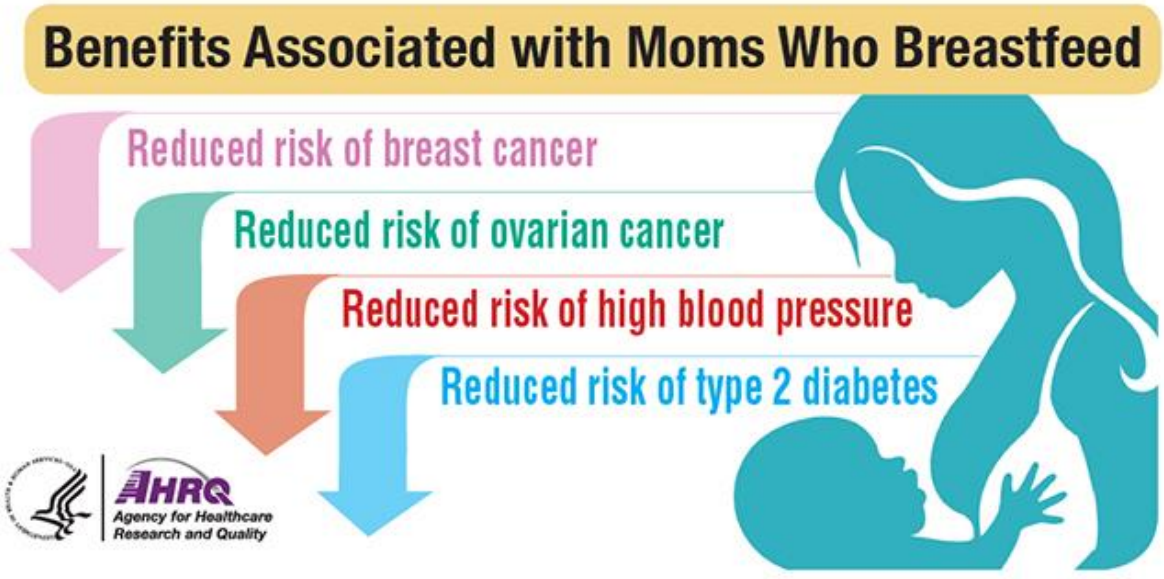
Source:(https://calgaryguide.ucalgary.ca/benefits-of-breast-milk-to-infants-mechanism-of-action/)

When a child is not breastfed, that child is less likely to survive. He or she is more likely to contract life-threatening illnesses and be less able to fight off sicknesses. As per UN Inter-agency Group for Child Mortality Estimation. Infant mortality rate in India is 28 per 1000 live births as estimated in the year 2019. (UNICEF, WHO, World Bank, UN DESA Population Division)

In the fetal origin of adult diseases, a link has been clearly established between fetal and infant growth with cardiovascular health. Infant food composition plays a crucial role in motor development of pre-term infants and lipid metabolism programming. Schizophrenia and obstructive lung diseases in children are also impacted by maternal environment. (Barker *DJP, 2003)*

Breastfeeding has been identified as one of the most economical preventative measures for non-communicable diseases including obesity later in life. (*Rollins NC et al, 2016)*

Benefits of breastfeeding is depicted in Fig 1.3



(Breastfeeding Programs and Policies, Breastfeeding Uptake, and Maternal Health Outcomes in Developed Countries. Comparative Effectiveness Review No. 210. AHRQ Publication No. 18-EHC014-EF. July 2018.)

Recent NFHS-5 (2015-16) data has reported the IYCN Practices for Gujarat which is shown in Fig.1.4, 1.5 and 1.6

Around, 41.6 % of the children under 3 yrs of age were breastfed within 1 hr of birth. 54.9% children in India under 6 months of age are breastfed.

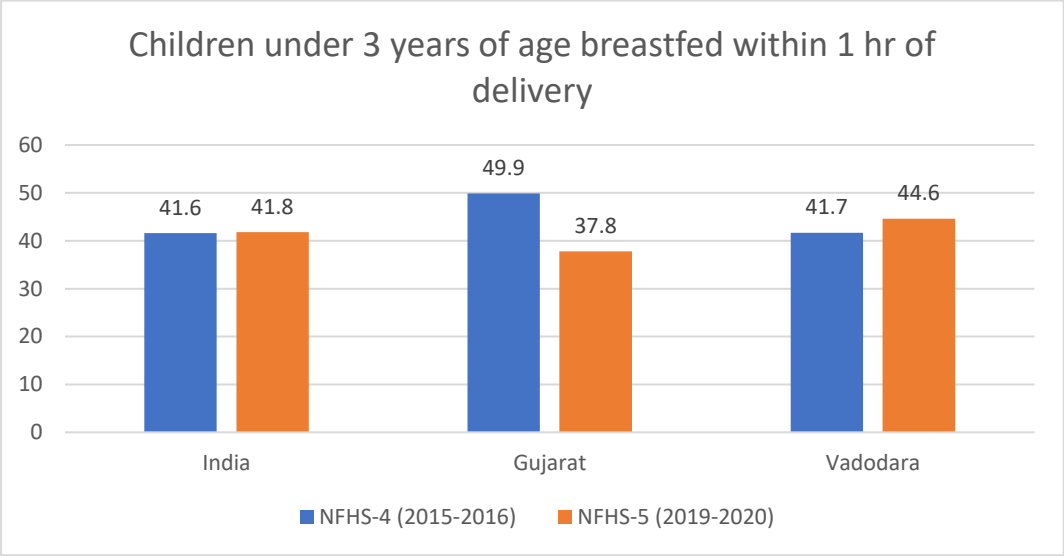
49.9% children under 3 yrs of age were breastfed within 1 hr of birth. 55.8% children under 6 months of age are breastfed in Gujarat.

As per NFHS-5 Vadodara factsheets that 44.6 % of children under 3 years of age were breastfed with 1 hr of birth. Around 68.8% of children under 6 months of age were breastfed in Gujarat. (NFHS-4, NFHS-5)

As per NFHS-5 data, the rates of exclusive breastfeeding have increased to about 7-9 % both in India as well as Gujarat.

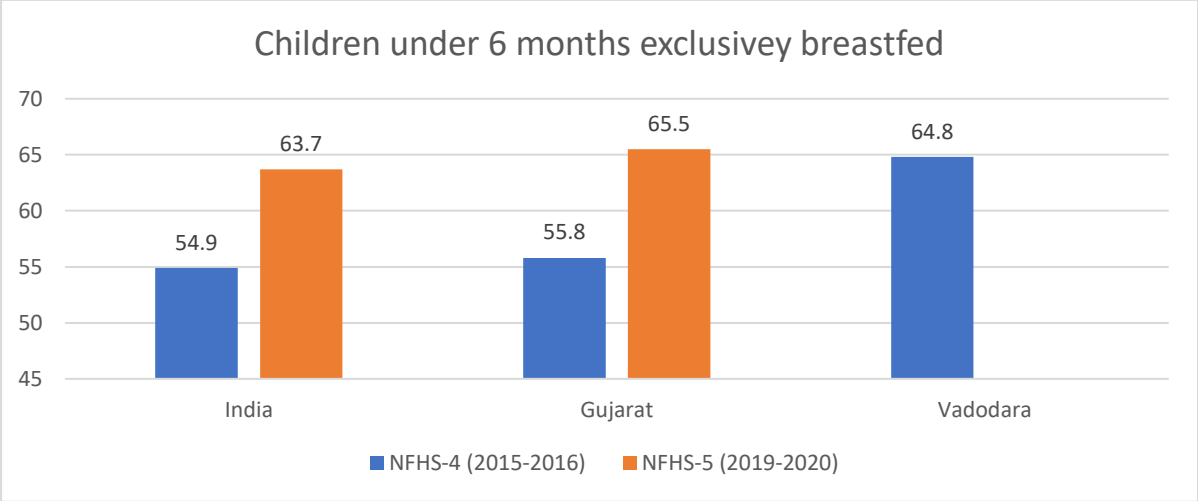
On comparing the relation between child feeding practices and malnutrition through NFHS-4 & NFHS-5 data, the rate of early initiation of breastfeeding is decreased by almost 10-12%, with increase in exclusive breastfeeding rates by approx. 10%. The rates of the components of malnutrition like stunting wasting and underweight remained almost constant and no notable decline was observed from NFHS-4 to NFHS-5 data.

Fig – 1.4 Prevalence of Early Initiation of Breastfeeding in children under 3 years of age



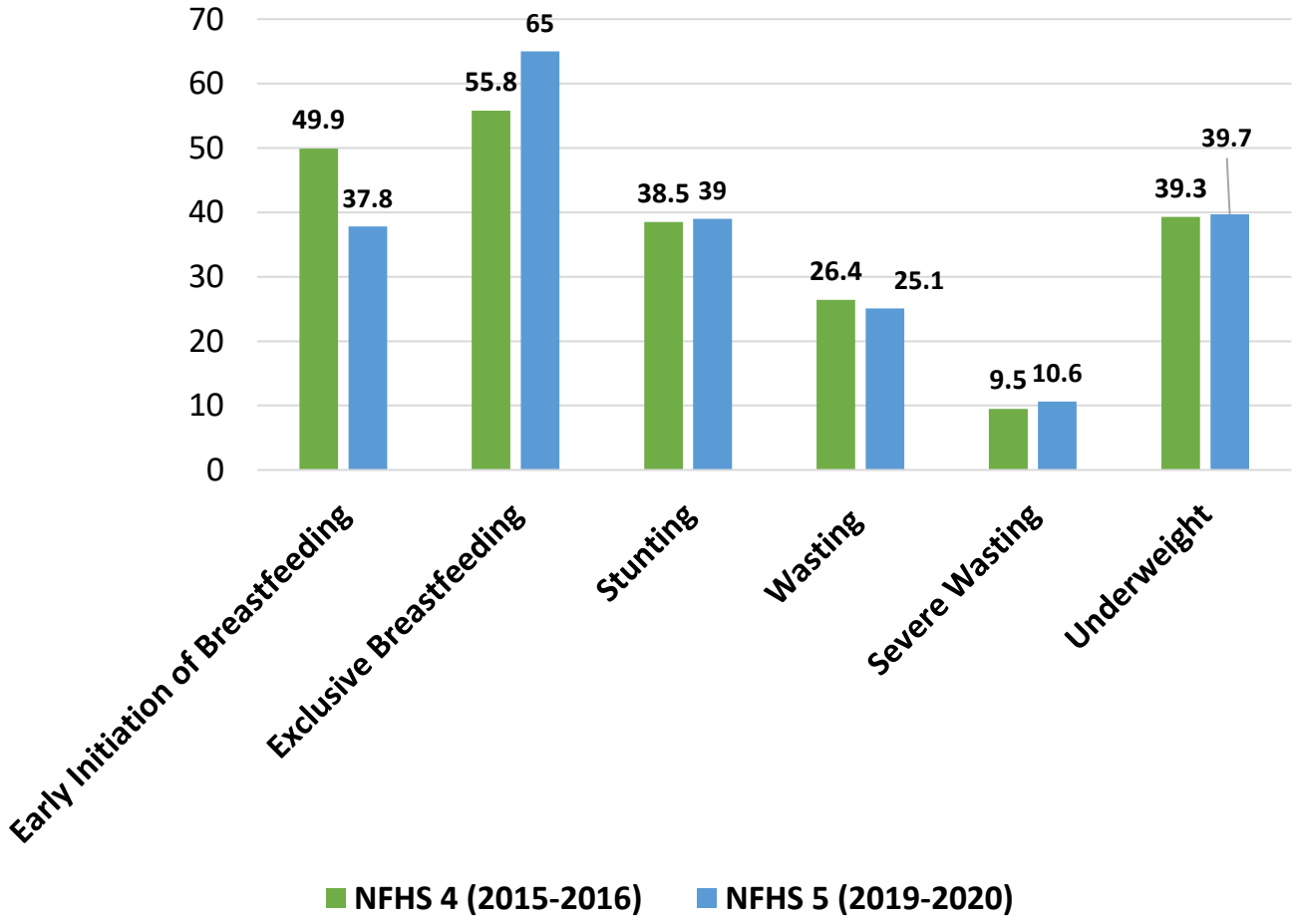
(NFHS-4, NFHS-5)

Fig – 1.5 Prevalence of Exclusive Breastfeeding in children under 6 months of age.



(NFHS-4, NFHS-5)

Fig- 1.6 Child Feeding Practices and Nutritional Status of Children in the State of Gujarat



BARRIERS FOR INITIATION AND CONTINUATION OF BREASTFEEDING

Physiological barriers

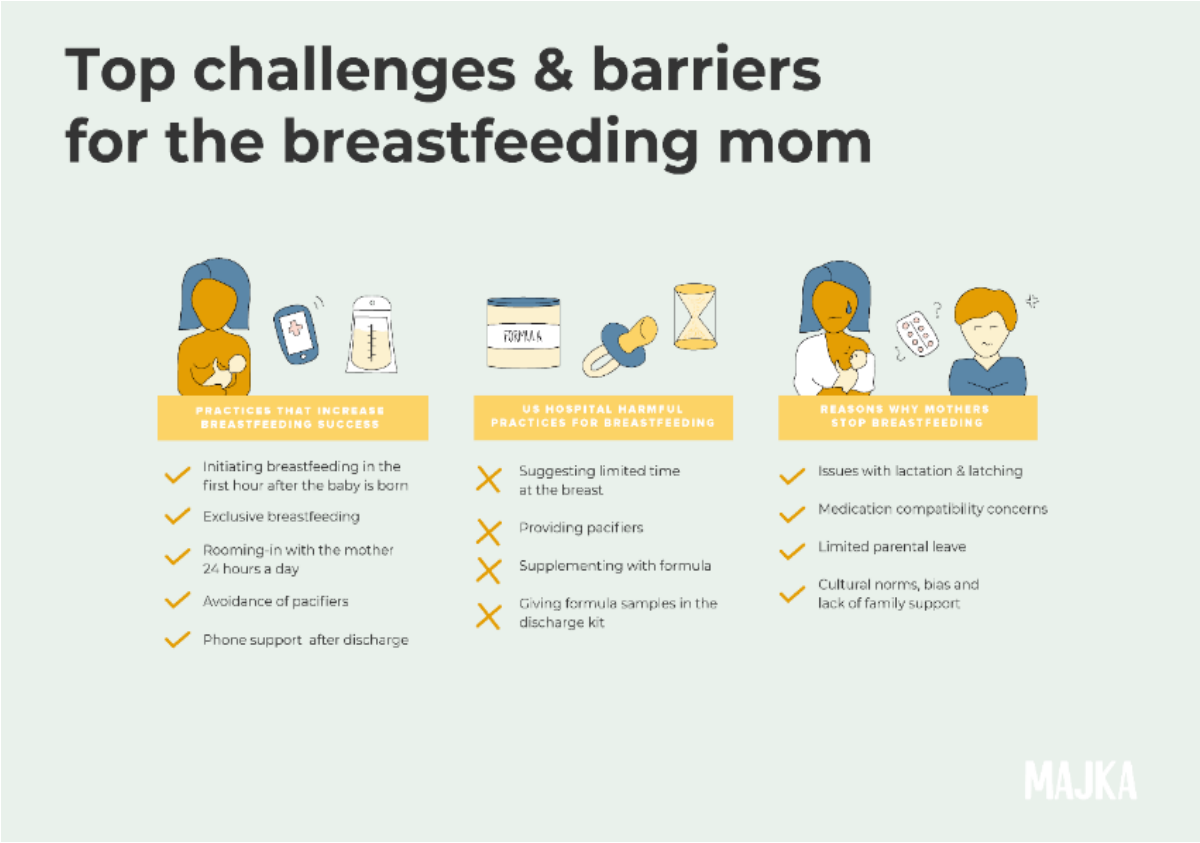
- Delayed childbearing age of mother
- High rates of caesarean birthing mode
- Stressful labour lasting more than 1 hour
- Obesity
- Primiparity
- Mammary hypoplasia
- Difficulty in latching
- Challenges in milk supply
- Parents with a history of trauma like physical abuse during pregnancy, psychological abuse or sexual trauma
- Mothers with serious medical conditions like cancer.
- Mothers' own perception about milk secretion.

Other barriers

- Post- partum depression.
- Lack of proper prenatal counselling, lactation counsellors.
- Resistance of mothers with complex medical condition. for breastfeeding due to medications.
- Barriers for lesbian, Gay, Bisexual or LGBTQ+ persons.
- Incarcerated parents.
- Lack of awareness about optimal IYCN practises and correct information
- Lack of specialised lactation support at existing health facilities
- Excessive commercial influence on infant milk substitutes

(Hernández-Cordero, S. (2020); McCann MF (2007); The Surgeon General's Call to Action to Support Breastfeeding (2011).)

Challenges and Barriers of breastfeeding is depicted in Fig 1.7



Source:

(https://cdn.shopify.com/s/files/1/2160/2717/files/6_TopChallengesandBarriersForTheBreastfeedingMom2-02.png?v=1597794774)

PROLACTIN

What is Prolactin?

Prolactin (also known as lactotropin and PRL) is a hormone that's responsible for lactation, certain breast tissue development and contributes to hundreds of other bodily processes. **(**Al-Chalabi M, Bass AN, Alsalman I.,2022)

Prolactin levels are normally low in people assigned male at birth (AMAB) and non-lactating and non-pregnant people. They're normally elevated in people who are pregnant or breastfeed**.**

Most of your prolactin comes from your pituitary gland. It makes and releases (secretes) the hormone.

Your pituitary gland is a small, pea-sized gland located at the base of your brain below your hypothalamus. It's a part of your endocrine system and is in charge of making many different important hormones, including prolactin. Dopamine (a brain chemical) and estrogen (a hormone) control prolactin production and release from your pituitary gland.

Your central nervous system, immune system, uterus and mammary glands are also capable of producing prolactin. The following factors can contribute to prolactin creation in these tissues:

- Nipple stimulation.
- Exercise.
- Stress

Al-Chalabi M, Bass AN, Alsalman I.,2022 has discussed how prolactin affect the body ;

Prolactin contributes to hundreds of bodily functions, but its two main functions include:

- The development of mammary glands within breast tissues and milk production.
- Lactation and breastfeeding.

Prolactin's role in mammary gland development and milk production (Al-Chalabi M, Bass AN, Alsalman I.,2022)

During pregnancy, the hormones prolactin, estrogen and progesterone stimulate breast tissue development and milk production.

Prolactin promotes the growth of a certain type of breast tissue called mammary alveoli, which are the components of the mammary gland where the production of milk occurs. Prolactin also stimulates the breast alveolar cells to create milk components, including:

- Lactose (the carbohydrate component of milk).
- Casein (the protein component of milk).
- Lipids (components that provide energy, essential fatty acids and cholesterol).

Prolactin's role in lactation and breastfeeding

After delivery of your baby, progesterone levels drop, which increases the number of prolactin receptors on the mammary alveolar cells. This allows for milk secretion through your nipple, commonly known as lactation. (Al-Chalabi M, Bass AN, Alsalman I.,2022)

After delivery, prolactin levels don't remain constantly elevated. Prolactin levels will only spike during periods of nipple stimulation through suckling by your baby. As long as your baby maintains suckling, prolactin levels stay elevated. During periods when you're not breastfeeding, your prolactin levels decrease, and milk production reduces. If a person doesn't breastfeed their baby, prolactin levels fall to non-pregnant levels after one to two weeks.

Phases of Lactogenesis (Kraus 14th Edition)

Lactogenesis 1

This is the secretory differentiation phase where the mammary epithelial cells differentiate into secretory mammary epithelial cells with the capacity to synthesize milk constituents such as lactose, total proteins and immunoglobulins.

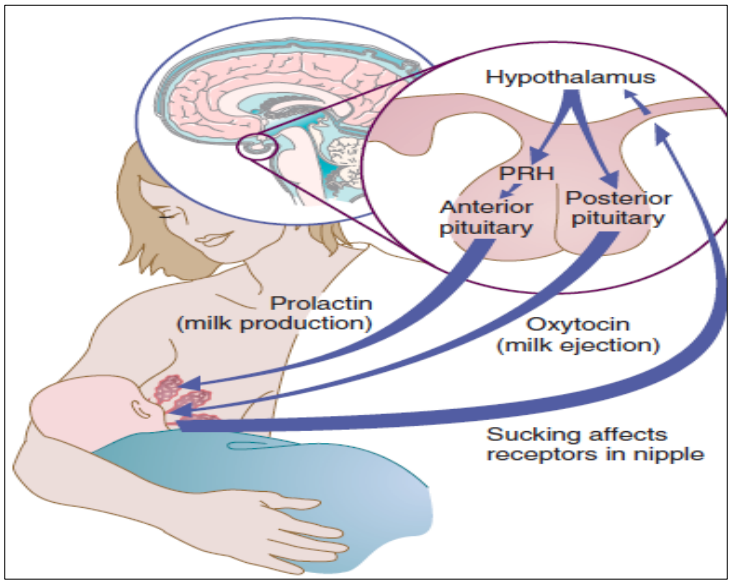
Lactogenesis 2

After parturition, the secretory phase of lactogenesis or lactogenesis II is triggered by the rapid decline of serum maternal progesterone that occurs with the expulsion of the placenta; in addition, this leads to a drop in estrogen levels while prolactin levels remain high along with insulin and cortisol.

Colostrum is produced during the first 4 days postpartum, followed by transitional milk secretion for the next 10 days followed by mature milk production. Milk volume rapidly increases after the first 24 h postpartum and stabilizes after 1 month postpartum to an average volume of 750–800 mL/24 h for the term infant.

Prolactin is required to maintain milk yield while oxytocin is required for milk ejection. Subcutaneous nerves of the areola send a message via the spinal cord to the hypothalamus, which in turn transmits a message to the pituitary gland, where the anterior and posterior areas are stimulated. Oxytocin causes the contraction of myoepithelial cells surrounding mammary alveoli triggering milk ejection, "milk let-down".

Physiology of milk secretion through prolactin hormone is depicted in Fig 1.8



Source: Krause (14th Edition)

PROLACTIN LEVELS DURING NON-PREGNANCY, PREGNANCY & LACTATION

Serum Prolactin Baseline Levels in Normal Females Table 1.1

Typical Baseline Serum Prolactin Levels in Females	Values	References
Non pregnant / Non-Lactating/ Normal Females	<25ng/ml	Walker p. 65, Riordan p. 76, Seri et al. p. 575
Pregnant, at term	200 ng/mL	Walker p. 65
Lactating, 7 days postpartum	100 ng/mL	Riordan p. 76
Lactating, 3 months postpartum	100 ng/mL	Walker p. 65
Lactating, menstruation not started before 180 days	110 ng/mL	Riordan p. 76
Lactating, menstruation started before 180 days	70 ng/mL	Riordan p. 76
Lactating, 6 months postpartum	50 ng/mL	Walker p. 65, Riordan p. 76

GENERAL INFANT WEIGHT GAIN PATTERN DURING 6 MONTHS OF AGE

World Health Organization (WHO) (2006), release the data of growth pattern and weight gain pattern of breastfeeding babies.

The following table shows the figures of 50th percentile weight gains of male babies. In case of female babies, the mean weight gain is marginally less.

Following chart was declared by WHO which depicts the average weight gain pattern of infant monthly Table 1.2

Age	Average Weight gain in grams	
	Per week	Per month
Birth to 4 weeks	266	1100
1-2 months	266	1100
2-3 months	194	800
3-4 months	145	600
4-5 months	121	500
5-6 months	103	425

Source: WHO, Growth standards, 2006

WAYS TO PROMOTE ADEQUATE MILK SECRETION IN POST PARTUM MOTHERS

One of the challenges for exclusive breastfeeding is to have optimal secretion of breastmilk. Many neo lactating mothers perceived that their milk secretion is not enough for the baby. In the literature, various ways to promote milk secretion are available. Therefore, ways to promote milk secretion are presented in Fig-1.8

The most common and feasible approach is to create awareness about Infant and Young Child Nutrition (IYCN) Practices in lactating mothers, to educated mother about adequacy of breastmilk and how to solve Breastfeeding problems.

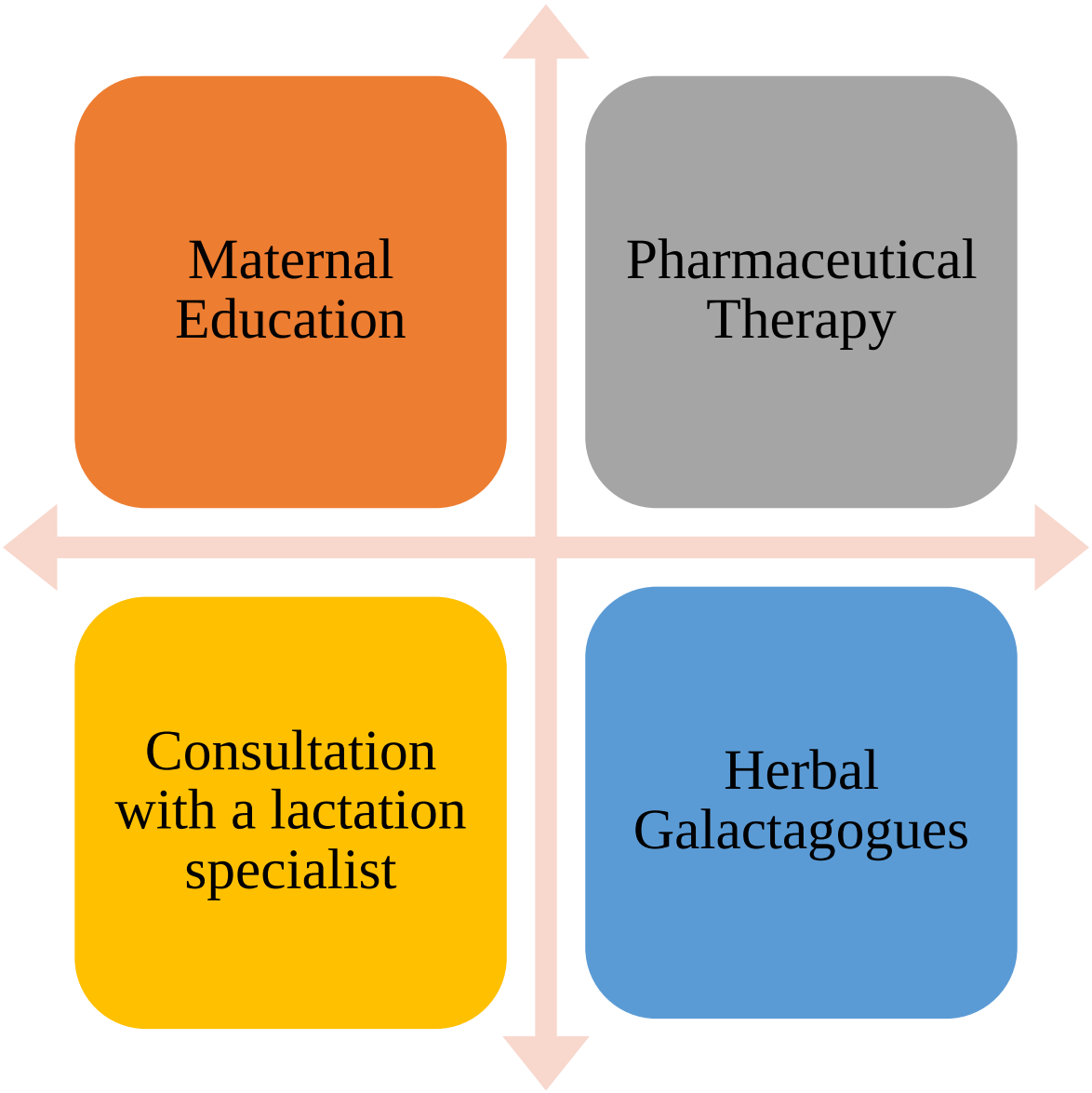
The objectives of MAA Program are

- Build an enabling environment for breastfeeding through awareness generation activities, targeting pregnant and lactating mothers, family members and society in order to promote optimal breastfeeding practices. Breastfeeding to be positioned as an important intervention for child survival and development
- Reinforce lactation support services at public health facilities through trained healthcare providers and through skilled community health workers.
- To incentivize and recognize those health facilities that show high rates of breastfeeding along with processes in place for lactation management.

(Source: https://www.nhm.tn.gov.in/en/nhm-programsrmncha/mothers-absolute-affection-maa-programbaby-friendly-hospital-initiative-bfhi)

Another traditional way is to consume galactagogues foods. In Indian indigenous system, role of certain foods as galactagogue is well established.

Fig- 1.9 Ways to promote milk secretion



Galactagogue

A Galactagogue is a food, herb or drug that increases the production of breast milk. If the milk supply is not enough despite correct positioning, latching, skin-to-skin contact, breast massaging, breast compression then galactagogue should be tried on. Even normal lactating women can also consume herbal and natural galactagogue for good milk production

What is the need?

For those mothers in whom milk production has declined and is not responding to pharmacologic galactagogues & nonpharmacologic measures, the use of herbal galactagogues is often considered.

Worldwide, maternal perception of insufficient milk production is the most common reason reported by mothers for early cessation of breastfeeding; reported prevalence is between 30% and 80%. (*Mannion C, Mansell D. 2012*).

National Health Survey conducted in 2001 by the Australian Bureau of Statistics revealed that 30% women self-reported reason for discontinuation of breastfeeding was inadequate breast milk supply.

Estimated consumption of herbal galactagogues

- In the United States, it is estimated that 15% of breastfeeding women use herbal galactagogues. (*The National Children's Study. Use of herbal products in pregnancy, breastfeeding and childhood workshop. 2003*)
- Whereas, in a Norwegian study, this estimate is 43%. (*Nordeng H, Havnen GC. 2004*)

Traditional Galactagogue

Edible Gum (Gond)

Fenugreek (Methi)

Fennel Seeds (Variyali)

Clarified butter (Ghee)

Shatavari Root

Peepramul Root (Ganthoda)

MORINGA OLEIFERA

Moringa oleifera is grown commercially in India, Africa, South and Central America, Mexico, Hawaii, and throughout Asia and Southeast Asia.

Seeds, leaves, oil, sap, bark, roots, and flowers are widely used in traditional medicine in many countries.

The leaves have contained desirable nutritional balance, containing vitamins, minerals, amino acids, and fatty acids. Additionally, the leaves are reported to contain various types of antioxidant compounds such as ascorbic acid, flavonoids, phenolics, and carotenoids.

According to several research papers, various preparations of M. oleifera are used for their anti-inflammatory, anti-hypertensive, diuretic, antimicrobial, antioxidant, antidiabetic, antihyperlipidemic, antineoplastic, antipyretic, antiulcer, cardio-protectant, and hepatoprotection activities.

Active galactagogue component in Moringa Oleifera

Phytosterols (β-sitosterol, camphasterol, stigmasterol) are believed to improve and expedite the production of milk by increasing the prolactin levels.

(Moringa Direct)

RATIONALE

Yabes and Lim (1996), conducted a Pooled community study of 2 communities. Therein they found that Adequacy of breastmilk volume can be judged by improvement in infant's weight gain. The lactation enhancing impact of moringa oleifera was studied by administering 2 capsules of 250 mg moringa capsules to term Filipino women immediately after birth. After administration of moringa oleifera leaves extract the prolactin levels rose after 48 hours and 4 months along with a significant improvement in the infants' weight gain.

Yabes and Lim (1996), conducted an interventional study. An investigation was undertaken to determine the effectiveness of Moringa oleifera as galactagogue among 30 hypertensive women with blood pressure greater than or equal to 140/90. Significantly higher prolactin levels were obtained after 4 months with the experiment group at accompanied by observed gains in weights among these babies.

Estrella et al. (2005), conducted a randomized controlled trail. The trial concluded that Moringa oleifera leaves increased the volume of breastmilk post-partum day 3-5 in nursing mothers of pre-term infants. The human subjects were given 250 mg moringa oleifera leaves in a capsule form twice a day. There was a 28-32% increase in the mean breastmilk volume in favour of the study.

Kiranawati, T. M., & Nurjanah (2017), conducted a Quasi experimental Study on pregnant mothers. There were 30 respondents out of which 15 are respondents of interventional group and rest 15 are respondents of controlled group. A significant increase in prolactin levels and sleep duration but no significant effect was observed in infant's weight

Table 1.3 Various studies conducted on Moringa oleifera impact on Prolactin levels and infant weight gain pattern.

YEAR/ PLACE/JOURNAL NAME	AUTHORS	SAMPLE SIZE	TYPE OF STUDY	FINDINGS
1996, Filipino	**Yabes & Lim**	73 samples from 2 community pooled study	Human Study	Adequacy of breastmilk volume can be judged by improvement in infant's weight gain. The lactation enhancing impact of moringa oleifera was studied by administering 2 capsules of 250 mg moringa capsules to term Filipino women immediately after birth. After administration of moringa oleifera leaves extract the prolactin levels rose after 48 hours and 4 months along with a significant improvement in the infants' weight gain

2018, JOURNAL OF MEDICAL SCIENCE AND CLINICAL RESEARCH	**Yuliastuti S. et al**	15 women	Human Study	In this quasi-experimental study that enrolled 15 women each in experimental and control group, two doses of 250 mg moringa oleifera leaf powder was administered as post-partum intervention daily for 2 weeks. Moringa oleifera was proven to increase breast milk production with indicator of breast milk fat and baby weight

1996, Philippines.	**Yabes & Lim**	30 women	Human Study	An investigation was undertaken to determine the effectiveness of Moringa oleifera as galactagogue among 30 hypertensive women with blood pressure greater than or equal to 140/90. Significantly higher prolactin levels were obtained after 4 months with the experiment group at accompanied by observed gains in weights among these babies
2013, Philippines	**King J.S. et al**	366 participants	Meta-analysis	In systematic review and pooled data analysis of 5 randomized control trials involving 366 participants, breast milk volume showed statistically significant increase following treatment with moringa oleifera

				capsules on different days of administration. Two RCTs reported increase in infant weight gain as an outcome of moringa oleifera administration. No adverse event was reported in any of the outcome
2021, Thailand	**Fungtammasan S, Phupong V**	88 women	Human Study	A randomized, double-blinded, placebo controlled-trial was performed on 88 on pregnant women having more than 37 weeks of gestation. Consent enrollment was made after doing necessary health checkups. The study group was bifurcated in two groups: treatment group and placebo group. 2 Moringa oleifera capsules of 450mg were given to them before meals for

				3 days. The intervention was initiated after 6 hours of birth. Milk output on the third day post-partum was measured with consecutive daily milk volume for consecutive 3 days. Infant weight started to record after 48 hrs of delivery. Infant was weight before and after every feed
2017, Indonesia	**Kiranawati, T. M., & Nurjanah, N.**	15 pregnant women	Human Study	A Quasi-experimental study with controlled group was held among 30 respondents out of which 15 are respondents of interventional group and rest 15 are respondents of controlled group. A significant increase in prolactin levels and sleep duration but no significant effect was observed in infant's weight

2013, Indonesia	**Mutiara T.K. et al**	24 white rats	Animal study	In the study white rats were divided into four groups: group fed supplemental moringa leaf powder with boiling treatment, group fed with moringa leaf powder with steaming treatment, group fed with moringa leaf powder boiled with sodium bicarbonate and control mice group. The results showed that Moringa leaves significantly can increase milk production. Dose 0.042 mg / g body weight to the parent mice had increased milk production. Steaming treatment in the manufacture of powder was the best treatment
2014, Indonesia	**Titi Mutiara Kiranawati,**	4 Wister Rats	Animal study	It was a randomized block design study to observe the effect of

	Nunung Nurjanah			moringa leaves as galactagogue. 2 rats were the controlled group, 2 were given moringa leaf flour(85g) mixed noodles. 40g meal was given thinking 20g/day will be consumed. Food was given to rats on 14^{th} day of pregnancy till 10^{th} day post-partum. Weight gain of 0.25-0.37g/dietary noodles was observed in infants breastfed of female rats given moringa. Moringa had positive effect on the breastmilk secretion
2000, Indonesia	**Estrella et al.**	68 post-partum mothers	Human Study	It was concluded in the randomised controlled trial that Moringa oleifera leaves increased the volume of breastmilk post-partum day 3-5 in nursing mothers of

				pre-term infants. The human subjects were given 250 mg moringa oleifera leaves in a capsule form twice a day. There was a 28-32% increase in the mean breastmilk volume in favour of the study

Rationale of the study is

As can be seen, from the table 1.3, very few human studies of impact of Moringa oleifera on Prolactin levels is carried out globally.

Not a single similar study, to best of our knowledge from published data, we could find in Indian context.

Studies already carried out are on preterm infants, very small duration of intervention and lactating mothers with comorbidities.

The cost of not breastfeeding in India is US$14.5 billion (*Walters, D. D (2019)*. Investing in services and healthcare that support women who want to breast feed for longer is more economic. Evidence shows the negative impact of using breastmilk substitutes; GI infection, lower respiratory tract infection and acute otitis media in infants; necrotizing enterocolitis in preterm babies.

Region specific data for consumption pattern of galactagogues is scarce.

Since Moringa oleifera is an indigenous plant, it is very economical to reap its benefits

Studies investigating impact of moringa oleifera on maternal serum prolactin levels, and infant weight gain in Indian population are miniscule

Therefore, present study is planned on healthy mother child dyad with the following Broader Objective

BROAD OBJECTIVE

To investigate impact of moringa oleifera leaves tablet on serum prolactin levels in post-partum mothers & to assess the weight gain pattern in neonates.

The Specific Objectives of the study are:

SPECIFIC OBJECTIVES

- To assess the background information of enrolled pregnant & lactating women.
- To assess the knowledge and practises of selected IYCN practises.

- To understand frequency of use of galactagogues by the enrolled mothers
- To assess maternal serum prolactin levels at the interval of 0,7 days post-partum.
- To provide Moringa Oleifera leaves capsules and Placebo capsules on day 0 postpartum for 30 days.
- To record the compliance of capsules in both the groups for 30 days.
- To track weight gain pattern of neonates on 0,7,15 and 30 days post-partum in experimental and control group.

REVIEW OF LITERATURE

RIEVIEW OF LITERATURE

BACKGROUND

Prolactin's role in mammary gland development and milk production (Al-Chalabi M, Bass AN, Alsalman I.,2022)

During pregnancy, the hormones prolactin, estrogen and progesterone stimulate breast tissue development and milk production. Prolactin promotes the growth of a certain type of breast tissue called mammary alveoli, which are the components of the mammary gland where the production of milk occurs. After delivery of your baby, progesterone levels drop, which increases the number of prolactin receptors on the mammary alveolar cells. This allows for milk secretion through your nipple, commonly known as lactation.

World Health Organization (WHO) & United Nation Child's Fund (UNICEF) recommended that the infant should be breastfed exclusively for 6 months and its growth and development sheerly depend on the breastfeed. Therefore, increase in prolactin levels is directly proportional to the milk secretion and which is proportional to infant weight gain eventually.

The present study is planned on healthy mother child dyad.

The broad objective of the study is to investigate the impact of Moringa Oleifera leaves tablet on serum prolactin levels in post-partum mothers and to assess the neonates weight gain pattern. **The specific objectives were**:

- To assess the background information of enrolled pregnant & lactating women.
- To assess the knowledge and practises of selected IYCN practises.
- To understand frequency of use of galactagogues by the enrolled mothers
- To assess maternal serum prolactin levels at the interval of 0,7 days post-partum.
- To provide Moringa Oleifera leaves capsules and Placebo capsules on day 0 postpartum for 30 days.
- To record the compliance of capsules in both the groups for 30 days.

- To track weight gain pattern of neonates on 0,7,15 and 30 days post-partum in experimental and control group

To understand the role of Prolactin, milk secretion and weight gain pattern in the regional context, review of existing literature was carried out. It is presented in following subheads:

- Region Specific Knowledge and Practices of selected IYCN Practices.
- Physiology of Prolactin.
- Impact of Galactagogues on increasing milk production.
- Impact of Galactagogues on infant weight gain.
- Composition of Moringa Oleifera.

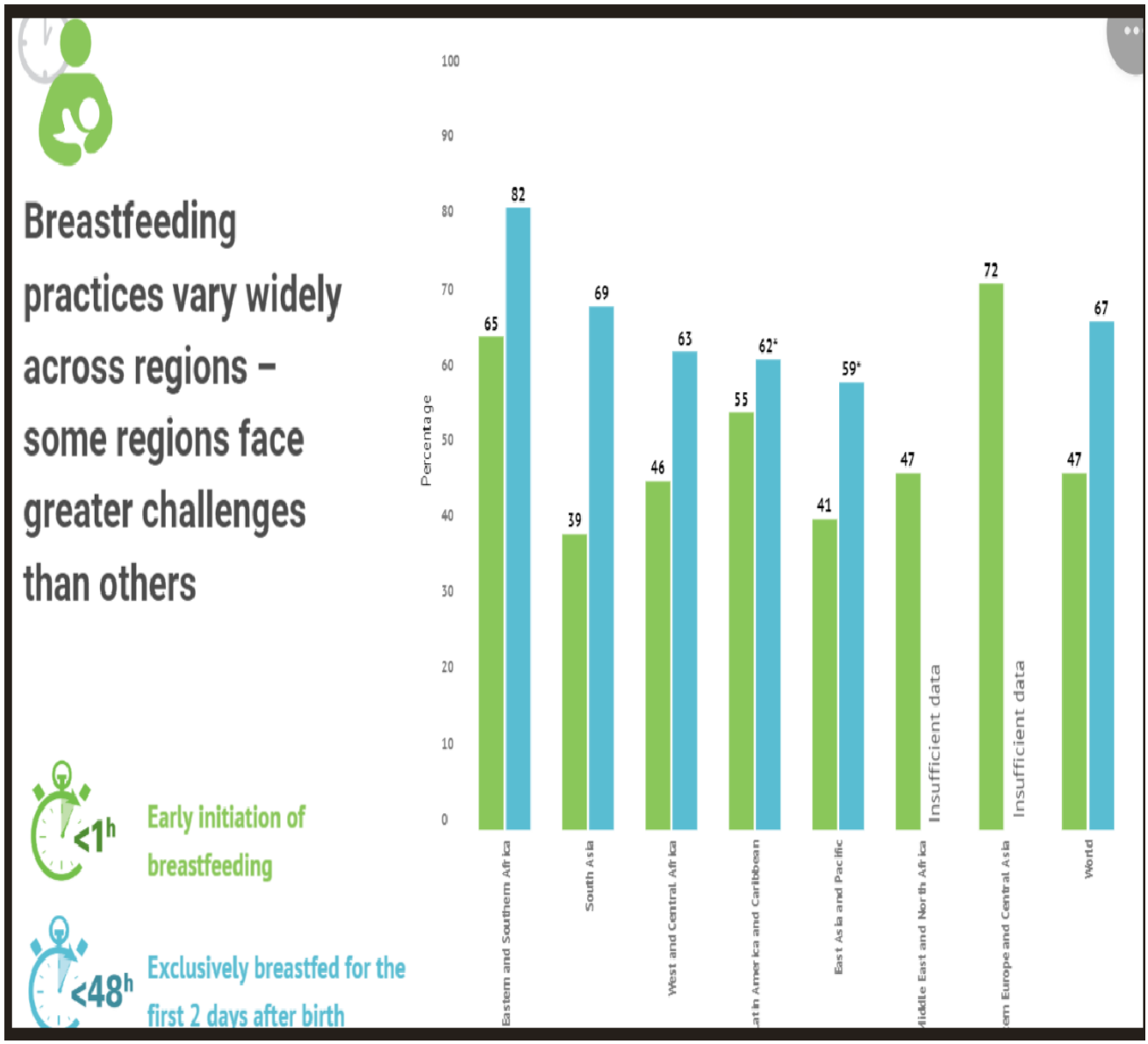
REGION SPECIFIC KNOWLEDGE AND PRACTICES OF SELECTED IYCN PRACTICES

World Health Organization (WHO) under their section of health topics stated that Breastfeeding is one of sustainable and effective method considered for a child's survival, growth and development. Breast milk is considered as an ideal food for infant, provides all the essential nutrients in sufficient amounts needed in first new months of life. It is sterile, safe and contains antibodies which helps as an immunity factor providing defense against infections. About 1/2 & 1/3 of child's nutritional requirements are fulfilled by breastmilk in second half of first year and second year of life respectively.

Breastfeeding helps in combating malnutrition (undernutrition & overnutrition), helps in giving healthy start to the life, helps in developing appropriate IQ.

UNICEF (2022), data reported depicted that 39% children in last 1 year, were made to breastfeed in a golden hour (Early initiation of Breastfeeding). 69% children were exclusively breastfed for first 2 days post-partum.

Fig-2.1 Depicts the data on Breastfeeding practices of UNICEF



As per NFHS-5 (2015-16) reported the IYCN Practices for Gujarat which is shown in Fig.2.2, 2.3 and 2.4

Around, 41.6 % of the children under 3 yrs of age were breastfed within 1 hr of birth. 54.9% children in India under 6 months of age are breastfed.

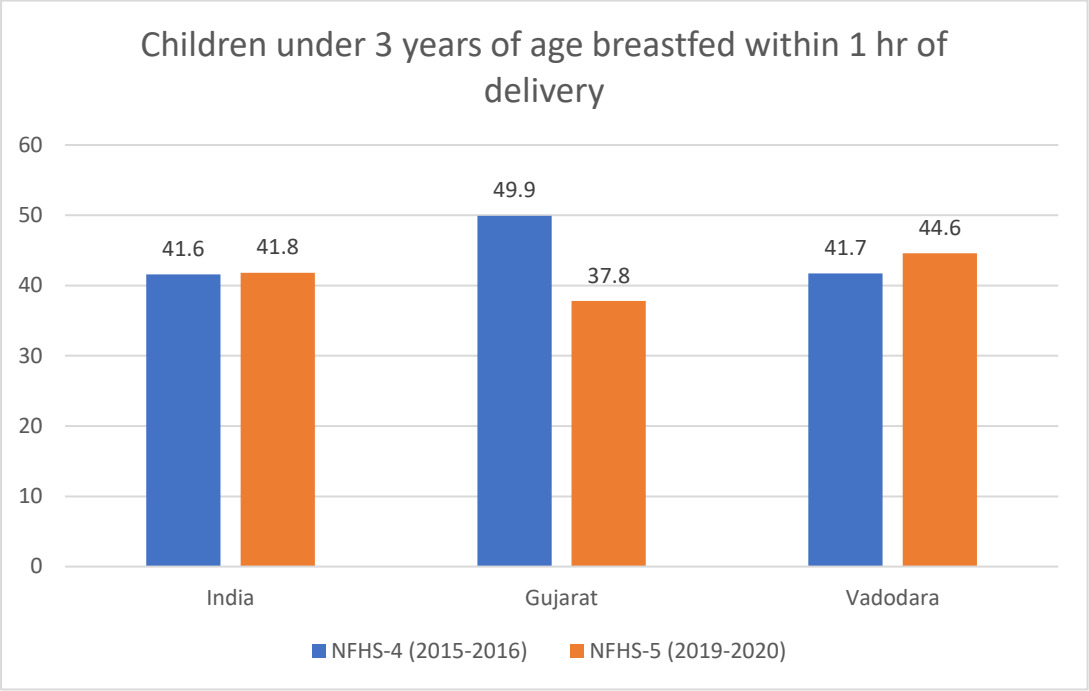
49.9% children under 3 yrs of age were breastfed within 1 hr of birth. 55.8% children under 6 months of age are breastfed in Gujarat.

As per NFHS-5 Vadodara factsheets that 44.6 % of children under 3 years of age were breastfed with 1 hr of birth. Around 68.8% of children under 6 months of age were breastfed in Gujarat. (NFHS-4, NFHS-5)

As per NFHS-5 data, the rates of exclusive breastfeeding have increased to about 7-9 % both in India as well as Gujarat.

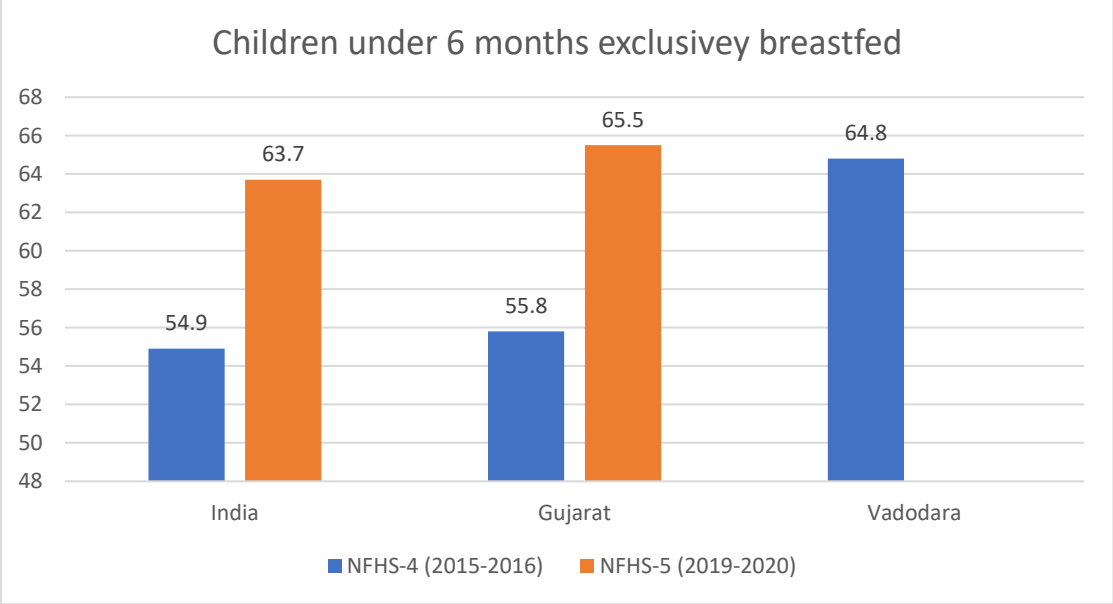
On comparing the relation between child feeding practices and malnutrition Fig 2.4 through NFHS-4 & NFHS-5 data, the rate of early initiation of breastfeeding is decreased by almost 10-12%, with increase in exclusive breastfeeding rates by approx. 10%. The rates of the components of malnutrition like stunting wasting and underweight remained almost constant and no notable decline was observed from NFHS-4 to NFHS-5 data.

Fig – 2.2 Prevalence of Early Initiation of Breastfeeding in children under 3 years of age



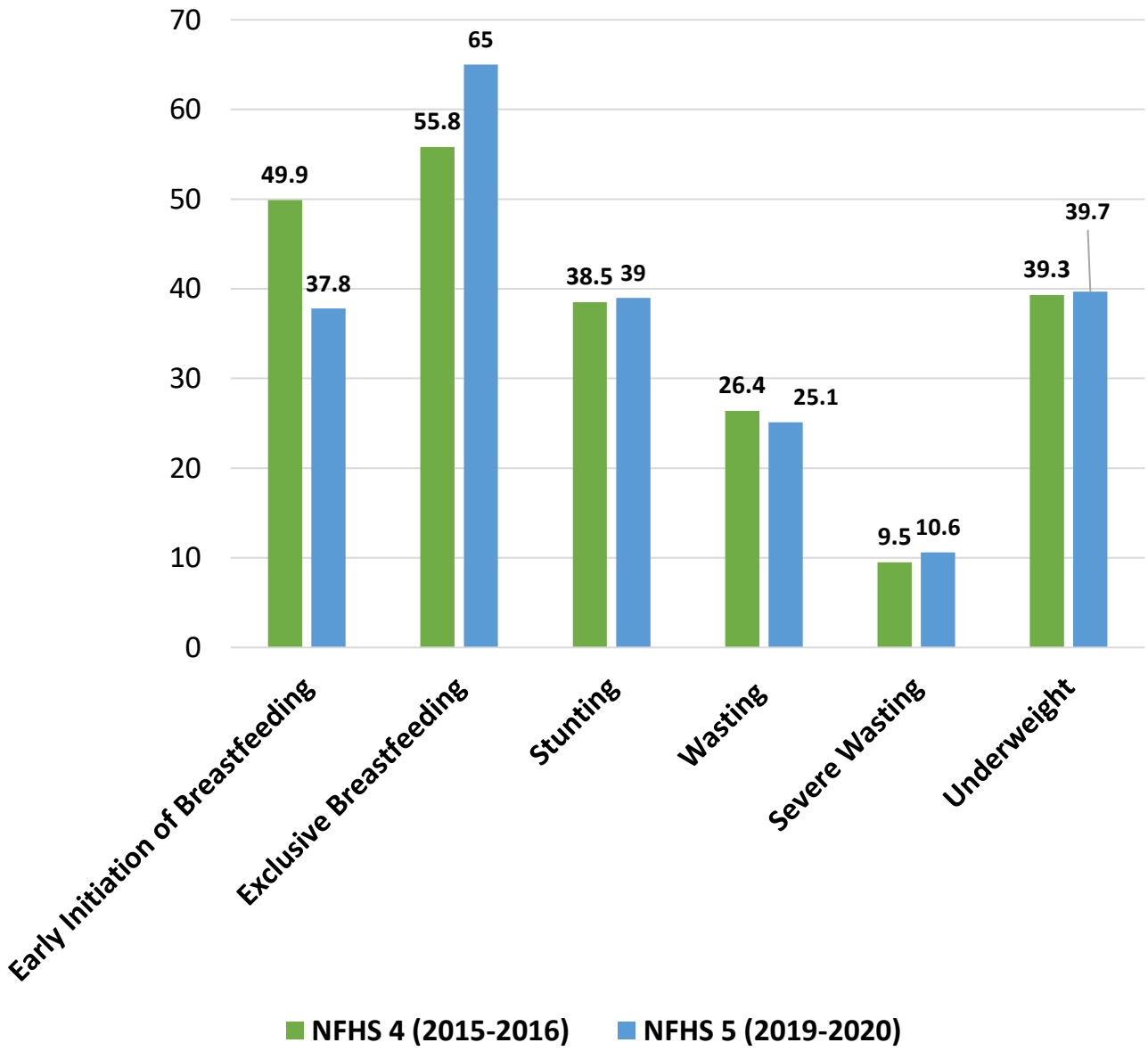
(NFHS-4, NFHS-5)

Fig – 2.3 Prevalence of Exclusive Breastfeeding in children under 6 months of age.



(NFHS-4, NFHS-5)

Fig- 2.4 Child Feeding Practices and Nutritional Status of Children in the State of Gujarat



WHO under their section of health topics stated that Breastfeeding is one of sustainable and effective method considered for a child's survival, growth and development. Breast milk is considered as an ideal food for infant, provides all the essential nutrients in sufficient amounts needed in first new months of life. It is sterile, safe and contains antibodies which helps as an immunity factor providing defense against infections. About 1/2 & 1/3 of child's nutritional requirements are fulfilled by breastmilk in second half of first year and second year of life respectively.

Breastfeeding helps in combating malnutrition (undernutrition & overnutrition), helps in giving healthy start to the life, helps in developing appropriate IQ.

B. Adhisivam et.al (2016) conducted a study in South India to assess the impact of postnatal video based on nutritional education program for the promotion of exclusive breastfeeding among primiparous mothers. Results depicted that out of 878 mothers enrolled, 94% mothers fed colostrum and 43% women did early initiation of breastfeeding. 96% women had correct attachments also 13% had lactation problems. Therefore, it can be concluded that video had positive impact towards the goal.

Supriya Nikam et.al (2019) conducted a study in India on the prevalence and determinants of undernutrition among children less than 2 yrs of age in urban slums of Pune, Maharashtra. In the research, parameters like food security, anthropometric measurements, maternal and child characteristics were studied of 400 children. Results came as prevalence of stunting, wasting and undernutrition was 34%, 15.3%, 21.8%. Wasting and stunting was majorly seen in children of 7-12 months. This undernutrition was seen due to less prevalence of colostrum.

Suresh Jungari et.al (2020) conducted a study in Pune to assess the prevalence and determinants early initiation, Exclusive breastfeeding and Prelacteal feeding amongst 0-24 months of infants. A cross-sectional study of 1443 mother child dyads were assessed for the study. The prevalence of early initiation, prelacteal feeding, exclusive breastfeeding was 45.2%, 37.5%, 23.7% respectively. Caesarean delivery affected the early initiation and exclusive breastfeeding and increased the prelacteal feeding. Delivery in public health again promoted the early initiation and exclusive breastfeeding and decreased the prelacteal feeding. In low birth babies' early initiation and exclusive breastfeeding was significantly low and prelacteal feeding was more. Religion other than Hindu and Muslim, age of mothers

of 26-30 yrs has more early initiation and exclusive breastfeeding rates and parity also has positive prelacteal feeding rates.

Muluken Amare Wudu (2022) conducted a study in Ethiopia on the determinants and prevalence of early days of new born feeding malpractices among recently delivered mothers of the year 2020 of Ethiopia. Sample size of 487 mother child dyad was taken for the study. Prevalence of prelacteal feeding, delayed initiation of breastfeeding, and colostrum avoidance was 21.9%, 35.5% and 15.5% respectively. Determinants found from the study were mother's knowledge regarding the risk of prelacteal provision, parity, exposure to infant formula milk advertising, absence of education due to home visits, spontaneous vaginal birth.

Rune Nathaniel Philemon et.al. (2022) carried out a study in Tanzania to assess the optimal breastfeeding among HIV+ mothers of Tanzania. 524 mother child dyads were enrolled from 5 high loaded clinical facility. The result came as prevalence of breastfeeding was 73.1 %, 19% infants were not exclusively breastfed. Out of 247 infants of 12 yrs of age, 43.3 % stopped breastfeeding before 12 months.

Davra (2022) stated through her study in Vadodara, although it is recommended to initiate breastfeeding within 1st hr of delivery, only few mothers actually complied. Majority of the mothers were exclusively breastfeeding but the frequency of feeds within 24 hrs was very low. Considering the benefits of exclusive breastfeeding, every mother interaction opportunity should be utilized such as within health facilities like immunization and Antenatal checkups for promoting correct IYCN practices

Suzon Ahmed et.al (2023) conducted a study in Bangladesh to determine the prevalence of EIBF in Jashore area and also investigated the associated factors among the infants of 0-6 months of age. Results depicted the prevalence of EIBF as 46.3%. mothers who did kangaroo mother care, provided colostrum and initiated breastfeeding within 1 hr of delivery.

PHYSIOLOGY OF PROLACTIN

Prolactin (also known as lactotropin and PRL) is a hormone that's responsible for lactation, certain breast tissue development and contributes to hundreds of other bodily processes. **(**Al-Chalabi M, Bass AN, Alsalman I.,2022)

Prolactin levels are normally low in people assigned male at birth (AMAB) and non-lactating and non-pregnant people. They're normally elevated in people who are pregnant or breastfeed**.**

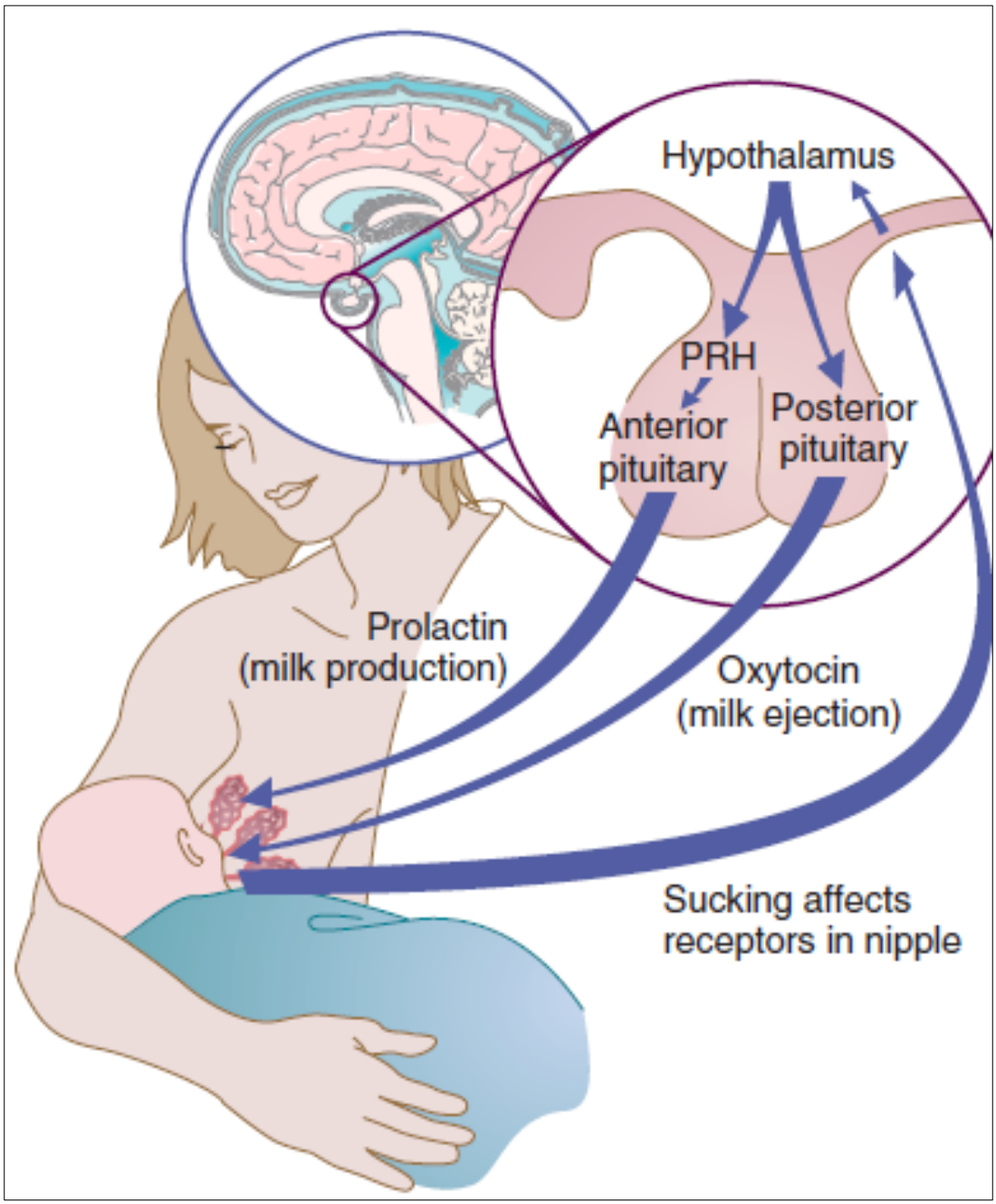
Most of your prolactin comes from your pituitary gland. It makes and releases (secretes) the hormone.

Prolactin's role in mammary gland development and milk production (Al-Chalabi M, Bass AN, Alsalman I.,2022)

During pregnancy, the hormones prolactin, estrogen and progesterone stimulate breast tissue development and milk production. Prolactin promotes the growth of a certain type of breast tissue called mammary alveoli, which are the components of the mammary gland where the production of milk occurs. After delivery of your baby, progesterone levels drop, which increases the number of prolactin receptors on the mammary alveolar cells. This allows for milk secretion through your nipple, commonly known as lactation.

Prolactin is required to maintain milk yield while oxytocin is required for milk ejection. Subcutaneous nerves of the areola send a message via the spinal cord to the hypothalamus, which in turn transmits a message to the pituitary gland, where the anterior and posterior areas are stimulated. Oxytocin causes the contraction of myoepithelial cells surrounding mammary alveoli triggering milk ejection, "milk let-down".

Fig 2.5 depicts the Milk-let-down Reflex



Source: Krause (14th Edition)

Marc E. Freeman et.al (2000) explained Prolactin structure, function and regulation of secretion. They reported that prolactin can be found in both epithelial cells of mammary gland and milk of the lactating mothers. Prolactin is produced in hypothalamus and comes into the milk through circulation. Maximum of it absorbed by the body and be present in the epithelial cells of the mammary gland. Still a significant amount of radiolabelled prolactin can be reported in the milk.

Elsa Regina Justo Giugliani (2004) conducted a updated review on common problems breastfeeding and their management. Some of the common problems during breastfeeding are breast engorgement, plugged milk duct, breast infection and insufficient milk supply. The origin of all these problems are mothers not able to empty their breast completely. Incorrect position, incorrect techniques, not frequently feeding on interval timings. The solutions of all these problems are very much fundamental but lead to early weaning if not treated timely. Therefore, emotional support and action should be showed to mothers lactating. Also, all the measures should be taken so that the mothers can empty their breast completely.

Mengying Li et.al, (2020) did a case control study on 107 GDM mothers and 214 non GDM mothers. Blood samples were collected at 10-14, 15-26, 23-31 and 33-39 wees of gestation. At 10-14 weeks of gestation, there was significant higher prolactin levels and lower progesterone levels. High prolactin levels are significantly positively associated with GDM risk. Similar result was observed at 15-26 weeks of gestation. Therefore, it was concluded that higher prolactin is positively associated with the GDM risk in early pregnancy.

Robert D Utiger, (2023) explained that the major function of prolactin is to secrete and sustain lactation. Tactile stimulation or suckling stimulation by infant blocks the secretion of dopamine which inhibits prolactin therefore the concentration of prolactin increases rapidly and drop severely when sucking stops. Higher concentration of prolactin inhibits gonadotrophic hormones therefore, also acts as normal contraceptive. The prolactin levels can be increased by increasing estrogen as well.

Robert D Utiger, (2023) explained the deficiency and excess of prolactin. Prolactin deficiency arises as result of deficiency of general pituitary hormone. The primary cause of pituitary hormone deficiency is pituitary tumour. The most common reason for deficiency is Sheehan syndrome, in which the anterior pituitary gland of pregnant women get entirely of

partially or completely destroyed just soon after the birth or during the birth. This syndrome often occurs in mothers who had excessive bleeding during delivery. These women cannot produce milk and lactate their children.

Mustafa Al Chalabi et.al (2023) stated in their study on physiology of prolactin that prolactin is a hormone responsible for lactation, breast development and other bodily processes. Prolactin levels are low in males, non-pregnant and non-lactating females. It is released by pituitary gland which is pea sized, located below the hypothalamus of the brain. It is a part of endocrine system. Prolactin hormone is influenced by dopamine and oestrogen hormones.

Mustafa Al Chalabi et.al (2023) stated in their study on physiology of prolactin that prolactin affects the body by imparting its role in marry glands development in the breast, milk production in lactation. It promotes the growth of mammary alveoli, where milk gets produce. It also stimulates to produce milk components like lactose, casein and lipids.

Mustafa Al Chalabi et.al (2023) stated in their study on physiology of prolactin that post-partum, the levels of progesterone drop, as a result, receptors for prolactin increases in mammary glands. This induces lactation, milk secretion through nipples. Post partum, prolactin levels don't remain spiked constantly. They get elevated through the suckling stimulation of the baby. More the suckling baby continue, prolactin levels remain elevated. During periods, it decreases causing reduction in milk production.

Mustafa Al Chalabi et.al (2023) reported that apart from lactation many other factors cause abnormal increase in prolactin levels such as prolactinoma, certain medications like antipsychotic medication, high blood pressure medication, pain relievers, certain health conditions, like kidney disease, hypothyroidism, Shingles, pituitary tumours. Some situations like stress, physical pain, exercise, eating a meal, nipple stimulation unrelated to breastfeeding, sexual intercourse also increases the prolactin levels.

Mustafa Al Chalabi et.al (2023) reported the normal range of prolactin levels which vary person to person. They stated that for a non-pregnant and non-lactating women normal ranges are less than 25 ng/mL, for males those are less than 20ng/mL and for lactating and pregnant

women are 80 to 400ng/mL. they also stated that prolactin estimation can be done through the blood sample in any pathological laboratory.

The following figure depicts the trends of prolactin levels studied by various researchers and published in their papers Table- 2.1

Typical Baseline Serum Prolactin Levels in Females	Values	References
Non pregnant / Non-Lactating/ Normal Females	<25ng/ml	Walker p. 65, Riordan p. 76, Seri et al. p. 575
Pregnant, at term	200 ng/mL	Walker p. 65
Lactating, 7 days postpartum	100 ng/mL	Riordan p. 76
Lactating, 3 months postpartum	100 ng/mL	Walker p. 65
Lactating, menstruation not started before 180 days	110 ng/mL	Riordan p. 76
Lactating, menstruation started before 180 days	70 ng/mL	Riordan p. 76
Lactating, 6 months postpartum	50 ng/mL	Walker p. 65, Riordan p. 76

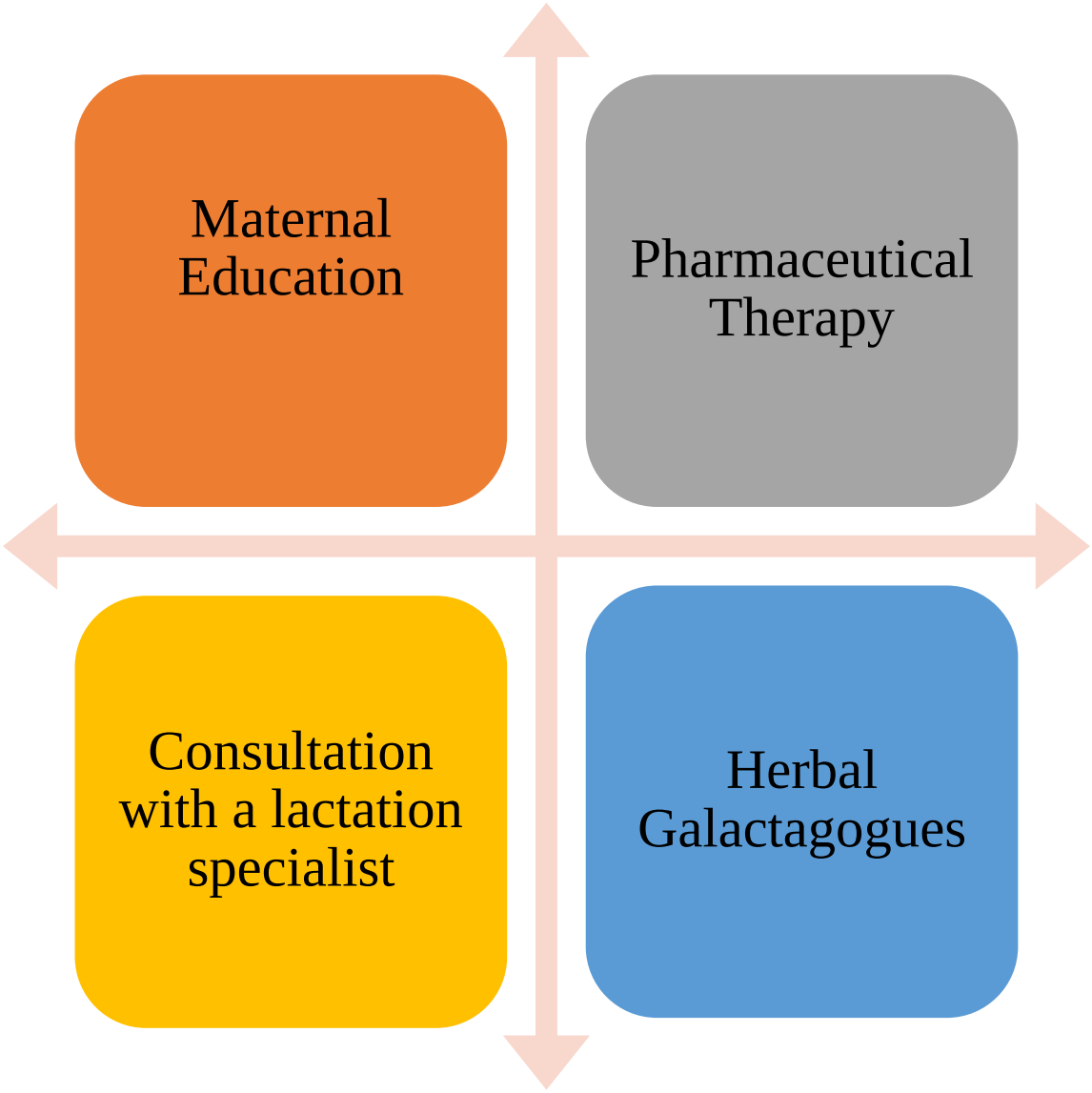
WAYS TO PROMOTE ADEQUATE MILK SECRETION IN POST PARTUM MOTHERS

One of the challenges for exclusive breastfeeding is to have optimal secretion of breastmilk. Many neo lactating mothers perceived that their milk secretion is not enough for the baby. In the literature, various ways to promote milk secretion are available. Therefore, ways to promote milk secretion are presented **in Fig-2.6**

The most common and feasible approach is to create awareness about Infant and Young Child Nutrition (IYCN) Practices in lactating mothers, to educated mother about adequacy of breastmilk and how to solve Breastfeeding problems.

Another traditional way is to consume galactagogues foods. In Indian indigenous system, role of certain foods as galactagogue is well established.

Fig- 1.8 Ways to promote milk secretion



GALACTAGOGUE

A Galactagogue is a food, herb or drug that increases the production of breast milk. If the milk supply is not enough despite correct positioning, latching, skin-to-skin contact, breast massaging, breast compression then galactagogue should be tried on. Even normal lactating women can also consume herbal and natural galactagogue for good milk production

What is the need?

For those mothers in whom milk production has declined and is not responding to pharmacologic galactagogues & nonpharmacologic measures, the use of herbal galactagogues is often considered.

Worldwide, maternal perception of insufficient milk production is the most common reason reported by mothers for early cessation of breastfeeding; reported prevalence is between 30% and 80%. (*Mannion C, Mansell D. 2012*).

National Health Survey conducted in 2001 by the Australian Bureau of Statistics revealed that 30% women self-reported reason for discontinuation of breastfeeding was inadequate breast milk supply.

FREQUENCY AND CONSUMPTION OF GALACTAGOGUES AMONGST THE PREGNANT AND LACTATING MOTHERS

Dog, Tieraona, (2009) did a survey study regarding usage of botanicals during pregnancy and lactation. It was reported that out of 578 pregnant women of United States, 45% used herbal galactagogues. Out of 588 women of Australia, 36% women used at least 1 herbal galactagogue in pregnancy. It came to know female preferred herbal galactagogue because of their easy access, no side effects, and widespread availability of their knowledge. It was also found that women don't share their herbal galactagogue usage with their doctors in regards on not offending them. Also, the safety of any galactagogue can be determined by conducting clinical trials on pregnant and lactating women.

Syuhadah Nur et.al (2014) conducted a study on behavioral aspect of Herbal Galactagogue usage among lactating mothers in Malaysia. They stated that breastfeeding is very much essential for physiological and health benefits of both mother and child. However, the problem of insufficient milk production, or no secretion at all is widespread amongst the lactating mothers worldwide. Therefore, they conducted a study in which data on the usage of any herbal galactagogue was collected through pre tested questionnaire. The result was concluded as most the mothers consumed herbal galactagogue due to insufficient milk secretion. A larger scale survey to be conducted was suggested by them in order to get more clarity on the herbal galactagogue usage.

Emelia Oppong Bekoe et.al (2019) studied the use of medicinal plants as galactagogue. They stated that mothers who opt for exclusive breastfeeding become victims of many nutritional and non-nutritional challenges which results in insufficient milk production (hypogalactia) or no milk production (agalactia). Therefore, many pharmacological galactagogues are used as treatment causing many permanent side effects in mothers' bodies. Therefore, usage of traditional plants as galactagogues is recommended which has no side effects in fact are beneficial not only as galactagogues but in other parameters to these mothers.

Siew Cheng Foong et.al (2020) carried a study in Marasco to assess the impact of oral galactagogues (pharmacological and natural) for increasing breastmilk production in non-hospitalized term infants' mothers. Randomized control trails and quasi randomized control trails with published abstracts were selected from various international institutes. Clustered trails were also registered of some institutes. Women immediately post-partum were enrolled. Effect of pharmacological galactagogues showed little or no increase in infant weight gain but slight increase in milk output was seen. In case of natural galactagogues, mother's tea has no significant effect on both parameters. Fennel and fenugreek improve the infant weight but moringa and mixed botanical tea increased infant weight gain compared to placebo. Moringa reported increase in milk output but meta-analysis was not possible due to heterogeneity. They concluded high quality RCTs should be done to have concrete evidences.

IMPACT OF GALACTAGOGUES ON BREAST MILK PRODUCTION

JC Allen et.al (1991) studied in United States of America that many certain macronutrients and ion are present in the human milk during lactation (birth to 8 day) and late lactation (till 6 months of age). Postpartum changes sodium, lactose, chloride, induces the closure of paracellular pathway during 1-2 days. On day 2-4 post-partum, initiation of copious milk started with significant increase in citrate, phosphate free, glucose and calcium concentration and decline in pH. These changes were observed in milk volume with concentration less than 400mL/d. therefore, concluded that, to maintain the concentration of these minerals in composition of human milk, milk output with at least one feed per day is important. Therefore, maintaining of good milk output is very much important.

Yabes and Lim (1996) conducted a Pooled community study of 2 communities in Philippines. Therein they found that Adequacy of breastmilk volume can be judged by improvement in infant's weight gain. The lactation enhancing impact of moringa oleifera was studied by administering 2 capsules of 250 mg moringa capsules to term Filipino women immediately after birth. After administration of moringa oleifera leaves extract the prolactin levels rose after 48 hours and 4 months along with a significant improvement in the infants' weight gain.

Yabes and Lim (1996) conducted an interventional study in Philippines. An investigation was undertaken to determine the effectiveness of Moringa oleifera as galactagogue among 30 hypertensive women with blood pressure greater than or equal to 140/90. Significantly higher prolactin levels were obtained after 4 months with the experiment group at accompanied by observed gains in weights among these babies.

Estrella et al. (2005) conducted a randomized controlled trail in Philippines. The trial concluded that Moringa oleifera leaves increased the volume of breastmilk post-partum day 3-5 in nursing mothers of pre-term infants. The human subjects were given 250 mg moringa oleifera leaves in a capsule form twice a day. There was a 28-32% increase in the mean breastmilk volume in favour of the study.

Espinosa-Kuo (2005) reported in Filipino that moringa oleifera can be used as an alternative treatment for post-partum women to increase breastmilk volume and prolactin hormone levels.

Mradu Gupta, Badri Shaw (2011) carried out a double-blind, randomized, placebo-controlled, parallel-group study help in Kolkata by involving 60 lactating mothers. Fresh shatavari root powder was converted into capsules and provided as intervention. Increase in mother and infant.

Mutiara T.K. et al (2013) conducted an interventional study on animal in Indonesia. The study was conducted on 24 white rats. In the study white rats were divided into four groups: group fed supplemental moringa leaf powder with boiling treatment, group fed with moringa leaf powder with steaming treatment, group fed with moringa leaf powder boiled with sodium bicarbonate and control mice group. The results showed that Moringa leaves significantly can increase milk production. Dose 0.042 mg / g body weight to the parent mice had increased milk production. Steaming treatment in the manufacture of powder was the best treatment.

King J.S. et al (2013) did meta-analysis of 5 randomized control trial study in Philippines. In systematic review and pooled data analysis of 5 randomized control trials involving 366 participants, breast milk volume showed statistically significant increase following treatment with moringa oleifera capsules on different days of administration.

Two RCTs reported increase in infant weight gain as an outcome of moringa oleifera administration. No adverse event was reported in any of the outcome.

Titi Mutiara Kiranawati*, Nunung Nurjanah, (2014) undertaken an animal study in Indonesia on Wister rats. It was a randomized block design study to observe the effect of moringa leaves as galactagogue.

2 rats were the controlled group, 2 were given moringa leaf flour(85g) mixed noodles. 40g meal was given thinking 20g/day will be consumed. Food was given to rats on 14^{th} day of pregnancy till 10^{th} day post-partum.

Weight gain of 0.25-0.37g/dietary noodles was observed in infants breastfed of female rats given moringa. Moringa had positive effect on the breastmilk secretion.

Peter Francis et.al (2014) created an update on previously carried systematic review of impact of moringa in increasing breastmilk and infant weight gain in Philippines. Results of pooled data of 73 patients depicted the significant increase of milk output by 124ml by Day 7 and of Day 4 and 5 also favoured the moringa. An increase 11.9% in infant weight gain was seen after a month, favouring moringa.

Asokan Keloth Manapatt et.al (2014) investigated the pattern of prolactin secretion in vaginal and caesarean deliveries in India. The study was carried out in 101 women out of which 56 mothers had normal deliveries and 45 had C-section deliveries. Serum prolactin was collected on 24hr and 48hrs. it was concluded that the values of prolactin were higher in mothers who underwent vaginal deliveries as compared to mothers with C-section deliveries.

Muis M, et.al (2014) reported a study in Indonesia on pregnant non anemic informal mothers. The first half group received moringa capsules and the other half were given IFA capsules. A decrease in oxidative stress and increase in nutritional status of women who consumed moringa capsules was observed and reported.

Khuzaimah el.al (2015) in Indonesia enrolled pregnant women of 3rd trimester who were passive smokers. These were administered by 1000mg of moringa oleifera extract + IFA+ honey Capsules/ day. These capsules can prevent the increase of MDA and 8-OHDG levels of pregnant women. Placenta weight was also increased.

Tina Endah Pratiwi. et al (2016) conducted a Quasi experiment with pretest and posttest design in Indonesia to assess the effectiveness papaya leaf extract on prolactin levels. Samples of 48 post-partum mothers were taken. They were then equally divided into experimental and control group. Intervention was effective on giving the dose of 800mg of papaya extract by depicting increase of prolactin levels.

Kiranawati, T. M., & Nurjanah, (2017) conducted a Quasi experimental Study in Indonesia on pregnant mothers. There were 30 respondents out of which 15 are respondents of interventional group and rest 15 are respondents of controlled group. 250mg of Moringa leaves powder capsules were given twice a day to experimental group. A significant increase in prolactin levels and sleep duration but no significant effect was observed in infant's weight.

Yuliastuti S. et al (2018) conducted a quasi-experimental study that enrolled 16 women each in experimental and control group, two doses of 250 mg moringa oleifera leaf powder was administered as post-partum intervention daily for 2 weeks. Moringa oleifera was proven to increase breast milk production with indicator of breast milk fat and baby weight.

Asztalos E.V (2018) concluded after the experiment in Canada on 99 women that many non-pharmacological measures have been found to contribute to variable levels of success in augmenting the breast milk production in mothers of preterm infants. It is critical to emphasize that the primary effective strategy for optimizing breast milk volume is frequent and effective

E. Ozalkya et.al (2018) conducted a randomized control trail to evaluate the effect of herbal tea mixture on the breast milk production, serum prolactin levels of mothers, weight gain in preterm babies. 21 mothers with more than 37 weeks of gestation with babies not less than 2 kg of weight were enrolled. Interventional group of 32 mothers were given herbal tea for 1 week whereas control group of 31 mothers received the lactation counselling; placebo group of 32 women were given fruit tea for 1 week. Weight gain of infants and serum prolactin levels were recorded. Increase in milk output of 80% was observed in 1-week post-partum with herbal tea provision. Not much significant increase in prolactin levels of day 1 and day 7 and weight gain was recorded as babies were fed infant formula on insufficient breastfeeding.

B. Babitha, B.Vyshnavi (2018) assessed the impact of supplementation moringa oleifera and emblica officinalis on atherosclerosis patients in India. 60 subjects of age group 60-70yrs of age were selected. 50 subjects were experimental group served meal with 10gm of moringa and amla powder for 40 days and remaining 10 were in control group. Results showed the reduction in anthropometric measurements, serum total cholesterol, LDL levels, triglycerides and increase in HDL cholesterol levels in experimental group. No significant effect was seen in control group.

Setiasin et. al (2019) did a study in Russia to view the impact of moringa leaf extract on rabbit milk production and mammary gland histology. The feed of Moring Leaf extract was given to 7 group of rats with dosage proportion 0%, 0.13% 0.26%, 0.37%, 0.74%, 0.54%, 1.08% respectively. Average milk production, daily weight of rats, and mammary gland

histology was recorded. Twice a day milk production was noted on 7 a.m and 4 a.m and weight were measured before and after suckling. Dosage of 0.54% moringa leaves showed a positive difference in milk production by increasing the mammary cells of mammary gland of these rabbits.

B. Satheesh Kumar (2020) conducted a prospective and analytical study in India on 50 hospitalized CKD patients with complications to study the correlation between serum prolactin levels and the adverse cardiovascular events in CKD patients. Out of 50 patients, 28 patients had raised PRL levels and out these 17 had raised CIMT. It was concluded that hyperprolactinemia was observed in CKD patients. This raise is associated with increase in CIMT and occurrence of adverse cardiovascular events amongst them.

Reena Ravi, Jasmine Joseph (2020) conducted the experimental study in India to know the impact of fenugreek, one of the herbal galactagogue, on breastmilk production and infant weight gain in first week of life. Sample was equally divided into 2 groups of post-natal mothers such as 30 in each of the experimental and control group. 7.5 g of overnight soaked fenugreek water was administered daily in the morning for 1 week. Frequency of urination and infant weight gain were assessed on day 1, 3, 5 & 7. The results showed increase in breast milk production, urine frequency and infant weight.

weight gain was observed with the increase in subjective satisfaction regarding lactation.

Nadimin, et.al (2020) proposed a study in Indonesia on pregnant non anemic women. The interventional group was administered by 4 moringa leaves capsules and other with IFA capsules. Moringa leaves capsules are equally effective as IFA capsules in preventing anemia amongst pregnant women.

Fungtammasan S, Phupong V (2021) undertaken a randomized, double-blinded in Thailand, placebo controlled-trial was performed on 88 on pregnant women having more than 37 weeks of gestation. Consent enrollment was made after doing necessary health checkups.

The study group was bifurcated in two groups: treatment group and placebo group. 2 Moringa oleifera capsules of 450mg were given to them before meals for 3 days. The intervention was initiated after 6 hours of birth. Milk output on the third day post-partum was measured with

consecutive daily milk volume for consecutive 3 days. Infant weight started to record after 48 hrs of delivery. Infant weight was measured before and after every feed.

breast draining. Mothers need to maintain pumping to facilitate the autocrine regulatory mechanism.

Nadimin, Muhammad Haseeb Zia et.al (2021) carried a nutritional intervention study in Indonesia to assess the impact of moringa leaf powder in preventing stunting in first 1000 days of life. The target audience included pregnant women, lactating mothers and children 6-24 yrs of age. Single dose of moringa leaf extract or flour along with honey and IFA was introduced to the samples. Moringa intervention either in form of leaves of flour had positive impact on nutritional status, hemoglobin levels, prevent oxidative stress in pregnancy and low birth weight babies in pregnant women. Moringa intervention helps in increasing breastmilk production in post-partum mothers. Usage of moringa flour as food mix helped in improving the nutritional status of under 5 yrs old children. Therefore, concluded that moringa was effective in preventing stunting by increasing children weight in first 1000 days of life.

Sumeer Brar et.al (2022) carried out a systematic review of the impact of supplementation of moringa leaves on human and animal nutrition, growth and milk production. Their research included 148 unique studies out of which 33 studies were included. Of which 7 were human studies and 28 animal studies. Results concluded as consumption of moringa 14-30g/d not less than 10g showed improved hemoglobin in children iron deficiency anemia, improved Hb and Vitamin A in post-partum mothers and also increased BMI in HIV+ patients who were undernourished. Also, Moringa (0.5g / 500mg) also resulted increase in milk production. In animals, moringa increased milk production in some studies, increase inconsistently the growth and had no effect in Hb status or anemia and Vit A status.

IMPACT OF GALACTAGOGUES ON INFANT WEIGHT GAIN

World Health Organization (WHO) (2006), release the data of growth pattern and weight gain pattern of breastfeeding babies.

The following table shows the figures of 50th percentile weight gains of male babies. In case of female babies, the mean weight gain is marginally less.

Following chart was declared by WHO which depicts the average weight gain pattern of infant monthly Table 2.2

Age	Day		Week		Calendar Month	
	ounces	grams	ounces	grams	ounces	grams
Birth to 4 weeks*	1.3	38 g	9.4	266 g	38.8	1100 g
1–2 months	1.3	38 g	9.4	266 g	38.8	1100 g
2–3 months	1	28 g	6.8	194 g	28.2	800 g

Source: WHO, Growth standards, 2006

Yabes and Lim (1996) conducted a Pooled community study of 2 communities in Philippines. Therein they found that Adequacy of breastmilk volume can be judged by improvement in infant's weight gain. The lactation enhancing impact of moringa oleifera was studied by administering 2 capsules of 250 mg moringa capsules to term Filipino women immediately after birth. After administration of moringa oleifera leaves extract the prolactin levels rose after 48 hours and 4 months along with a significant improvement in the infants' weight gain.

Yabes and Lim (1996) conducted an interventional study in Philippines. An investigation was undertaken to determine the effectiveness of Moringa oleifera as galactagogue among 30 hypertensive women with blood pressure greater than or equal to 140/90. Significantly higher prolactin levels were obtained after 4 months with the experiment group at accompanied by observed gains in weights among these babies.

Estrella et al. (2005) conducted a randomized controlled trail in Philippines. The trial concluded that Moringa oleifera leaves increased the volume of breastmilk post-partum day 3-5 in nursing mothers of pre-term infants. The human subjects were given 250 mg moringa oleifera leaves in a capsule form twice a day. There was a 28-32% increase in the mean breastmilk volume in favour of the study.

Mradu Gupta, Badri Shaw (2011) carried out a double-blind, randomized, placebo-controlled, parallel-group study help in Kolkata by involving 60 lactating mothers. Fresh shatavari root powder was converted into capsules and provided as intervention. Increase in mother and infant weight gain was observed with the increase in subjective satisfaction regarding lactation.

Mutiara T.K. et al (2013) conducted an interventional study on animal in Indonesia. The study was conducted on 24 white rats. In the study white rats were divided into four groups: group fed supplemental moringa leaf powder with boiling treatment, group fed with moringa leaf powder with steaming treatment, group fed with moringa leaf powder boiled with sodium bicarbonate and control mice group. The results showed that Moringa leaves significantly can increase milk production. Dose 0.042 mg / g body weight to the parent mice had increased milk production. Steaming treatment in the manufacture of powder was the best treatment.

King J.S. et al (2013) did meta-analysis of 5 randomized control trial study in Philippines. In systematic review and pooled data analysis of 5 randomized control trials involving 366 participants, breast milk volume showed statistically significant increase following treatment with moringa oleifera capsules on different days of administration.

Titi Mutiara Kiranawati*, Nunung Nurjanah, (2014) undertaken an animal study in Indonesia on Wister rats. It was a randomized block design study to observe the effect of moringa leaves as galactagogue.

2 rats were the controlled group, 2 were given moringa leaf flour(85g) mixed noodles. 40g meal was given thinking 20g/day will be consumed. Food was given to rats on 14^{th} day of pregnancy till 10^{th} day post-partum.

Weight gain of 0.25-0.37g/dietary noodles was observed in infants breastfed of female rats given moringa. Moringa had positive effect on the breastmilk secretion.

Peter Francis et.al (2014) created an update on previously carried systematic review of impact of moringa in increasing breastmilk and infant weight gain in Philippines. Results of pooled data of 73 patients depicted the significant increase of milk output by 124ml by Day 7 and of Day 4 and 5 also favoured the moringa. An increase 11.9% in infant weight gain was seen after a month, favouring moringa

Kiranawati, T. M., & Nurjanah, (2017) conducted a Quasi experimental Study in Indonesia on pregnant mothers. There were 30 respondents out of which 15 are respondents of interventional group and rest 15 are respondents of controlled group. 250mg of Moringa leaves powder capsules were given twice a day to experimental group. A significant increase in prolactin levels and sleep duration but no significant effect was observed in infant's weight

Two RCTs reported increase in infant weight gain as an outcome of moringa oleifera administration. No adverse event was reported in any of the outcome.

Yuliastuti S. et al (2018) conducted a quasi-experimental study that enrolled 16 women each in experimental and control group, two doses of 250 mg moringa oleifera leaf powder was

administered as post-partum intervention daily for 2 weeks. Moringa oleifera was proven to increase breast milk production with indicator of breast milk fat and baby weight.

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Nadimin, Muhammad Haseeb Zia et.al (2021) carried a nutritional intervention study in Indonesia to assess the impact of moringa leaf powder in preventing stunting in first 1000 days of life. The target audience included pregnant women, lactating mothers and children 6-24 yrs of age. Single dose of moringa leaf extract or flour along with honey and IFA was introduced to the samples. Moringa intervention either in form of leaves of flour had positive impact on nutritional status, hemoglobin levels, prevent oxidative stress in pregnancy and low birth weight babies in pregnant women. Moringa intervention helps in increasing breastmilk production in post-partum mothers. Usage of moringa flour as food mix helped in improving the nutritional status of under 5 yrs old children. Therefore, concluded that

moringa was effective in preventing stunting by increasing children weight in first 1000 days of life.

COMPOSITION & PROPERTIES OF MORINGA OLEIFERA

As per IFCT, 2017, following are the nutritive value of Moringa Oleifera Leaves in Table 2.3

Moringa Oleifera Leaves	Amount	Moringa Oleifera Leaves	Amount
Moisture	75.65 gm	**Calcium**	314 mg
Carbohydrate	5.62 gm	**Iron**	4.56 mg
Protein	6.41 gm	**Magnesium**	97.09 mg
Fat	1.64 gm	**Phosphorus**	109 mg
Total Fibre	8.21 gm	**Potassium**	397 mg
Energy	67.4 kcal	**Selenium**	5.95 ug
Riboflavin	0.45 mg	**Camphasterols**	4.27 mg
Niacin	0.82 mg	**Stigmasterol**	2.02 mg
Pantothenic acid	0.39 mg	**Beta-Sitosterol**	28.92 mg
Pyridoxine B6	0.87 mg	**Phytate**	128 mg
Biotin	2.26 mg	**Alpha tocopherol**	0.31 mg
Folates	42.89 mg	**Phylloquinones (K1)**	479 ug
Ascorbic acid	108 mg	**Beta carotene**	17542 ug

Rajanandh MG et.al (2010) did the quantitative estimation in India of beta sitosterol, total phenolic and flavonoids in Moringa Oleifera leaves. A hydroalcoholic extract of leaves were taken for estimation. Before the actual testing, primary quantitative testing was done thereafter final testing was done by visible spectroscopy. The result came as 90mg/g beta sitosterol, 8µg/mL and 27µg/mL phenolic and flavonoids present in the leaves of Moringa.

Temitayo Olabisi et.al (2013) in Nigeria, reported the results Phytochemical screening and estimation of toxicity in methanol extracted moringa seeds. Phytochemical screening revealed the presence of saponins, tannins, terpenes, alkaloids, flavonoids, carbohydrates. Acute toxicity was observed at the level of 4000mg/kg and mortality at 5000mg/kg. no adverse effect was seen for levels below 3000mg/kg.

Laxmipriya Gopalakrishnan, Kruthi Doriya, Devarai Santhosh Kumar (2016) reported nutritive importance and medicine properties of moringa of India. The moringa leaves are rich source of vitamins and phytochemicals. They are used to deal with malnutrition, galactagogue, antioxidant, anticancer

Yang Yang et.al (2016) conducted the study in China to know content of Sitosterol, Camphasterol, Stigmasterol in moringa oleifera leaves from countries like Xishuangbanna, Shaoguan, Angola, India and Yunnan through gas chromatography. There is content of beta sitosterol as 30mg/ 100g in Moringa oleifera leaves of India, Camphasterol levels as 8mg/100g in Moringa oleifera leaves of India and stigmasterol of 2-12mg/100g of Moringa Oleifera leaves of India.

Alessandro Leone et.al (2016) did research on moringa oleifera seeds and oil characteristics and its uses for Human Health. They stated that moringa oleifera had many food and non-food applications, because of their high MUFA and saturated fat ratio like tocopherols, sterols. Also, they are rich in proteins containing Sulphur. Apart from that, it has some uses as biofuel instead of human crop exploitation. Details of its physical, chemical, nutritional composition was being studied and highlighted here

Yogesh Prasad Rajbhar et.al (2018) stated Moringa as miraculous tree on earth because of its many physiological and medicinal properties. Due to this it is of very high value commercially. They described the benefits of all the parts of moringa, flowers, roots, leaves,

fruit. Leaves are rich in phytochemicals and minerals which helps in combating malnutrition, less milk production in lactation. It also has some anti-inflammatory, anti-cancer, anti-diabetic properties.

Dina M. Sakr et.al (2020) of Egypt, stated the composition, nutritive value of Moringa Oleifera leaves and its role in maintaining bone integrity in albino rats on purified diet. The research was mainly divided into two phases. Phase 1 to determine the proximate composition of moringa leaves (dried) and to estimate the composition of bioactive compounds present in it. and the Phase 2 included the assessment of impact of these moringa leaves of by doing dietary fortification of the diets of 30 albino rates on serum parameters, femur bone density, strength and mineral contents of albino rats. Results found that it had significant impact on parameters like serum cholesterol, triglycerides, but no significant result was observed in bone density, strength and mineral contents of albino rats.

Thakur Shalini et.al (2020) carried out a study in India how malnutrition which is 21st century challenge can be combated by ayurveda through Moringa leaves. Nutritive diet has become an epicenter to solutions of malnutrition. But still it is a cause of many diseases of the world and 45% deaths of children under 5 yrs. Due to interrelated nutrition of mother child, it is said if the mother gets nutritive diet during breastfeeding the child also becomes healthy. Moringa as food for lactating mothers has been of great potential, therefore, a combination of Moringa, wheat flour, jaggery was formulated. It is nutritious, cheap, super affordable and easily available to all economical class group mothers. Therefore, 100g nutritive value of these dried leaves were carried out in the study.

Bin Su et.al (2020) carried out a study in China on current status and potential of Moringa Oleifera leaf as an alternative protein source for animal feeds. They stated that the needs for animal protein in human diet is increasing globally. Therefore, it became essential to maintain the diet of livestock so that the nutrients in it are in appropriate proportion. Moringa oleifera is a tree of miracle richly packed with all essential nutrients, phytochemicals, antioxidants. Therefore, new initiative of using moringa oleifera as new protein feed stock is very much potential.

Paula Garcia Milla et.al (2021) conducted a study in Spain with the aim to assess the application of Moringa Oleifera leaves in bakery products reformulation of different commonly products with improved nutritional and functional value. They stated that moringa had a broad range of nutritional and bioactive compounds including prolactin, essential amino acids, carbohydrates, lipids, fibre, vitamins, minerals, phenolic compounds, phytosterols and others. It also has pharmacological properties anti-inflammatory, anticancer, antioxidant, antidiabetic, antimicrobial, hepatoprotective properties. As such the entire moringa plant is edible but leaf is the safest part. Therefore because of these properties, its application in various commonly consumed bakery products was assessed to elevate the nutritional and medicinal properties of these bakery food items.

DEPARTMENTAL STUDIES ON MORINGA OLEIFERA LEAVES

Nambiar & Seshadri (2001/3) conducted an experiment on 40 male albino rats in India. A synthetic Vit A deficient diet was fed for 4 weeks. Out of the 34 serving rats, 5 continued on Vit A deficient diet for more than 4 weeks, rest 24 were provided vit A in form of Vit A acetate (n=8), fresh drumstick leaves (n=8), or dehydrated drumstick leaves for 4 weeks. Out of the remaining 10 rats continued on vit A adequate diet for 4 and 8 weeks respectively each with n=5. Depletion in serum Vit A & liver vita A was observed at the end of 4 weeks when fed vit A deficient diet. Body weight gain was maximum in group fed dehydrated drumstick leaves. Results say $\beta - carotene$ from drumstick leaves was effective against Vit A deficiency and growth

Nambiar, Seshadri (2003) carried out a detailed study in Western state of Gujarat to identify all vegetables & fruits grown in rural & tribal belt which are rich in carotenoid pigments particularly- carotene. Two GLVs were found but were not sold in markets named Kanjero leaves (Digera arvensis) & Drumstick leaves (Moringa Oleifera) & their potential for meeting the nutritional needs of population.

Nambiar (2003) conducted the study in India to know the nutrition potential of drumstick leaves in Indian perspective to combat micronutrient malnutrition in children like Vit A, iron, Calcium, deficiency. Th such bio-diverse country like India, plenty of plant foods with low/negligible cost is available but underutilised. This alone is logical & sustainable strategy to avoid both nutritional deficiencies and disease due to macro-nutrient excess.

Nambiar, Bhadalkar, Daxini, (2005) carried out the pilot study in India to assess the feasibility & acceptability of Dehydrated Drumstick Leaves, as a source of vit A into salty recipes of super food component in ICDS & Nutrition communication. An integrated approach by comprehensive training sessions for the staff of ICDS, NGO involved in supplementary feeding preparation were involved. 40 children of 1 anganwadi accepted pretested DDL recipes (5-7gDDL/ 100 g product) with nutrition communication for 1 month. It was acceptable to ICDS authorities & NGO as well.

Nambiar, Parnami (2008) conducted the study in India to standardize & organoleptically evaluate freshly blanched leaves of drumstick tree into 3 traditional recipes- mung, kabuli chana and desi chana. 30 g raw ulse had 20g fresh drumstick leaves/each serving. Recipes were acceptable by the panel (18-21 yrs women). Each serving had 355mcg β- carotene, 46 mg Ascorbic acid, 1.6 mg iron. Benchmark of ½ of the RDA was used. Analysis suggested industrial production of ready-to-eat foods may incorporate drumstick leaves.

Nambiar, et.al (2010) conducted an experiment in India in which, 20 hyperlipidaemic subjects with serum total cholesterol levels 180mg/dl or serum triglycerides 140mg/dL were observed the impact of dehydrated drumstick leaves tablets of 575mg. The experimental group received 8 tablets/day equivalent to 4.6 g for 50 days. Drumstick leaves are rich source of antioxidants like polyphenols & carotenoids, beneficial for prevention of chronic degenerative disorders (CCDs).

Nambiar, Patel, Gosai et.al (2012) carried out the preliminary trial in India to study the effect of β- carotene from dehydrated drumstick leaf powder on haematological indices of non-pregnant & non- lactating young women of 18-25 yrs. 20 unmarried women (18-25yrs), consuming typical Gujarati food were enrolled, bifurcated into experimental and control group. Experimental group received 4g/day DDL powder (692mcg β- carotene) for 25 days. Effect of shade dehydrated drumstick leaves powder on the haematological indices of women was seen in form of positive shift of anemic girls to non anemic category with mild increase in Hb & increase in normocytic normochromic cells.

Nambiar (2015) conducted the study in India to observe Moringa oleifera leaves to improvise nutritional status and oxidative stress and reducing anemia. The drumstick leaves which are underutilized have strong antioxidant capacity due to phenolic compound presence. People with iron deficiency anemia has more oxidative stress, depletion of antioxidant enzyme and production of Reactive oxygen species. The study highlights the antioxidant capacity of moringa leaves & the impact of pilot clinical trials on the haematological indices by measuring the positive shift of anemic girls to non-anemic category due to the phytochemical content of drumstick leaves.

METHODOLOGY

METHODOLOGY

Breastfeeding play vital role in combating malnutrition in young children, helps in giving healthy start to the life, helps in developing appropriate IQ.

Region specific data on maternal factors, knowledge and practices of IYCN practices, Serum prolactin levels of lactating mothers and weight gain pattern of infant has to be documented to reduce the prevalence of undernutrition in first 1000 days of life itself to attain SDG Goal 3.

Therefore, the present study was planned with the following broad objective

Broad Objective

To investigate impact of moringa oleifera leaves tablet on serum prolactin levels in post-partum mothers & to assess the weight gain pattern in neonates.

Specific Objectives of the study were

- To assess the background information of enrolled pregnant & lactating women.
- To assess the knowledge and practises of selected IYCN practises.
- To understand frequency of use of galactagogues by the enrolled mothers
- To assess maternal serum prolactin levels at the interval of 0,7 days post-partum.
- To provide Moringa Oleifera leaves capsules and Placebo capsules on day 0 postpartum for 30 days.
- To record the compliance of capsules in both the groups for 30 days.
- To track weight gain pattern of neonates on 0,7,15 and 30 days post-partum in experimental and control group.

Ethical Approval

The study was approved by the Institutional Ethics Committee for Human Research (IECHR), Faculty of Family and Community Sciences, The Maharaja Sayajirao University of Baroda. The study has been allotted ethical approval number IECHR/FCSc. /MSc. /2022/32 (Appendix II)

The study is also approved and registered in Clinical Registry Trails of India, Indian Council of Medical Research (ICMR) with the CTRI No. CTRI/2023/02/049402

Study site: Study was carried out in Urban Vadodara. Out of 3 major government hospitals of Vadodara, Jamnabai General Hospital was chosen as study site.

Study design: It was a hospital based interventional study. Jamnabai General Hospital was selected purposively. Pregnant women who were registered in Jamnabai General Hospital were the study population for the prospective study.

Detailed experimental design is explained in figure –3.1

Study was divided into following 2 phases:

Phase 1

- To assess the knowledge and practises of selected IYCN practises.

Phase 2

- Impact of moringa oleifera on maternal serum prolactin level and neonates weight gain pattern.

Phase 1-To assess the knowledge and practises of selected IYCN practises

There are 3 government hospital in Vadodara district. Jamnabai General Hospital was selected purposively as maximum no. of deliveries takes place in the hospital and also women from local nearby area generally comes for ANC check-ups also.

All women who were registered in Jamnabai General Hospital for delivery and were in last gestational month were enrolled for the study.

Data was collected on:

1. Background information of enrolled mothers and EDD
2. Knowledge & age-appropriate practices of IYCN practice.
3. Use of galactagogues.
4. Consumption of galactagogues foods.
5. Pregnancy Outcome.

Necessary permission was obtained from the concerned hospital authorities. Pregnant mothers who gave written consent were enrolled for the study. (Appendix I)

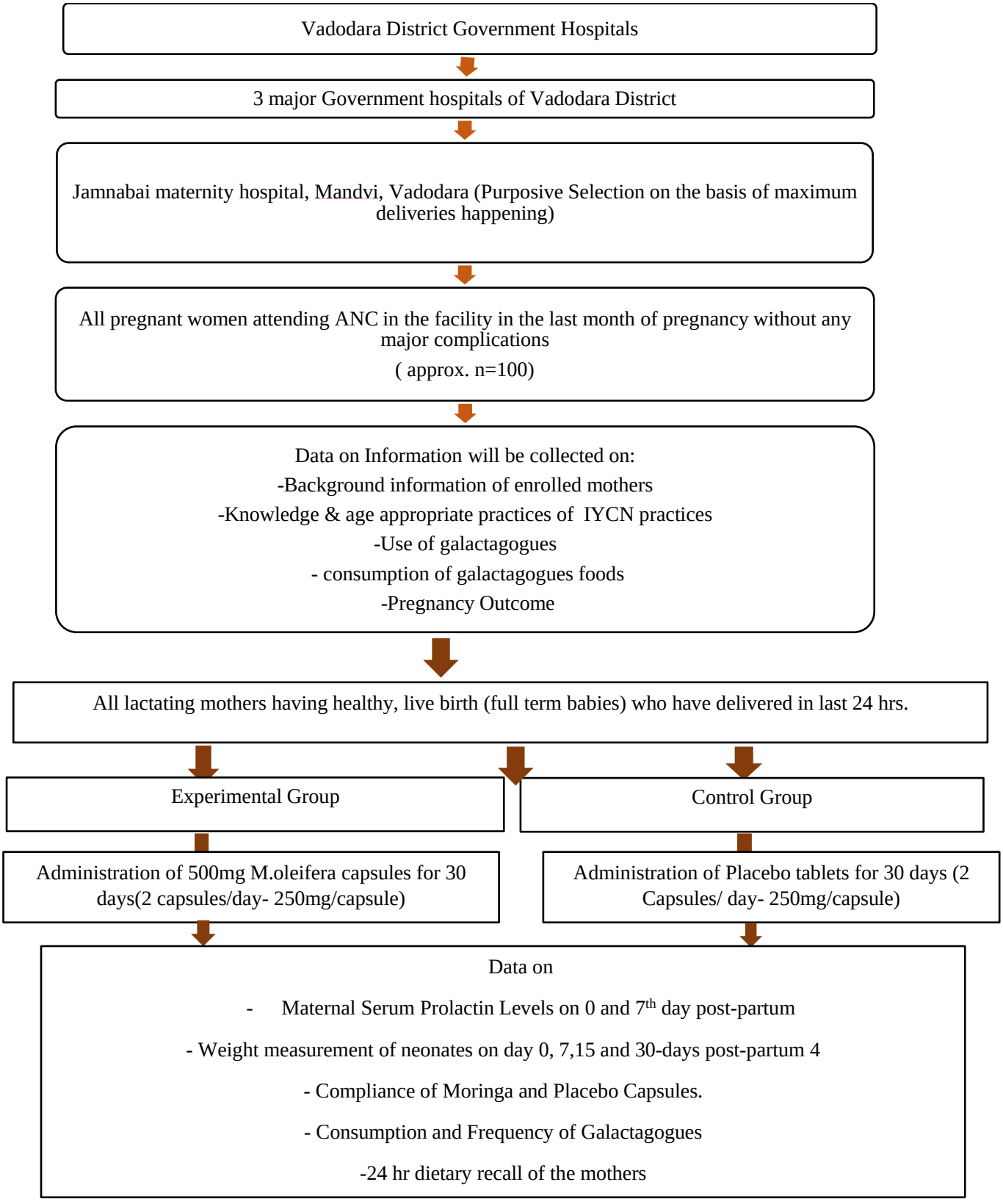
In Phase 1, All pregnant women in the 9^{th} month of their pregnancy, who came for their Antenatal Checkups in Jamnabai General Hospital and also willed to deliver in the same facility were enrolled. A pre tested semi- structured questionnaire was used to receive information. (Appendix IV)

Information regarding their socio-economic background like age of the mothers, religion, education of the mothers, Occupation of the mothers and their husbands, socio-economic status were collected.

Antenatal history was also assessed here. Information regarding early initiation of breastfeeding, no. of ANC checkups, last menstrual date, expected delivery date or any food allergies were recorded.

Knowledge about IYCN practices amongst the mothers was also assessed. Knowledge regarding early initiation of breastfeeding, prelacteal avoidance, colostrum provision, exclusive breastfeeding, initiation of complementary feeding was recorded. Knowledge regarding awareness of galactagogues and their usage in pregnancy was also recorded.

Fig- 3.1 EXPERIMENTAL DESIGN



Phase 2- Impact of moringa oleifera on maternal serum prolactin level and neonates weight gain pattern

In Phase 2, All lactating mothers who gave birth to full term live babies within 24 hrs in the selected facility with no medical complication and who gave consent were enrolled. These enrolled mothers were randomly then distributed to Experimental Group and Control Group. Experimental Group was administered by Moringa Oleifera Capsules and Control Group was administered by Placebo Capsules.

IYCN Practices and Consumption of Galactagogues

In phase 2, information regarding the practices of IYCN was recorded. Data on early initiation of breastfeeding, colostrum provision, prelacteal avoidance, post feed analysis were noted.

Information regarding galactagogues usage by the mothers, frequency of galactagogues were also recorded.

24-hr dietary recall of the mothers to assess the dietary diversity amongst the lactating mothers was also recorded. List of food groups consumed by the women were prepared and MDD-W was computed as per FANTA USAID Minimum Dietary Diversity for Women (2016). Ten food groups were: Grain, white roots and tubers, and plantains, Pulses, Nuts and seeds, Dairy, Meat, poultry and fish, Eggs, Dark green leafy vegetables, Other vitamin-A rich fruits and vegetables, Other vegetables, Other fruits. The score was given if the women have consumed the food groups, then we have given as 1 score and if they had not consumed then we have given them 0 score for each food groups.

Information on frequency of consumption of various food groups was also recorded using pre-tested food frequency questionnaire. Food frequency included a checklist of all the food groups.

Preparation of Moringa Oleifera leaves powder Capsules and Placebo Capsules

Moringa oleifera freeze dried powder were obtained from a Local Food drying Industry to avoid adulteration and to retain maximum nutritional benefits. It was encapsulated by a Local Pharmacy company. Each Capsule contained 250mg of Moringa Oleifera. Placebo Capsules

containing Starch powder was also manufactured in the same facility. Each Capsule contained 250mg of Placebo. Each bottle of intervention contained 30 capsules

Intervention of Moringa Oleifera leaves powder Capsules and Placebo Capsules

30 tablets properly packed were given to enrolled mothers on day of delivery and another 30 tablets were given on 15th day post-partum.

Each tablet contained 250mg of Moringa Oleifera Leave Powder and 250mg of Placebo.

The bottles and capsules of both the interventional groups were alike in appearance. To differentiate the Bottles, identification criteria was known by the investigator.

Compliance was monitored using a self-filled compliance card and telephonic monitoring by the investigator (Appendix III)

Cost Expenditure of Moringa Oleifera intervention is depicted in Table-3.1

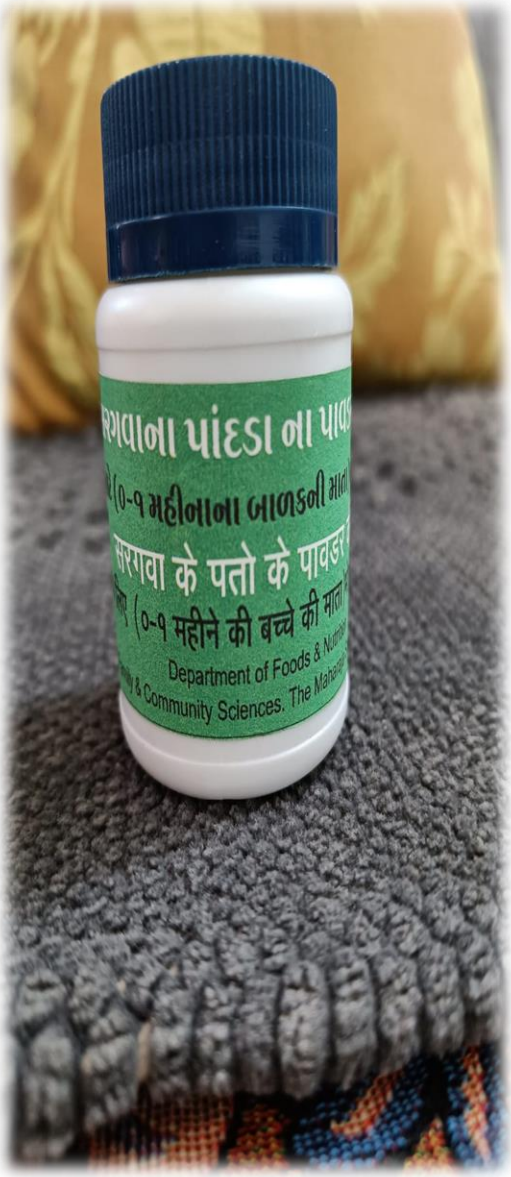
PARTICULARS	**AMOUNT**	**COST**
Freeze Dried Moringa Oleifera Leaves Powder	1200g	Rs 2100 (inclusive 30% Student Discount)
Cost of containers	95 bottles of M. Oleifera leaves capsules	Rs 2733 (Minimal Packaging charge was only taken)
Labelling cost of the containers	95 bottles	Rs 546
	Total	**Rs 5379**

Therefore, the Total cost expenditure for 95 bottles was ***Rs 5379.*** Each bottle contained 30 capsules. Therefore, 2850 Capsules cost expenditure was ***Rs 5379.*** Therefore, 1 Capsule costed ***Rs 1.8 approx.***

Cost of intervention per lactating women for 30 days 1.8*2*30= Rs 108/month

The freeze dried Moringa Oleifera leaves powder used for encapsulation

The bottles made for intervention Both for Moringa and Placebo.



Alike capsules with different fillings

Identification criteria in M.oleifera Capsules bottles v/s Placebo Capsules bottles

Estimation of Prolactin Levels

To assess the prolactin level on 0-day, Venous blood collection were done by a trained technician in the labour room. Again on 7th day, post-delivery, venous blood were collected by trained technician.

Prolactin levels were tested in a NABL certified pathology laboratory.

Prolactin levels (PRL) were assessed through Chemiluminescence ImmunoAssay (CLIA) test method in the laboratory. It is based on immunoassay for quantitative detection of PRL in human serum or plasma using the ALTA CLIAlyzer.

Consumption of any galactagogue foods by the enrolled women were asked during the intervention period. (Weekly consumption pattern).

Tracking of weight of neonates

A Calibrated infant weighing scale was used which was placed on a flat surface for neonates' weight tracking.

The mother was asked to remove all the clothing of the infant. A clean towel was placed on the weighing scale, its weight was tared making the reading of the monitor zero.

The infant was placed on the center of the weighing scale on his/her back. The reading of the weighing scale was recorded.

Every week, the same method of weighing was used.

Infant weighing scale was calibrated each time before weighing. On the day of delivery, Birth weight was collected from hospital record. For measuring Weekly weight gain of neonates calibrated infant weight scale was used. Neonates weight were monitored on 0,7,15,30 days post-delivery.

Inclusion Criteria

- Phase 1: All pregnant women attending ANC clinic in selected facility in the last month of pregnancy with no medical complications, willing to deliver in the selected hospital will be selected. Selection will be consensual.
- Phase 2: All lactating women who have a gestational age of 36-37 weeks, who will deliver healthy, live infants with no medical complications, and are willing to breastfeed exclusively. Selection will be consensual.

Exclusion Criteria

Pregnant or lactating women with medical complications like breast abnormalities or hypertension, diabetes mellitus, or any other illness that requires medication regularly.

Lactating women with pre-term/still birth babies/ low birth weight babies or full-term babies/lactating women with complications were excluded.

Women who didn't give consent was not be enrolled for this study.

Tools & Techniques used in study is depicted in Table-3.2

Parameters	**Tools**
Information on IYCN practices, knowledge about galactagogues, 24 hours dietary recall	Pre-tested Semi-Structured Questionnaire
Nutrient composition of moringa oleifera leaves capsules	analyzed by NABL accredited laboratory.
Serum prolactin level	CMIA Technique in accredited laboratory
Neonate weight gain pattern	Digital infant weighing scale
Dietary diversity	USAID- FANTA 2016 Publication

Data Collection

An in-depth pre-tested semi structured questionnaire was developed to assess:

1. Socio-economic factors
    - Age of the mothers
    - Religion
    - Education of the mothers
    - Husband's Occupation
    - Socio-economic Status
    - Occupation of the mothers

2. Ante- Natal History
    - Early registration in Anganwadi.
    - Number of Anganwadi checkups
    - Last Menstrual Date
    - Expected Delivery Date
    - Any Food Allergies reported

3. Knowledge and Practices of IYCN
    - Colostrum Provision
    - Early initiation of Breastfeeding
    - Prelacteal Provision
    - Exclusive Breastfeeding
    - Timely Initiation of Complementary Feeding

4. Use of Galactagogue
    - Awareness of Galactagogue
    - Consumption of galactagogue in pregnancy

- Consumption of galactagogue in lactation
- Consumption of Moringa Oleifera in pregnancy
- Consumption of Moringa Oleifera in lactation

5. Food Frequency of galactagogue
6. 24-hr Dietary Recall

Adverse events/side-effects management

Prospectively stopping rules were defined in the consent form. The subject had the liberty to discontinue the intervention if some side-effect or feels uncomforted.

Data Management

Data was recorded through pre-tested questionnaire. Recorded data was then entered into Microsoft Excel. Data cleaning. Sorting, filtering and Analysis was done to establish the concerned result.

Statistical Analysis

The collected data was entered into the Microsoft Excel. Microsoft Excel was used for sorting, filtering the data. Microsoft Excel was used for data analysis

Significance of Serum Prolactin levels and Weight gain trends of neonates on Baseline and Endline was analyzed through SPSS version 29.0. Appropriate statistical analysis was carried out.

Determinants of Serum Prolactin and neonate weight gain factors were also assessed through SPSS version 29.0. Appropriate statistical analysis was carried out.

RESULTS & DISCUSSIONS

RESULTS AND DISCUSSION

Breastfeeding is one of sustainable and effective method considered for a child's survival, growth and development. Breast milk is considered as an ideal food for infant, provides all the essential nutrients in sufficient amounts needed in first new months of life. It is sterile, safe and contains antibodies which helps as an immunity factor providing defense against infections. About 1/2 & 1/3 of child's nutritional requirements are fulfilled by breastmilk in second half of first year and second year of life respectively.

Breastfeeding helps in combating malnutrition (undernutrition & overnutrition), helps in giving healthy start to the life, helps in developing appropriate IQ. (WHO)

Early initiation of breastfeeding and exclusive breastfeeding is on stake for mothers due to low milk supply. Therefore, mothers often get diverted in the directed towards the provision of formula milk, animal milk or additional foods, which hinders the infant's growth and development therefore, resulting in non-breakage of vicious cycle for malnutrition. Yet there are some of the ways to promote adequate milk secretion in post-partum mothers; Maternal education, pharmaceutical therapy, Consultation with a lactation specialist, and herbal galactagogues. Some of the traditional galactagogues of India are Edible Gum, Fenugreek, Sepu seeds, Fennel seeds, Peepramul roots, Shatvari roots, Ghee and Moringa Oleifera leaves.

Keeping into consideration above points, the present study was planned taking into consideration **the broad objective of the study**, to investigate the impact of Moringa Oleifera leaves tablet on serum prolactin levels in post-partum mothers and to assess the neonates weight gain pattern. **The specific objectives of the study were:**

- To assess the background information of enrolled pregnant & lactating women.
- To assess the knowledge and practises of selected IYCN practises.
- To understand frequency of use of galactagogues by the enrolled mothers
- To assess maternal serum prolactin levels at the interval of 0,7 days post-partum.
- To provide Moringa Oleifera leaves capsules and Placebo capsules on day 0 postpartum for 30 days.

- To record the compliance of capsules in both the groups for 30 days.
- To track weight gain pattern of neonates on 0,7,15 and 30 days post-partum in experimental and control group

The Findings are presented in following phases

PHASE 1: To assess the knowledge and practises of selected IYCN practices

PHASE 2: Impact of moringa oleifera on maternal serum prolactin level and neonates weight gain pattern.

The study was carried out in Jamnabai General Hospital, one of the govt. hospitals of Vadodara District with cooperative coordination of Department of Gynecology and Obstetrics and Department of Pediatrics.

PHASE 1

ENROLLEMENT OF THE WOMEN

All 106 pregnant women in their last 9th month of pregnancy who came to the selected facility for ANC checkups and who delivered in selected facility were enrolled.

Background details of enrolled pregnant women in the study is shown in Table 4.1

As per Table-4.1, Out of 106 women enrolled, women who belonged to the age group of 19-25yrs of age were 67%. Followed by 25% women in the age group of 26-30yrs of age. 56% belonged to BPL category, 46% women that attained their education till secondary followed by 42% women who received their education till primary. 4% women responded to be illiterate. All the enrolled women were housewives. 58% of the husbands were found to be in the service category group followed by 27% who were entrepreneurs and 15% of labour category. 1% unemployment was also seen in the household.

ANTENATAL HISTORY OF ENROLLED MOTHERS

Antenatal history of the enrolled mothers was collected through pretested questionnaire. Information of parity, gestational age, early registration of pregnancy, place of ANC check-ups and No. of ANC check-ups, were recorded and is presented in Table 4.2

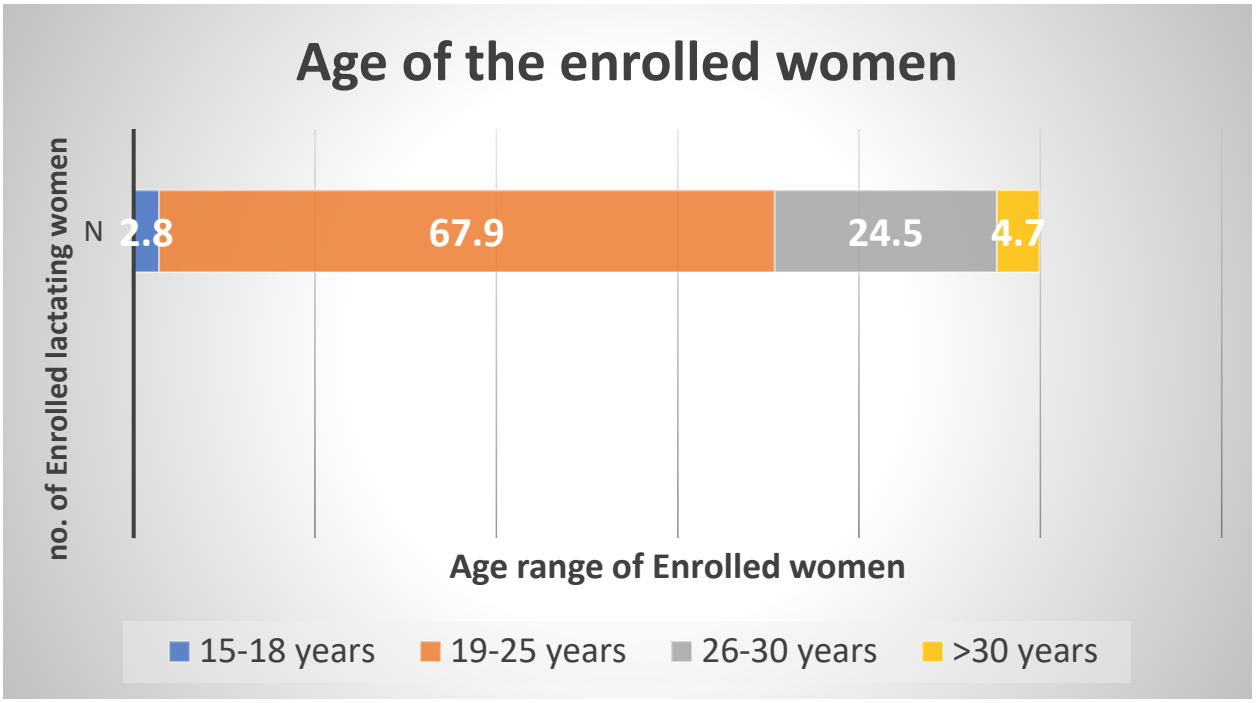
As can be seen from Table 4.2, Fig-4.6, 4.7 and 4.8, 57% women were multipara and 43% were Primipara. All the mothers enrolled were in their 9th month of gestational period. 93% women did early registration within 12 weeks of gestation but 7% women registered themselves after 12 weeks of gestation. 44% women went to both AWC and Jamnabai Hospital for ANC checkups followed by 32% women who only came to Jamnabai Hospital for ANC checkups. 12% women went to all three AWC, Private hospital and Jamnabai hospital for ANC checkups. 95% women underwent more than 4 ANC checkups. There were 2% women who didn't go any checkups at all till last month of pregnancy.

Table-4.1 Background Characteristics of enrolled mothers

Particulars	**N**	**%**
Age of women		
15-18 years	3	2.8
19-25 years	72	67.9
26-30 years	26	24.5
>30 years	5	4.7
Mean Age	**24 ± 3**	
	106	
Religion		
Hindu	50	47.2
Muslim	56	52.8
	106	
Economic Category		
APL	47	44.3
BPL	59	55.6
	106	
Women's Education		
Primary (1^{st} to 8^{th} Std)	44	41.5
Secondary (9^{th} and 10^{th} Std)	49	46.2
Higher Secondary (11^{th} and 12^{th} Std)	6	5.6
Graduate	3	2.8
Not formally educated	4	3.7
	106	
Women's Occupation		
Housewife	106	100
	106	
Husband's Occupation		
Labourer	16	15
Service	61	57.5

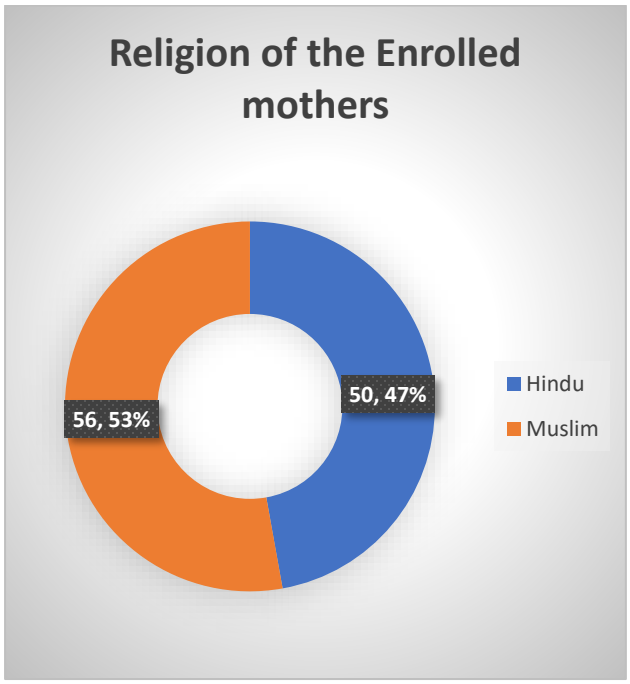
Entrepreneur	28	26.4
Unemployed	1	0.9
	106	

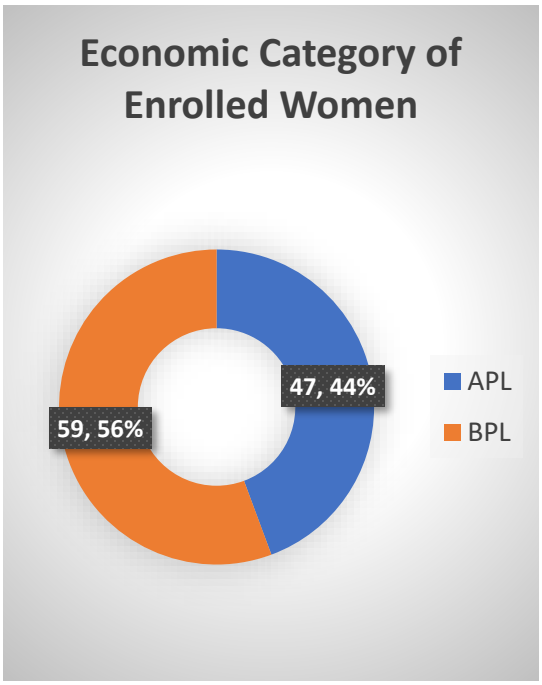
Age range of the mothers (n=106) is depicted in Fig- 4.1



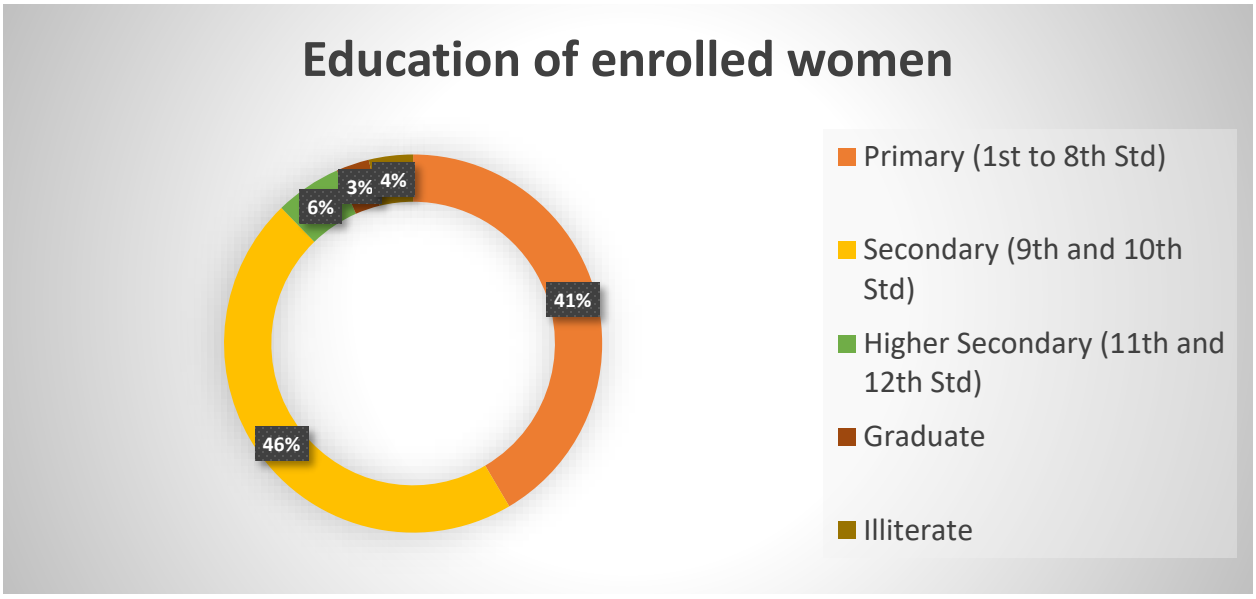
Religion of the mothers (n=106) is depicted in Fig- 4.2

Economic Category of the mothers is shown in Fig 4.3





Education of the mothers (n=106) is depicted in Fig- 4.4



Occupation of the husbands of enrolled women (n=106) is depicted in Fig- 4.5

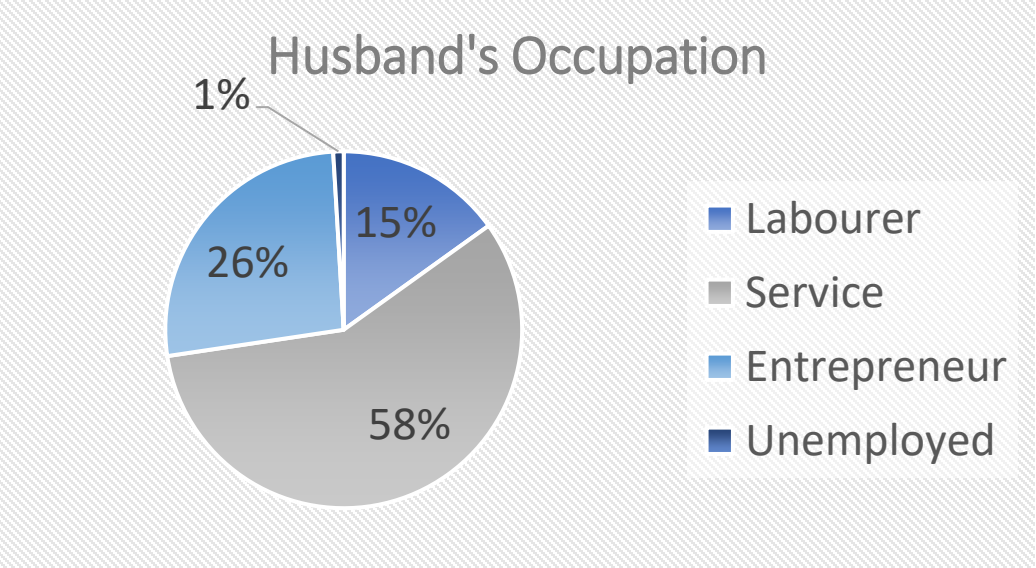


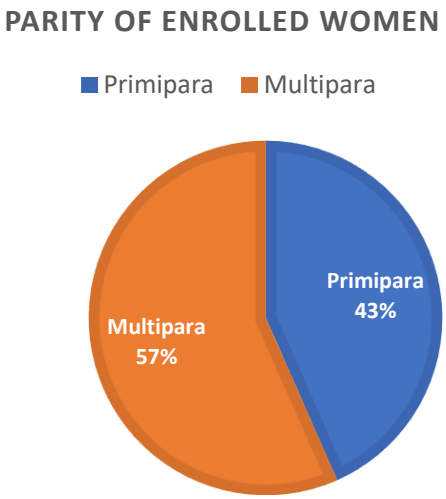
Table -4.2 Antenatal (ANC) history of enrolled women (n=106)

Particulars	**N**	**%**
Parity		
Primipara	46	43.4
Multipara	60	56.6
	106	
Gestational age of Enrolled Mothers		
3rd Trimester	106	100
	106	
Time of registration in AWC/ Health facility		
<12 weeks	99	93.3
>12 weeks	7	6.6
	106	
Place of ANC Check-ups*		
AWC (Mamta Diwas) & Jamnabai Hospital	47	44.3

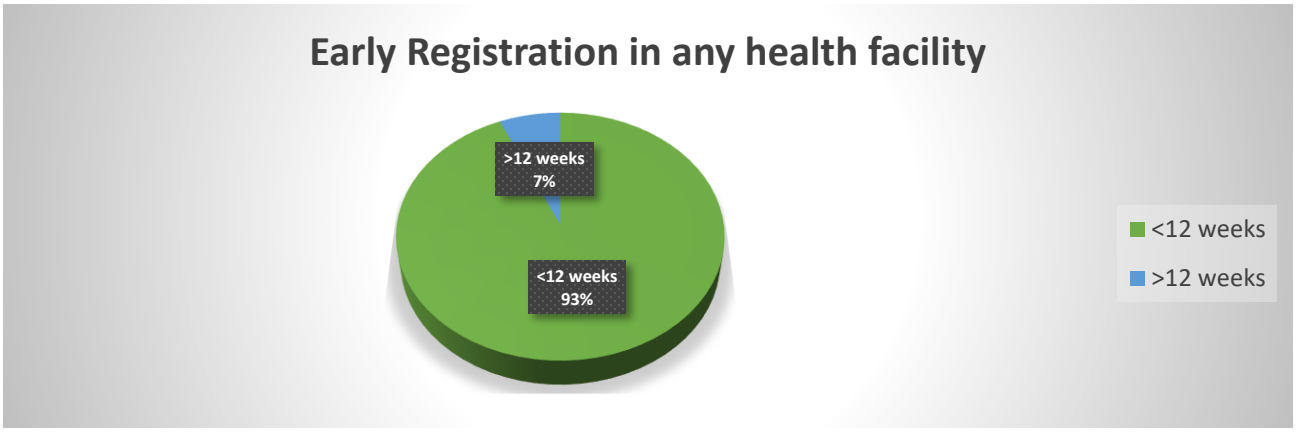
UHC & Jamnabai Hospital	5	4.7
Jamnabai Hospital	34	32.1
Private Hospital & Jamnabai Hospital	13	12.3
AWC, Private Hospital & Jamnabai Hospital	7	6.6
Total No. of ANC check-ups		
>4	101	95.3
<4	3	2.8
No check-ups at all	2	1.9
	106	

*Multiple response

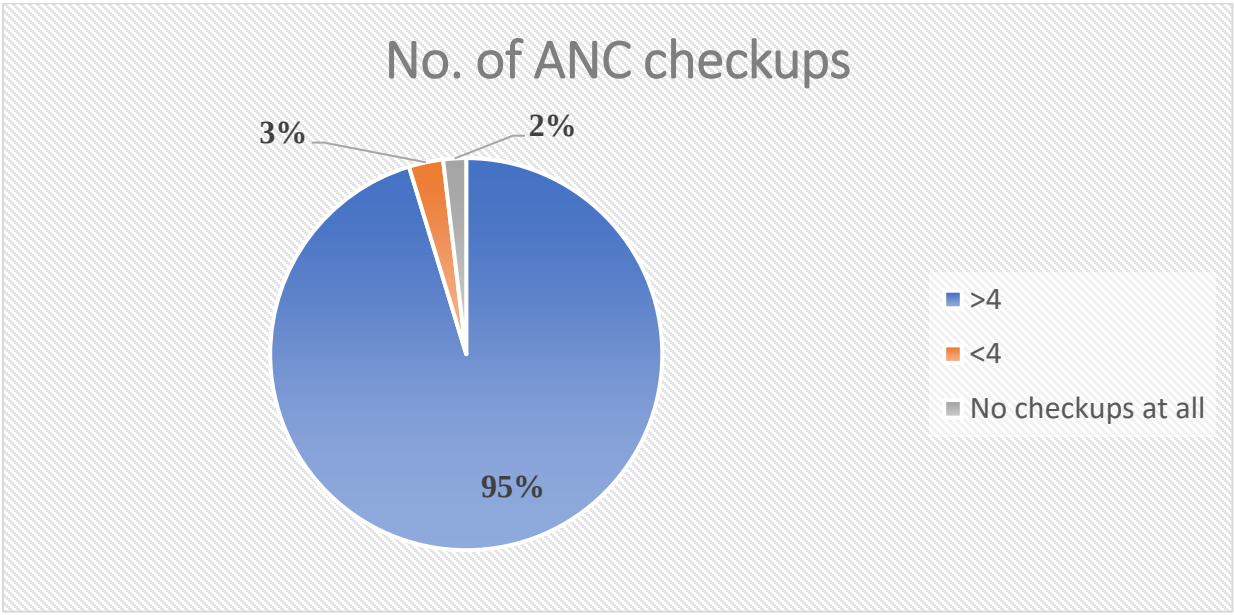
Parity of the enrolled mothers (n=106) is depicted in Fig-4.6



Early Registration of the mothers (n=106) is depicted in Fig-4.7



Number of ANC checkups of the mothers (n=106) is depicted in Fig-4.8



KNOWLEDGE ABOUT THE SELECTED INFANT AND YOUNG CHILD NUTRITION PRACTICES AND AWARENESS OF GALACTAGOGUES AMONGST WOMEN

Since women were in their last month of gestational period, their knowledge about selected IYCN Prolactin were elicited. It is discussed in Table-4.3, Fig-4.9 to Fig 4.17

As far as knowledge of IYCN is concerned, 98% women stated that only breast milk should be given immediately to the child immediately after birth. 58% women opined that the breastmilk should be initiated within 1 hr. of delivery followed by 35% who reported that the breastfeeding should be initiated the same day of delivery. 8% women didn't know about Early Initiation of Breastfeeding. 93% women were aware of colostrum but only 57% women were aware about benefits of colostrum. 43% women responded that colostrum provision is healthy for the baby. 36% women believed that prelacteals should be avoided but only 35% women knew about its benefits. Out of which 28% women believed that it is not healthy for the baby followed by 18% women who believed that it brings disease for the baby. Hardly 8% women stated that doctor suggested that prelacteals should be avoided.

Women who responded that the child should be exclusively breastfed for 6 months of age were 92% and same percent women believed that the complementary feeding should be initiated after 6 months of age. 50% women opined that if the child sleeps soundly then he/she is not hungry followed by 40% women who believed if the child doesn't cry frequently then he/she is satisfied with the meal followed by 30% who believe the child will leave the nipple when will get full. Only 1 % women knew that if child urinates more than 6 times a day, then it is getting full. Also, 96% women were aware of galactagogues.

PRACTICES OF SELECTED INFANT AND YOUNG CHILD NUTRITION PRACTICES AMONGST ENROLLED MOTHERS

Information regarding the practice of early initiation of breastfeeding, colostrum provision, prelacteal avoidance, frequency of breastfeeding was elicited and is presented in Table-4.4

As per table 4.4, it was reported that all the children here ever breastfed, Only, 28% women-initiated breast-feeding in the golden hour post-delivery. Majority 60% women mothers-initiated breastfeeding on the same day. 11% women still initiated the breastfeeding after 24hrs of delivery. Only 22% women gave solely breastmilk to the child after delivery. 57% women gave both breast milk and formula milk to child post-delivery followed by 19% women who gave only formula milk to child. This clearly depicts the stakes on exclusive breastfeeding amongst the children.

Women who gave colostrum to their children were 89% which is a positive indicator. Women avoided prelacteal provision to their children were 81% still 18% women gave prelacteal to the children of which when asked for reason 84% mothers believed that providing prelacteal is their cultural ritual. Majority of the women 54%, breastfed the child 3-4 times a day followed by 33% mothers who fed 5-6times a day. Only 8% women optimally fed children 6-12 times a day.

Table -4.3 Knowledge of about selected Infant and Young Child Nutrition (IYCN) practices and awareness of galactagogues.

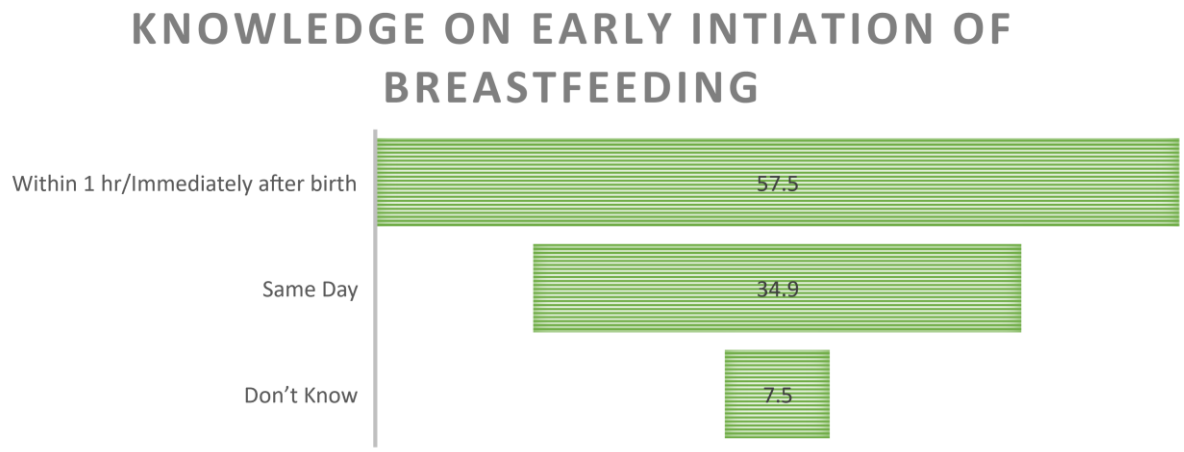
Particulars	**N**	**%**
Mother's knowledge on what to be immediately fed to the child after birth		
Only Breast Milk	104	98.1
Water	1	0.9
Animal/ Formula Milk	1	0.9
	106	
Mother's knowledge on Early Initiation of Breastfeeding (EIBF)		
Within 1 hr/Immediately after birth	61	57.5
Same Day	37	34.9
Don't Know	8	7.5
	106	
Awareness about colostrum		
Yes	99	93.4
No	5	4.7
Don't Know	2	1.9
	106	
Awareness of benefits of colostrum		
Yes	60	56.6
No	6	5.7
Don't Know	40	37.7
	106	
Benefits of colostrum		
Healthy for the baby	45	42.5
Doctor suggested	5	4.7
First Vaccine	5	4.7
Nutritious for the baby	6	5.7
Don't know	45	42.5
	106	

Awareness of prelacteals not to be given		
Yes	38	35.8
No	67	63.2
Don’t Know	1	0.9
	106	
Benefits of prelacteals avoidance		
Yes	37	34.9
No	38	35.8
Don’t Know	31	29.2
	106	
Reasons for prelacteals avoidance		
Not healthy for the baby	19	27.9
Doctor suggested	5	7.4
Bring disease to the baby	12	17.6
Cannot digest	1	1.5
Don’t know	31	45.6
	68	
Duration for Exclusive Breast Feeding (EBF)		
6 months	97	91.5
<6 months	9	8.5
	106	
Ways to know breastfeeding is enough or not*		
Child urinates more than 6 times in a day	1	0.9
Doesn’t cry frequently	43	39.8
Sleeps Soundly	53	50
Leaves the nipples by itself	32	30.2
Don’t know	24	22.6
Age of initiation for complementary feeding		
6 months	97	91.5

<6 months	9	8.5
	106	

*Multiple response

Knowledge on Early Initiation Breastfeeding (EIBF) of the mothers (n=106) is depicted in Fig-4.9



Knowledge on Awareness and Benefits Colostrum amongst the mothers (n=106) is depicted in Fig-4.10 and Fig-4.11

Fig-4.10

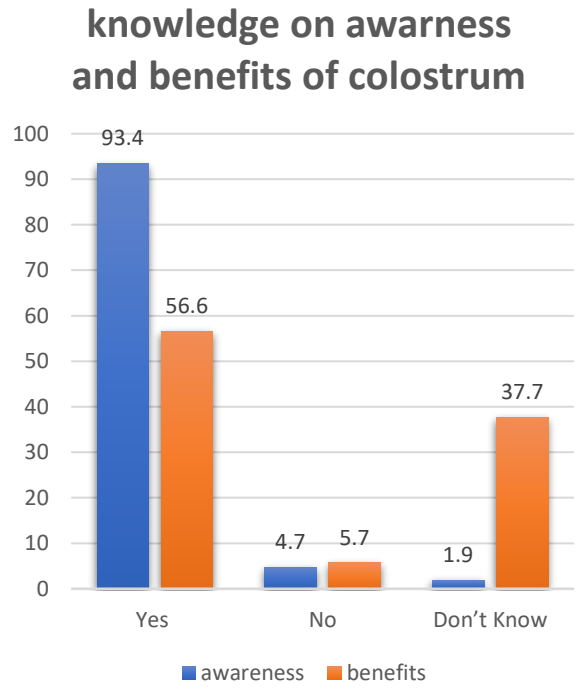
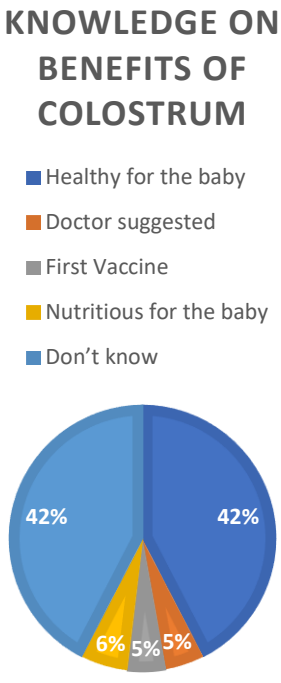
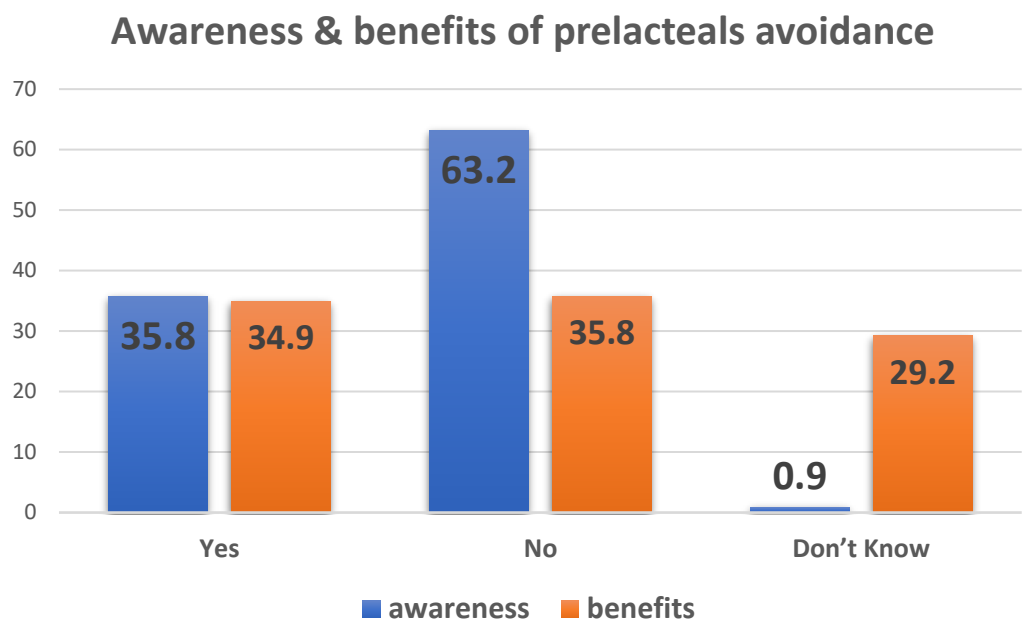
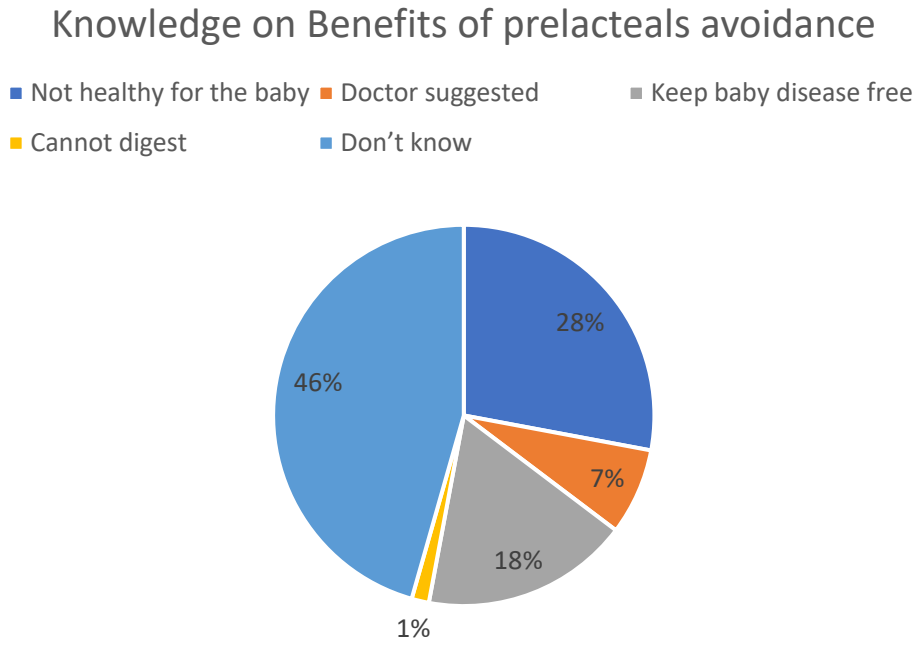


Fig- 4.11

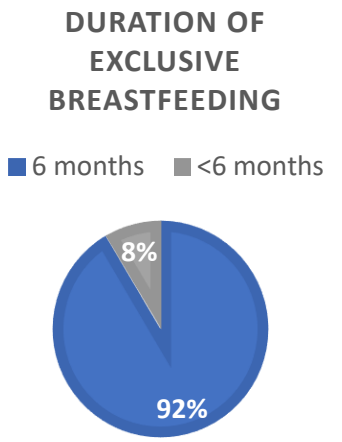


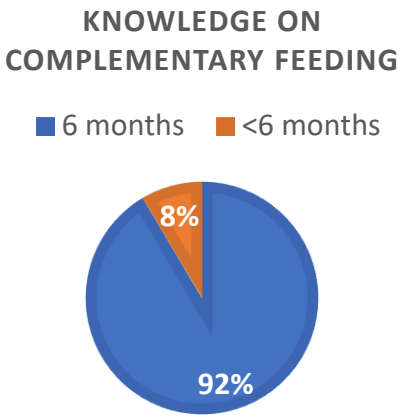
Knowledge on Awareness and Benefits of prelacteal avoidance amongst the mothers (n=106) is depicted in Fig-4.12 and Fig-4.13



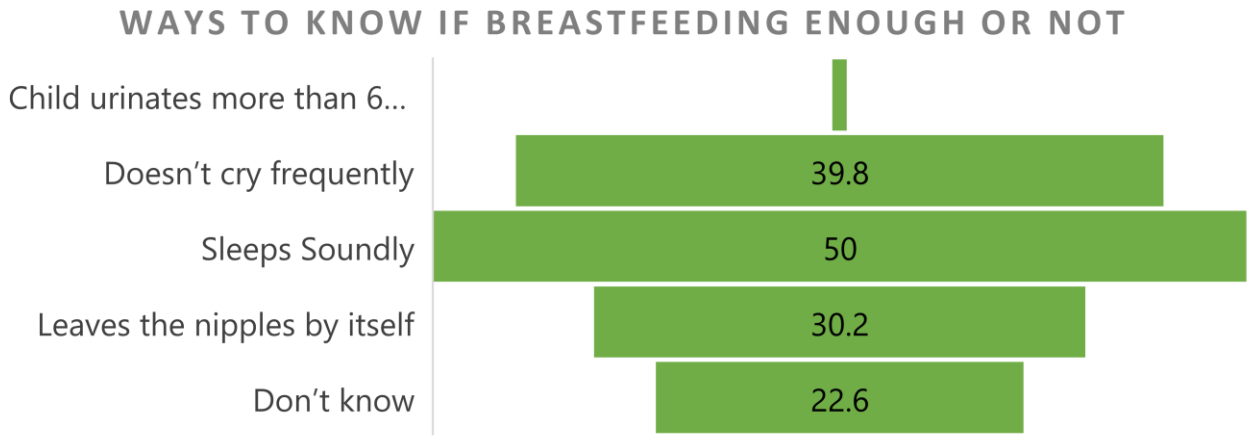


Knowledge on exclusive breastfeeding and complementary feeding amongst the mothers (n=106) is depicted in Fig-4.14 and Fig-4.15





Knowledge on post feed analysis amongst the mothers (n=106) is depicted in Fig-4.16



Awareness of Galactagogues amongst the mothers (n=106) is depicted in Fig-4.17

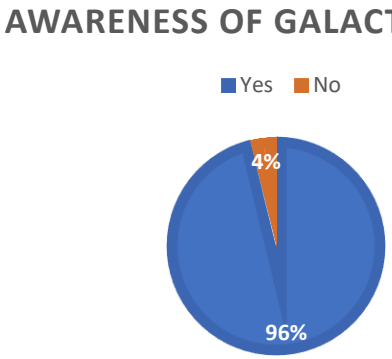


Table – 4.4 IYCN practices (n=106)

Particulars	**N**	**%**
Mothers who initiated breastfeeding		
Immediately within 1 hr	30	28.3
Same day	64	60.4
Next day	12	11.3
	106	
First feed provided to the child		
Only Breast Milk	23	21.7
Only Formula Milk	20	18.9
Both Breast Milk and Formula Milk	62	56.6
Both Breast Milk and Animal Milk	1	0.9
	106	
Provision of Colostrum		
Yes	94	88.7
No	12	11.3
	106	
Mothers who gave Prelacteals to the child		
Yes	19	17.9
No	86	81.1
	106	
Reasons for prelacteal provision given by the mothers		
Cultural belief	16	84.2
Help the child to suck if breast milk is not coming	2	10.5
To stop baby from crying	1	5.2
Total	**19**	
Frequency of breastfeeding in a day (including nights)		

	N	**%**
3-4 times	57	53.8
5-6 times	35	33
6-10 times	3	2.8
10-12 times	5	4.7
Just Delivered	3	2.8
	106	

KNOWLEDGE V/S PRACTICES OF IYCN PRACTICES AMONGST MOTHERS IS DEPICTED IN FIG- 4.18

It was interesting to compare Knowledge v/s Practice about selected IYCN aspects. It is presented in Fig- 4.18

From the Fig-4.18, it can be said that 57.5% enrolled women knew about early initiation of breastfeeding but only 28.3% actually practiced.

Women who were aware of colostrum feeding were 93.4% and 88.7% women actually practiced it; which depicts that the knowledge is more or less converted to practice.

Women who were aware about the avoidance of prelacteal were 35.8% but 81.1% women didn't give prelacteals which shows positive result in practice

HYGIENCE AND SANITATION PRACTICE FOR BREASTFEEDING AMONGST MOTHERS

Practices on Sanitization practices were also collected which is shown in Table-4.5

Looking at the reported values of table- 4.5, 76% mothers washed their hands before breastfeeding the child. Amongst which 96% women washed their hands with water. Hardly, 4% washed hands with soap. 53% women washed their breast before breastfeeding the child of which 54% washed with only water followed by 45% who just wiped their breast with wet cloth.

PREGNANCY OUTCOME

Information regarding type of deliveries mothers undergone, place of the delivery, type of births and birth order was collected and depicted in Table- 4.6 and Fig-4.19, Fig-4.20

As per the table 4.6 majority of the mothers i.e 67% underwent normal delivery and 33% had c-section deliveries. All the deliveries of the enrolled mothers were done in Jamnabai General

Hospital itself. 97% births were reported as live births but unfortunately 3% still births were also reported due to some medical complications. Majority 43% women gave birth to their first child followed by 42% women who had their second delivery. 13% and 2% women had their third and fourth child delivery respectively during the research.

Fig-4.18 depicts the Knowledge v/s Practices of selected IYCN amongst women

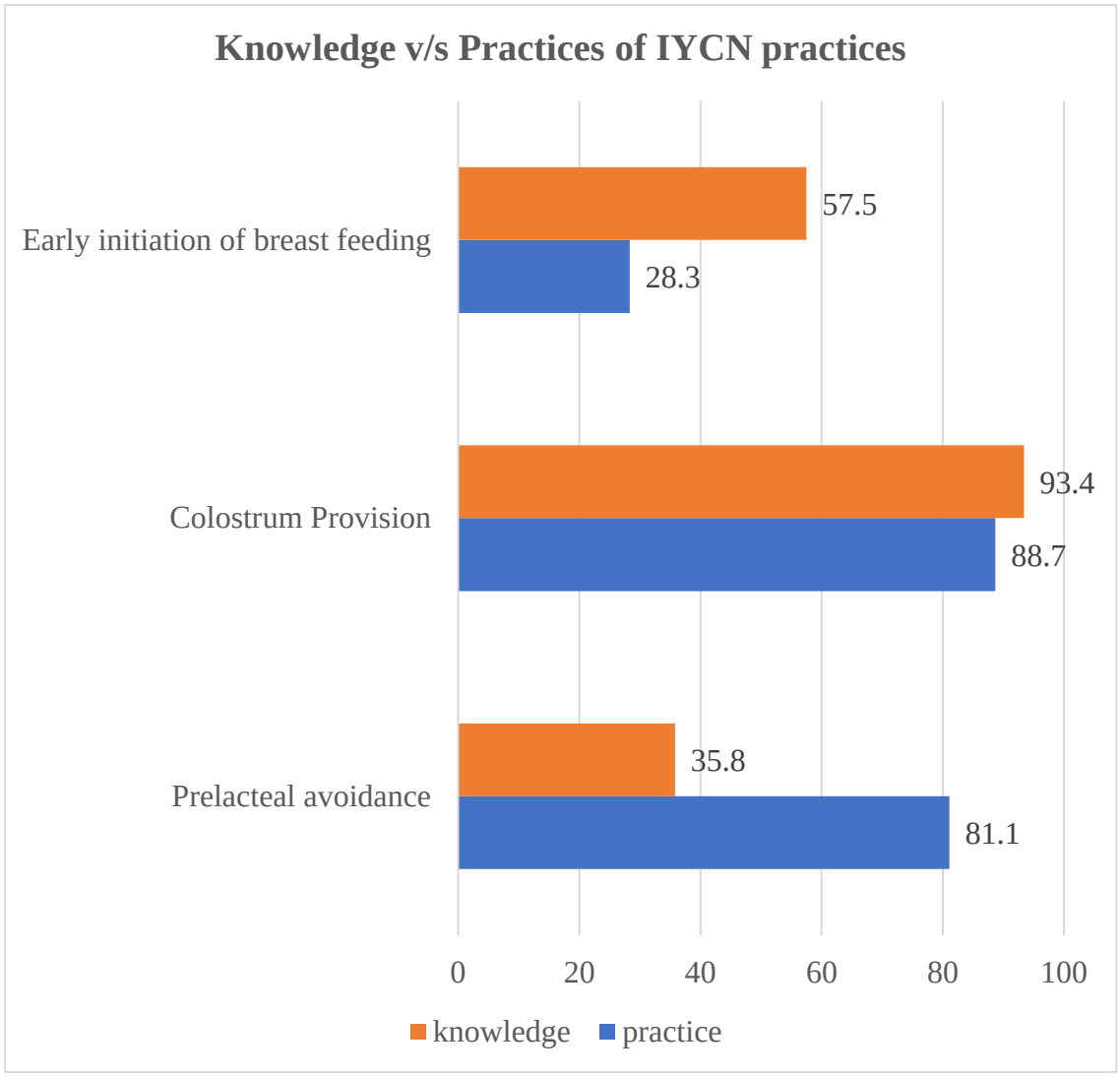


Table- 4.5 Hygiene and Sanitation Practice for breastfeeding

Particulars	**N**	**%**
Mothers who washed their hands before breastfeeding	80	75.5
Mothers who did not wash their hands before breastfeeding	26	24.5
	106	
Mothers who washed their Breast before breastfeeding	56	52.8
Mothers who did not wash their Breast before breastfeeding	50	47.2
	106	

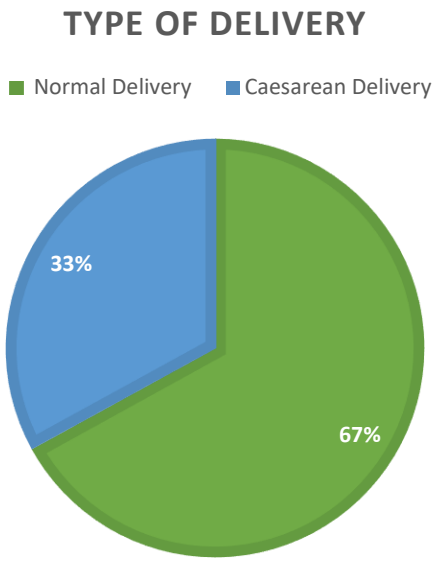
Particulars	**Mothers who washed their hands before breastfeeding**	
	With water	**With water and soap**
Number (n)	77	3
Percentage (%)	96.3	3.6
Total	**80**	

Particulars	**Mothers who washed their breasts before breastfeeding**		
	With water	**With water and soap**	**Wiped with wet cloth**
Number (n)	30	1	25
Percentage (%)	53.6	1.8	44.6
Total	**56**		

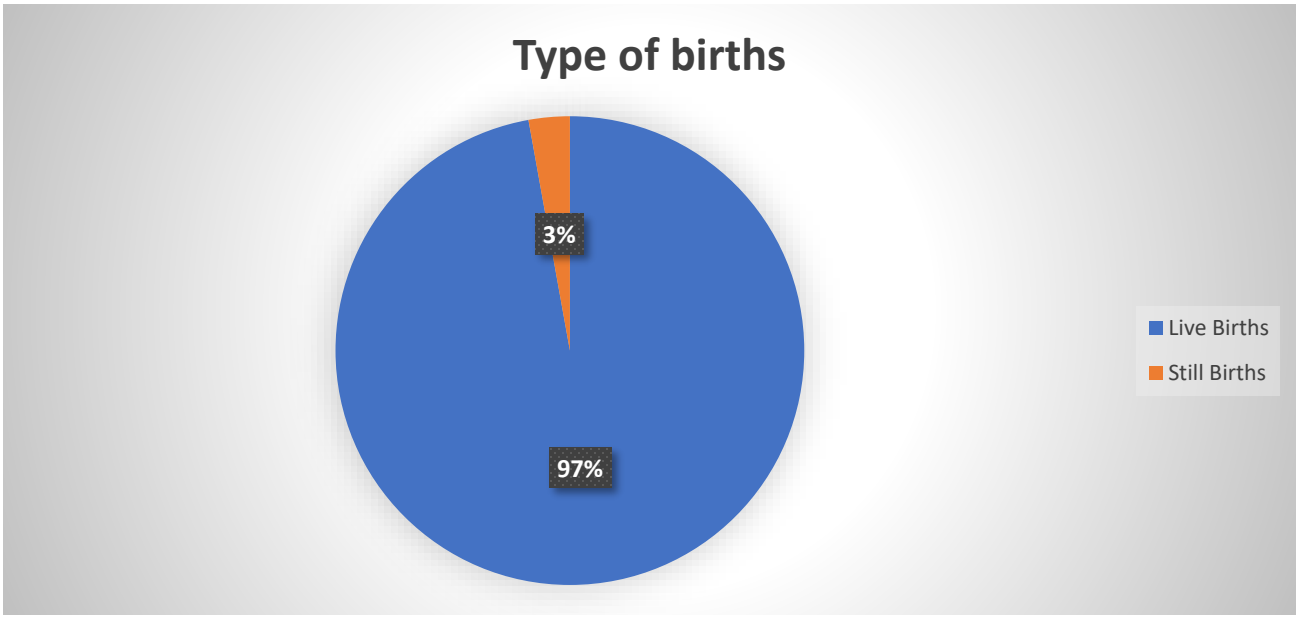
Table- 4.6 Pregnancy outcome of the enrolled mothers.

Particulars	**N**	**%**
Type of Delivery		
Normal Delivery	71	66.9
Caesarean Delivery	35	33
	106	
Place of Delivery		
Jamnabai Hospital	106	100
	106	
Type of birth		
Live Births	103	97.2
Still Births	3	2.8
	106	
Birth Order		
1	46	43.4
2	44	41.5
3	14	13.2
>3	2	1.9
	106	

Type of Deliveries of the mothers (n=106) is depicted in Fig-4.19



Type of Births of the babies of the enrolled mothers (n=106) is depicted in Fig-4.20



CONSUMPTION OF GALACTAGOGUES

Information on galactagogues was elicited to know their practises of consuming it in which is depicted in Table-4.7

As seen in table 4.7, 96% women were aware of any galactagogues, foods that increases milk secretion in lactating mothers when consumed.

Majority of the mothers (96%) knew Shepu seeds (Suva seeds) as galactagogues followed by 77.6% of mothers who knew Dry Ginger and 78.6% Edible Gum as galactagogues. 39% mothers knew fenugreek as galactagogues. Not a single mother was aware of Moringa as a galactagogue.

Data on Knowledge and Practice of galactagogue by enrolled mother is presented in 4.8 and Fig- 4.21

As per Table 4.8 and Fig- 4.21 depicts that all the women who were enrolled for the study, 44% and 56% women consumed any form of galactagogues like Suva Paani, Fenugreek, Sond, Gunder during pregnancy and lactation respectively.

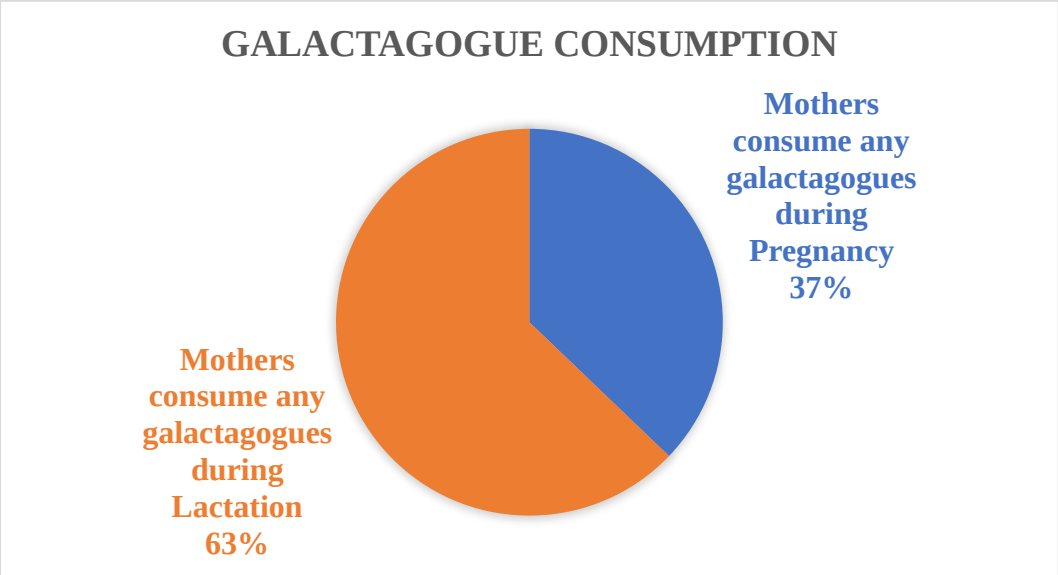
Table – 4.7 Awareness about Galactagogue as reported by mothers

	Fenugreek	Moringa	Sonth	Suva	Fennel seeds	Yakhni	Salan	Gunder	Coconut
N	40	0	80	99	7	5	14	81	19
%	38.8	0	77.6	96.1	6.8	4.8	13.6	78.6	18.4

Table-4.8 Consumption of Galactagogue

PARTICULARS		**N**	**%**
Mothers consume any galactagogues during Pregnancy	Yes	63	44
	No	43	40.6
		106	
Mothers consume any galactagogues during lactation	Yes	61	74.4
	No	21	25.6
		82	

Fig- 4.21 Consumption of Galactagogue



Highlights of the Findings

Background information

- 67.9% women were in the age range of 19-25 yrs.
- 46% women completed their secondary education.
- 56% of the women belonged to BPL category
- All the women enrolled were housewives

Antenatal History

- Women enrolled completed their 36-37 weeks of gestation.
- Primi mothers constitute 43% and Multipara mothers constitute 57% of the total enrolled mothers.
- 93% women registered themselves in within 12 weeks of gestation. 95% of the women did at least 4 antenatal check-ups

Knowledge and Practices of selected IYCN

- 57.5% enrolled women knew about early initiation of breastfeeding but only 28.3% actually practiced.
- 93.4% women were aware of colostrum provision and 88.7% women actually practiced
- Only, 35.8% women were aware about the avoidance of prelacteal but 81.1% women didn't give prelacteals which shows positive result in practice
- Only 21.7 % mothers gave solely breast milk to the child post-delivery.
- Very few (3 & 5%) mothers optimally fed the child for 6-12 times a day.

Highlights of the Findings

Awareness about Galactagogues

- 96% of the enrolled women were aware of galactagogues, foods that increases milk secretion in lactating mothers when consumed.
- Majority of the mothers (96%) knew shepu seeds (suva seeds) as galactagogues followed by 77.6% of mothers who knew dry ginger and 78.6% edible gum as galactagogues foods

Pregnancy Outcome

- All the deliveries of the enrolled mothers were done in a public hospital.
- 67% and 33% had normal and C-section deliveries respectively.
- All were full term babies with a ratio of 97% live births

PHASE 2 - Impact of moringa oleifera on maternal serum prolactin level and neonates weight gain pattern.

In Phase 2, data on dietary diversity, impact of Moringa Oleifera leaves powder on prolactin, hemoglobin and neonates weight gain pattern was collected.

MINIMUM DIETARY DIVERSITY OF WOMEN (MDD-W)

Data on dietary diversity of women was calculated based on FANTA USAID Minimum Dietary Diversity (MDD) for women (2016) and is presented in Table 4.9

Food group consumption of 82 mothers was done. As can be seen from table-4.9, food groups like grains, white roots and tubers and plaintains are consumed by all the mothers. Pulses (beans, peas and lentils), other vegetables, Dairy, Nut and seeds were consumed majorly. Meat, poultry and fish, eggs, and Dark green leafy vegetables were consumed by 20-30% of the women. Other Vitamin-A rich fruits and vegetable and other fruits were least consumed by the mothers.

As per Table-4.10, 38% of the mothers consumed 6 food groups followed by 26% mothers who consumed 5 food groups and 24% mothers who consumed 7 food groups. 9% mothers consumed less than 5 food groups.

Minimum Dietary Diversity (MDD) of lactating mothers is presented in Fig-4.22

As can be seen from Fig-4.22, 91%, consumed more than or equal to 5 food groups in their diets and 9% women consumed less than 5 food groups. 91% of mothers had minimum dietary diversity.

CONSUMPTION OF GALACTAGOGUES AND ITS FREQUENCY AMONGST THE ENROLLED MOTHERS FOR INTERVENTIONAL STUDY.

Since the present study is focusing on galactagogues and its impact on prolactin levels. It was thought worthwhile to understand practice and frequency of galactagogues consumption by enrolled mother. Data is presented in Fig- 4.23 and Table 4.11

Fig-4.23 depicts that all the mothers who were enrolled for interventional study, their galactagogue consumption was recorded. Out of which, 74.4% women consumed small

amount of galactagogues in any form. 47.5% experimental group mothers and 52.5% control group mothers consumed small amount of galactagogue in any form.

FOOD FRQUENCY OF GALACTAGOGUES OF LACTATING MOTHERS

As per table- 4.11, 24.4% enrolled mothers consumed fenugreek (seeds or bhaji) in any form. 69.5% mothers consumed edible gum (gunder) in any form. 65.8% mothers consumed suva in any form. 64.6% mothers consumed dry ginger (sonth), 20.7% consumed fennel seeds in any form. Only, 3.7% mothers consumed Moringa leaves bhaji. On the whole, moringa as a galactagogue was not prominently consumed by mothers.

CONSUMPTION OF CALORIE DENSE FOODS

From the table 4.12, 94% mothers did not consume calorie dense foods in pregnancy. Around 68% mothers consumed calorie dense foods in lactation. Out of which 55% women of experimental group and 47% women of control group consumed calorie dense foods in lactation

Table 4.9- Food groups consumed by mothers

Food Groups	N (n=82)	%
1. Grains, white roots and tubers and plaintains	82	100
2. Pulses (beans, peas and lentils)	67	81.7
3. Nuts and seeds	68	64.2
4. Dairy	69	65.1
5. Meat, poultry and fish	38	35.8
6. Eggs	24	22.6
7. Dark green leafy vegetables	36	33.9
8. Other vitamin-A rich fruits and vegetable	5	4.7
9.Other vegetables	71	66.9
10. Other fruits	21	19.8

Table 4.10 – No. of Food groups consumed by mothers

No. of Food groups consumed	N (n=82)	%
1	0	0
2	0	0
3	2	2.4
4	5	6.1
5	21	25.6
6	31	37.8
7	20	24.4
8	3	3.6
9	0	0
10	0	0

Fig- 4.22 Dietary Diversity of lactating mothers

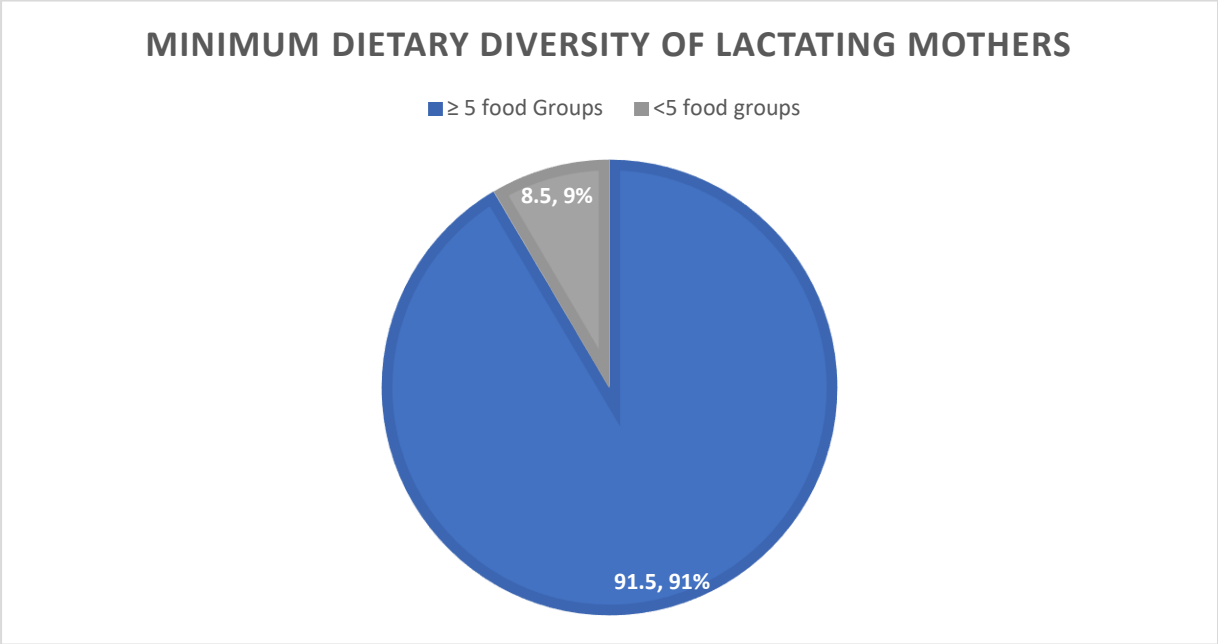


Fig-4.23 depicts the consumption of galactagogue during lactation

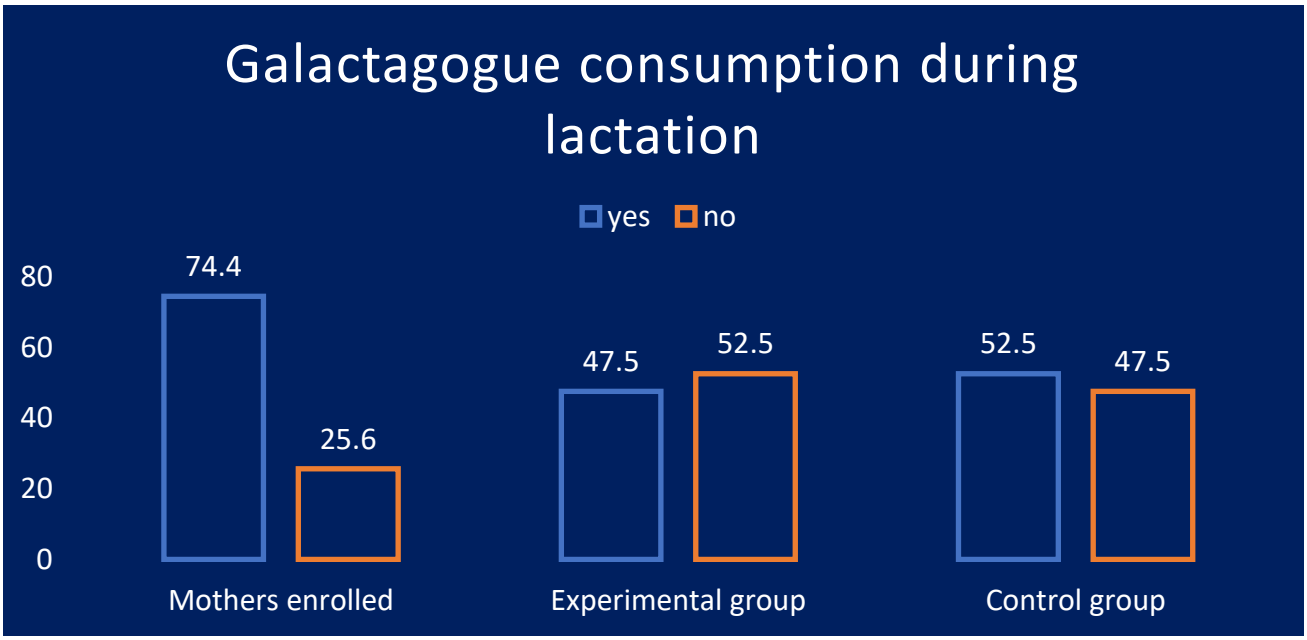


Table – 4.11 Food Frequency

Galactagogues (n=82)	Everyday		Twice a week		Once Weekly		Once in a month		Occasionally/ Rarely		Never		Seasonally	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Fenugreek (seeds or bhaji)	40	24.4	6	4	72	43.9	4	2.4	6	3.3	36	44	0	0
Gunder	57	69.5	0	0	0	0	0	0	14	17	11	13	0	0
Garlic	82	100	0	0	0	0	0	0	0	0	0	0	0	0
Suva (seeds or bhaji)	54	65.8	6	7	62	75.6	4	4.8	8	9.5	30	36	0	0
Ghee	82	100	0	0	0	0	0	0	0	0	0	0	0	0
Sonth	53	64.6	0	0	2	2.4	0	0	18	22	9	11	0	0
Moringa (leaves)	3	3.7	9	11	5	6	28	34	30	36.6	13	16	0	0
Fennel seeds	17	20.7	1	1	0	0	2	2.4	43	52.4	19	23	0	0
Satavari	0	0	0	0	0	0	0	0	5	6	77	94	0	0

Table – 4.12 Calorie dense foods consumption

PARTICULARS		**N**	**%**
Mothers who consume any calorie dense foods in pregnancy	Yes	6	5.7
	No	100	94.3
		106	
Mothers who consume any calorie dense foods in lactation	Yes	56	68.3
	No	26	31.7
		82	
Experimental group who consumed any calorie dense foods in lactation		31	55.4
Control group who consumed any calorie dense foods in lactation		25	44.6
		56	

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EFFECT OF MORINGA OLEIFERA LEAVES ON MATERNAL SERUM PROLACTIN (PRL) LEVLES AND WEIGHT GAIN PATTERN IN NEONATES

PERCENT RESPONSE RATE FOR THE INTERVENTION STUDY

Table- 4.13 depicts the percent response rate for the intervention. Total 106 women were enrolled which were then distributed into Experimental group (56 mothers) and control group (45 mothers) randomly. Out of the 56 experimental group mothers, 45 mothers constituting the response rate of 80.3 % and out of 50 control group mothers, 37 mothers constituting the response rate of 74% did complete compliance of the intervention respectively. Therefore, the cumulative response rate of both the groups is 77.4%.

HOMOGENEITY OF BOTH THE GROUPS PRE- INTERVENTION

Table 4.14 depicted that both experimental and control group were very much comparable in terms of Age, Parity and Baseline PRL levels of the mothers.

Table – 4.13 Percentage response rate for intervention of Moringa Oleifera leaf powder capsules & Placebo capsules

CATEGORY	No. OF ENROLLED LACTATING MOTHERS	No. OF MOTHERS WHO DID 100% COMPLAINCE	% RESPONSE RATE	% AVERAGE RESPONSE RATE
Experimental Group	56	45	80.3	77.4
Control Group	50	37	74	

Table – 4.14 Homogeneity of both the experimental group and control groups before intervention.

PARTICULARS		EXPERIMENTAL GROUP	CONTROL GROUP
AGE (in yrs.)		24 ± 3	24 ± 3
PARITY	Primipara	28	18
	Multipara	28	32
Baseline S. Prolactin (PRL) Levels		120.5 ± 42.17 ng/ml	126.7 ± 43.93 ng/ml

IMPACT OF M. OLEIFERA CAPSULES ON SERUM PROLACTIN (PRL) BASELINE & ENDLINE (POOLED DATA)

Table 4.15 depicts mean baseline and endline prolactin levels of pooled data. Mean Baseline PRL values is 123.1 ± 42.65ng/ml for which reference values are >200ng/ml and Mean Baseline PRL values 115.7 ± 32.90 ng/ml for which the reference values are >100ng/ml.

PROLACTIN LEVELS OF BOTH THE GROUPS AT BASELINE

The table 4.16 data on Baseline PRL of both experimental and control group separately. Mean Baseline PRL values of Experimental group (56) 120.5 ± 42.17 ng/ml and that of Control group is126.7 ± 43.93 ng/ml

Experimental group mothers of 50% and 54% of control group mothers were having PRL values of > 200ng/ml.

This depicts that Baseline PRL data of both experimental and control group was homogeneous by distributing enrolled mothers randomly in interventional and control group.

PROLACTIN LEVELS OF BOTH THE GROUPS AT ENDLINE

Table-4.17 depicts the impact of M. oleifera on Endline PRL levels.

Mean PRL levels of experimental group mothers (45) enrolled was 126.6 ± 28.66 ng/ml on Day 7 of post-partum to which values of control group was 101.9 ± 32.93 ng/ml. 82% of Experimental group mothers and 60% of control group mothers were having PRL values of 100ng/ml.

This depicts that Endline PRL data of experimental group was significantly more as compare to control group

Fig- 4.24 clearly depicts that post intervention, the PRL values of experimental group were significantly more than the control group.

Table- 4.15 Prolactin levels of the enrolled lactating mothers at 0 Day& 7 Day Post Partum (n=82) (Pooled Data)

Prolactin levels of the enrolled lactating mothers (ng/mL)	**Baseline (Day 0)**		**Recommended Value**	**Prolactin levels of the enrolled lactating mothers** (ng/mL)	**Endline (Day 7)**		**Recommended Value**
	N (n=106)	%	>200 ng/ml		N (n=82)	%	>100 ng/ml
Mean Value	123.1± 42.65 ng/mL			**Mean Value**	115.7 ± 32.90 Ng/mL		
>200	55	51.9		>100	59	73.75	
150-200	16	15.1		50-100	20	25	
<150	35	33		<50	3	3.75	
Total	**106**			**Total**	**82**		

Table- 4.16 Prolactin (PRL) levels of the lactating mothers at Baseline

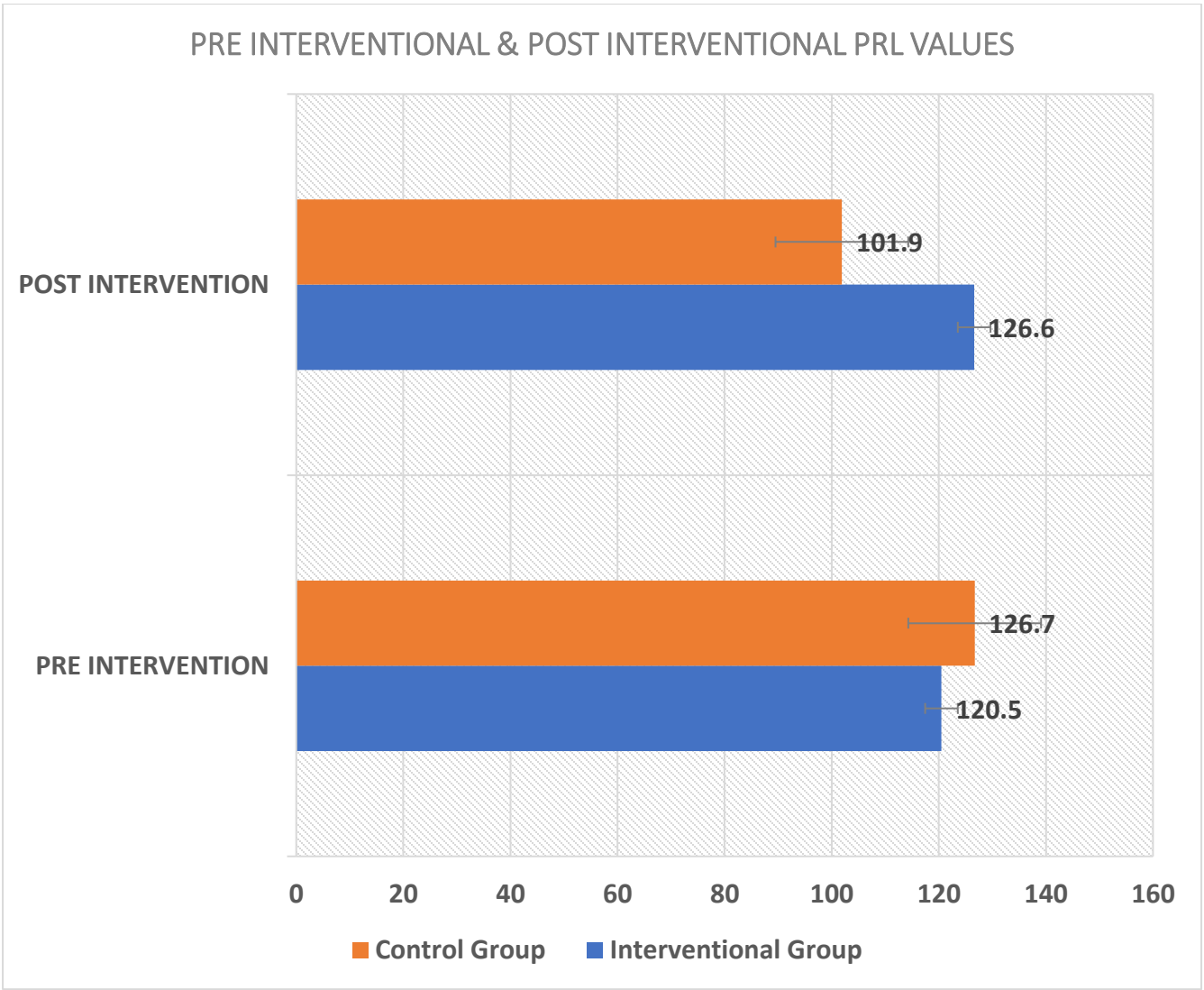
Experimental Group				**Control Group**			
Prolactin levels of the lactating mothers administered by Moringa Oleifera Capsules (ng/mL)	**Baseline (Day 0)**		**Recommended Value**	**Prolactin levels of the enrolled lactating mothers** (ng/mL)	**Baseline (Day 0)**		**Recommended Value**
	N (n=56)	%	>200 ng/mL		N (n=50)	%	>200 ng/mL
			Mean Value				**Mean Value**
			120.5 ± 42.17 ng/mL				126.7 ± 43.93 ng/mL
>200	28	50		>200	27	54	
150-200	7	12.5		150-200	8	16	
<150	21	37.5		<150	15	30	
Total	**56**			**Total**	**50**		

Table- 4.17 Prolactin levels of the lactating mothers at Endline

Experimental Group				**Control Group**				
Prolactin levels of the lactating mothers administered by Moringa Capsules (ng/mL)	**Endline (Day 7)**		**Recommended Value**	**Prolactin levels of the enrolled lactating mothers administered by Placebo Capsules** (ng/mL)	**Endline (Day 7)**		**Recommended Value**	**P-Value**
	N (n= 45)	%	>100 (ng/mL)		N (n= 37)	%	>100 (ng/mL)	**0.04***
			Mean Value				**Mean Value**	
			126.6 ± 28.66 (ng/mL)				101.9 ± 32.93 (ng/mL)	
>100	37	82.2		>100	22	59.5		
50-100	8	17.7		50-100	12	32.4		
<50	0	0		<50	3	8.1		
Total	**45**			**Total**	**37**			

*Significant. p-value <0.05

Fig-4.24 Endline and Baseline PRL values of both the groups



IMPACT OF MORINGA OLEIFERA ON WEIGHT GAIN PATTERN OF NEONATES

AVERAGE WEIGHT GAIN PATTERN OF NEONATES (POOLED DATA)

As per table- 4.18, average birth of respondent children was 2.853 ± 0.380 kg. Average weight after 7 days of respondent children was 2.907kg ± 0.407. Average weight after 15 days of respondent children was 3.256Kg ± 0.429. and lastly after a month the average weight of neonates was 3.691kg ± 0.414.

AVERAGE WEIGHT GAIN PATTERN OF NEONATES OF EXPERIMENTAL GROUP

As per table- 4.19, average birth of respondent children was 2.854 ± 0.389 kg. Average weight after 7 days of respondent children was 2.94 ± 0.393 kg. Average weight after 15 days of respondent children was 3.291 ± 0.434 kg and lastly after a month the average weight of neonates was 3.731 ± 0.431 kg. The average weight gain after a month was still less than the recommended average weight gain.

AVERAGE WEIGHT GAIN PATTERN OF NEONATES OF CONTROL GROUP

As per table- 4.20, average birth of respondent children was 2.851± 0.373 kg. Average weight after 7 days of respondent children was 2.864 ± 0.413kg. Average weight after 15 days of respondent children was 3.21 ± 0.424 kg and lastly after a month the average weight of neonates was 3.637 ± 0.390 kg. The average weight gain after a month was still less than the recommended average weight gain.

AVERAGE NEONATES WEIGHT GAIN

As per table 4.21 and Fig-4.25, average neonatal weight gain after day 7 of experimental group was 114g and that of control group was 25g. weight gain after 15 days of experimental group was 350g and that of control was 338. And lastly after a month the neonatal weight gain of experimental group 905g and that of control group was 786g. therefore, it can be concluded that average weight gain of neonates enrolled in experimental group was significantly more as that of control group.

Fig-4.25, shows the neonates weight gain trend through the one month of intervention in both group

Table- 4.18 Average neonates weight gain pattern (Pooled Data)

Average birth weight of the respondent children	**7 days**	**15 days**	**30 days**	**Recommended average weight gain per month**
	Average weight of the respondent children	**Average weight of the respondent children**	**Average weight of the respondent children**	
2.853 ± 0.380	2.907kg ± 0.407	3.256Kg ± 0.429	3.691kg ± 0.414	1100g

Table- 4.19 Average neonates weight pattern whose mothers are administered by Moringa Oleifera Capsules

Average birth weight of the respondent children whose mothers were administered by Moringa Oleifera Capsules (n=56)	**7 days**	**15 days**	**30 days**	**Recommended average weight gain per month**
	Average weight of the respondent children (n=45)	**Average weight of the respondent children**	**Average weight of the respondent children**	
2.854 ± 0.389	2.94 ± 0.393	3.291 ± 0.434	3.731 ± 0.431	1100g

Table- 4.20 Average neonates weight pattern whose mothers are administered by Placebo Capsules

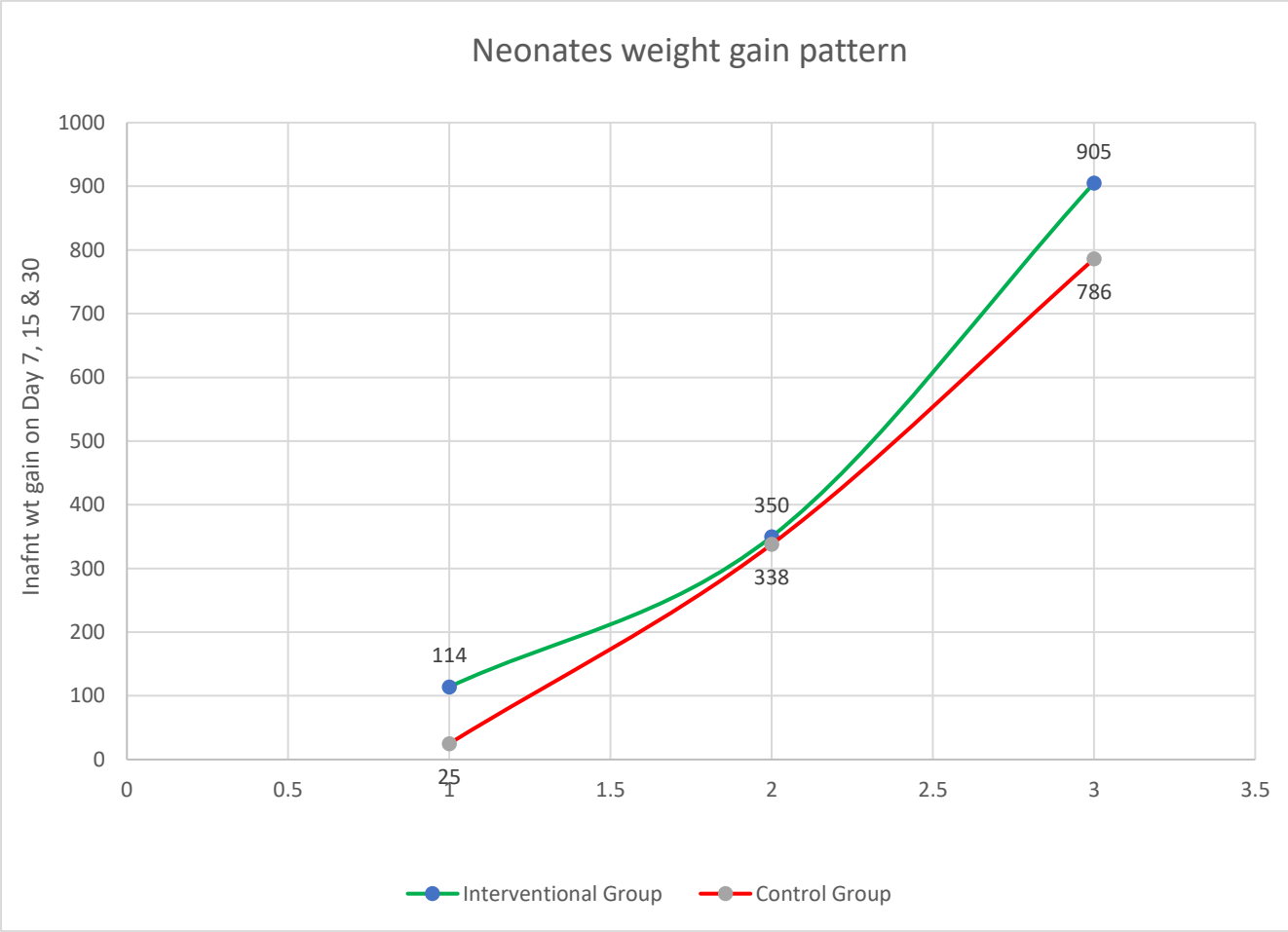
Average birth weight of the respondent children whose mothers were administered by Placebo Capsules (n=50)	**7 days**	**15 days**	**30 days**	**Recommended average weighet gain per month**
	Average weight of the respondent children (n=37)	**Average weight of the respondent children**	**Average weight of the respondent children**	
2.851± 0.373	2.864 ± 0.413	3.21 ± 0.424	3.637 ± 0.390	1100g

Table- 4.21 Average neonates weight Gain Pattern

Particulars	**Infants whose mothers administered with**		**P-Value**		
Average Weight gain of Infants (in g)	**Moringa Oleifera Capsules (n=45)**	**Placebo Capsules (n=37)**		**Recommended average weight gain per week**	**Recommended average weight gain per month**
On day 7	**114**	**25**	**0.01***	266g	1100g
On day 15	**350**	**338**	**0.00001***		
On day 30	**905**	**786**	**0.00003***		

*Significant. p-value <0.05

Fig-4.25 Neonates Weight Gain Trend during one month of intervention in both the groups



DETERMINANTS FOR SERUM MATERNAL PROLACTIN LEVELS

As per Table-4.22, it can be seen that factors like consumption of galactagogue, Type of delivery, Parity, Early Initiation of Breastfeeding and Frequency of Breastfeeding didn't enter the equation for multiple Regression test.

DETERMINANTS FACTORS AFFECTING NEONATES WEIGHT GAIN PATTERN AFTER ONE MONTH

As per Table-4.23, it can be seen that factors like Birth weight, Type of delivery, Parity, Early Initiation of Breastfeeding and Frequency of Breastfeeding are likely to affect neonates weight gain pattern didn't enter the equation for multiple Regression test.

Table- 4.22 represents determinants affecting serum prolactin levels.

Coefficients								
Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95.0% Confidence Interval for B	
		B	Std. Error	Beta			Lower Bound	Upper Bound
1	(Constant)	136.058	31.493		4.320	<.001	72.358	199.758
	Consumption of any Galactagogue	1.046	10.552	.016	.099	.922	-20.297	22.389
	Type of delivery	34.400	18.510	.308	1.858	.071	-3.040	71.840
	Parity	-.435	8.076	-.009	-.054	.957	-16.770	15.901
	EIBF	-16.149	8.988	-.295	-1.797	.080	-34.329	2.031
	Frequency of breastfeeding	-4.246	5.306	-.130	-.800	.428	-14.978	6.487
a. Dependent Variable: Endline PRL								

Table- 4.23 represents determinants affecting neonates weight gain

Coefficients								
Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95.0% Confidence Interval for B	
		B	Std. Error	Beta			Lower Bound	Upper Bound
1	(Constant)	1.264	1.966		.643	.524	-2.717	5.244
	Type of delivery	.100	.770	.022	.130	.897	-1.458	1.658
	Parity	.347	.308	.172	1.126	.267	-.277	.971
	EIBF	.486	.377	.219	1.289	.205	-.277	1.248
	Frequency of breastfeeding	.035	.210	.027	.167	.868	-.391	.461
	Endline PRL	-.008	.006	-.192	-1.199	.238	-.021	.005
	Birth weight	.448	.434	.159	1.033	.308	-.430	1.327
a. Dependent Variable: weight gain after a month								

PROLACTIN HORMONE & NEONATES WEIGHT BEFORE AND AFTER INTERVENTION IN THE INTERVENTION AND CONTROL GROUP

The mean PRL Values of both the interventional and control group pre and post intervention is highlighted in this table 4.24. along with that mean weight on neonates at Day 0, 7,15 and 30 post-partum is also shown. The maximum and minimum ranges of the constitute parameters are also depicted.

Table- 4.25, summaries the findings of the whole study (Phase 2). It shows the impact of Moringa Oleifera powder Capsules on Prolactin and weight gain. PRL values showed significant difference in experimental and control group.

Weight gain of neonates also showed significant gain in experimental and control group

Table- 4.24 Prolactin hormone & neonates weight before and after intervention in the intervention and control group

Variable	N	Mean	SD	Min	Max
Prolactin Level					
Interventional (pre)	56	120.5	± 42.17	49.41	>200
Control (pre)	50	126.7	± 43.93	32.74	>200
Interventional (post)	45	126.6	± 28.66	71.5	>200
Control (post)	37	101.9	± 32.93	25.34	>200
Weight Pattern in kg					
Weight (Day 0)	106	2.853	± 0.380	2.499	4
Intervention	56	2.854	± 0.389	2.499	4
Control	50	2.851	± 0.373	2.5	3.55
Weight (Day 7)	106	2.907	± 0.407	2.05	3.81
Intervention	45	2.94	± 0.393	2.13	3.81
Control	37	2.864	± 0.413	2.05	3.66
Weight (Day 15)	106	3.256	± 0.429	2.27	4.13
Intervention	45	3.291	± 0.434	2.27	4.13
Control	37	3.210	± 0.424	2.54	3.99
Weight (Day 30)	106	3.691	± 0.414	2.56	4.64
Intervention	45	3.731	± 0.431	2.56	4.64
Control	37	3.637	± 0.390	2.99	4.32

Table- 4.25 Effect of Moringa on changes in Prolactin hormone & Infant weight gain before and after intervention in the intervention and control group

Variable	**N**	**Mean PRL values (ng/ml)**	**SD**	**p-value**
Prolactin				
Interventional group	56	120.5	± 42.17	0.04*
	45	126.7	± 43.93	
Weight Pattern (in g)				
Weight (Day 7)				
Intervention	45	114	± 0.24	0.01*
Control	37	25	± 0.23	
Weight (Day 15)				
Intervention	45	350	± 0.233	0.00001*
Control	37	338	± 0.311	
Weight (Day 30)				
Intervention	45	905	± 0.338	0.00003*
Control	37	786	± 0.311	

*Significant. p-value <0.05

IMPACT OF M. OLEIFERA ON PREVALENCE OF ANEMIA AMONGST ENROLLED MOTHERS.

IMPACT OF M. OLEIFERA ON PREVALENCE OF ANEMIA OF POOLED DATA.

As per table 4.26, mean baseline hemoglobin levels of the mothers were 10.6g/dL and that of endline is 11.8g/dL. In baseline, 41% mothers were in normal category which in endline got increased to 72%. 1% women were severely anemic in baseline which got nullified in endline.

IMPACT OF M. OLEIFERA ON PREVALENCE OF ANEMIA OF EXPERIMENTAL GROUP.

As per table 4.27, mean baseline hemoglobin levels of the mothers was 10.9g/dL and that of endline is 12.3g/dL. In baseline, 28% mothers were in normal category which in endline got increased to 85%. The percentage increase was 34% in experimental group.1% women were severely anemic in baseline which got nullified in endline.

IMPACT OF M. OLEIFERA ON PREVALENCE OF ANEMIA OF CONTROL GROUP.

As per table 4.28, mean baseline hemoglobin levels of the mothers were 10.3g/dL and that of endline is 11.1g/dL. In baseline, 32% mothers were in normal category which in endline got increased to 57%. The percent increase was 25% in control group.

Thus, we can conclude that the percent increase in endline hemoglobin levels was significantly more in experimental group as that of control group.

REDUCTION IN PREVALENCE OF ANEMIA AMONGST TH MOTHERS

Table-2.9, depicts that pre-intervention there were 50% mothers of experimental group and 32% mothers of control group in normal category which got increased to 84.4% and 56.7% in experimental and control group respectively after intervention.

There was 32% reduction of Prevalence of anemia in experimental group as compare to 25% reduction in control group significantly. This depicts that moringa was impactful.

Table- 4.26 Prevalence of Anemia in enrolled lactating mothers at baseline and endline (Pooled Data)

Mothers with Haemoglobin levels	**Baseline**		**Mean (n=106) 10.6**	**Endline**		**Mean (n=106) 11.8**
	N (n=106)	**%**		**N (n=82)**	**%**	
Normal (Greater than 11 g/dL)	44	41.5		59	71.9	
Mildly anemic (10-10.9 g/dL)	30	28.3	**SD (n=106) ±1.4**	13	15.8	**SD (n=106) ±1.6**
Moderately anemic (7-9.9 g/dL)	31	29.24		10	12.1	
Severely anemic (<7 g/dL)	1	0.9		0		

Table- 4.27 Prevalence of Anemia in lactating mothers administered by Moringa Oleifera Capsules at baseline and Endline

Mothers administered with Moringa Oleifera Haemoglobin levels	**Baseline**		**Mean (n=56) 10.9**	**Endline**			**Mean (n=45) 12.3**	**P -value**
	N (n=56)	**%**		**N (n=45)**	**%**	**% increase**		
Normal (Greater than 11 g/dL)	28	50		38	84.4	34.4		**0.00001***
Mildly anemic (10-10.9 g/dL)	15	26.7	**SD (n=56) ±1.4**	5	11.1	-15.6	**SD (n=45) ±1.5**	
Moderately anemic (7-9.9 g/dL)	12	21.4		2	4.4	-17		
Severely anemic (<7 g/dL)	1	1.7			0	0		

*Significant. p-value <0.05

Table- 4.28 Prevalence of Anemia in lactating mothers administered by Placebo Capsules at Baseline and Endline

Mothers administered with Placebo Haemoglobin levels	**Baseline**		**Mean (n=50) 10.3**	**Endline**		**% increase**	**Mean (n=37) 11.1**	**P value**
	N (n=50)	**%**		**N (n=37)**	**%**			
Normal (Greater than 11 g/dL)	16	32		21	56.7	24.7		**0.005***
Mildly anemic (10-10.9 g/dL)	15	30	**SD (n=50) ±1.5**	8	21.6	-8.4	**SD (n=37) ±1.6**	
Moderately anemic (7-9.9 g/dL)	19	38		8	21.6	-16.4		
Severely anemic (<7 g/dL)	0			0	0	0		

*Significant. p-value <0.05

Table- 4.29 Reduction in Prevalence of Anemia

REDUCTION IN PREVELANCE OF ANEMIA	**% OF EXPERIMENTAL GROUP MOTHERS**	**% OF CONTROL GROUP MOTHERS**
Pre-intervention	50	32
Post-intervention	84.4	56.7
% Reduction	34.4	24.7 p-value= 0.0005*

*Significant. p-value <0.05

Highlights of the Findings

Minimum dietary diversity

- 91 % of women had MDD

Consumption of Galactagogues

- All the women who were enrolled for the study, 44% and 56% women consumed any form of galactagogues like Suva Paani, Fenugreek, Sond, Gunder during pregnancy and lactation respectively.
- 74.4% women consumed small amount of galactagogues in any form occasionally. 47.5% experimental group mothers and 52.5% control group mothers consumed small amount of galactagogue in any form occasionally.
- Only, 3.7% mothers consumed Moringa leaves bhaji. On the whole, moringa as a galactagogue was not prominently consumed by moth

Impact of Moringa Oleifera on Serum Prolactin Levels

- Mean Baseline PRL values of Experimental group (56) 120.5 ± 42.17 ng/ml and that of Control group (50) is126.7 ± 43.93 ng/ml at 0 day postpartum
- A significant difference was found in mean Endline PRL levels of experimental group mothers (45) - 126.6 ± 28.66 ng/ml on Day 7 of post-partum versus of control group (37) - 101.9 ± 32.93 ng/ml

Highlights of the Findings

Impact of Moringa Oleifera on Neonates Weight Gain Pattern

- Average weight gain of neonates of experimental group and control group was 114g and 25g respectively on Day 7.
- On day 15, average weight gain of infants of experimental and control group was 350g and 338g respectively.
- After a month the average weight gain of infants of experimental and control group was 905g and 786g respectively which was found to be significant

Impact of Moringa Oleifera on Anemia

- 50% mothers of Experimental Group were under normal category which got significantly increased to 84.4% after one month compliance of M. Oleifera capsules
- 32% mothers of Control Group were under normal category which got increased to 56.7% one month after delivery

DISCUSSIONS

The key findings of present study are discussed below.

Phase 1- To assess the knowledge and practice of selected IYCN practices

As per our study, 93% women did early registration and 95% women did at least 4 antenatal checkups. My Co researcher Ms. Palak Nilesh Bhagat in the current study period, also reported data from urban mothers. She reported that 100% had early registration and 100 % had 8 number of ANC checkups. As per NFHS 5 data factsheet for Gujarat it was reported to be 83.7% women did early registration and 82.4% women did at least 4 antenatal checkups which is depicted in Fig-4.26

Current study also compared the Knowledge v/s Practices of selected IYCN amongst enrolled women.

Early Initiation of Breastfeeding, was found to be by 28.3% of mothers. 60.4% of mothers initiated Breastfeeding the same day. Prelacteal Avoidance was in 81.1 % and Colostrum feeding was by 88.7% mothers.

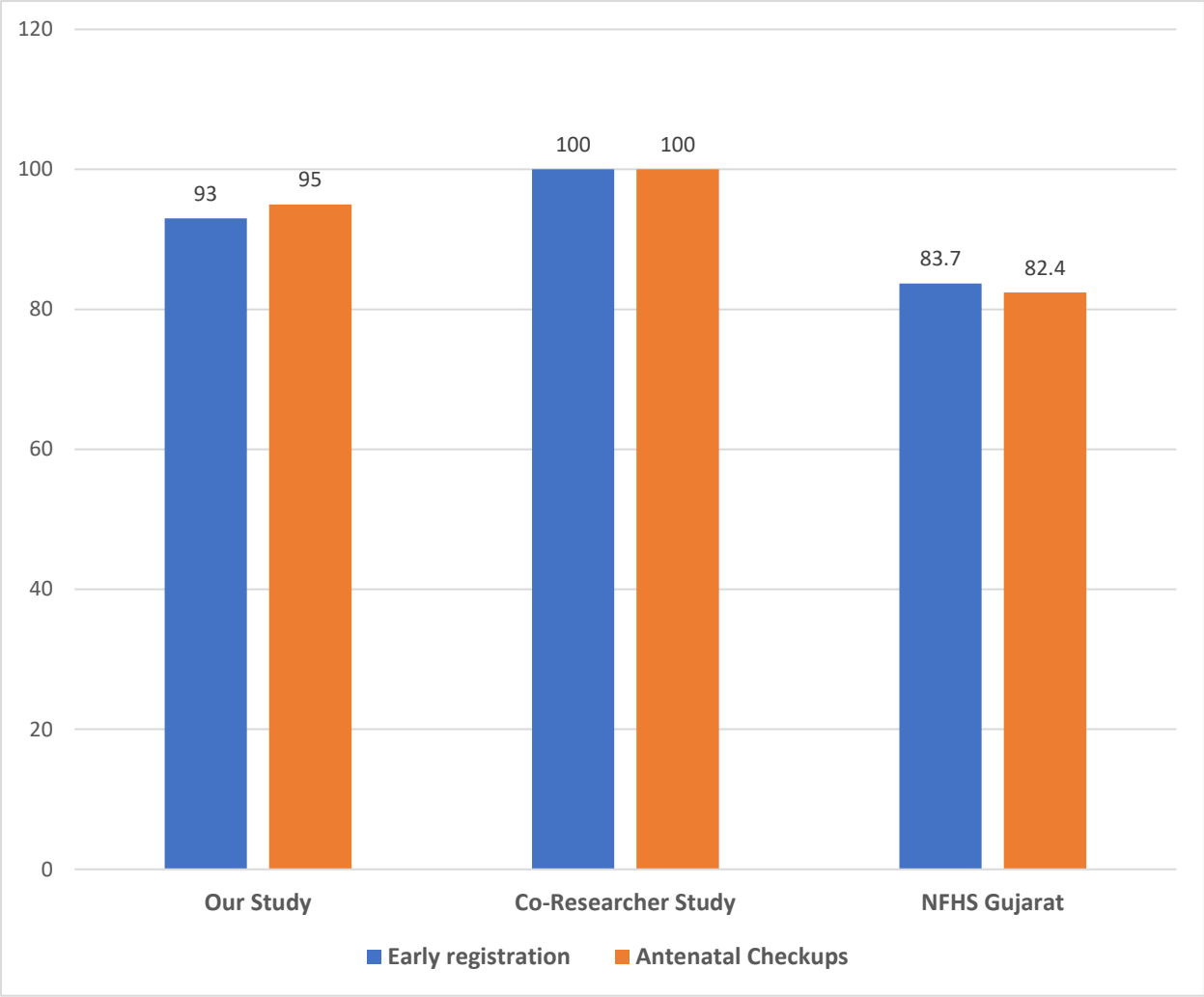
As per NFHS-5 Data, Prevalence of Early initiation of Breastfeeding in India, Gujarat and Vadodara is 42%, 38%, 45% respectively where as our study reported 28% (n=106).

As per UNICEF (2022) Data, Prevalence of Early initiation of Breastfeeding in South Asia is 39% of which in our study is 28% (n=106).

Muluken Amare Wudu, 2022, Ethiopia, conducted a study which concluded the prelacteal feeding, delayed initiation of breastfeeding, and colostrum avoidance was 21.9%, 35.5% and 15.5% respectively.

Comparing that with our study, Prevalence of delayed initiation of breastfeeding is 71.7%, colostrum avoidance is 11.3 % and that of prelacteal feeding is 18.9%. therefore, it can be concluded that more mothers of our study group practiced prelacteal avoidance and colostrum provision but prevalence of early initiation of breastfeeding is still not better.

Fig-4.26 Comparison of Data on Early Registration and Antenatal Checkups



Adhisivam et.al, (2016) stated the Prevalence of early initiation of breastfeeding was 28% and colostrum provision was 89%

Findings are almost similar to our study but the prevalence of EIBF of our study is half as compared to this study.

Suzon Ahmed et.al (2023) conducted a study in Bangladesh for which results depicted the prevalence of EIBF as 46.3%. Mothers who did kangaroo mother care, provided colostrum and initiated breastfeeding within 1 hr. of delivery.

Suresh Jungari et.al. (2020), stated early initiation, pre lacteal feeding, exclusive breastfeeding to be 45.2%, 37.5%, 23.7% respectively.

The main focus of the current study was to assess the effect of Moringa Oleifera leaf powder capsules on Prolactin level & t weight gain pattern of neonates after one month compliance of the capsules. In our study all healthy women without medical complications were enrolled.

Phase 2 – Impact of Moringa Oleifera on Maternal Serum Prolactin levels and weight gain pattern of neonates.

A significant impact on mean endline PRL is seen in interventional group as compare to control group post intervention is depicted in Fig-4.27

Also, a significant impact on neonates' weight gain at 7-, 15- and 30-days post-partum was observed in both interventional and control group and is depicted in Fig-4.28

Yabes and Lim, (1996) conducted a Pooled community study of 2 communities in Philippines. After administration of moringa oleifera leaves extract the prolactin levels rose after 48 hours and 4 months along with a significant improvement in the infants' weight gain.

In our study a significant rise in prolactin levels after 7 days were observed with a significant increase on neonates' weight gain weekly till 1 month.

Yabes and Lim, (1996) conducted an interventional study in Philippines on hypertensive women. After the administration of Moringa Oleifera, significantly higher prolactin levels were obtained after 4 months with the experiment group at accompanied by observed gains in weights among these babies.

Kiranawati, T. M., & Nurjanah, (2017) conducted a Quasi experimental Study in Indonesia on pregnant mothers. After the administration of Moringa Oleifera, a significant increase in prolactin levels and sleep duration was observed but no significant effect was observed in infant's weight in experimental group.

King J.S. et al, (2013) did meta-analysis of 5 randomized control trial study in Philippines. Breast milk volume showed statistically significant increase following treatment with moringa oleifera capsules on different days of administration. Two RCTs reported increase in infant weight gain as an outcome of moringa oleifera administration. No adverse event was reported in any of the outcome.

Fig-4.27 Endline and Baseline PRL values of both the groups

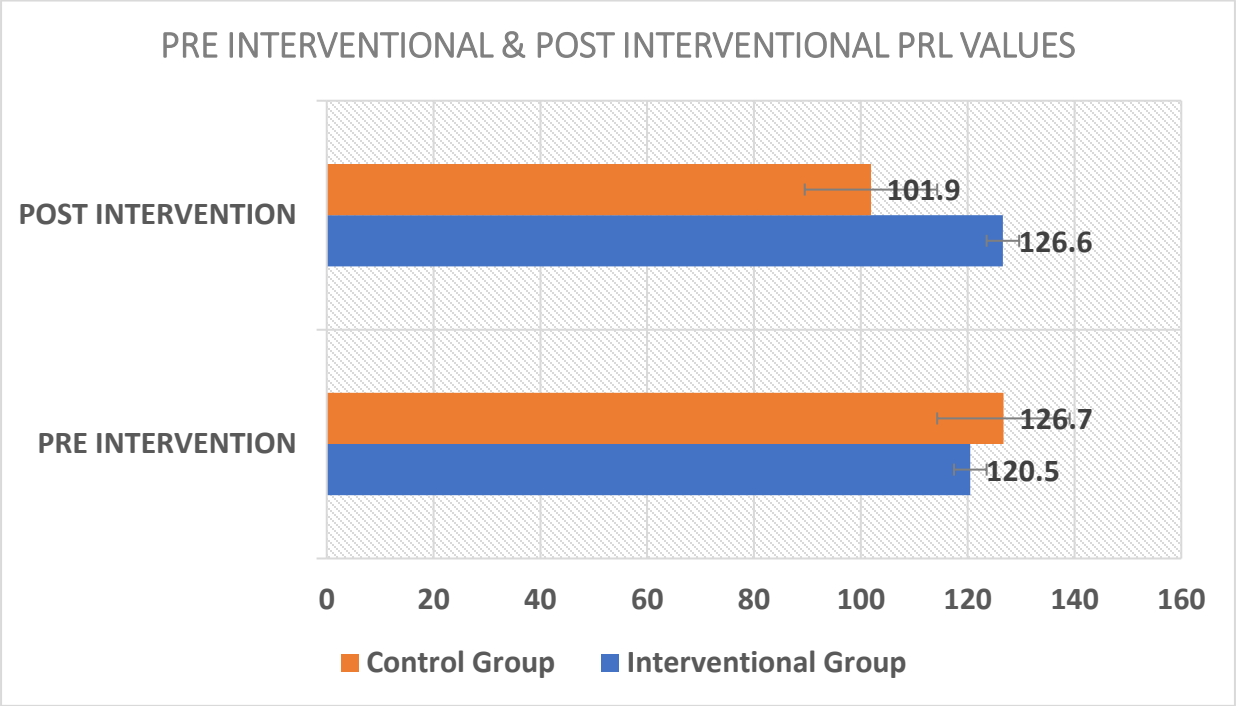
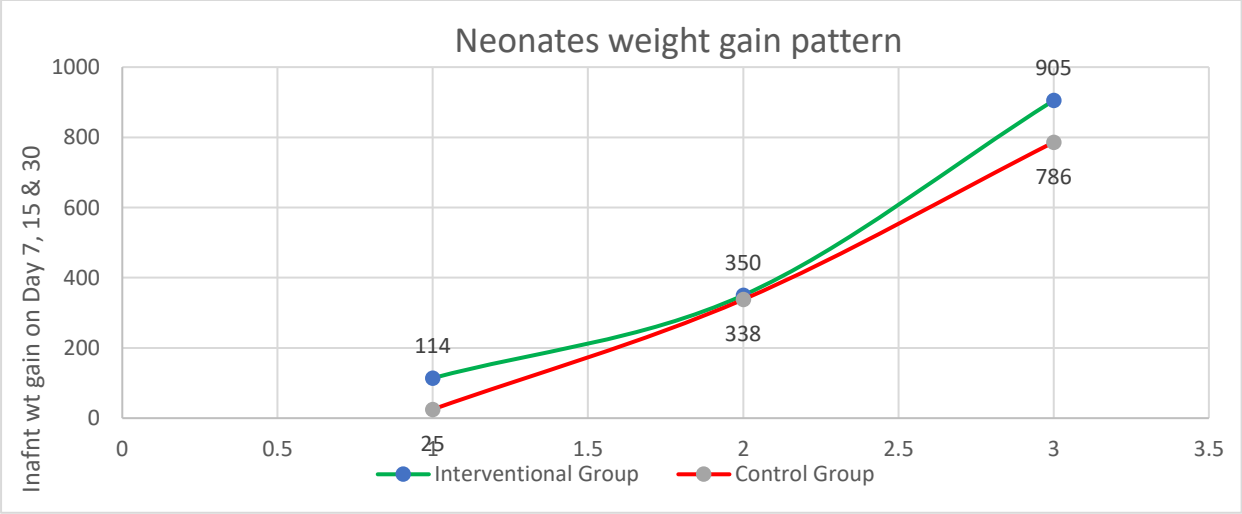


Fig-4.28 Weight Gain pattern in Neonates during one month of intervention in both the groups



Titi Mutiara Kiranawati*, Nunung Nurjanah, (2014) undertaken an animal study in Indonesia on Wister rats. It was a randomized block design study to observe the effect of moringa leaves as galactagogue. Weight gain of 0.25-0.37g/dietary noodles was observed in infants breastfed of female rats given moringa. Moringa had positive effect on the breastmilk secretion.

Fungtammasan S, Phupong V, (2021) undertaken a randomized, double-blinded, placebo controlled-trial in Thailand, performed on 88 on pregnant women having more than 37 weeks of gestation with a dosage of 450mg Moringa oleifera capsules within 6 hours of delivery. Infant weight gain was recorded after 48hrs. There was a significant weight gain and significant increase in milk volume was observed on 3th day post-delivery.

In our study, 82 full term lactating mothers were enrolled within 24 hrs. post-delivery. A dosage of 500mg Moringa Oleifera leaves (250mg M. oleifera capsules- 2 times a day). Infant weight gain from birth till 1 month was recorded. A significant rise in prolactin levels after 7 days were observed with a significant increase of neonates' weight gain, weekly till 1 month in experimental group as compared to control group. Mean neonate weight increase of 89g, 12g, 119g was observed on Day 7, 15 and 30^{th} Day post-partum.

Peter Francis et.al, (2014) in Philippines, created an update on previously carried systematic review of impact of moringa in increasing breastmilk and infant weight gain. Results of pooled data of 73 patients depicted the significant increase of milk output by 124ml by Day 7 and of Day 4 and 5 also favoured the moringa. An increase 11.9% in infant weight gain was seen after a month, favouring moringa.

Impact of Moringa Oleifera on prevalence of anemia of pooled data

Mean baseline hemoglobin levels of the mothers was 10.6g/dL and that of endline is 11.8g/dL. In baseline, 41% mothers were in normal category which in endline got increased to 72%. 1% women were severely anemic in baseline which got nullified in endline which is depicted in Table-4.30

In our study, the hemoglobin levels of experimental group increased by 34% and of control group increased by 24% on 7^{th} day post-partum. Thus, the result was in favour of Moringa.

Muis M, et.al, (2014) reported a study in Indonesia on pregnant non anemic informal mothers. The first half group received moringa capsules and the other half were given IFA capsules. A decrease in oxidative stress and increase in nutritional status of women who consumed moringa capsules was observed and reported

Nadimin, et.al (2020) carried out a study in Indonesia on pregnant non anemic women. The interventional group was administered by 4 moringa leaves capsules and other with IFA capsules. Moringa leaves capsules are equally effective as IFA capsules in preventing anemia amongst pregnant women.

Nurdin et al., (2018) conducted the research in Indonesia on pregnant women in 3^{rd} trimester of non-anemic and anemic category. The interventional group was given moringa leaf extract capsules and control was given moringa leaf extract capsules and IFA for 3 months. Hemoglobin levels of all were decreased.

Table-4.30 Prevalence of Anemia in enrolled lactating mothers at baseline and endline (Pooled Data)

Mothers with Haemoglobin levels	**Baseline**		**Mean (n=106) 10.6**	**Endline**			**Mean (n=106) 11.8**
	N (n=106)	**n%**		**N (n=82)**	**n%**	**% increase**	
Normal (Greater than 11 g/dL)	44	41.5		59	71.9	30.4	
Mildly anaemic (10-10.9 g/dL)	30	28.3	**SD (n=106) ±1.4**	13	15.8	-12.5	**SD (n=106) ±1.6**
Moderately anaemic (7-9.9 g/dL)	31	29.24		10	12.1	-17.15	**P-value 0.0005***
Severely anaemic (<7 g/dL)	1	0.9		0		-0.9	

*Significant. p-value <0.05

SUMMARY & CONCLUSION

SUMMARY AND CONCLUSION

Breastfeeding is one of sustainable and effective method considered for a child's survival, growth and development. Breast milk is considered as an ideal food for infant, provides all the essential nutrients in sufficient amounts needed in first new months of life. It is sterile, safe and contains antibodies which helps as an immunity factor providing defense against infections. About 1/2 & 1/3 of child's nutritional requirements are fulfilled by breastmilk in second half of first year and second year of life respectively.

Breastfeeding helps in combating malnutrition (undernutrition & overnutrition), helps in giving healthy start to the life, helps in developing appropriate IQ. (WHO)

Not a single similar study, to best of our knowledge from published data, we could find in Indian context. Studies already carried out are on preterm infants, very small duration of intervention and lactating mothers with comorbidities.

Region specific data for consumption pattern of galactagogues is scarce. Since Moringa oleifera is an indigenous plant, it is very economical to reap its benefits. Studies investigating impact of moringa oleifera on maternal serum prolactin levels, and infant weight gain in Indian population are miniscule

Ethical Approval

The study was approved by the Institutional Ethics Committee for Human Research (IECHR), Faculty of Family and Community Sciences, The Maharaja Sayajirao University of Baroda. The study has been allotted ethical approval number IECHR/FCSc. /MSc. /2022/32

The study is also approved and registered in Clinical Registry Trails of India (CTRI), Indian Council of Medical Research (ICMR) with the CTRI No. CTRI/2023/02/049402

Therefore, present study is planned on healthy mother child dyad with the following broader objective

Broad Objective

To investigate impact of moringa oleifera leaves tablet on serum prolactin levels in post-partum mothers & to assess the weight gain pattern in neonates.

Specific Objectives of the study were:

- To assess the background information of enrolled pregnant & lactating women.
- To assess the knowledge and practises of selected IYCN practises.
- To understand frequency of use of galactagogues by the enrolled mothers
- To assess maternal serum prolactin levels at the interval of 0,7 days post-partum.
- To provide Moringa Oleifera leaves capsules and Placebo capsules on day 0 postpartum for 30 days.
- To record the compliance of capsules in both the groups for 30 days.
- To track weight gain pattern of neonates on 0,7,15 and 30 days post-partum in experimental and control group.

Methodology

Study was divided into following 2 phases:

Phase 1

- To assess the knowledge and practises of selected IYCN practises.

Phase 2

- Impact of moringa oleifera on maternal serum prolactin level and neonates weight gain pattern.

Phase 1-To assess the knowledge and practises of selected IYCN practises.

Jamnabai General Hospital was selected purposively as maximum no. of deliveries takes place in the hospital and also women from local nearby area generally comes for ANC check-ups also.

All women who were registered in Jamnabai General Hospital for delivery and were in last gestational month were enrolled for the study.

Data was collected on:

6. Background information of enrolled mothers and EDD
7. Knowledge & age-appropriate practices of IYCN practice.
8. Use of galactagogues.
9. Consumption of galactagogues foods.
10. Pregnancy Outcome.

Highlights of the Phase 1 findings are:

Background information

- 67.9% women were in the age range of 19-25 yrs.
- 46% women completed their secondary education.
- 56% of the women belonged to BPL category
- All the women enrolled were housewives

Antenatal History

- Women enrolled completed their 36-37 weeks of gestation.
- Primi mothers constitute 43% and Multipara mothers constitute 57% of the total enrolled mothers.
- 93% women registered themselves in within 12 weeks of gestation.
  95% of the women did at least 4 antenatal check-ups

Knowledge and Practices of selected IYCN

- 57.5% enrolled women knew about early initiation of breastfeeding but only 28.3% actually practiced.

- 93.4% women were aware of colostrum provision and 88.7% women actually practiced
- Only, 35.8% women were aware about the avoidance of prelacteal but 81.1% women didn't give prelacteals which shows positive result in practice
- Only 21.7 % mothers gave solely breast milk to the child post-delivery.
- Very few (3 & 5%) mothers optimally fed the child for 6-12 times a day.

Awareness about Galactagogues

- 96% of the enrolled women were aware of galactagogues, foods that increases milk secretion in lactating mothers when consumed.
- Majority of the mothers (96%) knew Sepu seeds (Suva seeds) as galactagogues followed by 77.6% of mothers who knew Dry Ginger and 78.6% Edible Gum as galactagogues foods

Pregnancy Outcome

- All the deliveries of the enrolled mothers were done in a Public Hospital.
- 67% and 33% had normal and C-section deliveries respectively.
- All were full term babies with a ratio of 97% live births

Phase 2- Impact of moringa oleifera on maternal serum prolactin level and neonates weight gain pattern.

In Phase 2, All lactating mothers who gave birth to full term live babies within 24 hrs in the selected facility with no medical complication and who gave consent were enrolled. These enrolled mothers were randomly then distributed to Experimental Group and Control Group. Experimental Group was administered by Moringa Oleifera Capsules and Control Group was administered by Placebo Capsules.

Data was collected on:

1. Consumption and Frequency of Galactagogue.
2. Minimum Dietary Diversity of the mothers.

3. Impact of Moringa Oleifera leaves capsules on serum prolactin levels and neonates weight gain.
4. Impact of Moringa Oleifera leaves capsules on prevalence of anemia.

Moringa Oleifera leaves capsules and Placebo capsules were administered on Day 0 post-partum to the mothers of experimental and control group respectively for 30 days. Dosage of 250mg M. Oleifera capsules and Placebo capsules were administered twice a day. Total of 500mg intervention was administered. Serum prolactin levels at Day 7 was recorded. Neonates weight at 7, 15 and 30 days from the birth was recorded to assess neonates weight gain pattern.

Highlights of the Phase 2 findings are:

Minimum dietary diversity

- 91 % of women had MDD

Consumption of Galactagogues

- All the women who were enrolled for the study, 44% and 56% women consumed any form of galactagogues like Suva Paani, Fenugreek, Sond, Gunder during pregnancy and lactation respectively.
- 74.4% women consumed small amount of galactagogues in any form occasionally. 47.5% experimental group mothers and 52.5% control group mothers consumed small amount of galactagogue in any form occasionally.
- Only, 3.7% mothers consumed Moringa leaves bhaji. On the whole, moringa as a galactagogue was not prominently consumed by moth

Impact of Moringa Oleifera on Serum Prolactin Levels

- Mean Baseline PRL values of Experimental group (56) 120.5 ± 42.17 ng/ml and that of Control group (50) is126.7 ± 43.93 ng/ml at 0 day postpartum
- A significant difference was found in mean Endline PRL levels of experimental group mothers (45) - 126.6 ± 28.66 ng/ml on Day 7 of post-partum versus of control group (37) - 101.9 ± 32.93 ng/ml .

Impact of Moringa Oleifera on Neonates Weight Gain Pattern

- Average weight gain of neonates of experimental group and control group was 114g and 25g respectively on Day 7.
- On day 15, average weight gain of infants of experimental and control group was 350g and 338g respectively.
- After a month the average weight gain of infants of experimental and control group was 905g and 786g respectively which was found to be significant

Impact of Moringa Oleifera on Anemia

- 50% mothers of Experimental Group were under normal category which got significantly increased to 84.4% after one month compliance of M. Oleifera capsules
- 32% mothers of Control Group were under normal category which got increased to 56.7% one month after delivery.

CONCLUSION

- It can be concluded that in urban lactating mothers IYCN practises were sub-optimal.
- Moringa Oleifera helped in improving S. PRL On 7^{th} Day as compared to placebo.
- Weight gain pattern in neonates was better in experimental group as compared to placebo group. Therefore, Moringa Oleifera may have helped in increasing milk secretion.
- Prevalence of anaemia decreased in experimental group as compared to control group

RECOMMENDATION LIMITATION & POLICY IMPLICATION

RECOMMENDATIONS

It can be recommended that moringa oleifera leaves powder can be incorporated in THR Matrushakti and on the spot feeding program in POSHAN Sudha yojana.

It can also be supplemented in capsule form along with IFA.

POLICY IMPLICATIONS

Data generated through current study will help program managers to promote kitchen gardening containing M oleifera

To promote use of M Oleifera leaves/powder to curtail undernutrition in young children

LIMITATION OF THE STUDY

Milk output and Milk Volume weren't measured in enrolled lactating mothers.

BIBLIOGRAPHY & WEBLIOGRAPHY

BIBLIOGRAPHY

Ajibade, Temitayo & Arowolo, Ruben & Olayemi, Funsho. (2013). Phytochemical screening and toxicity studies on the methanol extract of the seeds of Moringa oleifera. Journal of complementary & integrative medicine.

Al-Chalabi M, Bass AN, Alsalman I. Physiology, Prolactin. 2020.

Allen, J. C., Keller, R. P., Archer, P., & Neville, M. C. (1991). Studies in human lactation: milk composition and daily secretion rates of macronutrients in the first year of lactation. *The American journal of clinical nutrition.*

Angeline Jeyakumar, Supriya Nikam & Shwetha Nayak (2019) Prevalence and Risk Factors of Undernutrition among Children Less than 2 Years in Urban Slums of Pune, Maharashtra, India, Ecology of Food and Nutrition.

Angeline Jeyakumar, Suresh Jungari, Raji Nair, Pramila Menon, Prasad Babar, Barai Bhushan, Hulsurkar Yogita, Janan Ali, Marathe Saddichha, Mitragotri Bhagyashree, Phadake Monika & Sneha Sakshi (2021) Prevalence and Determinants of Early Initiation (EI), Exclusive Breastfeeding (EBF), and Prelacteal Feeding among Children Aged 0-24 Months in Slums of Pune City, in Maharashtra, Ecology of Food and Nutrition.

B. Adhisivam, B. Vishnu Bhat, Rachel Poorna, Mahalakshmy Thulasingam, Femitha Pournami & Rojo Joy (2017) Postnatal counseling on exclusive breastfeeding using video – experience from a tertiary care teaching hospital, south India, The Journal of Maternal-Fetal & Neonatal Medicine

Babitha B, Vyshnavi B, Impact of supplementation of moringa oleifera and emblica officinalis powder on atherosclerosis patients. J Nutr Metab Health Sci2018.

Brar, Sumeer & Haugh, Carolyn & Robertson, Nicole & Owuor, Patrick & Waterman, Carrie & Fuchs, George & Attia, Suzanna. (2022). The impact of Moringa oleifera leaf supplementation on human and animal nutrition, growth, and milk production: A systematic review. Phytotherapy Research.

Dog, Tieraona. (2009). The use of botanicals during pregnancy and lactation. Alternative therapies in health and medicine.

Espinosa-Kuo Cl. A Randomized Controlled Trial on The Use of Malunggay (Moringa Oleifera) For Augmentation O (The Volume of Breastn1ilk Among Mothers of Term Infants R ·, Res Done by Sugarpod Nat. 2005.

Estrella Mcp, Bias J, Man V, David Gz, Taup Ma. A Double-Blind, Randomized Controlled Trial on The Use of Malunggay (Moringa Oleifera) For Augmentation of The Volume of Breastmilk Among Non-Nursing Mothers of Preterm Infants. Philipp Journa Pediatr. 2000.

Foong SC, Tan ML, Foong WC, Marasco LA, Ho JJ, Ong JH. Oral galactagogues (natural therapies or drugs) for increasing breast milk production in mothers of non-hospitalised term infants. Cochrane Database Syst Rev. 2020

Freeman ME, Kanyicska B, Lerant A, Nagy G. Prolactin: structure, function, and regulation of secretion. Physiol Rev. 2000.

Fungtammasan S, Phupong V. The effect of Moringa oleifera capsule in increasing breastmilk volume in early postpartum patients: A double-blind, randomized controlled trial. PLoS One. 2021.

Gihan M. El Moghazy, Dina M. Sakr, Abdel Aal M. H. and A. E. Hasanein. (2020). Effect of dietary fortification by dried Moringa oleifera leaves on the expression of some lipids and immune related genes in albino rats fed purified diet. Int. J. Adv. Res. Biol. Sci.

Giugliani, Elsa. (2004). Common problems during lactation and their management. Jornal de pediatria.

Gopalakrishnan, L., Doriya, K., & Kumar, D. S. (2016). Moringa oleifera: A review on nutritive importance and its medicinal application. *Food science and human wellness.*

Gupta M, Shaw B. A Double-Blind Randomized Clinical Trial for Evaluation of Galactagogue Activity of Asparagus racemosus Willd. Iran J Pharm Res. 2011.

IFCT,2017.

In: Yabes-Almirante C, DeLuna M, eds. Increasingly Safe and Successful Pregnancies. Elsevier Science, New York

Jacelie S. King, MD. et al. (2013). *Moringa Oliefera (Malunggay) as a Galactagogue for Breastfeeding Mothers: A Syistematic Review and Meta-Analysis of Randomized Controlled Trials.* The Philipines Journal of Pediatrics.

Khuzaimah A, Hadju V, As S, Abdullah N, Bahar B, Riu Ds. Effect Of Honey and Moringa Oleifera Leaf Extracts Supplementation for Preventing DNA Damage in Passive Smoking Pregnancy. Int J Sci Basic Appl Res. 2015

King, Jacelie & Raguindin, Peter Francis & Dans, Leonila. (2013). Moringa oleifera (Malunggay) as a Galactagogue for Breastfeeding Mothers: A Systematic Review and Meta-Analysis of Randomized Controlled Trials. The Philippine journal of pediatrics.

Kiranawati TM, Nurjanah N. Improvement of noodles recipe for increasing breastmilk: Design of the moringa noodles. American Journal of Food Science and Technology. 2014

Krause (14th Edition)

Leone, Alessandro & Spada, Alberto & Battezzati, Alberto & Schiraldi, Alberto & Aristil, Junior & Bertoli, Simona. (2016). Moringa oleifera Seeds and Oil: Characteristics and Uses for Human Health. International Journal of Molecular Sciences.

Li M, Song Y, Rawal S, Hinkle SN, Zhu Y, Tekola-Ayele F, Ferrara A, Tsai MY, Zhang C. Plasma Prolactin and Progesterone Levels and the Risk of Gestational Diabetes: A Prospective and Longitudinal Study in a Multiracial Cohort. Front Endocrinol (Lausanne). 2020

Manapatt AK, Anoop L, Tharammal D, Sathyapal A, Muneer Y. Pattern of Prolactin Secretion after Normal Vaginal Delivery and in Cesarean Delivery. Int J Infertility Fetal Med 2014.

Milla, P. G., Peñalver, R., & Nieto, G. (2021). Health Benefits of Uses and Applications of Moringa oleifera in Bakery Products.

Muhammad Syafruddin Nurdin, Veni Hadju, Ansariadi, Andi Zulkifli Aia. The Effect Of Moringa Leaf Extract And Powder To Haemoglobin Concentration Among Pregnant Women In Jeneponto Regency. Indian J Public Heal Res Dev. 2018

Muis M, Hadju V, Russeng S, Naiem F. Effect of Moringa Leaves Extract On Occupational Stress And Nutritional Status Of Pregnant Women Informal Sector Workers. Intjcurrresacarev. 2014.

Muluken Amare Wudu (2021) Determinants of Early Days of Newborn Feeding Malpractice Among Mothers of Children Less Than One Year of Age in Mizan-Aman Town, Southwestern Ethiopia, 2020, Pediatric Health, Medicine and Therapeutics.

Nadimin (2021) Nutritional Intervention Based on Moringa Leaf Flour to Prevent Stunting in First 1000 Days of Life (1000 HPK): Review Articles. *Systematic Reviews in Pharmacy*

Nadimin, Hadju V, As S, Buchari A, Haruna, Hartono R. Increasing Of Nutrition Status Of Pregnant Women After Supplementation Of Moringa Leaf Extract (Moringa Oliefera) In The Coastal Area Of Makassar , Indonesia. Indian J Public Heal Res Dev. 2019

Nadimin, Hadju V, As S, Bukhari A, Imam A. A Comparison Between Extract Moringa Oleifera and Iron Tablet on Prevention Low Birth Weight In Pregnant Mothers In Makassar, Indonesia ☪. Enfermería Clínica [Internet]. 2020

Nadimin, Hadju V, As'ad S, Buchari A. The Extract of Moringa Leaf Has an Equivalent Effect to Iron Folic Acid in Increasing Hemoglobin Levels Of Pregnant Women: A Randomized Control Study In The Coastal Area Of Makassar. Int J Sci Basic Appl Res. 2015.

Nadimin. The Influence Provision Of Moringa Leaf Extract (Moringa Oliefera) Against The Level Of Mda (Malondialdehyde) In Pregnant Women. Int J Sci Basic Appl Res. 2016

NFHS 4 GUJARAT FACT SHEET (2015-2016)

NFHS 4 INDIA FACT SHEET (2015-2016)

NFHS 4 VADODARA FACT SHEET (2015-2016)

NFHS 5 GUJARAT FACT SHEET (2019-2020)

NFHS 5 INDIA FACT SHEET (2019-2020)

NFHS 5 VADODARA FACT SHEET (2019-2020)

Nur, Syuhadah & che lamin, Rozazinur & Othman, Che Noriah. (2014). Exploring Behavior on the Herbal Galactagogue Usage among Malay Lactating Mothers in Malaysia. Procedia - Social and Behavioral Sciences

Oppong Bekoe, E., Kitcher, C., Ama Mireku Gyima, N., Schwinger, G., & Frempong, M. (2019). Medicinal Plants Used as Galactagogues.

Özalkaya E, Aslandoğdu Z, Özkoral A, Topcuoğlu S, Karatekin G. Effect of a galactagogue herbal tea on breast milk production and prolactin secretion by mothers of preterm babies. Niger J Clin Pract. 2018.

Pratiwi, T.E (2017). Exclusive Breastfeeding Improvement Program Using Carica Papaya Leaf Extract on the Levels of Prolactin Hormones. International Journal of Science and Research (IJSR)

Raguindin, Peter Francis & Dans, Leonila & King, Jacelie. (2014). Moringa oleifera as a Galactagogue. Breastfeeding Medicine

Raguindin, Peter Francis & Dans, Leonila & King, Jacelie. (2014). Moringa oleifera as a Galactagogue. Breastfeeding Medicine

Rajanandh, M. G., & Kavitha, J. (2010). Quantitative estimation of β-sitosterol, total phenolic and flavonoid compounds in the leaves of Moringa oleifera. *International Journal of PharmTech Research.*

Rajbhar YP, Rajbhar G, Rawat PL, et al. Grow Moringa (Moringa oleifera), the miracle tree on the earth. *Horticult Int J*. 2018.

Reena Ravi, J.J. (2020). Effect of fenugreek on breastmilk production and weight gain among infants in first week of life. Clinical Epidemiology and Global health, 656-660

Rune Nathaniel Philemon, Blandina T Mmbaga, John Bartlett, Jenny Renju, Tara B Mtuy, Innocent B Mboya & Sia E Msuya (2022) Adherence to Optimal Breastfeeding Practices Among HIV-Positive Mothers in Kilimanjaro, Tanzania, Patient Preference and Adherence.

Satheesh Kumar, B. (2020). *Association between Serum Prolactin Levels and Adverse Cardiovascular Events in Chronic Kidney Disease Patients*.

Setiasih, & Wahjuningsih, S. & Winarsih, Sri & Soetanto, Hendrawan. (2019). The effects of adding moringa oleifera leaves extract on rabbit does' milk production and mammary gland histology. Russian Journal of Agricultural and Socio-Economic Sciences

Shalini, Thakur & Guleria, Ashish & Umesh, Shukla. (2020). Malnutrition-challenge moringa leaves. International Journal of Research in AYUSH and Pharmaceutical Sciences.

Su, Bin & Chen, Xiaoyang. (2020). Current Status and Potential of Moringa oleifera Leaf as an Alternative Protein Source for Animal Feeds. Frontiers in Veterinary Science

Sulistiawati Y, Suwondo A, Hardjanti Ts, Soejoenoes A. Effect of Moringa Oleifera on Level of Prolactin and Breast Milk Production in Postpartum Mothers. Belitung Nurs J. 2017.

Sulistiawati, Y., Suwondo, A., Hardjanti, T. S., Soejoenoes, A., Anwar, M. C., & Susiloretni, K. A. (2017). Effect of moringa oleifera on level of prolactin and breast milk production in postpartum mothers. *Belitung Nursing Journal*

Suzon Ahmed, Niaz Mahmud, Nisat Farzana, Mst. Irin Parvin & Md Alauddin (2023) Early Initiation of Breastfeeding (EIBF) and Its Associated Factors Among Mothers With Infants Aged 0 to 6 Months in Jashore District, Bangladesh: A Cross-Sectional Study, Journal of the American Nutrition Association.

Titi MK, Harijono ET, Endang SW. Effect lactagogue moringa leaves (Moringa oleifera Lam) powder in rats white female wistar. Journal of Basic and Applied Scientific Research. 2013;

Urbain Zongo, Boubacar Savadogo, Steve Leonce Zoungrana, Dia Sanou, Aly Savadogo, Mamoudou Hama Dicko As, Sanou D, Savadogo A. Effect of Moringa Leaves Powder Consumption on Young Children Nutritional. Int J Nutr Food Sci. 2018.

Utiger, R. D. (2023). *prolactin*. *Encyclopedia Britannica*

Yabes-Almirante C, Lim M. Effectiveness of natalac as a galactagogue. J Phil Med Assoc 1996

Yabes-Almirante C, Lim M. Enhancement of breastfeeding among hypertensive mothers.
Yang Yang et.al (2016), Content determination of phytosterol in Moringa Oleifera leaves from different areas by gas chromatography.

Yuliastuti S, Kuntjoro T, Sumarni S, Widyawati Mn. Kelor (Moringa Oliefera) As an Alternative in Increasing Breast Milk Production. Jmscr 2018.

Zongo, U., Savadogo, B., Zoungrana, S. L., Sanou, D., Savadogo, A., Dicko, M. H., & SababenedyoTraore, A. (2018). Effect of moringa leaves powder consumption on young children nutritional and serum retinol status in Burkina Faso rural area. Asztalos E V. Supporting Mothers of Very Preterm Infants and Breast Milk Production: A Review of The Role of Galactogogues. Nutrients [Internet]. 2018

(Breastfeeding Programs and Policies, Breastfeeding Uptake, and Maternal Health Outcomes in Developed Countries. Comparative Effectiveness Review No. 210. AHRQ Publication No. 18-EHC014-EF. July 2018.)

WEBLIOGRAPHY

https://www.babycareadvice.com/blogs/growth/average-weight-gain-for-babies

http://dx.doi.org/10.3390/plants10020318

https://www.who.int/health-topics/breastfeeding#tab=tab_1

https://kellymom.com/bf/normal/prolactin-levels/

https://www.canada.ca/en/public-health/services/health-promotion/childhood-adolescence/stages-childhood/infancy-birth-two-years/breastfeeding-infant-nutrition/10-great-reasons-breastfeed-your-baby.html

https://calgaryguide.ucalgary.ca/benefits-of-breast-milk-to-infants-mechanism-of-action/

https://femina.wwmindia.com/content/2018/aug/info1533210087.jpg

https://calgaryguide.ucalgary.ca/benefits-of-breast-milk-to-infants-mechanism-of-action/

https://cdn.shopify.com/s/files/1/2160/2717/files/6_TopChallengesandBarriersForTheBreastfeedingMom2-02.png?v=1597794774

https://www.healthline.com/health/breastfeeding/11-benefits-of-breastfeeding

https://my.clevelandclinic.org/health/articles/15274-benefits-of-breastfeeding

https://www.healthline.com/health/galactagogues

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8248610/

APPENDICES

APPENDIX I

PERMISSION LETTER FROM JAMNABAI GENERAL HOSPITAL

DEPARTMENT OF FOODS AND NUTRITION
FACULTY OF FAMILY & COMMUNITY SCIENCES
THE MAHARAJA SAYAJIRAO UNIVERSITY OF BARODA
VADODARA 390 002 - INDIA

Phone : } 0265-2795526
Tele. } 0265-2795522 [Ext.33]
Grams : } "HOMSCIENCE"

Date: 21/09/2022

No. F. C. Sc./ FND / 128

To,
The Medical Superintendent.
Jamnabai Maternity Hospital,
Vadodara, Gujarat.

SUB: Permission to enrol last trimester pregnant women and who will deliver babies in the hospital for the MSc. Dissertation work.

Respected Sir/Ma'am,

Miss Dhwani Arora is a Sr. MSc. Public Health and Nutrition student working on her dissertation topic **"Impact of Moringa Oleifera leaves on Prolactin Levels in Post- Partum Mothers & the Weight Gain Pattern in Neonates".** Detailed proposal is enclosed here for your kind percussion. We will be highly obliged if your gynae ward authorities can facilitate the student for the following.

1. To provide list of pregnant women who are registered in the hospital for delivery and who EDD are between 1st Oct- 30th Jan, residing in Urban Vadodara or nearby villages. We need to enrol around 100 mothers.
2. Student will collect basic information through interview with them.
3. We are planning to give Moringa Oleifera tablets (500 Microgram moringa leaves powder). For this we need to enrol 60 women on the day of delivery; 30 for experimental and 30 for control. For this all the biochemical estimation charges will be borne by the student but we need your help in collecting blood sample to access prolactin levels on day of delivery. Rest of the tracking and data collection will be done by student.

Kindly, facilitate the student for dissertation work. Hoping for a favourable reply.

Thanking you,

H.J.Gandhi

Dr. Hemangini Gandhi.
Assistant Professor (CES)
Department of Foods and Nutrition
The Maharaja Sayajirao University of Baroda

Dept. of Foods & Nutrition
Faculty of Family & Community Sciences
The M. S. University of Baroda
Vadodara - 390 002.

DR. R chauhan

30/9/22

30/9/22

Terms & Conditions to be enclosed with the study are as follows:

- Study will be unlinked and anonymous. No identity of any patient will be revealed (like name, contact number, address)
- All the details and data will be kept confidential. No data will be revealed in any sort of electronic or print media.
- The study is only for educational purpose and not for any other purposes.
- The study will be published in concerned magazines or research sites after the completion.
- Required permission from the hospital will be taken by the researcher in case of any edgy situation.

Dhwani Arora
M.Sc. Public Health Nutrition
Dept. of Foods & Nutrition
The Maharaja Sayajirao University
of Baroda
Vadodara, Gujarat.

APPENDIX II

ETHICAL CLEARANCE CERTIFICATE FROM THE ETHICAL COMMITTEE

Institutional Ethics
Committee for Human
Research
(IECHR)

FACULTY OF FAMILY AND COMMUNITY SCIENCES
THE MAHARAJA SAYAJIRAO UNIVERSITY OF BARODA

Ethical Compliance Certificate 2022 – 2023

This is to certify that Ms. Dhwani Arora's study titled, "**Impact of Moringa Leaves Tablets on Prolactin Levels of Lactating Women and Weight Gain Pattern of Infants**" from Department of Foods and Nutrition has been approved by the Institutional Ethics Committee for Human Research (IECHR), Faculty of Family and Community Science, The Maharaja Sayajirao University of Baroda. The study has been allotted the ethical approval number ***IECHR/FCSc/MSc/2022/32.***

Prof Mini Sheth
Member Secretary
IECHR

Prof Shagufa Kapadia
Chairperson
IECHR

Chair Person
IECHR
Faculty of Family & Community Sciences
The Maharaja Sayajirao University of Baroda

APPENDIX III

CONSENT FORM FOR SUPPLEMENTATION OF MORINGA OLEIFERA LEAVES CAPSULE (OR PLACEBO SUGAR CAPSULES)

STUDY TITLE

Impact of moringa leaves tablets on prolactin levels of lactating women and weight gain pattern of infants delivered in Jamnabai maternity hospital of Vadodara district.

PRINCIPAL INVESTIGATOR

Dr Hemangini Gandhi

RESEARCH STUDENT

Dhwani Arora

Sr. MSc. Public Health and Nutrition

PURPOSE OF THE STUDY

As breastfeeding rates are poor in India, infants are more prone to infant morbidities and mortality and infant nutrition status is abysmal in the nation. Many women face the issue of lactation failure due to multiple reasons. Thus, the study has been planned to help increase breastmilk volume by the administration of moringa oleifera leaves capsules.

PROTOCOL FOR THE STUDY

If you decide to join this supplementation trial, you will be asked to consume the moringa oleifera leaves capsule on a daily basis for a period of 60 days beginning from 30 days before the estimated date of delivery. Information regarding mode of delivery, gestational age, parity, food frequency, dietary diversity, knowledge on breastfeeding, timing & frequency of breastfeeding, knowledge and consumption of galactagogues will be assessed with the help of a questionnaire. A trained laboratory technician will draw your blood (5 ml) to estimate your prolactin levels on the day of delivery, and 7-day post-delivery. Your child's anthropometric measurements (weight) will be measured on day of birth, 7-day, 15-day and 30-days post birth by the investigator.

COSTS

This study requires only your time and co-operation. All the costs incurred for the moringa oleifera capsules, placebo sugar capsules, blood tests will be borne by the researchers and there is no financial compensation for your participation this research.

POSSIBLE BENEFITS AND RISKS

The study will help to increase scientific knowledge about the impact of administration of moringa oleifera leaves in improving breastmilk volume. The risk of participation is minimal as only disposable needles and syringes will be used for drawing blood which will be done by a trained and authorized technician. Daily consumption of Sg or more of the moringa oleifera leaves powder has not shown any side effects. If you feel any kind of side effects due to ingestion of the tablet you can immediately stop the consumption and inform the researcher about the side effects.

RIGHT TO WITHDRAW

Your decision to join this study is voluntary. You may quit at any time. for any reason without notice. We hope you will take part for the entire study period because we need all the information to draw correct conclusion.

VOLUNTARY CONSENT

Your co-operation is important to the success of this study. Unless many volunteers like you agree to join, this study will not be possible. In order for this study to be valid, you should not join other health studies where you would be assigned to receive a medication, special test, or special treatment.

AVAILABILITY OF RESULTS AND CONSULTATION

A copy of the report will be provided to you for future use. If any abnormality is seen in the biochemical profile, you would be advised to contact your doctor, with the reports provided to you. If you have any questions about any part of the study or your rights as a volunteer, you can contact the investigators.

INVESTIGATOR'S STATEMENT

I have explained the research program, the purpose of the study, the possible benefits and risks to the participant The participant was given an opportunity to discuss these procedures and to ask any additional questions.

_____

Signature of Investigator with date

Dhwani Arora – MOB: 9427476382

Dr Hemangini Gandhi- MOB: 9824320554

Prof. (Dr) Mini Sheth- MOB:

PARTICIPANT STATEMENT

I certify that I have read or had read to me and that I understand the description of the study. By signing this form, I am attesting that I have read and understood the information above. I give my consent to be included as a subject in the study being carried out by Dr Hemangini Gandhi and her student Miss Dhwani Arora of The Maharaja Sayajirao University of Baroda to investigate the effectiveness of moringa oleifera leaves tablet to increase breastmilk production. I understand that the study requires the participants to consume the moringa oleifera leaves tablet daily for 30 days depending upon the group and to undergo blood test measure prolactin levels three times for which, the participants would be required to provide 5 ml blood sample. The participants infant will be weighed three times.

Name:

Signature:

APPENDIX III

CONSENT FORM FOR SUPPLEMENTATION OF MORINGA OLEIFERA LEAVES CAPSULE (OR PLACEBO SUGAR CAPSULES) IN GUJARATI

સરગવાના પાનની ટેબલેટ વિષય મા જાનાવા માટે સંમતિ ફોર્મ

અભ્યાસ શીર્ષક

વડોદરા જિલ્લાની જમનાબાઈ પ્રસૂતિ હોસ્પિટલમાં પોસ્ટ-પાર્ટમ મધર્સમાં બ્રેસ્ટમિલક ઉત્પાદન વધારવા માટે મોરિંગા ઓલિફેરા લીવ્સ ટેબ્લેટની અસરકારકતાની તપાસ

પ્રિન્સિપલ ઇન્વેસ્ટિગેટર

ડૉ. હેમાંગીની ગાંધી

સંશોધન વિદ્યાર્થી

ધ્વની અરોરા

સિનિયર એમએસસી પી એચ એન

અભ્યાસનો હેતુ

ભારતમાં સ્તનપાનનો દર નબળો હોવાથી, શિશુઓ શિશુ બિમારીઓ અને મૃત્યુદર માટે વધુ સંવેદનશીલ હોય છે અને રાષ્ટ્રમાં શિશુ પોષણની સ્થિતિ અત્યંત ખરાબ છે. ઘણી સ્ત્રીઓને અનેક કારણોસર સ્તનપાન નિષ્ફળતાની સમસ્યાનો સામનો કરવો પડે છે. આમ, સરગવાના પાંદડાની કેપ્સ્યુલ્સના વહીવટ દ્વારા માતાના દૂધની માત્રા વધારવામાં મદદ કરવા માટે અભ્યાસનું આયોજન કરવામાં આવ્યું છે.

અભ્યાસ માટે પ્રોટોકોલ

જો તમે આ અભ્યાસ મા જોડાવાનું નક્કી કરો છો, તો તમને ડિલિવરીની અંદાજિત તારીખના 30 દિવસ પહેલાથી શરૂ કરીને 60 દિવસના સમયગાળા માટે દરરોજ સરગવાના પાંદડાની કેપ્સ્યુલનું સેવન કરવાનું કહેવામાં આવશે. ડિલિવરી પદ્ધતિ, સગર્ભાવસ્થાની ઉંમર, સમાનતા વિશેની માહિતી,

ખોરાકની માહિતી, આહારની વિવિધતા, સ્તનપાન અંગેનું જ્ઞાન, સ્તનપાનનો સમય અને કેટલીવાર આપોચો ધાવન વધાર વાનો ખોરાક ના વપરાશનું મૂલ્યાંકન પ્રશ્નાવલીની મદદથી કરવામાં આવશે. પ્રશિક્ષિત

લેબોરેટરી ટેકનિશિયન ડિલિવરીના દિવસે તમારા પ્રોલેક્ટીનના સ્તરનો અંદાજ કાઢવા માટે તમારું લોહી (5 મિલી) લેશે

, અને ડિલિવર પછીના 7 દિવસે લેવામા આવશે •. તમારા બાળકના ઊંચાઈ અને વજન એ જ લેબોરેટરી ટેકનિશિયન દ્વારા જન્મના દિવસે અને જન્મ પછીના 7, 15 અને 30 દિવસમાં માપવામાં આવશે.

ખર્ચ

આ અભ્યાસ માટે ફક્ત તમારો સમય અને સહકાર જરૂરી છે. સરગવાના પાનની કેપ્સ્યુલ્સ અને રક્ત પરીક્ષણો માટેનો તમામ ખર્ચ સંશોધકો દ્વારા ઉઠાવવામાં આવશે અને આ સંશોધનમાં તમારી ભાગીદારી માટે કોઈ નાણાકીય વળતર નથી.

સંભવિત લાભો અને જોખમો

આ અભ્યાસ માતાના દૂધના જથ્થાને સુધારવામાં સરગવાના પાંદડાઓના અસર વિશે વૈજ્ઞાનિક જ્ઞાન વધારવામાં મદદ કરશે. સહભાગિતાનું જોખમ ન્યૂનતમ છે કારણ કે લોઇપરીક્ષણ માટે માત્ર ડિસ્પોઝેબલ સોય અને સિરીંજનો ઉપયોગ કરવામાં આવશે જે પ્રશિક્ષિત અને અધિકૃત ટેકનિશિયન દ્વારા કરવામાં આવશે. દરરોજ 8 ગ્રામ કે તેથી વધુ મોરિંગા ઓલિફેરા પાંદડાના પાઉડરના સેવનથી કોઈ આડઅસર જોવા મળી નથી. જો તમને ટેબ્લેટ લેવાથી કોઈ પણ પ્રકારની આડઅસર લાગે તો તમે તરત જ તેનું સેવન બંધ કરી શકો છો અને સંશોધકને તેની આડઅસરો વિશે જાણ કરી શકો છો.

પાછો ખેંચવાનો અધિકાર

આ અભ્યાસમાં જોડાવાનો તમારો નિર્ણય સ્વૈચ્છિક છે. તમે કોઈપણ સમયે છોડી શકો છો. નોટિસ વિના કોઈપણ કારણોસર. અમે આશા રાખીએ છીએ કે તમે સમગ્ર અભ્યાસ સમયગાળા માટે ભાગ લેશો કારણ કે અમને સાચા નિષ્કર્ષ પર પહોંચવા માટે બધી માહિતીની જરૂર છે.

સ્વૈચ્છિક સંમતિ

આ અભ્યાસની સફળતા માટે તમારો સહકાર મહત્વપૂર્ણ છે. જ્યાં સુધી તમારા જેવા ઘણા સ્વયંસેવકો જોડાવા માટે સંમત ન થાય ત્યાં સુધી આ અભ્યાસ શક્ય બનશે નહીં. આ અભ્યાસ માન્ય રહેવા માટે, તમારે અન્ય આરોગ્ય અભ્યાસમાં જોડાવું જોઈએ નહીં જ્યાં તમને દવા, વિશેષ પરીક્ષણ અથવા વિશેષ સારવાર મેળવવા માટે સોંપવામાં આવશે.

પરિણામો અને પરામર્શની ઉપલબ્ધતા

રિપોર્ટની એક નકલ તમને ભવિષ્યના ઉપયોગ માટે આપવામાં આવશે. જો બાયોકેમિકલ પ્રોફાઈલમાં કોઈ અસાધારણતા જોવા મળે, તો તમને આપવામાં આવેલા રિપોર્ટ સાથે તમારા ડૉક્ટરનો સંપર્ક કરવાની સલાહ આપવામાં આવશે. જો તમને અભ્યાસના કોઈપણ ભાગ વિશે અથવા સ્વયંસેવક તરીકેના તમારા અધિકારો વિશે કોઈ પ્રશ્નો હોય, તો તમે તપાસકર્તાઓનો સંપર્ક કરી શકો છો.

તપાસકર્તાનું નિવેદન

મેં સંશોધન કાર્યક્રમ, અભ્યાસનો હેતુ, સહભાગીને સંભવિત લાભો અને જોખમો સમજાવ્યા છે. સહભાગીને આ પ્રક્રિયાઓની ચર્ચા કરવાની અને કોઈપણ વધારાના પ્રશ્નો પૂછવાની તક આપવામાં આવી હતી.

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તારીખ સાથે તપાસકર્તાની સહી

ડૉ.હેમાંગીની ગાંધી

ધ્વની અરોરા (9327825940)

પ્રો.મીની શેઠ

સહભાગી નિવેદન

હું પ્રમાણિત કરું છું કે મેં વાંચ્યું છે અથવા મને વાંચ્યું છે અને હું અભ્યાસનું રીત સમજું છું. આ ફોર્મ પર સહી કરીને હું પ્રમાણિત કરું છું કે મેં ઉપરની માહિતી વાંચી અને સમજી લીધી છે. ડો. હેમાંગીની ગાંધી અને તેમના વિદ્યાર્થી ધ્વની અરોરા દ્વારા મહારાજા સયાજીરાવ યુનિવર્સિટી ઓફ બરોડામાં માતાના દૂધના ઉત્પાદનમાં વધારો કરવા માટે સરગવાના પાંદડાની ગોળીની અસરકારકતાની તપાસ કરવા માટે કરવામાં આવી રહેલા અભ્યાસમાં સામેલ થવા હું મારી સંમતિ આપું છું. હું સમજું છું કે અભ્યાસમાં સહભાગીઓએ જૂથના આધારે 60 દિવસ માટે દરરોજ સરગવાના પાંદડાની ટેબ્લેટનું સેવન કરવાની જરૂર છે અને પ્રોલેક્ટીનના સ્તરને માપવા માટે ત્રણ વખત રક્ત પરીક્ષણમાંથી પસાર થવું પડશે જેના માટે, સહભાગીઓએ 5 મિલી લોય આપવાની જરૂર પડશે. સહભાગી શિશુનું ત્રણ વખત વજન કરવામાં આવશે

નામ:_____

સહી:_____

APPENDIX IV

QUESTIONNAIRE
CODE **NO:**
DATE:

APPENDIX:1

Sr. NO	**BACKGROUND INFORMATION**	
1	Name of the mother	
2	Date of birth	
3	Current age of mother in yrs.	
4	Contact number	
5	Religion	• Hindu • Muslim • Christian • Sikh • Others
6	Education	• Primary • Secondary • Higher secondary • Graduate • Others
7	Type of family	• Joint family • Nuclear family • Extended Nuclear
8	Socio-economic Status	• APL • BPL
9	Total monthly income (Rs)	
10	Occupation	• Housewife • Service • Self-employed • Own business

	ANC HISTORY	
11	Have you registered to any Anganwadi center?	• Yes • No
	If yes, when	• <12 weeks • >12 weeks
	If yes, Which Anganwadi center have you registered?	
12	Where do you go for ANC checkups	• AWC • UHC • Govt. Hospital (specific)
13	Till now how many ANC checkups have you gone through?	• <4 • 3-4 • <3 • No checkups at all
14	What is your last menstrual date?	
15	What is your expected delivery date?	
16	Do you suffer from any of these diseases?	• Diabetes mellitus/ Gestational Diabetes • Hypertension • Hypo/Hyperthyroidism • TB • HIV • Hyperlipidemia • Epilepsy
17	Mention known any food allergies?	
18	Tentative place of delivery	
	KNOWLEDGE ABOUT IYCN	
19	Are you aware of colostrum?	• Yes • No
	If yes, what is it?	
	If yes, what are the advantages?	

20	What should be given to the child soon after birth?	• Only Breast milk • Water • Other animal/ formula milk • Breast Milk
21	When should breastfeeding be initiated?	• Within 1 hr • 2-3 hrs • In 24 hrs • More than 1 day
22	Does any prelacteal to be given?	• Yes • No
	If no, why?	
23	How long child should be breast fed exclusively?	• 4-6 months • 6 months • Any other
24	Do you know when to start Complementary feeding?	• 4-6 months • 6 months • 6-8 months
25	How do you know that child is having enough Breast milk	• If the child urinates 6-8 times • Does not being cranky • Sleeps soundly • Any other (specify)
	PREGNANCY OUTCOME	
26	Place of delivery	
27	Type of delivery	• Normal • 2Caesarean
28	Gestational period	• <36-37 weeks • 36-37 weeks
29	Birth order	
	AGE- APPROPRIATE PRACTICE OF IYCN	

30	Are you Breast feeding at present?	• Yes • No
31	Was any prelacteals given after the birth	• Yes • No
	If yes, what?	
	If yes, why?	
32	What did you give to the child soon after birth?	• Only Breast milk • Water • Other animal/ formula milk Breast Milk
33	When was the breast feeding initiated?	• Within 1 hr • 2-3 hrs • In 24 hrs • More than 1 day
34	How often do you breastfeed your child in a day	• 5-6 times a day • 6-10 times a day • 10-12 times a day
35	Do you wash your hands before breastfeeding the child	• Yes • No
	If yes, with soap or water?	
36	Do you wash your breast before breastfeeding the child`	• Yes • No
	If yes, with what?	
37	Do you bottle feed the child?	• Yes • No
	USE OF GALACTAGOGUES	
38	Do you know what are galactagogues?	• Yes • No
	If yes, tick the galactagogues that you know	• Fenugreek • Moringa oleifera

		• Garlic • Dry garlic • Sepu • Satavari • Fennel seeds
39	During the pregnancy, did you consume any galactagogues?	• Yes • No
40	Do you consume moringa in any form during pregnancy?	• Yes • No
41	Are you consuming any galactagogue now?	• Yes • No
42	Do you consume moringa in any now?	• Yes • No
43	Any calorie dense food did you eat during pregnancy	• Yes • No
	If yes, what?	
44	Any calorie dense food did you eat now?	• Yes • No
	If yes, what?	• Methi pak • Gunder pak • Adad pak • Vasanu • Panjiri • Tal-gud laadoo • Any other (specify)

APPENDIX V

FOOD FREQUENCY

Food Group	Everyday	Twice a week	Once weekly	Once in Month	Occasionally / rare	Never	Seasonally
Galactagogues Methi Gond Garlic Suva ni bhaaji Suva seeds Ghee Dry ginger Moringa Fennel seeds Satavari Any other (specify)							

24 HR DIETARY RECALL (amount of galactagogues if consumed)

Day: **Date:**

Time	What was eaten	Raw materials	Amount consumed by lactating mothers

PHOTOGALLERY

rFreeze Dried Moringa Leaves Powder, Encapsulated in M. Oleifera Capsules and Placebo Capsules, packed into small labelled bottles and its provision to the interventional group is depicted below figures

Enrollment of the lactating mothers for the study, Provision of Moringa Capsules, Serum Blood Collection by a technical person, Compliance monitoring and neonates weight measurement is depicted in below figures.

Beautiful Gesture and Cooperation from the Gynaecology and Paediatrics Department of Jamnabai General Hospital.