Fit for Two – Pilot study on physical activity during pregnancy

Fit4Two

Study protocol

Number of the Ethical Approval: BB002/20

AUGUST 10, 2020

1. *Background*

More than two thirds (81.6 %, 87.7%) of German women in childbearing age (18–29, 30-39 don't meet the recommendations of 150 minutes of moderate-intensity physical activity weekly (Krug S et al., 2013). For healthy pregnant women, the guidelines of the American College of Obstetrician and Gynecologists recommend to be physically active of moderate-intensity level at least 150 minutes per week. Despite the known benefits of physical activity**,** studies have shown that the majority of pregnant women do not engage in regular physical activity. Moreover, fewer than 15% of pregnant women achieve the recommended levels of physical activity (Pearce et al, 2013). Therefore, more research is needed aiming to increase pregnant women's physical activity level.

2. *Objectives*

The primary aim of the study is to examine extent and intensity levels of physical activity in different periods (trimesters) of pregnancy. Secondary outcomes are (1) parameters of cardia ultrasound examination (Left ventricular mass index [LVMI], Global longitudinal strain [GLS], Ratio of maximum early and late diastolic flow velocity of mitral valve [E/ A], Deceleration time [DT] and Isovolumetric relaxation time of the left ventricle [IVRT]), (2) Well-beeing, and (3) Strength of the mother-child-bond.

3. *Methods/ Study design*

The study region is Greifswald, a city with approximately 58.000 inhabitants in Northeast of Germany. Fit4two is a prospective study consisting of up to three measurement periods of physical activity via accelerometry, up to three self-administered surveys as well as up to three cardia ultra sound examinations and one follow-up assessment 12 weeks after the (anticipated) delivery. The flow chart of the study design is depicted in figure 1.

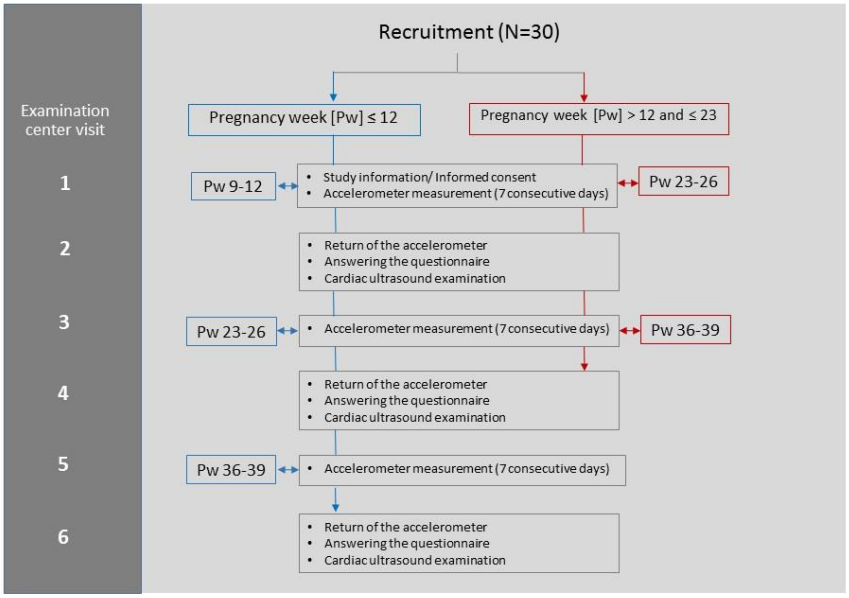

Figure 1 Flow chart

Study population

The study population consists of pregnant women who meet the following inclusion criteria:

1. Current pregnancy ≤ 23 weeks,
2. Sufficient language skills, and
3. No seriously cognitive impairments

Recruitment

Pregnant women will be recruited in the following ways:

1. Advertisement in local newspapers and social media (e.g. facebook)
2. Distribution of leaflets in all gynecological practices of the city
3. Distribution of leaflets in nurseries and public institutions (supermarket, restaurants)

Potential participants contact the study staff by telephone or E-mail. A short telephone screening is performed to assess the inclusion criteria. For women who meet the inclusion criteria, an appointment for the first visit at the examination center of the German Centre for Cardiovascular Research (DZHK) Greifswald is made.

First visit (Trimester 1, week 9-12 or Trimester 2, week 23-26)

- Women are informed (face-to face and by leaflet) about the study. Written informed consent will be obtained. Upon consent, women receive an acclereometer *(ActiGraph GT 3X®, ActiGraph, Pensacola, FL, USA).* The validated three-axis device captures and

records physical activity and sedentary time. Data will be recorded at a sampling frequency of 30 Hz. Participants are instructed to wear the accelerometer during a period of seven days on the right hip at daytime and to remove it for water-based activities (e.g., swimming). The second visit will be scheduled.

Second visit

- The accelerometer will be collected from the participant. Women were asked to fill in a self-administrative paper-pencil questionnaire. Thereafter, a cardiac ultrasound examination will be conducted. Thereafter the third visit will be scheduled.

Third visit (Trimester 2, week 23-26 or Trimester 3, week 36-39)

- Again, women receive an acclereometer. They are instructed to wear the accelerometer during a period of seven days on the right hip at daytime and to remove it for water-based activities (e.g., swimming). An appointment for the fourth visit will be made.

Fourth visit

- The accelerometer will be collected from the participant. Women were asked to fill in a self-administrative paper-pencil questionnaire to assess. Thereafter, a cardiac ultrasound examination will be conducted. The collection of data (acclerometer, questionnaires, cardiac ultrasound examinations) has been completed for women who entered the study in trimester 2. An appointment for the fifth visit will be made with women, who entered the study in the first trimester of their pregnancy.

Fifth visit (Trimester 3, week 36-39)

- Again, women receive the acclereometer. They are instructed to wear the device during a period of seven days on the right hip at daytime and to remove it for water-based activities (e.g., swimming). An appointment for the last visit will be made.

Sixth visit (Trimester 3, week 36-39)

- The accelerometer will be collected from the participant. Women were asked to fill in a self-administrative paper-pencil questionnaire. Thereafter, a cardiac ultrasound examination will be conducted. The collection of data (acclerometer, questionnaire, cardiac ultrasound examination) has been completed now.

Documentation, data storage, and data security

All participants receive a study ID at the first visit in the examination center to ensure their correct assignment over time. Data from the accelerometer, data from the self-administered questionnaire and data from the cardiac ultrasound examination will be stored in a central data base. Personal data (name, address, telephone number) will not be entered in the data base. The data storage is managed according to the standards for data security and data privacy. Only the staff member of the project team have access to personal data during the study.

Data analysis

ActiLife software (version 6.13.2 or later, ActiGraph,Pensacola, FL, USA) will be used for data download and data processing. A valid measurement is defined as a record, of ≥ 10 h wearing time per day, and a record time of ≥ 5 days. In a first step, accelerometer based data (light physical activity, moderate- to vigorous physical activity, and sedentary time) will be descriptively analyzed. Subsequently, associations between patterns of physical activity/ sedentary time and (1) measures from cardia ultrasound examination, (2) well-beeing, and (3) mother-child bond will be analyzed. The software package STATA (version 15.1) will be used.