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Measures to Address Maternal Anxiety

Submission date	Recruitment status	[_] Prospectively registered
07/03/2011	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
07/03/2011	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
24/02/2016	Other	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
9932

Study information

Scientific Title
Measures to Address Maternal Anxiety: a randomised control study

Acronym
MAMA

Study objectives
This is a factorial randomised controlled trial of two different interventions in the same population, to answer two different questions. The first intervention compares two adrenaline auto-injector devices, namely Anapen® and EpiPen®, to evaluate whether one is easier than the other for parents of a food allergic child to learn to use effectively. The second intervention compares two different methods for discussing risks associated with food allergy with mothers of food allergic children, to evaluate their effect on maternal anxiety. 200 mothers with children who have food allergy will be randomised to one of four groups in a 2x2 factorial study design. The primary outcome measure for the comparison of adrenaline auto-injectors is effective delivery of adrenaline in a simulated scenario 6 weeks after training, using a trainer auto-injector device. The primary outcome measure for the informational intervention is maternal state anxiety score 6 weeks after the intervention.

Ethics approval required
Old ethics approval format

Ethics approval(s)
West London Research Ethics Committee 2, ref: REC10/H0711/76

Study design
Randomised interventional process of care

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topic: Medicines for Children Research Network; Subtopic: All Diagnoses; Disease: All Diseases

Interventions
Adrenaline auto-injector: participants will be randomised to receive training with either Anapen® or EpiPen®.
Informational intervention: participants will be randomised to receive either a new approach to discussing food allergy or current standard of care.

Study Entry: Single Randomisation only

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
State anxiety (STAI) score; Timepoint(s): 6 weeks (primary outcome) and 12 months (secondary outcome)

Key secondary outcome(s))

Successful administration of adrenaline using a trainer device, judged by an independent observer; Timepoint(s): 6 weeks (primary) and 12 months (secondary)

Completion date
02/03/2012

Eligibility

Key inclusion criteria
Pilot phase:
Parents of children attending the paediatric outpatient department at St Mary's Hospital food allergic/atopic/healthy groups categorised according to diagnoses made by the treating clinician. Food allergic group will be limited to those with IgE-mediated food allergy.

Main study:
1. Children aged 0-18 with food allergy (and their mother) diagnosed at a tertiary paediatric allergy clinic and need for adrenaline auto-injector prescription due to risk of anaphylaxis
2. Patient weight = 7.5 kg
3. Ability to converse fluently and read instructions in English or with an appropriate translator

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Upper age limit
18 years

Sex
All

Key exclusion criteria
Pilot phase:
Parents of children with known non-atopic chronic diseases likely to impact on maternal anxiety and stress will be excluded from this pilot phase

Main study:
1. Previous training to use an injectable adrenaline device
2. Known psychiatric morbidity such as psychotic disorders which might be expected to impact on the validity and appropriateness of the psychological intervention
3. Poor English language fluency and/or poor reading ability

Date of first enrolment
28/02/2011

Date of final enrolment

02/03/2012

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Wright-Fleming Institute
London
United Kingdom
W2 1PG

Sponsor information

Organisation
Imperial College London (UK)

ROR
https://ror.org/041kmwe10

Funder(s)

Funder type
Industry

Funder Name
Lincoln Medical (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2015		Yes	No