

# Preliminary Feasibility and Clinical Results of a Pilot Study of Treatment by Homeopaths for Children with ADHD using the Trials within Cohorts (TwiCs) Design

Philippa Fibert, Clare Relton

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## Background:

There is a need to improve outcomes for attention-deficit hyperactivity disorder (ADHD) which is a strain on stakeholder services and at risk of negative outcomes. Information is required about treatments that can achieve improvements in emotional regulation, criminality, school disruption, and ADHD in autism. Trials of individualised homeopathic remedies for ADHD show positive results. Trials of treatment of children with ADHD by a homeopath as experienced in clinical practice can provide useful information about the potential of homeopathic treatment to improve outcomes.

## Methods:

This study used the Trials within Cohorts (TwiCs) design. Participants were recruited to a long-term observational ADHD cohort and their outcomes of interest (ADHD symptoms, quality of life, school disruption, resource use and criminality) measured every 6 months. A random selection was offered treatment by a homeopath (arm 1) or a nutritional therapist (arm 2), while the remainder acted as a virtual treatment as usual (TAU) control arm (arm 3). The effectiveness of the interventions, feasibility of recruiting to the cohort, delivering the interventions, and measuring outcomes were assessed.

## Results:

Assessment of 6-month outcomes will be conducted in March 2017. One hundred and fifty participants were recruited to the cohort between September 2015 and 2016, of whom 124 were eligible for the pilot study. Measurement of outcomes was feasible, although non-return of measures was a feature. Delivery of the interventions face to face and online was feasible and provided flexibility for this population.

## Conclusion:

This pragmatic trial design allows the testing of treatment by homeopaths as experienced in usual practice over the long term. It provides important information to stakeholders about the potential effects of homeopathic treatment. Attrition and non-attendance were features. They are common in ADHD trials, and providing evidence about the acceptability of interventions is therefore useful.