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Guilherme Augusto Rago Ferraz

Efeitos da prática do Reiki sobre a qualidade de vida de gestantes diabéticas: Ensaio Clínico Randomizado

Tese apresentada à Faculdade de Medicina, Universidade Estadual Paulista "Júlio de Mesquita Filho", Campus de Botucatu, para obtenção do título de Doutor em Tocoginecologia.

Orientadora: Profa. Emérita Marilza Vieira Cunha Rudge
Coorientadora: Profa. Associada Silvana Andrea Molina Lima

Botucatu
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Guilherme Augusto Rago Ferraz

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Orientadora: Profa. Emérita Marilza Vieira Cunha Rudge

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Botucatu, 27 de agosto de 2021

- *Dedico em memória dos meus avós Yolanda Agassi Rago, Antonio Orlando Rago e Sérgio Luiz Ferraz.*
- *Dedico em memória de todas as vítimas que faleceram em decorrência da Covid-19 .*
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“Se recebo dor, te devolvo amor.”

Pabllo Vittar

Resumo

FERRAZ, G.A.R. **Efeitos da prática do Reiki sobre a qualidade de vida de gestantes diabéticas: Ensaio Clínico Randomizado**. 2021. 69 f. Tese (Doutorado) – Faculdade de Medicina de Botucatu, Universidade Estadual Paulista, Botucatu, 2021.

Introdução: Reiki, um tratamento não medicamentoso usado em pessoas que sofrem de ansiedade, depressão ou ambos, parece ser uma abordagem intrigante para tratar o impacto psicológico da resposta de uma mulher a um diagnóstico de hiperglicemia na gravidez com comprometimento fetal. No entanto, são necessários ensaios clínicos randomizados comparando várias técnicas de aplicação de Reiki.

Objetivos: O objetivo deste ensaio é analisar se a modalidade terapêutica de imposição das mãos (Reiki) aplicada por um terapeuta habilitado em Reiki, por meio presencial ou a distância, pode ser eficaz em gestantes com hiperglicemia.

Métodos: Um ensaio clínico randomizado, com 134 gestantes que apresentaram hiperglicemia por DM pré-gravidez tipo 2, glicemia em jejum ≥ 92 mg/dl no primeiro trimestre ou 75g-OGTT entre 24-28 semanas de gestação foi conduzido no Centro de Pesquisas do Diabetes Perinatal, Hospital Universitário, Faculdade de Medicina de Botucatu, UNESP, Brasil. As participantes foram randomizadas e alocadas em 3 grupos: Reiki presencial (47), Reiki a distância (43) ou Placebo (47). As análises consistiram nos resultados primários das mudanças de respostas obtidas por meio do questionário de qualidade de vida da Organização Mundial de Saúde, inventário de depressão de Beck e de ansiedade-traço após 7 sessões completas, todos os questionários aplicados são validados na língua portuguesa. Os dados obtidos foram submetidos à análise estatística por meio dos testes ANOVA, WALD, Tukey e Qui-quadrado. O ensaio foi registrado com o Número Internacional de Ensaios Clínicos Randomizados (ISRCTN), isrctn.com ISRCTN69018802; https://doi.org/10.1186/ISRCTN69018802.

Resultados: Não houve diferenças significativas entre os grupos controle e intervenção nas características basais. A terapia de Reiki presencial e a distância promoveu o mesmo efeito na qualidade de vida das participantes. Considerando a qualidade de vida, no Reiki presencial, os aspectos físicos aumentaram significativamente de 58,86 para 82 ($p = 0,0012$), os aspectos psicológicos aumentaram de 69,5 para 84,75 ($p < 0,0001$), os sociais melhoraram de 70,83 para 87,17 ($p < 0,0001$) e os ambientais de 67,69 para 83,75 ($p < 0,0001$). Da mesma forma, o inventário de depressão de Beck (BDI) foi significativamente afetado pelo Reiki presencial, uma vez que diminuiu de 10,06 para 6,72 ($p = 0,0208$), assim como os inventários de ansiedade traço-estado, que caíram de 41,64 para 34 ($p < 0,0001$) e 42,5 a 33,66 ($p < 0,0001$), respectivamente. Além disso, o grupo do Reiki a distância apresentou resultados semelhantes ao do presencial, enquanto o Placebo não apresentou diferença entre os dados basais e após a simulação da técnica do Reiki. Além disso, os três grupos nos proporcionaram um alto nível de consistência, de acordo com as características da linha de base.

Conclusão: Reiki melhorou todos os aspectos relacionados à qualidade de vida, bem como diminuiu a depressão e a ansiedade das gestantes diabéticas.

Palavras-chave: Reiki, toque terapêutico, gravidez, diabetes mellitus gestacional, práticas de saúde complementares e integrativas, pré-natal

Abstract

FERRAZ, G.A.R**. Reiki practice and the quality of life of diabetic pregnant women: a randomized clinical trial**. 2021. 69 p. Thesis (PhD) – Botucatu Medical School, São Paulo State University (UNESP), Botucatu, 2021.

Background: 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 hyperglycaemia in pregnancy (HIP) with foetal compromise. However, randomized controlled trials comparing various Reiki strategies are required.
Objectives: 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 the burden of HIP diagnosis among women.
Methods: A randomized controlled experiment comprising 134 women with HIP diagnosed by pre-pregnancy Type 2 DM, fasting glycemia≥ 92 mg/dl in first trimester or 75g-OGTT between 24-28 gestational weeks was conducted at the Perinatal Diabetes Research Centre, University Hospital, Botucatu Medical School, UNESP, Brazil. The participants were randomized to Face-to-Face Reiki (47), Remote Reiki (43) or Sham-Reiki (47). Changes in 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. The obtained data were subjected to statistical analysis using ANOVA, WALD, Tukey´s and chi-square tests. The trial was registered with International Standard Randomised Controlled Trial Number (ISRCTN), isrctn.com ISRCTN69018802; https://doi.org/10.1186/ISRCTN69018802.
Results: There were no significant differences between control and intervention groups in baseline characteristics. Face-to-face and Remote Reiki therapy had same effect on participants' quality of life. For Face-to-Face Reiki, the physical aspects significantly increased from 58.86 to 82 ($p=0.0012$), psychological aspects rose from 69.5 to 84.75 ($p<0.0001$), social elements improved from 70.83 to 87.17 ($p<0.0001$) and environmental factors enhanced from 67.69 to 83.75 ($p<0.0001$). Similarly, Beck's depression inventory (BDI) was significantly affected by Face-to-Face Reiki; although, it declined from 10.06 to 6.72 ($p=0.0208$), as did the state-trait anxiety inventories, which dropped from 41.64 to 34 ($p<0.0001$) and 42.5 to 33.66 ($p<0.0001$), respectively. Moreover, the outcomes related to Remote Reiki presented similar results as the Face-to-Face, while Sham Reiki did not present any significant difference between baseline and after Reiki application. Besides that, the three groups provided us with a high level of consistency, according to baseline traits.
Conclusion: Reiki improved all aspects of the World Health Organization Quality-of-Life questionnaire, as well as lowered depression and anxiety in Beck's inventories in HIP women.

Keywords: Reiki, therapeutic touch, pregnancy, gestational diabetes mellitus, complementary alternative medicine, antenatal care

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ARTIGO ORIGINAL I

Study Protocol

Global Academic Nursing Journal

PROTOCOL

Effectiveness of Reiki practice in diabetic pregnant women: randomized clinical trial protocol

Efectividad de la práctica de Reiki en embarazadas diabéticas: protocolo de ensayo clínico aleatorizado

Efetividade da prática do Reiki em gestantes diabéticas: protocolo de ensaio clínico randomizado

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Abstract

The aim was to outline the protocol of a randomized clinical trial (RCT) with the objective of identifying the effectiveness of the practice of Reiki in diabetic pregnant women. 150 pregnant women with diabetes were included and randomized into three groups: control/placebo group (mimicking of Reiki therapy), intervention (with face-to-face Reiki therapy technique) and remote intervention (with remote Reiki therapy) in the period of March from 2016 to December 2018. The intervention comprised seven Reiki sessions compared to the simulation of laying on of hands, in person or at a distance. Quality of life and anxiety will be measured, in addition to perinatal outcomes such as: gestational age at birth, Apgar score, birth weight, classification of gestational age at birth (term or preterm), classification of newborn weight by gestational age, type of care (joint accommodation, nursery and NICU) and perinatal death. Statistics will comprise a descriptive analysis with the calculation of mean and standard deviation for quantitative variables and frequencies and percentages for categorized variables. The literature has few works on Reiki in obstetrics, highlighting the need to carry out studies that introduce integrative and complementary therapies in Brazilian public health.

Descriptors: Complementary Therapies; Therapeutic Touch; Diabetes Mellitus; Pregnancy in Diabetics; Randomized Controlled Clinical Trial.

Resumén

El objetivo fue perfilar el protocolo de un ensayo clínico aleatorizado (ECA) con el objetivo de identificar la efectividad de la práctica de Reiki en embarazadas diabéticas. Se incluyeron 150 mujeres embarazadas con diabetes y se aleatorizaron en tres grupos: grupo control / placebo (imitando la terapia de Reiki), intervención (con técnica de terapia de Reiki cara a cara) e intervención remota (con terapia de Reiki remota) en el período de marzo de 2016 a diciembre de 2018. La intervención comprendió siete sesiones de Reiki frente a la simulación de imposición de manos, en persona o a distancia. Se medirá la calidad de vida y la ansiedad, además de los resultados perinatales como: edad gestacional al nacer, puntaje de Apgar, peso al nacer, clasificación de la edad gestacional al nacer (a término o prematuro), clasificación del peso del recién nacido por edad gestacional, tipo de cuidados (acomodación conjunta, guardería y UCIN) y muerte perinatal. La estadística comprenderá un análisis descriptivo con el cálculo de media y desviación estándar para variables cuantitativas y frecuencias y porcentajes para variables categorizadas. La literatura tiene pocos trabajos sobre Reiki en el área de la obstetricia, destacando la necesidad de realizar estudios que introduzcan terapias integradoras y complementarias en la salud pública brasileña.

Descriptores: Terapias Complementarias; Toque Terapéutico; Diabetes Mellitus; Embarazo en Diabéticos; Ensayo Clínico Controlado Aleatorizado.

Resumo

Objetivou-se delinear o protocolo de um ensaio clínico randomizado (ECR) com o objetivo de identificar a efetividade da prática do Reiki em gestantes diabéticas. Foram incluídas 150 gestantes diabéticas que foram randomizadas em três grupos, sendo: grupo controle/placebo (mimetização da terapêutica Reiki), intervenção (com a técnica terapêutica Reiki presencial) e intervenção à distância (com a terapêutica Reiki à distância) no período de março de 2016 a dezembro de 2018. A intervenção compreendeu em sete sessões de Reiki em comparação a simulação de imposição das mãos, de forma presencial ou à distância. Serão mensurados a qualidade de vida e ansiedade, além de desfechos perinatais como: idade gestacional ao nascimento, índice de Apgar, peso ao nascer, classificação da idade gestacional ao nascimento (termo ou pré-termo), classificação do peso do recém-nascido por idade gestacional, tipo de atendimento (alojamento conjunto, berçário e UTI Neonatal) e morte perinatal. A estatística compreenderá uma análise descritiva com o cálculo de média e desvio padrão para variáveis quantitativas e frequências e percentuais para as variáveis categorizadas. A literatura dispõe de poucos trabalhos sobre Reiki na área de obstetrícia, evidenciado a necessidade da realização de estudos que introduzam as terapias integrativas e complementares na saúde pública brasileira.

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Introduction

Pregnancies complicated by diabetes mellitus (DM) are associated with increased maternal and neonatal complications[1]. The most routine complications include macrosomia with a consequent increased risk of birth trauma and intrapartum hypoxia/asphyxia, high rates of cesarean section, delayed pulmonary maturation and metabolic disorders at birth, including hypoglycemia, hypocalcemia and HIPomagnesemia[2].

Regardless of the diagnosis of the type of diabetes or whether mild hyperglycemia occurs, the perinatal outcome is related to maternal metabolic control. The improvement in maternal and perinatal outcomes in diabetic pregnant women, described in the literature in recent decades, is related to obtaining maternal euglycemia[3-4]. To treat and maintain strict blood glucose control, pregnant women are treated in an outpatient clinic or with frequent and short hospitalizations[5-7].

In frequent and short hospitalizations and in prenatal consultations, maternal glycemic levels, and the need for inclusion and/or changes in the dose of insulin are analyzed. For gestational diabetics, this type of intensive insulin control can preserve the maternal pancreatic beta cell from exhaustion and reduce the possibility of future development of type diabetes[8].

In this sense, complementing the medical treatment of pregnant diabetic women, alternative therapies can be used together with allopathic treatment to improve the quality of life. There are "Integrative and Complementary Practices in Health" (PICS)[9], such as meditations, oriental body therapies (Acupuncture, Yoga, Ayurveda, and Reiki), anthroposophical therapies, among many others.

Therapists of integrative and complementary practices in health aim to provide more humanized care through self-awareness and perception, as well as the context around them. The gestational stage of the embryo is essential for the formation of the individual, not only in the material sense of the new family, but also in changing the routine, family habits and rhythm that this family will experience[10]. To bring this balance to both the pregnant woman and the newborn, it is necessary to understand the entire vital process of both, in health and in disease. Therefore, pregnant women who have diabetes before pregnancy and gestational diabetes are somehow out of energy balance, which can have consequences on their quality of life and well-being.

Currently, the world population is looking for new forms of health treatment, a way that is more natural and less invasive. Due to this, integrative and complementary practices in health have been gaining more and more space around the world, given the humanized and holistic view, as well as respect for the routines and rhythms of each person's life. Such treatments aim at the energy balance of people and are integrated with allopathic health[11].

In this sense, the practice of Reiki is being increasingly diffused as one of the integrative and complementary practices in health to promote balance between body, mind and spirit. Reiki is a hands-on technique whose aim is to use mantras and mantras to promote energy balance in the body, mind, and spirit.

Literature lacks the study of Reiki in obstetrics, as there is a notorious scarcity on the subject. Therefore, this randomized clinical trial (RCT) protocol aims to assess the effectiveness of the therapeutic modality of laying on of hands (Reiki) in diabetic pregnant women.

Methodology

Study design

This study protocol proposes a randomized clinical trial comparing the effectiveness of reiki in diabetic pregnant women. This study follows the Consolidated Standards of Reporting Trials (CONSORT)[12] recommendations to ensure transparency and methodological rigor in the writing of the study.

The study is being developed at the Center for Investigation of Perinatal Diabetes, Hospital das Clínicas, Faculty of Medicine of Botucatu (CIDP/HC/FMB – Unesp), characterized as a tertiary care center responsible for treating high-risk pregnant women with diabetes (pregestational and gestational) and with mild hyperglycemia, from diagnosis, treatment, and pre- and postnatal care. Data collection took place from March 2016 to December 2018, where they will be analyzed later.

The ethical aspects provided for in Resolution No. 466/12 of the National Health Council will be preserved. The project was approved by the Research Ethics Committee of the Botucatu School of Medicine, UNESP, under the number CAAE 52734216.1.0000.5411, with the opinions 1,440,349 (version 1, March 7, 2016) and 2,888,954 (version 2, September 12, 2018).

Participants

All pregnant women with DM, gestational or prepregnancy, confirmed by (TTG100g) and/or (PG) attended at the study collection site during the data collection period were included. The pregnant women in the study were accompanied by a team composed of obstetricians specialized in high-risk pregnancies, residents, nutritionists, nurses, and neonatologists. Positive screening for gestational diabetes was considered with fasting glucose ≥ 90mg/dL and/or a risk factor; in addition to the diagnosis made by the 100g TTG and glycemic profile. The cutoff points for TTG were those proposed by Carpenter & Coustan[13,14] and for the glycemic profile those proposed by Gilmer et al.[15].

Thus, the pregnant women being followed up at the institution were randomized into three groups: The control

group, without application of Reiki; the intervention group with the application of face-to-face Reiki and the remote intervention group, with the application of Reiki at a distance.

Interventions

Seven sessions of Reiki or simulation of laying on of hands were applied, in person or at a distance, in pregnant women with diabetes prior to pregnancy and gestational diabetes.

The face-to-face intervention group received medical and nursing treatment like the control, however, Reiki was applied during pregnancy for 7 face-to-face sessions after the diagnosis of gestational diabetes or pregnancy. The sessions were applied individually by the student responsible for this project, with experience in Reiki Therapy and with authorization from the pregnant woman through the consent form for free clarification. Reiki sessions were scheduled on the same day the pregnant woman returned for prenatal care, with the duration of each session lasting 30 minutes.

The remote intervention group received medical and nursing treatment like the control, however, Reiki was applied during pregnancy for 7 remote sessions, after the diagnosis of gestational diabetes or pregnancy. The sessions were applied individually by the student responsible for this project, with experience in Reiki Therapy, and with authorization from the pregnant woman through the consent form for free clarification.

The remote Reiki sessions were scheduled on the same day the pregnant woman returned for prenatal care, with the duration of each session lasting 30 minutes. Participants in the control group received medical and nursing care during pregnancy and at the time of delivery, according to the protocol established by the institution, as well as the intervention group, the control received a simulation of laying on of hands (simulation of Reiki therapy). This mimicry occurred with the same touch movements as the intervention group, however without knowledge of Reiki practice. The process of Reiki therapy was extremely equal in all groups and only the research members knew who was from the control and intervention groups, but the patients did not have access to such information.

Outcomes

Pregnant women were evaluated at two times during the experiment:

- T1 – corresponding to the first prenatal consultation for pregnant women with type 1 Diabetes mellitus (DM1) and type 2 Diabetes mellitus (DM2) or to the diagnosis of the disease, for pregnant women with Gestational Diabetes mellitus (GDM).
- T2 – corresponding to hospitalization for childbirth when all pregnant women with diabetes were evaluated.

In both moments of evaluation, three questionnaires administered by the interviewer and/or selfadministered, duly validated for all pregnant women included in the study, were applied to measure quality of life, anxiety, and depression. The instruments were the Whoqol–Bref to assess quality of life, Beck Depression Inventory and Anxiety Inventory.

The WHOQOL BREF contains 26 questions comprising four fields: physical, psychological, social relationships and environment[16]. The Beck Depression Inventory, consisting of 21 items, each with four alternatives, with scores from 0 to 3, with 3 being the worst condition. The total score is the result of the sum of the individual scores of the items (maximum of 63 points) and allows the classification of depression intensity levels (10-18 points: mild; 19-29: moderate; ≥ 30: severe)[17]; the anxiety inventory – trait and state, composed of two scales to assess the anxious state and the anxious trait. Each is made up of 20 statements (each with a scale of 1 to 4 points). Thus, the total score of one of these two scales can range from 20 to 80 points; scores of 20-30 points indicate a low level of anxiety; 31-49 points, medium level and ≥ 50 points, high level of anxiety[18].

Data were collected from mothers for: type of vaginal delivery, blood glucose levels, maternal death, gestational age greater than or equal to 37 weeks of gestation until birth, time, and number of consultations during pregnancy. In addition, data from newborns were collected, such data referring to the care provided: clinical history with gestational age (weeks) at birth, Apgar score, birth weight, classification of gestational age at birth (term or preterm), classification of newborn weight by gestational age (adequate for gestational age=AGA, small for gestational age=SGA and large for gestational age=GIG), type of care (rooming, nursery and NICU) and perinatal death.

Sample size

The sample consisted of pregnant women who had pre-gestational diabetes and gestational diabetes during prenatal care. Pregnant women with pre-pregnancy and gestational diabetes were randomized into control and intervention. The sample size corresponded to the number of pregnant women with pre-gestational and gestational diabetes who were attended from March 2016 to December 2018. The population was 150 diabetic pregnant women attended during the period (the service serves about 50 diabetic patients per year); therefore 50 patients will be seen with face-to-face Reiki therapy, 50 with distance Reiki therapy and 50 without therapeutic intervention (control/placebo group).

Randomization

Randomization was performed using validated software accessible on the website www.randomization.com by Staepe/FMB. The confidentiality of the list was maintained through opaque envelopes so that the investigators responsible for the inclusion of patients had no way of predicting which group the patient was allocated to. The copy of this randomization is under the custody of Staepe of FMB/UNESP.

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Statistical methods

The data obtained will be entered into an Excel spreadsheet and submitted to statistical analysis. Initially, a descriptive analysis will be performed with the calculation of mean and standard deviation for quantitative variables and frequencies and percentages for variables categorized in general and stratified by group.

Comparisons of means will be made using ANOVA followed by Tukey's multiple comparison test for data that presented normal distribution. For data with skewed distribution, the comparison of means will be made by fitting a gamma distribution followed by Wald's multiple comparison test.

For count data, comparisons will be made using Poisson regression followed by Wald's multiple comparison test. The associations of categorized variables with groups will be made using the chi-square test. Data analysis of the questionnaires was performed using a repeated measures design evaluating the interaction groups versus moments using ANOVA followed by Tukey's multiple comparison test. In all tests, the significance level of 5% or the p-value was fixed. All analyzes will be done by the SAS for Windows, v.9.4 software.

Discussion

There are few works in the literature on Reiki in the field of obstetrics. The FMB Diabetes and Pregnancy Research Group conducted a systematic review of the effectiveness of Reiki in pregnant women to reduce pain during childbirth (cesarean section). In this review, only one study on the subject was found, which did not show strong evidence of the influence of Reiki in reducing pain during labor[19].

A study that aimed to assess how pregnant women diagnosed with diabetes understand and accept the use of integrative and complementary practices in health, especially Reiki, during prenatal care identified that pregnant women have knowledge of some integrative and complementary practices in health and that they would receive such therapies if they were available in the Unified Health System, but Reiki therapy proved to be unknown among patients. Thus, there is a need for a study to introduce integrative and complementary therapies in Brazilian public health, especially in the context of pregnant women[11].

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ARTIGO ORIGINAL II

Randomized Clinical Trial Development

Efeitos da prática do Reiki sobre a qualidade de vida de gestantes diabéticas: Ensaio Clínico Randomizado

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Resumo

Introdução: A medicina baseada em tratamentos energéticos, como o Reiki, está ganhando popularidade entre a população em geral. Essas práticas podem ser benéficas à saúde, assim como ser progressivamente adotadas no Sistema Único de Saúde brasileiro.

Objetivo: O objetivo deste estudo foi determinar se a terapia em Reiki presencial ou a distância impactam na melhora da qualidade de vida de mulheres grávidas com hiperglicemia na gravidez.

Métodos: Um ensaio clínico randomizado envolvendo 134 grávidas hiperglicêmicas e brasileiras [47 (grupo controle) e 44 (Reiki presencial) e 43 (Reiki a distância)], acompanhadas no Centro de Pesquisa em Diabetes Perinatal - faculdade de Medicina de Botucatu- UNESP, Brasil. A avaliação inicial (Momento 1) e após 7 sessões de terapia de Reiki presencial, à distância ou placebo (Momento 2) incluiu questionários de qualidade de vida, inventários de depressão de Beck e inventários de traço e estado de ansiedade, validados na língua portuguesa. Os dados obtidos foram submetidos à análise estatística por meio dos testes ANOVA, WALD, Tukey e Qui-quadrado. O ensaio foi registrado com o Número Internacional de Ensaios Clínicos Randomizados (ISRCTN), isrctn.com ISRCTN69018802; https://doi.org/10.1186/ISRCTN69018802.

Resultados: Tanto o Reiki presencial como a distância promoveram o mesmo efeito na qualidade de vida das participantes. Considerando a qualidade de vida, no Reiki presencial, os aspectos físicos aumentaram de 58,86 para 82 ($p=0.0012$), os aspectos psicológicos aumentaram de 69,5 para 84,75 ($p<0.0001$), os elementos sociais melhoraram de 70,83 para 87,17 ($p<0.0001$) e os fatores ambientais passaram de 67,69 para 83,75 ($p<0.0001$). Da mesma forma, o inventário de depressão de Beck (BDI) caiu de 10,06 para 6,72 ($p=0.0208$), assim como os inventários de ansiedade traço-estado, que caíram de 41,64 para 34 ($p<0.0001$) e 42,5 para 33,66 ($p<0.0001$), respectivamente. Portanto, os dados obtidos da terapia de Reiki a distância foi semelhante aos do Reiki presencial, enquanto o placebo não apresentou diferença entre os dois momentos. Além disso, os três grupos tiveram alto índice de consistência, mas sem diferença significativa nos dados clínicos maternos e perinatais .

Conclusão: O Reiki melhorou todos os aspectos de qualidade de vida e reduziu os níveis de depressão e ansiedade nas gestantes hiperglicêmicas.

Palavras-chave: Prática Reiki; gravidez, diabetes mellitus gestacional, práticas de saúde complementares e integrativas, pré-natal; qualidade de vida;

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

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Abstract

Background: 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 hyperglycaemia in pregnancy (HIP) with foetal compromise. However, randomized controlled trials comparing various Reiki strategies are required.

Objectives: 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 the burden of HIP diagnosis among women.

Methods: A randomized controlled experiment comprising 134 women with HIP diagnosed by pre-pregnancy Type 2 DM, fasting glycemia≥ 92 mg/dl in first trimester or 75g-OGTT between 24-28 gestational weeks was conducted at the Perinatal Diabetes Research Centre, University Hospital, Botucatu Medical School, UNESP, Brazil. The participants were randomized to Face-to-Face Reiki (47), Remote Reiki (43) or Sham-Reiki (47). Changes in 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. The obtained data were subjected to statistical analysis using ANOVA, WALD, Tukey´s and chi-square tests. The trial was registered with International Standard Randomised Controlled Trial Number (ISRCTN), isrctn.com ISRCTN69018802; https://doi.org/10.1186/ISRCTN69018802.

Results: There were no significant differences between control and intervention groups in baseline characteristics. Face-to-face and Remote Reiki therapy had same effect on participants' quality of life. For Face-to-Face Reiki, the physical aspects significantly increased from 58.86 to 82 ($p=0.0012$), psychological aspects rose from 69.5 to 84.75 ($p<0.0001$), social elements improved from 70.83 to 87.17 ($p<0.0001$) and environmental factors enhanced from 67.69 to 83.75 ($p<0.0001$). Similarly, Beck's depression inventory (BDI) was significantly affected by Face-to-Face Reiki; although, it declined from 10.06 to 6.72 ($p=0.0208$), as did the state-trait anxiety inventories, which dropped from 41.64 to 34 ($p<0.0001$) and 42.5 to 33.66 ($p<0.0001$), respectively. Moreover, the outcomes related to Remote Reiki presented similar results as the Face-to-Face, while Sham Reiki did not present any significant difference between baseline and after Reiki application. Besides that, the three groups provided us with a high level of consistency, according to baseline traits.

Conclusion: Reiki improved all aspects of the World Health Organization Quality-of-Life questionnaire, as well as lowered depression and anxiety in Beck's inventories in HIP women.

Keywords: Reiki, therapeutic touch, pregnancy, gestational diabetes mellitus, complementary alternative medicine, antenatal care

Introduction

Hyperglycaemia in pregnancy (HIP) is a major public health concern in low- and middle-income countries, with serious short- and long-term health implications for both the mother and her child. HIP is linked to an increased risk of maternal and newborn issues. The risk of acquiring type 2 diabetes in the next 10-12 years after birth is the most severe maternal complication[1,2,3,4]. Besides foetal macrosomia that increases the risk of birth trauma and intrapartum hypoxia/asphyxia, high rates of Caesarean section, delayed pulmonary maturation, which increases the risk of respiratory distress syndrome, and metabolic disorders at birth, such as hypoglycaemia, hypocalcaemia, and hypomagnesemia are all perinatal complications[1,2,3,4]. All these issues impair the newborn prognosis and raise the risk of perinatal death.

When a pregnant woman receives a hyperglycaemia diagnosis during pregnancy, the clinical staff does so in an objective and accurate manner, which throws her off balance because she has gone from the happiest moment of her life to a challenging reality that can affect her health and that of her child, as well as being warned of all the potential dangers she may face[5,6,7,8].

As a result, a multidisciplinary team of health care providers, such as a physician, dietitians, psychologists, nurses, physical therapists, physical educators, and other health care practitioners, is necessary to address this public health concern and ensure the pregnant women' well-being.

The perinatal outcome is closely connected to maternal metabolic management, regardless of whether the mother has diabetes or mild hyperglycaemia[1,2,3,4]. Perinatal complications are caused by maternal hyperglycaemia. Diabetes control is managed with an exclusive diet or an insulin-assisted diet, with the goal of successfully normalizing blood glucose and preventing poor perinatal outcomes[1,2,3,4]. Inadequate glycaemic management, defined as a glycaemic mean above 130 mg/dl in the third trimester, was associated with 52.4 percent macrosomia, 14.3 percent foetal mortality, and 8.2 percent abnormalities in pregnant women[1,2,3,4]. Maternal and perinatal outcomes in hyperglycaemic pregnant women have improved in recent decades, and this has been linked to achieving maternal euglycemia.

The Perinatal Diabetes Research Centre/ Clinical Hospital of Botucatu Medical School (PDRC/HC FMB) is a tertiary centre that was established in the 1980s to meet health care demands with numerous social and financial benefits, such as outpatient monitoring of pregnant women with diabetes during pregnancy.

Therefore, HIP patients are benefited from short and frequent hospitalizations, as maternal hyperglycaemia levels and the necessity for insulin dosage adjustments are investigated in depth[6,7]. This sort of rigorous insulin management for hyperglycaemic pregnant women can protect the maternal pancreatic beta cell from exhaustion and minimize the risk of type 2 diabetes later in life[1,2,3,4]. Currently, the HIP therapy model is foetal-centric, ignoring maternal psychological disorders, such as anxiety and depression that may impair the women's overall well-being[9,10].

Given the reality shock that a pregnant woman experiences after receiving a diabetes diagnosis, complementary and alternative medicine (CAM) could be used to supplement medical therapy and enhance quality of life. Meditations, acupuncture, yoga, Ayurveda, Reiki, and Anthroposophy are just a few of the integrative and complementary techniques available[11,12].

The global population is currently on the lookout for new kinds of health care that are more natural and less intrusive. As a result of this, integrative and complementary health approaches have been gaining more and more attraction throughout the world, thanks to the humanized and holistic perspective, as well as respect for each person's routines and rhythms. People's energy balance is the goal of these therapies, which can be easily integrated with allopathic medicine[11,12].

Since the publication of the Brazilian National Health Policy for Integrative and Complementary Practices (NPICP) in 2006, we may note significant accomplishments and obstacles in the process of integrating integrative practices in the Brazilian Health System, henceforth referred to as SUS[10]. Along the way, we can see a growth in the supply of these practices, particularly in Primary Health Care (PHC), with 29 different practices[13-18], as well as rising public support and an increase in the number of scientific publications on the issue. In terms of difficulties, we must be aware how these practices and qualified practitioners are been trained and working to integrate in the SUS, especially Reiki[13-19].

Reiki is becoming more popular as an integrative and alternative health approach for promoting body, mind, and spirit harmony[11,12]. Reiki is a hand-laying method with the goal of promoting energy balance in the body, mind, and spirit via the use of mantras and yantras[19,20]. Reiki reappeared in the mid-19th century and the practitioners believe that the therapist canalizes the energy of the cosmos with the hands on the body and sends it to the body of the person receiving treatment, refilling the energy of the person which gathers physical, emotional, mental, and spiritual benefits[11,12,19,20].

"Rei" and the "Ki" are Japanese syllables, which denote "spirit" and "energy", i.e., the life force of the universe. Reiki is an energy-based method of healing that can be used in every living being. Usui was a Japanese university lecturer from the nineteenth century, who revived and documented this historic energy-based treatment since it was previously cited about 620 BC in some East nations[19]. Master Mikao Usui therefore travelled for more than 10 years to the United States, India, and Tibet to rekindle the ancient Reiki[19,20]. Usui began researching the Reiki symbols of spiritual masters utilizing the Buddhistic practice known as *Isyu guo*, which involves 21 days of meditations, fasting, prayers and songs[19]. In the year 1926, Mikao Usui died. However, he has documented all his studies and has trained a large number of Reiki therapists how to practice and promote this energy-based field of healing[11,12,19,20].

Reiki does not have negative energy, does not have side effects or religious connotations, can be practiced in any setting and the patient may be in any position[19,20]. It is reasonable to state that Reiki is an inclusive energy-based healing method centred on the Eastern therapeutic practices. Patients are, therefore, the centre of the treatments, not illnesses, which indicates anything that is out of balance and that it must be restored to its normal state. Reiki Practitioners work as energy channels to re-balance the cosmic energy into the patient's body. This therapeutic method is not intended to replace Western-based medicine; rather, it is intended to integrate the requirements of a community seeking alternatives to pharmacological approaches. Therefore, Reiki will help the patient while also integrating the allopathic treatment[11,12,19,20].

The laying on of hands technique, which includes placing your hands on a patient and activating the Universe's energy to bring the patient back into balance, will be used by the Reiki therapist[19]. The procedure of laying on of hands might be applied to the head, thoracic area, or abdomen. There is no such thing as a predetermined period for energy therapy; nevertheless, the amount of time necessary varies from patient to patient[11,12,19,20]. Reiki therapy may, however, also be used from a distance, that is, when practitioners envision and transfer energies to persons, no difference in the fundamentals of Reiki is stated between locally or remotely treatments[11,12,19,20].

A randomized clinical trial (RCT) must be established to incorporate science in this setting. RCT is the most rigorous and robust research approach for evaluating if there is a cause–effect relationship between an intervention and an outcome[21]. RCTs are seen to be at the summit of the evidentiary pyramid. When possible, it is suggested that clinical practice decisions be based on data from well-conducted RCTs[22].

Before proposing a randomized clinical trial, the lead author and some of the other authors performed a systematic review of the literature using a meta-analysis to see if there were any studies involving Reiki and hyperglycaemic pregnant women, but only studies involving pregnant women and evaluating pain or type of delivery after Reiki therapy were found and included[23,26,27]. The same authors then decided to undertake a qualitative and educational study at the PDRC to explore pregnant women's understanding and acceptance of such therapeutic practice[24]. Leading questions were asked, and the Reiki therapy was thoroughly explored, to determine whether the women would accept being treated with it during pregnancy[24].

Since there have only been a few Reiki studies in the field of obstetrics, mostly on the usefulness of Reiki in pregnant women to alleviate discomfort during labour, and to also assess the type of delivery, which was added to the systematic review conducted by the lead author and the research group[26,27]. Moreover, this review did not offer significant evidence of Reiki's effectiveness in decreasing discomfort during childbirth as well as no changes in the delivery type[23,26,27]. Furthermore, the researches advised that further randomized controlled trials must be conducted[25].

Simultaneously, we must regard CAMs as comprehensive health systems within their principles and fundamentals, which differs from the reductionist perspective of Western health practices in that it sees the entire health problem rather than a single aspect of it[27]. Thus, to unite both Traditional Chinese Medicine's ancient knowledge of health practices and Western practices, we chose to use quality of life as an outcome tool, as it goes beyond reductionist knowledge and finds a holistic point of view, i.e.., respecting both Reiki within its principles, as well as the integration with Western assessment practices by using a randomized controlled trial, which is thought to be the optimum design for assessing the efficacy of a novel treatment. Because of the benefits of randomization, it is widely thought to decrease unintended bias, such as selection bias, and to provide a framework for applying probability theory.

The purpose of this study was to use an RCT to determine whether the therapeutic modality of laying on of hands (Reiki) could improve quality of life while also lowering depression and anxiety levels in hyperglycaemic pregnant women, as well as to calculate the sample size power for comparing depression and anxiety scores (state and trait) between the three study groups (Sham Reiki, Remote Reiki and Face-to-Face Reiki).

Methods

Study design, Subject recruitment, and Randomization

The researchers followed the CONSORT guidelines and conducted a randomized clinical trial. All pregnant women with pre-gestational and gestational diabetes who were monitored at the prenatal care clinic of the Perinatal Diabetes Research Centre/ Clinical Hospital of Botucatu Medical School (PDRC/HC FMB) and volunteered to participate in the trial, as well as deliveries at the University Hospital, were included and randomized to one of three groups in this study from 2016 to 2018.

In a single-blind study, a researcher from study group drew up a randomization list before the trial began, which was stratified. Patients were, therefore, allocated at random by the chief nurse into one of the three groups Sham, Face-to-Face or Remote Reiki at PDRC/HC FMB. 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. Thus, 150 diabetic pregnant women were then randomly assigned to one of three groups based on the sequence in which they were enrolled in the procedure (Figure 1).

Of the 150 patients assessed for eligibility, one was excluded because she refused to participate (n = 01) (Figure 1). 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 group allocation was done via a sealed envelope, thus the investigators in charge of patient inclusion had no means of knowing which group the patient was assigned to39,40. EAP has maintained a duplicate of this randomization. The trial was registered with International Standard Randomised Controlled Trial Number (ISRCTN), isrctn.com ISRCTN69018802; https://doi.org/10.1186/ISRCTN69018802.

The study complied with the Declaration of Helsinki. The ethical features of the National Health Council's Resolution No. 466/12 were retained. This research protocol was approved by the Institutional Research Bureau of Botucatu Medical School, UNESP, under the number CAAE 52734216.1.0000.5411, with the opinions 1,440,349 (version 1, March 7, 2016) and 2,888,954 (version 2, September 12, 2018). A written informed consent was obtained from all pregnant women before data collection.

Eligibility criteria for participants

A team of obstetricians specializing in high-risk pregnancies, residents, dietitians, nurses, and neonatologists accompanied the pregnant women in the research. Fasting glucose 92 mg/dl and/or a risk factor were deemed positive screening for Gestational Diabetes Mellitus (GDM), with the diagnosis made by the 75g oral glucose tolerance test (GTT) and glycaemic profile (GP)[1,2,3,4,29]. From March 2016 to December 2018, all pregnant women with DM, gestational or pre-pregnancy, who visited PDRC/ HCFMB UNESP were, therefore, approached and invited to this study.

Study settings

The study was conducted at the Perinatal Diabetes Research Centre/ Clinical Hospital of Botucatu Medical School (PDRC/HC FMB UNESP). In the 1980s, the PDRC was established with funding from the Brazilian Health System (SUS), Ministry of Brazilian Public Health (MS) and the São Paulo Research Foundation (FAPESP). PDRC provides support to high-risk pregnant women with hyperglycaemia (pre-gestational and gestational diabetes) and mild hyperglycaemia, including diagnosis, treatment, pre- pregnancy, and post-natal monitoring.

Interventions

Between March 2016 and December 2018, hyperglycaemic pregnant women who were diagnosed before pregnancy or who had gestational diabetes and agreed to participate in this study had seven sessions of Face-to-Face, Remote or Sham Reiki.

After diabetes diagnosis, all groups received the same medical and nursing therapy. Thus, the Face-to-Face intervention group had 7 sessions throughout prenatal care. The lead author 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 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.

Based on literature, the research team proposed a Reiki protocol that concentrated the Reiki session on the body's seven major chakras, remaining in each for around 3-5 minutes[11,12,19,20]. The symbols employed in this approach were 'Dai Ko Myo', 'Hon Sha Ze Sho Nen', 'Sei He Ki', and 'Cho Ku Rei', they were mentally pictured and intonated three times in this sequence[11,12,19,20]. The same symbols and length of time were used in Remote Reiki group. By using the patient's enrolment data, the Reiki practitioner projected the symbols to this group from his mind for around 30 minutes on the same day they returned to the outpatient clinic for their following appointment.

Outcomes

During the trial, participants were assessed twice, as follows: baseline that corresponded to the initial prenatal appointment for pregnant women with type 1 diabetes (DM1) and type 2 diabetes (DM2), or the medical diagnosis of Gestational Diabetes Mellitus (GDM); and after 7 Reiki sessions that was prior to delivery hospitalization, when all hyperglycaemic pregnant women who were involved were last evaluated for this study group.

Study Outcomes

The major goal was to evaluate the effect of Sham Reiki versus Face-to-Face or Remote Reiki on quality of life, depression, and anxiety levels in HIP pregnant women in the third trimester of pregnancy at PRDC, UNESP, Brazil.

The secondary goal was to evaluate the effect of Reiki intervention on gestational glycaemic means derived from all glycaemic profiles taken throughout pregnancy using the PDRC protocol[29].

Measures

The investigation took the form of a diagnostic survey employing questionnaires. The World Health Organization Quality of Life-Test Bref (WHOQOL-BREF), Beck Depression Inventory, Beck Anxiety trait and state inventory, and a standardized interview questionnaire

were used to collect sociodemographic information from all HIP pregnant women. HIP was diagnosed in accordance with the most recent IADPSG, WHO, and ADA standards[30,31,32].

HIP Diagnosis

Maternal clinical history was used to diagnose type 2 diabetes. Gestational Diabetes Mellitus (GDM) was diagnosed using IADPSG criteria and a glycaemic profile in the first trimester with fasting glycemia ranging from 92mg/dl to 126mg/dl or at 24–28 GW with a single 2-h 75-g oral glucose tolerance test[29]. The women were treated at the PDRC in accordance with local recommendations[29]. As previously stated, nutritional recommendations, lifestyle treatments, and, if necessary, insulin are used to manage maternal hyperglycaemia[29]. These guidelines applied to all HIP women's organizations, regardless of whether they practiced Reiki or Sham Reiki. The insulin dosage was changed weekly based on the glycaemic profile. The gestational glycaemic means for each patient were calculated using the findings of all glycaemic profiles.

Quality of Life, Beck Depression Inventory and Beck State-Trait Anxiety Survey

Furthermore, three questionnaires adequately validated in Portuguese. were administered to all pregnant women involved in the research at both application time (baseline and after 7 Reiki sessions), besides each questionnaire application day lasted about 20 minutes.

(i) Quality of life evaluation using World Health Organization Quality-of-life (WHOQOL) questionnaire. WHOQOL–Bref is a condensed version of the Whoqol-100, including only 26 items with the best psychometric results[26]. As a result, there are just four fields in this condensed version: physical, psychological, social, and environmental factors all have a role in a person's overall health; thus, the higher the questionnaire outcome the better the quality of life[33].

(ii) Beck Depression Inventory, consisting of 21 items, each with four alternatives, with scores from 0 to 3, with 3 being the worst condition. The total score is the result of the sum of the individual scores of the items (maximum of 63 points) and allows the classification of depression intensity levels (10-18 points: mild; 19-29: moderate; ≥ 30: severe)[34,35,36].

(iii) Beck Anxiety trait and state inventory, which consists of two measures to assess the anxious state and trait. Each one is made up of 20 statements (each with a scale of 1 to 4 points). Thus, the total score on one of these two scales can vary from 20 to 80 points; scores

of 20-30 points indicate a moderate degree of worry, 31-49 points indicate a medium level of anxiety, and 50 points indicate a high level of anxiety[37,38].

Maternal and newborn outcomes

At baseline, the pregnant women's sociodemographic data were collected using a standardized interview form. Scholarity, marital status, having or wanting more children, employment status, partner loss, health status, health concerns, health care treatment, usage of insulin, diabetes classification and time of diagnosis were all obtained.

The following data was also collected: type of vaginal delivery, blood glucose levels, maternal mortality, gestational age more than or equal to 37 weeks till birth, and number of consultations during pregnancy and hospital discharge were all gathered from Institutional Medical Record. In addition, data from newborns was collected, including clinical history, gestational age (weeks) at birth, Apgar score, birth weight, newborn weight and length/ gestational age classification, that is, appropriate for gestational age (AGA), small for gestational age (SGA), and large for gestational age (LGA).

Sample size

All pregnant women who received prenatal care at PDRC were approached, invited, and enrolled in the study. Previously, all participants had a diagnosis of pre-gestational diabetes or gestational diabetes and, therefore, randomized into Face-to-Face, Remote, or Sham Reiki; consequently, the placebo/control and intervention groups were formed.

The sample size corresponded to the number of pregnant women with pre-gestational and gestational diabetes who were attended from March 2016 to December 2018. During the study, 150 diabetic pregnant women were seen (the service sees about 50 diabetic patients per year). Therefore, 50 patients were enrolled to Face-to-Face Reiki treatment, 50 patients to Remote Reiki therapy, and 50 patients to Sham Reiki. They were assessed throughout this study with questionnaires and medical data collection. However, there was a drop in follow-up since some of the women did not give birth at this hospital, limiting access to additional data on maternal and perinatal outcomes; thus, the 134 women who remained were from 47 for Sham Reiki, 43 for Remote Reiki, and 44 for Face-to-Face Reiki.

Statistical methods

A person blinded to the Reiki allocation of participants entered the data into an Excel spreadsheet and statistical analysis was performed on it. Also, a biostatistician blinded to the Reiki allocation of participants performed the statistical analyses. The mean and standard deviation for quantitative variables, as well as frequencies and percentages for variables classified in general and stratified by group, were calculated initially in a descriptive analysis.

For data with a normal distribution, mean comparisons were conducted using ANOVA, followed by Tukey's multiple comparison test. The means were compared using a gamma distribution and Wald's multiple comparison test for data having an asymmetric distribution. Poisson regression was used to compare count data, followed by Wald's multiple comparison tests.

The chi-square test was used to determine the relationships between classified variables and groups. The questionnaire data was analysed using a repeated measures method, with ANOVA and Tukey's multiple comparison test used to evaluate the interaction groups vs moments.

For sample size power, the method of comparing the mean between groups involves setting the level of significance (or alpha error type I) at 5% and utilizing the mean, standard deviation, and group size numbers from the current sample to compute the sample's power, according to Hulley et al. (2007). The sample size was then estimated to provide a 80% power and a 5% threshold of significance (or alpha error type I). The following computer program was used for statistical analysis: version 9.2 of the SAS System for Windows (Statistical Analysis System). SAS Institute Inc, Cary, NC, USA, 2002-2008.

Results

The overall design and subject flow through the study is illustrated in Fig. 1. A total of 150 patients were randomized in the study and 134 patients were included in the final analysis due to a lack of follow-up. A total of 134 HIP women were included and randomly assigned to one of the three Reiki treatment groups Sham Reiki (SR), Remote Reiki (RR), and Face-to-Face Reiki (FtFR).

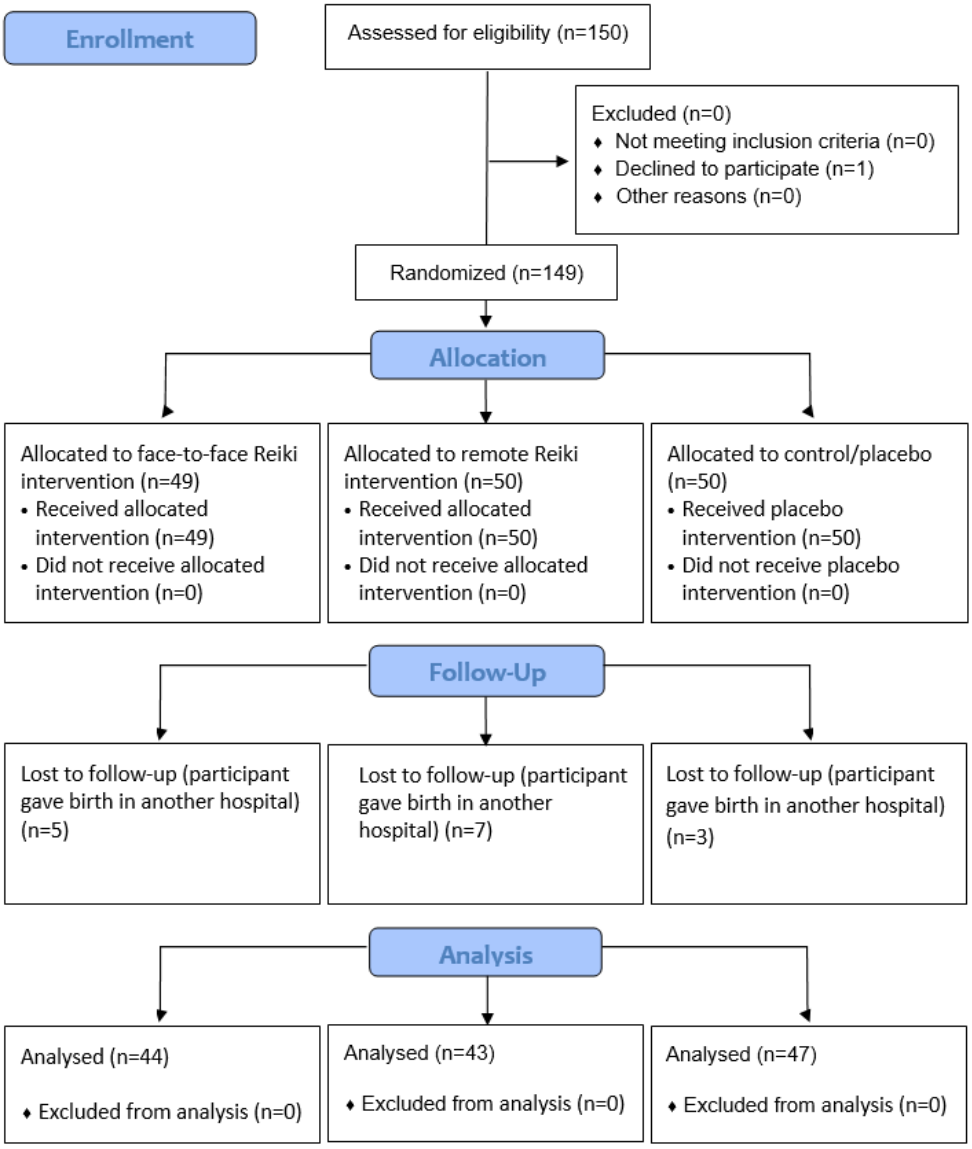

Figure 1. Consort flowchart of inclusion of diabetic pregnant women

There were no significant differences in the baseline characteristics among the three groups, as shown in Table 1. Furthermore, there was no difference between participants in the sociodemographic profile and clinical variables at baseline in Sham Reiki (SR), Remote Reiki (RR), and Face-to-Face Reiki (FtFR). It should be noted that 16 patients did not complete the trial because the deliveries were outside the University Maternity Hospital, where this study was carried out due to family issues and long travel distance to the hospital.

Most patients in the three groups met the following profile: they had finished high school, were married, had children prior to this pregnancy, and did not want any more children. The researcher administrators completed nearly all the surveys, and none of the patients lost their

partners (Table 1).

It was discovered that most patients in the three groups fit the following profile: they claim to be in excellent health, are in outpatient care, do not take insulin, and have GDM. All the patients in this research had diabetes and were pregnant, and practically all of them got outpatient treatment. It is also worth mentioning that the majority had a Caesarean section and that the postpartum mother and infant hospital discharge were shortly after birth (Table 1).

Table 1. Demographic and medical variables of diabetic pregnant women at baseline randomized to the Sham Reiki (SR), Remote Reiki (RR) and Face-to-Face Reiki (FtFR).

Variables	Categories	Group						Total	p-value
		SR	%	RR	%	FtFR	%		
Scholarity	Illiterate	0	0.00	2	4.65	2	4.55	4	0.5649
	Complete_Primary and lower secondary education	2	4.26	2	4.65	0	0.00	4	
	Unfinsihed_Primary and lower secondary education	3	6.38	5	11.63	5	11.36	13	
	Complete_Upper Secondary School	19	40.43	17	39.53	19	43.18	55	
	Unfinsihed_Upper Secondary School	16	34.04	7	16.28	10	22.73	33	
	Complete_Higher Education	6	12.77	5	11.63	5	11.36	16	
	Unfinsihed_Higher Education	1	2.13	2	4.65	1	2.27	4	
	Complete_Postgraduation	0	0.00	3	6.98	1	2.27	4	
	UnfinsihedPostgraduation	0	0.00	0	0.00	1	2.27	1	
	Total	47		43		44		134	
Marital status	Married	28	59.57	29	67.44	29	65.91	86	0.1726
	Divorced	1	2.13	0	0.00	1	2.27	2	
	Single	3	6.38	1	2.33	7	15.91	11	
	Living together	15	31.91	13	30.23	7	15.91	35	
	Total	47		43		44		134	
Questionnaires' administration method	Administered by the interviewer	42	89.36	37	86.05	42	95.45	121	0.0705
	Assisted by interviewer	5	10.64	2	4.65	1	2.27	8	
	Self-administered	0	0.00	4	9.30	1	2.27	5	
	Total	47		43		44		134	
Children before diabetes?	No	13	27.66	17	39.53	17	38.64	47	0.4157
	Yes	34	72.34	26	60.47	27	61.36	87	
	Total	47		43		44		134	
Do you want to have more children?	No	40	85.11	33	76.74	34	77.27	107	0.5362
	Yes	7	14.89	10	23.26	10	22.73	27	
	Total	47		43		44		134	
Employed?	No	24	51.06	20	46.51	22	50.00	66	0.9045
	Yes	23	48.94	23	53.49	22	50.00	68	
	Total	47		43		44		134	
Loss of partner after illness?	No	47	100.0	43	100.0	44	100.0	134	
	Total	47		43		44		134	
How is your health?	Good	24	51.06	24	55.81	20	45.45	68	0.4203
	Bad	3	6.38	2	4.65	1	2.27	6	
	Very good	0	0.00	4	9.30	3	6.82	7	
	Very bad	4	8.51	1	2.33	2	4.55	7	
	Neither bad nor good	16	34.04	12	27.91	18	40.91	46	
	Total	47		43		44		134	
1st Health issue	Diabetes	47	100.00	43	100.00	44	100.00	134	
	Total	47		43		44		134	

2nd Health issue	Pregnancy	47	100.00	43	100.00	44	100.00	134	
	Total	47		43		44		134	
3rd Health issue	No Health Issue	28	60.87	25	58.14	29	65.91	82	0.4914
	Bronchitis or emphysema	0	0.00	0	0.00	1	2.27	1	
	Bronchitis and emphysema	1	2.17	0	0.00	0	0.00	1	
	High blood pressure	13	28.26	15	34.88	10	22.73	38	
	High Blood Pressure and uterine myoma	1	2.17	0	0.00	0	0.00	1	
	Heart condition and high blood pressure	0	0.00	0	0.00	1	2.27	1	
	Kidney disease	0	0.00	1	2.33	0	0.00	1	
	Syphilis and low blood pressure	1	2.17	0	0.00	0	0.00	1	
	Obsessive-compulsive disorder	0	0.00	1	2.33	0	0.00	1	
	High cholesterol levels	1	2.17	0	0.00	0	0.00	1	
	Sinusitis	0	0.00	0	0.00	1	2.27	1	
	Thyroid disease	1	2.17	1	2.33	2	4.55	4	
	Total	46		43		44		133	
	Frequency Missing = 1								
Healthcare regime	Outpatient	43	91.49	39	90.70	43	97.73	125	0.3522
	Without treatment	4	8.51	4	9.30	1	2.27	9	
	Total	47		43		44		134	
Insulin-dependent?	No	35	74.47	29	67.44	29	65.91	93	0.6381
	Yes	12	25.53	14	32.56	15	34.09	41	
	Total	47		43		44		134	
Diabetes classification	1	2	4.26	1	2.33	6	13.64	9	0.2578
	2	9	19.15	9	20.93	9	20.45	27	
	Gestational	36	76.60	33	76.74	29	65.91	98	
	Total	47		43		44		134	
Timing of GDM diagnosis	Pre-diabetes	12	25.53	10	23.26	14	31.82	5	0.645
	Gestational	35	74.47	33	76.74	30	68.18	1	
	Total	47		43		44		1	
Type of delivery	Caesarea	25	53.19	26	60.47	26	59.09	46	0.7569
	Vaginal	22	46.81	17	39.53	18	40.91	31	
	Total	47		43		44		2	
Hospital discharge	Discharge after surgery	1	2.13	0	0.00	0	0.00	1	0.5925
	Discharge with expected return for patient follow-up	2	4.26	1	2.33	0	0.00	3	
	Discharge cured	0	0.00	1	2.33	0	0.00	1	
	Postpartum mother discharge and newborn permanence	12	25.53	10	23.26	9	20.45	31	
	Postpartum mother and newborn discharge	32	68.09	31	72.09	34	77.27	97	
	Improved discharged	0	0.00	0	0.00	1	2.27	1	
	Total	47		43		44		134	
Newborn weight/ gestational age classification	Adequate (AGA)	33	73.33	32	74.42	34	77.27	99	0.61
	Large (LGA)	5	11.11	4	9.30	7	15.91	17	
	Small (SGA)	7	15.56	7	16.28	3	6.82	17	
	Total	45		43		44		133	

Table 2 depicts a comparative analysis of maternal and perinatal outcomes from 134 participants in this study; however, all means were equal in all groups (Sham, Remote, and Face-to-Face Reiki), that is, the means on age group, age of onset of diabetes, gestational age at delivery, length of hospital stay, number of medical appointments, glycemic profile, as well as perinatal data such as newborn weight and length, Apgar score at 1 and 5 minutes. As a result, we may conclude that there was no difference between groups in any of these outcomes. This fact is significant in demonstrating the clinical trial's homogeneity (Tables 1 and 2). As previously stated, 16 patients were lost to follow-up because they were born at a location other than the one where this study was conducted.

Furthermore, the pregnant women in the Face-to-Face group had a mean age of 31 years old, whereas the mean age of diabetes diagnosis was 27 years old; additionally, the pregnant women were hospitalized for about 116.70 hours and had a gestational age of 38 weeks (Table 2). In terms of newborns, the average weight was 3,579 kg, the average length was 48.59 cm, and Apgar scores varied from 1 to 5, corresponding to 8.05 to 9.13 (Table 2). Furthermore, according to the standard classification, the measures given were adequate for the gestational age. The other groups had comparable results (Table 2).

Table 2. Comparative analysis of maternal and perinatal outcomes from the Institution Medical Data at baseline of the clinical trial until delivery.

Label	Group						p-value
	SR		RR		FtFr		
	Mean	SD	Mean	SD	Mean	SD	
Age*	30.19	6.64	30.91	6.55	31.07	5.67	0.7742
Age of onset of diabetes*	28.96	7.37	28.63	7.15	27.05	9.24	0.4732
Weeks of pregnancy*	37.86	1.36	37.88	1.94	37.98	2.13	0.9958
Newborn weight*	3486.71	936.88	3280.26	637.77	3379.49	701.73	0.4828
Newborn length*	48.85	2.17	48.14	2.54	48.59	2.96	0.4601
APGAR at 1 minute*	8.05	1.58	8.29	1.15	8.05	1.72	0.6915
APGAR at 5 minutes*	9.00	0.79	9.22	0.72	9.13	0.88	0.4441
Length of hospital stay*	100.98	46.59	94.77	44.78	116.70	78.43	0.1188
Number of medical appointaments*	32.36	8.72	31.77	11.26	32.84	12.53	0.6777
Glycaemic profile*	101.69	19.58	100.66	32.08	100.92	31.31	0.783

*Not significant.

Regarding the main outcome of the study, the interaction between groups and the moments in Table 3 shows statistical significance on participants' quality of life. For Face-to-Face Reiki, the physical aspects significantly increased from 58.86 to 82 ($p=0.0012$), psychological aspects rose from 69.5 to 84.75 ($p<0.0001$), social elements improved from 70.83 to 87.17 ($p<0.0001$) and environmental factors enhanced from 67.69 to 83.75 ($p<0.0001$).

Similarly, Beck's depression inventory (BDI) was significantly affected by Face-to-Face Reiki, since it declined from 10.06 to 6.72 ($p=0.0208$), as did the state-trait anxiety inventories, which dropped from 41.64 to 34 ($p<0.0001$) and 42.5 to 33.66 ($p<0.0001$), respectively.

Moreover, the outcomes related to Remote Reiki presented similar results as the Face-to-Face, that is, the physical aspects significantly increased from 60.42 to 69.44 ($p=0.0012$), psychological aspects rose from 72.96 to 81.46 ($p<0.0001$), social elements improved from 68.03 to 80.1 ($p<0.0001$) and environmental factors enhanced from 68.05 to 78.44 ($p<0.0001$). Similarly, Beck's depression inventory (BDI) was significantly affected by Face-to-Face Reiki, since it declined from 9.12 to 7.37 ($p=0.0208$), as did the state-trait anxiety inventories, which dropped from 41 to 35.14 ($p<0.0001$) and 40.47 to 35.86 ($p<0.0001$), respectively. However, all evaluated variables did not present any significant change regarding to Sham Reiki.

Based on the findings, it is feasible to confirm a substantial improvement in the four areas of the WHOQOL-BREF questionnaire in both Remote and Face-to-Face Reiki treatments. When the physical realm was examined, no differences between the groups were discovered at baseline. On the other hand, the physical domain ratings of the patients in the Remote and Face-to-Face Reiki groups increased significantly after 7 Reiki sessions. Data from the psychological, social, and environmental domains exhibited a similar pattern. These findings reveal and imply that pregnant women who got Reiki therapy, either Face-to-Face or Remote, had a better quality of life.

For WHOQUOL-Bref, Beck Depression Inventory and Beck State-Trait Anxiety inventories, Sham Reiki did not differ at times, while Remote and Face-to-Face Reiki differed at times; besides that, Sham Reiki differed from both Reiki groups after 7 Reiki sessions. Anxiety levels fell in both Reiki therapy methods, once the score attributes in the Beck inventory dropped after 7 Reiki Therapy, whereas Sham Reiki had no difference between baseline and after the simulation time. This decrease in anxiety and depression levels backs up the results of the previous survey on psychological domains of their WHOQOL_Bref improvement.

These data show and indicate that pregnant women who received Reiki therapy, whether Face-to-Face or Remote, experienced less depression and anxiety. Glycemic means, on the other hand, indicated no significant variations across times and groups, as expected given that the Hospital practices fulfilled these criteria, i.e., from 109.12 to 94.09 Sham Reiki, 11.33 to 88.86 Remote Reiki, and 108.96 to 91.81 Face-to-Face Reiki ($p=0.4986$).

Table 3. Outcomes of three study groups at baseline and after seven sessions by evaluating interaction group versus moments in Face-to-Face, Remote and Sham Reiki regarding to the trait scores of WHOQOL-Bref questionnaire, Beck depression Inventory, Beck trait-state surveys and Glycemic Means.

Survey Variables		Application Time	Group						p-value
			Sham Reiki		Remote Reiki		Face-to-face Reiki		
			Mean	SD	Mean	SD	Mean	SD	
WHOQOL-Bref	Physical	Baseline	60.08aA	19.28	60.42aA	19.64	58.86aA	21.96	0.0012
		After 7 Reiki sessions	60.22aA	19.11	69.44bB	20.83	72bB	21.35	
	Psychological	Baseline	65.23aA	17.35	72.96bA	14.11	69.5abA	19.42	<0.0001
		After 7 Reiki sessions	65.23aA	17.12	81.46bB	16.99	84.75bB	17.24	
	Social	Baseline	69.93aA	17.25	68.03aA	18.82	70.83aA	21.77	<0.0001
		After 7 Reiki sessions	69.93aA	19.80	80.1bB	22.94	87.17bB	19.72	
	Environmental	Baseline	61.5aA	17.73	68.05aA	16.94	67.69aA	18.89	<0.0001
		After 7 Reiki sessions	63.3aA	19.10	78.44bB	21.63	83.75bB	18.59	
Beck Depression Inventory		Baseline	11.14aA	7.44	9.12aA	7.53	10.06aA	9.82	0.0208
		After 7 Reiki sessions	10.73aA	7.51	7.37bB	7.57	6.72bB	8.03	
Beck State of Anxiety		Baseline	44.37aA	11.07	41aA	10.55	41.64aA	11.17	<0.0001
		After 7 Reiki sessions	45.39aA	12.18	35.14bB	12.18	34.4bB	11.44	
Beck Trait of Anxiety		Baseline	45.41aA	11.73	40.47bA	11.58	42.5abA	11.25	<0.0001
		After 7 Reiki sessions	47.12aA	12.20	35.86bB	12.59	33.66bB	10.34	
Glycemic Means		Baseline	109.12aA	21.75	111.33aA	40.34	108.96aA	39.73	0.4986
		After 7 Reiki sessions	94.09aB	13.57	88.86aB	11.04	91.81aB	12.94	

Tukey's test finds no difference between means preceded by the same lowercase letter (fixing moments) at the 5% level. Tukey's test shows that means preceded by the same capital letter (fixed groups) do not vary at the 5% level.

Table 4 shows the sample power calculations for comparing the mean of state and trait depression and anxiety ratings between the three study groups (Sham Reiki, Remote Reiki, and Face-to-Face Reiki) using estimates from the current sample, with the threshold of significance set at 5%. The depression score had a power of 68.2 %, the state anxiety score had a power of 99.2 %, and the trait anxiety score had a power of 99.9 %. A sample of n=60 patients per group was estimated for a power of 80% for the depression score.

Table 4. Results of the sample power calculation for comparing the mean of depression and anxiety state and trait scores between the three study groups (Sham Reiki, Remote Reiki, and Face-to-Face Reiki), according to data from the current sample.

Variable	Sham Reiki	Remote Reiki	Face-to-face Reiki	Sample size power	Sample size per group (n)*	Total sample size (n)
Depression (BDI)	M=10.73, DP=7.51	M=7.37, DP=7.57	M=6.72, DP=8.03	0.682	60	180
Anxiety -Trait (BSA)	M=45.39, DP=12.18	M=35.14, DP=12.18	M=34.40, DP=11.44	0.992	20	60
Anxiety – State (BTA)	M=47.12, DP=12.20	M=35.86, DP=12.59	M=33.66, DP=10.34	0.999	13	39

*Sample power was calculated using the mean (M) and standard deviation (SD) values in each group, with the level of significance alpha set at 5% (type I error), and the sample size (n=47 Sham Reiki, n=43 Remote Reiki, and n=44 Face-to-Face Reiki). Sample size was calculated using an 80 % power level and a 5% significance level. Beck Depression Inventory (BDI) is an instrument for evaluating depression. BSA stands for Beck State of Anxiety. BTA refers to Beck Trait of Anxiety. After 7 Reiki sessions, the following values were obtained.

Discussion

In low- and middle-income countries, hyperglycaemia in pregnancy (HIP) is a major public health problem, with substantial short- and long-term health consequences for both the woman and her child[41]. A mother's quality of life might be harmed by a diagnosis of a health problem such as HIP because she feels nervous or scared that something bad will happen to her and her baby[42]. The HIP treatment approach is currently foetal-centric, disregarding mother psychological factors that affect women's overall well-being[43]. The purpose of this RCT was to investigate whether Reiki therapy could reduce adverse maternal mental impact of a HIP diagnosis on foetal health and her duty to avoid all these issues without having a detrimental influence on the major pregnancy outcomes.

This trial enrolled patients at a tertiary University Hospital to establish reliable non-drug instruments to guide the therapy of HIP maternal-fetal binomial cases.

The purpose of this research was to develop a scientific instrument that may be applied at the Brazilian Health System as part of complementary health policies[13,14,15,16,17,18] Despite this, some members of the health care team have continuously contested me, arguing that the rationale for Reiki and other energy-based therapies are debatable. This is, unfortunately, a typical occurrence in the scientific community[44]. To prevent not only local misinterpretation but also worldwide rejection of “new-old” Reiki therapy, RCT was defined as a scientific research design based on the likelihood of randomly assigning individuals to treatment groups to assure comparability, and it was used to establish the basis of statistical inference and discover treatment effects. However, because RCTs have the explicit objective purpose of

evaluating the efficacy and safety of novel treatments, medical equipment, and procedures, rather to just reaching therapeutic conclusions, the judgments should preferable be determined by probability[45]. Accordingly, in comparison to the Sham Reiki group, the results of our RCT clearly indicate an improvement in QoL, anxiety, and depression in HIP mothers treated with Remote or Face-to-Face Reiki, leading to the conclusion that the difference is treatment caused[46].

The following impacts are clearly demonstrated by the results of this study, as follows: first, either Remote or Face-to-Face Reiki is effective in increasing QoL and decreasing depression and anxiety levels in HIP mothers when compared to Sham Reiki after 7 sessions, highlighting Reiki therapy as an important intervention within Complementary Alternative Medicine for HIP women. Second, there is strong evidence that Remote and Face-to-Face Reiki are equally effective. Finally, no significant variations in Gestational Glycemic means were seen in HIP pregnancies subjected to Sham Reiki, Remote Reiki, or Face-to-Face Reiki, implying that the stimulus for glycemic control during pregnancy is reliant on nutritional, lifestyle, and insulin therapy.

To the best of our knowledge, this Reiki trial is the first to be published from a low- and middle-income country on its impact on maternal mental health and quality of life. Preeclampsia, obstructed labor, postpartum hemorrhage, macrosomia, preterm deliveries, stillbirths, congenital malformations, birth traumas, and perinatal death are among risks that a HIP pregnant woman and her kids face in the worst-case scenario[29,47,48]. Furthermore, long-term Type 2 diabetes, cardiovascular disease, and urinary incontinence development are all risks for women and their progeny[3,49]. With all this knowledge, it is simple to comprehend how pregnant women react to the diagnosis of GDM and the psychological effects[50] it has. According to several research, women's immediate reaction was one of shock[51,52], sadness and guilt[52].

The increased prevalence of HIP and the wide range of psychosocial problems caused by HIP diagnosis and treatment highlight the need to support these pregnant women with non-drug treatments such as Reiki, which has been shown to be effective in people with anxiety, depression, or both[53-66], using a randomized clinical trial (RCT), i.e., gold standard for scientific studies of treatment effects[39,40,45,46].

Reiki appears at a time when we need to reconsider therapeutic practices to meet the current needs of the global population. The efficacy of Reiki therapy was evaluated in this randomized controlled trial (RCT) by randomly assigning all eligible participants in a sample

to treatment and control groups. The treatment groups in this study received either Face-to-Face or Remote Reiki therapy, while the control group received Sham Reiki sessions. Assuming a large enough sample size, which was about the number of gestational diabetes participants seen in the PDRC throughout the study period, who agreed to participate. This RCT eliminated selection bias by ensuring that the control and treatment groups were comparable in both apparent and hidden attributes. The first and only difference between the treatment and control groups is that two of them participated in the intervention; nevertheless, the disparity in their outcomes shows that the intervention was successful[67].

This study aimed to compare the effects of Remote, Face-to-Face and Sham Reiki on QoL, anxiety, and depression levels. A considerable improvement in QoL, as well as a decrease in depression and state-trait anxiety assessments, support the benefits of complementary alternative medicine; comparable results have been found in likely investigations[53-66].

At baseline, questionnaires and medical records offered a clear picture of the participants' backgrounds from the start, which is comparable to other research on diabetic pregnant women and their quality of life conducted at the same PDRC[6,7,47,48]. After 7 Reiki sessions, the second questionnaire revealed no significant changes in single variables pertaining to the medical record of both mothers and newborns. However, the significant improvement in quality of life has demonstrated that Reiki benefits the whole person, not just the disease or condition, meeting the World Health Organization's definition of health, as well as respecting such complementary alternative medicine's holistic perspective[51-66].

Reiki could thus be considered a comprehensive health system due to its own principles, which are closely related to Traditional Chinese Medicine (TCM), a prominent natural health system that promotes the balance of two opposing yet complementary forces: Yang and Yin, as well as the maintenance of Qi (the natural flow of energy)[19,68-71]. This health system provides a novel approach to understanding human physiology to Western based practitioners, since TCM is based on historical precedent and observations stretching back over four thousand years[68-71]. TCM focuses on regulating the body's natural resistance to disease and develops highly customized treatment based on syndrome distinction, e.g., acupuncture, Chi Gong, meditation, massage, phytotherapy and energy-based treatments such as Reiki[68-71].

The aetiology of diabetes in Chinese medicine is defined as a shortage of Yin and stagnation of Qi, resulting in excessive heat and dryness, and is categorized as a ‘Xiao ke’ (i.e., a condition marked by excessive drinking and urination) [19,68-71]. TCM also believes that changes in the social environment and lifestyle have also impacted the development of diabetes[19,68-71].

Diabetes mellitus was characterized in The Yellow Emperor's Classic of Internal Medicine[24] as having 'three excess' and 'one loss', which corresponds to an increase in thirst, appetite, and urine, as well as a loss of weight[68]. The lung, spleen, and kidney are the primary organs impacted, consequently, the TCM therapies for *Diabetes mellitus* focuses on techniques to tonify Yin and relieve heat and dryness in these organs[19,68-71]. According to Chinese Medicine, pregnancy is the union of Yin and Yang, with Yin representing repose, accumulation, and storage, and Yang representing the need for birth[19,68-71]. The spleen is thought to be the source of foetal growth and development, while the kidneys store the foetus' nourishment essence[19,68-71]. Thus, the lack of energy balance in pregnant women who have diabetes is connected to those three organ levels[69,70]. In TCM, such organs are also known to be responsible for emotions, such as fear for the kidneys, worry for the spleen, sadness, and grief for the lung, which may have an impact on mental health as well[68,69,70].

Any nonpharmacological interpersonal intervention, such as Reiki, that changes heat, cold, congestion, circulation, or sensory processes is referred to as energy medicine[8,9,16,17,18]. The presence and/or hands of the therapist induce a shift in heat, cold, or congestion, as well as altering the client's perception of pain or other diseases[11,12,19,20,67,72]. Quantum physics supports the concept of energy fields and what is known as the mind-body-spirit link[67,72]. Today, physicists propose a phenomenon known as "non-local reality", which may explain distant healing[11,12,67,72]. Some authors refer to distant healing as non-local healing, they also describe beneficial aspects of intercessory prayer delivered from various locations rather than at a patient's bedside[12]. Reiki is thus an energy-based therapy in which practitioners' access into the "universal life force" to promote healing either locally or remotely. In this study, there was no significant difference between Face-to-Face and Remote Reiki treatments, both of which made a difference in the participants' quality of life, depression, and state-and-trait anxiety inventories in both intervention groups.

Energy-based medicine can be linked to Einstein's relativity theory, since all matter, energy, time, and space are relative to one another; therefore, implying that energy may be produced from matter, but matter is a very slow-moving energy[12,72]. In addition, Einstein proved that the observer is intimately linked to these factors, such as the Reiki practitioners and users. Because every change in time, space, or matter must be perceived by the senses[12,72]. The "experimenter effect" says that the experimenter's ideas, boundaries, attitudes, expectations, and intentions influence the experiment outcome[12,72]. This novel method explained the enormous disparities discovered between observers trained in Western science and those

immersed in Eastern traditions, such as Traditional Chinese Medicine. Following Einstein, subsequent scientists explored subatomic concepts of matter and energy further and began to examine the impact of the smallest builders in the atomic world, i.e., quanta of individual photons or energy packets[12,72]. These quantum physicists have provided fresh insights into how areas interact at spectrum's lowest energy state. Most researchers believe that in the here and now, the material world comes about through the interplay of energy forces and mechanisms, including ours, that structure and control the actual universe which we all share[12,72], such as the use of a universal energy force to heal people in need. This interaction is described as defined and sequential by certain quantum theorists[12,72]. Others feel that there isn't always a clear cause and effect link, and that the interaction of energy forces and systems is an example of chaos theory[12,72].

Although studies on energy-based therapies on pregnant women are particularly scarce[12,23,26,27,28], the use of Reiki on hyperglycaemic pregnant women in this study presented some beneficial aspects by balancing the two opposing yet complementary forces (Yang and Yin), as well as the maintenance of Qi[68-72]. Reiki modified the electric flow in the body, while maintaining the women's and perinatal health. Even though they potentially achieved normoglycemia by attending the diabetes in pregnancy protocols at PDRC/HC, Reiki helped them to improve their quality of life and well-being. Energy-based therapies appear to have the ability to promote a sense of well-being, which in turn impacts behaviours that allow for better control of glycated haemoglobin levels (HbA1c), according to preliminary research studies conducted across cultures[18,20,22,23,51-64]. Further trials with large populations in different locations are also recommended to examine the efficacy of Reiki therapy and quality of life in hyperglycaemic pregnant women, according to this research group.

Finally, our results support the effectiveness of Reiki therapy either Remote or Face-to-Face. Thus, efforts must be made to incorporate into public health in the nearby future, we expect that the Reiki therapists will be included in the health care provider team to address a need from the population for a multi-faceted approach that involves spirituality in the field of health.

Strength and Limitations

Our study has some limitations related to sample size for our study that was previously established based on the number of HIP patients at the University Hospital per year and,

therefore, may compromise the statistical power for other maternal and perinatal outcomes evaluated. Consequently, the first limitation of our study was in data collecting, as all approached patients in the outpatient department were utilized in the study, which did not leave us much room for error, we made a determined attempt to lose as few participants as possible.

The homogeneous groups used in the experiment are credited with the study's strength. The results showed that all groups were comparable[49,50]. This randomized controlled trial (RCT) assessed the efficacy of Reiki therapy by randomly assigning all eligible participants in a sample to treatments and control groups[49,50].

A further strength is that it covers diverse glucose statuses, such as prior Type 2 DM, GDM diagnosed by 75g-OGTT, and Mild Gestational hyperglycaemia identified by glucose profiles and uses well-defined diagnostic and management protocols with adequate sample size from a unique referral centre.

In addition, our results confirm the potential benefit of Reiki therapy improving QoL and decreasing the anxiety and depression levels caused by the burden of HIP diagnosis, treatment, and maternal responsibility.

Conclusions

Reiki therapy, Remote or Face-to-Face, is more effective for maternal mental health approach than routine clinical prenatal care alone, according to this randomized clinical trial of women with HIP. Reiki improved all aspects of QoL while also lowering depression and trait-and-state anxiety. Even though Reiki therapy had no effect on any medical-related factor linked to mother and newborn outcomes. These findings should be confirmed in larger-scale research on the impact of Reiki therapy on diabetic pregnant women's treatments in Brazilian or other low- and middle-income countries with similar demographics.

Acknowledgments

No potential conflicts of interest relevant to this article were disclosed by the authors.

MVCR , SAML, BGP and IMPC were involved in the conception and design of the study, designed the study groups, provided educational flyers to the study participants, drafted the manuscript, and was involved in the interpretation of data and the subsequent edits to the manuscript.

GARF, MRKR, GLM and VTB were involved in the conception and design of the study, provided the Reiki application in both treated and untreated groups: Remote, Face-to-Face and Sham Reiki; collected data; were involved in the interpretation of data, designed an educational flyer to explain Reiki to participants, drafted the manuscript and subsequent edits to it.

IMPC, RC and CM provided medical management to the study participants, and M.B., collected data.

All the authors contributed to the discussion and read and approved the final manuscript.

GARF and MVCR are the guarantor of this study and, as such, had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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Study protocol

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ANEXO I
PARECER CONSUBSTANCIADO DO COMITÊ DE ÉTICA E PESQUISA (CEP)

FACULDADE DE MEDICINA DE BOTUCATU -UNESP

PARECER CONSUBSTANCIADO DO CEP

DADOS DO PROJETO DE PESQUISA

Título da Pesquisa: Efeitos da prática do Reiki sobre a qualidade de vida de gestantes diabéticas: Ensaio Clínico Randomizado

Pesquisador: Guilherme Augusto Rago Ferraz

Área Temática:

Versão: 1

CAAE: 52734216.1.0000.5411

Instituição Proponente: Departamento de Ginecologia e Obstetrícia

Patrocinador Principal: Financiamento Próprio

DADOS DO PARECER

Número do Parecer: 1.440.349

Apresentação do Projeto:

O diabetes é uma condição associada a riscos perinatais e tardios, tanto para as gestantes já previamente diabetes quanto para aquelas que desenvolvem o chamado "diabetes gestacional". Em todos os casos, há impacto fisiológico e psicológico relevante. Nesse contexto, é possível que "Práticas Integrativas e Complementares em Saúde" tenham efeito benéfico sobre qualidade de vida e prevenção da ansiedade e depressão. Uma dessas práticas é o Reiki, que envolve imposição das mãos como técnica de "canalizar a energia do universo para a pessoa que está recebendo o tratamento". Os pesquisadores propõem a realização de ensaio clínico randomizado para identificar os benefícios do Reiki sobre a gestação e o parto, e também sobre qualidade de vida, ansiedade e depressão em gestantes diabéticas atendidas no Hospital das Clínicas da Faculdade de Medicina de Botucatu (UNESP). Ao todo, 150 gestantes serão randomizadas para o grupo de intervenção ou grupo controle. Todas receberão a conduta multiprofissional usual. A única diferença é que no grupo intervenção elas serão submetidas a 7 seções de Reiki, enquanto as do grupo controle serão submetidas a simulação de imposição das mãos. Portanto, o estudo será cego para sujeitos da pesquisa. As gestantes serão avaliadas na primeira consulta pré-natal ou ao diagnóstico do diabetes, e posteriormente no momento do parto. Serão avaliados parâmetros clínicos/laboratoriais da gestação e características do nascituro. Além disso, serão calculados

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scores validados para qualidade de vida, ansiedade e depressão.

Objetivo da Pesquisa:

Avaliar o impacto da terapia Reiki sobre a gestação de diabéticas, com ênfase na qualidade de vida.

Avaliação dos Riscos e Benefícios:

A proposta apresenta vários benefícios potenciais, diretos (caso o Reiki demonstre efetividade no grupo de intervenção) e indiretos (possível práticas complementares no pré-natal). Os riscos são pequenos, dada a não invasividade do método.

Comentários e Considerações sobre a Pesquisa:

Trata-se de pesquisa sobre tema pertinente, aplicando um método científico "ocidental" para analisar eficácia de uma prática complementar. O estudo é factível nas condições propostas.

Considerações sobre os Termos de apresentação obrigatória:

Apresentam-se os documentos necessários. O TCLE é redigido de forma clara, concisa e com linguagem acessível.

Recomendações:

Conclusões ou Pendências e Lista de Inadequações:

Recomendo aprovação sem necessidade de envio à CONEP.

Considerações Finais a critério do CEP:

Projeto de pesquisa APROVADO, deliberado em reunião do CEP de 07 de março de 2016, sem necessidade de envio à CONEP.

O CEP solicita aos pesquisadores que após a execução do projeto em questão, seja enviado para análise o respectivo "Relatório Final de Atividades", o qual deverá ser enviado via Plataforma Brasil na forma de "NOTIFICAÇÃO".

Este parecer foi elaborado baseado nos documentos abaixo relacionados:

Tipo Documento	Arquivo	Postagem	Autor	Situação
Informações Básicas do Projeto	PB_INFORMAÇÕES_BÁSICAS_DO_PROJETO_648377.pdf	26/01/2016 12:42:52		Aceito
TCLE / Termos de Assentimento / Justificativa de	TCLE2.doc	26/01/2016 12:42:23	Guilherme Augusto Rago Ferraz	Aceito

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Telefone: (14)3880-1608 **E-mail:** capellup@fmb.unesp.br

Ausência	TCLE2.doc	26/01/2016 12:42:23	Guilherme Augusto Rago Ferraz	Aceito
Outros	termodeanuencia.pdf	25/01/2016 18:27:04	Guilherme Augusto Rago Ferraz	Aceito
Folha de Rosto	folhaderosto.pdf	25/01/2016 18:23:37	Guilherme Augusto Rago Ferraz	Aceito
Projeto Detalhado / Brochura Investigador	projetoespiritualidade.doc	10/01/2016 15:57:47	Guilherme Augusto Rago Ferraz	Aceito

Situação do Parecer:
Aprovado

Necessita Apreciação da CONEP:
Não

BOTUCATU, 07 de Março de 2016

Assinado por:
Trajano Sardenberg
(Coordenador)

Endereço: Chácara Butignolli , s/n
Bairro: Rubião Junior **CEP:** 18.618-970
UF: SP **Município:** BOTUCATU
Telefone: (14)3880-1608 **E-mail:** capellup@fmb.unesp.br

PARECER CONSUBSTANCIADO DO CEP

DADOS DA EMENDA

Título da Pesquisa: Efeitos da prática do Reiki sobre a qualidade de vida de gestantes diabéticas: Ensaio Clínico Randomizado

Pesquisador: Guilherme Augusto Rago Ferraz

Área Temática:

Versão: 2

CAAE: 52734216.1.0000.5411

Instituição Proponente: Departamento de Ginecologia e Obstetrícia

Patrocinador Principal: Financiamento Próprio

DADOS DO PARECER

Número do Parecer: 2.888.954

Apresentação do Projeto:

Apresenta-se emenda que inclui um grupo a mais no ensaio clínico: gestantes que realizarão o Reiki à distância. Enfatiza-se que esse grupo será criado por redistribuição do total de sujeitos, não havendo alteração desse total.

Objetivo da Pesquisa:

Avaliar os efeitos da prática do Reiki sobre a qualidade de vida de gestantes diabéticas

Avaliação dos Riscos e Benefícios:

Mantêm-se os benefícios e não se adicionam riscos.

Comentários e Considerações sobre a Pesquisa:

Mantêm-se a relevância.

Considerações sobre os Termos de apresentação obrigatória:

Apresenta-se solicitação de emenda.

Conclusões ou Pendências e Lista de Inadequações:

Após análise, o Colegiado deliberou APROVAÇÃO da emenda ao projeto de pesquisa apresentada.

Considerações Finais a critério do CEP:

Conforme deliberação do Colegiado em reunião ordinária do Comitê de Ética em Pesquisa da FMB/UNESP, realizada em 03 de setembro de 2018, o documento enviado na forma de "Emenda",

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se encontra APROVADO, sem (com) necessidade de envio à CONEP.

Atenciosamente,

Comitê de Ética em Pesquisa da Faculdade de Medicina de Botucatu – UNESP

Este parecer foi elaborado baseado nos documentos abaixo relacionados:

Tipo Documento	Arquivo	Postagem	Autor	Situação
Informações Básicas do Projeto	PB_INFORMAÇÕES_BÁSICAS_1200336_E1.pdf	14/08/2018 12:11:37		Aceito
Projeto Detalhado / Brochura Investigador	ECR_DOUTORADO_2016.doc	14/08/2018 12:08:30	Guilherme Augusto Rago Ferraz	Aceito
Outros	Emenda.docx	14/08/2018 12:06:07	Guilherme Augusto Rago Ferraz	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	TCLE2.doc	26/01/2016 12:42:23	Guilherme Augusto Rago Ferraz	Aceito
Outros	termodeanuencia.pdf	25/01/2016 18:27:04	Guilherme Augusto Rago Ferraz	Aceito
Folha de Rosto	folhaderosto.pdf	25/01/2016 18:23:37	Guilherme Augusto Rago Ferraz	Aceito

Situação do Parecer:
Aprovado

Necessita Apreciação da CONEP:
Não

BOTUCATU, 12 de Setembro de 2018

Assinado por:
Trajano Sardenberg
(Coordenador)

ANEXO II
TERMO DE CONSENTIMENTO LIVRE E ESCLARECIDO

TERMO DE CONSENTIMENTO LIVRE E ESCLARECIDO

Vimos convidá-la para participar da pesquisa: **"Efeitos da prática do Reiki sobre a qualidade de vida de gestantes diabéticas: Ensaio Clínico Randomizado"**, que tem como objetivo Avaliar se a modalidade terapêutica de imposição de mãos (Reiki) produz melhoria de qualidade de vida em gestantes diabéticas na assistência prenatal de gestantes com diabete, atendidas no Centro de Investigação do Diabete Perinatal (CIDP) do HC/FMB–Unesp. Esta pesquisa será realizada pelo pesquisador Guilherme Augusto Rago Ferraz e colaboradores, sob coordenação da Dra Marilza Vieira Cunha Rudge e Dra Silvana Andrea Molina Lima. Na pesquisa as gestantes diabéticas do Centro de Investigação do Diabete Perinatal (CIDP) do HC/FMB–Unesp serão sorteadas para receber a terapia Reiki no mesmo dia da sua consulta ambulatorial.Todos os demais procedimentos que fazem parte do seu acompanhamento pré-natal neste Serviço serão mantidos.

Essa pesquisa permitirá verificar se a prática terapêutica de imposição das mãos (Reiki) contribuirá com melhorias na qualidade da vida das gestantes portadoras de diabete. Os riscos são mínimos representados pela imposição de mãos durante a terapia e por entrevistas estruturadas para análise da qualidade de vida, a qual terá duração média de 40 minutos por paciente.

Sei que ao participar desta pesquisa terei a garantia de sigilo da minha participação e que Guilherme e as Dras Silvana e Marilza estarão disponíveis para responder às perguntas ou dúvidas que eu tenha. Também há garantia do direito de sair do estudo a qualquer momento, sem que haja prejuízo do meu tratamento neste serviço. Poderei procurar o atendimento da maternidade do HC – UNESP a qualquer dia e horário, se julgar necessário.

Assim, tendo sido satisfatoriamente informada, aceito participar da pesquisa "Efeitos da prática do Reiki sobre a qualidade de vida de gestantes diabéticas: Ensaio Clínico Randomizado". Para tanto assino este Termo de Consentimento Livre e Esclarecido declarando que li e entendi todas as informações acima, tive oportunidade de fazer perguntas e todas as minhas dúvidas foram respondidas a contento. Este formulário está sendo assinado voluntariamente em duas vias, sendo uma entregue a mim e a outra será guardada pelos pesquisadores.

OBS: "Qualquer dúvida adicional, você poderá entrar em contato com o Comitê de Ética em Pesquisa, através do fone: (14) 3880-1608/ 3880-1609".

Botucatu, _____/_____/_____.

_____ _____

Nome do participante Assinatura do participante

_____ _____

Nome do Pesquisador Assinatura do pesquisador

Guilherme Augusto Rago Ferraz
PG GOM - FMB - Unesp

Botucatu - SP
Fone: (14) 38116227
Cel. (14) 981575951
e-mail: guilhermerago@yahoo.com.br

Profa Dra Marilza Viera Cunha Rudge
Depto de Ginecologia e Obstetrícia
FMB-Unesp
Botucatu - SP
Fone: (14) 3811-6227

e-mail: mrudge@fmb.unesp.br

ANEXO III - WHOQOL–BREF / AVALIAÇÃO DA QUALIDADE DE VIDA

WHOQOL–BREF / AVALIAÇÃO DA QUALIDADE DE VIDA
Versão validada em português

PARTE 1 – FICHA DE INFORMAÇÕES SOBRE O RESPONDENTE

NOME: _____

IDADE (em anos completos): _____

DATA DE NASCIMENTO: ____/____/____

NÍVEL EDUCACIONAL:

Analfabeto _____(1)
I grau incompleto _____(2)
I grau completo _____(3)
II grau incompleto _____(4)
II grau completo _____(5)
III grau incompleto _____(6)
III grau completo _____ (7)
Pós-Graduação incompleto _____(8)
Pós-Graduação completo _____(9)

ESTADO CIVIL:

Solteiro (a) _____(1)
Casado (a) _____(2)
Vivendo como casado (a) _____(3)
Separado (a) _____(4)
Divorciado (a) _____(5)
Viúvo (a) _____(6)

COMO ESTÁ A SUA SAÚDE:

Muito ruim _____(1)
Fraca _____(2)
Nem ruim nem boa _____(3)
Boa _____(4)
Muito boa _____(5)

FORMA DE ADMINISTRAÇÃO DO QUESTIONÁRIO:

Auto-administrado _____(1)
Assistido pelo entrevistador _____(2)
Administrado pelo entrevistador _____(3)

PROBLEMA DE SAÚDE ATUAL/CONDIÇÃO PRESENTE (marcar somente <u>uma</u>, que é a mais relevante para a presente busca de um serviço de saúde)

Nenhum problema _____00
Problema de coração _____01
Pressão alta _____02
Artrite ou reumatismo _____03
Câncer _____04
Enfisema ou bronquite _____05
Diabetes _____06
Catarata _____07
Derrame _____08
Osso quebrado ou fraturado _____09
Problema nervoso crônico ou emocional _____10
Problema crônico de pé (joanete, unha encravada) _____11
Hemorróidas ou sangramento no ânus _____12
Doença de Parkinson _____13
Gravidez _____14
Depressão _____15
Doença de pele _____16
Queimaduras _____17
Problema de álcool ou drogas _____18

Outros (especificar) _____

TEMPO DE DIAGNÓSTICO: _____

IDADE NO DIAGNÓSTICO: _____

REGIME DE CUIDADOS DE SAÚDE:
Sem tratamento(1) Ambulatório(2) Internação(3)

USA INSULINA?
Sim_____ (1)
Não_____ (2)

FILHOS ANTES DA DOENÇA?
Sim_____(1)
Não_____(2)

DESEJA TER MAIS FILHOS?
Sim_____ (1)
Não_____ (2)

ESTÁ EMPREGADA?
Sim _____ (1)
Não_____ (2)

PERDA DO COMPANHEIRO APÓS A DOENÇA?
Sim_____ (1)
Não_____ (2)

ANEXO III (continuação)

WHOQOL–BREF / AVALIAÇÃO DA QUALIDADE DE VIDA
Versão validada em português

PARTE 2–AVALIAÇÃO DA QUALIDADE DE VIDA

NOME: _____No. Registro _____

Instruções:
Este questionário é sobre como você se sente a respeito de sua qualidade de vida, saúde e outras áreas de sua vida. Por favor, responda a todas as questões. Se você não tem certeza sobre que resposta dar em uma questão, por favor, escolha entre as alternativas a que lhe parece mais apropriada. Esta, muitas vezes, poderá ser sua primeira escolha.

Por favor, tenha em mente seus valores, aspirações, prazeres e preocupações. Nós estamos perguntando o que você acha de sua vida, tomando como referência as duas últimas semanas. Por exemplo, pensando nas duas ultimas semanas, uma questão poderia ser:

	Nada	Muito pouco	Médio	Muito	Completamente
Você recebe dos outros o apoio de que necessita?	1	2	3	4	5

Você deve circular o número que melhor corresponde a quanto você recebe dos outros o apoio de que necessita nestas últimas duas semanas. Portanto, você deve circular o numero 4 se você recebeu "muito" apoio como abaixo.

	Nada	Muito pouco	Médio	Muito	Completamente
Você recebe dos outros o apoio de que necessita?	1	2	3	4	5

Você deve circular o número 1 se você não recebeu "nada" de apoio.

Por favor, leia cada questão, veja o que você acha e circule no número que lhe parece a melhor resposta.

		Muito ruim	Ruim	Nem ruim nem boa	Boa	Muito boa
1	Como você avaliaria sua qualidade de vida?	1	2	3	4	5

		Muito insatisfeito	Insatisfeito	Nem satisfeito nem insatisfeito	Satisfeito	Muito satisfeito
2	Quão satisfeito (a) você está com sua saúde?	1	2	3	4	5

As questões seguintes são sobre o quanto você tem sentido algumas coisas nas ultimas duas semanas.

		Nada	Muito pouco	Mais ou menos	Bastante	Extrema-mente
3	Em que medida você acha que sua dor (física) impede você de fazer o que você precisa?	1	2	3	4	5
4	O quanto você precisa de algum tratamento médico para levar sua vida diária?	1	2	3	4	5
5	O quanto você aproveita a vida?	1	2	3	4	5
6	Em que medida você acha que sua vida tem sentido?	1	2	3	4	5
7	O quanto você consegue se concentrar?	1	2	3	4	5
8	Quão seguro (a) você se sente em sua vida diária?	1	2	3	4	5
9	Quão saudável é o seu ambiente físico (clima, barulho, poluição, atrativos)?	1	2	3	4	5

As questões seguintes perguntam sobre quão completamente você tem sentido ou é capaz de fazer certas coisas nestas últimas duas semanas.

		Nada	Muito pouco	Médio	Muito	Completa-mente
10	Você tem energia suficiente para seu dia-a-dia?	1	2	3	4	5
11	Você é capaz de aceitar sua aparência física	1	2	3	4	5
12	Você tem dinheiro suficiente para satisfazer suas necessidades?	1	2	3	4	5
13	Quão disponíveis para você estão as informações que precisa no seu dia-a-dia?	1	2	3	4	5
14	Em que medida você tem oportunidade de atividade de lazer?	1	2	3	4	5

As questões seguintes perguntam sobre quão bem ou satisfeito você se sentiu a respeito de vários aspectos de sua vida nas últimas duas semanas.

		Muito ruim	Ruim	Nem ruim nem bom	Bom	Muito bom
15	Quão bem você é capaz de se locomover?	1	2	3	4	5

		Muito insatisfeito	Insatisfeito	Nem satisfeito nem insatisfeito	Satisfeito	Muito satisfeito
16	Quão satisfeito (a) você está com o seu sono?	1	2	3	4	5
17	Quão satisfeito (a) você está com sua capacidade de desempenhar as atividades do seu dia-a-dia?	1	2	3	4	5
18	Quão satisfeito (a) você está com sua capacidade para o trabalho?	1	2	3	4	5
19	Quão satisfeito (a) você está consigo mesmo?	1	2	3	4	5
20	Quão satisfeito (a) você está com suas relações pessoais (amigos, parentes, conhecidos, colegas)?	1	2	3	4	5
21	Quão satisfeito (a) você está com sua vida sexual?	1	2	3	4	5
22	Quão satisfeito (a) você está com o apoio que você recebe de seus amigos?	1	2	3	4	5
23	Quão satisfeito (a) você está com as condições de local onde mora?	1	2	3	4	5

24	**Quão satisfeito (a) você está com o seu acesso aos serviços de saúde?**	**1**	**2**	**3**	**4**	**5**
25	**Quão satisfeito (a) você está com o seu meio de transporte?**	**1**	**2**	**3**	**4**	**5**

As questões seguintes referem-se a com que freqüência você sentiu ou experimentou certas coisas nas últimas duas semanas.

		Nunca	**Algumas vezes**	**Freqüentemente**	**Muito freqüentemente**	**Sempre**
26	**Com que freqüênciavocê tem sentimentos negativos tais como mau humor, desespero, ansiedade, depressão?**	**1**	**2**	**3**	**4**	**5**

Alguém lhe ajudou a preencher este questionário?

Quanto tempo você levou para preencher este questionário?

Você tem algum comentário sobre o questionário?

OBRIGADO PELA SUA COLABORAÇÃO

ANEXO IV - INVENTÁRIO DE DEPRESSÃO DE BECK – IDB

INVENTÁRIO DE DEPRESSÃO DE BECK – IDB

NOME: _____

Este questionário consiste em 21 grupos de afirmações. Depois de ler cuidadosamente cada grupo, faça um circulo em torno do número (0, 1, 2 ou 3) diante da afirmação, em cada grupo, que se descreve melhor a maneira como você tem se sentido nesta semana, incluindo hoje. Se várias afirmações num grupo parecerem se aplicar igualmente bem, faça um circulo em cada uma.

Tome o cuidado de ler todas as afirmações, em cada grupo, antes de fazer a sua escolha.

1. 0 - Não me sinto triste.

1 - Eu me sinto triste.
2 - Estou sempre triste e não consigo sair disso.
3 - Estou tão triste ou infeliz que não consigo suportar

2. 0 - Não estou especialmente desanimada quanto ao futuro

1 - Eu me sinto desanimada quanto ao futuro.
2 - Acho que nada tenho a esperar.
3 - Acho o futuro sem esperança e tenho a impressão de que as coisas não podem melhorar.

3. 0 - Não me sinto um fracasso.

1 - Acho que fracassei mais do que uma pessoa comum.
2 - Quando olho para trás, na minha vida, tudo o que posso ver é um monte de fracasso.
3 - Acho que, como pessoa, sou um completo fracasso

4. 0 - Tenho tanto prazer em tudo como antes.

1 - Não sinto mais prazer nas coisas como antes.
2 - Não encontro um prazer real em mais nada.
3 - Estou insatisfeita ou aborrecida com tudo.

5. 0 - Não me sinto especialmente culpada.

1 - Eu me sinto culpada às vezes.
2 - Eu me sinto culpada na maior parte do tempo.
3 - Eu me sinto sempre culpada.

6. 0 - Não acho que esteja sendo punida.

1 - Acho que posso ser punida.
2 - Creio que vou ser punida.
3 - Acho que estou sendo punida.

7. 0 - Não me sinto decepcionada comigo mesma.

1 - Estou decepcionada comigo mesma.
2 - Estou enojada de mim.
3 - Eu me odeio.

8. 0 - Não me sinto de qualquer modo pior que os outros.

1 - Sou crítica em relação a mim devido a minhas fraquezas ou a meus erros.
2 - Eu me culpo sempre pôr minhas falhas.
3 - Eu me culpo pôr tudo de mal que acontece.

9. 0 - Não tenho quaisquer ideias de me matar.

1 - Tenho ideias de me matar, mas não as executaria.
2 - Gostaria de me matar.
3 - Eu me mataria se tivesse oportunidade.

10. 0 - Não choro mais que o habitual.

1 - Choro mais agora do que costumava.
2 - Agora, choro o tempo todo.
3 - Costumava ser capaz de chorar, mas agora não consigo mesmo que o queira.

11. 0 - Não sou mais irritada agora do que eu já fui.

1 - Fico molestada ou irritada mais facilmente do que costumava
2 - Atualmente me sinto irritada o tempo todo.
3 - Absolutamente não me irrito com as coisas que costumavam irritar-me.

12. 0 - Não perdi o interesse nas outras pessoas.

1 - Interesso menos do que costumava pelas outras pessoas.
2 - Perdi a maior parte do meu interesse nas outras pessoas.
3 - Perdi todo meu interesse nas outras pessoas

13. 0 - Tomo decisões mais ou menos tão bem como em outra época.

1 - Adio minhas decisões mais do que costumava.
2 - Tenho maior dificuldade em tomar decisões do que antes.
3 - Não consigo mais tomar decisões.

14. 0 - Não sinto que minha aparência seja pior que costumava ser.

1 - Preocupo-me pôr estar parecendo velha ou sem atrativos.
2 - Sinto que há mudanças permanentes em minha aparência que me fazem parecer sem atrativos.
3 - Considero-me feia.

15. 0 - Posso trabalhar mais ou menos tão bem como antes.

1 - Preciso de um esforço extra para começar qualquer coisa.
2 - Tenho de me esforçar muito até fazer qualquer coisa.
3 - Não consigo fazer nenhum trabalho.

16. 0 - Durmo tão bem quanto de hábito

1 - Não durmo tão bem quanto costumava
2 - Acordo uma ou duas horas mais cedo do que de hábito e tenho dificuldade para voltar dormir.
3. Acordo várias horas mais cedo do que costumava e tenho dificuldade para voltar a dormir.

17. 0 - Não fico mais cansada que de hábito.

1 - Fico cansada com mais facilidade do que costumava.
2 - Sinto-me cansada ao fazer qualquer coisa.
3 - Estou cansada demais para fazer qualquer coisa.

18. 0 - Meu apetite não está pior do que de hábito.

1 - Meu apetite não é tão bom quanto costumava ser.
2 - Meu apetite está muito pior agora.
3 - Não tenho mais nenhum apetite.

19. 0 - Não perdi muito peso, se é que perdi algum ultimamente.

1 - Perdi mais de 2,5 Kg.
2 - Perdi mais de 5 Kg.
3 - Perdi mais de 7,5 Kg.

Estou deliberadamente tentando perder peso, comendo menos:

SIM ( ) NÃO ( )

20. 0 -Não me preocupo mais que o de hábito com minha saúde.

1 - Preocupo-me com problemas físicos como dores e aflições ou perturbações no estômago ou prisão de ventre.
2 - Estou muito preocupado com problemas físicos e é difícil pensar em outra coisa que não isso.
3 - Estou tão Preocupado com meus problemas físicos que não consigo pensar em outra coisa.

21. 0- Não tenho observado qualquer mudança recente em meu interesse sexual.

1 - Estou menos interessado pôr sexo que costumava.
2 - Estou menos interessado em sexo atualmente.
3 - Perdi completamente o interesse pôr sexo

ANEXO V - PARTE I –INVENTÁRIO DE ANSIEDADE ESTADO

PARTE I –INVENTÁRIO DE ANSIEDADE ESTADO

NOME: _____

Leia cada pergunta e faça um circulo ao redor do número à direita que melhor indicarcomo você se sente agora, neste momento.

Não gaste muito tempo em uma afirmação, mas tente dar a resposta que mais se aproximar de como você se sente neste momento.

Muitíssimo.....4 **Um pouco 2**
Bastante.....3 **Absolutamente não..... 1**

1.Sinto-me calma	**1**	**2**	**3**	**4**
2. Sinto-me segura	**1**	**2**	**3**	**4**
3. Estou tensa	**1**	**2**	**3**	**4**
4. Estou arrependida	**1**	**2**	**3**	**4**
5. Sinto-me à vontade	**1**	**2**	**3**	**4**
6. Sinto-me perturbada	**1**	**2**	**3**	**4**
7. Estou preocupada com possíveis infortúnios	**1**	**2**	**3**	**4**
8. Sinto-me descansada	**1**	**2**	**3**	**4**
9. Sinto-me ansiosa	**1**	**2**	**3**	**4**
10. Sinto-me “em casa”	**1**	**2**	**3**	**4**
11. Sinto-me confiante	**1**	**2**	**3**	**4**
12. Sinto-me nervosa	**1**	**2**	**3**	**4**
13. Estou agitada	**1**	**2**	**3**	**4**
14. Sinto-me uma pilha de nervos	**1**	**2**	**3**	**4**
15. Estou descontraída	**1**	**2**	**3**	**4**
16. Sinto-me satisfeita	**1**	**2**	**3**	**4**
17. Estou preocupada	**1**	**2**	**3**	**4**
18. Sinto-me superexcitada e confusa	**1**	**2**	**3**	**4**
19. Sinto-me alegre	**1**	**2**	**3**	**4**
20. Sinto-me bem	**1**	**2**	**3**	**4**

ANEXO V (continuação) - PARTE II –INVENTÁRIO DE ANSIEDADE TRAÇO

PARTE II –INVENTÁRIO DE ANSIEDADE TRAÇO

NOME: _____

Leia cada pergunta e faça um circulo ao redor do número à direita que melhor indicar como você geralmente se sente.

Não gaste muito tempo em uma afirmação, mas tente dar a resposta que mais se aproximar de como você se sente geralmente.

Quase sempre.....4	**Ás vezes 2**
Freqüentemente.....3	**Quase nunca..... 1**

1.Sinto-me bem	**1**	**2**	**3**	**4**
2. Canso-me facilmente	**1**	**2**	**3**	**4**
3. Tenho vontade de chorar	**1**	**2**	**3**	**4**
4. Gostaria de poder ser tão feliz quanto os outros parecem ser	**1**	**2**	**3**	**4**
5. Perco oportunidades porque não tomo decisões rapidamente	**1**	**2**	**3**	**4**
6. Sinto-me descansada	**1**	**2**	**3**	**4**
7. Sinto-me calma, ponderada e senhora de mim mesma	**1**	**2**	**3**	**4**
8. Sinto que as dificuldades estão se acumulando de tal forma que não consigo resolver	**1**	**2**	**3**	**4**
9. Preocupo-me demais com coisas sem importância	**1**	**2**	**3**	**4**
10. Sou feliz	**1**	**2**	**3**	**4**
11. Deixo-me afetar muito pelas coisas	**1**	**2**	**3**	**4**
12. Não tenho muita confiança em mim mesma	**1**	**2**	**3**	**4**
13. Sinto-me segura	**1**	**2**	**3**	**4**
14. Evito ter que enfrentar crises ou problemas	**1**	**2**	**3**	**4**
15. Sinto-me deprimida	**1**	**2**	**3**	**4**
16. Estou satisfeita	**1**	**2**	**3**	**4**
17. Às vezes idéias sem importância me entram na cabeça e ficam-me preocupando	**1**	**2**	**3**	**4**
18. Levo os desapontamentos tão a sério que não consigo tirá-los da cabeça	**1**	**2**	**3**	**4**
19. Sou uma pessoa estável	**1**	**2**	**3**	**4**
20. Fico tensa e perturbada quando penso em meus problemas do momento	**1**	**2**	**3**	**4**