

**Supplementary Table 5. Incidence of AEs according to the study design**

Author (year)	Acupuncture group (No. of AEs reported/ no. of sessions (%))	Control group (No. of AEs reported/ no. of sessions (%))	Incidence of AEs related to acupuncture treatment in acupuncture group (No. of AEs related/ no. of sessions (%))
<b>RCTs/quasi-RCTs</b>			
<b>Acupuncture as an adjunct</b>			
Vas (2013) <sup>1</sup>	2/1865 (0.1)	0/NA (—)	2/1865 (0.1)
Guerreiro da Silva (2012) <sup>2</sup>	2/200 (1.0)	0/NA (—)	2/200 (1.0)
Do (2011) <sup>3</sup>	0/200 (0.0)	0/NA (—)	0/200 (0.0)
Wang (2009) <sup>4</sup>	2/112 (1.8)	1/NA (—)	2/112 (1.8)
Guerreiro da Silva (2007) <sup>5</sup>	4/253 (1.6)	0/NA (—)	4/253 (1.6)
Yang (2006) <sup>6</sup>	0/1442 (0.0)	0/1442 <sup>†</sup> (0.0)	0/1442 (0.0)
Elden (2005) <sup>7-8</sup>	76/1380 (5.5)	8/NA (—)	76/1380 (5.5)
Guerreiro da Silva (2005) <sup>9</sup>	1/125 (0.8)	0/NA (—)	1/125 (0.8)
Du (2005) <sup>10</sup>	0/250 (0.0)	21/700 <sup>†</sup> (3.0)	0/250 (0.0)
Guerreiro da Silva (2004) <sup>11</sup>	6/270 (2.2)	0/NA (—)	5/270 (1.9)
Neri (2004) <sup>12</sup>	0/456 (0.0)	0/NA (—)	0/456 (0.0)
Chen (2004) <sup>13</sup>	0/438 (0.0)	0/414 <sup>‡</sup> (0.0)	0/438 (0.0)
Smith (2002) <sup>14-15</sup>	96/1340 (7.2)	53/NA (—)	0/1340 (0.0)
Lin (2002) <sup>16</sup>	0/454 (0.0)	0/1510 <sup>§</sup> (0.0)	0/454 (0.0)
Total	189/8785 (2.2)	21/4066 (0.5)	92/8785 (1.0)
<b>Acupuncture vs. sham acupuncture</b>			
Vas (2013) <sup>1</sup>	2/1865 (0.1)	3/1865 (0.2)	2/1865 (0.1)
Manber (2010) <sup>17</sup>	40/456 (8.8)	24/407 (5.9)	34/456 (7.5)
Wang (2009) <sup>4</sup>	2/112 (1.8)	4/104 (3.8)	2/112 (1.8)
Elden (2008) <sup>18</sup>	72/672 (10.7)	70/624 (11.2)	72/672 (10.7)
Smith (2002) <sup>14-15</sup>	96/1340 (7.2)	53/668 (7.9)	0/1340 (0.0)
Knight (2001) <sup>19</sup>	11/103 (10.7)	8/100 (8.0)	11/103 (10.7)
Carlsson (2000) <sup>20</sup>	0/212 (0.0)	0/207 (0.0)	0/212 (0.0)
Total	223/4760 (4.7)	162/3975 (4.1)	121/4760 (2.5)
<b>Acupuncture vs. usual care</b>			

Manber (2010) <sup>17</sup>	40/456 (8.8)	13/NA (—)	34/456 (7.5)
Guittier (2009) <sup>21</sup>	0/1050 (0.0)	0/NA (—)	0/1050 (0.0)
Mao (2009) <sup>22</sup>	0/420 (0.0)	0/630 <sup>..</sup> (0.0)	0/420 (0.0)
Yang (2007) <sup>23</sup>	0/1967 (0.0)	0/1956 <sup>†</sup> (0.0)	0/1967 (0.0)
Wedenberg (2000) <sup>24</sup>	2/300 (0.7)	4/192 <sup>††</sup> (2.1)	2/300 (0.7)
Cardini (1998) <sup>25</sup>	9/1779 (0.5)	16/NA (—)	2/1779 (0.1)
Total	51/5972 (0.9)	4/2778 (0.1)	38/5972 (0.6)
<b>Acupuncture vs. no treatment</b>			
Guerreiro da Silva (2009) <sup>26</sup>	1/201 (0.5)	0/NA (—)	1/201 (0.5)
Guittier (2008) <sup>27</sup>	3/56 (5.4)	0/NA (—)	0/56 (0.0)
Cardini (2005) <sup>28</sup>	29/1085 (2.7)	0/NA (—)	25/1085 (2.3)
Kvorning (2004) <sup>29</sup>	18/222 (8.1)	0/NA (—)	12/222 (5.4)
Habek (2003) <sup>30</sup>	0/204 (0.0)	0/NA (—)	0/204 (0.0)
Total	51/1768 (2.9)	0/NA (—)	38/1768 (2.1)
<b>RCTs total</b>	<b>374/17512 (2.1)</b>	<b>187/10819 (1.7)</b>	<b>251/17512 (1.4)</b>

### CCTs

#### Acupuncture vs. usual care

Liang (2004) <sup>31</sup>	0/3080 (0.0)	222/3416 (6.5)	0/3080 (0.0)
Xiong (1991) <sup>32</sup>	0/840 (0.0)	0/NA (—)	0/840 (0.0)

#### Acupuncture vs. no treatment

Cardini (1993) <sup>33</sup>	7/25 <sup>##</sup> (28.0)	0/NA (— 0)	0/25 <sup>##</sup> (0.0)
<b>CCTs total</b>	<b>7/3945 (0.2)</b>	<b>222/3416 (6.5)</b>	<b>0/3945 (0.0)</b>

#### Case series/case reports

De Jonge-Vors (2011) <sup>34</sup>	6/43 <sup>##</sup> (14.0)	NA	6/43 <sup>##</sup> (14.0)
Ahn (2011) <sup>35</sup>	3/5 (60.0)	NA	0/5 (0.0)
Tang (2010) <sup>36</sup>	0/15 (0.0)	NA	0/15 (0.0)
Lei (2010) <sup>37</sup>	0/12 (0.0)	NA	0/12 (0.0)
Lee (2010) <sup>38</sup>	0/20 (0.0)	NA	0/20 (0.0)
O (2009) <sup>39</sup>	0/143 (0.0)	NA	0/143 (0.0)
Rouse (2008) <sup>40</sup>	0/9 (0.0)	NA	0/9 (0.0)
Bourne (2007) <sup>41</sup>	1/4 (25.0)	NA	1/4 (25.0)
Cummings (2003) <sup>42</sup>	2/18 (11.1)	NA	2/18 (11.1)

Forrester (2003) <sup>43</sup>	0/9 (0.0)	NA	0/9 (0.0)
Neri (2002) <sup>44</sup>	0/12 <sup>††</sup> (0.0)	NA	0/12 <sup>††</sup> (0.0)
Yang (2002) <sup>45</sup>	0/7 (0.0)	NA	0/7 (0.0)
Kvorning Ternov (2001) <sup>46</sup>	36/167 <sup>††</sup> (21.6)	NA	31/167 <sup>††</sup> (18.6)
CCPKMCC (2001) <sup>47</sup>	0/71 (0.0)	NA	0/71 (0.0)
CCPKMCC (2001) <sup>48</sup>	0/84 (0.0)	NA	0/84 (0.0)
Koh (1989) <sup>49</sup>	0/207 (0.0)	NA	0/207 (0.0)
Case total	48/826 (5.8)	NA	40/826 (4.8)
<b>Total</b>	<b>429/22283 (1.9)</b>	<b>409/14235 (2.9)</b>	<b>291/22283 (1.3)</b>

\*Incidence calculated by including AEs evaluated as certainly, probably, or possibly due to acupuncture treatment in the causality assessment.

<sup>†</sup>Knee-chest position in control group twice a day for seven days.

<sup>‡</sup>Raising buttocks in a lateral position in control group twice a day for three days.

<sup>§</sup>Knee-chest position in control group twice a day for mean 12.8 days.

<sup>\*\*</sup>Phenobarbital 30 mg in control group three times a day for seven days.

<sup>††</sup>Once or twice a week-physiotherapy in control group, totalling 10 sessions within six-eight weeks.

<sup>††</sup>The number of participants replaced the number of acupuncture sessions because information was not available.

AE, adverse event; CCPKMCC, Collection of Clinical Practice in Korean Medicine Compilation Committee; CCT, controlled clinical trial; NA, not applicable; no., number; NR, not reported; RCT, randomised controlled trial.

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