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Delivering for Nutrition in South Asia

Towards Impact at Scale

Impact of supplementation with fortified balanced energy–protein during pregnancy on birth outcomes: a community-based randomized trial among pregnant women in southern Nepal

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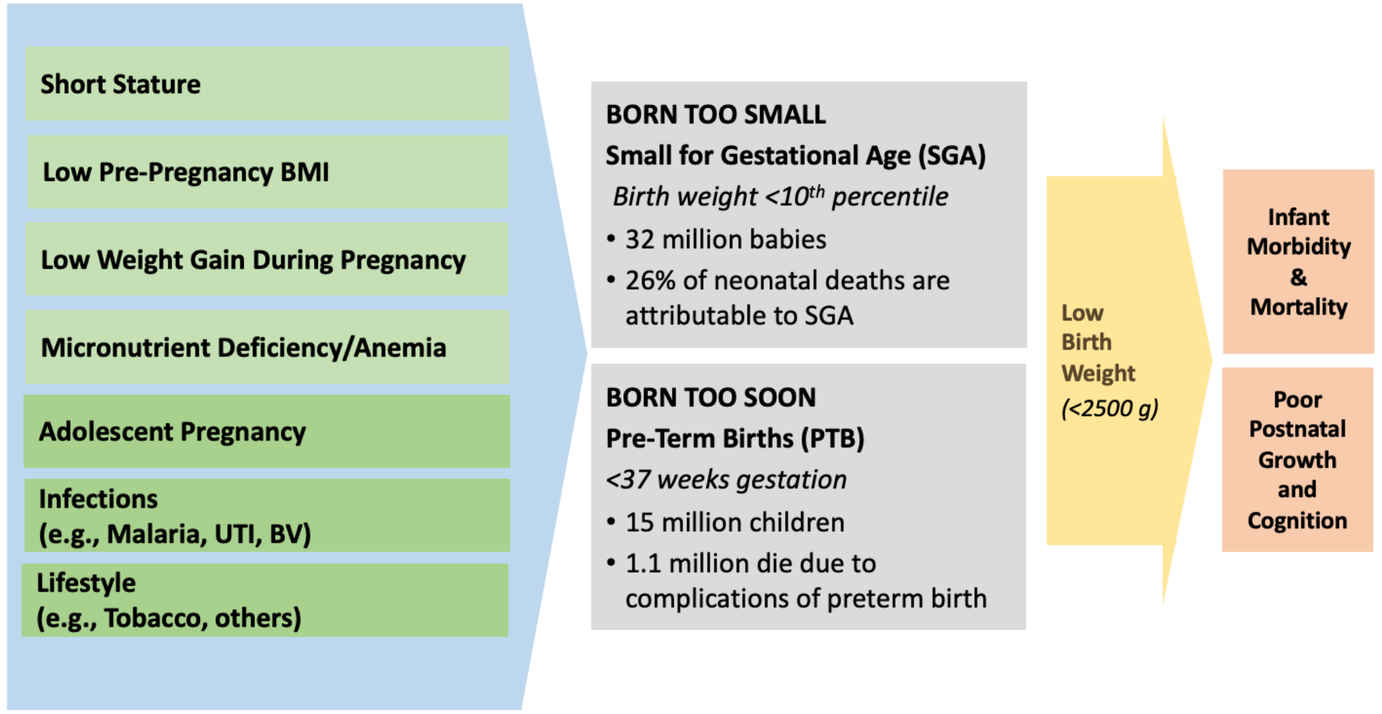
Maternal undernutrition leads to adverse birth outcomes

- **WHO recommends antenatal balanced energy protein (BEP) supplementation** in undernourished contexts

- **Gates Foundation expert group** developed specifications for nutrition composition, format of a BEP supplement

- **High rates of adverse birth outcomes in Nepal's Terai**
  - SGA birth: 40%
  - LBW: 30%
  - Maternal short stature (<150 cm): 41%
  - Maternal underweight: 31%
  - Maternal literacy: 55%



Christian et al. BMJ Glob Health. 2020 Mar 18;5(3):e002186

Objective and Study Design

Overall objective:

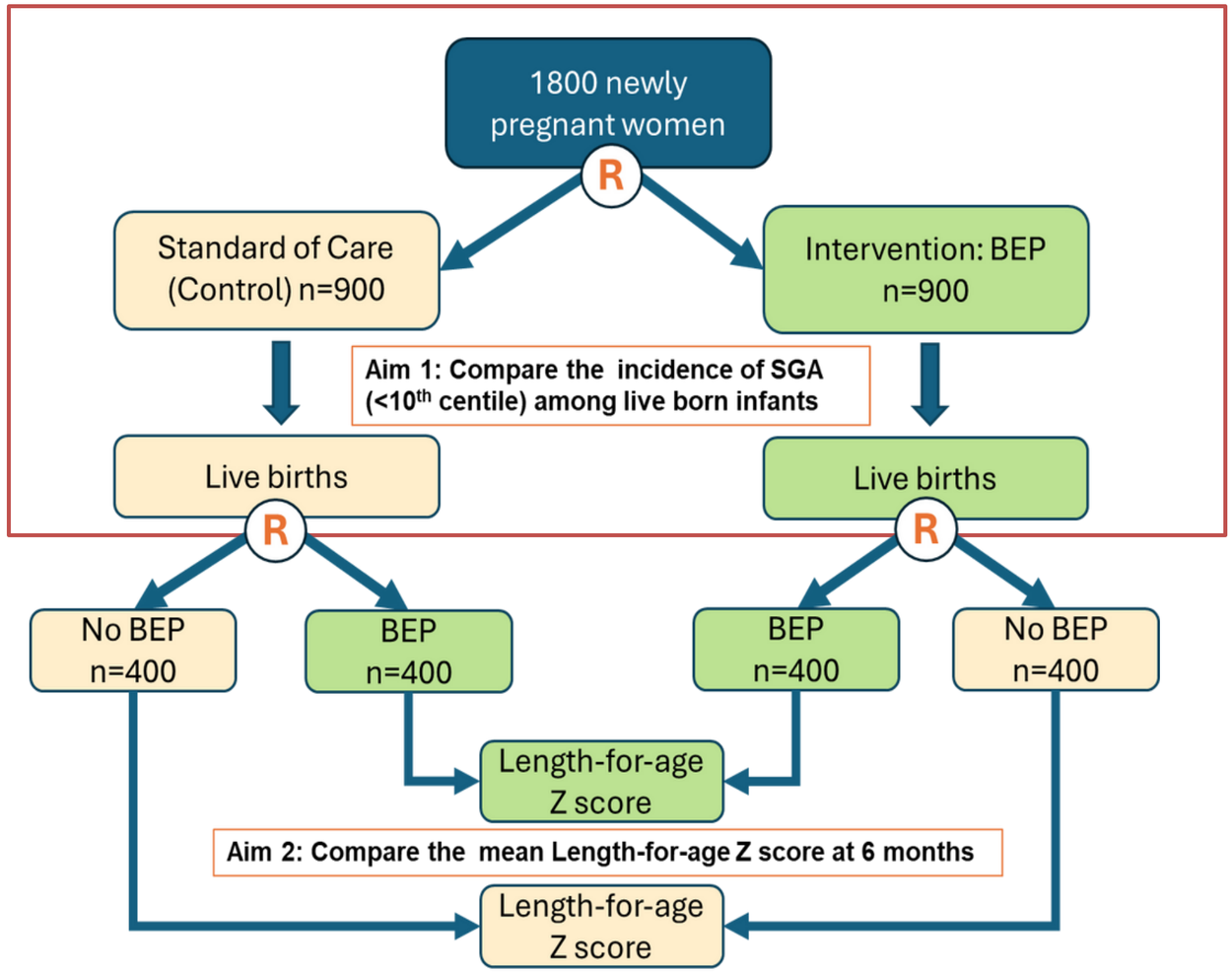
To evaluate efficacy of daily fortified BEP supplement given during pregnancy and 6 months postpartum **on birth outcomes** and infant growth in rural Nepal.

Design

- 2X2 factorial, household randomized efficacy trial
- Enrolled period: Nov 2021 to Aug 2023
- Sample size: 1800 pregnancies, ~1600 livebirths

Study Area:

- 2 rural municipality and 4 municipality in Sarlahi district



Methods: Intervention

Standard of care (all groups)

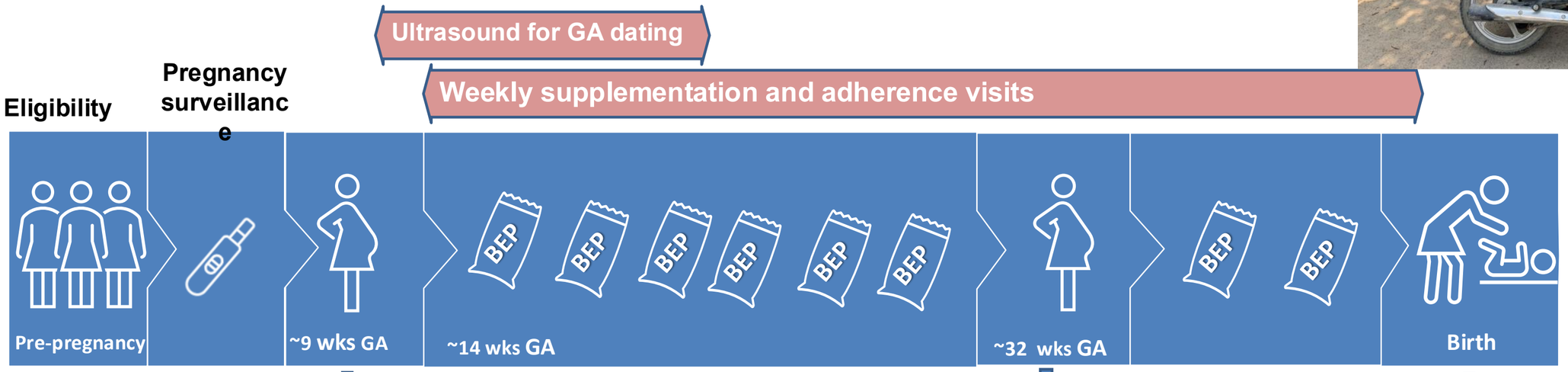
1. ANC and certified birthing facility recommendation
2. Counselling on nutrition, hygiene, and IYCF
3. Clean birthing kit
4. Albendazole and IFA

BEP intervention

72-gram daily sachet

- ~400 kcal
- ~14.5 g protein
- 15 multiple micronutrients
- 500 mg calcium

Methods: Data Collection



Enrollment visit:
Household SES, food security
Pregnancy history
30-day morbidity, diet diversity
Tobacco and alcohol use
Hemoglobin, blood pressure
Anthropometry: weight, height, MUAC

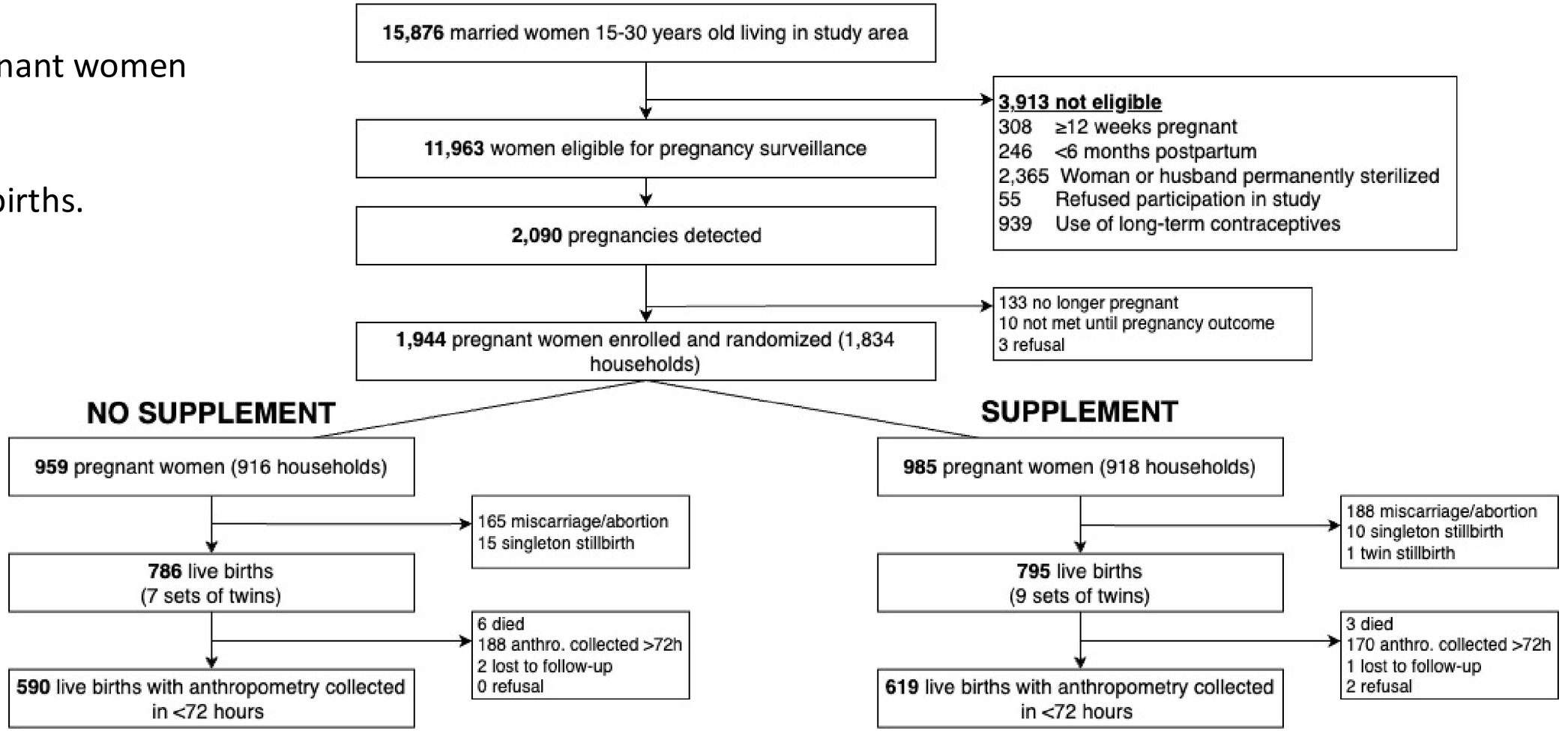
Late pregnancy visit:
30-day morbidity, diet diversity
HH food security
Tobacco and alcohol use
Depression scale
Hemoglobin, blood pressure
Anthropometry: weight, MUAC

Birth assessment visit:
Newborn anthropometry
Labor and delivery
Maternal anthropometry (weight, MUAC)

Study Flowchart

1,944 pregnant women enrolled

1,581 live births.



Erchick et al. BMJ Paediatr Open. 2023 Nov;7(1):e002229

Baseline Characteristics

Characteristics[1]	No pregnancy supplement n=959	Pregnancy supplement (BEP) n=985
	n, % or mean (SD)	n, % or mean (SD)
Age at enrollment, y	24.6 (3.6)	24.5 (3.5)
Parity: Nulliparous	111, 11.6%	99, 10.1%
Gestational age at enrollment, wks	9.2 (2.9)	9.3 (2.9)
Height, cm	151.2 (5.4)	151.1 (5.2)
BMI, Underweight, <18.5	287, 29.9%	289, 29.3%
Overweight or obese, >25	80, 8.3%	99, 10.0%
Education: None	424, 44.2%	452, 45.9%
Primary and lower secondary, <11 yrs	457, 47.7%	466, 47.3%
Upper sec./professional/bachelor's, >12 yrs	78, 8.1%	67, 6.8%
Religion[2]: Hindu	745, 77.7%	770, 78.2%
Muslim	210, 21.9%	211, 21.4%
Household food security[3]: Food secure	748, 78.0%	740, 75.2%

[1] Data missing for MUAC (n=1) and food security (n=1); [2] 4 households in each arm were of Buddhist religion (n=8); [3] Household food insecurity measured using the Household Food Insecurity Access Scale (HFAIS).

Primary results: Risk of adverse birth outcomes by supplement group (n=1,209)

	No supplement group (n=590)	Supplement group (n=619)	Risk of outcome	
Primary outcome	**N (%)**	**N (%)**	**Unadjusted relative risk (95% CI)**	**Adjusted relative risk* (95% CI)**
SGA (<10%)	247 (41.9%)	252 (40.8%)	0.99 (0.86, 1.13)	1.00 (0.88, 1.14)
Secondary outcomes	**N (%)**	**N (%)**	**Unadjusted relative risk (95% CI)**	**Adjusted relative risk* (95%CI)**
PTB (<37 wks)	45 (5.7%)	50 (6.3%)	1.09 (0.74, 1.62)	1.03 (0.71, 1.51)
LBW (<2,500g)	129 (21.9%)	119 (19.2%)	0.87 (0.70, 1.09)	0.93 (0.75, 1.16)
ShGA (<10%)	195 (33.1%)	181 (29.3%)	0.90 (0.77, 1.06)	0.92 (0.78, 1.08)
	mean (SD)	**mean (SD)**	**Unadjusted mean difference (95% CI)**	**Adjusted mean difference* (95%CI)**
Weight-for-age centile	19.7 (19.7)	22.7 (21.6)	**2.82 (0.53, 5.12)****	**2.28 (0.08, 4.49)****
Gestational age (wks)	39.3 (1.5)	39.3 (1.7)	0.01 (-0.15, 0.17)	0.02 (-0.13, 0.17)
Birth weight (grams)	2789.9 (388.9)	2829.3 (411.9)	37.4 (-6.9, 81.8)*	23.3 (-18.5, 65.3)
Birth length (cm)	47.7 (2.0)	47.9 (2.1)	0.20 (-0.03, 0.43)*	0.12 (-0.09, 0.34)
Head circumference (cm)	33.4 (1.3)	33.6 (1.3)	**0.23 (0.09, 0.38)****	**0.19 (0.05, 0.34)****

*Adjusted for maternal age (years), maternal height (cm), BMI, parity (number of previous live births and stillbirths), education (years of schooling), infant sex, and multiple birth.
**p<0.05

Summary of other results

- No evidence of effect modification by maternal short stature, underweight, age, education or infant sex or proportion of intended supplements consumed for primary outcome, incidence of SGA
- No evidence of dietary substitution due to supplementation (24-h dietary data in subsample)
- No difference in incidence of LGA births or C-section rates
- Adjustment for covariates, clustering by household did not change the findings

Implications for scaling and policy

- Daily fortified BEP, started in 2nd trimester, may be insufficient to reduce incidence of SGA births in a rural South Asian population with high rates of undernutrition
- BEP may provide small benefits for other adverse birth outcomes
- Other analyses remain: to explore BEP effect on gestational weight gain and biological mechanisms, such as changes in infant gut microbiome
- Future trials should explore: targeted strategies, preconception interventions, addressing adolescent undernutrition, or integrated intervention packages

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