Issues in Quantitative Research

Professor Cate D'Este,

Professor of Biostatistics

Deputy Head (Public Health), School of Medicine and Public Health

Director, Centre for Clinical Epidemiology and Biostatistics

21st October 2010

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Format

- Designing a study
- Collecting data
- Entering / managing data
- Analysing data
- Reporting results
- Writing statistical methods

- Discussion of examples / practical applications

Designing a Study

- Need to consider statistical issues from the start – consult a statistician if appropriate
- Clear (and very specific) aims and hypotheses
- Hypotheses should include outcomes and differences to be detected
- Aims / methods / analyses all need to be consistent
- Develop statistical analysis plan
- Determine sample size

Designing a Study – Sample size

- Need sample size for ALL aims / hypotheses – including primary AND secondary
- Many available packages: Stata, PS (free from Vanderbilt University)
- Sample size for precision (ie power not relevant) versus hypothesis test
- Should justify difference to be detected
- Consider whether equal numbers in groups compared
- Clustering / lack of dependence of observations
- Adjust for non-consent, attrition

Collecting Data

- Data collected must be consistent with aims
- Check data collection instrument / method will allow easy data entry / scanning, web delivery
- Always have an ID number
- Collect data in highest level of detail – can combine later (eg date of birth or age in years rather than categories)
- Be careful with information which can be presented in different forms; eg if requesting weight or height specify units
- Think about how data will be entered / analysed
- Do not be tempted to ask for more data than you need

Entering / Managing Data

- Preferable to enter data as numeric
- Code book / data dictionary
- One variable per column
- Missing / not applicable values
- Be careful with dates
- Label variable names and values
- Merging of data from different datasets / forms
- Format of data – long versus wide; eg if multiple observations per individuals ? One record / line per observation (long) or per individual (wide)
- often need in different format for different analyses but can generally transform

Analysing Data

- Check data quality first
- exploratory data analysis
- simple analysis first then complex
- Statistical test appropriate for aims / hypothesis / type of data (eg continuous or categorical)
- check assumptions for test
- be careful with use of statistical package
- interpretation of output / results

Analysing Data

- Need to consider:
  - type of variables - categorical or continuous
  - whether estimating or comparing groups
- For estimation:
  - describe sample
  - report estimate and 95% CI
- For hypothesis testing
  - compare groups at baseline
  - compare outcomes between groups
  - ??? Other variables to consider /confounders
  - regression

Reporting Results

- Results should be consistent with aims and methods
- Logical sequence
- Simple → Complex
- Tables provide explicit details
- Figures provide rapid overview to reader
- Avoid duplicative text

Reporting Results

- begin with description of sample / comparison of groups
- Then describe analyses :
  - univariate
  - regression
  - other issues ? Clustering, etc

Reporting Results

- Clear description of the data
- Details on important variables for validity and interpretation
- Graphical methods may be helpful
- Note deviations from intended design
- Describe non-participants and non-compliers
- Threats to validity (e.g. baseline comparability)
- Describe generalisability

Reporting Results – Descriptive Statistics

- Report numbers with appropriate precision
- Report denominators for rates, ratios, proportions, percentages
- Define and justify cutpoints for continuous variables
- Normal data: mean, SD; NOT mean ± SEM
- Non-normal data: median, quartiles
- Distinguish between absolute and relative change
- Use coefficient of variation to compare variability of 2 or more sets of data

Reporting Results – Tables

- Tables should be able to “stand alone” from text
- Title should be self explanatory, but not include information in column, row headings
- Row, column headings should include units
- Headings should include ‘thousands’ rather than ‘x10^3’
- All entries in column should have same units
- Columns belonging together can be linked under common heading
- Dates should include name of month
- Row versus column percentages
- Check number of observations appropriate
- Check numbers, % add up to totals
- Footnotes can be used to explain abbreviations, etc and labelled with numbers, letters or characters

Reporting Results –Statistical Tests

- Report the test statistic (name and value)
- Give actual *p*- values
- Specify which data were used
- Distinguish > and < correctly
- Do not report $p = 0.000$; write as $p < 0.001$
- Effect measures and confidence intervals for main outcomes

Reporting Results – Regression

- Describe relationship of interest or purpose of analysis
- Describe variables to be used and summarise
- Verify assumptions met and how checked
- Describe how explanatory variables chosen for inclusion / removal from models
- Report treatment of outliers
- Specify whether collinearity, interactions assessed

Reporting Results – Regression

- Provide summary table of result including:
  - number of observations
  - coefficient estimate or OR, RR (reference group)
  - standard error of estimate
  - 95% CI
  - p value
- Report model checking
- coefficient of determination (adj. R^2) for linear regression
- Goodness of fit
- residuals
- Specify whether model validated
- Statistical package used

Reporting Results – Interpretation

- Null hypothesis rejected or not rejected (ie not “accepted”) on basis of p value and significance level
- Significance level is an arbitrary cut point
- If using 5% significance then
- “reject” null hypothesis if p = 0.049 (ie conclude difference between groups)
- do not reject if p = 0.051 (ie conclude NO difference between groups
- This is a difference in p value of 2 in 1000!!!

Tables – linear regression

TABLE-1 Sample Table for Reporting a Multiple Linear Regression Model with Three Explanatory Variables

Variable	Coefficient (β)	Standard Error	95% CI	Wald X^2	P
Intercep	40.79	2.55	–	–	–
t	3.98	2.37	-0.67 to 8.63	1.68	0.10
X_1	1.23	0.29	0.66 to 1.80	4.20	<0.001
X_2	-2.09	0.28	-2.64 to –1.54	-7.34	<0.001
X_3					

Tables – logistic regression

Table-2 Sample Table for Reporting a Multiple Logistic Regression Model with Four Explanatory Variables.

Variable	Odds Ratio	95% CI	Wald X^2	P value
Intercept	–	–	–	–
	4.2	1.32 to 13.33	5.93	0.02
	0.43	0.111 to 1.66	1.51	0.22
	21.01	1.78 to 248.29	5.84	0.02
	9.03	1.30 to 62.83	4.94	0.03

Reporting Results – Commonly Misused Terms

- CORRELATION - has a specific meaning
- INCIDENCE - rate of new events
- NON-PARAMETRIC - refers primarily to the analysis, not to the data
- PARAMETER
  - does not mean "variable"
  - does not mean "limit" (e.g. "within the parameters")

Writing Statistical Methods

- Begin with analysis; then sample size
- Need to describe all analyses to be undertaken (for all aims / hypotheses)
- Then describe analyses :
- univariate
- regression
- which factors adjusted for / how
- how to determine which variables to consider
- how “significance” determined
- other issues ? Clustering, etc
- significance level

Writing Statistical Methods

- Characteristics of consenters and nonconsenters were compared using the ttest (or a non parametric equivalent) for continuous variables and the chisquare test for categorical variables
- The proportion of individuals with depression (defined by K10 score > XXX) was determined with 95% confidence interval.
- univariate analyses involved comparison of characteristics of participants with and without depression using the ttest (or a non parametric equivalent) for continuous variables and the chisquare test for categorical variables

Writing Statistical Methods

- Multiple backward stepwise logistic regression analysis was undertaken to determine factors associated with depression, while adjusting for confounders. Variables were included in the model if they had a p value of 0.25 or less on univariate analyses and removed from the model if they had a p value of 0.1 or more on likelihood ratio tests. Odds ratios and 95% confidence intervals are reported and the model was assessed using the Hosmer Lemeshow goodness of fit test.
- Analyses were adjusted for clustering of pateints within GPs using……

Writing Statistical Methods - Sample Size

- **Example - estimation**
- **A sample of (x) is adequate to estimate the prevalence of depression, with the 95% confidence interval to be within +/- (Y) of the point estimate, assuming a prevalence of approximately 20%.**

Writing Statistical Methods – Sample Size

- Include for hypothesis testing:
- significance level
- power
- difference to be detected
- expected % in groups, or
- standard error

Writing Statistical Methods – Sample Size

- **A sample size of (N) per group will allow detection of a difference between patients with and without depression of 15% for binary explanatory variables and 0.3 of a standard deviation for continuous explanatory variables, with a 5% significance level and 80% power; assuming a prevalence of depression of approximately 20% [or (Y) standard deviation], and a design effect due to clustering of patients within GPs of 1.2**

- **need to make sure numbers for all hypotheses included**

Calculating Sample Size - Precision

Mean

$$n = \left(z \frac{\sigma}{\Delta} \right)^2$$

Where

- **Z = 1.95 for 95% confidence Interval**
- **σ is standard deviation**
- **Δ precision (= ½ width of confidence interval)**

Calculating Sample Size - Precision

Proportion

$$n = \left(\frac{1.96}{\Delta}\right)^2 p(1-p)$$

Where

- **Z = 1.95 for 95% confidence Interval**
- **p is estimate of proportion (use 50% if unknown)**
- **Δ precision (= ½ width of confidence interval)**

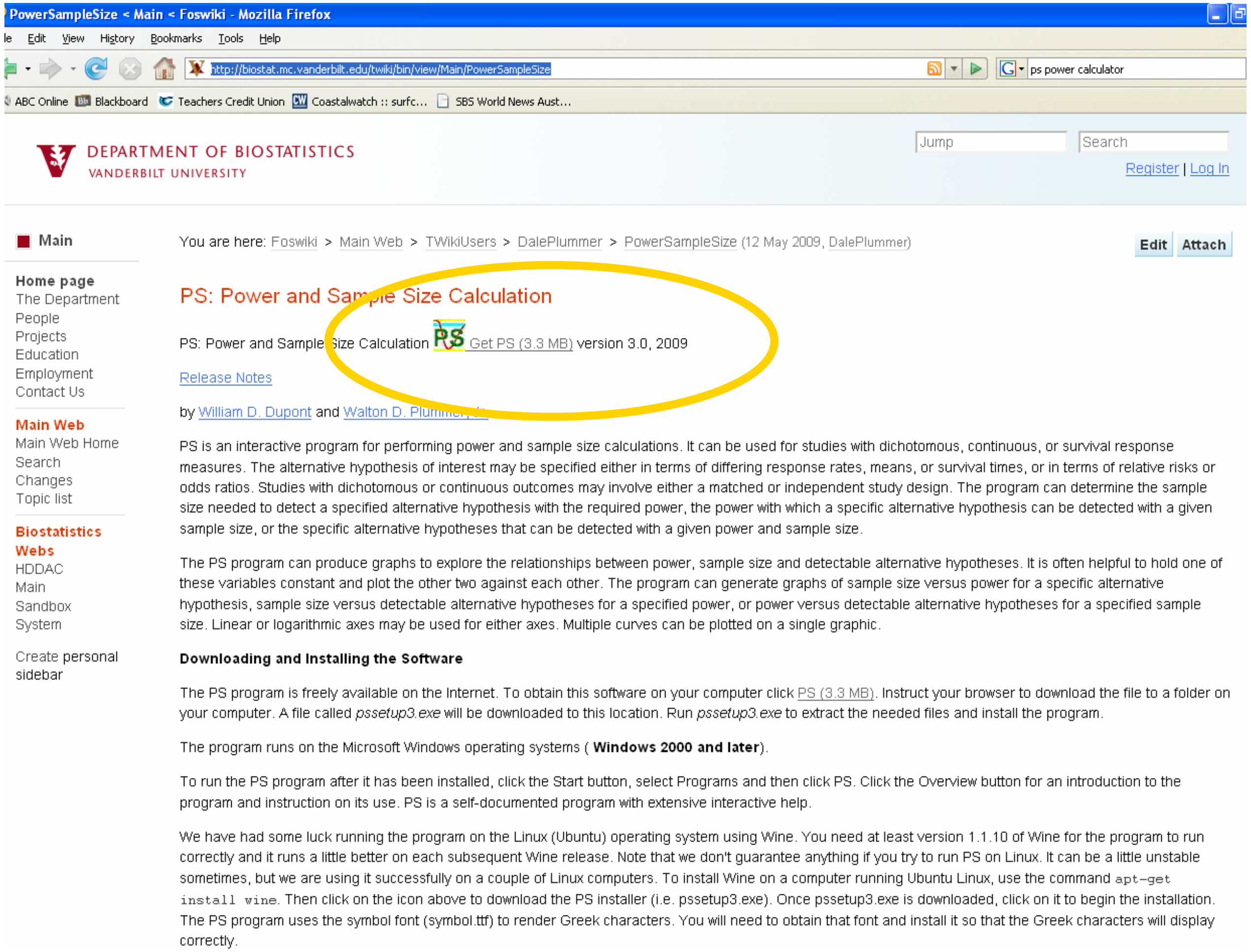
Calculating Sample Size – Hypothesis Testing

	"truth"	
Hypothesis test	**Null hypothesis true**	**Null hypothesis NOT true**
Do not reject H0 (conclude H0 true)	✔	Type II error **β** (1 – power)
Reject H0 (conclude H0 not true)	Type I error **α** (significance level)	✔

PS Power

The PS (power program) can be downloaded from:

http://biostat.mc.vanderbilt.edu/twiki/bin/view/Main/PowerSampleSize



PowerSampleSize < Main < Foswiki - Mozilla Firefox

http://biostat.mc.vanderbilt.edu/twiki/bin/view/Main/PowerSampleSize

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You are here: Foswiki > Main Web > TWikiUsers > DalePlummer > PowerSampleSize (12 May 2009, DalePlummer)

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PS: Power and Sample Size Calculation

PS: Power and Sample Size Calculation Get PS (3.3 MB) version 3.0, 2009

Release Notes

by William D. Dupont and Walton D. Plummer, Jr.

PS is an interactive program for performing power and sample size calculations. It can be used for studies with dichotomous, continuous, or survival response measures. The alternative hypothesis of interest may be specified either in terms of differing response rates, means, or survival times, or in terms of relative risks or odds ratios. Studies with dichotomous or continuous outcomes may involve either a matched or independent study design. The program can determine the sample size needed to detect a specified alternative hypothesis with the required power, the power with which a specific alternative hypothesis can be detected with a given sample size, or the specific alternative hypotheses that can be detected with a given power and sample size.

The PS program can produce graphs to explore the relationships between power, sample size and detectable alternative hypotheses. It is often helpful to hold one of these variables constant and plot the other two against each other. The program can generate graphs of sample size versus power for a specific alternative hypothesis, sample size versus detectable alternative hypotheses for a specified power, or power versus detectable alternative hypotheses for a specified sample size. Linear or logarithmic axes may be used for either axes. Multiple curves can be plotted on a single graphic.

Downloading and Installing the Software

The PS program is freely available on the Internet. To obtain this software on your computer click PS (3.3 MB). Instruct your browser to download the file to a folder on your computer. A file called *pssetup3.exe* will be downloaded to this location. Run *pssetup3.exe* to extract the needed files and install the program.

The program runs on the Microsoft Windows operating systems (**Windows 2000 and later**).

To run the PS program after it has been installed, click the Start button, select Programs and then click PS. Click the Overview button for an introduction to the program and instruction on its use. PS is a self-documented program with extensive interactive help.

We have had some luck running the program on the Linux (Ubuntu) operating system using Wine. You need at least version 1.1.10 of Wine for the program to run correctly and it runs a little better on each subsequent Wine release. Note that we don't guarantee anything if you try to run PS on Linux. It can be a little unstable sometimes, but we are using it successfully on a couple of Linux computers. To install Wine on a computer running Ubuntu Linux, use the command `apt-get install wine`. Then click on the icon above to download the PS installer (i.e. pssetup3.exe). Once pssetup3.exe is downloaded, click on it to begin the installation. The PS program uses the symbol font (symbol.ttf) to render Greek characters. You will need to obtain that font and install it so that the Greek characters will display correctly.

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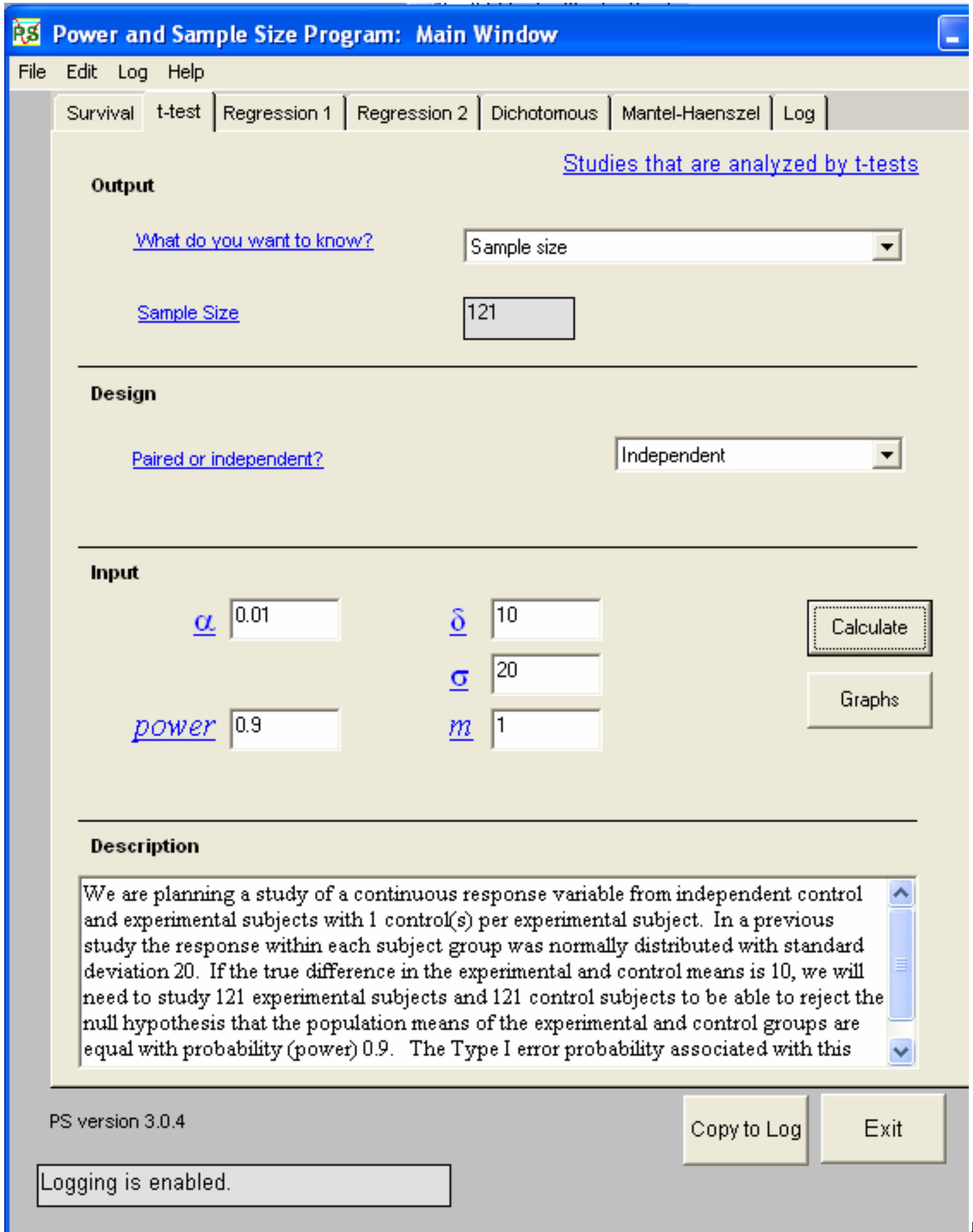
Example - Differences between means

Calculate the sample size when α= 0.01, *power* (1-β)= 90%, Δ= 10, *s* = 20 and *m* = 1.

The result is 121 subjects per group. The result is the number of "cases".

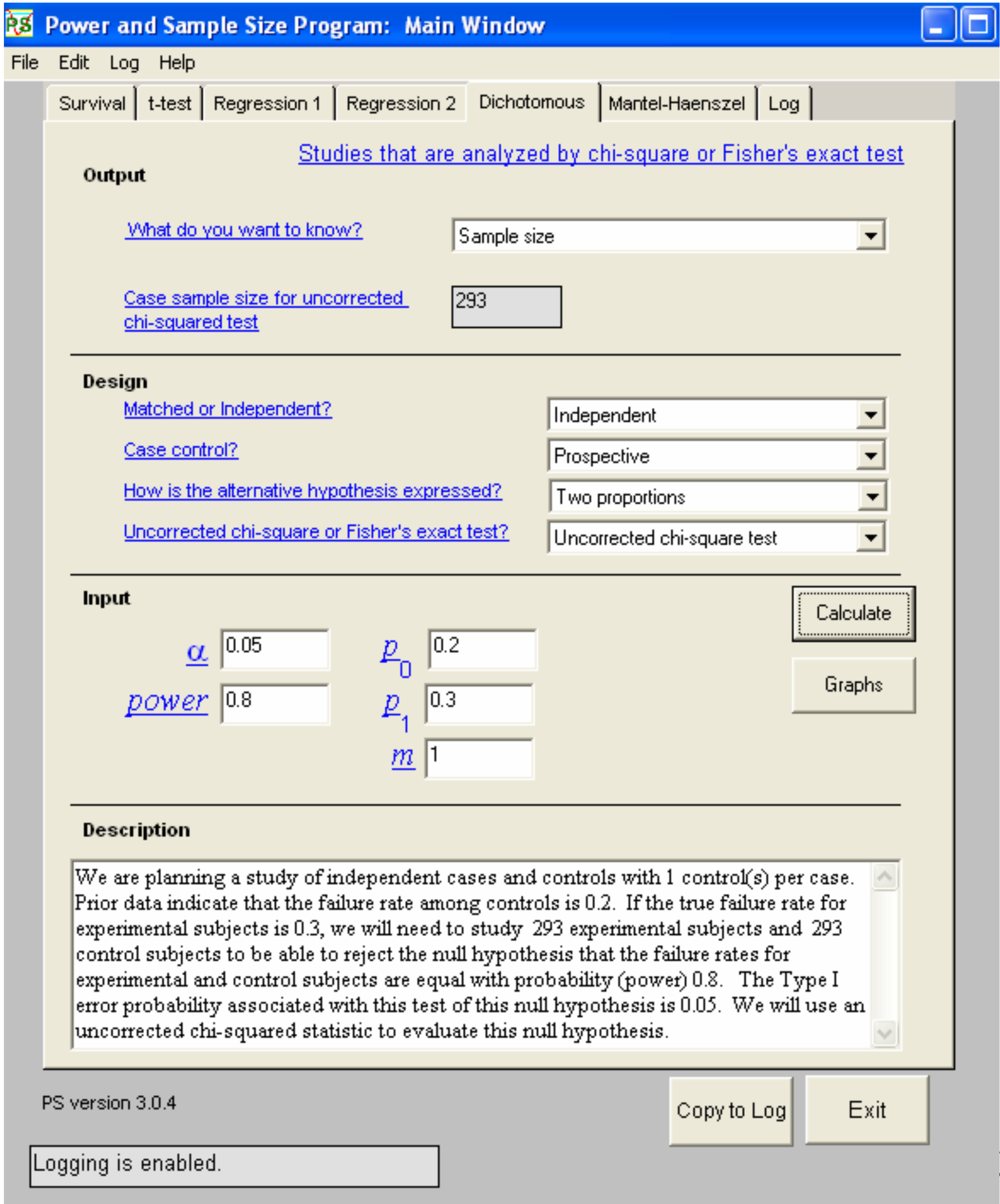


Example - Differences between proportions

Calculate the sample size when
$\alpha = 0.05$,
power = 80%,
$p_0 = 0.2$,
$p_1 = 0.3$ and
$m = 1$

Sample size, for uncorrected chi-squared test is 293 per group.

Sample size for Fisher's exact test, slightly higher (313).

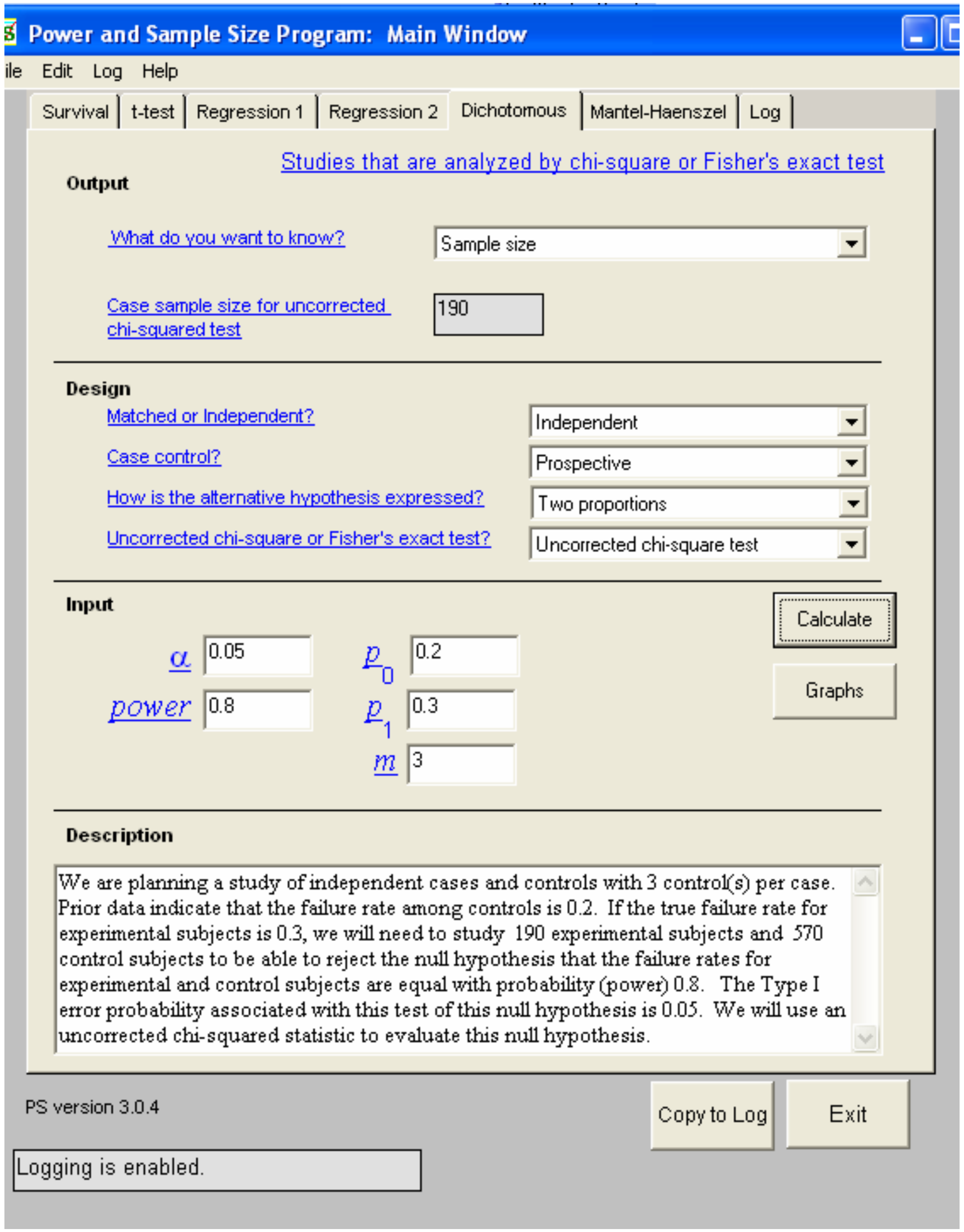


Example – Unequal sized groups

Case-control study for alcohol and breast cancer. Approximately 20% of controls and 30% of cases have ≥ three alcohol drinks/ week. The ratio of cases and controls is 1:3. What sample size is required?

$\alpha = 0.05$.
power = 80%,
$p_0 = 0.2$,
$p_1 = 0.3$ and
$m = 3$.

We require 190 cases and 190 x 3 = 570 controls.



Calculating Sample Size – other issues

- If relevant need to adjust for clustering of observations within units (eg GPs, nursing homes, care facilities)

- Remember to seek advice whenever possible / applicable

THANK YOU

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YOUR TURN!!!!!!