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Table 2: Randomized clinical trials of acupuncture for chemotherapy-associated nausea and vomiting published since the systematic reviews

Source: Karen Pilkington, CAM-Cancer Consortium. Acupuncture for chemotherapy-associated nausea and vomiting [online document]. <u>https://cam-cancer.org/en/acupuncture-chemotherapy-associated-nausea-and-vomiting</u>, February 2021.

Trials of acupuncture/acupressure using the P6 acupuncture point

First author, year, (ref)	Study design	Participants (number, diagnosis)	Interventions (experimental treatments, control)	Main outcome measures	Main results	Comments
Avc 2016	RCT 3 arms	90 patients with acute myeloblastic leukemia	Acupressure at P6 using wrist bands or finger pressure or no acupressure	Self-scoring using a visual analogue scale	Acupressure band reduced frequency and severity of nausea-vomiting (p<0.05); Finger pressure did not have an effect (p>0.05)	Quasi-randomised (by order of admission) Not blinded; self-assessed. Attrition not reported. Power was adequate assuming there was no attrition.
Cheng 2020	RCT 3 arms	105 patients with lung cancer	Pre-chemotherapy (PRG) acupuncture at P6 and ST23, post- chemotherapy (POG) acupuncture or no acupuncture	Number of cases Severity (NCI-CTC 4.0). INVR scale	Frequency of nausea and of acute vomiting (1-4 days) was significantly lower in the two acupuncture groups (p<0.05); Based on INVR, there was no statistical difference between POG and controls, but there was a statistical difference between PRG and controls	Randomisation and allocation concealment unclear. Blinding not possible. Attrition reasonable and power adequate. Results differed according to outcome measure used.
Dupuis 2018	RCT Single blinded	165 children 4 to 18 years of age receiving highly emetogenic chemotherapy	Acupressure wrist bands versus sham bands (no stud)	Pediatric Nausea Assessment Tool (PeNAT)	Acupressure bands did not reduce CIN severity in the acute phase (odds ratio (OR): 1.33; 95% CI 0.89 to 2.00) or delayed phase or affect daily vomiting. No adverse effects.	Randomisation: adequate Allocation concealed except for team member fitting band Single blinded

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						Power calculated but trial discontinued before recruitment complete. Authors predicted that large sample unlikely to change outcome.
Fang 2012	RCT	60 breast cancer patients	Portable moxibustion combined with acupoint massage in addition to the treatment in the control group: control group: intravenous anti- emetic before and after chemotherapy.	Vomiting (treatment and prevention)	Total effective rates in the treatment group and the control group were 88.2 and 38.5%, respectively. Significant difference in curative effect of the two groups (P <0.01). 'Portable moxibustion combined with acupoint massage therapycan effectively treat vomiting after chemotherapy'.	Randomisation and allocation concealment: not able to determine (full article not available) Not blinded. Method of outcome assessment: not able to determine Power and attrition: not able to determine
Genc 2012	RCT single- blinded	120 patients with breast, gynaecological, and lung cancer	Nausea wristband (Sea- Band) (acupressure at P6) versus 'placebo nausea band' (no further details).	Patient description form INVR scale FACT-G	No difference was found between groups. Concluded that acupressure wristband was not an effective approach in preventing CINV	No details of randomization Reported as single-blinded Attrition not reported. Study was adequately powered assuming there was no attrition.
Ghezelbash 2017	RCT single blind, placebo controlled	120 hospitalised school age children with ALL (8-12 years)	Finger acupressure on p6 and ST36 (true points) versus on SI3 and LI12 (sham points)	Fatigue intensity: VAS Nausea- vomiting 12 h post-intervention: Adapted Rhodes Index of Nausea and Vomiting for Pediatrics by Child (ARINVc)	Significant differences in nausea intensity immediately and an hour post-intervention (P < 0.001) but not after 12 hours	Randomisation appears appropriate Single blinded No information on power or attrition although it appears that all patients were followed up

Kaur 2015	RCT	40 cancer patients	Acupressure at P6. Control intervention not stated but assumed to be usual care.	MASCC Antiemesis tool (MAT)	No significant difference in acute period (first 24 hours); significant difference in number of episodes of nausea, of vomiting and in severity of nausea on days 2- 5 (p<0.05)	No details of randomization Not blinded. Outcomes self- reported. Attrition and power not reported.
Liu 2015	RCT	60 patients with gynaecological tumors	Wrist-ankle acupuncture and ginger moxibustion, versus tropisetron hydrochloride and dexamethasone	Simple scoring system for frequency of nausea Anti-emetic effect Adverse events	Significant difference in nausea on 2nd-5th days of chemotherapy (p<0.01). Significant difference in vomiting only on 3rd day (p<0.05) Incidence of constipation lower in treatment group 1 patient suffered a post- acupuncture side effect (subcutaneous blood stasis)	Randomization and allocation adequate Not blinded except to statisticians No attrition reported. No power calculation as pilot study.
Molassiotis 2013 (also reported as Molassiotis 2014)	RCT 3 arms, sham- controlled	500 chemotherapy- naive cancer patients	Wristband versus sham wristband versus standard care only	INVR scale MASCC Antiemesis Tool FACT-G	No statistically significant differences between the three arms in terms of nausea, vomiting and quality of life (FACT-G scale) Some transient local adverse effects were reported	Randomisation was adequate and accounted for gender, age and three levels of emetogenic chemotherapy Some unblinding of patients took place Power based on initial data and adequate

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Perkins 2020	RCT	57 palliative care patients with advanced cancer.	Active versus placebo acupressure wristbands	Number of vomits; Visual Analogue Scale for subjective score; medication doses	Active acupressure wristbands were no better than placebo	Randomisation and blinding adequate. Allocation concealment unclear. States that adequately powered and low attrition rate (2 patients only) but calculation not reported.
Rithirangsriroj 2015	RCT cross-over	70 cancer patients	Acupuncture at P6 point before chemotherapy infusion versus ondansetron intravenously	Emetic episode, severity of nausea score of 0-10 and adverse events	Acupuncture is effective in preventing delayed CINV and in promoting better QOL. Significantly higher rate of prevention of delayed CINV (p=0.02), lower delayed nausea (p=0.004), nausea score (p<0.001), less medication (p=0.002) in acupuncture group, less frequent constipation (p=0.02) and insomnia (p=0.01).	Random sequence generated by random number generator, no information on allocation No mention of blinding of assessors Adequate sample size based on power calculation and no loss to follow-up reported
Suh 2012	RCT 4 arms	120 breast cancer patients	P6 acupressure plus nurse-provided counselling; counselling only; P6 acupressure only, and control (placebo on SI3)	Nausea, retching, vomiting	'Synergic effects of P6 acupressure with nurse- provided counseling appeared to be effective in reducing CINV in patients with breast cancer.'	Randomisation and allocation concealment adequate. Not blinded and outcomes self-reported Adequate sample size based on power calculation and attrition not significantly different across the groups.
Widgren and Enblom 2017	RCT 3 arms	68 patients with gynaecological, colorectal, other cancer types	Acupuncture at P6 versus sham (non- penetrating needle)	Emesis questionnaire designed for the study	Non-significant difference in nausea (p=0.074) although more patients required	Sub-group from a larger, adequately randomized trial. Single-blinded

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(57 randomised; 11 concurrent control)		antiemetics in the sham group $(p=0.019)$.	1 patient lost to follow up but power unclear as sub-
			group from a larger trial.

FACT-G: Functional Assessment of Cancer Therapy - General INVR: Rhodes Index of nausea, vomiting and retching MASCC Multinational Association of Supportive Care in Cancer NCI-CTC: National Cancer Institute Common Toxicity Criteria RCT: Randomized controlled trial

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Trials using other acupuncture points and/or other techniques

First author, year, (ref)	Study design	Participants (number, diagnosis)	Interventions (experimental treatments, control)	Main outcome measures	Main results	Comments
Eghbali 2016	RCT crossover	48 breast cancer patients	Auricular acupressure at 5 points versus no acupressure	Morrow standard questionnaire (1984)	Intensity and frequency of nausea was reduced by acupressure (p < 0,001) except for frequency in acute period (p<0.07). Vomiting was improved by acupressure. Note: results were unclear	No details of randomization Blinding was unclear Attrition not reported
Kong 2018	RCT single-blind	110 gastric cancer patients	Acupressure applied to specific auricular points versus non-specific points	Patient recording based on NCI-CTC 2.0 for nausea, vomiting and diarrhoea	Incidence was similar (p>0.05) but less severe (p>0.05) in the intervention group.	'restricted randomization methods' were used Single blinded Attrition: 15 patients lost to follow up; no reasons given
Li 2020	RCT	134 patients with advanced cancer (lung, breast or gynaecological)	Acupuncture versus sham acupuncture (non-specific points)	Common Terminology Criteria for Adverse Events (CTCAE)	No significant difference in complete response rates. Severity of nausea or vomiting reduced by true acupuncture (days 3-4 to day 21, P < 0.05)	Randomisation was appropriate but allocation not concealed from investigators. Single blinded. Attrition reasonable and power adequate.
McKeon 2018	RCT pilot, 3 arms	60 patients with various cancers	Electroacupuncture at 8 points versus sham (non- specific points) versus standard care	FLIE (Functional Living Index Emesis) a validated, nausea and vomiting- specific, patient- centred measure	No difference was detected between groups but this was a small pilot study intended to inform a subsequent RCT.	Randomisation was adequate Patients and outcome assessors were blinded 11 patients were lost to follow-up with no reason given

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Shen 2015	RCT	103 patients diagnosed with primary or metastatic liver cancer	Acustimulation at the K1 acupoint compared with electrostimulation at a placebo point on the heel. (both groups also received tropisetron)	Rate, intensity, and duration of nausea and vomiting, quality of life	No differences were found between groups with regard to the incidence and degree of nausea or vomiting	Randomisation and allocation concealment adequate Patients were blinded and nurses not practitioners delivered treatment and conducted assessments Adequately powered
Varejão 2019	RCT Single blinded	18 children aged 6 - 17 years being treated for solid tumours	Laser acupuncture on a range of body acupoints versus sham laser acupuncture (non- acupoints)	Diary recording of nausea intensity and number of vomiting episodes	A significant difference was found in relief of nausea within 5 days of chemotherapy (<.0005) and in number of episodes of vomiting on Days 2 and 3 after chemotherapy	Randomisation and allocation concealment unclear (states cycles were randomized but appears that patients were) Single blinded Power based on cycles not patients so that attrition is unclear
Xie 2017	RCT single-blind	142 liver cancer patients	Transcutaneous electrical acupoint stimulation (TEAS) at 3 points versus placebo acupuncture	Patient recorded frequency and severity of nausea and vomiting	No significant differences	Randomisation by minimization; no further details. Single-blinded No attrition
Zhang 2014	RCT	72 cancer patients	Needleless transcutaneous electroacupuncture (TEA) at Neiguan (PC6) and Jianshi (PC5) versus electroacupuncture at non-acupoints (plus ondansetron)	Acute phase and delayed phase nausea and vomiting	Needleless transcutaneous electroacupuncture at PC6 improves emesis and reduces nausea in the delayed phase of chemotherapy but did not have additive effects in the acute phase.	Random sequence computer generated, no information on allocation Level of blinding, power and attrition not reported
Zhou 2017	RCT	56 gastric cancer patients	Acupuncture at 5 points versus no acupuncture	Self-reported frequency of vomiting and diarrhoea, duration	Significant beneficial effects were reported in the acupuncture group.	No details of randomization. Not blinded and self- assessed. Attrition not reported

		of nausea, and abdominal pain	

FACT-G: Functional Assessment of Cancer Therapy - General

INVR: Rhodes Index of nausea, vomiting and retching

MASCC Multinational Association of Supportive Care in Cancer

NCI-CTC: National Cancer Institute Common Toxicity Criteria

RCT: Randomized controlled trial