A pragmatic cost-effectiveness clinical trial of electro-acupuncture in the treatment of symptomatic gallstone diseases

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Where is the evidence?

Review of randomised controlled trials of traditional Chinese medicine

Jin-Ling Tang, Si-Yan Zhan, Edzard Ernst

Many randomised trials of traditional **chinese medicine** exist but are of poor quality
3. [No authors listed]
BMJ. 1999 Jul 17;319(7203):F. No abstract available.
PMID: 10406791 Free PMC Article
Related citations

Review of randomised controlled trials of traditional **Chinese medicine**.
4. Tang JL, Zhan SY, Ernst E.
BMJ. 1999 Jul 17;319(7203):160-1. No abstract available.

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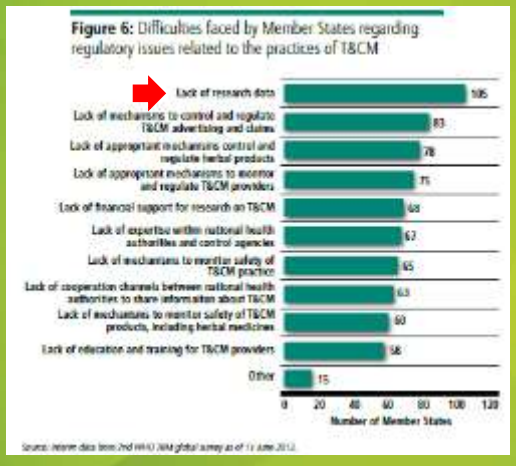
TANG, J.L., S.-Y. ZHAN, AND E. ERNST, *REVIEW OF RANDOMIZED CONTROLLED TRIALS OF TRADITIONAL CHINESE MEDICINE.* BRITISH MEDICAL JOURNAL, 1999. 319: P. 160-161.

How we should evaluate the evidence?



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The best clinical trial impact the industry

Is classical RCT adequate to evaluate the effectiveness of CAM?

Objective.— To determine whether Chinese herbal medicine (CHM) is of any benefit in the treatment of IBS.

Design.— Randomized, double-blind, placebo-controlled trial conducted during 1996 through 1997.

Intervention.— Patients were randomly allocated to 1 of 3 treatment groups: individualized Chinese herbal formulations (n=38), a standard Chinese herbal formulation (n=43), or placebo (n=35). Patients received 5 capsules 3 times daily for 16 weeks and were evaluated regularly by a traditional Chinese herbalist and by a gastroenterologist. Patients, gastroenterologists, and herbalists were all blinded to treatment group.

- **Results.—** Compared with patients in the placebo group, patients in the active treatment groups (standard and individualized CHM) had significant improvement in bowel symptom scores as rated by patients (P = .03) and by gastroenterologists (P = .001), and significant global improvement as rated by patients (P=.007) and by gastroenterologists (P=.002). Patients reported that treatment significantly reduced the degree of interference with life caused by IBS symptoms (P=.03). Chinese herbal formulations individually tailored to the patient proved no more effective than standard CHM treatment. On follow-up 14 weeks after completion of treatment, only the individualized CHM treatment group maintained improvement.
- **Conclusion.—** Chinese herbal formulations appear to offer improvement in symptoms for some patients with IBS.

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An illustrated example
Unmet needs of gallstone disease in HK

- Gallstone disease is affecting 10%-15% adult population[1]
- 2-3% in Hong Kong[2]
- 20-30% are symptomatic[1]
- Cholecystectomy within 24-hours is the gold standard treatment for acute cholecystitis[3, 4]
- Hong Kong: Average waiting time ranged from 9 months to years

- Aims:
- to evaluate the effectiveness and safety of EA
- to explore the cost of additional acupuncture services against usual care
- Randomized, assessor-blinded, wait-list control study

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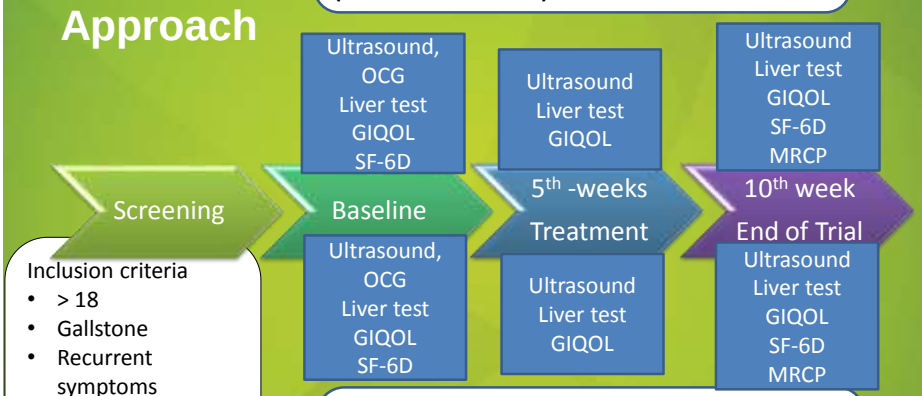
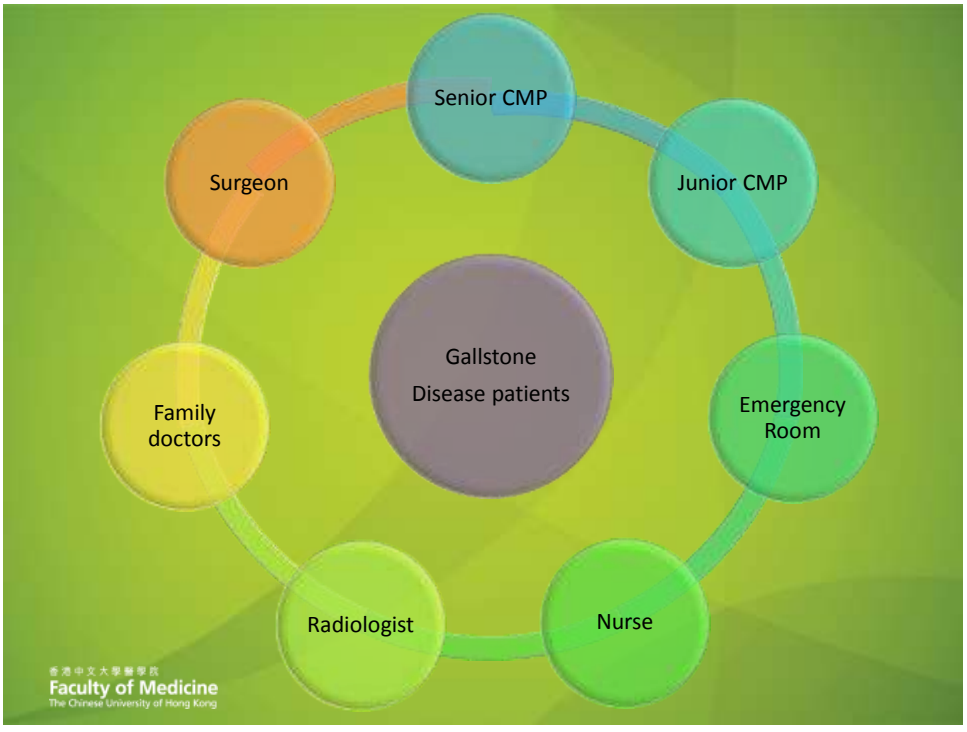
Protocol Driven Approach

Treatment group
Acupuncture and assessment
(twice a week)



Inclusion criteria
- > 18
- Gallstone
- Recurrent symptoms
- Waiting for surgery
- Largest gallstone <0.8CM

Control group
Usual care and assessment
(twice a week)



Electro-acupuncture treatment

Chinese Medicine theory driven approach recommended by WHO

- 1) Ancient TCM literature;
- 2) Published literature;
- 3) Experts clinical experience

(I) Increase gallbladder secretion function
(II) Increase relaxation of the Sphincter of Oddi
(III) Increase secretion of bile

- Dangerous but highly effective acupuncture

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Outcomes

- At baseline, 5th week (mid of treatment) and 10th week post treatment
- proportion of patients to have total excretion of gallstones.
- Successful excretion of gallstones defined as negative ultrasonography of gallstones results
- The proportion of patients who complete the whole course of the treatment, days in treatment or withdrawal), will be investigated

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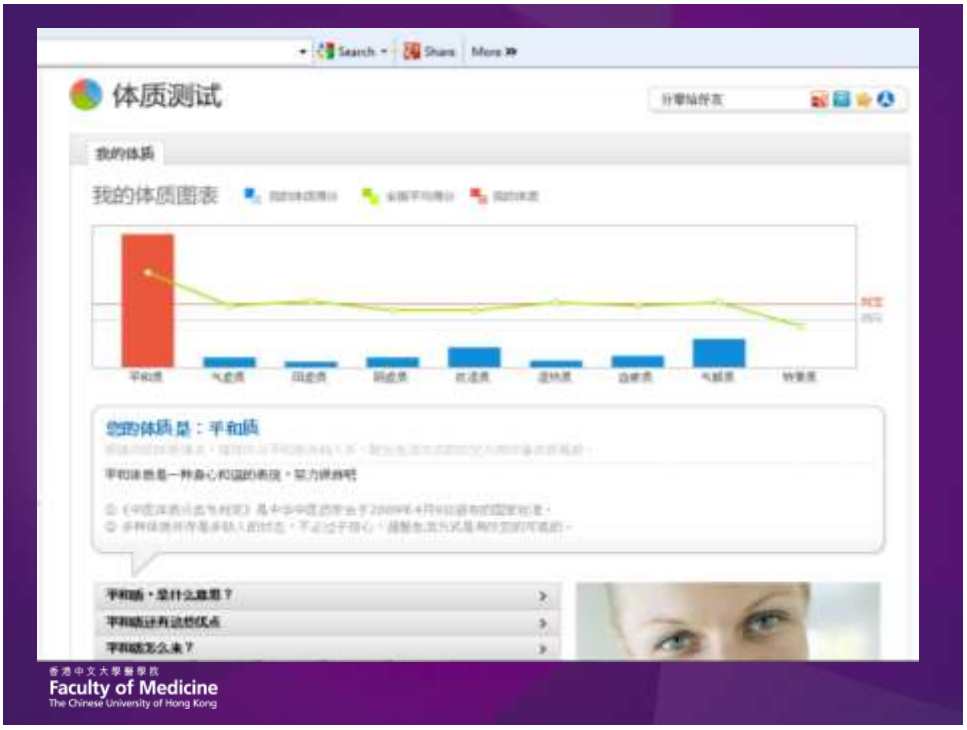

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Estimating Cost

- Patients level
  - Out of pocket
  - Time (Home ⇔ Clinic/ Hospital)
  - Consultation fee
  - Medication fee
  - Quality of Life adjusted life years (QALYs) – EQ5D or SF-6D
- Clinic Level
  - Process of Care
  - Number of additional staff
  - Equipment purchased (i.e. office space, printer, needles etc)
  - Promotional items

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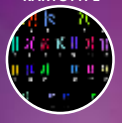
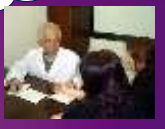
OBJECTVE DATA

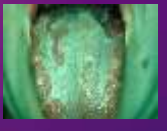
KARYOTYPE



HEMOGLOBIN

Can we trust subjective data?





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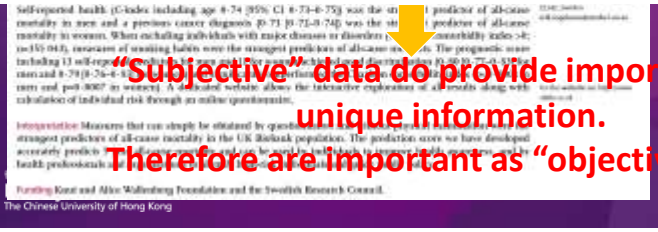
How reliable is the information we can obtain from patient's self-reports?

Ganna A, Ingelsson E, Lancet. 2015 Aug 8;386(9993):533-40.

Findings About 500 000 participants were included in the UK Biobank. We excluded participants with more than 80% variables missing (n=746). Of 498 103 UK Biobank participants included (54% of whom were women) aged 37–73 years, 8532 (39% of whom were women) died during a median follow-up of 4·9 years (IQR 4·33–5·22). Self-reported health (C-index including age 0·74 [95% CI 0·73–0·75]) was the strongest predictor of all-cause mortality in men and a previous cancer diagnosis (0·73 [0·72–0·74]) was the strongest predictor of all-cause mortality in women. When excluding individuals with major diseases or disorders (Charlson comorbidity index >0; n=355 043), measures of smoking habits were the strongest predictors of all-cause mortality. The prognostic score including 13 self-reported predictors for men and 11 for women achieved good discrimination (0·80 [0·77–0·83] for men and 0·79 [0·76–0·83] for women) and significantly outperformed the Charlson comorbidity index ($p<0·0001$ in men and $p=0·0007$ in women). A dedicated website allows the interactive exploration of all results along with calculation of individual risk through an online questionnaire.

Interpretation Measures that can simply be obtained by questionnaires and without physical examination were the strongest predictors of all-cause mortality in the UK Biobank population. The prediction score we have developed accurately predicts 5 year all-cause mortality and can be used by individuals to improve health awareness, and by health professionals and organisations to identify high-risk individuals and guide public policy.



"Subjective" data do provide important and unique information.

Therefore are important as "objective" data

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Psychometric properties of the C
(HK version) in Chinese and We
settings
Research Article
Validation of the Constitution in Chinese Medicine Questionnaire: Does the Traditional Chinese Medicine Concept of Body Constitution Exist?
Wendy Wong, Cindy Lo Kuen Lam, Vivian Taam Wong, Zhi Min Yang, Eric T. C. Zieu, and Andrew Ka Lun Kwan
n = 3,525
Patients Reported outcomes
Socio-demographic data
Health status
n = 6,393
Body constitution prevalence
Socio-demographic data
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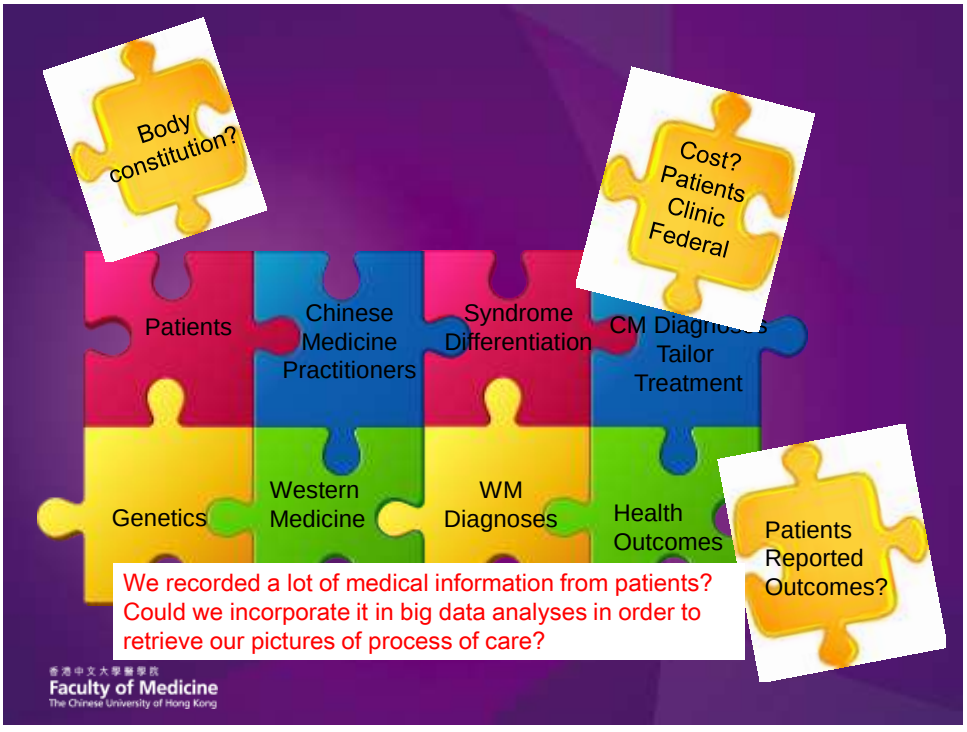
Body constitution?
Cost?
Patients
Clinic
Federal
Patients
Chinese Medicine Practitioners
Syndrome Differentiation
Tailor Treatment
Genetics
Western Medicine
WM Diagnoses
Health Outcomes
Patients Reported Outcomes?
We recorded a lot of medical information from patients?
Could we incorporate it in big data analyses in order to retrieve our pictures of process of care?
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Establishment of ACCLAIM (Analytic and Clinical Cooperative Laboratory for Integrative Medicine)

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Hong Kong Institute of Integrative Medicine

- Only academic institute of Integrative Medicine in HK
- Inaugurated on 28 September 2014
- Strong support from Innovation and Technology Commission
- Donations from Hong Kong Jockey Club, Lanson Foundation, Mr. and Mrs. KH Law, Dr. and Mrs. Edwin Yu
- Converted from a ward of 5000 sq. ft.

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Mission

- **Research**
  - Applied clinical research that changes practice and policy
  - Innovations in Chinese medicine
- **Education**
  - Mutual understanding of healthcare professionals from different disciplines
  - Clinical research expertise in Chinese medicine
- **Service**
  - Pioneering integration of Chinese medicine in conventional Western healthcare service
  - Practicalities of integrative medicine

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Distinctive Features

- Evidence-based practice driven by original research
  - Systematic review, meta-analysis, clinical trial, big data
- Chinese medicine-led model
  - Western clinician as gatekeeper
- Dedicated clinical team model
  - Specialty-based team with high level of communication
- Reach out to the community
  - Primary care networking led by Family Physicians
  - Public education and volunteer service
- Go international
  - International alliance in research, education and service

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Practice of Integrative Medicine

- Multidisciplinary model
  - Designated team of Western clinicians, Chinese medical practitioners and paramedics
  - Clinician-initiated referral
  - Joint initial assessment
  - Independent Chinese medical treatment
  - Monitoring of safety and adverse events by Family Physicians or Specialist
  - Regular joint follow-up consultation

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Key research projects underway

- **Integrative care model**
  - Stroke rehabilitation
  - Chronic low back pain
  - Palliative care for pancreatic cancer
  - Auricular stimulation for diabetes mellitus
- **Big data and database**
  - Stroke (with University of Sydney)
  - Herb safety (Multi-centre)
- **Clinical trials**
  - Curcumin for inflammatory bowel disease
  - Berberine for diabetes mellitus
  - Trilex® for influenza
  - Acupuncture for functional dyspepsia, irritable bowel syndrome, carpal tunnel syndrome and gallstone

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Coming soon…

- Integrative Palliative Care
  - Cancer and non-cancer patients
- Integrative Elderly Care
  - Outreach preventive care programme for singleton elders and elderly homes
  - Chinese medicine dietetic programme
- Public education campaign and surveillance programme
  - Herb-drug interaction: risks and benefits
  - Herb safety

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