知情同意书•知情告知页

尊敬的先生/女士：

医生已经确诊您为肺癌相关性失眠。我们将邀请您参加一项“电针治疗肺癌相关性失眠”的随机对照研究。在您决定是否参加这项研究之前，请尽可能仔细阅读以下内容，它可以帮助您了解该项研究以及为何要进行这项研究，研究的程序和期限，参加本研究后可能给您带来的益处、风险和不适。如果您愿意，您也可以和您的亲属、朋友一起讨论，或者请您的医生给予解释，帮助您做出决定。

研究介绍

一、研究背景和研究目的

肿瘤相关性失眠是与肿瘤和肿瘤治疗相关的一个高发生率结果事件,可造成患者白天的疲乏，认知的负面作用（例如注意力和记忆力的减退）、抵抗力下降、情绪抑郁焦躁，严重影响患者的健康和生活质量。肺癌现位居我国恶性肿瘤发病及死亡的首位。有研究发现，失眠在肺癌患者中高发，并且明显高于其他恶性肿瘤患者。国内外大量研究中发现针灸可以有效调节肿瘤相关临床症状和相关病理表现,作为安全无毒副作用的治疗手段对失眠具有一定疗效，可有效控制疾病发展，尤其在降低西药药量、不良反应及生活质量方面尤其突出。

本研究将在上海市中医医院、上海胸科医院、上海市普陀区中心医院针灸科进行，预计共有 252 名受试者自愿参加。本研究已经过以上三家医院伦理委员会审核，是遵从中国国家相关法规和赫尔辛基宣言等保护受试者权益的伦理原则的。

二、哪些人不宜参加研究

（1）抑郁症、焦虑症、恐慌症等其他精神类疾患导致的继发性失眠；咖啡因、酒精及药物滥用和依赖所致失眠者；

（2）肿瘤引发的疼痛分级指数≥4；

（3）试验期间有手术、化疗计划；

（4）患有严重的认知障碍，不能参与合作的患者；

（5）针刺部位有严重溃疡、脓疮、皮肤感染等；

（6）严重心、脑、肝、肾功能不全，失代偿肺功能不全或合并其他系统严重疾病者；

（7）怀孕或哺乳期妇女；

（8）近一个月内参加其他临床医学试验研究；

三、如果参加研究将需要做什么？

1.在您入选研究前，您将接受以下检查以确定您是否可以参加研究，医生将询问、记录您的病史，对您进行体格检查。

2.若您以上检查符合入选条件，研究者将根据随机抽样结果，安排您接受治疗组或对照组进行治疗。参加这项研究的患者有 50%的概率被分入这两组。治疗组与对照组均采用针刺治疗，治疗共 24 次，持续 8 周，每周 3 次。我们将在您第 0 周，第 4 周，第 8 周，第 12 周，第

20 周进行评估。

3.需要您配合的其他事项:您必须按医生指导按时来进行治疗，并请您在每次治疗后及时、客观地向医生反映自己的病情变化，按时填写各项评分表进行评估。如您有其他疾病须继续服用的药物，请您务必告知您的医生。在研究期间如您确实需要其它治疗，请事先与您的医生取得联系。治疗期间保持心情舒畅，尽可能情绪平稳。

四、参加研究的受益

您将可能从本项研究中受益。您的病情和生活质量有可能获得改善，但不排除此项研究对您的病情没有改善,您可以向医生询问有可能获得的替代治疗方法。

五、参加研究的风险

如果在研究期间您出现任何不适，或病情发生新的变化，或任何意外情况，不管是否与治疗有关，均应及时通知您的医生，我们将对此作出判断和医疗处理。课题负责单位将尽全力预防和治疗由于本研究可能带来的伤害。如果在临床试验中出现不良事件，医学专家委员会将会鉴定其是否与本治疗有关。经专家委员会认定，不良事件与本试验中的治疗有关，课题组将对于试验相关的损害提供相应的经济赔偿。

您在研究期间需要按时到我们门诊进行治疗和随访,这些都可能给您造成麻烦或带来不方便。

六、有关费用

我们将在治疗期间为您提供免费针刺治疗。此外，课题组将在您完成评估及最终随访时给予您参加该临床试验的交通补偿费，共计 200 元/人。

七、个人信息是保密的吗？

您的医疗记录（研究病历、CRF 等）将完整地保存在医院。研究者、申办者代表、伦理委员会将被允许查阅您的医疗记录。任何有关本项研究的公开报告将不会披露您的个人身份。我们将在法律允许的范围内，尽一切努力保护您个人医疗资料的隐私。

八、怎样获得更多的信息？

您可以在任何时间提出有关本项研究的任何问题。

您的医生将给您留下他/她的电话号码以便能回答您的问题。

如果在研究过程中有任何重要的新信息，可能影响您继续参加研究的意愿时，您的医生将会及时通知您。

九、可以自愿选择参加研究和中途退出研究

是否参加本研究完全取决于您的自愿。您可以拒绝参加此项研究，或在研究过程中的任何时间退出本研究。如果您选择退出此研究，您的受益将不会受到影响，也不会因此而受到歧视或报复。

出于对您的最大利益考虑，医生或研究者可能会随时中止您参加本项研究。

如果您因为任何原因从研究中退出，您可能被咨询有关治疗情况。如果医生认为需要，

您也可能被要求进行实验室检查和体格检查。

十、现在该做什么？

是否参加本项研究由您自己决定。您可以和您的家人或者朋友讨论后再做出决定。

在您做出参加研究的决定前，请尽可能向您的医生询问有关问题，直至您对本项研究完全理解。

感谢您阅读以上材料。如果您决定参加本项研究，请告诉您的医生，他/她会为您安排一切有关研究的事务。

请您保留这份资料。

知情同意书•同意签字页

项目名称：电针治疗肺癌相关性失眠的随机对照试验

版本号：V1.0

版本日期：2019 年 09 月 20 日

同意声明

我已经阅读了上述有关本研究的介绍，而且有机会就此项研究与医生讨论并提出问题。

我提出的所有问题都得到了满意的答复。

我知道参加本研究可能产生的风险和受益。我知晓参加研究是自愿的，我确认已有充足时间进行考虑，而且明白：

• 我可以随时向医生咨询更多的信息。

• 我可以随时退出本研究，而不会受到歧视或报复，医疗待遇与权益不会受到影响。

我同样清楚，如果我中途退出研究，我若将原因告诉医生，完成相应的体格检查和理化检查，这将对我本人和整个研究十分有利。

如果因患病的需要采取任何其他的药物治疗，我会在事先征求医生的意见，或在事后如实告诉医生。

我同意上海市中医医院医生、伦理委员会等部门代表查阅我的研究资料。

我将获得一份经过签名并注明日期的知情同意书副本。

最后，我决定同意参加本项研究，并保证尽量遵从医嘱。

受试者签名：_____ 日期：_____ 年 _____ 月_____日

受试者联系电话：_____

我确认已向受试者解释了本研究的详细情况，包括其权利以及可能的受益和风险，并给其一份签署过的知情同意书副本。

研究者签名：_____ 日期：_____ 年_____ 月_____日

研究者联系电话：_____

Informed Consent Form-Information page

Dear participant:

You have been diagnosed with lung cancer-related insomnia by doctors. So now we are inviting you to participate in a randomized controlled trial of electroacupuncture intervention for insomnia in lung cancer patients. Before you decide whether to participate in this study, please read the following contents carefully as much as possible. If you prefer, you can also discuss with your relatives or friends, or ask your doctor for explanation to help make a decision.

Research introduction

1. Research background and purposes

Cancer-related insomnia (CRI) is one of the most prevalent complaints among cancer survivors, resulting in negative effects, such as fatigue, attention impairment, irritability, daytime sleepiness, all of which severely impairs the overall quality of life and even prognosis of cancers. We have conducted plenty of conclusive work of electro-acupuncture on CRI. EA has been found to effectively relieve cancer related symptoms with advantages of good clinical curative effect on insomnia, taking effect fast, and safe with few side effects.

The study will be conducted in Shanghai Municipal Hospital of Traditional Chinese Medicine, Shanghai Chest Hospital, and Putuo District Central Hospital. A total of 252 participants are expected to participate voluntarily. This research was reviewed by the Ethics Committee of the above hospitals, complying with the relevant national laws and regulations and the Helsinki Declaration and other ethical principles to protect the rights of subjects.

2. Who are not suitable for the trial

(1) A plan for surgery or chemotherapy during the trial;

(2) A diagnosis of secondary insomnia caused by depression, anxiety or other psychiatric disorders and addition of caffeine, alcohol or drugs;

(3) Index of cancer pain measured by the numeric rating scale≥4;

(4) A diagnosis of severe cognitive deficit failing to cooperate;

(5) A diagnosis of severe diseases of the cardiovascular, hepatic, renal, cerebrovascular, or hematopoietic systems;

(6) Acupuncture area with skin infection, ulcer and soars;

(7) Pregnant or breastfeeding women;

(8) Having participated in other clinic trials within 4 weeks of the beginning of this

trial;

3. What will be needed if participate in the research?

3.1 Before enrolling in the study, you will receive the some assessments to determine whether you can participate in the study. The doctor will ask and record your medical history and conduct a physical examination for you.

3.2 If you meet the inclusion criteria，the investigator will arrange for acupuncture or placebo acupuncture according to the randomization. Patients who participated in the study had a 50% probability of being assigned to one group. The intervention will be lasted for 30min every time, three times per week for 2 months. We will make some assessments at week 0, week 4, week 8, week 12 and week 20, for a total of 10 assessments.

3.3 Other matters that you need to cooperate with: You must follow the doctor's instructions to treat on time, report your changes to the doctor after each treatment promptly and objectively, and fill in the questionnaires for assessments on time. If you have any other medications that you have to take, please let your doctor know. If you do need other treatments during the study, please contact your doctor. Keep your mood comfortable during treatment.

4. Benefit from participating in the study

You may benefit from the research. Your condition and quality of life may improve but it does not rule out the condition that this study does not improve your condition. You can ask the doctor for alternative treatments.

5.Risk of participating in the study

If there are any discomfort during the study, or a new change in the condition, or any unforeseen conditions, you should notify your doctor promptly and he will make corresponding judgments and medical treatments. We will do our utmost to prevent harm which may be caused by the research. If adverse events occurs during the clinical trial, the Medical Expert Committee will authenticate whether it is related to the treatment. Corresponding economic compensation will been provided if adverse events are related to the trial.

During the study period, you will need to go to our clinic for treatment and follow-up on time which may cause trouble or inconvenience to you.

6. **Detailed expense**

We will provide free acupuncture treatment for you. And you will get adequate transportation allowance if you have completed all the treatment and follow-up.

6. Is personal information confidential?

Your medical records (research medical records/CRF, physical and chemical examination reports, etc.) will be kept in the hospital. Researchers, sponsor representatives, and ethics committees will be allowed to access your medical records. Any public report about this study will not disclose your personal status. We will make every effort to protect the privacy of your personal medical information to the extent permitted by law.

7. How can I get more information?

You can ask any questions about this research at any time.

Your doctor will leave you his/her phone number to answer your questions.

Your doctor will notify you immediately if there is any important new information during the study that may affect your willingness to continue your research.

8. You can choose to participate or drop out of research voluntarily

Participate in this study is entirely up to you. You can decline to participate the study or withdraw from the study at any time. Your benefits will not be affected and you will not be discriminated or retaliated if you choose to quit.

Your doctor or researcher may discontinue the study at any time for your best interest.

If you withdraw from the study for any reason, you may be consulted about the interventions. You may also be asked to perform laboratory and physical examinations if necessary.

9. What should I do now?

It is up to you to decide whether to participate in this study. You can discuss it with your family or friends before making a decision.

Before you make a decision , please ask your doctor as much as possible until you fully understand.

Thank you for reading the above materials. If you decide to participate in this study, please tell your doctor that he/she will arrange all the research for you.

Please keep this form.

Informed consent form • signature page

Project Name: Electro-acupuncture for insomnia in patients with lung cancer : A Study for a Randomized Controlled Trial

Version number: V1.0

Version date: September 10, 2019

Agree with the statement

I have read the above introduction to this study and have the opportunity to discuss and ask questions with the doctor about this study.

All the questions I raised were answered satisfactorily.

I understand the risks and benefits that may arise from participating in this study. I know that participating in the study is voluntary. I confirm that I have enough time to consider it and understand that:

· I can ask the doctor for more information at any time.

· I can withdraw from the study at any time without discrimination or retaliation, and medical treatment and benefits will not be affected.

I also know that if I withdraw from the study, I will tell the doctor about the change of the condition and complete the physical examination and physical and chemical examination. This will be very beneficial to me and the whole study.

If I take any other medications for illness, I will ask the doctor for advice beforehand or tell the doctor truthfully afterwards.

I agree with the responsible doctor of the project, the ethics committee of Shanghai Municipal Hospital of Traditional Chinese Medicine, and other departments to check my research data.

I will receive a copy of the signed and dated informed consent form.

Finally, I decided to participate in the study and follow my doctor's advice.

Patient signature：_____ Date：_____

Patient contact number：_____

I confirm that I have explained the details of the study, including the rights, potential benefits and risks, and gave him or her a copy of the signed informed consent.

Researcher signature：_____ Date：_____

Researcher contact number：_____