Title	Crying, unsettled and distressed infants: Swiss arm of an international randomised controlled trial to test the effectiveness of osteopathic care
Acronym	CUTIES-CH
Status (Begin-End)	Ongoing, scheduled to end in February 2022
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Collaboration/Partnership	• University College of Osteopathy (UK) (www.uco.ac.uk) • European School of Osteopathy (UK) (https://www.eso.ac.uk) • Southern Cross University (Australia) (www.scu.edu.au) • Macquarie University (Australia) (www.mq.edu.au)
Funding (Funding partners in Switzerland)	• Swiss Osteopathic Science Foundation (www.osteopathyfoundation.ch) • HES-SO (www.hes-so.ch)
Abstract	**Background and Rationale** Infants who excessively cry and are perceived as unduly distressed and unsettled may be otherwise healthy and thriving. However, these symptoms can have a marked impact on family life. Around 1 in 6 families are affected by excessive infant crying (Hiscock, Jordan 2004). It is associated with maternal issues such as depression, anxiety and loss of parenting confidence (Johnson et al 2015, Kurth et al 2010). The peak age for crying in infants, at week six, is the same as the peak age for severe infant injury or death as a result of abuse (Kato 2016, Berkowisz 2017). Health care resource use by parents is higher in an infant's first 6 months of life, indicating a greater need for support during this period (Johnson et al 2015). One of the major reasons for this increase includes unsettled infant behaviour and problems with sleeping and feeding (Morris et al., 2001). Many parents seek alternative care such as osteopathy for their "colicky" infants. Osteopathic treatment for "colicky" infants commonly involves gentle touch and movement (Prevost et al., 2019). Treatment includes gentle application of light tactile pressure to areas that are perceived to demonstrate palpably increased soft tissue tone. There is little evidence to support the mechanism of action underpinning this approach with the rationale for treatment theoretically driven. Leuchter et al., (2013) postulated that infants with colicky crying were less able to regulate their responses to everyday stimuli. This led to the hypothesis that osteopathic affective touch may be able to modulate stimuli produced within the gut and other internal organs (interoceptive stimuli) in a direction that reduced symptoms such as crying and distress (D'Alessandro et al., 2016, Cerritelli et al., 2017). Regardless of the physiological rationale or explanation for this approach, there is limited, low to moderate quality evidence to show that osteopathic and chiropractic care can help to reduce crying time in infants (Dobson et al., 2012; Carnes et al., 2018; Prevost et al., 2019). More scientifically robust definitive trials on the topic are needed to clarify the situation. Parents/carers are often in

	crisis when they seek support and care for their "colicky" infants and that they expect the outcome of that care to have an almost immediate effect. Normally the symptoms of excessive crying, unsettledness and distress are self-limiting and start resolving around nine to 12 weeks of age (Wolke et al., 2017). This sudy is therefore designed to look at short-term impact of care on reducing crying time in infants with unsettled crying. **Aim** To evaluate the effectiveness of osteopathic light touch manual therapy care for excessively crying, unsettled and distressed infants. **Method** We propose a two-arm pragmatic randomised controlled trial, 112 infants will be randomised to either: (i) Specific osteopathic light touch manual therapy with best practice advice and support or, (ii) Non-specific light touch with best practice advice and support. Parents will be blinded to group allocation. **Population** Healthy infants under 10 weeks old, reported by their parents as excessively crying, fussing, unsettled, distressed and difficult to console using the Rome IV criteria (>3 hours of crying per day, for 3 days or more, for 1 week or more). Infants with diagnosed health conditions for which they are receiving medical treatment or who are unsuitable for osteopathic care will be excluded from the study. Thirty UK, Australian and Swiss osteopaths will recruit participants in their own clinics. In Switzerland, at least 10 osteopaths are to be recruited **Outcomes** The primary outcome is reduced infant mean crying time over 14 days, collected via parent reported diaries. Secondary outcomes are: (i) Parental self-efficacy, (ii) Parent perceived global improvement, (iii) Satisfaction and experience with treatment, (iv) Adverse events, and (v) Direct cost. **Discussion** The results from this study will provide information that osteopaths, other health care professionals and parents can use to inform their decisions about treatment choices.
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Dissemination (Publications, Conferences)	• Publication of the overall CUTIES study protocol: Carnes, D., Bright, P., Carrol, K., Engel, R., Grace, S., Vogel, S., & **Vaucher, P.** (2020). Crying Unsettled and disTressed Infants Effectiveness Study of osteopathic care (CUTIES trial): Pragmatic randomised superiority trial protocol. *International Journal of Osteopathic Medicine, 38*, 31-38. doi: 1016/j.ijosm.2020.08.001