

Supplementary Table 3. Severe adverse events/death in acupuncture studies for pregnant women

Author (year) Country	Condition/ mean gestational weeks	Acupuncture group (A) and control group (C)	How AE data were collected	Details of AEs	Incidence per group	Severity <sup>†</sup>	Association with acupuncture <sup>‡</sup>	Practitioner
<b>RCTs/quasi-RCTs</b>								
Vas (2013) <sup>1</sup> Spain	Fetal malposition/ A: 34.0 C1: 33.0 C2: 34.0	A: Moxa plus usual care C1: Sham moxa plus usual care C2: Usual care	(Presumably) Participant/ obstetrician reported	<b>Maternal:</b> Did not progress due to lack of uterine contractions PROM <b>Fetal:</b> Fetal hiccup Cord pathology	6/NA 5/NA 5/NA 6/NA			Family member
Manber (2010) <sup>2</sup> United States	Depression/ A: 19.8 C1: 21.3 C2: 21.1	A: MA C1: Sham MA C2: Prenatal massage	Participant/ practitioner reported	<b>Maternal:</b> Preeclampsia Preterm delivery of twins Pregnancy loss Hospitalisation for oesophageal spasms Hospitalisation for dehydration and low amniotic fluid Hospitalisation for isolated atrial fibrillation Hospitalisation for premature contractions <b>Fetal:</b> Neonatal death  Receiving prolonged NIC Congenital defects	A 2/456 A 1/456 C1 1/407 C2 1/NA C1 1/407 C2 1/NA C2 1/NA A 1/456 A 1/456; C2 1/NA	Severe Severe	Unlikely Unlikely	Acupuncturist
Guittier (2008) <sup>3</sup> Switzerland	Fetal malposition/ 34-36	A: Moxa C: No moxa	(Presumably) Participant/ obstetrician reported	<b>Maternal:</b> Hypertension, later developed preeclampsia Cesaerean delivery PROM	A 1/56 A 1/56 A 1/56	Severe Severe Severe	Unlikely Unlikely Unlikely	NR
Du (2005) <sup>4</sup> China	Fetal malposition/ 24-28	A: Moxa plus knee-chest position C: Knee-chest position	(Presumably) Participant/ obstetrician reported	<b>Maternal:</b> Vaginal redness Vaginal running water Placental abruption <b>Fetal:</b> Abnormal fetal heart rate	C 5/NA C 3/NA C 3/NA C 5/NA	Severe Severe	Unlikely Unlikely	NR
Cardini (2005) <sup>5</sup>	Fetal malposition/	A: Moxa C: No moxa	(Presumably) Participant/	<b>Maternal:</b> Preterm delivery at 34 weeks <sup>§</sup>	A 2/1085	Severe	Unlikely	Participant

Italy	32.4-33.4		obstetrician reported										
Smith (2002) <sup>6-7</sup> Australia	Nausea and vomiting/ 8.5	A1: Traditional MA plus usual care A2: PC6 MA plus usual care C1: Sham MA plus usual care C2: Usual care	Participant reported or study investigator collected data by a telephone with participants or from case notes	<b>Maternal:</b> Pregnancy termination due to unspecified reasons Antepartum haemorrhage/abruption or placenta praevia Hypertension Preeclampsia** Preterm delivery Miscarriage <b>Fetal:</b> Stillbirth Congenital abnormality Musculoskeletal disorders congenital hip dislocations (8) polydactyly (1) Cardiovascular disorders (all congenital heart defects) Gastrointestinal disorders pyloric stenosis (1) cleft lip (2) Urogenital disorders hypospadias (1) undescended testes (2) Metabolic disorders microphthalmia (1) cystic fibrosis (1) Chromosomal abnormality Neonatal death	A1 2/668; C1 2/668 A1 2/668; A2 4/672; C1 6/668; C2 4/NA A1 6/668; A2 10/672; C1 10/668; C2 5/NA A1 11/668; A2 7/672; C1 8/668; C2 7/NA A1 9/668; A2 5/672; C1 6/668; C2 12/NA A1 4/668; A2 11/672; C1 6/668; C2 9/NA A1 1/668; C1 1/668; C2 4/NA A1 6/668; A2 5/672; C1 6/668; C2 5/NA A1 4/668; A2 2/672; C1 2/668; C2 1/NA A1 1/668; A2 1/672; C1 2/668 A2 2/672; C1 1/668 A1 1/668; C2 2/NA C1 1/668; C2 1/NA C2 1/NA C1 1/668	Severe Severe Severe Severe Severe Severe Death related to AE Severe Severe Severe Severe Severe Severe Severe Severe Severe	Unlikely Unlikely Unlikely Unlikely Unlikely Unlikely Unlikely Unlikely Unlikely Unlikely Unlikely Unlikely Unlikely Unlikely Unlikely Unlikely Unlikely Unlikely Unlikely	Acupuncturist					
Cardini (1998) <sup>8</sup> China	Fetal malposition/ 33	A: Moxa C: Usual care	(Presumably) participant/obstetrician reported	<b>Maternal:</b> Tachycardia and atrial sinus arrhythmia PROM Preterm delivery <sup>††</sup> <b>Fetal:</b> Intrauterine fetal death	A 1/1779 A 4/1779; C 12/NA A 2/1779; C 3/NA C 1/NA	Severe Severe Severe Severe	Unlikely Unlikely Unlikely Unlikely	Participant					

\*The incidence was calculated as the number of AEs per number of acupuncture sessions. When the information was not

available, the number of participants replaced the number of acupuncture sessions.

†Severity of the AEs was assessed using the National Cancer Institute Common Terminology Criteria for Adverse Events (CTCAE) scale v4.0<sup>14</sup>; mild, moderate, severe, life-threatening, and death.

‡Association with acupuncture was evaluated using the WHO-UMC Causality categories<sup>15</sup>; certain, probable/likely, possible, unlikely, conditional/unclassified, and unassessable/unclassifiable.

§One was caused by PROM after five days of treatment. The other was due to uterine contractions which began on the 10<sup>th</sup> day of treatment, just after sexual intercourse, and were preceded by blood loss and suspected PROM.

\*\*Blood pressure  $\geq$  140/90 mmHg, proteinuria  $\geq$  0.3 g/IL from the 20<sup>th</sup> week of pregnancy.

††Two preterm deliveries in acupuncture group were all at 37 weeks. Three preterm deliveries in control group occurred at 34, 35, and 37 weeks, respectively.

AE, adverse event; CCT, controlled clinical trial; MA, manual acupuncture; Moxa, moxibustion; NA, not applicable; NIC, neonatal intensive care; NR, not reported; PROM, premature rupture of the membranes; RCT, randomised controlled trial.

## References

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