

- 17 . Wei J. Z., Shen X. Y., Zhou Y. et al. The study of the volt-ampere curve nonlinearity and hysteresis characteristics of human acupoints. *Chin. Asso.Acu. Mox.* – 2009 Sept. – Part One. - P.63-69.
- 18 . Zhang X. Q., Zheng L. Y., Wang X. et al. A research of the channel and points- entrails effect of rat. *Chin. Arch. TCM.* – 2010 Dec. –28(12). - P.2573-2575.
- 19 . Di Z. Ancient medical literature study about the suitable diseases that zu sanli (ST 36) acupoints can cure. *Shandong. S. U. TCM.* –2006 Apr. –P.1-91.
- 20 . Xu D. M., Xie Y. H., Yu N. D. et al. An observation of skin impedances to five-shu points in healthy people. *J. Guiyang Med. Col.* – 2005 Dec. –30(6). - P.523-524.

The Value of Qualitative Research in Polycystic Ovary Syndrome

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Abstract

As a heterogeneous condition, polycystic ovary syndrome (PCOS) is not only a physical disorder of reproductive women but is also associated with psychosocial distress. It is important to treat the physical symptoms to improve their quality of life by understanding their concerns and expectations. In this aspect, quantitative approaches in research may not provide sufficient information or capture the specific problem. Qualitative methods can serve as a good complement. Due to the paucity of research concerning the value of qualitative research in PCOS, this article introduces qualitative research and discusses how it can be applied the study of PCOS.

1 Introduction

Polycystic ovary syndrome (PCOS) is a common endocrine disorder with variable presentations. Apart from the typical symptoms including anovulation/oligoovulation, hyperandrogenism with excessive hair growth, acne and/or male pattern baldness, and polycystic ovaries (PCO), it is also related to metabolic disturbances including obesity and insulin resistance with a high risk of developing type 2 diabetes, and cardiovascular disease[1,2].

Recently, more researches have focused on the health-related quality of life (HRQoL) in women with PCOS. A meta-analysis of 423 patients and 285 controls from 5 articles that used the Short Form 36 (SF-36) questionnaire showed that women with PCOS score lower in each dimension of the SF-36, mostly in the emotional role function[3]. Another study also showed that the HRQoL is poorer in women with PCOS even when compared with other serious health conditions using the Polycystic Ovary Syndrome Questionnaire (PCOSQ) [4]. The main symptoms of PCOS such as infertility, menstrual dysfunctions, hirsutism and obesity can, by themselves, cause increased psychosocial stress. Although most clinicians recognize that the “score” is lower and HRQoL is poorer in women with PCOS, there has been a paucity of research that focuses on the psychosocial aspects of living with this syndrome and coping with psychosocial distress[5,6].

What matters to most women with PCOS are how well they are able to function and how they feel about their day-to-day life as individuals. Understanding patients' concerns and expectations is important for the measurement of healthcare quality, delivery of health services and costs of care, but the quantitative approaches may not provide the necessary information. Thus, it becomes increasingly more important to use qualitative approaches to understand the significant processes and the meanings experienced by women with PCOS[7].

However, only six related qualitative studies were found by May 2013(Table 1). Thus, the purpose of this paper is to introduce qualitative research and to discuss aspects in which it might be used in research of women with PCOS.

2 Qualitative Research

2.1 What is Qualitative Research?

The origin of qualitative research dates back to early 15th- and 16th-century anthropological studies. It has been used in health-care research since the 1970s and become crucial in health communication research[8]. The definition of qualitative research varies, depending on different study areas[9-11]. For medical research, qualitative research entails the use of qualitative methods of data collection and analysis. The common feature of the qualitative approach is that it does not primarily seek to provide quantified answers to research questions. Its goal is the development of concepts which help us to understand social phenomena in natural (rather than experimental) settings, giving due emphasis to the meanings, experiences, and views of all the participants.

Qualitative methods are integrated closely with different stages of quantitative research: in study design, sampling or analysis. Data collection methods commonly used in medical and health care area includes observational studies, interview studies and documentary source[12]. Qualitative data are almost always text-based and are analyzed using some forms of content analysis depending on the research aim. The study design changes a lot during the process of data collecting and analysis. Instead of randomized sampling, the principle of qualitative sample is information-oriented or purpose-oriented. Like quantitative research, qualitative research embodies a number of different theoretically-based approaches, for example biography[13], ethnography[14], case study[15], phenomenology[16] and grounded theory[17,18]. These have evolved separately within various social science and humanities disciplines and as a result tend to have different emphases and applications of particular qualitative techniques and methods. Each of these traditions has "a distinguished history in one of the disciplines" and has "spawned books, journals, and distinct methodologies that characterize its approach." [11]

Qualitative research has a crucial role in influencing clinical practice, by shedding light on patient experience. The role of the qualitative researcher is to try to understand and interpret what is going on from the point of view of those being studied. Since it is impossible for researchers, who are living humans with their own thoughts, to detach themselves completely from their own beliefs and personality, qualitative researchers constantly try to reflect on how their own convictions and experiences may influence the ways in which they observe and interpret phenomena. These reflections form part of the data that qualitative researchers collect in what is technically referred to as a reflexive account. Different from quantitative research, which is often framed by a formal hypothesis, qualitative research is not governed by the same kinds of formal rules. The choice of methods and techniques in qualitative work has to be considered carefully, justified and applied faithfully to make sure the study rigorous. The wrong choice will result in failure just as it would in quantitative work[19].

2.2 Use Value

The growing usefulness of qualitative research in published health services and management research has been described [20]. Although the publication rate of qualitative research articles has not kept pace with that of quantitative research articles, citation analysis suggests that qualitative research articles contribute comparably to the field's knowledge base. However, the value of qualitative research has been questioned by Martin Lipscomb[21], because qualitative work lacks external validity and it cannot be generalized[22]. He stress that qualitative researchers should make it clear that their work cannot inform practice. Alternatively, if this claim is advanced the process by

which this is to be achieved should be explicitly stated. So when we talk about the usefulness of qualitative research, we cannot ignore its rigor. Importantly, qualitative research is hypothesis generating.

2.3 Rigor in Qualitative Research

In 2001, Rosaline S Barbour proposed that in medical research the question about qualitative methods is no longer whether they are valuable but how rigor can be ensured or enhanced[23]. The concern with the rigor and credibility of qualitative methods has led to the development of a number of checklists for assessing qualitative research[24-26]. Checklists play an important role in improving qualitative research methods, but overzealous and uncritical use can be counterproductive. Reducing qualitative research to a list of technical procedures is overly prescriptive. If we succumb to the lure of “one size fits all” solutions, we risk being in a situation where the tail (the checklist) is wagging the dog (the qualitative research)[23]. There were different opinions about improving quality, for example, Robert Power said “Questioning the validity of checklists and the prevailing methodological orthodoxy in qualitative research is useful, but of greater relevance is the need to promote (and teach) a more observational paradigm for qualitative health research” while Brian Williams thought “Rigor may lie in the unreported details, peculiarities, and idiosyncrasies of studies as much as in the overarching issues contained in a checklist. The challenge is finding a way of making it possible and acceptable to report these openly [27,28].

A review in 2004, which described the quality of the development of qualitative research in oncology and palliative care, found that the publication increased during the nineties and the use of descriptive checklists allowed to focus on the whole picture of methodological components of qualitative research. This way contributes to the raising of awareness regarding the lack of attention to some methodological aspects, in particular to those specific of qualitative paradigm[29]. Recently editors of Patient Education and Counseling published an editorial describing four broad questions that authors could ask themselves in drafting papers to assess the quality of qualitative research. The four questions they brought are: what is known, what is new and why does it matter; what are the methods, and are they appropriate ones; do the presented data support the findings ; is the language clear and concise. They also state that they do not wish to propose a prescriptive set of criteria that will constrain future researches because the special value of qualitative research is to minimize the constraint that what we already know imposes on what we can find out[30]. These different suggestions need every qualitative researcher’s consideration to achieve a complete affirmation of qualitative methodology in the medical field with high methodological standards and an appropriate reporting of fundamental methodological aspects.

3 What Can Qualitative Research Do in PCOS?

In the field of health service and management research, qualitative methods are used to understand patients’ experiences, processes, evaluate policy, explore patient-clinician relationships and, increasingly, to complement quantitative methods. Similarly, there are multiple potential purposes for which qualitative research might be used in relation to PCOS.

3.1 Understanding Patients’ Experience

As a chronic medical condition, PCOS has clinical implications across the lifespan and present with a variety of serious clinical sequel[31]. Considering various physical manifestations of PCOS, the potential for emotional distress in living with the disorder is great. Although we know that PCOS women may have psychological problems such as reduced quality of life, poor self-esteem, depression, anxiety using quantitative questionnaires [5,32], qualitative findings can give us the real value about quantitative results and enhance the validity of the study as a whole. While quantitative data can answer ‘what?’ and ‘how many?’ qualitative methods can get answers on ‘why?’ questions. Undoubtedly, this thought is more than ‘just anecdote’ because it has been put into effect by some researchers. Kitzinger and Willmott of the United Kingdom conducted the first qualitative study of women with PCOS to explore the impact of PCOS within a feminist framework[7]. This study interviewed 30 women aged 21 to 42 years and uncovered their feelings of frustration and anger toward health professionals for delayed diagnosis and lack of information,

and feelings of “freakishness” about their hirsutism, menstrual irregularities, and of being “captive” by the need to strive for the ideals of “normal femininity”. A similar phenomenological study conducted in the northeastern United States with women with PCOS aged 21 to 48 years likewise revealed troubling hirsutism and femininity issues and echoed the theme of wanting to be normal[6]. Given that the points of focus vary in PCOS according to different age level, a qualitative study designed by Theresa R. Weiss and Sandra Minor Bulmer described young women’s experiences of living with PCOS and found that they are marked by daily physical, social and emotional challenges[33]. As qualitative research is relatively new in PCOS research, there is still work to do in understanding patients’ experience. It’s necessary to design qualitative researches in different countries among different age groups because people’s experience varies according to his/her living environment, religion and education. For instance, considering the great influence of infertility to PCOS women, studies involving patients at different stages of their fertility experience are essential; furthermore, subfertile women with PCOS from China and America may share different thoughts about infertility considering the only child policy in China. These potential research areas may provide rich descriptions of what it is like to experience illness or suffering and should be an essential component of health services researches[34].

3.2 Assessing Effects of Complementary and Alternative Medicine

Despite the high prevalence of PCOS, there is no standard long term treatment. Current treatments for PCOS are only moderately effective at controlling symptoms and preventing complications. On this occasion, people will ask complementary and alternative medicine (CAM) for help. A study shows that when 648 women were asked, “If your PCOS could be safely and effectively helped by something else besides fertility drugs or birth control pills, would that interest you?”, 99% responded yes[35]. Another landmark study shows that one in three Americans use CAM[36]. The rate of using CAM in China may be much higher since Traditional Chinese Medicine (TCM), part of CAM, has been used for thousands of years and is often administered as a complement to Western medicine. CAM methods like acupuncture, mindfulness meditation, herbs and dietary supplement are also used to treat PCOS. However, despite of the high prevalence, the evidence base lags behind its usage[37]. CAM methods may be associated with particularly potent placebo effects such as patient–practitioner relationships and healing changes occur in interactive, iterative ways[38]. Facing this contradictory information, on one hand, some researchers appeal that larger, well-designed RCTs are needed to further evaluate the safety, effectiveness and mechanisms of CAM treatments for PCOS[37]. On the other hand, there are doubts that whether RCT model suitable to assess the complex intervention characterized CAM[39]. We would wish to look at why patients flock to CAM so that we may better understand their needs and therapeutic perceptions. Qualitative research is an appropriate tool to this purpose. A previous study showed, although most patients sought a cure or improvement in their condition, they were also looking for hope, reassurance, explanations, advice, and understanding[40]. A recent qualitative study elucidating how women with PCOS experience treatment with acupuncture, implied similar information[41]. They found that acupuncture treatment with a combination of manual and electrical stimulation provides a possibility for patients to gain hope as the treatment showed results. The results empowered the patients to take responsibility for their future well-being, although they may have been initially skeptical to the treatment. Because the syndrome had affected them for a long time, even small changes offered them a probability to feel that their bodies were capable of normal function.

We need a broad spectrum of information if we are to understand not only which treatments work but also how and why they work (or do not work). It’s essential for more qualitative researches to know why women with PCOS value CAM therapies.

3.3 A Complement to Quantitative Research

Although combining qualitative and quantitative approaches has been questioned on the grounds of incompatibility of epistemological assumptions that underpin the two paradigms[42], there were researchers challenge the review by highlighting the existence of several qualitative traditions, each with its own distinctive set of assumptions about what constitutes appropriate

research questions et al[43]. Furthermore, this mixed methodology has been valued by more medical researchers and increasingly used to augment clinical trials[44-48]. For instance, Creswell et al expand on this theme by stating that "when used in combination, both quantitative and qualitative data yield a more complete analysis, and they complement each other"[45]. Qualitative research within and around randomized controlled trials can be used to improve the quality of trials[49]. Catherine Pope and Nick Mays concluded the following aspects that qualitative and quantitative methods can be characterized as complementary rather than exclusive[34]: Qualitative work can be conducted as an essential preliminary to quantitative research. Qualitative techniques such as observation, in depth interviews, and focus groups (which are covered in subsequent papers in this series) can be used to provide a description and understanding of a situation or behavior; Qualitative methods can be used to supplement quantitative work. This can be part of the validation process, as in "triangulation," where three or more methods are used and the results compared for convergence (for example, a large scale survey, focus groups, and a period of observation), or as part of a multi-method approach which examines a particular phenomenon or topic on several different levels; Qualitative research can complement quantitative work by exploring complex phenomena or areas not amenable to quantitative research. There are research conducted using mixed methodologies and the value of this stand is gaining more attention. One outstanding example is about improving design and conduct of a ProtecT (prostate testing for cancer and treatment) trial prostate cancer randomized trial by embedding it in qualitative research[50]. As the recruitment of this trial was difficult, in-depth interviews were used to investigate the process of recruitment and initial qualitative findings showed that recruiters had difficulty in discussing equipoise and presenting treatments equally; they unknowingly used terminology that was misinterpreted by participants. Findings were used to determine changes to content and presentation of information and the recruitment rate increased from 40% to 70%, all treatments became acceptable, and the three arms trial became the preferred design. The findings support the contention that the conduct of trials is not straightforward. It also implies that qualitative research methods applied in combination with open minded clinicians and flexible or innovative trial designs may enable even the most difficult evaluative questions to be tackled and have substantial impacts even on apparently routine and uncontroversial trials.

As for PCOS, no article using mixed methodology is found except for a discussion between Moreira SN, Azevedo GD and Elsenbruch et al[51]. They discussed about adding qualitative methods to a study using self-reported measures to characterize PCOS patients at risk of psychiatric disease and to assess the impact of emotional distress on quality of life because Moreira and Azevedo thought there's limitation of purely quantitative instruments to assess essentially subjective aspects[52]. Regardless other details about the study, they came to an agreement that "different approaches are possible and in fact necessary to expand our yet limited understanding of the psychological aspects of PCOS. Mixed methodology combining quantitative and qualitative methods may reveal complementary results". Their statement "we are looking forward to yet unexplored ways to characterize and, in the end, help these women cope with PCOS and its consequences" is here endorsed. We argue for an augmented, mixed methodology that integrates basic mechanism studies to obtain a more rigorous understanding of PCOS.

3.4 Improving Service Quality

As research in PCOS is rapidly advancing, it is vital that research evidence is translated to knowledge and action among women, healthcare professionals and policy makers[31]. Just as implicated in a qualitative research about the information needs of PCOS women[53]. In this study ten South Australian women aged 28 to 38 years were recruited using in-depth qualitative interviews to explore the complexity and in-process nature of meanings attached to PCOS. They found that the internet rather than physicians proved to be a most versatile and beneficial source of information source for women with PCOS when its limitations are taken into consideration. Women with PCOS need to be consulted and involved with creating the design, and assessment of quality of information about their condition, so that this is relevant to their lifestyle and they need information and guidance about how to do this to enable them to take control of their own health. Due to the

message they got from the study, they suggested that information should be provided to PCOS women with a "sample bag" of information at their diagnosis, and follow this information with a review session where the women can ask considered questions about their syndrome. This is a good example that qualitative research be used to improve service quality. Clinical guidelines are made for patients' benefit and they can be well developed only when physicians know what patients need and their expectations. With qualitative tools we our patients are telling us their need and expectations. In recent qualitative report, ten women with PCOS participated in individual, semi-structured interviews which related to the living experience in the management of their disorder and the meaning of that experience for them [54]. This study found that women with PCOS face many challenges in managing their disorder and desire to gain control, balance, and well-being through a comprehensive treatment plan. The findings have implications for health care providers in addressing quality of life issues and overall health outcomes. These researches in PCOS provide an opportunity for consumer involvement in decision-making, and development of clinical guidelines as well as directed health promotion. Moreover, given the troubles with talk between doctors and patients[55], it can offer physicians more information about patient-clinician communications so as to help patients make appropriate treatment choices[56].

4 Summary

PCOS is a heterogeneous condition and can cause psychosocial stress. Qualitative methods are suitable to understand PCOS women's experience, assess effects of complementary and alternative medicine, be a complementary to quantitative research and improve service quality. But qualitative research will only be accepted and understood if it is of good quality and rigor. The ultimate goal of researches is to help PCOS women coping with this disease and its consequences, so regardless of qualitative or quantitative study, researchers must make sure results of such studies do have use value, i.e., they can influence practice.

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Table 1: Qualitative articles concerning PCOS

| Article Title | Theory | Data collection | Journal Title | Published year |
|----------------------------------------------------------------------------------------------------------------------------|---------------|----------------------------|-------------------------------------------------------|----------------|
| The thief of womanhood': women's experience of polycystic ovarian syndrome | Phenomenology | Semi-structured Interviews | Social Science and Medicine | 2002 |
| The lived experience of women diagnosed with polycystic ovary syndrome | Phenomenology | Semi-structured Interviews | Journal of Obstetric Gynecologic and Neonatal Nursing | 2006 |
| The information needs of women diagnosed with Polycystic Ovarian Syndrome – implications for treatment and health outcomes | Not reported | Semi-structured Interviews | BMC Women's Health | 2007 |
| Managing Polycystic Ovary Syndrome: What Our Patients Are Telling Us | Phenomenology | Semi-structured Interviews | Journal of Holistic Nursing | 2011 |
| Young Women's Experiences Living with Polycystic Ovary | Phenomenology | Semi-structured Interviews | Journal of Obstetric Gynecologic | 2011 |

| | | | | |
|----------------------------------------------------------------------------------------------------------------------------------------------|---------------|----------------------------|--------------------------------------------|------|
| Syndrome | | | and Neonatal Nursing | |
| Acupuncture with manual and low frequency electrical stimulation as experienced by women with polycystic ovary syndrome: a qualitative study | Phenomenology | Semi-structured Interviews | BMC Complementary and Alternative Medicine | 2012 |

Reference

2. Rotterdam ESHRE/ASRM-Sponsored PCOS Consensus Workshop Group, "Revised 2003 consensus on diagnostic criteria and long-term health risks related to polycystic ovary syndrome (PCOS)," *Hum Reprod*, vol. 19, no. 1, pp. 41-47, 2004.
3. R. J. Norman, D. Dewailly, R. S. Legro, T. E. Hickey, "Polycystic ovary syndrome," *Lancet*, vol. 370, no. 9588, pp. 685-697, 2007.
4. Y. Li, Y. Li, Hung Yu Ng E and E. Stener-victorin et al., "Polycystic ovary syndrome is associated with negatively variable impacts on domains of health-related quality of life: evidence from a meta-analysis," *Fertil Steril*, vol. 96, no. 2, pp. 452-458, 2011.
5. S. Coffey, G. Bano, H. D. Mason, "Health-related quality of life in women with polycystic ovary syndrome: a comparison with the general population using the Polycystic Ovary Syndrome Questionnaire (PCOSQ) and the Short Form-36 (SF-36)," *Gynecol Endocrinol*, vol. 22, pp. 80-86, 2006.
6. M. J. Himelein, S. S. Thatcher, "Polycystic Ovary Syndrome and Mental Health: A Review" *Obstetrical and Gynecological Survey*, vol. 61, no. 11, pp. 723-732, 2006.
7. B. S. Snyder, "The lived experience of women diagnosed with polycystic ovary syndrome" *JOGNN*, vol. 35, no. 3, pp. 385-392, 2006
8. C. Kitzinger, J. Willmott, "'The thief of womanhood': women's experience of polycystic ovarian syndrome," *Soc Sci Med*, vol. 54, pp. 349-361, 2002.
9. N. Britten, "Qualitative research on health communication: what can it contribute?" *Patient Educ Couns*, vol. 82, pp. 384-388, 2011.
10. D. R. Krathwohl, "Methods of educational and social science research: An integrated approach," *Qual Health Care*, vol. 10, pp. 10-16, 2001.
11. C. Ratner, "Cultural psychology and qualitative methodology," New York, Lenum Press, 1997
12. J. W. Creswell, "Qualitative inquiry and research design: Choosing among five traditions" Thousand Oaks, Sage, P15, 1998.
13. J. P. Liu, "Qualitative research methodology in evidence-based Chinese medicine," Beijing, People's Medical Publishing House, P60, 2009.
14. N. K. Denzin, "Interpretive biography," Newbury Park, Sage, 1989a
15. M. Hammersley, P. E. Atkinson, "Principles in Practice," London, Routledge, 1995
16. R. Stake, "The art of case study research," Thousand Oaks, CA, Sage, 1995.
17. A. Shultz, "The phenomenology of the social world," Evanston, Northwestern University Press, 1967.
18. B. G. Glaser, A. L. Strauss, "The discovery of grounded theory," London, Weidenfeld and Nicolson, 1968.
19. A. L. Strauss, J. Corbin, "Basics of qualitative research: Grounded Theory Procedures And Techniques" Newbury Park, California, Sage, 1990
20. C. Pope, R. Campbell, "Qualitative research in obstetrics and gynaecology," *BJOG*, vol. 10, pp. 233-237, 2001.
21. B. J. Weiner, H. R. Amick, J. L. Lund and S. D. Lee et al., "Use of Qualitative Methods in Published Health Services and Management Research: A 10-Year Review," *Med Care Res Rev*, vol. 68, no. 1, pp. 3-33, 2011.

- 22.L. Martin, "Questioning the use value of qualitative research findings," *Nursing Philosophy*, vol. 13, pp. 112–125, 2012
- 23.M. David, C.D. Sutton, "Social Research: An Introduction," London, Sage, 2011.
- 24.R. S. Barbour, "Checklists for improving rigour in qualitative research: a case of the tail wagging the dog?" *BMJ*, vol. 322, pp. 1115-1117, 2001.
- 25.C. Seale, "The quality of qualitative research," London, Sage, 1999.
- 26.W. Stiles, "Evaluating qualitative research," *Evid Based Ment Health*, vol. 2, pp. 99-101, 1999.
- 27.Cochrane Qualitative Research Methods Group, "10 Questions to help you make sense of Qualitative Research," In: *Book 10 Questions to help you make sense of Qualitative Research* City, 2000.
- 28.R. Power, "Checklists for improving rigour in qualitative research. Never mind the tail (checklist), check out the dog (research)," *BMJ*, vol. 323, no. 7311, pp. 514-515, 2001.
- 29.B. Williams, "Checklists for improving rigour in qualitative research. Including personal reflections might help" *BMJ*, vol. 323, no. 7311, pp. 515, 2001.
- 30.C. Borreani, G. Miccinesi, C. Brunelli, M. Lina, "An increasing number of qualitative research papers in oncology and palliative care: does it mean a thorough development of the methodology of research?" *Health and Quality of Life Outcomes*, vol. 2, no. 7, 2004.
- 31.P. Salmon, "Assessing the quality of qualitative research," *Patient Education and Counseling* vol. 90, pp. 1-3, 2013.
- 32.H. Teede, A. Deeks, L. Moran, "Polycystic ovary syndrome: a complex condition with psychological, reproductive and metabolic manifestations that impacts on health across the lifespan," *BMC Medicine*, vol. 8, no. 41, 2010.
- 33.A. A. Deeks, M. E. Gibson-Helm, H. J. Teede, "Anxiety and depression in polycystic ovary syndrome: a comprehensive investigation," *Fertil Steril* vol. 93, pp.2421-2423, 2010.
- 34.T. R. Weiss, S. M. Bulmer, "Young Women's Experiences Living with Polycystic Ovary Syndrome," *J Obstet Gynecol Neonatal Nurs*, vol. 40, pp. 709-718, 2011.
- 35.C. Pope, N. Mays, "Reaching the parts other methods cannot reach: an introduction to qualitative methods in health and health services research," *BMJ* vol. 311, pp. 42-45. 1995.
- 36.E. S. Sills, M. Perloe, M. J. Tucker and Kaplan CR et al., "Diagnostic and treatment characteristics of polycystic ovary syndrome: descriptive measurements of patient perception and awareness from 657 confidential self-reports" *BMC Womens Health*, vol. 1, no. 3, 2001
- 37.D. M. Eisenberg, R. C. Kessler, C. Foster and F. E. Norlock, "Unconventional medicine in the United States. Prevalence, costs, and patterns of use," *N Engl J*, vol. 328, pp. 246–252, 1993.
- 38.N. Raja-Khan, E. Stener-Victorin, X. K. Wu, R. S. Legro, "The physiological basis of complementary and alternative medicines for polycystic ovary syndrome," *Am J Physiol Endocrinol Metab*, vol. 301, pp. 1-10, 2011.
- 39.T. J. Kaptchuk, "The placebo effect in alternative medicine: can the performance of a healing ritual have clinical significance?" *Ann Intern Med*, vol. 136, pp. 817–825, 2002.
- 40.G. T. Lewith, P. J. White, T. J. Kaptchukz, "Developing a Research Strategy for Acupuncture," *Clin J Pain*, vol. 22, pp. 632–638, 2006.
- 41.A. Mitchell, M. Cormack, "The therapeutic relationship in complementary health care," Edinburgh, Churchill Livingstone, 1998.
- 42.A. Billhult, E. Stener-Victorin. "Acupuncture with manual and low frequency electrical stimulation as experienced by women with polycystic ovary syndrome: a qualitative study," *BMC Complementary and Alternative Medicine* vol. 12, no. 32, 2012.
- 43.J. Mason, "Linking qualitative and quantitative data analysis. In A. Bryman & R.G. Burgess (Eds.), *Analyzing qualitative data*," London, Routledge, pp. 89-110.
- 44.R. S Barbour, "Mixing qualitative methods: quality assurance or qualitative quagmire?" *Qual Health Res*, vol. 8, no. 3, pp. 352-361, 1998.
- 45.W. L. Miller, B. F. Crabtree, "Clinical research," *Handbook of Qualitative Research* 2nd edition. Edited by: Denzin N K and Lincoln Y S. Thousand Oaks, Sage Publications, pp. 607-631, 2001.

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 research,” *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, “Incorporating qualitative approaches is the path to adequate understanding of the psychosocial impact 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 Reprod* 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 study,” *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 a randomized, double-blinded, sham-controlled trial

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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 EA on menstrual condition of young girls with PCOS by controlled with sham acupuncture. Seventy-two young girls with PCOS between 18 and