Information about the trial available to women in antenatal clinics and antenatal wards

Woman admitted to maternity unit and meets eligibility criteria

Woman gives written informed consent

Birth imminent
(preparing for caesarean section, or in established labour)

Check woman’s eligibility
- continues to meet eligibility criteria
- oral confirmation of agreement to participate

Woman gives oral assent
- if insufficient time for written informed consent, because the woman is in established labour or having an emergency caesarean section, assent may be oral*

Randomisation

* Women will be approached to give oral assent in established labour or at emergency caesarean section only if the attending clinicians consider it appropriate. Women will not be approached if there is insufficient time to give a brief oral summary of the trial, or they do not speak fluent English and no translator is available. How long will be required for oral assent will depend on factors such as how much the woman already knows about the study, and her knowledge and wishes about care during the third stage. If the woman does not give oral assent she will not be recruited.

If oral assent for recruitment is given:
- women will be approached before discharge from hospital to give written consent to participation in follow-up and access to their data
- Chief Investigator notified within 15 days, and monitoring by Trial Steering Committee