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Whilst most treatments are received by patients individually, some are delivered to patients in groups. Examples include exercise classes for the treatment of musculo-skeletal disorders, group therapies for psychological problems and self-help groups for smoking cessation or alcohol problems. Outcome for patients in the same therapy group may be more similar than for patients in different groups due to shared experience of delivery and interaction between patients [1]. This will be particularly so where interaction between patients is an important component of the group treatment. The design and analysis of trials of group administered treatments should therefore assume lack of independence of patients in the same therapy group. This has implications for design, including sample size estimation, and methods of statistical analysis [2], similar to cluster randomised trials.

Non-compliance poses a particular problem for trials evaluating group administered treatments. At the time of randomisation a patient may be allocated to a particular therapy group, but some patients may not attend. Patients may be included in an analysis taking account of clustering effects using either the intended or actual treatment group. Using the actual group, non-compliant patients would therefore be assumed to be independent. Alternatively, groups or classes may not be established immediately after randomisation, but wait until sufficient patients have been randomised to the group administered treatment within a particular centre before assigning a group. Defaulting patients may never therefore be assigned to a specific therapy group and so may be considered to be independent.

Recently, Jo et al [3] investigated the implication of clustering of non-compliance for estimation of ITT and causal effects in cluster randomised trials. This presentation will compare methods of causal analyses that may be used for the analysis of trial of group administered treatments. Methods will be illustrated by data from a trial comparing active group based program of exercise and CBT for chronic lower back pain with patient information.

References

- 1 Hoover DR. Clinical trials of behavioural interventions with heterogeneous teaching subgroup effects. *Statistic in Medicine* 2002; 21: 1351-63.
- 2 Roberts C, Roberts SA. Design and analysis of clinical trials with clustering effects due to treatment. *Clinical Trials* 2005; 2: 152-62.
- 3 Jo, B., Asparouhov, T., Muthén, B., Ialongo, N. & Brown, H. (2007). Cluster randomized trials with treatment noncompliance. Accepted for publication in *Psychological Methods*.