# REQUEST FOR PARTICIPATION IN A RESEARCH PROJECT

## Effects of Physical Activity on Glucose Metabolism and Related Metabolic Signatures in South Asian and Nordic Women with Previous Gestational Diabetes (DIASA-Ex)

This is an invitation for you to participate in a research project called **DIASA-Ex**, which aims to investigate the effects of physical activity on risk factors for type 2 diabetes. The project includes **four group-based training sessions per week for 8 weeks** at the **Norwegian School of Sport Sciences**, led by qualified instructors.

You will receive scientifically proven effective training, including both **endurance training** (activities that improve heart and lung function, such as running or cycling) and **strength training** (activities that increase muscle strength, such as weight training or body-weight exercises). The combination of these training modalities is considered the most effective approach to reducing the risk of type 2 diabetes.

You are receiving this information because you previously participated in **DIASA-1** and consented to being contacted again. You are invited because you have a background from a **South Asian country** (Pakistan, India, Bangladesh, Sri Lanka) or a **Nordic country** (Norway, Sweden, Denmark, Finland, Iceland), and because you have previously had **gestational diabetes**.

Gestational diabetes can be considered a form of **prediabetes**, meaning a condition in which glucose regulation is impaired but not sufficient for a diagnosis of type 2 diabetes. This condition carries an increased risk of developing type 2 diabetes later in life. The aim of this study is to examine whether this risk can be reduced through physical activity.

A total of **40 participants** will be included in DIASA-Ex. **Oslo University Hospital** is responsible for the study.

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## FINDINGS FROM PREVIOUS DIASA STUDIES

Previous DIASA studies have revealed signs of increased **insulin resistance** (a condition in which the body's cells respond poorly to insulin, a hormone that facilitates glucose uptake from the blood into cells) after gestational diabetes. Increased insulin resistance is a major risk factor for type 2 diabetes.

Insulin resistance was found to be more pronounced in South Asian women compared with Nordic women. In particular, adipose tissue showed increased insulin resistance, leading to accumulation of fat in the liver, which is a known risk factor for type 2 diabetes. Imaging studies also showed that South Asian women had slightly lower muscle mass and higher fat mass compared with Nordic women.

However, insulin resistance can be reduced, muscle mass increased, and fat mass decreased through physical activity, thereby reducing the risk of type 2 diabetes. Therefore, you are invited to participate in **DIASA-Ex**, an **8-week exercise intervention** involving group training together with other women who previously participated in DIASA-1.

You will also receive information about your health status before and after the intervention to assess health improvements.

## WHAT DOES PARTICIPATION INVOLVE?

DIASA-Ex includes comprehensive assessments of glucose and lipid metabolism, including **oral glucose tolerance testing**, **continuous glucose monitoring before and after the intervention**, **indirect calorimetry**, **strength and endurance testing**, and **imaging of fat and muscle tissue** (e.g., liver, pancreas, and abdominal fat) using **DXA, CT, MRI, and bioimpedance**.

To better understand how physical activity reduces the risk of type 2 diabetes, we will also study processes at the cellular level. Therefore, multiple **blood samples**, **urine samples**, and **tissue samples** from abdominal subcutaneous fat and thigh muscle will be collected at the beginning and end of the intervention. These procedures are safe and provide valuable scientific information.

After baseline examinations, the **8-week training intervention** will begin. All examinations will then be repeated to assess changes following the intervention. You will be contacted by telephone **two weeks after the final examination** to ensure your well-being.

Throughout the project, you will receive explanations of your results and how your health was affected by the training.

## POTENTIAL BENEFITS AND DISADVANTAGES

### Benefits

Participation provides a thorough assessment of physical fitness, body composition, and glucose and lipid metabolism. You will receive supervised training over 8 weeks. Knowledge gained may help prevent or delay diabetes development in women with previous gestational diabetes.

Training is **free of charge**, and **public transport travel expenses** related to training and testing may be reimbursed. Lost income is not reimbursed unless otherwise agreed.

You will receive **gift cards/reimbursement** for each test day. There are **six test days** in total (clinical testing ×2, oral glucose tolerance tests ×2, tissue sampling ×2). Two are full-day visits and four are half-day visits. Total compensation is **NOK 3,100**, in addition to travel reimbursement. If childcare is required for children not attending kindergarten, compensation of **NOK 500 per test day** may be provided.

### Disadvantages

Participation requires time commitment. Some procedures may cause temporary discomfort, including blood sampling, glucose ingestion, imaging procedures, and local anesthesia prior to tissue sampling. Mild pain, bruising, bleeding, or fluid leakage may occur. These

procedures are generally safe and complications are rare. Any concerns should be reported to the study physician.

## DATA PROTECTION AND STORAGE

All data and samples will be used solely for research purposes described in this study. Information will be processed without names or personal identification numbers. A coded key linking your identity to the data is stored securely and accessible only to authorized study personnel.

Biological material will be destroyed at project completion. Data will be stored for a mandatory **5-year documentation period**. The project is planned to end on **31 January 2033**. In accordance with REK approval, personal data will be stored until **31 January 2038**, after which they will be anonymized or deleted.

## VOLUNTARY PARTICIPATION AND RIGHT TO WITHDRAW

Participation is voluntary. You may withdraw at any time without providing a reason and without consequences for your healthcare. If you withdraw, you may request deletion of collected data and samples unless they have already been included in analyses or publications.

For questions, contact the project leader and study physician:

**Dr. Sindre Lee-Ødegård**
Phone: +47 958 60 506
Email: sindre.lee@medisin.uio.no

# CONSENT TO PARTICIPATE IN THE STUDY

I have received written and oral information about the study and have had the opportunity to ask questions. I understand that participation is voluntary and that I may withdraw at any time.

I consent to participate in the research project **DIASA-Ex**.

## Participant Consent

**Place and date:**

**Participant's signature:**

**Participant's name (printed in capital letters):**

### Confirmation by Study Personnel

I confirm that I have provided information about the project to the participant.

**Place and date:**

**Signature:**

**Role in the project:**

## SUPPLEMENTARY CONSENT FOR 1-YEAR FOLLOW-UP

You have previously participated in the DIASA-Ex study. We now invite you to a **single follow-up examination approximately 12 months after completion of the training program**, to assess whether the effects of the intervention are sustained.

### What does this involve?

• One follow-up day with simplified testing, including:
– Shortened oral glucose tolerance test (2 hours, no tracers)
– Bioimpedance body composition analysis
– Weight, waist and hip circumference
– Blood pressure
– Blood samples only (5 sets)
– New period with continuous glucose monitoring (CGM)
– Questionnaires on diet and physical activity (IPAQ and PYTPAQ)

You will receive your results explained in your preferred language. Compensation will be provided for time spent.

Participation in this follow-up is voluntary and can be declined without consequences.

## Consent to 1-Year Follow-Up

I consent to be contacted and to participate in the 1-year follow-up examination described above.

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## Participant Consent (Follow-Up)

**Place and date:**

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**Participant's signature:**

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**Participant's name (printed in capital letters):**

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## Confirmation by Study Personnel

I confirm that I have provided information about the follow-up study to the participant.

**Place and date:**

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**Signature:**

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**Role in the project:**

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