

The effect of TCM acupuncture on
hot flushes among menopausal
women (ACUFLASH) Study.

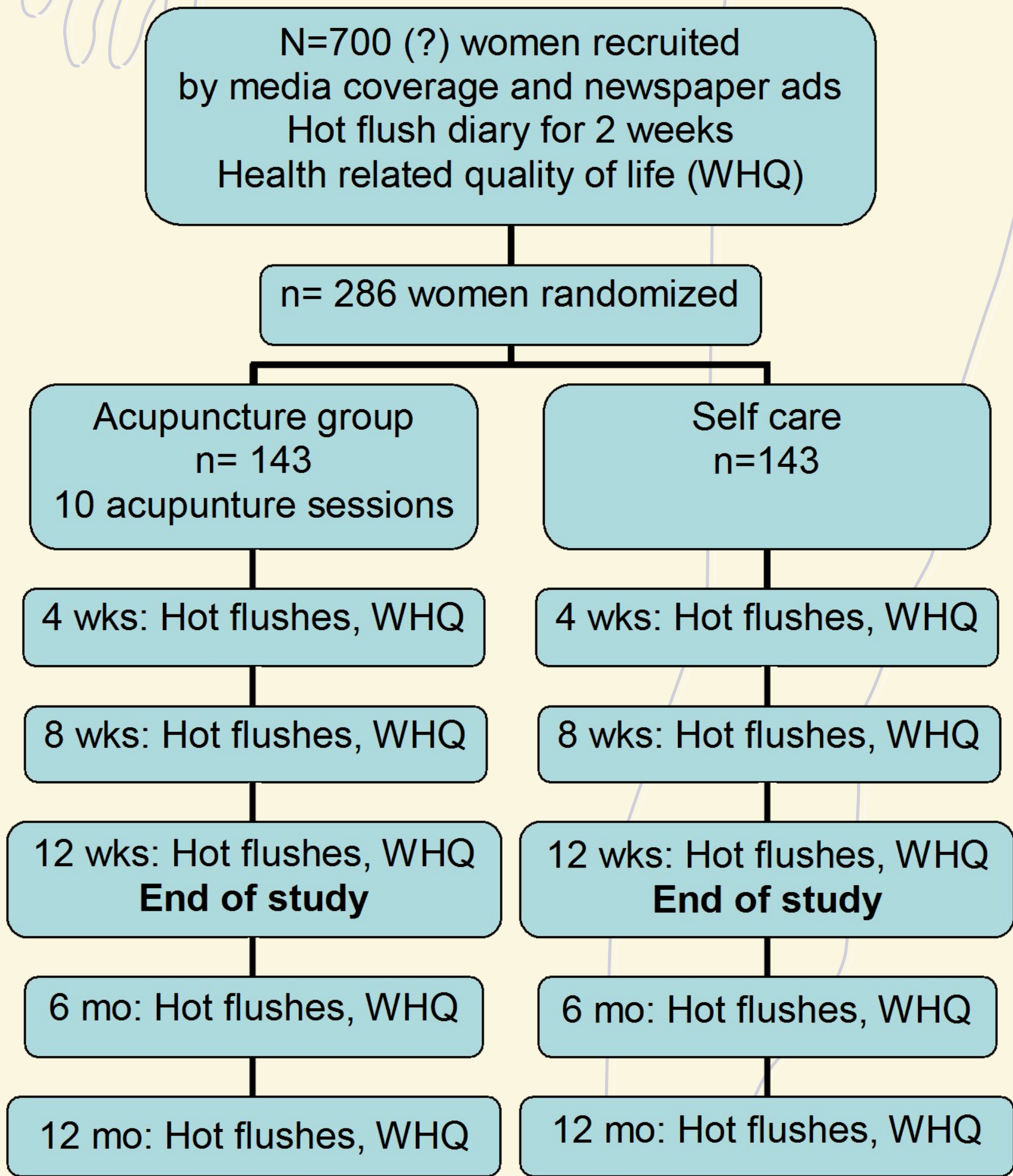
A study protocol of an ongoing multi-centre
randomised controlled clinical trial.

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Background

After menopause, 10-20% of all women have nearly intolerable hot flushes. Long term use of hormone replacement therapy involves a health risk, and many women seek alternative strategies to relieve climacteric complaints. Acupuncture is one of the most frequently used complementary therapies in Norway. We designed a study to evaluate whether Traditional Chinese Medicine acupuncture-care together with self-care is more effective than self-care alone to relieve climacteric complaints.

Flow diagram of study design



Materials/Design

The study is a multi-centre pragmatic randomised controlled trial with two parallel arms. Participants are postmenopausal women who document ≥ 7 flushes/24 hours and who are not using hormone replacement therapy or other medication that may influence flushes. According to power calculations 200 women are needed to detect a 50% reduction in flushes, and altogether 286 women will be recruited to allow for a 30% dropout rate.

The treatment group receives 10 sessions of Traditional Chinese Medicine acupuncture-care and self-care; the control group will engage in self-care only. A team of experienced Traditional Chinese Medicine acupuncturists give acupuncture treatments. The study tests acupuncture as a complete treatment package including the therapeutic relationship and expectation. The intervention period lasts for 12 weeks, with follow up at 6 and 12 months. Primary endpoint is change in daily hot flush frequency in the two groups from baseline to 12 weeks; secondary endpoint is health related quality of life, assessed by the Women's Health Questionnaire. We also collect data on Traditional Chinese Medicine diagnoses, and we examine treatment experiences using a qualitative approach. Finally we measure biological variables, to examine potential mechanisms for the effect of acupuncture. The study is funded by The Research Council of Norway.

Trial Registration:
ClinicalTrials.gov NCT00284492

Table 1. Eligibility criteria

Inclusion criteria
Postmenopausal (>1 year past last menstruation)
Willing to receive acupuncture
Mean value of ≥ 7 hot flushes/24 hours during a time period of 7 days
Exclusion criteria
Surgical menopause
History of cancer within the past five years
Use of anticoagulant drugs
Heart valve disease
Poorly controlled hypertension
Poorly controlled hypothyroidism
Hyperthyroidism
Poorly controlled diabetes mellitus
Organ transplant
Mental disease
Overt drug or alcohol dependency
Inability to complete study forms
Use of HRT (Wash out period: 8 weeks for systemic and 4 weeks for local use)
Use of SSRI (Wash out period: 8 weeks)

Table 2. Data collection schedule

	Qualifying period 2 wks	Baseline Randomisation			End	Follow-up	
Visit number		1			2		31
Week number	≤ -2	0	4	8	12	26	52
Participant provided data							
Hot flush diary	X		X	X	X	X	X
WHQ		X			X	X	X
EQ-5D		X			X	X	X
Sociodemographic variables		X					
Beck depression inventory1		X			X	X	X
Hopkins symptoms check-list2		X					
SF362		X					
Lifestyle / physical activity		X	X	X	X	X	X
Medical history		X					
Use of health care services 3		X	X	X	X	X	X
Dietary supplements / herbs		X	X	X	X	X	X
OTC-drugs		X	X	X	X	X	X
Prescribed drugs		X	X	X	X	X	X
Side effects			X	X	X		
Biological variables 1							
Sex hormones, creatinine		X			X		
CGRP, NPY		X			X		
Autonomous nerve system		X			X		
Bone mass density		X					X
Qualitative data 2					X		
Acupuncturist provided data							
TCM diagnose		X			X		
Acupoints used		X X	X X X	X X X	X X		
Side effects			X	X X X	X X X	X X	

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