Low Birth Weight South Asia Trial (LBWSAT) Nepal

Naomi M. Saville, Anthony Costello

The study was run by The Institute for Global Health at University College London together with Mother and Infant Research Activities (MIRA), a Nepalese NGO. Save the Children assisted with setting up and implementing food and cash transfers. World Food Programme provided a food supplement and advice about its distribution.

This (non-blinded) cluster randomised controlled trial assessed the impact on birth weight and weight-for-age Z-score in children aged 0–16 months of a nutrition Participatory Learning and Action behaviour change strategy (PLA) for pregnant women through women’s groups, with or without unconditional transfers of food or cash to pregnant women in two districts of southern Nepal. PLA comprised a series of open women’s group meetings which pregnant women were encouraged to attend. A Female Community Health Volunteer facilitated each group, supported by a nutrition mobiliser. The groups (n=539) identified and prioritised problems associated with improving women’s intake of nutritious food in pregnancy, low birth weight and hand hygiene and implemented strategies for addressing these. Women received up to 7 monthly transfers per pregnancy: cash was NPR 750 (~US$7) and food was 10 kg of fortified sweetened wheat-soya Super Cereal per month. The unit of randomisation was a rural village development committee (VDC) cluster (population 4000–9200, mean 6150) in southern Dhanusha or Mahottari districts.

80 VDCs were randomised to four arms using a participatory ‘tombola’ method. Twenty clusters each received: PLA; PLA plus food; PLA plus cash; and standard care (control). Outcomes pertained to the individual level. Primary outcomes were birth weight within 72 h of birth and infant weight-for-age Z-score measured cross-sectionally on children born of the study. We added this second primary outcome to the trial in Feb 2015 due to low capture rate of the birth weight primary outcome and lack of funds to continue birth weight measurement. Secondary outcomes were prevalence of LBW, eating behaviour and weight during pregnancy, maternal and newborn illness, preterm delivery, child Z-scores for length-for-age and weight-for-length, head circumference, and postnatal maternal BMI and mid-upper arm circumference.

Exposure to women’s groups, food or cash transfers, home visits, and group interventions were measured. Results showed that 94-97% of pregnant women attended PLA plus food/cash groups and food/cash groups participants received a mean of four transfers over their pregnancies. In the PLA only arm, 49% of pregnant women attended groups. Response rate for birthweight was low at 22% (n=2087), but response rate for endline nutritional and dietary measures exceeded 83% (N=9242). Compared to the control arm mean birthweight was significantly higher in the PLA plus food arm and not significantly higher in PLA only and PLA plus cash arms. Mean weight-for-age z-scores of children aged 0-16 months (average age 9 months) sampled cross-sectionally at endpoint, were not significantly different from those in the control arm. Amongst many secondary outcomes tested, compared with control, more institutional deliveries and less colostrum discarding were found in the PLA plus food arm.

Dates of activities:

Mapping of clusters and exclusion of ineligible clusters - 17 Dec 2012 to 22 Feb 2013;

Participatory randomisation to allocate clusters - 1 Mar 2013;

Consent with cluster guardians -Mar to May 2013;

Population census - Aug to Nov 2013;

Menstrual monitoring to identify pregnancies / births - 1 Dec 2013 to 15 Feb 2015;

Recruitment of pregnant women into trial - 29 Dec 2013 to 28 Feb 2015;

Run-in period of surveillance incl. birth weight measurement - 29 Dec 2013 to 4 Jun 2014;

'Full trial' follow-up incl. birth weight measurement - 5 Jun 2014 - 31 Mar 2015;

16 weeks exposure to intervention before delivery possible - 4 Jun 2014;

Political disturbance affected data collection - Sep to Dec 2014 especially;

Closure of trial recruitment due to political disturbance - 28 Feb 2015;

Earthquake affected Nepal - Major quakes 25 Apr and 12 May 2015;

Cross-sectional endpoint follow-up of child/mother anthropometry - 20 Jun to 19 Oct 2015;

Final Data Monitoring Committee meeting - Nov 2015;

Data analysis and write-up - Oct 2015 to Mar 2016.

The trial's protocol is published: Saville NM, Shrestha BP, Style S, Harris-Fry H, Beard BJ, Sengupta A, et al. Protocol of the Low Birth Weight South Asia Trial (LBWSAT), a cluster-randomised controlled trial testing impact on birth weight and infant nutrition of Participatory Learning and Action through women’s groups, with and without unconditional transfers of fortified food or cash during pregnancy in Nepal. BMC Pregnancy and Childbirth. 2016. DOI: <https://doi.org/10.1186/s12884-016-1102-x>

The data collection system is described in: Style S, Beard BJ, Harris-Fry H, Sengupta A, Jha S, Shrestha BP, et al. Experiences in running a complex electronic data capture system using mobile phones in a large-scale population trial in southern Nepal. Global Health Action. 2017 <https://doi.org/10.1080/16549716.2017.1330858>

The trial paper is published in PLOS One: Saville NM, Shrestha BP, Style S, Harris-Fry H, Beard BJ, Sen A, et al. Impact on birthweight and child growth of Participatory Learning and Action women’s groups with and without transfers of food or cash during pregnancy: findings of the Low Birth Weight South Asia cluster-randomised controlled trial (LBWSAT) in Nepal. Plos One. 2018 DOI: <https://doi.org/10.1371/journal.pone.0194064>

The effect of trial interventions on women’s agency is available at: Gram L, Morrison J, Saville N, Yadav SS, Shrestha B, Manandhar D, et al. Do Participatory Learning and Action Women’s Groups Alone or Combined with Cash or Food Transfers Expand Women’s Agency in Rural Nepal? The Journal of Development Studies. 2018:1-17. doi: 10.1080/00220388.2018.1448069. <https://www.tandfonline.com/doi/full/10.1080/00220388.2018.1448069>