46.J. W. Creswell, M. D. Fetters, N. Y. Ivankova "Designing a mixed methods study in primary care" Annals of Family Medicine vol. 2, pp. 7-12, 2004.
47.C. Foss , B. Ellefsen, "The value of combining qualitative and quantitative approaches in nursing research by means of method triangulation" J Adv Nurs, vol. 40, no. 2, pp. 242-248, 2002.
48.L. Conboy, M. T. Quilty, C. Kerr and J. Shaw et al., "A Qualitative Analysis of Adolescents' Experiences of Active and Sham Japanese-Style Acupuncture Protocols Administered in a Clinical Trial," J ALTERN COMPLEM MED , vol. 14, no. 6, pp. 699–705, 2008.
49.S. Moffatt, M. White, J. Mackintosh, D. Howel, "Using quantitative and qualitative data in health services reasearch," BMC Health Services Research, vol 6, no. 28, 2006.
50.K. Rusinová, F. Pochard, N. Kentish-Barnes, M. Chaize, É. Azoulay, "Qualitative research: adding drive and dimension to clinical research," Critical Care Medicine, vol. 37, pp. 140–146, 2009.
51.J. Donovan, N. Mills, M. Smith et al., "Improving design and conduct of randomised trials by embedding them in qualitative research: ProtecT (prostate testing for cancer and treatment) study," BMJ, vol. 325, no. 5, pp. 766-770, 2002.
52.S. N. Moreira, G. D. Azevedo, "Incorporatingqualitativeapproaches is the path to adequateunderstanding of the psychosocialimpact of polycystic ovary syndrome," Hum Reprod, vol. 21, no. 10, pp. 2723-2724, 2006.
53.S. Elsenbruch, S. Benson , S. Hahn and S. Tann et al., "Determinants of emotional distress in women with polycystic ovary syndrome," Hum Repord vol. 21, no. 4, pp. 1092-1099, 2006.
54.J. C. Avery, A. J. Braunack-Mayer, "The information needs of women diagnosed with Polycystic Ovarian Syndrome – implications for treatment and health outcomes," BMC Women's Health, vol. 7, no. 9, 2007. doi:10.1186/1472-6874-7-9
55.J. Crete, P. Adamshick, "Managing Polycystic Ovary Syndrome: What Our Patients Are Telling Us," Journal of Holistic Nursing, vol. 29, no. 4, pp. 256-266, 2011.
56.C. West, "Routine Complications - Troubles With Talk Between Doctors and Patients," Bloomington , Indiana University Press, 1984.
57.J. Richardson, "What patients expect from complementary therapy: a qualitative stydy," Am J Public Health, vol. 94, pp. 1049-1053, 2004.

Effect of low frequency electric acupuncture on menstrual frequency of young women with polycystic ovary syndrome: study protocol for arandomized, double-blinded,sham-controlled trial

Qing Wang[1,2], *Dongmei Huang*[1*], *Xiaoke Wu*[2], *Shuang Wu*[3]

[*] Correspondence: hdmjcr@qq.com

[1]Institute of Integrated Traditional Chinese and Western Medicine, Tongji hospital, Huazhong University of Science and Technology,Jiefang Road 1095 #, Wuhan, China.

[2]HeilongjiangUniversity of Traditional Chinese Medicine, Haerbin, China.

[3]HubeiUniversity of Traditional Chinese Medicine, Wuhan, China.

Abstract

It has been reported that electroacupuncture (EA) is effective for restoring regular menstruation, regular ovulation and decreasing androgenic hormones for women with polycystic ovary syndrome (PCOS). The aim of this randomized, double-blinded, sham-controlled clinical trial is to prove and declare the effects of low-frequency EAon menstrual condition of young girls with PCOS by controlled with sham acupuncture. Seventy-two young girlswith PCOS between 18 and

28 years of age and without bearing requirement within 4 months will be recruited and randomly divided into the true acupuncture group and the sham acupuncture group, with 36 cases in each group receiving 16 weeks treatment. Menstrual condition will be the primary outcome. HCG stimulation testwill be done to test serum 17-OHP before and after the treatment. At baseline and in a week after the treatment, the short form 36 (SF-36) and the Chinese Quality of Life (ChQOL) will be used to evaluate health related quality of life, Zung Self-Rating Anxiety Scale and Zung Self-reported Depression Scale (SAS and SDS) will be used to detect symptoms of anxiety and depression, Polycystic Ovary Syndrome Questionnaire (PCOS-QOL) will be investigated. Adverse events will be recorded during the treatment.

Key words: Electro-acupuncture, Polycystic ovary syndrome, Ovulation rate, Oligomenorrhea, HCG stimulation test, Sex steroid.

Polycystic ovary syndrome (PCOS) is the most common ovulatory disorder, present in 12-21% of women of reproductive age [1]. For young women with PCOS without demands for children, disturbance ofmenstruation is often concerned as a big problem. Those methods such as clomiphene citrate, exogenous gonadotropin therapy, andlaparoscopic ovarian drilling which are commonly used to induceovulation [2] are not suitable for them. Therefore, it's necessary to found a new treatment for improve menstrual frequency for young women with PCOS.

Acupuncture, as an important part of traditional Chinese medicine (TCM), has a history of over 3000 years. Recently, the utilization and effect of acupuncture in the treatment of reproductive endocrine diseases and infertility has caught more and more attention all over the world [3-5]. Moreover, it has hardly any negative side effects. Several studies have found that electro-acupuncture (EA)is effective in treating women with PCOS [6-9]. However, only one of them was controlled with shame acupuncture which was performed with the validated Park sham device [10-11]. And the study came to a conclusion that the efficacy ofthose two acupuncture methods was similar. The studies could not observe the difference between true acupuncture and sham acupuncture. What about other design of the sham acupuncture? If we chose other control design, is the conclusion suitable either? Therefore, the conclusion needs more rigorous randomized blinded controlled clinical trials to confirm. The efficacy of the EA in treating PCOS needs more RCT to evaluate.

Materials and methods

Design This study is a prospective, randomized, double-blinded, sham-controlled clinical trial with two parallel arms. We intend to compare the effects of true EA and sham EA in treating PCOS and to evaluate the efficacy of EA further. The trial has been registered with United States National Institutes of Health Clinical Trials Registry (NCT 01812161) and Chinese Clinical Trials Registry (ChiCTR-TRC-12002529). This trial has been approved by Chinese Ethics Committee of Registering Clinical Trials (ChiECRCT-2012030).

Participant Seventy-two patients with PCOS between18-28 years old will be recruited between September 2012 and December 2013, and the patients should meet with the inclusion criteria and out of the exclusion criteria as follows at the same time. Those 72 patients will be randomly divided into true acupuncture group and sham acupuncture group, each group 36patients.Inclusion criteriaincludes Young girlswith age between 18 and 28 years and without bearing requirement within 4 months;②Confirmed diagnosis of PCOS according to the Rotterdam criteria: Oligomenorrhea(Menstrual cycle> 35 days, and less than 8 cycles per year), or amenorrhea (Menstrual cycle> 90 days) and one of the following two criteria: clinical or biochemical hyperandrogenism and/or polycystic ovarian morphology. Exclusion criteriaincludes ①Patients with hyperprolactinemia;②Patients with androgens secrete increased abnormal which caused by adrenal or ovarian tumors ;③Patients with uncorrected thyroid disease（TSH <0.2 uIU/mL or >5.5 uIU/mL） except the patients with normal TSH in the past 1 year;④Suspected Cushing syndrome patients ;⑤Patients who received estrogen, progesterone or oral contraceptives oral contraceptives

and hormone medications within the past 1 month. It takes at least one month to eliminate these medicines, or it will influence the results;⑥Patients who received other medications that have influence on reproductive function or metabolism within the past 2 months(such as anti-obesity medications, anti-diabetic medications, traditional Chinese medicine and so on);⑦Patients who take acupuncture treatment within the past 3 months;⑧Patient who are unwilling to give written consent to the study.

Sample size calculation Based on prior research about the effect of electro-acupuncture on PCOS [9], the ovulation rate was 38% in the true acupuncture and 9% in the sham acupuncture during 2 months treatment. We make a hypothesis that the ovulation rate during 4 months treatment will be equal to that of two months treatment. Using a two-sided trend test, this study is designed to have >80% power at the significance level of 0.05. The following formula is used to calculate sample size: $n=(U\alpha+U\beta)^2*2*P*(1-P)/(P1-P0)^2$, $P=(P1+P0)/2*100\%$. The sample size inflates from 30 to 36 per arm to allow for a dropout rate of 20%, totally 72 cases for two arms.

Recruitment Participants will be recruited through advertisements in local websites and on bulletin boards in local hospitals (Department ofIntegrated Traditional Chinese and Western Medicine department of gynaecology and obstetrics, Tongji hospital of Huazhong University of Science and Technology; and department of obstetrics and gynecology of hubei province hospital of traditional Chinese medicine; department of obstetrics and gynecology, National Key Discipline and Clinical Base, Heilongjiang University of Chinese Medicine.

Treatment details We base the rationale of acupuncture protocols on Western Medical theories and the study protocol follows the CONSORT and STRICTA recommendations with detailed descriptions of the treatment including number of needle used, how needles will be stimulated (manual, electrical),frequency of sessions and length of treatment period. We will use fixed acupuncture protocol 1 (true acupuncture) and 2 (sham acupuncture) in two groups respectively. All participants will receive treatment twice a week, and each treatment sessionshould be separated by an interval of 2-4 days, with32 treatment sessions during 16 weeks. Each treatment session lasts for 30 minutes. Acupuncture treatment will start as soon as a spontaneous period or a withdrawal bleeding following progestin is over. *Acupuncture protocol 1 (true acupuncture)*Two sets of acupoints will be used alternatively every second treatment. The first set consists of conception vessel (CV) 3, CV 6, and stomach (ST) 29 bilaterally and in the muscles below the knee, spleen (SP) 6, SP 9 bilaterally, large intestine (LI) 4 bilaterally and governor vessel (GV) 20. Disposable, single-use, sterilized needles (0.25 x 30 mm and 0.30 x 40/50mm) made of stainless steel (Wuxi Jiajian Medical Instrument, 251226Wuxi, China) will be inserted into a depth of 15–35 mm and be stimulated manually to evoke needle sensation (de qi). CV 3, CV 6, ST 29, SP 6, and SP 9 will thereafter be connected to electrical stimulator (Export Abteilung, Schwa-Medico GmbH,Wetzlarer Str. 41-43;35630 Ehringshausen) and stimulated with low-frequency EA of 2Hz, 0.3 ms pulse length and the intensity will be adjusted to produce local muscle contractions without pain or discomfort. Needles not connected to the electrical stimulator will be manually stimulated to evoke needle sensation every 10 min, in total 4 times. The second set consists of stomach (ST) 25 and 29 bilaterally (electrical stimulation), CV3 and CV6 (manual stimulation), SP6 and liver (LR) 3 bilaterally (electrical stimulation), pericardium (PC) 6 bilaterally and GV20 (both manual stimulation). The method of stimulation is the same as the above. *Acupuncture protocol 2 (sham acupuncture)*There are four points to be choosed, two in each shoulder and the other two in each upper arm at non-acupoints.Disposable, single-use, sterilized needles (0.20 x 20 mm) made of stainless steel (Wuxi Jiajian Medical Instrument, 251226 Wuxi, China) will be inserted superficially to a depth of <5 mmwithout evoking needle sensation (de qi). Placement of needles there is unlikely to affect ovulation in women with PCOS.Electrodes will be attached to the needles and the stimulator will be turned on at an intensity of zero (no active current) in order to mimic EA in the acupuncture protocol 1. No manual stimulation of the needles will be performed.***Primary outcome measurements*** As the primary outcome menstruation condition will be recorded including menstrual time /period/ and amount during the treatment period.We will giveHCG stimulation test

to every subject to detect serum 17-OHP. ***Secondary outcome measurements*** Physical examination: Physical examination including vital signs, height, weight, hip and waist measurements, BMI andassessment of hirsutism by Ferriman-Gallwey score and acne standard acne lesion counts will be performed at baseline and 16 weeks.Also, four questionnairesHRQoL (SF-36, PCOS-QOL, ChQOL, SAS and SDS) will be assessed at baseline and 16 weeks.Laboratory examination: Serum levels of Sex hormone steroids including blood follicle-stimulating hormone, luteinizing hormone, estrogen, progesterone,prolactin, total testosterone will be evaluated at baseline and 16 weeks.

Data analysis The primary analysis will use an intent-to-treat approach to examine differences in the ovulation rate and menstrual frequency between the two arms. Primary efficacyanalysis will be done by comparing the two groups with respect to the primary outcome of ovulationrate using the Pearson chi-square test. Missing data during the period of treatment will be replaced using the method of last observation carried forward. Descriptive statistics are presented as means ± SD. $P < 0.05$ (two-sided) was considered statistically significant. Analyses will be performed with Statistical Program for Social Sciences（SPSS）v.16.0.

Results and discussion

In evidence-based medicine, randomized controlled trials (RCTs) are the preferred method for evaluating the efficacy ofinterventions [12].True and sham acupuncture have been shown similar efficacy in treating PCOS base on the RCT [7].In that study, sham acupuncture control was performed with the validated Park sham device. But the device couldn't overcome the problem of double-blinding [13]. Thus, the therapeutic effects of EA couldn't be assessed objectively and more RCTs about EA in treating PCOS are needed. The result also highlights the difficulty in designing the control group in acupuncture RCTs. In this trial, the sham acupuncture control group will be performed as we have mentioned above. And we expect the control design may eliminate placebo effect and provide a more objective assessment on EA efficacy in treating PCOS. Thus, we hypothesized that the true acupuncture would be more effective on improve menstrual frequency than sham acupuncture.

Olio-menstruation is usually the big problem disturbing young girls with PCOS who haven't demand for children and also usually the reason for them to see a doctor for the first time. Thus, it's necessary to investigate their quality of life. And in this trail, four questionnaires (SF-36, PCOS-QOL, ChQOL, SAS and SDS) will be used to assess health related quality of life of the subjects at baseline and the 16th week.

Based on our previousobservation, most of the girls can have spontaneous menstruation during the following three months after 16weeks treatment. So, we will record the menstruation condition during the 3 months of follow-up to assess the hysteretic effect of EA on menstrual frequency.

References

1、Teede HJ. Polycystic ovary syndrome: An update. Australian Family Physician.-2012-41(10).-p.752-756.

2、Anonymous. Consensus on infertility treatment related to polycysticovary syndrome. Hum Reprod.-2008. - 23(3).-p.462–477.

3、Coulson C, Jenkins J. Complementary and alternative medicine utilisation in NHS and private clinic settings: a United Kingdom survey of 400 infertility patients. J Exp Clin Assist Reprod. –2005Apr.-2.-p.5.

4、Smith JF, Eisenberg ML, Millstein SG, et al. The use of complementary and alternative fertility treatment in couples seeking fertility care: data from a prospective cohort in the United States. Fertil Steril.-2010.-93(7).-p.2169-2174.

5、Stankiewicz M, Smith C, Alvino H, Norman R. The use of complementary medicine and therapies by patients attending a reproductive medicine unit in South Australia: a prospective survey. Aust N Z J Obstet Gynaecol.-2007.-47.-p.145-149.

6、Jedel E, Labrie F, Oden A, et al. Impact of electro-acupuncture and physical exercise on hyperandrogenism and oligo/amenorrhea in women with polycystic ovary syndrome: a randomized controlled trial. Am J Physiol Endocrinol Metab.-2011.-300.-p.37-45.
7、Pastore LM, Williams CD, Jenkins J, Patrie JT.True and sham acupuncture produced similar frequency of ovulation and improved LH to FSH ratios in women with polycystic ovary syndrome.J Clin Endocrinol Metab.-2011.-96(10).-p.3143-3150.
8、Julia Johansson, Leanne Redman, Paula P. Veldhuis, Antonina Sazonova,FernandLabrie, Göran Holm, Gudmundur Johannsson and Elisabet Stener-Victorin Acupuncture for ovulation induction in polycystic ovarysyndrome: a randomized controlled trial..Am J Physiol Endocrinol Metab.-2013.-304.-p.E934-E943,
9、Stener-Victorin E, Waldenstrom U, Tagnfors U, Lundeberg T, Lindstedt G, Janson PO. Effects of electro-acupuncture on anovulation in women with polycystic ovary syndrome. Acta Obstet Gynecol Scand. -2000.-79.-p.180-188.
10、Park J, White A, Stevinson C, Ernst E, James M 2002 Validating a new non-penetrating sham acupuncture device: two randomized controlled trials.Acupunct Med.-2002.- 20.-p.168-174.
11、Helms J 1995 Acupuncture energetics: a clinical approach for physicians. Berkeley, CA: Medical Acupuncture Publishers.
12、Jaung-Geng Lin, Chao-Hsun Chen, Yu-Che Huang, and Yi-HungChen.How to design the Control Group in Randomized ControlledTrialsof Acupuncture? Evid Based Complement Aiternat Med.-2012.2012n:875284.
13、T.J. Kaptchuk, "Placebo needle for acupuncture," The Lancet.-1998.- 352 (9132).-p.992.

Children Facial Neuritis Treated By Shallow Needling

Ming-ming NIU, ZOU Wei, Xiao-wei SUN

Heilongjiang University of Chinese medicine,Harbin, Heilongjiang, China

Abstracts: Objective: To review the therapeutic efficacy of shallow needling in curing children facial neuritis. **Methods:** 70 children patients were assigned into two groups randomly: the treatment group (shallow needling method) and the control group (mild reinforcing-reducing method). Classify the facial nerve function with Programmer of criteria for clinical evaluation and assessment of therapeutic effects of peripheral facial paralysis after they were needled at the same points. **Result:** Before treatment, the basic conditions and the facial nerve function did not differ significantly （$p>0.05$）. After treatment, the two groups both achieved significant changes in criteria for facial nerve grading ($p<0.05$); the differences in facial nerve grading between the two group were not statistically significant ($p>0.05$). The effective rate of treatment group was 97.14%, and the rate of control group was 85.71%. **Conclusion:** Shallow needling treatment and mild reinforcing reducing method are all effective and the shallow needling treatment is a superior therapy in the treatment of children facial neuritis.

Key words: Shallow needling; Children Facial neuritis; Clinical observation

Introduction

Facial neuritis also called facial nerve palsy or Bell palsy refers to the nerve acute non-suppurative inflammation in stem mastoid process hole, which is one of the common clinical diseases treated by acupuncture. Through clinical observation, the therapeutic efficacy of shallow needling in curing children facial neuritis was significantly。