Chelsea and Westminster Hospital
NHS Foundation Trust

Short Title/Acronym:

Spoken animation for labour epidural (SAFE)

Ethics Ref: TBC

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Title: Evaluation of spoken animation as a tool for imparting information about epidural labour analgesia

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Sponsor: Chelsea and Westminster Hospital NHS Foundation Trust

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Funder: Joint Research Committee

Chief Investigator Signature:

Confidentiality Statement

This document contains confidential information that must not be disclosed to anyone other than the Sponsor, the Investigator Team, host organisation, and members of the Research Ethics Committee, unless authorised to do so.

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1. SYNOPSIS

Study Title	Evaluation of spoken animation as a tool for imparting information about epidural labour analgesia	
Short Title/Acronym	Spoken animation for labour epidural (SALE)	
Study Design	Prospective, randomised controlled trial with a pre-post design, as well as a qualitative analysis of user acceptability	
Study Participants	Primiparous women presenting for planned induction of labour at The Queen Mary Maternity Unit (QMMU), West Middlesex University Hospital	
Planned Sample Size	60 in control group, 60 in intervention group (120 in total)	
Planned Study Period	6 months	
	Objectives	**Endpoints**
Primary	To evaluate the efficacy of a novel animated information film designed to improve uptake of information regarding labour epidural to expectant people	Change in decisional conflict score regarding choice of epidural analgesia before and after exposure to the animated film, as well as change in subjective anxiety and satisfaction rating.

2. ABBREVIATIONS

CI	Chief Investigator
CRF	Case Report Form
CWFT	Chelsea and Westminster Hospital Foundation Trust
GCP	Good Clinical Practice
GP	General Practitioner
ICF	Informed Consent Form
NHS	National Health Service
NRES	National Research Ethics Service
PI	Principal Investigator
PIS	Participant/ Patient Information Sheet
R&D	NHS Trust R&D Department
REC	Research Ethics Committee
SOP	Standard Operating Procedure

3. BACKGROUND AND RATIONALE

Informed consent for labour epidural at the time of delivery is often challenging, particularly when language and cultural barriers are present. A recent survey of 28 maternity units across Greater London revealed that, many women cannot recall being adequately informed prior to receiving an epidural [1]. With support from CW+ charity, we recently produced a short, animated film titled “An Introduction to Epidural Pain Relief” with the aim of improving basic understanding and enhancing the decision-making process regarding labour analgesia.

Having produced the film, we wish to carry out this research for the following reasons:

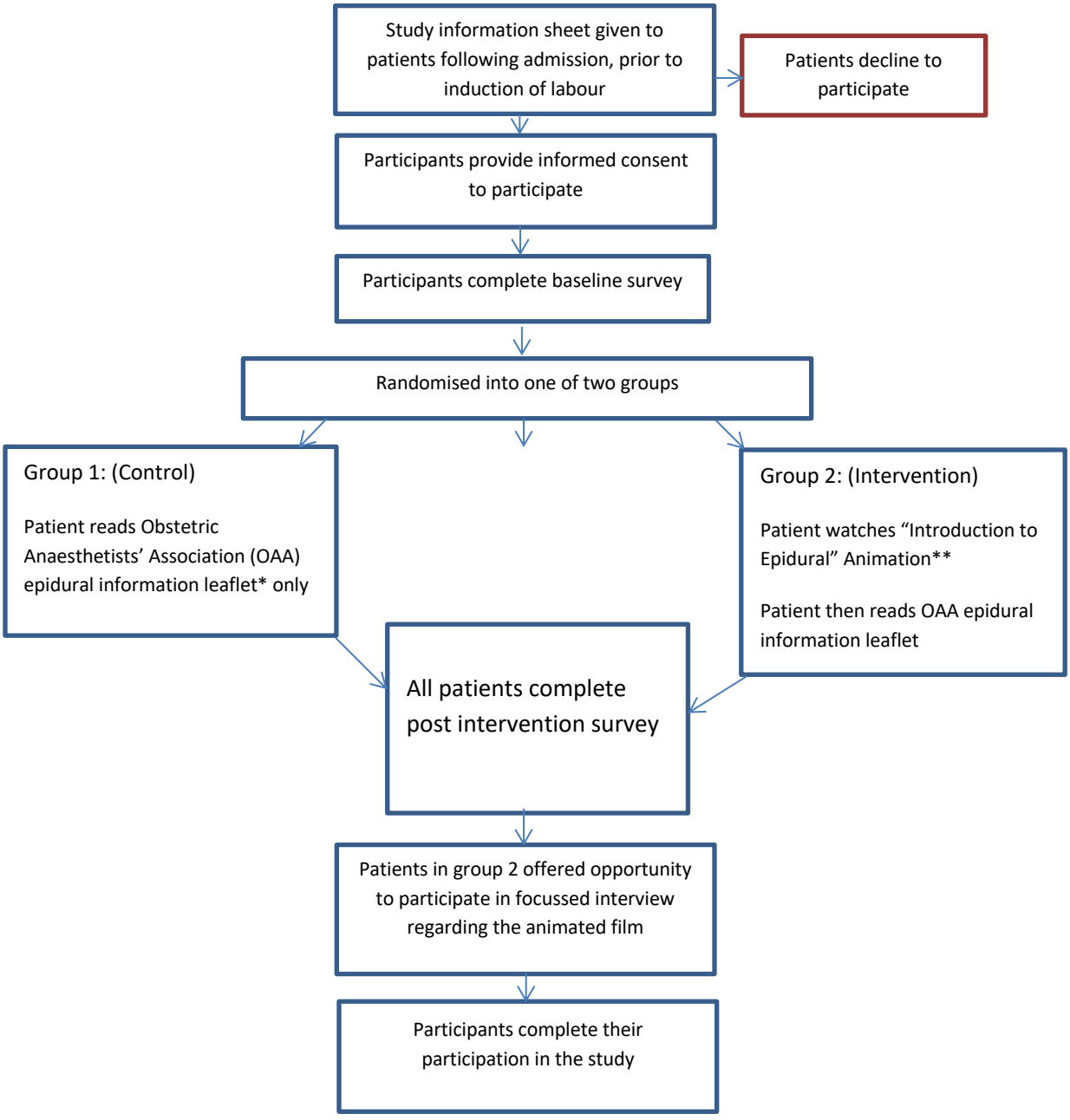
- To justify and inform larger scale research on the impact of spoken animation on uptake of epidural and other outcomes.
- To potentially support uptake of the film more widely throughout NHS maternity services.
- Evaluate efficacy and user acceptance of the animated film within our Maternity Unit.
- To inform any editing or modification to the film that may be necessary.
- To identify any particular benefits in groups of specific demographic, cultural or ethnic characteristics.

4. OBJECTIVES AND OUTCOME MEASURES/ENDPOINTS

Objectives	**Outcome Measures/Endpoints**
Primary Objective	Primary outcome: change in total Decisional Conflict Score (DCS) regarding labour epidural, before and after exposure to information material.
Secondary Objectives	Change in the following DCS subscore categories: uncertainty, informed, values clarity, support, effective decision. Self-reported Likert scale outcomes for understanding of the epidural procedure, associated anxiety and overall satisfaction with information received.
Tertiary Objectives	Focussed qualitative interviews involving a smaller patient group - to assess acceptability and specific feedback for the animated film itself.

5. STUDY DESIGN

Amend as necessary – insert all steps which participants will go through.



* OAA leaflet – validated written information card produced by the Obstetric Anaesthetists' Association

** "Introduction to Epidural Pain Relief" animation produced by our group with support from CW+

6. PARTICIPANT IDENTIFICATION

6.1. Study Participants

Study participants will be identified from booking records for Induction of Labour on the Queen Mary Maternity Unit, West Middlesex Hospital, antenatal ward.

6.2. Inclusion Criteria

- Primiparous birthing people presenting for induction of labour at QMMU

6.3. Exclusion Criteria

The participant may not enter the study if any of the following apply:

- Patient refusal
- Unable to speak English or any of the seven language translations provided
- Epidural contraindicated
- Previous Epidural for any reason
- Any significant health concerns

7. STUDY PROCEDURES

7.1. Recruitment

Potential participants will be identified on the day of admission to the antenatal ward and approached by one of the research team, whom will check their eligibility criteria and explain the study, as well as providing the PIS, before taking informed consent.

7.2. Informed Consent

Participants will personally sign and date the ICF, before any study specific procedures are performed. Written and verbal versions of the PIS and ICF will be presented to the participants detailing the exact nature of the study and what it will involve for the participant. It will be clearly stated that the participant is free to withdraw from the study at any time for any reason without prejudice to future care, and with no obligation to give the reason for withdrawal. A copy of the signed ICF will be given to the participant, and a copy of the signed ICF will be placed in the patient's medical notes. The original signed form will be retained at the study site in the Investigator Site File. The participant will be allowed as long as necessary, but at least prior to commencing induction of labour, to consider the information, and the opportunity to ask questions to decide whether they will participate in the study.

7.3. Potential risks and benefits

No material risk to patient as standard information is being presented in a new animated format, alongside traditional written information.

Those in the intervention group may benefit from clearer and more digestible information regarding the fundamental aspects of labour epidural, in an animated format.

7.4. Screening and Eligibility Assessment

Participants will be asked the eligibility questions prior to obtaining informed consent and complete a checklist for each participant, which will be attached to the consent form in the study folder.

7.5. Randomisation, blinding and code-breaking

Randomisation to the intervention or control group will be carried out with block randomisation using a sealed envelope method. Randomisation will be stratified by ethnicity to ensure an even distribution of ethnic groups.

7.6. Baseline Assessments

Participants will be asked to:

1. Complete the pre-intervention survey

7.7. Subsequent Assessment

2. Watch animation (intervention group only)
3. Read OAA information card
4. Complete post-intervention survey
5. If in intervention group, to be offered the opportunity to participate in short, structured interview about the animation (depending on timing of induction of labour)

7.8. Discontinuation/Withdrawal of Participants from Study

Each participant has the right to withdraw from the study at any time. In addition, the Investigator may discontinue a participant from the study at any time if the Investigator considers it necessary for any reason including:

- Ineligibility (either arising during the study or retrospectively having been overlooked at screening)
- Significant non-compliance with study requirements
- Withdrawal of consent
- Expedition of induction of labour not allowing enough time for participation in study
- Any significant change in clinical circumstances preceding induction of labour that interrupt the study process or may cause distress to the participant, as judged by the Investigators.

If a participant withdraws from the study, data already collected with consent will be retained and used in the study. But no further data will be collected or any other research procedures carried out on or in relation to the participant. The reason for withdrawal will be recorded in the CRF.

7.9. Definition of End of Study

The end of the study will be when the planned number of participants have been recruited and data collected.

8. INTERVENTIONS

The intervention in this study involves the provision of information regarding labour analgesia options, specifically epidural, prior to induction of labour.

Control group: Information provided in the form of the gold standard, validated OAA written information card.

Intervention group: Information provided in the form of novel CW+ "Introduction to epidural pain relief" animation, followed by the OAA written information card.

9. STATISTICS AND ANALYSIS

9.1 Description of Statistical Methods

The primary analysis population will include all eligible participants for whom data is available. Participants will be analysed according to their randomised group assignment irrespective of the intervention they actually received. Every effort will be made to follow up all participants in both arms for research assessments. All type 1 error rates will be fixed at two-sided 5% level. There are no planned interim analyses.

Analyses will be conducted in Stata, and/or R, and/or Python. Descriptive statistics within each randomised group will be presented for baseline DCS score values. These will include counts and percentages for binary and categorical variables, and means and standard deviations, or medians with lower and upper quartiles, for continuous variables, along with minimum and maximum values and counts of missing values. There will be no tests of statistical significance or confidence intervals for differences between randomised groups on any baseline variable.

Pre- and post- test Likert scale data for perceived understanding, anxiety and satisfaction will be visualised using histograms.

Primary and secondary endpoints in treatment period:

Treatment effects on primary and secondary outcomes will be estimated using generalised linear mixed models. Fixed effects will be baseline assessment for the outcome under investigation, randomisation, timepoint (pre- or post- intervention), and timepoint*randomisation group interactions. Participants will be included as random intercepts. Marginal treatment effects will be estimated for outcomes at each time point, and reported separately as adjusted mean differences in scores between the groups with 95% confidence intervals and 2-sided p-values.

The primary outcome is the change in DCS score from pre- to post- intervention, and the difference between the two groups will be estimated from a linear mixed model as described above. For all

continuous secondary outcomes in the treatment period (DCS sub-scores), the same analysis will be employed. The random effect structure of the main analysis will account for repeated measures. Missing data on individual measures will be pro-rated if more than 80-90% of the items are completed; otherwise the measure will be considered as missing.

As soon as the last patient visit has been completed, data will be cleaned and locked.

9.2 Sample Size Determination

Assuming a baseline-endpoint correlation of 0.5 and two-sided type 1 error rate of 0.05, to detect a standardised between group effect size of 0.51 with 80% power requires 60 participants per group (120 in total).

For structured interviews regarding animation content and acceptability, we will aim for 20 participants.

9.3 Analysis Populations

For the primary and secondary analyses, the population will include all eligible participants for whom data is available. Participants will be analysed according to their randomised group assignment irrespective of the intervention they actually received.

10. DATA MANAGEMENT

10.1. Access to Data

Direct access will be granted to authorised representatives from the Sponsor or host institution for monitoring and/or audit of the study to ensure compliance with regulations. The study may be monitored, or audited in accordance with the current approved protocol, ICH GCP, relevant regulations and standard operating procedures.

10.2. Data Recording and Record Keeping

Data will be stored on secure computers at the Queen Mary Maternity Unit, Chelsea & Westminster NHS Trust.

11. ETHICAL AND REGULATORY CONSIDERATIONS

11.1. Declaration of Helsinki

The Investigator will ensure that this study is conducted in accordance with the principles of the Declaration of Helsinki.

11.2. ICH Guidelines for Good Clinical Practice

The Investigator will ensure that this study is conducted in full conformity with relevant regulations and with the ICH Guidelines for Good Clinical Practice.

11.3. Approvals

All relevant documentation will be submitted to the NHS Research Ethics Committee (REC), and host institution R&D departments. The Investigator will submit and, where necessary, obtain approval from the above parties for all substantial amendments to the original approved documents.

11.4. Reporting

An End of Study notification and final report will be submitted to the same parties. Study will be registered to clinicaltrials.gov.

11.5. Participant Confidentiality

The acquired data will be stored on a computer that is password protected. Data will be held in the NHS database of the host institution. Data will be kept for 3 years.

All paperwork will be stored in a locked clinical office within the Department of Anaesthesia of the host institution.

A unique patient/volunteer identification number will be used to prevent identification of subjects involved in the study.

12. FINANCE AND INSURANCE

12.1. Funding

Joint Research Committee, Chelsea & Westminster Hospital NHS Foundation Trust.

12.2. Insurance

Chelsea and Westminster Hospital NHS Foundation Trust has appropriate indemnity arrangements in place.

13. PUBLICATION POLICY

The Investigators will be involved in reviewing drafts of the manuscripts, abstracts, press releases and any other publications arising from the study. Authorship will be determined in accordance with the ICMJE guidelines and other contributors will be acknowledged.

14. REFERENCES

1. Brinkler R, Edwards Z, Abid S, Oliver C, Lo Q, Stewart A, et al. A survey of antenatal and peripartum provision of information on analgesia and anaesthesia. Anaesthesia. 2019;74(9):1101-11.

2. Eley VA, Donovan K, Walters E, Brijball R, Eley DS. The effect of antenatal anaesthetic consultation on maternal decision-making, anxiety level and risk perception in obese pregnant women. International Journal of Obstetric Anesthesia. 2014;23(2):118-24.

3. Kohn MA, Senyak J. Sample Size Calculators [website]. UCSF CTSI. 28 September 2024. Available at https://www.sample-size.net/ [Accessed 30 September 2024]

15. AMENDMENT HISTORY

Amendment No.	Protocol Version No.	Date issued	Author(s) of changes	Details of Changes made