NICMAN Scale

	Item **Author of study** **Person extracting the study**	**Yes:** the item is adequately **reported/described** and **meets a satisfactory standard.**	**No**: the item is **EITHER** adequately **reported/described** but does not meet a satisfactory standard, **OR it is not reported at all**	**Unclear:** the item is **partially described** and you are unable to make a judgement **OR,** you think the response only partially satisfies the standard	**Not applicable:** the item may meet the non applicable criteria if the study item is not relevant. No score to be given.
1	clearly described population	2	0	1	
2	clearly described intervention	2	0	1	
3	clearly described comparator	2	0	1	
4	clearly described outcome	2	0	1	
5	the study design is appropriate for the research question	3	0	1 or 2	
6	a differential diagnosis (if undertaken) is stated (2 points for yes, 0 for no, 1 for unclear or partial agreement)	2	0	1	
7	acupuncture points selected are consistent with chosen treatment principles. A statement is provided stating the acupuncture prescription is consistent with literature review, expert opinion or text books.	2	0	1	

	Item **Author of study** **Person extracting the date**	**Yes:** the item is adequately **reported/described** and **meets a satisfactory standard.**	**No**: the item is **EITHER** adequately **reported/described** but does not meet a satisfactory standard, **OR it is not reported at all**	**Unclear:** the item is **partially described** and you are unable to make a judgement **OR,** you think the response only partially satisfies the standard	**Not applicable:** the item may meet the non applicable criteria if the study item is not relevant. No score to be given.
8	<u>Needling: depth and manipulation</u> i) needle brand and dimension is used *consistently* across all participants and sessions. We use the term 'consistently' to provide an aspect relating to quality rather than focus on reporting ii) depth of needle insertion is reported and referenced to a standard text or mm or range is stated iii) needle manipulation is justified. (In the absence of needle manipulation justification is provided of the decision not to undertake needle manipulation) iv) needle sensation was sought and described v) electro acupuncture device should be identified and approved in country of use **NOTE to award 2 points all 5 sub categories need to be met**	2	0	1	

	Item **Author of study** **Person extracting the date**	**Yes:** the item is adequately **reported/described** and **meets a satisfactory standard.**	**No**: the item is **EITHER** adequately **reported/described** but does not meet a satisfactory standard, **OR it is not reported at all**	**Unclear:** the item is **partially described** and you are unable to make a judgement **OR,** you think the response only partially satisfies the standard	**Not applicable:** the item may meet the non applicable criteria if the study item is not relevant. **No score to be given.**
9	Point location i) published standard acupuncture location texts are used as a reference, or ii) location described in anatomical terms and/or an accurate proportional method for locating acupoints is used	2	0	1	
10	Number of treatments: i) if a chronic condition a minimum of six treatments are administered, if fewer treatments are delivered appropriate justification is documented. ii) if an acute or subacute condition, no minimum of treatments are specified, but appropriate justification is to be provided.	2	0	1	
11	i) the acupuncturist administering the intervention, is registered with a regulatory authority, or meets at least the minimum WHO standard (WHO 1999). ii) the practitioner undertaking the TCM differential diagnosis is adequately trained , for example registered with a regulatory authority, or meets at least the minimum WHO standard (if no differential diagnosis √NA)	2	0	1	
Total score					

NICMAN Scale explanatory notes.

We recommend the NICMAN scale is used together with the CONSORT Statement and STRICTA.

Checklist Items

- **Items 1-4**

  A research question clearly expresses the essential components, and the aim of the clinical trial/study. The next four items assess whether items 1-4 clearly identify the population with the clinical condition, the acupuncture intervention, the comparator or control used in the study and the primary outcome measure. These components should easily be identified in the title, introduction or background of the study.

  For example, does manual acupuncture versus standard care improve pain and function in elderly patients with chronic mechanical low back pain? In this case the population is elderly patients with chronic mechanical low back pain, the intervention is manual acupuncture (rather than electro-acupuncture), the comparator is standard care and the outcome measure is described as improvement in pain and function.

- **Item 5- The study design is appropriate for the research question.**

  This item refers to how the research question explicitly align with the study design.

- **Item 6- A differential diagnosis (if undertaken) is stated**

  Acupuncture as currently practised is characterised by a diverse number of paradigms, for example TCM acupuncture, trigger point acupuncture, or Japanese acupuncture. Each paradigm is different with each having a different underlying theoretical framework. Therefore, it is important that the diagnosis and treatment associated with the active intervention is supported by the underlying acupuncture paradigm.

  > *For instance, within the TCM paradigm the diagnosis and treatment is related to the use of channels or syndromes, however within the dry needling paradigm the use of palpation and knowledge of the central nervous system is used as a basis for diagnosis and treatment.*

  For example: all women recruited to a trial of dysmenorrhea underwent a TCM diagnosis to identify the TCM pattern. Acu-points for each TCM pattern were selected according to the TCM framework.

- **Item 7- Acupuncture points selected are consistent with the chosen treatment principles. A statement is provided, stating the acupuncture prescription is consistent with a literature review, expert opinion or text books.**

  The acupoints used in the study should be selected according to the differential diagnosis.

  > *For example, the acupoint BL23 was needled to supplement the Kidney qi.*

A trigger point located in the erector spine muscle and quadratus lumborum was needled for posterior lower back and leg

Acupoints may be listed in a standardised protocol based on as a review of acupoints used in several published studies.

For example, the acupoint PC6 was needled for a trial of vomiting because several studies have shown positive results to treat nausea using this acupoint. Alternatively, the acupoints LI 10, LI11 and TH5 were needled in a tennis elbow trial because a review of six previous tennis pain studies have consistently used this set of acupoints.

- **Item 8 - Needling: depth and manipulation**
  Please note: assess and score each of the five items individually but to award 2 points all sub categories need to be met

  a) Needle brand and dimension is used consistently across all participants and sessions.
  (Please note that this question does not apply for pragmatic and effectiveness studies).
  It is important that the needle brand and gauge are used consistently within the study across all participants and sessions.

  For example, Serein needles (Japan) 0.3 x 40mm were consistently used at body points, and Serein auricular press tacks 0.22 X 1.5mm *gauge were consistently used at auricular points.*

  b) Depth of needle insertion is reported and referenced to a standard text, it is expressed in millimetres, or reported as a range

  Example, LU7 5mm (Deadman,2007), and CV12 15-20mm (WHO, 2007).

  c) Needle manipulation is justified. In the absence of needle manipulation justification of this decision should be provided of the decision not to undertake needle manipulation.

  For example; during the treatment session all needles were manipulated once and midway through the treatment the needle was rotated 90-180 degrees for 10 times within 10 seconds.

  d) Needle sensation was sought and described.

  For example, we did not employ vigorous manipulation in order to elicit a strong de qi sensation (Schnyer et al 2008). Practitioners focussed instead on the response to stimulation as an "echo" sensation experienced on the receiving hand, while the active hand performed the actual needling.

  e) Electro acupuncture device should be identified and approved in country of use

  The physical specifications of the device should be defined and reported. This would include the name and model of device, the name of the manufacturer and the device

approval status (e.g. for Australia that the electro stimulator has been approved by the Therapeutic Goods Administration as a medical device).

For example, CEFAR Model 44 (Acustim Pty Ltd, Sweden), approved by the TGA as a medical device.

- **Item 9 - Point location**
  This item needs to meet either a OR b.

  a) Point location: published standard acupuncture location texts are used as reference

  The location of the acupoints used in the study should be accurately described in terms of modern anatomy, and as described in a standard acupoint location text for example, Deadman A Manual of Acupuncture (2007), or the WHO Standard Acupuncture Point Locations in the Western Pacific Region (2007). Alternatively, the site is described in anatomical terms. For example, the trigger point needled was located in the supraspinatus muscle.

  b) Point location: location is described in anatomical terms and/or an accurate proportional method for locating acupoints is used

  If a proportional method to located acupoints is used the use of a calibrated elastic ribbon, or Newman ACI locator device would be appropriate.

  For example: the acupoints LI10 and CV6 were located using the Newman ACI locator device for accurate proportional measurement.

- **Item 10 - Number of treatments**

  a) If a chronic condition a minimum of six treatments are administered, if fewer treatments are delivered appropriate justification is documented.

  The number of treatments in the study should reflect the nature of health condition being treated. If a chronic condition a minimum of six treatments should be administered, if fewer treatments are delivered appropriate justification should be given. The minimum of six treatments was based on reviews of the research literature conducted by Ezzo et al 2000. and Sherman et al. In these reviews they reported at least six treatments were necessary to optimise a therapeutic effect from acupuncture (Ezzo et al 2000; Sherman et al 2001).

  b) If an acute or subacute condition no minimum of treatments are specified, but appropriate justification should be provided.

  For example, post-operative nausea four sessions of acupuncture were given for post-operative nausea based on the management of side effects from pain medication. For example, the subject received acupuncture treatments for 5 weeks, in total 10 sessions.

- **Item 11**

a) The acupuncturist administering intervention, is registered with a regulatory authority, or meets at least the minimum WHO standard (WHO 1999).

If a non-medical acupuncturist is administering the intervention, they should be registered with a regulatory authority, or meet the minimum WHO standard (WHO 1999).

For example, the acupuncture researcher was registered with the Victorian Chinese Medicine Registration Board, British Acupuncture Council, or the National Certification Commission for acupuncture and oriental medicine, or meets the WHO standard of 2500 training hours.

For example, the acupuncturist administering the treatment was registered with British Acupuncture Council. If a medical acupuncturist is administering the acupuncture they should be registered with a regulatory body e.g. Australian Medical Acupuncture Society or meet the minimum WHO standard of 200 hours. *For example, the acupuncturist administering the treatment had received training of 240 hours.*

b) The practitioner undertaking the TCM differential diagnosis is adequately trained, for example undertaken evidence is provided that the acupuncturist meets at least the WHO standard (WHO 1999), or is registered with a regulatory authority.

The researcher/practitioner undertaking the Asian differential diagnosis (TCM, Japanese, Korean, 5 elements) should be registered with a regulatory authority (e.g. Victorian Chinese Medicine Registration Board, or the National Certification Commission for acupuncture and oriental medicine), or meet the minimum WHO standard (WHO 1999).

For example, the acupuncture researcher was registered with the or meets the WHO standard of 2500 training hours. The researcher/practitioner graduated from a five-year full time course in China and was accredited by the China State Academy.

Where a western scientific approach is being used as a basis for diagnosis (e.g. trigger point, neuroanatomical concepts) the acupuncturist/researcher should be registered with a regulatory body (e.g. Australian Medical Acupuncture Society) or meets the minimum WHO standard of 200 hours.

For example, the acupuncturist administering the treatment was a member of the American Academy of Medical Acupuncture.

Term definitions

Paradigm: "a philosophical and theoretical framework of a scientific school or discipline within which theories, laws, and generalizations and the experiments performed in support of them are formulated; *broadly*: a philosophical or theoretical framework of any kind" (The Merriam-Webster Online dictionary).

Clinical Reasoning: "the thinking and decision making processes associated with clinical practice.[2-5] This reasoning is influenced by: the personal context of the client; the context of the clinical setting; the personal and professional framework of the clinician; and the context of the health care system. Clinical reasoning is comprised of three interactive components: knowledge, cognition and meat-cognition. Cognition relates to the thinking skills of analysis, synthesis and evaluation of data whereas meta-cognition is the awareness of thinking and the ability to assess one's knowledge base" (https://otl.curtin.edu.au/tlf/tlf2000/ladyshewsky.html; accessed 14th April, 2010)

References

Deadman P, Al-Khafaji M, Baker K. A manual of acupuncture. 2nd ed. London: Journal of Chinese Medicine Publications; 2007. 675 p.

Ezzo J, Berman B, Hadhazy VA, Jadad AR, Lao L, Singh BB. Is acupuncture effective for the treatment of chronic pain? A systematic review. Pain. 2000;86(3):217-25.

Han J-S. Recent Advances in the Mechanisms of Acupuncture Analgesia. World Journal of Acupuncture (no date).

Sherman KC, Hogeboom CJ, Cherkin DC. How traditional Chinese medicine acupuncturists would diagnose and treat chronic low back pain: results of a survey of licensed acupuncturists in Washington State. Complement Ther Med. 2001;9(3):146-53.

Sherman K, Linde K, White A. Comparing treatment effects of acupuncture and other types of healthcare. In: MacPherson H, Lewirth G, Schyner R. Acupuncture Research strategies for establishing an evidence base. Churchill Livingston Elsevier; 2007.

White A, Foster NE, Cummings M, Barlas P. Acupuncture treatment for chronic knee pain: a systematic review. Rheumatology (Oxford). 2007;46(3):384-90.

White P, Linde K, Schyner RN. Investigating the components of acupuncture treatment. In Acupuncture Research strategies for establishing an evidence base. In: MacPherson H, Lewirth G, Schyner R. Acupuncture Research strategies for establishing an evidence base. Churchill Livingston Elsevier; 2007.

World Health Organization. Guidelines on basic training and safety in acupuncture. Geneva: World Health Organization; 1999. Available from: http://apps.who.int/medicinedocs/en/d/Jwhozip56e/