Title

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Journal

Acupuncture in Medicine, 40(2)

ISSN

0964-5284

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Publication Date

2022-04-01

DOI

10.1177/09645284211055754

Peer reviewed

HHS Public Access

Author manuscript

Acupunct Med. Author manuscript; available in PMC 2022 April 01.

Published in final edited form as:

Acupunct Med. 2022 April ; 40(2): 152–159. doi:10.1177/09645284211055754.

Feasibility and preliminary efficacy of acupuncture for angina in an underserved diverse population

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Abstract

Purpose: Stable angina is ischemic chest pain on exertion or with emotional stress. Despite guideline-directed therapy, up to 30% of patients have suboptimal pain relief. The aims of this study were to: (1) determine the feasibility and acceptability of a randomized controlled trial (RCT) of acupuncture; and (2) evaluate preliminary efficacy of acupuncture with respect to reduction of pain and increased functional status and health-related quality of life (HRQoL).

Methods: Participants with stable angina for ⩾1 month received either a standardized acupuncture protocol, twice per week for 5 weeks, or an attention control protocol. Measures included the McGill Pain Questionnaire (average pain intensity (API), pain now) and the Seattle Angina Questionnaire–7 (functional status, symptoms, and HRQoL). Feasibility was defined as ⩾80% recruitment, ⩾75% retention following enrollment, and ⩾80% completion. Descriptive statistics and mixed-effects linear regression were used for analysis.

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Contributors

HAD, JMS, and HYC conceptualized this study. HAD, JMS, HYC, JEB, and ARS contributed to the design and plan for analysis. Acquisition of the data was completed by JMS and GU. Analysis and interpretation of the data were performed by HAD and JMS. The manuscript was drafted by HAD, JMS, HYC, ARS, JEB, AA, and DH. HAD, JMS, HYC, ARS, JEB, AA, LR, and DH edited and revised the manuscript for content. All authors read and approved the final version of the manuscript accepted for publication.

Declaration of conflicting interests

The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Results: The sample (n = 24) had a mean age of 59 ± 12 years, was predominantly female (63%), and represented minority groups (8% White, 52% Black, 33% Hispanic, and 8% Other). Feasibility was supported by 79% retention and 89% completion rates. The recruitment rate (68%) was slightly lower than expected. Acceptability scores were 87.9% for the acupuncture group and 51.7% for the control group. Outcomes were significantly better for the acupuncture versus control groups (API, b = −2.1 (1.1), p = 0.047; functional status, b = 27.6 (7.2), p < 0.001; and HRQoL, b = 38.8 (11.9), p = 0.001).

Conclusions and implications: Acupuncture was feasible and acceptable in our diverse sample. We were slightly under the recruitment target of 80%, but participants who started the study had a high likelihood of completing it. Acupuncture shows promise for stable angina, but its effectiveness needs to be confirmed by a larger, adequately powered RCT.

Trial registration number: NCT02914834 (ClinicalTrials.gov).

Keywords

acupuncture; integrative therapy; ischemic heart disease; stable angina

Introduction

Stable angina and its sequelae

Despite a notable 32.7% decline in mortality from ischemic heart disease (IHD) since 1999,[1] the prevalence of stable angina has not decreased.[2] Stable angina is defined as predictable chest pain on exertion or under mental or emotional stress.[3] Stable angina signifies partial obstruction of coronary flow[4] or microvascular changes[5] and comes with substantial lifetime consequences, including heart failure,[6] atrial fibrillation,[7] reinfarction,[8] and cardiac arrest.[8] Nearly 9 million Americans have stable angina,[3] and heart disease is now the leading disability-adjusted disease globally. Stable angina is associated with multiple symptoms,[9] impaired functional status,[10,11] and reduced quality of life.[4,12] From 1988 to 2012, angina symptoms declined for Whites but not for Blacks.[13] Failure to adequately address disparate risk factors among Blacks compared to Whites is thought to have contributed to differences in the reduction of anginal symptoms nationally.[14] Social and structural disadvantages that disproportionally affect Blacks have been linked to increased health disparities between races in the United States, including for IHD.[15] For example, the association between perceived discrimination and inflammatory markers, which increase the risk of IHD, has been reported.[16] Limited availability and access to resources that enhance health, such as recreational facilities and healthy food, increase the risk for IHD, and limited availability, accessibility, and acceptability of quality primary and specialized health care result in suboptimal prevention and treatment outcomes among underserved populations.[17] Finally, a recent review found that 10% to 30% of stable angina patients experienced symptoms despite treatment.[18] In our prior prospective study (n = 668), 55.5% of participants (n = 371) reported a mean of 3.1 anginal symptoms 6 months following hospital discharge.[19]

Physiologic benefits of acupuncture

Acupuncture modulates the autonomic nervous system, the midbrain and the brain stem, by releasing dynorphins and endorphins with a resultant decrease in the production of norepinephrine and epinephrine.[20,21] These changes lead to a reduction in sympathetic stimulation of the heart and blood vessels, manifesting in reduced heart rate, blood pressure, and centrally mediated arrhythmias.[22] Acupuncture may also reduce the pain of stable angina by activating μ opioid receptors,[20] increasing β endorphins,[23] and reducing inflammation by downregulating M1 macrophages and other cytokines.[24]

Acupuncture for the treatment of stable angina

A major gap in acupuncture research for stable angina is the paucity of high-quality randomized controlled trials (RCTs), lack of publications in English, and lack of standardized acupuncture protocols in these studies. To our knowledge, there is no literature on the impact of acupuncture on the pathophysiologic mechanisms of stable angina and how acupuncture specifically modifies pain and symptoms. An earlier systematic review of 25 RCTs[25] and a meta-analysis of 8 RCTs[26] of acupuncture for the treatment of stable angina showed relief of angina symptoms for acupuncture-treated participants compared to controls. However, there was no reduction in ischemia as measured by electrocardiography (ECG) or reduction in nitroglycerin use. All but two studies (Scandinavian) were performed in China.[27,28] Serious limitations of the studies included heterogeneous samples, lack of adjustment for potential confounders, lack of standardization of the acupuncture intervention (e.g. traditional acupuncture point prescriptions), varying medication prescriptions, and different outcome measures. One study conducted in Sweden[28] included only 21 individuals (2 women). Patients in the acupuncture group reported a mean reduction in angina episodes from 10.6 to 6.1 per week during the 4 weeks of therapy. Based on available, low-quality evidence, an American Heart Association (AHA) writing group concluded that acupuncture has not been studied sufficiently to warrant its recommendation as a treatment option for the relief of angina symptoms for patients with stable angina.[29] Hence, high-quality RCTs performed in an American population are necessary.

Acupuncture therapy has the potential to significantly reduce the pain and associated symptoms (e.g. shortness of breath or fatigue) of stable angina by offering therapy that is complementary to optimal medical management. Symptom management is critical to reduce disability and improve quality of life for women and men with angina. The aims of this study were to: (1) determine the feasibility and acceptability of an RCT of acupuncture for stable angina; and (2) evaluate the preliminary efficacy of acupuncture for the reduction of pain, increased functional status, and health-related quality of life (HRQoL). We hypothesized: (1) that acupuncture therapy would be feasible (80% recruitment, completion, and acceptability; 75% retention rates) and acceptable for adults with stable angina; and (2) that there would be a reduction in pain and an improvement in functional status, symptoms, and HRQoL.

Methods

Design, setting, and participants

This was a randomized attention-controlled pilot study conducted in adult patients recruited from the Cardiology clinic at a Midwestern Academic Health Center. The health system serves a diverse population with 48% of patients identifying as African American, 24% Hispanic or Latino, 20% Caucasian, and 8% Asian or Pacific Islander. In 2017, over 75% of patients had either public insurance or were uninsured, and 99% reported being at or below 200% of the poverty income level. The eligibility criteria were as follows: (1) confirmed diagnosis of stable angina (pressure, pain, and/or discomfort in the chest or other areas for 1 month or longer); (2) experiencing symptoms at least once per week; (3) aged 21 years or older; (4) ability to speak and read English; and (5) Canadian Cardiovascular Society (CCS) Class I–III angina (CCS Class IV is unstable angina which is defined as angina at rest for more than 20 min). Exclusion criteria were as follows: (1) physical or cognitive limitations preventing completion of study protocols; (2) exacerbation of heart failure (brain natriuretic peptide (BNP) > 500 pg/mL, escalating dose of diuretic or hospital admission for heart failure in the past 3 months); (3) autoimmune dysfunction (use of steroid or prescription anti-inflammatory medications); and (4) moderate (treated with short-acting bronchodilators with antibiotics and/or oral steroids) to severe (requiring visits to the emergency department and/or hospital admissions) chronic obstructive pulmonary disease (COPD). The study was approved by the institutional review board at the sponsoring institution and prospectively registered at ClinicalTrials.gov (NCT02914834) on 26 September 2016, and recruitment took place between January 2019 and March 2020.

The research specialist screened and consented eligible individuals. Potential participants were informed that they would be randomized into either the acupuncture group (10-acupuncture session protocol, 2 treatments per week for 5 weeks) or the attention control group. Data were collected on tablet computers, via REDCap, at each session.

Research protocol

The research specialist explained the nature of the study, risks, benefits, the voluntary nature of participation, and the right to discontinue participation at any time without consequences. After informed consent was obtained, participants were randomized to the acupuncture or attention control group via REDCap's randomization module, based on a stratified, permuted block schedule prepared by the biostatistician.

In conformance with STRICTA (Standards for Reporting Interventions in Clinical Trials of Acupuncture) guidelines,[30] we developed a 12-point standardized traditional acupuncture point prescription[31] (Figure 1) through prior Traditional Chinese Medicine (TCM) clinical assessments and TCM pattern diagnoses of stable angina patients. We chose the most important point locations from these TCM patterns to construct the protocol used for study participants with stable angina based on our clinical experience of assessing and treating patients with stable angina, followed by the formulation of their individual TCM pattern diagnoses. Our 12-point standardized point prescription was developed for research to ultimately examine the efficacy and effectiveness of acupuncture for the treatment of all

patients with stable angina regardless of TCM pattern diagnosis. This research protocol was not intended to replace individualized TCM pattern assessments, diagnoses and treatments used by TCM practitioners. Rather, it was a balanced standardized protocol incorporating what are considered to be the most therapeutic acupuncture needling locations selected to treat each of the three most common patterns of stable angina. We anticipated that using this standardized treatment protocol would enable a reliable research protocol to be tested and validated in a fully powered RCT of acupuncture for stable angina.

Participants received two acupuncture treatments each week for 5 weeks, for a total of 10 treatments. All treatments were delivered by four licensed, National Certification Commission for Acupuncture and Oriental Medicine (NCCAOM) certified acupuncturists who had been in practice for an average of 14 years. DBC™ Korean 0.25 × 40 stainless steel needles with wound stainless steel heads were inserted and rotated until a *de qi* response was obtained. Even rotation was performed every 10 min and needles were retained for 30 min. The needles were inserted at CV17 (*Shanzhong*) transversely to a depth of 0.5 *cun*,[32] and bilaterally at LR14 (*Qimen*) transversely to a depth of 0.5 *cun*, LU7 transversely to a depth of 0.5 *cun*, PC4 (*Ximen*) perpendicularly to a depth of 0.5 *cun*, PC6 (*Neiguan*) perpendicularly to a depth of 0.5 *cun*, HT7 (*Shenmen*) perpendicularly to a depth of 0.3 *cun*, LI4 (*Hegu*) perpendicularly to a depth of 1 *cun*, ST36 (*Zusanli*) perpendicularly to a depth of 1 *cun*, ST40 (*Fenglong*) perpendicularly to a depth of 1 *cun*, KI6 (*Zhaohai*) obliquely to a depth of 0.3 *cun*, SP3 (*Taibai*) perpendicularly to a depth of 0.5 *cun*, and LR3 (*Taichong*) perpendicularly to a depth of 1 *cun*. All acupuncture sessions were monitored by the research specialist to ensure protocol fidelity (needle insertions and removals). Each acupuncture session lasted a total of 1 h including participant completion of all measures.

Our study design did not use sham acupuncture, whereby needles are inserted into the body at sites not corresponding to any traditional acupuncture point location. RCTs employing sham acupuncture have been criticized as inferior to those with an attention control design because needles inserted anywhere may have therapeutic effects.[33,34] We therefore used an attention control with the participants engaged for an equivalent amount of time as those in the acupuncture intervention group.

The attention control group watched health videos from the NOVA Science NOW™ series on PBS (Public Broadcasting Service). Topics did not contain content that was considered to have the potential to improve pain. Videos were viewed from weeks 1 to 5 (five time points) with a duration equal to that of the acupuncture in the experimental group (10 h).[35] Titles include *Can we live forever?; Cracking your genetic code; Vaccines: Calling the shots; How does the brain work?; What are dreams?; How smart can we get?; Memory hackers; Cracking the code of life*; and *Can Alzheimer's be stopped?* The videos were shown in clinical research rooms. Standardized content was considered to assure complete fidelity to the control protocol.

Measures

Demographic data (i.e. age, sex, race, employment status, comorbidities, marital status, number of household members, annual income, and educational attainment of participants) were collected at baseline prior to the start of the study protocol. All participants completed

the following measures at baseline: pain now (current pain) and average pain intensity (API (average of pain now, and least and worst pain in the last 24 h)) on the McGill Pain Questionnaire (MPQ)[36] and the Seattle Angina Questionnaire–7 (SAQ-7).[37]

API on the MPQ[38] was scored on a Likert-type scale with 0 = *no pain* to 10 = *excruciating pain*. The MPQ has been well validated in cardiac populations.[39–42] The SAQ-7 consists of seven items across three domains (functional status, symptoms, and quality of life) measuring the impact of angina on participants' health status. Item responses are coded sequentially from worst to best status and range from 1 to 6, except quality of life (range = 1–5). Scores are generated for each domain and are scaled 0 to 100, with 0 the worst and 100 the best possible status.[37] The SAQ-7 has been validated among patients with stable IHD, undergoing coronary interventions and after acute myocardial infarction.[43] The investigator-designed "protocol acceptability scale for treating angina with acupuncture" is a nine-item instrument used to measure acceptability of the study processes and protocols. Items are measured on a scale of 0 (*negative response*, i.e. did not like acupuncture) to 2 (*positive response*). The protocol was deemed to have high acceptability if 80% of participants scored ⩾80% points out of the total possible on the acceptability scale.

We used descriptive statistics (means, standard deviations, frequencies, and percentages) to summarize the data. Glass's delta statistic was used to measure effect sizes; 95% confidence intervals (CIs) were estimated for feasibility measures. Mixed-effect linear regression models were used to examine treatment-by-time intervention effects for patient-reported outcomes using random intercepts to account for dependency due to repeated measurements.

Results

Participants included 24 adults with an average age of 59 ± 12 years, of whom 15 (63%) were female and 9 (37%) male. The sample included 2 (8%) White, 11 (46%) Black/African American, and 9 (38%) Hispanic participants, and 2 (8%) who identified as belonging to Other groups. The participants were predominantly members of minority groups (11 Blacks, 9 Hispanics; 83%), lower income (96%; annual income <US$50,000), unmarried (n = 17; 71%), and insured by Medicare or Medicaid (n = 20; 83%).

Our enrollment rate was 68% (95% CI = 54%–79%) of those approached at the Cardiology clinic. Among those who enrolled, 79% (95% CI = 63%–90%) began the study protocol. Those who were retained were very likely to complete the protocol (96%; 95% CI = 79%–100%; Table 1). When the COVID-19 pandemic struck and we were compelled to suspend the study, there were two participants who had not completed the entire 10-session protocol. One participant was in the acupuncture group and had completed one session, and one participant was in the attention control group and had completed two sessions.

The proportion of participants endorsing the highest acceptability score ranged from 38% to 91%, with a mean of 87.9% in the acupuncture group compared to 51.7% of control group participants. Table 2 shows the acceptability questions and percent giving the highest rating by treatment arm. While the highest rating was not always endorsed, lowest ratings were given by five control participants who felt the study was too long and one participant

responded that they had not enjoyed participating. Conversely, five acupuncture participants felt the study was not long enough. One acupuncture participant gave the lowest rating, noting that acupuncture was painful and four participants rated acupuncture as somewhat painful.

Effect sizes and differences in pain and HRQoL

Effect sizes were very large, ranging from −0.98 to 1.91 (Table 3) for our outcomes of interest: pain, functional status, symptoms, and HRQoL. We examined within- and between-group changes in pain and HRQoL after determining that effect sizes were large. Mixed-effect regression models showed that API decreased in the acupuncture group (2.15 (standard error (SE) = 1.26) points more than the control group ($p = 0.047$)). The two remaining constructs of pain, worst pain in the last 24 h and pain now (b (SE) = −2.51 (1.26), $p = 0.013$, and b (SE) = −3.76 (1.51), $p = 0.046$, respectively), showed similar changes, whereas least pain in the last 24 h did not (b (SE) = −0.15 (0.95), $p = 0.878$). There were also significant improvements in the three domains of the SAQ-7, functional status (b (SE) = 27.64 (7.24), $p < 0.001$), symptoms (b (SE) = 24.74 (6.10), $p < 0.001$), and HRQoL (b (SE) = 38.84 (11.95), $p < 0.001$), as well as the total score (b (SE) = 28.54 (6.40), $p < 0.001$) for the acupuncture group. All results favored the acupuncture arm, which showed a reduction in pain and improved functional status, symptoms, and HRQoL (Table 3).

Discussion

Our pilot data demonstrated that administration of acupuncture for stable angina to underserved diverse patients receiving medical care in an inner-city Cardiology clinic is feasible and acceptable. This is consistent with the literature from China.[25] The multiple trained acupuncturists implemented the standardized 12-point acupuncture protocol for the treatment of angina with no deviations. To our knowledge, a standardized acupuncture protocol has not been adopted in prior research.[44] The participant acceptability criteria were met in the acupuncture group. We were able to enroll and retain all participants except two who we believe would likely have completed all study measures had it not been for the suspension of the study due to the COVID-19 pandemic.

The literature supports the efficacy of acupuncture for angina in Chinese participants,[45] so we expected medium to large effect sizes for this study. The data revealed large effect sizes for the reduction of pain and improvement in HRQoL. Only “least pain in the past 24 hours” had a small effect, which was expected since the least amount of pain experienced by participants was extremely low. Also, we would expect no change in least pain since it often equates to no pain (thus exerting a basement effect).

Our pilot findings suggest that individuals with angina receiving the 12-point acupuncture protocol experienced a reduction in pain and symptoms and improved HRQoL. This is consistent with a previous report on the use of acupuncture for the treatment of stable angina.[45]

Strengths and limitations

There were many strengths to our study including a rigorous RCT design and a completion rate of 89%, which was beyond our target rate of 80%. We chose a pilot RCT design because our main aim was to demonstrate feasibility in our population. In the future, we may consider conducting a pragmatic trial using a group community acupuncture model with a group attention control. Arguably, if it had not been for COVID-19, we may have achieved a 96% completion rate, taking into account two additional participants. Also, we view it as a strength that, even though we were slightly under our recruitment target of 80%, the participants who were recruited were dedicated to completing the acupuncture protocol and therefore likely to be reflective of the group we aim to treat in clinical practice. Both groups were satisfied with their participation in the study; however, unsurprisingly, the experimental group viewed the study more favorably.

To our knowledge, this is the first study of acupuncture to treat stable angina using a standardized acupuncture treatment protocol, which enabled all participants with varying TCM patterns to be treated. We believe that use of a standardized point protocol will facilitate study replication, systematic literature reviews, and meta-analyses in the future. Also, we used a rigorous and standardized attention control protocol, ensuring that all participants in the control arm viewed the same videos with the same exposure time.

A limitation was the inability to complete all acupuncture sessions due to the COVID-19 pandemic. Also, neither participants nor acupuncturists were blind to group allocation, which may have introduced bias in either or both groups. Generalizability of the findings to a broader population cannot be made based on findings from this pilot feasibility study.

Conclusion

We have demonstrated the feasibility of conducting a fully powered RCT of our rigorous standardized treatment protocol, which is virtually free from side effects, to examine whether acupuncture can reduce the symptom burden in subjects with stable angina receiving medical therapy. Our pilot study has demonstrated feasibility and acceptability of a 12-point acupuncture protocol for the treatment of angina in an underserved population who receive care in an inner-city Cardiology clinic. In addition, we found significant reductions in pain and improved HRQoL for the acupuncture group. However, we were not powered to show effectiveness with respect to these outcomes in this feasibility trial (with high risk of a type I error). If these findings can be replicated in a larger, adequately powered trial, acupuncture for the treatment of stable angina may become an important complementary therapy that, if made available and accessible to underserved populations, could increase their quality of life and contribute to health equity.

Acknowledgements

The authors would like to thank acupuncturists Stephanie Marynus, LAc, Elizabeth Kettner, LAc, Sunae Son, LAc, Lisa Alvarez, LAc, and Jun Fu, PhD, LAc for their dedication to this research.

Funding

The authors disclosed receipt of the following financial support for the research, authorship, and/or publication of this article: This publication was made possible by grant no. R21 NR017705 from the National Institutes of Health, National Institute of Nursing Research (NINR). Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the NINR. The final peer-reviewed manuscript is subject to the National Institutes of Health Public Access Policy.

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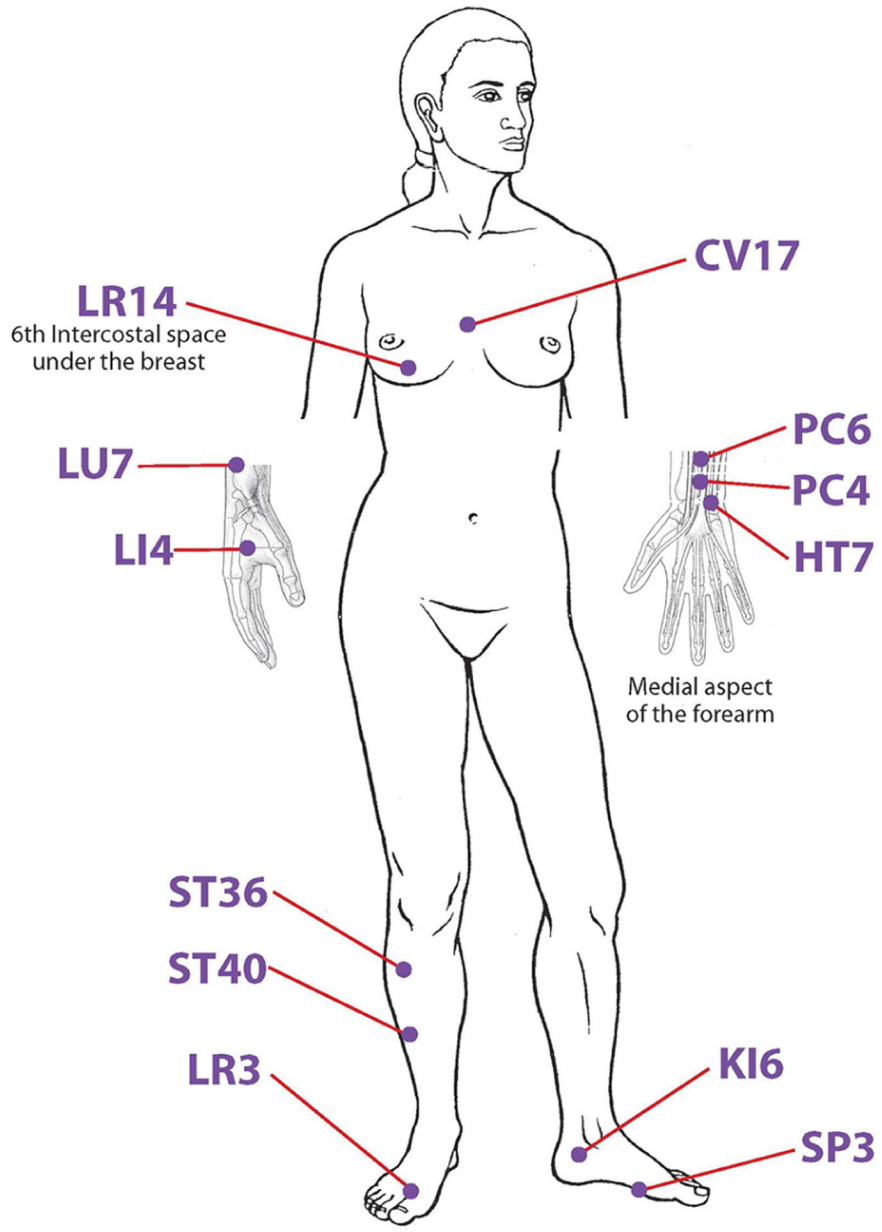

Figure 1.
Standardized traditional acupuncture point prescription.

Table 1.

Feasibility measures.

Outcome measure	Target (%)	Female n (%)	Male n (%)	Total N (%)
Eligibility		31 (62.0)	19 (38.0)	50
Recruitment	80	23 (74.2)	11 (58.0)	34 (68.0)
Retention	75	17 (73.9)	10 (90.9)	27 (79.4)
Completion	80	15 (88.2)[a]	9 (90.0)[a]	24[a] (88.9)

[a]One male withdrew. Two females could not complete the study when stay-at-home orders were issued and campus research was suspended due to COVID-19. Notwithstanding, the completion rate could have reached 96%.

Table 2.

Mean acceptability score per question and total.

Acceptability scale score questions	**Acupuncture group *n* = 11 Mean ± SD**	**Control group *n* = 13 Mean ± SD**
Total mean scores (SD)	15.8 ± 1.6	9.3 ± 2.6
1. Was participating hard?	1.9 ± 0.3	1.7 ± 0.5
2. Instructions easy to understand?	1.9 ± 0.3	1.6 ± 0.5
3. Rushed to complete?	1.9 ± 0.3	1.8 ± 0.4
4. Did you enjoy participating?	1.8 ± 0.4	1.6 ± 0.7
5. What did you think of acupuncture?	1.7 ± 0.5	NA
6. Acupuncture painful?	1.5 ± 0.7	NA
7. Get acupuncture again?	1.7 ± 0.5	NA
8. Others will enjoy receiving acupuncture?	1.9 ± 0.3	1.6 ± 0.7
9. Think the study was right length?	1.5 ± 0.5	1.0 ± 0.9
Total mean score (highest possible score: 18)	15.8 ± 1.6	9.3 ± 2.6
Total mean acceptability scores	87.9%	51.7%

SD: standard deviation; NA: not applicable.

Table 3.

Effect sizes for pain and health-related quality of life.

Group	Acupuncture			Control			
Outcome measures	**Baseline, *n* = 12 Mean ± SD**	**Completion, *n* = 11 Mean ± SD**	**Change**	**Baseline, *n* = 15 Mean ± SD**	**Completion, *n* = 13 Mean ± SD**	**Change**	**Effect size**
Pain							
Pain now	3.08 ± 2.47	0.73 ± 1.10	−2.35	2.67 ± 2.77	2.85 ± 2.79	−0.18	−0.98
Worst pain in the past 24 h	6.58 ± 2.23	2.55 ± 1.52	−4.03	5.67 ± 3.39	5.38 ± 2.93	−0.29	−1.29
Least pain in the past 24 h	1.75 ± 2.22	0.36 ± 0.81	−1.39	1.93 ± 2.28	0.69 ± 1.18	−1.24	−0.07
Average pain intensity[a]	3.81 ± 1.99	1.21 ± 1.13	−2.60	3.42 ± 2.56	2.97 ± 1.96	−0.45	−0.94
Seattle Angina Questionnaire–7							
Functional status[a]	16.67 ± 15.18	35.55 ± 13.33	30	29.78 ± 26.77	16.92 ± 19.36	−12.86	1.38
Symptoms	55.00 ± 20.23	72.73 ± 15.55	17.73	62.67 ± 13.35	56.15 ± 8.70	−6.52	1.44
Quality of life	20.83 ± 26.82	54.55 ± 23.90	33.72	16.67 ± 13.91	11.54 ± 12.97	−5.13	1.91
Total score[a]	29.29 ± 13.01	49.16 ± 11.91	27.15	36.57 ± 16.14	27.51 ± 9.21	−18.48	1.93

SD: standard deviation.

[a]Main outcomes: average pain intensity, functional status, and overall health-related quality of life effect sizes were −0.94, 1.38, and 1.93, respectively.