A COMPUTER PROGRAM FOR CALCULATION OF SAMPLE SIZE

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(Received on March 5, 1996)

Abstract: Sample size must be determined while planning a study to ensure that valid conclusions can be drawn when the study is over. Different formulae for calculating the required size of the sample are used for different study designs and situations. A computer program is described here to ease the complexity of calculation of sample size for studies designed to use Student's 't' test.

Key words: sample size computer program

INTRODUCTION

A priori calculation of sample size is a must for statistical as well as ethical reasons (1). A sample size larger than required will lead to waste of resources and energy whereas no valid conclusions can be obtained from a study using inadequate number of subjects or animals. However, many times the researchers do not calculate sample size before they embark on a study. This is mainly because of the difficulty in deriving the data/information required and the intricacies involved in the calculation of sample size.

Information Required

To calculate sample size the investigator has to specify the following elements:

(a) The expected difference in the means between groups. (This has to be decided by the investigator).

(b) The expected variation of the parameter to be studied. (Standard deviation of the difference in case of single sample study or standard deviations of both the groups in case of two sample study. This information can be obtained from either a pilot study or the previously published results).

(c) Level of significance: (The level at which the investigator would consider his results significant. This is known as alpha, e.g. P < 0.05).

(d) Power: (The ability of the test to detect a true difference).

Formulae

Having known the above information the sample size for a study designed to use Student's 't' test for statistical analysis can be calculated using the following formulae (2):

a) Paired 't' test

\[
\frac{n}{(in \ each \ group)} = \frac{(u+v)^2 \times (SD \ of \ difference)^2}{(\mu_1 - \mu_2)^2} \quad \text{(formula 1)}
\]

b) Unpaired 't' test

\[
\frac{n}{(in \ each \ group)} = \frac{(u+v)^2 \times (SD_1^2 + SD_2^2)}{(\mu_1 - \mu_2)^2} \quad \text{(formula 2)}
\]

where \(u\) is 'one-sided' percentage point of the normal distribution corresponding to 100% – the power, for e.g. if power = 90%, \(u = 1.28\)
Computer Program

To reduce the complexity of sample size calculation a computer program written in

\[ n = \frac{(1.96 + 1.28)^2 \times (10.4^2 + 10.4^2)}{15^2} \]
\[ = \frac{10.49 \times 216.32}{225} \]
\[ = \frac{2269.20}{225} = 10.08 \]

So 10 volunteers in each group are needed to detect a difference of 15 h at 5% significance level with 90% power.
BASIC is presented here. Program code is given below. The program requires the user to enter only standard deviations and the expected difference in the means. The sample size required is calculated for different power and significance levels and displayed on the screen. A sample output is given.

Program

```
10 CLS
20 PRINT "Sample size calculation. (c) Dr. R.
Raveendran"
30 PRINT
40 PRINT "1. Single Sample (Paired) 2. Two Sample
(Unpaired)"
50 PRINT: INPUT "Your choice by number"; CHOICE
60 PRINT
70 IF CHOICE = 1 THEN PRINT "SD of difference";
:INPUT SD
80 IF CHOICE = 2 THEN PRINT "Enter SD of group
1"; : INPUT SD1
90 IF CHOICE = 2 THEN PRINT "Enter SD of group
2"; : INPUT SD2
100 PRINT
110 PRINT "Expected difference between means"; : INPUT
DM
120 REM Assign U, Beta, V, Alpha values
130 REM U & V are percentage points of standard normal
distribution for beta & alpha respectively
140 DATA 0.84, 80, 1.28, 90, 1.64, 95
150 FOR I = 1 TO 3: READ U(I), BETA(I): NEXT
160 DATA 1.96, 5, 2.33, 2, 2.58, 1
170 FOR I = 1 TO 3: READ V(I), ALPHA(I): NEXT
180 CLS
190 PRINT "Sample size calculation"
200 PRINT
210 PRINT "Power", "Level of", "Size required
for each group"
220 PRINT, "significance";
230 IF CHOICE = 2 THEN PRINT "for each group"
240 PRINT:PRINT
250 FOR I=1 TO 3
260 FOR J=1 TO 3
270 POWERPP = U(J)
280 POWER = BETA(J)
290 SIGLEVELPP = V(I)
300 SIGNI = ALPHA(I)
310 GOSUB 350
320 NEXT J
330 NEXT I
340 END
350 IF CHOICE = 1 THEN SAMSIZE = (((POWERPP+SIGLEVELPP) ^ 2) * ((SD1 ^ 2) + (SD2 ^ 2))) / (DM ^ 2)
360 IF CHOICE = 2 THEN SAMSIZE = (((POWERPP+SIGLEVELPP) ^ 2) * ((SD1 ^ 2) + (SD2 ^ 2))) / (DM ^ 2)
370 SAMSIZE = (INT (SAMSIZE + .5)) : REM make a
round figure
380 PRINT POWER; ",", SIGNI; ",", SAMSIZE
390 RETURN
```

Sample output

<table>
<thead>
<tr>
<th>Power</th>
<th>Level of significance</th>
<th>Size required for each group</th>
</tr>
</thead>
<tbody>
<tr>
<td>80%</td>
<td>5%</td>
<td>8</td>
</tr>
<tr>
<td>90%</td>
<td>5%</td>
<td>10</td>
</tr>
<tr>
<td>95%</td>
<td>5%</td>
<td>12</td>
</tr>
<tr>
<td>80%</td>
<td>2%</td>
<td>10</td>
</tr>
<tr>
<td>90%</td>
<td>2%</td>
<td>13</td>
</tr>
<tr>
<td>95%</td>
<td>2%</td>
<td>15</td>
</tr>
<tr>
<td>80%</td>
<td>1%</td>
<td>11</td>
</tr>
<tr>
<td>90%</td>
<td>1%</td>
<td>14</td>
</tr>
<tr>
<td>95%</td>
<td>1%</td>
<td>17</td>
</tr>
</tbody>
</table>

The program can be used by either GWBASIC, QBASIC or QuickBASIC without any modification. REM statements are included in appropriate places to make it more understandable for those who wish to modify the program to suit their needs. The program code can be compiled using Quick BASIC to make a stand alone EXE file which can be run independently. Those who wish to obtain a copy of it on a diskette may write to the author.

Limitations

The formulae given here (and used in the program) are useful for single sample and two sample studies when the variable is continuous and is normally distributed. Ideally the program can be used for studies designed to use Student’s ‘t’ test. It must be borne in mind that there are possibilities that actual variation encountered
in the study may be different from the one stipulated for calculation. When the actual variation is substantially greater and the difference between the means is not statistically significant, a posteriori power calculation is advisable if the investigator wishes to conclude no difference between the groups tested (4).

In the above example the SD was assumed to be 10.4 in both the groups and the expected difference in the means was 15 h. Suppose the actual study which used 10 subjects per group based on the calculation showed a difference in means on the expected lines (for e.g. 16.2 h) but a greater variation in the data obtained (for e.g. SD in control and study groups were 10.5 and 17.67 respectively). Had this true variation been used, the sample size calculation would have yielded a value higher than 10. If the actual data obtained were used the sample size required would be 17. But the study had used only 10 subjects which would considerably reduce the power i.e. the ability of the test to detect the true difference. Since the sample size is inadequate, no valid conclusion whatsoever can be drawn especially when power is less than 80% and null hypothesis test shows a non-significant difference (e.g. P > 0.05 in the above example). Hence a posteriori power calculation is a must before concluding 'no difference between groups'.

ACKNOWLEDGEMENTS

The author wishes to thank Professor and Head CH. Shashindran and Professor C. Adithan, Department of Pharmacology, JIPMER, Pondicherry for their critical comments.

REFERENCES