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The EQUIPTT Study: Evaluating whether clinicians using the QUIPP app make more appropriate management decisions for women who arrive to hospital thinking they may be in preterm labour

Submission date
08/01/2018

Recruitment status
No longer recruiting

Registration date
16/01/2018

Overall study status
Completed

Last Edited
27/02/2023

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Accurate diagnosis of preterm labour is desirable in order ensure the best management of those most at risk of preterm birth and to prevent the maternal and fetal risks incurred by unnecessary interventions to the majority of women who do not deliver within a week of presentation. Current over-intervention results in many women being transferred unnecessarily out of their local hospital and most women receiving unnecessary drugs, such as steroids. It also prevents appropriate transfers as neonatal cots are blocked unnecessarily, resulting in more dangerous ex-utero transfers. Our group has developed the QUIPP App which is a clinical decision-making aid based on quantitative fetal fibronectin (fFN) values (a fibronectin protein produced by fetal cells that binds the fetal sac to the uterus), cervical length and previous outcomes of women with threatened preterm labour. The aim of this study is to introduce the App and a management algorithm in 13 sites with the aim of reducing inappropriate management for threatened preterm labour. This study also performs a health economics evaluation of the QUIPP app and explores women's views of its implementation via a qualitative sub-study.

Who can participate?
Woman aged 18 and older who are between 23 to 34+6 weeks gestation and have symptoms of threatened preterm labour.

What does the study involve?
Participating hospitals are randomly allocated to one of two groups. Those in the first group do not use the app and those in the second group use the app. The different hospital sites start the study at the same time. Participants who arrive to a hospital in threatened preterm labour are either treated as per normal hospital guidelines if they are in the first group. Those in the second

group receive the normal treatment as well as their doctors and midwives use the app (if they are in the second group). Anonymous data is collected on the participants to see if using the app affects how doctors and midwives make decisions about their care.

What are the possible benefits and risks of participating?
There are no direct benefits or risks to participants in the study. They will still be treated by a clinician at their hospital unit who will manage them in the way that they think is best. The anonymous information that is collected about them will help us evaluate if the app is successful, and therefore may help women in threatened preterm labour in the future.

Where is the study run from?
This study is being run by King’s College London and takes place in hospitals in the UK.

When is the study starting and how long is it expected to run for?
January 2017 to July 2019

Who is funding the study?
1. Guy's and St Thomas' Charity (UK)
2. Tommy's The Baby Charity (UK)

Who is the main contact?
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Contact information

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
35947

Study information

Scientific Title
Evaluation of the QUIPP App for Triage and Transfer: reducing inappropriate management for threatened preterm labour

Acronym
EQUIPTT (Evaluation of QUIPP app for Triage and Transfer)

Study objectives
The implementation of the QUIPP App and management algorithm will decrease inappropriate management for threatened preterm labour.

Ethics approval required
Old ethics approval format

Ethics approval(s)
London Bridge Research Ethics Committee, 23/11/2017, ref: 17/LO/1802

Study design
Non-randomised; Interventional; Design type: Process of Care, Management of Care

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Individual consent is not required for the EQUIPTT study, therefore no participant information sheet is available.

Health condition(s) or problem(s) studied
Specialty: Reproductive health and childbirth, Primary sub-specialty: General Obstetrics/ Midwifery; UKCRC code/ Disease: Reproductive Health and Childbirth/ Maternal care related to the fetus and amniotic cavity and possible delivery problems

Interventions
This is a parallel cluster randomised control trial across 13 hospital sites. For the first 6 weeks all sites are continuing with their normal hospital routine management. For a nine month period, seven sites are randomised to using the QUIPP App to aid clinical decision making while the remaining six sites continue with normal routine management. For the final six weeks of the study, all 13 hospital sites will use the QUIPP App to aid clinical decision making. Data is collected on participants pregnancy details, their visit to hospital when they thought they may be in threatened preterm labour, and postnatal details (up until discharge or 28 days – whichever is sooner).

Intervention Type
Other

Primary outcome measure
Inappropriate management for threatened preterm labour is measured by number of inappropriate admission and in-utero transfer decisions: admitted to hospital/ transferred and delivery interval >7 days, or not admitted to hospital/ transferred and delivery interval <7 days.

Secondary outcome measures
1. Maternal clinical outcomes (e.g. new onset gestational diabetes) measured from the post-delivery outcome data
2. Neonatal clinical outcomes (e.g. gestational age at delivery) measured from the post-delivery outcome data
3. Process measures (e.g. days of maternal hospitalisation) measured from the post-delivery outcome data
4. Compliance to management recommendations measured from their visit to hospital data and post-delivery outcome data

Overall study start date
02/01/2017

Completion date
01/06/2020

Eligibility

Key inclusion criteria
1. Women who are pregnant
2. Any age range
3. With symptoms of threatened preterm labour (contractions or abdominal pain)
4. Between 23+0 and 34+6 weeks gestation

If they are having the QUIPP App used in their care management:
5. Participants must have a quantitative fetal fibronectin assessment and/or a transvaginal ultrasound scan as part of their clinical care

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
Planned Sample Size: 580; UK Sample Size: 580

Total final enrolment

2584

Key exclusion criteria
1. Definitive diagnosis of labour (i.e. regular painful contractions with cervical change > 3cm on speculum or digital examination)
2. Confirmed ruptured membranes (on speculum examination)
3. Significant vaginal bleeding

Exclusion Criteria for Qualitative study
1. Unable or unwilling to give informed consent
2. Under 16 years of age
3. Unable to understand English language sufficiently to complete the questionnaire booklet

Date of first enrolment
12/02/2018

Date of final enrolment
12/02/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
St Thomas' Hospital (lead centre)
Westminster Bridge Road
London
United Kingdom
SE1 7EH

Study participating centre
Chelsea and Westminster Hospital
369 Fulham Road
London
United Kingdom
SW10 9NH

Study participating centre
Croydon University Hospital
530 London Road

Thornton Heath
United Kingdom
CR7 7YE

Study participating centre
Frimley Hospital
Portsmouth Road
Camberley
United Kingdom
GU16 7UJ

Study participating centre
Kingston Hospital
Galsworthy Road
Kingston Upon Thames
United Kingdom
KT2 7QB

Study participating centre
Lewisham University Hospital
Lewisham High Street
London
United Kingdom
SE13 6LH

Study participating centre
Northampton General Hospital
Cliftonville
Northampton
United Kingdom
NN1 5BD

Study participating centre
University College London Hospital
235 Euston Road
London
United Kingdom
NW1 2BU

Study participating centre
West Middlesex Hospital
Twickenham Road
Isleworth
United Kingdom
TW7 6AF

Study participating centre
Whittington Hospital
Magdala Avenue
London
United Kingdom
N19 5NF

Study participating centre
Queen Elizabeth Hospital Woolwich
Stadium Road
London
United Kingdom
SE18 4QH

Study participating centre
Royal London Hospital
Whitechapel Road
London
United Kingdom
E1 1BB

Study participating centre
Newham Hospital
Glen Road
London
United Kingdom
E13 8SL

Sponsor information

Organisation
Kings College London/ Guys and St Thomas' Trust co-sponsorship

Sponsor details
NIHR GSTFT/KCL Biomedical Research Centre
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Charity

Funder Name
Guy's and St Thomas' Charity

Alternative Name(s)
Guy's and St Thomas' Charity, Guy's and St Thomas' Foundation, GSTTFoundation

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Funder Name
Tommy's The Baby Charity

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
01/09/2021

Individual participant data (IPD) sharing plan
The anonymised datasets generated during the EQUIPTT study will be available for access (e.g. for secondary analysis or IPD meta-analysis), upon request from the Chief Investigator Prof. Andrew Shennan (andrew.shennan@kcl.ac.uk). Access will generally be granted, after a 1 year period of embargo from publication of the main paper; or 2 years after the end of the grant if no paper has appeared.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		20/12/2017	16/01/2018	No	No
Protocol article	protocol	13/02/2019		Yes	No
Results article		06/07/2021	07/07/2021	Yes	No
Other publications	Clinicians' experiences of app	18/11/2021	27/02/2023	Yes	No
HRA research summary			28/06/2023	No	No