

Training in Ultrasound to Determine gestational Age (TUDA)

Submission date 24/01/2020	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 16/04/2020	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 04/02/2022	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

The study is part of a large programme of work to prevent preterm birth and stillbirth, DIPLOMATIC.

This is an implementation study of a training package for midwives to accurately assess gestational age from ultrasound scan 'in the first 24+6 weeks of pregnancy. Training in Ultrasound to Determine gestational Age (TUDA) forms the initial part of Work Package 5 within the DIPLOMATIC Programme, a National Institute for Health Research funded global health research programme, which aims to identify optimal interventions for the prevention of preterm birth and stillbirth in Malawi and Zambia.

Prevention and treatment of preterm birth requires an accurate assessment of gestational age during pregnancy. This is best achieved through ultrasound scanning (USS) measurements prior to 24 weeks gestation. The World Health Organisation (WHO) endorses the use of one ultrasound scan before 24 weeks gestation for all pregnant women. Such a goal is currently unattainable in many Low and Middle-Income Countries (LMIC) due to lack of availability of trained staff and ultrasound machines.

This pilot study aims to provide an ultrasound training program to enable staff to reach competency in determining the gestational age, the number of fetuses and fetal viability in early pregnancy. The establishment of accurate pregnancy dating by ultrasound scan in the selected settings is in keeping with current WHO recommendations (WHO 2016). We anticipate this information will inform the roll-out of an effective training package in Malawi and potentially also in Zambia

Who can participate?

1. The pilot will involve 8- 12 individual staff trainees per two sites and 3 trainers. Midwives and Clinical officers will be identified through the District nursing officers and District Health officers and those self-motivated and willing to gain ultrasound skills will be asked to write personal statements that would be scrutinized by the study investigators. Eligible participants will be

notified then invited for training.

2. Around 120 (per training site) antenatal women will consent to be scanned by more than one trainee.

What does the study involve?

For trainees, there will be one week of training, using the program designed for the TUDA study, followed by a four-week supervised evaluation of training. During the evaluation, midwives across the two participating health centres will be supervised closely to ascertain how much ongoing support is required to incorporate the scans into their routine pregnancy care. Questionnaires will be used to explore the midwives' views and experience of the training package.

For patients, trainee midwives will use an ultrasound scan to assess how far along in their pregnancy they are.

What are the possible benefits and risks of participating?

No risks are anticipated to either trainees or women participating in this study.

Trainees will learn basic ultrasound skills and in time may be asked to help teach this to other people.

It will be possible to determine accurately how far along in their pregnancy women who participate currently are and this can be helpful if problems develop and the baby needs to be delivered early. Women will also be compensated for their time and travel.

Where is the study run from?

The training of staff and recruitment of women will take place in Malawi Liverpool Wellcome Trust (Malawi) and Mzuzu Central Hospital (Malawi)

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

April 2018 to May 2021

Who is funding the study?

National Institute for Health Research (UK)

Who is the main contact?

Dr. Alex Viner, A.Viner@ed.ac.uk (UK)

Dr. Luis Gadama, lgadama@medcol.mw (Malawi)

Study website

<https://www.ed.ac.uk/centre-reproductive-health/diplomatic/diplomatic-study>

Contact information

Type(s)

Public

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number**ClinicalTrials.gov number**

Nil known

Secondary identifying numbers

Version 2

Study information

Scientific Title

The evaluation and implementation of a training package teaching ultrasound-naive midwives to become competent in establishing number of fetuses, fetal viability and gestational age prior to 24+6 weeks gestation

Acronym

TUDA

Study objectives

To evaluate the optimum methodology and minimum duration of training for ultrasound naive midwives to develop competency in performing scans to establish number of fetuses, fetal viability and determine gestational age under 24+6 weeks gestation

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 22/11/2019, University of Malawi College of Medicine Research and Ethics Committee (COMREC, College of Medicine, P Bag 360, Blantyre), ref: P.06/19/2714

Study design

This is a mixed-methods pilot study

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Hospital

Study type(s)

Other

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Pregnancy

Interventions

8 to 12 health care workers from each of the participating centres will be trained over a period of one week using a bespoke training package designed to teach ultrasound naive midwives to perform ultrasound scans in the first 24 weeks of pregnancy to establish number of fetuses, fetal viability and determine gestational age using either crown-rump length or femur length measurements.

This will include classroom and clinical training. They will go for 4 weeks of mentorship at their respective facilities and their ultrasound competencies will be assessed. Ongoing competency will be based on the review of images and measurements sent from the midwives during the subsequent 4 week supervisory period. Continued support is also offered for a period of up to 6 weeks or longer if required. A small number will be invited to complete an interview about their experience of the training.

240 pregnant women will be recruited and will receive up to 4 fetal ultrasound scans in one day from trainees to determine accurately how far in pregnancy they are.

Intervention Type

Other

Primary outcome measure

Gestation using measurement of either crown-rump length or femur length as compared with the trainers' results, through observation of the trainees' global clinical skills and through ongoing assessment of the trainees' images during the subsequent supervisory phase

Secondary outcome measures

1. To identify the experiential learning requirements which must be met after formal training to facilitate independent practice over a four week period. Trainee competency will be based on the achievement of 5 consecutive measurements that are within 10% of those obtained by the trainers and a global assessment from the trainers as to whether they deem the candidate ready based on observation of their performance. If they are not competent at the end of the week competency will be assessed based on review of their submitted images during the supervisory phase.
2. To evaluate whether femur length measurements alone are adequate to assess fetal gestation in the study population using ultrasound scan assessed by comparing the estimated due date determined by the trainers' 3 femur length measurements to the estimated due date given by the trainers' composite measurements of head circumference, abdominal circumference and femur length
3. To explore the midwives' views and experience of the training package using questionnaires and interviews to discuss their confidence in performing scans independently at the end of the 4 weeks mentorship.

Overall study start date

01/04/2018

Completion date

31/05/2021

Reason abandoned (if study stopped)

The planned follow up period was not possible due to the significant impact of the COVID-19 pandemic

Eligibility

Key inclusion criteria

1. Patients who are:
 - a. Pregnant
 - b. Estimated age ≥ 18 years
 - c. Signed (and witnessed, if applicable) informed consent given
2. Trainees who are:
 - a. Self-motivated midwives registered by the nurses and midwives council of Malawi and Clinical officers registered by the Medical Council of Malawi
 - b. Informed consent given

Participant type(s)

Mixed

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Patients 240, Trainees 25

Total final enrolment

111

Key exclusion criteria

≥ 26 weeks' gestation based on clinical assessment prior to recruitment (note, where the trainer's femur length measurement subsequently suggests that the pregnant woman is more than 24+6 weeks' gestation the data will be discarded)

Date of first enrolment

20/01/2020

Date of final enrolment

31/05/2021

Locations**Countries of recruitment**

Malawi

Study participating centre**Malawi Liverpool Wellcome Trust**

Queen Elizabeth Central Hospital

College of Medicine

PO Box 30096

Chichiri

Blantyre

Malawi

n/a

Study participating centre**Mzuzu Central Hospital**

Private Bag 209

Mzuzu

Malawi

n/a

Sponsor information

Organisation

University of Edinburgh

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Sponsor type

University/education

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ROR

<https://ror.org/01nrxf90>

Funder(s)

Funder type

Government

Funder Name

National Institute for Health Research

Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Results and Publications

Publication and dissemination plan

Research findings will be presented to the Ministry of Health Safe Motherhood technical working Group, the Association of Obstetricians and Gynaecologists of Malawi, regulatory bodies in Malawi, the NIHR global health research group on preterm birth and stillbirth at the University of Edinburgh (the DIPLOMATIC collaboration) and conferences on Maternal and Child Health.

Research findings will also be published in peer-reviewed journals and a copy will be sent to the College of Medicine Research Ethics Committee (COMREC).

Intention to publish date

01/05/2022

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