



CRYING, UNSETTLED, DISTRESSED INFANTS: EFFECTIVENESS STUDY

One day Training Course for participating Osteopaths

Prior to the course: reading the protocol and basic information about Good Clinical Practice in research (GCP)

10.00 Welcome and introductions

10.20 Introduction to the aims and basic structure of the trial

10.40 What it means to be part of a randomised controlled trial (RCT)

The law and research

Good Clinical Practice

Research ethics

Scientific rigour – the protocol

12.00 Lunch

12.45 Trial procedures

Health screening and eligibility (including potential non-eligibility and referrals)

Eligibility, recruitment and consent

Randomisation

1.30 The interventions

Practical – targeted tension release group

Practical – generic tension release group

The paperwork/trial documentation

3.00 Break

3.30 Safeguarding

3.45 Adverse event(s) handling and reporting

Managing upset infants

Managing upset parents

Situations involving suspecting parent harm to self, infant, or others

4.15 Protocol deviations and reporting

4.30 Questions and next steps (full discussion about choice and ability to participate)

5.00 Close