HEALTHY PARENTS, HEALTHY CHILD INITIATIVE:

Report of intervention that promoted health of women desiring pregnancy and reduced Low Birth Weight and New Born Deaths in Nashik, Maharashtra, India

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MESSAGE

It is a great pleasure to know that the Public Health Department of Government of Maharashtra has successfully completed, in partnership with UNICEF and Bharati Vidyapeeth (Deemed to be University) Medical College, Pune, the community intervention trial in four blocks of Nashik district for promoting the health of the women during the preconception period for preventing adverse pregnancy outcomes, which was implemented during 2018 to 2020. The preliminary results show that the prevalence of low birth weight and neonatal mortality in the intervention blocks of Peth and Sinnar are significantly lower than the control blocks of Niphad and Trimbakeshwar of Nashik district.

In Maharashtra, the health and nutrition status of adolescent girls and women of reproductive age group needs improvement. A large proportion of women at the time of conception are medically unhealthy to conceive. As per National Family Health Survey 4, 2015-16, as high as 25.1% of Women aged 20-24 years married before age 18 years; 23.5% of Women aged 15-49 years have their Body Mass Index (BMI) below normal (BMI < 18.5 kg/m^2) and 23.4% of women age 15-49 years are overweight or obese (BMI ≥ 25.0 kg/m^2); 47.9% of non-pregnant women age 15-49 years are anaemic (<12.0 g/dl). Further, the deficiency of multiple micronutrients is also very high as shown in the Comprehensive National Nutrition Survey 2016-17. All these factors increase the risk of low birth weight babies and as high as 19.5% of the babies are born every year with a weight less than 2.5 Kg. These low birth weight babies are at high risk of death, malnutrition, poor cognitive development, various birth defects, and premature death in adult life due to non-communicable diseases.

I congratulate Public Health Department, UNICEF, and Bharati Vidyapeeth (Deemed to be University) Medical College, Pune, for this path-breaking innovation, which can be easily replicated across the state and India and will go a long way for promoting women's health and preventing adverse pregnancy outcomes.

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MESSAGE

Promoting overall health and preventing anemia among adolescent boys and girls and women in the reproductive age group are important priorities for the Government of Maharashtra. Department of Public Health has also been implementing several schemes for spacing and family planning during the last several years. Further Government has supported several initiatives for promoting the reproductive health of women in the state.

I am happy that Public Health Department pioneered the Healthy Parent, Healthy Child Initiative in two blocks of Nashik since 2018 and within two years of intervention, the innovation has been scaled up to ten districts of the state with the support of the National Health Mission. I appreciate the support of UNICEF and Bharati Vidyapeeth Deemed to be University Medical College during the implementation of this important intervention. Further, a study to assess the impact of this complex public health intervention for preventing adverse pregnancy outcomes was undertaken.

The results of this study show significant improvement in women's health, even though during last eight months of the follow-up of women (March to October 2020), Covid 19 pandemic upended lives of the people in the state. The Covid 19 pandemic resulted in lockdown in March to May 2020 and reverse migration from cities to villages, disruption of service delivery including health service delivery, reduced coverage of services like antenatal care and resulted in difficulty in the mobility of the people in Nashik district. Officials of the health department in Nashik continued the Covid 19 containment, treatment as well as health service delivery for implementation of this intervention as well as regular health services. I congratulate ASHAs, ANMs, Block Facilitators, Medical Officers, Taluka Health Officers, and all other health care workers involved in the implementation of various interventions. I hope that the learnings from this study will be very useful for guiding policy at the state and national level for promoting the health of eligible couples and preventing adverse pregnancy outcomes including maternal death, newborn death, low birth weight, and childhood malnutrition.

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FOREWORD

Public Health Department, Government of Maharashtra has pioneered the primary health care innovation in two blocks of Nashik district for promoting the health of women at the preconception period for preventing different adverse pregnancy outcomes. The department partnered with UNICEF and Bharati Vidyapeeth (Deemed to be University) Medical College, Pune for rollout of this innovation since 2018. These interventions resulted in significant improvement in the health of women in terms of reducing anaemia and in promoting weight and thus the body mass index among those women who participated in the study in the intervention blocks, Significant improvement in the body mass index (BMI) among women who had low (BMI < 18.5 kg/m^2) was demonstrated within a short period of a month from the baseline assessment. Further, there was a significant improvement in the Hb% among the anaemic women. Therefore the state decided to scale up the innovation in the ten most disadvantaged districts in the state (the entire district in nine districts and two blocks of Amravati district) since 2019 in a phased manner with the support of the National Health Mission, Government of India.

The health department intends to intensify the intervention in the eligible aspiring couples in these ten districts including promotion of consumption of green leafy vegetables for improving multiple micronutrients consumption during 100 days before conception.

There is evidence that this innovation has greatly facilitated the work of health care providers in mobilizing the community for different Reproductive Preconception, Maternal, Neonatal, Child health, and adolescents (RPMNCHA) programme in the intervention areas. The department is committed to promoting this innovation in a major way to ensure that every pregnancy is planned and wanted, which will greatly empower women to decide on reproductive health issues and in that process promote having a healthy intelligent newborn.

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Date : 26/07/2021

Message

The pre-conception care has been found to substantially decline the maternal and neonatal mortality in western countries. The pre-conception care is a missing aspect in our RMNCH+A program. WHO and Government of India have recommended universal inclusion of pre-conception care in the program. Directorate of Health Services, Public Health Department Government of Maharashtra, in collaboration with Bharati Vidyapeeth Deemed to be University Medical College, Pune, with UNICEF's support have successfully implemented the pre-conception care project in two blocks in Nashik District. The Department of Community Medicine was very enthusiastic while implementing the project. The project included two comparison blocks also. The results have been found to be promising in the background of results of NFHS rounds of surveys. The adverse pregnancy outcomes, low birth weight, preterm delivery and neonatal mortality declined along with an improvement in BMI and anemia among women.

Bharati Vidyapeeth Deemed to be University Medical College, Pune, would be pleased to work in these areas with UNICEF and the Maharashtra Government in the future also. Upscaling of these services has already been executed. I am sure it will benefit the women from rural and tribal areas. I wish a grand success in upscaling the project and anticipate a steady decline in neonatal mortality in Maharashtra.

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ABBREVIATIONS

Abbreviation	Complete term
ANC	Antenatal Care
ANM	Auxiliary Nurse Midwife
ASHA	Accredited Social Health Activist
AV	Audio-visual
AWW	Anganwadi workers
BCC	Behavioral Change and Communication
BF	Block Facilitator
BMI	Body Mass Index
CTRI	Clinical Trial Registry of India
DLHS	District Level Household Survey
DOHaD	Developmental Origins of Health and Disease
EDD	Expected Delivery Date
FA	Folic Acid
FGD	Focus Group Discussions
GOM	Government of Maharashtra
GOI	Government of India
Hb	Haemoglobin
HIV	Human Immunodeficiency Virus
HSC	Higher Secondary-school Certificate
IFA	Iron and Folic Acid
INAP	India Newborn Action Plan
ITI	Industrial Training Institute
LBW	Low Birth Weight
LHV	Lady Health Visitor
LMICs	Low- and Middle-Income Countries
MO	Medical Officer
MPW	Multi-purpose Worker
NCDs	Non-communicable Diseases

ABBREVIATIONS

Abbreviation	Complete term
NFHS	National Family Health Survey
OGTT	Oral Glucose Tolerance Test
PAHO	Pan American Health Organization
PCC	Preconception Care
PG	Post Graduate
PHC	Primary Health Centers
RBSK	Rashtriya Bal Swasthya Karyakram
RMNCHA	Reproductive, Maternal, Neonatal, Child health and Adolescent
RPMNCHA	Reproductive, Preconception Maternal Neonatal Child Health and Adolescents programme
RTI	Reproductive Tract Infection
SC	Sub-center
SD	Standard Deviation
SDG	Sustainable Development Goals
SGA	Small for Gestational Age
SMS	Short Message Service
SPSS	Statistical Package for Social Sciences
SSC	Secondary School Certificate
STI	Sexually Transmitted Infection
TSH	Thyroid Stimulating Hormone
UNICEF	United Nations Children Funds
VDRL	Venereal Disease Research Laboratory
VHSND	Village Health Sanitation and Nutrition Day
WHO	World Health Organization

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EXECUTIVE SUMMARY

Since the nineteen-eighties, there has been growing evidence on the benefits of preconception health promotion for preventing adverse pregnancy outcomes[1] and in 2006, for the first time in the world, a national health authority recommended strategies for preconception care for the entire country in the United States.[2]

For the first time during the nineteen eighties, the association between premature death due to ischemic heart disease in adult life and poor nutrition in early life in England and Wales was also described[3]. In 1994, Prof. David Barker, analysing the association between birth weight and adult coronary diseases in Hertfordshire near London, hypothesized that fetal environment is a significant determinant of non-communicable diseases, such as cardiovascular disease, stroke, hypertension, type 2 diabetes, and obesity in adult life[4].

In the rural Gambia, researchers observed that adults conceived during the rainy season of July to November in the nineteen forties live longer as compared to those who were conceived during the remaining period of the year. Fetal programming of the immune system was considered to be the reason behind the association of longevity and season of conception[5]. Plenty of green leafy vegetables, rich in different B complex vitamins and folic acid, grow during the rainy season in Gambia. These green leafy vegetables, consumed by would-be mothers, help in the methylation of genes of the female gamete, which regulate the immune system of the offspring[6]. The functioning of genes during the entire life is modulated through these 'epigenetic' modifications of the genes, such as tagging gene regions with methyl groups of chemicals. As mentioned already, this methylation process requires key nutrients including folate, vitamins B2, B6 and B12, choline and methionine[7]. It is said that "You are what you eat". In addition, evidence emerged: "You are what your mother ate[8] (some two weeks before conception and within first two days or so of conception)"[9,10].

In India, despite the decline in neonatal mortality in recent times, the sheer number of these deaths is considerably large. The common causes of neonatal mortality are low birth weight (LBW) and preterm birth, birth asphyxia, and infection. In Maharashtra, the prevalence of LBW and preterm babies is very high and despite extensive efforts for prevention of these, the success has been limited. The indirect causes of LBW and neonatal mortality are unplanned pregnancies, maternal under-nutrition, pregnancies in adolescents, poor quality services or inability to access care during the antenatal period, during labor, and during the neonatal period, etc.

Malnutrition is the predominant risk factor for death in children younger than 5 years in India in 2017, and as high as 68.2% of under five death in India is caused by under-nutrition, which is much

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10 https://www.bbc.com/news/magazine-34222452.

higher than the global average of 45%. Under nutrition is the leading risk factor for health loss for all ages, responsible for 17.3% of the total disability-adjusted life years (DALYs). The prevalence of low birth weight in India in 2017 was 21.4%; child stunting 39.3%, child wasting 15.7%, child underweight 32.7%, anaemia in children 59.7%, anaemia in women 15–49 years of age 54.4%, exclusive breastfeeding 53.3%, and child overweight 11.5%.[11]

Primary Health care interventions may be implemented for promoting women's health and nutrition status and promoting preconception care (PCC), for preventing low birth weight and prematurity. Yet, PCC and interventions for the prevention of LBW and prematurity have not been systematically scaled up in Maharashtra or in India as yet.

Public Health Department, Government of Maharashtra implemented the innovation of Healthy Parents, Healthy Child Initiative in Peint and Sinnar blocks of Nashik district during 2018 to 2020 with support from UNICEF and Bharati Vidyapeeth (Deemed to be University) Medical College, Pune. This complex public health intervention aimed to assess the feasibility and impact of promoting health among eligible women age 15-45 years, who were planning pregnancy, through a combination of social mobilization and behaviour change communication and provision of health services (including clinical examination, laboratory tests, treatment as appropriate) for preventing adverse pregnancy outcomes among themselves and the newborn babies. The focus was on the prevention of LBW, prematurity, birth defects, and neonatal mortality. The innovation was conceptualized primarily for the prevention of low body mass index (BMI), anaemia, and adolescent pregnancy among women planning pregnancy thereby preventing LBW and prematurity, and neonatal mortality. India being the capital of underweight adolescents, women, and LBW babies in the world, the successful implementation of such a project can generate evidence for state or nationwide replication for promoting the health of women and preventing adverse pregnancy outcomes. Other potential benefits in newborn includes prevention of congenital anomalies, childhood malnutrition, cognitive impairment and premature mortality, and risk of non-communicable diseases in adult life as LBW and prematurity increases the risk of all these conditions.

The study implemented for assessing the effect of this complex public health intervention[12] included community-based intervention trials and focus group discussions and data triangulation from different sources. The community-based intervention trial had two arms of an equal number of geographical blocks. We selected four blocks from Nashik district, Maharashtra (two each in intervention and comparison arms). Each of the study arms included one tribal and one non-tribal block. The PCC interventions were implemented in Peint (tribal) and Sinnar (non-tribal) blocks, in addition to routine Reproductive, Maternal, Neonatal, Child Health and Adolescent (RMNCHA), whereas in the adjacent Trimbakeshwar (tribal) and Niphad (non-tribal) blocks, only routine RMNCHA services were implemented. A total of 7,874 women were enrolled in the project who desired pregnancy during the succeeding year: 3,574 women in the intervention and 4,301 women in the comparison arm. They were called **eligible aspiring women**,

11 India State-Level Disease Burden Initiative Malnutrition Collaborators The burden of child and maternal malnutrition and trends in its indicators in the states of India: the Global Burden of Disease Study 1990–2017, The Lancet Child and Adolescent Health, Volume 3, Issue 12, P 855-870, December 1, 2019 DOI:https://doi.org/10.1016/S2352-4642(19)30273-1.

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as they were in the reproductive age group and were aspiring to have a healthy intelligent newborn. The following were focus areas for PCC interventions that were implemented in the study arm of eligible aspiring women:

1. Achieving normal (BMI) before conception.
2. Preventing and treating anaemia with Iron Folic Acid and deworming medicines.
3. Periconceptional folic acid to reduce neural tube defects.
4. Quitting tobacco, alcohol to reduce LBW.
5. Preventing pregnancy in adolescent girls to avoid hazards of teenage pregnancy and to have optimal inter-pregnancy interval following miscarriage or childbirth.
6. Detecting and treating RTI/STIs before conception.
7. Detecting and managing chronic diseases before conception.

The Interventions involved clinical examination; laboratory investigations; treatment, counselling, and referral as needed; six-monthly deworming; prophylactic IFA supplementation to all women; folic acid supplementation either with iron and/or separately; family planning services. All interventions were supported by BCC using different communication channels. The women were followed up and provided services for a period of 27 months (from August 2018- October 2020). The project was approved by Bharati Vidyapeeth (Deemed to be University) Medical College Institutional Ethics Committee. The study was registered under Clinical Trial Registry India (CTRI) vide registration number CTRI/2018/06/014657 dated 28th June 2018. Written informed consent was obtained from all participants before inclusion in the study.

Significant improvement in the BMI from baseline to 27 months follow-up was observed in the intervention arm. The mean BMI at baseline was 19.45 ± 3.03 kg/m^2 that changed to 20.79 ± 2.36 kg/m^2 at the last visit. It was observed that the proportion of low BMI (<18.5 kg/m^2) had decreased over the period (40.7% to 15.35%) and that of normal BMI (18.5-25 kg/m^2) had increased (54.16% to 80.6%). Further, there was a reduction in weight and BMI among women with BMI>25 kg/m^2 at baseline and was statistically significant. The mean Haemoglobin (Hb%) at baseline was 10.56 ± 1.25 gm%, which changed to 11.10 ± 1.07 gm% at quarter 7 visit. There was a slight reduction in the mean Hb at quarter 8 visit in August 2020 (10.28 ± 1.35 gm%); that may be due to the impact of the COVID- 19 pandemic, which started in Maharashtra in March 2020. It is observed that the proportion of low Hb <11 had decreased (71.96% to 57.37%) over the period. The improvement in BMI and anaemia with the number of visits was statistically significant (chi-square for trend p<0.001).

The prevalence of hypertension among enrolled women in intervention blocks at enrolment was 2.27%. The prevalence of other chronic conditions like diabetes, hypothyroidism, or reproductive or sexually transmitted infections was very low. Only one woman was diagnosed with Human Immunodeficiency Virus (HIV) positive and Venereal Disease Research Laboratory (VDRL) positive. There was no woman diagnosed with sickle cell disease.

Among 7,875 enrolled women, 45.63% (1,721) and 43.52% (1,872) from intervention and comparison blocks respectively conceived and had pregnancy outcomes during the study period. **The prevalence of LBW, preterm birth, and early neonatal death was significantly lower in the intervention blocks as compared to the comparison blocks; which implies the positive effect of intervention in reducing the adverse pregnancy outcomes.** The improvement in women's health and reduction in adverse

pregnancy outcomes is a remarkable achievement for three reasons:

1. There has been no improvement in the reduction of the prevalence of underweight (low BMI) and anaemia among women aged 15-49 years in Nashik district between 2015-16 and 2019-20 as shown in National Family Health Survey (NFHS) 5- 2019-20. The proportion of women aged 15-49 years with low BMI remained at 25.8% and 25.6% and the proportion of non-pregnant women aged 15-49 years who are anaemic (< 12 gram/dl) remained at 55.4% and 54.6% during 2015-16 and 2019-20 respectively in Nashik district[13]. At the state level, during this period, while the proportion of women aged 15-49 years with low BMI reduced slightly from 23.5% to 20.8% and the proportion of non-pregnant women age 15-49 years who are anaemic (< 12 gram/dl) increased from 47.9% to 54.5%[14]. The improvement in BMI and anaemia among women in intervention blocks remained significant despite the economic slowdown, Covid 19 pandemic, and evidence of rural economic distress.
2. This is probably the first intervention in the world, where the health and nutrition status of women in the preconception period have improved primarily through BCC utilizing the existing government programme like Anaemia Mukt Bharat, without any supplementary nutrition or cash transfer. Among underweight women, weight and BMI significantly improved primarily through BCC.
3. The results were achieved through a low-cost primary health care approach, involving the existing government health system utilizing a very low budget, which can be replicated not only in Maharashtra but in whole India and probably other low and middle-income countries of the world for promoting women's health in the preconception period and reducing the adverse pregnancy outcomes.

To our knowledge, this is one of the first interventions in the world, where optimizing BMI, preventing anaemia among married women aged 15-45 years planning pregnancies resulted in prevention of LBW, prematurity, and early neonatal mortality. Recent evidence highlights that low BMI in the preconception period is one of the most important determinants of LBW and small for gestational babies[15,16]. In India, the prevalence of moderate and severe underweight among girls of 5-19 years was 22.7%, which is highest among all the countries of the world in 2016[17]. Further, India has the highest burden of underweight among women of reproductive age group, estimated at 100 million, contributing to almost 42% of the global burden of underweight women[18]. In effect, India is also the capital of LBW babies and contributed to 42% of the global LBW burden in 2010[19].

13 Ministry of Health and Family Welfare, Government of India, National Family Health Survey 5, 2019-20 State Fact Sheet Maharashtra, 2020 (http://rchiips.org/nfhs/NFHS-5_FCTS/MH/Nashik.pdf).

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18 Al Kibria GM, Swasey K, Hasan MZ, Sharmeen A, Day B. Prevalence and factors associated with underweight, overweight and obesity among women of reproductive age in India. *Glob Health Res Policy.* 2019;4:24. Published 2019 Sep 6. doi:10.1186/s41256-019-0117-z.

19 Lee AC, Katz J, Blencowe H *et al.* National and regional estimates of term and preterm babies born small for gestational age in 138 low-income and middle-income countries in 2010 [published correction appears in Lancet Glob Health. 2013 Aug;1(2):e76]. *Lancet Glob Health.* 2013;1(1):e26-e36. doi:10.1016/S2214-109X(13)70006-8.

Within a few weeks of improved dietary practices (increasing the quantity and frequency of meals) at the household level, there was a statistically significant improvement in the weight and BMI of women planning their pregnancies, which also probably contributed to the reduction in anaemia together with the consumption of Iron Folic Acid tablets.

Following the improvement in the health status of enrolled women in Peint and Sinnar blocks of Nashik during the year 2019, the Government of Maharashtra (GOM) started to scale up the programme in four aspirational districts of Gadchiroli, Nandurbar, Washim and Osmanabad, and Melghat region of Amravati district. Further in 2020-21, GOM initiated the scale up the programme in five tribal districts of Nashik, Palghar, Chandrapur, Yavatmal, and Gondia. The scale-up is supported by the Government's National Health Mission. Based on the experience and evidence of implementation of the innovation in Nashik, our recommendations are as follows:

a. Scale-up these interventions at the primary health care level to the entire state and beyond:

This is a classic primary health care innovation that promotes universal health coverage among women in the reproductive age group. This innovation should be replicated across the state for promoting the health and nutrition status of the women in the preconception period, which was very poor even before the Covid 19 pandemic. Covid 19 pandemic has greatly worsened the situation further. Systematic social and BCC strategies can be implemented within a short period, while simultaneously strengthening the health system for delivering PCC health services. The PCC should be integrated with the medical and nursing curriculum as well as for secondary school curriculum. The concept of the first 1000 days of life should be expanded to 1200 days of life, in which 200 days before conception are included; to prioritize the promotion of the health of eligible aspiring couples to promote their health before conception.

b. Integrate monitoring of the weight and body mass index of all children and adolescents and women of reproductive age group in the existing government programmes

As the prevalence of underweight girls aged 5 to 19 years and women of reproductive age group is very high in India, it is very important to integrate monitoring of the weight and BMI to the existing adolescent health programmes like Rashtriya Kishore Swasthya Karyakram, Rashtriya Bal Swasthya Karyakram, School Health and Wellness Ambassador Initiative as well as women's health programme and implement BCC and food supplementation programme especially among those with low BMI. Self assessment tools may be promoted.

c. Expand evidence-based strategies like promotion of diets rich in multiple micronutrients in the preconception period:

There is a high prevalence of multiple micro-nutrients deficiencies among adolescent girls in Maharashtra. A combination of promoting a balanced diet, food fortification, and the use of multiple micronutrients should be implemented for addressing the multiple micronutrient deficiencies during the preconception period. This will assist in preventing birth defects and other adverse pregnancy outcomes. Further, simple interventions like promoting consumption of green leafy vegetables, locally available nutrient-rich food items during the

preconception period should be promoted which will prevent multiple micronutrient deficiencies. A recent trial in Indian and Pakistani women demonstrated that commencing daily lipid-based multiple micronutrient supplements at least three months before conception was associated with decreases of 44% in stunting, 24% in wasting, and 26% SGA when compared to the control group.[20]

d. Promote preconception health among men:

It is very critical to promote the PCC among men as the couple needs to decide and ensure that every pregnancy is wanted and planned. Further, it is an opportunity for involving men for ensuring healthy pregnancy outcomes, promoting women's reproductive health, preventing gender bias and discrimination against women, preparing men for fatherhood.

e. Strengthen primary health care and design social protection schemes for poor women in the preconception period for preventing the intergenerational cycle of malnutrition

There is strong evidence between poverty and poor health. Social protection schemes in the form of subsidized food grains or cash transfers to the newly married couple through public distribution system may be initiated for promoting the health of women for those women, whose BMI is less than 18.5 kg/m^2 during the preconception period.

20 Dhaded SM, Hambidge KM, Ali SA, Somannavar M, Saleem S, Pasha O, et al. (2020) Preconception nutrition intervention improved birth length and reduced stunting and wasting in newborns in South Asia: The Women First Randomized Controlled Trial. PLoS ONE 15(1): e0218960. https://doi.org/10.1371/journal. pone.0218960

i. Importance of preconception care (PCC) for health and longevity

Since the nineteen-eighties, there has been growing evidence on the benefits of preconception health promotion for preventing adverse pregnancy outcomes and in 2006, for the first time in the world, a national health authority recommended strategies for preconception care for the entire country in the United States.

During the nineteen-eighties, for the first time, the association between premature death due to ischemic heart disease in adult life and poor nutrition in early life in England and Wales was described. In 1994, Prof. David Barkar, analysing the association between birth weight and adult coronary diseases in Hertfordshire near London, hypothesized that fetal environment is a significant determinant of non-communicable diseases, such as cardiovascular disease, stroke, hypertension, type 2 diabetes, and obesity in adult life.

In the rural Gambia, researchers observed that adults conceived during the rainy season of July to November live longer as compared to those who were conceived during the remaining period of the year. Fetal programming of the immune system was considered to be the reason behind the association of longevity and season of conception. Plenty of green leafy vegetables, rich in different B complex vitamins and folic acid, grow during the rainy season in Gambia. These green leafy vegetables, consumed by would-be mothers, help in the methylation of genes of the female gamete, which regulate the immune system of the offspring. The functioning of genes during the entire life is modulated through these 'epigenetic' modifications of the genes, such as tagging gene regions with methyl groups of chemicals, As mentioned already, this methylation process requires key nutrients including folate, vitamins B2, B6, and B12, choline and methionine. It is said that "You are what you eat". In addition, evidence emerged: "You are what your mother ate[21] (some two weeks before conception and within first two days or so of conception)".

The health of would-be parents during the preconception period is one of the most critical determinants of the health of the offspring. Factors like diet and nutrition, smoking and alcohol consumption, presence of different diseases in would-be parents modulate the genetic programming of the male and female gamete, which affect the long-term risk of the disease, health, and life expectancy of the offspring. Preconception health promotion in women and men prevents death and morbidity among the offspring in addition to preventing low birth weight (LBW), prematurity, and poor cognitive development.[22] Further, preconception care prevents childhood malnutrition and non-communicable diseases (NCDs) in the adult life of the offspring by preventing LBW and prematurity. The first-ever Lancet series that promoted PCC was published in 2018[23]. Rashtriya Bal Swasthya Karyakram: Journey of The First 1000 Days was launched by the Ministry of Health and Family Welfare, Government of India[24] in April 2018, which

21 Kuzawa, C., You are what your mother ate? May 2013 American Journal of Clinical Nutrition 97(6). https://www.researchgate.net/publication/236665104_You_are_what_your_mother_ate/stats.
22 Dean SV, Imam AM, Lassi ZS, Bhutta ZA. Systematic Review of Preconception Risks and Interventions, 2014, Division of Women and Child Health, Aga Khan University, Karachi, Pakistan: https://globalmotherchildresearch.tghn.org/site_media/media/articles/Preconception_Report.pdf.
23 Preconception Health. The Lancet series. April 17, 2018. (https://www.thelancet.com/series/preconception-health).
24 Rashtriya Bal Swasthya Karyakram: Journey of The First 1000 Days was launched by Ministry of Health and Family Welfare, Government of India.

focuses on educating the parents and caregivers about healthy behaviour and practices during preconception, antenatal and postnatal period for ensuring the best during first 1000 days of life of the child.

ii. Situation of LBW, preterm birth complication, and under-five mortality (U5M) in India

In India, preterm birth complications are the most important cause of U5M (25%); followed by pneumonia (13%); intrapartum-related events (11%); and diarrhea (10%)[25]. India has the largest number of LBW babies in the world. LBW is defined as a newborn with a birthweight less than 2500 grams. Out of an estimated 18 million LBW infants born globally every year, about 7.5 million are born in India (42%). Globally, LBW babies constitute only about 14% of children born but they account for 60–80% of neonatal deaths[26]. Further, LBW babies are at increased risk of stunting and poor cognitive development, and NCDs in the adult life[27]. Preterm birth is defined as birth taking place before 37 completed weeks of pregnancy. In 2012, an estimated 15 million babies worldwide (11% of live births) were born preterm. Preterm babies are at very high risk of dying during the neonatal and post-neonatal period, growth retardation, poor cognitive development, and chronic diseases in adulthood.

After the pioneering work by Prof. David Barker that LBW babies have a higher risk of premature death, many trials were initiated for the prevention of LBW in India[28]. Cohort studies were implemented in Mysore, Vellore, Delhi, and Pune for understanding the risks associated with LBW[29]. A randomized controlled trial was implemented in 2005 in Mumbai to assess the impact of improving dietary intake of multiple micronutrients by providing a snack made of green leafy vegetables, fruits, and milk powder. The trial was conducted among women in the preconception period and during ANC, for reducing LBW babies, however it did not show a significant reduction[30]. The Healthy Life Trajectories Initiative, which follows a developmental origin of health and diseases (DOHaD), was initiated with funding from the National Natural Science Foundation of China, the Department of Biotechnology of India, the Medical Research Council of South Africa, and the Canadian Institutes of Health Research, in collaboration with the World Health Organization (WHO). The initiative is based on the concept that environmental factors interact with genes during conception, fetal life, infancy, and early childhood, and that this programming affects the individual's health later in life. As a part of this initiative, four intervention studies were implemented in Soweto, Mysore, Shanghai, and three provinces of Canada[31].

25 Liu L *et al.* Global, regional, and national causes of child mortality in 2000–13, with projections to inform post-2015 priorities: an updated systematic analysis; Lancet 2015; 385: 430–40 Published Online October 1, 2014 http://dx.doi.org/10.1016/S0140-6736(14)61698-6.
26 Lee AC, Katz J, Blencowe H *et al.* National and regional estimates of term and preterm small for gestational-age in 138 low-middle income countries in 2010. Lancet Glob Health 2013; 1: e26–36.
27 Black RE, Victora CG, Walker SP *et al.* Maternal and child undernutrition and overweight in low-income and middle income countries. Lancet 2013; 382: 427–51. 2.
28 Fall CHD. Multiple micronutrient supplementation during pregnancy in low-income countries: A meta-analysis of effects on birth size and length of gestation, *Food and Nutrition Bulletin*, vol. 30, no. 4 © 2009 (supplement), The United Nations University.
29 Yajnik CS *et al.* Neonatal anthropometry: the thin fat baby. The Pune Maternal Nutrition Study. The International Journal of Obesity, 27, 173-180 (2003).
30 Potdar RD *et al.* Improving women's diet quality preconceptionally and during gestation: effects on birth weight and prevalence of low birth weight—a randomized controlled efficacy trial in India (Mumbai Maternal Nutrition Project), Am J Clin Nutr 2014;100:1257–68.
31 Government of Canada. Canadian Institutes of Health Research. (http://www.cihr-irsc.gc.ca/e/49510.html).

The risk factors for LBW include poor maternal nutrition including maternal underweight[32], maternal anaemia (in low-income countries, 25% of LBW is attributable to maternal anaemia during pregnancy[33]), medical conditions related to chronic hypertension and preeclampsia/eclampsia[34], and maternal age. Pre-pregnancy BMI is an important predictor of LBW and preterm babies and is more important than weight gain during pregnancy[35]. Infants born to teenagers and women at an advanced age are at greater risk for stillbirth, preterm birth, neonatal death, congenital anomaly, and LBW[36].

Maternal education, BMI less than 18.5 kg/m^2, short stature (height less than 145 cm), and lack of antenatal visits (less than 4 visits) are significant predictors of LBW in India. Women with 'no education had the greatest risk of giving birth to an infant with LBW followed by women with "primary education[37]. BMI of mothers is a major risk factor for childhood undernutrition in India. The five most important predictors of childhood stunting and underweight include maternal underweight along with short maternal stature, a mother with no education, extreme poverty, and poor dietary diversity[38].

iii. Primary Health Care approach for promoting the health of women in the preconception period for preventing adverse pregnancy outcomes

The Global Primary Health Care movement was launched in 1978 in Alma Ata for achieving Health for All by 2000. The Asthana Declaration 2018 reaffirmed Primary Health Care as the cornerstone for achieving Universal Health Coverage and SDG3. The elements of Primary Health Care include 1. Health Education to the people prevailing health problems and methods of preventing and controlling them; 2. Promotion of food supply and proper nutrition; 3. An adequate supply of safe water and basic sanitation; 4. Maternal and child health care and family planning; 5. Immunization against the major infectious diseases; 6. Prevention and control of locally endemic disease; 7. Appropriate treatment of common diseases and injury, 8. Provision of essential drugs[39].

Access to food and adequate nutrition, safe water, and basic sanitation play a major role in the health of the individual and the population. These, together with education, employment, income, and poverty are broadly included as social determinants of health, which play a major role in the health of

32 Zhen H *et al.* Maternal underweight and the risk of preterm birth and low birth weight: a systematic review and meta-analyses, International Journal of Epidemiology 2011;40:65–101 doi:10.1093/ije/dyq195.
33 Rahman MM, Abe SK, Rahman MS *et al.* Maternal anaemia and risk of adverse birth and health outcomes: systematic review and meta-analysis. Poster presentation. Twenty-second Cochrane colloquium, Hyderabad India, 26 September 2014 (https://colloquium. cochrane.org/abstracts/maternal-anaemia-and-risk-adverse-birth-andhealth-outcomes-low-and-middle-income, accessed 13 October 2014.
34 Ota E, Ganchimeg T, Morisaki N *et al.* Risk factors and adverse perinatal outcomes among term and preterm infants born small-for-gestational-age: secondary analyses of the WHO Multi-Country Survey on Maternal and Newborn Health. PLoS One. 2014;9 (8):e105155. doi:10.1371/journal.pone.0105155.
35 Nohr EA *et al.* Combined associations of prepregnancy body mass index and gestational weight gain with the outcome of pregnancy. Am J Clin Nutr 2008; 87: 1750–59.
36 Weng YH, Yang CY, Chiu YW. Risk Assessment of Adverse Birth Outcomes in Relation to Maternal Age. PLoS ONE. 2014; 9(12): e114843. doi:10.1371/journal.pone. 0114843.
37 Kader M and Perera NK. Socio-Economic and Nutritional Determinants of Low Birth Weight in India. North American Journal of Medical Sciences. 2014 Jul; 6(7): 302–308. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4114006/?report=classic.
38 Corsi DJ *et al.* Risk factors for chronic undernutrition among children in India: Estimating relative importance, population attributable risk and fractions, Social Science & Medicine, online November 14, 2015, doi: 10.1016/j.socscimed.2015.11.014.
39 World Health Organization, UNICEF, Declaration of Alma-Ata International Conference on Primary Health Care, Alma-Ata, USSR, 6-12 September 1978.

the population. It is estimated that socio-economic factors like education, employment, income and poverty, family and social support contribute to 40% of population health; behaviours like diet and exercise, tobacco and alcohol use, sexual behaviour contribute to 30%; health care (access and quality) contribute to 20% and physical environment (housing, environmental quality) contribute to 10%; which eventually contributed to the quality and length of life[40].

A recent analysis of the under-five mortality trend between 1990 and 2010 found that about half of the reduction is attributable to the non-health sector factors including better gender equality, education, infrastructure, improved water and sanitation, and economic growth[41].

One of the fundamental guiding principles of sustainable development goals (SDGs) is the interdependence between different goals. The SDG 3 of good health and wellbeing cannot be achieved without achieving the SDG 1 of no poverty, SDG 2 of zero hunger, SDG 4 of quality education, SDG 5 of gender equality, and SDG 6 of clean water and sanitation. Thus, social mobilization and behaviour change at the household level are critical for promoting these goals.

Maharashtra is one of the most prosperous states in India, yet anaemia and underweight in women are a major public health concern. As high as 48% of the ever-married women of 15–49 years of age were anemic, 23.5% had low BMI (< 18.5 kg/m^2) and 23.4% had high BMI (> 25 kg/m^2) during 2015–16. Also, 25% of women aged 20-24 years were married before the legal age of 18 years and 8.3% of women aged 15-19 years were mothers or were pregnant at the time of the National Family Health Survey (NFHS) 4, 2015-16. These factors contribute to the high prevalence of LBW babies in the state (19.5%)[42]. The brainstorming sessions between UNICEF and Public Health Department officials on promoting the health of women during the preconception period for preventing LBW babies paved way for planning the Primary Health Care Initiative in a few blocks on a pilot basis in 2016. The guidelines including the reporting formats were drafted; training and communication materials were designed during 2017. Finally, the programme was rolled out in Sinnar (non-tribal) and Peint (tribal) blocks of Nashik district in 2018. The programme was named as Healthy Parents Healthy Child Initiative to highlight the importance of health promotion in couples for the promoting health of the newborn and for preventing adverse birth outcomes along the continuum of Reproductive, Preconception, Maternal, Newborn, Child Health and Adolescents (RPMNCHA). For assessment of the effect of this innovation in terms of reduction of adverse birth outcomes, a study was implemented in both, the intervention blocks as well as in two comparison blocks of Niphad (non-tribal) and Trimbakeshwar (tribal), which were similar in socioeconomic and demographic parameters. The detailed goal and objectives, design and methodology, findings and discussion, and recommendations are given below.

40 Hood *et. al.* County Health Rankings: Relationships Between Determinant Factors and Health Outcomes Am J Prev Med 2016;50(2):129–135.
41 Bishai DM, Cohen R, Alfonso YN, Adam T, Kuruvilla S, Schweitzer J. Factors Contributing to Maternal and Child Mortality Reductions in 146 Low- and Middle-Income Countries between 1990 and 2010. PLoS ONE. 2016; 11(1): e0144908. doi:10.1371/journal.pone.0144908 Editor: Niko Speybroeck, Université.
42 Government of India, Ministry of Health and Family Welfare, National Family Health Survey 2015-16.

CHAPTER TWO

GOAL AND OBJECTIVES

Goal:

To assess the effect of the interventions to reduce the preconception risk factors among women desiring pregnancy and thereby prevent adverse pregnancy outcomes in them as well as in newborn babies in the selected blocks of Nashik district, Maharashtra.

Primary objective:

To measure the change in pregnancy outcomes (LBW, premature delivery, abortion, stillbirth, early neonatal death).

Secondary objectives:

i. To measure the change in known selected risk factors (low BMI, and anaemia)among women planning their pregnancy.

ii. To measure the association of pregnancy outcomes with selected known risk factors (addiction, consanguineous marriages, age at marriage, low BMI, and anaemia).

CHAPTER THREE

METHODS AND MATERIALS

i. Study design:

The main project was the implementation of a package of preconception interventions to measure its effect on pregnancy outcomes in four blocks of Nashik district, Maharashtra.

However, the project comprised several steps before intervention study and used three different approaches:

- **Cross-sectional baseline survey:** A cross-sectional survey was carried out to collect the baseline information about preceding year pregnancy outcomes, and selected risk factors through house-to-house visits. A similar end line survey was also planned, however could not be conducted due to the Covid-19 situation.
- **Qualitative study:** Focus Group Discussions (FGDs) were conducted among women (2 FGDs in each block) to determine their knowledge, attitude, and practices regarding PCC. Similarly, FGDs were conducted among health care providers (1 FGD in each block) to determine knowledge, attitude regarding PCC and determine challenges and solutions in introducing PCC in the public health care system.
- **Intervention study:** Community-based intervention trial was carried out among the women enrolled at the beginning of the study to determine the effect of the intervention package on their health status and pregnancy outcome. The study had two arms, intervention and comparison arm. The following seven aspects were focused on through intervention provided to the women enrolled in the intervention arm.
- Achieving normal BMI before conception.
- Preventing and treating anaemia with Iron Folic Acid and deworming medicines.
- Periconceptional folic acid to reduce neural tube defects.
- Quitting tobacco, alcohol to reduce LBW.
- Preventing pregnancy in adolescent girls to avoid hazards of teenage pregnancy and to have optimal inter-pregnancy interval following miscarriage or childbirth.
- Detecting and treating RTI/STIs before conception.
- Detecting and managing chronic diseases before conception.

The Interventions involved

- Clinical examination.
- Laboratory investigations.
- Treatment, counselling, and referral as needed.
- Six monthly deworming.
- Prophylactic IFA supplementation to all women.
- Folic acid supplementation either with iron and/or folic acid supplementation.
- Family planning services.
- BCC inclusive of the above points.

All these interventions had social mobilization and BCC using different media as well as service delivery at existing government health facilities.

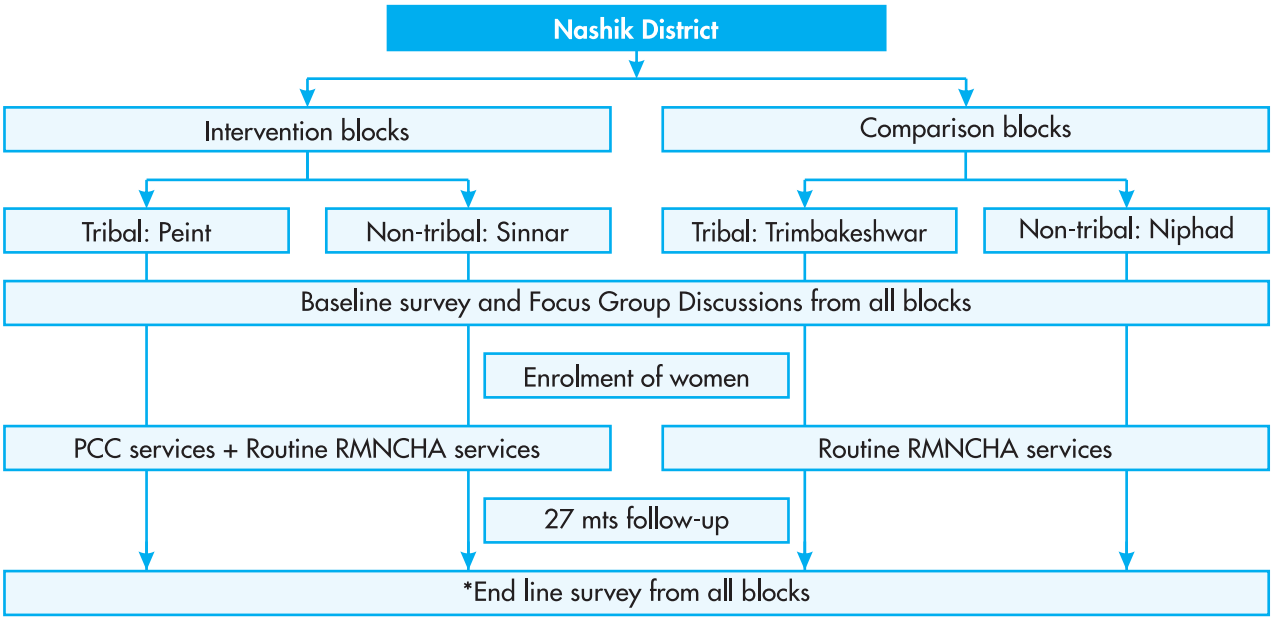
ii. Study settings:

The study was carried out in Nashik district, Maharashtra, India. The district has about 57.5% rural population and 25.6% tribal population. The Government of Maharashtra (GOM) had notified nine out of 15 blocks as tribal. The geographical location of these blocks is given in Figure 1.

Figure 1: Geographical location of study blocks, Nashik District, 2018-19

As mentioned above, one tribal (Peint) and one non-tribal (Sinnar) block were randomly selected for intervention, and one adjacent tribal (Trimbakeshwar) and non-tribal (Niphad) block were selected for comparison (Figure 2). The comparison arm received the routine RMNCHA services while the intervention arm received the selected preconception interventions in addition to routine RMNCHA services, as highlighted above.

Figure 2: Illustration of the study design



*End line survey could not be conducted due to COVID-19 pandemic. The results up to the last follow-up in October 2020 are presented hereafter.

The study area covered 28 PHCs, details of which are been provided in table 1. The total population of these four blocks as per the last census (Census 2011) was 1,127,902 (rural and urban). The study is implemented in rural and tribal areas covered a population of 976,149 individuals as per Census 2011. Table 1 describes the demographic information of these selected blocks as per Census 2011.

Table 1: Demographic information of study area as per Census 2011.

Block	Population as per Census	Area (km^2)	Pop. Density	PHCs	No. of villages
Sinnar (Non-tribal, Intervention)	281091	1,343.79	258	6	129
Peint (Tribal, Intervention)	119838	556.64	215	7	144
Niphad (Non-tribal, Comparison)	418853	1,048.63	470	9	134
Trimbakeshwar (Tribal, Comparison)	156367	900.27	187	6	125

iii. Study period:

The overall study period was from April 2018 to July 2021. The baseline survey was conducted from May to July 2018; the FGDs were conducted in June 2018; the women were enrolled in July – August 2018, after the clinical trial registry (CTRI); and the intervention period was from August 2018-October 2020 (27 months).

iv. Sample size estimation:

The information from District Level Household Survey – 4 (DLHS) about a few adverse pregnancy outcomes in Nashik district is given in table 2; based on which the sample size was estimated.

Table 2: Proportion of adverse pregnancy in Nashik District, 2015-16.

Pregnancy outcome	Total (%)	Rural (%)
Live Births	94.20	92.60
Still Birth	1.20	1.30
Induced abortion	2.00	2.40
Spontaneous abortion	2.60	3.70
LBW (below 2.5 kg)	14.00	13.90

Based on the adverse outcomes mentioned in the above table, although stillbirth rate was the least common event, followed by abortion; stillbirth and spontaneous abortion occur due to fetal chromosomal abnormalities or may have unexplained etiology. Both these outcomes are not easily amenable for correction. For estimation of sample size for an intervention study, the prevalence of LBW was considered. Further, for bringing about a 25% reduction in the proportion of low birth weight with 80% power and 95% confidence, the sample size was estimated using the following formula.

$$n = \frac{r+1}{r} \frac{\bar{p}(1-\bar{p})(Z_{\beta} + Z_{\alpha.2})^2}{(p_1 - p_2)^2}$$

Where r is the ratio between study participants and participants in the comparison group, p is pooled estimate, p1 and p2 are proportions before and after the intervention.

The sample size was estimated to be about 1374 outcomes in each arm.

v. Data collection tool:

Following tools were developed through a consultative process, validated by experts, translated in the local language (Marathi), back-translated, pretested, and used for data collection. Besides, tools were also prepared for providing and monitoring intervention services.

Interview schedule for baseline survey:

It was a printed yellow-coloured form including a consent form. The interview schedule included demographic information, details of pregnancy, its outcome, and risk factors associated with adverse pregnancy outcomes.

Tool for identification of congenital anomalies:

For identification of congenital anomalies, a coloured pictorial printed leaflet was prepared in local language based on RBSK tool and was given to each Accredited Social Health Activist (ASHA).

Qualitative research tools: FGD interview guide for FGDs with women and health care providers:

Two separate interview guides were prepared based on a literature search. The tools for FGDs consisted of domain areas and probes and were open-ended to allow the participants to elaborate their thoughts and experiences freely.

The FGD guide for women had the following sub-themes to elicit participants' responses: planning of pregnancy, age of the woman, height and weight of the woman, physical work, nutrition, medical/health advice before pregnancy, tobacco and alcohol consumption, and preconception services.

The tool for FGDs with HCPs consisted of questions regarding their knowledge, perception and practices; challenges; and possible strategies to deliver PCC services.

Proforma of enrolment at baseline survey :

It was a blue-coloured printed form including a consent form. The interview schedule included sections on socio-demographic variables including age, occupation, religion/caste, and type of family. Other information included obstetric history, substance abuse, nutritional information, physical assessment in the form of height and weight, and 24-hour dietary recall. Information on 12 risk factors was collected; age less than 20, age more than 35, illiteracy, multiparity (more than 3 children), consanguineous marriage, BMI less than 18.5, BMI more than 25, calorie intake <50% of recommended daily allowance (RDA), protein intake <50% of recommended daily allowance, tobacco consumption in any form [smoking, eating, Mishri (roasted tobacco application), snuff and passive smoking], alcohol consumption and history of adverse outcome for last pregnancy (abortion or stillbirth).

vi. Variables:

The variables were mainly of three types. The first type of independent variables included the following demographic variables; age, family type, education, occupation. The second type of independent variables included the following potential risk factors; consanguinity, heavy work in the last six months of pregnancy, tobacco consumption, alcohol consumption, exposure to pesticides, domestic violence, existing illness, etc. The outcome variables were abortion, stillbirth, preterm birth, low birth weight, congenital physical defect, and early neonatal death. Information about all these variables was based on responses given by the participants. The definitions of outcome variables used in the study are as below:

- Abortion: The termination of pregnancy, spontaneous or induced, before 20 weeks of gestation.

- Stillbirth: A loss of a baby at or after 20 weeks of pregnancy.
- Preterm: A baby born alive before 37 weeks of pregnancy is completed.
- Low birth weight (LBW): Birth weight less than 2500 gm.
- Congenital anomaly: Physical defect(s) present in the child since birth or may have become apparent during the neonatal period.
- Early neonatal death: Death of a newborn between zero and 7 completed days after birth.

vii. Ethical considerations:

The Bharati Vidyapeeth Medical College, Institutional Ethics Committee (DCGI Reg. no ECR 518/ Inst/MH/2014/RR-17) approved the study, vide letter no. BVDUMC/IEC/11 dated 30th April 2018. The study was registered under Clinical Trial Registry India (CTRI) vide CTRI registration number CTRI/ 2018/06/014657 dated 28th June 2018. The trial was registered before the initiation of enrolment of the participants for interventions. Written informed consent was obtained from all participants for participation and subsequent publication from all before recruitment.

viii. Intervention: BCC tools

Following tools were used for BCC to the enrolled women during her follow-up visits:

- Health Care manual.
- Oral communication using flipbook.
- Audio-video session including Audio-visual (AV) documentary film.
- Short Message Service (SMS) and voice recorded messages.
- Diet chart for women especially with low or high BMI.

ix. Training

Rigorous training was conducted on baseline and enrolment tools mentioned above for ASHA, ANM, Block facilitator (BF), MO and other health staff from all 4 blocks. Additionally, PHC health staff from intervention blocks were trained for providing all the interventions mentioned above.

x. Study participants:

a. *Baseline survey:*

All those women in the reproductive age group and who had been pregnant and the outcome of pregnancy occurred in specified one year period (1st April 2017 to 31st March 2018) and were residents of the area (residing or intends to reside for more than six months) were included in the study. Those women who were unable to understand Marathi, Hindi, or English or unable to respond due to psychotic illness were excluded.

b. *Qualitative research:*

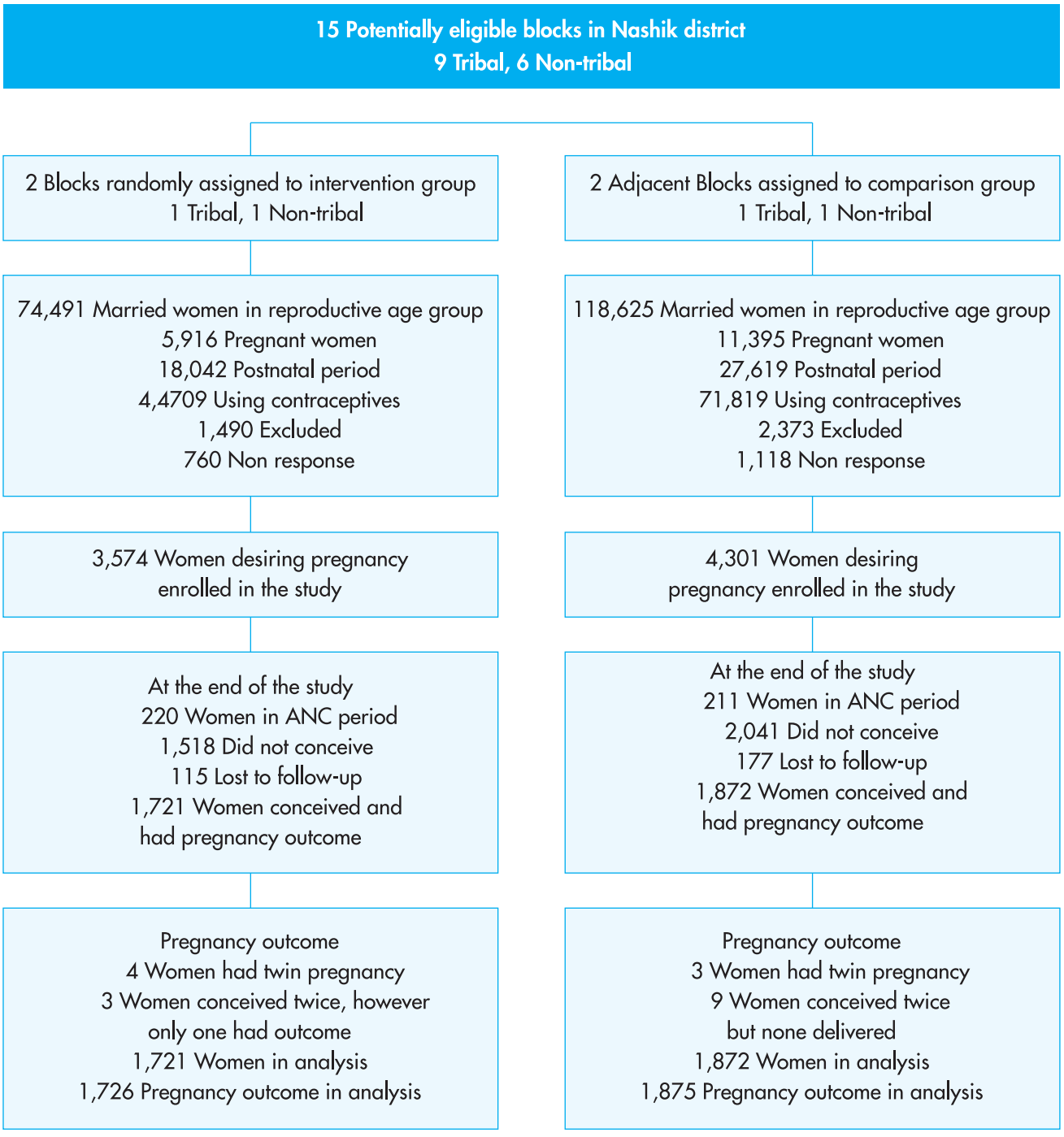
FGD among women: Women of reproductive age, desiring pregnancy in succeeding one year were included in the study.

FGD among HCP: ANM and Multi-purpose Worker (MPW) working at PHC and SC were included in the study.

c. *Enrolment:*

The women in the reproductive age group and desiring to conceive within one year, residing in the area (or intend to reside for more than six months) were included and enrolled in the study. Those women who were unable to understand Marathi, Hindi or English or unable to respond due to psychotic illness were excluded.(Figure 3).

Figure 3: Flow diagram of participation of women in the study, Nasik District, 2018-2020



xi. Meeting for the launch of the Programme

This first-ever comprehensive PCC programme for women planning their pregnancies was launched on 7th April 2018, World Health Day, by the policymakers and senior officials of the state and district levels, together with officials from UNICEF (Figure 4).

Figure 4: The official launch meeting of the Healthy Parent, Healthy Child Initiative at the Office of the Nashik Zilla Parishad, Nashik on the World Health Day, 7 April 2018

xii. Data collection:

Baseline survey:

ASHAs collected the data through house-to-house visits from eligible women, using the interview schedule. If a woman was not present during the home visit, she was visited later on, within the month. ANM, BF, and Lady Health Visitor (LHV) supervised the activity. The survey was conducted from May – July 2018.

Qualitative research:

FGD among women: Eight sub-center villages were randomly selected for conducting FGDs among women. ASHAs from selected villages invited all women in the reproductive age group who desired pregnancy in the succeeding one year for FGD (about 10-15 women from each village).

FGDs among HCPs: For FGDs among HCPs, Female health workers (ANM) and male health care workers (MPW) were the study participants, who worked at PHC and SC.

xiii. Enrolment:

ASHAs collected the data through house-to-house visits from eligible women, using the interview schedule. Physical assessment of enrolled women was done by measuring the height and weight of the women using standard equipment at home or Anganwadi, or the nearest health facility (SC or PHC). ASHAs recorded height to the nearest 0.1 cm and weight to the nearest 0.1 kg. Women were lightly clothed barefoot. ANM, BF, LHV supervised the activity.

Special camps were organized at a village or sub-center level for collecting blood samples for laboratory investigations of enrolled women in intervention blocks at the first follow-up visit. These investigations included haemoglobin estimation, ABO grouping, and Rh typing, blood sugar level estimation, oral glucose tolerance testing (OGTT) among women who had high random blood sugar levels, thyroid-stimulating hormone (TSH), HIV and VDRL tests.

Figure 5: Weighing of a woman during VHSNDs

Then, every enrolled woman was contacted by ASHA through the monthly house-to-house visits for promoting behaviour change communication and for mobilizing the woman to the Village Health Sanitation and Nutrition Day (VHSND); for monthly follow-up.

Figure 6: BCC sessions and distribution of Iron Folic Acid tablets during VHSNDs

The ANM would check for weight on monthly basis, haemoglobin levels every quarter and provide IFA or FA and deworming tablets as per the guidelines. As per the guidelines issued in 2018 (before Anaemia Mukta Bharat Programme), women with anaemia (<12 gm %) were treated with IFA (100 mg iron + 0.5 mg folic acid) daily one tablet. Women with no anaemia (>12 gm %) were given IFA (100 mg iron + 0.5 mg folic acid) once a week as prophylaxis. For deworming, tablet Albendazole (400 mg) was given to women once every 6 months. Folic acid tablets or IFA tablets were given for the prevention of neural tube defects. ANM would also enquire for RTI/ STI symptoms or any other signs or symptoms and would provide appropriate counselling.

During the follow-up visits, BCC using different tools mentioned before were given in local language during VHSND session. BCC activities were carried out using the flipbook and a health care manual (Figure 7).

Figure 7: Health care manual provided to each eligible aspiring woman during VHSND

ANMs showed a short documentary film to enrolled women on VHSND. Group communication activities were carried out (Figure 8).

Figure 8: Group counselling session in a VHSND

The third BCC was imparted through giving messages on mobile phones. In all, 12 recorded voice messages and 12 text messages were given, two messages per week on the registered mobile numbers to the women. These messages were given over 6 weeks. Besides, counselling along with specific diet charts was given to women with low BMI or high BMI for helping them to bring their BMI in the normal range before conception. All these services were given by ANM with the help of ASHAs. MO and LHV monitored the activities.

xv. Supportive supervision visits

There were several supportive supervision visits to Peint and Sinnar blocks by the officials of the Government of Maharashtra and Government of India, UNICEF, and Bharati Vidyapeeth Medical University (Figures 9-11).

Figure 9: Interaction with eligible women desiring to start a family at Dapur PHC, Sinnar Block during the visit of the Dr. Dinesh Baswal, Additional Commissioner of Maternal Health, Ministry of Health and Family Welfare, GOI, Dr. Archana Patil, Director of Health Services, GOM, Dr. Yasmin Ali Haque, Representative of UNICEF India, Ms. Rajeshwari Chandrasekar, Chief of Field Office, UNICEF Maharashtra, Prof. Prakash Doke, Bharati Vidyapeeth Medical University, Pune on 26 June 2019

Figure 10: Team of Dapur Primary Health Center, Sinnar Block during the visit of the Dr. Dinesh Baswal, Additional Commissioner of Maternal Health, Ministry of Health and Family Welfare, GOI, Dr. Archana Patil, Director of Health Services, GOM, Dr. Yasmin Ali Haque, Representative of UNICEF India, Ms. Rajeshwari Chandrasekar, Chief of Field Office, UNICEF Maharashtra, Prof. Prakash Doke, Bharati Vidyapeeth Medical University, Pune on 26 June 2019

Figure 11: Prof. (Dr.) Mrudula Phadke, Ex. Vice Chancellor of Maharashtra University of Health Sciences and Prof. (Dr.) Deepak Raut, Director, National Institute of Public Health Training and Research, Mumbai, Dr. Sanjay Chauhan, Director grade Scientist G, ICMR-National Institute of Research in Reproductive Health, Mumbai, Dr. S. A. Saharia, Director, Mumbai Maternal Nutrition Project Center for the Study of Social Change (CSSC), Bandra East, Mumbai interacting with health care workers of Karanjali Primary Health Center, Karanjali, Peint block, Nashik on 20 February 2019

xv. Review meetings at the state level

Further, many review meetings were conducted at the block, district, and state levels. On 27 June 2019, a review meeting organized, was attended by senior officials of the Government of Maharashtra and India, Officials and consultants of UNICEF, Officials of Bharati Vidyapeeth Medical University, Obstetrician from H.B.T. Medical College, and Dr. R. N. Cooper Municipal General Hospital, Mumbai and senior economist from Scottish Church College, Kolkata, and Nutritionist from National Center of Excellence and Advanced Research on Diet, Lady Irwin College, Delhi and Expert from Mumbai Maternal Nutrition Project (Figure 12). Few key action areas that emerged following the review of the progress of the innovation including strategies to reach migrated eligible aspiring couples, emphasis should be given on locally available food items with high nutrition content. These areas were further added during implementation.

Figure 12: Meeting of the technical group for reviewing the Healthy Parent, Healthy Child Initiative on 27th June 2019.

xvi. Follow up of the enrolled women and reporting of the pregnancy outcomes

Reporting in intervention blocks

The follow-up information of all enrolled women was recorded in the register by ANM. This information was then entered by the block facilitator (BF) with the help of ANM in provided Microsoft excel format sheets on monthly basis. Once the woman become pregnant, her name was entered in Antenatal Care (ANC) register, and routine services were offered. After Expected Delivery Date (EDD), the woman was contacted physically or telephonically, frequently till information on pregnancy outcome was available. The outcome of pregnancy was reported as live birth with birth weight, prematurity, physical congenital anomalies, abortion, stillbirth, and early neonatal death. An Application was also developed and given to ANMs on a tablet. ANMs were trained to use and report the follow-up data and pregnancy outcome information, using the Application. The Application was user-friendly, in the local language (Marathi), and provided a summary and upcoming visits to ANM on the dashboard. The Application could be used offline and required internet connection only while uploading the data. The Application was also used by supervisors to monitor the activities. Follow-up data was compiled, downloaded and preliminary analysis reports were generated through the Application.

Reporting in comparison blocks

A similar procedure was used to collect the information about pregnancy outcomes of enrolled women except for software Application use.

xvii. Data reporting and quality checks for the enrollment and baseline surveys

Filled data forms (hard copy) were first deposited at the subcenter and then transferred to PHC, where forms were

checked and signed by Medical Officer. These forms were then sent to the Bharati Vidyapeeth, Pune fortnightly. A unique identification code for each participant was generated. Received forms were primarily screened for completeness of data, legibility, and accuracy before data entry. Incomplete forms were reverted to the PHC and informed about the lacking information to be completed and sent back. Similarly, the monitoring sheets were also screened. Teams from Bharati Vidyapeeth also had frequent field visits to monitor the data collection process, providing intervention, monthly review, and reporting of follow-up; throughout the study period. Data entry, validity, data cleaning, and data analysis were concurrently carried out.

xviii. Data analysis and presentation:

Statistical analysis for quantitative data was conducted using a Statistical Package for Social Sciences (SPSS) version 25.0 and STATA version 15.0.

a. Baseline survey:

For categorical variables, data are presented as proportions and percentages. For continuous variables, mean and Standard Deviation (SD) are calculated. The Chi-square test is used to find an association between variables. A univariate followed by a multivariate analysis is carried out to find the Adjusted Prevalence Ratio (APR) for adverse pregnancy outcomes. The level of significance was taken at $p<0.05$.

b. Qualitative research:

Qualitative data was analyzed using MAXQDA version 20.2. All FGDs were transcribed verbatim, checked against recordings and notes for accuracy, and reviewed to familiarize. Data were analyzed using a content analysis deductive approach. Three researchers independently identified codes and themes. Further, codes were discussed and finalized through discussion among the research team. Any disagreement in codes was discussed and resolved. The transcripts were translated into English.

c. Intervention study:

Information at enrolment:

The findings are presented as absolute numbers, proportions and chi-square tests are applied. The level of significance was taken at $p<0.05$.

Follow up:

Data were coded, anonymized, collated, and analyzed. The change in BMI is calculated as the difference in BMI at baseline and pre-pregnancy or last available BMI and tested for linear trend. Similarly, the change in Haemoglobin is calculated as the difference in Haemoglobin at baseline and pre-pregnancy or last available Haemoglobin level and tested for linear trend. The pregnancy outcome at the end of the study in intervention blocks is compared with the pregnancy outcome in comparison blocks. The pregnancy outcome at the end of the study is also compared with the baseline data, preceding one year to the study period.

xix. Data storage and availability:

The filled data forms are stored at Bharati Vidyapeeth Medical College, Department of Community Medicine, Pune. The data is entered in the software database, coded, anonymized, and stored with the Principal investigator. This data is available for researchers on request.

CHAPTER FOUR

RESULTS AND DISCUSSION

i. Findings of the baseline survey among women age 15-45 years in four blocks who had any pregnancy outcome during April 1, 2017 to March 31, 2018

In the study area, 9,307 (tribal=3298, non-tribal 6009; study=4766, comparison=4541) women reported pregnancy outcome in the aforesaid period.

a. Socio-demographic characteristics:

Their socio-demographic details are shown in Table 3. The overall mean age was 23.91+3.23 years. Overall, 26.02% of women had completed their Secondary School Certificate (SSC); 13.32% were illiterate, and only 2.18% were postgraduate or had a professional degree. Educational status was significantly different in both the study and comparison groups.

Table 3: Socio-demographic profile of women having an outcome in the preceding year in Nasik district, India, 2017-18

Characteristics	Intervention n (%)	Comparison n (%)	$\chi 2$, (p)	Total*n (%)
Age in years				
15-19	232 (5.1)	207 (4.9)	9.84 (0.08)	439 (5.0)
20-24	2674 (58.6)	2370 (56.1)		5044 (57.4)
25-29	1408 (30.8)	1402 (33.2)		2810 (32.0)
30-34	206 (4.5)	209 (4.9)		415 (4.7)
35-39	38 (0.8)	32 (0.8)		70 (0.8)
40-44	9 (0.2)	3 (0.1)		12 (0.1)
Family Type				
Nuclear	840 (18.9)	883 (20.8)	5.94 (0.051)	1723 (19.8)
Joint	3563 (80.1)	3305 (77.9)		6868 (79.0)
Other	47 (1.1)	52 (1.2)		99 (1.1)
Education				
PG/ Professional	98 (2.2)	98 (2.3)	20.76 (0.002)	196 (2.2)
Graduation	176 (3.9)	237 (5.6)		413 (4.7)
HSC/ ITI	1009 (22.4)	912 (21.7)		1921 (22.0)
SSC	1170 (25.9)	1099 (26.1)		2269 (26.0)
7th pass	860 (19.1)	738 (17.6)		1598 (18.3)
<7th pass	623 (13.8)	538 (12.8)		1161 (13.3)
Illiterate	578 (12.8)	583 (13.9)		1161 (13.3)
Occupation				
Working	3195 (68.9)	2333 (53.5)	224.43 (<0.001)	5528 (61.5)
Homemaker	1441 (31.1)	2025 (46.5)		3466 (38.5)
* Total does not tally because of non-response by the participants.				
PG=Post Graduate; HSC=Higher Secondary-school Certificate; SSC- Secondary School Certificate; ITI=Industrial Training Institute.				

b. *Past pregnancy outcome:*

Details of adverse outcomes are given in Table 4. Overall, abortion was reported by 4.1% of women. We did not differentiate whether abortion was spontaneous or induced. The difference was observed across all the blocks. It was least in Peintblock and maximum in Niphad block. Stillbirth was reported by 1.6% of women; preterm birth by 4.1%; low birth weight by 13.2%; congenital physical anomaly by 2.8%, and early neonatal death by only 0.6% of women. In tribal blocks, three maternal deaths were reported, and none in nontribal blocks.

Table 4: Prevalence of adverse pregnancy outcome in the preceding year in Nasik district, India, 2017-18

Adverse outcome	pregnancy	Intervention n (%)	Comparison n(%)	$\chi 2$ (P)	Total *n(%)
Abortion	Yes	140 (2.9)	242 (5.3)	33.79	382 (4.1)
	No	4626 (97.1)	4299 (94.7)	(<0.001)	8925 (95.9)
Still Birth	Yes	62 (1.3)	87 (1.9)	5.58	149 (1.6)
	No	4704(98.7)	4454 (98.1)	(0.02)	9158 (98.4)
Preterm Birth	Yes	141 (4.5)	101 (3.7)	2.67	242 (4.1)
	No	2961 (95.5)	2636 (96.3)	(0.10)	5597 (95.9)
Low Birth weight	Yes	538 (12.9)	502 (13.4)	0.47	1040 (13.2)
	No	3626 (87.1)	3232 (86.6)	(0.492)	6858 (86.8)
Congenital birth defect	Yes	116 (2.5)	129 (3.0)	2.07	245 (2.8)
	No	4484 (97.5)	4138 (97.0)	(0.15)	8622 (97.2)
Early Neonatal deaths	Yes	22 (0.5)	30 (0.7)	1.90	52 (0.6)
	No	4604 (99.5)	4269 (99.3)	(0.168)	8873 (99.4)
*** Total does not tally because of non-response by the participants.**					

c. *Risk factors and their association:*

The distribution of risk factors among women in study and comparison areas is given in Table 5. A national survey in India pointed higher range of consanguineous marriages from 28% to 38%, including Maharashtra[43]. The commonest form of tobacco consumption was applying *Mishri* (roasted tobacco) on gums and teeth. The study observed lesser tobacco consumption during pregnancy than otherstudies[44,45,46]. Alcohol consumption in Indian women is less compared to women from western countries and

43 Kuntla S, Goli S, Sekher TV et al. Consanguineous Marriages and Their Effects on Pregnancy Outcomes in India. International Journal of Sociology and Social Policy. 2013;Vol.33(7/8), pp.437-452.
44 Gupta PC, Subramoney S. Smokeless tobacco use, birth weight, and gestational age: population-based, prospective cohort study of 1217 women in Mumbai, India. BMJ. 2004 Jun 26;328(7455):1538.
45 Singh S, Mini GK, Thankappan KR. Tobacco use during pregnancy in rural Jharkhand. India.Int J Gynaecol Obstet. 2015 Nov;131(2):170-3.
46 Bloch M, Althabe F, Onyamboko M et al. Tobacco use and secondhand smoke exposure during pregnancy: an investigative survey of women in 9 developing nations. Am J Public Health. 2008;98(10):1833–40.

during pregnancy is rare. In the present study, alcohol consumption was lower than a study from Karnataka, India[47]. Various studies have reported the prevalence of domestic violence from 7.1 to 18.0%, far higher than the present study[48,49,50]. Indian women are reluctant to divulge such information, so these figures may be just the tip of the iceberg.

Risk factors that were significantly associated with abortion include existing illness at the time of conception and performing heavy work in the last six months of pregnancy. Consanguinity, tobacco consumption during pregnancy, and pre-existing illness were identified as risk factors for stillbirth. Significant risk factors for low birth weight were heavy work in the last six months of pregnancy, pre-existing illness, and residence in a tribal area.

Table 5: Prevalence of risk factors during pregnancy in the preceding year in Nasik district, India, 2017-18

Potential risk factors		**Intervention n(%)**	**Comparison n(%)**	**$\chi 2$ (P)**	***Total n(%)**
Consanguinity	Yes	794 (17.4)	848 (17.4)	8.12	1642 (18.5)
	No	3771 (82.6)	3446 (82.6)	(0.004)	7217 (81.5)
Heavy work in last	Yes	708 (16.2)	869 (21.3)	36.57	1577 (18.7)
6 Months	No	3664 (83.8)	3206 (78.7)	(<0.001)	6870 (81.3)
Tobacco	Yes	234 (4.9)	283 6.2)	7.64	517 (5.6)
	No	4523 (95.1)	4257 (93.8)	(0.006)	8780 (94.4)
Alcohol	Yes	26 (0.6)	18 (0.4)	1.15	44 (0.5)
	No	4668 (99.4)	4488 (99.6)	(0.283)	9156 (99.5)
Exposure to pesticides	Yes	78 (1.6)	131 (2.9)	16.57	209 (2.3)
	No	4671 (98.4)	4389 (97.1)	(<0.001)	9060 (97.7)
Domestic violence	Yes	32 (0.7)	42 (0.9)	1.90	74 (0.8)
	No	4683 (99.3)	4445 (99.1)	(0.167)	9128 (99.2)
Existing illness	Yes	95 (2.0)	109 (2.4)	1.57	204 (2.2)
	No	4591 (98.0)	4409 (97.6)	(0.209)	9000 (97.8)
***Total does not tally because of non-response by the participant.**					

47 Nath A, Patil C, Naik VA. Prevalence of consanguineous marriages in a rural community and its effect on pregnancy outcome. Indian Journal of Community Medicine. Jan-Mar,2004; XXIX(1):41-43.
48 Babu BV & Kar SK. Abuse against women in pregnancy: a population-based study from Eastern India. WHO South-East Asia Journal of Public Health. 2012;1(2):133-143.
49 Peedicayil A, Sadowski LS, Jeyaseelan L *et al.* Spousal physical violence against women during pregnancy. BJOG. 2004 Jul;111(7):682-7.
50 Jagtap V. Samant P. Association of adverse pregnancy outcome and domestic/intimate partner violence. Int J Reprod Contracept Obstet Gynecol. 2017 Jun;6(6):2527-2531.

ii. Findings of Qualitative study:

a. FGD among women:

A total of 76 women having a mean age of 23.97 years (SD=4.12, range 18-39 years) participated in the 8 FGDs. Most of them (46.05%) had completed 10 years of education. Women perceived that about 50% of pregnancies are planned. The decision about the first pregnancy is influenced by the mother-in-law. Women were aware of the fact that they should not conceive before 20 years of age and their suboptimal weight may have an adverse impact on the health of new-born. There are many myths about food like, 'hot and cold foods' and 'forbidden food' etc. Women had less knowledge about the adverse effects of tobacco and alcohol use, very few consumed these. Most of them did not practice behaviors or access services related to PCC.

b. FGD among HCP:

In all, there were 45 participants; 31 female and 14 male HCP in four FGDs. HCPs had some knowledge about PCC though limited to adolescent health and family planning services. HCPs perceived community factors as barriers including lack of knowledge, curtailed decision capacity among women, gender bias, and the influence of elderly women of the household, myths, and taboos. Lack of human resources and specialized services; workload; discrepancies in payments and lack of guidelines were identified institutional barriers. Community counseling for demand generation, women empowerment, social mobilization, and capacity building of HCPs were recommended for promoting PCC.

iii. Findings of the enrolment survey among all women age 15-45 years desiring pregnancy in the succeeding 12 months:

a. Socio-demographic characteristics at enrolment:

In the study of 7,875 women were enrolled. Out of the total women, 37.8% belonged to tribal blocks. The majority (88.6%) were Hindu. The minimum age of desiring women was 14.42 and the maximum age was 45.50 (mean 23.19±3.71). Table 6 gives the socio-economic information at enrolment of women about occupation, caste, and type of family. Overall, the most common occupation among women was farming (48.0%). Joint families are more common (74.3%). It was observed that most of the variables were statistically significant between the intervention and control groups ($p<0.05$). This statistical significance was observed sheer due to the large sample size.

Table 6: Socio-demographic characteristics of women desiring pregnancy in Nashik District, India, 2018-19

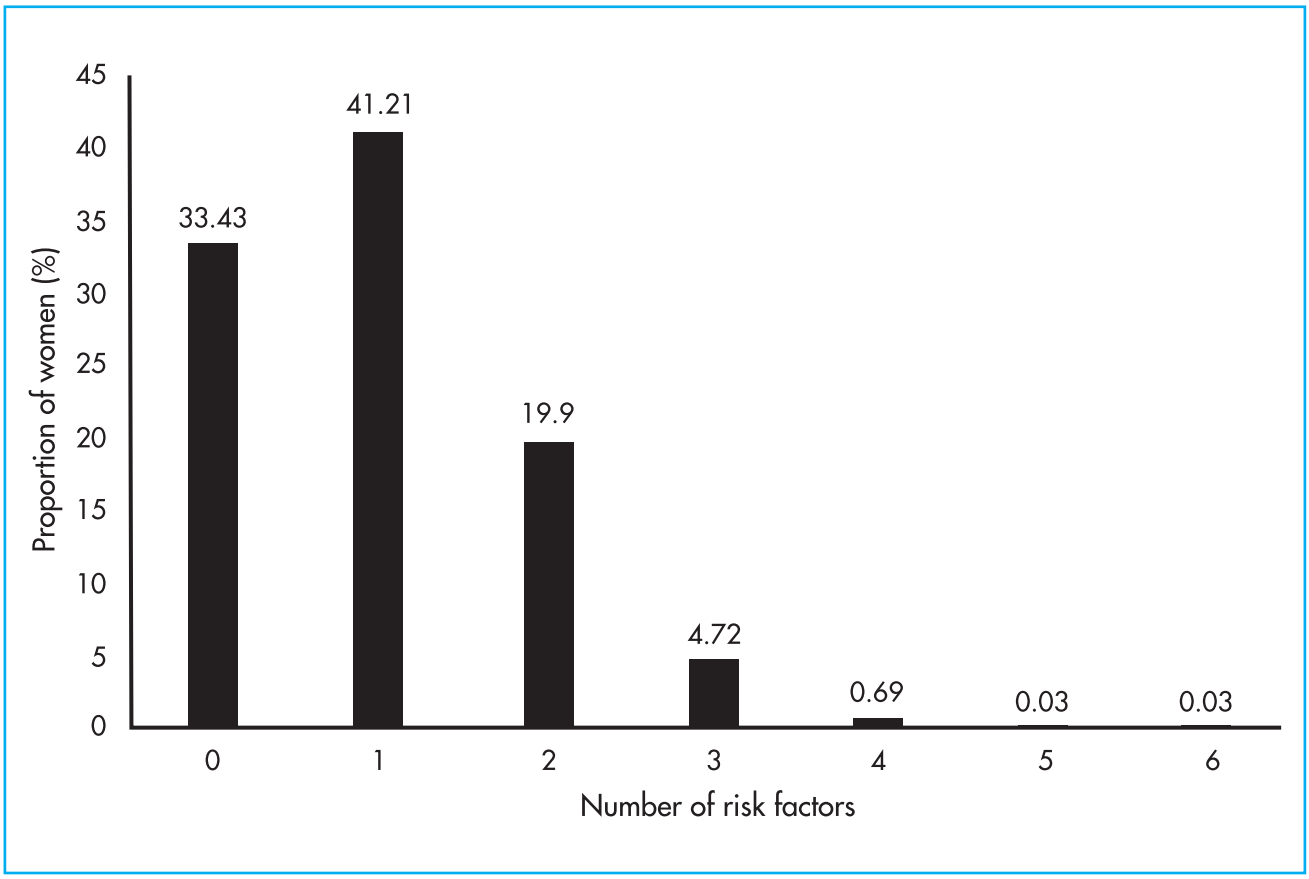
Characteristics	Intervention n (%)	Comparison n (%)	$\chi 2$ (p)	Total n (%)
Occupation (n=7364)				
Professional	36(1.0)	97(2.3)	197.17 (<0.001)	133(1.7)
Semi professional	13(0.4)	12(0.3)		25(0.3)
Clerical	3(0.1)	17(0.4)		20(0.3)
Shop Owner	57(1.6)	89(2.1)		146(1.9)
Farmer	2032(56.9)	1747(40.6)		3779(48.0)
Skilled worker	77(2.2)	125(2.9)		202(2.6)
Semiskilled worker	42(1.2)	54(1.3)		96(1.2)
Unskilled worker	110(3.1)	160(3.7)		270(3.4)
Unemployed	1027(28.7)	1666(38.7)		2693(34.2)
Caste (n=6437)				
Scheduled Caste	495(13.9)	804(18.7)	160.4 (<0.001)	1299(16.5)
Scheduled Tribe	1493(41.8)	1097(25.5)		2590(32.9)
OBC	3(0.1)	10(0.2)		13(0.2)
Open	462(12.9)	546(12.7)		1008(12.8)
Other	675(18.9)	852(19.8)		1527(19.4)
Type of family (n=6990)				
Nuclear	446(12.5)	559(13.0)	13.32 (<0.001)	1005(12.8)
Joint	2723(76.2)	3128(72.1)		5851(74.3)
Other	42(1.2)	92(2.1)		134(1.7)

b. Risk factors for adverse pregnancy outcome at enrolment:

About two-thirds of women had at least one risk factor whereas, 41.21% of women had only one risk factor. Fig 13 gives the details of women having several risk factors. Among women having only one risk factor, the commonest was no formal education (44.35%), calorie intake less than 50% of daily recommended allowance, and age less than 20 years (13.68%). Only two women had five risk factors and two women had six risk factors. Another study in an urban area considered 22 risk factors and revealed that all women had at least one risk factor.[51]

51 Gund P, Bhide P. Prevalence of Periconception Risk Factors for Adverse Pregnancy Outcomes in a Cohort of Urban Indian Women: Implications for Preconception Health Education. J Womens Heal Care. 2016;05(01):1–5. doi: 10.4172/2167-0420.1000296.

Figure 13: Proportion of enrolled women with identified risk factors at enrolment, Nashik district, 2018-19



The prevalence of selected risk factors and their comparison are given in Table 7.

Adolescent pregnancy:

Early marriage and adolescent unplanned pregnancy are known risk factors significantly associated with postnatal complications and adverse pregnancy outcomes[52,53,54]. Social pressure to marry early, and pressure for early childbearing soon after marriage, often prevents these married women and young girls from accessing and accepting contraception.

52 Godha D, Hotchkiss DR, Gage AJ. Association between child marriage and reproductive health outcomes and service utilization: A multi-country study from south asia. J Adolesc Heal. 2013;52(5):552–8. doi:10.1016/j.jadohealth.2013.01.021.

53 McClendon KA, McDougal L, Ayyaluru S et al. Intersections of girl child marriage and family planning beliefs and use: qualitative findings from Ethiopia and India. Cult Heal Sex. 2018;20(7):799–814.

54 Kamal SMM, Hassan CH. Child marriage and its association with adverse reproductive outcomes for women in Bangladesh. Asia-Pacific J Public Heal. 2015;27(2):NP1492–506. doi:10.1177/1010539513503868.

Table 7: Risk factors among enrolled women during preconception phase, Nashik, India, 2018-19

S.N	Risk factor	Intervention n=3574	Comparison n=4301	$\chi 2$ (p)
1	Age ≤19 years (n=7783)	602	654	3.03 (0.08)
2	Age ≥35 years (n=7783)	58	56	3.25 (0.07)
3	Illiterate (n=7482)	325	408	0.70 (0.40)
4	Consanguinity (n=7137)	613	879	20.36 (<0.001)
5	Multiparity ≥4 (n=7647)	48	58	0.0008 (0.98)
6	Tobacco consumption (n=7804)	205	219	1.84 (0.17)
7	Alcohol consumption (n=7804)	18	30	1.14 (0.29)
8	Less calorie intake (n=7872)	40	71	3.97 (0.046)
9	Less protein intake (n=7872)	33	71	7.93 (0.01)
10	BMI <18.5 (n=7169)	1,355	1400	13.57 (<0.001)
11	BMI ≥ 25 (n=7169)	167	273	13.55 (<0.001)
12	Previous adverse outcome (n=3656)	81	106	0.762 (0.38)

Consanguinity:

Few studies considered consanguineous marriage as a risk factor and prevalence was 2.9 and 20%[55,56]. A study in Karnataka, India reported history of consanguineous marriage among 23.9%[57], while the present study reported it to be 20.9%.

Tobacco consumption:

Smoking in the preconception period is linked to delayed conception and infertility. Indirect evidence of the impact of smoking on the population is evident through smoke-free legislation in different countries, which has been associated with significant reductions in preterm births. A meta-analysis reported maternal active and passive smoking associated with a higher risk of congenital heart disease among the offspring. In the current study, the prevalence of tobacco consumption in any form was 3.8%, which was low than that in another study (11%)[58]. *Mishri* use is very common in the tribal area.

Alcohol consumption:

Maternal alcohol consumption leads to spontaneous abortion and a variety of fetal alcohol spectrum disorders. The current study reported very low alcohol consumption as 0.7% compared to other studies[59].

55 Pandolfi E, Agricola E, Gonfiantini MV *et al.* Women participating in a web-based preconception study have a high prevalence of risk factors for adverse pregnancy outcomes. BMC Pregnancy Childbirth. 2014;14(1):1–6. doi: 10.1186/1471-2393-14-169.
56 Gund P, Bhide P. Prevalence of Periconception Risk Factors for Adverse Pregnancy Outcomes in a Cohort of Urban Indian Women: Implications for Preconception Health Education. J Womens Heal Care. 2016;05(01):1–5. doi: 10.4172/2167-0420.1000296.
57 Bellad M, Goudar S, Edlavitch S et al. Consanguinity, prematurity, birth weight and pregnancy loss: a prospective cohort study at four primary health center areas of Karnataka, India. J Perinatology. 2012;32:431–437.
58 Mistry R, Ba AD. Brief report Antenatal Tobacco Use and Secondhand Smoke Exposure in the Home in India. Nicotine Tob Res. 2017;1–4. doi:10.1093/ntr/ntx049.
59 Anderson JE, Ebrahim S, Floyd L, Atrash H. Prevalence of risk factors for adverse pregnancy outcomes during pregnancy and the preconception period - United States, 2002-2004. Matern Child Health J. 2006;10(1):101–6. doi: 10.1007/s10995-006-0093-z.

BMI:

ASHAs measured the height and weight of 7,167 women (91.0%). The Mean BMI of women was 19.73 (SD 3.51). In the present study, almost one-third of women were undernourished (BMI<18.5) similar to other studies[60].

iv. Follow up of the enrolled women planning a pregnancy in the succeeding 12 months

As mentioned earlier, all women enrolled at the beginning of the study and were followed up for their pregnancy status. Women in intervention blocks were followed up every month for their health status, weight, and BMI, while Hb% was estimated every quarter.

a. Prevalence of different illnesses among enrolled women in intervention blocks at enrolment:

The prevalence of hypertension was higher among enrolled women in intervention blocks at enrolment (2.27%). The prevalence of other chronic conditions like diabetes, hypothyroidism was very low. Only one woman was diagnosed HIV positive and VDRL positive respectively. There were no women diagnosed with sickle cell (Table 8).

Table 8: Prevalence of different illnesses among enrolled women in intervention blocks at enrolment, Nashik, 2018-19

Illness	N	n	%
Hypertension (BP>120/80mmHg)	2554	58	2.27
BSL>140	2049	70	3.42
Diabetes Mellitus confirmed with OGT (tested Positive)	2049	6	0.29
TSH >5	1581	17	1.08
RTI Symptoms	2412	2	0.08
HIV	2408	1	0.04
VDRL	2451	1	0.04

b. Follow-up of enrolled women:

Table 9 shows the follow-up status of enrolled women. About 182 enrolled women (5.09%) did not receive any follow-up and preconception care services. The mean number of follow-up visits among enrolled women was 9.47 ± 6.89. The mean number of follow-up visits during the preconception period among women who became pregnant women was 7.18 ± 5.33and that among non-pregnant women was 12.17 ± 7.52.

60 Liu P, Xu L, Wang Y, Zhang Y, Du Y, Sun Y et al. Association between perinatal outcomes and maternal pre-pregnancy body mass index. Obes Rev. 2016;17(11):1091–102. doi: 10.1111/obr.12455.

Table 9: Follow-up of enrolled women till the end of the study in intervention blocks, Nashik, 2018-2020

Number of visits	Became Pregnant		Did not become pregnant		Total*	
	n	%	n	%	n	%
0	100	5.15	82	5.02	182	5.09
1-3	482	24.83	201	12.31	683	19.11
4-6	428	22.05	132	8.08	560	15.67
7-9	319	16.43	215	13.17	534	14.94
10-12	272	14.01	256	15.68	528	14.77
13-15	180	9.27	196	12.00	376	10.52
16-18	80	4.12	138	8.45	218	6.10
19-21	68	3.50	152	9.31	220	6.16
22-24	9	0.46	212	12.98	221	6.18
25-27	3	0.15	49	3.00	52	1.45
Total	1941	100	1633	100	3574	100
*p<0.05						
Those who were pregnant were further taken to the cycle of ANC care. Total of 1,946 women were transferred to ANC care from follow-up at various visits.						

c. Characteristics of women who did not come for any visit:

In all, 182 (5.09%) women from intervention blocks did not attend any visit for PCC services throughout the intervention period. Most of the women were from non-tribal block Sinnar (148 women, 81.32%). The mean age of these women was 21.98 years ± 2.98; that was not statistically different from the mean age of enrolled women. Almost half of these women (98 women) became pregnant and data on outcome was available. Among them, 3.06 % of women had an abortion and 96.94% had a live birth. This distribution is also similar to the outcome of all enrolled women.

d. Effect among enrolled women in intervention blocks:

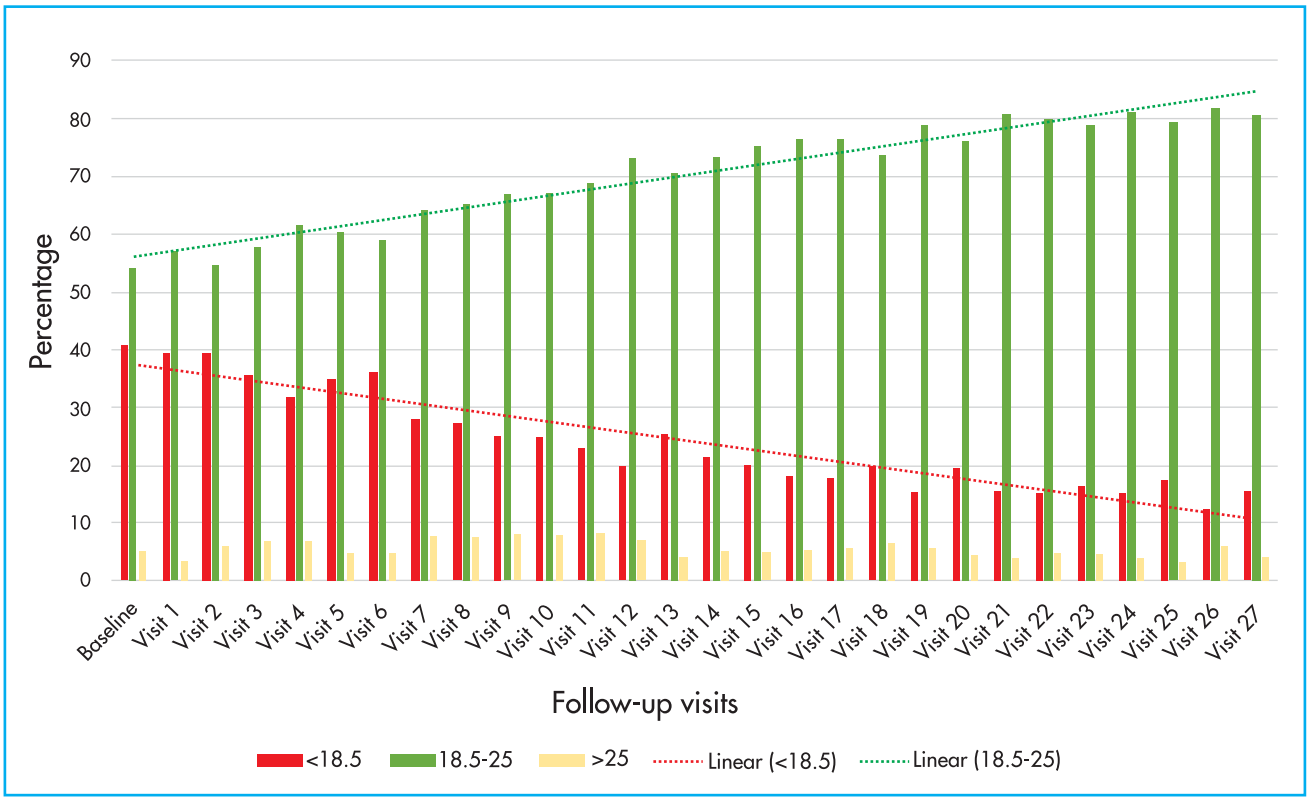
BMI monitoring:

Change in BMI from baseline to 27 months follow-up is seen in Fig 14. The mean BMI at baseline was 19.45±3.03 kg/m^2 that changed to 20.79 ± 2.36 kg/m^2 at the last visit 27. It is observed that the proportion of low BMI (<18.5 kg/m^2) had decreased over the period (40.7% to 15.35%) and that of normal BMI (18.5-25 kg/m^2) had increased (54.16% to 80.6%).The change in BMI was statistically significant using paired t-test for baseline with visit 2 follow-up onwards, which implies that within at least two months of intervention, the BMI can be improved among those with BMI

less than 18.5 kg/m^2.During the discussions with study participants, many women narrated that they simply increased the frequency of meals from 2 to 3 meals, which probably contributed to improvement in the BMI among those who had BMI less than 18.5 kg/m^2. This implies that efforts can be made to reduce the percentage ofunderweight women in Maharashtra, primarily through monitoring of BMI at the VHSNDs and implementing BCC for improved dietary frequency and quality.

The proportion of undernourished women decreased with the number of visits (chi-square for trend = 1243.48, p<0.001). To our knowledge, this is probably the first intervention in the world that has demonstrated significant improvement in the proportion of women with low BMI only through BCC interventions. Since over 100 million women of the reproductive age group are underweight in India (42% of the global burden of underweight women in the reproductive age group); this innovation will be very useful in reducing the proportion of underweight women in India. Also, there was a reduction in weight and BMI among women with BMI>25 kg/m2 at baseline over a period of time and was statistically significant.

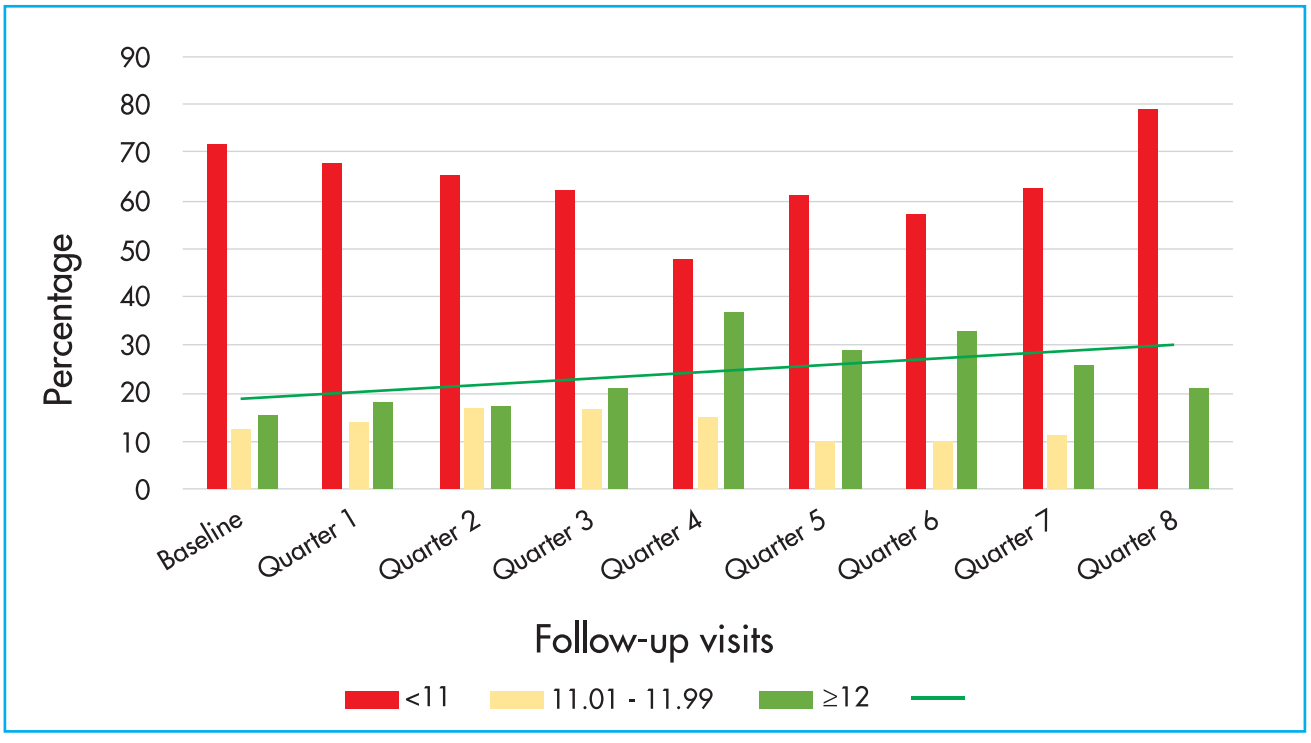
Figure 14: Change in BMI among enrolled women in intervention blocks from baseline to 27 months follow-up, Nashik, 2018-2020



Haemoglobin monitoring:

Change in haemoglobin levels from baseline to 27 months follow-up is seen in fig 15. The mean Hb at baseline was 10.56 ± 1.25 gm%, which changed to 11.10 ± 1.07 gm% at quarter 7 visit. There was a slight reduction in the mean Hb at quarter 8 visit (10.28 ± 1.35 gm%); that may be due to reduced follow-up and services during the COVID-19 pandemic. It was observed that the proportion of low Hb (<11 gm %) had decreased (71.96% to 57.37%) over the period till quarter 6 visit, but there was a slight increase in this proportion at quarter 7 visit and quarter 8 visit (62.76% and 78.94% respectively). The proportion of normal Hb (>12gm %) had increased (15.45% to 32.93%) over the period till quarter 6 visit, but there was a slight decrease in this proportion at quarter 7 visit and quarter 8 visit (25.88% and 21.05% respectively). Severe and moderate anaemia are clubbed together in moderate anaemia (<11 gm%) since the number of women with severe anaemia was very less. The proportion of normal women (non-anaemic) increased with the number of visits (chi-square for trend = 21.88, p<0.001). Reduction of the proportion of underweight and anaemic women in the intervention blocks is an extremely significant finding as there is no reduction in the proportion of women 15-49 years whose Body Mass Index (BMI) is below 18.5 kg/m2 during the National Family Health Survey 4 (2015-16) and 5 (2019-20)[61].

Figure 15: Change in Haemoglobin levels (quarterly) among enrolled women in intervention blocks from baseline to last quarter (quarter 8 visit) follow-up, Nashik, 2018-2020



61 Ministry of Health and Family Welfare, Government of India, National Family Health Survey 5, 2019-20 State Fact Sheet Maharashtra, 2020 (http://rchiips.org/nfhs/NFHS-5_FCTS/FactSheet_MH.pdf).

Therapeutic and prophylactic use of IFA for anaemia:

Anaemia was diagnosed among 2041 women (57.11%), of which severe anaemia (<8 gm%) was among 1.08% women, moderate anaemia (8-11 gm%) was among 70.88% women and mild anaemia (11.01-11.99 gm%) was among 12.59% women at baseline. These women were treated with IFA. The mean number of months of IFA treatment received was 5.40 ± 4.21. Detailed number of IFA tablets given for prophylactic and therapeutic Iron Folic Acid during the monthly follow up visits is given in table 10.

Table 10: Prophylactic and therapeutic Iron and folic acid supplementation during the preconception period, Nashik 2018-2020

No. of visits IFA received	Hb <8 gm%		Hb 8-11 gm%		Hb 11.01 -11.99 gm%		Hb >12 gm%		Total		$\chi 2$	p-value
	n	%	n	%	n	%	n	%	n	%		
0	1	3.85	27	1.58	3	0.99	21	5.63	52	2.15	79.05	<0.01
1-3	4	15.38	444	25.95	68	22.37	76	20.38	592	24.52		
4-6	8	30.77	418	24.43	73	24.01	100	26.81	599	24.81		
7-9	4	15.38	310	18.12	73	24.01	96	25.74	483	20.01		
10-12	6	23.08	315	18.41	70	23.03	68	18.23	459	19.01		
13-15	3	11.54	157	9.18	16	5.26	12	3.22	188	7.79		
>15	0	0.00	40	2.34	1	0.33	0	0.00	41	1.70		
Total	26	100	1711	100	304	100	373	100	2414	100		

Preconception folic acid supplementation:

The mean number of months of FA supplementation received (IFA or FA) during the preconception period was 6.77 ± 6.89. Folic acid supplementation was not observed to be statistically significant with a congenital anomaly.

e. Pregnancy Outcome:

Out of 7,875 enrolled women, 45.63% (1,721) and 43.52% (1,872) from intervention and comparison blocks respectively became pregnant and had outcomes during the study period. Twin pregnancy was observed among 4 and 3 women respectively from intervention and comparison blocks. About 3 and 9 women had conceived twice during the study period from intervention and comparison block respectively. At the end of the study, about 3.22% and 3.71% of enrolled women could not be followed up for the latest status from intervention and comparison blocks respectively. It was also observed that the number of visits and follow-up reduced during the COVID -19 pandemic.

Table 11 depicts the adverse pregnancy outcome. Preterm births and LBW were lower in the intervention blocks as compared to the comparison blocks; which signifies the positive effect of intervention in reducing the adverse pregnancy outcomes. Further pre-term births are significantly lower in the intervention blocks as compared to the comparison blocks.

Table11: Adverse Pregnancy outcome among enrolled women at the end of the study, Nashik, 2018-2020

Outcome event		Intervention n (%)	Comparison n (%)	Total n (%)	χ2 (p-value)
Outcome among live birth					
Low Birthweight	Yes	146 (9.23)	195 (11.25)	341 (10.29)	3.62
	No	1,435 (90.77)	1,539 (88.75)	2,974 (89.71)	(0.057)
Congenital anomaly	Yes	26 (1.62)	15 (0.84)	41 (1.21)	4.40
	No	1,575 (98.38)	1,779 (99.16)	3,354 (98.79)	(*0.036)
Early Neonatal Death	Yes	3 (0.19)	9 (0.50)	12 (0.35)	2.37
	No	1,598 (99.81)	1,785 (99.50)	3,383 (99.65)	(0.123)
Preterm	Yes	179 (11.18)	269 (14.99)	448 (13.20)	10.79
	No	1,422 (88.82)	1,525 (85.01)	2,947 (86.80)	(*<0.001)
Fetal wastage Abortion	Yes	95 (5.52)	69 (3.69)	164 (4.56)	6.87
	No	1,631 (94.50)	1,806 (96.32)	3,437 (95.44)	(*0.009)
	Induced	21 (22.11)	40 (57.97)	61(37.20)	22.09
	Spontaneous	74 (77.89)	29 (42.03)	103 (62.80)	(*<0.001)
Stillbirth#	Yes	30 (1.74)	12 (0.64)	42 (1.17)	9.40
	No	1,696 (98.26)	1,863 (99.36)	3,559 (98.83)	(*0.002)
*p<0.05					
#Fetal deaths between 20-28 weeks of gestation are included in Stillbirth					

The proportion of congenital anomalies was higher among intervention blocks, which may be attributable to the extensive training and regular follow-up in intervention blocks that increase the identification and reporting of congenital anomalies. However, this extensive training was not done in comparison blocks that might have caused under-diagnosis and under-reporting of congenital anomalies in comparison blocks. Further commonest birth defects in India like are congenital heart defects, neural tube defects are not clinically diagnosed in the newborn period unless there is a gross anomaly. Further blood disorders (*e.g.*, thalassemia, sickle cell disease) and Glucose-6-phosphate dehydrogenase deficiency cannot be diagnosed without laboratory tests.[62]

Maternal death was reported among one woman from the intervention block during 27 months of follow-up. In the baseline survey, three maternal deaths were reported during 12 month period.

The pregnancy outcome at the end of the study was compared to the baseline estimates using Z-test for two proportions (Table 12 and Table 13). The significant reduction in the proportion of low birth weight (28.56%), congenital anomaly (35.71%), and early neonatal death (60.41%) in the intervention blocks as compared to the baseline estimates; may be attributable to the PCC interventions (table 12).

62 Mathur S. B., Mukherjee, S. B. Congenital Malformations to Birth Defects – The Indian Scenario; Indian Pediatr 2017;54: 587-588.

Table 12: Comparison of adverse pregnancy outcomes among live births at study end with baseline estimates in intervention blocks, Nashik, 2017-2020

Pregnancy outcome	Baseline (N=4,766)			Study end (N=1726)			% change	p-value
	N	n	Proportion	N	n	Proportion		
Low Birthweight	4164	538	12.92	1581	146	9.23	-28.56	*0.0001
Congenital anomaly	4600	116	2.52	1601	26	1.62	-35.71	*0.038
Early Neonatal Death	4626	22	0.48	1601	3	0.19	-60.41	0.115
Preterm	3102	141	4.55	1601	179	11.18	145.71	*<0.001
*p<0.05								

The reduction in the proportion of low birth weight in comparison blocks was lower (16.29% in comparison blocks versus 28.57% in intervention blocks).

Table 13: Comparison of adverse pregnancy outcome among live births at study end with baseline estimates in comparison blocks, Nashik, 2017-2020

Pregnancy outcome	Baseline (N=4,541)			Study end (N=1,875)			% change	p-value
	N	n	Proportion	N	n	Proportion		
Low Birthweight	3734	502	13.44	1734	195	11.25	-16.29	*0.02
Congenital anomaly	4267	129	3.02	1794	15	0.84	-72.19	*<0.001
Early Neonatal Death	4299	30	0.70	1794	9	0.50	-28.57	0.372
Preterm	2737	101	3.69	1794	269	14.99	306.21	*<0.001
*p<0.05								

Women with extremely low BMI (<16kg/m^2) have higher morbidity and mortality. India has the highest prevalence of women aged 20 to 49 years with extremely low BMI among 60 low-and-middle-income countries of the world at 6.2%, (average in these countries:1.8%). This prevalence was observed to be higher than many other countries from South Asia like Bangladesh (3.9%), Pakistan (2.1%), and Nepal (1.9%) and even from sub-Saharan Africa [Madagascar (3.4%), Senegal (2.5%),Sierra Leone (2.2%), Ethiopia (2.0%), and the Democratic Republic of the Congo (1.9%)][63]. There were women, with extremely low BMI (<16 kg/m^2) in both the blocks at the time of enrolment. The majority of them in intervention blocks improved only through dietary improvement at the household level before conception and delivered a healthy newborn (Figure 16).

63 Razak F, Corsi DJ, Slutsky AS *et al.* Prevalence of Body Mass Index Lower Than 16 Among Women in Low- and Middle-Income Countries. JAMA. 2015;314(20):2164–2171. doi:10.1001/jama.2015.15666.

Figure 16: Improvement of a severely underweight and anaemic woman through PCC, who had a healthy pregnancy and a healthy newborn

Mrs. Hemlata Mahendra Sahare, age 20 years from Jalame village, post office Hatrundi, Kumbhale subcenter, Peint block was enrolled in the HPHCI in July 2018. Smt Vaishali Chaudhari, ASHA from the village, Smt. Padmavati Bhalerao, ANM from the subcenter and Dr. Purushottam Charude, MO PHC Kumbhale provided her necessary counselling, treatment, and required PCC services during the preconception period. She is educated up to class X and is a homemaker. There was no history of chronic illness and substance abuse. She was a primiparous, desired for a baby; and hence was enrolled in the project. She received counselling and BCC from ASHAs, ANM about preconception care in the form of a booklet, video, etc. She highlighted that the information given in the booklet "Health care manual" in pictorial form was easy to understand, read and that helped her a lot. Her weight was only 32 kg at the time of enrolment and her BMI at enrolment was 13.15 kg/m^2 that improved to 18.49 kg/m^2 while her haemoglobin was 10.4 gm% at enrolment that improved to 10.7 gm% before conception. In all, she attended 12 visits of follow-up during her preconception period. She delivered a baby at 38 weeks of gestational age and normal vaginal delivery. It was an institutional delivery at Rural Hospital, Peint and the birth weight was 3500 gm. Now, the baby is 11 months old. She highlighted that she became aware of the importance of her health before conception for the health of the newborn because of this project.

f. Strengths and Limitations of the study related to follow-up of enrolled women

As mentioned already, we implemented a complex public health intervention and employed the methodology of assessment of complex public health intervention for promoting the health of women during the preconception period on preventing adverse pregnancy outcomes like low birth weight. This is perhaps one of the first studies, which has demonstrated that promoting women's health and nutrition through behaviour change communication and existing government programmes may result in the reduction of low birth weight and neonatal mortality.

There are a few limitations to the study. Firstly since the baseline assessment and follow-up of eligible aspiring women were conducted in control and intervention blocks, women in the control blocks may have become aware of preconception care and may have started healthy behaviour and practices. From March 2020, the follow-up visits were drastically reduced, otherwise better results may have been reported. An end-line survey could not be carried out due to the COVID-19 pandemic. Further certain variables studied in the baseline survey like preterm birth may be subjected to recall bias as many women may not remember the last menstrual period or the date of birth.

g. Scale-up of the Innovation:

The government of Maharashtra started the scale-up of the programme to four aspirational districts and Melghat region of

Amravati district and in five major tribal districts of Maharashtra (Nashik, Gondia, Palghar, Chandrapur, and Yavatmal) using National Health Mission resources.

Ministry of Health and Family Welfare, Government of India has already included preconception nutrition algorithm in the POSHAN Abhiyan in Village Health Sanitation, Nutrition Day guideline (Annexure 1).

Further, the process of drafting the national PCC guideline has been initiated by the Ministry of Health and Family Welfare, Government of India by involving professional associations like the Federation of Obstetrics and Gynecological Associations of India (FOGSI), Department of Obstetrics and Gynecology of academic institutions like All India Institute of Medical Sciences, University College of Medical Sciences, Delhi, Safdarjung Hospital, Delhi, development partners like UNICEF, World Health Organization, Family Health International 360, Alive and Thrive, Public Health Foundation of India, National Center of Excellence for Advanced Research on Diet, Lady Irwin College, Delhi.

a. Programme Related

i. Scale-up this primary health care intervention to the entire state and beyond

This innovation should be replicated across the state for promoting the health of individuals and the family, devastated by the Covid 19 pandemic. Systematic social and behavioural change communication strategies can be implemented within a short period, while simultaneously integrating the health system strengthening initiatives to include preconception care. The preconception care should be integrated with the medical and nursing curriculum as well as for secondary school curriculum. The concept of the first 1000 days of life may be expanded by adding 200 days and making it as first 1200 days of life. In this, 200 days before conception are included to prioritize the promotion of the health of eligible aspiring couples. As mentioned earlier, to our knowledge, this is the first intervention in the world that has demonstrated significant improvement in the proportion of women with low BMI only through BCC interventions. Since more than 100 million women in the reproductive age group are underweight in India, which is contributing to 42% of the global burden of underweight women in the reproductive age group, this innovation will be a crucial aspect in reducing the proportion of underweight women in India. This will also contribute in a major way to reducing the LBW prevalence in India. This is extremely critical as Covid 19 has worsened the under nutrition pandemic in Low- and Middle-Income Countries. It is estimated that by 2022, COVID-19-related disruptions could result in an additional 9.3 million wasted children and 2.6 million stunted children, 168,000 additional child deaths, 2.1 million maternal anaemia cases, 2.1 million children born to women with a low BMI. Most of these wasted and stunted children and child deaths will be in South Asia and sub-Saharan Africa. Governments and donors must maintain nutrition as a priority, continue to support resilient systems, and ensure the efficient use of new and existing resources.[64]

ii. Integrate monitoring of the weight and body mass index of all children, adolescents, and women of reproductive age group in the existing government programmes and in the private sector

It is very important to integrate monitoring of the weight and BMI to the existing adolescent health programmes like Rashtriya Kishore Swasthya Karyakram, Rashtriya Bal Swasthya Karyakram, School Health, and Wellness Ambassador Initiative and implement BCC and food supplementation programmes among those with low BMI.

iii. Expand evidence-based strategies like multiple micronutrients

Comprehensive Nutrition Survey of India implemented under the guidance of the Ministry of Health and Family Welfare in collaboration with the United Nations Children's Fund (UNICEF), showed a very high prevalence of multiple micronutrients deficiency among age groups of 10 to 19 years[65].

64 Osendarp S, Akuoku JK, Black RE et al. The COVID-19 crisis will exacerbate maternal and child undernutrition and child mortality in low- and middle-income countries. Nat Food (2021). https://doi.org/10.1038/s43016-021-00319-4.
65 Ministry of Health and Family Welfare, Government of India. Comprehensive Nutrition Survey, preliminary fact sheet, Maharashtra 2016-17.

Around the world, pregnant women and children under 5 years of age are at the highest risk of multiple micronutrient deficiencies. Iron, iodine, folate, vitamin A, and zinc deficiencies are the most widespread deficiencies and are common contributors to poor growth, intellectual impairment, perinatal complications, and increased risk of morbidity and mortality[66]. In the Gambia, the effect of conception during seasonal food availability and epigenetic changes in offspring is well documented[67]. This highlights the need for a behaviour change communication campaign for promoting the consumption of green leafy vegetables at the time of conception, which can be done in the rural areas through kitchen gardening at the household level.

iv. Promote preconception health among men

Implementation of preconception care among men is critical as the couple needs to decide and ensure that every pregnancy is wanted and planned. Further, it is an opportunity for involving men for ensuring healthy pregnancy outcomes, promote women's reproductive health, prevent gender bias and discrimination against women, preparing men for fatherhood. Panchayat functionaries, as well as adolescent boys' groups, may be involved through existing programmes like Rashtriya Kishore Swasthya Karyakram, School Health and Wellness Ambassador's initiative for promoting preconception health among men.

v. Strengthen primary health care and design social protection schemes for women whose health needs improvement in the preconception period for preventing the intergenerational cycle of malnutrition

The association between poverty, health, and health care is complex. A child from a poor family is twice at risk of dying as compared to a child from a non-poor family. In a multi-country national analysis of 34 developing countries including India, it was found that higher national income was associated with lower under-five mortality . This evidence needs to be translated to the policy of strengthening primary health care for the poor and disadvantaged population as well as designing social protection schemes for promoting the health of women during the preconception period in the form of subsidized food grains to the newly married couple through the public distribution system.

b. Further Research

It will be interesting to study the demographic aspects like reduction of fertility rates, and its impact on the reduction of maternal and under-five mortality. Further, the malnutrition and early childhood development of the offspring born to the women receiving pre-conception care may be studied. Cost-effectiveness studies may be implemented to understand the cost and savings in terms of reduction of out-of-pocket expenses.

66 Bailey RL, West KP, Black RE. The Epidemiology of Global Micronutrient Deficiencies. Ann Nutr Metab 2015;66 (suppl 2):22-33. doi: 10.1159/000371618.

67 Waterland RA, Kellermayer R, Laritsky E, Rayco-Solon P, Harris RA, Travisano M, Zhang W, Torskaya MS, Zhang J, Shen L, Manary MJ. Season of conception in the rural Gambia affects DNA methylation at putative human metastable epialleles. PLoS genetics. 2010 Dec 23;6(12):e1001252.

68 Houweling T, Kunst AE, Looman C and Mackenbach JP. Determinants of under-5 mortality among the poor and the rich: a cross-national analysis of 43 developing countries, International Journal of Epidemiology 2005;34:1257–1265. doi:10.1093/ije/dyi190.

CHAPTER SIX

CONCLUSION

Healthy parents and healthy child initiative is a complex public health intervention, which generated evidence that it is feasible to demonstrate positive pregnancy outcomes primarily through behavior change communication and intensification of existing RMNCHA programmes. The assessment of impact involved the methodology for evaluation of the complex public health interventions and scale-up of this innovation will go a long way in health promotion of women and children and reducing the intergeneration cycle of malnutrition.

ANNEXURE-1

1. Preconception Nutrition algorithm for integration in the Village Health Sanitation Nutrition Days.

सत्यमेव जयते

POSHAN Abhiyaan
PM's Overarching Scheme for Holistic Nourishment
सही पोषण – देश रोशन

NATIONAL HEALTH MISSION
राष्ट्रीय स्वास्थ्य मिशन

9th of Every Month

5 ACTIONS FOR PRECONCEPTION NUTRITION SERVICES IN VILLAGE HEALTH SANITATION AND NUTRITION DAY

1 NUTRITION ASSESSMENT

ANM & ASHA

2 GIVE

3 COUNSEL

ASHA & AWW

4 CLASSIFY NUTRITIONAL RISK

5 ACTIONS BY NUTRITIONAL RISK

ANM

1 NUTRITIONAL ASSESSMENT

1.1 ASK

- ☑ Age
- ☑ Obstetric history
- ☑ Recurrent or prolonged illness
- ☑ Planning pregnancy
- ☑ Last menstrual period

Symptoms

- ☑ Fever
- ☑ Cough
- ☑ Blood in sputum
- ☑ Increased urinary frequency /burning during urination
- ☑ Fatigue
- ☑ Palpitation
- ☑ Shortness of breath
- ☑ Worm infestation
- ☑ Night blindness
- ☑ Sudden weight loss

Eating habits and physical activity

- ☑ Number and frequency of meals
- ☑ Food habits
- ☑ Snacking and fasting pattern
- ☑ Caffeine, alcohol, tobacco, substance abuse
- ☑ Food restrictions
- ☑ Physical activity (Type, duration, frequency)

1.2 MEASURE

☑ Height

☑ Weight

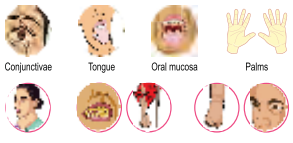
☑ Mid-upper arm circumference (MUAC)

☑ Blood pressure

☑ Compute body mass index (BMI)

1.3 LOOK FOR

☑ Pallor



Conjunctivae | Tongue | Oral mucosa | Palms

☑ Palpable goitre | ☑ Dental and skeletal fluorosis | ☑ Pedal edema and puffiness of face

1.4 TEST

☑ Blood test (haemoglobin, oral glucose tolerance)

☑ Urine test (albumin and sugar)

*Other tests like HIV, VDRL, Hep B recommended during pregnancy

2 GIVE

☑ Folic acid supplements (if planning pregnancy)

☑ Iron folic acid (IFA) tablets (weekly)

☑ Albendazole, preferably directly observed treatment (once, in six months)

3 COUNSEL

☑ 20 minutes group counselling of women and husband using flipbook

4 CLASSIFY BY NUTRITIONAL RISK

Short | Young | Low BMI/thin | Very low MUAC | Obese | Any anemia

- ☑ Height <145 cm
- ☑ Age <20 years
- ☑ BMI <18.5 kg/m² OR Weight <45 kg OR MUAC <23 cm
- ☑ MUAC <21 cm
- ☑ BMI ≥25 kg/m² OR MUAC ≥33 cm
- ☑ Haemoglobin <12 g/dL

☑ Check for co-existence of medical illness

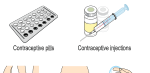
- Hypertension
- Diabetes mellitus
- Malaria
- Tuberculosis
- Fluorosis
- Goitre
- Hypothyroidism and hyperthyroidism
- Urinary tract infection
- Sexually transmitted infection
- Human immunodeficiency virus

5 ACTIONS BY NUTRITIONAL RISK

☑ 15 minutes individual counselling

- ☑ Treat mild to moderate anemia with daily two IFA tablets for 3 months (monitor)
- ☑ Refer to Primary Health Centre (or nearest facility) for
  - Treatment of severe anemia
  - Confirmation and treatment of medical illness
- ☑ Fortnightly home visits by ASHA and monthly by ANM to encourage compliance to advise and treatment
- ☑ Refer to Health and Wellness Centre for
  - Management of thinness and obesity
  - Behavioural counselling and deaddiction program

☑ Advise and provide family planning options



Contraceptive pills | Contraceptive injections

Male condom | IUD (copper T) | Female condom

ANNEXURE-2

URL to Guideline and resource materials of the innovation.

- **Department of Public Health, Government of Maharashtra**

- https://arogya.maharashtra.gov.in/pdf/Arogya%20Pustika%20Eng.pdf
- https://arogya.maharashtra.gov.in/pdf/Arogya%20pustika.pdf
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- **UNICEF Maharashtra**

- https://iec.unicef.in/document/healthy-parents-healthy-child-initiative-5816
- https://iec.unicef.in/document/healthy-parents-healthy-child-initiative

- **Bharati Vidyapeeth Medical College, Pune**

- https://youtube.com/channel/UC4K90Z7jzayqKg1HO1zd-Qw

ANNEXURE-3

- **Research articles published:**

- Doke P *et al*. Meagre perception of preconception care among women desiring pregnancy in rural areas; a qualitative study using focus group discussions. Frontiers in Public Health, 2021.
- Doke P *et al*. Are adverse pregnancy outcomes associated with preceding risk factors? An analytical cross-sectional study. BMC Pregnancy and childbirth, 2021.

- **Research articles submitted and under revision or review:**

- Gothankar J *et al*. Prevalence of preconception risk factors among women from tribal and non-tribal blocks in Nashik District, India: A cross-sectional study. BMC Journal of Reproductive Health, 2021.
- Chutke A *et al*. Perceived challenges and solutions among health care providers towards introducing preconception care through public health system: a qualitative research. BMC Archives of Public Health, 2021.

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