Sample size calculation method

The sample size was calculated based on the following assumptions and by applying the formula below [7]:

$$N = (r+1/r) \frac{P\ (1-P)\ (Z_\beta + Z_{\alpha/2})^2}{(P_1 - p_2)^2}$$

Whereas:

N=Sample size in the case group

r=ratio of control to cases

p_1= Proportion of cases exposed

p_2=Proportion exposed in the control group

P= $(P_1 + p_2)/2$

p_1 is calculated using the formula: $p_1 = \dfrac{OR \times p_2}{p_2 \times (OR-1) + 1}$

OR= Minimum Odd Ratio to detect (OR=2)

Z_β= represent the desired type II error (at 90% of power, Z_β=1.28)

$Z_{\alpha/2}$= level of statistical significance=1.96

In this case:

p_2= 75%

r=3:1

OR=1.2

Z_β= desired power= 0.955(for 95%)

$Z_{\alpha/2}$= 1.96

P1 = [(1.8 * 0.75)]/[0.75 * (1.8 -1) + 1] = 1.35/1.6 = 0:84

P= $(p_1 + p_2)/2$= (0.86+0.75)/2= **0.80**

The sample size in the case will be **N** = $4/3 * \dfrac{(0.795 * 0.205) * (1.28 + 1.96)^2}{(0.84 - 0.75)^2}$ = **259**

The number of controls was **777** and the total sample size was therefore **1036**