Evaluating the impact of the EpiSafe bundle on care and clinical outcomes for pregnant women with epilepsy and their babies: A cluster randomised hybrid implementation-effectiveness trial, process evaluation and qualitative study with economic evaluation

Aim: To evaluate the impact of using the EpiSafe bundle at antenatal bookings on the care and clinical outcomes of pregnant women with epilepsy and their babies.

Study design: This is a multicentre, parallel, two-arm cluster randomised trial with baseline. Clusters are maternity units in which pregnant women with epilepsy are booked for antenatal care. The cluster randomisation in the trial means that participating maternity units will be randomised into either the intervention arm (EpiSafe bundle) or the control arm. The intervention is applied at the cluster level and all pregnant women with epilepsy booked in the participating units will be included.

Primary objective: To evaluate the impact of using the EpiSafe bundle at antenatal bookings on the proportion of high-risk pregnant women with epilepsy accessing specialist epilepsy care before 14 weeks' gestation.

Key secondary objective: To evaluate the impact of using the EpiSafe bundle at antenatal bookings on the proportion of all pregnant women with epilepsy who have seizures at any time in pregnancy until discharge from the hospital after birth.

Other secondary objectives: To evaluate the impact of the EpiSafe bundle on the following outcomes: worsening seizure control, status epilepticus, maternal death, seizures that impair awareness, accidents or trauma due to seizures, admissions to hospital for seizures, admission to high dependency or intensive care unit, antiseizure medications adherence, pre-eclampsia, mode of birth, preterm labour, premature rupture of membranes, placental abruption, peripartum haemorrhage, miscarriage, ectopic pregnancy, termination of pregnancy, breastfeeding initiation.

The offspring outcomes will include: stillbirth, neonatal death, congenital abnormalities, preterm birth, small for gestational age, APGAR at 1 and 5 minutes, neonatal intensive care unit admission, hypoglycaemia, need for resuscitation, hypoxic-Ischemic encephalopathy.

Implementation outcomes: proportion of women who receive EpiSafe bundle, proportion of healthcare professionals trained on EpiSafe bundle, individual components of the bundle executed as specified, number of intervention components modified, proportion of EpiSafe bundle components delivered, and perceived fit of the EpiSafe bundle in care of pregnant women with epilepsy.

Qualitative outcomes: acceptability of the EpiSafe intervention to women, healthcare professionals, adaption, feasibility and equity of EpiSafe bundle, barriers to intervention

delivery and study conduct, patient reported experience measures (PREMs) on process of care: dignity, information, trust, positive birth experience.

What data is being used?

We will use anonymised routinely collected information to evaluate the impact of the EpiSafe bundle on the outcomes of pregnant women with epilepsy and their babies. We will not access or process any identifiable information and will comply with ethical and legal guidelines of data protection.

If you do not wish for your anonymised information to be used for this and other research purposes, you can opt out through the National Data Opt-Out website or call 0300 303 5035 for further information.

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