SESSION 11

Sample Size Determination Practical

A new drug is to be compared with placebo in the treatment of patients with Alzheimer's Disease (AD). The primary response measure is the Clinical Global Impression of Change (CGIC) assessed six months after entry into the study. Based on previous data collected on patients with AD it is expected that the percentage of patients in the placebo group falling into the various CGIC categories will be

Markedly improved	5%
Slightly improved	20%
No change	40%
Slightly worse	25%
Markedly worse	10%

If the percentage of outcomes in categories "Markedly improved" and "Slightly improved" is increased from 25% to 35% this would be considered clinically important.

Calculate the required sample size, assuming a proportional odds model for ordered categorical data, a power of 0.8 and a 5% significance level (two-sided), based on

a) 5 separate categories

b) 4 categories with "Markedly improved" and "Slightly improved" combined into one category

c) 3 categories
- Markedly improved + Slightly improved
- No change
- Slightly worse + Markedly worse

d) 2 categories
- Markedly improved + Slightly improved
- No change + Slightly worse + Markedly worse

Note: The standard Normal Distribution

u	$P(U \leq u)$ where $U \sim N(0,1)$
0.842	0.8
1.282	0.9
1.645	0.95
1.960	0.975