

# Sample size

In a study by Mlay et al, 2020, the mean weight gain and standard deviation for babies whose first feed was within 48 hours of life was 14.3g/kg/day and 4.8. Mean weight gain and standard deviation for babies whose first feed was more than 48 hours of life was 10.2g/kg/day, and 4.8. Using a Type 1 error ( $\alpha$ ) of 0.05, a Type 2 error ( $\beta$ ) of 20%, an average weight gain of 15g/kg/day in those without the exposure, and 12.5g/kg/day for those with the exposure, and assuming the number of neonates without the exposure will be twice those with exposure, we determine the sample size using the formula by Chow et al below:

$$n_1 = r * n_2 \quad \text{and} \quad n_2 = \left(1 + \frac{1}{r}\right) \left(\sigma \frac{z_{1-\alpha/2} + z_{1-\beta}}{\mu_1 - \mu_2}\right)^2$$

Where,  $\mu_1$  and  $\sigma_1$  are the mean and standard deviation of weight gain in infants without exposure.  $\mu_2$  and  $\sigma_2$  are the mean and standard deviation of weight gain in infants with exposure  $\alpha$  is Type I error  $\beta$  is Type II error, thus power is  $1 - \beta$  and  $r$  is the ratio of the numbers unexposed to the exposed.

Substituting into the formula:

The number of unexposed and exposed neonates required are 87 and 44 respectively.

Total sample size = 131

Adjusting for 20% non-response rate we have a final sample size of 164