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Conhecimento e aceitação das práticas integrativas e complementares na saúde, em especial a terapia Reiki, de gestantes diabéticas atendidas num centro terciário: uma abordagem qualitativa

Dissertação apresentada à Faculdade de Medicina, Universidade Estadual Paulista "Júlio de Mesquita Filho", Câmpus de Botucatu, para obtenção do título de Mestre em Ginecologia, Obstetrícia e Mastologia.

Orientadora: Profa. Titular Marilza Vieira Cunha Rudge
Coorientadora: Profa. Dra. Silvana Andréa Molina Lima

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Guilherme Augusto Rago Ferraz

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Dissertação apresentada à Faculdade de Medicina de Botucatu – Unesp, Programa de Pós-Graduação em Ginecologia, Obstetrícia e Mastologia. Área de concentração: Tocoginecologia, para obtenção do título de Mestre.

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Botucatu, 21 de fevereiro de 2017

- *Dedico aos meus pais Ligia e Luiz obrigado por tudo, pela paciência e pelo companheirismo nas horas mais difíceis e pelo incentivo constante de nunca desistir dos meus sonhos.*
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“Reiki, é a arte secreta de convidar a felicidade.”

- Mikao Usui-

Resumo

FERRAZ, G.A.R. **Conhecimento e aceitação das práticas integrativas e complementares na saúde, em especial a terapia reiki, de gestantes diabéticas atendidas num centro terciário: uma abordagem qualitativa**. 2017. 56 f. Dissertação (Mestrado) – Faculdade de Medicina de Botucatu, Universidade Estadual Paulista, Botucatu, 2017.

Introdução: As práticas integrativas e complementares na saúde vêm ganhando cada vez mais espaço em diversos países, visto que um grande número de pessoas, especialmente mulheres, estão buscando abordagens mais naturais para solucionar uma variedade de problemas. O objetivo do estudo foi avaliar como as mulheres grávidas diagnosticadas com diabetes compreendem e aceitam o uso de práticas integrativas e complementares na saúde, especialmente Reiki, durante o atendimento pré-natal.

Material e métodos: Trata-se de um estudo qualitativo exploratório e descritivo, utilizando entrevistas para 12 gestantes diabéticas atendidas no Centro de Investigação do Diabetes Perinatal da Faculdade de Medicina de Botucatu. Foram elucidados três temas que compreendem o conhecimento e a aceitação do paciente sobre práticas integrativas na saúde, assim como o conhecimento e aceitação da terapia Reiki. As entrevistas foram audiogravadas e transcritas para posterior análise.

Resultados: A maioria das mulheres gestantes diagnosticadas com diabetes demonstrou conhecer algumas das práticas integrativas e complementares na saúde. Além disso, um grande número de entrevistadas receberia tais terapias se estas fossem disponíveis no Sistema Único de Saúde, porém a terapia reiki mostrou ser desconhecida entre as pacientes.

Conclusão: O presente estudo serve como ponto de partida para profissionais de saúde introduzirem as terapias integrativas e complementares na saúde pública brasileira. Estudos adicionais em outras populações são necessários para obter uma visão mais profunda e detalhada do perfil das pacientes em diferentes regiões.

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

Abstract

FERRAZ, G.A.R. **Toward understanding the knowledge and acceptance of complementary alternative medicine, especially Reiki, of pregnant women with diabetes in a Brazilian tertiary centre: a qualitative study**. 2017. 56 f. Thesis (Master) – Medical School, São Paulo State University (UNESP), Botucatu, 2017.

Introduction*:* The use of complementary alternative medicine has increased in several countries; besides that, a great number of people, especially women, are seeking for more natural approaches during their life-span. Therefore, the current study aimed to assess the knowledge and acceptability of diabetic pregnant women toward complementary alternative medicine, especially Reiki, during antenatal care.

Material and methods*:* A qualitative exploratory and descriptive study using in-depth interviews of a total of 12 pregnant women with diabetes attending the Perinatal Diabetes Centre (CIDP) of the Medical School of Botucatu Hospital (HCFMB). Topics included patient knowledge and acceptance toward complementary alternative medicine, especially Reiki. Semi-structured interviews were audio-recorded, transcribed verbatim and analyzed thematically.

Results*:* Most pregnant women, who have been diagnosed with diabetes, demonstrated knowing some complementary alternative medicine. Moreover, most of them would receive such treatments whether they were available in the Brazilian public healthcare setting; while reiki therapy was unknown among them.

Conclusion*:* The current study serve as focal points for both conventional and holistic health practitioners to introduce such practice in Brazilian public healthcare. Further studies in other populations are needed to enhance generalizability of the emergent theory.

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

Sumário

ARTIGO ORIGINAL

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O efeito do reiki ou oração no alívio da dor durante a hospitalização da cesárea? Uma revisão sistemática e meta-análise de ensaios clínicos randomizados

Is reiki or prayer meditation effective in relieving pain during hospitalization for caesarean? A systematic review and meta-analysis of randomized controlled trials

RESUMO

CONTEXTO E OBJETIVO: Esta revisão sistemática considerou o reiki e a oração ao uso de medicamentos, a fim de aliviar a dor durante a internação da cesárea, visto que há um aumento na popularidade da medicina integrativa e cura espiritual. Esta revisão teve como objetivo avaliar se o reiki ou oração são eficazes no alívio da dor durante a hospitalização da cesárea.

TIPO DE ESTUDO E LOCAL: Revisão sistemática com meta-análise na Faculdade de Medicina de Botucatu UNESP, São Paulo, Brasil.

MÉTODOS: As seguintes bases de dados foram pesquisados até março de 2016: MEDLINE, EMBASE, LILACS e CENTRAL. Nesse sentido, foram incluídos ensaios clínicos randomizados publicados em inglês e português. Dois revisores rastrearam independentemente artigos elegíveis; extraíram dados; e avaliaram o risco de viés. A tabela GRADE foi realizada para avaliar o risco de viés.

RESULTADOS: Evidências com alto índice de viés encontraram uma diminuição estatisticamente significativa na redução da dor (diferença média (MD) -1,68 [intervalo de confiança (IC) de 95% -1,92 a -1,43; P < 0,00001, I2 = 92%]), com o uso de reiki e oração sobre o grupo protocolar. Além disso, não houve diferença estatisticamente significativa na frequência cardíaca, pressão arterial sistólica e diastólica.

CONCLUSÃO: Evidência com alto índice de viés sugeriu que reiki e meditação oração podem ser associadas com a redução da dor.

PALAVRAS-CHAVE: Espiritualidade. Parto obstétrico. Terapias complementares. Grau de risco. Revisão.

ABSTRACT

CONTEXT AND OBJECTIVE: A systematic review considered reiki and prayer meditation to drugs, in order to relieve pain during hospitalization for cesarean, as there is an increase in the popularity of integrative medicine and spiritual healing. Therefore, this review aimed to evaluate if reiki or prayer meditation are effective in relieving pain during cesarean section.

DESIGN AND SETTING: Systematic review with meta-analysis at Botucatu Medical School, UNESP, Sao Paulo State, Brazil.

METHODS: The following databases were searched to March 2016: MEDLINE, EMBASE, LILACS and CENTRAL. Therein, randomized controlled trials published in English or Portuguese were included. Two reviewers independently screened eligible articles; extracted data; and assessed risk of bias. GRADE approach was performed to rate overall certainty of the evidence.

RESULTS: Low-certainty evidence found a statistically significant decrease in pain score (Mean Difference (MD) -1.68 [Confidential interval (CI) 95% -1.92 to -1.43; $P < 0.00001$, $I^2 = 92\%$]) with reiki and prayer meditation over usual care. Furthermore, no statistically significant difference in heart rate, systolic and diastolic blood pressures.

CONCLUSION: Low-certainty evidence has suggested that reiki and prayer meditation might be associated with pain reduction.

KEYWORDS: Spirituality. Delivery, obstetric. Complementary therapies. Risk Factor. Review.

INTRODUCTION

Complementary therapies have been practiced since ancient times, but there is still little scientific evidence on their real efficiency. Most of these therapies originated from oriental cultures, such as in India with Ayurveda treatments; China with acupuncture and moxibustion therapies; and Japan with reiki therapy. Moreover, complementary therapies are implemented both alone and alongside conventional medicine. Thus, complementary therapies tend to take a holistic approach in other to treat the entire person, i.e. body, mind and soul. In other words, they use a comprehensive set of techniques, such as meditation, body therapies, energy manipulation, art and music therapy, dietary therapy and other procedures that involve healthcare, according to the National Center for Complementary and Alternative Medicine.[1-5]

Reiki is an ancient Japanese form of hands-on healing. The term comes from combining two Japanese words: rei, a universal spirit; and ki, meaning universal life energy.[1] Despite being a Japanese form of healing, use of reiki has already spread worldwide. It is mainly used for pain relief.[2] Additionally, prayer meditation is also considered to be an adjunctive therapy involving a non-invasive method with a low-cost procedure.[5] Thus, it improves psychological, social, spiritual and physical health by means of nourishing the environment through peacefulness and mindfulness.[6,7]

A previous systematic review of clinical trials[2] compared reiki therapy with the usual care or with placebo among women undergoing breast biopsy, women with abdominal hysterectomies, cancer patients, individuals with depression, and chronically ill patients. However, that review seemed to have serious limitations with regard to its methodological aspects. For example, it presented a variety of conditions, i.e. 12 articles included and therefore 12 different types of conditions, but no data on pregnant women. In other words, the review was quite generalist. Moreover, it did not use the GRADE approach to rate the quality of scientific evidence. Consequently, the review was unable to provide any conclusion about the effectiveness of reiki and the suggestion made was that new studies on this topic would be necessary.

In the literature, a few studies[1-11] have reported that spirituality and complementary therapies have provided improvements regarding quality of life and benefits in relation to several health conditions.[6-8] Moreover, it has been suggested that non-pharmacological practices could be considered in order to reduce excessive use of allopathic medication in obstetrics and consequently to reduce the costs of care.

OBJECTIVE

The aim of this systematic review of randomized controlled trials (RCTs) was to evaluate whether reiki or prayer meditation is effective for controlling pain among women undergoing cesarean section.

METHODS

The Cochrane Handbook for Intervention Reviews[12] guided our choice of methods. Our reporting adhered to the Preferred Reporting Items for Systematic Reviews and Meta-analysis (PRISMA) statement.[13]

Eligibility criteria

We included RCTs or quasi-RCTs that compared reiki therapy and prayer meditation with the usual care among pregnant women undergoing cesarean section, including any of the following maternal outcomes before and after receiving the intervention or usual care: pain control; heart rate; diastolic and systolic blood pressure; or medication intake. Furthermore, a

single study[9] recorded postpartum physical activities through Milestone questionnaire.

Data source and searches

Pertinent literature was identified through Medline (from 1966 to March 2016); EMBASE (from 1980 to March 2016); LILACS (from 1982 to March 2016); and Cochrane controlled trials (CENTRAL) (up to March 2016), using the terms spirituality, reiki, prayer, cesarean and labor pain (**Table 1**). The data-gathering was restricted to Portuguese and English-language studies. There were no publication status restrictions. A review of relevant references in previous systematic review articles[1,2] and primary studies[3-11] was conducted.

Selection of studies

Randomized controlled trials or quasi-RCTs published in English or Portuguese were included. Two reviewers, working independently, screened all titles and abstracts that were identified through the literature search. Furthermore, they selected potential studies by obtaining the full-text articles, and then evaluated them, in accordance with the eligibility criteria.

Data extraction and risk-of-bias assessment

Two reviewers independently screened all the potential quantitative results or critical data from some preselected studies, with regard to the participants, interventions, control conditions, outcome measurements and results. Subsequently, disagreements between the reviewers were discussed with the researcher chief, in order to reach a consensus.

The reviewers independently assessed risk of bias by using a version of the Cochrane Collaboration's tool for assessing risk of bias.[14] This includes nine domains: adequacy of sequence generation; allocation sequence concealment; blinding of participants and caregivers; blinding of data collectors; blinding for outcome assessment; blinding of data analysts; incomplete outcome data; selective outcome reporting; and presence of other potential sources of bias not accounted for in the previously cited domains. For incomplete outcome data, we stipulated that low risk of bias consisted of loss to follow-up of less than 10% and a difference in missing data between the intervention and control groups of less than 5%.

Certainty of evidence

The reviewers used the Grading of Recommendations for Assessment, Development and Evaluation (GRADE) methodology to rate the certainty of scientific evidence for each outcome, which was categorized as high, moderate, low or very low.[15] The GRADE approach assessed the following: overall risk of bias,[16] imprecision,[17] inconsistency,[18] indirectness[19] and publication bias.[20] Thus, the results were summarized in an evidence table, i.e. as a GRADE evidence profile.

The reviewers independently assessed eligibility, risk of bias and data abstraction. Disagreements were resolved by reaching a consensus or by obtaining a third reviewer's opinion if needed.

Data synthesis and statistical analysis

We pooled the data to calculate pooled risk ratios (RRs) or mean differences, with 95% confidence intervals (CIs), using a fixed-effect model by considering the last follow-up outcome measured in each study included. We assessed heterogeneity by means of the I^2 statistic and evaluated the quality of the evidence by using the GRADE method. All of the analyses were conducted using the Review Manager (RevMan) software.[21]

RESULTS

Selection of titles

Approximately 496 titles were identified in the databases cited above, but only 34 studies were selected for detailed evaluation.[12] Ultimately, it was found that only three studies that included 343 patients were eligible for the current review (**Figure 1**).

These studies presented different interventions, i.e. distant reiki,[9] regular reiki[10] and prayer meditation,[11] but they all presented a similar outcome, i.e. they measured pain through a visual analogue scale (VAS) and also measured heart rate and diastolic and systolic blood pressure. In the literature, all reiki healers consider that distant reiki[9] and regular reiki[10] are the same, with the only difference that in one, the patient`s physical body is absent, while it is present in the other[1,2,9]

Although prayer meditation[11] may seem to have been the odd one out, we analyzed this study in depth and decided to plot it together with the two reiki studies,[9,10] because all the

information from this study with regard to the prayer meditation background, the objectives of the study and the methods used to evaluate the intervention were in line with these other studies.[9,10] Moreover, these factors were in line with our aim in this systematic review, which was to evaluate perceived pain among women undergoing cesarean section. Moreover, both reiki and prayer meditation are non-invasive and non-pharmacological practices, and both of them can be considered to be spiritual interventions.[1,2,9-11]

Study characteristics

Table 2 describes the studies characteristics relating to the study design, setting, number of participants, the intervention and the usual care treatments received by the patients according to each study methods and hospital protocol, mean age, inclusion and exclusion criteria and follow-up after caesarean section. One study was conducted in Canada,[9] and the other two were conducted in the Middle East, in Turkey[10] and Iran.[11] The sample sizes ranged from 40[9] to 80[11] pregnant women aged in their twenties or thirties. All the studies included pregnant women undergoing cesarean section.

The following exclusions of patients were made in one or more of these studies: previous experience with reiki;[9,10] perception of pain on a visual analogue scale (VAS) > 3;[11] not planning to use standard postoperative pain medication;[10,11] not being able to answer the questions;[9-11] visual and hearing impairment;[10,11] any complications during anesthesia or surgery;[10,11] history of drug abuse;[10,11] operation performed under spinal and epidural anesthesia;[10] use of patient-controlled analgesia in the treatment;[10] and presence of any psychiatric disease or allergy to analgesic drugs.[10] The length of the follow-up ranged from 6 hours to 3 days.

Risk-of-bias assessment

Figure 2 describes the risk-of-bias assessment for RCTs. The overall methodological quality of the studies examined was evenly separated into unclear and low risk-of-bias categories. However, the main concern was the risk of bias relating to random sequence generation in the study by Vandervaart et al.[9] Additionally, the allocation concealment and blinding of participants/personnel were uncertain in the studies by Midilli and Eser[10] and Beiranvand et al.[11] Finally, none of the three studies[9-11] showed any certainty with regard to blinding of the outcome assessment.

Effects of reiki and prayer meditation: meta-analysis

Pain score

Regarding the pain scores measured by means of a VAS in the overall analysis, the results from three RCTs[9-11] found a statistically significant difference favoring reiki and prayer meditation over the usual care: mean difference (MD) = -1.68; 95% confidence interval (CI): -1.92 to -1.43; $P < 0.00001$; $I^2 = 92\%$. In relation to the following subcategories, we also found statistically significant differences favoring the integrative practices over the usual care: prayer meditation (MD = -1.70; 95% CI: -2.00 to -1.40; $P < 0.00001$; I^2 = not applicable); and reiki (MD = -2.52; 95% CI: -3.07 to -1.97; $P < 0.00001$; I^2 = not applicable). However, there was no statistically significant difference between the distant and regular reiki groups: MD = -0.20; 95% CI: -0.90 to 0.50; P = 0.58; I^2 = not applicable. The certainty of the evidence was downrated to low because of inconsistency and publication bias (**Figure 3, Table 3**).

Heart rate

With regard to heart rate in the overall analysis, the results from two RCTs[9,10] did not show any statistically significant difference that favored regular and distant reiki over the usual care: MD = -2.04; 95% CI: -4.93 to 0.84; P = 0.41; $I^2 = 0\%$. Therefore, we found no statistically significant difference favoring reiki over the usual care: MD = -3.58; 95% CI: -8.26 to 1.10; P = 0.17; I^2 = not applicable. In addition, there was no statistically significant difference between the distant and regular reiki groups: MD = -1.10; 95% CI: -4.76 to 2.56; P = 0.17; I^2 = not applicable. The certainty of the evidence was downrated to low because of imprecision and publication bias (**Figure 4, Table** 3).

Diastolic blood pressure

For diastolic blood pressure, the results from two RCTs[9,10] did not show any statistically significant difference favoring regular and distant reiki over the usual care: MD = -1.74; 95% CI: -4.18 to 0.70; P = 0.16; $I^2 = 0\%$. Therefore, we also found no statistically significant difference favoring reiki over the usual care: MD = -0.58; 95% CI: -4.10 to 2.94; P = 0.37; I^2 = not applicable. In addition, there was no statistically significant difference between the distant and regular reiki groups: MD = -2.80; 95% CI: -6.17 to 0.57; P = 0.37; I^2 = not applicable. The certainty of the evidence was downrated to low because of imprecision and publication bias

(**Figure 5, Table 3**).

Systolic blood pressure

In the overall analysis with regard to systolic blood pressure, the results from two RCTs[9,10] showed that there was no statistically significant difference favoring reiki over the usual care: MD = -3.59; 95% CI: -6.79 to 0.39; P = 0.03; I^2 = 26%. Therefore, we also found no statistically significant difference favoring reiki over the usual care: MD = -1.71; 95% CI: -6.21 to 2.79; P = 0.25; I^2 = not applicable. In addition, there was no statistically significant difference between the distant and regular reiki groups: MD = -5.50; 95% CI: -10.04 to -0.96 P = 0.25; I^2 = not applicable. The certainty of the evidence was downrated to moderate because of inconsistency and publication bias (**Figure 6, Table 3**).

Effect of first-time activity through Milestone questionnaire and patients' need for opioids in VanderVaart study[9]

Regarding the activity milestone questionnaire, which is used in women post-elective caesarean to evaluate the rate of healing, a single RCT[9] showed that there was no statistically significant difference between distant reiki and the usual care in any of the following categories: time to first hunger; time to first eating of solid food; time to first flatus; time to first bowel movement; time to first spontaneous voiding; and time to first ambulation (**Figure 1**). Moreover, the same study[9] described the patients' need for opioids, but showed that there was no statistically significant difference between distant reiki and the usual care on the day of admission to hospital (relative risk, RR = 0.81; 95% CI: 0.66 to 1.30; P = 0.64; I^2 = not applicable); or on the next day (RR = 1.22; 95% CI: 0.74 to 1.63; P = 0.65; I^2 = not applicable) (**Figure 2**).

DISCUSSION

This study evaluated the use of reiki and prayer meditation for pain control among women undergoing caesarean section. It was the first-ever study to evaluate spiritual healing in relation to this issue, given that most previous studies and reviews focused on severe chronically ill patients and their quality of life.[1-7]

It should be noted that a language restriction had to be imposed during the selection process due to lack of funds to pay for translation services prior to the search. Thus, it was necessary to restrict the current systematic review to English and Portuguese-language publications. This consequently constitutes one of the limitations of this study. Therefore, all English and Portuguese studies were assessed since the beginning and none study was excluded for being written in other language, as it was not found by the search methods.

A recent study[22] showed that around 26% of women in the United States receive spiritual healing treatment if they were non-smokers, non-drinkers or low-risk drinkers, had symptoms of severe tiredness, depression, anxiety, diagnosed cancer or major illnesses. In another study on women in the southern and midwestern United States regions (i.e. extremely religious areas), the proportion that received prayers for health was estimated to be 53%.[23] The fact that the study by Beiranvand et al.[11] presented a significant outcome, i.e. pain control among women undergoing caesarean sections, with high follow-up rates, may have been due the presence of highly religious women in their sample. According to Bell et al.,[23] people who usually use prayer meditation, are also likely to use some other form of complementary or alternative medicine (e.g. reiki or acupuncture). Additionally, the more religious the people are, the more likely it is that they will use preventive healthcare.[20]

Among the studies included, some limitations were reported, as follows: the sample size;[9-11] presence of only one reiki therapist;[9] absence of information about the mechanism of action of distant reiki;[9] use of shared rooms;[10] and a noisy environment.[10] In addition to the methodological limitations, this current review also presented a limitation relating to the results obtained through meta-analysis: although the perceived pain seemed to have decreased significantly, the heterogeneity of results was extremely high, i.e. I^2 = 92% (**Figure 3**). This can be explained by the fact that there were three different types of intervention.

On the other hand, regular and distant reiki work in the same way as foundations for this type of therapy[9] and, therefore, they were not different at all. Moreover, prayer meditation is a form of adjunctive therapy within many cultures.[11,20,23,24] Thus, both prayer meditation and reiki are forms of spiritual healing. According to Benor,[24] spiritual healing is defined as a systematic and purposeful intervention by practitioners that has the aim of helping other people to improve their health condition through focused intention, which can include hand contact or hand movement. Thus, these three studies[9-11] presenting similar methodological aspects and outcomes were plotted together. Within Systematic reviews is known that meta-analysis that included less than 10 studies cannot estimate heterogeneity.

The meta-analysis did not show any statistical significant difference before and after

receiving the treatments in both intervention and usual care groups for heart rate (**Figure 4**), diastolic and systolic blood pressure (**Figure 5** and **6**, respectively). In other words, these results were concordant with those of the previous review.[2] However, to reach definitive conclusions regarding the effectiveness of such therapies, larger populations in good RCTs are needed.

With regard to the methodological aspects, the present review noted that there were risks of bias relating to random sequence generation;[9] allocation concealment;[10,11] blinding of participants/personnel;[10,11] and blinding of outcome assessment. This concern corroborates what was reported in the systematic review on reiki conducted by vanderVaart:[2] all of the 12 studies included had failings in at least in one of the following areas: randomization, blinding and accountability of all patients. Therefore, both reviews can be classified as presenting low-quality evidence, and the main issue in this regard is the poor evidence from the RCTs. We sent emails to the respective corresponding authors of the studies selected for this review,[9-11] regarding points in these studies that were unclear to us or not reported, but no replies had been received by the time of submitting this review.

The previous review[2] attempted to evaluate the effectiveness of reiki therapy under several conditions and presented 31 different outcomes within the 12 studies included. Not all of these studies were RCTs; no meta-analysis was performed, and the findings were based on Jadad scores. The previous review also did not include any study on pregnant women undergoing a cesarean section. On the other hand, the present systematic review included three studies[9-11] in which there were similarities regarding methods, outcomes and populations, based our evidence from the GRADE profile for continuous outcomes (**Table 3**), and this review also included a meta-analysis.

Additionally, the major limitation of the current study was that only a very small number of studies considering spiritual healing approaches to pain management after cesarean section have been published. Therefore, there is still a need for high-quality RCTs on this issue, with the aim of assessing the real effectiveness of reiki and prayer meditation in relation to pain control among women undergoing cesarean section.

CONCLUSION

Low-certainty evidence suggested that use of reiki and prayer meditation might be associated with pain reduction.

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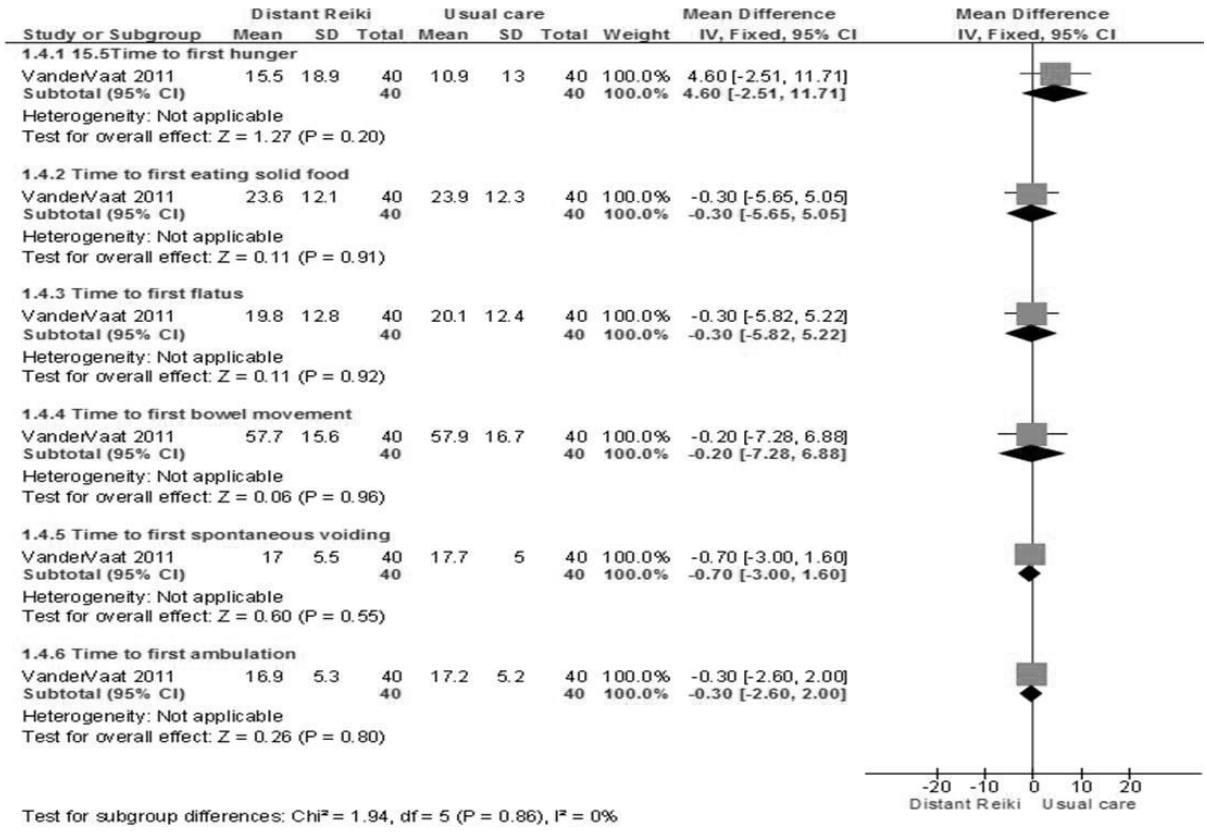
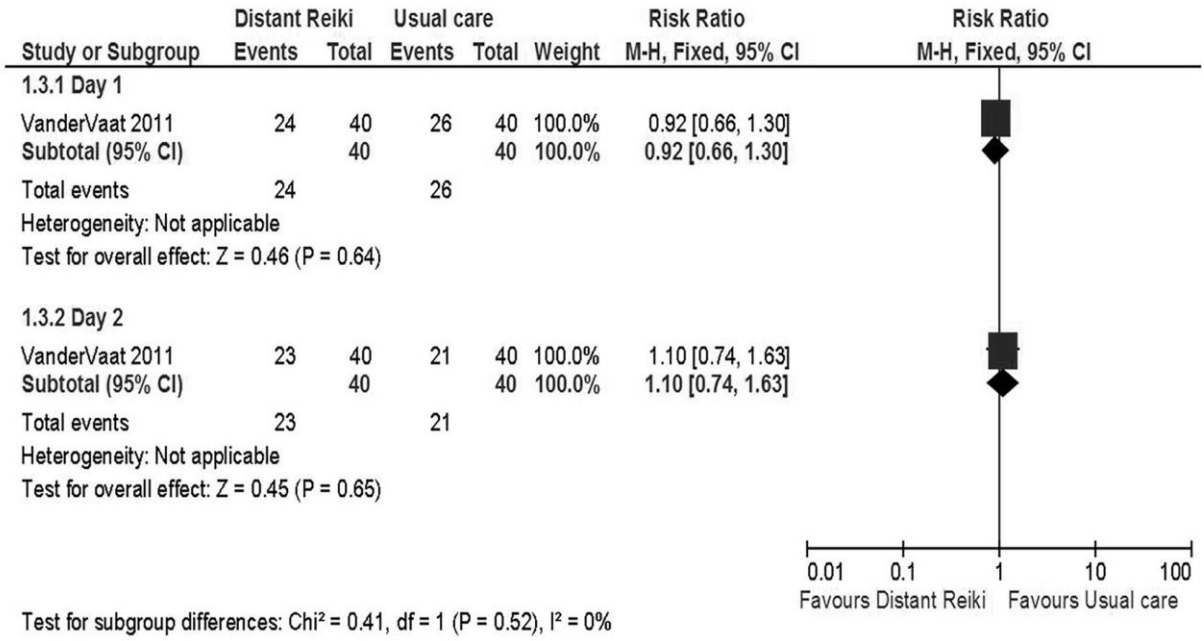


Appendix Figure 1. Representation of meta-analysis of the activity milestone questionaire



Appendix Figure 2. Representation of meta-analysis of patients on opioids

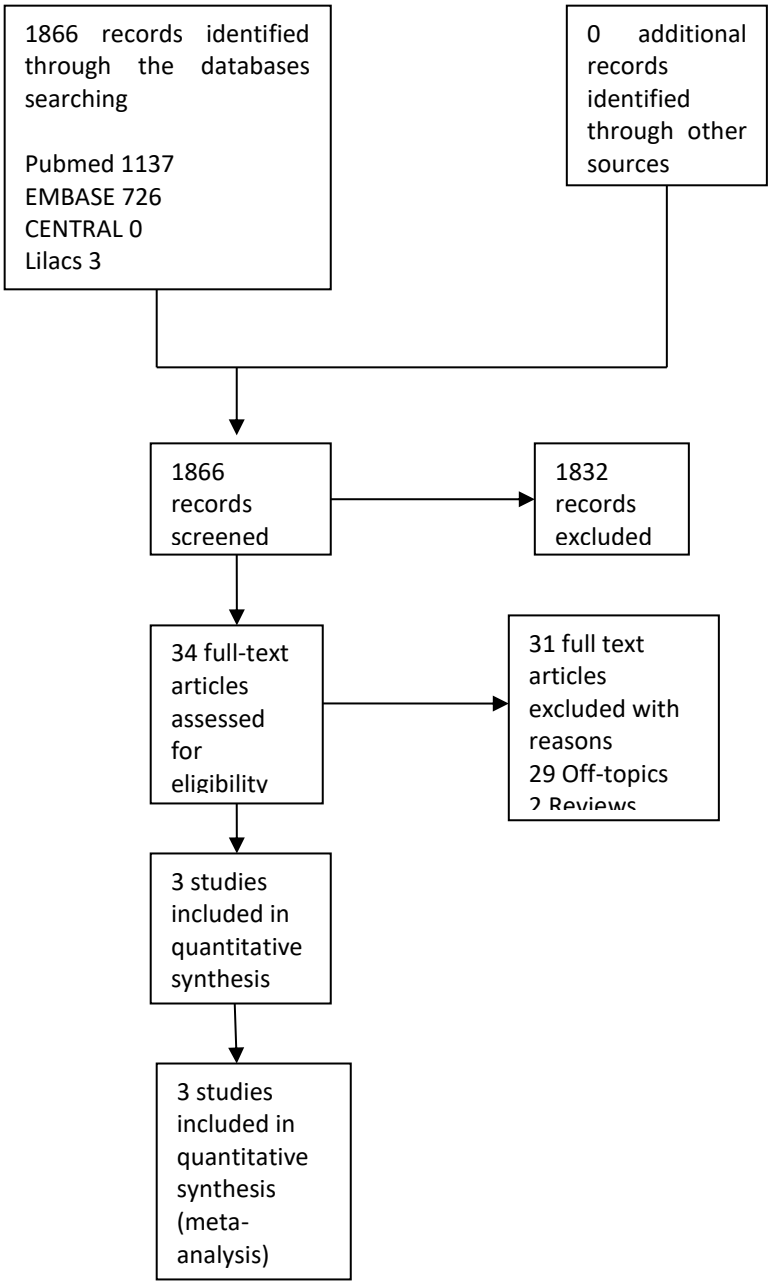


Figure 1. PRISMA Flowchart

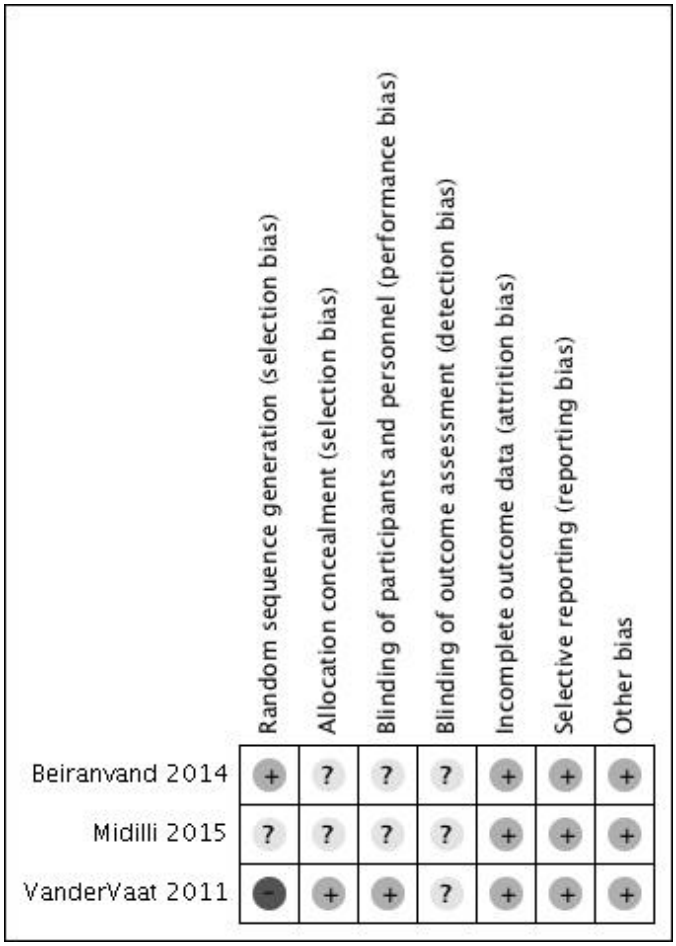


Figure 2. Risk of bias assessment

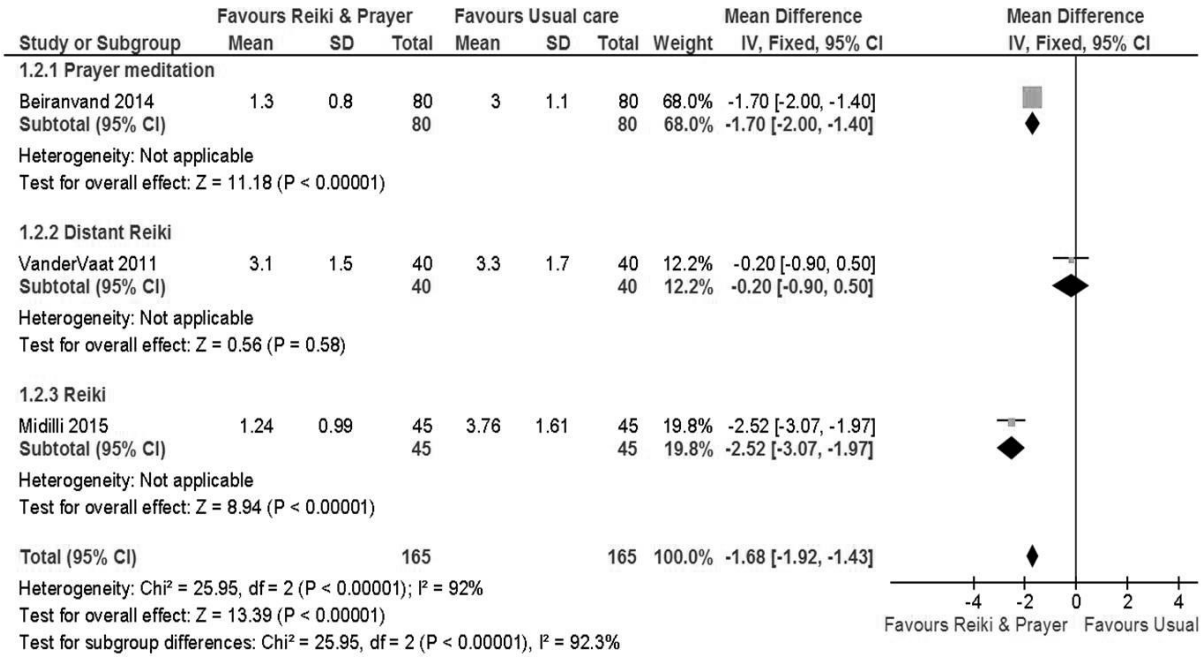


Figure 3. Meta-analysis of mean pain score measured by Visual Analogue Scale (VAS)

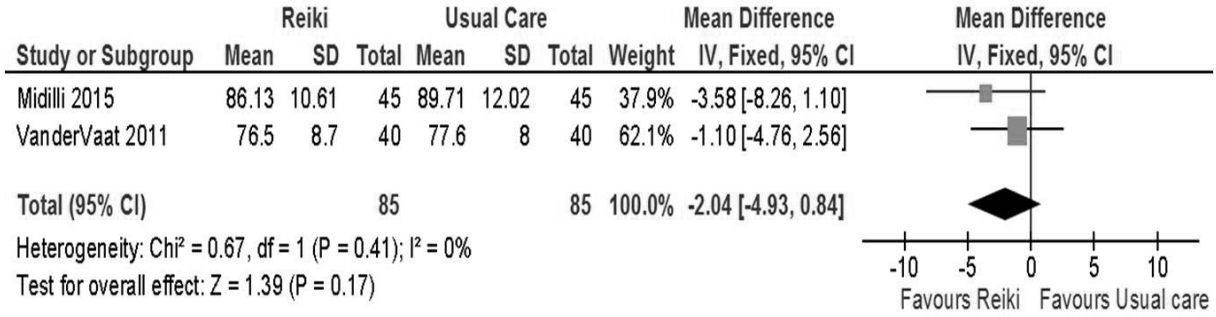


Figure 4. Meta-analysis of heart rate

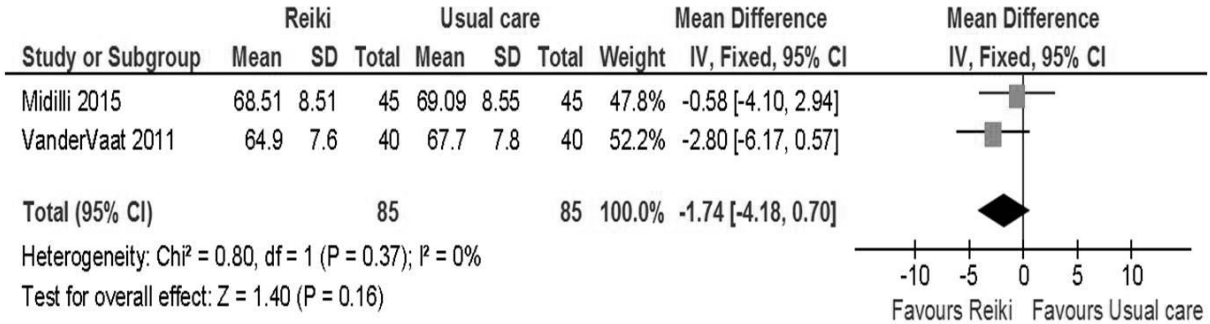


Figure 5. Meta-analysis of diastolic blood pressure

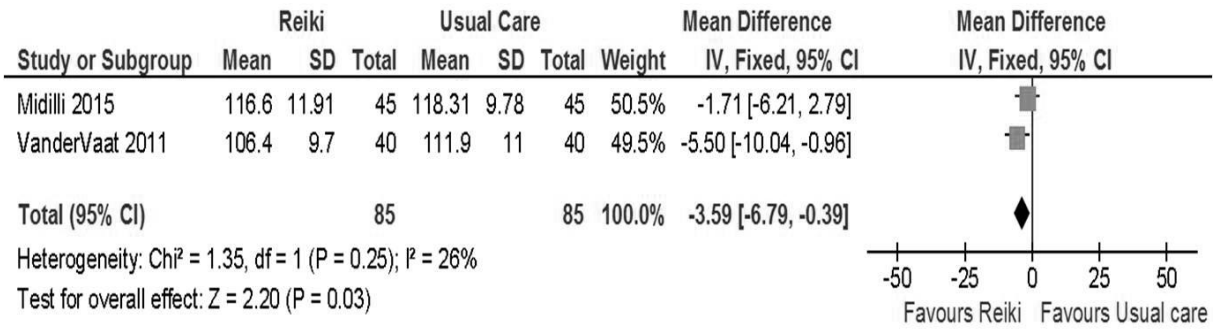


Figure 6. Meta-analysis of systolic blood pressure

Table 1. Search strategies for MEDLINE via PUBMED; CENTRAL; LILACS and EMBASE.

Medline via Pubmed
#1"Spirituality"[Mesh] OR Spiritualities OR "Reiki"[Mesh] OR "`Touch, Therapeutic" OR "Laying on of Hands" OR "Prayer Healing"[Mesh] OR "Faith Healing" OR "Prayer"[Mesh] OR Beliefs OR "Spiritual Healing"[Mesh] OR "Spiritual Therapies"
#2"Cesarean"[Mesh] OR "Cesarean Sections" OR "Cesarean Section" OR "Abdominal Deliveries" OR "Abdominal Delivery" OR "Caesarean Section" OR "Caesarean Sections" OR C-Section OR "C Section" OR C-Sections OR "Post caesarean Section".
#3"Pain, Labor"[Mesh] OR "Obstetric Pain" OR "Pain, Obstetric"
STRATEGY: #1 AND #2 AND #3

CENTRAL
"Spirituality" OR "Spiritualities" OR "Reiki" OR ('Touch, Therapeutic" OR "Laying on of Hands" OR "Prayer Healing" OR "Faith Healing") OR "Prayer" OR "Beliefs" OR "(Spiritual Healing" OR "Spiritual Therapies") AND "Cesarean" OR ("Cesarean Sections" OR "Cesarean Section" OR "Abdominal Deliveries" OR "Abdominal Delivery" OR "Caesarean Section" OR "Caesarean Sections" OR C-Section OR "C Section" OR C-Sections OR "Post caesarean Section") AND "Pain, Labor" OR ("Obstetric Pain" OR "Pain, Obstetric")

Lilacs
Espiritualidade OR Reiki OR (Toque terapêutico) OR (Superposição de mãos) OR (Cura Espiritual) OR (Terapias espirituais) OR (Cura pela Fé) AND Cesárea OR (Parto Abdominal) OR (Parto Obstétrico) AND (Dor do Trabalho de Parto) OR (Dores do Trabalho de Parto) OR (Dor de Parto) OR (Dores de Parto) OR (Dores do Parto)

EMBASE
#1 'reiki'/exp OR
#2'religion/exp OR 'prayer'
#3 'spirituality'/exp
#4 'cesarean section'/exp OR 'birth' OR 'abdominal operation' OR 'birth, caesarean' OR 'caesarean birth' OR 'caesarean section' OR 'caesarian birth' OR 'caesarian section' OR 'cesarean delivery' OR 'cesarean section' OR 'repeat; cesarian section' OR 'elective repeat cesarean section' OR 'sectio caesarea'
#5 'labor pain'/exp OR 'delivery pain' OR 'labour pain' OR 'pain, delivery' OR 'pain, labor' OR 'pain, labour'
STRATEGY: #1 OR #2 OR #3 AND #4 AND #5

Table 2. Study characteristics related to setting, number of participants, mean age, intervention and control group description, inclusion and exclusion criteria, assessed outcomes and follow-up.

Author, year	Location	No.* participants	Mean age	Description of intervention group (randomized patients, n)	Description of control groups (randomized patients, n)	Inclusion criteria	Exclusion criteria	Measured outcomes	Follow-up (hours) after caesarean
Midilli 2015 [21]	Turkey	100	Reiki: 27.61** Usual care: 27.61**	Usual care (specified)*** and reiki therapy for 30 minutes for two days (n=50)	Usual care (specified)*** and 30 minutes rest for 2 days (n=50)	Planned or unplanned cesarean delivery; age between 18-45 years; length of stay of at least two days at the hospital; orientation to place and time; operation performed under general anesthesia; and only using a monopoid analgesic drug prescribed by a doctor (diclofenac 75mg/3mL, intramuscular).	Operation performed under spinal and epidural anesthesia; any psychiatric disease or allergy to analgesic drugs; hearing and visual impairment; previous experience with Reiki; serious complication with the patient or infant(s) during or after cesarean delivery; or use of a patient controlled analgesia in treatment.	Pain intensity by using a horizontal VAS (0-10); anxiety by using STAI; hemodynamic parameters score.	48
Beiranvand 2014 [22]	Iran	160	Prayer: 27.4 Usual care: 29.4	Usual care (not specified) and pray meditation therapy for 20 minutes after C-section (n=80)	Usual care (not specified) (n=80)	Muslim women candidate for cesarean surgery under spinal anesthesia, with mild pain (VAS < 1-3).	Muslim women with VAS > 3; hearing disorder; history of drug abuse; administration of analgesics; any	Pain score by using VAS < 3; blood pressure (diastolic and systolic); heart rate; mother´s respiratory rate;	6

						complications during anesthesia or surgery; or being unable to answer the questions.	PONV; and relaxation.	
VanderVaart 2011 [18]	Canada	83	Reiki: 35.1 Usual care: 32.9	Usual medical and nursing care accordingly to Pfannenstiel protocol associated with distant Reiki sessions, one each morning (30 minutes before the C-section morning, second and third sessions were administered on the following mornings at about 8 am) (n=42)	Usual medical and nursing care accordingly to Pfannenstiel protocol (n=41)	Pregnant women.	Patients who have had previous experience with Reiki or not planning to use postoperative pain medication; or being unable to answer the questions.	AUC for pain (in movement) for days 1-3 by using VAS; AUC for pain in motion for days 1, 2 and 3, separately; mean VAS (in motion) from days 1-3; mean VAS (in rest) from days 1-3; number of patients in need of opioid pain medication; adverse events to opioid, such as constipation, itchiness; mother´s respiratory rate; heart rate; blood pressure; and time of first activity (e.g., first hunger, first walk) by using the Milestone Questionnaire.	72

no.: number; RCT: randomized controlled trial; ml: milliliter, mg: milligram; VAS: Visual Analogue Scale; STAI: State-Trait Anxiety Inventory; cm: centimeters; C-section: caesarean section; ml: milliliters; PONV: incidence of postoperative nausea and vomiting

*Randomized participants.

**Patients were equalized by age into two groups (18-31 and 32-45 years old).

***Day 1 (24 hours postoperation): Patients were given the first dose of the standard analgesic (intramuscular, 75 mg/3 mL diclofenac at 9.00 a.m. and 9.00 p.m.); Day 2 (48 hours postoperation): Patients were given the third dose of the standard analgesic (intramuscular, 75 mg/3 mL diclofenac at 9.00 a.m. and 9.00 p.m.); Day 3 (72 hours postoperation): Minoset 500 mg, tablet (every 4-6 hours, as needed) was administered according to the analgesic protocol, and at 72 hours only the number of analgesics required by the patient was determined by face-to-face interview or telephone call.

Table 3. GRADE evidence profile of continuous outcomes: complementary alternative medicine for C-section.

Quality assessment						Illustrative comparative risks (95% CI)		Certainty in estimates OR Quality of evidence
						Assumed risk	Corresponding risk	
No of participants (studies) *Range follow-up time in weeks*	*Risk of bias*	*Inconsistency*	*Indirectness*	*Imprecision*	*Publication bias*	Usual care	Reiki and Prayer meditation	
Pain score measured by VAS								
343 (3) 6-72	No serious limitation	Very serious limitation[1]	No serious limitation	No serious limitation	Serious limitation[3]	The mean in change in pain score was 3.0 (SD 1.1)*	The mean in changes in pain score in the intervention group was on average 1.68 fewer (1.92 fewer to 1.43 fewer)	Low
Heart rate								
183 (2) 48-72	No serious limitation	No serious limitation	No serious limitation	Very serious limitation[2]	Serious limitation[3]	The mean in change in heart rate frequency was 77.6 (SD 8)**	The mean in changes in heart rate in the intervention group was on average 2.04 fewer (4.93 fewer to 0.84 more)	Low
Systolic Blood Pressure								
183 (2) 48-72	No serious limitation	Serious limitation[3]	No serious limitation	No serious limitation	Serious limitation[3]	The mean in change in systolic blood pressure was 118.31 (SD 9.78)***	The mean in changes in systolic blood pressure in the intervention group was on average 3.59 fewer (6.79 fewer to 0.39 fewer)	Moderate
Diastolic Blood Pressure								
183 (2) 48-72	No serious limitation	No serious limitation	No serious limitation	Very serious limitation[2]	Serious limitation[3]	The mean in change in diastolic blood pressure was 67.7 (SD 7.8)**	The mean in changes in diastolic blood pressure in the intervention group was on average 1.74 fewer (4.18 fewer to 0.70 more)	Low

CAM = complementary alternative medicine; SD = standard deviation; std. = standardized; VAS = visual analogue scale

[1]There was a substantial heterogeneity (I^2=92.3%) provided per different interventions used in the included studies (i.e., distant reiki; reiki; and prayer meditation).

[2]95% CI for absolute effects include benefit and harm.

[3]There was heterogeneity (I^2=26%) provided per different interventions used in the included studies (i.e., distant reiki; reiki; and prayer meditation).

*Baseline risk estimates for pain come from control arm of study by Beiranvand et al.[113] (largest randomized trial in the meta-analysis); †); **Baseline risk estimates for heart rate, systolic and diastolic blood pressure come from control arm of study by Midilli (2015)[22]

ARTIGO ORIGINAL 2

Formatado de acordo com as normas de publicação da Acta Obstetricia et Gynecologica Scandinavica e submetido no dia 08 de Janeiro de 2017 (AOGS-17-0005).

Conhecimento e aceitação das práticas integrativas e complementares na saúde, em especial a terapia Reiki, de gestantes diabéticas atendidas num centro terciário: uma abordagem qualitativa

Toward understanding the knowledge and acceptance of complementary alternative medicine, especially Reiki, of pregnant women with diabetes in a Brazilian tertiary centre: a qualitative study

Resumo

Introdução: As práticas integrativas e complementares na saúde vêm ganhando cada vez mais espaço em diversos países, visto que um grande número de pessoas, especialmente mulheres, estão buscando abordagens mais naturais para solucionar uma variedade de problemas. O objetivo do estudo foi avaliar como as mulheres grávidas diagnosticadas com diabetes compreendem e aceitam o uso de práticas integrativas e complementares na saúde, especialmente Reiki, durante o atendimento pré-natal.

Material e métodos: Trata-se de um estudo qualitativo exploratório e descritivo, utilizando entrevistas para 12 gestantes diabéticas atendidas no Centro de Investigação do Diabetes Perinatal da Faculdade de Medicina de Botucatu. Foram elucidados três temas que compreendem o conhecimento e a aceitação do paciente sobre práticas integrativas na saúde, assim como o conhecimento e aceitação da terapia Reiki. As entrevistas foram audiogravadas e transcritas para posterior análise.

Resultados: A maioria das mulheres gestantes diagnosticadas com diabetes demonstrou conhecer algumas das práticas integrativas e complementares na saúde. Além disso, um grande número de entrevistadas receberia tais terapias se estas fossem disponíveis no Sistema Único de Saúde, porém a terapia reiki mostrou ser desconhecida entre as pacientes.

Conclusão: O presente estudo serve como ponto de partida para profissionais de saúde introduzirem as terapias integrativas e complementares na saúde pública brasileira. Estudos adicionais em outras populações são necessários para obter uma visão mais profunda e detalhada do perfil das pacientes em diferentes regiões.

Palavras-chave: gravidez, diabetes mellitus gestacional, práticas da sáude complementares e integrativas, pré-natal

Abstract

Introduction*:* The use of complementary alternative medicine has increased in several countries; besides that, a great number of people, especially women, are seeking for more natural approaches during their life-span. Therefore, the current study aimed to assess the knowledge and acceptability of diabetic pregnant women toward complementary alternative medicine, especially Reiki, during antenatal care.

Material and methods*:* A qualitative exploratory and descriptive study using in-depth interviews of a total of 12 pregnant women with diabetes attending the Perinatal Diabetes Centre (CIDP) of the Medical School of Botucatu Hospital (HCFMB). Topics included patient knowledge and acceptance toward complementary alternative medicine, especially Reiki. Semi-structured interviews were audio-recorded, transcribed verbatim and analyzed thematically.

Results*:* Most pregnant women, who have been diagnosed with diabetes, demonstrated knowing some complementary alternative medicine. Moreover, most of them would receive such treatments whether they were available in the Brazilian public healthcare setting; while reiki therapy was unknown among them.

Conclusion*:* The current study serve as focal points for both conventional and holistic health practitioners to introduce such practice in Brazilian public healthcare. Further studies in other populations are needed to enhance generalizability of the emergent theory.

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

Introduction

All over the world, there is a trend among both men and women to use complementary alternative medicine (CAM) (1-22). In general, women tend to seek healthcare more often than men (23). Such interest in CAM began in the 1960s, when the counterculture movement had increased American and European population interest in more natural and traditional healing approach. Counterculture movement was characterized by protesting medical care cost and pharmaceutical industry's dominance (24) Furthermore, this movement quickly spread to Latin America.

In Europe and United States, CAM represents several therapies that are based on ancient, folkloric and traditional systems of medicine that consist of both maintaining and improving physical and mental illnesses through a variety of practices (1-22). Additionally, the

use of CAM depends on each country, i.e. either outside conventional health care or adapted by conventional health care (1,2,25).

Since 2006, the term Integrative and Complementary Practice has been used to describe a wide variety of CAM and has brought conventional and complementary approaches together in a coordinated way (1,2,25). In 2006, Brazilian Healthy Ministry approved a National Policy (Ordinance nº 971) on Integrative and Complementary Practices (PNPIC) within Brazilian Unified Health System (SUS); therefore, homeopathy; acupuncture and traditional Chinese medicine; medicinal plants and herbs; hydrotherapy/crenotherapy and anthroposophical medicine have been accepted into public health practice (20, 26). In 2016, the National Policy on CAM also included community therapy, circle dance, yoga, massage and auriculotherapy (26). Additionally, art and music therapy, meditation, naturopathy, osteopathy, chiropraxy and Reiki have been recently introduced on the same National Policy (January 13, 2017) (26).

In the United States, the National Centre for Complementary and Integrative Health (NCCIH) classified most complementary health approaches into one of two subgroups: natural products (e.g. vitamins and minerals; herbs and probiotics) or mind and body practices (e.g. yoga; chiropractic and osteopathic manipulation; meditation; massage therapy; acupuncture; tai chi; qi qong; healing touch; hypnotherapy and movement therapies such as Pilates) (25). Although, most of the natural products and mind and body practices fall into complementary health approaches, some CAM has not been fit into either of these groups, such as traditional healers, traditional Chinese medicine, Ayuverdic medicine, homeopathy and naturopathy (25).

In the United States, the medical world is currently changing its biomedical point of view to a more holistic, which moves away from the reductionist view of biomedicine to one that views the human as a complex system (19,27); thus, make it necessary to approach healthcare from multiple perspectives, in other words, not only biology, biophysics, biochemistry and psychology, but also energy medicine that is based on the principle that all living systems generate and respond to energy fields as integral aspects of physiological regulation, as described by Rubik (27). Most Eastern medicine have been working with such concept that all living creatures have life force energy that sustain all living organisms; and this life force has several names such as Ki (Japanese medicine), Qi (Chinese medicine) and Prana (Ayurveda) (19,27).

Reiki is among energy medicine, is composed of two Japanese words: Rei (i.e. universal or higher knowledge or spiritual consciousness) and Ki (i.e. life energy) (27). Reiki is a natural form of healing that uses both subtle energy systems in the body and universal life force energy to bring the organism into balance and equilibrium. Reiki was rediscovered as a healing

modality and brought back into practice by Mikao Usui in Japan in the early 1900s (19). This healing modality involves gently laying the hands on or above the body and the directing of healing energy from the universal life energy through the practitioner to the client (27).

Additionally, pregnancy plays a crucial role in any women´s life, besides that when a woman has been diagnosed with a chronicle disease during pregnancy, such as diabetes, there are potential complications for either woman or perinatal; therefore, bringing a lot of worries and stress during that time. To stablish a balance and equilibrium back to the women´s life is interesting to consider CAM, especially Reiki. A small amount of clinical trials has been conducted to investigate Reiki during pregnancy and the evidence is still very limited (21,22). Through a PubMed, CENTRAL, Lilacs and EMBASE search of Reiki treatments used in pregnancy returned 2 clinical trials (21,22). Whilst these studies only evaluated if Reiki reduced pain after caesarean section.

There are many ethical and practical difficulties of conducting research during pregnancy, but women are using these treatments, therefore it is important to investigate the efficacy and safety. However, prior to propose a clinical trial it is important to consider the knowledge and acceptance of CAM, especially Reiki, of pregnant women who have been diagnosed with diabetes in Brazilian tertiary care centre.

Material and methods

Participants

Eligible patients were Portuguese speaker and pregnant women who have been diagnosed with type 1 or 2 diabetes before getting pregnant; and gestational diabetes. To participate in the interview, all patients had to attend their antenatal care in the Perinatal Diabetes Centre (CIDP) of the Medical School of Botucatu Hospital (HCFMB) of Sao Paulo State University (UNESP). No relationship was established prior to the interview.

Procedures

A descriptive exploratory qualitative study with in-depth interviews was carried out. A purposive sample of pregnant women with diabetes at CIDP HCFMB were recruited between March and June 2016.

Eligible patients provided informed consent and completed a 10-20 minute semi-structured interview conducted by the first author (a holistic health practitioner) between March and June 2016. First author has conducted a few qualitative researches and attended some

trainings before. The interview was audio-recorded and later transcribed. The transcripts were ordered and participants were coded from A1 to A12.

Firstly, interviewer obtained demographic information from patients, such as age, ethnics and family status, educational level, employment status, number of previous live-born children, gestational age, type of diabetes and religion background (Appendix Figure 1).

Afterwards, a semi-structured interview guide (Appendix Figure 1) was used, which consisted of primary questions with emphasis on CAM and Reiki, i.e. if they have ever known any kind of complementary alternative medicine; if they would receive/accept a complementary alternative medical treatment; and if they have ever heard or received Reiki.

After the semi-structured interview, a flyer (Appendix Figure 2) was previously designed by the research group and given to each interviewee to promote Reiki. Therefore, the flyer contained some basic information of Reiki background and its benefits through short texts and photographs. After handling the flyer, the interview was stopped. By the time that all transcriptions were completed, the recordings were destroyed.

Analysis

Interview transcripts were analyzed as they were completed. Patient recruitment continued until theoretical saturation was achieved. This was pre-defined as the point at which new data become redundant with existing thematic categories and the properties of categories are sufficiently understood. Therefore, 13 pregnant women with diabetes were approached. One interviewee refused the invitation to participate and the reason was not sought. None dropped out.

Interview transcripts were analyzed qualitatively through thematic content analysis, as described by Bardin (28). The qualitative approach was adopted, as it expands meanings and identifies issues that could go unnoticed. Analysis of the interview data involved several phases: pre-analysis, material exploration and data processing (i.e. data analysis and interpretation). Demographic data were pooled together. Then, participants' speeches were grouped by similarities of meanings into one of the three analytical categories based on the semi-structured script: knowledge about CAM; acceptance in receiving CAM; and knowledge/acceptance about Reiki. Finally, two more themes have been identified through analysis, such as the use of CAM instead of prescribed drugs during antenatal care and the availability of CAM in Brazilian Unified Health System (SUS).

This study followed consolidated criteria for reporting qualitative research (COREQ) (28), which comprises a 32-item checklist for interviews and focus group.

Ethics

Committee for ethics in research involving human subjects of the Medical School of Botucatu approved the study (CAAE: 52720616.1.0000.5411).

Results

Sample characteristic

Overall 13 met all the eligibility criteria, 1 refused, 12 were enrolled and interviewed until saturation was achieved. The mean age was 32.83; gestational weeks were of 30.00. 91.67% were married; 66.67% black and studied until elementary school; 83.33% have kids before current pregnancy, being 33.33% with three kids; 50% were employed; 91.67% were diagnosed with gestational diabetes mellitus and declared to be Christian (catholic and Brazilian protestants) (Table 1).

Topics

Since no one of the 12 participants dropped out during the interviews; all answers, which are related to each of the three categories, are presented accordingly:

Toward understanding the knowledge of complementary alternative medicine

The first question of the semi-structured guide (Appendix Figure 1) assessed the knowledge of pregnant women with diabetes on CAM that are currently practiced in our society, as it follows:

Yes, I know, as I studied physical education, it is easier for me, it gives even a self-esteem to women, even more pregnant, who think they cannot do anything, is very interesting (A1)

I have heard of massage. (A2)

No, I have never heard of, like massage, acupuncture, yoga, meditation (A3)

I have not heard of them, it is the first time I have heard of them. (A4)

Already. I did yoga three times a week and I liked it a lot, because it reduces anxiety, it improves muscularity and the balance as well. I stopped three to four years ago, and I do not intend to go back, since I do not have that elasticity anymore. (A5)

Yes, acupuncture, yoga, massage, meditation. (A6)

Yes, I have heard of acupuncture. (A7)

I have heard of some of them, I think massage, yoga, meditation, acupuncture; but I am not sure how it works. (A8)

I have heard of Reiki and the new born massage that I have seen on the internet. (A9)

Yes, massage. (A10)

I do not think I have heard. Is yoga a type of therapy?! Massage?! (A11)

I have only heard of acupuncture. (A12)

Toward understanding the acceptance of complementary alternative medicine

The second question focused on their acceptance in receiving CAM and most of them expressed that they would receive such treatment, as it follows:

I would do any kind of CAM without any problem, I accept everything. (A1)

I never did massage, but I would. (A2)

I would not do acupuncture because of the needles; I would not do yoga either; I would do massage and meditation. (A3)

I guess I would not, because I'm so tired, and I'm calm enough. (A4)

I do not know, I do not have the courage to do acupuncture; and I am sore by the time someone touches me during massage. (A5)

Although I have not received any CAM, I would like to receive, it would be good. (A6)

Yes, I would like to have, because it would help more during pregnancy and I believe many people would need it too. (A7)

Never did. But if I had the opportunity I would, I also think that some people would like it, right? (A8)

I would certainly do, as it reduces stress, it is a nice way to relax and I would do that new-born massage, too, with oil, playing it lightly; reiki look like this, does not it? (A9)

I would only do it on the same day I come here. (A10)

I never did, but I would do a massage. (A11)

I do not know if I would, because I do not know how it works, but if I knew how it works, I could think straight. (A12)

Toward understanding the knowledge and acceptance of Reiki Therapy

The last question focused on Reiki and if they would consider such treatment during antenatal care. From their answers, interviewees unknow about Reiki, but also showed some openness in receiving such therapy after the flyer was handled to them, as it follows:

I do not know reiki, but with the explanation here in the flyer is very interesting. I think reiki is cool within the outpatient clinic, there are many women who are unaware here, have no completed their studies, and are very plundered during gestation; thus, reiki would help them to control their feeling, which is hormonal. Then it would be awesome, whenever it is available here. And if it would be available here, I would like to receive, because anything that brings benefits will be welcome, even more if it is on my doctor appointment´s day, which is very good, because it is kind of tedious to wait; then I receive reiki, time goes fast, I relax, go to the doctor and leave. (A1)

I have never heard of it. Hold on. The flyer is cool. Pregnant women have a lot of pains and right now there is not much medicine I can take. I certainly would. (A2)

I have never heard of it. But looking at the flyer here is cool right. I would like to receive Reiki. This therapy is for people who have a lot of worry, stress, insomnia. I would like to have reiki. (A3)

I do not know what that is. But even seeing the flyer here, I would not. But I think it's interesting to have here in the hospital, and I think other pregnant women would do. (A4)

No, I do not know reiki, but I would do. It helps a lot, but for me, at 37 weeks, so super anxious, it will not even help, but it would help others. (A5)

I have never heard of it, but seeing the flyer and reading, I would like to receive Reiki. The flyer helped me to understand very well what it is. (A6)

No, but after reading the flyer, I would receive Reiki, and I think it would be very nice to have it here, since we cannot take much medicine (A7)

I do not know, but after reading the flyer and seeing the images I think it is cool to take a little stress right, if I had it on the same day of my doctor appointment, I would like to receive, since I am very stressed lately. (A8)

Yes, I have heard of and I would do reiki. Reiki is easy, right? And it would help the child, too. (A9)

I have not known Reiki since I read this flyer, it's important if you had it here at UNESP and I would like to receive. It is important to have something new, right? (A10)

I do not know. I think it is cool to have Reiki here. I would do it here if it was on the same day as the doctor appointment. Oh, it is relaxing and I need that so much. (A11)

I do not know Reiki, but after reading the flyer, I reckon it is very interesting, well explained, it may help pregnant women, right? I would rather do. I really liked the idea of Reiki. (A12)

Discussion

There are few studies in Brazil on the use of CAM such as Reiki (13,30), but none on the understanding and acceptance of CAM OF pregnant women who have been diagnosed with diabetes. The demographic data found in the current study corroborates with studies that presented CAM users in Malaysia (7) and Turkey (8), where the mean age, educational level and socio-economic status are similar for pregnant women who seeks CAM. This fact is contradictory in developed countries, where pregnant women in their middle age with higher education seems to search more for CAM, e.g. Switzerland (1) and Australia (4). Although these studies were only conducted with pregnant women, none of them was carried out on pregnancy followed by chronicle diseases, such as diabetes. It is noteworthy consider that the public health system in Brazil, Malaysia and Turkey attends more low income people that have not completed their studies, while in Australia and Switzerland cover the whole population background.

From 1960s to 1970s, a social urban movement known as counterculture started to question the efficiency of public health policies, the empowerment of pharmaceutical industries and high health care costs mainly in the United States and France. Therefore, this social group became more interested in other healing treatments that have been promoting health since ancient time, i.e. traditional Chinese, Japanese and Ayurvedic medicine (24,31). Currently, NCCIH has been tracking the rapid growth of such therapies (25).

Furthermore, 10 out 12 interviewees demonstrated some knowledge and some understanding of CAM, e.g. *I have heard of some of them, I think massage, yoga, meditation, acupuncture; but I am not sure how it works*. (A8). Also, others thought not knowing CAM, but their understanding was correct, such as *No, I have never heard of, like massage, acupuncture, yoga, meditation* (A3). Although a great number of interviewees have not completed their mainstream education, they are all connected to various types of media, i.e. television, radio and internet, which were known to popularize CAM in some countries (8,22, 31).

Additionally, CAM has grown faster in western countries since the 1980s, through the opening of several homeopathic pharmacies, herbal fairs and private holistic health practice; other studies have also suggested that such popularization is due to the search by the population for more natural way of life that was experienced by our ancestors when suffered any kind of illness; and to reduce the habit of self-medication and its side effects (8,22,26).

The current study has shown that 10 out 12 interviewees would receive some CAM, e.g. *Yes, I would like to have, because it would help more during pregnancy and I believe many people would need it too* (A7). Although, the current study only assessed knowledge and acceptance of CAM in a Brazilian tertiary care centre, one could also state that such results corroborate with the ones conducted in Malaysia (7) and Turkey (8). where most of the women are CAM users during antenatal care. Turkey and Malaysia are under development countries like Brazil and CAM users are mostly from low educational level and socio-economic status. But Switzerland and Australia are developed countries and have shown that most CAM users were from higher education background and from average to high income level (1,4). Independently from the women background, patients, who are in a state of physical and/or mental pain, try to find any solution in order to alleviate their suffering, which may explain the acceptance of pregnant women, who have been diagnosed with any type of diabetes, on receiving CAM, since they are concerned with their gestation and well-being.

Only one interviewee demonstrated to have heard of Reiki, while others have just accepted receiving such therapy from the moment the flyer was handled to them. The lack of knowledge cause certain limitation in order to introduce CAM in the outpatient clinics, as the interviewee A12 stated when asked if she would accept to receive any CAM: *I do not know if I would, because I do not know how it works, but if I knew how it works, I could think straight*. (A12). Thus, the flyer allowed them to understand of how Reiki works and its benefits; contributing to supply a literature gap, due to the scarce disclosure of CAM in Brazil (13,30), since all of them showed to accept Reiki after reading the flyer, e.g. …*the flyer helped me to understand very well what it is* (A6).

Throughout the analysis process, became evident two concerns of pregnant women in receiving CAM in a Brazilian tertiary centre such as an alternative to prescriptions and when CAM would be part of the antenatal care.

Natural practices when accepted by both pregnant women and multidisciplinary team can be used to relief pain, e.g. *...Pregnant women have a lot of pains and right now there is not much medicine I can take. I certainly would...* (A2). Beiranvand (32) stated that pain control with non-pharmacological practices decreases the psychological effect of pain, allowing self-control and improving sleep levels.

Furthermore, a major concern has become evident through data analysis in which the main concern was related to when Reiki would be performed at CIDP HCFMB, e.g. *… I would do it here if it was on the same day as the doctor appointment …*(A11) This fact is due to many Brazilian patients struggle to be seen by a health practitioner, since there are a sort of infra-

structure matter within Brazilian outpatient clinics and hospitals, e.g. constantly strikes; lack of trained staff and medications; broken equipment and long exams queuing (ultrasound and blood test). This fact is already part of many public health users life and has become part of their routine either queueing for long periods or not be seen by the health team due emergency outbreaks (33).Therefore, patients generally need to reorganize their daily tasks, such as work, household chores and childcare (33), influencing their daily rhythm, causing a distance from their family members; consequently, it could be a fact of non-acceptance of CAM treatments that need regularly appointments to solve their suffering.

Around the world, CAM have been used to reduce physical and mental illnesses to decrease the use of allopathic drugs (1-22,31). Reiki has been classified by the NCCIH as a form of energy healing by the hands (25). Therefore, the disclosure of such therapy to diabetic pregnant women in antenatal care to improve the quality of life, integrated with a multidisciplinary approach, would contribute to the treatment. A multidisciplinary team must be composed by highly trained professionals who work together to solve a variety of dilemma. In Brazil, holistic health practitioners fulfil a gap that is not covered by any health course programme. Holistic health practitioners have a genuine and empirical approach to the alleviation of physical and spiritual discomfort, since almost all heath courses are not covered by a holistic view of mankind (i.e. physical, spiritual, social, and soul) (25). Furthermore, there is a lack of good quality evidence based medicine and mechanisms of effect of CAM that leads to some mistrust, even to repudiation by the health care team. Although, no one can contest the inherent benefits of such therapies as they increase relaxation, well-being and quality of life (1-22, 25, 26,31).

The current study has established some ground information on the participants' profile of specific area in Brazil, while it is necessary to conduct further studies in other locations to have a wider view of other population, since Brazil is large country in population and size. In this way, qualitative methods enable to expand the meaning to perceive certain areas that would go unnoticed in any quantitative study. Although, the number of participants could be considered as a limitation, it is noteworthy to consider that no other study on pregnant women, who have been diagnosed with diabetes, has been conducted so far. Moreover, 12 pregnant women comprised almost all women attended in the local tertiary care centre at the study period. Therefore, the current study enriches literature by contributing to further researches on other populations. Currently, a randomized controlled trial has been introduced at the CIDP HCFMB to investigate the efficiency of Reiki on the quality of life of pregnant women who have been diagnosed with type 1, 2 or gestational diabetes.

Conclusion

The potential benefits of evidence based CAM approach delivered through a complex antenatal care are novel and promising. Therefore, the current study serve as focal points for practitioners to introduce such practice in Brazilian public healthcare. Randomized controlled trials should be done to assess the efficacy of CAM, especially Reiki, on pregnancy and diabetes, but also other qualitative studies should be done to characterize other populations. Nevertheless, the current study provided a holistic openness and contributed to clarify about Reiki therapy, as it provided a demographic data and profile of pregnant women who have been diagnosed with diabetes and their understanding of CAM, especially Reiki, as well as their acceptance.

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Figure and Table legends

1. **Appendix Figure 1** Semi-structured guide
2. **Appendix Figure 2** Flyer specifically designed for the current study
3. **Table 1** Demographic characteristics of pregnant patients with diabetes (*N* =12).

Part 1

Demographic data **Date of the interview:**

Name:

Age:

Level of education:

Race:

Marital Status:

Gestational Age:

Children before pregnancy: () yes () no

Number of children:

Employment status: () yes () no

Type of *Diabetes mellitus*:

Religion: () yes () no

Type of religion:

Part 2

Issues related to the knowledge and acceptance of complementary alternative medicine (CAM)

1. Have you ever heard of complementary alternative medicine? If yes, give me some examples ...

2. Have you ever received a complementary alternative medical treatment? If yes, what kind of CAM did you receive? If no, would you consider receiving some of them? What kind?

3. Have you ever heard of Reiki? If yes, what do you know about Reiki? If no, have a look at the flyer and tell me if you would consider receiving Reiki during antenatal care?

Appendix Figure 1 - Semi-structured guide

Appendix Figure 2 - Flyer specifically designed for the current study

Table 1. Demographic characteristics of pregnant patients with diabetes (*N* =12).

	Mean	**SD***
Age	32.83	5.59
Gestational weeks	30.00	6.52
Family status	**N**	**%**
Single	1	8.33
Married	11	91.67
Widowed	0	0.00
Racial/Ethnic status		
Caucasian	4	33,33
Black	8	66,67
Education level		
Elementary school	8	66.67
Uncomplete High School	2	16.67
High school	1	8.33
Graduate degree	1	8.33
Sons before current pregnancy		
Yes	10	83.33
No	2	16.67
Number of previous live-born children		
0	2	16.67
1	3	25.00
2	3	25.00
3	4	33.33
Employment		
Yes	6	50.00
No	6	50.00
Type of DM**		
GDM***	11	91.67
Type 2	1	8.33
Religion		
Catholic	6	50.00
Brazilian protestant	5	41.67
Atheist	1	8.33

*SD: Standard deviation **DM *Diabetes mellitus* ***GDM Gestation *Diabetes mellitus*

ANEXOS

Anexo 1 – Parecer consubstanciado do CEP

FACULDADE DE MEDICINA DE BOTUCATU -UNESP

PARECER CONSUBSTANCIADO DO CEP

DADOS DO PROJETO DE PESQUISA

Título da Pesquisa: A Terapia Reiki em Gestantes Diabéticas. Conhecimentos de gestantes diabéticas atendidas num centro terciário: uma abordagem qualitativa

Pesquisador: Guilherme Augusto Rago Ferraz

Área Temática:

Versão: 1

CAAE: 52720616.1.0000.5411

Instituição Proponente: Departamento de Ginecologia e Obstetrícia

Patrocinador Principal: Financiamento Próprio

DADOS DO PARECER

Número do Parecer: 1.440.288

Apresentação do Projeto:

O diabetes em gestantes (sejam elas previamente diabéticas ou acometidas pelo "diabetes gestacional") tem impacto psicológico e fisiológico e acarreta riscos para mãe e filho. As "Práticas Integrativas e Complementares em Saúde" são uma opção para melhorar qualidade de vida e talvez outros aspectos da gestação. Propõe-se um projeto para avaliar o conhecimento de gestantes diabéticas de um centro de referência sobre a terapia Reiki, que consiste na imposição das mãos para canalizar energia. Esse projeto será conduzido concomitantemente a outro, em que um ensaio clínico randomizado avaliará o impacto do Reiki sobre a gestação. Propõe-se de uma abordagem qualitativa, fundamentada na análise de conteúdo de Bardin. Ao todo, 20 gestantes devem ser incluídas no estudo. Estas serão entrevistadas, e suas entrevistas submetidas a análise pelo referencial teórico referido acima.

Objetivo da Pesquisa:

Compreender o grau de conhecimento e aceitação da terapia Reiki de gestantes portadoras de diabetes, com assistência pré-natal realizada por acompanhamento ambulatorial.

Avaliação dos Riscos e Benefícios:

Os riscos são mínimos, desde que garantidas a confidencialidade e a autonomia. Os benefícios podem ser diretos (um melhor conhecimento das gestantes entrevistadas sobre o impacto

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potencial do Reiki) e indiretos (pela possibilidade de integrar o Reiki na rotina de pré-natal).

Comentários e Considerações sobre a Pesquisa:

Trata-se de pesquisa realizada no âmbito de outra maior (um ensaio clínico). É factível nas condições apresentadas e pertinente ao tema.

Considerações sobre os Termos de apresentação obrigatória:

Apresentam-se os documentos exigidos. O TCLE é conciso, mas bastante claro e em linguagem acessível.

Recomendações:

Conclusões ou Pendências e Lista de Inadequações:

Recomendo aprovação.

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_648301.pdf	25/01/2016 18:32:43		Aceito
Outros	termodeanuencia.pdf	25/01/2016 18:31:33	Guilherme Augusto Rago Ferraz	Aceito
Folha de Rosto	folhaderosto.pdf	25/01/2016 18:31:02	Guilherme Augusto Rago Ferraz	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	TCLE.doc	10/01/2016 15:33:30	Guilherme Augusto Rago Ferraz	Aceito
Projeto Detalhado / Brochura Investigador	projetoconhecimento.doc	10/01/2016 15:32:44	Guilherme Augusto Rago Ferraz	Aceito

Situação do Parecer:

Aprovado

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Necessita Apreciação da CONEP:
Não

BOTUCATU, 07 de Março de 2016

Assinado por:
Trajano Sardenberg
(Coordenador)

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Anexo 2 – Mudança de título em projeto de pesquisa

unesp UNIVERSIDADE ESTADUAL PAULISTA "JÚLIO DE MESQUITA FILHO" Campus de Botucatu

FACULDADE DE MEDICINA FMB 1963 BOTUCATU

MUDANÇA DE TÍTULO EM PROJETO DE PESQUISA

Objetivo Acadêmico:

( ) Pós Doutorado
( ) Tese Doutorado
(X) Dissertação de Mestrado
( ) Trabalho científico
( ) Outros: Especificar

Título Inicial: A Terapia Reiki em Gestantes Diabéticas. Conhecimentos de gestantes diabéticas atendidas num centro terciário: uma abordagem qualitativa

Título Final: Conhecimento e aceitação das práticas integrativas e complementares na saúde, em especial a Terapia Reiki, de gestantes diabéticas atendidas num centro terciário: uma abordagem qualitativa

Data da reunião do CEP que aprovou o parecer inicial: 07/03/2016

Declaro que o trabalho não sofreu alterações nos objetivos e/ou conteúdo metodológico da época de apresentação para análise do CEP.

Profa. Titular Marilza Vieira Cunha Rudge

Guilherme Augusto Rago Ferraz

- **Projetos submetidos via Plataforma Brasil:** Preencher o formulário, digitalizar, protocolar no CEP e postar no sistema Plataforma Brasil.
- **Projetos submetidos anteriormente à Plataforma Brasil:** Preencher o formulário em duas vias e protocolar no CEP que emitiu o parecer inicial de aprovação.

16:00 04/01/2017 000000 COMITE DE ETICA EM PESQUISA FMB - UNESP

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