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TITLE PAGE

“Big needles, small bodies”--

the absence of acupuncture treatment for infants in contemporary Shanghai: a qualitative study

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Abstract

Objective- To explore contemporary practices and clinical recommendations regarding the use of acupuncture for infants by Traditional Chinese Medicine (TCM) practitioners in Shanghai.

Design- A qualitative study consisting of four field visits between February 2014 and March 2015. Data was collected using participant observation, focus group interview, in-depth interview, textbook page analysis, and informant validation.

Participants- 14 Shanghainese professionals, including interpreters and TCM practitioners, of which seven were acupuncturists.

Setting- The Longhua Hospital (pediatric, acupuncture, and Tui na departments) in southern Shanghai and the campus of the Shanghai University of Traditional Chinese Medicine.

Results- The Longhua Hospital outpatient acupuncture clinic receives 400 consultations on average per day. Children, including patients from the pediatric department, are referred to this clinic. During three days of participant observations at this department, we saw two children. No infants. Formal interviews and informal conversations with acupuncturists and other TCM professionals revealed that acupuncture was neither routinely practiced nor recommended for infants and small children. Acupuncture was considered potentially painful for this young patient population. Alternative treatment options such as herbal treatments or medical massage were widely available and preferred. Western medical diagnostics and treatment were also used, recommended, and trusted.

Conclusions- Acupuncture for infants is not a preferred therapeutic method among TCM practitioners working in contemporary Shanghai. Acupuncture on broad indications in infants appears to be a Western construct with little basis in TCM tradition or modern-day practice.

Strengths and limitations of this study

This is the first qualitative study exploring actual actual experiences with and recommendations of acupuncture for infants among contemporary Traditional Chinese Medicine(TCM) practitioners in the city of Shanghai.

To improve credibility(internal validity) in a setting with language and logistical challenges we used a flexible multi-angle approach, and conducted participant observations, interviews, textbook page analyzing and informant validations.

A limitation is the small number of informants, 14 in total, and that we were only able to conduct one in-depth and one focus group interview.

The study was carried out in one hospital in one city, and the transferability (external validity) may be limited.

Background

Acupuncture is a part of Traditional Chinese Medicine (TCM). There are three main pillars of TCM: herbal medicine, acupuncture and moxibustion (needles and heating), and Tui na (medical massage). Herbal medicine is the mainstay of TCM in China, while acupuncture/moxibustion and Tui na are regarded as auxiliary and complementary therapies. Acupuncture is used widely in Western Europe, North America, and Australia.(1-6). The treatment principles of acupuncture are relatively straightforward, especially for treatment of various pain conditions in adults, and the mechanisms for the neurophysiological effects of acupuncture are fairly well understood (7). In acupuncture, thin steel needles are penetrated through the skin and into connective tissue and muscle fibers to elicit effects. Compared to no treatment or treatment-as-usual, specific needle effects are small, with standardized mean differences (SMD) ranging from 0,15 to 0,23. The overall effectiveness is larger, with a SMD of about 0,5 SMD.(8) This larger overall effect is attributed to acupuncture being a particularly good placebo irrespective of treatment approach or practitioner style or experience.(9)

Acupuncture in children, including infants, has also gained acceptance in the West.(10-13) However, there are concerns surrounding the ethical aspects of this treatment,(14-16) as it is a potentially painful method.(17, 18) In contrast to adults and older children, infants lack the ability to provide informed consent, and this requires a higher threshold for interventions.(19) The relatively large placebo effects of acupuncture through the activation of the anticipation/reward systems, deemed important in the treatment of adults, would arguably not occur in this young patient population. Acupuncture in experienced hands is considered safe,(20) also in children.(21) Yet the scientific evidence on the effectiveness of acupuncture treatment for young children is sparse or non-existent,(10, 11) and randomized controlled trials regarding the efficacy of acupuncture for pain conditions in infants are few with conflicting results.(18, 22, 23) Western-based textbooks of acupuncture argue that acupuncture effects in infants and small children are swift, and often stronger than in adults, (24-27) contradicting the few existing randomized controlled studies.(11, 23)

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3 These textbook notions seem to be based on references to TCM tradition and on the authors'
4
5 personal views or clinical observations rather than evidence from randomized, controlled clinical
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7 trials. Published case reports and qualitative studies are also generally supportive of acupuncture in
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9 infants and small children, and recommend acupuncture for broad indications in pediatric
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11 populations.(12, 28, 29)
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13
14 There is little scientific knowledge regarding the nature and extent to which acupuncture is used for
15
16 pain conditions in pediatric populations in modern-day China. Chinese-English language textbooks
17
18 consider herbal remedies as the primary treatment method in children(30), followed by Tui na,
19
20 although acupuncture is often mentioned as an adjunct treatment.(31, 32) A literature search
21
22 conducted by the first author of major databases (Cochrane, Medline, Embase, AMED, Maternity and
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24 Infant Care, Global Health, PsycINFO, Anthropology Plus, Sociological Abstracts, ISI-Web of
25
26 knowledge, IBSS , AIO, BASE, and Wanfang Data, including conference proceedings from academic
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28 conferences in China) identified no English-language studies describing contemporary TCM clinical
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30 practices or clinical guidelines on the use of acupuncture for infants or small children from the
31
32 People's Republic of China, Taiwan, Singapore and Hong Kong. Survey studies of TCM in children
33
34 have been reported from Singapore and Taiwan(33, 34), but we found no English-language studies or
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36 published abstracts on TCM practitioners' views and attitudes toward acupuncture treatment for
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38 infants and small children.
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43 The purpose of this study was to investigate current opinions and clinical practices regarding needle
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45 acupuncture for infants among TCM clinicians in Shanghai.
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48 **Method**

49 We chose a qualitative approach, including participant observations, interviews and literature
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51 searches. This study was informed by methods described in "Qualitative Research Design" by J.
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53 Maxwell.(35) The combination of qualitative methods used reflects the validity threats and logistical
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3 challenges of carrying out such a study. Field notes and interviews were transcribed and analyzed
4
5 according to the principles of thematic analysis.(36)
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8 **Setting**

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10 The first author conducted four field visits between February 2014 and March 2015 to Longhua
11
12 Hospital, which is a teaching hospital of the Shanghai University of Traditional Chinese Medicine
13
14 (SHUTCM) (**Figure 1- Study flow chart**). Longhua Hospital is a municipal TCM hospital with 2000
15
16 beds. The acupuncture department is an outpatient clinic with 42 beds, staffed by ten doctors and 20
17
18 interns who receive an average of 400 consultations per day. The pediatric department receives
19
20 about 130 outpatient consultations per day, with an average of ten inpatients admitted daily to the
21
22 unit at any given time. There is also a small Tui na department which runs an outpatient service,
23
24 staffed by five doctors who receive approximately 50 consultations per day. The WHO Collaboration
25
26 Centre at SHUTCM facilitated study access and granted permission to collect data at Longhua
27
28 Hospital. The first author is a male general practitioner and acupuncturist with 25 years of
29
30 experience, with an established working relationship with the WHO Collaboration Centre.
31
32
33

34 **Data collection**

35
36 The field visits consisted of the following:

37
38 1: Three days of participant observation in the pediatric department, three days of participant
39
40 observation in the acupuncture department, and one day of participant observation in the Tui na
41
42 department. An interpreter who was either an English-speaking TCM doctor or an English-Chinese
43
44 linguist was present at any time. We followed the daily routines and engaged in informal
45
46 conversations with several acupuncturists, and pediatric and Tui na specialists. The interpreters
47
48 themselves were also a rich source of information.
49
50

51
52 2: A 90-minute, semi-structured focus group interview using a pre-defined interview guide, not pilot-
53
54 tested. The interview was conducted in English and without an interpreter, outside the workplace.
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56 The informants were three leading officials of acupuncture units in Shanghai, all of whom had clinical
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3 and administrative responsibilities. No parallel field notes were taken during the interview, and
4
5 transcripts were not returned. We did not succeed in recruiting regular clinicians for this interview,
6
7 because they felt they lacked sufficient knowledge of, and had minimal experience with, pediatric
8
9 acupuncture.

10
11
12 3: A 60-minute, in-depth individual interview using a pre-defined interview guide, not pilot-tested,
13
14 with a non-acupuncture TCM practitioner who had academic credentials, including work and
15
16 research experience in Western Europe. The interview was conducted in Chinese with an English-
17
18 Chinese interpreter outside the workplace. No parallel field notes were taken during the interview,
19
20 and transcripts were not returned..

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22
23
24 4: A comprehensive search of the People's Republic of China's national textbooks used for teaching
25
26 acupuncture, Tui na and herbal medicine at SHUTCM for the MD China, a common five-year TCM
27
28 program. The search was assisted by a linguist fluent in Chinese and English. We counted section
29
30 pages and case pages to gauge the factual emphasis on using TCM therapeutic methods for pediatric
31
32 populations in the national textbooks.

33
34
35
36 5: Two stages of informant validation on the main and final results. Main results by one central
37
38 informant, and final results by two independent informants.

39
40
41 A total of 14 informants were included during the field study. Informants had diverse clinical
42
43 backgrounds representing several TCM specialty areas, including seven acupuncturists. (**Figure 2-**
44
45 **Participants- informants**). There were six women and eight men between 35 and 60 years of age,
46
47 with a minimum of ten years clinical experience. To maintain anonymity, further details on the
48
49 participants are not disclosed.

50 51 52 53 54 55 **Data analysis**

1
2
3 All data were used, including notes from participant observations, informal conversations, semi-
4
5 structured interviews, and textbook page analysis. The field notes were structured and systematized,
6
7 including the participant observations and the information gathered from informal conversations.
8

9
10 The focus group and in-depth interviews were recorded on two parallel, portable tape recorders and
11
12 transcribed in verbatim. The sound files were transferred to a USB storage pen and securely stored.

13
14 The original sound tracks on the tape recorders were erased.

15
16 The data analyses were carried out using thematic analysis.(36) The analyses were done by hand and
17
18 coding was primarily on semantic (manifest) content.(36) We did not seek saturation. The first
19
20 author read through the texts several times to define broad categories from the interviews and field
21
22 notes with subsequent coding and re-categorization. The main categories and selected opinion
23
24 statements were then sequenced into tables. We did not use a coding tree. The initial analysis was
25
26 then reviewed by the second author before refinement and undergoing final organization. All quotes
27
28 have been retained in their original form.

29
30
31 The study is reported in accordance with the Consolidated Criteria for Reporting Qualitative Research
32
33 (COREQ) checklist.(37)
34

35 36 **Ethics**

37
38 The Regional Ethical Committee of Southeastern Norway, REK- South East granted this project an
39
40 exemption from formal approval owing to the lack of patient data (Ref: 2014/197/REK South East).

41
42 The informants who participated in formal interviews were informed of the purpose of the study and
43
44 they signed a written consent form. The head or acting head of the three departments at the
45
46 Longhua hospital were informed of the purpose of the study and they signed a written consent form.
47
48

49 50 51 **Results**

52 53 54 **The absence of children**

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During the 3-day field visit at the acupuncture department at Longhua TCM hospital, we moved freely between the consultation rooms, waiting rooms, and reception area.

In total, we saw two children. No infants. (Table 1-I).

Table 1. Results in numbers

I.

Patients observed to have acupuncture during 3 days in Longhua Acupuncture department (400 consultations a day, only out-patients)

Infants	0	
Children	2	

II.

The Shanghai TCM acupuncturists (7 informants)

Do they have experience in needle acupuncture on infants?

Very little or no experience	5	All acupuncture clinicians, one acupuncturist-official
Some experience	2	Two acupuncturist-officials
Regular or daily experience	0	

III.

All Shanghai TCM professionals (12 informants)

Do they recommend needle acupuncture on infants?

No	9	All acupuncture clinicians, both TCM pediatricians, both Tui na specialists and the TCM herbalist
Yes, but only as the last choice	3	All acupuncturist-officials
Yes	0	

IV.

Amount specifically on pediatric conditions in Standard national textbook in undergraduate Traditional Chinese Medicine (TCM) studies, Shanghai.

Herbal Medicine:	
Special textbook on Pediatric herbal medicine:	140 pages
Tui na / medical massage:	
Pediatric section of general textbook:	57 of 248 pages
Acupuncture and moxibustion:	
No pediatric section in general textbook.	
Conditions relating to children:	6 of 328 pages

“Nobody does pediatric acupuncture.” Lack of experience

During informal conversations with clinicians at the acupuncture department, we were informed that children and infants were very seldom referred for treatment, and thus, the clinicians stated they lacked experience with needle acupuncture treatment on children. Several of the acupuncturists

1
2
3 reported they had treated only one or two children last year. None of the clinicians had treated
4
5 infants. As one TCM acupuncturist described, *“Not so many children here. I treated two patients last*
6
7 *year. Six-year olds. Facial paralysis and poor concentration. No infants.”* During the formal focus
8
9 group interview with the leading officials of acupuncture units in Shanghai, two of three reported
10
11 some past experience in treating children, including infants. However, they did not provide
12
13 information on whether this occurred on a regular basis. **(Table 1-II).**

14 15 16 17 18 **“Not convenient.” Lack of recommendations**

19
20 Formal interviews and informal conversations with TCM clinicians revealed that acupuncture for
21
22 infants and a small children was not recommended. The focus group interview confirmed this finding,
23
24 and the officials from the acupuncture clinics stated that acupuncture therapy for infants and small
25
26 children was considered “the last choice” **(Table 1-III)**. One TCM acupuncturist stated, *“Never used*
27
28 *acupuncture, especially with small children. How could you? Not convenient. Big needles, small*
29
30 *bodies. We use Tui na and herbs.”* A TCM pediatrician expressed *“Acupuncture is considered invasive.*
31
32 *We are reluctant to do that on infants.”* One exception to this consensus included neurological
33
34 conditions such as cerebral palsy, neurological birth defects, and recently, ADHD, which is regarded
35
36 as a neurological disease. For these conditions, needle acupuncture was considered a possible
37
38 treatment method.

39 40 41 42 **“No classic, no modern.” Lack of textbooks and training**

43
44 In interviews and informal conversations, TCM clinicians reported a lack of specialized textbooks and
45
46 training in performing needle acupuncture on children. In contrast, textbooks and specialized
47
48 courses exist for pediatric herbal medicine and pediatric Tui na. Traditional and modern teaching in
49
50 acupuncture does not distinguish between acupuncture point combinations for adults versus
51
52 children. As one TCM acupuncturist explained, *“Never been taught pediatric acupuncture in MD*
53
54 *China or postgraduate education. No special points, no special treatments, no special meridians, no*
55
56 *special organ systems.”*

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3 A five-year program of integrated Western and TCM coursework is required for MD China,
4
5 which qualifies for certification as a TCM herbalist, acupuncturist or Tui na specialist. A search of the
6
7 national textbooks at SHUTCM- Shanghai University of Traditional Chinese Medicine revealed the
8
9 following page counts and specific chapter dedicated to children per textbook:
10

11 -National Standard Textbook of Pediatric Herbal Medicine: 140/140 pages (38)

12 -National Standard Textbook of Tui na: 57/256 pages. 1 pediatric chapter (pages 171-228) (39)

13 -National Standard Textbook of Acupuncture and Moxibustion: 6 of 328 pages, no pediatric chapter.

14
15 In the treatment chapters, children are mentioned on page 254 (enuresis), malnutrition (page 255),
16
17 polio sequelae (page 255), mumps (page 258), convulsions (page 274), and otitis media (page
18
19 266).(40) (Table 1-IV)

20 21 22 23 24 **“For now, zero.” The lack of a strong research base**

25
26 During the focus group interview, we explored the informants’ knowledge regarding research on
27
28 acupuncture treatment for infants and small children. Despite being familiar with numerous studies
29
30 on herbal treatments and Tui na in pediatric samples, they reported no knowledge of ongoing or
31
32 existing research on needle acupuncture in infants and small children.

33 34 35 **“Of course it is painful.” The possibility of pain**

36
37 Pain as a consequence of needle acupuncture was discussed with all the TCM clinicians, including
38
39 pediatricians, Tui na specialist, and acupuncturists. Prevailing attitudes among clinicians was that
40
41 acupuncture was painful for infants and small children. The potential for pain was stated as a primary
42
43 reason for the overall limited use of needle acupuncture in infants. For example, one TCM
44
45 acupuncturist stated, *“We have very few children. No infants. It is hard to make good acupuncture*
46
47 *treatment. And it is painful.”* Two of the leading acupuncture officials diverged in opinion, however,
48
49 stating that needle acupuncture in children could be painless when done in the right way with the
50
51 proper method. One TCM official reported, *“There are some special methods, though, for inserting*
52
53 *the needle without pain. Too many adults and children are just scared of the needles.”*

54 55 56 57 **“Eighty percent of acupuncture on children is CP or other neurology.” Indications for acupuncture**

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3 Acupuncturists and other TCM clinicians expressed the clear opinion that acupuncture was indicated
4 for very few conditions in children. Indications included neurological diseases in which other
5 treatment options were limited. However, two of the TCM acupuncturists/hospital officials diverged
6 in opinion by recommending broader indications for children, including asthma, malnutrition, and
7 digestive problems. There was broad consensus that acupuncture was not a treatment option in
8 modern TCM for infants. A Tui na specialist stated, *“Acupuncture has such a long history, it never
9 separated kids and adults. But you mentioned under one year, but this only for these acute problems,
10 like convulsions, high fever, emergency. Then they may use needles.”*
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24 **“TCM pediatrics is herbs.” The availability of TCM alternatives: Herbal medicine and Tui na**

25
26 Historically, several TCM treatments have been available for pediatric patients. In particular,
27 treatments with herbal medicine and Tui na have been specifically developed for children. For
28 contemporary Shanghaiese TCM practitioners working with children, treatment is largely focused
29 upon herbal medicine in the form of orally-administered drugs or herbal paste applied to
30 acupuncture points. As explained by a TCM herbalist, *“We focus on herbs. And some Tui na. Always
31 like that. If acupuncture points, we use moxibustion.”* This approach to treatment was confirmed
32 during the participant observations at the TCM pediatrics department. The vast majority of pediatric
33 outpatients were prescribed herbal treatment combinations, and some were recommended Tui na. If
34 acupuncture comprised the treatment, the specific recommendation included herbal paste, often
35 heated, as a point application. We did not observe needle acupuncture treatment, nor did we
36 observe any recommendations provided for acupuncture during the field visit to the pediatrics
37 department. Penetrating needle acupuncture on infants was not considered a treatment option for
38 most TCM pediatric conditions.
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54 **“Now parents take children to the Western Children Hospitals.” Trust in Western pediatrics**

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3 There are four governmental Children's Hospitals in Shanghai. These hospitals are large Western
4
5 medical hospitals with inpatient wards and specialized outpatient clinics staffed solely with medical
6
7 doctors and other clinical staff educated in Western medicine. The vast majority of pediatric cases in
8
9 Shanghai, particularly infants and toddlers, are treated at these hospitals. These hospitals provide
10
11 treatment for a range of illnesses, from minor ailments to chronic or life-threatening conditions.

12
13
14 Western medical hospitals are widely regarded as the first choice by Shanghainese parents seeking
15
16 assessment, consultation, and treatment for their children. The TCM professionals themselves
17
18 provide recommendations and referrals to the hospitals for infants and small children, as indicated
19
20 by a TCM pediatrician, *"They have better diagnostic equipment at Western hospitals, for example the*
21
22 *pediatric ultrasound, for abdominal diagnostics. We do not have that."* A TCM herbalist stated, *"Now*
23
24 *parents take children to the Western Children Hospitals. If needed, herbs in addition. Acupuncture is*
25
26 *never in their minds"*.

27
28
29 **"The whole TCM world is shrinking in China, or at least in Shanghai." The money and the system**

30
31 During the field study at Long Hua hospital, there was a general sense that traditional TCM practice
32
33 was diminishing in importance and facing challenges from Western medicine, even in the TCM
34
35 hospitals. The ratio of Western to TCM hospitals in Shanghai is seven to one. By law, all hospitals are
36
37 required to have a TCM department. Long Hua is an integrated hospital, such that TCM and Western
38
39 medical approaches to diagnostics and treatment are combined. The TCM clinicians at Long Hua
40
41 confirmed that TCM is losing ground to Western medicine. In the pediatric department, for example,
42
43 the majority of the outpatient consultations we observed included a Western medical prescription.
44
45 For example, the inpatients, many of whom had respiratory tract infections and/or asthma
46
47 exacerbations, received antibiotics and/or corticosteroid medication. The clinicians reported that
48
49 traditional Chinese medicine departments were being reduced in terms of beds and staff, and that
50
51 entire departments in other TCM hospitals had merged or been significantly reduced in size. Financial
52
53 reasons were identified to explain this trend. In brief, the hospitals are financed through
54
55 governmental funding as well as patient fees for procedures, medicines, and consultation fees.
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3 Although basic equipment is free, the more advanced, and consequently, more Western equipment
4 is more expensive. All hospitals, including TCM and Western, increase their earnings by focusing on
5 Western medical therapeutics. As such, the general trend in TCM hospitals is toward greater
6 utilization of Western medical treatment and procedures. An anonymous informant stated, *“One
7 surgeon can earn for the hospital as much as a hundred TCM doctors. TCM herbal medicines is cheap-
8 little money.”*

15 **“It is a vicious cycle”- The slipping confidence**

16
17 Several of the TCM practitioners reported changing attitudes towards healthcare, with increasingly
18 assertive parents and a more critical, consumer-driven approach towards treatment and healthcare
19 professionals, especially for treatment of children. The TCM practitioners were reluctant to advise
20 against parents’ wishes and they were similarly reluctant to do anything that could elicit unpleasant
21 reactions in the child, like crying. Acupuncture was generally considered painful, and in turn, TCM
22 clinicians were increasingly hesitant to recommend acupuncture for treatment in children. This trend
23 perpetuated a cycle which limited experience, limited expertise, and lowered confidence. One TCM
24 practitioner reported, *“It has also two sides, because at first the parents are reluctant to go, but
25 doctors they need experience. Because they have less and less patients, they don’t have that
26 expertise. They don’t have confidence. It is a vicious cycle.”*

32 **“I have one cerebral palsy patient, 6 months old, who tolerates needles with no pains”- the 33 divergent point of view**

34
35 The formal focus group interview differed in many aspects from the individual, in-depth interviews
36 and the informal conversations with clinicians. Specifically, opinions voiced during the focus group
37 differed with regard to tradition, experience, indications for acupuncture, and the question of
38 whether acupuncture was a painful intervention. Among the three hospital officials, there was a
39 general reluctance to limit the possibility of acupuncture as a universal treatment option. This
40 viewpoint contrasted with TCM practitioners, among whom there was broad agreement regarding
41 the limitations of needle acupuncture in infants and small children.

Discussion

Main findings

This qualitative study explored the use and recommendations for needle acupuncture on infants and small children by traditional Chinese medicine (TCM) practitioners in Shanghai. During three days of participant observations at the Longhua hospital outpatient acupuncture clinic, which receives on average 400 patients per day, we observed only two children and no infants. During formal interviews and informal conversations with TCM practitioners representing different specialties, the prevailing opinion was that needle acupuncture for infants and small children is considered painful, is inconvenient, and is not indicated for routine clinical practice, except for certain neurological diseases. We learned that TCM methods for children have traditionally focused on herbal medical treatments, and to a lesser extent, on Tui na. Acupuncture had historically been used for certain acute illnesses, which are now treated in Western hospitals. The majority of acupuncturists, and all of the non-acupuncture TCM practitioners, had limited or no experience treating children or infants with needle acupuncture and would not recommend it as a therapeutic option. The exceptions were the opinions of two TCM acupuncture officials. The reason for the non-use of acupuncture in small children seemed to revolve around two main themes 1) internal TCM traditions and practices, which do not support the routine practice of needle acupuncture in infants and toddlers, and 2) external system changes which increasingly limit the use of acupuncture specifically, and TCM practices in general.

Internal TCM tradition and practice- The most important reasons for the lack of acupuncture in infants and small children attribute to TCM traditions and practices. Specifically, herbal medical

1
2
3 treatments or Tui na are widely available and universally recommended as a first-choice TCM
4
5 treatment for pediatric populations.
6

7 **External system changes-** System changes within the general healthcare system in Shanghai over the
8
9 past years are also relevant in explaining the lack of pediatric acupuncture. TCM departments and
10
11 practices, including acupuncture, are losing ground to Western medicine, with widespread
12
13 consequences. Even original TCM hospitals and institutions are losing credentials and resources to
14
15 Western diagnostics and treatment, which offers greater financial compensation than traditional
16
17 TCM practices. This is also true for pediatrics.
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19

20 21 **Strength and weaknesses**

22
23 Strengths of the study include the uniformity of the participant observations and the information
24
25 collected from the TCM clinicians, the variety of sources of information, the triangulation of
26
27 methods, and the validation process.(41). The discrepant voices were the officials who had both
28
29 clinical and administrative responsibilities, who regarded acupuncture as a universal method of
30
31 treatment. Limitations of the study involved the challenges of conducting qualitative research in
32
33 situations requiring interpreters, or in which both the researchers and informants have English as
34
35 their second language. We relied entirely upon our Shanghai contacts to gain access and organize
36
37 interviews with TCM practitioners and officials, and as such, the selection of informants may be
38
39 biased. It is worth noting that the situation in Shanghai might differ substantially from TCM in other
40
41 cities and provinces in China. However, the centralized and uniform organization of education and
42
43 the practice of TCM in Shanghai and the People's Republic of China, arguably strengthens external
44
45 validity. An important consideration is the first author's prejudices and standard of reflexivity in the
46
47 information gathering and analyzing process. (42) Qualitative research designs run the risk of biased
48
49 and selective reporting. The use of a diversity of informants, several information gathering methods,
50
51 and a detailed description of the methodological aspects of the process might, however, counteract
52
53 such bias.
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56 57 **Implications for practice**

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3 This study adds to the ongoing discussion on the evidence, utility, and limitations of acupuncture in
4 children, as well as in medicine in general.(43-47) Contrary to our observations in Shanghai,
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This study adds to the ongoing discussion on the evidence, utility, and limitations of acupuncture in children, as well as in medicine in general.(43-47) Contrary to our observations in Shanghai, acupuncturists in the Western world encourage acupuncture for children, including infants.(29, 48, 49) One rationale underpinning this trend is that acupuncture is widely considered in the West to be an integral part of TCM tradition, for patients of all ages. According to our study, Western beliefs that acupuncture is routinely indicated and recommended for infants and small children within TCM are unfounded. Such beliefs appear to be a Western construct, and are not based on actual Chinese modern-day practices or therapeutic recommendations. Recent controlled trials investigating the efficacy of acupuncture treatment in the infant population (11, 18, 23) yield conflicting results, and little clear empirical evidence is available to support the use of acupuncture.

As such, it appears that the rise of infant acupuncture in the West is largely attributable to Western acupuncturists' own clinical observations. In line with the principles of biomedical ethics, (50) however, this study underscores that this rationale is insufficient to recommend a potentially painful treatment for infants and small children who lack the competence to provide informed consent.

Conclusion

Acupuncture for infants and small children is neither routinely practiced nor recommended by TCM clinicians working in Shanghai. It is generally considered a potentially painful therapeutic method. Alternative TCM treatments are widely available and preferred by TCM practitioners in Shanghai, including herbal treatments and medical massage (Tui na). Needle acupuncture on broad indications in infants appears to be a Western construct, with little basis in Chinese TCM tradition or contemporary practice.

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The authors would like to thank the clinicians at Longhua hospital and the teachers and translators at Shanghai University of Traditional Chinese Medicine for their invaluable cooperation and support.

Competing Interests

No, there are no competing interests

Contributorship Statement

HS and MB developed the original idea, developed the flexible study process and wrote the initial protocol. HS carried out the field study in Shanghai,, transcribed the interviews and field notes and carried out the initial analyzing. MB reanalyzed the field notes and interviews. HS wrote the initial draft of the article. MB reviewed and structured the article. HS is the guarantor of the study.

Data Sharing Statement

No additional data are available.

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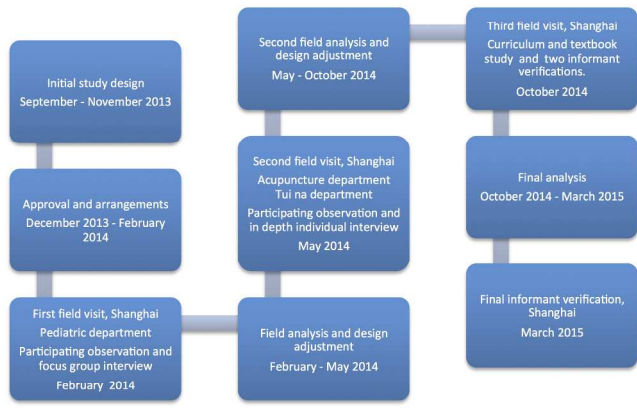
36 Figure Legends

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38 Figure 1: Participants- informants

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41 Figure 2: Study flow chart

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Study flow chart
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14 informants in total. Experienced TCM professionals and English-Chinese linguists/translators, 35-65 years		
<p>7 TCM professionals Longhua hospital</p> <ul style="list-style-type: none"> • 2 pediatricians • 4 acupuncturists • 1 Tui na specialist 	<p>5 TCM professionals, other TCM institutions in Shanghai</p> <ul style="list-style-type: none"> • 3 acupuncturist (2 of them also translators) • 1 Tui na specialist • 1 herbalist 	<p>4 translators</p> <ul style="list-style-type: none"> • 2 linguists • 2 acupuncturists

Participants-informants
209x296mm (300 x 300 DPI)

Consolidated criteria for reporting qualitative studies (COREQ): 32-item checklist

“Big needles, small bodies”--

the absence of acupuncture treatment for infants in contemporary Shanghai: a qualitative study

No Item Guide questions/description

Domain 1: Research team and reflexivity

Personal Characteristics

1. Interviewer/facilitator Which author/s conducted the interview or focus group?

Yes. *First author Holgeir Skjeie*

2. Credentials What were the researcher’s credentials? E.g. PhD, MD

Yes. *Holgeir Skjeie. General practitioner and acupuncturist, Mette Brekke, professor.*

3. Occupation What was their occupation at the time of the study?

Yes. *Holgeir Skjeie. General practitioner, Mette Brekke, professor.*

4. Gender Was the researcher male or female?

Yes. *Holgeir Skjeie, male. Mette Brekke, female.*

5. Experience and training What experience or training did the researcher have?

Yes. *Holgeir Skjeie. General practitioner and acupuncturist for 25 years.*

Relationship with participants

6. Relationship established Was a relationship established prior to study commencement?

Yes. *A working relationship with the WHO Collaboration Centre, SHUTCM, Shanghai.*

7. Participant knowledge of the interviewer. What did the participants know about the researcher?

e.g. personal goals, reasons for doing the research.

Yes. *A prior working relationship, and consent forms with information.*

8. Interviewer characteristics What characteristics were reported about the interviewer/facilitator?

e.g. Bias, assumptions, reasons and interests in the research topic.

Yes. *In the information on page 9 (The first author is a male general practitioner and acupuncturist with 25 years of experience, with an established working relationship with the WHO Collaboration Centre.), and in the Discussion.*

Domain 2: study design

Theoretical framework

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2
3 9. Methodological orientation and Theory
4

5 What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse
6 analysis, ethnography, phenomenology, content analysis.

7 Yes. *Thematic analysis.*
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9

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13 Participant selection

14 10. Sampling How were participants selected? e.g. purposive, convenience, consecutive, snowball.

15 Yes. *Purposive and convenience.*
16
17

18 11. Method of approach How were participants approached? e.g. face-to-face, telephone, mail,
19 email.

20 Yes. *Face-to face.*
21
22

23 12. Sample size How many participants were in the study?

24 Yes. *14 in total. 3 in the focus group interview, 1 in the in-depth interview. 10 in the informal*
25 *conversations during participant observations, including the interpreters.*
26
27

28 13. Non-participation How many people refused to participate or dropped out? Reasons?

29 Yes. *All ordinary clinicians approached to participate in the focus group interview declined on reasons*
30 *of lack of experience.*
31
32

33 Setting

34 14. Setting of data collection Where was the data collected? e.g. home, clinic, workplace.

35 Yes. *The informal conversations at the participating observation periods in the workplace/clinic. The*
36 *interviews outside the workplace.*
37
38

39 15. Presence of non-participants Was anyone else present besides the participants and researchers?

40 Yes. *An interpreter was present at the in-depth interview and at the informal conversations in the*
41 *participating observations..*
42
43

44 16. Description of sample What are the important characteristics of the sample? e.g. demographic
45 data, date.

46 Yes. *Practicing acupuncturist, non-acupuncture TCM clinicians, and interpreters, see informants table.*
47
48

49 Data collection

50 17. Interview guide Were questions, prompts, guides provided by the authors? Was it pilot tested?

51 Yes. *We used a predefined interview guide in the in depth and focus group interview. Not pilot tested.*
52
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54 18. Repeat interviews Were repeat interviews carried out? If yes, how many?

55 Yes. *No repeat interviews.*
56
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58 19. Audio/visual recording Did the research use audio or visual recording to collect the data?

59 Yes. *Portable audio tape recorders.*
60

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3 20. Field notes Were field notes made during and/or after the interview or focus group?

4 Yes. *No field notes during the interviews..*

5
6 21. Duration What was the duration of the interviews or focus group?

7 Yes. *Focus group: 90 minutes. In depth interview: 60 minutes.*

8
9 22. Data saturation Was data saturation discussed?

10 Yes. *We did not seek saturation with our flexible approach.*

11
12 23. Transcripts returned Were transcripts returned to participants for comment and/or correction?

13 Yes. *Transcripts were not returned.*

14
15 Domain 3: analysis and findings

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17 Data analysis

18
19 24. Number of data coders How many data coders coded the data?

20 Yes. *The first author, Holgeir Skjeie, coded the data.*

21
22 25. Description of the coding tree Did authors provide a description of the coding tree?

23 Yes. *We did make use of a coding tree.*

24
25 26. Derivation of themes Were themes identified in advance or derived from the data?

26 Yes. *They were derived from the data, and surprising to us.*

27
28 27. Software What software, if applicable, was used to manage the data?

29 Yes. *Analysis were done by hand.*

30
31 28. Participant checking Did participants provide feedback on the findings?

32 Yes. *We validated main and final results independently by one, and then by and two informants, respectively.*

33
34 Reporting

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36 29. Quotations presented Were participant quotations presented to illustrate the themes / findings?

37 Was each quotation identified? e.g. participant number.

38 Yes. *They were identified as type of informant, but not by number.*

39
40 30. Data and findings consistent Was there consistency between the data presented and the findings?

41 Yes.

42
43 31. Clarity of major themes Were major themes clearly presented in the findings?

44 Yes.

45
46 32. Clarity of minor themes Is there a description of diverse cases or discussion of minor themes?

47 Yes. *The divergent point of view.*

BMJ Open

"Big needles, small bodies"-- the absence of acupuncture treatment for infants in contemporary Shanghai: a qualitative study

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Manuscript ID	bmjopen-2015-009486.R1
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Secondary Subject Heading:	Qualitative research, Paediatrics
Keywords:	COMPLEMENTARY MEDICINE, QUALITATIVE RESEARCH, PAEDIATRICS

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3 **TITLE PAGE**
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7 **“Big needles, small bodies”--**
8 **the absence of acupuncture treatment for infants in contemporary Shanghai: a qualitative**
9 **study**
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11 Holgeir Skjeie, Mette Brekke

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22
23 Key words: acupuncture, infants, ethics, Traditional Chinese Medicine (TCM)

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25 Word Count: 4559

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27 References: 51
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Abstract

Objective- To explore contemporary practices and clinical recommendations regarding the use of acupuncture for infants by Traditional Chinese Medicine (TCM) practitioners in Shanghai.

Design- A qualitative study consisting of four field visits between February 2014 and March 2015. Data was collected using participant observation, focus group interview, in-depth interview, textbook page analysis, and informant validation.

Participants- 14 Shanghainese professionals, including interpreters and TCM practitioners, of which seven were acupuncturists.

Setting- The Longhua Hospital (pediatric, acupuncture and Tui na departments) in southern Shanghai and the campus of the Shanghai University of Traditional Chinese Medicine.

Results- The Longhua Hospital outpatient acupuncture clinic receives 400 consultations on average per day. Children, including patients from the pediatric department, are referred to this clinic. During three days of participant observations at this department, we saw two children. No infants. During three days at the pediatric department and one day at the Tui na department we saw no referrals. Formal interviews and informal conversations with acupuncturists and other TCM professionals revealed that acupuncture was neither routinely practiced nor recommended for infants and small children. Acupuncture was considered potentially painful for this young patient population. Alternative treatment options such as herbal treatments or medical massage were widely available and preferred. Western medical diagnostics and treatment were also used, recommended, and trusted.

Conclusions- Acupuncture for infants is not a preferred therapeutic method among TCM practitioners working in contemporary Shanghai. Acupuncture on broad indications in infants appears to be a Western practice with little basis in TCM modern-day practice.

Strengths and limitations of this study

This is the first qualitative study exploring actual experiences with and recommendations of acupuncture for infants among contemporary Traditional Chinese Medicine (TCM) practitioners in the city of Shanghai.

To improve credibility (internal validity) in a setting with language and logistical challenges we used a flexible multi-angle approach, and conducted participant observations, interviews, textbook page analyzing and informant validations.

A limitation is the small number of informants, 14 in total, and that we were only able to conduct one in-depth and one focus group interview.

The study was carried out in one hospital in one city, and the transferability (external validity) may be limited.

Background

Acupuncture is a part of Traditional Chinese Medicine (TCM). There are three main pillars of TCM: Herbal medicine, acupuncture-moxibustion (needling and heating), and Tui na (medical massage). Herbal medicine is the mainstay of TCM in China, while acupuncture-moxibustion and Tui na are regarded as auxiliary and complementary therapies. Acupuncture is used widely in Western Europe, North America, and Australia.(1-6) The treatment principles of acupuncture are relatively straightforward, especially for treatment of various pain conditions in adults, and the mechanisms for the neurophysiological effects of acupuncture are fairly well understood.(7) In acupuncture, thin steel needles are penetrated through the skin and into connective tissue and muscle fibers to elicit effects. Compared to no treatment or treatment-as-usual, specific needle effects are small, with standardized mean differences (SMD) ranging from 0,15 to 0,23. The overall effectiveness is larger, with a SMD of about 0,5 SMD.(8) This larger overall effect is attributed to acupuncture being a particularly good placebo irrespective of treatment approach or practitioner style or experience.(9)

Acupuncture in children, including infants, has also gained acceptance in the West.(10-13). But there is scant evidence for treatment effects,(10, 11) no clinical guidelines exist, and practices vary substantially between countries. Individual textbook recommendations cover the whole range of pediatric indications from ear infections to autism(14) and from asthma to inflammatory bowel disease.(15) There are concerns regarding the ethical aspects of this treatment,(16-18) as it is a potentially painful method.(19, 20) In contrast to adults and older children, infants lack the ability to provide informed consent, and this requires a higher threshold for interventions.(21) The relatively large placebo effects of acupuncture through the patient's belief in the treatment being effective,(8) deemed important in the treatment of adults, would arguably not occur in this young patient population. Acupuncture in experienced hands is considered safe.(8) It is also, with experienced practitioners, considered safe in children.(22) Yet the scientific evidence on the effectiveness of acupuncture treatment for young children is sparse or non-existent,(10, 11) and

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3 randomized controlled trials regarding the efficacy of acupuncture for pain conditions in infants are
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5 few with conflicting results.(20, 23, 24) Western-based textbooks of acupuncture argue that
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7 acupuncture effects in infants and small children are swift, and often stronger than in adults,(25-28)
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9 contradicting the few existing randomized controlled studies.(11, 24) These textbook notions seem
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11 to be based on references to TCM tradition and on the authors' personal views or clinical
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13 observations rather than evidence from randomized, controlled clinical trials. Published case reports
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15 and qualitative studies are also generally supportive of acupuncture in infants and small children, and
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17 recommend acupuncture for broad indications in pediatric populations.(12, 29, 30) There is little
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19 scientific knowledge regarding the nature and extent to which acupuncture is used for pain
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21 conditions in pediatric populations in modern-day China. Chinese-English language textbooks
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23 consider herbal remedies as the primary treatment method in children(31), followed by Tui na,
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25 although acupuncture is often mentioned as an adjunct treatment.(32, 33) A literature search of
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27 major databases conducted by the first author (Cochrane, Medline, Embase, AMED, Maternity and
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29 Infant Care, Global Health, PsycINFO, Anthropology Plus, Sociological Abstracts, ISI-Web of
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31 knowledge, IBSS, AIO, BASE, and Wanfang Data, including conference proceedings from academic
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33 conferences in China) identified no English-language studies describing contemporary TCM clinical
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35 practices or clinical guidelines on the use of acupuncture for infants or small children from the
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37 People's Republic of China, Taiwan, Singapore and Hong Kong. Survey studies of TCM in children
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39 have been reported from Singapore and Taiwan,(34, 35) but we found no English-language studies or
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41 published abstracts on TCM practitioners' views and attitudes toward acupuncture treatment for
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43 infants and small children.
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49 The purpose of this study was to investigate current opinions and clinical practices regarding needle
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51 acupuncture for infants among TCM clinicians in Shanghai.
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56 Method

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3 We chose a qualitative approach, with participating observations, interviews and literature
4 searches. An extended, flexible approach was developed, and a combination of qualitative
5 methods was used, reflecting the validity threats and logistical challenges of conducting
6 qualitative research on the attitudes towards and use of pediatric acupuncture among TCM
7 clinicians in Shanghai, China. Subject knowledge matters, as described in Kvale and
8 Brinkmann,(36), guided the decision not to do surveys or rely on focus group interview(37) as the
9 only sources of information. The study process was informed by “Qualitative Research Design”
10 by J. Maxwell.(38) Special emphasis was on validity threats: We used Maxwell’s eight point
11 checklist to strengthen validity as a guide when designing and carrying out the study and in the
12 analyzing process. His recommendations of several information gathering methods to ensure
13 validity was central to our decisions:(39) Long-term involvement- we included four field visits over
14 the course of fourteen months. Rich data- we transcribed ad verbatim all field notes, quotes from
15 informal conversations and formal interviews. Respondent validation- we had two stages of
16 informant validation. Intervention- this was not appropriate in our study. Searching for Discrepant
17 Evidence and negative Cases- we did search for and do report discrepant evidence.

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Triangulation-we used both participant observation and informal conversations, formal interviews
and textbook searches. Numbers- we counted opinions, pages and patients, and report it in a
table. Comparison- we had participant observations at three departments and at different times.
The main analyses of the transcribed field notes and interviews were informed by Thematic
analysis,(40) focused on manifest content, and is further described in the Data Analysis section.

Setting

The first author conducted four field visits between February 2014 and March 2015 to Longhua
Hospital, which is a teaching hospital of the Shanghai University of Traditional Chinese Medicine
(SHUTCM) (**Figure 1- Study flow chart**). Longhua Hospital is a municipal TCM hospital with 2000
beds. The acupuncture department is an outpatient clinic with 42 beds, staffed by ten doctors and 20
interns who receive an average of 400 consultations per day. The pediatric department receives
about 130 outpatient consultations per day, with an average of ten inpatients admitted daily to the

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2
3 unit at any given time. There is also a small Tui na department which runs an outpatient service,
4
5 staffed by five doctors who receive approximately 50 consultations per day. The WHO Collaboration
6
7 Centre at SHUTCM facilitated study access and granted permission to collect data at Longhua
8
9 Hospital. The first author is a male general practitioner and acupuncturist with 25 years of
10
11 experience, with an established working relationship with the WHO Collaboration Centre.
12

13 **Data collection**

14 The field visits consisted of the following:

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17 1: Three days of participant observation in the pediatric department, three days of participant
18
19 observation in the acupuncture department, and one day of participant observation in the Tui na
20
21 department. An interpreter who was either an English-speaking TCM doctor or an English-Chinese
22
23 linguist was present at any time. We followed the daily routines and engaged in informal
24
25 conversations with several acupuncturists, and pediatric and Tui na specialists. The interpreters
26
27 themselves were also a rich source of information.
28
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31
32 2: A 90-minute, semi-structured focus group interview using a pre-defined interview guide, not pilot-
33
34 tested. The interview was conducted in English and without an interpreter, outside the workplace.
35
36 The informants were three leading officials at acupuncture units in Shanghai, all of whom had clinical
37
38 and administrative responsibilities. They were experienced acupuncturists. No parallel field notes
39
40 were taken during the interview, and transcripts were not returned. We did not succeed in recruiting
41
42 regular clinicians for this interview, because they felt they lacked sufficient knowledge of, and had
43
44 minimal experience with, pediatric acupuncture. Five experienced acupuncture clinicians were
45
46 contacted in succession, all declined for the same reasons. Only then did we decide to go up one
47
48 level and invite leading officials. We had to take into consideration the probability of group norm
49
50 answers,(37) but this would also give valuable information, and expand the triangulation.
51
52
53
54 3: A 60-minute, in-depth individual interview using a pre-defined interview guide, not pilot-tested,
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56 with a non-acupuncture TCM practitioner who had academic credentials, including work and
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3 research experience in Western Europe. The interview was conducted in Chinese with an English-
4
5 Chinese interpreter outside the workplace. No parallel field notes were taken during the interview,
6
7 and transcripts were not returned..
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9

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11 4: A search in the standard national textbooks used for teaching acupuncture, Tui na and herbal
12
13 medicine at Shanghai University of Traditional Chinese Medicine, one book for each curriculum.
14
15 These textbooks are compulsory nation-wide. They form part of the basis for the various five year
16
17 TCM teaching programs to qualify as herbalist, acupuncturist or Tui na practitioner in the People's
18
19 Republic of China. The search was assisted by a linguist fluent in Chinese and English. We counted
20
21 section pages and case pages to gauge the factual emphasis on using TCM therapeutic methods for
22
23 pediatric populations in the national textbooks.
24
25

26
27 5: Two stages of informant validation on the main and final results. Main results by one central
28
29 informant, and final results by two independent informants. We presented main and final results
30
31 personally in written form on a paper, the first time with five major preliminary findings, the second
32
33 time with the Results section of the study. The validity of the findings was then discussed, minor
34
35 ambiguities were corrected, and the Results section was then accepted as valid in the opinion of
36
37 these informants.
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40
41 A total of 14 informants were included during the field study. Informants had diverse clinical
42
43 backgrounds representing several TCM specialty areas, including seven acupuncturists. **(Figure 2-**
44
45 **Participants- informants)**. There were six women and eight men between 35 and 60 years of age,
46
47 with a minimum of ten years clinical experience. To maintain anonymity, further details on the
48
49 participants are not disclosed.
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51

52 53 54 **Data analysis**

55
56 All data were used, including notes from participant observations, informal conversations, semi-
57
58 structured interviews, and textbook page analysis. The field notes were structured and systematized,
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3 including the participant observations and the information gathered from informal conversations.

4
5 The focus group and in-depth interviews were recorded on two parallel, portable tape recorders and
6
7 transcribed in verbatim by the first author. The sound files were transferred to a USB storage pen
8
9 and securely stored. The original sound tracks on the tape recorders were erased.

10
11 The data analyses were carried out using thematic analysis.(40) The analyses were done by hand and
12
13 coding was primarily on semantic (manifest) content.(40) We did not seek saturation. The first author
14
15 read through the texts several times to define broad categories from the interviews and field notes
16
17 with subsequent coding and re-categorization. The main categories and selected opinion statements
18
19 were then sequenced into tables. We did not use a coding tree. The initial analysis was then
20
21 reviewed by the second author before refinement and undergoing final organization. All quotes have
22
23 been retained in their original form.

24
25 The study is reported in accordance with the Consolidated Criteria for Reporting Qualitative Research
26
27 (COREQ) checklist.(41)

30 31 Ethics

32
33 The Regional Ethical Committee of Southeastern Norway, REK- South East granted this project an
34
35 exemption from formal approval owing to the lack of patient data (Ref: 2014/197/REK South East).

36
37 The informants who participated in formal interviews were informed of the purpose of the study and
38
39 they signed a written consent form. The head or acting head of the three departments at the
40
41 Longhua hospital were informed of the purpose of the study and they signed a written consent form.

46 47 Results

48 49 The absence of children

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51 During the 3-day field visit at the acupuncture department at Longhua TCM hospital, we moved
52
53 freely between the consultation rooms, waiting rooms, and reception area.

54
55 In total, we saw two children. No infants. (Table 1-I).

Table 1. Results in numbers**I.****Patients observed to have acupuncture during 3 days in Longhua Acupuncture department (400 consultations a day, only out-patients)**

Infants	0	
Children	2	

II.**The Shanghai TCM acupuncturists (7 informants)****Do they have experience in needle acupuncture on infants?**

Very little or no experience	5	All acupuncture clinicians, one acupuncturist-official
Some experience	2	Two acupuncturist-officials
Regular or daily experience	0	

III.**All Shanghai TCM professionals (12 informants)****Do they recommend needle acupuncture on infants?**

No	9	All acupuncture clinicians, both TCM pediatricians, both Tui na specialists and the TCM herbalist
Yes, but only as the last choice	3	All acupuncturist-officials
Yes	0	

IV.**Amount specifically on pediatric conditions in Standard national textbook in undergraduate Traditional Chinese Medicine (TCM) studies, Shanghai.**

Herbal Medicine:	
Special textbook on Pediatric herbal medicine:	140 pages
Tui na / medical massage:	
Pediatric section of general textbook:	57 of 248 pages
Acupuncture-moxibustion:	
No pediatric section in general textbook.	
Conditions relating to children:	6 of 328 pages

“Nobody does pediatric acupuncture.” Lack of experience

During informal conversations with clinicians at the acupuncture department, we were informed that children and infants were very seldom referred for treatment, and thus, the clinicians stated they lacked experience with needle acupuncture treatment on children. Several of the acupuncturists reported they had treated only one or two children last year. None of the clinicians had treated infants. As one TCM acupuncturist described, “*Not so many children here. I treated two patients last year. Six-year olds. Facial paralysis and poor concentration. No infants.*” During the formal focus

1
2
3 group interview with the leading officials of acupuncture units in Shanghai, two of three reported
4
5 some past experience in treating children, including infants. However, they did not provide
6
7 information on whether this occurred on a regular basis. **(Table 1-II)**.
8
9

10 11 **“Not convenient.” Lack of recommendations**

12
13 Formal interviews and informal conversations with TCM clinicians revealed that acupuncture for
14
15 infants and a small children was not recommended. The focus group interview confirmed this finding,
16
17 and the officials from the acupuncture clinics stated that acupuncture therapy for infants and small
18
19 children was considered “the last choice” **(Table 1-III)**. One TCM acupuncturist stated, *“Never used*
20
21 *acupuncture, especially with small children. How could you? Not convenient. Big needles, small*
22
23 *bodies. We use Tui na and herbs.”* A TCM pediatrician expressed *“Acupuncture is considered invasive.*
24
25 *We are reluctant to do that on infants.”* One exception to this consensus included neurological
26
27 conditions such as cerebral palsy, neurological birth defects, and recently, ADHD, which is regarded
28
29 as a neurological disease. For these conditions, needle acupuncture was considered a possible
30
31 treatment method.
32
33

34 35 **“No classic, no modern.” Lack of textbooks and training**

36
37 In interviews and informal conversations, TCM clinicians reported a lack of specialized textbooks and
38
39 training in performing needle acupuncture on children. In contrast, textbooks and specialized
40
41 courses exist for pediatric herbal medicine and pediatric Tui na. Traditional and modern teaching in
42
43 acupuncture does not distinguish between acupuncture point combinations for adults versus
44
45 children. As one TCM acupuncturist explained, *“Never been taught pediatric acupuncture in MD*
46
47 *China or postgraduate education. No special points, no special treatments, no special meridians, no*
48
49 *special organ systems.”*
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51

52
53 A five-year program of integrated Western and TCM coursework is required for MD China,
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55 which qualifies for certification as a TCM herbalist, acupuncturist or Tui na specialist. A search of the
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3 national textbooks at SHUTCM- Shanghai University of Traditional Chinese Medicine revealed the
4 following page counts and specific chapter dedicated to children per textbook:

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6
7 -National Standard Textbook of Pediatric Herbal Medicine: 140/140 pages.(42)

8
9
10 -National Standard Textbook of Tui na: 57/256 pages. 1 pediatric chapter (pages 171-228).(43)

11
12 -National Standard Textbook of Acupuncture-Moxibustion: 6 of 328 pages, no pediatric chapter.

13
14 In the treatment chapters, children are mentioned on page 254 (enuresis), malnutrition (page 255),
15 polio sequelae (page 255), mumps (page 258), convulsions (page 274), and otitis media (page
16 266).(44) (Table 1-IV)

17 18 19 20 **“For now, zero.” The lack of a strong research base**

21
22 During the focus group interview, we explored the informants’ knowledge regarding research on
23 acupuncture treatment for infants and small children. Despite being familiar with numerous studies
24 on herbal treatments and Tui na in pediatric samples, they reported no knowledge of ongoing or
25 existing research on needle acupuncture in infants and small children.

26 27 28 29 30 **“Of course it is painful.” The possibility of pain**

31
32 Pain as a consequence of needle acupuncture was discussed with all the TCM clinicians, including
33 pediatricians, Tui na specialist, and acupuncturists. Prevailing attitudes among clinicians was that
34 acupuncture was painful for infants and small children. The potential for pain was stated as a primary
35 reason for the overall limited use of needle acupuncture in infants. For example, one TCM
36 acupuncturist stated, *“We have very few children. No infants. It is hard to make good acupuncture
37 treatment. And it is painful.”* Two of the leading acupuncture officials diverged in opinion, however,
38 stating that needle acupuncture in children could be painless when done in the right way with the
39 proper method. One TCM official reported, *“There are some special methods, though, for inserting
40 the needle without pain. Too many adults and children are just scared of the needles.”*

41 42 43 44 45 46 47 48 49 50 51 52 **“Eighty percent of acupuncture on children is CP or other neurology.” Indications for acupuncture**

53
54 Acupuncturists and other TCM clinicians expressed the clear opinion that needle acupuncture was
55 indicated for very few pediatric conditions in general. Indications included neurological diseases in
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1
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3 which other treatment options were limited. However, two of the TCM acupuncturists/hospital
4
5 officials diverged in opinion by recommending broader indications for children, including asthma,
6
7 malnutrition, and digestive problems. Specifically concerning the infant population, there was broad
8
9 consensus that needle acupuncture was not a treatment option in modern TCM. A Tui na specialist
10
11 stated, *“Acupuncture has such a long history, it never separated kids and adults. But you mentioned*
12
13 *under one year, but this only for these acute problems, like convulsions, high fever, emergency. Then*
14
15 *they may use needles.”*

16
17
18 **“TCM pediatrics is herbs.” The availability of TCM alternatives: Herbal medicine and Tui na**

19
20 Historically, several TCM treatments have been available for pediatric patients. In particular,
21
22 treatments with herbal medicine and Tui na have been specifically developed for children. For
23
24 contemporary Shanghaiese TCM practitioners working with children, treatment is largely focused
25
26 upon herbal medicine in the form of orally-administered drugs or herbal paste applied to
27
28 acupuncture points. As explained by a TCM herbalist, *“We focus on herbs. And some Tui na. Always*
29
30 *like that. If acupuncture points, we use moxibustion.”* This approach to treatment was confirmed
31
32 during the participant observations at the TCM pediatrics department. The vast majority of pediatric
33
34 outpatients were prescribed herbal treatment combinations, and some were recommended Tui na. If
35
36 acupuncture comprised the treatment, the specific recommendation included herbal paste, often
37
38 heated, as a point application. We did not observe needle acupuncture treatment, nor did we
39
40 observe any recommendations provided for acupuncture during the field visit to the pediatrics
41
42 department. Penetrating needle acupuncture on infants was not considered a treatment option for
43
44 most TCM pediatric conditions.

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48 **“Now parents take children to the Western Children Hospitals.” Trust in Western pediatrics**

49
50 There are four governmental Children’s Hospitals in Shanghai. These hospitals are large Western
51
52 medical hospitals with inpatient wards and specialized outpatient clinics staffed solely with medical
53
54 doctors and other clinical staff educated in Western medicine. The vast majority of pediatric cases in
55
56 Shanghai, particularly infants and toddlers, are treated at these hospitals. These hospitals provide
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3 treatment for a range of illnesses, from minor ailments to chronic or life-threatening conditions.

4 Western medical hospitals are widely regarded as the first choice by Shanghainese parents seeking
5 assessment, consultation, and treatment for their children. The TCM professionals themselves
6 provide recommendations and referrals to the hospitals for infants and small children, as indicated
7 by a TCM pediatrician, *"They have better diagnostic equipment at Western hospitals, for example the
8 pediatric ultrasound, for abdominal diagnostics. We do not have that."* A TCM herbalist stated, *"Now
9 parents take children to the Western Children Hospitals. If needed, herbs in addition. Acupuncture is
10 never in their minds"*.

11 **"The whole TCM world is shrinking in China, or at least in Shanghai." The money and the system**

12 During the field study at Long Hua hospital, there was a general sense that traditional TCM practice
13 was diminishing in importance and facing challenges from Western medicine, even in the TCM
14 hospitals. The ratio of Western to TCM hospitals in Shanghai is seven to one. By law, all hospitals are
15 required to have a TCM department. Long Hua is an integrated hospital, such that TCM and Western
16 medical approaches to diagnostics and treatment are combined. The TCM clinicians at Long Hua
17 confirmed that TCM is losing ground to Western medicine. In the pediatric department, for example,
18 the majority of the outpatient consultations we observed included a Western medical prescription.
19 For example, the inpatients, many of whom had respiratory tract infections and/or asthma
20 exacerbations, received antibiotics and/or corticosteroid medication. The clinicians reported that
21 traditional Chinese medicine departments were being reduced in terms of beds and staff, and that
22 entire departments in other TCM hospitals had merged or been significantly reduced in size. Financial
23 reasons were identified to explain this trend. In brief, the hospitals are financed through
24 governmental funding as well as patient fees for procedures, medicines, and consultation fees.

25 Although basic equipment is free, the more advanced, and consequently, more Western equipment
26 is more expensive. All hospitals, including TCM and Western, increase their earnings by focusing on
27 Western medical therapeutics. As such, the general trend in TCM hospitals is toward greater
28 utilization of Western medical treatment and procedures. An anonymous informant stated, *"One*

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3 surgeon can earn for the hospital as much as a hundred TCM doctors. TCM herbal medicines is cheap-
4
5 little money.”

7 **“It is a vicious cycle”- The slipping confidence**

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9 Several of the TCM practitioners reported changing attitudes towards healthcare, with increasingly
10
11 assertive parents and a more critical, consumer-driven approach towards treatment and healthcare
12
13 professionals, especially for treatment of children. The TCM practitioners were reluctant to advise
14
15 against parents’ wishes and they were similarly reluctant to do anything that could elicit unpleasant
16
17 reactions in the child, like crying. Acupuncture was generally considered painful, and in turn, TCM
18
19 clinicians were increasingly hesitant to recommend acupuncture for treatment in children. This trend
20
21 perpetuated a cycle which limited experience, limited expertise, and lowered confidence. One TCM
22
23 practitioner reported, *“It has also two sides, because at first the parents are reluctant to go, but*
24
25 *doctors they need experience. Because they have less and less patients, they don’t have that*
26
27 *expertise. They don’t have confidence. It is a vicious cycle.”*

30 **“I have one cerebral palsy patient, 6 months old, who tolerates needles with no pains”- the** 31 32 **divergent point of view**

33
34 The formal focus group interview differed in many aspects from the individual, in-depth interviews
35
36 and the informal conversations with clinicians. Specifically, opinions voiced during the focus group
37
38 differed with regard to tradition, experience, indications for acupuncture, and the question of
39
40 whether acupuncture was a painful intervention. Among two of the three hospital officials, there
41
42 was a general reluctance to limit the possibility of acupuncture as a universal treatment option. This
43
44 viewpoint contrasted with TCM practitioners, among whom there was broad agreement regarding
45
46 the limitations of needle acupuncture in infants and small children.
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51 **Discussion**

52 **Main findings**

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3 This qualitative study explored the use and recommendations for needle acupuncture on infants and
4 small children by traditional Chinese medicine (TCM) practitioners in Shanghai. During three days of
5 participant observations at the Longhua hospital outpatient acupuncture clinic, which receives on
6 average 400 patients per day, we observed only two children and no infants. During formal
7 interviews and informal conversations with TCM practitioners representing different specialties, the
8 prevailing opinion was that needle acupuncture for infants and small children is considered painful, is
9 inconvenient, and is not indicated for routine clinical practice, except for certain neurological
10 diseases. We learned that TCM methods for children have traditionally focused on herbal medical
11 treatments, and to a lesser extent, on Tui na. Acupuncture had historically been used for certain
12 acute illnesses, which are now treated in Western hospitals. The majority of acupuncturists, and all of
13 the non-acupuncture TCM practitioners, had limited or no experience treating children or infants
14 with needle acupuncture and would not recommend it as a therapeutic option. The exceptions were
15 the opinions of two TCM acupuncture officials. The reason for the non-use of acupuncture in small
16 children seemed to revolve around two main themes 1) internal TCM traditions and practices, which
17 do not support the routine practice of needle acupuncture in infants and toddlers, and 2) external
18 system changes which increasingly limit the use of acupuncture specifically, and TCM practices in
19 general.

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Internal TCM tradition and practice- The most important reasons for the lack of acupuncture in
48 infants and small children attribute to TCM traditions and practices. Specifically, herbal medical
49 treatments or Tui na are widely available and universally recommended as a first-choice TCM
50 treatment for pediatric populations.

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External system changes- These were opinioned in informal conversations throughout the study
period, and by several of the informants, and are not taken from official sources or literature. The
topic might be a sensitive issue. System changes within the general healthcare system in Shanghai
over the past years are also relevant in explaining the lack of pediatric acupuncture. TCM
departments and practices, including acupuncture, are losing ground to Western medicine, with

widespread consequences. Even original TCM hospitals and institutions are losing credentials and resources to Western diagnostics and treatment, which offers greater financial compensation than traditional TCM practices. This is also true for pediatrics.

Strength and weaknesses

Strengths of the study include the uniformity of the participant observations and the information collected from the TCM clinicians, the variety of sources of information, the triangulation of methods, and the validation process.(39) The discrepant voices were two of the officials who had both clinical and administrative responsibilities, who regarded acupuncture as a universal method of treatment. Limitations of the study involved the challenges of conducting qualitative research in situations requiring interpreters, or in which both the researchers and informants have English as their second language. We relied entirely upon our Shanghai contacts to gain access and organize interviews with TCM practitioners and officials, and as such, the selection of informants may be biased. It is worth noting that the situation in Shanghai might differ substantially from TCM in other cities and provinces in China. However, the centralized and uniform organization of education and the practice of TCM in Shanghai and the People's Republic of China, arguably strengthens external validity. An important consideration is the first author's prejudices and standard of reflexivity in the information gathering and analyzing process.(45) He is a medical doctor, acupuncturist, with 25 years of clinical experience and 15 years of teaching acupuncture and general principles in TCM. His main field of interest is pediatric acupuncture. He has in recently published a blinding-validated multicenter randomized controlled study on the effect of acupuncture on infantile colic that showed no clinically relevant effect of the intervention.(24) Qualitative research designs run the risk of biased and selective reporting. The use of a diversity of informants, several information gathering methods, and a detailed description of the methodological aspects of the process might, however, counteract such bias.

Implications for practice

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3 This study adds to the ongoing discussion on the evidence, utility, and limitations of acupuncture in
4 children, as well as in medicine in general.(46-50) Contrary to our observations in Shanghai,
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This study adds to the ongoing discussion on the evidence, utility, and limitations of acupuncture in children, as well as in medicine in general.(46-50) Contrary to our observations in Shanghai, acupuncturists in the Western world encourage acupuncture for children, including infants.(14, 15, 30) One rationale underpinning this trend is that acupuncture is widely considered in the West to be an integral part of TCM tradition, for patients of all ages. According to our study, Western beliefs that acupuncture is routinely indicated and recommended for infants and small children within TCM are unfounded. Such beliefs **may** appear to be a Western interpretation, and are not based on actual Chinese modern-day practices or therapeutic recommendations. Recent controlled trials investigating the efficacy of acupuncture treatment in the infant population(11, 20, 24) yield conflicting results, and little clear empirical evidence is available to support the use of acupuncture. As such, it appears that the rise of infant acupuncture in the West could be partly attributable to Western acupuncturists' own clinical observations and theoretical beliefs. In line with the principles of biomedical ethics,(51) however, this study underscores that this rationale is insufficient to recommend a potentially painful treatment for infants and small children who lack the competence to provide informed consent.

Conclusion

Acupuncture for infants and small children is neither routinely practiced nor recommended by TCM clinicians working in Shanghai. It is generally considered a potentially painful therapeutic method. Alternative TCM treatments are widely available and preferred by TCM practitioners in Shanghai, including herbal treatments and medical massage (Tui na). Needle acupuncture on broad indications in infants appears to be a Western practice, with little basis in Chinese TCM contemporary practice.

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Competing Interests

No, there are no competing interests

Contributorship Statement

HS and MB developed the original idea, developed the flexible study process and wrote the initial protocol. HS carried out the field study in Shanghai,, transcribed the interviews and field notes and carried out the initial analyzing. MB reanalyzed the field notes and interviews. HS wrote the initial draft of the article. MB reviewed and structured the article. HS is the guarantor of the study.

Data Sharing Statement

No additional data are available.

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56 Figure Legends

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58 Figure 1: Participants- informants

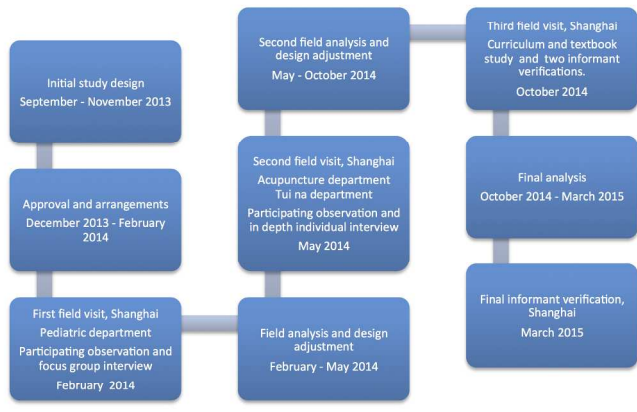
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Figure 2: Study flow chart

For peer review only

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Study flow chart
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14 informants in total. Experienced TCM professionals and English-Chinese linguists/translators, 35-65 years		
7 TCM professionals Longhua hospital <ul style="list-style-type: none">• 2 pediatricians• 4 acupuncturists• 1 Tui na specialist	5 TCM professionals, other TCM institutions in Shanghai <ul style="list-style-type: none">• 3 acupuncturist (2 of them also translators)• 1 Tui na specialist• 1 herbalist	4 translators <ul style="list-style-type: none">• 2 linguists• 2 acupuncturists

Participants-informants
209x296mm (300 x 300 DPI)

Consolidated criteria for reporting qualitative studies (COREQ): 32-item checklist

“Big needles, small bodies”--

the absence of acupuncture treatment for infants in contemporary Shanghai: a qualitative study

No Item Guide questions/description

Domain 1: Research team and reflexivity

Personal Characteristics

1. Interviewer/facilitator Which author/s conducted the interview or focus group?

Yes. *First author Holgeir Skjeie*

2. Credentials What were the researcher’s credentials? E.g. PhD, MD

Yes. *Holgeir Skjeie. General practitioner and acupuncturist, Mette Brekke, professor.*

3. Occupation What was their occupation at the time of the study?

Yes. *Holgeir Skjeie. General practitioner, Mette Brekke, professor.*

4. Gender Was the researcher male or female?

Yes. *Holgeir Skjeie, male. Mette Brekke, female.*

5. Experience and training What experience or training did the researcher have?

Yes. *Holgeir Skjeie. General practitioner and acupuncturist for 25 years.*

Relationship with participants

6. Relationship established Was a relationship established prior to study commencement?

Yes. *A working relationship with the WHO Collaboration Centre, SHUTCM, Shanghai.*

7. Participant knowledge of the interviewer. What did the participants know about the researcher?

e.g. personal goals, reasons for doing the research.

Yes. *A prior working relationship, and consent forms with information.*

8. Interviewer characteristics What characteristics were reported about the interviewer/facilitator?

e.g. Bias, assumptions, reasons and interests in the research topic.

Yes. *In the information on page 9 (The first author is a male general practitioner and acupuncturist with 25 years of experience, with an established working relationship with the WHO Collaboration Centre.), and in the Discussion.*

Domain 2: study design

Theoretical framework

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3 9. Methodological orientation and Theory
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5 What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse
6 analysis, ethnography, phenomenology, content analysis.

7 Yes. *Thematic analysis.*
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13 Participant selection

14 10. Sampling How were participants selected? e.g. purposive, convenience, consecutive, snowball.

15 Yes. *Purposive and convenience.*
16
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18 11. Method of approach How were participants approached? e.g. face-to-face, telephone, mail,
19 email.

20 Yes. *Face-to face.*
21
22

23 12. Sample size How many participants were in the study?

24 Yes. *14 in total. 3 in the focus group interview, 1 in the in-depth interview. 10 in the informal*
25 *conversations during participant observations, including the interpreters.*
26
27

28 13. Non-participation How many people refused to participate or dropped out? Reasons?

29 Yes. *All ordinary clinicians approached to participate in the focus group interview declined on reasons*
30 *of lack of experience.*
31
32

33 Setting

34 14. Setting of data collection Where was the data collected? e.g. home, clinic, workplace.

35 Yes. *The informal conversations at the participating observation periods in the workplace/clinic. The*
36 *interviews outside the workplace.*
37
38

39 15. Presence of non-participants Was anyone else present besides the participants and researchers?

40 Yes. *An interpreter was present at the in-depth interview and at the informal conversations in the*
41 *participating observations..*
42
43

44 16. Description of sample What are the important characteristics of the sample? e.g. demographic
45 data, date.

46 Yes. *Practicing acupuncturist, non-acupuncture TCM clinicians, and interpreters, see informants table.*
47
48

49 Data collection

50 17. Interview guide Were questions, prompts, guides provided by the authors? Was it pilot tested?

51 Yes. *We used a predefined interview guide in the in depth and focus group interview. Not pilot tested.*
52
53

54 18. Repeat interviews Were repeat interviews carried out? If yes, how many?

55 Yes. *No repeat interviews.*
56
57

58 19. Audio/visual recording Did the research use audio or visual recording to collect the data?

59 Yes. *Portable audio tape recorders.*
60

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3 20. Field notes Were field notes made during and/or after the interview or focus group?

4 Yes. *No field notes during the interviews..*

5
6 21. Duration What was the duration of the interviews or focus group?

7 Yes. *Focus group: 90 minutes. In depth interview: 60 minutes.*

8
9 22. Data saturation Was data saturation discussed?

10 Yes. *We did not seek saturation with our flexible approach.*

11
12 23. Transcripts returned Were transcripts returned to participants for comment and/or correction?

13 Yes. *Transcripts were not returned.*

14
15 Domain 3: analysis and findings

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17 Data analysis

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19 24. Number of data coders How many data coders coded the data?

20 Yes. *The first author, Holgeir Skjeie, coded the data.*

21
22 25. Description of the coding tree Did authors provide a description of the coding tree?

23 Yes. *We did make use of a coding tree.*

24
25 26. Derivation of themes Were themes identified in advance or derived from the data?

26 Yes. *They were derived from the data, and surprising to us.*

27
28 27. Software What software, if applicable, was used to manage the data?

29 Yes. *Analysis were done by hand.*

30
31 28. Participant checking Did participants provide feedback on the findings?

32 Yes. *We validated main and final results independently by one, and then by and two informants, respectively.*

33
34 Reporting

35
36 29. Quotations presented Were participant quotations presented to illustrate the themes / findings?

37 Was each quotation identified? e.g. participant number.

38 Yes. *They were identified as type of informant, but not by number.*

39
40 30. Data and findings consistent Was there consistency between the data presented and the findings?

41 Yes.

42
43 31. Clarity of major themes Were major themes clearly presented in the findings?

44 Yes.

45
46 32. Clarity of minor themes Is there a description of diverse cases or discussion of minor themes?

47 Yes. *The divergent point of view.*