BMJ Open

Effect of a specific exercise programme during pregnancy on diastasis recti abdominis: study protocol for a randomised controlled trial

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To cite: Theodorsen N-M, Fersum KV, Moe-Nilssen R, *et al*. Effect of a specific exercise programme during pregnancy on diastasis recti abdominis: study protocol for a randomised controlled trial. *BMJ Open* 2022;**12**:e056558. doi:10.1136/bmjopen-2021-056558

► Prepublication history for this paper is available online. To view these files, please visit the journal online (http://dx.doi.org/10.1136/bmjopen-2021-056558).

Received 20 August 2021
Accepted 22 December 2021

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ABSTRACT

Introduction Diastasis recti abdominis (DRA) is a common condition in pregnant and postpartum women. Evidence for the treatment of DRA is both sparse and weak. As this condition occurs during the last two trimesters of pregnancy and there is a paucity of high-quality studies on a pregnant population, we will conduct a randomised trial on the effect of a specific exercise programme during pregnancy on DRA.

Methods and analysis This is an exploratory, assessor-blinded, randomised parallel group trial carried out in a primary healthcare setting in a Norwegian city. 100 pregnant women, both primigravida and multigravida, in gestation week 24 presenting with DRA of ≥28 mm will be included. Participants will be allocated to either an intervention group or a control group by block randomisation. The intervention group will participate in a 12-week specific exercise programme. The control group will not participate in any exercise intervention. Data collection will take place prior to intervention, postintervention at gestation week 37, and 6 weeks, 6 and 12 months postpartum. The primary outcome measure will be change in the inter-recti distance, measured by two-dimensional ultrasonography. Data will be analysed and presented in accordance with international Consolidated Standards of Reporting Trials guidelines and analysed according to the intention-to-treat principle.

Ethics and dissemination Ethical approval has been obtained by the regional ethical committee (76296), and all procedures will be performed in adherence to the Helsinki declaration. The study has been registered with ClinicalTrials.gov. Results from this study will be presented at scientific conferences and in peer-reviewed scientific journals.

Trial registration number NCT04960800; Pre-results.

Strengths and limitations of this study

- This will be the first randomised controlled trial to investigate the effect of a specific exercise programme on diastasis recti abdominis during pregnancy.
- Methodological qualities include assessor blinding, randomisation, concealed allocation, and controlled, parallel group trial.
- All measurements will be done using ultrasonography.
- Blinding of the participants and the instructor is not possible.

INTRODUCTION

The linea alba is the connective tissue connecting the two muscle bulks of the recti abdominis muscle. The distance between these two muscle bulks is referred to as the inter-recti distance (IRD).[1] Pregnancy-related diastasis recti abdominis (DRA) is defined as the widening of the linea alba increasing the IRD and is caused by a stretch on the abdominal wall and surrounding connective tissue by the growing fetus.[1 2] This is a common condition in both pregnant and postpartum women, with a reported prevalence of 70% in the last trimester of pregnancy, 60% 6 weeks postpartum and 30% 12 months postpartum.[3 4]

The normal width of the linea alba in nulliparous women is reported to be less than 15 mm at the xiphoid level, 22 mm at 3 cm above the umbilicus and 16 mm at 2 cm below the umbilicus.[5] Mota *et al*[6] reported that in gestation week 35–41, the IRD increased and is considered normal up to 86 mm at 2 cm above the umbilicus and 79 mm at 2 cm below the umbilicus.[6] There is no international consensus on the cut-off point for clinically significant DRA, and the literature suggests several classifications ranging from 20 mm to 27 mm.[7 8]

Location of DRA may vary along the length of the linea alba from the superior origin at the xiphoid process of the sternum to the inferior insertion at the pubic symphysis, and it occurs most commonly above, below and/

or at the level of the umbilicus.[2] Ultrasonography using two-dimensional ultrasound imaging of the IRD is the most reliable and recommended measurement tool when defining and measuring the presence of DRA.[7 9 10]

Treatment aims for both prevention and reduction of DRA, and conservative treatment and physiotherapy are the primary treatment of choice.[11 12] However, to date, there is no generally accepted protocol of how to treat DRA, and there is contradicting evidence of the effect of abdominal exercise therapy for this condition.[12] To our knowledge, there is only one study investigating the effect of exercise on DRA in a pregnant population. Due to this paucity of high-quality studies on the subject, together with the fact that DRA occurs and develops during the two last trimesters of pregnancy,[2 6] we want to fill this knowledge gap by conducting a randomised controlled trial (RCT) on the effect of a specific exercise programme on DRA during pregnancy .

Aim and hypothesis

The aim of this RCT was to investigate the effect of a specific exercise programme carried out during pregnancy on DRA during pregnancy and 1 year postpartum.

More specifically, we will examine the difference in change in IRD at rest between the intervention group and the control group measured at baseline (gestation week 24) and immediately after the 12-week intervention period at gestation week 37, and 6 weeks, 6 months and 12 months postpartum.

The null hypothesis to be tested is that there is no difference in change in IRD between the intervention group and the control group at the different measurement timepoints.

METHODS

Design and setting

This will be an exploratory, assessor-blinded, randomised, controlled parallel group trial, and this study will be carried out in a primary healthcare setting in a large Norwegian city.

Outcome measures

The primary outcome measure will be change in IRD in millimetre, measured by two-dimensional ultrasonography.[7 10]

Participants

Participants will be recruited from local physiotherapy clinics, pregnancy exercise classes, local health centres and social media platforms like Facebook and Instagram. Screening and enrolment will continue until the target number of participants is achieved, and planned start and end dates for this study are September 2021 and December 2023, respectively. The trial registry has been updated, to clarify that participants will be assessed for eligibility criteria in gestation week 24, and start intervention at gestation week 25.

Inclusion criteria are healthy pregnant women aged ≥18 years, in gestation week 24, presenting with a IRD of 28 mm or more at the level of the umbilicus, and/or 2 cm above and below the umbilicus at rest on initial assessment.[10] Participants presenting with a protrusion along the linea alba will also be included, even if they do not meet the inclusion criteria with an IRD of 28 mm or more.[13] These cut-off values have been chosen to ensure a clinically significant DRA and to include all variations regarding location.[7 12] Both primigravida and multigravida women will be included, and there will be no limitations on the number of fetuses.

Exclusion criteria at initial assessment will be pregnancies where exercise is contraindicated,[14] serious illnesses regarding both mother and fetus, inability to understand Scandinavian languages, failure to complete and present an informed consent form, and presence of chronic physical or mental illness incompatible with the intervention. Exclusion criteria during the study period are stillbirth or premature birth before gestation week 37, onset of serious illnesses regarding both mother and fetus, and pregnancies where exercise is contraindicated.[14] Participant timeline and trial design are described in figure 1.

Procedure

Data collection

Data collection (before and after intervention) will take place at a private physiotherapy clinic in Bergen, Norway. Participants will, however, be offered to have the postpartum assessments done in their own home to reduce drop out. Data collection will take place at gestation week 24, at gestation week 37, 6 weeks, and 6 and 12 months postpartum. The same equipment will be used during all assessments and will include a physiotherapy treatment plinth, pillow, tape measure and marker pen, gloves, ultrasound gel, paper sheets and paper towels, (portable) ultrasound diagnostic scanner and software program to process images. The same physiotherapist will perform all assessments. Current local and national COVID-19 infection control measures will be adhered to.[15]

Ultrasound imaging

The participants will be examined for presence of a clinically significant DRA using two-dimensional ultrasound at initial assessment.[7] If they meet the criteria for inclusion, images of the IRD at rest will be collected. The same images of the IRD at rest will also be collected after the intervention period at gestation week 37 and at 6 weeks and 6 and 12 months postpartum.

Ultrasound images (B mode) of the IRD will be collected using a two-dimensional ultrasound diagnostic scanner with a linear probe (Alpinion EC8Diamond, L8-17 MHz transducer). Mota *et al*[10] found the intratester reliability of the ultrasound analyses to be very good with an intraclass correlation coefficient for IRD at rest of 0.98 measured 2 cm above and 0.96 measured 2 cm below the umbilicus. The SE of measurements (1.04–0.97 mm) and minimal detectable change (MDC) values were low.

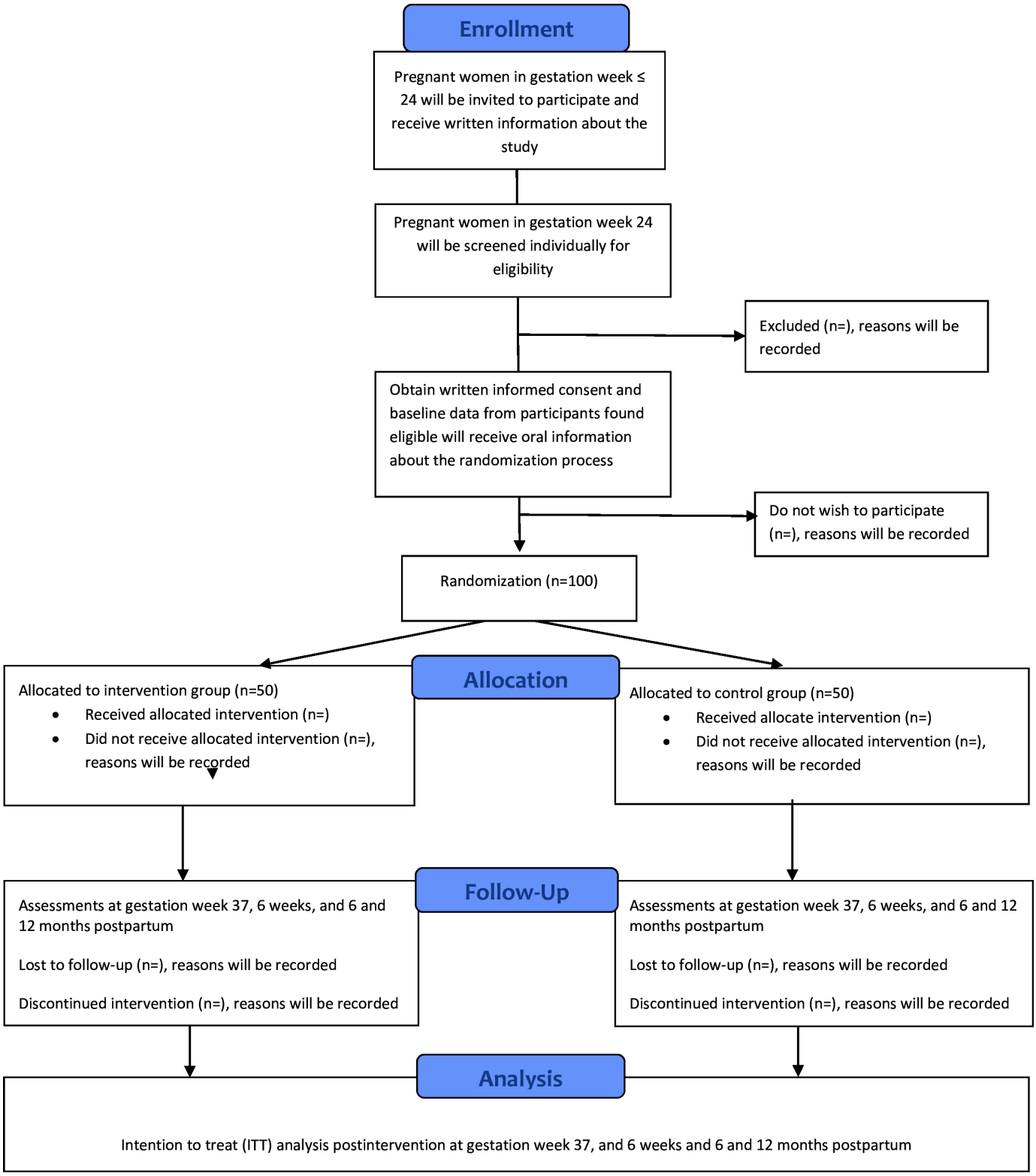

Figure 1 Participant timeline. This flow diagram illustrates the participant timeline and trial design from enrolment to allocation of participants to either the intervention group or the control group, through to follow-up assessments and the analysis of data.

MDCs with IRD at rest above and below the umbilicus were 2.9 and 2.7 mm, respectively.[10]

The position of the subject during imaging is supine, knees hip-width apart and bent 90°, feet resting on plinth, arms resting alongside the body and head resting on a pillow. Images of the IRD at rest will be collected at two different premarked locations: 2 cm above and 2 cm below the umbilicus to standardise the position of the transducer.[10] The transducer will be placed transversely along the midline of the abdomen, and the bottom edge of the transducer will correspond with the skin marker. The transducer will then be moved laterally until the

medial borders of the recti abdominis muscles are visualised. Images will be collected immediately at the end of exhalation as recommended by Teyhen *et al*,[16] and care will be taken so that the pressure of the probe does not cause a reflexive response of the abdominal muscles.[10 16]

Images taken will be transformed to JPG format and saved on an encrypted memory stick. Images will then be transferred to a safe server and stored. Blinding of the assessor will be ensured by allocating images a random number. This will be administrated by the project manager (IH). The assessor will then perform all measurements at a later stage using the free Microdicom software. All measurements are to be performed by the same assessor (N-MT), a women's health physiotherapist with 21 years of clinical experience with both specific training and clinical experience in the use of ultrasound imaging of the pelvic floor and abdomen prior to data collection.[17 18] Once the offline measurements are completed, the IRD values of all participants, locations and timepoints will be imported into Stata software for statistical analysis, together with the retrieved background data.

Preliminary information and questionnaires

Potential participants will be sent written information about the study on email with an invitation to participate in the study, and a suggested date and time for data collection. They will be asked to respond and confirm their participation at an initial screening assessment if they are willing to participate in the study. Participants will receive both oral and written information prior to data collection and will be asked to sign a written consent form. Data on background variables including age, height, weight, marital status, educational level, occupation, smoking, obstetric history, physical activity levels, heavy lifting, symptoms of urinary incontinence, symptoms of low back and pelvic girdle pain (PGP) in pregnancy, health-related quality of life and comorbidity will be collected at initial assessment and prior to each assessment timepoint after the intervention period using electronic questionnaires.

Symptoms of urinary incontinence will be assessed using the International Consultation on Urinary Incontinence Short Form Questionnaire (ICIQ-UI-SF).[19] The ICIQ- UI-SF is reported to have good reliability, good discriminant validity and moderate convergent validity.[19] The Modified Oswestry Disability Index will be used to assess for back pain and is considered a valid and reliable tool to score self-perceived disability in patients with low back pain.[20] Symptoms of PGP will be assessed by the Pelvic Girdle Questionnaire (PGQ).[21] The PGQ is a condition-specific measure, with acceptably high reliability and validity in people with PGP during both pregnancy and postpartum period.[21] Enrolment and baseline assessments will be administrated by the assessor (N-MT).

Randomisation and blinding

To ensure randomisation to the two groups in the RCT, participants, following baseline assessments, will be allocated to the two groups by block randomisation. Blocking will be masked and not stated in the protocol to avoid selection bias. The group allocation will be administrated by a research assistant to ensure blinding of the assessor. The randomisation will be concealed. This study is assessor blinded only, as participants and the physiotherapist running the intervention groups cannot be blinded.

Interventions

Both the intervention and control groups will be administrated by a research assistant. This implies allocation to groups, any contact with the participants throughout the study period and administration of the exercise diaries.

National guidelines for general exercise during pregnancy recommends pregnant women to engage in regular physical activity of moderate intensity for 30 min/day. This activity should include cardiorespiratory training, strength exercises for largest muscle groups of the body and including the pelvic floor muscles, and exercises to maintain normal mobility.[14] Participants in both the intervention group and the control group will receive information about these guidelines and their recommendations.

Intervention group

The participants in the intervention group will participate in a 12-week specific exercise programme led by an experienced women's health physiotherapist. These groups will take place at a private physiotherapy clinic twice a week. In addition, the participants will be asked to carry out a self-managed exercise programme twice weekly for the same 12-week period. The participants will be provided with an exercise diary so that adherence to the self-managed intervention can be registered and monitored. This exercise diary will be sent to the participants once a week as an electronic questionnaire; this will ensure that the information recorded is standardised and that the research assistant can aid the participants to register their activity and encourage the participants to adhere to the intervention. The participants will also be provided with contact information to both the physiotherapist leading the group exercises and the research assistant if they need any additional information or have any questions regarding the exercises throughout the intervention period.

Both the group exercise programme and the home exercise programme will be based on the national guidelines for general exercise during pregnancy[14] and will follow current strength training recommendations.[22]

Control group

The control group will not participate in any exercise intervention. The importance of a control group in RCTs will be explained to the participants in the control group, and the participants will be advised to continue with their normal activity levels. They will, however, be advised to follow national guidelines for general exercise during pregnancy and will receive information about these guidelines.[14]

The participants in the control group will receive an electronic questionnaire three times (after 4, 8 and 12 weeks) during the 12-week intervention period where they are asked to report on their activity levels. This is to reduce recall bias and to give and register information of the participants' activity levels.

Data management

Personalised data variables collected will be limited to a minimum, and in line with both the purpose of the study and with similar projects. All study data retrieved and processed, including data analysis, will be saved and stored at the SAFE server, University of Bergen, the University's information technology department database, to secure access to sensitive personal information. All data containing names and personal identifying information will be stored separately at the SAFE server and identified by individual secure codes. Only the project manager (IH) will have access to the connection key. When the blinded assessor receives all images for measurements, the individual codes will be replaced by an unrelated sequence of numbers. All paper-based documents and data will be stored in a secured filing cabinet at the University location.

Background variables are collected with the online Norwegian software solution Infopad, where the participants receive all questionnaires electronic through an email link. Data are directly transferred to a secure database where it can be accessed from Infopad's website, which is only accessible for the assessor. The data are stored in an Excel (Version 2112) file and transferred to the SAFE server and Stata, the statistical software used to analyse the data.

There are no plans for granting public access to the data set.

Statistical analysis

Based on an estimated important clinical difference of 6 mm in the resting value of the IRD following intervention and 10% loss to follow-up, 100 primigravida and multigravida women will be included (assuming a two-tailed 5% type I error rate and 80% power) and randomised to either the intervention group or the control group.

Background variables will be presented as means with SD and ranges, or numbers and percentages. Data will be analysed and presented in accordance with international Consolidated Standards of Reporting Trials guidelines and analysed according to the intention-to-treat principle. We will use linear mixed model with random intercept for individuals and possibly also random coefficients if needed to improve model fit. Data will be analysed in long format with IRD as a continuous dependent variable, intervention group as a binary independent variable (1=intervention, 0=control) and time as a categorical independent variable with five levels (baseline=gestation week 24, gestation week 37, 6 weeks, and 6 and 12 months postpartum) with the baseline measurement as the reference category. The effect of the intervention will be estimated as the regression coefficient for interaction terms between the binary intervention group variable and the dummy variables for time.[23] The interpretation of the coefficients for the interaction terms will be the difference in change in IRD from baseline to the different timepoints in question between the intervention group and the control group, after adjustment for baseline values of IRD. We will also analyse time as a continuous variable to achieve estimates of differences in slope for change over time between the two groups. If we observe differential loss to follow-up according to background variables, we will do sensitivity analyses with adjustment for these background variables.

Ethics and dissemination

Ethical considerations

All procedures will be performed in adherence to the Helsinki declaration. Ethical approval from the Norwegian Regional Ethical Committee (REK) has been granted (76296), and the study has been registered with ClinicalTrials.gov.

The anonymity and confidentiality of the participants in this study will be ensured and maintained according to laws and regulations. Participants will be presented with thorough oral and written information about the study, and they will be asked to sign a consent form before enrolling in the study. As participants may be recruited by their physiotherapist, GP, midwife or nurse, it is important that consent to participate in the study is not based on dependency and is not to be obtained in a treatment setting. Informed consent will be obtained by a neutral part, and reflection time will be given.

Due to ethical reasons, women in the control group cannot be discouraged to be physically active during their pregnancies. National guidelines recommend pregnant women to exercise regularly throughout the pregnancy.[14]

Protocol amendments

Administrative changes of the protocol that have no effect on the way the study is to be conducted, will be agreed on by the project management committee (IH, N-MT, KB, RM-N and KVF), and will be documented in a memorandum. Modifications to the protocol which may impact on the conduct of the study will require a formal amendment to the protocol. Such amendment will be agreed on by the project management committee and approved by REK prior to the implementation of the modifications.

Dissemination

Results from this study will be presented at international and national scientific conferences, and in peer-reviewed scientific journals.

Acknowledgements The authors thank Jannicke Igland, Senior Engineer at Department of Global Public Health and Primary Care, University of Bergen, for valuable contribution to planning the statistical analysis.

Contributors Each author of this paper met the criteria for authorship. N-MT, KB, IH and RM-N designed the study. N-MT drafted the article, and KVF, RM-N,

IH and KB critically revised the article for important intellectual content. The final manuscript was seen and approved by all authors.

Funding This work is supported by the Norwegian Fund for Post-Graduate Training in Physiotherapy (grant number 129 673).

Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, conduct, reporting or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement No data are available. There are no plans for granting public access to the data set.

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