ISRCTN69018802 https://doi.org/10.1186/ISRCTN69018802

Reiki practice and the quality of life of diabetic pregnant women

Submission date
01/08/2021

Recruitment status
No longer recruiting

Registration date
02/08/2021

Overall study status
Completed

Last Edited
12/04/2022

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Women may get a type of diabetes that only happens in pregnancy. This is called gestational diabetes. Pregnancy can change how a woman's body uses glucose. This can make diabetes worse, or lead to gestational diabetes.
Reiki, a non-drug treatment used on people suffering from anxiety, depression, or both, appears to be an intriguing approach to treating the psychological impact of a woman's response to a diagnosis of gestational diabetes. However, randomized controlled trials comparing various Reiki strategies are required. The purpose of this trial is to analyse if the therapeutic modality of laying on of hands (Reiki) delivered by a trained Reiki practitioner, either face-to-face or remotely, was more effective than Sham-Reiki in controlling anxiety and depression in pregnant women with gestational diabetes.

Who can participate?
Pregnant women with hyperglycaemia.

What does the study involve?
The participants were randomized to Face-to-Face Reiki, Remote Reiki, or Sham-Reiki. Changes in the World Health Organization Quality of Life questionnaire, Beck depression inventory and Beck State-Trait anxiety surveys were the primary outcomes after 7 full Reiki sessions by applying standardized and validated surveys in Portuguese.

What are the possible benefits and risks of participating?
Benefits are related to the improvement of quality of life as well as lowering the levels of depression and anxiety, in addition to have a holistic approach throughout prenatal care. There are no risks involved, since the Sham group continued to receive the medical and nursing care as all the groups. The only difference is that two groups received genuine Reiki while the other not.

Where is the study run from?
Botuctu Medical School (Brazil)

When is the study starting and how long is it expected to run for?
March 2016 to March 2019

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Guilherme Ferraz, guilhermerago@hotmail.com

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CAAE 52734216.1.0000.5411

Study information

Scientific Title
Reiki practice and the quality of life of diabetic pregnant women: a randomized clinical trial

Study objectives
The aim of this study was to determine whether the therapeutic modality of laying on of hands (Reiki) may enhance the quality of life, as well as reducing depression and anxiety levels in hyperglycaemic pregnant women

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 07/03/2016, Institutional Research Bureau of Botucatu Medical School, UNESP (Chacára Butignoli s/n, Rubião Júnior. Botucatu, State of São Paulo, 18618-970, Brazil; +55 14 3880-1609; cep.fmb@unesp.br), ref: CAAE 52734216.1.0000.5411

Study design
Double-blinded randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet.

Health condition(s) or problem(s) studied
Depression and anxiety levels in hyperglycaemic pregnant women

Interventions
Patients were allocated at random by the chief nurse into one of the three groups Sham, Face-to-Face or Remote Reiki at PDRC/HC FMB. Randomization was carried out by the Research Support Office (EAP) of FMB/UNESP using verified software, which is available on the website www.randomization.com.

The participants and those evaluating the outcomes were all blinded. The control or intervention groups were only known to the Reiki therapist and Reiki simulation researchers.

The Face-to-Face intervention group had 7 sessions throughout prenatal care. The lead researcher is a licensed Reiki Master and has expertise with Reiki Therapy and has personally carried out the sessions with the approval of the pregnant person by a free explanation of permission and signed informed consent form. Reiki treatments were arranged on the same day as the pregnant woman's outpatient appointment, lasting 30 minutes each.

The Remote intervention group also had 7 sessions, which were also carried by the lead author. The remote treatments were planned on the same day that the pregnant woman returned for her outpatient visit, but without her presence, and lasted 30 minutes each session.

In the control group, participants received a simulation of laying on of hands, the hands' position used in the simulation was the same as the intervention group. This placebo was carried out by

another research member who had been trained to imitate the session using the identical touch motions as the intervention group but had neither previous knowledge of Reiki nor competence. In the end, Sham Reiki replicated the identical technique as Face-to-Face Reiki therapy; however, only the researchers who used genuine and sham Reiki knew, and the patients had no idea who was in the control or intervention groups.

Intervention Type
Behavioural

Primary outcome measure
Measured at baseline and after 7 sessions:
1. Quality of life measured using the World Health Organization Quality of Life questionnaire
2. Depression measured using the Beck depression inventory
3. Anxiety measured using the Beck State-Trait anxiety survey questionnaire

Secondary outcome measures
Glycaemic profile measured by blood tests taken throughout pregnancy

Overall study start date
07/03/2016

Completion date
20/03/2019

Eligibility

Key inclusion criteria
1. Pregnant women
2. Fasting glucose 92 mg/dl and/or a risk factor for diabetes
3. Positive screening for Gestational Diabetes Mellitus (GDM), with the diagnosis made by the 75g oral glucose tolerance test (GTT) and glycaemic profile (GP).

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
150

Total final enrolment
134

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
08/03/2016

Date of final enrolment
20/12/2018

Locations

Countries of recruitment
Brazil

Study participating centre
Perinatal Diabetes Research Centre
Av. Prof. Montenegro, s/n
Distrito de Rubião Júnior
Botucatu
Brazil
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Sponsor information

Organisation
São Paulo State University

Sponsor details
Botucatu Medical School
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Sponsor type
University/education

Website
https://www.fmb.unesp.br/

ROR
https://ror.org/00987cb86

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
01/08/2022

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request (guilhermerago@hotmail.com).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		02/06/2021	02/08/2021	Yes	No
Thesis results		27/08/2021	12/04/2022	No	No