# Design Issues arising from Therapist Variation in Psychotherapy Trials

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Clinical trials of psychotherapies make up a significant proportion of all clinical trials carried out in mental health. The importance of variability in patient outcomes between therapists has been recognised by researchers and clinicians since the origin of the field (see Wampold 2001). Yet relatively few explicitly take the therapist into account either in the design or in the analysis of randomised psychotherapy trials (see Martindale 1978; Crits-Christoph & Mintz 1991). Furthermore, we found no evidence of any reviewers attempting to take therapist variation into account in a recent review of Cochrane reviews involving the meta-analysis of psychotherapy trials. As with cluster randomised trials, between cluster (i.e. therapist) variation can lead to a lack of independence of patient outcomes with implications for sample size, analysis and the precision of trial results. Non-random allocation of psychotherapies to therapists can lead to confounding of treatment effects with therapist characteristics even where psychotherapies are randomly allocated to patients. Non-random allocation of therapists to patients can lead to confounding of therapist effects with patient characteristics. Therapist selection criteria can affect the generalisability of trial results in the same way as patient eligibility criteria can. Confounding and generalisation issues have important implications for the interpretation of trial results and imply the need for greater care in defining research questions in this setting. Design issues arising from therapist variation within psychotherapy trials will be discussed with the reference to examples from published and ongoing clinical trials.