Project7

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Introduction

We want to conduct a comparative analysis of two distinct diets, namely diet A (Group 1) and diet B (Group 2), among a population of diabetic patients. The hypothesis is that diet A will be better in terms of reduced blood glucose levels compared to diet B. To investigate this, we want to obtain a random sample of diabetic patients and allocate them randomly into either Group 1 or Group 2. Following a 6-week intervention period, each participant will undergo a fasting blood glucose test. We want to determine the necessary sample size for each group, assuming equal sizes.

These are the fixed terms of the analysis:

- The expected difference in the average blood glucose is set at $\delta = \mu_A - \mu_B = 10$ mg/dl. With μ_A unknown the average blood glucose in group 1 and μ_B unknown the average blood glucose in group 2.
- The standard deviations of blood glucose for Group 1 and Group 2 are the same and set at $\sigma = \sigma_A = \sigma_B = 15$ mg/dl
- The alpha level, the probability of Type I error, rejecting the null hypothesis when it is actually true, is set at $\alpha = 0.05$
- The level of statistical power, the probability of rejecting the null hypothesis when it is actually false, is set at $1 - \beta = 0.8$
- The groups' sample size are equal, meaning the allocation ratio of N_A to N_B is $\frac{N_A}{N_B} = 1$.

Hypothesis Testing

The hypothesis test of the dietitian can be formulated as follows (to statistically test whether diet A is better than diet B).

- H_0 (Null Hypothesis): There is no difference in blood glucose level between group A and group B.
- H_1 (Alternative Hypothesis): Diet A will be better than diet B (in terms of lower blood glucose).

Our statistical test will either reject H_0 (and therefore conclude H_1) or not reject H_0. So if we want to conclude that diet A is better than diet B, we want to reject H_0.

Power analysis

Power analysis is a statistical method to determine the minimum sample size necessary to reasonably likely achieve detecting an effect of a specified magnitude.

The effect size refers to the magnitude of the average difference in blood glucose measures between the two groups (diet A and diet B).

To quantify the effect size we use the Cohen's d [Cohen, 1988]:

$$d = \frac{\delta}{\sigma}$$

Where δ and σ were defined before. So in our case it will be $d = \frac{10}{15} = 0.667$.

To statistically test H_0 vs H_1, we use the so called *two sample t-test*, which is the common test to determine whether two population means are equal or not. When applying the two sample t-test to our data, we have the following assumptions (that need to be satisfied in order for our test to work).

1. The observations (subjects) from group 1 should be independent to the observations from group 2.
2. The blood glucose level of observations from group 1 should have approximately the same *standard deviation* as in group 2. The standard deviation in a group describes how spread out the set of blood glucose numbers from its subjects is. In our case, we assume the standard deviation in both groups to be 15 mg/dl (a typical value for the standard deviation in blood glucose).
3. The individuals have been assigned randomly to either group 1 or group 2.

The fourth assumption is a little bit more technical: We assume that the data is approximately *normal distributed*. It refers to a specific shape of the data when we plot it on a graph. If the data is normal distributed, most of the datapoints are concentrated around the middle. It turns out that many different kinds of data are normal distributed.

According to [Wang and Ji, 2020] we can use the following formula to calculate the sample size:

$$n = 2\left(z(1-\alpha) + z(1-\beta)\right)^2 \frac{1}{d^2} \tag{1}$$

Assuming that all the assumptions are respected, it is obtained that the needed sample size for each group will be $N = N_A = N_B = 28$

Changing parameters

Note that if we change the standard deviation of blood glucose, our results will also change. A higher standard deviation indicates that blood glucose levels are more spread out. Therefore, we need a larger number of subjects to detect a difference in means between our groups, assuming we maintain the same significance level and power.

Similarly, the significance level also plays a crucial role. Decreasing the significance level (the probability of rejecting the Null Hypothesis H_0 when it is true) necessitates an increase in the sample size, assuming a constant power level and standard deviation. If we want to use a higher power level (the probability of correctly rejecting the Null Hypothesis H_0 when H_1 is true), we need more subjects provided we keep the same significance level and standard deviation.Similarly, to achieve a higher power level (the ability to correctly reject the Null Hypothesis H_0 when H_1 is true), an increased sample size is necessary, assuming the maintenance of the same significance level and standard deviation.

Due to the above effects, in Figure 1 we compare different scenarios of standard deviations, significant levels and power levels.

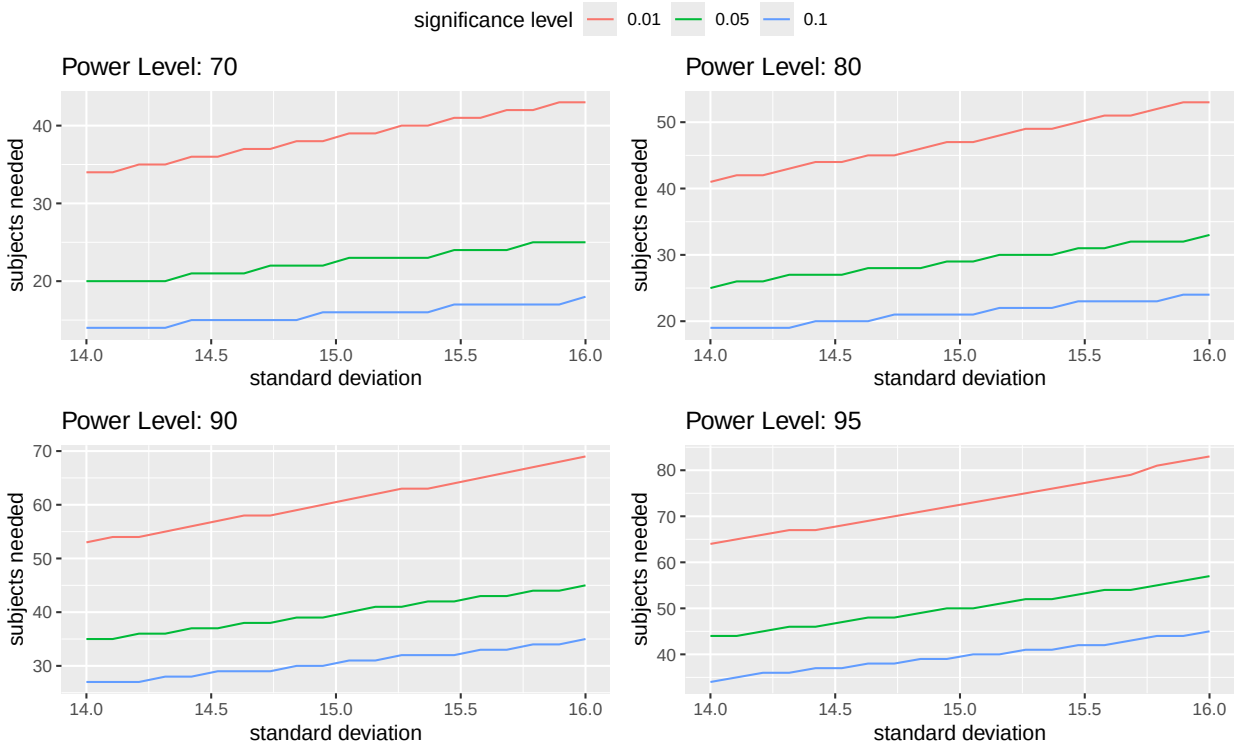

Figure 1: Number of subjects needed per group varying standard deviations, power levels and significance levels.

Recommendations

To effectively compare the two different diets, it is recommended to randomize the diabetic patients to ensure balanced groups. This means for example avoiding significant differences in average diabetes levels between the groups. Additionally, it is important to ensure that ethnic diversity is evenly distributed between the groups, rather than having one group predominantly of one ethnicity and the other of different ethnicities. Age should also be balanced to avoid one group having a significantly higher average age than the other.

Similarly, patients with serious coexisting diseases should be evenly distributed between the groups to prevent bias.

These are some examples of considerations for proper randomization. It is crucial to create well-randomized groups to avoid biases that could arise from poor randomization. For instance, young people may respond better to treatment than older, and such factors need to be balanced across the groups.

Conclusion

Our power analysis utilized the two sample t-test to determine the minimum sample size needed to achieve the performance goals. The analysis found that at least 28 participants were required to meet the specified objectives and assuming standard deviation of blood glucose being $15mg/dl$, a significance level of 5 and a power level at 80, assuming certain assumptions met. Importantly, it should be noted that different types of power analyses, considering variations in standard deviations, significance levels, and power levels, may produce different outcomes. This suggests the importance of exploring and considering alternative approaches. Additionally, it is recommended to randomize the patients effectively within the two groups to ensure balanced distributions of factors such as diabetes severity, ethnicity and age. Proper randomization helps avoid biases that could affect the comparison of the two diets and ensures the validity of the study results.

References

- Wang, Xiaofeng, and Xinge Ji. (2020). *Sample Size Estimation in Clinical Research: From Randomized Controlled Trials to Observational Studies.* Chest. doi: 10.1016/j.chest.2020.03.010
- Cohen, Jacob. (1988). *Statistical Power Analysis for the Behavioral Sciences.* Routledge. ISBN 978-1-134-74270-7.