

INFORMATION SHEET FOR PARTICIPATION IN A CLINICAL TRIAL AND CONSENT FORM
for an adult patient capable of giving consent personally
Version 1.0 dated 02/16/2026

TITLE: Physical Activity for Women's Health: Effects of a Sensory-Motor Protocol on Body Image and Posture in Women After Pregnancy

Sponsor: University of Rome "Foro Italico"

Coordinating Center: Isola Tiberina – Gemelli Isola Hospital DEPARTMENT/CLINIC/SERVICE:

Obstetrics and Obstetric Pathology Unit PRINCIPAL INVESTIGATOR: Dr. Brigida Carducci

PHONE: 06 6837547/536

Dear Ms.,

The information contained in the following information sheet is very detailed. We ask that you agree to participate in the trial ONLY after carefully reading this sheet and having a THOROUGH DISCUSSION with a member of the research team, who will take the TIME NECESSARY to ensure you fully understand what is being proposed. It is your right to be informed about the purpose and characteristics of the trial so that you can make an informed and voluntary decision about whether to participate. This document is intended to inform you about the nature of the trial, its purpose, and what participation will entail for you, including your rights and responsibilities. We invite you to read the following carefully. The researchers involved in this project, listed at the beginning of this document, are available to answer your questions. No question you may have is trivial: please do not hesitate to ask! In addition to discussing the proposal in this document with us, you may also discuss it with your family doctor, your family members, and other people you trust. Please take all the time you need to decide. You may take home an unsigned copy of this document to think it over or discuss it with others before making a decision.

If you decide not to participate in the trial, you will still receive the best possible care available for patients with your condition.

Your refusal will in no way be interpreted as a lack of trust.

The Principal Investigator

INFORMATION SHEET

Dear Madam,

A study titled ***“Physical Activity for Women’s Health: Effects of a Sensomotor Protocol on Body Image and Posture in Women After Pregnancy”*** is scheduled to ***take place*** at the ***Ospedale Isola Tiberina – Gemelli Isola*** facility.

This is a *national, single-center* study designed to analyze the effect of a 24-week personalized sensorimotor training program combining Pilates, GYROKINESIS®, and Yoga on body image awareness—assessed using the Body Image Scale—and on postural alignment in women during the postpartum period.

To conduct this research, we would like to rely on the cooperation and willingness of people who, like you, meet the scientific criteria for the evaluation that will be carried out. Whether or not you decide to participate in this study will have no impact on the care you receive, and the doctors will continue to treat you with the utmost care.

Before you decide whether to accept or decline participation, however, please read these pages carefully, taking all the time you need, and ask for clarification if anything is unclear or if you need further explanation. Additionally, if you wish, you may consult with your family members or a trusted physician before making your decision.

WHAT THE STUDY AIMS TO ACHIEVE

The study’s overall objective is to analyze the effect of a 24-week personalized sensorimotor training program combining Pilates, GYROKINESIS®, and Yoga on body image awareness—assessed using the Body Image Scale—and on postural alignment in women during the postpartum period.

WHAT THE STUDY INVOLVES

The experimental design of this study involves assigning the women included in the study to one of the **three groups** described below:

- ***SENSOMOTOR training group (SEN*** experimental treatment 1): will follow a specific sensomotor training program based on a combination of Pilates, GYROKINESIS®, and yoga. This is considered the experimental treatment and is the primary focus of the evaluation.
- ***Counter-Resistance Training Group (CR*** experimental treatment 2): will participate in a strength training program, considered a treatment already widely used in clinical practice and postpartum functional rehabilitation.
- ***USUAL CARE group (UC)***: will not follow any structured training program, but will receive usual care guidelines from medical staff. This group

allows us to distinguish the specific effects of the two programs compared to the absence of treatment.

The study is defined **as randomized** because the assignment of participants to one of the three groups (sensory-motor training, counter-resistance training, usual care group) will be done on a random basis.

This means that:

- neither the researcher nor the participant can influence the choice of group;
- random assignment reduces bias related to individual characteristics and ensures greater validity of the results.

The study is **not double-blind**, as the nature of the interventions (physical training programs) makes it impossible to conceal the type of treatment from both participants and staff.

WHAT YOUR PARTICIPATION IN THE STUDY ENTAILS

If you agree to participate in this study, you will undergo an **initial screening visit** to verify that your condition meets the criteria for participation in the study. During this visit, the medical staff at Isola Tiberina Hospital will perform the following procedures:

- **A general obstetric examination** to confirm that the pregnancy is normal and not at risk.
- **Exclusion of any obstetric conditions** that may contraindicate participation (e.g., threatened preterm labor, placenta previa, preeclampsia, uncontrolled gestational diabetes, gestational hypertension, etc.).
- Current and past **medical history**, with particular attention to any concomitant non-obstetric conditions, such as: musculoskeletal disorders, cardiovascular conditions, metabolic disorders.

If you are found eligible to participate in the study, you will undergo further evaluations scheduled for the subsequent phases (T0, T1, T2, T3, T4), as outlined below:

- **T0 - third trimester of pregnancy (baseline assessment)**

During this phase, psychological questionnaires will be administered:

Psychometric questionnaires:

- Body Image Scale (BIS): subjective perception of body image (10 items).
- Edinburgh Postnatal Depression Scale (EPDS): assessment of perinatal depressive symptoms (10 items).
- Perceived Stress Scale (PSS): assessment of subjective perception of stress over the past month (10 items).

- Pittsburgh Sleep Quality Index (PSQI): assessment of sleep quality over the past month (19 items).
- Short Form Health Survey 36 (SF-36): multidimensional assessment of general health.
- International Physical Activity Questionnaire (IPAQ): assessment of physical activity over the past 7 days, converted to MET-min/week.

Postural and functional assessments (at the Laboratory of Exercise and Sports Sciences at the University of Rome "Foro Italico"):

- Non-invasive three-dimensional analysis of the spine and pelvis under static and dynamic conditions using Formetric Spinometry and Moti-Physio.
- Analysis of postural oscillations and balance using the Gyko-Microgate inertial sensor

• **(T1) Baseline – 3 months postpartum (before the start of the project activities)** In

addition to the assessments scheduled for T0, fitness tests will be conducted (at the Laboratory of Exercise and Sports Science at the University of Rome "Foro Italico"):

Strength and functional tests:

- Handgrip Strength Test: assessment of isometric upper limb strength.
- 30-second Sit-to-Stand Test: assessment of lower limb strength, balance, and fall risk.
- Mobility and flexibility tests:
- Sit and Reach Test: assessment of spinal flexibility and the posterior kinetic chain.
- Trunk Rotation Test (with GYKO sensor): assessment of trunk mobility.
- Scratch Test: assessment of glenohumeral and scapulohumeral mobility.

Static and dynamic balance tests:

- Step Test: assessment of dynamic balance on a single leg.
- Single Leg Stance: assessment of static balance on a single leg.
- Y Balance Test: assessment of three-dimensional dynamic balance in three directions.

- **(T2) – Interim assessment 3 months after the start of the project activities** During this phase, all assessments performed at T1 will be repeated to monitor changes in psychophysical and functional conditions.

• **(T3) – Final assessment End of the protocol (after 6 months of project activities)**

All assessments scheduled for T1 and T2 will be repeated to evaluate the final effects of the protocols on participants' physical, mental, and functional conditions at the conclusion of the intervention.

• **(T4) – Follow-up 6 months after the end of the project activities**

All assessments scheduled for T3 will be repeated to monitor the maintenance of benefits in the medium term.

Assessment	Variable assessed	Assessment timing
Body Image Scale	Self-acceptance	T0, T1, T2, T3, T4
Edinburgh Postnatal Depression Scale	Postnatal depressive symptoms	T0, T1, T2, T3, T4
Perceived Stress Scale	Perceived Stress	T0, T1, T2, T3, T4
Pittsburgh Sleep Quality Index (PSQI)	Perceived sleep quality	T0, T1, T2, T3, T4
Short Form Health Survey 36 (SF-36)	Perceived physical, mental, and general health	T0, T1, T2, T3, T4
IPAQ	PA level	T0, T1, T2, T3, T4
<i>Physical Functioning Assessment</i>		
Formetric Spinometry Moti-Physio	Body Posture	T0, T1, T2, T3, T4
Gyko Insertion Sensor	Postural alignment	T0, T1, T2, T3, T4
Trunk Rotation, Scratch Test, and Sit and Reach	Range of motion and flexibility	T0, T1, T2, T3
Y-Balance Test, Single-Leg Stance Test, and Step Test	Balance (static and dynamic) and postural sway (using an inertial sensor)	T0, T1, T2, T3
Handgrip Strength Test and Biceps Isometric Strength	Overall muscle power	T0, T1, T2, T3
30-second Sit-to-Stand Test	Indirect lower limb strength and power	T0, T1, T2, T3

Table 1: Assessments and Timing

The collaboration requested of you involves a commitment to follow all instructions and planned procedures to ensure the validity of the results and your safety. Specifically, the tasks required during the trial include:

- **Participation in the scheduled assessments at the specified times:**
 - T0 (last trimester of pregnancy): clinical clinic visit, interview, medical history interview, administration of questionnaires, and postural/functional assessments;
 - T1 (3 months postpartum, before the start of the intervention): repetition of all T0 assessments, as well as fitness tests;
 - T2 (3 months after the start of the protocol): interim reassessment to monitor longitudinal changes;
 - T3 (end of protocol, 24 weeks): complete repetition of previous assessments to measure the effects of the intervention;
 - T4 (6 months after the end of the protocol): further reassessment to analyze the maintenance of results.
- **Adherence to the intervention program**

Participation in at least **75% of the scheduled sessions** is required (at least 36 out of 48 sessions). Assignment may fall into one of the three intervention groups:

 1. *Sensomotor training group*: Pilates, GYROKINESIS®, and Yoga exercises;
 2. *Strength/Endurance Training Group*: exercises designed to improve muscle strength and endurance;
 3. *Usual Care Group*: general advice on maintaining a healthy and active lifestyle.

Groups 1 and 2 **meet twice a week for sessions** of about one hour each, divided as follows:

- One **in-person session** at the gym of the University of Rome "Foro Italico";
- One **online session** via a dedicated platform.

The activities will be led by kinesiologists specializing in Preventive and Adapted Physical Activity, who will ensure the adaptability and safety of the interventions.

- **Completion of questionnaires and participation in tests**

The form must be completed in full and in accordance with the instructions provided, avoiding omissions or unauthorized changes.

- **Required conduct during the study:**
 - Avoid intense physical activity or unauthorized sports;
 - Do not take any medications, supplements, or substances not authorized by the research team;

- Limit consumption of alcohol or foods/beverages that may interfere with your health or the required assessments.

Importance of cooperation

All required activities and precautions are primarily intended to safeguard your health. Failure to follow instructions or comply with established procedures could compromise the safety, quality, and validity of the study results, rendering the scientific significance of your participation null and void.

Total duration of participation

Each participant's involvement will last approximately 18 months, broken down as follows:

1. Baseline assessments during pregnancy (T0)

- Third trimester of pregnancy: clinical examination, medical history interview, administration of questionnaires, and postural and functional assessments.

2. Pre-intervention assessments (T1)

- 3 months postpartum, before the start of the protocol: repetition of all T0 assessments, with the addition of strength, mobility, and balance tests.

3. Intervention

- Duration: 24 weeks (6 months).
- Frequency: two weekly sessions, one in-person at the gym of the University of Rome "Foro Italico" and one online via a dedicated platform.
- Groups: sensorimotor training (Pilates, GYROKINESIS®, Yoga), strength/endurance training, or control group.

4. Assessments during the procedure (T2)

- Three months after the start of the protocol: complete repetition of the previous assessments to monitor longitudinal changes.

5. Post-intervention assessments (T3)

- At the end of 24 weeks: repetition of all T1 and T2 assessments to measure the effects of the training programs.

6. Follow-up (T4)

- 6 months after the end of the protocol: repetition of all assessments to analyze the maintenance of results in the medium term.

A total of 45 subjects will participate in this study.

Upon completion of recruitment and the experimental phase, the research group will conduct data analysis and interpretation in the following year.

Participation in the study will not incur any additional costs for you, nor will it provide any compensation.

WHAT ARE THE RISKS ASSOCIATED WITH PARTICIPATING IN THE STUDY?

All functional/psychological assessments and training sessions have been designed and/or planned to minimize risks or discomfort associated with the protocol, which in any case does not pose any direct health risks.

WHAT BENEFITS CAN YOU EXPECT FROM PARTICIPATING IN THE STUDY?

Participation in this study is expected to yield the following benefits: improved body awareness, better posture, and increased strength and stability—aspects that are often compromised in the postpartum period.

Regular physical activity, performed in a guided and safe manner, can also help reduce musculoskeletal pain, improve balance and motor control, and, more generally, lead to a faster and more effective recovery of daily functional abilities.

A benefit to psychological well-being is also anticipated: consistent practice can reduce stress, anxiety, and distress related to postpartum physical changes, promoting better emotional adjustment and a higher quality of life.

Finally, participation in the study could help women develop more active and mindful movement habits, which are also beneficial in the long term for health and the prevention of future disorders.

STUDY RESULTS AND CONFIDENTIALITY OF COLLECTED INFORMATION

All your data will be pseudonymized, meaning you will be assigned a code that cannot be directly traced back to you, and it will be recorded in electronic format. This code will not allow you to be identified outside the medical treatment center.

With regard to the processing of personal data, please refer to the specific privacy notice regarding consent to the processing of personal data, which will be provided to you at the same time on a separate sheet.

WHAT HAPPENS IF YOU DECIDE NOT TO PARTICIPATE IN THE STUDY—POSSIBLE ALTERNATIVE TREATMENTS.

You are free to choose not to participate in the study. In this case, you will continue to receive all standard therapies and treatments for your condition without any penalty, and the doctors will continue to monitor you with the appropriate level of care.

WHAT HAPPENS IN THE EVENT OF HARM

We inform you that insurance coverage is in place to cover any personal injury resulting from the trial, in accordance with the provisions of the Ministerial Decree of the Ministry of Health dated July 14, 2009, Official Gazette

No. 213 of September 14, 2009. Specifically, this study is insured with *UnipolSai (General Liability)*: Policy No. 191924013, and this insurance coverage provides a maximum liability limit of 5,000,000.00 euros per patient, with a limit of 5,000,000.00 euros per protocol.

The policy applies exclusively to damages that have manifested no later than 1 month after the end of the trial and for which a claim for compensation has been filed within 1 month of the trial's conclusion.

Exceeding the aforementioned limits and the aforementioned restrictions do not, however, affect your right to seek compensation directly from the party responsible for the damage. By signing this informed consent form, you are not waiving any of your legal rights.

Before participating in this trial, if you have a private insurance policy, you should check with your insurer to ensure that your participation will not affect your coverage.

WITHDRAWAL FROM THE STUDY

Your participation in this research program is entirely voluntary, and you may withdraw from the study at any time by notifying the Investigator. In this case, the data collected up to the time of withdrawal will be included in the results in an aggregated and anonymous form for the final analysis.

Similarly, the trial may be discontinued if:

1. the physician does not observe any benefit, or if adverse effects occur, or for other reasons;
2. if new information becomes available and participation in the trial is no longer in your best interest;
3. you do not follow the agreed-upon rules for participating in the trial;
4. the trial is discontinued by the regulatory authorities or the sponsor.

INFORMATION ABOUT THE STUDY RESULTS

If you request it, at the end of the study you may be informed of the study results in general and, specifically, those that pertain to you.

FURTHER INFORMATION

For further information and updates during the study, you may contact the following staff: Sponsor, University of Rome "Foro Italico"

Elisa Grazioli: elisa.grazioli@uniroma4.it , 0636733532

Department of Obstetrics and Obstetric Pathology - Isola Tiberina – Gemelli Isola

Hospital Dr. Brigida Carducci: brigida.carducci@fbf-isola.it , 066837547/536

The protocol for the study that has been proposed to you has been reviewed and approved by the Lazio Area 3 Regional Ethics Committee (CET). Among other things, the CET has verified that the study complies with the Guidelines for Good Clinical Practice and the ethical principles set forth in the Declaration of Helsinki, and that your safety, rights, and well-being have been protected.

If you feel it is appropriate to report events or facts related to the study you have joined to individuals not directly involved in the study itself, you may contact the CET that approved the study: CET Lazio Area 3 email address: comitatoetico.lazioarea3@policlinicogemelli.it

WHO IS ORGANIZING AND SPONSORING THIS STUDY?

The study is sponsored by the University of Rome "Foro Italico."

We thank you for your attention and the time you have dedicated to reading and discussing this document.

If you decide to participate in the study, you will be given a copy of this Information Sheet and a signed Consent Form to keep.

CONSENT FORM

I DECLARE

- ☐ that I have received from Dr. _____ exhaustive explanations regarding the request to participate in the research in question, as described in the information section of which I was given a copy earlier, which is part of this consent, and of which I was given a copy on _____
- ☐ that the nature, purposes, procedures, expected benefits, possible risks and drawbacks, and alternative treatment options to the proposed clinical trial have been clearly explained to me and I have understood them;
- ☐ that I have had the opportunity to ask the study investigator any questions and have received satisfactory answers;
- ☐ that I have had sufficient time to reflect on the information received;
- ☐ that I had sufficient time to discuss this with third parties;
- ☐ that I have been informed that the trial protocol and all forms used have been approved by the competent Ethics Committee;
- ☐ that I am aware the study may be discontinued at any time;
- ☐ that I have been informed that I will be notified of any new information that could compromise the safety of the research and that, for any problems or further questions, I may contact the principal investigator or his/her staff;
- ☐ that, for the best protection of my health, I am aware of the importance of informing my primary care physician about the trial in which I agree to participate.
- ☐ I am aware of the importance of providing the investigator with all relevant information (medications, side effects, etc.) concerning me;
- ☐ that I have been informed that the results of the study will be disclosed to the scientific community, while protecting my identity in accordance with current privacy regulations;
- ☐ that I am aware that any choice expressed in this consent form may be revoked at any time and without any justification;

☐ that I have received a copy of this consent form.

Place and date _____

Patient's First Name Last Name (in block letters)

Patient's Signature

If the patient is unable to read or sign, a witness independent of the investigator and the sponsor must be present throughout the entire informed consent discussion. The witness must personally sign and date the informed consent form after the form itself and any other written information have been read and explained to the subject and the subject has given verbal consent to participate in the study.

In this case:

I Signed hereby certify that the Dr.
.....has thoroughly explained to Ms.
.....

the characteristics of the experimental study in question, as described in the attached information sheet, and that the participant, having had the opportunity to ask all the questions they deemed necessary, freely agreed to participate in the study.

Date..... Signature of the independent witness

Date..... Signature of the physician who provided the information to the patient
.....

STATEMENT BY THE PHYSICIAN WHO OBTAINED CONSENT

I, the undersigned (FIRST NAME-

LAST NAME), in my capacity as

- ☐ Principal Investigator
- ☐ Delegate of the Principal Investigator

DECLARE

that the patient has voluntarily consented to participate in the trial

I further declare that:

- ☐ have provided the Patient with comprehensive explanations regarding the purpose of the trial, the procedures, the possible risks and benefits, and the available alternatives;
- ☐ have verified that the Patient has sufficiently understood the information provided to him/her;
- ☐ having given the Patient the necessary time and opportunity to ask questions regarding the trial;
- ☐ having clearly explained the possibility of withdrawing from the trial at any time or of changing the choices made;
- ☐ not to have used any coercion or undue influence in requesting this consent;
- ☐ to have provided the patient with information on how the results of the trial will be communicated to him or her.

Place and date _____

First Name Last Name (in block letters) of the physician who provided the information and obtained consent

Signature (and stamp)

This form is an integral part of the informed consent form and must be kept together with it