

Research Protocol
One month follow up study

Title	The effect of nicotine exposure one month after birth
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Funding	ESRC doctoral scholarship
Start date	03/09/2018
Estimated study competition	01/03/2021
Project summary	<p>This research is a follow up to a study assessing the effects of nicotine on fetal behaviour at 32- and 36-weeks gestational age using 4D ultrasound scans.</p> <p>The proposed study assesses these same mother-infant pairs at approximately one month of age using the Neonatal Behavioural Assessment Scale (NBAS) (Brazelton & Nugent 1995).</p> <p>Smoking is directly correlated with infant irritability, attention, hypertonicity and decreased response to auditory stimuli (Mansi et al., 2007; Stroud et al., 2009a), with early motor development associated with later cognitive and behavioural outcomes (Hitzert et al., 2014). Infants who are prenatally exposed to cigarettes also demonstrate a greater need for handling, lower self-regulation (Stroud et al., 2009b) and lack of focused attention (Wiebe et al., 2009). However, research has not yet been conducted assessing the impact of prenatal exposure to e-cigarettes on infant neurobehaviour. This is an important area of research to explore as animal studies indicate that exposure to nicotine disrupts brain development subsequently leading to neurodevelopmental changes (Slotkin et al., 2006).</p> <p>To assess infant behaviour the NBAS will be used. This assessment has been used in multiple studies assessing the impact of smoke exposure on newborn behaviour. It is a sensitive assessment that can identify differences between those who have had no exposure and those exposed to cigarettes during pregnancy through the mother (Hernández-Martínez et al., 2012).</p>
Hypotheses	<p>Infants who are prenatally exposed to cigarettes will demonstrate poorer birth outcomes (lower birth weight, earlier delivery, reduced head circumference) in comparison to non-exposed and e-cigarette exposed infants. Those exposed to cigarettes and e-cigarettes will demonstrate poorer neurobehavioural outcomes (e.g. less responsive to stimuli, poor motor maturity, decreased regulation, greater abnormal reflexes).</p>
Methodology	<p><i>Design:</i> This is a case-control observational study.</p> <p><i>Participants:</i> An estimate of 100 mother-infant pairs will participate in this research. Women who are invited to participate in this research will be a part of the prenatal study that aimed to assess fetal behavioural profiles as a result of nicotine exposure. These</p>

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	<p>women are from the North East of England (Middlesbrough, UK). Cigarette smokers, e-cigarettes users and non-smokers were recruited into the prenatal study and thus will be invited to participate in the follow up study.</p> <p><i>Eligibility:</i> Mothers must have already participated in the prenatal phase of the research. The newborn must have been born >37 weeks' gestation and not receiving treatment from NICU at 4 weeks.</p> <p><i>Materials:</i> The Perceived Stress Scale (Cohen et al., 1994), the Hospital Anxiety and Depression Scale (Zigmond & Snaith, 1983), the Postnatal Attachment Scale (Condon & Corkindale, 1998), a questionnaire assessing smoking status and a smokerlyser CO breath test will be completed by the mothers.</p> <p>The Neonatal Behavioural Assessment Scale (Brazelton & Nugent 1995) will be conducted with the infants. The scale involves 28 behavioural items involving assessment of orientation, habituation, motor maturity, self-regulation, automatic stability and range of states. The NBAS also includes eighteen reflexes that will be assessed.</p>
Data analysis	<p>Due to the known impact of nicotine, maternal stress, depression and anxiety on fetal brain development, prenatal scores on these items will be used (32 weeks gestation).</p> <p>An ANOVA will assess whether birthweight, gestation, head circumference, and neurobehaviour differs amongst the nicotine exposure groups.</p> <p>An ANCOVA will be conducted to control for maternal stress, depression, anxiety and maternal age.</p>
Dissemination	<p>The study will be published in a peer review journal. Findings will also be presented at conferences.</p>
References	<p>Brazelton, T. B., & Nugent, J. K. (1995). <i>Neonatal behavioral assessment scale</i> (No. 137). Cambridge University Press.</p> <p>Cohen, S., Kamarck, T., & Mermelstein, R. (1994). Perceived stress scale. <i>Measuring stress: A guide for health and social scientists</i>, 10, 1-2.</p> <p>Condon, J. T., & Corkindale, C. J. (1998). The assessment of parent-to-infant attachment: Development of a self-report questionnaire instrument. <i>Journal of Reproductive and Infant Psychology</i>, 16(1), 57-76.</p> <p>Hernández-Martínez, C., Val, V. A., Subías, J. E., & Sans, J. C. (2012). A longitudinal study on the effects of maternal smoking and secondhand smoke exposure during pregnancy on neonatal neurobehavior. <i>Early Human Development</i>, 88(6), 403-408.</p>

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