方案版本号及日期： 知情同意书版本号及日期：

知情同意书

尊敬的患者：

我们将邀请您参加一项临床研究。本知情同意书提供给您一些信息以帮助您决定是否参加此项临床研究。请您仔细阅读，如有任何疑问请向负责该项研究的研究者提出。

您参加本项研究是自愿的。本次研究已通过常州市妇幼保健院医学伦理委员会审查。

如果您愿意，请仔细阅读以下内容。

方案名称：团体生物反馈辅助治疗伴心身症状的妊娠剧吐
研究中心：常州市妇幼保健院
主要研究者：崔雪莲，王丽，顾建东。

一、研究目的

妊娠呕吐（HG）的特征是脱水，电解质失衡，缺乏营养以及体重减轻至少 5%。孕妇的 HG 率在 0.3%至 3%的范围内，被认为是最重要的妊娠相关并发症之一，始于孕早期，可持续整个妊娠期，尽管症状通常会在第 20 周消退。该病通常需要经常去急诊室就诊并反复住院以进行静脉补液，这严重破坏了生活质量。住院率因人群而异，在美国为 1%至 2%，但在中国上海据报道为 10.8%。 HG 的并发症包括多种营养缺乏症，甚至包括 Wernicke 脑病，食道裂伤，心理社会影响（终止妊娠，并担心随后怀孕），以及孕妇的有创复苏，早产和胎儿低出生体重。妊娠剧吐发病原因不明确，现研究认为是多因素疾病，其中自主神经功能紊乱和心理因素也是可能的原因。但是目前研究中用来评估心理因素的工具存在缺陷和不足，而且尚没有较好的干预伴心身症状的妊娠剧吐的方法。因此本研究拟探索非侵入性的团体生物反馈治疗对妊娠剧吐的恶心呕吐症状以及患者的生活治疗、经济负担是否有改善作用。

二、研究过程

如果您同意参与这项研究，我们将对您进行编号，建立病历档案。在研究过程中我们仅需要采集一些您的电生理数据，因为这不是向您身体输入任何东西，所以不会对胎儿造成影响。您将被电脑随机分配到试验组或对照组，每组接受的治疗方式不完全相同，具体治疗方法由入组之后的治疗师向您讲解。试验时间为期 2 周，试验结束后会有工作人员对您进行电话随访，询问您的妊娠情况。

三、风险与不适

对于您来说，所有的信息将是保密的。这项研究所采用的干预方法不会对胎儿造成任何风险。

四、受益

通过对您的数据检测将有助于对疾病的干预效果作出诊断，为您的治疗提供必要的建议，或为疾病的研究提供有益的信息。

五、责任

作为受试者，您有以下职责：提供有关自身病史和当前身体状况的真实情况；告诉研究医生自己在本次研究期间所出现的任何不适；不得服用受限制的药物、食物等；告诉研究医生自己在最近是否曾参与其他研究，或目前正参与其他研究。

六、隐私问题

如果您决定参加本项研究，您参加试验及在试验中的个人资料均属保密。可以识别您身份的信息将不会透露给研究小组以外的成员，除非获得您的许可。所有的研究成员和研究申办方都被要求对您的身份保密。您的档案将保存在有锁的档案柜中，仅供研究人员查阅。为确保研究按照规定进行，必要时，政府管理部门或伦理审查委员会的成员按规定可以在研究单位查阅您的个人资料。这项研究结果发表时，将不会披露您个人的任何资料。

除本研究以外，有可能在今后的其他研究中会再次利用您的医疗记录、血/尿/病理检查标本。您现在也可以声明拒绝除本研究外的其他研究利用您的医疗记录和病理标本。

七、权利

如果您因参与这项研究而受到伤害：如发生与该项临床研究相关的损害时，您可以获得免费治疗和/或相应的补偿。

您可以选择不参加本项研究，或者在任何时候通知研究者要求退出研究，您的数据将不纳入研究结果，您的任何医疗待遇与权益不会因此而受到影响。

如果您需要其它治疗，或者您没有遵守研究计划，或者发生了与研究相关的损伤或者有任何其它原因，研究医师可以终止您继续参与本项研究。

您可随时了解与本研究有关的信息资料和研究进展，如果您有与本研究有关的问题，或您在研究过程中发生了任何不适与损伤，或有关于本项研究参加者权益方面的问题您可以随时与研究者联系。

Informed Consent

Dear participants,

We will invite you to participate in a clinical study. This informed consent gives you some information to help you decide whether to participate in this clinical study. Please read it carefully and ask the investigator responsible for the study if you have any questions.

Your participation in this research is voluntary. This study has been reviewed by the Medical Ethics Committee of Nanjing Medical University.

If you like, please read the following carefully.

Project name: Group Biofeedback for Treatment of Hyperemesis Gravidarum with Psychosomatic Symptoms

Research institute: Changzhou Maternity and Child Healthcare Hospital.

Principle investigator: Xuelian Cui, Li Wang, Jiandong Gu.

1. Aims

Hyperemesis Gravidarum (HG) is a condition characterized by dehydration, electrolyte imbalance, lack of nutrition, and at least 5% loss in body weight. HG rates in pregnant women range from 0.3% to 3%, and it is considered one of the most important pregnancy-related complications. HG appears in the first half and can last throughout the pregnancy, although the symptoms usually resolve within 20 gestational weeks. This condition generally requires frequent visits to the emergency room and repeated hospitalizations for intravenous hydration, which severely compromise quality of life (QoL). Hospitalization rates for HG vary between populations: from 1% to 2% in the United States, 10.8% in Shanghai, China. The complications of HG include multiple nutritional deficiencies, Wernicke's encephalopathy, esophageal laceration, terminate the desired pregnancy and fear of subsequent pregnancy, preterm birth and low birth weight. The etiology and pathogenesis of HG remain uncertain, but should be multi-factorial with biologic, psychological and socio-economic antecedents [6], including maternal endocrine disorders, hepatic abnormalities, gastrointestinal dysfunction, pituitary axis

malfunction, autonomic nervous dysfunction, and psychosomatic factors. However, the methodological flaws in studies have left the concept that anxiety and depression as a cause or outcome of HG unsupported by evidence, and there is no good way to intervene in Hyperemesis Gravidarum with psychosomatic symptoms. The present study aims to explore the efficacy of group biofeedback treatment on nausea/vomiting and quality of life of HG patients with psychosomatic symptoms.

2. Procedures

If you agree to participate in this study, we will number you and create a medical record file. During the research we only need to collect some of your electrophysiological data, because this is not input to your body, so it will not affect the fetus. You will be randomly assigned to the experimental group or the control group by the computer. Each group receives different treatment methods. The specific treatment method will be explained to you by the therapist in the group. The duration of the test is 2 weeks. After the test, a staff member will follow up with you on the phone to inquire about your pregnancy.

3. Risks

For you, all information will be kept confidential. The interventions used in this study pose no risk to the fetus and pregnant women.

4. Benefits

From testing your data in this study, it will help diagnose the efficacy of disease interventions, provide necessary advice for your treatment, and provide useful information for disease research.

5. Responsibilities

As a participant, you have the following responsibilities: provide truthful information about your medical history and current physical condition; tell the researcher about any discomforts that you have experienced during this study period; do not take restricted drugs, food, etc ; tell the researcher whether you have participated in other research recently, or is currently participating in other research.

6. Privacy

If you decide to participate in this study, your personal information in the trial and during the trial will be kept confidential. Information that can identify you will not be shared with members outside the research team unless you have obtained your permission. All research members and research sponsors are required to keep your identity confidentially. Your files will be kept in locked file cabinets for research personnel only. To ensure that research is carried out in accordance with regulations, members of government administrations or ethics review committees can access your personal data at the research unit as required. When this research is published, no personal information about you will be disclosed.

7. Rights

If you are harmed by participating in this study: If damage occurs in connection with the clinical study, you can get compensation.

You can choose not to participate in the study, or notify the researcher at any time to request to withdraw from the study, your data will not be included in the study results, and any of your medical treatment and rights will not be affected.

The research physician may terminate your continued participation in the study if you require additional treatment, or if you do not follow the study plan, or if there is any injury related to the study, or for any other reasons.

You can keep informed of the information and research progress related to this research at any time, if you have questions related to this research, or if you have any discomfort and injury during the research, or have questions about the rights of participants in this research, you can contact the researcher at any time.