Shaystah Dean: Report on sample size calculations

prepared by James Stanley, Biostatistician

Version as per 21/11/2011

1 General notes

All calculations performed in R 2.13.0 (R Foundation, Vienna, Austria.)

1. All of the sample size calculations below are based around the comparison of number of sessions attended between the motivational interviewing (MI) and control group arms. This is essentially a cluster randomised trial scenario.

2. I've used some hypothetical likelihoods of attending a certain number of sessions – these work out to an average of slightly over 4 sessions/5 for the MI group, and 3 (and a bit) sessions /5 for the control group. This is a difference on average of almost one more attendance in the MI group.

3. The calculations as they stand are based around having independent groups for the MI/control CBT sessions. As discussed, this unmixed groups design will require a slightly larger sample size than having mixed groups of MI/control participants, but avoids the issue of potential influences from the MI and control arms on each other within a group therapy session.

   The larger sample size for the unmixed groups design should however translate into lower between-groups variability in terms of numbers of sessions attended (less inter-group variation,) and so the actual required difference in sample size required to detect a difference between groups is likely to be minimal.

4. I kept group size constant at 6 people per group. If you could get as many as 8 people per group, then you might require fewer groups than specified below, but the overall sample size wouldn't change very much. From a statistical point of view, more groups of a moderate size would be preferable, rather than fewer groups with more participants per group.

5. As noted earlier, analysis of the primary outcome is based around a cluster-analysis approach. For other comparisons (e.g. comparison of changes in preparedness to engage in therapy) where the collection of outcome measures occurs prior to the group therapy sessions you can simply use analysis methods appropriate for an individually randomised RCT design (e.g. a t-test where data are appropriate).

2 Sample size assumptions

Figure 1 below gives the likelihood of attending X number of sessions, according to Control group training or motivational interviewing training grouping. Assuming this pattern of attendances, you would need the following sample sizes to have at least 80% power to detect a difference between the two treatment arms. This is based on the following analysis plan for statistical testing for this hypothesis:

1. Calculate the mean number of sessions attended on a group-by-group basis.
2. Perform an unpaired t-test as to whether the average number of sessions attended per group is significantly different between the two groups (i.e. you use the inputs from the first step in the t-test calculation.) This analysis approach takes care of the fact that there will be clustering according to group membership (that is, members of the same CBT group are likely to have an attendance record that is more similar to other members of that group than to members of another group.)

In practical terms, this means that what you are doing is looking at the effectiveness of MI on improving attendance in group CBT. The unit of analysis for this, to allow for clustering, is the group, rather than the individual.

```
[1] number of ppts per group is: 6

[1] n of groups PER ARM OF STUDY is: 8

[1] Total sample size is equal to 96

[1] Power based on t-test is equivalent to 0.831
```

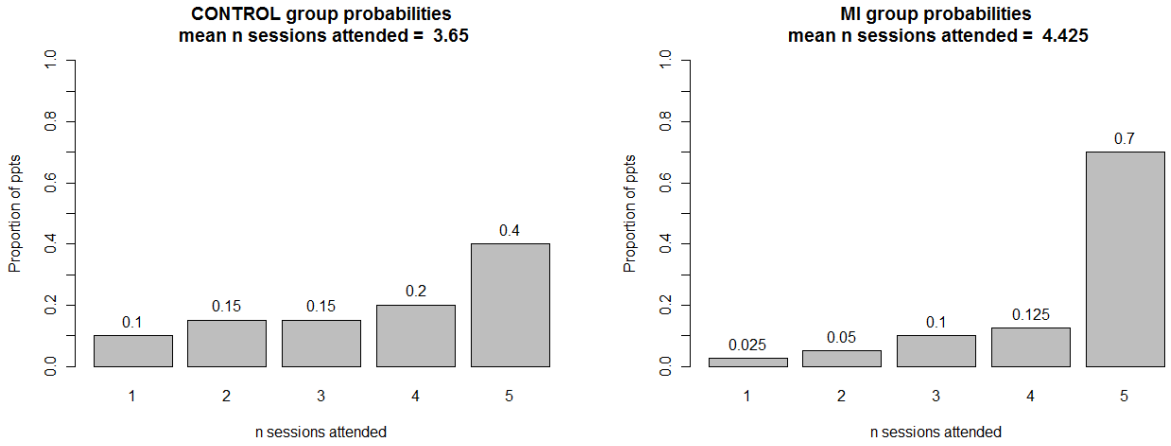

Figure 1: Likelihood of attending n sessions by study arm