

# A double-blind randomized controlled pilot trial examining the safety and efficacy of ther. touch

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To explore the hypothesis that nontouch therapy such as therapeutic touch (TT) reduces stress to a clinically important degree and is safe to use in preterm infants. DESIGN: A pilot randomized, double-blind, controlled trial. SUBJECTS: Two groups of 10 infants were enrolled and randomly assigned to treatment or nontreatment groups. Gestational age was less than 29 weeks. Demographic descriptions of the 2 groups were statistically similar. METHODS: The observer and staff were blinded to assignment; the TT practitioner was blinded to observed measurements. Each infant received either TT or no therapeutic touch (NTT) for 5 minutes on 3 consecutive days at the same time of day, behind a curtain. Heart period variability (HPV) was measured 5 minutes before, during, and after the treatment phase. RESULTS: Examination of the parameters of oxygen saturation and episodes of apnea demonstrated no increase in adverse events in TT group compared with NTT group. Repeated-measures multivariate analysis of variance on HPV revealed differences in the interaction of group assignment with low-frequency, high-frequency, and low-to-high-frequency ratio interaction ( $F_{2,143} = 8.076$ ,  $P = .000$ ) and for group, day, and low-frequency, high-frequency, and low-to-high-frequency ratio ( $F_{2,288} = 3.146$ ,  $P = .015$ ), and in the posttreatment time period ( $F_{1,16} = 6.259$ ,  $P = .024$ ), reflective of greater parasympathetic activity in TT group. CONCLUSION: In this pilot trial, HPV showed an increase for the TT group compared with the NTT group. The study reveals no adverse effects of TT in preterm infants.

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