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AVALIAÇÃO DE RESILIÊNCIA E ESTRESSE NA GRAVIDEZ: UM ENFOQUE EM VULNERABILIDADE E DESFECHOS GESTACIONAIS EM UMA COORTE DE NULÍPARAS

Measuring resilience and stress during pregnancy: a focus on vulnerability and pregnancy outcomes in a nulliparous cohort study

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Measuring resilience and stress during pregnancy: a focus on vulnerability and pregnancy outcomes in a nulliparous cohort study

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Dissertation presented to the Post-Graduate Program of Obstetrics and Gynaecology from the School of Medical Sciences of the University of Campinas as part of the requirements needed for obtaining the MSc degree on Health Sciences, concentration area of Maternal and Perinatal Health.

ORIENTADOR: RENATO TEIXEIRA SOUZA
COORIENTADOR: JOSÉ GUILHERME CECATTI

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COORIENTADOR: JOSÉ GUILHERME CECATTI

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2. PROF. DR. RODOLFO DE CARVALHO PACAGNELLA

3. PROF. DR. ALEXANDRE FAISAL CURY

Programa de Pós-Graduação em Tocoginecologia da Faculdade de Ciências Médicas da Universidade Estadual de Campinas.

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RESUMO

Introdução: Ao mecanismo de enfrentamento em um contexto de risco ou adversidade se dá o nome de resiliência, característica individual, dinâmica e contextual. A baixa resiliência já foi previamente associada a piores resultados da gravidez. Porém um determinado fator estressor pode ser interpretado de forma individual, ao que se chama de estresse percebido. A percepção do estresse e esse padrão de resposta resiliente se relacionam a atributos de personalidade e do meio social. Um contexto de alta vulnerabilidade social na gravidez pode ter um papel negativo na resiliência e, consequentemente, na percepção do estresse. **Objetivo**: Avaliar a resiliência e o estresse percebido na gestação, avaliar suas associações com características sociodemográficas e com desfechos maternos e perinatais e avaliar comparativamente a Escala de Resiliência (RS-25) e sua versão reduzida (RS-14). **Métodos:** Duas análises dos dados do *Maternal Actigraphy Exploratory Study I,* coorte prospectiva multicêntrica. Incluiu 381 nulíparas com gestação única entre 19+0 e 21+0 semanas em quatro centros da Rede Brasileira de Estudos em Saúde Reprodutiva e Perinatal. Entre 27+0 e 29+0 semanas, foram autopreenchidas as Escala de Resiliência de Wagnild e Young e a Escala de Estresse Percebido de Cohen et al. No primeiro estudo os escores das escalas foram analisados por sua distribuição na amostra, segundo características sociodemográficas, condições de saúde e desfechos adversos maternos e perinatais. Critérios de vulnerabilidade social foram associados aos graus de resiliência e estresse percebido. Na segunda análise, foram avaliadas e comparadas as versões RS-25 e RS-14. A RS-14 teve avaliada sua confiabilidade e consistência interna. **Resultados**: Parte significativa das gestantes foi classificada com resiliência baixa (<125); metade ficou abaixo de 124. Quanto maior o grau de resiliência, menor o estresse percebido e 91,4% das gestantes com baixa resiliência tinham algum critério de vulnerabilidade (renda familiar baixa, etnia não-branca, baixa escolaridade, ser adolescente ou sem parceiro na gestação (solteira, viúva ou divorciada). A comparação da RS-25 com a RS-14 não mostrou boa correlação e a versão reduzida parece superestimar os níveis de resiliência em relação à escala original. Em relação às propriedades psicométricas houve boa consistência interna (grau de confiabilidade) da escala reduzida (RS-14) com Cronbach´s $\alpha = 0,947$. A correlação entre os escores individuais de cada item da escala foi maior que 0,500 para todos eles, exceto o item

3 que teve 0,305. A exclusão do item 3 aumentou o Chronbach´s alpha do instrumento. **Conclusão:** A resiliência parece ser fator importante a ser considerado na gestação. Nossos dados chamam atenção para níveis baixos de resiliência, altas taxas de estresse percebido e proporção considerável de gestantes com algum grau de vulnerabilidade. Acreditamos em um possível papel da resiliência na percepção do estresse materno e como fator atuante em contextos de vulnerabilidade. O uso da RS-14 otimiza a aplicação da escala, porém não parece ser uma boa métrica de avaliação nas gestantes. São necessários mais estudos a fim de construir uma abordagem com aplicabilidade clínica dos fatores mais relevantes na saúde mental na gestação.

Palavras-chave: resiliência, estresse, gravidez, vulnerabilidade, validação, escala, complicações gestacionais.

ABSTRACT

Introduction: The coping mechanism in a context of risk or adversity is called resilience, an individual, dynamic and contextual characteristic. Low resilience has previously been associated with worse pregnancy outcomes. However, a certain stressor can be interpreted individually, which is called perceived stress. The perception of stress and this pattern of resilient response are related to personality and social environment attributes. A context of high social vulnerability during pregnancy can have a negative role in resilience and, consequently, in the perceived stress. **Objective:** To assess resilience and perceived stress during pregnancy, assess their associations with sociodemographic characteristics, maternal and perinatal outcomes, and comparatively evaluate the Resilience Scale (RS-25) and the reduced version (RS-14). **Methods:** We studied data from the Maternal Actigraphy Exploratory Study I, a multicentric prospective cohort. It included 381 nulliparous women with a single gestation, between 19+0 and 21+0 weeks, in the four centers of the Brazilian Network for Studies in Reproductive and Perinatal Health. Between 27+0 and 29+0 weeks, the Wagnild and Young Resilience Scale and the Cohen et al. Perceived Stress Scale were answered. In the first study, the scale scores were analyzed according to their distribution in the sample, according to sociodemographic characteristics, health conditions and maternal and perinatal adverse outcomes. Social vulnerability criteria were associated with degrees of resilience and perceived stress. In the second analysis, the RS-25 and RS-14 versions were evaluated and compared. The RS-14 reliability and internal consistency were evaluated. **Results:** A significant part of the pregnant women were classified as having low resilience (<125): half were below 124. Higher resilience score was associated with lower perceived stress score. 91.4% of pregnant women with low resilience had some vulnerability criteria (low family income, low level of education, adolescent, non-white or marital status without partner (widow, single or divorced). The comparison between RS-25 and RS-14 did not show a good correlation and seems to overestimate the levels of resilience when compared to the original scale. Regarding psychometric properties, there was good internal consistency of the reduced scale (RS-14) with Cronbach's $\alpha = 0.947$. The correlation between the individual scores of each item on the scale was greater than 0.500 for all of them, except for item 3, which had 0.305. The exclusion of item 3 increased the

instrument's Chronbach's alpha. **Conclusion:** Resilience seems to be an important factor to be considered during pregnancy. Our data draw attention to low levels of resilience, high rates of perceived stress and a considerable proportion of pregnant women with some degree of vulnerability. We believe in a possible role of resilience in the perception of maternal stress and as an active factor in contexts of vulnerability. The use of RS-14 optimizes the application of the scale, but it does not seem to be a good metric for evaluating pregnant women. More studies are needed in order to build an approach with clinical applicability of the most relevant factors in mental health during pregnancy.

Keywords: resilience, stress, pregnancy, vulnerability, validation, scale, pregnancy complications.

LISTA DE ABREVIATURAS E SIGLAS

AGA - *Adequate for Gestational Age*

APO - *Adverse perinatal outcome*

BMC - BioMed Central

BMI - *Body mass index*

BRL - *Brazilian* Real

CAISM - Centro de Atenção Integral à Saúde da Mulher

CD-RISC / **CD-RISC 25** - *Connor-Davidson Resilience Scale*

CD-RISC-10 - *10 Item Connor-Davidson Resilience Scale*

CE - Ceará

CEP - Comitê de Ética em Pesquisa

CFA - *Confirmatory factor analysis*

CI - *Confidence interval*

CNS - Conselho Nacional de Saúde

CONEP – Comissão Nacional de Ética em Pesquisa

CRH - *Corticotrophin-releasing Hormone*

C-section - *Caesarean section*

FMJ - Faculdade de Medicina de Jundiaí

GDM - *Gestational Diabetes Mellitus*

GHQ-12 - *General Health Questionnaire*

HIV - *Human Immunodefiency Virus*

HPA - *Hypothalamic-pituitary-adrenal axis*

IBM - *International Business Machines Corporation*

IMC - Índice de massa corpórea

IRB - *Institutional Review Board*

LES - Lúpus Eritematoso Sistêmico

LGA - *Large for gestational age*

MAES-I - *Maternal Actigraphy Exploratory Study I*

MEAC - Maternidade Escola Assis Chateaubrianjd

NICU - *Neonatal Intensive Care Unit*

OR - *Odds ratio*

PE - Pernambuco

PILTest-12 - *12-Item Purpose-in-Life Test*

pi-PTB – *Provider-initiated Preterm Birth*

PSS / **PSS 14** - *Perceived Stress Scale* – versão 14 itens

PSS 10 - *Perceived Stress Scale* – versão 10 itens

PSS 4 - *Perceived Stress Scale* – versão 4 itens

RR - *Relative risk*

RS - *Resilience Scale*

RS-14 - *14 item Resilience Scale*

SAF - Síndrome Antifosfolípide

SGA - *Small for gestational age*

SP - São Paulo

SPSS - *Statistical Packages for the Social Sciences*

STROBE - *Strengthening the Reporting of Observational Studies in Epidemiology*

UFC - Universidade Federal do Ceará

UFPE - Universidade Federal de Pernambuco

UNICAMP - Universidade Estadual de Campinas

US - *United States*

UTIN - Unidade de Terapia Intensiva Neonatal

w - *Weeks*

WHO - *World Health Organization*

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1. INTRODUÇÃO

A introdução dessa tese foi transformada em uma revisão narrativa introdutória sobre o tema que foi publicada na revista *The Scientific World Journal* e cujo texto aparece a seguir.

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Review Article

Resilience and Stress during Pregnancy: A Comprehensive Multidimensional Approach in Maternal and Perinatal Health

A. C. Alves, J. G. Cecatti, and R. T. Souza

Department of Obstetrics and Gynecology, School of Medical Sciences, University of Campinas, Campinas, SP, Brazil

Correspondence should be addressed to R. T. Souza; renatotsouzasp@gmail.com

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This narrative review addresses resilience and stress during pregnancy, which is part of a broader concept of maternal health. Pregnancy and postpartum are opportune periods for health promotion interventions, especially because the close contact of the women with health professionals. In this way, it can be considered a useful window of opportunity to identify women at higher risk for adverse outcomes. Integrated health is a concept that aims at providing comprehensive care related to the promotion of individuals' physical, mental, and social well-being. In this context, stress during pregnancy has been targeted as a remarkable condition to be addressed whether due to individual issues, social issues, or specific pregnancy issues, since it is directly and indirectly associated with pregnancy complications. Stress is associated with preterm birth, postpartum depression, anxiety, child neurodevelopment, and fetal distress. The way that an individual faces a stressful and adverse situation is called resilience; this reaction is individual, dynamic, and contextual, and it can affect maternal and fetal outcomes. Low resilience has been associated with poorer pregnancy outcomes. The social context of pregnancy can act as a protective or contributory (risk) factor, indicating that environments of high social vulnerability play a negative role in resilience and, consequently, in perceived stress. A given stressor can be enhanced or mitigated depending on the social context that was imposed, as well as it can be interpreted as different degrees of perceived stress and faced with a higher or lower degree of resilience. Understanding these complex mechanisms may be valuable for tackling this matter. Therefore, in the pregnancy-puerperal period, the analysis of the stress-resilience relationship is essential, especially in contexts of greater social vulnerability, and is a health-promoting factor for both the mother and baby.

1. Pregnancy and Maternal Health: Remarkable Concepts beyond the Fairy Tale

The broadest concept of health defined by the World Health Organization (WHO) is based not merely on the absence of disease, but in the presence of physical, mental, and social well-being of an individual [1]. Women's reproductive healthcare, including diverse specificities of the pregnancy-puerperal cycle, could be no different. One of the greatest challenges in obstetric healthcare is to assure the quality of prenatal care, improve indicators related to morbidity and mortality due to preventable causes during this period, and also guarantee a positive experience during prenatal care, assuring the promotion and inclusion of social, cultural, emotional, and psychological aspects [2].

At the same time that pregnancy is considered a transitory process, maternity causes definitive modifications in a woman. Changes in a pregnant woman who assumes a maternal role have been studied in the theory elaborated by Ramona Mercer, titled "Attainment of the Maternal Role" [3]. This theory addresses the construction of maternal identity, while redefining a woman's self-perception, and the physical and emotional modifications in her sociocultural dynamics. This interactive evolutionary biopsychosocial complex process between the mother and child, according to the author, consists of four phases. The first is the commitment and preparation phase. It starts in early pregnancy and encompasses social and emotional adaptations inherent in the gestational period [3]. Thus, the Women's Integrated Healthcare National Policy Guidelines of 2004 in Brazil [4] recommends the promotion of qualified humanized

Review Article

Resilience and Stress during pregnancy: a comprehensive multi-dimensional approach in maternal and perinatal health

Alves AC[1], Cecatti JG[1], Souza RT[1]*

1- Department of Obstetrics and Gynecology, School of Medical Sciences, University of Campinas, Brazil

*Corresponding author:
Renato T Souza
Department of Obstetrics and Gynecology, University of Campinas
101 Alexander Fleming, Cidade Universitária, Campinas/SP, Brazil
ZIP Code 13087-500
E-mail: renatotsouzasp@gmail.com

Abstract

This narrative review addresses resilience and stress during pregnancy, which is part of a broader concept of maternal health. Pregnancy and postpartum are opportune periods for health promotion interventions especially because the close contact of the women with health professionals. In this way, it can be considered a useful window of opportunity to identify women at higher risk for adverse outcomes. Integrated health is a concept that aims at providing comprehensive care related to the promotion of individuals' physical, mental and social well-being. In this context, stress during pregnancy has been targeted as a remarkable condition to be addressed whether due to individual, social issues or specific pregnancy issues, since it is directly and indirectly associated with pregnancy complications. Stress is associated with preterm birth, postpartum depression, anxiety, child neurodevelopment and fetal distress. The way that an individual faces a stressful and adverse situation is called resilience; this reaction is individual, dynamic and contextual, and it can affect maternal and fetal outcomes. Low resilience has been associated with poorer pregnancy outcomes. The social context of pregnancy can act as a protective or contributory (risk) factor, indicating that environments of high social vulnerability play a negative role in resilience and, consequently, in perceived stress. A given stressor can be enhanced or mitigated depending on the social context that was imposed, as well as it can be interpreted as different degrees of perceived stress and faced with a higher or lower degree of resilience. Understanding these complex mechanisms may be valuable for tackling this matter. Therefore, in the pregnancy-puerperal period, the analysis of the stress-resilience relationship is essential, especially in contexts of greater social vulnerability, and is a health-promoting factor for both mother and baby.

Keywords: maternal health, resiliency, stress, pregnancy, vulnerability

Pregnancy and maternal health: remarkable concepts beyond the fairy tale

The broadest concept of health defined by the World Health Organization (WHO) is based not merely on the absence of disease, but in the presence of physical, mental and social well-being of an individual (1). Women's reproductive healthcare, including diverse specificities of the pregnancy-puerperal cycle, could be no different. One of the greatest challenges in obstetric healthcare is to assure the quality of prenatal care, improve indicators related to morbidity and mortality due to preventable causes during this period, and also guarantee a positive experience during prenatal care, assuring the promotion and inclusion of social, cultural, emotional and psychological aspects (2).

At the same time that pregnancy is considered a transitory process, maternity causes definitive modifications in a woman. Changes in a pregnant woman who assumes a maternal role have been studied in the theory elaborated by Ramona Mercer, titled: "Attainment of the Maternal Role". (3). This theory addresses the construction of maternal identity, while redefining a woman's self-perception, and the physical, emotional modifications in her sociocultural dynamics. This interactive evolutionary biopsychosocial complex process between mother and child, according to the author, consists of four phases. The first is the commitment and preparation phase. It starts in early pregnancy and encompasses social and emotional adaptations inherent in the gestational period (3). Thus, the Women's Integrated Healthcare National Policy Guidelines of 2004 in Brazil (4), recommends the promotion of qualified humanized obstetric and neonatal care. According to these guidelines:

"Integrated healthcare in women encompasses management of a woman from a broad perception of life context, from the time that she presents a certain demand, as well as her singularity and conditions as an individual capable (of) and responsible for her own choices" (4).

Humanization in healthcare is a continuous process that demands reflection, since physical and emotional issues are inseparable aspects. Nevertheless, it is worth mentioning that the Health Ministry recommendations for prenatal care are limited to concepts of sickness, risk of complications and

interventions for disease identification or prevention. There is little mention of the importance of the evaluation and management of the emotional demands of the pregnant woman, contrary to the concept of quality of care that should refer to a group of aspects including physical and biopsychosocial issues (4-6).

Stress and pregnancy

The term stress is more widely used, despite other meanings such as “tension”, “fatigue” and “tiredness.” Nevertheless, the term has become popular in colloquial language and in Medicine. Nowadays, the concept has other meanings that go beyond these aspects (7-9). According to Filgueira and Hippert, "stress" is a state manifested by a specific syndrome, consisting of all nonspecific alterations produced in a biological system. According to those authors, stress (physical, psychological or social) may be understood as a term encompassing a group of reactions and stimuli that cause disturbances in body equilibrium, frequently with damaging effects (7).

Stress can be defined, therefore, as a natural reaction of an organism to adverse situations that disturb its homeostasis or balance. The body responds in a state of alert, implying different physical and emotional alterations, which generate different degrees of adaptation to the causative agent. These agents may be acute or chronic, and result from the external environment. Interpersonal, family and work may be involved, in addition to physical injuries, diseases and others. This means that these agents may result from the environment where the individual is inserted. They may also derive from internal factors, related to exhaustion, tension and other emotional factors. (8, 9)

In a lower or higher intensity, pregnancy is a period of emotional alterations, resulting from both social and psychological factors, as well as typical hormonal alterations. (10, 11) Some stressors are related to both specific events and physiological adaptations expected in the maternal body: nausea, weight gain, insomnia, emotional lability. Individual factors, such as unplanned pregnancies, changes in family dynamics such as the relationship with a partner, acquired responsibilities with neonatal care, and the risk of complications during pregnancy and labor are other stressors. (10-12) Another

important factor which can be an aggravating stressor for pregnant women is the socioeconomic context: low income, domestic violence, use of drugs and alcohol, lack of a family support network and other vulnerabilities (13).

In a study of 2010 including more than 1,500 women, stress was evaluated by the Prenatal Psychosocial Profile stress scale. Research results show that 6% (n=91) of the women were classified as having a high level of stress, the large part of these pregnant women, 78% (n = 1.190) reported low or moderate stress and only 16% (n = 241) demonstrated no stress (14).

Some studies show that this exposure during pregnancy, mainly if persistent or long-term, may be related to adverse maternal and perinatal outcomes. In the last decades, various studies have demonstrated that stress in pregnancy may predispose to preterm labor (before 37 weeks) and pregnancies resulting in small for gestational age newborns (less than the 10^{th} percentile of the expected weight for gestational age) (15-19). The literature also indicates that there is a higher incidence of psychiatric disturbances in a woman during pregnancy and the postpartum period. Adequate care and follow-up are required for timely detection and opportune intervention. (20, 21). Knowing the perceptions and experiences of a woman related to stress experienced in the pregnancy-puerperal cycle, may favor a healthy labor and postpartum period, and is an opportunity to welcome and support women, families and community as a whole (6-14). A research from 2017 described an association between the number of stressor events during pregnancy and the impact on the pregnant woman, with the occurrence of postpartum depression and other common mental disorders in pregnancy, including anxiety and insomnia (22). Primipara, who are going through the experience of pregnancy for the first time, deserve special care, since the unprecedented physiological and psychological changes in the gestational period, as well as transition to the social maternal role may by itself represent a stressor factor. It is important to identify pregnant women or groups at risk for stress and anxiety, to prevent adverse outcomes in maternal and perinatal healthcare (14).

Nevertheless, it is known that perception of a stressor factor is individual and dependent on the personal capacity to elaborate. A woman may or not have significant stress symptoms in the presence of a stressor factor. According

to Cohen & Williamson (23, 24), there is more than one way to measure stress. Specific stressor agents may, for example, be demonstrated, quantified and qualified. Physical and psychological symptoms originating from exposure to stress may be identified. Finally, the individual perception of stress, irrespective of triggering stressors, may be measured. Researchers have developed a perceived stress scale, aimed at measuring individual perception of subjects exposed to stressful situations. This scale was named Perceived Stress Scale (PSS) and had 14 items (PSS 14) (23), but was later validated with ten items (PSS 10) (23-25), and even more briefly in another version with four questions (PSS 4) (24, 25). PSS 4 has been especially used during situations where there is a short time to measure the perception of stress, as in telephone surveys. According to the authors, the items were developed to identify how much individuals considered their lives unpredictable and uncontrollable and how much they felt overwhelmed (24, 25). These parameters have been considered fundamental in the individual's perception of stress. An advantage of PSS is the lack of specific context questions, which makes its transcultural validation, as well as its applicability and demographic contexts possible (26-28). After all, the same context and/or stressor factor may be perceived in different degrees by each individual, generating distinct consequences and outcomes, increasing the importance of this evaluation (23-25).

A more recent approach in stress measurement during pregnancy focuses on pregnancy-specific stress i.e., conditions directly related to pregnancy that increase a woman's level of stress (29-31). Among these conditions, we could include body changes and pregnancy-related adaptations, pregnancy-specific symptoms, in addition to concerns and tensions inherent to maternity and the new social relationship that is constructed with the pregnancy (30, 31). Study results by Lobel et al from 2008, indicated that pregnancy-specific stress may be the best predictor of adverse perinatal outcomes rather than the evaluation of general stress factors, such as the degree of anxiety or stress perceived in general (29). Pregnancy-specific stress was associated with preterm labor and unhealthy habits in relation to feeding, physical activity and smoking. The latter was related to low birthweight. By association, the

pregnancy-specific stress would be indirectly related to this adverse outcome (29).

Maternal stress may be related not only to short-term perinatal outcomes. In the newborn, the consequences may be seen in late neonatal life or infancy. There is evidence that stress, depression and anxiety during pregnancy are related to neurodevelopmental effects on infants, including lower cephalic circumference, worse cognitive development and behavioral disturbances in infancy (32). A prospective study investigated stress during pregnancy in a sample of 170 nulliparous and followed the development of newborns at 3 and 8 months. The results demonstrated a higher rate of delay in motor and mental development in children whose mothers demonstrated higher stress levels during pregnancy (33).

Furthermore, a recent study demonstrated that gestational stress may even interfere in fetal longevity. Send et al studied fetal and maternal telomeres, considered biomarkers of aging (34). Research results took into consideration telomere length of 319 newborns and 318 mothers and demonstrated that perceived stress during pregnancy was associated with shorter telomeres in newborn infants, but there was no relationship with maternal telomere length. This demonstrates that fetal development is probably vulnerable to the exposure to stress (34).

A study of 227 Chinese pregnant women showed an association between perceived stress and quality of sleep during pregnancy, demonstrating that higher levels of stress were negatively associated with the quality of sleep in these pregnant women. Furthermore, it showed that higher levels of resilience were significantly associated with a better quality of sleep, and were considered protective factors. Resilience had a mediating role between maternal stress and quality of sleep ($p < 0.01$) (35).

It is perceived that the ability to deal with stressful situations is also determined by a series of complex genetic mechanisms that are strongly influenced by individual factors, sex, age and temperament, as well as by social environmental action (36-38).

Resilience: human capacity between stress and "wellbeing"

Psychology has studied the individual human reaction to adverse circumstances and/or stressor factors, termed resilience. This reaction is independent of the intensity or quality of the stressors. It considers individual response and coping mechanisms that should be analyzed in a specific context in the face of an expected response (for example, same age group, sociocultural context, etc.) (39).

Resilience may be defined as the capacity to adapt to life adversities and is considered a subjective measure of this response that encompasses concepts such as inner strength, competence and flexibility. It may be inversely related to depression, perception of stress and anxiety (40). This is a dynamic characteristic, as studies have shown in the evaluation of elderly adults. Some authors suggest that resilience may increase during adult life, probably due to a positive effect of overcoming limits and adversities during life (40, 41). At the same time, it is not necessarily an increasingly constant attribute, but rather a relative adaptable behavior, according to individual circumstances and contexts. People that deal successfully with stress and adversity during a certain period of life, may react adversely in other situations and other time periods (39-41).

The bibliographic review of instruments for the evaluation of resilience in the Brazilian context showed that there is still a lack of instruments for a direct evaluation of this characteristic. A large part of the constructs approved for use, indirectly evaluate resilience through risk factors and protection related to the concept: personality, psychopathologies (especially stress and anxiety), family history and environmental/social factors (42). Only two scales meet these characteristics: the Wagnild and Young and Connor-Davidson Resilience Scale (43, 44). Both were validated and translated to Portuguese with the original reduced versions available, as explained below.

The Wagnild & Young Resilience Scale from 1993 is one of the most widely used instruments in the evaluation of resilience (43, 45). Its transcultural adaptation to Portuguese was presented by Pesce et al (2005). According to them, the Cronbach's alpha scores, a coefficient that measures the reliability of questions contained in a certain assessment instrument of the Brazilian version

are similar to that reported by Wagnild & Young in 1993, demonstrating satisfactory internal consistency of the adapted scale (Alfa de Cronbach: 0.80) (46).

The instrument consists of 25 items, each scored from 0 to 7, according to the Likert scale, varying in “Agree” (sub classified as: weakly, strongly or totally), “I neither agree, nor disagree” and “Disagree” (weakly; strongly or totally). It was proposed that the level of agreement is the degree of concordance among items that reflect the theoretical definition of resilience. It is composed of two factors, as established by the original study (Wagnild & Young). Factor I: Personal competence, indicates self-confidence, independence, decision, invincibility, power, ingenuity and perseverance. Factor II: Acceptance of self and life, represents the capacity to adapt, balance, be flexible and have a stable life perspective that coincides with accepting life with serenity, despite the adversities (43, 45). The Resilience Scale has a reduced and validated version of 14 items (RS-14), a version published in 2009 by Gail Wagnild, one of the authors of the original scale, and a good level of reliability was maintained (47).

For the evaluation of resilience in studies addressing the subject, another commonly used instrument is the Connor-Davidson Resilience Scale (CD-RISC). The instrument was developed by Connor and Davidson in 2003 and revalidated by Campbell-Sills and Stein in 2007 (44, 48). The original Connor and Davidson scale has 25 items. However, in confirmatory factor analysis, Campbell-Sills and Stein identified a 10-item version that was renamed CD-RISC-10, differentiating it from the original form. (48) CD-RISC-10 was validated into the Brazilian context by Lopes and Martins in 2010 (49).

In a case-control study in 2010, Salazar-Pousada et al analyzed 302 pregnant women, comparing differences between resilience and depressive symptoms in groups of adolescents and adults. In that analysis, the 14 item-Wagnild &Young resilience scale was applied. The adolescent group had lower scores (less resilience) and higher scores that were lower than the median calculated in the sample ($p < 0.05$). Having an adolescent and preterm birth were factors related to a higher risk of low resilience (OR, 3.0 95%CI 1.43-6.55, $p = 0.004$) (50).

The relationship between resilience and mood disorders has been investigated in pregnant women. Some studies showed that individuals with high levels of resilience tend to have less symptoms of depression and are more emotionally balanced (51, 52). Therefore, in pregnancy, a time of important psychosocial adaptation, a high level of resilience would be important to adapt to changes inherent to the gestational period and maternity. A study of 531 pregnant women indicated that those with high trait-anger were more inclined to have lower levels of resilience, which probably is related to the development of higher rates of postpartum depression in this group (53).

Psychobiology, also known as behavioral neuroscience, offers a possible explanation for the association between resilience and mood disorders. Physiologically, an organism undergoing stressful situations releases corticotrophin-releasing hormone (CRH) by the hypothalamus, activating the hypothalamic-pituitary-adrenal axis (HPA), ultimately leading to cortisol release by the adrenal glands. The defense response to stress (fight or flight) is related to autonomic, cognitive, emotional and behavioral alterations in normal conditions. In the short term, cortisol has a protective action and enables an adequate response to the situation, whether it is a physical or emotional stressor, and cortisol levels return to baseline values after stimulus cessation. Nevertheless, sustained exposure to abnormally increased cortisol levels may be damaging, and result in hypertension, immunosuppression, cardiovascular disease and other health problems. Neuroscience attempts to establish the biological role of resilience in this chain: associating higher levels of resilience with individual capacity of a complex negative feedback system that balances glucocorticoid and mineralocorticoid receptors at an optimal level of response. It is believed that resilience would cause the hypothalamic-pituitary-adrenal (HPA axis) to reach an ideal activation level, i.e., so that it responds to a stressor factor, as required, but does not exacerbate reactions such as anxiety, excessive fear and depression (54).

The evaluation of the level of resilience in pregnant women may facilitate coping with difficulties inherent to the period, such as fears related to body changes and adaptations, as well as fears related to labor, social problems, among other reasons in each pregnant woman (55). Identifying groups with a

lower level of resilience may help detect individuals who are at a higher risk and have less access to resources required to face pregnancy-specific difficulties. This may contribute to individual care of each pregnant woman and target intervention strategies in conformity (55, 56).

The concept of social vulnerability may be applied to individuals experiencing adversities in their daily living, i.e., it may be associated with risk factors that negatively affect the social reality of this individual. It is characterized as an unfavorable situation, in comparison to other population groups. The more risks factors compose this reality, the lower the protection, the greater the vulnerability and thus, the higher the probability of adverse consequences for psychosocial development. (57-59) Risks factors are considered behaviors or conditions that are damaging to an individual's health and well-being, as well as the lack of protective or attenuating factors in the social context. Diverse factors are highlighted: socioeconomic, environmental and demographic conditions, social relationships and subjectivity (60).

The distribution of vulnerability factors in pregnant women is not homogeneous. There may be an accumulation in some of these women, who would be exposed to a greater risk of adverse maternal and perinatal results. An early identification of these vulnerability factors may aid in management and promote a subjective and individual action in women that have a higher exposure to risk. In addition to providing the formulation of proper public policies and programs in the promotion of individual and collective health, this approach may substantiate the identification of more resilient pregnant women, modulating the perception of stress and coping skills. As a result, morbidity and mortality could decrease and gestational health would be addressed in a broad integrated manner (61).

In a prospective cohort study from 2016, Maxson et al analyzed gestational outcomes in an approach termed psychosocial health profiles. Women were grouped together into clusters and classified as: Resilient, Moderate and Vulnerable. The Vulnerable profile grouped pregnant women with a higher level of perceived stress and depression, lower self-confidence, less paternal support and lower interpersonal support network. Women also differed in sociodemographic characteristics: these women tended to be younger, had

lower schooling and were not in a stable relationship. Women in the Resilient group had lower rates of premature delivery than women in the other two groups. Of the 1313 women analyzed, 186 (14.1%) had premature deliveries (before 37 weeks), and the rates were 11% in the Resilient group, and 16.2% in the other two groups. Comparatively, the Resilient group had a 52% lower rate of preterm delivery, compared to the Vulnerable group and a 40% lower rate compared to the Moderate (adjusted OR and 95% CI). In addition to higher preterm birth rates, this group also had higher rates of unplanned and unwanted pregnancy. Multidimensional analysis of health in pregnancy helps in the identification of this vulnerability profile, and is an important window of opportunity for interventions that decrease risks and consequences, since prenatal care is a singular time when health care provides regular access to these women (62).

Final considerations

In the presence of one or more stressor factors, a woman will have her individual perception and face adversities according to her resilience. It is known that resilience varies, depending on personal characteristics and the context in which the woman is inserted. (53,55) In a more encompassing view of integrated health care, it is equally important to evaluate the sociodemographic contexts and individual aspects permeating stress and resilience in a woman during pregnancy. Although the social environment is a source of stress (63), it may also be a protective factor in crisis interventions, since social support may aid in coping. In the same manner, the lack of a favorable context may act as a vulnerability factor for the pregnant woman (62). There are tools available for stress and resilience assessments that may be applied during pregnancy and can help in the multidimensional evaluation of maternal health. The aim of this proposal was to obtain a broader view of subjectivity in maternal health, considering disease prevention, seeking the promotion of a positive maternity experience as early as prenatal care (2, 5).

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Contributors

Campos A, Souza RT and Cecatti JG conceived and planned the concept of the current manuscript. Campos A collated material for the first draft of the manuscript. All the authors read, reviewed and approved the final version of the manuscript.

Competing interests

The authors declare no competing interests.

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2. OBJETIVOS

2.1. Objetivo Geral

Avaliar a resiliência e o estresse percebido na gravidez, suas associações com características maternas e desfechos gestacionais, e comparar as versões curta e longa da escala de resiliência.

2.2. Objetivos Específicos

2.2.1. Conhecer a distribuição do estresse percebido e da resiliência em gestantes.

2.2.2. Avaliar a associação entre estresse percebido e resiliência em gestantes.

2.2.3. Avaliar os fatores maternos associados com resiliência e estresse em gestantes.

2.2.4. Avaliar a associação de resiliência e estresse com graus de vulnerabilidade social.

2.2.5. Avaliar os desfechos maternos e perinatais associados com graus de resiliência e estresse percebido.

2.2.6. Avaliar a concordância entre a versão resumida da escala de resiliência (RS-14), utilizando a escala original de 25 itens (RS-25) como referência na população de gestantes.

2.2.7. Avaliar a confiabilidade e consistência interna da versão curta da Escala de Resiliência em gestantes.

3. MÉTODOS

Os resultados da presente dissertação foram frutos da análise dos dados originais do estudo de coorte prospectivo multicêntrico, o *Maternal Actigraphy Exploratory Study I* (MAES-I) (1). Este estudo foi realizado em quatro centros integrantes da Rede Brasileira de Estudos em Saúde Reprodutiva e Perinatal: o Centro de Atenção Integral à Saúde da Mulher - CAISM da Universidade Estadual de Campinas (Campinas, SP), o Hospital Universitário - FMJ (Jundiaí, SP), a Maternidade do Hospital de Clínicas – UFPE (Recife, PE) e a Maternidade Escola Assis Chateaubriand/MEAC - UFC (Fortaleza, CE).

A coorte incluiu gestantes nulíparas com gestações únicas, entre 19+0 e 21+0 semanas, até o parto, entre março de 2018 a junho de 2020 e tinha por objetivo primário identificar preditores de complicações gestacionais por meio de dados gerados por tecnologias vestíveis/móveis (actígrafos) relativos ao sono-vigília e atividade física.

O protocolo do estudo contendo os detalhes metodológicos, técnicos e operacionais relacionados ao estudo MAES-I foram publicados anteriormente (Anexo 1). O estudo foi aprovado no CEP do centro coordenador (Anexo 2) e em todos os centros participantes.

O cálculo amostral da coorte foi baseado na prevalência de um conjunto de desfechos (*composite outcome*) de acordo com os principais desfechos adversos obstétricos cuja prevalência estimada está entre 3 e 20% (incluindo pré-eclâmpsia, restrição de crescimento fetal, diabetes gestacional, complicações hemorrágicas) (2). Foi baseado em uma população teórica de referência acima de 1 milhão de gestantes e considerada uma margem de erro

aceitável de 4%, com intervalo de confiança de 95%. O cálculo estimou um número mínimo de 384 mulheres a serem incluídas na coorte.

Foram consideradas elegíveis as gestantes nulíparas, ou seja, que nunca tiveram parto de feto vivo ou com mais de 22 semanas de gravidez, com gestação atual com feto único e idade gestacional de 19 semanas + 0 dias até 21 semanas + 0 dias. Foram considerados critérios de exclusão: antecedente de abortos de repetição; malformação fetal comprovada; Hipertensão Arterial Crônica com uso de anti-hipertensivo prévio à gestação; hipertensão moderada/grave (>160/100) na admissão ao estudo; diagnóstico prévio à gestação de Diabetes, nefropatia, Lúpus Eritematoso Sistêmico (LES), Síndrome antifosfolípide (SAF), doença falciforme ou retrovirose; malformação uterina; antecedente de cerclagem uterina; cone a frio; diagnóstico de rotura prematura de membrana na admissão ao estudo; uso crônico de corticosteroides (por mais de três meses); uso de 60-150mg/dia de aspirina; uso de Cálcio (mulheres em uso de >1g/dia); uso óleo de peixe (mulheres em uso de 2,7g ou mais por dia); uso de vitamina C >1000mg ou Vitamina E>400UI por dia; uso atual de Heparina sódica ou heparina de baixo peso molecular; doenças da tireoide, em uso ou não de medicação atualmente; uso de agentes antidepressivos e/ou ansiolíticos; ter alguma condição que limite ou inviabilize a prática de exercícios físicos e condições acompanhadas de alterações cognitivas que dificultassem a compreensão e seguimento das orientações quanto ao uso do actígrafo.

As pacientes elegíveis e que concordaram em participar foram incluídas no estudo na primeira visita (entre 19 +0 semanas e 21+0 semanas), quando, então, receberam o actígrafo. A participante foi orientada a usar o dispositivo

em seu punho, por tempo máximo estimado de 22 semanas (possibilidade de ser incluída com 19 semanas e ter o parto com 41 semanas), durante o dia e durante a noite. Nesta mesma visita foram coletadas amostras de cabelo e sangue e coletadas informações sobre a gestação atual, antecedentes pessoais e familiares e dados sociodemográficos. Os dados da pesquisa foram coletados e atualizados primordialmente nestas 3 visitas do estudo: a primeira, descrita anteriormente, entre 19+0 e 21+0, a segunda entre 27+0 e 29+0 e a terceira entre 37+0 e 39+0. Todas foram realizadas no ambiente onde as gestantes realizaram o pré-natal, após sua consulta, em sala reservada e privativa. As mulheres, em sua maioria, seguiram o pré-natal nos respectivos centros de pesquisa, segundo protocolos de cada instituição. Aquelas que optaram por manter o pré-natal em outra instituição compareceram aos centros para trocas de actígrafos e para as 3 visitas do estudo. A coleta dos dados pós-parto foi realizada na maternidade onde a participante teve seu parto, através de prontuário médico ou dados e documentos fornecidos pela própria gestante. Todas as informações foram transcritas para o para o sistema online informatizado MedSciNet®.

Na segunda visita, foram aplicados os questionários de resiliência (Anexo 3) e estresse percebido (Anexo 4), ambos validados e amplamente utilizados em pesquisas na literatura. Os questionários foram autopreenchidos após orientações do pesquisador responsável; posteriormente, foram transcritos para o sistema online e suas análises são o foco principal desta dissertação.

Para avaliação da resiliência foi aplicada a Escala de Resiliência de Wagnild e Young (1993) (3) traduzida para o português e adaptada transculturalmente por Pesce e colaboradores em 2005 (4). A escala original

possui 25 itens e pontua com respostas tipo Likert que variam de 1 (discordo totalmente) a 7 (concordo totalmente). Os escores finais da escala foram obtidos somando-se de forma direta essas pontuações e, portanto, pontuam no mínimo 25 e no máximo 175 pontos. Dentre as classificações, uma das mais utilizadas, segundo sugestão das autoras é de alta resiliência acima de 125, moderada entre 125 e 145 e pontuações abaixo de 125 indicam baixa resiliência (5) e foi a classificação utilizada nos estudos.

O estresse percebido foi avaliado através da aplicação da Escala de Estresse Percebido de Cohen e colaboradores (6), a qual foi traduzida em 2007 por Luft e colaboradores (7) e já foi, inclusive, aplicada por Yokokura e colaboradores na população de gestantes da coorte BRISA (8). A escala é composta por 14 itens os quais se referem a sentimentos e pensamentos durante o último mês, ou seja, com qual frequência o sujeito se sentiu de uma determinada maneira neste período. As respostas variam de zero a quatro (0=nunca; 1=quase nunca; 2=às vezes; 3=quase sempre 4=sempre). Cabe ressaltar que a escala possui 7 questões consideradas de conotação positiva e que devem ter sua soma realizada de forma inversa (0=4; 1=3; 2=2, 3=1 e 4=0) e 7 questões de conotação negativa cujas pontuações devem ser somadas de forma direta aos seus respectivos valores. O escore total da escala é composto pela soma dessas pontuações e pode variar de zero a 56. Quanto mais alta a pontuação, maior o estresse percebido.

Os escores de resiliência e estresse foram obtidos a partir da aplicação destas escalas de Resiliência e Estresse Percebido, avaliados conforme a análise estatística descrita posteriormente e descritos segundo sua distribuição na população.

A fim de avaliar os fatores maternos associados com resiliência e estresse, essas variáveis foram analisadas segundo as características sociodemográficas e condições de saúde das gestantes da amostra. Os dados sociodemográficos analisados nos estudos componentes dessa dissertação foram: região brasileira (Sudeste ou Nordeste conforme local de inclusão); idade materna (categorizada em ≤19 e >19 anos); etnia (autodeclarada e categorizada em branca e não-branca), estado civil (autorreferido e categorizado em com parceiro ou sem parceiro), ocupação materna (autodeclarada e categorizada em "trabalha ou estuda" e "não trabalha nem estuda"); escolaridade (autodeclarada e categorizada em ensino primário, secundário e terciário ou mais); renda familiar mensal (autorreferida e categorizada em <1,000, 1,001-2,000 e >2,000 Reais); tipo de cuidado pré-natal (categorizado em público e particular/convênio ou misto), tabagismo, consumo de álcool, outras drogas e histórico de uso de qualquer substância (categorizados em nunca ou uso prévio/durante a gravidez). As associações com as seguintes condições de saúde maternas foram avaliadas: infecção do trato urinário ou de qualquer outra infecção, de sangramento vaginal e hospitalização na primeira metade da gravidez.

Os dados sobre estresse e resiliência também foram avaliados segundo sua associação com vulnerabilidade social. A variável Vulnerabilidade foi definida, na presente pesquisa, visto que não há definição unívoca ou estudos sobre categorização de componentes deste conceito como variável na literatura atual. Baseados em um dos conceitos de vulnerabilidade social no âmbito da psicologia (a partir de uma noção multidimensional) (9) e na disponibilidade de informações do Estudo MAES-I, utilizamos 5 variáveis/condições como critérios

para definir vulnerabilidade. São elas: presença de baixa escolaridade (menos de 12 anos inteiros), ser adolescente (idade igual ou menor de 19 anos), não ter a presença do parceiro na gestação (incluindo solteiras, divorciadas e viúvas), baixa renda familiar (renda familiar mensal menor que 1.000,00 Reais) e etnia não branca. O *continuum* de vulnerabilidade foi estabelecido da seguinte forma: nenhum critério de vulnerabilidade presente, presença de qualquer critério de vulnerabilidade, presença de exatamente um critério, presença de exatamente dois critérios e presença de três ou mais critérios. A vulnerabilidade foi então analisada frente aos dados de resiliência e estresse percebido da população de gestantes do estudo.

Também foram analisados os seguintes desfechos maternos e perinatais: início espontâneo do trabalho de parto, parto pré-termo, via de parto (vaginal versus cesárea), dias de alta após o parto, adequação do peso neonatal ao nascimento, status fetal não tranquilizador (conforme constava em prontuário médico; incluindo alteração no Doppler, cardiotocografia ou ausculta intermitente do batimento cardíaco fetal anotado conforme Partograma), morte fetal ou neonatal, admissão em UTI neonatal, Apgar baixo (<7 no 5º minuto), intubação ao nascimento, pré-eclâmpsia, hipertensão gestacional, diabetes gestacional, near-miss neonatal (definido como peso ao nascer <1.750g, Apgar no 5º minuto <7 ou idade gestacional no parto <33 semanas) e presença de desfecho perinatal adverso (definido como tendo pelo menos um dos seguintes: admissão na UTIN, intubação, hipoglicemia, Apgar de 5º minuto <7, oxigenioterapia ou ventilação mecânica).

Com o objetivo de avaliar a concordância entre a versão resumida da escala de resiliência (RS-14), utilizando a escala original de 25 itens (RS-25)

como referência, foi também realizada análise do escore de resiliência de acordo com a RS-14 (6). A escala resumida consiste basicamente na exclusão de 11 itens da RS-25, conforme sugere a própria autora Wagnild (2009), resultando em escores que variam de 14 a 98. A classificação da versão reduzida também seguiu as categorias baixa, moderada e alta, tendo sido os intervalos: entre 14-65, entre 65-81 e entre 82-98, respectivamente. Para possibilitar a comparabilidade entre as escalas, os escores de ambas foram convertidos para uma versão "escore relativo" (variando de 0 a 100). Os escores obtidos na RS-25 foram multiplicados por 100 e, posteriormente, divididos pelo valor máximo da pontuação da escala (175). Os escores obtidos para escala reduzida, foram igualmente multiplicados por 100 e esse resultado dividido por 98, que é a pontuação máxima a ser obtida na RS-14. Dessa fora os escores tanto da RS-25, como da RS-14, puderam ser comparados nos seus valores relativos. Na publicação da escala original em 1993 (3), a definição conceitual de resiliência permitiu a identificação de 5 fatores relacionados ao constructo, sendo eles: vida significativa, perseverança, autossuficiência, equanimidade e solidão existencial. Foram também analisados tais fatores nos dados obtidos com a coorte do estudo e os 5 fatores foram analisados por análise fatorial confirmatória em ambas versões.

Na comparação entre as versões RS-25 e RS-14 foram utilizados os escores relativos com suas medianas e desvios-padrão além dos percentis 5,10, 25, 75, 90 e 95.

Análise Estatística

Foi utilizado o software estatístico SPSS versão 20.0 (IBM *Corp. Released* 2020. IBM SPSS *Statistics for Windows, Version 27.0*. Armonk, NY: IBM Corp) na análise e processamento dos dados extraídos do banco.

Para atender aos objetivos 2.2.1. ao 2.2.4., realizamos o seguinte planejamento analítico:

A distribuição do escore de resiliência e de estresse percebido analisados através da distribuição de medida de tendência central e da distribuição dos graus de resiliência (baixa, moderada ou alta). Essas distribuições também foram analisadas segundo o perfil sociodemográfico da população.

Foi avaliada a distribuição do escore de resiliência e de estresse percebido por análise da distribuição de medida de tendência central e frequência de graus de resiliência, e utilizada análise bivariada para avaliar a associação com fatores sociodemográficos, de saúde materna e da gravidez.

Para comparação entre os percentis, foi utilizado o teste qui-quadrado, na comparação entre medianas os testes U de Mann-Whitney para as variáveis de duas categorias e Kruskal-Wallis para a comparação de medianas das variáveis de três categorias. Foram calculados os riscos relativos para baixa resiliência e alto estresse percebido de acordo com os graus de vulnerabilidade usando razões de risco e os respectivos intervalos de confiança de 95%. O risco relativo para desfechos adversos também foi calculado de acordo com os graus de resiliência com intervalo de confiança 95%. O p-valor $<0,05$ foi considerado estatisticamente significativo.

Para atender aos objetivos 2.2.5. e 2.2.6., o seguinte planejamento analítico foi adotado:

Na comparação entre as versões RS-25 e RS-14 foram utilizados os escores relativos com suas medianas e desvios-padrão, além dos percentis 5,10, 25, 75, 90 e 95. As diferenças entre as médias foram testadas com o teste de Wilcoxon e entre os percentis foi usado o teste de McNemar. O coeficiente de correlação de Pearson foi utilizado para medir o grau de correlação linear entre as versões original e reduzida da escala. A concordância entre os escores das escalas foi avaliada segundo a análise de concordância entre métodos de Bland-Altman e o teste de Pitman para comparar as variações. A significância estatística considerada foi de p-valor <0.05.

A consistência interna da RS-14 foi avaliada através de análise fatorial confirmatória, usando o método dos mínimos quadrados generalizados, rotação ortogonal Varimax, com normalização Kaiser e o coeficiente alfa de Cronbach. Para retenção fatorial foi utilizado o critério de Kaiser-Guttman, mais conhecido como *Eigenvalue* > 1.

Aspectos Éticos

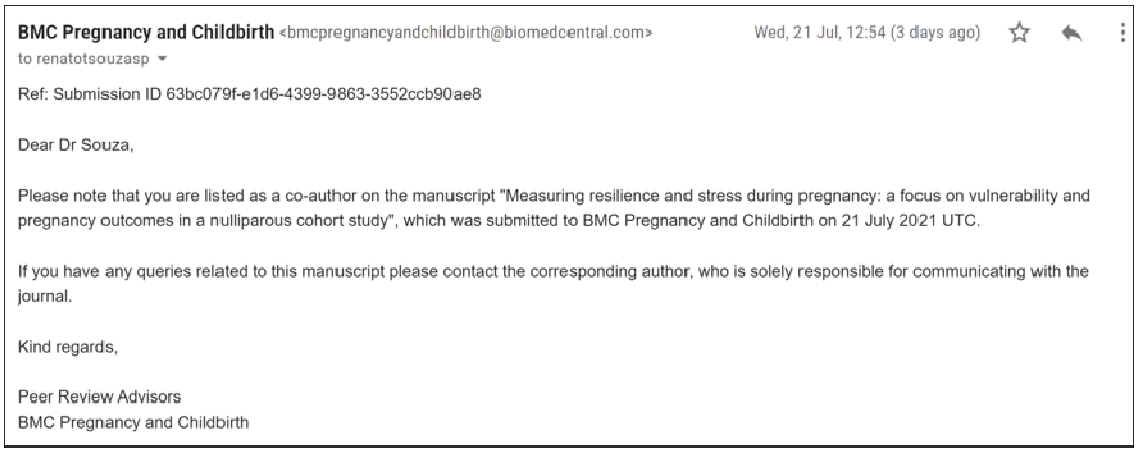
O estudo MAES-I foi aprovado pelo Comitê Ética em Pesquisa (CEP) do centro coordenador e de todos os outros centros participantes (Carta de aprovação 1.834.116 emitida em 24 de novembro de 2016). As escalas de resiliência e estresse percebido não são aprovadas para uso na prática clínica e, portanto, não forneceram dados que pudessem ser clinicamente transformados em um diagnóstico patológico de doença mental. Porém, a

qualquer percepção de algum sinal ou sintoma psiquiátrico, os profissionais responsáveis pelo cuidado pré-natal procederam para garantir o tratamento oportuno e/ou encaminhamento das gestantes, conforme protocolo institucional de cada centro participante. Ademais aos procedimentos do estudo e suas visitas, as pacientes receberam os mesmos cuidados de rotinas dos pré-natais e procedimentos institucionais locais. As participantes foram formalmente informadas sobre o estudo e aquelas que concordaram em participar assinaram o Termo de Consentimento Livre e Esclarecido. Os procedimentos metodológicos e os aspectos éticos do presente estudo seguiram a Declaração de Helsinque alterada em Hong Kong em 1989 e os princípios éticos brasileiros do Conselho Nacional de Saúde (Resolução CNS 466/12).

4. RESULTADOS

4.1 Artigo *Measuring resilience and stress during pregnancy: a focus on vulnerability and pregnancy outcomes in a nulliparous cohort study*

Artigo original que foi submetido a publicação na revista BMC Pregnancy and Childbirth cujo texto aparece a seguir.



BMC Pregnancy and Childbirth <bmcpregnancyandchildbirth@biomedcentral.com> Wed, 21 Jul, 12:54 (3 days ago)

to renatotsouzasp

Ref: Submission ID 63bc079f-e1d6-4399-9863-3552ccb90ae8

Dear Dr Souza,

Please note that you are listed as a co-author on the manuscript "Measuring resilience and stress during pregnancy: a focus on vulnerability and pregnancy outcomes in a nulliparous cohort study", which was submitted to BMC Pregnancy and Childbirth on 21 July 2021 UTC.

If you have any queries related to this manuscript please contact the corresponding author, who is solely responsible for communicating with the journal.

Kind regards,

Peer Review Advisors
BMC Pregnancy and Childbirth

(Submetido para publicação em 21 de julho de 2021)

ORIGINAL RESEARCH

Measuring resilience and stress during pregnancy: a focus on vulnerability and pregnancy outcomes in a nulliparous cohort study

Anic C Alves[1], Renato T Souza[1], Jussara Mayrink[1], Rafael B. Galvao[1], Maria L. Costa[1], Francisco E. Feitosa[2], Edilberto A Rocha Filho[3], Débora F Leite[3], Ricardo P Tedesco[4], Danielly S Santana[4], Karayna G Fernandes[4], Maria J Miele[1], Joao P. Souza[5], Jose G Cecatti[1*] for the MAES-I Study Group#

[1] Department of Obstetrics and Gynecology, School of Medical Sciences, University of Campinas (UNICAMP), Campinas, SP, Brazil

[2] MEAC – Maternity School of the Federal University of Ceará, in Fortaleza, CE, Brazil

[3] Department of Gynecology and Obstetrics, Medical Sciences School, Federal University of Pernambuco, Recife, PE, Brazil

[4] Department of Obstetrics and Gynecology, Jundiaí Medical School, Jundiaí, SP, Brazil

[5] Department of Social Medicine, Ribeirão Preto Medical School, University of Sao Paulo, Ribeirão Preto, SP, Brazil

#Membership of the MAES-I study group is provided in the Acknowledgments section.

*Corresponding author:
Jose G Cecatti
Department of Obstetrics and Gynecology, University of Campinas
101 Alexander Fleming, Cidade Universitária, Campinas/SP, Brazil
ZIP Code 13087-500
email: cecatti@unicamp.br

Abstract

Background: Resilience reflects coping with pregnancy-specific stress, including physiological adaptations of the maternal organism or factors arising from the socioeconomic context, such as low income, domestic violence, drug and alcohol use, lack of a support network and other vulnerability characteristics. Resilience is a dynamic characteristic that should be comparatively evaluated within a specific context; its association with perceived stress and social vulnerability during pregnancy is still not fully understood. This study aimed at exploring maternal resilience, perceived stress and social vulnerability during pregnancy and its associated factors and outcomes. **Methods:** Prospective multicenter cohort study of nulliparous women in Brazil determining resilience (Resilience Scale; RS) and stress (Perceived Stress Scale; PSS) at 28 weeks of gestation (+/- 1 week). Resilience and stress scores were compared according to sociodemographic characteristics related to maternal/perinatal outcomes and social vulnerability, defined as having low level of education, low family income, being adolescent, without a partner or non-white. **Results:** We included 381 women who completed the RS and PSS instruments. The majority of women showed low resilience scores (median: 124.0). Women with a low resilience (RS <125) were more likely from the Northeast region, adolescents, non-whites, did not study or work, had a low level of education, low family income, and received public prenatal care. Higher scores of perceived stress were shown in the Northeast, non-whites, at low levels of education, low annual family income and public prenatal care. Pregnant women with a low resilience had higher perceived stress scores and at least one vulnerability criterion (91.4%). **Conclusion**: Our results reinforce the role of resilience in protecting women from vulnerability and perceived stress. It may prevent complications and build a positive experience during pregnancy.

Keywords: resilience, stress, pregnancy, vulnerability, validation, scale

Background

Pregnancy is a period of challenges emotional, arising from social and psychological factors and hormone changes related to this phase (1). Stressors are related to both specific events and physiological adaptations of the maternal organism. Pregnancy symptoms include nausea, weight gain, insomnia, and emotional lability. Individual factors include unplanned pregnancy, changes in family dynamics, prenatal complications, or fear of developing complications (2, 3). The socioeconomic context may also aggravate stressors for these pregnant women: low-income situations, domestic violence, use of drugs and alcohol, lack of a family support network and other vulnerabilities (4). Literature have demonstrated that 3 out of 4 pregnant women report some symptoms that indicate a level of stress (5). Long-term exposure to these factors during pregnancy is associated with adverse maternal and perinatal outcomes, including premature rupture of membranes, preterm labor and delivery, and small for gestational age fetuses (2, 6). Studies have established an association between intrauterine stress and repercussions on cognitive and motor development, and behavioral alterations in childhood (7). A higher incidence of psychological disturbances occurs in women during pregnancy and postpartum (8). These women require proper care and follow-up for adequate detection and intervention (9, 10).

Psychology has studied individual human reactions to adverse circumstances and/or stress factors, termed resilience (11, 12). This reaction is independent of the intensity or quality of stressors, taking into consideration the response and coping mechanisms of the individual. The concept of resilience is the capacity

to adapt to adversities in life. It is considered a subjective indication of this response, which encompasses internal strength, competence, and flexibility concepts, and may be inversely related to depression, perceived stress, and anxiety (13, 14). Resilience can be analyzed as a dynamic characteristic, as demonstrated by the evaluation of elderly adults (15). Some authors suggest that resilience may increase in adult life, probably deriving from a positive effect of overcoming limits and adversities during a lifetime (15, 16). Resilience in women during pregnancy is still poorly studied.

Resilience should be assessed comparatively in a specific context and considering the expected response (e.g., same age group, social and cultural context, etc.) (17). Resilience and social vulnerability are interrelated, and they are regarded as opposed by some authors. An individual in a context of vulnerability may be susceptible to higher exposure to risk factors and aggravating factors, leading to different coping levels, in a particular context and according to individual characteristics (4, 17, 18).

Resilience may help pregnant women cope with psychosocial problems, apart from pregnancy-specific concerns. Women may fear the changes and physiological adaptations during pregnancy, and fear childbirth and the postpartum period (19, 20). Therefore, identifying less resilient groups in contexts of higher vulnerability may facilitate assisting women who are at higher risk and have less access to resources necessary to cope with inherited difficulties in pregnancy. This may contribute to the individual care of each pregnant woman and can support specific intervention strategies (21, 22). It would be remarkably important for nulliparous women, who are facing maternity for the first time.

The current study aims to explore maternal resilience, perceived pregnancy-related stress and factors associated with vulnerability in a population of nulliparous pregnant women. Furthermore, the purpose is to evaluate the associated sociodemographic characteristics, health conditions, maternal and perinatal outcomes.

Methods

This was a multicenter prospective cohort study. It was conducted in four referral obstetric care units in Brazil, within the Brazilian Network for Reproductive and Perinatal Health Studies (23). The primary objective of the MAES-I study (Maternal Actigraphy Exploratory Study – I) was to identify the predictors of gestational complications, using data generated by wearable/mobile technology (wrist-worn sensors) to monitor sleep vigilance and physical activity. Methodological details and procedures related to the MAES-I study are described elsewhere (24). Briefly, sample size calculation of the cohort was based on a 3 to 20% prevalence of major obstetric complications (e.g. preeclampsia, fetal growth restriction, gestational diabetes, bleeding complications). A theoretical population of more than 1 million pregnant women was considered, with an acceptable margin of error of 4%, and a 95% confidence interval, resulting in 384 women. The final sample was calculated at 400 pregnant women. This article follows the STROBE (*Strengthening the Reporting of Observational Studies in Epidemiology*) checklist for reporting a cohort study (25).

From March 2018 to March 2020, the four participating centers included nulliparous pregnant women at low-risk, singleton pregnancy, gestational age

confirmed between 19 and 21 weeks. Table S1 (Supplementary Material) shows that exclusion criteria were: history of repeat abortions (≥3), preexistent diabetes, stage II chronic arterial hypertension or in use of medication, thyroid disease, kidney disease, HIV, hepatitis B or C, suspicion of major fetal anomaly, antidepressant or anxiolytic use, among others. Data collection of epidemiological and clinical characteristics of the woman, pregnancy, delivery, postpartum and newborn occurred during pregnancy at three in-person antenatal visits (19-21, 27-29 and 37-39 weeks of gestation) and the review of the medical records of mother and newborn. During pregnancy, data collection included information on sociodemographic and anthropometric characteristics, maternal nutrition, lifetime habits, health history, gestational complications, resilience, and stress.

Data collection on resilience and perceived stress occurred around 28 weeks (+/- 1 week). Pregnant women were interviewed in a private room in the prenatal care unit. Standardized and validated (self-administered) instruments were applied and records were transcribed to the *MedSciNet* web-based platform system.

Resilience was assessed by the Wagnild and Young Resilience Scale (1993) (26). The scale was translated into Brazilian Portuguese, adapted transculturally, and validated by Pesce et al in 2005 (27). The original scale comprises 25 items, with a 7-point Likert scale, ranging from 1 (strongly disagree) to 7 (strongly agree); the total score ranges from 25 to 175. Scores over 145 indicate a high level of resilience, scores between 125 and 145 indicate a moderate level of resilience, and scores under 125 indicate a low level of resilience (28).

Stress was evaluated according to the perceived stress scale developed by Cohen et al. (29) and translated into Brazilian Portuguese and validated in 2007 by Luft et al. (30). The perceived stress scale has 14 items, 7 with a positive connotation and 7 with negative connotation, scoring from 0 to 4. Questions with a positive connotation should be inversely added (0=4; 1=3; 2=2, 3=1 and 4=0), and negative questions should be added directly to their respective scoring values. The sum of all 14 items obtains the total scale score which does not have a cut-off for degrees of perceived stress. Scores may range from zero to 56. Higher scores refer to higher perceived stress (29). Questions from both instruments refer to the women's perception from the last month.

Data of sociodemographic characteristics and pregnancy included Brazilian region (Southeast or Northeast, according to inclusion site); maternal age (categorized as ≤19 and >19 years old); ethnicity/skin colour (self-reported and categorized as white and non-white), marital status (self-reported and categorized as with or without a partner), maternal occupation (self-reported and categorized as "Paid work or studying" or "Neither working nor studying"); schooling (self-reported and categorized as having had primary, secondary, college or higher education); monthly family income (self-reported local currency categorized as <1,000, 1,001-2,000 and >2,000 Brazilian *Reais* (BRL); estimated currency exchange rate at the time of the study was 1 US Dollar = 5 BRL); source of antenatal care, smoking, alcohol consumption, other drug use and history of any substance use. Data collection on maternal health conditions included urinary tract infection or any other infection in the first half of pregnancy, vaginal bleeding, and hospitalization in this period.

Vulnerability was defined by a theoretical-social concept based on five sociodemographic characteristics: low level of education (less than 12 full years of schooling), adolescent (age 19 or younger), monthly family income <1,000 BRL, without a partner during pregnancy (including single, divorced, and widowed) or non-white ethnicity. In order to understand the impact of vulnerability, we thought to consider an analysis of its continuum as follows: no criterion of vulnerability, any criteria of vulnerability, exactly one criterion, exactly two criteria and three or more criteria.

Maternal and perinatal outcomes were onset of spontaneous labor, preterm delivery, route of delivery (vaginal versus cesarean), postnatal discharge, adequate weight at birth, non-reassuring wellbeing fetal status (according to medical records of Doppler, cardiotocography or partogram), fetal or neonatal death, neonatal intensive care unit (NICU) admission, low Apgar score, intubation at birth, preeclampsia, gestational hypertension, gestational diabetes, neonatal near-miss events, adverse perinatal outcome or any severe obstetric complication. Neonatal near miss was defined as having birthweight <1750g, 5^{th} minute Apgar<7 or gestational age at delivery <33 weeks. Any adverse perinatal outcome (APO) was defined as having at least one of the following: NICU admission, intubation, hypoglycemia, 5th minute Apgar <7, oxygen therapy or mechanical ventilation.

Resilience and perceived stress scores were analyzed by the distribution of measures of central tendency and rate of resilience levels, according to the sociodemographic profile of the population. The chi-square test was used for percentage comparisons. Mann-Whitney U and Kruskal-Wallis tests were used to compare the medians of two and three categorical variables, respectively.

The bivariate analysis assessed the association between sociodemographic factors, maternal health and pregnancy with resilience and perceived stress. Correlation between resilience and perceived stress scores was assessed by Pearson´s correlation coefficient. Risk estimates for low resilience and high perceived stress were estimated according to degrees of vulnerability using risk ratios and 95% confidence intervals. Also, we calculated risk for pregnancy outcomes according to levels of resilience, using risk ratios and respective 95% confidence intervals. The p-value <0.05 was considered significant.

Ethical aspects

The MAES-I study was approved by the Institutional Review Board (IRB) of the coordinating center and all the remaining participating centers (Letter of Approval 1.834.116, issued on November 24, 2016). Perceived stress and resilience scales are not routinely used in clinical and obstetric practice for screening or diagnosis of mental disorders. Thus, the application of resilience and perceived stress scales did not generate information that could be clinically translated into a diagnosis of normality or abnormality. The prenatal care team was responsible for interpreting the results obtained by assessment scales, potentially identifying mental disorders (e.g. anxiety, depression) or even recognizing the need for psychological or psychiatric follow-up, and timely intervention. These healthcare workers considered other types of information about the woman, her routine prenatal care, and local institutional protocols. The participants were duly informed and signed the Consent Term, prior to study inclusion. Methodological procedures and ethical aspects of the current study were in compliance with the Declaration of Helsinki, amended in Hong

Kong in 1989, and Brazilian ethical principles of the Brazilian National Health Council (Resolution CNS 466/12).

Results

The MAES-I study identified 468 eligible women as eligible to participate in the cohort, and a total of 400 women were included (Figure 1). For this analysis, 381 women that had adequately answered/completed the resilience and perceived stress scales were analyzed.

Figure 2 addresses the association and correlation between perceived levels of stress and resilience. Data demonstrated that there is a moderately weak and negative linear correlation between resilience and perceived stress scores (Pearson's correlation coefficient -0.379, $p<0.001$). The distribution of perceived stress was different for women with different levels of resilience; the higher the level of resilience, the lower the perceived stress.

Table 1 describes in detail the distribution of resilience and perceived stress. The mean and median resilience scores were 118.5 and 124.0, respectively. Resilience scores ranged from 33 to 167, and the 10th and 90th percentiles were 77.0 and 152.0. The mean and median perceived stress scores were 26.7 and 27.0, respectively. The perceived stress scores ranged from 9.0 to 50.0, and the 10^{th} and 90^{th} percentiles were 18.0 and 34.0.

Levels of resilience were distributed according to sociodemographic characteristics, as described in Table 2. When compared to highly resilient women, the population with low resilience was comprised of a higher proportion of women living in the Northeastern region of Brazil (79.8%), adolescents

(28.8%), non-whites (81.8%), those who did not work or study (44.2%), had lower schooling level (14.1%), had a monthly family income under 1,000 BRL (46.5%), and received public prenatal care (95.5%). Any criterion of vulnerability was presented in 91.4% of the women with low resilience. The majority of women with low resilience was non-smokers or had quit smoking when they learned they were pregnant (97.5%), never used alcohol or stopped when they found out they were pregnant (94.4%). Regarding any substance use (e.g. tobacco, alcohol, drugs or other drugs), 90.9% reported never using these substances during pregnancy.

Table 3 describes the distribution of the perceived stress score according to sociodemographic characteristics of the study population. Maternal characteristics showing higher perceived stress scores were observed in the Northeast region (median 28.0, p-value <0.001), non-whites (median 28.0, p-value 0.011), with secondary level of education (median 28.0, p-value 0.002) or lower (median 27.0, p-value 0.002), family income between 1001,00 and 2000,00 BRL (median 29.0, p-value <0.001) or less (median 28.0, p-value <0.001), public prenatal care (median 27.0, p-value 0.016), no history of drug use (median 27.0, p-value 0.014), no history of any substance use (median 27.0, p-value 0.024) and low resilience scores (median 28.0, p-value <0.001).

The study population's distribution of resilience and perceived stress are presented in the supplementary material (Figures S1).

Concerning previous BMI (body mass index), there was no significant difference between higher perceived stress scores and maternal age, marital status, maternal occupation, smoking, alcohol use, maternal comorbid conditions, baseline BMI at the first prenatal visit, urinary tract infection or any other

infection, vaginal bleeding, hospitalization and sexual intercourse in the first half of pregnancy.

Table 4 evaluated the estimated risks for low resilience and high perceived stress according to degrees of vulnerability. Women with any criteria of vulnerability had a higher risk of low resilience (RR 2.31, 95% CI [1.51-3.52]), as well as those with only one criterion (RR 1.89, 95%CI [1.20- 2.98]); two criteria (RR 2.31, 95%CI [1.48- 3.60]); or three or more criteria (RR 2.77, 95%CI [1.80- 4.27]). Regarding the risk for perceived stress score above the 3rd quartile of the population sampled, only women with only one criterion of vulnerability showed a significantly increased risk (RR 1.96; 95%CI [1.07-3.60]). There was no significant association when only perceived stress ≥ 90th percentile was analyzed.

Maternal and perinatal outcomes of the sample population were analyzed according to levels of resilience (Table 5). Data on pregnancy outcomes from 374 women were available for analysis. There was no significant difference between maternal and perinatal outcomes in women with low or moderate/high resilience. Outcomes were also analyzed in comparison to perceived stress scores in the sample. No significant difference was observed between each outcome and perceived stress score (Table 6).

Discussion

To the best of our knowledge, this is the first study to address resilience, perceived stress and vulnerability in a low-risk obstetric population. Women with low resilience had a higher proportion of sociodemographic characteristics

related to social vulnerability. These characteristics included being from the Northeast, adolescent, non-white, having a low level of education, not studying or working, having a low family income, and receiving public prenatal care. The perceived stress scale identified higher scores in women from the Northeast region of Brazil, non-whites, with a low level of education, low monthly family income, and public prenatal care. It is important to emphasize that our participating centers are public services, however a small number of women had prenatal care outside these centers, but chose to participate in the study.

There is a paucity of studies that apply the Wagnild & Young scale (26) to assess resilience in pregnant women. In general, the resilience of a woman is measured indirectly, taking into consideration stress factors, depression, maturity, and self-esteem (31-33). Salazar-Pousada et al used a reduced version of the scale (version with 14 questions - RS14) in a case-control study (34) that evaluated depressive symptoms and resilience in pregnant adolescents. The scale, however, was applied in the postpartum period and not during pregnancy, which may have different implications on the interpretation of the context and significance of these results. Resilience is usually assessed in women experiencing a significant level of stress or health conditions during pregnancy. In a qualitative study, Kaye et al. (33) evaluated resilience and vulnerability in 36 pregnant women admitted to the hospital with severe complications (near-miss). Olajubu et al assessed resilience (RS-14) and perceived stress (reduced version with 10 questions - PSS-10) in a population of 241 adolescents: 80.5% of the sample were categorized as having a moderate level of perceived stress related to pregnancy and 77.2% were

classified as having low resilience, and also found an inverse relationship between perceived stress and resilience (35).

A North American study by Johnson et al (36) evaluated resilience using the 25-item Connor–Davidson Resilience Scale (CD-RISC 25) in a population of 30 pregnant women of a predominantly minority community, the majority of which were multiparous women with a mean antenatal resilience score of 82.0, while Connor et al found that the general population had a resilience score of 80.4 (36). This study demonstrated the association between lower scores with a history of depression and antidepressant use, anxiety medication or insomnia and did not find an association between previous obstetric complications and substance abuse. In our study population comprised of low-risk nulliparous pregnant women, there was a higher proportion of women with low resilience (51.7% with resilience score <125,); only 21.7% were classified as having high resilience. These results raise some questions about 1) whether the cut-off points to classify degrees of resilience apply to the obstetric population; 2) the existence of particularities intrinsic to pregnancy that may be associated with a higher rate of low resilience.

About the first question, we do not believe that the obstetric population needs different cut-offs. Resilience, as exposed, is a dynamic and contextual concept. Therefore, the maintenance of classifications would be important, including for intrapersonal comparisons in different moments of life, such as during pregnancy (15, 16). Furthermore, as reinforced by the authors themselves, the scale's questions always refer to the individual's subjective perception of general situations and can thus be extrapolated to different stages of life (28).

In reference to the second question, in our study, it was more likely that various factors related to social vulnerability were identified in women with low resilience and higher perceived stress. Factors such as ethnicity, low level of education, low-income level and marital status without a partner during pregnancy, have already been explored in the literature in the context of possible effects on physical and mental health (37-39). The most vulnerable women had worse gestational outcomes, either directly related to clinical complications or delays in identifying disease and health care provision (40). It is believed that the presence of stress factors alone is not sufficient to promote alterations in physical or mental health, since it depends on individual perception of the stressor. Furthermore, an individual can manage these factors. Coping may also depend on the social context where the individual is inserted, acting as a risk factor or health promotion (41). This complex interaction explains our results showing that perceived stress is higher in women with low resilience and lower in those with high resilience. Furthermore, low resilience was seemed to be much more common in women that have some degree of vulnerability; 91.4% of women with low resilience had some vulnerability criterion.

Concerning the use of substances, our results were not consistent with the expected, according to the literature (42-44). It is known that the use of drugs and/or alcohol may be considered a mechanism to cope with stress (42, 43, 45). Other studies using the perceived stress scale have already reported an association between alcohol use and a high level of stress (45). Nevertheless, our data showed that in those with low resilience, there was a higher proportion of women that never smoked, drank, or used any type of substance. In contrast,

the higher rates of perceived stress were not significantly related to smoking or alcohol use during pregnancy. Identification of the use of alcohol and drugs during pregnancy is challenging. While some voluntarily report their habit, others underestimate social use or hide for fear of stigmatization related to substance use during pregnancy. Therefore, self-reported data lose accuracy (44).

No significant associations between maternal and perinatal outcomes and resilience or perceived stress scores were found. Since it was a sample composed of low-risk nulliparous women, the frequency of expected adverse outcomes is usually low (46, 47). Mgaya et al. published that multiparity was associated with higher maternal and perinatal risk compared to nulliparity (46). The sample had a larger number of women under the age of 35, who generally have better perinatal outcomes (47, 48). In addition, the presence of a previous health condition, including diabetes, hypertension taking medication, and thyroid disease, were exclusion criteria, which may have contributed to the low incidence of adverse effects in the sample. In addition, we evaluated only short-term outcomes and that condition might reflect on long term and behavior outcomes in the offspring which were not included in this study. Also, the perceived stress scale is not used as a diagnostic method. It is only applied as a research instrument. Therefore, there are no classifications or value ranges to be analyzed for classification. According to Cohen et al., there is a loss of statistical accuracy when this variable is categorized (29).

Further studies evaluating resilience in other populations of pregnant women are necessary to better evaluate this relationship with morbidity and complications. It should also be considered that among the outcomes to be

evaluated in the MAES-I study, those related to mental health were not included, such as quality of life, anxiety and depression related to resilience in other studies (35, 49, 50). Outcomes may also be affected by participation bias and some degree of the Hawthorne effect, since the pregnant women were known to be from the research study. These women were evaluated, interviewed, and examined during study visits by health care professionals (researchers). The examination included blood pressure measurement, urinalysis strip test, and diabetes tracking, i.e., to search for information about complications of the study, prenatal care may have been facilitated and prevented worse outcomes (51).

Pregnancy is a period of changes in both the pregnant woman and the social environment. Physiological adaptations of pregnancy, and typical pregnancy symptoms (e.g. nausea, lumbar pain, pelvic pain, constipation and insomnia) may affect a woman's wellbeing. Childbirth and postpartum anxiety also contribute to a higher incidence of psychological disturbances during the gestational and puerperal periods (52). All these stressors, either specific to pregnancy or the social environment, may influence the women's health but are subjectively perceived by each woman (53). Prenatal care is a unique time to evaluate how a pregnant woman perceives stressors and withstand their effects. The establishment of bonds, promotion and stimulation of personal resources, and construction of a social support network can provide this group with a positive experience during pregnancy (54). Through individual evaluation of perceived stress, maternal resilience and identification of vulnerability criteria, broader individual health care, sensitivity to the needs of the woman,

perceiving, preventing, and treating adverse maternal and perinatal outcomes (55).

In order to achieve comprehensive health care for pregnant women, it is essential to identify sociodemographic and psychosocial factors associated with increased stress or social vulnerability (56, 57). Partner Disengagement, i.e., demonstrates an association with higher levels of stress, anxiety, maternal depression and has been studied in relation to other complications, including higher rates of fetal death in some studies (58, 59). Racial inequities are also an issue with worse prenatal, childbirth, and postpartum care among non-whites, in comparison to whites (60). Low maternal schooling is associated with increased maternal mortality, preterm birth, low birth weight and lower antenatal care attendance (61, 62). The maternal age group is another characteristic that should be taken into consideration. In particular, adolescence is associated with more adverse perinatal outcomes, hypertensive disorder of pregnancy, preterm birth, and low birth weight (63).

A limitation of this study is that we did not address additional mental health aspects in the investigation, hindering their relationship with constructs as shown in the literature (35, 49, 50). Furthermore, similar to perceived stress, resilience was only assessed in pregnancy during one-time period. It should be highlighted that the dynamic nature of resilience and perceived stress assessed by the questions of the scale refer to the “last month”. Therefore, it is only an instant picture of these characteristics. Nevertheless, there is a paucity of literature on this type of evaluation and further studies are required to identify the best time to evaluate and whether a reassessment is necessary (35, 36). Another limitation is that both scales used were approved for research only,

preventing current clinical evaluation and contextualization of the data obtained (26-28). However, we envision that these scales could be applied in an intervention study aiming to evaluate mental health issues and related pregnancy outcomes.

Conclusions

This study reinforces the importance of a multidimensional approach to health during pregnancy. We believe that antenatal care may be a window of opportunity to identify the psychosocial predictors of vulnerability, perceiving contexts that provide scarce resources to overcome and reverse pregnancy stress factors, either specific to pregnancy or the social environment. Therefore, access to resilience scores in pregnant women may be useful to develop individual and targeted coping strategies for the strength and support of women at higher risk. The field of mental health in pregnancy, focusing on the association of resilience, stress and vulnerability is still not fully understood. Further studies are necessary to reinforce the relevance of resilience and other key variables and its role in preventing complications and construction of a positive experience in pregnancy

List of abbreviations

APO: Adverse perinatal outcome
BMI: Body mass index
BRL: Brazilian Reais
CD-RISC 25: 25-item Connor–Davidson Resilience Scale
IC: Confidence interval
IRB: Institutional Review Board
MAES-I: Maternal Actigraphy Exploratory Study – I

NICU: Neonatal intensive care unit

PSS: Perceived Stress Scale

PSS-10: 10-item perceived stress scale

RR: Relative risk

RS: Resilience Scale

RS-14: 14-item Resilience Scale

STROBE: Strengthening the Reporting of Observational Studies in Epidemiology

Declarations

Ethics approval and consent to participate and to publish

The MAES-I study was approved by the Institutional Review Board (IRB) of the coordinating center and all the remaining participating centers (Letter of Approval 1.834.116, issued on November 24, 2016). The participants were duly informed and signed the Consent Term prior to study inclusion.

Consent for publication

The participants agreed with the publication of their anonymized data, following the Brazilian ethical principles of the Brazilian National Health Council (Resolution CNS 466/12).

Availability of data and materials

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

JGC, JPS conceived and planned the cohort. JGC, RTS, DFL, FEF, EARF, RBG, JM, MLC, RPT, DSS, KGF, MJM, AAC developed all related procedures, implemented and carried out the cohort. RTS, AAC, and JGC designed and performed the current analysis. AAC wrote the first draft manuscript under the supervision of RTS and JGC. All authors, including those from the MAES-I study group, read, reviewed and approved the final version of the manuscript.

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Figure Legends

Figure 1. Flowchart of the MAES-I study – analysis of resilience and perceived stress during pregnancy

Figure 2. Association (A) and linear correlation (B) between Resilience and Perceived Stress scores among women from MAES-I study.

Legend: (A) Distribution of maternal stress according to categories of resilience. Kruskal-Wallis test showed a significant difference of stress scores between groups($p<0.001$). (B) Pearson´s correlation coefficient of -0.379 (p-value<0.001) shows that there was a significant linear correlation between resilience and perceived stress scores.

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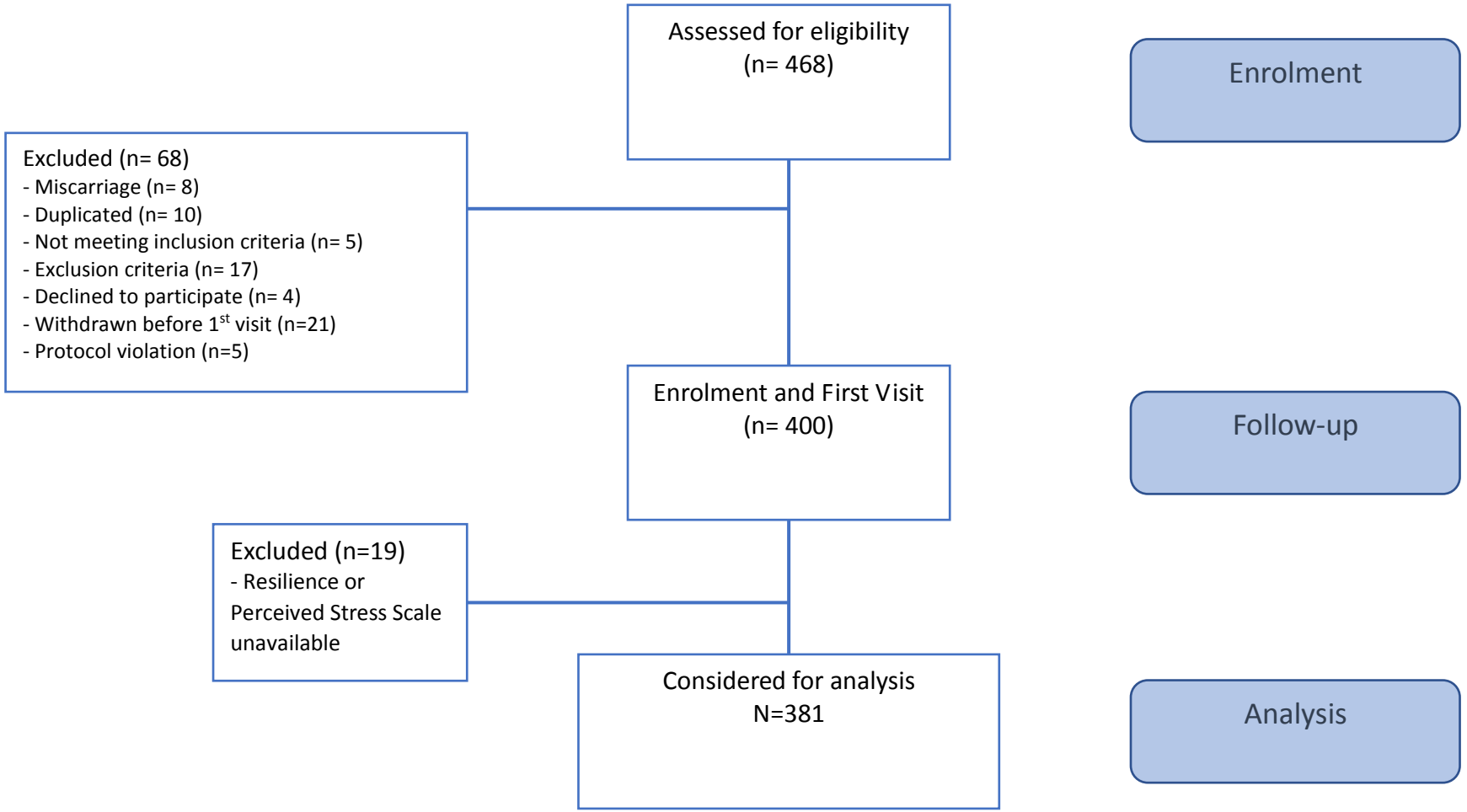


Figure 1. Flowchart of the MAES-I study – analysis of resilience and perceived stress during pregnancy

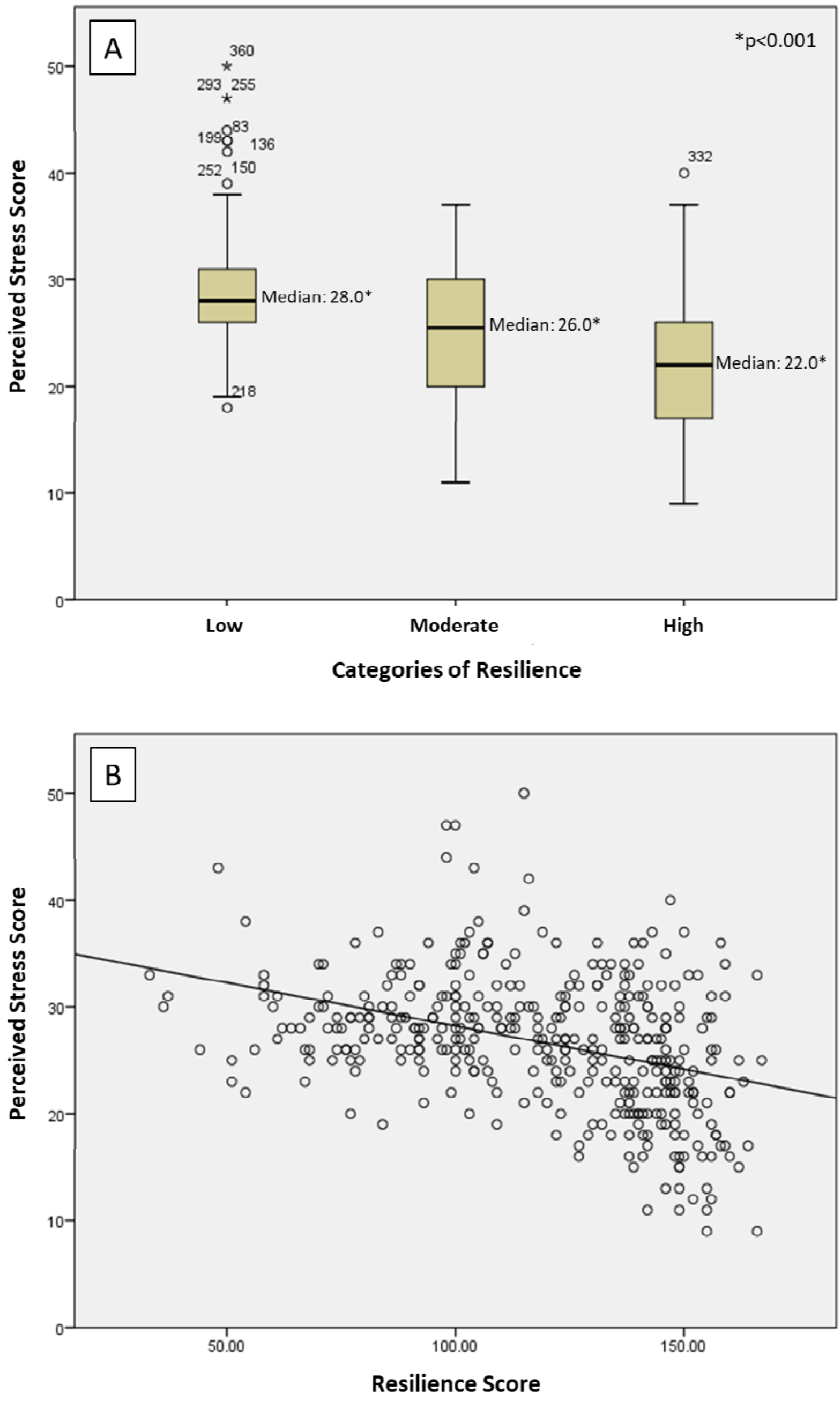


Figure 2. Association (A) and linear correlation (B) between Resilience and Perceived Stress scores among women from MAES-I study.

Table 1. Resilience and Perceived Stress score among participants of the MAES-I study

Characteristics	**Resilience score** n=381	**Perceived Stress score** n=381
Mean	118.5	26.7
Std Deviation	29.4	6.27
Minimum	33.0	9.0
Maximum	167.0	50.0
Percentile 5	66.1	16.0
Percentile 10	77.0	18.0
Percentile 25	98.0	23.0
Percentile 50 (median)	124.0	27.0
Percentile 75	143.0	30.0
Percentile 90	152.0	34.0
Percentile 95	156.0	36.0

Std deviation: Standard deviation.

Table 2. Distribution of resilience according to socio-demographic characteristics (n=381)

	Resilience			
Characteristics	**Low n= 198**	**Moderate n= 100**	**High n= 83**	**p-value**
Region				**<0.001**
Northeast	158 (79.8%)	27 (27.0%)	24 (28.9%)	
Southeast	40 (20.2%)	73 (73.0%)	59 (71.1%)	
Maternal age				**0.013**
≤19	57 (28.8%)	18 (18.0%)	12 (14.5%)	
>19	141 (71.2%)	82 (82.0%)	71 (85.5%)	
Ethnicity				**<0.001**
White	36 (18.2%)	51 (51.0%)	36 (43.4%)	
Non-white	162 (81.8%)	49 (49.0%)	47 (56.6%)	
Marital status				0.269
With partner	152 (76.8%)	74 (74.0%)	56 (67.5%)	
Without partner	46 (23.2%)	26 (26.0%)	27 (32.5%)	
Maternal Occupation [a]				**0.005**
Paid work or studying	110 (55.8%)	74 (74.0%)	57 (68.7%)	
Neither working nor studying	87 (44.2%)	26 (26.0%)	26 (31.3%)	
Schooling				**0.001**
Primary	28 (14.1%)	6 (6.0%)	1 (1.2%)	
Secondary	140 (70.7%)	67 (67.0%)	65 (78.4%)	
College or more	30 (15.2%)	27 (27.0%)	17 (20.5%)	
Monthly Family Income (R$)				**<0.001**
0-1000	92 (46.5%)	18 (18.0%)	19 (22.9%)	
1001 to 2000	61 (30.8%)	29 (29.0%)	16 (19.3%)	
>2000	45 (22.7%)	53 (53.0%)	48 (57.8%)	
Source of antenatal care				**0.011**
Public	189 (95.5%)	86 (86.0%)	78 (94.0%)	
Private/insurance/mixed	9 (4.5%)	14 (14.0%)	5 (6.0%)	
Vulnerability	181 (91.4%)	68 (68.0%)	64 (77.1%)	**<0.001**
Smoking				**0.079**

Currently or during pregnancy	5 (2.5%)	4 (4.0%)	7 (8.4%)	
Never	193 (97.5%)	96 (96.0%)	76 (91.6%)	
Alcohol drinking				**0.033**
Currently or during pregnancy	11 (5.6%)	12 (12.0%)	12 (14.5%)	
Never	187 (94.4%)	88 (88.0%)	71 (85.5%)	
Other drugs				0.507
Currently or during pregnancy	3 (1.5%)	3 (3.0%)	3 (3.6%)	
Never	195 (98.5%)	97 (97.0%)	80 (96.4%)	
History of use of any substance				**0.005**
Currently or during pregnancy	18 (9.1%)	20 (20.0%)	18 (21.7%)	
Never	180 (90.9%)	80 (80.0%)	65 (78.3%)	
Previous maternal conditions	30 (15.2%)	29 (29.0%)	18 (21.7%)	**0.018**
Urinary tract infection in the first half of pregnancy	28 (14.1%)	15 (15.0%)	16 (19.3%)	0.548
Vaginal bleeding in the first half of pregnancy	31 (15.7%)	15 (15.0%)	14 (16.9%)	0.941
Intercourse in the first half of pregnancy	164 (82.8%)	89 (89.0%)	65 (78.3%)	0.144
Occurrence of any infection in the first half of pregnancy	62 (31.3%)	25 (25.0%)	33 (39.8%)	0.101
Hospitalization in the first half of pregnancy	3 (1.5%)	3 (3.0%)	0 (0%)	0.267

Missing information for a) 1.

Table 3. Distribution of perceived stress according to socio-demographic characteristics (n=381)

Characteristics	Perceived Stress Scale				
	n	Median	Mean	SD	p-value #
Region					**<0.001**
Northeast	209	28.0	27.9	5.2	
Southeast	172	25.0	25.2	7.0	
Maternal age (years)					0.112
≤19	87	28.0	27.4	5.3	
>19	294	27.0	26.4	6.5	
Ethnicity					**0.011**
Non-white	260	28.0	27.3	5.9	
White	121	26.0	25.4	6.8	
Marital status					0.301
Without partner	99	28.0	27.4	6.4	
With partner	282	27.0	26.4	6.2	
Maternal Occupation [a]					0.381
Neither working nor studying	139	28.0	26.9	5.3	
Paid work or studying	241	27.0	26.5	6.7	
Schooling (years)					**0.002 ‡**
Primary	35	27.0	28.3	5.2	
Secondary	272	28.0	27.1	6.2	
College or more	74	25.0	24.4	6.3	
Monthly Family Income (R$)					**<0.001 ‡**
0-1000	129	28.0	27.5	5.7	
1001 to 2000	106	29.0	28.0	5.3	
>2000	146	25.0	25.0	6.9	
Source of antenatal care					**0.016**
Public	353	27.0	26.9	6.1	
Private/insurance/mixed	28	24.5	24.4	7.7	
Vulnerability					**0.001**
Yes	313	28	27.2	6.0	
No	68	25	24.5	6.7	
Smoking					0.951
Currently or during pregnancy	16	26.0	27.1	6.9	
Never	365	27.0	26.7	6.2	
Alcohol drinking					0.223
Currently or during pregnancy	35	26.0	26.4	7.7	
Never	346	27.0	26.7	6.1	
Other drugs					**0.014**
Currently or during pregnancy	9	22.0	22.2	4.2	
Never	372	27.0	26.8	6.2	
History of use of any substance					**0.024**

Yes	56	25.0	25.7	7.7	
No	325	27.0	26.8	5.9	
Previous maternal conditions					0.987
Yes	77	27.0	26.8	6.5	
No	304	27.0	26.7	6.2	
Urinary tract infection in the first half of pregnancy					0.075
Yes	59	28.0	28.1	7.0	
No	322	27.0	26.4	6.0	
Vaginal bleeding in the first half of pregnancy					0.160
Yes	60	28.0	27.9	6.9	
No	321	27.0	26.5	6.1	
Intercourse in the first half of pregnancy					0.727
Yes	318	27.0	26.6	6.1	
No	63	27.0	27.1	6.8	
Occurrence of any infection in the first half of pregnancy					0.451
Yes	120	27.0	27.1	6.5	
No	261	27.0	26.5	6.1	
Hospitalization in the first half of pregnancy					0.128
Yes	6	22.0	22.8	6.1	
No	375	27.0	26.7	6.2	
Resilience					**<0.001 ‡**
Low	198	28.0	29.1	5.1	
Moderate	100	25.5	25.5	5.7	
High	83	22.0	22.4	6.8	

Missing information for a) 1. #Mann-Whitney U test for all comparisons, except for ‡ Kruskal-Wallis test.

Table 4. Risk estimates for low resilience and high perceived stress according to degrees of vulnerability (n=381)

	Vulnerability								
	None	**Any**	**RR [95%CI]**	**Only one condition**	**RR [95%CI]**	**Two conditions**	**RR [95%CI]**	**Three or more conditions**	**RR [95%CI]**
Resilience									
Low	17 (25%)	181 (57.8%)	**2.31 [1.51-3.52]**	52 (47.3%)	**1.89 [1.20-2.98]**	59 (57.8%)	**2.31 [1.48-3.60]**	70 (69.3%)	**2.77 [1.80-4.27]**
Moderate/High	51 (75%)	132 (42.2%)	Ref.	58 (52.7%)	Ref.	43 (42.2%)	Ref.	31 (30.7%)	Ref.
Perceived Stress Scale									
≥3rd Quartile	11 (16.2%)	85 (27.0%)	1.66 [0.94-2.95]	35 (31.8%)	**1.96 [1.07-3.60]**	22 (21.6%)	1.33 [0.69-2.56]	26 (25.7%)	1.59 [0.84-3.00]
<3rd Quartile	57 (83.8%)	230 (73.0%)	Ref.	75 (68.2%)	Ref.	80 (78.4%)	Ref.	75 (74.3%)	Ref.
≥ 90th centile	5 (7.4%)	42 (13.3%)	1.81 [0.74-4.41]	17 (15.5%)	2.10 [0.81-5.43]	11 (10.8%)	1.46 [0.53-4.03]	14 (13.9%)	1.88 [0.71-4.99]
< 90th centile	63 (92.6%)	273 (86.7%)	Ref.	93 (84.5%)	Ref.	91 (89.2%)	Ref.	87 (86.1%)	Ref.

Conditions considered as vulnerability criteria: low level of education (less than 12 complete years of schooling); adolescent (age 19 or younger); monthly family income <1,000; without a partner during pregnancy (including single, divorced and widowed) or non-white ethnicity.

Table 5. Resilience and Maternal and Perinatal Outcomes (n=372)

	Resilience		
	Low	**Moderate/High**	**RR [95% CI]**
Onset of Labour			
Spontaneous	126 (66.0%)	115 (63.5%)	Ref.
Induced/Elective C-section	65 (34.0%)	66 (36.5%)	0.94 [0.76-1.17]
Preterm			
pi-PTB	10 (5.2%)	4 (2.2%)	1.39 [0.98-1.96]
Spontaneous	10 (5.2%)	15 (8.2%)	0.77 [0.47-1.27]
No	171 (89.6%)	162 (89.6%)	Ref.
Mode of delivery			
Vaginal	98 (51.3%)	99 (54.7%)	Ref.
C-section	93 (48.7%)	82 (45.3%)	1.06 [0.87-1.30]
Postpartum discharge [a]			
1-3 days	152 (80.0%)	145 (81.5%)	Ref.
>3 days	38 (20.0%)	33 (18.5%)	0.95 [0.75-1.22]
Non-reassuring fetal status [b]	22 (19.6%)	23 (16.2%)	1.13 [0.81-1.59]
Adequacy of birth weigh			
SGA	25 (13.1%)	23 (12.7%)	0.99 [0.74-1.33]
AGA	155 (81.1%)	141 (77.9%)	Ref.
LGA	11 (5.8%)	17 (9.4%)	0.75 [0.46-1.20]
Fetal death	1 (0.5%)	0 (0%)	-
Neonatal death [c]	0 (0%)	2 (1.1%)	-
NICU admission	12 (6.3%)	15 (8.3%)	0.85 [0.55-1.32]
Low 5-minute Apgar Score	2 (1.0%)	2 (1.1%)	0.97 [0.36-2.60]
Intubation at birth [c]	2 (1.1%)	3 (1.7%)	0.77 [0.26-2.29]
GDM [d]	32 (22.1%)	29 (17.1%)	1.17 [0.89-1.55]
Pre-eclampsia [e]	14 (7.3%)	11 (6.1%)	1.10 [0.76-1.57]
Any Great Obstetric Syndrome [f]	58 (39.2%)	51 (29.7%)	1.24 [0.98-1.57]
APO	12 (6.3%)	16 (8.8%)	0.82 [0.53-1.27]
Neonatal Near Miss	7 (3.7%)	6 (3.3%)	1.05 [0.62-1.75]
Maternal mortality	1 (0.5%)	2 (1.1%)	0.64 [0.13-3.21]
Total	**191**	**183**	

Missing information for a) 4, b) 18, c) 1, d) 55, e) 48, f) 52 cases. AGA: adequate for gestational age; APO: adverse perinatal outcomes; GDM: gestational diabetes mellitus; LGA: large for gestational age; NICU: neonatal intensive care unit; pi-PTB: provider initiated Preterm Birth; SGA: small for gestational age. APO was defined as having at least one of the following: NICU admission, intubation, hypoglycemia, 5th minute Apgar <7, oxygen therapy or mechanical ventilation.

Table 6. Perceived stress and maternal and perinatal outcomes (n=372)

		Stress			
	n	**Median**	**Mean**	**SD**	**p-value#**
Onset of Labour					0.164
Spontaneous	241	28.0	27.0	6.4	
Induced/Elective C-section	131	26.0	26.1	6.0	
Preterm					0.468‡
pi-PTB	14	30.5	27.9	6.8	
Spontaneous	25	28.0	26.5	5.0	
No	333	27.0	26.6	6.3	
Mode of delivery					0.377
Vaginal	197	27.0	26.5	6.2	
C-section	175	27.0	26.9	6.3	
Postpartum discharge					0.918
1-3 days	297	27.0	26.7	6.5	
>3 days	71	27.0	26.6	5.5	
Non-reassuring fetal status					0.364
Yes	45	27.0	27.3	6.6	
No	209	27.0	26.5	6.5	
Adequacy of birth weigh					0.230‡
SGA	48	28.5	27.7	6.0	
AGA	296	27.0	26.6	6.3	
LGA	28	26.5	25.1	6.5	
Neonatal death					0.853
Yes	2	27.5	27.5	7.7	
No	369	27.0	26.7	6.3	
NICU admission					0.229
Yes	27	29.0	27.7	6.0	
No	345	27.0	26.6	6.3	
Low 5-minute Apgar Score					0.670
Yes	4	24.5	25.7	6.2	
No	368	27.0	26.7	6.3	
Intubation at birth					0.654
Yes	5	25.0	25.6	6.2	
No	366	27.0	26.7	6.3	
GDM					0.571
Yes	61	26.0	26.3	5.4	
No	254	27.0	26.6	6.7	
Pre-eclampsia					0.715
Yes	25	26.0	26.4	5.4	
No	347	27.0	26.6	6.8	
Any Great Obstetric Syndrome					0.944
Yes	109	27.0	26.6	5.3	

No	211	27.0	26.5	7.0	
APO					0.344
Yes	28	29.0	27.4	6.1	
No	344	27.0	26.6	6.3	
Neonatal Near Miss					0.338
Yes	13	29.0	28.0	5.5	
No	359	27.0	26.6	6.3	
Maternal mortality					0.905
Yes	3	27.0	25.6	9.0	
No	369	27.0	26.7	6.3	

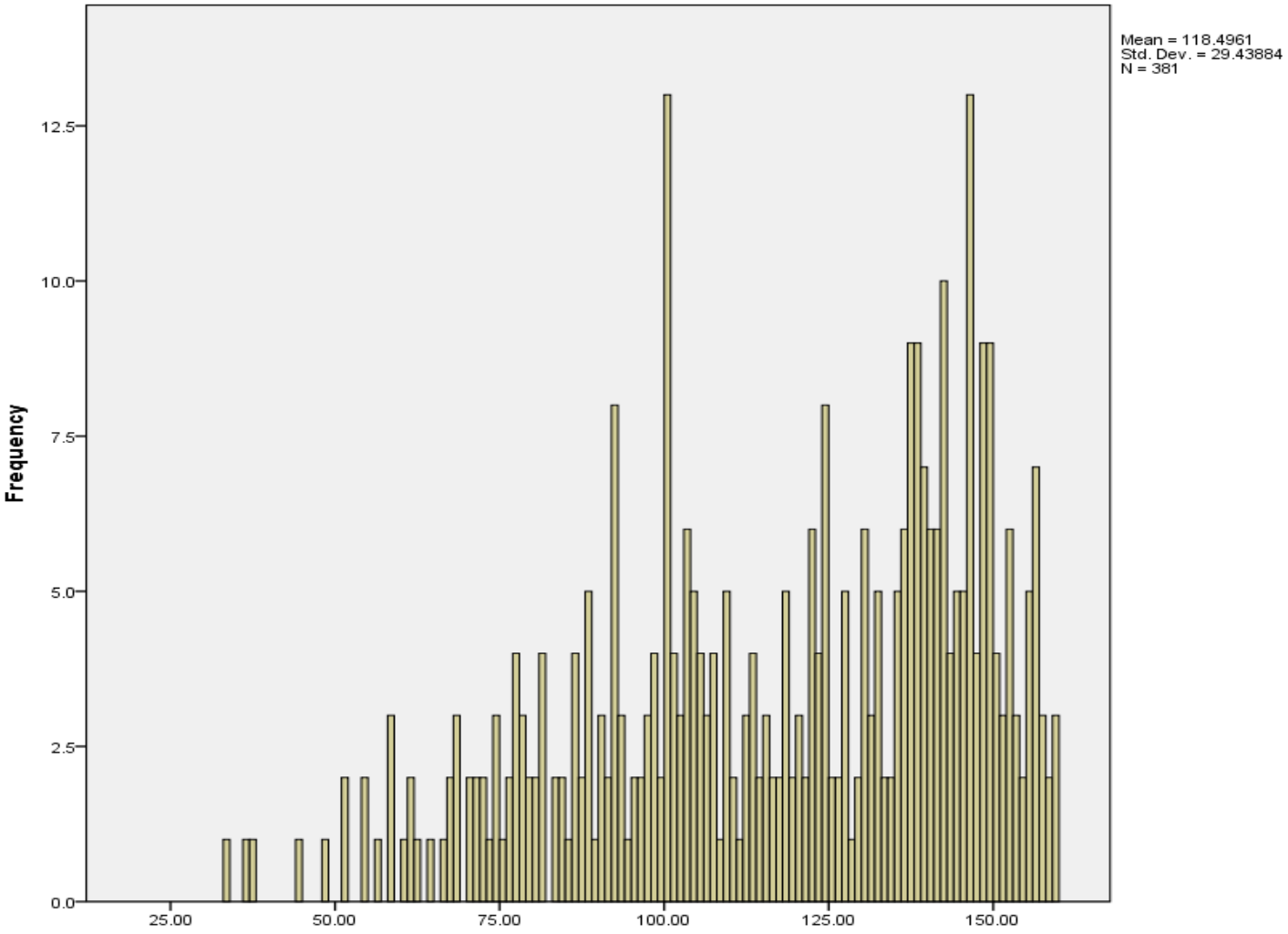
#Mann-Whitney U test for all comparison, except for ‡ Kruskal-Wallis test. AGA: adequate for gestational age; APO: adverse perinatal outcomes; GDM: gestational diabetes mellitus; LGA: large for gestational age; NICU: neonatal intensive care unit; pi-PTB: provider initiated Preterm Birth; SGA: small for gestational age. APO was defined as having at least one of the following: NICU admission, intubation, hypoglycemia, 5th minute Apgar <7, oxygen therapy or mechanical ventilation

Supplementary Material

Table S1. Inclusion and exclusion criteria of Maternal Actigraphy Exploratory Study I (MAES-I)

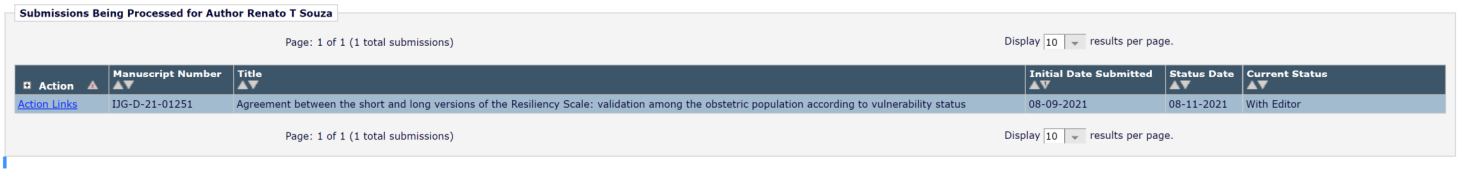
Inclusion criteria
Singleton pregnancy
Nulliparous (who had never given birth before)
Between 19+0 and 21+0 weeks of gestation
Exclusion criteria
Unsure last menstrual period and unwilling to date the ultrasound.
≥3 Miscarriages.
Major fetal anomaly/abnormal karyotype
Essential hypertension treated before pregnancy.
Moderate-severe hypertension at booking (≥160/100 mm Hg) or chronic hypertension using antihypertensive medication.
Prepregnancy diabetes.
Renal disease.
Systemic lupus erythematosus.
Antiphospholipid syndrome.
Sickle cell disease.
HIV or hepatitis B or hep C positive.
Any condition that limits the performance of physical activity.
Major uterine anomaly.
Cervical suture.
Knife cone biopsy.
Ruptured membranes.
Use of long-term steroids.
Use of low-dose aspirin.
Use of calcium (>1 g/24 hours).
Use of eicosapentaenoic acid (fish oil) >2.7 g.
Use of vitamin C ≥1000 mg and vitamin E ≥400 UI.
Use of heparin/LMW heparin.
Untreated thyroid disease.
Use of antidepressant and/or anxiolytic agents.

Figure S1. Distribution of Resilience scores among women from MAES-I study.



4.2 Artigo *Agreement between the short and long versions of the Resiliency Scale: validation among the obstetric population according to vulnerability status*

O segundo resultado dessa dissertação é um artigo original que foi submetido para publicação no *International Journal of Gynecology & Obstetrics* cujo texto aparece a seguir.



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Action Links	IJG-D-21-01251	Agreement between the short and long versions of the Resiliency Scale: validation among the obstetric population according to vulnerability status	08-09-2021	08-11-2021	With Editor

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ORIGINAL RESEARCH

Agreement between the short and long versions of the Resiliency Scale: validation among the obstetric population according to vulnerability status

Anic C. Alves [1], Jose G. Cecatti [1], Jussara Mayrink[1], Rafael B. Galvao[1], Maria L. Costa[1], Francisco E. Feitosa[2], Edilberto A. Rocha Filho[3], Débora F. Leite[3], Ricardo P. Tedesco[4], Danielly S. Santana[4], Karayna G Fernandes[1,4], Maria J Miele[1], Joao P. Souza[5], Renato T. Souza[1]* for the MAES-I Study Group#

[1]- Department of Obstetrics and Gynecology, School of Medical Sciences, University of Campinas, Brazil

[2] MEAC –Maternity School of the Federal University of Ceará, in Fortaleza, CE, Brazil

[3] Department of Maternal and Child Health, Maternity of Clinic Hospital, Federal University of Pernambuco, in Recife, PE, Brazil

[4] Department of Obstetrics and Gynecology, Jundiaí Medical School, Jundiaí, SP, Brazil

[5] Department of Social Medicine, Ribeirão Preto Medical School, University of Sao Paulo, Ribeirão Preto, SP, Brazil

#Membership of the MAES-I study group is provided in the Acknowledgments.

*Corresponding author:

Renato T Souza

Department of Obstetrics and Gynecology, University of Campinas

101 Alexander Fleming St, Cidade Universitaria, Campinas/SP, Brazil

ZIP Code 13087-500

email: rtsouza@unicamp.br

Synopsis

Our findings suggest that the short version of the Resilience Scale (RS-14) may not be suitable replacement for the original version (RS-25) in the obstetric population.

Abstract

Objectives: To compare the 14-tem Resilience Scale (RS-14) and the original 25-item scale (RS-25) in the obstetric population, including women with and without vulnerability. **Methods:** A Brazilian prospective cohort study including nulliparous singleton pregnant women from Mar/2018 to Mar/2020. Women who filled the RS-25 at 27-29 weeks gestation were included in the analysis. We compared medians, standard deviations and centiles between versions, for the general, vulnerable and no vulnerable populations. Correlation, concordance and internal consistency and reliability analyses were performed. A p-value <0.05 was considered statistically significant. **Results:** In total, 381 women who completed the RS-25 were included. Medians of RS-14 and RS-25 scores were significantly different (73.4 and 70.8, respectively; p<0.001), regardless of the vulnerability status. The RS-14 showed a high correlation (Pearson´s correlation coefficient of -0.379 (p-value<0.001), but no agreement (Pitman's test of difference in variance: r= 0.422; *P* <0.001) with the RS-25 version. RS-14 showed high internal consistency and reliability with only one component (Variance of 59.82%, Cronbach´s Alpha 0.947). **Conclusions:** The RS-14 may overestimate the RS-25 score and different domains may not be assessed by the short version. The psychometric properties of the RS-14 and the clinical relevance of the variation between versions require further evaluation.

Keywords: resilience, pregnancy, pregnancy complications, vulnerability, scale

Introduction

In the face of adversity, an individual may react to difficult situations differently that can range from succumbing to overcoming. Resilience is the personal resource for coping with difficulties (1, 2). During pregnancy, a woman may experience resilience according to her social position, psychological resources, interpersonal relationships, and other biopsychosocial characteristics (3).

The World Health Organization (WHO) promotes an approach to maternal care that goes beyond the prevention of pregnancy complications and focuses on achieving a positive experience during pregnancy and childbirth (4, 5). For this purpose, WHO developed tools to improve the multidimensional measurement of maternal health including individual and social factors, and access to health services (6, 7).

The Wagnild & Young Resilience Scale (RS-25), published in 1993, is one of the main instruments to measure this capacity (13,14). It was developed in 1987 with 24 North American women who were selected due to overcoming serious adversities in life (8). The scale was developed to identify degrees of individual resilience, including dimensions such as personal competence, acceptance of herself, and acceptance of life. These dimensions reflect positive psychosocial adaptations to cope with adverse situations (8, 9). The scale is composed of 25 items with Likert type of responses, ranging from “totally disagree” (1 point) to “totally agree” (7 points). In 2009, the same authors shortened and validated the initial 25-item version to a 14-item scale (RS-14). The RS-14 demonstrated good internal consistency and adequate psychometric properties (Cronbach’s alpha coefficient of 0.93) and has been used in the last years [10, 11]. In 2005, Pesce et al transculturally validated and adapted the scale to Brazilian Portuguese using 7th and 8th middle school students and 1st and 2nd years

high school students in Rio de Janeiro (12). The Brazilian Portuguese version showed a good internal consistency (Cronbach's Alpha of 0.80).

A comprehensive approach may require a great number of instruments which may turn the evaluation of the women's wellbeing very challenging (13-15). The validation of shorter instruments is important, therefore, to facilitate the multidimensional assessment during antenatal care visits. Both the RS-25 and the RS-14 scales have been validated and translated to Brazilian Portuguese. These scales were transculturally adapted and also applied to different populations (10, 11, 16). According to Wagnild, the average time for applying the original scale was 5-7 minutes and the time decreased by half, when the short version (RS-14) was used (17).

The aim of this study was to compare and validate the short version of the resilience scale (RS-14), using the original 25-item scale (RS-25) as reference, in a population of nulliparous pregnant women (with and without maternal vulnerability).

Methods

Study design and participants

The MAES-I (Maternal Actigraphy Exploratory Study I) project is a prospective cohort study that included nulliparous singleton pregnant women from mid-pregnancy to childbirth in 4 Brazilian centers from March 2018 to March 2020. The study protocol has been previously published.[18] Briefly, the study was designed to explore predictors of gestational complications, including clinical conditions and patterns of physical activity and sleep, based on actigraphy data by means of a wearable wrist actigraphy device used 24 hours/day uninterruptedly, from 19 to 21 weeks until childbirth. Singleton pregnant women until 21 weeks of gestation were considered eligible. Exclusion Criteria are described in Table S1 (Supplementary Material) and include history of repeat abortions, confirmed fetal

malformation, chronic arterial hypertension with use of anti-hypertensives before pregnancy, moderate/severe hypertension (>160/100) on study admission, diagnosis of diabetes before pregnancy, uterine malformation: bicornuate uterus or uterine septum, history of uterine cerclage, thyroid disease, in current use of medication, use of antidepressants/anxiolytic agents, among others. Sample calculation was based on the prevalence of a composite outcome, dependent on the main adverse obstetric outcomes (gestational diabetes mellitus, preeclampsia, bleeding complications, etc.), resulting in a minimal number of 384 women for inclusion in the cohort.

Procedures

Follow-up of each participant occurred from the time of study inclusion to childbirth at three visits (at 19-21w, 27-29w, 37-39w, and postpartum before discharge). Sociodemographic data, history of maternal health and pregnancy outcomes were collected during study visits. Pregnancy and childbirth outcomes were analyzed on medical chart review.

Resilience Scale and vulnerability

The Resilience Scale was applied during the 27-29 weeks visit. The participant was instructed on completing the scale in a dedicated room. The research assistant reviewed completion of the scale to confirm whether any question had been left unanswered. Subsequently, data was entered into the electronic database system. The current study used the Portuguese version of the Wagnild & Young Resilience Scale (RS-25) (1993) (8), translated by Pesce et al (2005) (12), which was applied during the second visit.

Both RS-25 [8] and RS-14 (10, 11) versions are composed of questions with Likert type responses rated on a scale of 1 to 7 points, according to level of agreement (Table 1). It ranged from “totally disagree” (minimum score of 1) to “totally agree” (maximum score of 7). Resilience scores according to the original (RS-25) and short version (RS-14) were

calculated by the sum of the responses to each question, ranging from 25 to 175 and 14 to 98 scores, respectively. Resilience can also be classified as low, moderate and high (10, 11) (Table 1). Both versions of the scale can be divided into 5 domains for assessment of resilience, including self-reliance, meaningfulness, equanimity, perseverance, and existential aloneness (Table 1).

Afterwards, the scores of both scales were converted into a “relative score” version, in which both scores ranged from 0 to 100. For this, scores of the long and short version were submitted to the following equations: (RS-25)*100/175 and (RS-14)*100/98. This proportional conversion allowed for the comparison between different versions of the resilience scales.

We collected information on aspects related to maternal vulnerability, defined as one of the following conditions: low family income (less than 1,000 Brazilian Reais per month), lack of a partner (single, widow, divorced), adolescent (age under 19 years), ethnicity non-white, and low level of schooling (less than 12 years). Similarly, women without any previous criteria were classified as not being vulnerable.

Statistical analysis

Data extracted from the online database were processed and analyzed by SPSS Version Statistics 20.0 software (IBM SPSS Statistics for Windows, Version 27.0). To compare the scores between the RS-14 and RS-25 versions, we used medians (and standard deviations) and percentiles. Differences in medians were tested by related samples, using the Wilcoxon signed rank test. A linear correlation between the short and original versions was analysed using Pearson´s correlation coefficient. Agreement between the RS-14 and RS-25 scores was assessed using the Bland-Altman plot to analyse the mean and variance of the difference between scores, and the Pitman test of difference in variance. A p-value <0.05

was considered statistically significant. Finally, to evaluate internal consistency of the RS-14 instrument, we performed a confirmatory factor analysis (CFA), using the Generalized Least Squares method, Varimax rotation with Kaiser Normalization and Cronbach´s alpha coefficient. An Eigenvalue greater than 1 was used to retain the number of factors.

Ethics

The MAES-I study was approved by the National Research Ethics Committee in Brazil (CONEP) and by the Institutional Review Board (IRB) of the coordinating center (Letter of approval 1.834.116, issued on November 24, 2016) and all other Brazilian participating centers. An invitation was extended to all women considered eligible for this study, and all signed an informed consent form to participate. Methodological procedures and ethical aspects of the current study were in compliance with the Declaration of Helsinki, amended in Hong Kong in 1989, and Brazilian ethical principles of the Brazilian National Health Council (Resolution CNS 466/12). Methodological and ethical aspects of the study also followed the STROBE guidelines (19).

Results

Of the 400 women originally included in the MAES-I study, 381 women completed the 25-item Resilience Scale during the 27-29 weeks visit (Figure S1). Sixty-eight women did not have any criterion of vulnerability and 313 had at least one criterion of vulnerability (Table 2).

The distributions of the RS-14 and RS-25 scores were significantly different, regardless of the status of vulnerability shown by these women (Figure 1). Medians were 73.4 and 70.8 ($p<0.001$), respectively (Table 2). The 50^{th} (median), 75^{th}, 90^{th} and 95^{th} centiles were significantly different between both versions of the resilience scale (Table2). RS-14 scores had statistically significant higher values than RS-25 scores for these centiles. Resilience scores differed between women with and without vulnerability, regardless of the version of

resilience scale (Table 2). Vulnerable women had lower medians of resilience scores according to RS-14 (82.1 vs 69.3, p<0.001) and RS-25 (78.8 vs 67.7, p<0.001) (Table 2).

Figure 2 shows that the RS-14 and RS-25 versions had strongly correlated scores (Pearson´s coefficient of -0.379 (p-value<0.001)). However, Bland-Altman (Figure 3) showed an asymmetric distribution of the difference in mean scores between scales (Pitman test of difference in variance r=0.422, p-value<0.001). These results demonstrate that there was no agreement between the scales, and the RS-14 scale seems to overestimate the values of resilience, when compared to the RS-25.

Confirmatory factorial analysis showed that only one component obtained an Eigenvalue that was greater than 1 for the RS-14, with a variance of 59.82%. Cronbach's alpha of this version of the scale was 0.947, showing a high reliability and internal consistency. The correlation between individual scores from each item ranged from 0.305 to 0.634 (Table S2), and question 3 of the RS-14 is the only one with a correlation <0.500 (0.305). Question 3 of the RS-14 was also the only one that caused an increase in Cronbach's alpha of the instrument when deleted (Table S3).

Discussion

Our findings suggest that the short version of the Resilience Scale (RS-14) is not a suitable replacement for the original version (RS-25) in the obstetric population since there was poor agreement between versions. If used in this population, caution should be exercised as the short version (RS-14) seems to provide only an overall analysis of resilience and overestimate it.

Concerning psychometric properties, our study showed that there was high internal consistency (degree of reliability) of the short version in this population (Cronbach´s α = 0.947). Reliability was higher than the obtained by Wagnild and Young in 1993 (Cronbach´s

α = 0.91) (19), Damasio et al in 2011 (Cronbach´s α = 0.82) (26) and Pinheiro & Matos in 2013 (Cronbach´s α = 0.945) (30). Although there was a high general internal consistency for the instrument, there are indications that the instrument might benefit from modifications related to the exclusion of certain items. In 2011, Damasio et al 2011 analyzed the psychometric properties of the Brazilian version of the RS-14 in a sample of 1,139 individuals aged 14 to 59 years (16). The authors demonstrated that when item 3 was excluded, the resiliency scale had better goodness of fit indexes and internal consistency (Cronbach's alpha of 0.83). In addition, the authors validated the proposed 13-item scale (Brazilian 13-item), comparing resilience with other aspects that are associated with resilient responses, including "meaning in life", using the 12-Item Purpose-in-Life Test (PILTest-12), and "depression" and "self-efficacy", using the General Health Questionnaire (GHQ-12) (16). The RS-13 correlated positively with meaning in life and self-efficacy and correlated negatively with depression, which was considered intuitive and expected. In our study, while all other items of the scale had a correlation greater than 0.500 between them, item 3 showed a correlation of 0.305. Furthermore, exclusion of this item was the only one that elevated Cronbach's alpha of the instrument. In this context, exclusion of item 3 should be considered.

In the original study that developed the scale, resilience has been defined as a multidimensional phenomenon [8]. In addition, resilience could be assessed by factors that encompass the construction of the process of resilience (Wagnild & Young, 1993): equanimity, perseverance, self-reliance, meaningfulness, and existential aloneness (8). Nevertheless, confirmatory factorial analysis has showed discordant results, indicating the existence of only two main factors: "Personal Competence" and "Acceptance of Self and Life". Both factors explained 44% of the variance in the construct. In 2009, Wagnild explored a new version of the scale aiming at assessing a shorter version with good reliability and

that could address the initially proposed multiple domains (10). The RS-14 showed an excellent correlation with the RS-25 (r=0.97) and internal consistency (Cronbach´s α of 0.93) (10, 11). However, further analyses indicated a unifactorial solution, responsible for 53% of total variance (11). Similarly, our results demonstrated that only one factor resulted from confirmatory factorial analysis, which indicates that the short version should be reserved for the global analysis of resilience, precluding the evaluation per domain. In general, we observed that validation of the short version of the instrument, particularly addressing the domains of resilience, may vary in different studies and populations, requiring further specific exploration (10-12, 16).

Our study has strengths and limitations that need to be acknowledged. This is one of the first studies applying the different versions of the Resilience Scale in an obstetric population. We highlight the need to evaluate the scale in different periods of life, in view of the dynamic concept of resilience (20, 21). The instrument was applied by different examiners, in different centers, with self-administered questionnaires for pregnant women during the same pregnancy period (27-29 weeks). In addition, social vulnerability factors were taken into account in the concordance analysis. Resilience may result from the combination of individual and social contexts, including family and socioeconomic cultural environment, providing an individual with a dynamic process to overcome adverse situations (22, 23). Different degrees of vulnerability may act as a protective or risk factor for the individual and his ability to cope (23). Therefore, addressing resilience according to vulnerability status may confer a more contextual analysis to the construct, which is in agreement with the concept of resilience. Despite the relevance of the current study, there are some limitations.

The study sample only included low-risk pregnant women. It is known that resilience encompasses the ability to overcome adversities. A low-risk population may result in decreased incidence of pregnancy complications (24). We highlight the importance of further

studies to confirm findings in a more diversified and representative sample of Brazilian pregnant women. Another aspect regarding the profile of the study population was that it included only nulliparous women. The majority of these women were facing pregnancy/maternity for the first time. We stress the need to evaluate women in other contexts that may also include women that had a previous motherhood experience, since it may offer a different perspective on resilience. Our study did not assess other important information on mental health, e.g. depression, anxiety or other mood disorders. These components are associated with resilience (25) and may add to the evaluation of the construct, conferring a more complete approach to global (and mental) health and its relationship with variation in resilience.

Our results indicated that there is a probable need to adjust the instrument for the assessment of resilience in the obstetric population. The exclusion of item 3 of the RS-14 has been corroborated by other authors (16), and could potentially contribute to the improvement of the instrument. Further studies are required to evaluate reproducibility of the instrument in pregnant women, since the short scale (RS-14) did not agree with the original scale (RS-25). Assessment of the performance of the short version that classifies women into a low, moderate and high category of resilience, may aid in the evaluation of the applicability of version RS-14. Furthermore, a short version of the instrument could be applied in clinical practice for the multidimensional evaluation of women's health, since there are several other important components to be part of the evaluation, including mental health (26, 27).

Declarations

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Availability of data and material

The dataset used and analysed during the current study is available from the corresponding author upon reasonable request.

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

JGC and JPS conceived and planned the cohort. JGC, RTS, DFL, FEF, EARF, RBG, JM, MLC, RPT, DSS, KGF, MJM, AAC developed all related procedures, implemented and carried out the cohort. RTS, AAC, and JGC designed and performed the current analysis. AAC wrote the first draft manuscript under supervision of RTS and JGC. All authors,

including those from the MAES-I study group, read, reviewed and approved the final version of the manuscript.

Figure Legends

Figure 1. Boxplot of total scores of the 25-item and 14-item Resilience Scales for all women and for women with and without vulnerability criteria in the MAES-I study (n= 381).

Figure 2. Correlation between the 25-item and 14-item Resilience Scale (RS).

Legend: Pearson´s Correlation coefficient of 0.984; p-value <0.001 (n=381).

Figure 3. Bland-Altman comparison of the 25-item and 14-item Resilience Scales.

Legend: Limits of agreement (reference range for difference): -8.17 to 5.23; mean difference: -1.47 (SD=3.41). Pitman test of difference in variance: r= 0.422; P <0.001 (n=381).

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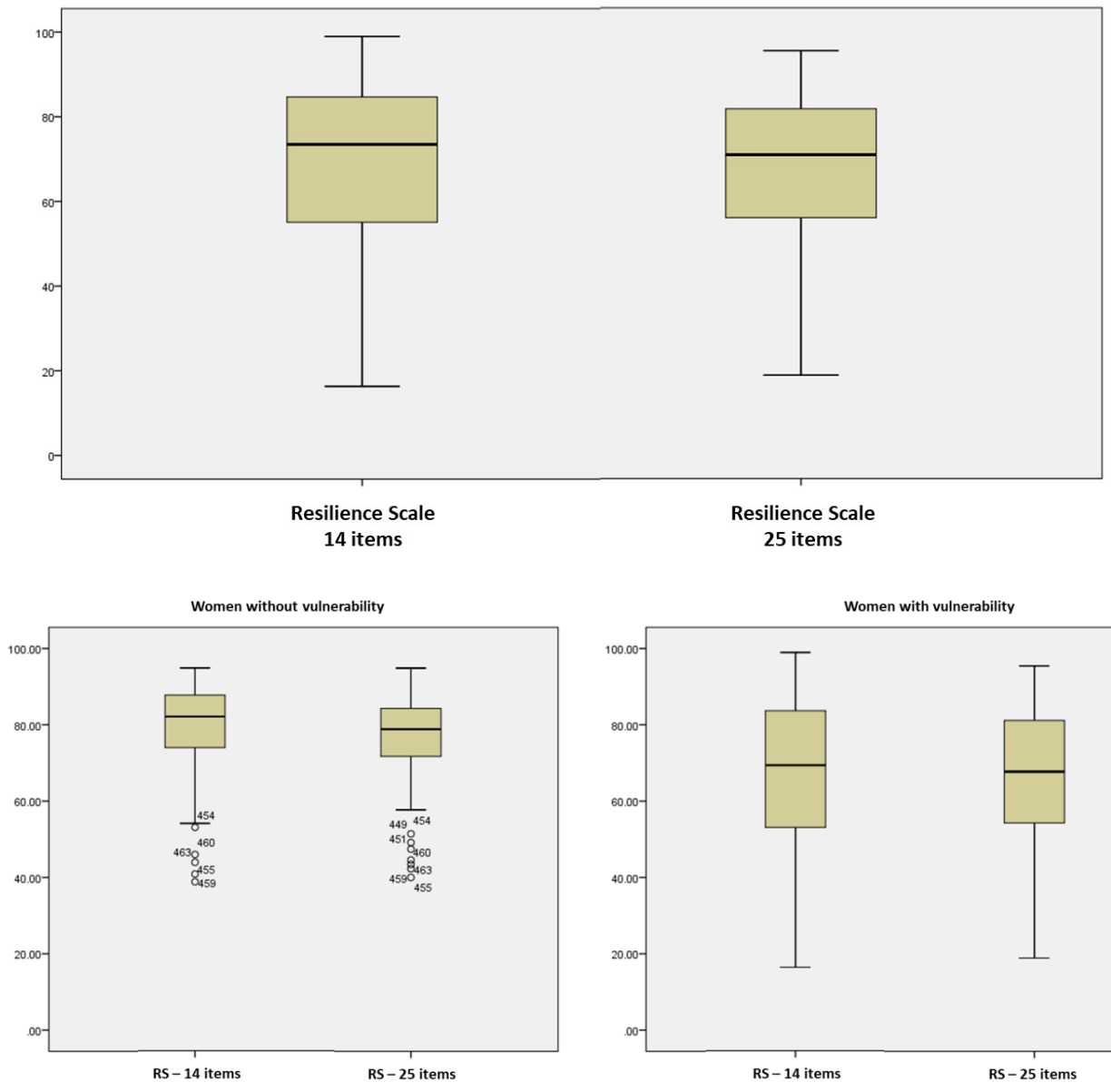


Figure 1. Boxplot of total scores of the 25-item and 14-item Resilience Scales for all women and for women with and without vulnerability criteria in the MAES-I study (n= 381).

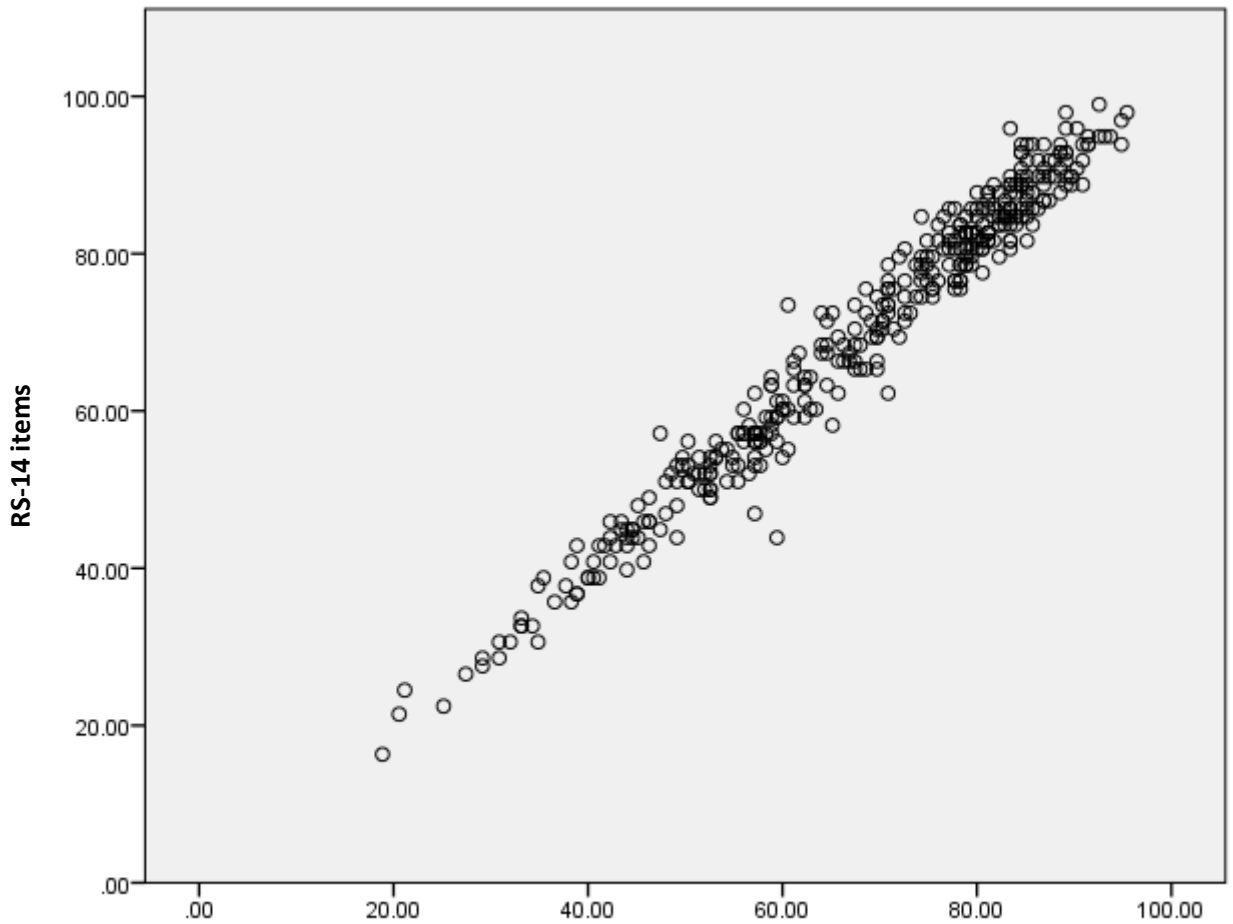


Figure 2. Correlation between the 25-item and 14-item Resilience Scale (RS). Pearson´s coefficient of -0.379; p-value <0.001 (n=381).

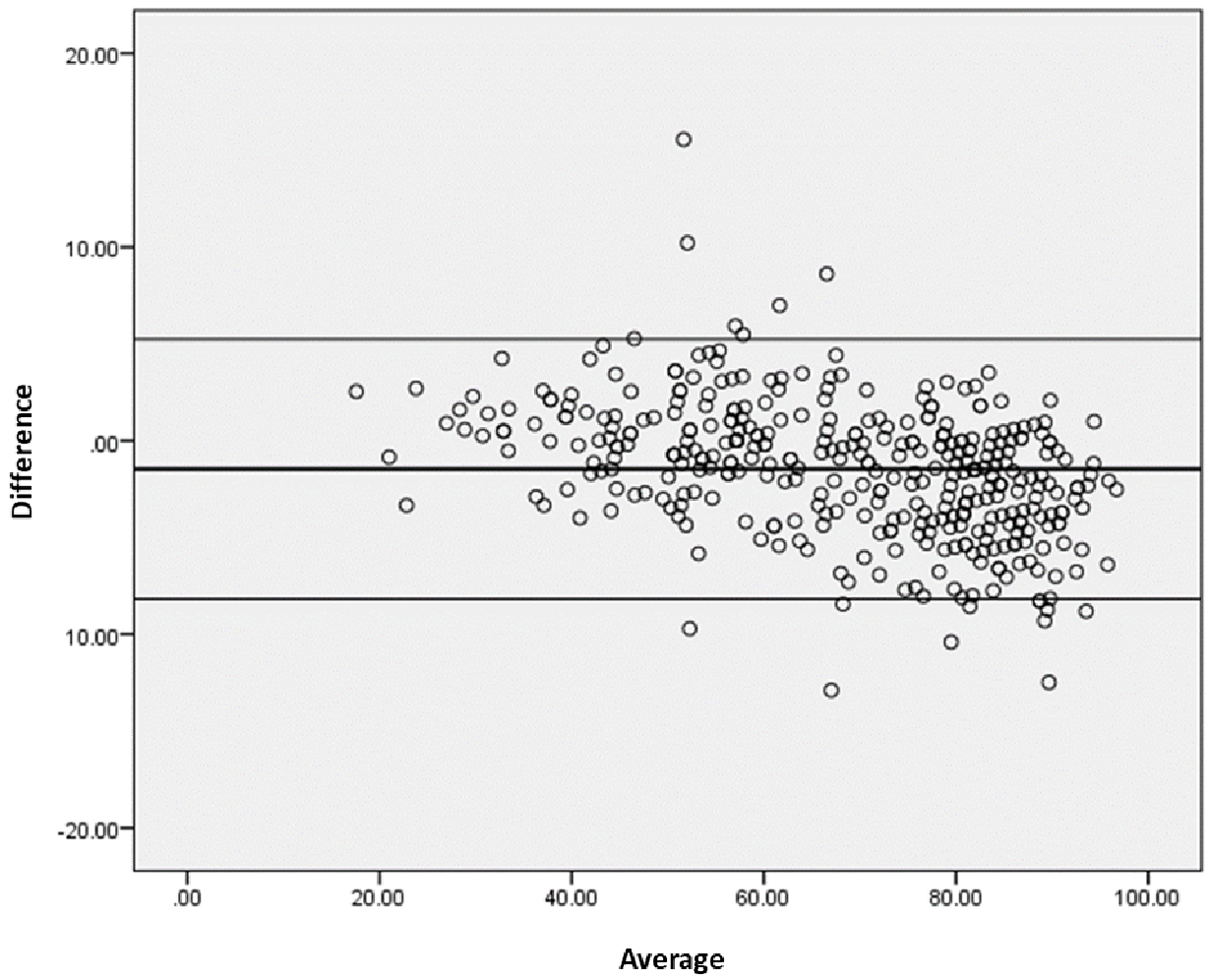


Figure 3. Bland-Altman comparison of the 25-item and 14-item Resilience Scales.
Limits of agreement (reference range for difference): -8.17 to 5.23; mean difference: -1.47 (SD=3.41). Pitman test of difference in variance: r= 0.422; P <0.001 (n=381).

Table 1. Characteristics of the short and long versions of the resilience scales

Characteristics	**RS-14**	**RS-25**
Min-max	14 to 98	25 to 175
High Resilience	>81	>145
Moderate Resilience	65-81	125-145
Low Resilience	<65	<125
Questions		
I usually manage one way or another	Q1	Q2
I feel proud that I have accomplished things in life	Q2	Q6
I usually take things in stride	Q3	Q7
I am friends with myself	Q4	Q8
I feel that I can handle many things at a time	Q5	Q9
I am determined	Q6	Q10
I can get through difficult times because I've experienced difficulty before	Q7	Q13
I have self-discipline	Q8	Q14
I keep interested in things	Q9	Q15
I can usually find something to laugh about	Q10	Q16
My belief in myself gets me through hard times	Q11	Q17
In an emergency, I'm someone people can generally rely on	Q12	Q18
My life has meaning	Q13	Q21
When I'm in a difficult situation, I can usually find my way out of it	Q14	Q23

Domains		
Self-reliance	Q1, Q5, Q7, Q12, and Q14	Q3, Q7, Q9, Q22, Q23, and Q24
Meaningfulness	Q2, Q9, and Q13	Q6, Q8, Q15, Q16, and Q20
Equanimity	Q3 and Q10	Q1, Q2, Q5, Q12, Q13, Q17, and Q18
Perseverance	Q6 and Q8	Q4, Q10, Q14, and Q19
Existential aloneness	Q4 and Q11	Q11 and Q21

Table 2. Reliability of the 14 and 25 items of the Brazilian Portuguese version of the Resilience Scale, including women with (n=313) and without (n=68) vulnerability criteria

	Resiliency 14-items Scale	**Resiliency 25-items Scale**	**p-value**
Overall			**<0.0001***
Mean	69.2	67.7	
SD	18.2	16.8	
Median	73.4	70.8	
Percentile 5			
No vulnerability	44.8	43.9	
Vulnerable	35.6	34.8	
Total	36.9	37.8	
Percentile 10			
No vulnerability	55.9	51.2	
Vulnerable	42.8	42.3	
Total	43.8	44.0	
Percentile 25			
No vulnerability	73.7	71.2	
Vulnerable	53.0	54.1	
Total	55.1	56.0	
Percentile 50			
No vulnerability	82.1	78.8	

Vulnerable	69.3	67.7
Total	73.4	70.8
Percentile 75		
No vulnerability	87.7	84.4
Vulnerable	83.6	81.1
Total	84.7	81.7
Percentile 90		
No vulnerability	89.8	86.8
Vulnerable	91.9	88.6
Total	89.8	86.8
Percentile 95		
No vulnerability	93.8	90.3
Vulnerable	93.8	89.1
Total	93.8	89.1

*Related samples Wilcoxon signed rank test.

Table 3. Confirmatory factor analysis (CFA) of the Portuguese version of the 14-item Resilience Scale

Questions and domains	Factor
	1
Self-reliance	
Q1. I usually manage one way or another	0.720
Q5. I feel that I can handle many things at a time	0.721
Q7. I can get through difficult times because I've experienced difficulty before	0.727
Q12. In an emergency, I'm someone people can generally rely on	0.830
Q14. When I'm in a difficult situation, I can usually find my way out of it	0.778
Meaningfulness	
Q2. I feel proud that I have accomplished things in life	0.795
Q9. I keep interested in things	0.830
Q13. My life has meaning	0.843
Equanimity	
Q3. I usually take things in stride	0.444
Q10. I can usually find something to laugh about	0.821
Perseverance	
Q6. I am determined	0.850
Q8. I have self-discipline	0.753
Existential aloneness	

Q4. I am friends with myself	0.826
Q11. My belief in myself gets me through hard times	0.801
Explained Variance, %	59.82
Eigenvalue	8.37
Cronbach´s alpha	0.947

Kaiser-Meyer-Olkin of 0.958; Bartlett´s test *P*<0.001.

Supplementary Material

Table S1. Inclusion and exclusion criteria of Maternal Actigraphy Exploratory Study I (MAES-I)

Inclusion criteria
Singleton pregnancy
Nulliparous (who had never given birth before)
Between 19+0 and 21+0 weeks of gestation
Exclusion criteria
Unsure last menstrual period and unwilling to date the ultrasound.
≥3 Miscarriages.
Major fetal anomaly/abnormal karyotype
Essential hypertension treated before pregnancy.
Moderate-severe hypertension at booking (≥160/100 mm Hg) or chronic hypertension using antihypertensive medication.
Prepregnancy diabetes.
Renal disease.
Systemic lupus erythematosus.
Antiphospholipid syndrome.
Sickle cell disease.
HIV or hepatitis B or hep C positive.
Any condition that limits the performance of physical activity.
Major uterine anomaly.
Cervical suture.
Knife cone biopsy.
Ruptured membranes.
Use of long-term steroids.
Use of low-dose aspirin.
Use of calcium (>1 g/24 hours).
Use of eicosapentaenoic acid (fish oil) >2.7 g.
Use of vitamin C ≥1000 mg and vitamin E ≥400 UI.
Use of heparin/LMW heparin.
Untreated thyroid disease.
Use of antidepressant and/or anxiolytic agents.

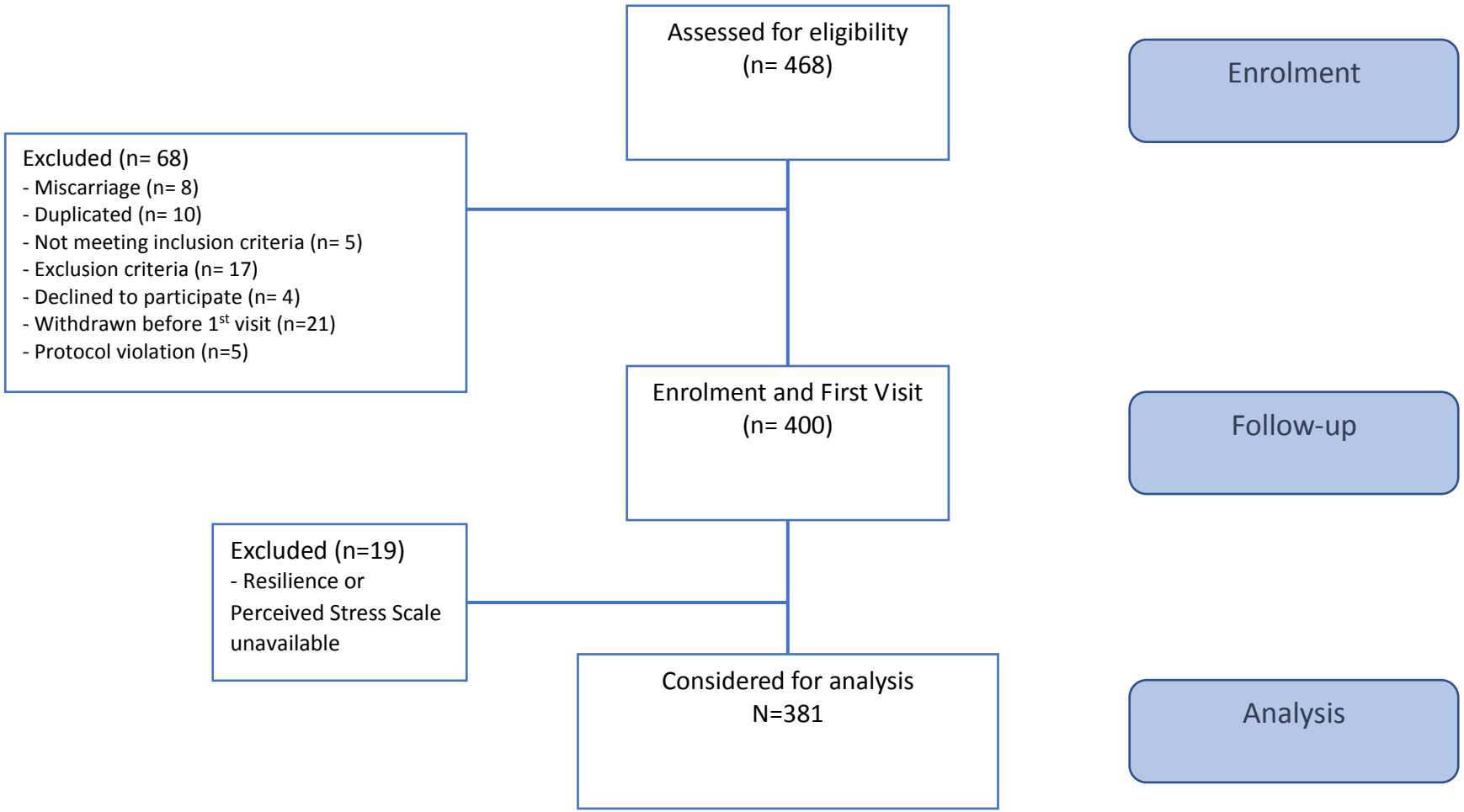
Table S2. RS-14 Inter-Item Correlation Matrix (n=381)

Inter-Item Correlation Matrix														
	Item-2	**Item-6**	**Item-7**	**Item-8**	**Item-9**	**Item-10**	**Item-13**	**Item-14**	**Item-15**	**Item-16**	**Item-17**	**Item-18**	**Item-21**	**Item-23**
Item-1	1.000													
Item-2	.634	1.000												
Item-3	.305	.345	1.000											
Item-4	.588	.689	.425	1.000										
Item-5	.521	.494	.449	.605	1.000									
Item-6	.604	.674	.313	.712	.650	1.000								
Item-7	.438	.485	.278	.521	.509	.549	1.000							
Item-8	.433	.473	.282	.533	.507	.635	.629	1.000						
Item-9	.503	.618	.328	.620	.523	.687	.630	.717	1.000					
Item-10	.535	.627	.287	.642	.517	.664	.536	.559	.713	1.000				
Item-11	.533	.581	.279	.602	.506	.626	.574	.581	.640	.678	1.000			
Item-12	.575	.629	.264	.681	.514	.664	.566	.591	.629	.676	.713	1.000		
Item-13	.567	.705	.297	.682	.521	.683	.569	.602	.685	.698	.626	.698	1.000	
Item-14	.532	.559	.289	.573	.533	.624	.549	.547	.589	.622	.627	.640	.651	1.000

Table S3. RS-14 Item-Total Statistics (n=381)

	Scale Mean if Item Deleted	Scale Variance if Item Deleted	Corrected Item-Total Correlation	Squared Multiple Correlation	Cronbach's Alpha if Item Deleted
Item-2	63.13	281.672	.675	.503	.944
Item-6	62.78	269.808	.755	.645	.942
Item-7	64.02	295.054	.401	.264	.951
Item-8	62.83	269.708	.793	.669	.941
Item-9	63.45	282.274	.681	.539	.944
Item-10	62.95	271.772	.815	.703	.940
Item-13	63.15	277.420	.679	.518	.944
Item-14	63.20	278.474	.706	.610	.943
Item-15	62.95	275.668	.794	.701	.941
Item-16	62.70	274.229	.780	.658	.941
Item-17	62.79	275.896	.759	.623	.942
Item-18	62.68	271.884	.790	.673	.941
Item-21	62.57	269.188	.806	.687	.941
Item-23	62.98	279.021	.734	.562	.943

Figure S1. Flowchart of the MAES-I study – analysis of resilience and perceived stress during pregnancy



5. DISCUSSÃO GERAL

Nessa dissertação, nosso objetivo foi estudar e demonstrar a relevância de aspectos relacionados à morbidade materna não-grave, como a resiliência e estresse e suas interações (10).

Segundo o Grupo de Trabalho em Morbidade Materna, convocado pela OMS em 2012 (11), se considera morbidade materna:

"Qualquer condição de saúde atribuída à complicação na gestação e/ou parto que possa ter um impacto negativo sobre o bem-estar e/ou funcionalidade da mulher".

Portanto, a avaliação da resiliência e da forma com que esta mulher percebe o estresse, são considerados importantes aspectos nesta abordagem multidimensional do cuidado pré-natal, justificada na atenção integral e no amplo cuidado durante o período gestacional (12, 13).

Acreditamos que explorar a relação entre estresse e resiliência possa resultar em uma oportunidade estratégica em incrementar o cuidado à saúde e de possibilitar o fortalecimento das gestantes como indivíduos. Heródoto (14), historiador grego da antiguidade (séc. V a.C.) e considerado pelo filósofo Cícero o pai da História, retratou parte dessa relação:

"*A adversidade tem o efeito de atrair a força e as qualidades de um homem que as teria adormecidas na sua ausência*."

Ou seja, podemos considerar que sem a adversidade não há oportunidade de superação e melhoria das capacidades de enfrentamento. Como se, sem estímulos de crescimento e algum grau de desafio, a vida levasse a um contexto de apatia, monotonia e, portanto, destituído de realização pessoal, ao que Farnè denominou distresse (estresse maléfico) por ativação escassa de mecanismos de enfrentamento (15).

Seria utópico pensar ser possível controlar e poupar as gestantes de situações de estresse. Ademais, como já mencionado, acredita-se que algum grau de estresse seja benéfico. Segundo Farnè (15), este grau de exposição poderia ser considerado “eustresse” ou estresse benéfico, que é advindo de uma ativação razoável dos mecanismos de enfrentamento, melhorando a vitalidade, foco, capacidade de adaptação e resolução criativa de problemas. Porém, o grau de estresse pode depender da interpretação individual de cada um. Em outras palavras, pode depender do estresse percebido. Por outro lado, estresse excessivo ou condições de estressores crônicos e/ou intensos podem causar distresse (estresse maléfico), dessa vez por ativação excessiva. Situações que demandam além da capacidade do indivíduo, desastres, catástrofes, traumas ou situações de constante desconforto e exigência são alguns dos fatores causais de distresse, ou estresse excessivo. Nestes casos, o estresse percebido mostra-se intenso e tem relação com desfechos adversos como depressão e ansiedade (16, 17). O questionamento que cerne esse primeiro ponto é: até que ponto o estresse pode ser salutar e fonte de superação? Quais fatores seriam colaboradores nessa adaptação entre estresse e enfrentamento diante dos desafios da gravidez?

A própria gravidez e o puerpério podem apresentar manifestações que podem ser consideradas estressores às mulheres (12, 18). Podemos citar as mudanças do período gestacional, como os sintomas típicos de enjoo, dor lombar, alterações do sono, alterações do humor, dores pélvicas, entre outros (19). Bem como as dificuldades enfrentadas no puerpério como a amamentação, a privação de sono, a demanda de atenção integral ao recém-nascido e ainda as alterações sociais advindas da consecução do papel social da maternidade (20, 21). Conclui-se, então, que alguns fatores estressores podem ser considerados previsíveis, especialmente no período gestacional. Porém essa previsibilidade não se traduz, necessariamente, em uma uniformidade de interpretação e adaptação por todas as mulheres. É nesse contexto de percepção do estresse que podemos observar entrar em ação as habilidades individuais de enfrentamento. Conforme Sabbag (22) descreve bem:

"O eustresse gera foco e concentração, a resiliência é comprovada e o desempenho costuma melhorar. Todavia, se o indivíduo apresenta baixa resiliência, ao invés de eustresse, essas situações geram distresse, acompanhadas de descrença, sensação de perda de controle, insegurança e vacilação. Repetindo: não encontro melhor antídoto para essa alternância do que o esforço persistente para elevar a resiliência desses indivíduos"

Segundo a *American Psychological Association* (23), resiliência pode ser definida como o "*processo e resultado de se adaptar com sucesso as experiencias de vida difíceis ou desafiadoras, especialmente através da*

flexibilidade mental, emocional e comportamental, e ajustamento a demandas externas e internas".

Neste contexto, acredito ainda mais na importância da promoção da resiliência como forma de promoção de saúde destas gestantes, já que o caminho da maternidade pode trazer consigo muitas mudanças, dúvidas e incertezas. A avaliação da resiliência neste grupo pode corroborar na identificação de grupos de baixa resiliência dentro dos quais tem-se uma oportunidade de implementação de ações de promoção das habilidades e recursos pessoais que possam facilitar a superação dos contextos adversos (24).

A resiliência aplicada no contexto da gravidez, conforme a literatura disponibilizada nesta dissertação, ainda é pouco estudada. Estudos vêm investigando a relação da resiliência com distúrbios de humor em gestantes, demonstrando que aquelas com taxas maiores de resiliência, parecem ter menores taxas de depressão e serem mais equilibradas emocionalmente. Alguns estudos demonstraram ainda que a resiliência pode ser inversamente relacionada com o estresse percebido e ansiedade (25, 26). Outro estudo, com 531 gestantes indicou que aquelas com alto traço de raiva pareceram ter menores níveis de resiliência, o que pode ter relação com maiores taxas de depressão pós-parto neste grupo (13). Por ser considerada como uma característica dinâmica e composta por características cognitivas, comportamentais e emocionais, acredita-se que haja benefício em aprimorá-la, buscando alcançar, por exemplo, maiores níveis de propósito de vida, controle interno e autoestima (24, 27).

Destaca-se, por exemplo, dos grupos de apoio como forma de promoção da competência social, autoestima e empatia. Estimular o compartilhamento de experiências e vivências do período gestacional, pode facilitar o enfrentamento. Ademais, sentir-se parte de um grupo pode ser uma forma de manter-se em equilíbrio, mesmo em períodos de instabilidade e insegurança (28). Outra abordagem pode acercar-se do reforço das habilidades pessoais de enfrentamento: vida significativa, perseverança, autossuficiência, equanimidade, solidão existencial (ou senso de singularidade), todos estes fatores considerados integrantes da resiliência (3). É claro que apenas isso não basta e que muitas outras formas, metodologias, e ações podem representar intervenções positivas que busquem fortalecer essa mulher frente ao enfrentamento da maternidade e seus desafios, promovendo uma experiência positiva na gestação (29). Para isso, acredito que demonstrar a importância do tema seja um passo importante.

Nossos resultados demonstraram que nas gestantes com níveis mais baixos de resiliência, estavam em maior proporção as características sociodemográficas consideradas como de maior vulnerabilidade social, sendo elas: da região Nordeste, adolescente, não branca, ter baixa escolaridade, não estudar nem trabalhar, ter baixa renda familiar e realizar pré-natal em serviço público. Da mesma forma, nossos dados mostraram maiores taxas de estresse percebido em mulheres com algumas características de vulnerabilidade como: ser da região Nordeste, não branca, com baixa escolaridade, com baixa renda familiar mensal e pré-natal realizado em serviço público. Além disso, segundo nossos resultados, o estresse percebido é maior em mulheres com baixa

resiliência e menor naquelas com alta resiliência. E ainda, a baixa resiliência parece ser mais frequente em mulheres com algum grau de vulnerabilidade (91,4% das gestantes com baixa resiliência tinham algum critério de vulnerabilidade).

O contexto social como determinante na saúde teve sua importância reforçada em 2010, quando a OMS conceitualizou os “Determinantes sociais das iniquidades em saúde” (30). De acordo com o documento, os mecanismos estruturais responsáveis pela interação entre indivíduo (contexto) e posição socioeconômica, configuram e mantêm as hierarquias sociais, que mais do que apenas um status social, definem hábitos de vida, acesso aos recursos e serviços de saúde, capacidade de evitar riscos, curar lesões ou doenças e preveni-las. De acordo com os pesquisadores, os estratificadores estruturais mais importantes e os indicadores proxy são: renda, educação, ocupação, classe social, gênero e raça/etnia (30).

Por este motivo, a nossa abordagem manteve-se com foco na resiliência, estresse percebido, mas também levou em conta o contexto dessa população, através da análise dos constructos em diferentes situações consideradas como de vulnerabilidade social. Nessa visão mais abrangente de atenção integrativa à saúde, julgamos ser importante a análise do contexto sociodemográfico entre os aspectos individuais que permeiam o estresse e resiliência na gestação. Já que estes estratificadores sociais podem ser fontes de agentes estressores, atuar como um fator de risco e de vulnerabilidade para esta gestante, mas também representar fatores protetores frente às situações

adversas, já que a rede de apoio e o suporte social podem auxiliar na promoção da saúde (31, 32).

No segundo artigo apresentado como resultado, comparamos as versões curta e longa da escala de resiliência de Wagnild e Young. Segundo os dados, a versão reduzida da escala de resiliência (RS-14) (33) pode não ser, a princípio, uma boa ferramenta para substituir a versão original (RS-25), pois não houve concordância entre os escores de resiliência entre as diferentes versões, pelo menos para essa população obstétrica que estudamos. Se utilizada, a versão curta (RS-14) parece ser um instrumento aplicável apenas na análise global de resiliência e a superestimação do escore deve ser considerada. Além de comparar as escalas, o estudo fomenta a discussão sobre falta de constructos aplicáveis à população obstétrica de forma fidedigna e, principalmente, aplicáveis à prática clínica. A abordagem dessa dissertação traz como um de seus questionamentos se há no contexto da gravidez benefício de mensurar a resiliência nesta fase. Ou seja, mais estudos seriam necessários para primeiro, reforçar a importância da resiliência e sua mensuração no contexto da gravidez, em mais contextos como populações de alto risco, de multiparidade e outros contextos sociodemográficos. Visto que se tem no pré-natal uma janela de oportunidade de intervenções no âmbito de promoção de saúde mental e no fortalecimento dessas mulheres em relação à maternidade e seu papel social (34, 35). Segundo, para identificar a melhor forma de avaliação do constructo na gestação. Haja vista a complexidade da saúde mental e de fatores considerados importantes neste âmbito: quais seriam os demais fatores a serem levados em consideração nesta avaliação?

Quais e quantos momentos seriam oportunos nesta avaliação no ciclo gravídico puerperal? E principalmente: qual seria a melhor maneira de avaliar esses e outros aspectos da saúde mental durante a gestação?

Como referido, nossa abordagem não teve como objetivo esgotar o tema e sim explorar a importância da individualização e da humanização do cuidado pré-natal. Ao mesmo tempo em que identificar contextos de maior vulnerabilidade, permite identificar grupos com maiores taxas de complicações e desfechos adversos, e possivelmente grupos de maior necessidade de atenção (31, 32), a análise do estresse percebido individualiza essa percepção dos estressores nestes grupos e o impacto em cada mulher (28). Por fim, a identificação dos grupos de menor resiliência permite planejar estratégias de promoção e aprimoramento das habilidades pessoais de enfrentamento das adversidades (24, 27).

6. CONCLUSÃO

Objetivo 1: Explorar a distribuição do estresse percebido e da resiliência em gestantes.

Nossos resultados demonstraram que a maioria das mulheres nulíparas de baixo risco apresentou-se com baixa resiliência e menos de 22% teve escores compatíveis com alta resiliência. A distribuição do estresse percebido prejudique uma avaliação individual do grau de estresse, mas de forma geral o estresse percebido pode ser considerado como alto nessa população obstétrica. O contexto de vulnerabilidade social e maior estresse percebido pode ter atuado como fator de risco essa condição. Essas complexas interações merecem ser melhor exploradas para que possamos atuar oportunamente no período pré-natal a fim de promover uma abordagem multidimensional à saúde da mulher.

Objetivo 2: Avaliar a associação entre estresse percebido e resiliência em gestantes

Embora tenha havido fraca correlação entre o estresse percebido e o grau de resiliência das gestantes, houve uma clara associação entre essas condições; mulheres com maiores graus de resiliência tiveram menor estresse percebido. A promoção da resiliência pode ser ferramenta importante a fim de amenizar o estresse percebido por essa população.

Objetivo 3: Avaliar os fatores maternos associados com resiliência e estresse em gestantes.

Houve associação significativa entre maior escore de estresse percebido e baixa resiliência com fatores maternos relacionados à vulnerabilidade social. Esse achado corrobora que a resiliência é uma estratégia de enfrentamento, que implica em competência social, temperança e capacidade de aceitação de si e da vida. Essa e outras características são fortalecidas na presença de um contexto de rede de apoio que, infelizmente, costuma ser mais frágil ou ausente naquelas com maior vulnerabilidade social.

Objetivo 4: Avaliar a associação de resiliência e estresse com graus de vulnerabilidade social.

A somatória de fatores relacionados à vulnerabilidade social foi associada com maior risco de baixa resiliência e, em alguns casos, maior estresse. A identificação de grupos de maior vulnerabilidade social, levando em conta fatores como idade materna, escolaridade, etnia, renda e presença de parceiro, pode indicar as gestantes sobre as quais se deve ter maior atenção na promoção de resiliência. Isso corrobora a importância de melhorar a percepção materna sobre os fatores estressores nessa população mais vulnerável, com o intuito de gerar uma experiencia positiva na gravidez e de fortalecer esta mulher na consecução do papel social materno.

Objetivo 5: Avaliar os desfechos maternos e perinatais associados com graus de resiliência e estresse percebido.

Não foram encontradas relações significativas entre os desfechos maternos e perinatais e os escores de resiliência ou de estresse percebidos. Haja visto o caráter dinâmico da resiliência e as mudanças ao longo da

gestação, seriam importantes novos estudos a fim de identificar o melhor momento para esta avaliação.

Objetivo 6: Avaliar a concordância entre a versão resumida da escala de resiliência (RS-14), utilizando a escala original de 25 itens (RS-25) como referência na população de gestantes.

Na nossa análise não houve concordância entre os escores da escala de resiliência reduzida (RS-14) e da versão original (RS-25) na população obstétrica estudada. A versão reduzida pode não ser uma boa ferramenta para substituir a versão original e parece superestimar os valores de resiliência quando em comparação com a RS-25.

Objetivo 7: Avaliar a confiabilidade e consistência interna da versão curta da Escala de Resiliência em gestantes.

Embora um instrumento mais curto possa ser de maior interesse para prática clínica, uma melhor investigação para determinar sua composição ideal ainda é necessária. Nossos achados sugerem que a exclusão do item 3 da escala pode ser uma modificação que pode melhorar o instrumento.

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ANEXO 1 – Artigo do Protocolo do estudo MAES-I

Open access Protocol

BMJ Open

Identification of earlier predictors of pregnancy complications through wearable technologies in a Brazilian multicentre cohort: Maternal Actigraphy Exploratory Study I (MAES-I) study protocol

Renato T Souza,[1] Jose Guilherme Cecatti,[1] Jussara Mayrink,[2] Rafael Bessa Galvão,[1] Maria Laura Costa,[1] Francisco Feitosa,[3] Edilberto Rocha Filho,[4] Debora F Leite,[4] Janete Vettorazzi,[5] Ricardo P Tedesco,[6] Danielly S Santana,[1] Joao Paulo Souza,[7] on behalf of the MAES-I Study Group

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For numbered affiliations see end of article.

Correspondence to
Professor Jose Guilherme Cecatti; cecatti@unicamp.br

ABSTRACT

Introduction Non-invasive tools capable of identifying predictors of maternal complications would be a step forward for improving maternal and perinatal health. There is an association between modification in physical activity (PA) and sleep–wake patterns and the occurrence of inflammatory, metabolic, pathological conditions related to chronic diseases. The actigraphy device is validated to estimate PA and sleep–wake patterns among pregnant women. In order to extend the window of opportunity to prevent, diagnose and treat specific maternal conditions, would it be possible to use actigraphy data to identify risk factors for the development of adverse maternal outcomes during pregnancy?

Methods and analysis A cohort will be held in five centres from the Brazilian Network for Studies on Reproductive and Perinatal Health. Maternal Actigraphy Exploratory Study I (MAES-I) will enrol 400 low-risk nulliparous women who will wear the actigraphy device on their wrists day and night (24 hours/day) uninterruptedly from 19 to 21 weeks until childbirth. Changes in PA and sleep–wake patterns will be analysed throughout pregnancy, considering ranges in gestational age in women with and without maternal complications such as pre-eclampsia, preterm birth (spontaneous or provider-initiated), gestational diabetes, maternal haemorrhage during pregnancy, in addition to perinatal outcomes. The plan is to design a predictive model using actigraphy data for screening pregnant women at risk of developing specific adverse maternal and perinatal outcomes.

Ethics and dissemination MAES-I has been reviewed and approved by each institutional review board and also by the National Council for Ethics in Research. Detailed information about the study is provided in the Brazilian Cohort website (www.medscinet.com/samba) and findings will be published in the scientific literature and institutional webpages.

Strengths and limitations of this study

- This multicentre cohort will collect comprehensive data on major maternal and perinatal complications such as pre-eclampsia, small for gestational age/fetal growth restriction, preterm birth and gestational diabetes mellitus.
- Physical activity and sleep patterns will be estimated by an innovative wearable device used in the natural environment of the study subject.
- Physical activity and sleep patterns will be estimated from the beginning of the second half of pregnancy until delivery, covering a wide interval during pregnancy, allowing for the study of changes in physical activity and sleep patterns throughout pregnancy.
- One possible limitation is the first half of pregnancy at a time when this information was not covered.

BACKGROUND

Reducing the global maternal mortality ratio to less than 70 per 100 000 live births by 2030 is one of the targets of the new United Nations Sustainable Development Goals.[1] Multiple challenges need to be tackled to achieve this target, but the 2016–2030 health and development agenda goes well beyond mortality reduction. The aim of the Global Strategy for Women's, Children's and Adolescent's Health is to ensure that every newborn, woman and child not only survives but thrives. This will only be possible if a transformative agenda centred on innovation is put into action.[2]

One of the major challenges lies in optimising earlier predictors and identifiers of maternal and perinatal complications. Delays

in diagnosing and managing maternal complications have been associated with poor outcomes.[3] Decreased self-perception of clinical signs related to maternal complications, difficulties in accessing the health system and poor quality of care may contribute to late identification of complications and a worse prognosis. The development of a non-invasive antenatal care (ANC) tool for identifying maternal subclinical signs during pregnancy may provide a window of opportunity for an earlier identification of abnormal patterns of physiological parameters related to pregnancy complications. Earlier identification occurs when recognition is made before clinical presentation by standard criteria based on clinical signs, symptoms and supplementary tests. Shortening the time between the onset of a complication and the initiation of appropriate management enables secondary prevention and reduction of maternal morbidity and mortality.[3–7]

Pervasive computing (ie, the trend towards embedding microprocessors in everyday-life objects so they can generate data) and wearable technology (ie, clothing and accessories incorporating computer and advanced electronic technologies such as sensor wristbands and/or waistbands) are ubiquitous and can generate a new dataset that requires correlation with pregnancy outcomes. Preterm birth and pre-eclampsia are two important pregnancy complications that have a relatively long subclinical phase before the appearance of signs or symptoms.[8 9] It is plausible that during subclinical phases of certain conditions the pattern of physical activity (PA) or sleep–wake rhythm is affected in some way and wearable devices could capture these changes. Although some studies have shown that PA patterns (actigraphy parameters) may be related to systemic inflammation and diseases in the general population,[10 11] there is a paucity of published literature that correlates wearable technology data with maternal complications.

The human circadian rhythm is regulated by endogenous physiological mechanisms and environmental stimuli.[12] Solid evidence indicates that modification in circadian rhythm or sleep and PA patterns are underlying conditions related to inflammatory, degenerative and/or metabolic chronic diseases such as diabetes, hypertension and cancer.[13] Circadian misalignment is defined as inappropriately timed sleep and wake, misplaced feeding periods and modification in PA behaviour.

Determining a cause or effect relationship between these modifications and the development of pathological conditions is a complex task. It seems that changes in appetite-stimulating hormones, glucose metabolism, inflammatory markers and mood are some of the related pathways.[13–15] Leproult *et al*[15] evaluated the effect of circadian misalignment on metabolic and inflammation markers in cardiovascular disease. Insulin action and release, and also levels of some inflammatory markers that are predictors of cardiovascular disease, were abnormal in individuals with circadian misalignment. The mechanisms involved in the association between changes in PA pattern and pathological conditions seem to have multiple aetiologies. Sani *et al* assessed circadian rhythms of more than 2300 African adult descendants. In addition to the evaluation of PA itself, the aim of those authors was to identify chronobiological patterns of adults from different socioeconomic settings. The study described that chronobiological behaviour can vary depending on individual BMI, socioeconomic background, work type and time of sunlight exposure. Many other factors, such as pathological conditions, may be potentially involved in a modification in chronobiological behaviour. Some metabolic, cognitive, cardiovascular and other chronic degenerative diseases have been associated with particular patterns of PA and sleep.[10 11 16–18] A previous observational study assessed various sleep parameters during pregnancy, that is, sleep onset latency (SOL), wake after sleep onset (WASO) and total nocturnal sleep time (TST). Difficulty in initiating sleep in early pregnancy was associated with higher body mass index, greater weight gain and higher blood pressure during pregnancy.[17] Palagini *et al*[19] reviewed the clinical evidence between chronic sleep loss and adverse pregnancy outcomes, discussing common mechanisms of stress system activation. Low-quality evidence suggests an association between sleep loss and prenatal depression, gestational diabetes, pre-eclampsia, abnormal length of labour, caesarean delivery, abnormal fetal growth and preterm birth. Those results corroborate with other findings regarding pregnancy and sleep disorders.[20–23]

Assessment of PA and sleep patterns can be performed by wearing small wrist (or waist) devices similar to a regular watch (actigraphy technology). More recently, substantial advance has been made in types of sensors, batteries, materials and output data, leading to lower cost, comfort, discretion and performance of the devices.[24] Nowadays, portable, lightweight devices have a large capacity to store data, including software with automatic scoring algorithm packages for the detection of wakefulness, sleep periods and PA.[24 25] Actigraphy estimation of PA and sleep patterns is validated as a proxy for chronobiological behaviour[26–29] and the use of an actigraphy device for 7–14 days provides reliable estimates of PA behaviour in older adults.[30–32] The performance of both hip and wrist devices has been shown to be reliable and acceptable for estimating PA and sleep–wake patterns.[33–36]

The main advantages of using wearable devices for actigraphy are non-invasiveness, 24/7 monitoring of PA and circadian patterns, and information about sleep habits and parameters in the natural environment of the subject.[24 25 28] We propose an innovative and strategic approach to monitor PA and sleep–wake patterns during pregnancy, establishing a large database comprised of clinical, epidemiological, PA and sleep–wake variables that are potentially capable of composing a prediction model for maternal complications during pregnancy. The main goal of this study is to identify earlier predictors of pregnancy complications by establishing a correlation between data on PA and sleep patterns using wearable devices (sensor wristbands) and maternal and perinatal complications and outcomes.

Box 1 Participating centres in the Maternal Actigraphy Exploratory Study I

- The Maternity of Centro de Atenção Integral à Saúde da Mulher (CAISM), University of Campinas, in Campinas, SP, Brazil;
  - Local principal investigator: Maria Laura Costa.
- Maternity of the Clinic Hospital, Federal University of RS, Porto Alegre, RS, Brazil;
  - Local principal investigator: Janete Vettorazzi.
- Maternity of the University Hospital, Jundiaí Medical School in Jundiaí, SP, Brazil;
  - Local principal investigator: Ricardo Porto Tedesco.
- Maternity of Clinic Hospital, Federal University of Pernambuco, in Recife, PE, Brazil;
  - Local principal investigator: Edilberto A Rocha Filho.
- Maternidade Escola Assis Chateaubriand (MEAC) – School Maternity of the Federal University of Ceará, in Fortaleza, CE, Brazil.
  - Local principal investigator: Francisco Edson de Lucena Feitosa.

METHODS/DESIGN

Study design

We will conduct a cohort study of 400 pregnant women using sensor wristbands capable of capturing information on daily PA and sleep patterns (exposure). This cohort study will be implemented in five ANC clinics linked to obstetric units in three different regions of Brazil that are already part of the Brazilian Network for Studies on Reproductive and Perinatal Health,[37] as shown in box 1. During an 8-month period, the ANC clinics will identify cases that are eligible to use the sensor wristband. Wearable technology data will be correlated with the occurrence of pregnancy and childbirth complications and outcomes, such as hypertensive disorders, gestational diabetes mellitus, fetal growth restriction and prematurity.

Eligible women will be identified up to 21 weeks of gestation and invited to participate in the study. A proper consent form will be applied and women who agree to participate will receive a sensor wristband to wear continuously from 19 to 21 weeks until childbirth.

Study setting and population

Brazil is a multiethnic mixed-race population of diverse resourced settings.[38] Despite the high global overall human development index (HDI 0.727) in 2010, the HDI of Brazilian municipalities ranged from 0862 to 0418.[39] A mixed population is suitable for exploring information on patterns of maternal mobility and sleep, maximising external validity and comparisons to other populations. The following reasons support a study population of low-risk nulliparous women: (1) Previous obstetric history can refer to known risk factors for many maternal complications such as preterm birth, pre-eclampsia and diabetes.[13 40] Therefore, nulliparous women permit unbiased sampling regarding obstetric history. (2) Women with previous morbidities such as hypertension, diabetes, nephropathy or other chronic/degenerative diseases are more likely to present abnormalities in sleep–wake rhythms or PA patterns during pregnancy.

Sampling

The five participating centres are regional referral obstetric units responsible for antenatal care of mainly high-risk pregnant women. Participating centres are listed in box 1. Nevertheless, there are primary healthcare units strategically linked to these participating centres, enabling the identification and enrolment of women with non-pathological pregnancies. Recruitment strategies include approaching all eligible women in these participating centres and their linked facilities. An informed consent form will be applied for women who agree to participate.

Eligible women: low-risk pregnant subjects

There is a lack of international consensus on criteria for low-risk pregnancies, although several factors are known to be associated with maternal and perinatal adverse outcomes. A recent study evaluating complications of 'low-risk' pregnancies of US Americans (10 million births from 2011 to 2013) indicated that 29% of low-risk women experienced an unexpected complication that required no routine obstetric/neonatal care.[41] This illustrates the difficulty in establishing a 'low-risk profile' for maternal/

Box 2 Inclusion and exclusion criteria of Maternal Actigraphy Exploratory Study I

Inclusion criteria

- Singleton pregnancy.
- Nulliparous (who had never given birth before).
- Between 19+0 and 21+0 weeks of gestation.

Exclusion criteria

- Unsure last menstrual period and unwilling to date the ultrasound.
- ≥3 Miscarriages.
- Major fetal anomaly/abnormal karyotype.*
- Essential hypertension treated before pregnancy.
- Moderate-severe hypertension at booking (≥160/100 mm Hg) or chronic hypertension using antihypertensive medication.
- Prepregnancy diabetes.
- Renal disease.
- Systemic lupus erythematosus.
- Antiphospholipid syndrome.
- Sickle cell disease.
- HIV or hepatitis B or hep C positive.
- Any condition that limits the performance of physical activity.
- Major uterine anomaly.
- Cervical suture.
- Knife cone biopsy.
- Ruptured membranes.
- Use of long-term steroids.
- Use of low-dose aspirin.
- Use of calcium (>1 g/24 hours).
- Use of eicosapentaenoic acid (fish oil) >2.7 g.
- Use of vitamin C ≥1000 mg and vitamin E ≥400 UI.
- Use of heparin/LMW heparin.
- Untreated thyroid disease.
- Use of antidepressant and/or anxiolytic agents.

*All information on fetal anomalies will be properly recorded.

perinatal complications. To make a better identification of eligible low-risk pregnant women, we excluded known potential confounders of prepregnancy conditions that could be related to adverse maternal or perinatal outcomes as shown in box 2, so we could assess PA and sleep patterns of a mostly 'normal' population. Nonetheless, features such as lifestyle habits and body composition (body mass index, height), and some non-severe chronic diseases including non-severe anaemia and/or asthma are not exclusion criteria in this study. However, these features and conditions may be a part of subgroup analyses (eg, composition of any previous disorder). Intra-individual and interindividual analyses of PA and sleep patterns can avoid possible bias by identifying potential confounders that may affect primary outcomes. A comparative analysis will be conducted, in which parameters of PA and sleep patterns will be collected in different stages of pregnancy from the same participant (intraindividual analysis) and compared with data collected at the same stage of pregnancy from different participants (interindividual analysis).

Eligible women are to be enrolled at 04–21 weeks of gestation. Inclusion and exclusion criteria are shown in box 2.

Data collection methods

Essentially, Maternal Actigraphy Exploratory Study I (MAES-I) is composed of 4 key set points—three clinical visits during pregnancy and a postnatal visit. Clinical visits will be held at (1) 19–21 weeks, (2) 27–29 weeks and (3) 37–39 weeks. On the first, second, third and postnatal visits, additional information on maternal history, details of pregnancy complications, maternal biophysical data (weight, height, skinfolds) and adverse pregnancy outcomes will be collected following a specific standard operating procedure specially developed for MAES-I. Furthermore, the Perceived Stress Scale[42] and Resilience Scale[43] will be applied during the 27–29 weeks visit. Figure 1 shows the set points of MAES-I.

Eligible women will be invited to use a 43x40x13 mm water-resistant wrist device similar to a regular watch (GENEActiv Original – Activinsights). The device contains an accelerometer for PA calculation and sensors for estimation of sleep–wake patterns by light and temperature measurements, using a proper software algorithm.

At the first set point of MAES-I (between 19+0 and 21+0 weeks of gestation), eligible women who agreed to participate will be instructed to wear the wrist bracelet device on the non-dominant wrist night and day (24 hours/day), uninterruptedly until childbirth (including bathing or recreational water activities). Participants will not need to press any buttons and functioning of the device requires no special care. The device will be configured to register PA and sleep–wake data automatically from the moment it is delivered to the participant during antenatal care visit. In addition, the battery charge will be held by the research assistant before delivering the device to the study participant.

The acquisition of actigraphy data can be performed in different frequencies (from 10 to 100 Hz). Since the frequency of data acquisition has an impact on battery life of the device (inverse relationship), measurement frequency will be set according to gestational age of the participant (table 1). This information will be registered in the database accordingly. Cumulative data will be downloaded during antenatal care visits, according to maximum return periods shown in table 1. Calculation of maximum return periods will be based on expected battery life. At each antenatal care visit, the used device will be returned to the research team and a new charged device will be provided to the participant.

A leaflet with detailed information and frequently asked questions about the device will also be provided. Women will also have a cell phone number to call in case of any

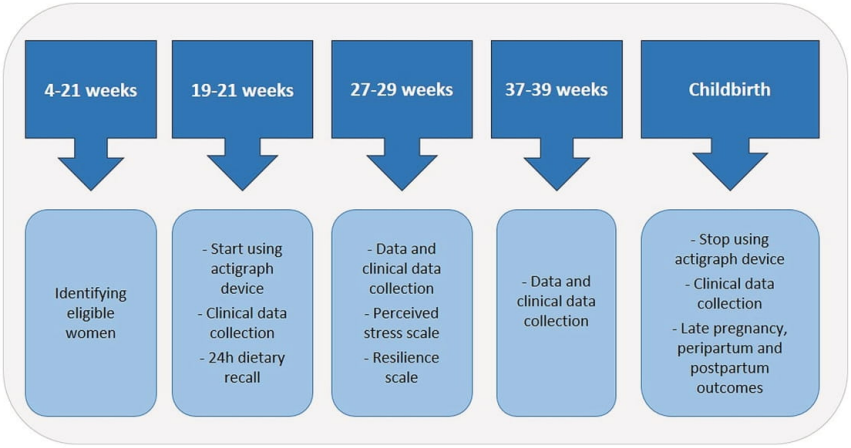

Figure 1 Set points of Maternal Actigraphy Exploratory Study I.

Table 1 Measurement frequency and maximum return periods according to gestational age—Maternal Actigraphy Exploratory Study I

Gestational age (weeks)	Measurement frequency (Hz)	Maximum return period (weeks)
19–32	20	4
33–36	30	2
37–42	50	1

doubts regarding use of the device, or if any technical or medical concern arises.

During each antenatal care visit, the wrist device will be connected to a charge base which can be connected to a computer through an Universal Series Bus (USB) connection. All actigraphy data will be extracted to the computer as raw data '.bin' file. A proper open source software (Geneactiv Software) will allow the conversion of this file into '.csv' compressed epoch files for each 30 min of registered data, which can be read in Excel program. The actigraphy data will then be uploaded to an online database platform developed by MedSciNet, where all clinical study data will also be registered.

The actigraphy software uses several algorithms to translate numerical information obtained from epoch files into PA and sleep–wake patterns, which will compose the independent variables of this study. This is a centralised, secure, internet-based database that allows several procedures for prospective and retrospective monitoring, hierarchical access (local user, general manager, etc). The database will be translated into Portuguese and English, facilitating data collection for Portuguese-speaking teams and international monitoring. A correspondent paper form will be available for data collection if necessary (eg, internet connection failure for instance).

Decision to start monitoring PA and sleep patterns between 19 and 21 weeks

There are various underlying mechanisms involved in the development of maternal and perinatal adverse outcomes that will be assessed, such as preterm birth, pre-eclampsia, gestational diabetes, fetal growth restriction and small for gestational age. Each disease may have a different preclinical phase, depending on environmental and individual aspects. In this phase, there are no clinical signs or symptoms. So far, the study of adverse maternal and perinatal predictors has been focused on early pregnancy (first trimester, <14 weeks of gestation) to maximise the window of opportunity for the performance of preventive interventions. However, we hypothesised that modifications in PA and/or sleep pattern due to underlying changes in maternal biological function might not be evident at a very early stage in pregnancy before the beginning of the preclinical phase. Our hypothesis is that changes might occur shortly before the manifestation of symptoms.

Furthermore, we took into account that major maternal complications, including pre-eclampsia, fetal growth restriction and preterm birth, occur more commonly in late pregnancy and established the period between 19 and 21 weeks as an appropriate time to start assessment of PA and sleep patterns. A recent cross-sectional study conducted in 20 referral centres in Brazil, including the five participating centres of this proposal, showed that the occurrence of preterm birth before 28 weeks comprised less than 1% of all births and less than 8% of all preterm births.[44] In addition, the early onset of pre-eclampsia (before 34 weeks of gestation) complicates less than 0.4% of all pregnancies, according to a large retrospective cohort of more than 450 000 deliveries in the USA.[45] Figure 2 outlines the predicted prevalence of preterm birth and pre-eclampsia in the second trimester. Clinical presentation, when classic symptoms and signs of a certain disease/complication occur, is highlighted by pregnancy in red. Our hypothesis is that alterations in PA and sleep patterns may occur closer to clinical presentation, still in the preclinical phase when there are no symptoms or signs.

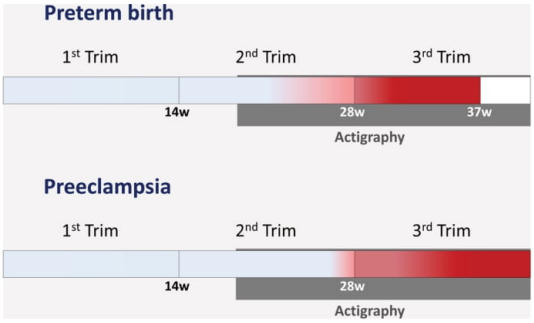

Figure 2 Estimated prevalence of preterm birth and pre-eclampsia according to gestational age (red represents the majority of cases) and evaluation period of physical activity and sleep patterns (in grey).

Briefly, an exploratory study required an arbitrary decision about the interval for monitoring PA and sleep patterns. To that end, we considered that: (1) the main maternal/perinatal complications of interest occur in the second half of pregnancy, more precisely in late pregnancy (figure 2); (2) any potential change in PA or sleep patterns occurred hypothetically days or weeks before the onset of maternal or perinatal complications. Then, we focused on monitoring women during the second half of pregnancy.

Thus, starting assessment at 19–21 weeks seems to be quite reasonable, providing a wide interval to monitor and predict major maternal and perinatal adverse outcomes.

Actigraphy device

The actigraphy device that will be used for monitoring PA and sleep–wake patterns is the GENEActiv Original (GENEActiv, Activinsights, Huntingdon, UK). The device has multiple sensors including a microelectromechanical (MEMS) accelerometer, temperature (linear active

Table 2 Performance of wrist and hip actigraphy methods according to different activities

	Hip			Wrist		
	Sens	Spec	BA	Sens	Spec	BA
Sitting	0.894	0.923	0.908	0.883	0.870	0.876
Vehicle	0.870	0.987	0.929	0.823	0.964	0.893
Walking/running	0.687	0.981	0.834	0.574	0.983	0.779
Standing	0.797	0.929	0.851	0.687	0.904	0.795
Average	0.812	0.955	0.881	0.742	0.930	0.836

Adapted from Ellis K *et al*.[34]
BA, balanced accuracy; sens, sensitivity; spec, specificity.

thermistor) and light (silicon photodiode) sensors, providing crude raw data for a variety of applications.

Wrist versus waist wear: advantages and performance

Wrist-worn actigraphy devices are more comfortable to use during wake and sleep periods and provide the highest wear time compared with waist-worn monitors.[33 46] A non-systematic review published in 2011 showed that actigraphy is a useful and reliable tool to assess sleep patterns and circadian rhythm disorders, although there are some limitations in the diagnosis of sleep disorders or measurement of sleep stages.[25] Actigraphy had a very good concordance with polysomnography for assessment of sleep parameters in healthy subjects (ie, sensitivity >90% in estimating total sleep time). A recent study evaluated the concordance of PA estimation by wrist device in free-living settings in forty overweight or obese women.[34] Those women used both wrist and hip devices, and a small camera that captured participant behaviour for 7 days, monitoring PA behaviour (gold-standard comparison). There was a difference in hip and wrist machine learning classifiers, resulting from different methods/algorithms used to measure PA.[34] The sensitivity and specificity of hip and wrist estimations according to Ellis *et al*[34] are shown in table 2.

Two years previously, the same author published a similar evaluation of 40 adult women and men, showing that hip and wrist accelerometers predicted types of PA with an average accuracy of 92.3% and 87.5% respectively.[47]

Staudenmayer *et al*[48] investigated 20 participants who also wore two devices (wrist and hip), and concluded that wrist actigraphy can estimate energy expenditure in an accurate and relatively precise manner. Another study evaluated PA patterns in women at the top 40% or bottom 40% of the distribution of daily PA who wore wrist devices in a free-living environment. There was agreement in classification between hip and wrist accelerometers in about 75% of those women.[49] Additionally, total activity (counts per day) was moderately correlated (Spearman's r=0.73) with wrist-worn and hip-worn devices.

To the best of our knowledge, there are no systematic reviews or other high-quality evidence-based recommendations that support a particular method. Although a wrist-worn actigraphy device is not the most traditional method, it might be the best choice for assessment of prolonged periods of PA or sleep patterns, considering that it performs similarly to a waist-worn device. The current proposal has no intention of diagnosing pathological behaviours or diseases, but it plans to identify different patterns throughout pregnancy and in different subgroups of women. Evidence suggests that wrist-worn actigraphy devices can accurately and more comfortably estimate PA and sleep patterns, mainly during prolonged periods and in free-living environments. Therefore, the MAES-I group adopted a wrist-worn device.

Main variables

Independent variables assessed as potential predictors of maternal complications will be related to the sleep–wake cycle and mobility as:

'Sleep' variables

SOL: time elapsed between full wakefulness and sleep.
TST: the amount of actual sleep *time* in a sleep episode (excluding time awake).
WASO: defined as total amount of time awake after sleep.
Sleep efficiency: the ratio between TST and time in bed.

The actigraphy device collects many pieces of information related to body position and body movements to estimate the described sleep variables. The actigraphy software will then be used to analyse data and generate output variables.

'Physical activity' variables

Actigraphy technology estimates PA through various parameters collected by the actigraphy device. Briefly, according to Freedson *et al*,[50] the triaxial sensors stressed by acceleration forces can estimate movement intensity. The acceleration signal is converted to a digital signal and summed over a user-specified time interval (epoch). At the end of each epoch the activity count is stored. Then, according to count per minute (CPM) cut points, PA intensity can be categorised. The software translates information into quantitative variables using appropriate algorithms as follows:

Sedentary (hours/day): the number of hours per day when the CPM ranges from 0 to 99.
Light activity (hours/day): the number of hours per day when the CPM ranges from 100 to 1951.
Moderate activity (minutes/day): the number of hours per day when the CPM ranges from 1952 to 5724.
Vigorous activity (minutes/day): the number of hours per day when the CPM ranges from 5725 to 9498.
Very vigorous activity (minutes/day): the number of hours per day when the CPM is 9499–∞.
Metabolic equivalent (MET) rates: METs are also commonly used to express the intensity of PA. One MET is the energy cost of resting quietly, often defined by oxygen uptake as 3.5 mL/kg/min. MET rate expresses the working metabolic rate of subjects in

comparison to their resting metabolic rate. Briefly, the triaxial piezoelectric sensors stressed by acceleration forces can estimate movement intensity, converted to oxygen consumption required to perform such a movement.

Step counts/day: estimated step counts per day (estimated by proper algorithms using accelerometer data.)

Outcomes

Primary outcomes are late pregnancy complications such as:

- Pre-eclampsia: hypertension after 20 weeks of gestation, systolic blood pressure (BP) ≥140 mm Hg and/or diastolic BP ≥90 mm Hg (Korotkoff V) on at least two occasions 4 hours apart with: (1) proteinuria 300 mg/24 hours or spot urine protein: creatinine ratio 30 mg/mmol creatinine or urine dipstick protein ≥ (+) OR, in the absence of proteinuria, hypertension and (2) any multisystem complication that are: haematological abnormalities; thrombocytopenia (platelets $<100\times10^9$/L); disseminated intravascular coagulation and haemolysis; liver disease: increased aspartate transaminase and/or alanine transaminase >45 IU/L and/or severe right upper quadrant or epigastric pain, liver rupture; neurological problems: eclampsia, imminent eclampsia (severe headache with hyper-reflexia and persistent visual disturbance), cerebral haemorrhage; acute renal insufficiency: new increase in serum creatinine to >100 mmol/L antepartum or >130 mmol/L postpartum; pulmonary oedema confirmed by chest X-ray.[51]
- Gestational diabetes: new diabetes developing in pregnancy according to the WHO recommendation[52] that defines gestational diabetes as:
  - Fasting plasma glucose ≥92 mg/dL or
  - One-hour plasma glucose tolerance test (75 g load) ≥180 mg/dL or
  - Two-hour plasma glucose tolerance test (75 g load) ≥153 mg/dL.
- Spontaneous preterm birth: spontaneous onset of preterm labour or premature rupture of membranes leading to preterm birth, childbirth before 37 weeks of gestation.
- Provider-initiated preterm birth: defined as childbirth occurring at less than 37 weeks, medically indicated due to maternal/fetal compromise or both.
- Maternal haemorrhage: classified as (1) antepartum haemorrhage defined as bleeding from the genital tract after 24 weeks of gestation; (2) primary postpartum haemorrhage defined as the loss of at least 500 mL blood from the genital tract within 24 hours of childbirth.

Secondary outcomes include childbirth variables and neonatal adverse outcomes such as fetal death, caesarean section, small for gestational age (defined as birth weight below percentile 10 for gestational age), Apgar score <7 at 5 min, neonatal severe morbidity (table 3) and neonatal mortality before discharge.

Plans for analyses

Sample size estimation

This is an exploratory and innovative study focused on a specific population (pregnant women) and therefore there are no previously published parameters available for sample size estimation. Considering that the rate of pregnancy-related complications is 3%–20% (including pre-eclampsia, fetal growth restriction, gestational diabetes, haemorrhage, preterm birth, etc), assuming a large population (above one million pregnant women), an acceptable margin of error of 4%, involvement of five clusters (participating centres) and a 95% level of confidence, the study would require 384 women. Therefore, we rounded up this estimation to 400 initially low-risk pregnant women for enrolment in the study. We estimated the incidence of some main maternal complications considering the following studies:

Pre-eclampsia: an international prospective cohort study with nulliparous women termed Screening Of Pregnancy Outcomes (SCOPE) used similar criteria for low-risk profile, with a 5% of incidence of pre-eclampsia.[53]

Preterm birth: a recent cross-sectional study conducted in 20 referral obstetric centres in Brazil, including the five participating centres, showed that preterm birth was prevalent in 12.3% of all births.[44]

Gestational diabetes: in the previously mentioned SCOPE international cohort, the prevalence of gesta-

Table 3 Severe neonatal morbidity definition according to term/preterm status

Preterm	Term
Grade III and IV intraventricular haemorrhage.	Grade II or III hypoxic ischaemic encephalopathy.
Chronic lung disease (home O_2 therapy or O_2 therapy at 36 weeks' gestation.	Ventilation >24 hours.
Necrotising enterocolitis.	Neonatal intensive care admission >4 days.
Retinopathy of prematurity, stage 3 or 4.	Apgar score <4 at 5 min.
Sepsis (blood or Cerebral Spinal Fluid (CSF) culture proven).	Cord arterial PH <7.0 and/or base excess >−15.
Cystic periventricular leukomalacia.	Neonatal seizures.

tional diabetes was 8.9% in screened low-risk nulliparous women, according to the National Institute for Health and Care Excellence guidelines.[54]

Fetal growth restriction/small for gestational age: the previously mentioned SCOPE international cohort had a prevalence of 10.7% of small for gestational age newborns, according to customised centiles of birth weight (<10%).[55]

Details of statistical analysis

According to the studies above, the predicted incidence of complications seems reasonable and reproducible in our cohort. Therefore, sample size estimation may ensure a sufficient number of cases of maternal and perinatal complications for the current proposal.

The epoch files obtained from Geneactv Software by reading data on sleep variables and PA parameters will be translated into numerical results and then averaged in 7 day periods. Therefore, only one value will be employed in statistical analysis for each variable per week of use of the wrist-worn device.

First, we will identify PA and sleep–wake patterns of women who did not develop adverse maternal or perinatal outcomes. This will permit the recognition of normal PA and sleep–wake patterns in a low-risk population without complications during pregnancy. We will use the same population to analyse changes in PA and sleep–wake patterns throughout pregnancy, allowing for gestational age periods.

Subsequently, we will compare PA and sleep–wake patterns of women who developed specific adverse maternal or perinatal outcomes with those who did not have any complications. Differences between groups may be identified and used as potential markers for specific pregnancy complications.

Afterwards, we will analyse changes in PA and sleep–wake patterns of women who developed adverse maternal or perinatal outcomes throughout pregnancy, comparing patterns in an attempt to discover which changes occurred before the onset of symptoms that could be related to pregnancy complications. If possible, we will conduct a subgroup analysis including a subpopulation with a potentially higher risk for maternal complications (confounder variables), including obesity, smoking and so on.

Finally, we will develop a predictive model for screening pregnant women at risk of specific adverse maternal and perinatal outcomes using PA and sleep–wake data estimated by actigraphy technology.

Analysis will be performed using the actigraphy software that translates collected information into PA and sleep–wake parameters. In addition, SOL, WASO and TST as well as sleep efficiency will be compared between participants throughout pregnancy using the Friedman and Wilcoxon tests for paired samples. The analysis of variance and t-test will be used to compare sleep parameters between participants per week of gestational age for repeated measures. The same tests will be applied to analyse quantitative data on the median number of hours per day that different types of PA (sedentary, light, moderate, vigorous and very vigorous) are performed, MET rates and estimate of steps/day through the entire gestational period examined, and the comparison between participants per week of gestational age. Also, we will address the sensitivity, specificity and likelihood ratio for altered PA and sleep patterns or for their changes throughout pregnancy.

Discontinuation of participants

Criteria for discontinuation include:

Withdrawal of consent.

Irregular use of the actigraphy device for prolonged periods, less than 50% of the whole planned time. Information of improper use of the device will be recorded if women notify the MAES-I team. Otherwise, the low level of use of the device will be observed after data discharge during antenatal care visits.

Loss to follow-up, preventing us from downloading actigraphy data.

Women who decide to withdraw from follow-up care will be called by telephone and asked to return the wrist device. The last visit will be scheduled to regain the wrist monitor and direct the woman to a proper antenatal care service to continue medical consultations.

Data and sample quality

All entered data will be prospectively and retrospectively monitored by local research assistants and a global monitor. Internal consistency of variables will be constantly performed by database and error messages are automatically flagged. A local research assistant will be responsible for checking all forms and actigraphy data before locking forms, assuring the good quality of data (ie, double-checking entered data and checking for inconsistencies between variables). The local principal investigator (PI) will be in charge of signing the case which will then be incorporated into the final database. The University of Campinas will coordinate, implement and monitor the study in the five participating centres. A general manager and a global monitor are also part of the coordinating team. The local team of each participating centre is composed of a local PI and research assistants.

ETHICS AND DISSEMINATION

MAES-I focuses on low-risk nulliparous Brazilian pregnant women. Although classified as low risk for maternal and perinatal complications, these women are not free from suffering complications. Furthermore, first and second delays, defined as a delay in deciding to seek care and delay in reaching a healthcare facility,[56] are not uncommon. A barrier is created between earlier recognition of symptoms and timely intervention for the successful treatment of potentially life-threatening conditions. We believe that women will feel encouraged, empowered and willing to participate in a study aimed at developing a potentially useful prenatal care tool to identify the risk for maternal

and perinatal morbidity and mortality. Following national ethical regulations, the participants will not receive any financial compensation.

Women who agree to participate in the study will not have any disadvantage or difficulties in prenatal care. On the contrary, they will receive a contact number to find clinical researchers at any time (24/7 service), maintaining a closer contact with researchers and care providers. The MAES-I team is committed to contact healthcare providers if any potential complication arises.

Participating women will not be held accountable for any loss, theft or damage to the wrist device. These women will only be required to wear the device as a regular wristwatch and no self-damage is expected.

Participating women will not be able to identify any PA or sleep parameters at any stage of the study. Data can only be downloaded through proper licensed software of the device. The actigraphy devices provided to participating women have a unique code which will be recorded in the database along with the interval of use per woman. Actigraphy data will be labelled using participant ID, device number, gestational age when the device was initially used and the return date of each device. Codes, ID number and numbers will ensure confidentiality of all participating women. The identity of all women will be kept confidential.

All women enrolled in the MAES-I cohort will sign an informed consent form.

Ethical principles of the Brazilian National Heath Council (Resolution CNS 466/12) will be upheld at every stage of this study. Anonymity of the source of information will be guaranteed and the woman will receive care irrespective of her agreement to participate in the study. The study also complies with the Declaration of Helsinki amended in Hong Kong in 1989. Methodological and ethical aspects of MAES-I protocol were developed following the Strengthening the Reporting of Observational Studies in Epidemiology guidelines.[57]

Patient and public involvement

Patients and the public were not involved in this study for the development of the research question and outcome measures. However, the choice of a wrist device was based on user preference as reported. Participants of the study will have access to information available at the open-access website.

Detailed information about the study is provided in the Brazilian Cohort website (www.medscinet.com/samba). Publications of the results of the study can be found in the scientific literature and Institutional webpages. We intend to disseminate our findings to a scientific peer-reviewed journal, general free access website, specialist conferences and our funding agencies.

DISCUSSION

Actigraphy is an innovative, non-invasive, non-operator dependent, wearable technology, that is capable of measuring diverse variables related to mobility, PA, sleep–wake and circadian cycle patterns under real-life conditions. Actigraphy devices have a high sensitivity in detecting sleep–wake parameters and are currently highly recommended by the American Sleep Disorder Association for diagnosis and therapy response of circadian rhythm disorders.[27 28 58] Although some studies show that using the actigraphy device for 7–14 days provides reliable estimates of PA behaviour in older adults, it is not absolutely clear how many days are needed to estimate habitual PA by using the wrist/waist device during pregnancy. In general, it seems to depend mainly on the type of actigraphy device, wear location and target population.[30 33] Nevertheless, MAES-I will provide sufficient data to assess different patterns throughout pregnancy.

The use of wearable PA monitors has increased considerably, owing to interest in the relationship between the pathophysiology of diseases and patterns of PA and sleep. A recent study on the use of PA monitors in human physiology research unravels current and potential use of the actigraphy device. The device can be applied in strategies that promote a healthier behaviour or predict outcomes.[59] The authors conclude that PA monitors, as well as other new 21st century technologies, have already transformed physiology research, revolutionising how we assess patients and opening new areas of interest. In addition, the use of objective measures to evaluate habitual sleep duration and outcomes in pregnancy is critical, considering recent reports of little agreement between objective and subjective assessments of sleep time.[60]

Alterations in sleep patterns, including less deep sleep and more nocturnal awakenings can be observed in pregnancy as early as in 10–12 weeks' gestation.[61] Sleep disturbances during pregnancy have been associated with preterm delivery, gestational hypertensive disorders, glucose intolerance and increased risk of caesarean delivery.[19] Shortened nocturnal sleep time was also associated with hyperglycaemia.[62] Persistent sleep deprivation has been correlated with depressive symptoms and stress perception by pregnant women.[61] These studies explored a correlation between PA patterns and sleep disturbances that determine complications through a well-established relationship between cause and effect. However, this correlation could not always be adequately determined due to study design.[17]

In a distinct manner, the intent of our analysis is to discover whether a maternal complication can be identified before the manifestation of its clinical signs, by evaluating PA and/or sleep patterns modifications of pregnant women. Considering existing evidence, we speculate that patterns of PA and/or sleep change days or weeks before clinical presentation of the complication. In general, the signs and symptoms of some maternal outcomes are part of the gold-standard criteria for diagnosis (high blood pressure, proteinuria and/or oedema in pre-eclampsia; premature contractions and cervical ripening/dilation in preterm birth; abnormal placental blood flow and insufficient fetal growth in intrauterine growth restriction). We

acknowledge that there are potential confounders and limitations in predicting maternal and perinatal complications using PA and sleep patterns estimated by actigraphy devices. The population in our research is expected to have different subgroups of women with different risks and associated factors contributing to maternal complications, such as obesity, smoking habit and with age under 20 or over 40 years old, for instance. None of those factors was considered an exclusion criterion. If possible, we intend to conduct a subgroup analysis of the maternal subgroups, since they may have different PA and sleep patterns. Nonetheless, we decided to adopt a pragmatic approach and not exclude such a common factor from our sample.

The use of actigraphy device during prenatal visits has the potential to become a new tool for monitoring pregnant women. It may improve maternal healthcare and identify altered PA and/or sleep patterns. Changes can be objectively measured by actigraphy before the occurrence of signs and symptoms. The focus is on providing new technology to monitor the development of potential maternal complications. Other positive points in our study are the data collection period (from 19 weeks until delivery) and the low-risk profile of the cohort, enabling us to describe PA and sleep patterns in a low-risk pregnant population and make a better interpretation of actigraphy data among pregnant women. Current clinical and biological predictors of major maternal complications such as pre-eclampsia, preterm birth, maternal haemorrhage and gestational diabetes still lack effective sensitivity and specificity.

If our hypothesis is confirmed, this will be an important step for introducing non-invasive screening procedures into prenatal care to identify women at higher risk for those conditions. Women could receive specific advice on the prevention and earlier detection of the condition, take immediate action and seek professional healthcare to receive appropriate treatment. This would avoid delays, the most significant factors contributing to low-quality healthcare in underprivileged women, which increase the still substantial burden of maternal morbidity and mortality. If we succeed in identifying 'specific patterns of physical activity and sleep' that are predictors of pregnancy complications, further validation studies are recommended to assess the effectiveness of screening procedures in management of these conditions. In addition, MAES-I will permit further specific studies among a high-risk population and also help to identify the best gestational age for monitoring, targeting a specific gestational age interval.

Author affiliations
[1]Obstetrics and Gynecology, Universidade Estadual de Campinas, Campinas, Brazil
[2]Faculdade de Ciencias Medicas, Universidade Estadual de Campinas, Campinas, Brazil
[3]Maternidade Escola, Universidade Federal do Ceara, Fortaleza, Brazil
[4]Obstetrics and Gynecology, Universidade Federal de Pernambuco, Recife, Brazil
[5]Obstetrics and Gynecology, Universidade Federal do Rio Grande do Sul, Porto Alegre, Brazil
[6]Obstetrics and Gynecology, School of Medicine of Jundiai, Campinas, Brazil
[7]Social Medicine, Faculdade de Medicina de Ribeirao Preto, Universidade de Sao Paulo, Ribeirao Preto, Brazil

Acknowledgements The MAES - I study group also included: Carina B Luiz and Luiza C Brust, School of Medicine, Federal University of Rio Grande do Sul, Porto Alegre, Brazil; Danilo Anacleto and Lívia C Nascimento, School of Medicine, Federal University of Pernambuco, Recife, Brazil; Daisy Lucena and Denise Ellen F Cordeiro, School of Medicine, Federal University of Ceará, Fortaleza, Brazil; Mariana B Rogerio, Departament of Obstetrics and Gynecology, Jundiaí Medical School, Jundiaí, Brazil.

Collaborators The MAES-I Study Group also includes: Carina B Luiz; Luiza C Brust; Danilo Anacleto; Lívia C Nascimento; Daisy Lucena; Denise E F Cordeiro; Mariana B Rogerio.

Contributors All authors contributed to the overall study design and specific methodologies. RTS, JGC, JM, MLC and JPS conceived the study design and wrote the first version of the study protocol. In a first meeting, the protocol was discussed and incorporated suggestions from RBG, FF, ERF, DFL, JV, RPT and DSS. RTS, JGC, JM and RBG planned the implementation of the study and developed the necessary material. RTS, JM, MLC and JGC drafted the manuscript that was afterwards revised by all other authors who gave suggestions. All authors discussed and made important contributions to the manuscript, read and approved the final version for submission.

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ANEXO 2 **–** Aprovação ética no CEP

COMITÊ DE ÉTICA EM PESQUISA DA UNICAMP - CAMPUS CAMPINAS

PARECER CONSUBSTANCIADO DO CEP

DADOS DO PROJETO DE PESQUISA

Título da Pesquisa: Desenvolvimento de um modelo preditor de complicações gestacionais por meio de ¿tecnologias móveis¿: estudo de coorte

Pesquisador: Jose Guilherme Cecatti

Área Temática:

Versão: 2

CAAE: 60820016.9.1001.5404

Instituição Proponente: Hospital da Mulher Prof. Dr. José Aristodemo Pinotti - CAISM

Patrocinador Principal: Financiamento Próprio

DADOS DO PARECER

Número do Parecer: 1.834.116

Apresentação do Projeto:

A redução da mortalidade materna mundial para níveis abaixo de 70 por 100.000 nascidos vivos é um dos 17 Objetivos de Desenvolvimento Sustentável (ODS – PNUD) propostos pelas Nações Unidas (1). Sabidamente, desde a década de 90 houve melhora significativa das condições de saúde materno-fetal, com queda da taxa de mortalidade materna em cerca de 50%, bem como ampliação do acesso aos cuidados de pré-natal (2). Entretanto, ainda há desafios a serem vencidos. Dentre esses desafios, está a viabilização do reconhecimento precoce de possíveis identificadores de complicações maternas e perinatais. Sabidamente, o atraso no diagnóstico da complicação, associado à dificuldade de acesso ao sistema de saúde e à assistência médica questionável compõem um cenário desfavorável de condições que culminarão, via de regra, com sérios agravos à saúde materna, fetal e neonatal (3). Hipótese: Exista uma lacuna na literatura científica sobre o uso de actimetria em gestantes para identificar marcadores que permitam prevenção ou intervenção sobre agravos materno-fetais. O desenvolvimento de um modelo preditor de complicações gestacionais, que se utilize desse método não invasivo, baseado em funções de sono-vigília e atividade física de sua usuária, traria inúmeros benefícios na prevenção e pronta intervenção sobre agravos maternos e fetais. A identificação precoce de complicações prevalentes e de alta morbimortalidade materna e perinatal como préeclâmpsia e parto prematuro,

Endereço: Rua Tessália Vieira de Camargo, 126
Bairro: Barão Geraldo **CEP:** 13.083-887
UF: SP **Município:** CAMPINAS
Telefone: (19)3521-8936 **Fax:** (19)3521-7187 **E-mail:** cep@fcm.unicamp.br

por exemplo, poderia ampliar a janela de oportunidade para intervenções clínicas oportunas. Caso se confirme a hipótese de que alguns desfechos gestacionais estão relacionados com mudanças no padrão de sono-vigília e atividade física habitual, teremos um potencial modelo preditor não invasivo, de baixo custo, capaz de identificar gestantes de alto risco. A identificação mais precoce, com melhor o tempo de ação para medidas preventivas e, em última análise, a aplicação e estudos de novas intervenções, reduzindo assim a morbidade materno-fetal. Ademais, esse é um estudo exploratório que deverá ser futuramente validado através de estudos complementares, caso seja possível desenvolver o modelo preditor • uma população de gestantes de baixo risco, sem complicações durante a gestação, o padrão de atividade física mais prevalente será de intensidade considerada sedentária ou leve, com baixa prevalência de atividade moderada e vigorosa. O padrão de sono-vigília mais prevalente será o de mulheres com baixa eficiência de sono (abaixo de 75% de sono eficiente).• A prevalência de atividade leve ou sedentária aumentará com a evolução da gestação, chegando ao seu máximo após as 36 semanas de gestação numa população de gestantes de baixo risco e sem complicações durante a gestação. A eficiência do sono diminuirá ao longo das semanas, atingindo seu mínimo após as 36 semanas de gestação.•Numa população de gestantes de baixo risco, as mulheres que tiveram complicações durante a gestação apresentarão uma mudança significativa do padrão de atividade física e do ciclo sono-vigília, além do esperado para a evolução da gestação. A proporção de atividade sedentária dobrará de valor e a eficiência do sono diminuirá pela metade. • Numa população de mulheres gestantes com desfechos desfavoráveis haverá mudança do padrão habitual de atividade física, sono e vigília ao longo da gravidez, com mais de uma semana de antecedência da manifestação clínica do agravo gestacional. • Será possível desenvolver um modelo preditor contendo as variáveis extraídas do actígrafo e que seja promissor em predizer quais as mulheres com maior risco de desenvolver complicações na gestação.

Metodologia Proposta: Desenho do estudo:Estudo de coorte com gestantes nulíparas de baixo risco, que usarão um sensor de punho (actígrafo) capaz de captar informações diárias sobre atividade física, sono e vigília (exposição) e sua associação com complicações maternas e perinatais (efeitos). Tamanho da amostra:O estudo de coorte aqui proposto é exploratório e inovador. Por esse motivo, não há dados publicados disponíveis que permitam a realização de um cálculo amostral, como seria possível na maioria das vezes. Entretanto, para alcançarmos os principais objetivos acima apresentados, será necessário um número suficiente de gestantes de baixo risco que não apresentem complicações durante a gestação, da mesma forma que

precisaremos de um número suficiente de gestantes com os desfechos gestacionais a serem avaliados. Portanto, considerando que a prevalência das principais complicações obstétricas varia entre 3 e 20% (incluindo pré-eclâmpsia, restrição de crescimento fetal, diabetes gestacional, complicações hemorrágicas, etc.), considerando uma população teórica de referência acima de 1 milhão de gestantes, com uma margem de erro aceitável de 4%, com envolvimento de cinco centros participantes e intervalo de confiança de 95%, serão necessárias 384 mulheres. Consideraremos como cálculo amostral final o número de 400 gestantes inicialmente de baixo risco. O assistente de pesquisa de cada centro participante preencherá uma ficha de pré-seleção (anexo 1) após identificar alguma gestante elegível. Ao concordarem em participar do estudo, após assinatura do termo de consentimento livre e esclarecido (anexo 2), essas gestantes usarão um dispositivo semelhante a um relógio (actígrafo) que contém um sensor capaz de estimar atividade física e padrões de sono e vigília, pela aplicação de algoritmos. A participante usará o dispositivo em seu punho, por cerca de 10-12 semanas, durante o dia e durante a noite, podendo retirá-lo para banho e atividades aquáticas. A gestante receberá todas as orientações sobre seu uso e será orientada que um membro da equipe de pesquisadores irá abordá-la após consulta de pré-natal entre 37 e 39 semanas de gestação, para que as informações armazenadas sejam descarregadas no computador designado para essa função, em cada centro participante. No intuito de estreitar ainda mais o contato com a participante, lhe será fornecido um número de celular, para que a mesma possa entrar em contato no caso de alguma dúvida em relação ao actígrafo ou ao seu uso. As gestantes de cada centro serão estimuladas a fazerem o acompanhamento prénatal no centro de pesquisa participante, não sendo esse um critério de exclusão caso esse seguimento seja inviável. Também no primeiro contato, as participantes responderão um questionário aplicado pelo assistente de pesquisa local com diversas informações sobre a gestação atual, antecedentes pessoais e familiares (anexo 3). Essas informações serão oportunamente armazenadas numa base de dados eletrônica. Instrumento para coleta de dadosSerão uma ficha de pré-seleção (anexo 1) e um formulário de coleta de dados (anexo 3) a serem preenchidas pelo assistente de pesquisa de cada centro, seguindo as instruções de treinamento. Elas serão arquivadas após serem incluídas num sistema online informatizado, o MedSciNet. Será desenvolvido um manual de operações com a clara definição das variáveis utilizadas e orientações para coleta de dados. Na primeira abordagem da participante, se essa concordar em participar da pesquisa, lhe será entregue o actígrafo e serão feitas as orientações cabíveis sobre seu uso. Em cada centro participante, o software que lê o arquivo com as informações acumuladas pelo actígrafo será instalado num computador do pesquisador do centro participante, designado para isso. O actígrafo, da marca

ActiGraph - modelo ActiGraph Link, é um aparelho que pesa 14 gramas que será acompanhado de uma pulseira de silicone. O aparelho é resistente à água, mas deve ser evitada a imersão.

Critério de Inclusão: Esse estudo será implementado em 5 locais de assistência pré-natal, localizados em três diferentes regiões do Brasil, que integram a Rede Brasileira de Estudos em Saúde Reprodutiva e Perinatal. Durante seis meses, os centros participantes identificarão mulheres elegíveis para o uso dos sensores (actígrafos). Os dados coletados pelos sensores (actimetria) serão correlacionados à ocorrência de agravos maternos e perinatais. As mulheres que desejarem participar do estudo deverão assinar um termo de consentimento livre esclarecido.Os cinco centros brasileiros selecionados são: • Maternidade do CAISM da Universidade de Campinas, Unicamp, em Campinas, SP, Brasil; Investigador Principal Local: Maria Laura Costa.• Maternidade da Faculdade de Medicina de Botucatu, UNESP, SP, Brasil; Investigador Principal Local: Iracema de Matos Paranhos Calderon.• Maternidade do Hospital de Clínicas, Universidade Federal do Rio Grande do Sul, em Porto Alegre, RS, Brasil; Investigador Principal Local: Janete Vettorazzi.• Maternidade do Hospital de Clínicas, Universidade Federal de Pernambuco, em Recife, PE, Brasil; Investigador Principal Local: Edilberto A. Rocha Filho.• MEAC – Maternidade Escola da Universidade Federal do Ceará, em Fortaleza, CE, Brasil. Investigador Principal Local: Francisco Edson L. Feitosa. Muito embora sejam serviços de referência para obstetrícia de alto risco, esses centros estão interligados a unidades de atendimento primário, de onde as mulheres participantes do estudo serão em sua maioria selecionadas. Na dependência das características das atividades de cada centro participante, a continuidade do cuidado pré-natal poderá ser feito tanto na Unidade Básica de Saúde como no centro participante, mas as visitas para a entrega do aparelho e para a coleta das informações deverão ocorrer no centro participante.Critérios de inclusão:• Mulheres grávidas nulíparas, ou seja, nunca tiveram parto de feto vivo ou com mais de 22 semanas de gravidez;• Gestação atual com feto único;• Idade gestacional de 27sem +0d até 29sem +0d;• Consentimento informado para participar do projeto de pesquisa.

Critério de Exclusão: Critérios de exclusão:• Idade gestacional igual ou superior 30 sem incompletas de gestação na avaliação inicial (30sem +0d);• Antecedente de abortos de repetição: 3 abortos prévios (<20semanas);• Malformação fetal comprovada; • Hipertensão Arterial Crônica com uso de anti-hipertensivo prévio à gestação;• Hipertensão moderada/grave (>160/100) na admissão ao estudo; (obs: hipertensão leve e antecedentes de hipertensão, sem uso de medicação são aceitáveis);• Diagnóstico de Diabetes prévio à gestação;• Nefropatia: patologia renal, como

glomerulonefrite, insuficiência renal ou transplante renal;• Lúpus Eritematoso Sistêmico (LES) - diagnóstico firmado- sem incluir mulheres que tenham resultado anticoagulante lúpico e/ou anticardiolipina associado a um ou mais dos antecedentes clínicos: 3 abortos de primeiro trimestre, óbito fetal ou trombose arterial ou venosa;• Doença falciforme;• Retrovirose – positividade para o teste do HIV;• Malformação Uterina: como útero bicorno ou septo uterino;• Antecedente de cerclagem uterina;• Cone a frio;• Diagnóstico de rotura prematura de membrana na admissão ao estudo;• Uso crônico de corticosteroides (uso por mais de três meses). Obs.: não excluir mulheres em uso de corticoide inalatório para tratamento de Asma;• Uso de aspirina (mulheres em uso de 60-150mg/dia de aspirina);• Cálcio (mulheres em uso de >1g/dia); (obs: não excluir mulheres em uso de dosagens menores- como parte de suplementação- polivitamínicos);• Óleo de peixe (mulheres em uso de 2,7g ou mais por dia); (obs: não excluir mulheres em uso de dosagens menores- como parte de suplementação- polivitamínicos);• Vitamina C >1000mg ou Vitamina E>400UI por dia; (obs: não excluir mulheres em uso de dosagens menores- como parte de suplementação- polivitamínicos);• Uso atual de Heparina sódica ou heparina de baixo peso molecular;• Doenças da tireoide, em uso ou não de medicação atualmente;• Uso de agentes antidepressivos e/ou ansiolíticos; • Ter alguma condição que limite ou inviabilize a prática de exercícios físicos.• Condições acompanhadas de alterações cognitivas que dificultem a compreensão e seguimento das orientações quanto ao uso do actígrafo.Critérios para descontinuação• Retirada do consentimento informado pela mulher participante;• Caso a participante informe perda ou roubo do aparelho e não seja possível sua reposição;• Tempo de uso do actígrafo inferior a 50% do tempo esperado; • Perda de follow-up: não participação na segunda visita do estudo e impossibilidade de recuperar dados do actígrafo e/ou do parto e pós-parto.

Objetivo da Pesquisa:

Objetivo Primário: O objetivo desse estudo é identificar preditores precoces de complicações gestacionais, por meio de dados gerados por tecnologias vestíveis ou móveis (sensores de punho) relativos ao sonovigília e atividade física.

Objetivo Secundário: • Identificar padrões de atividade física, sono e vigília numa população de gestantes de baixo risco e sem complicações durante a gestação, a partir do terceiro trimestre da gestação (em torno de 27-29 semanas).• Identificar nessa população mudanças no padrão de atividade física, sono e vigília ao longo das semanas de gestação até o parto.• Comparar os padrões de atividade física, sono e vigília de gestantes que tenham apresentado complicações na

gestação (condições específicas de agravo) e gestantes de baixo risco sem intercorrências ao longo da gestação.• Comparar os padrões de atividade física, sono e vigília em diferentes semanas da gestação de mulheres que tenham apresentado complicações na gestação.• Desenvolver modelos preditores de risco que incluam padrões de atividade física, sono e vigília como marcadores de identificação de agravos, que deverão ser validados posteriormente.

Avaliação dos Riscos e Benefícios:

Riscos (segundo o pesquisador): Este projeto seguirá as diretrizes e normas regulamentadoras de pesquisa envolvendo seres humanos contidas na resolução 466/12, estando em plena conformidade com os princípios enunciados na Declaração de Helsinque e emendada em Hong-Kong em 1989. Os dados obtidos dos sujeitos se destinam exclusivamente aos propósitos da pesquisa acima expostos. Cada participante será adequadamente esclarecida sobre os objetivos e metodologia do estudo. Apenas participarão da pesquisa os sujeitos que concordarem em fazê-lo, após ler, tirar dúvidas e assinar o termo de consentimento livre e esclarecido TCLE (Anexo 2). O sujeito ou seu responsável legal, no caso dos participantes menores de 18 anos, assinarão o termo e ficarão com uma cópia idêntica do mesmo. O indivíduo será informado de que é livre para retirar seu consentimento em participar do estudo a qualquer momento. As mulheres que desejarem interromper sua participação não perderão seu direito ao tratamento e assistência na instituição onde estará sendo realizada a pesquisa. A identidade desses sujeitos será mantida em sigilo, mesmo que os dados da pesquisa sejam publicados em revistas ou apresentados em congresso. Toda documentação da pesquisa será preservada por cinco anos após seu término.Todas participantes receberão uma cópia do manual de instruções do actígrafo, além de receber o devido suporte técnico ou de dúvidas diretamente dos pesquisadores. Ao final do estudo (após o parto), a devolução do aparelho será requerida pelos pesquisadores, porém a sua não entrega não acarretará implicações éticas, legais ou financeiras à participante ou ao seu responsável legal. O mesmo valerá para panes ou acidentes que danifiquem o aparelho. Não são previstos nem descritos acidentes como choque elétrico alergias ou outros agravos relacionados ao uso do actígrafo. Entretanto, a paciente receberá todo suporte necessário referente a qualquer dano proveniente do uso do aparelho. No nono mês, durante a consulta de pré-natal de rotina, e após o nascimento, a equipe de pesquisa entrará em contato com a participantes para que as informações armazenadas em seu actígrafo sejam transferidas para um computador. Esse procedimento de transferência de dados deve durar em torno de 10 minutos.

Benefícios (segundo o pesquisador): Não são previstos benefícios diretos para a atual gestação da participante. Entretanto, futuramente poderemos utilizar os resultados desse estudo para identificar gestantes que estejam em risco de desenvolver alguma complicação e assim agirmos a tempo de evitarmos um mal maior para a gestante e para o seu bebê. Essas informações sobre riscos e benefícios estão esclarecidas no TCLE e no TALE (Anexos 2 e 3). O estudo dos padrões de atividade física e de sono usando a actigrafia podem ser ferramentas úteis na detecção de agravos relacionados com o sono ou de hábitos não saudáveis de atividade física. Entretanto, a proposta do estudo MAES I é de utilizar os algoritmos contidos no software compatível com o actígrafo para estimar atividade física ou períodos de sono-vigília, além ter algumas variáveis do sono. Não serão gerados dados passíveis de serem traduzidos clinicamente em diagnóstico de normalidade ou patologia. Dessa forma, não será possível, e não é objetivo do estudo, a realização de rastreio ou diagnóstico de patologias da mobilidade ou do ciclo vigília-sono. As participantes saberão dessa informação através do TCLE. Em caso de participantes menores de 18 anos, será solicitado, além do consentimento da participantes, o consentimento de um responsável legal conforme TCLE.Controle de Qualidade Os pesquisadores da Disciplina de Obstetrícia da Unicamp têm uma vasta experiência em estudos multicêntricos tanto internacionais como nacionais. O estudo será conduzido pela Rede Brasileira de Estudos em Saúde Reprodutiva e Perinatal e contará também com o Centro de Estudos em Saúde Reprodutiva de Campinas (Cemicamp), uma organização privada sem fins lucrativos que é o braço de pesquisa do Departamento de Obstetrícia e Ginecologia da Universidade de Campinas, com experiência no planejamento, execução e administração de estudos clínicos e epidemiológicos.Os cinco centros envolvidos apresentam condições adequadas para conduzirem o estudo. Em cada um dos centros participantes haverá um pesquisador responsável pela coordenação do estudo e que receberá treinamento sobre o actígrafo e o software ActiLIFE 6 antes do início da coleta de dados. O sistema eletrônico para armazenamento de dados (MedSciNet) é a plataforma de escolha para o estudo e permite confidencialidade e segurança no armazenamento dos dados. O estudo contará com um monitor geral, designado para realizar a checagem em tempo real dos dados armazenados no banco de dados, verificando possíveis consistências internas e/ou erros de preenchimento.

Comentários e Considerações sobre a Pesquisa:

Ver item "Conclusões ou Pendências e Lista de Inadequações".

Considerações sobre os Termos de apresentação obrigatória:

Foram apresentados:

1.Folha de rosto devidamente assinada e datada.

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Bairro: Barão Geraldo **CEP:** 13.083-887
UF: SP **Município:** CAMPINAS
Telefone: (19)3521-8936 **Fax:** (19)3521-7187 **E-mail:** cep@fcm.unicamp.br

2.Projeto de pesquisa: detalhado, com embasamento da literatura. Estudo multicêntrico.
3. Formulário de informações básicas do projeto na Plataforma Brasil: preenchimento adequado.
4. Parecer consubstanciado de Projeto de Pesquisa analisado pelo CAISM: devidamente assinado e datado.
5.TCLE: Ver item "Conclusões ou Pendências e Lista de Inadequações".
6. Termo de Assentimento: Ver item "Conclusões ou Pendências e Lista de Inadequações".

Recomendações:

No TALE, substituir "Termo de Consentimento Livre e Esclarecido" no último parágrafo, item "Responsabilidades do Pesquisador", por "Termo de Assentimento Livre e Esclarecido".

Conclusões ou Pendências e Lista de Inadequações:

1. Formulário de informações básicas do projeto na Plataforma Brasil: a) No item "Riscos" descrever todos os possíveis riscos e incômodos que a participante pode ter no decorrer do estudo. Caso a participante da pesquisa tenha que responder questionários, descrever o tempo que será despendido para o mesmo e o possível incômodo. b) No item "Benefícios" descrever se a participante da pesquisa terá um benefício direto.
ANÁLISE: Pendências atendidas.

2. TCLE: a)Incluir um item separado para os "Riscos", descrever todos os possíveis riscos e incômodos que o participante pode ter no decorrer do estudo. Caso a participante da pesquisa tenha que responder questionários, descrever o tempo que será despendido para o mesmo e o possível incômodo. Quantas vezes terá que retornar aos pesquisadores para acompanhamento, etc. b)Conforme Resolução CNS nº 466 de 2012, itens IV.3.g e h, devem esta explícitos no TCLE os direitos a indenização e assistência integral frente a dano decorrente da pesquisa, mesmo que estes sejam eventuais e não possam ser previstos. Dessa forma, solicita-se que tal informação seja incluída no TCLE, no item "Ressarcimento". c) Incluir no TCLE a garantia às participantes da pesquisa o acesso as suas informações médicas e da pesquisa, sempre quando solicitado. d)Além do endereço e telefone de contato do CEP, incluir uma breve descrição do mesmo: "O CEP é responsável pela avaliação e acompanhamento dos aspectos éticos de todas as pesquisas envolvendo seres humanos, visando a salvaguardar a dignidade, os direitos, a segurança e o bem-estar dos participantes da pesquisa." e)Incluir no rodapé de todas as páginas do TCLE, um campo para rubrica do pesquisador responsável e para a participante da pesquisa ou seu responsável legal.
ANÁLISE: Pendências atendidas.

3. Termo de Assentimento: a) Esclarecer se menores de idade irão participar do estudo. Caso haja previsão da participação de menores de idade, além da assinatura do TCLE pelo responsável legal, deverá ser apresentado o Termo de Assentimento para a adolescente. Favor adequar.
ANÁLISE: Pendência atendida. Verificar item "Recomendações" desse parecer.

Considerações Finais a critério do CEP:
- O sujeito de pesquisa deve receber uma via do Termo de Consentimento Livre e Esclarecido, na íntegra, por ele assinado (quando aplicável).

- O sujeito da pesquisa tem a liberdade de recusar-se a participar ou de retirar seu consentimento em qualquer fase da pesquisa, sem penalização alguma e sem prejuízo ao seu cuidado (quando aplicável).

- O pesquisador deve desenvolver a pesquisa conforme delineada no protocolo aprovado. Se o pesquisador considerar a descontinuação do estudo, esta deve ser justificada e somente ser realizada após análise das razões da descontinuidade pelo CEP que o aprovou. O pesquisador deve aguardar o parecer do CEP quanto à descontinuação, exceto quando perceber risco ou dano não previsto ao sujeito participante ou quando constatar a superioridade de uma estratégia diagnóstica ou terapêutica oferecida a um dos grupos da pesquisa, isto é, somente em caso de necessidade de ação imediata com intuito de proteger os participantes.

- O CEP deve ser informado de todos os efeitos adversos ou fatos relevantes que alterem o curso normal do estudo. É papel do pesquisador assegurar medidas imediatas adequadas frente a evento adverso grave ocorrido (mesmo que tenha sido em outro centro) e enviar notificação ao CEP e à Agência Nacional de Vigilância Sanitária – ANVISA – junto com seu posicionamento.

- Eventuais modificações ou emendas ao protocolo devem ser apresentadas ao CEP de forma clara e sucinta, identificando a parte do protocolo a ser modificada e suas justificativas e aguardando a aprovação do CEP para continuidade da pesquisa. Em caso de projetos do Grupo I ou II apresentados anteriormente à ANVISA, o pesquisador ou patrocinador deve enviá-las também à mesma, junto com o parecer aprovatório do CEP, para serem juntadas ao protocolo inicial.

- Relatórios parciais e final devem ser apresentados ao CEP, inicialmente seis meses após a data deste parecer de aprovação e ao término do estudo.

-Lembramos que segundo a Resolução 466/2012 , item XI.2 letra e, “cabe ao pesquisador apresentar dados solicitados pelo CEP ou pela CONEP a qualquer momento”.

Este parecer foi elaborado baseado nos documentos abaixo relacionados:

Tipo Documento	Arquivo	Postagem	Autor	Situação
Informações Básicas do Projeto	PB_INFORMAÇÕES_BÁSICAS_DO_PROJETO_790058.pdf	18/11/2016 14:07:17		Aceito
Outros	RespostaParecerCEP.pdf	18/11/2016 14:06:57	Jose Guilherme Cecatti	Aceito
Projeto Detalhado / Brochura Investigador	MAESIActigrafia.pdf	18/11/2016 14:06:25	Jose Guilherme Cecatti	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	TALE.pdf	18/11/2016 12:07:39	Jose Guilherme Cecatti	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	TCLE.pdf	18/11/2016 12:07:26	Jose Guilherme Cecatti	Aceito
Outros	ParecerCircunstanciado.pdf	01/10/2016 10:27:44	Jose Guilherme Cecatti	Aceito
Folha de Rosto	folhaDeRostoActigrafia.pdf	11/09/2016 11:14:00	Jose Guilherme Cecatti	Aceito

Situação do Parecer:
Aprovado

Necessita Apreciação da CONEP:
Não

CAMPINAS, 24 de Novembro de 2016

Assinado por:
Renata Maria dos Santos Celeghini
(Coordenador)

Continuação do Parecer: 1.834.116

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Telefone: (19)3521-8936 **Fax:** (19)3521-7187 **E-mail:** cep@fcm.unicamp.br

ANEXO 3 – Modelo da Escala de Resiliência aplicada na pesquisa

Desenvolvimento de um modelo preditor de complicações gestacionais por meio de "tecnologias móveis": estudo de coorte

Maternal Actigraphy Exploratory Study - MAES-I

ESCALA DE RESILIÊNCIA DE WAGNILD E YOUNG (1993)

	Marque o quanto você concorda ou discorda com as seguintes afirmações:	Discordo			Nem Concordo Nem Discordo	Concordo		
		Totalmente	Muito	Pouco		Pouco	Muito	Totalmente
1	Quando eu faço planos, eu levo eles até o fim.	1	2	3	4	5	6	7
2	Eu costumo lidar com os problemas de uma forma ou de outra.	1	2	3	4	5	6	7
3	Eu sou capaz de depender de mim mais do que qualquer outra pessoa.	1	2	3	4	5	6	7
4	Manter interesse nas coisas é importante para mim.	1	2	3	4	5	6	7
5	Eu posso estar por minha conta se eu precisar.	1	2	3	4	5	6	7
6	Eu sinto orgulho de ter realizado coisas em minha vida.	1	2	3	4	5	6	7
7	Eu costumo aceitar as coisas sem muita preocupação.	1	2	3	4	5	6	7
8	Eu sou amigo de mim mesmo.	1	2	3	4	5	6	7
9	Eu sinto que posso lidar com várias coisas ao mesmo tempo.	1	2	3	4	5	6	7
10	Eu sou determinado.	1	2	3	4	5	6	7
11	Eu raramente penso sobre o objetivo das coisas.	1	2	3	4	5	6	7
12	Eu faço as coisas um dia de cada vez.	1	2	3	4	5	6	7
13	Eu posso enfrentar tempos difíceis porque ja experimentei dificuldades antes.	1	2	3	4	5	6	7
14	Eu sou disciplinado.	1	2	3	4	5	6	7
15	Eu mantenho interesse nas coisas.	1	2	3	4	5	6	7
16	Eu normalmente posso achar motivo pra rir.	1	2	3	4	5	6	7
17	Minha crença em mim mesmo me leva a atravessar tempos difíceis.	1	2	3	4	5	6	7
18	Em uma emergência, eu sou uma pessoa em quem as pessoas podem contar.	1	2	3	4	5	6	7
19	Eu posso geralmente olhar uma situação de diversas maneiras.	1	2	3	4	5	6	7
20	Às vezes eu me obrigo a fazer coisas querendo ou não.	1	2	3	4	5	6	7
21	Minha vida tem sentido.	1	2	3	4	5	6	7
22	Eu não insisto em coisas as quais eu não posso fazer nada sobre elas.	1	2	3	4	5	6	7
23	Quando eu estou numa situação difícil, eu normalmente acho uma saída.	1	2	3	4	5	6	7
24	Eu tenho energia suficiente para fazer o que eu tenho que fazer.	1	2	3	4	5	6	7
25	Tudo bem se há pessoas que não gostam de mim.	1	2	3	4	5	6	7

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ANEXO 4 – Modelo da Escala de Estresse Percebido aplicada na pesquisa

Desenvolvimento de um modelo preditor de complicações gestacionais por meio de "tecnologias móveis": estudo de coorte

Maternal Actigraphy Exploratory Study - MAES-I

ESCALA DE ESTRESSE PERCEBIDO

As questões nesta escala perguntam sobre seus sentimentos e pensamentos durante o último mês. Em cada caso, será pedido para você indicar o quão frequentemente você tem se sentido de uma determinada maneira. Embora algumas das perguntas sejam similares, há diferenças entre elas e você deve analisar cada uma como uma pergunta separada. A melhor abordagem é responder a cada pergunta razoavelmente rápido. Isto é, não tente contar o número de vezes que você se sentiu de uma maneira particular, mas indique a alternativa que lhe pareça como uma estimativa razoável. Para cada pergunta, escolha as seguintes alternativas:

0 = nunca 1 = quase nunca 2 = ás vezes 3 = quase sempre 4 = sempre

Neste último mês, com que frequencia...		Nunca	Quase nunca	Ás vezes	Quase sempre	Sempre
1	Você tem ficado triste por causa de algo que aconteceu inesperadamente?	0	1	2	3	4
2	Você tem se sentido incapaz de controlar as coisas importantes em sua vida?	0	1	2	3	4
3	Você tem se sentido nervosa e "estressada"?	0	1	2	3	4
4	Você tem tratado com sucesso dos problemas difíceis da vida?	0	1	2	3	4
5	Você tem sentido que está lidando bem as mudanças importantes que estão ocorrendo em sua vida?	0	1	2	3	4
6	Você tem se sentido confiante na sua habilidade de resolver problemas pessoais?	0	1	2	3	4
7	Você tem sentido que as coisas estão acontecendo de acordo com a sua vontade?	0	1	2	3	4
8	Você tem achado que não conseguiria lidar com todas as coisas que você tem que fazer?	0	1	2	3	4
9	Você tem conseguido controlar as irritações em sua vida?	0	1	2	3	4
10	Você tem sentido que as coisas estão sob o seu controle?	0	1	2	3	4
11	Você tem ficado irritada porque as coisas que acontecem estão for a do seu controle?	0	1	2	3	4
12	Você tem se encontrado pensando sobre as coisas que deve fazer?	0	1	2	3	4
13	Você tem conseguido controlar a maneira como gasta seu tempo?	0	1	2	3	4
14	Você tem sentido que as dificuldades se acumulam a ponto de você acreditar que não pode superá-las?	0	1	2	3	4

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