Date: 04/05/2021

NON-DRUG / NON-INTERVENTIONAL CLINICAL TRIALS'
FOR 'PREGNANT WOMEN'
INFORMED CONSENT FORM-
Version 2

PLEASE READ CAREFULLY !!

You have been invited to participate in a scientific research study, the details of which are given below. Before agreeing to take part in this study, you should fully understand the purpose of the study and make your decision freely after being informed about the study. This information form has been specially prepared for you in order to familiarise you with the study in detail. Please read this form carefully. If there are any points about the research that you do not understand or realise that they are not mentioned in this form, please ask the researcher and ask for clear answers to your questions. You are free to participate in this research or not. Participation in the study is voluntary. After you have been fully informed about the research, the researcher will give you time before you sign the form so that you can freely make your decision and think about it. If you agree to participate in the study, please sign the form.

You have been invited to take part in a study titled 'Effect of Pilates and Kegel exercises during pregnancy on postpartum urinary and fecal incontinence in women.' in which Hitit University Faculty of Medicine, Department of Obstetrics and Gynecology, Assoc. Prof. Dr. Cihan TOĞRUL is the responsible researcher and is planned to be carried out in pregnant women applying to 'pregnancy school'.

'Kegel' in the title means pelvic floor exercise, "faecal incontinence" means faecal incontinence and "urinary incontinence" means urinary incontinence. Psychological changes (anxiety, stress, fear, self-confidence, negative thoughts) that develop due to hormones can be experienced with pregnancy, and the pelvic floor muscles (the muscle that is effective in having a more comfortable pregnancy) caused by mechanical and hormonal changes can be adversely affected by the pregnancy process, and this can cause conditions such as urinary and faecal incontinence in pregnant women. The reason you are invited to this study is that we will enable you to have a more comfortable and healthy birth and postpartum period by having you apply exercises that can minimise or prevent these negative situations. Before deciding whether or not to take part, it is important that you understand why the study is being carried out, how your information will be used, what the study involves and the possible benefits, risks and issues that may cause discomfort. Please take time to read the following information carefully and, if you wish, discuss it with your personal or family doctor.

Do I have to participate in this study?

The decision whether or not to participate in the study is entirely yours. If you decide to participate in the study, you will be given this 'Informed Consent Form' to sign. If you decide to participate, you are free to leave the study at any time. If you wish, your physician/family doctor will be informed about your participation in this study.

Aim of the Study:

The aim of this study was to investigate the effect of Pilates and Kegel exercises on faecal and urinary incontinence in the postpartum period.

Which Institution Reviewed This Study?

This research has been approved by the Hitit University Faculty of Medicine Clinical Research Ethics Committee, which is an organisation responsible for protecting the rights and safety of volunteers participating in research studies, and the Scientific Research Platform of the Ministry of Health. During your participation in this research, you can call Hitit University Faculty of Medicine Clinical Research Ethics Committee at 0 364 2221100/5027.

Duration of your participation in the study:

The exercises to be applied in our research will last for 8 weeks. For 8 weeks, according to your request and the group you have decided and included with the researchers; PEG (Pilates Exercise Group) will have 40 minutes of floor pilates 2 days a week, KEG (Kegel Exercise Group) will have 3 sessions of pelvic floor muscle exercise 4 days a week, and KG (Control Group) will not have any exercise during this 8-week period.

Estimated Number of Volunteers to Take Part in the Study:

66 volunteers will participate in our research.

Exercises to be applied in the research:

The exercises to be applied to you are as follows;

1. Group: PEG (Pilates Exercise Group) floor pilates will be performed 2 days a week for 40 minutes with auxiliary tools (mini ball, pilates circle, pilates tyre).
2. Group: KEG (Kegel Exercise Group) 3 sessions per day 4 days a week (30 repetitions per day for the first 2 weeks-3. Week 60 repetitions per day- Week 4 90 repetitions and last 4 weeks 120 repetitions) pelvic floor muscle exercise will be performed.
3. Group: CG (Control Group) will not perform any exercise during this 8-week period. They will be asked to continue their normal lives.

Pilates exercise is done as follows: It is a type of exercise that can be easily preferred by pregnant women with auxiliary apparatus (mini ball, pilates circle, pilates tyre) on the mat, mostly in supine, side, standing and sitting position, which includes the movements of contracting and relaxing the pelvic (hip) muscles that facilitate birth.

Kegel exercise is done as follows: It includes movements consisting of contraction and relaxation of the pelvic muscle, which plays an important role in facilitating birth. Kegel exercise can be done easily at any time and in any place. These exercises, which have no side effects, can be performed by men as well as women.

Tests to be applied to the researcher:

At the beginning of our study, all groups were asked to fill out a personal information form prepared by the researchers before starting the exercises, in which socio-demographic characteristics such as age, height, body fat percentage, body weight, education level, income level, smoking, alcohol use, sports history, chronic disease and pregnancy characteristics such as number of pregnancies, total number of pregnancies, total number of abortions and number of births were asked. Then, we will start exercises for 8 weeks with those in the exercise group, while those in the control group will not have any exercise in this process. After the exercises are completed, we will wait for your birth to take place in a healthy and problem-free manner. After your birth takes place, we will ask you to fill out forms and scales that determine your 'urinary and faecal' incontinence and determine how much this affects your quality of life at the end of the 1rd month and 3rd month after birth, and we will make an evaluation based on the raw data we will obtain from the scales, we will see the level of effect

of the exercises you do by making a comparison between the groups that exercise and do not exercise.

Risks or Discomforts You Will Be Exposed to in the Study:
In this study, no exercise will be performed that will put the health of the baby or pregnant women at risk. On the contrary, the exercises to be applied will be of a type that will benefit the health of the pregnant woman or a comfortable birth.

What will be the anticipated benefits after the treatment to be applied in the research?
With the exercises performed, it is expected that the pregnant women will have a more comfortable and easy birth by increasing the pelvic floor muscle strength, and it is expected to increase their quality of life by reducing the level of faecal and urinary incontinence in the postpartum period.

Will there be insurance in the research?
No insurance or private insurance contract will be made in our research.

Will I be paid if I take part in this research?
Volunteers who take part in our research will not be paid by us in any name such as travel, food, accommodation or participation fee etc.

What are my responsibilities in this study?
- To participate in the exercises to be performed during the study uninterruptedly and regularly.
- To follow the instructor carefully during the exercise and not to do anything other than what is said/shown.
- To give complete and truthful answers to the data collection forms and scales to be filled in.

In which cases can I be removed from this study by the researchers?
If you do not participate in the tests or exercise programmes to be applied by the principal and co-investigators in our study, you will be removed from the study and you will be informed. In addition, our study only includes pregnant women who will give birth normally, so if it is certain that you will give birth by caesarean section, you can participate in the exercises if you wish, but your data cannot be used in our study.

Can I End My Participation in the Study?
You can leave our study at any time. No payment, penalty, compensation, etc. will be imposed on you for leaving the study. Leaving the study will not affect your normal protocols with your doctor and your pregnancy process in any way.

Will my medical information be kept confidential?
The information we receive from you in our research and your records that will reveal your identity will be kept confidential and will not be disclosed to the public; even if the research results are published, your identity will remain confidential.

Who will see your medical information?
The principal investigator, co-investigator, ethics committee, institution and other relevant health authorities will have direct access to your original medical records, but this information will be kept confidential.

Can I get information about the research?

If you have any questions or concerns about this research, if you have given up participating in the study or if you think that it has caused any health problems, you can contact the Principal Investigator Assoc. Prof. Dr. Cihan TOĞRUL (Tel: 05056826919), the pregnant school education nurse Bengü YEMENİCİ (Tel: 05054871176) or your Sports Instructor Ph. Assist. Sibel YILDIRIM (Tel: 05536330031) at any time. You or your legal representative will be informed by the researchers in a timely manner when new information is obtained that is relevant to the subject of the research and that may affect your willingness to continue participating in the research.

(Participant's Declaration)

I have read all the explanations in the informed consent form regarding this research, stating that a medical research will be conducted by Assoc. Prof. Dr. Cihan TOĞRUL in Hitit University Department of Gynecology and Obstetrics. Written and verbal explanation about the research, the subject and purpose of which are stated above, was made to me by the physician named below.

I am aware that I am participating in the research voluntarily and that I can leave the research at any time, with or without justification. I agree to participate in this research voluntarily, without any pressure or coercion.

A copy of this signed form will be given to me.

Participant
Name, surname:
Address:
Tel:
Signature:
Date:

Physician interviewing the participant

Name, surname, title: Cihan TOĞRUL, Associate Professor
Address: Hitit Unv. Faculty of Medicine, Corum Gynaecology and Obstetrics.
Tel: 0505 682 69 19
Signature
Date:

The researcher who interviewed the participant

Name, surname, title: Sibel YILDIRIM, Research Assistant Doctorant
Address: Hitit Unv. Faculty of Sport Sciences Coaching Education
Tel: 0553 633 00 31
Signature
Date: