Trial Description

Title

Internet-based walking intervention for obese pregnant women with prenatal depression: a randomized controlled trial

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

Both severe obesity and depression during pregnancy involve substantial risks to the course of pregnancy and childbirth as well as for the health of mother and child. There is evidence that physical activity particularly walking has a positive effect on weight and depressive symptoms of pregnant woman. The aim of this study is therefore to evaluate the effectiveness of an eight-week internet-based walking intervention with regard to depressive symptoms of obese pregnant women. In addition, weight gain and quality of life are examined. While the intervention group receives both a walking intervention and a psycho-educational depression program, the control group only receives the depression program. After each treatment unit, women receive individual feedback by the therapist.

Brief Summary in Scientific Language

Both severe obesity and depression during pregnancy involve substantial risks to the course of pregnancy and childbirth as well as for the health of mother and child. There is evidence that physical activity particularly walking has a positive effect on weight and depressive symptoms of pregnant woman. The aim of this study is therefore to evaluate the effectiveness of an eight-week internet-based walking intervention with regard to depressive symptoms of obese pregnant women. In addition, weight gain and quality of life are examined. While the intervention group receives both a walking intervention and a psycho-educational depression program, the control group only receives the depression program. After each treatment unit, women receive individual feedback by the therapist.

Organizational Data

- DRKS-ID: **DRKS00005823**
- Date of Registration in DRKS: **2014/05/09**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
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Ethics Approval/Approval of the Ethics Committee: **Approved**

- (leading) Ethics Committee Nr.: **186/13-15072013 , Ethikkommission an der Medizinischen Fakultät der Universität Leipzig**

Secondary IDs

- Universal Trial Number (UTN): **U1111-1154-0340**

Health condition or Problem studied

- ICD10: **F32.0 - Mild depressive episode**
- ICD10: **F32.1 - Moderate depressive episode**
- ICD10: **E66 - Obesity**

Interventions/Observational Groups

- Arm 1: **Intervention: participants recieve an 8-week internet- based walking program in combination with a cognitive-behavioral depression program**

  Before the intervention starts, average daily steps of participants are measured with a pedometer. Particpants are then asked to walk 500 steps more each day than before. The step goal is increased every week by 500 steps until the goal of 10 000 steps a day are reached.

  Participants will recieve the cognitive-behavioral depression program once a week. It contains the following 8 treatment modules:

  1 Symptoms: What means prenatal depression and what kind of symptoms do I have?

  2 Risk factors: Which impact do depressive mood and obesity have on my pregnancy?

  3 Daily structure: What activities do I do and how do I experience them?

  4 Activity plan: How can I integrate positive activities in my daily schedule ?

  5 Thoughts: What impact do my thoughts have on my feelings?

  6 Alternative thoughts: What kind of alternative thoughts can I develop?

7 Relapse prevention : What I have learned and what strategies will help me in the future?

8 Summary

- Arm 2: **control: participants recieve an 8-weekinternet-based cognitive-beahvioral depression program**

  Participants will recieve the cognitive-behavioral depression program once a week. It contains the following 8 treatment modules:

  1 Symptoms: What means prenatal depression and what kind of symptoms do I have?

  2 Risk factors: Which impact do depressive mood and obesity have on my pregnancy?

  3 Daily structure: What activities do I do and how do I experience them?

  4 Activity plan: How can I integrate positive activities in my daily schedule ?

  5 Thoughts: What impact do my thoughts have on my feelings?

  6 Alternative thoughts: What kind of alternative thoughts can I develop?

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  8 Summary

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Active control**

Study Type: **Interventional**

Study Type Non-Interventional: **[---]***

Allocation: **Randomized controlled trial**

Blinding: **[---]***

Who is blinded: **[---]***

Control: **Active control**

- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Depression at post assesment (immediatly after the intervention) and follow-up assesment (8 weeks after the due day). Depression is assessed with the Beck-Depression-Inventory II (BDI-II) and the Edinburgh Postnatal Depression Scale (EPDS)

Secondary Outcome

-Health related quality of life assessed with the SF-12 Health survey

- Physical activity assessed with the International Physical Activity Questionnaire (IPAC)
- Sleeping duration and quality assessed with the Pitsburgh Sleep Quality Index (PSQI)

- Weight gain during the 8-week intervention

- number of steps compared to baseline assessed with apedometer (Beurer Activity Sensor)

- Weight and lenght of the child at birth, mode of birth.

All secondary Outcomes are assessed both directly after the intervention and 8 weeks after due day. Birth weight, length of the child and mode of birth are assessed 8 weeks after due day.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Klinik und Poliklinik für Psychosomatische Medizin und Psychotherapie Universitätsklinikum Leipzig Semmelweisstr. 10 04103 Leipzig, Germany anette.kersting@medizin.uni-leipzig.de Tel. +49-341-9718850, Leipzig**

Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2014/05/19**
- Target Sample Size: **42**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Female**
- Minimum Age: **14 Weeks of pregnancy**
- Maximum Age: **22 Weeks of pregnancy**

Additional Inclusion Criteria

- women that are at least 18 years old
- 14.-22. week of gestation
- BMI ≥ 30 kg/m² before pregnancy
- BDI-II values between 13-28
- clinically healthy with regard to the cardiovascular and pulmonary system
- access to the internet
- german language skills

Exclusion criteria

- BMI ≥ 40
- rheumatism
- diabetes
- thyroid disease
- herniated disc
- more than 2 hours physical activity a week
- complication of pregnancy (ongoing blooding after the 12th week of pregnancy as well as premature labour)
- more than two abortions in the past
- multiple birth
- Intrauterine growth restrictions
- suicidal tendency
- former postpartum depression oder psychosis
- drug consumption

Addresses

■ **Primary Sponsor**

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Sources of Monetary or Material Support

■ **Private sponsorship (foundations, study societies, etc.)**

Roland Ernst Stiftung
Ms. Jana Hennig

Private sponsorship (foundations, study societies, etc.)

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E-mail: **rahennig at web.de**
URL: **[---]***

Status

- Recruitment Status: **Recruiting planned**
- Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

** This entry means the parameter is not applicable or has not been set.*

**** This entry means that data is not displayed due to insufficient data privacy clearing.*