Reiki practice and the quality of life of diabetic pregnant women

Submission date	Recruitment status	Prospectively registered		
01/08/2021	No longer recruiting	[X] Protocol		
Registration date	Overall study status Completed	Statistical analysis plan		
02/08/2021		[X] Results		
Last Edited	Condition category	[] Individual participant data		
12/04/2022	Nutritional, Metabolic, Endocrine			

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

Contact name

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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 recruitmentBrazil

Study participating centre
Perinatal Diabetes Research Centre
Av. Prof. Montenegro, s/n
Distrito de Rubião Júnior
Botucatu
Brazil
18618-687

Sponsor information

Organisation

São Paulo State University

Sponsor details

Botucatu Medical School Av. Prof. Montenegro, s/n, Distrito de Rubião Júnior Botucatu Brazil 18618-687 +55 14 38801001 pg.tocoginecologia.fmb@unesp.br

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