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A study of maternity service users' and providers' experience of the Tommy's Clinical Decision Tool in four early adopter sites, and identification of factors to inform successful implementation

Submission date
20/10/2021

Recruitment status
No longer recruiting

Registration date
31/01/2022

Overall study status
Completed

Last Edited
11/09/2024

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Tommy's National Centre for Maternity Improvement wants to make it easier for midwives and obstetricians to provide the best possible care, without adding to already busy workloads. With this in mind, they have developed a digital tool that will process data already gathered at antenatal appointments, as well as information directly entered by women themselves, to more accurately assess a woman's risk of preterm birth and of developing pregnancy complications which can lead to preeclampsia, growth restriction of the unborn baby and stillbirth.
Current risk assessments involve a simple checklist and results can be unreliable. The Tommy's Centre Tool will provide healthcare professionals with personalised care recommendations for each woman to ensure she receives the right care at the right time. By raising the standard of antenatal care in all UK regions to the level of the top performing 20%, up to 12,000 preterm births and 600 stillbirths every year could be prevented.

Who can participate?
1. Healthcare professionals/providers providing and/or managing maternity care in participating Trusts.
2. Women booking for maternity care at participating Trusts who have registered for the Clinical Decision Tool and given permission for researchers to contact them following the birth of their baby.

What does the study involve?
This study is evaluating the second phase of the implementation programme, where the tool will be used in four early adopter NHS Trusts. The researchers will identify factors that may help or hinder its successful roll-out in the future. They will assess this through interviews and focus groups with maternity service users and healthcare providers, and through online postnatal questionnaires. They will also use aggregate data collected through the Tool itself to assess

whether it is being used as intended (fidelity) and by women who are representative of the whole maternity population (reach).

What are the possible benefits and risks of participating?
Maternity service user participants:
Participants may not benefit personally from taking part, but they will help the researchers to improve the Tool from the perspective of someone who has used it and experienced the care it recommended. This may lead to improvements that help women in the future. As a thank you for taking part, the researchers are offering all focus group and interview participants a shopping voucher worth £20. Women completing the postnatal questionnaire are offered the opportunity to be entered into a draw for a £100 shopping voucher.
Some interview and focus group participants may find talking about their experiences upsetting. They are reminded that they can choose to not discuss any particular issues, or to stop altogether. The researchers can also provide a resources document, where they will find details about organisations and contact details for further advice and support, and they can help participants to find appropriate support.

Healthcare professional/provider participants:
Participants may not benefit personally from taking part, but they will help the researchers to improve the Tool from the perspective of someone who has used it in practice and/or been involved with its implementation. This may ultimately lead to improvements in the maternity care and outcomes of childbearing women in the future. As a thank you for taking part, the researchers are offering interview and focus group participants a shopping voucher worth £10 and £20 respectively.
The researchers do not anticipate any risks associated with healthcare professionals or providers taking part. However, if they feel uncomfortable, at any time, they can choose not to answer any particular questions, or to stop the interview or leave the focus group altogether.

Where is the study run from?
King's College London (UK)

When is the study starting and how long is it expected to run for?
August 2021 to August 2023

Who is funding the study?
Tommy's Baby Charity (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
294819

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 50128, IRAS 294819

Study information

Scientific Title
Tommy's Clinical Decision Tool Phase II implementation evaluation study

Study objectives
There is no study hypothesis. This is a descriptive study exploring the experiences of maternity services users and providers, investigating barriers and facilitators to implementation that will inform future scale-up. The researchers are testing a theory of change.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 18/10/2021, London - Bromley Research Ethics Committee (Temple Quay House, 2 The Square, Temple Quay, Bristol, BS1 6PN, UK; +44 (0)207 104 8105, +44 (0)207 104 8063; bromley.rec@hra.nhs.uk), ref: 21/PR/1029

Study design
Observational cross-sectional study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Pregnancy complications

Interventions
Current intervention as of 17/10/2022:
This research project, which will run for 23 months, consists of three Work Packages:

1. Work Package 1: Evaluation of healthcare professionals' and providers' (HCPs) experience. This work package consists of an online questionnaire, interviews and focus groups with healthcare professionals/providers (HCPs). It will commence 3 months after implementation of the Clinical Decision Tool, giving a period of time for HCPs to become familiar with it.
1.1. Participants
Healthcare professionals and providers (HCPs) will be invited to participate in an online survey about their views and experiences of the tool. A number of survey respondents will be selected for interview and focus group participation through a process of purposive sampling. This method of sampling has been chosen to ensure that the experiences of a wide range of HCPs, e.g., clinicians with little or much experience, those in management of staff or IT systems, are investigated.

1.2. Sample size

We aim to recruit 50 HCPs at each site (10 from each of the following groups: a) midwives, b) doctors, c) sonographers, d) managers and team leaders and e) information governance andinformation technology specialists. Of these participants, a selection will be invited to interviews and focus groups that will be used to explore views and experiences in more detail. Five HCPs from each hospital site will be interviewed, and 5-8 HCPs will be invited to one of two focus groups per site. In total, there will be 25 HCP interviews, and 10 focus groups of 5-8 HCPs. This number of participants is feasible within the project timeframe and should result in sufficient data to result in meaningful findings.

1.3. Study procedures

HCPs will be identified and approached by local Champions, Research Midwives and by Trust email and invited to contact the research team for further information. A link (and QR code) to the online survey will be made available to HCPs through email and a poster/flyer. Willing respondents will be considered and if selected, they will be emailed a participant information sheet and consent form about the interviews and focus groups. On receipt of a signed (either typed or scanned) consent form, a researcher will contact them to arrange a virtual (e.g., MSTeams or Zoom) or telephone interview and/or invite them to a face-to-face or virtual focus group.

1.4. Data collection

The online survey will be managed through the KCL-approved Qualtrics online survey management system. Interviews will be conducted by telephone or “virtually” via MSTeams or Zoom, at a time convenient to the participant. Focus groups will be conducted face-to-face or virtually. The researcher will conduct the interview and facilitate the focus groups using a topic guide. This guide may change through the course of the study as the data is gathered and analysis develops.

Audio recordings of the interviews and focus groups will be made on an encrypted digital recording device or through the online application, and these will be uploaded to the KCL approved transcription service’s secure server. Transcripts will be produced and downloaded from the server to a secure KCL Microsoft Sharepoint site specific to this study.

1.5. Data analysis

Online questionnaires: Statistical software will be used to explore and analyse the quantitative data gathered through the questionnaires. Participant professional characteristics will be explored using descriptive statistics (i.e., frequencies and percentages) and groups will be compared using Pearson’s Chi-squared tests and multilevel logistic regression models. Differences between groups will be considered statistically significant if the p value is ≤0.05. Qualitative data gathered through free text boxes, (e.g., answers to the question: “Is there anything else you would like to tell us about your experience of using the tool?”) will be analysed using qualitative thematic analysis. Qualitative data will be managed through NVivo qualitative data software and analysed using a thematic framework approach. The Framework approach is a method of qualitative data analysis designed to generate findings that can inform practice and policy and the steps used within this approach lend themselves well to the data likely to be generated in this study. Data analysis will be informed by the NASSS (Non-adoption or Abandonment of technology by individuals and difficulties achieving Scale-up, Spread and Sustainability) framework in addition to inductive analysis (where the researcher is open to new themes emerging from the data). This framework was chosen because it is an evidence-based, theory-informed, and pragmatic framework to help predict and evaluate the success of a technology-supported health or social care program. A proportion of transcripts and identification of themes will be reviewed by another experienced researcher to increase validity. Data reporting and analysis will be guided by reporting standards for implementation research.

2. Work Package 2: Evaluation of women’s experience of using the tool and related care. This work package consists of, online questionnaires, focus groups and face-to-face, telephone or

“virtual” semi-structured interviews which will be used to investigate women’s experience of using the tool and any maternity care that was influenced by its use in risk assessment and care recommendations.

2.1. Participants

All pregnant women choosing to book their maternity care at participating Trusts and who register to use the tool at or before their booking appointment will be eligible. When they first register to use the tool they will see a page of text explaining the study. They will be asked to consider agreeing to their contact details and the expected and actual date of birth of their baby being passed to researchers. All women agreeing to contact by researchers will be texted and/or emailed a link to the participant information sheet and an invitation to complete the online questionnaires.

2.2. Sample size

In this implementation evaluation study, we aim to capture responses from as many women as possible. A sample size calculation is not appropriate. . Based on numbers of births in participating Trusts, with a 20% response rate, we estimate that we will achieve responses from 3,330 women completing the online questionnaires, over 9 months, starting 3 months after the Tool is launched at their site. Of these, 5-8 women will be invited to participate in one of two focus groups per site and 40 women will be purposively sampled and invited for interview.

2.3. Study procedures

Potential participants will be identified either through the Tool or by local Research Midwives. Women may also participate if they respond to a poster or flyer invitation to complete an online questionnaire. Women agreeing to contact from researchers may be telephoned, texted and/or emailed by researchers and will be texted and/or emailed a link to two online questionnaires, the first between 20 and 26 weeks of pregnancy, and another 2-3 weeks after their baby is born. They will be asked to indicate, at the end of the questionnaires, whether they agree to further contact should they be selected for focus group and/or interview. Reminders will be sent on 2 occasions, at 2 and 4 weeks after the first invitation was sent. Women selected for focus groups or interviews will be sent a text or email with information and an invitation to contact us if they are willing to participate. Reminders will be sent on 2 occasions, at 2 and 4 weeks after the first invitation was sent. (Appendix 8.2). In order to minimize potential distress to women who have experienced poor pregnancy outcomes, the message texts and online questionnaires have been sensitively composed and have been approved by our PPI group, some of whom have experienced poor pregnancy outcomes themselves. Participants will be reminded that they do not have to participate if they choose not to, and a link to a resources sheet, with contact details of organisations and charities providing support is provided.

To ensure a wide range of experiences and views are captured during focus groups and interviews, purposive sampling will be used to identify women with different backgrounds, (e.g., ethnicity, parity, social deprivation marker); risk status (low, moderate, high); previous pregnancy outcome (i.e., late miscarriage or stillbirth (n=5), neonatal death (n=5), preterm birth (n=5), other (n=25). Women selected for focus groups or interviews will be emailed links to participant information sheets and a consent form. On receipt of written consent (or verbal consent, if the participant is unable to access the necessary technology, see section 5.1) the researcher will contact them with details about the focus group or to arrange the interview, either face-to-face, by telephone or virtually via MSTeams or Zoom, depending on their preference, at a time convenient for them.

2.4. Data Collection

Focus groups: The focus groups will last around one and a half hours and be carried out either virtually (e.g. MSTeams or Zoom) or face-to-face. A topic guide will be used to guide the discussion and topics will include the participants’ understanding of the rationale for risk assessment and ongoing plan of care, of when, how and why the tool was used to raise concerns and for risk assessment, how information provided through the tool was used by women to inform decisions about their care. Participants will be encouraged to speak about elements of

tool they liked and didn't like or found difficult, and what could be done to improve it. The focus groups will be recorded, either on an encrypted digital recording device or through the online application. Recordings will be uploaded to the KCL-approved transcription service's secure server. Transcripts will be produced and downloaded by the researchers who will store them on a secure KCL Microsoft Sharepoint site specific to this study.

Antenatal and postnatal questionnaires: The antenatal questionnaire will capture views and experiences of the Tool and the care it recommended earlier in pregnancy, i.e. first impressions, and the preterm birth and placental function assessments that are carried out before 16 weeks of pregnancy. This will minimize recall bias caused by passage of time. The postnatal questionnaire will aim to capture views and experiences of using the Tool throughout the woman's pregnancy. If the woman has completed the antenatal questionnaire, she will not be required to complete questions on the earlier assessments again. The first pages of the questionnaires will have brief information about the study and a link to the full participant information sheet. Participants will be asked to confirm they have read this information sheet and are happy to proceed before moving forward with the questions. Participants will be asked questions on their background, risk assessments carried out using the tool, the care it recommended and pregnancy outcomes, as well as their use of the Information Hub and views on the tool itself. The final page of each questionnaire will notify participants that researchers would like to talk to some women in more detail and that if they would like more information and/or would be willing to consider being interviewed or participating in a focus group, they should enter their name and email address in the spaces provided.

Interviews: The semi-structured interviews will last around 1 hour and be organised at a time and place convenient to the participant. An interview schedule will be used to guide the interview and topics will include the participant's understanding of the rationale for risk assessment and ongoing plan of care, of when, how and why the tool was used to raise concerns and for risk assessment, how information provided through the tool was used by women to inform decisions about their care. Participants will be encouraged to speak about elements of tool they liked and didn't like or found difficult, and what could be done to improve it. The interviews will be recorded, either on an encrypted digital recording device or through the online application. Recordings will be uploaded to the KCL approved transcription service's secure server. Transcripts will be produced and downloaded by the researchers who will store them on a secure KCL Microsoft Sharepoint site specific to this study.

Women whose preferred language is not English will be offered the opportunity to answer the survey questions over the telephone and have the interview conducted through an interpreter. This will be organised through a King's College London approved translation and transcription service.

2.5. Data analysis

Online questionnaires: Statistical software will be used to explore and analyse the quantitative data gathered through the questionnaires. Participant demographic characteristics and risk profiles will be explored using descriptive statistics (i.e., frequencies and percentages) and groups will be compared using Pearson's Chi-squared tests and multilevel logistic regression models. Regression models will be adjusted to account for maternal demographic and risk characteristics. Differences between groups will be considered statistically significant if the p value is ≤0.05. Qualitative data gathered through free text boxes, (e.g., answers to the question: "Is there anything else you would like to tell us about your experience of using the tool?") will be analysed using qualitative thematic analysis.

Focus groups and interviews: Data will be managed through NVivo qualitative data software and analysed using a thematic framework approach.

3. Work Package 3: Evaluation of Reach and Fidelity

This part of the implementation evaluation study will explore the reach and fidelity of the implementation. These will be investigated by: a) analysis of data gathered through the tool itself which will be compared with participating Trusts' aggregate maternity statistics; b) analysis

of site registers of participants attending the implementation training activities and c) analysis of elements of the online questionnaires to examine fidelity from the HCPs and women's perspective.

3.1. Sample size

The number of records included in the aggregate data will depend on final numbers of women booking for maternity care and giving birth to their babies at the Trusts participating the Tommy' s Clinical Decision Tool Phase II implementation. Estimated sample sizes (; n=16,653 births) are based on the average number of births as recorded on NHS Digital's National Maternity Dataset between December 2020 and November 2021.

3.2. Data collection

Data collected through the tool will in the long term be hosted in the Cloud Centre for Excellence (Cloud CfE) by NHS Digital. The NHSD Cloud CfE environment will be in place by Autumn 2021. For the interim period between Summer and Autumn the RCOG will host the data in a secure, closed cloud storage in line with NHS Digital security standards before the data is securely migrated to NHS Digital hosting in Autumn. For the purposes of this implementation evaluation study only aggregate (not individual level) data will be transferred to the Tommy's Centre teams based at King's College London and the University of Bristol, under Data Sharing Agreements which will be in place before data is released. Aggregate data on characteristics and outcomes of women receiving maternity care at participating Trusts will be sought by researchers, either from individual Trusts or through NHS Digital's publicly available Maternity Services Data Set (MSDS).

3.3. Data analysis

Participant characteristics and risk status, care recommended and received, and outcomes will be explored using descriptive statistics (i.e., frequencies and percentages) and groups (women registered to use the tool and all women using maternity services) will be compared using Pearson's Chi-squared tests and multilevel logistic regression models. Regression models will be adjusted to account for maternal demographic and risk characteristics. Differences between groups will be considered statistically significant if the p value is ≤0.05. Apparent differences will be explored and described in detail and incorporated into the overall study conclusions and recommendations for future implementation roll-out.

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Previous intervention:

This research project, which will run for 15 months, consists of three Work Packages:

1. Evaluation of healthcare professionals and providers (HCPs) experience of the Clinical Decision Tool
2. Evaluation of women's experience of the Clinical Decision Tool and related care
3. Evaluation of the reach and fidelity of the Clinical Decision Tool using data collected through the tool

Work Package 1: Evaluation of healthcare professionals and providers (HCPs) experience.

This Work Package consists of interviews and focus groups with healthcare professionals /providers (HCPs) working in the four NHS Trusts. It will commence 3 months after implementation of the Clinical Decision Tool, giving a period of time for HCPs to become familiar with it.

HCPs will be identified and approached by Research Midwives and local Champions and by Trust email and will be invited to contact the research team for further information. Their interest in participation will be noted and if selected, they will be emailed a participant information sheet and consent form.

HCP participants will be selected from a pool of willing participants through a process of purposive sampling. This method of sampling has been chosen in order to ensure a wide range of HCPs, e.g. clinicians with little or much experience, those in management of staff or IT systems.

On receipt of a signed (either typed or scanned) consent form, a researcher will contact them to arrange a virtual (online) or telephone interview and/or invite them to a face-to-face or virtual focus group.

Five HCPs from each Trust will be interviewed, and 5-8 HCPs will be invited to one of two focus groups per Trust. In total, there will be 20 HCP interviews, and 8 focus groups of 5-8 HCPs. This number of participants is feasible within the project timeframe and should result in sufficient data to result in meaningful findings.

Interviews will be conducted by telephone or "virtually" via MSTeams or Zoom, at a time convenient to the participant. Focus groups will be conducted face-to-face or online. The researcher will conduct the interview and facilitate the focus groups using a topic guide. Interviews and focus groups will be recorded on an encrypted digital recording device or online application and the recording will be uploaded to the KCL approved transcription service secure server.

Data analysis
Data will be managed through NVivo qualitative data software and analysed using a thematic framework approach. The Framework approach is a method of qualitative data analysis designed to generate findings that can inform practice and policy and the steps used within this approach lend themselves well to the data likely to be generated in this study. Themes will be both deductive (based on the NASSS framework) and inductive (where the researcher is open to new themes emerging from the data). The researcher will use a topic guide, however, this may change through the course of the study as the data is gathered and analysis develops. A proportion of transcripts and identification of themes will be reviewed by another experienced researcher, to increase validity.

Work Package 2: Evaluation of women's experience of using the Clinical Decision Tool and related care.

This Work Package consists of focus groups, a postnatal online questionnaire and one-to-one face to face, telephone or "virtual" semi-structured interviews which will be used to investigate the women's experience of using the Tool and any maternity care that related to its risk assessment and care recommendations.

Participants: All pregnant women choosing to book their maternity care at any of the participating Trusts and who register to use the Clinical Decision Tool at or before their booking appointment. After registering to use the Clinical Decision Tool they will see a page of text explaining the evaluation study. They will be asked to consider agreeing to their contact details and date of birth of their baby being passed to researchers who will email them an invitation to complete an online questionnaire a few weeks after their baby is born.

Potential participants will be identified either through the Tool or by local Research Midwives. Women agreeing to contact will be sent an email with information about the study and a link to an online questionnaire 2-3 weeks following the birth of their baby. In order to minimize potential distress to women who have experienced poor pregnancy outcomes, the email invitation texts and postnatal questionnaire have been designed sensitively and approved by our

PPI group. Participants will be reminded that they do not have to participate if they choose not to, and there will be a link to a support resources page.

Focus groups will be carried out face-to-face or virtually (depending on circumstances e.g. restrictions to travel and in-person meetings). Purposive sampling will be used in the selection of participants to ensure the experiences of women with different backgrounds are explored in more detail, (e.g. age, ethnicity, parity, deprivation marker); risk status (low, moderate, high); outcome (e.g. term birth, late miscarriage, preterm birth or stillbirth). Two focus groups per site will be carried out, over the course of the study, involving up to 64 women.

The first page of the postnatal questionnaire will have brief information about the study and a link to the full participant information sheet. They will be asked to confirm they have read this information sheet and are happy to proceed before moving forward with the questions.

Participants will be asked questions on their background, risk assessments carried out using the tool, the care it recommended and pregnancy outcomes, as well as their use of the Information Hub and views on the tool itself. The final page of the questionnaire will notify participants that researchers would like to talk to some women in more detail and that if they would like more information and/or would be willing to consider being interviewed, they should enter their name and email address in the spaces provided.

Purposive sampling will be used in the selection of interview participants to ensure the experiences of women with different backgrounds are explored in more detail, (e.g. age, ethnicity, parity, deprivation marker); risk status (low, moderate, high); outcome (i.e. late miscarriage or stillbirth (n = 5), neonatal death (n = 5), preterm birth (n = 5), other (n=25). Interviews will be carried out with 40 women in total.

Women selected for focus groups or interviews will be emailed a participant information sheet and consent form appropriate to their age (for under 16-year-olds, an "assent" form plus parent /guardian consent form). On email receipt of a completed assent/consent form (typed or signed and scanned) the researcher will contact them to arrange the interview, either face-to-face, by telephone or online, depending on their preference, at a time convenient for them.

Focus groups and interviews will be guided by an interview schedule or topic guide. Topics will include understanding of rationale for assessment and ongoing plan of care, of when, how and why the tool was used to raise concerns and for risk assessment, how information provided through the tool was used by women to inform decisions about their care. The researchers will also encourage participants to speak about elements of the tool they liked and didn’t like or found difficult, and how it could be improved.

Focus groups will last approximately 1.5 hours, interviews approximately one hour, and will be recorded, either on an encrypted digital recording device or through the online application. Recordings will be uploaded to the KCL approved transcription services secure server. Transcripts will be produced and downloaded by the researchers to a secure KCL Sharepoint site specific to this study.

Women whose first language is not English will be offered the opportunity to have the interview conducted through an interpreter. This will be organised through a KCL approved company that provides interpretation services, whose interpreters are trained in client confidentiality and are compliant with data protection regulations.

Data analysis
Postnatal questionnaires: Appropriate descriptive and inferential statistical methods will be used to explore and analyse the quantitative data gathered through the questionnaires. Qualitative data gathered through free text boxes, (e.g. answers to the question: "Is there anything else you would like to tell us about your experience of using the tool?") will be analysed using NVivo software and qualitative content and thematic analysis.

Women's focus groups and interviews: Data will be managed through NVivo qualitative data software and analysed using a thematic framework approach as described above for Work package 1. The Tommy's Centre Women's Voices PPI group will be asked to contribute to the analysis and interpretation of results.

Work Package 3: Evaluation of Reach and Fidelity of the Clinical Decision Tool

Reach and fidelity will be investigated by analysis of data gathered through the tool itself. This data will be entered through the app by the women themselves and healthcare professionals.

REACH: the researchers will determine whether the tool was used for a representative proportion of the population. This will be done by comparing data collected through the tool with data from all maternity bookings in same period, for example: a) proportions of women who registered to use the tool in each: age group (<16, 16-19, 20-24, 25-29, 30-34, 35-39, 40-44, 45-49, 50+); parity (i.e. whether this is first pregnancy or not); ethnic group; index of multiple deprivation (IMD) centile; b) Proportion of women who registered to use the tool who had: late miscarriage, stillbirth, preterm birth, neonatal death, neonatal unit admission.

FIDELITY: the researchers will determine whether the tool and its implementation worked as intended, for example: a) In what % of women was risk assessment carried out at each assessment time point (initial risk assessments, unscheduled visits, timing of birth) in each: age group/parity/ethnic group/IMD centile? b) What % of women were in each risk category (low /moderate/high)? c) In what % of women in each risk group (low/moderate/high) was risk assessment carried out for a) changes in fetal movements and b) threatened preterm labour? d) What % of women were not eligible for risk assessment (i.e. those with pre-existing diabetes /high blood pressure and/or multiple pregnancies)? e) What proportion of women received aspirin/were referred for extra ultrasound scans/were referred to a preterm birth service when indicated? f) What were the proportions of women who accessed at least one concerns page? g) What proportion of women agreed to contact from the researchers? A site register of training activity participants will also be kept and analysed to explore the uptake of training in different professional groups.

Setting: The Trusts participating in Phase II of the implementation and the related evaluation study are: Ashford & St Peter's NHS Foundation Trust in Chertsey, Surrey, Bolton NHS Foundation Trust, Lewisham & Greenwich NHS Trust and Sheffield Teaching Hospital NHS Foundation Trust.

Data collection: Data collected through the tool will in the long term be hosted in the Cloud Centre for Excellence (Cloud CfE) by NHS Digital. The NHSD Cloud CfE environment will be in place by Autumn 2021. For the interim period between Summer and Autumn the RCOG will host the data in a secure, closed cloud storage in line with NHS Digital security standards before the data is securely migrated to NHS Digital hosting in Autumn. Aggregated data will be released to researchers in accordance with a Data Sharing Agreement which will be in place before data is released. Comparisons will be made between findings using this data and aggregate maternity statistics available from the individual Trusts and/or through NHS Direct.

Data analysis: Participant characteristics and risk status, care recommended and received and outcomes will be explored using descriptive statistics (i.e. frequencies and percentages) and groups (women registered to use the tool and all women using maternity services) will be compared using Pearson's Chi-squared tests and multilevel logistic regression models. Regression models will be adjusted to account for maternal demographic and risk characteristics. Differences between groups will be considered statistically significant if the p-value is ≤0.05. Apparent differences will be explored and described in detail, and researchers from KCL will incorporate the reports generated into the overall study conclusions and recommendations for future implementation roll-out.

Intervention Type
Other

Primary outcome measure
Current primary outcome measures as of 17/10/2022:
Acceptability and useability measured using:
1. Qualitative data from focus groups and interviews with women (two focus groups per site; 10 interviews per site) and healthcare professionals/providers (two focus groups per site; five interviews per site)
2. Tommy's App Healthcare professional, Antenatal and Postnatal Questionnaires, study-specific online questionnaires that includes the mHealth App Usability Questionnaire (MAUQ) for Standalone mHealth Apps .

Timepoints:
HCP focus groups: 3 and 6 months post-Tommy's App launch
HCP questionnaires; from 3 months post-Tommy's App launch
HCP interviews: 3-6 months post-Tommy's App launch
Antenatal questionnaire: from 20 weeks of pregnancy
Postnatal questionnaire: 3-6 weeks post-birth
Women's interviews: from 20 weeks of pregnancy to 6 weeks post-birth
Women's focus groups: from 20 weeks of pregnancy to 6 weeks post-birth

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Previous primary outcome measures:
Acceptability and useability measured using:
1. Qualitative data from focus groups and interviews with women (two focus groups per site; 10 interviews per site) and healthcare professionals/providers (two focus groups per site; five interviews per site)
2. Tommy's App Postnatal Questionnaire, a study-specific postnatal online questionnaire that includes the mHealth App Usability Questionnaire (MAUQ) for Standalone mHealth Apps Used by Patients

Timepoints:
Focus groups: 3 and 6 months post-Tommy's App launch
HCP interviews: 3-6 months post-Tommy's App launch
Postnatal questionnaire: 3-6 weeks post-birth
Women's interviews: 6-12 weeks post-birth

Secondary outcome measures

Current secondary outcome measures as of 17/10/2022:
1. Barriers and facilitators measured using: qualitative data from focus groups, interviews and postnatal questionnaires
2. Reach (whether the Tool is used by, and for risk assessment of, a representative sample of the population of maternity service users) measured using: qualitative data from focus groups and interviews; postnatal questionnaires; exploration of demographic characteristics, risk status, interventions and outcomes, and comparison of aggregate data collected through the Tool with Trust maternity data
3. Fidelity (whether implementation proceeds as expected) measured using: qualitative data from focus groups and interviews; postnatal questionnaires; exploration of demographic characteristics, risk status, interventions and outcomes, and comparison of aggregate data collected through the Tool with Trust maternity data
4. Unexpected consequences measured using: qualitative data from focus groups and interviews; questionnaires, as well as data collected through the App and Trust-wide maternity statistics

Timepoints:
HCP focus groups: 3 and 6 months post-Tommy’s App launch
HCP questionnaires; from 3 months post-Tommy's App launch
HCP interviews: 3-6 months post-Tommy’s App launch
Antenatal questionnaire: from 20 weeks of pregnancy
Postnatal questionnaire: 3-6 weeks post-birth
Women’s interviews: from 20 weeks of pregnancy to 6 weeks post-birth
Women's focus groups: from 20 weeks of pregnancy to 6 weeks post-birth
Women's focus groups: from 20 weeks of pregnancy to 6 weeks post-birth

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Previous secondary outcome measures:
1. Barriers and facilitators measured using: qualitative data from focus groups and interviews; postnatal questionnaires
2. Reach (whether the Tool is used by, and for risk assessment of, a representative sample of the population of maternity service users) measured using: qualitative data from focus groups and interviews; postnatal questionnaires; exploration of demographic characteristics, risk status, interventions and outcomes, and comparison of aggregate data collected through the Tool with Trust maternity data.
3. Fidelity (whether implementation proceeds as expected) measured using: qualitative data from focus groups and interviews; postnatal questionnaires; exploration of demographic characteristics, risk status, interventions and outcomes, and comparison of aggregate data collected through the Tool with Trust maternity data
4. Unexpected consequences measured using: qualitative data from focus groups and interviews; postnatal questionnaires, as well as data collected through the App and Trust-wide maternity statistics

Timepoints:
Focus groups: 3 and 6 months post-Tommy’s App launch
HCP interviews: 3-6 months post-Tommy’s App launch
Postnatal questionnaire: 3-6 weeks post-birth
Women’s interviews: 6-12 weeks post-birth

Overall study start date
01/08/2021

Completion date
31/08/2023

Eligibility

Key inclusion criteria
Current inclusion criteria as of 17/10/2022:
Work Package 1: Healthcare professionals/providers providing and/or managing maternity care in participating Trusts

Work Package 2: Women booking for maternity care at participating Trusts who have:
1. Registered for the Tommy's Clinical Decision Tool
2. Given permission for researchers to contact them
3. Consented to participate in this study.

Work Package 3: Aggregate data from women booking for maternity care at participating Trusts who have registered for the Clinical Decision Tool

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Previous inclusion criteria:
Work Package 1: Healthcare professionals/providers providing and/or managing maternity care in participating Trusts

Work Package 2: Women booking for maternity care at participating Trusts who have:
1. Registered for the Clinical Decision Tool
2. Given permission for researchers to contact them following the birth of their baby

Work Package 3: Aggregate data from women booking for maternity care at participating Trusts who have registered for the Clinical Decision Tool

Participant type(s)
Mixed

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 3580; UK Sample Size: 3580

Total final enrolment
1298

Key exclusion criteria
Current exclusion criteria as of 17/10/2022:
Work Package 1: unwilling to participate in the study

Work Package 2:
1. Women who have not registered to use the tool during this pregnancy
2. Those unwilling to give permission for researchers to contact them.

Work Package 3: women who have indicated their NHS data should not be used for research purposes

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Previous exclusion criteria:
Work Package 1: unwilling to participate in the study
Work Package 2: unwilling to participate in the study
Work Package 3: women who have indicated their NHS data should not be used for research purposes

Date of first enrolment
01/11/2021

Date of final enrolment
31/05/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
St Peters Hospital
Guildford Road
Chertsey
United Kingdom
KT16 0PZ

Study participating centre
The Royal Bolton Hospital
Minerva Road
Farnworth
Bolton
United Kingdom
BL4 0JR

Study participating centre
University Hospital Lewisham
Lewisham High Street

London
United Kingdom
SE13 6LH

Study participating centre
Jessops Wing
Royal Hallamshire Hospital
Glossop Road
Sheffield
United Kingdom
S10 2JF

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

Sponsor information

Organisation
King's College London

Sponsor details
c/o Prof. Reza Razavi
Room 5.31, James Clerk Maxwell Building
57 Waterloo Road
London
United Kingdom
SE1 8WA
+44 (0)207 8483224
reza.razavi@kcl.ac.uk

Sponsor type
University/education

Website
http://www.kcl.ac.uk/index.aspx

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Charity

Funder Name
Tommy's Baby Charity

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Several publications are planned in high-impact peer-reviewed journals within 1 year of the study end date. The researchers do not wish to publish any other study documents at this time.

Intention to publish date
28/02/2025

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		15/08/2022	16/08/2022	Yes	No
HRA research summary			28/06/2023	No	No