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	Recruitment status No longer recruiting	[X] Prospectively registered		
08/01/2018		[X] Protocol		
Registration date	Overall study status Completed	Statistical analysis plan		
16/01/2018		[X] Results		
Last Edited	Condition category	[] Individual participant data		
27/02/2023	Pregnancy and Childbirth			

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?

- 1. Professor Andrew Shennan (Scientific)
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- 2. Miss Naomi Carlisle (Scientific)

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3. Dr Ellie Watson (Scientific)

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Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number 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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s))

- 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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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

United Kingdom

England

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

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

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?
Results article		06/07/2021	07/07/2021	Yes	No
Protocol article	protocol	13/02/2019		Yes	No
Basic results		20/12/2017	16/01/2018	No	No
HRA research summary			28/06/2023	No	No
Other publications	Clinicians' experiences of app	18/11/2021	27/02/2023	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes