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Cost-effectiveness of acupuncture for tension-type headaches in Japan :a multicenter, prospective, single-arm clinical trial

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Abstract

[Background] Acupuncture is being increasingly used for treating patients with Tension-type headache (TTH); however, there remains a lack of evidence regarding its cost-effectiveness. The objective of this study is to clarify the cost-effectiveness of acupuncture for TTH.

[Patients and Methods] The study was designed as a multicenter, single-arm clinical trial. Nineteen acupuncture clinics participated in this study. Patients with TTH received acupuncture for 3 months, in addition to the usual treatment. Acupuncture was conducted according to a predetermined method. The average number of acupuncture sessions was 12.2 ± 4.5. The study enrolled 45 participants and the final analysis included 37 participants aged 47.7 ± 12.6 years, of which 2 were men and 35 women.

We measured patients' health-related quality of life, cost for headache, and intensity and frequency of headache at baseline and 3 months later to assess cost effectiveness.

[Results] The median ICER was JPY 484 [-13404, 2003] (USD 5 [-129, 19]). The mean ICER (95% CI) was JPY -3890 [-10525, 2744] (USD -37 [-101, 26]). The ICER per QALY gained from adding acupuncture to standard treatment would be within reasonable the range of the amounts that Japanese residents would be willing to pay per QALY.

[Conclusion] We demonstrated the cost-effectiveness of utilizing acupuncture for treating TTH in terms of ICER.

Key words: *acupuncture, tension-type headache, cost-effectiveness, incremental costeffectiveness ratio, quality-adjusted life year*

I. Introduction

Tension-type headaches (TTH) are the most prevalent (22.3%) primary headaches. Among these patients, 29.2% found TTH to interfere with their daily lives, with chronic TTH (CTTH) having a high rate of interference in daily life (40.5%)[1)]. According to the International Headache Society, their lifetime prevalence in the general population ranges between 30%.78%[2)]. In other words, TTH is common and several pharmacological and non-pharmacological therapies are available for patients. For patients with CTTH, the guidelines recommend antidepressants, such as amitriptyline, for pharmacological therapy. Non-pharmacological therapies include acupuncture, massage, behavioral treatments, and physiotherapy interventions. Among these, acupuncture is the most used complementary and alternative therapy for TTH to reduce the frequency and intensity of headaches. For example, a US study found that 9.9% of users used acupuncture for treating migraine or other headache types[3)]. A large, good-quality trial (409 patients) on TTH acupuncture in Germany showed that the effects of acupuncture persist after 6 months[4)].

According to clinical studies in Japan, acupuncture reduces the severity and frequency of TTH, frequent episodes of TTH require less treatment and a shorter duration of improvement than CTTH[5)].

Cost-effectiveness is a major criterion underpinning the decisions in mainstream healthcare. A systematic review was conducted to evaluate the effectiveness of

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acupuncture for the treatment or prevention of migraine, TTH, or chronic headache disorders. In this review, cost effectiveness analyses in the United Kingdom and Germany suggested acupuncture to be a cost-effective treatment option[6].

Acupuncture is increasingly used for patients with TTH, but there is a lack of evidence on its cost-effectiveness in other parts of the world. Thus, this study aims to determine the cost-effectiveness of acupuncture for TTH to provide an indication of the economic benefits of acupuncture for headaches in Japan, and to compare this indicator with results from overseas.

II. Patients and Methods

1. Study design

The study design is a multicenter, prospective, single-arm clinical trial. Nineteen acupuncture clinics participated in the study. Patients with TTH received acupuncture for 3 months, in addition to the usual treatment. We measured patients' health-related quality of life, cost used for headache, and intensity and frequency of headaches at baseline and 3 months later to assess cost effectiveness. This study was registered with the University Hospital Medical Information Network in Japan (UMIN, number 000025226), was approved by the Medical Research Ethics Committee

Table 1
Acupuncture points and stimulation method

Acupuncture points	Manual acupuncture	Electroacupuncture	Other	Total	% (n = 451)
GB21	409	15	1	425	94.2%
BL10	351	6	0	357	79.2%
GB20	339	14	2	355	78.7%
SI14	290	3	1	294	65.2%
GB12	250	0	0	250	55.4%
GV20	160	0	0	160	35.5%
Ex-HN5	158	0	0	158	35.0%
BL43	157	0	0	157	34.8%
BL15	126	0	2	128	28.4%
SI15	93	0	1	94	20.8%
BL13	83	0	3	86	19.1%
LI4	76	0	3	79	17.5%
LR3	55	0	11	66	14.6%
ST8	48	0	0	48	10.6%
BL14	43	0	0	43	9.5%
GB41	43	0	0	43	9.5%
BL2	37	0	0	37	8.2%
TE17	33	0	0	33	7.3%
BL17	16	0	0	30	6.7%
BL12	27	0	2	29	6.4%
LI10	26	0	0	26	5.8%
BL42	21	0	0	21	4.7%
TE20	17	0	0	17	3.8%
SI17	15	0	0	15	3.3%
BL44	14	0	0	14	3.1%
GB3	13	0	0	13	2.9%
BL41	14	0	0	14	3.1%
BL18	8	0	5	13	2.9%
BL9	3	9	0	12	2.7%
TE21	10	0	0	10	2.2%
ST7	9	0	0	9	2.0%
GB2	5	0	0	5	1.1%
BL11	5	0	0	5	1.1%
Other	79	8	18	105	23.3%

Table 1 shows the acupuncture points and stimulation methods. The most frequently used acupuncture point was GB21. Then followed by BL10 and GB20.

of Tsukuba University of Technology, and was conducted according to the Declaration of Helsinki and its later amendments.

2. Recruitment of study participants

The study participants were individuals who complained of headaches, which were then identified as TTH through a medical interview before the start of the study. The study participants met the diagnostic criteria for frequent episodic TTH or CTTH, as per the International Classification of Headache Disorders, third edition (beta version)[2]. They were recruited through leaflets displayed in acupuncture clinics.

3. Intervention method

The participants received acupuncture for 3 months in addition to the standard treatment they had already been receiving (i.e., examination/drug prescription by a medical institution, use of over-the-counter medication (OTC)).

The acupuncture points to be used were discussed in advance with the acupuncturists at all clinics and listed. Each acupuncturist chose the points from the list, using factors such as tenderness as a guide. Each treatment session lasted for a maximum of 1 hour, and the longest needle retention time was 15 minutes. The acupuncture points and stimulation methods used in each session were recorded.

The total number of acupuncture sessions was 451. The number of sessions per individual over the 3-month period was 12.2 ± 4.5. Table1 shows the acupuncture points and stimulation methods.

The median cost per acupuncture treatment was JPY 2,929 [interquartile range; 1,980, 4,000] (USD28 [19,38]). The average cost for one general acupuncture treatment in Japan is JPY 3,831 (USD 37)[7]. On the other hand, when using health insurance, the patient's cost burden (30% self-pay) is JPY 483 (USD5)[8].

One adverse event attributable to the intervention occurred. It consisted of post-treatment weakness that was resolved when the patient went to bed and had no effect on sleep.

4. Assessment parameters

The following parameters were assessed twice, once at baseline (before the start of treatment) and then immediately after the end of the 3-month treatment.

(1) Frequency of headaches

The participants were asked to recall the 3 months prior to the assessment and were asked how many days per month they experienced headaches on average.

(2) Severity of headaches

The participants were also asked to assess the average severity of their headaches during the month prior to the assessment using a visual analog scale. The possible scores ranged from no headache at the left-hand side (0mm) to the worst pain ever experienced at the right-hand side (100mm).

(3) Headache impact test-6

The degree to which the participants' headaches interfered with their daily lives was assessed using the headache impact test-6 (HIT-6). For each question, the participants chose one of the following responses: "Never" (6points), "Rarely" (8points), "Sometimes" (10points), "Very often" (11points), or "Always" (13points). The total score was then evaluated. The higher the total score, calculated as the sum of scores for each option (from a minimum of 36 points to a maximum of 78), the greater the impact on their daily lives.

(4) Japanese EQ-5D.5L score

Health-related quality of life (QOL) was assessed using the Japanese EQ-5D.5L[9]. The participants answered about their situation on the day they filled out the questionnaire. The participants filled in the designated questionnaire forms, grading their current state of health under the five dimensions of mobility, self-care, usual activities, pain/discomfort, and anxiety/depression on a five-level scale. The response pattern was expressed as a five-digit number, according to the level chosen for each parameter, and was then converted to an index value using a conversion tool[10].

(5) Headache-related costs

Headache-related costs were recorded as the amount of money spent by each participant to relieve or prevent headaches during the 3 months prior to the assessment. The participants reviewed as many receipts as they could from that period and recorded the amounts based on their memory. This amount included payments to medical institutions, cost of medication purchased at outlets other than medical institutions (e.g., drugstores), and payments to acupuncture clinics.

5. Statistical analysis

The changes in each parameter after the intervention period were compared with the baseline value. The Shapiro-Wilk test was used to assess the normality of the distribution of continuous variables. It was analyzed using a paired t-test and results were expressed as the mean and 95% Confidence Interval (95% CI) if normality was observed. It was analyzed using the Wilcoxon signed rank sum test and results were expressed as the median and interquartile range (IQR) if normality was not observed. The validity of the sample size was demonstrated by a post hoc power analysis. The sample size was calculated with effect size, detection power of 95%, and an alpha

value of 5%. The calculation of the effect size used the assessment data. Statistical analysis was carried out using SPSS for Windows version 26 (IBM Japan). All tests were two-tailed and $p < 0.05$ was considered significant. The data for the year of the survey (2016) were used for the US dollar and the abridged life table.

6. Incremental cost-effectiveness ratio and incremental quality-adjusted life years

The index value obtained by the EQ-5D. 5L and the cost of headache prevention and relief during the intervention period were used to calculate the incremental cost-effectiveness ratio (ICER) and investigate cost-effectiveness. The ICER is expressed as the ratio of the difference in costs between two strategies to the difference in effectiveness. A lower ICER can be interpreted as a more cost-effective intervention. The headache-related costs during the intervention period included payments to acupuncture clinics and payments to medical institutions (including drug prescription costs), the cost of medication purchased at outlets other than medical institutions (e.g., OTC medication from drugstores), and other costs. The ICER was calculated as (post-intervention cost. pre-intervention cost) / (post-intervention index value. pre-intervention index value).

The intervention index value can be expressed as the quality-adjusted life year (QALY). The QALY is used in economic evaluations to assess the value of medical interventions by combining quality of life (QOL) and life-year.

One QALY represents 1 year in perfect health, death is assigned 0 QALY. In cost-effectiveness evaluation, a higher QALY indicates higher effectiveness.

The quality-adjusted life year (QALY) was calculated as:

QALY = index value × duration of survival in the condition concerned.

Incremental QALY were calculated as follows:

Incremental QALY = post-intervention QALY. pre-intervention QALY

The mean life expectancy of each patient was determined based on the Abridged Life Table[9] published by the Ministry of Health, Labour and Welfare. The mean life expectancy determined by the Abridged Life Table was 27.7 ± 14.2 years and was based on the assumption that the post-intervention index value would remain unchanged.

The results were expressed as the median and IQR, mean and 95% CI, Minimum and maximum values. The Shapiro-Wilk test was used to assess the normality of the distribution of continuous variables.

III. Results

The study participants comprised 45 individuals who provided written informed consent. The number of registered participants at each acupuncture clinic is shown in the Table2. Figure1 shows the process from study recruitment to analysis. Seven participants dropped out during treatment because of personal reasons such as being too busy with work to attend appointments. One participant was excluded from the analysis because all post-intervention assessments were incomplete, leaving an analysis population of 37 participants (35 women and 2 men). However, there were 28 participants in the analysis of headache-related costs (excluding those who did not fill out some of the items related to headache-related costs). There were 17 participants in the ICER analysis (excluding those whose utility values did not change before and after the intervention and those who did not fill in some items regarding headache-related costs). Table3 shows the characteristics of the study participants.

Table 2
The number of registered participants at each acupuncture clinic.

acupuncture clinic	Location Prefecture	the number of registered participants (n =45)
A	Tokyo	9
B	Aichi	6
C	Aichi	5
D	Tokyo	4
E	Chiba	3
F	Kanagawa	3
G	Osaka	3
H	Aichi	2
I	Aichi	2
J	Aichi	2
K	Ibaraki	2
L	Aichi	1
M	Aichi	1
N	Saitama	1
O	Tokyo	1

Table 3
The characteristics of the study participants.

Median Age (years) [IQR]	46.0 [40.0, 53.8]
Mean Height (cm) [95%CI]	157.7 [155.6, 159.8]
Median Weight (kg) [IQR]	50.0 [46.3, 55.5]
Gender (male/female)	2/35

IQR: Interquartile Range
95%CI: 95% Confidence Interval

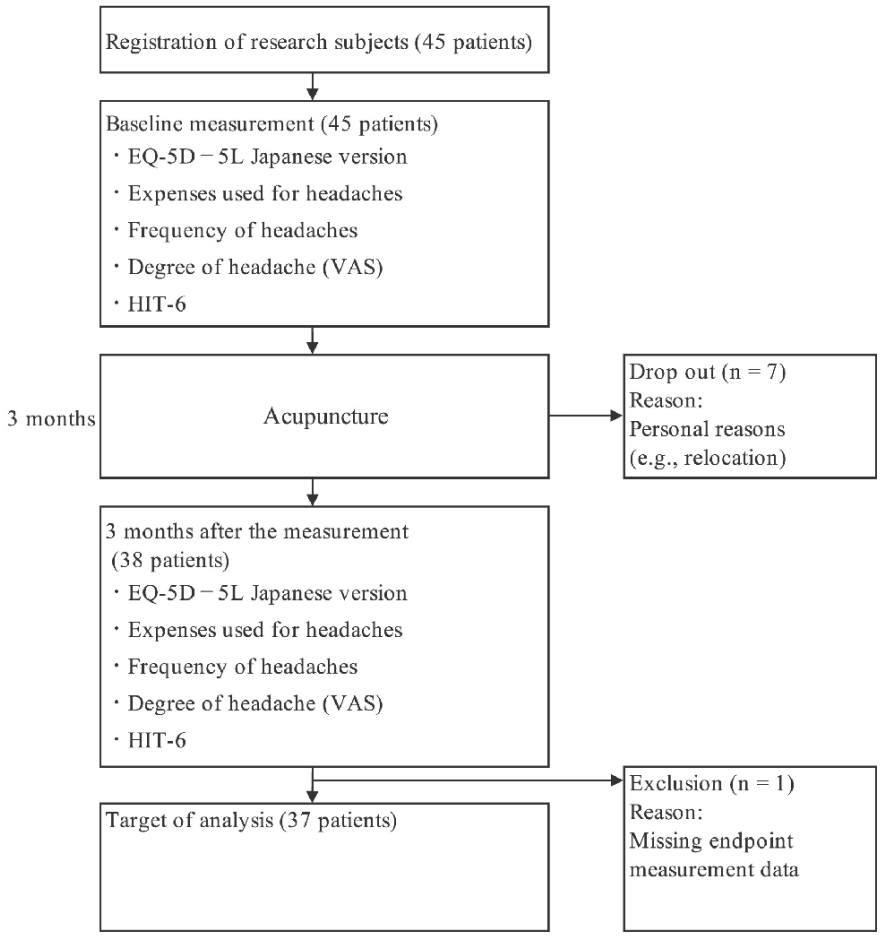

Figure 1 Flowchart of study protocol
The study participants comprised 45 individuals who provided written informed consent. Seven participants dropped out during treatment because of personal reasons such as being too busy with work to attend appointments. One participant was excluded from the analysis because all post- intervention assessments were incomplete, leaving an analysis population of 37 participants.

1. Effect on the frequency and severity of headaches and HIT-6 everyday activities

Table4 shows the effects on the frequency and severity of headaches and the HIT-6 impact on everyday activities. The frequency and severity of headaches both decreased significantly post-intervention ($p < 0.05$). The HIT-6 score for the impact on everyday activities also improved significantly post-intervention ($p < 0.05$).

2. EQ-5D-5L

The pre-intervention median (IQR) value was 0.83 [0.70, 0.90] and the post-intervention median (IQR) value was 0.90 [0.76, 0.94]. This was a significant change from baseline ($p < 0.05$). The participants' health status improved post-intervention (Table4).

3. Headache-related costs

The pre-intervention median (IQR) cost was JPY 8000 [1350, 45167] (USD 77 [13, 434]), and the post-intervention one was JPY 38700 [22800, 53300] (USD 372 [219, 513]). This difference was not significant ($p > 0.05$) (Table4).

4. ICER and Incremental QALY

The median ICER was JPY 484 [-13404, 2003] (USD 5 [-129, 19]). The mean ICER (95% CI) was JPY -3890 [-10525, 2744] (USD -37 [-101, 26]) (Table4).

The median Incremental QALY was 1.4 [0.0, 7.3]. The mean (95% CI) Incremental QALY was 3.2 [1.0, 5.4] (Table45). There was no normality for the continuous variables in ICER and Incremental QALY.

Table 4
Comparison of tension-type headache measurements at baseline and after 3 months

	Baseline	After 3 months	95%CI for the difference between the Baseline and After 3 months	*P* Value	Effect size (r)	Analysis
Median Days of headache per month [IQR], n = 37	6 [3, 16]	3 [2, 7]	[-6.5, -2.0]	0.000	0.68	W
Mean Degree of pain (VAS: mm) [95%CI] , n = 37	58.5 [52.9, 64.0]	30.7 [24.4, 37.0]	[21.4, 34.1]	0.000	0.83	T
Mean HIT-6 * [95%CI] , n = 37	58.2 [55.8, 60.7]	50.7 [48.3, 53.1]	[4.9, 10.2]	0.000	0.69	T
Median EQ-5D-5L [IQR], n = 37	0.83 [0.70, 0.90]	0.90 [0.76, 0.94]	[0.01, 0.13]	0.038	0.43	W
Median Expenses used for tension-type headaches (JPY) [IQR], n = 28	8000 [1350, 45167]	38700 [22800, 53300]	[-19600, 22600]	0.664	-	W

W: Wilcoxon signed rank sum test, T: Paired t-test, IQR: Interquartile range, 95% CI: 95% Confidence Interval
The effects on the frequency and severity of headaches and the HIT-6 impact on everyday activities. The frequency and severity of headaches both decreased significantly post-intervention ($p < 0.05$). The HIT-6 score for the impact on everyday activities also improved significantly post-intervention ($p < 0.05$).

Table 5
Acupuncture ICER and Incremental QALY for tension-type headache

		Interquartile Range			95%CI			
	Median	25%th	75%th	Mean	Lower	Upper	Min	Max
ICER（JPY/QALY）	484	-13404	2003	-3890	-10525	2744	-38848	18263
ICER（USD/QALY）	5	-129	19	-37	-101	26	-374	176
Incremental QALY（QALY）	1.4	0.0	7.3	3.2	1	5.4	-5.7	19.7

ICER:Incremental cost-effectiveness ratio. 95% CI:95% Confidence Interval
The ICER and Incremental QALY. The median ICER was JPY 484 (USD 5 [-129, 19]). The mean ICER (95% CI) was JPY -3890 (USD -37) . The median Incremental QALY was 1.4 [0.0, 7.3]. The mean (95% CI) Incremental QALY was 3.2 [1.0, 5.4].

5. Validity of the sample size

According to the post-hoc power analysis, the minimum number of observations required for each assessment parameter is as follows: days of headache per month, 54 people; degree of pain, 10 people; HIT-6, 21 people; and EQ-5D-5L, 56 people. The sample size for the degree of pain and HIT-6 was reasonable.

IV. Discussion

1. Efficacy of acupuncture for TTH

When patients with TTH received acupuncture for 3 months, the frequency and severity of their headaches decreased significantly. Their HIT-6 scores also decreased significantly, and their EQ-5D-5L index values increased significantly. This indicates their headaches were alleviated post-intervention and the impact on their everyday activities and state of health lessened.

Previous clinical studies have also demonstrated that acupuncture is effective for TTH. A study of 82 patients with episodic TTH and 139 with CTTH that did not respond to pharmacologic therapy over at least 1 month found that acupuncture was effective for 80.1% of those with episodic TTH and 59.9% of those with CTTH. The need for response assessment in episodic TTH that occurs three times or continues for 2 weeks and in CTTH that occurs nine times or continues for 5 weeks has also been demonstrated[5]. In a review of 15 clinical studies (with a total of 1,272 participants), Spyridon et al. reported that in the long term, acupuncture demonstrated a statistical (p=0.009) in the pain intensity and clinical benefit compared with placebo/sham[12]. A meta-analysis of 8 reviews showed that acupuncture for TTH reduced headache frequency and severity from a descriptive analysis. However, the generally low methodological and evidence quality of the included a meta-analysis limits the confidence in the results[13]. Therefore, as in previous studies, acupuncture appears to have an effect on the frequency and severity of tension-type headache in this study. However, it should be noted that no control group was established and other factors cannot be ruled out. Progress in the study regarding this event is expected in the future.

2. Cost-effectiveness of acupuncture for TTH

Continuous variables in ICER do not have normality, so the median value is used as a reference. The median ICER was JPY 484 (USD5). Therefore, this indicates that adding acupuncture to standard care would require an additional cost of JPY 484 (USD5) to gain 1 QALY.

The ICER is used as a decision-making criterion in cost-benefit analyses in the medical and public health fields. In Australia and Canada, it is applied to decisions on insurance coverage and prices of new drugs, but it is not used in this way in Japan. In Australia, the criterion is AUD 36,000 (USD27,730)[14] and in Canada CAD 20,000 (USD 15,701)[15], while in the United States it is USD 50,000[16] and in the United Kingdom GBP 30,000 (USD 40,754)[17].

In Japan, Ohkusa et al.[18] and Shiroiwa et al.[19] investigated the amount that Japanese residents would be willing to pay per QALY and identified a range of JPY 6.35.6.70 million (USD 61,057.64,423). Cost-effectiveness is reported to be excellent if the criterion is up to approximately JPY 6.7 million (USD 57,692.67,308). The mean cost per QALY in

this study was within the range of the amounts that Japanese residents would be willing to pay per QALY shown in previous studies[18,19].

However, few studies have addressed the cost-effectiveness of acupuncture for TTH. There are several previous studies on the ICER per QALY of acupuncture for primary headaches, including TTH.

One European study on the additional cost and cost-effectiveness of acupuncture for primary headaches, including TTH, found that the ICER per QALY was EUR 11657 (USD 104045). Although the costs incurred by the acupuncture group were greater than those of the control group, the study showed acupuncture to be a highly cost-effective treatment for primary headache patients when compared with international cost-benefit thresholds[20] . A cost-effectiveness study of acupuncture in the management of chronic headaches, primarily migraine, conducted in England and Wales gave a base case estimate of 9180 pounds (USD 11616) per QALY gained, it is relatively cost effective compared with a number of other interventions provided by the NHS[21]. For Japan, an assessment conducted by Shimizu et al[22]. showed that an extra economic burden of only around JPY 600 (USD 5.8) is required to avoid a single migraine attack. In general, triptans have been shown to be highly cost-effective. However, the cost to live in good health without a single attack is at least an extra JPY 2 million per year (USD 19,231 per year).

The ICER per QALY in this study was lower than in previous studies. One possible cause for is that previous studies compared acupuncture treatment alone with a control group, whereas this study compared standard treatment (pre-intervention) with usual treatment plus acupuncture (post-intervention). In addition, differences in types of headaches (Among the primary headache types, many clinical studies have focused on migraine patients), or differences in each country's economic conditions and healthcare systems should also be taken into account.

The ICER per QALY gained from adding acupuncture to standard treatment would be within reasonable the range of the amounts that Japanese residents would be willing to pay per QALY. Although, it should be noted that this study did not compare acupuncture alone for tension-type headaches with a control group. Future studies are needed to compare the ICER per QALY gained between acupuncture-only treatment and conventional treatment.

3. Limitations of the study

Although the cost-effectiveness of acupuncture for TTH appears promising according to the findings of this study, they still need to be interpreted with caution because of several limitations, including the small sample size ,having a gender imbalance and no control group. We confirmed that the treatment for TTH during the study period was limited to standard treatment and the acupuncture treatment used in this study, but there were no specific restrictions on treatments other than TTH, and did not confirm their content. The acupuncture procedures were conducted based on standardized protocols established in advance. However, no specific restrictions were imposed on the number of treatment sessions or the treatment fees, including the use of health insurance. At Japanese acupuncture clinics, patients who use health insurance are able to pay a reduced cost per treatment. In other words, differences between acupuncture clinics may act as confounding factors that affect the results. In this study, the number of patients enrolled was biased depending on the acupuncture clinic. Additionally, 7 out of 45 people dropped out. This may have influenced the research results. Further, the intervention in this study consisted of the addition of acupuncture to the routine treatment and thus, does not demonstrate the actual cost-effectiveness of acupuncture alone. The intervention period was only 3 months, implying its cost-effectiveness beyond this period remains unknown.

V. Conclusions

We carried out a multicenter prospective comparative study and demonstrated the cost-effectiveness of acupuncture for TTH in terms of its ICER and cost per QALY. To the best of our knowledge, this is the first study to evaluate the cost-effectiveness of acupuncture for TTH in Japan. In the context of the increasingly active debate on the cost-effectiveness of medical care, we investigated the economic effects of acupuncture on headaches, which cause major economic losses, and found that its effect is reasonable. Despite such interesting results, any generalization of these results needs to be made with caution given the different types of headaches, the different economic conditions and healthcare systems in the various countries. We hope that this study will be a starting point for further studies on the cost-effectiveness of acupuncture.

Statements

Acknowledgments

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Conflict of Interest Statement

The authors have no conflicts of interest to declare.

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Publication

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