Pragmatic Trial of Acupuncture for Chronic Low Back Pain in Older Adults (BackInAction)
Acupuncture Intervention Manual for Both Standard and Maintenance Periods

Purpose: This document describes the acupuncture intervention that will be used in the BackInAction (BIA) pragmatic trial, which enrolls adults at least 65 years old with chronic low back pain (cLBP). CLBP is defined as 3 months or more of pain on most or all days and includes patients with uncomplicated low back pain who may or may not have radiculopathy.

Our intervention is designed to be flexible and responsive to the most common scenarios anticipated and as they evolve over the course of care. In addition, the intervention is bound by the requirements of NIH and CMS, which specify a "needle only" trial.

There are three study arms of the trial: the standard acupuncture group, the enhanced acupuncture group and the usual medical care only group. Everyone randomized to receive acupuncture (two-thirds of trial participants) will have an initial 12-week treatment period (aka "standard acupuncture"). Half of the acupuncture recipients will receive "enhanced acupuncture", which consists of the standard acupuncture (12 weeks) followed by 12 weeks of "maintenance" acupuncture.

Process of Acupuncture Advisory Panel: Our panel included 8 expert members with 14-42 years of experience respectively; several physician acupuncturists (1 also an LAc, both in medical settings), a KPNC acupuncturist, medical director of a network that credentials acupuncturists, acupuncturist working with Medicaid patients, an academic dean, one private practitioner, and one who supervised protocol development and acupuncture care in a large trial on chronic pain. It also included a non-acupuncturist researcher with extensive experience conducting research on the treatments used by acupuncturists for chronic low back pain.

We used a modified Delphi process with three telephone discussions in 2019 (10/29, 11/5 and 11/26) and an email round of discussion between the 2nd and third call. Initial discussions were based on treatment data for cLBP patients extracted from Acupuncture Trialist Collaboration trials and more recent trials, a paper by Arthur Fan on the treatment of chronic low back pain (cLBP) in older adults and data surveyed from each panel member on how they typically treat cLBP in older adults. We obtained consensus at each meeting and confirmed consensus later before tackling additional items. We used the STRICTA checklist as a guide.

Intervention Descriptions:

Element of intervention	Rationale	Notes
Up to 15 treatments over 3 months in the standard acupuncture period, up to 6 in the 3-month maintenance acupuncture period. Thus, up to 21 treatments over 6 months (for those randomized to the enhanced acupuncture group).	From discussions with long-time practitioners and the greatest number of allowed treatments in some of the largest extant trials	Some trials used 10-12 treatments in their treatment period. We won't require acupuncturists to use all 15 treatments. For maintenance acupuncture, we won't require acupuncturists to use all 6 treatments.

		CMS will pay for up to 12 treatments in the first 90 days if the patient does not receive more than they need to demonstrate effectiveness. CMS will pay for up to 8 additional treatments over 12 months if the patient is improved. Our design differs slightly from the CMS decision and the study will pay for any treatments that cannot be reimbursed by CMS.
Eight sessions is the proposed minimum effective course of treatment in terms of critical number of sessions and frequency and how we might give treatments throughout the 3 months (standard acupuncture) if < 15 treatments needed. **[MINIMUM NUMBER OF TREATMENTS]**	Based on data from literature, we encourage at least 6-8 treatments in the first 2-months, with at least 1-2 treatments in the last months (standard acupuncture period) Based on the principal of tapering treatments over time, we encourage at least 4 treatments in the 3-months maintenance period	Strong recommendation, but the acupuncturist has some discretion.
Steps or staging of care would include 'asking'* interview and can include range of motion (ROM) observation, palpation of region, channels and Hara; should include point selection and needling (de qi at practitioner discretion); needle retention; removal of needles and resting or changing position to treat another 'part of the body', palpation and point selection and needling (de qi at practitioner discretion); needle retention, removal of needles and resting. End of session check in, assessment of pain and ROM, patient's readiness to leave the treatment room, self-care recommendations, and confirmation of next appointment.	Common steps in an acupuncture intervention	General consensus on the importance of a period of time of resting with needle retention and/or also after needles removed.

What about TCM pattern diagnosis	Our research found lots of inconsistencies for use in cLBP and advisory panel agreed not needed.	Will not capture
Panel of points Will include local (LB), regional (rest of torso), distal and ear. See appendix A for the list of points by area of the body	General consensus	We organized as points on relevant channels, distinguishing local, distal, and regional/torso (as in back points that are not LB points or points on the front of the body).
Auricular treatment	Auricular therapy, needling and extended therapy pressure with magnets or seeds, is effective for chronic pain.	Consensus on inclusion of auricular acupuncture and auricular acupressure seeds, to extend the treatment benefit between sessions.
Distal and local points are expected to be treated in each session	Local and distal point treatment is inherent aspect of acupuncture practice based in traditional East Asian medicine.	While this will be the norm, there can be exceptions when a patient is confined to being treated in a chair, or point selection is restricted for another reason. We will capture the name (channel and number) of all acupoints used within a session.
What about other microsystems (Richard Tan, Korean hand) or named treatments (Master Dong)	Commonly used in Northwest but no study data to support	We will proscribe the use of any microsystems besides auricular. In addition, we will proscribe the exclusive use of a trademarked treatment. It is Ok to use a point or two from these as part of a larger treatment with rationale.
Number of insertion sites: expected 6-20	Mean number of needles used: almost 70% used 5-14 needles. (Vickers et al, 2018)	Initial sessions might have less than 6 points. Unusual to go more than 20

		points. We will capture the number of needles used per session.
Range of needle retention time *For treatments using one position of the body, the typical retention time is 20-30 minutes. There is a minimum needle retention time* of *0 (De qi and removal) to maximum of 40 minutes for one position/area of the body* If treating both back and front in one session, the typical retention time is 15-20 minutes. There is a minimum needle retention time of 0 (de qi and removal) to a maximum of 25 minutes per area of body	Resting with needle retention is part of acupuncture therapy. No needle retention can mitigate effect of acupuncture needling. Excessive needle retention time can fatigue a patient.	Treatment is at the discretion of the practitioner. Expectation of relaxation with retained needles and or resting after withdrawal. Care taken in early sessions to assess a patients response to treatment. We will ask acupuncturists to give us the minimum, maximum and average needle retention time for each treatment.
Treatments will vary based on patient's unique presentation and as it evolves over time.	Effective acupuncture is responsive to unique and varying presentations as opposed to repeating a rote point prescription.	
Obtaining de qi	De qi felt by the patient and the practitioner is a unique part of acupuncture needling. Research demonstrates a role for obtaining de qi in the treatment of pain.	Obtaining de qi may be recommended as part of care but is at the discretion of the practitioner on any given day for any given patient. We will capture whether de qi was obtained (no, some acupoints, most/ all acupoints).
Information and recommendation re non-coated or coated needles	Research shows non-coated/'course' needles may enhance analgesic effect as opposed to silicone coated needles. Non-coated needles were used in large PCORI acup trials	Inform and recommend but not require. We will capture information on typical needles used by practitioner.
Needle gauge and length	We will collect data on this. Needle lengths must be less	Need to allow options for patients as they may vary from robust to frail

	than safe needling depths where there is risk of organ puncture or damage to other tissue.	We will ask about typical gauge and needle lengths per patient
Depth of needle insertion will be based on effective depths per point location, with information provided on safe depths based in the literature of reports of risks.	Recommendations are based on using needles whose length is 75% of safe depth for a particular point (to be described)	Practice of only very shallow needling not recommended as has been shown as a less effective sham in trials. We will ask generally about this but not for each acupoint.
Bloodletting needling	Some texts recommend to intentionally microbleed certain points in the treatment of cLBP	We will proscribe the application of bloodletting to acupoints
Total session time 45-60 minutes	Large meta-analysis shows 53% of sessions in trials were 20-30 minutes; 47% were 30 minutes or more.	We had a general consensus of 60 minutes for first sessions, and typically 45 (up to-60) minutes for follow-up sessions. We will capture this.
Self-care recommendations General/basic recommendations that extend the benefit of an acupuncture treatment from a Chinese medicine perspective. More detailed recommendations are shown in Appendix B	Trial restricted to acupuncture needling, omitting key components of an acupuncture therapy session so this is important. Want fairly high level recommendations	We will capture self care recommendations as follows: o None o Movement, activity, exercise o Meditative movement like Tai qi, Qi gong, yoga o Food/diet/water: general o Guidance on breathing awareness o Other_____
Other Trial Requirements Acupuncturists may not refer to other practitioners except for the patients/participants' primary care doctor	Part of study protocol	

Acupuncturist may not see the patient privately (outside of the trial sessions) during the duration of the trial (1 year from enrollment)		
Practitioner Qualifications Acupuncturists should be state-licensed and malpractice insured with no malpractice claims. Acupuncturists should have 5 years minimum post licensing practice (of at least 50% of the time in patient care) with experience treating older adults, cLBP, and patients with multi-morbidities. There may be exceptions for 3 years' experience per individual applicant, for example with other health care licensure. In addition to the above, they will be vetted by the health plans and/or lead acupuncturist (for example, at KPWA, we will recruit from our network of providers and at IFH, we will recruit from prior trials).	Makes sense to have people with experience	
Study Intervention Training They will all be trained in the protection of Human Subjects for research, as well as the study protocol, special safety issues for our study, and the logistics of delivering and recording study treatments. They will be certified for participation in the study.		

*'Asking' in traditional East Asian medicine is short hand for patient interview and history taking that typically includes questions about appetite, diet, digestion, stool, sleep, urination, sweating, menstrual cycle, senses, emotional state as well as description of presenting problem(s), including pain.

Appendix A List of acupuncture points for BIA* **(SEE GRID OF POINT OPTIONS ON SESSION FORM)**

Channel:	Local	'Local' region: back or front, related to LB	Distal
GV (Du)	2, 3, 4	11, 14	20
CV (Ren)		3,4,6,12	NA
BL (underlines =shu points)	Lower mid-lower back: BL 22, 23, 24, 25, 26-35; lateral BL channel 51-54	Upper and mid-back: BL 10, 11, 12, 13, 14, 15, 17, 18, 19, 20, 21, lateral BL channel 41-50 (43 Gao huang shu)	36-40 back of thigh 57, 58, 59, 60, 62 (w/SI 3 Du mo)
GB	31, 30, 29	20, 21, 26-27	33, 34, 37, 39, 40, 41
KI			3, 4,7
ST		25	36, 37
SP		2, 4, 6, 9	
TW/SJ			Tw5/Gb 41 (Dai mo)
Hua tuo jia ji: (HTJJ)	Any but especially mid and lower back; Lumbar 1-5	HTJJ upper and mid-back; Thoracic T1-3; 5-12	
Other calming			4 gates: Li 4, Liv 3
'Extra'	Yao yan, Shi qi zhui xia (point under 5th lumber), SI Joint, Pi Gen, Huan Zhong		Yin tang
Ah shi points	Per palpation	Per palpation	Per palpation
Ear points			Per palpation/sensitivity: Shen men, back, hip, leg, knee, ankle
Other points not on list selected with rationale			

*References:

1. Deadman P, Al-Khafaji M, Baker K. *A manual of acupuncture.* East Sussex, England; Vista, California: Journal of Chinese Medicine Publications; Distributed in North America by Eastland Press; 2016.
2. O'Connor J, Bensky D. *Acupuncture: a comprehensive text.* Seattle: Eastland Press; 1981.

Appendix B Self-care recommendations

Basic Traditional East Asian Medicine self-care recommendations that can be tracked with the using the question below:

1. Avoid excessive cold and sour food and drink.
2. Avoid extreme exercise or work, lifting or twisting. If there is a sense one can increase exercise already engaged in, increase in small intervals.
3. Or suggestion of meditative movement like Qi gong or Tai qi.
4. Eat regular warm cooked meals.
5. Drink enough water.
6. Guide on awareness breathing (used when there shortened breathing, Gan qi exacerbating pain and anxiety).
7. Recommendations re meditation or quiet reflective time in the day.

Did you give recommendations?

- None
- Movement, activity, exercise
- Meditative movement like Tai qi, Qi gong, yoga
- Food/diet/water: general
- Guidance on breathing awareness
- Other_____