Preventive Medicine Reports 43 (2024) 102796

Contents lists available at ScienceDirect

Preventive Medicine Reports

journal homepage: www.elsevier.com/locate/pmedr

Implementation of preconception care for preventing adverse pregnancy outcomes in rural and tribal areas of Nashik District, India

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A R T I C L E I N F O

Keywords:
Preconception care
Low birth weight
Preterm birth
Abortion
Stillbirth
Physical congenital anomaly
Behavioral change communication

A B S T R A C T

Introduction: The World Health Organization has suggested preconception care to improve pregnancy outcomes. Hence, the study aimed to compare the effect of preconception care on pregnancy outcomes, particularly prematurity and low birth weight.

Methods: We carried out interventions in one tribal and one non-tribal block. For comparison, one adjacent tribal block and one non-tribal block were included in Nashik district, India. The total study period was from April 2018 to July 2021. All reproductive age group women desiring pregnancy within one year in selected four blocks participated in the study. The services included clinical examination, laboratory investigations, treatment, six-monthly deworming, anemia management, folic acid supplementation, family planning services, and behavioral change communication using different media. The existing healthcare workers provided services to the women until they became pregnant or until the end of the follow-up period (27 months). We monitored pregnancy outcomes, including abortion, stillbirth, and live birth; among live births, low birth weight, preterm birth, congenital physical anomaly, and neonatal death.

Results: The study enrolled 7,875 women, and 3,601 had outcomes. The proportion of preterm births in the intervention and comparison block was 11.18 % and 14.99 %, respectively ($p = 0.001$), and the proportion of low-birth-weight babies was 9.23 % and 11.25 %, respectively ($p = 0.01$). The adjusted prevalence ratio showed that the risk of preterm births in the absence of intervention was 1.3 (CI: 1.1–1.6). Preterm birth was a mediator between preconception care and low birth weight.

Conclusion: Reduction in proportion of low birth weight and preterm babies can be achieved through preconception care using minimal additional resources.

1. Introduction

All countries desire to achieve Sustainable Development Goal 3 by 2030. Target 3.2, i.e., 'end all preventable newborn and under-five deaths,' is very challenging for India as it is one of the top ten countries with high neonatal mortality globally (World Health Organization, 2020). The neonatal mortality in India was 20/1,000 live births in 2020 (Registrar General Government of India, 2022), amounting to almost half of (47 %) under-five mortality. Preterm delivery, Low Birth Weight (LBW), intra-partum complications like asphyxia, infections, and

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https://doi.org/10.1016/j.pmedr.2024.102796
Received 18 September 2023; Received in revised form 7 June 2024; Accepted 8 June 2024
Available online 9 June 2024

congenital anomalies are leading causes of under-five mortality. Many causes are related to maternal health and nutritional status (March of Dimes, 2017; Gleason and Juul, 2018; Seid et al., 2019; Desalew et al., 2020; Abdul-Mumin et al., 2021). India has a high prevalence of LBW babies. Maternal under-nutrition, including iron deficiency, maternal underweight, and short stature, may retard fetal growth and increase the risk of LBW (Black et al., 2013).

Improved women's health before conception through Preconception Care (PCC) has improved birth outcomes (Atrash et al., 2006; Jourabchi et al., 2019; Lassi et al., 2020). Hence, preconception care supplements antenatal and intra-natal services. This preconception period is the appropriate time for addressing modifiable risk factors related to lifestyle, improving nutrition, promoting health, and planning the pregnancy. Despite the World Health Organization's recommendations, a few countries implement preconception care (World Health Organization, 2014).

India is yet to include preconception care in health programs. Hence, the research question was, does providing preconception care in addition to routine antenatal care through existing healthcare workers reduce adverse pregnancy outcomes? We hypothesized that women from rural including tribal areas, who receive preconception care, might have fewer adverse pregnancy outcomes than those who do not. The government has notified some communities as Scheduled Tribes (ST) that mainly reside in forest and hilly areas; hence, they constitute a disadvantaged population. They are socio-culturally different and are not ready to mix with the general population. The specific objectives were as follows;

To compare the effect of preconception care on premature delivery, low birth weight, congenital physical defects, and neonatal mortality in the intervention and comparison arms.

To compare the prevalence of pregnancy loss in the form of abortion and stillbirth in two arms.

2. Material and methods

2.1. Study design

The community-based implementation study included two randomly selected blocks in the intervention and two adjacent blocks in the comparison arm.

2.2. Study settings

The study was conducted in four blocks of Nashik district, Maharashtra State, India. We selected one tribal block (block having a high proportion of the Scheduled Tribes population) for intervention and an adjacent tribal block for comparison. Similarly, we chose one non-tribal block for intervention and one adjacent non-tribal block for comparison (Fig. 1). There were 13 Primary Health Centers (PHCs) in the intervention and 15 in the comparison blocks. Detailed information about the study setting has already been reported (Doke et al., 2022).

2.3. Study period

The total study period was from April 2018 (kick-off meeting) to July 2021 (report submission). The women in the intervention and comparison arms were enrolled from July to August 2018, and the intervention was provided from August 2018 to October 2020 (27 months).

2.4. Study participants and enrolment

All women aged 15 to 49 years in the selected blocks desiring pregnancy within one year and residents of the area were eligible and enrolled by Accredited Social Health Activists (ASHAs). ASHAs are women from the community and act as a bridge between government and the community. Detailed information about the participants' enrolment, baseline characteristics, and prevalence of selected risk factors was collected and published (Doke et al., 2022).

2.5. Intervention, data collection, and monitoring

Preconception care is defined as 'the provision of biomedical, behavioral and social health interventions to women and couples before conception occurs' (World Health Organization, 2014). It included the following components.

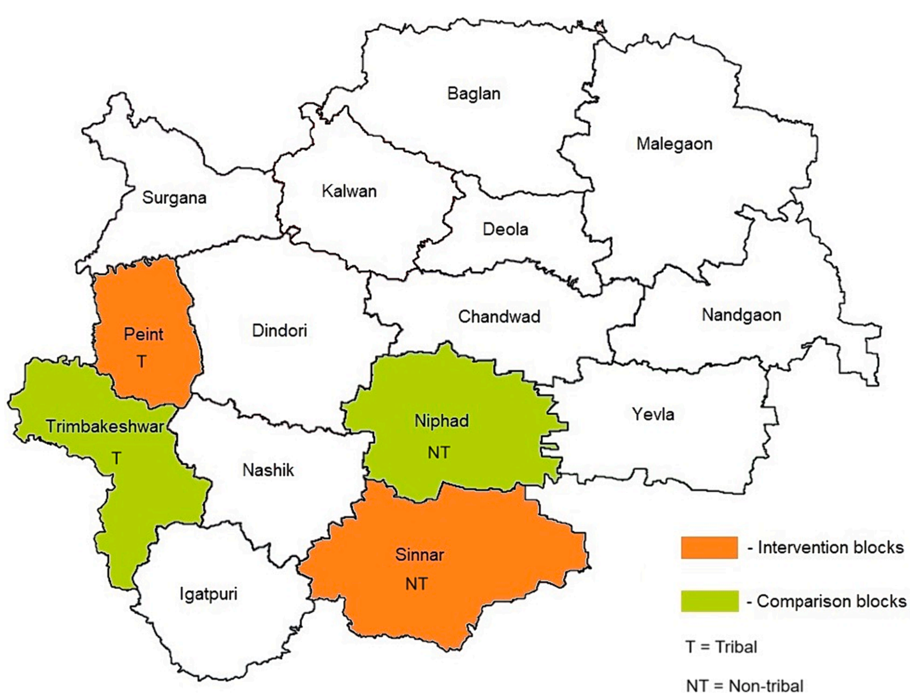

Fig. 1. Study setting of implementation of preconception care in Nashik district, India, 2018–2020.

1. Clinical examination, including height, weight, and blood pressure,
2. Laboratory investigations included checking blood group, random blood sugar, Thyroid Stimulating Hormone (TSH), Human Immunodeficiency Virus (HIV), Venereal Disease Research Laboratory (VDRL) at enrollment, hemoglobin every three months, and urine pregnancy test after the missing period,
3. Treatment, counseling, and referral as needed for a diagnosed condition,
4. Six monthly deworming using a single dose of 400 mg albendazole,
5. Anemia treatment and prevention; for anemic women, two tablets daily, each containing 100 mg elemental iron and 500 μg folic acid (IFA); and for non-anemic women, weekly same iron and folic acid tablets supplementation,
6. Daily folic acid supplementation during the pre-pregnancy period to anemic women as a constituent of IFA and to non-anemic women (receiving weekly iron supplementation) daily plain folic acid tablet (5 mg or 500 μg depending upon availability),
7. Family planning services; temporary methods for women in the adolescent age group, those having severe anemia, short inter-pregnancy interval, and/or low Body Mass Index (BMI),
8. Behavioral Change and Communication (BCC) included information about quitting alcohol and tobacco, safe abortion centers, BMI normalization in addition to all the above points.

The authors trained healthcare workers from the intervention blocks to provide preconception care, imparting BCC and monthly follow-ups of the enrolled women during Village Health Sanitation Nutrition Days (VHSNDs). Initially, all the enrolled women desiring pregnancy were examined by the Medical Officers of the PHCs. The laboratory investigations mentioned above were done at baseline. The women identified as having an illness like anemia, hypothyroidism, high blood sugar, or systemic illness were treated accordingly or referred to a higher center for further management. Women with low BMI were provided BCC with special emphasis on improving nutrition, and those with high BMI were guided to lower it. The ASHA closely followed up with anemic women for regular medication consumption and improvement in hemoglobin levels. ASHAs and Auxiliary Nurse Midwives (ANMs) executed BCC to the women at existing government health facilities. The BCC used three different modes of communication and covered all the points regarding preconception care awareness, education, and counseling. The first two modes of BCC were imparted on VHSND to women groups. The first mode included BCC using a flipbook and was an interactive session. The second mode was a specially produced documentary film of about 28 min shown on a laptop. In the third mode, the women received 12 audio and text messages of about one-minute each (three messages per week) on their mobile phone. Within six months of enrollment, each and every woman from all villages received the BCC intervention. We gave a pictorial handout based on the National Health Rural Mission handbook for screening visible birth defects to ASHA and ANM to detect physical congenital anomalies. Experts and government officers had reviewed all these tools.

Software was developed and installed on the tablets provided by the government to ANMs (only in intervention blocks). They entered the baseline demographic and clinical information and laboratory reports of the participants in the tablet. Subsequently recorded details of the monthly follow-up and preconception care services provided to enrolled women until they conceived or the study period ended. The ASHAs followed all the women and collected information about the pregnancy outcome mainly through home visits which were confirmed from the documents. The pregnancy outcomes were also recorded in the software. For the comparator arm, ANMs captured the baseline socio-demographic and nutritional details along with BMI. Later on, the birth outcomes of these women were also captured by them. The software company personnel trained all healthcare workers.

Authors considered the following 15 risk factors for adverse pregnancy outcome: age younger than 20 years and more than 35 years, nuclear family, scheduled tribe, education less than 10th standard, non-earning woman, consanguineous marriage, parity more than two, calorie intake less than 50 % of recommended daily allowance, protein intake less than 50 % of recommended daily allowance, BMI less than 18.5 kg/m^2 (underweight), BMI more than 25 kg/m^2 (overweight), tobacco consumption in any form, alcohol addiction and no preconception care.

After becoming pregnant, all participants received routine standard antenatal care through the government health system. All women were followed for pregnancy outcomes. The authors ensured the provision of all preconception care components during the monthly follow-ups and monitored women-wise details of visits and services in the intervention block.

2.6. Outcomes

The primary outcomes were live birth and fetal loss as abortion (spontaneous or induced before 20 weeks of gestation) or stillbirth (termination of pregnancy after 20 weeks up to 37 weeks). The secondary outcomes among live births were LBW (birth weight $<$ 2500 gm.), premature delivery, congenital physical anomalies, and neonatal mortality.

2.7. Sample size

Authors considered the prevalence of LBW in the rural Nashik district as 14 % (International Institute for Population sciences Ministry of Health and Family Welfare Government of India, 2020a) to estimate the sample size. Hypothesizing a 25 % reduction in the prevalence of low birth weight with 80 % power and 95 % confidence, the estimated sample size was 1,374 pregnancy outcomes in each arm. The probability of achieving the desired sample size was confirmed through precedent-year data from the health management information system.

2.8. Statistical methods

We calculated the difference between prevalence of pregnancy outcomes in both arms using the Z test. A major contribution to LBW is from preterm babies. Hence, mediation analysis was done using the Sobel test (Fairchild and MacKinnon, 2009). Initially, bivariate analysis was done to find the crude Prevalence Ratio (PR) for potential risk factors for adverse pregnancy outcomes. The risk factors identified as statistically significant were considered for calculating the adjusted prevalence ratio (APR). The APR at a 95 % Confidence Interval (CI) was calculated using a generalized linear regression model with a log link function and family of binomial distribution. The authors used Statistical Package for the Social Sciences (SPSS; version 25.0) and STATA (15.1 version) for analysis.

2.9. Ethics statement

Bharati Vidyapeeth (Deemed to be University) Medical College, Pune, Institutional Ethics Committee approved this study vide letter BVDUMC/IEC/11, Date: 30/04/2018. All participant women gave written informed consent for participation in the study.

2.9.1. Clinical trial registry India number

CTRI/2018/06/014657 dated 28 June 2018.

3. Results

The study enrolled 7,875 women desiring pregnancy from four blocks, 3,574 from intervention blocks, and 4,301 from comparison blocks. Out of the total women, 37.8 % belonged to tribal blocks. The age of women ranged from 14.42 to 45.50 years (mean 23.19 ± 3.71), and the majority (88.6 %) were Hindus. Non-nuclear families were more

Table 1
Distribution of the socioeconomic variables of the women at baseline collected from April to July 2018 having birth outcomes, Nashik District, Maharashtra, India.

Risk factors		Group		Total	χ^2	p
		Intervention (%)	Control (%)			
Age Group	<20	359 (20.93)	388 (20.94)	747 (20.94)	4.68	0.10
	20–35	1344 (78.37)	1461 (78.85)	2805 (78.62)		
	>35	12 (0.70)	4 (0.22)	16 (0.45)		
Caste	ST[@]	689 (46.24)	512 (35.53)	1201 (40.98)	34.75	<0.001
	Non-ST	801 (53.76)	929 (64.47)	1730 (59.02)		
Family type	Nuclear	173 (11.13)	207 (12.58)	380 (11.88)	1.61	0.21
	Non-nuclear	1381 (88.87)	1438 (87.42)	2819 (88.12)		
Education	<SSC[#]	591 (35.88)	699 (39.47)	1290 (37.74)	4.67	0.031
	≥SSC	1056 (64.12)	1072 (60.53)	2128 (62.26)		
Occupation	Employed	518 (31.60)	706 (40.98)	1224 (36.41)	31.85	<0.001
	Unemployed	1121 (68.40)	1017 (59.02)	2138 (63.69)		
BMI[$] (kg/m^2)	<18.5	681 (42.06)	659 (38.86)	1340 (40.42)	9.28	0.10
	18.5–25	880 (54.35)	943 (55.60)	1823 (45.99)		
	>25	58 (3.58)	94 (5.54)	152 (4.59)		
Consanguine marriage	Yes	282 (17.74)	435 (26.09)	717 (22.01)	33.21	<0.001
	No	1308 (82.26)	1232 (73.91)	2540 (77.99)		
Multiparty	≤2	1619 (96.31)	1749 (96.20)	3368 (96.26)	0.03	0.87
	>2	62 (3.69)	69 (3.80)	131 (3.74)		
Tobacco	Yes	84 (4.93)	92 (4.94)	176 (4.93)	0.00	0.99
	No	1619 (95.07)	1772 (95.06)	3391 (95.07)		
Calorie Intake*	<50 %	21 (1.22)	35 (1.87)	56 (1.56)	2.48	0.12
	≥50 %	1705 (98.78)	1840 (98.13)	3545 (98.44)		
Protein Intake*	<50 %	17 (0.98)	35 (1.87)	52 (1.44)	4.91	0.027
	≥50 %	1709 (99.02)	1840 (98.13)	3549 (98.56)		

@ST: Scheduled tribe #SSC: Secondary school certificate (10 years of schooling).
* With reference to recommended daily allowance (RDA), BMI: Body mass index.

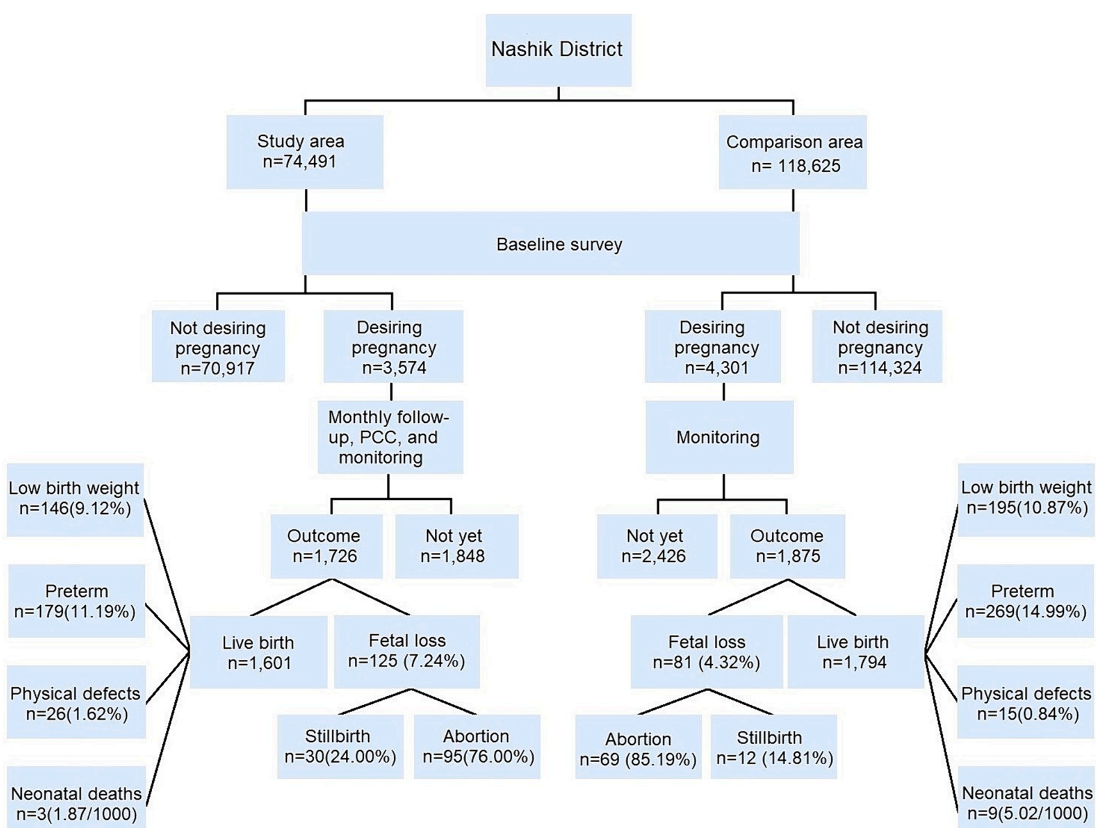

Fig. 2. Follow-up of enrolled women desiring pregnancy within a year, Nashik district, India, 2018–2020.

Table 2
Comparison of pregnancy outcomes in women receiving preconception care with those who did not receive the same during the period January 2019 to October 2020 in Nashik district, Maharashtra, India.

Pregnancy outcome	Intervention area		Comparison area		p
	N	n (%)	N	n (%)	
Outcome of all women delivered after enrollment in the study					
Live births					
Preterm births	1601	179 (11.18)	1794	269 (14.99)	0.001
Low birth weight	1581	146 (9.23)	1734	195 (11.25)	0.06
Congenital physical anomaly	1601	26 (1.62)	1794	15 (0.84)	0.04
Neonatal death	1601	3 (0.19)	1794	9 (0.50)	0.13
Fetal loss					
Spontaneous/induced abortion	1726	95 (5.50)	1875	69 (3.68)	0.001
Stillbirth	1726	30 (1.74)	1875	12 (0.64)	0.002
Outcome of women who became pregnant after six months (receipt of three modes of BCC)					
Live births					
Live births	746	681 (91.29)	1077	1023 (94.99)	0.002
Preterm births	681	86 (12.63)	1023	171 (16.72)	0.02
Low birth weight	681	70 (10.28)	1023	112 (10.95)	0.66
Congenital physical anomaly	681	11 (1.62)	1023	14 (1.37)	0.67
Neonatal death	681	2 (0.29)	1023	7 (0.68)	0.27
Fetal loss					
Spontaneous/induced abortion	746	53 (7.10)	1077	46 (4.27)	0.008
Stillbirth	746	12 (1.61)	1077	8 (0.74)	0.08

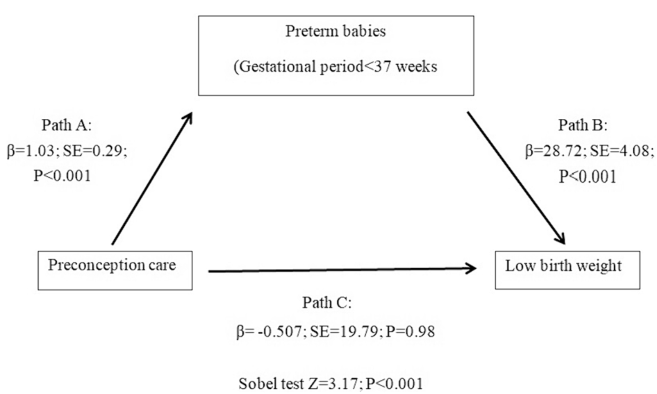

Fig. 3. Mediation analysis using Sobel test, Nashik district, India, 2018–2020.

common (74.3 %) than nuclear ones. The height and weight of 7,167 women (91.0 %) were measured, and the mean baseline BMI was 19.73 (±3.51) kg/m^2. Almost one-third of women were undernourished (BMI < 18.5) at baseline.

In the intervention area, about 182 enrolled women (5.09 %) did not attend any follow-up and availed the preconception care services. Overall, the mean number of follow-up visits was 9.47 ± 6.89. The women who did not become pregnant during the study period attended more follow-up visits than those who became pregnant.

Table 1 gives the socio-demographic and biological risk factors among the women who had pregnancy outcomes during study period. The data showed statistically significant differences for risk factors like caste, education, occupation, consanguineous marriages, and protein intake among women with pregnancy outcomes between the intervention and comparison arm ($p < 0.05$). More women with pregnancy outcomes belonged to a socially disadvantaged group (scheduled tribe) in the intervention area, whereas women with higher education, formal employment, and consanguineous marriages who reported pregnancy outcomes were more in the comparison arm. Overall, alcohol addiction was 0.62 % only; hence, it was not considered for analysis.

Fig. 2 gives detail follow up of enrolled women and pregnancy outcomes. A total of 3,593 pregnant women reported 3,601 pregnancy outcomes during the study period. The number of pregnancy outcomes was higher than that of pregnant women due to twin pregnancies or women conceiving twice during the study period. The pregnancy outcome number was 1,726 in the study area and 1,875 in the comparison area. Among the enrolled women, only 0.38 % was home deliveries during the follow-up period.

The overall adverse live birth outcomes (preterm, low birth weight, neonatal death) were lower in the intervention area. However, fetal loss (abortion of any type and stillbirth) and congenital physical anomalies were higher in the intervention area. Similar results were observed among women who conceived after receiving PCC including 3 modes of BCC (Table 2). Mediation analysis using the Sobel test denotes that preterm birth is a mediator between preconception care and low birth weight outcome (Fig. 3).

Bivariate analysis (Table 3) showed a significant prevalence ratio of risk factors associated with adverse pregnancy outcomes. (The numbers in different cells are available as a supplementary file.) Apart from intervention, age, family type, occupation, cast, and BMI showed some association with specific adverse outcomes. Adolescents from socially disadvantaged groups and low BMI had a significant prevalence ratio for low birth weight. The absence of preconception intervention had a significant prevalence ratio for preterm birth. Women in socially disadvantaged groups had a significant prevalence ratio for physical congenital anomalies. The prevalence ratio for abortion was significantly higher among women living in nuclear families, and stillbirth was higher among women from the socially disadvantaged group. A similar state was noted among women who became pregnant after receipt of the BCC intervention package.

An adjusted prevalence ratio was calculated to nullify the effect of confounding on the effect of risk factors identified by bivariate analysis. Table 3 also gives the adjusted prevalence ratio of adverse outcomes with confidence interval. The adjusted prevalence ratio for LBW was significantly higher among women from the socially disadvantaged group, low BMI, and obese. At the same time, preterm birth was significantly higher among women who did not receive preconception intervention.

4. Discussion

The current community study was one of its kind in India, where the authors studied the effect of preconception care on the following six adverse pregnancy outcomes: abortion, stillbirth, preterm birth, LBW, congenital physical anomaly, and neonatal mortality. Preconception care is expected to play a role by addressing the modifiable risk factors optimizing women's health and, consequently, adverse pregnancy outcomes. The interventions are mainly directed to minimize preconception risk factors through local resources (World Health Organization, 2014).

The prevalence of following risk factors: caste, education, occupation, consanguinity, and protein intake at baseline was dissimilar in the two arms. Hence, multivariate analysis was indispensable. In this, we included variables those were significantly associated with outcome variables in bivariate analysis for two reasons. First, with more variables included, the final number in the model gets reduced due to differential non-responses to the individual variables. Secondly, the chances of observing an association if it is not detected in the bivariate analysis are rare.

Besides the modifiable risk factors like BMI, a few non-modifiable risk factors like age above 35, caste, education, consanguineous

Table 3
Crude and adjusted prevalence ratio of risk factors for adverse pregnancy outcomes in women from Nashik District, India during the period January 2019 to July 2021.

Risk factor		LBW*		Pre-term		Congenital anomaly		N. death[@]	Abortion		Stillbirth	
		PR[#] (CI)	Ad. PR[$] (CI)	PR (CI)	Ad. PR (CI)	PR (CI)	Ad. PR (CI)	PR (CI)	PR (CI)	Ad. PR (CI)	PR (CI)	Ad. PR (CI)
Age	<20	1.3 (1.0-1.6)	1.2 (0.9-1.5)	0.9 (0.8-1.2)		0.6 (0.3-1.5)			1.0 (0.7-1.5)		0.8 (0.3-1.7)	
	20-35	1	1	1		1		1	1		1	
	>35	2.2 (0.8-6.1)	1.7 (0.5-5.8)	1.1 (0.3-3.9)		-		-	2.8 (0.8-10.2)		-	
Parity	>2	1.0 (0.5-1.7)		1.1 (0.7-1.7)		0.7(0.1-4.9)		-	1.5 (0.8-2.9)		0.7 (0.1-4.8)	
	≤2	1		1		1		1	1		1	
Family type	Nuclear	0.8 (0.6-1.2)		0.9 (0.7-1.3)		0.5 (0.1-1.9)		0.7 (0.1-5.5)	2.2 (1.5-3.1)	2.2 (1.5-3.1)	1.7 (0.7-3.8)	
	Non-nuclear	1		1		1		1	1	1	1	
Occupation	Employed	0.8 (0.7-1.0)		1.1 (0.9 -1.3)		0.6 (0.3-1.2)		0.9 (0.3-2.9)	1.4 (1.0-1.9)		0.4 (0.2-0.9)	0.5 (0.2-1.2)
	Unemployed	1		1		1		1	1		1	1
Education	<10th Pass	1.0 (0.8-1.2)		1.1 (0.9-1.3)		1.2 (0.6-2.2)		0.6 (0.2-2.0)	0.8 (0.6-1.1)		1.6 (0.8-2.9)	
	≥10th Pass	1		1		1		1	1		1	
Caste	ST^	1.3 (1.0-1.6)	1.3 (1.0-1.6)	0.8 (0.7-1.0)	0.8 (0.7-1.0)	2.1 (1.0-4.2)	1.9 (1.0-3.9)	1.2 (0.4-3.9)	0.8 (0.6-1.1)		2.6 (1.3-5.0)	2.0 (1.0-4.0)
	Non-ST	1	1	1	1	1	1	1	1		1	1
Consanguine marriage	Yes	1.1 (0.9-1.4)		1.0 (0.8-1.2)		0.8 (0.3-1.8)		1.5 (0.5-5.9)	1.0 (0.7-1.5)		0.8 (0.4-1.9)	
	No	1		1		1		1	1		1	
Calorie intake <50%**	Yes	1.0 (0.4-2.3)		1.0 (0.5-2.0)		-		-	1.2 (0.4-3.6)		-	
	No	1		1		1		1	1		1	
Protein intake <50% **	Yes	0.9 (0.3-2.3)		1.3 (0.7-2.4)		-		6.3 (0.8-48.1)	1.7 (0.7-4.4)		-	
	No	1		1		1		1	1		1	
Tobacco	Yes	1.1 (0.7-1.7)		1.4(0.8-1.6)		1.0 (0.2-4.1)		-	-		1.0 (0.2-4.0)	
	No	1		1		1		1	1		1	
BMI Group	<18.5	1.3 (1.0-1.6)	1.3 (1.0-1.6)	1.1 (0.9-1.3)		1.0 (0.5-1.8)		0.5 (0.1-1.9)	0.7 (0.5-1.0)	0.7 (0.5-1.0)	1.1 (0.6-2.1)	
	18.5-25	1	1	1		1		1	1	1	1	
	>25	1.5 (1.0-2.4)	1.7 (1.0-2.7)	1.1 (0.7-1.6)		0.5 (0.1-4.0)		-	0.7 (0.3-1.6)	0.5 (0.2-1.4)	1.1 (0.3-4.8)	
Intervention	No	1.2 (1.0-1.5)		1.3 (1.1-1.6)	1.3 (1.1-1.6)	0.5 (0.3-1.0)	0.4 (0.2-0.9)	2.7 (0.7-9.9)	0.7(0.5-0.9)	0.6 (0.5-0.9)	0.4 (0.2-0.7)	0.4 (0.2 -1.0)
	Yes	1		1	1	1	1	1	1	1	1	1

*Low birth weight, @Neonatal death, #Prevalence ratio,$ Adjusted prevalence ratio,^Scheduled tribe, **With reference to recommended daily allowance.

marriages, and higher parity were included. The multiple risk factors interact and affect different pregnancy outcomes (Doke et al., 2021). The reduction in low birth weight, preterm births, and neonatal mortality, apart from the services provided in the intervention area to some extent, may be attributable to BCC. The finding is consistent with a systematic review and meta-analysis demonstrating reduced neonatal mortality rates after improved behavior in some risk factors (Dean et al., 2014).

The adjusted prevalence ratio of preterm delivery among women not receiving preconception care intervention was significantly higher. Preterm birth and LBW overlap; hence, counting them is not mutually exclusive. Despite a significant overlap of about 67 % between preterm birth and LBW, their risk factors may differ (Blencowe et al., 2013). Maternal age below 20 years and no formal education were identified as risk factors for preterm birth in low and low-middle-income countries, with a parity of more than two in Kenya and India (Pusdekar et al., 2020). A few studies associated parental consanguinities with preterm birth (Mumtaz et al., 2010; Obeidat et al., 2010). Poor maternal nutrition, including being underweight as well as overweight/obese (Pusdekar et al., 2020); moderate/severe anemia (Pusdekar et al., 2020), medical conditions like chronic hypertension, diabetes mellitus (Wahabi et al., 2012; Ota et al., 2014; Wei et al., 2019), and tobacco consumption (Kyrklund-Blomberg et al., 2005) are known modifiable risk factors for preterm. In the present study, almost one-third of women were undernourished, which was higher than in the National Family Health Survey-5 in the district (International Institute for Population Sciences Ministry of Health and Family Welfare Government of India., 2020b) but similar to another study (Liu et al., 2019). However, we did not observe any association of maternal malnutrition with preterm birth. The present study observed an increased risk of preterm birth in the comparison area, similar to an Iranian study (Jourabchi et al., 2019).

The current study did not compare anemia among women as a risk factor because we did not measure the hemoglobin levels of the enrolled women from the comparison arm. Assessing the baby's gestational age at delivery is difficult compared to measuring the birth weight. However, recall bias for information on the last menstrual period is assumed to be similar in both arms.

Preconception care was not significantly associated with reduced LBW among the women in intervention areas. A meta-analysis of 58 studies reported the uncertain effect of preconception and periconception interventions on adverse pregnancy outcomes (Partap et al., 2022). However, the present study identified preterm birth as a mediator between preconception care and low birth weight. Preterm birth also mediated neonatal mortality (Yu et al., 2019).

The importance of LBW has been aptly emphasized by Professor David Barker, who first documented the association between birth weight and adult coronary heart disease in low and middle-income countries (Barker et al., 1989; Barker, 1999). A study in six Low and Low-Middle Income Countries observed that the overall risk factors for LBW were similar to that of preterm birth. Maternal age under 20 years, no formal or primary/secondary education, BMI less than 18.5 kg/m^2, and nulliparous state were identified as risk factors for LBW at overall sites (Pusdekar et al., 2020). The present study did not endorse parity > 2 as a risk factor for LBW. The association of LBW with undernourishment among women reported in a study was similar to the present study; however, there was no concordance between education and LBW (Kader and Perera, 2014). The present study analyzed BMI at baseline. There was an improvement in the BMI of the women after PCC (Pusdekar et al., 2020). We also observed an improvement in the BMI and hemoglobin levels of the women after PCC, and the results have been submitted for publication separately. Although we did not study, the compliance of advice during pregnancy, we assume it to be better among women who received preconception care.

Since the nineteen-eighties, assessing preconception risk factors for preventing adverse pregnancy outcomes is felt necessary (Moos and Cefalo, 1987). In 2006, globally for the first time, United States recommended strategies for preconception care (Johnson et al., 2006). Although various studies have reported the positive effect of preconception intervention on birth outcomes (Dhaded et al., 2020), (Jourabchi et al., 2019), systematic reviews have expressed the need for more studies for strong evidence about the effect of preconception care on pregnancy outcomes (Hussein et al., 2016; Partap et al., 2022; Withanage et al., 2022). We believe the current study provides some additional evidence in favor of preconception care.

Studies have shown that consumption of periconceptional folate/vitamin supplements reduced neural tube defects (Czeizel and Dudás, 1992), and preconception control of hyperglycemia reduced the risk of congenital anomaly (Kitzmiller et al., 1991). In the present study, congenital physical anomalies were lower in the non-PCC area. The training of the healthcare workers (ASHAs and ANMs) in the PCC area on identifying and reporting the congenital physical anomaly of newborns and giving pictorial handouts might have led to increased identification and reporting.

In comparison areas, congenital anomalies, abortions, and stillbirths are reported lesser than in intervention areas. Improving surveillance is known to increase early identification and diagnosis (Effler et al., 1999). The observation is particularly relevant to abortion and stillbirth. Several studies have observed gross underreporting of abortion (Singh et al., 2017; Moseson et al., 2021) and stillbirth (Dandona et al., 2017; United Nations Inter-agency Group for Child Mortality Estimation et al., 2020). The higher rates of abortion in intervention area may be attributable to regular follow-up, counseling women to plan pregnancy only after optimizing their health status, and providing informed choice for termination of termination. The nuclear family type was a risk factor for abortion because women from nuclear families are more independent in deciding abortion than those living in joint families. The other reason may be the lack of support for rearing a child.

The effect might have been better if the regular follow-up had continued for the entire study period; however, in March 2020, due to the COVID-19 pandemic, the government imposed the first nationwide lockdown and then restricted movements. The results were achieved through a primary healthcare approach involving the existing government health system. The authors are aware that there are many confounding factors. However, the statistics adjusted for most of the known confounders showed significant differences. All the investigations we have carried out are advised in the government programs. The study preponed one-time investigations from the antenatal phase to the preconception phase and increased the frequency of some investigations with a minimal additional budget. The system is in place. There is no need to regenerate BCC material; even the software may be evaded for replication. Government of Maharashtra has already included preconception care component in the comprehensive maternal and child health program, '*Vatsalya*'. Thus, as per the WHO guidelines and based on the results of a few previous studies and the current study, preconception care may be introduced in low and middle-income countries to promote women's health in the preconception period and reduce adverse pregnancy outcomes.

4.1. Strengths and limitations of this study

It was a reasonably large study conducted with the existing system in 28 primary health centers. It used various media for behavioral change communication. The desired results were achieved without offering any cash incentive or food supplementation. After March 2020, the regularity of monthly follow-ups was considerably hampered due to restrictions imposed by the COVID-19 pandemic. We did not include urban areas.

5. Conclusions

Preconception care addresses modifiable risk factors, particularly improving nutrition and optimizing women's health. It decreases the risk of preterm birth and low birth weight. The interventions can be carried out with the existing health system with minimal additional resources. Hence, the government sector may introduce preconception care in addition to routine antenatal care.

6. Disclaimer

The funders had no major role in designing, implementing, or interpreting study findings except in initial interactions with ANS, KKB, and MVK on the prepared draft. The implementing study team members were independent of the funders.

Funding

UNICEF Maharashtra supported the study through the Government of Maharashtra Department of Public Health. There is no grant number.

CRediT authorship contribution statement

Prakash Prabhakarrao Doke: Writing – original draft, Software, Methodology, Data curation, Conceptualization. **Amruta Paresh Chutke:** Writing – review & editing, Supervision, Methodology. **Sonali Hemant Palkar:** Writing – review & editing, Supervision, Methodology. **Jayashree Sachin Gothankar:** Writing – review & editing. **Prasad Dnyandeo Pore:** Writing – review & editing. **Archana Vasantrao Patil:** Supervision, Data curation. **Aniruddha Vinayakrao Deshpande:** Supervision. **Khanindra Kumar Bhuyan:** Writing – review & editing, Conceptualization. **Madhusudan Vaman Karnataki:** Methodology, Conceptualization. **Aparna Nishikant Shrotri:** Writing – review & editing, Methodology, Conceptualization. **Ravindra Gopal Chaudhari:** Supervision, Data curation. **Mohan Sitaram Bacchav:** Supervision, Data curation. **Motilal Bajirao Patil:** Supervision, Data curation. **Rupeshkumar Balasaheb Deshmukh:** Formal analysis.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Data availability

The details (excluding the names) of enrolled women's follow-up, the results of investigations, and the outcome of pregnancy sub center wise are available from the corresponding author on reasonable request. There is no plan to delete/remove the data in the near future.

The local language flipbook that was used for BCC is available from; https://mcpune.bharatividyapeeth.edu/media/pdfs/Report_of_the_-Healthy_Parents_Healthy_Child_Initiative_for_promoting_health_-of_women_in_preconception_period_Nashik_Maharashtra_India_160622.pdf.

The documentary used for BCC in the local language (*Sudrudh Palak Sudrudh Balak)* is available from the video gallery: https://mcpune.bharatividyapeeth.edu/index.php/video-gallery#sudrudh-palak-sudrudh-balak.

Acknowledgements

We thank all these blocks' medical officers, ANMs, ASHAs and Anganwadi workers. Thanks to all the participants (and their families) for participating in the study. We thank UNICEF Maharashtra for funding the research and the Public Health Department, Government of Maharashtra, for the extensive support.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.pmedr.2024.102796.

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