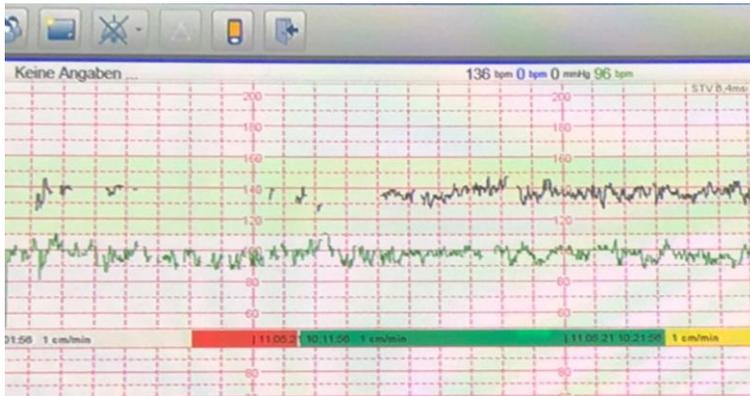


Benefit vs. Risks of Electronic Fetal Monitoring: - thoughts from Clinicians Perspective

LMU Frauenklinik | 14.03.2023 | Teresa Starrach, Uwe Hasbargen, Martin Daumer



One Year ago.....

First experience with fetal home monitoring

Clinical Obstetrics, Gynecology and Reproductive Medicine



Case Report

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Telemedical monitoring of a high-risk pregnancy with placental cyst in times of Corona: A case report

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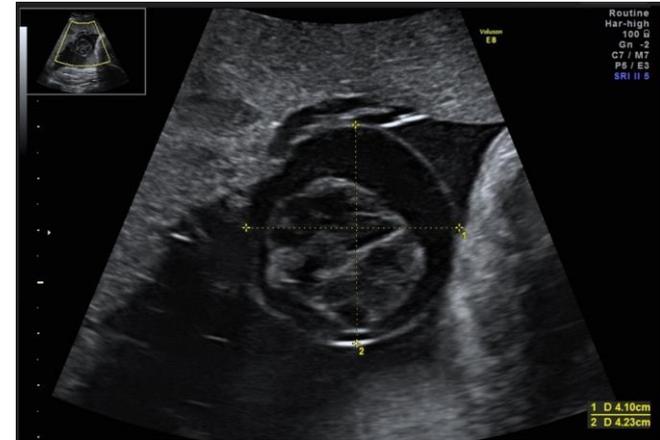
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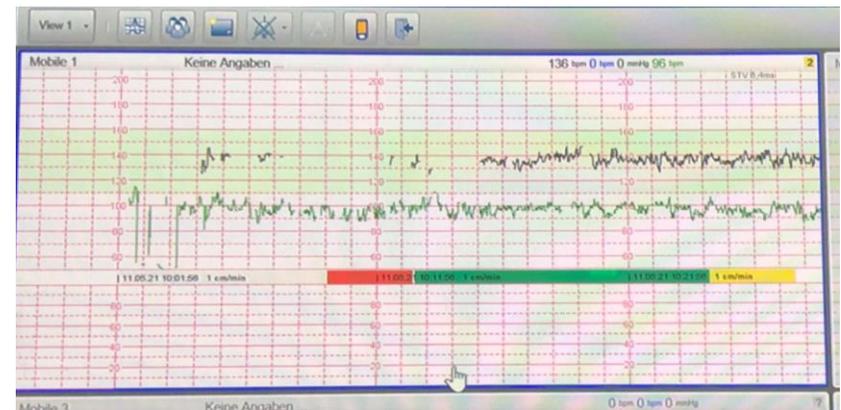
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One year ago.....Planned study

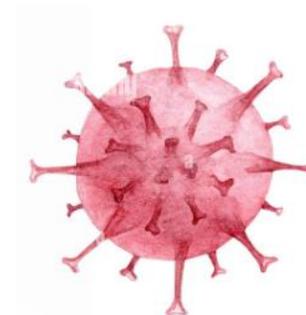
Fetal home monitoring in pregnant women with SARS-CoV-2 infection

Objective

- Close monitoring of pregnant women during and after SARS-Cov-2 infection
- Reduction of clinic visits by infectious patients to protect other pregnant women and clinic staff

Inclusion criteria

- Acute or resolved SARS-CoV2 infection during pregnancy
- $\geq 24+0$ weeks of pregnancy

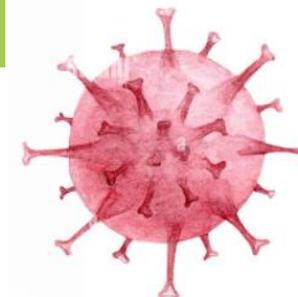


Exclusion criteria

- Twin pregnancy
- High-grade obesity
- Language barrier

Planned study – first idea

Fetal home monitoring in pregnant women with SARS-CoV-2 infection



Objective

- Close monitoring of pregnant women during and after SARS-Cov-2 infection
- Reduction of clinic visits by infectious patients to protect other pregnant women and clinic staff



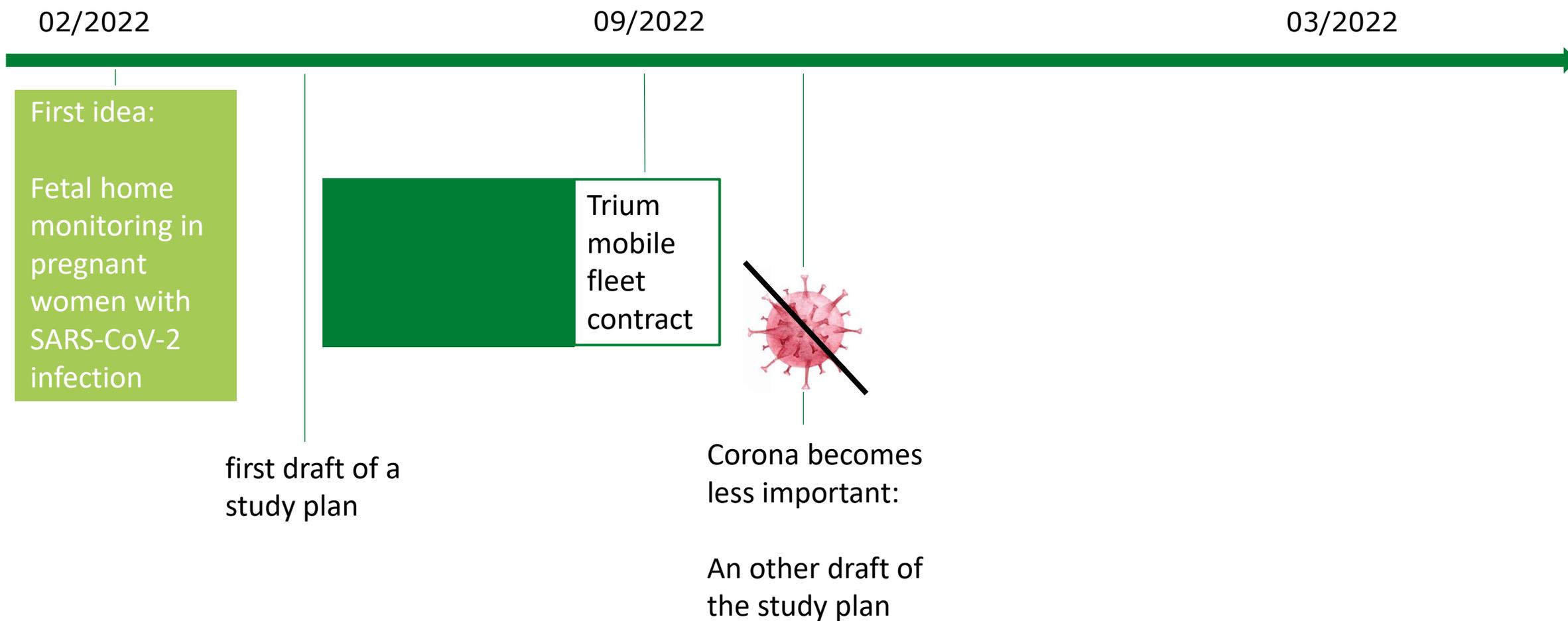
study plan



Trium mobile fleet contract

- How is it ensured that every CTG is seen by clinic staff in real time?
- Who is responsible if the pregnant woman writes a CTG outside the agreed time window?

The long road to starting a study



Second draft of a study plan

Telemedical monitoring of high-risk pregnant women to reduce hospital visits

Increased risks in the 3rd trimester

- Post-term pregnancy
- Maternal age >40
- Hypertension
- Preeclampsia
- Gestational diabetes
- Status after still birth
-

Prevention of premature
delivery/preterm birth

Avoidance of complications
and intrauterine death

Close monitoring

Many clinic or doctor
visits

Telemedical monitoring of high-risk pregnant women to reduce hospital visits

Study Design

Inclusion criterion:

- Need for more closely monitored care than provided by maternity guidelines
- ≥ 18 years
- ≥ 24 weeks of gestation

Exclusion criterion:

- Twin pregnancy
- Language barrier
- Pathological CTG at study inclusion
- Indication for delivery



Randomization into 2 groups:

home-monitoring versus controls in the clinic

Telemedical monitoring of high-risk pregnant women to reduce hospital visits

Project Goals

Primary objective:

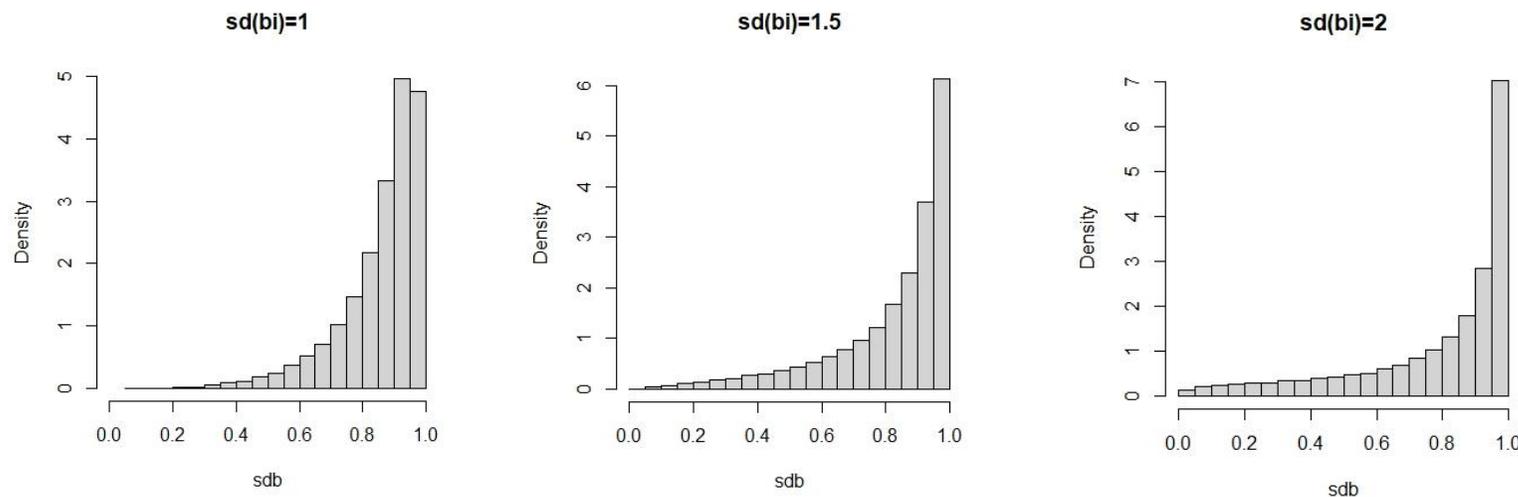
Does pregnancy monitoring at home using Trium mobile fleet have the same quality as controls in the clinic?

Secondary objectives:

- What is the patient satisfaction with telemedical pregnancy monitoring?
- Does telemedical monitoring have a positive effect on the outcome of pregnancy?
- Are CTG datasets applicable to the development and testing of AI or machine learning (ML)-based applications?
- Will there be a reduction in the number of staff required?

Sample size calculation/power analysis

The histograms show the individual probability of whether CTG recording at home is successful.



With $\text{Var}(b_i)=1$ the majority of pregnant women have a success rate > 0.5

With $\text{Var}(b_i)=2$ there are also some who almost never succeed in producing an evaluable CTG.

	Power	Type-1-Fehler
N=74	0.7950	0.0514
N=75	0.8048	0.0510

The long road to starting a study

02/2022

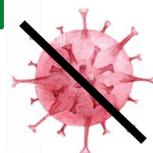
09/2022

03/2022

First idea:
Fetal home monitoring in pregnant women with SARS-CoV-2 infection

first draft of a study plan

Trium mobile fleet contract



Corona becomes less important:

An other draft of the study plan

Second plan:
Telemedical monitoring of high-risk pregnant women to reduce hospital visits

Veto of the data protection commissioner

Agreement on the processing of personal data in the context of commissioned processing according to Article 28 DSGVO

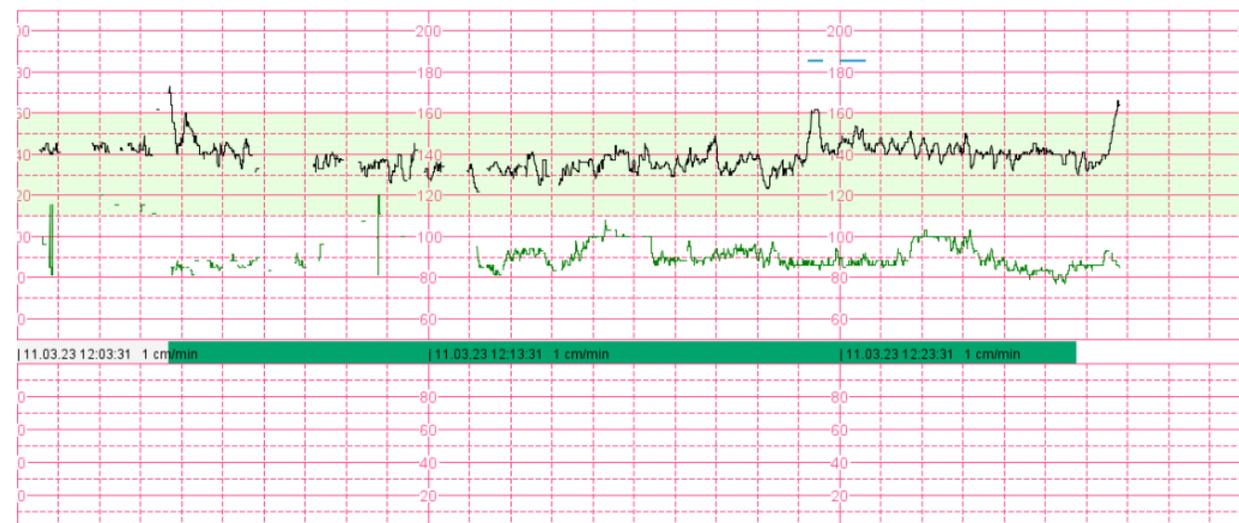
Sampe size calculation

Ethics statement

Start of study

Current case

- 36-year-old pregnant woman
- Premature rupture of membranes at 30+0 weeks of pregnancy
- Antenatal steroid prophylaxis
- Currently 34+6 weeks of pregnancy
- **CTG home monitoring**
- Blood draw at home by patient's husband (physician)
- 1x/week check-up in the clinic with ultrasound and vaginal smear test



Thank you for your attention!

