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The acupuncture treatment for postmenopausal hot flushes (Acuflash) study: traditional Chinese medicine diagnoses and acupuncture points used, and their relation to the treatment response

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ABSTRACT

Introduction: The multicentre, pragmatic, randomised controlled Acuflash study evaluated the effect of traditional Chinese medicine (TCM) acupuncture on postmenopausal vasomotor symptoms and health-related quality of life. It concluded that use of acupuncture in addition to self-care can contribute to a clinically relevant reduction of hot flushes and increased health-related quality of life. This article reports on the TCM syndrome diagnoses and acupuncture points used and their relation to the treatment response, and on treatment reactions and adverse events.

Methods: The acupuncture group (n = 134) received 10 acupuncture treatment sessions and advice on self-care; the control group (n = 133) received advice on self-care only. The study acupuncturists met the current membership criteria of the Norwegian Acupuncture Society, and had at least 3 years' experience of practising TCM acupuncture. They were free to diagnose and select acupuncture points for each participant, after initial discussion.

Results: Fifty per cent of the participants in the acupuncture group were diagnosed with Kidney *Yin Xu* as their primary TCM syndrome diagnosis. No statistically significant differences were demonstrated between the syndrome groups regarding the distribution of responders and non-responders, nor regarding the change in health-related quality of life scores. A core of common acupuncture points (SP6, HT6, KI7, KI6, CV4, LU7, LI4, and LR3) were used in all the syndromes, and in addition multiple idiosyncratic points. Core point selection and frequency of use did not differ between responders and non-responders. No serious adverse events were reported.

Conclusion: Factors other than the TCM syndrome diagnoses and the point selection may be of importance regarding the outcome of the treatment.

Acupuncture is one of the most frequently used complementary therapies in Norway. In two recent surveys, 28% reported lifetime use, and 10.8% reported use within the previous year.^{1,2} In the 2002 National Health Interview Survey in the USA, 4.1% reported lifetime use and 1.1% reported use of acupuncture within the preceding year.³ The theoretical framework, understanding and practice of acupuncture vary considerably. Traditional Chinese medicine (TCM) acupuncture is based on the traditional Chinese medical theories,⁴ whereas "Western medical" acupuncture draws on the principles of established medical physiology.⁵

Although TCM is one of the oldest healing systems in the world, it is a fully institutionalised part of Chinese healthcare, accounting for 10–20% of healthcare in China in 2006.⁶ Acupuncture is considered safe in the hands of competent practitioners.^{7,8}

A National Institutes of Health Consensus Development Panel on Acupuncture has recommended that future research should place an emphasis on "studies that examine acupuncture as used in clinical practice and that respect the theoretical basis for acupuncture therapy".⁹ Acupuncture researchers have suggested the use of a pragmatic trial design to answer practical questions.¹⁰ In the Acuflash study we aimed to estimate the effectiveness of "real life" acupuncture treatment on postmenopausal hot flush frequency and intensity and health-related quality of life as measured by the Women's Health Questionnaire (WHQ).¹¹ Hot flush frequency decreased by 5.8/24 h in the acupuncture group (n = 134) and 3.7/24 h in the control group (n = 133), a difference of 2.1 (p < 0.001). Hot flush intensity decreased by 3.2 units (1–10 visual analogue scale) in the acupuncture group and 1.8 units in the control group, a difference of 1.4 (p < 0.001). The acupuncture group experienced statistically and clinically significant improvements in the vasomotor (p < 0.001), sleep (p = 0.002) and somatic symptoms (p = 0.011) dimensions of the WHQ, compared with the control group.¹²

Previous research has suggested that, among patients with recurrent cystitis, those with TCM diagnosis of Kidney fare better than patients with other diagnoses.¹³ The objective of this paper is to report on the TCM syndrome diagnoses and the acupuncture points used in the Acuflash study. We report on secondary research questions: do TCM diagnoses predict the overall treatment response, and are patients with different diagnoses likely to experience a differential response in their symptoms? We also report on the relation between the acupuncture points used and the treatment response, on other treatment interventions used by the acupuncturists, and on treatment reactions and adverse events.

METHODS

The study was a multicentre (Tromsø, Bergen and Oslo), pragmatic, randomised controlled trial (RCT) with two parallel arms, conducted in 2006/2007. It was approved by the Norwegian

Data Inspectorate, the Norwegian Biobank Registry and the Regional Committee for Medical Research Ethics.¹¹

Altogether 267 women were included in the study. Mean (SD) age at inclusion was 53.8 (4.4) years, and mean (SD) age at menopause was 48.9 (3.7) years. For further sample characteristics, see table 1. The participants were stratified by centre and thereafter block randomised (random block size of four, six or eight) to receive additional acupuncture or not receive additional acupuncture. Block randomisation (organising study participants into blocks and randomising within each block) was used to ensure close balance of the numbers in each group at any time during the trial.

Practitioners of TCM acupuncture

The 10 study acupuncturists were trained in TCM acupuncture; nine were graduates from the “Akupunkturhøyskolen”, a school located in Oslo, offering a Bachelors degree in TCM acupuncture. Hence, the TCM acupuncture approach tested was TCM acupuncture as taught in Norway. They met the current

membership criteria of the Norwegian Acupuncture Society (NAFO) (2500 h of training), and had at least 3 years' experience of practising TCM acupuncture. They were suggested as study acupuncturists by NAFO. Two acupuncturists were teachers at the “Akupunkturhøyskolen”. There were four acupuncturists in Oslo, three in Bergen and three in Tromsø, all practising in private clinics. Before the start of the study, all the acupuncturists participated in a group meeting with the researchers to discuss the expected TCM diagnoses and the relevant acupuncture points.

Intervention

Both groups received a one-page leaflet with information about self-care strategies to relieve menopausal symptoms. This information included advice about sufficient sleep and rest, reduction of physical and psychological stress, regular exercise, healthy food and limited tobacco smoking and alcohol intake.

The participants in the acupuncture group had to receive 10 acupuncture sessions over 12 weeks. The minimum number of

Table 1 Baseline characteristics of the study participants in the Acufash study

Characteristics	Acupuncture group (n = 134)	Self-care group (n = 133)
Mean (SD) age at randomisation, years	53.5 (4.4)	54.1 (3.7)
Mean (SD) age at menopause, years	49.3 (4.0)	48.6 (4.9)
Mean (SD) baseline hot flush frequency/24 h	12.0 (4.3)	13.1 (4.9)
Mean (SD) baseline hot flush intensity (0–10)	6.7 (2.0)	7.1 (1.7)
Mean (SD) self-reported weight, kg	71 (12)	70 (12)
Mean (SD) self-reported height, cm	167 (6)	168 (6)
Years of education, n (%)		
≤ 10	60 (44.8)	64 (48.1)
11–13	12 (9.0)	13 (9.8)
14–17	31 (23.1)	18 (13.5)
> 17	31 (23.1)	36 (27.1)
Missing	0	2 (1.5)
Previous use of HRT, n (%)	71 (53.0)	61 (45.9)
Previous use of acupuncture, n (%)	86 (64.2)	85 (63.9)
Expect acupuncture relieves hot flushes, n (%)		
Yes	80 (59.8)	68 (51.1)
No	0 (0)	0 (0)
Uncertain	53 (39.5)	61 (45.9)
Missing	1 (0.7)	4 (3.0)
Self-reported health, n (%)		
Very bad	2 (1.5)	3 (2.3)
Bad	31 (23.1)	37 (27.8)
Good	78 (58.2)	74 (55.6)
Excellent	22 (16.4)	16 (12.3)
Missing	1 (0.7)	3 (2.3)
Sleep problems, n (%)		
Never	32 (23.9)	33 (24.9)
1–3 nights per month	22 (16.4)	19 (14.3)
Once a week	14 (10.4)	12 (9.0)
> Once a week	66 (49.3)	66 (49.6)
Missing	0	3 (2.3)
Tobacco smoking, n (%)		
Present	34 (25.4)	39 (29.3)
Past	67 (50)	53 (39.8)
Never	33 (24.6)	39 (29.3)
Missing	0	2 (1.5)
Teetotaler, n (%)	6 (4.5)	6 (4.5)
Mean (SD) baseline WHO score		
Vasomotor symptoms domain	0.98 (0.09)	0.98 (0.10)
Sleep problems domain	0.57 (0.33)	0.61 (0.32)
Somatic symptoms domain	0.48 (0.26)	0.55 (0.24)

HRT, hormone replacement therapy; WHO, Women's Health Questionnaire.

sessions accepted as “per protocol” was six. The acupuncturists were asked to use diagnostic methods according to the principles of TCM, and diagnose TCM syndromes associated with the menopausal symptoms. Only the participants in the acupuncture group were diagnosed. After the initial diagnosis, each participant had to be treated with points selected according to the syndrome diagnosis. The acupuncturists were free to add individualised points to treat other symptoms related to the menopause (ie, those included on the WHQ such as depression, anxiety, insomnia), but not unrelated symptoms. Point location was not standardised, but left to the acupuncturists to decide. They could use moxibustion (warmed needles) if indicated. Herbal treatment was not allowed during the study. *De qi* (a characteristic dull and numb sensation) had to be obtained, and needle manipulation with even, reducing or re-enforcing methods could be used.

Outcomes

The primary endpoint was change in mean hot flush frequency and intensity per 24 h. Participants were defined as responders if they gained a 50% or greater reduction in hot flush frequency. Secondary endpoint was health-related quality of life, measured by the WHQ.¹⁴ The questionnaire consisted of 36 items covering the following nine domains: depressed mood, somatic symptoms, anxiety/fears, vasomotor symptoms, sleep problems, sexual behaviour, menstrual symptoms, memory/concentration, and attractiveness. Within each domain, an average score between 0 and 1 was calculated, where 0 is an indicator of “good health status” and 1 is an indicator of “poor health status”.^{15 16} We selected the vasomotor symptoms, sleep problems and somatic symptoms domains for the present analysis because the participants in the acupuncture group reported significant improvements in these domains compared with the control group.

Statistical analysis

SPSS version 15.0 (SPSS Inc., Chicago, Illinois, USA) was used for all statistical analyses. The subgroup analysis was per protocol. Differences in change between groups were evaluated with two-sample t tests and analysis of variance, and χ^2 tests were used for categorical variables. Two-sided $p < 0.05$ was considered statistically significant.

Data collection form

The data collection form prompted for each of nine specific TCM syndrome diagnoses, as listed in table 3. The consensus of the group meeting between acupuncturists and researchers before the start of the study was to list the syndrome patterns described by Maciocia as the main causes of menopausal problems,¹⁷ with the addition of Liver Qi Stagnation and Stomach Heat. In addition, practitioners were free to diagnose any other syndrome pattern, without any restrictions. They were asked to record primary and secondary diagnoses at each session. Characteristic symptoms and signs in the most frequently used syndrome diagnoses are listed in table 2.

At each session, practitioners were asked to record acupuncture points used, and indicate laterality of needling, needle technique, whether *de qi* was obtained, and reasons for eventual change of acupuncture points from the previous treatment session. They were asked to record the use of moxa and use of other interventions (massage, cupping, electro-acupuncture, herbs or other). Finally, they had to record the prescription of

home-based self-treatment such as specific physical exercises, tai chi, yoga, self-massage, relaxation exercises or other.

If the acupuncturist gave advice on facilitating and supporting lifestyle changes such as dietary advice (low dairy, avoid wine and spirits, low wheat, stop/reduce coffee, ensure food is warm and cooked) or non-dietary advice (more exercise, stop/reduce smoking, more rest, protection from cold and damp, general support and empowerment or other), this had to be recorded.

The acupuncturists were asked to record treatment reactions and adverse events. Treatment reactions were reactions which could be positive indicators of treatment effect, but could be experienced as adverse by acupuncture-naïve participants. Treatment reactions were communicated spontaneously by the patient during or after treatment, or at the next visit (recorded under the headings light-headedness, energised, tired, relaxed, hungry, drowsy, other). Adverse events such as fainting, forgotten needle, fit (convulsions), broken needle, skin reactions, moxa burn, unacceptable bruising, pneumothorax, unacceptable bleeding, infection, unacceptable pain at a point from needling, unacceptable worsening of symptoms or other, had to be recorded. These events were listed, and the acupuncturists could tick the appropriate box.

In addition to the reporting carried out by the acupuncturist, the women in the acupuncture group were asked in the questionnaires they filled in at weeks 8 and 12 if they had experienced any of the following treatment reactions during the study: temporary worsening of hot flushes, dizziness, tiredness, increased energy, more relaxed, hungrier.

RESULTS

Between February 2006 and March 2007, 535 women contacted the study coordinators, and 267 met the inclusion criteria.¹² They were randomised to self-care plus acupuncture ($n = 134$) or self-care only ($n = 133$). Altogether 19 women (7%) dropped out: 16 in the control group and three in the acupuncture group. A total of 131 participants in the acupuncture group were included in the final analyses. The study groups were well balanced with respect to background characteristics at baseline (table 1).

At the first acupuncture treatment session, 127 participants received an initial primary syndrome diagnosis and 106 participants received an initial secondary syndrome diagnosis (table 3). During the treatment sessions, the primary syndrome was revised once in 11 participants, and twice in one participant. The secondary syndrome was revised once in 14 participants, twice in three, three times in three, and four times in one participant. Fifty per cent of the participants were diagnosed with Kidney *Yin Xu* as their primary syndrome (table 3).

Among the secondary syndromes, Liver Qi stagnation was the most prevalent diagnosis, with 19 per cent of the participants. The distribution of responders/non-responders and change in WHQ scores among primary syndromes are shown in tables 4 and 5. The distribution of responders and non-responders and change in WHQ scores did not differ statistically between the primary syndrome groups.

Altogether 131 participants received a total of 1285 treatment sessions. Of these participants, 123 received 10 treatment sessions, two received nine sessions, three received eight sessions, one received seven sessions and two received three sessions. The mean number of treatments per participant was 9.8, and the median number of points stimulated per treatment session was 6.0 (SD 2.8, range 9). A total of 8599 acupuncture

Table 2 Characteristic symptoms and signs in the most frequently used syndrome diagnoses in the Acuflyash study

Syndromes	Symptoms and signs
KI <i>Yin Xu</i> empty heat	Night sweating; hot flushes; restless; anxious; dry hair, skin, mouth; deep weak pulse; tongue red without coating
KI <i>Yang Xu</i> empty cold	Hot flushes but cold hands and feet; night sweating (early morning); tiredness; low energy; depressed; deep pulse; tongue pale
KI <i>Yin</i> and KI <i>Yang Xu</i>	Hot flushes but cold hands and feet; night sweating; frequent pale urination; flushed around neck when talking; tongue pale or red
KI and LR <i>Yin Xu</i> with LR yang rising	Hot flushes; irritability; dizziness; blurred vision; tongue red without coating
KI and HT not harmonised	Hot flushes; palpitations; insomnia; mental restlessness; poor memory; tongue red without coating, redder tip

point stimulations were performed during the study, and a total of 104 different acupuncture points were used once or more. The most commonly used acupuncture points are presented in fig 1 and table 6.

In the acupuncture group, 67 participants were responders, and 64 participants were non-responders. A total of 4217 point stimulations were performed among responders, and 4382 among non-responders. The 10 most frequently used points were identical among responders and non-responders (table 6), and these 10 points constituted two-thirds of the total number of point stimulations throughout the study. The distribution of points used according to syndrome diagnosis is shown in table 7. The eight most frequently used acupuncture points in total were among the 13 most frequently used points in every syndrome group.

Moxa was used in one treatment session during the study. Cupping, electro-acupuncture and Chinese herbs were not used at all. One of the 10 acupuncturists used massage in addition to needling in altogether 191 treatment sessions. Due to a significant number of missing values, we do not report on acupuncture point laterality, needling technique, reasons for eventual change of acupuncture points or if *de qi* was obtained.

The acupuncturists advised 13 participants to use massage as a home-based self-treatment, six participants to use relaxation techniques, and one was advised to use tai chi. They advised five participants to use a low dairy diet, two to use a low wheat diet, nine to ensure the food was warm and cooked, five to quit tobacco smoking, 11 to take more exercise, nine to take more rest, seven to avoid alcohol, and 15 to reduce coffee drinking. One participant was advised protection from cold and damp. Eighty-four participants were not given any of these recommendations.

Table 3 Primary and secondary traditional Chinese medicine syndromes on initial diagnoses in the Acuflyash study

Syndromes	n as primary (%)	n as secondary (%)
KI <i>Yin Xu</i> empty heat	67 (50)	17 (13)
KI <i>Yang Xu</i> empty cold	22 (16)	10 (7)
KI <i>Yin</i> and KI <i>Yang Xu</i>	11 (8)	8 (6)
KI and LR <i>Yin Xu</i> with LR yang rising	10 (8)	12 (9)
KI and HT not harmonised	14 (10)	18 (13)
Accumulation of phlegm and stagnation of <i>Qi</i>	1 (1)	12 (9)
LR <i>Qi</i> stagnation	0 (0)	25 (19)
Stomach heat	2 (2)	3 (2)
Stasis of blood	0 (0)	1 (1)
Missing	3 (2)	3 (2)
No syndrome	4 (3)	25 (19)
Total	134 (100)	134 (100)

Treatment reactions as reported by the acupuncturists and self-reported by the participants are shown in table 8. The acupuncturists reported one or more treatment reactions for 76 participants, and 120 participants self-reported one or more treatment reactions.

The distribution of responders and non-responders and change in health-related quality of life did not differ between the groups that were reported to experience these treatment reactions by the acupuncturists, and those that were not. Regarding the self-reported treatment reactions, it was an equal number of responders and non-responders within the groups experiencing these symptoms. However, the mean reduction in the WHQ vasomotor symptoms domain score from baseline to week 12 was significantly larger in the groups that had felt more relaxed and experienced increased energy, and the mean reduction in the WHQ sleep domain score was significantly larger in the group that had felt more relaxed (table 9). Change in health-related quality of life did not differ between those experiencing and not experiencing the other treatment reactions.

No fainting, convulsions or bleeding were reported during the treatment sessions. One skin reaction and one unacceptable bruising were reported, as were five episodes of unacceptable needling pain. Two episodes with a forgotten needle were reported, but no broken needle, moxa burn, pneumothorax or infections were reported.

DISCUSSION

In this study of acupuncture for menopausal hot flushes, seven different primary TCM syndromes were diagnosed (table 3), and 50 per cent of the participants in the study were diagnosed with Kidney *Yin Xu*. Distribution of responders and non-responders and change in health-related quality of life did not differ between the TCM syndromes. The most frequently used acupuncture points were identical among responders and non-responders, and the eight most frequently used acupuncture

Table 4 Distribution of responders and non-responders among primary syndromes in the Acuflyash study

Primary syndromes	n	Responder	Non-responder
KI <i>Yin Xu</i> empty heat	67	33	34
KI <i>Yang Xu</i> empty cold	22	14	8
KI <i>Yin</i> and KI <i>Yang Xu</i>	11	5	6
KI and LR <i>Yin Xu</i> with LR yang rising	10	5	5
KI and HT not harmonised	14	6	8
Other syndromes	3	1	2
No primary syndrome	4	3	1
Total	131	67	64

Table 5 Change in Women's Health Questionnaire (WHQ) scores in the vasomotor symptoms, sleep problems and somatic symptoms domains stratified on primary syndromes in the Acuflysh study

Primary syndromes	Change in WHQ vasomotor domain	Change in WHQ sleep domain	Change in WHQ somatic domain
KI Yin Xu empty heat (n = 67)	-0.32	-0.17	-0.10
KI Yang Xu empty cold (n = 22)	-0.15	-0.20	-0.14
KI Yin and KI Yang Xu (n = 11)	-0.23	-0.03	-0.10
KI and LR Yin Xu with LR yang rising (n = 10)	-0.20	-0.23	-0.31
KI and HT not harmonised (n = 14)	-0.29	-0.17	-0.08

points in total were among the 13 most frequently used points among all TCM syndromes. No serious adverse events were reported.

The primary goal for the TCM diagnostic process is to obtain a TCM syndrome diagnosis. This is a procedural process that may open up for constructive dialogue between the acupuncturist and the patient. It can introduce the patients for ways to reflect and understand their own disease/imbalance.

The diagnostic syndromes in TCM are clusters of different symptoms and signs. Symptom clusters were used to diagnose most diseases in Western medicine before the twentieth century, and Western medicine still uses symptom diagnoses when the biological mechanisms are not well understood.¹⁸ The concept of symptom clusters has gained new interest in Western medicine, and a symptom cluster has been defined as a "stable group of two or more concurrent symptoms that are related to each other and independent of other symptoms or symptoms clusters".¹⁹ The TCM diagnostic process divides individuals diagnosed with one biomedical diagnosis into several subgroups, each with a characteristic symptom cluster or syndrome. This process may contribute to new insight, for instance by identifying subgroups of individuals responding particularly well to an intervention or treatment.

The TCM syndrome diagnosis, defined by symptoms and signs, is guiding the treatment.⁶ Fifty per cent of the participants in the study were diagnosed with Kidney Yin Xu. According to a widely used TCM textbook by Maciocia, a Kidney deficiency is always at the root of menopausal problems.¹⁷ Zell *et al* found that "practitioners of TCM who diagnose postmenopausal women with vasomotor symptoms

are likely to make a diagnosis that includes Kidney Yin deficiency".²⁰ However, Scheid defines TCM as "that interpretation of Chinese medical practice that is presented to us in contemporary Chinese medical textbooks, emerging in the late 1950s".²¹ Menopausal problems, as such, have not been described in ancient Chinese medical texts, but a TCM approach towards menopausal symptoms was "constructed" by textbook authors in the 1960s for use in textbooks suitable for a Western audience.^{21, 22} According to Scheid, the TCM understanding of menopausal symptoms, like TCM itself, is a direct consequence of Chinese medical modernisation. Practitioners in contemporary China have, in addition to the above-mentioned modern textbooks, other sources of information to draw on, such as direct access to the classical medical texts and personal transmission of knowledge from teachers.²¹ These sources are not readily available in the West, and may suggest different syndrome patterns and point selection for the treatment of menopausal symptoms.²¹ Thus, the current interpretation of menopausal symptoms as mainly a result of Kidney deficiency is only one of several possible understandings, and the correct TCM diagnoses for menopausal vasomotor symptoms remain unclear. The TCM acupuncture practised in our study was mostly based on theories and principles from the above-mentioned textbooks from the 1960s and a more recent interpretation by Maciocia.¹⁷

The validity and reliability of the TCM diagnostic process has been questioned, as has the inter-rater reliability.²³ A study showed that TCM diagnosis and treatment recommendations for specific patients with chronic low back pain vary widely across practitioners,²⁴ as did a study assessing the variability in the TCM diagnoses among patients with rheumatoid arthritis.²⁵ Therefore, the validity and reliability of the diagnostic process in the present study may be low, resulting in "wrong" diagnoses in some or many cases. In addition, as discussed earlier, the correct TCM syndrome patterns for menopausal vasomotor symptoms remain unclear. These facts may obviously affect the study results, which must be interpreted with this in mind.

When stratifying the results on syndromes, we found the highest proportion of responders among the participants diagnosed with Kidney Yang Xu empty cold; 14 participants were responders and eight non-responders. This is comparable to what was found in a study of acupuncture for recurrent cystitis by Alraek and Baerheim.¹⁵ However, our study was not powered to identify differences between the syndrome groups. The differences regarding the ratio of responders to non-responders or change in WHQ scores between the syndrome groups were not statistically significant. Hence, being diagnosed with a certain syndrome was of no prognostic value for patients treated with acupuncture for menopausal complaints in this study. The acupuncture points used in this syndrome group did not differ from those used in the other syndrome groups, nor did the points differ between responders and non-responders.

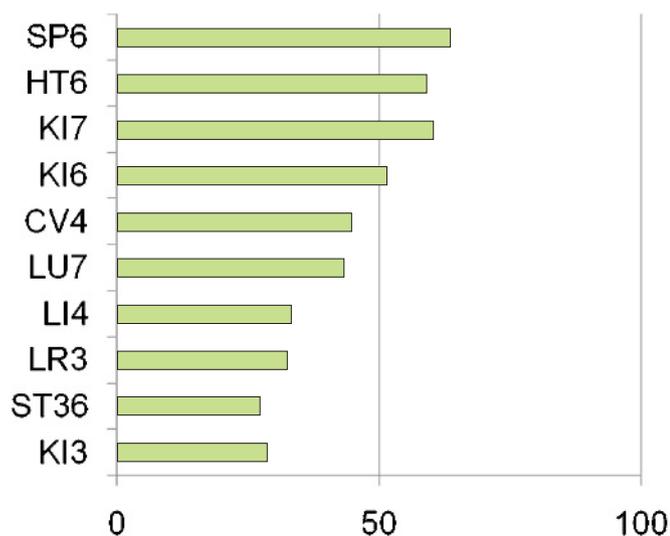
**Figure 1** Most commonly used acupuncture points in the Acuflysh study*. *Usage as percentage of total number of treatments (n = 1285).

Table 6 Acupuncture points used in the Acufash study

Responders* (n = 67)				Non-responders* (n = 64)			
Acupuncture points	Number of stimulations	Per cent of total	Cumulative per cent	Acupuncture points	Number of stimulations	Per cent of total	Cumulative per cent
SP6	424	10.1	10.1	SP6	390	8.9	8.9
HT6	419	9.9	20.0	KI6	368	8.4	17.3
KI7	416	9.9	29.9	KI7	359	8.2	25.5
KI6	291	6.9	36.8	HT6	336	7.7	33.2
CV4	262	6.2	43.0	CV4	313	7.1	40.3
LU7	260	6.2	49.1	LU7	293	6.7	47.0
LI4	199	4.7	53.9	LI4	227	5.2	52.2
LR3	196	4.6	58.5	LR3	219	5.0	57.2
ST36	177	4.2	62.7	KI3	193	4.4	61.6
KI3	173	4.1	66.8	ST36	171	3.9	65.5
GV20	115	2.7	69.5	GB34	119	2.7	68.2
LI11	109	2.6	72.1	PC6	96	2.2	70.4
PC6	106	2.5	74.6	GV20	95	2.2	72.5
CV12	94	2.2	76.9	CV12	85	1.9	74.5
SP4	91	2.2	79.0	LI11	79	1.8	76.3
LR8	78	1.8	80.9	LR8	64	1.5	77.7
GB34	73	1.7	82.6	SP4	62	1.4	79.2
68 other points†	734	17.4	100.0	65 other points‡	913	20.8	100.0
Total	4217				4382		

The eight most frequently stimulated acupuncture points in total are shown in bold.

*Responder: $\geq 50\%$ reduction in hot flush frequency, non-responder: $< 50\%$ reduction of hot flush frequency.

†32 points were stimulated 59–10 times, 36 points were stimulated < 10 times.

‡26 points were stimulated 59–10 times, 39 points were stimulated < 10 times.

The participants in the control group were not diagnosed according to TCM; hence we were not able to assess whether certain TCM syndrome patterns were generally more responsive regardless of whether acupuncture was provided.

The distribution of points used according to syndrome diagnosis is shown in table 7. Although the acupuncturists have applied different TCM diagnostic syndromes, eight “core” acupuncture points were used in all syndromes, with some differences regarding frequency of use. A possible reason for the application of eight “core” points in all syndromes may be that the points were used for “symptomatic” treatment of hot flushes, rather than addressing the TCM syndromes. However, the acupuncturists were asked to select acupuncture points and treat according to the syndrome diagnoses, and the majority of

“core” points are described in a TCM textbook¹⁷ as indicated for KI Xu (Kidney deficiency) syndromes (SP6, KI3 – nourish the Kidneys, KI7 – tonifies Kidney Yang, LU7 and KI6 – tonifies the Kidneys, CV4 – tonifies Kidney Yang). Thus, a TCM syndrome differentiation may not result in major differences regarding the selection of acupuncture points when treating women with postmenopausal vasomotor symptoms.

There was no difference between responders and non-responders regarding the acupuncture points used or their frequency of use. The point combination KI7–HT6 was frequently used throughout the study, regardless of the syndrome diagnosis. This point combination is described in the literature as indicated for the treatment of menopausal complaints, or more specifically to stop night sweating,¹⁷ and

Table 7 Acupuncture points used according to syndrome diagnosis in the Acufash study*

KI Yin Xu empty heat (n = 69)		KI Yang Xu empty cold (n = 22)		KI Yin and KI Yang Xu (n = 11)		KI and LR Yin Xu with LR yang rising (n = 10)		KI and HT not harmonised (n = 14)	
Acupuncture points*	No of stimulations†	Acupuncture points	No of stimulations	Acupuncture points	No of stimulations	Acupuncture points	No of stimulations	Acupuncture points	No of stimulations
SP6	6.3	SP6	7.1	KI7	6.5	CV4	6.0	CV4	7.8
KI7	5.7	KI7	6.5	HT6	5.4	LR8	5.0	KI6	7.6
HT6	5.5	HT6	6.4	SP6	5.2	HT6	4.7	KI7	7.1
KI6	5.1	KI6	5.0	LR3	3.5	KI7	4.0	SP6	7.1
CV4	4.3	LU7	4.6	CV4	3.4	LR3	3.9	LU7	6.9
LU7	4.1	LI4	2.6	KI3	3.3	KI6	3.8	HT6	6.6
KI3	3.7	CV4	2.4	LU7	3.3	LI11	3.8	CV15	4.1
LI4	3.6	ST36	2.3	KI6	3.0	SP4	3.8	LR3	3.8
ST36	3.3	PC6	2.1	CV12	1.8	LI4	3.5	LI4	3.7
LR3	3.3	LR3	2.0	GV20	1.7	GV20	3.4	GV20	2.3
GB34	1.9	SP4	1.8	LI4	1.6	PC6	3.1	KI3	1.9
LI11	1.5	KI3	1.7	ST36	1.6	LU7	3.0	SP4	1.9
CV12	1.3	CV12	1.5	KI10	1.5	SP6	2.9	HT7	1.9
66 other points	15.1	34 other points	13.3	32 other points	15.8	28 other points	24.5	32 other points	18.4

*The eight most frequently stimulated acupuncture points in total are shown in bold.

†Mean number of stimulations per participant.

Table 8 Number of participants in the acupuncture group (n = 134) experiencing treatment reactions as reported by acupuncturists and self-reported by participants

Treatment reactions	More relaxed	More energy	More tired	More hungry	Light-headed†	Drowsy†	Temporary worsening of hot flushes*	Dizziness*
Reported by acupuncturists	44	39	30	7	11	7	–	–
Self-reported	86	76	53	24	–	–	26	13

*The acupuncturists were not asked to report these treatment reactions.

†The participants were not asked to report these treatment reactions.

may have been used as “symptomatic” treatment in this study. The points selected and their frequency of use were almost similar among responders and non-responders. Hence, when treated with almost identical points, 50% of the participants in this study were responders, and 50% were non-responders. A more flexible approach, resulting in the selection of other acupuncture points for the treatment of women in the non-responder group, might have produced other results. Another possible interpretation of these results may be that factors other than the acupuncture point selection are of importance for the outcome of the treatment.

The 10 most frequently used acupuncture points constituted two-thirds of all point stimulations, and a total of 104 different acupuncture points were used once or more. Hence, the acupuncturists used a “core” of common acupuncture points in all syndromes and in addition to these a wide selection of idiosyncratic points. These findings correspond with the findings by Napadow *et al*, studying the points used in two acupuncture clinics in China.²⁶ When comparing the point selection in this study with the points used in other studies evaluating acupuncture for menopausal symptoms,^{27–32} the only point in common between all the studies was SP6. The agreement between the eight most frequently stimulated points in this study and the basic acupuncture points used in the studies cited was moderate, and varied between two of nine points,^{28–31} and two of three³⁰ and four of six.²⁷

A TCM diagnostic syndrome differentiation, leading to an appropriate selection of traditional acupuncture points, is considered mandatory in the practice of TCM.⁶ However, these postulates have not been confirmed in clinical studies.⁶ Cochrane reviews show that acupuncture is an effective treatment for preventing headaches, but for migraine, studies show similar results in groups receiving “true” acupuncture and groups receiving “sham” acupuncture (“interventions mimicking ‘true’ acupuncture/‘true’ treatment, but deviating in at least one aspect considered important by acupuncture theory, such as skin penetration or correct point location”).^{33–34} Superficial needling in non-acupuncture points (“minimal acupuncture”), often used as a placebo control in RCTs of acupuncture, most

likely has physiological and clinical effects.³⁵ In the Acuflex study, a “core” group of acupuncture points was used for all the TCM diagnostic syndromes, rendering a clinically and statistically significant effect.¹² However, we do not know whether these acupuncture points were superior to treat menopausal symptoms, nor if the acupuncture “dose” was optimal. The contribution of all the idiosyncratic acupuncture points used a few times during the study remains unknown. Needle location may not be as relevant as generally thought.

There is no agreement on what is adequate acupuncture point stimulation or “dose”.³⁶ In a systematic review of acupuncture for knee pain, adequate acupuncture was defined as “consisting of at least six treatments, at least one per week, with at least four points needed for each painful knee for at least 20 minutes, and either needle sensation (*de qi*) achieved in manual acupuncture, or electrical stimulation of sufficient intensity to produce more than minimal sensation”.³⁷ The acupuncture treatment in the present study satisfied these requirements.

The participants who felt more relaxed after treatment experienced a larger decrease in the WHQ vasomotor symptoms and sleep problems domains, and the participants feeling more energised experienced a larger decrease in the WHQ vasomotor symptoms domain. Consequently, both feeling relaxed and energised after acupuncture treatment is associated with a positive response on acupuncture therapy for menopausal symptoms. However, there were equal numbers of responders and non-responders within the groups experiencing these treatment reactions.

Acupuncture is described as a safe procedure, with few adverse events occurring among trained practitioners.^{7–8, 39} In this study, five episodes with unacceptable pain during needle insertion, one episode with unacceptable bruising, two episodes with a forgotten needle and one skin reaction were reported. Altogether nine events classified as side effects were reported, and a total of 1285 treatments were performed during the study. Hence, the frequency of adverse events per treatment was less than one per cent, confirming that TCM acupuncture is a safe procedure. No serious adverse events were reported.

Table 9 Change in Women’s Health Questionnaire (WHQ) scores in groups reporting treatment reactions at 12 weeks

WHQ dimensions	More relaxed* (n = 86)				Increased energy* (n = 76)			
	Yes	No	Mean difference	p Value	Yes	No	Mean difference	p Value
Vasomotor symptoms	–0.36 (0.40)	–0.13 (0.31)	–0.23	0.004	–0.35 (0.39)	–0.20 (0.39)	–0.15	0.045
Sleep problems	–0.21 (0.35)	–0.05 (0.39)	–0.16	0.033	–0.18 (0.38)	–0.15 (0.34)	–0.03	0.64

*Values are mean change in WHQ score from baseline to 12 weeks (SD).

CONCLUSION

The Acuflash study showed that TCM acupuncture as practised in Norway in addition to self-care can contribute to a clinically relevant reduction of hot flushes. The results did not differ between the TCM syndrome groups, and there were no major differences in point selection and frequency of use between responders and non-responders. Factors other than the TCM syndrome diagnoses and the point selection may be of importance regarding the outcome of the treatment.

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The acupuncture treatment for postmenopausal hot flashes (Acuflash) study: traditional Chinese medicine diagnoses and acupuncture points used, and their relation to the treatment response

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