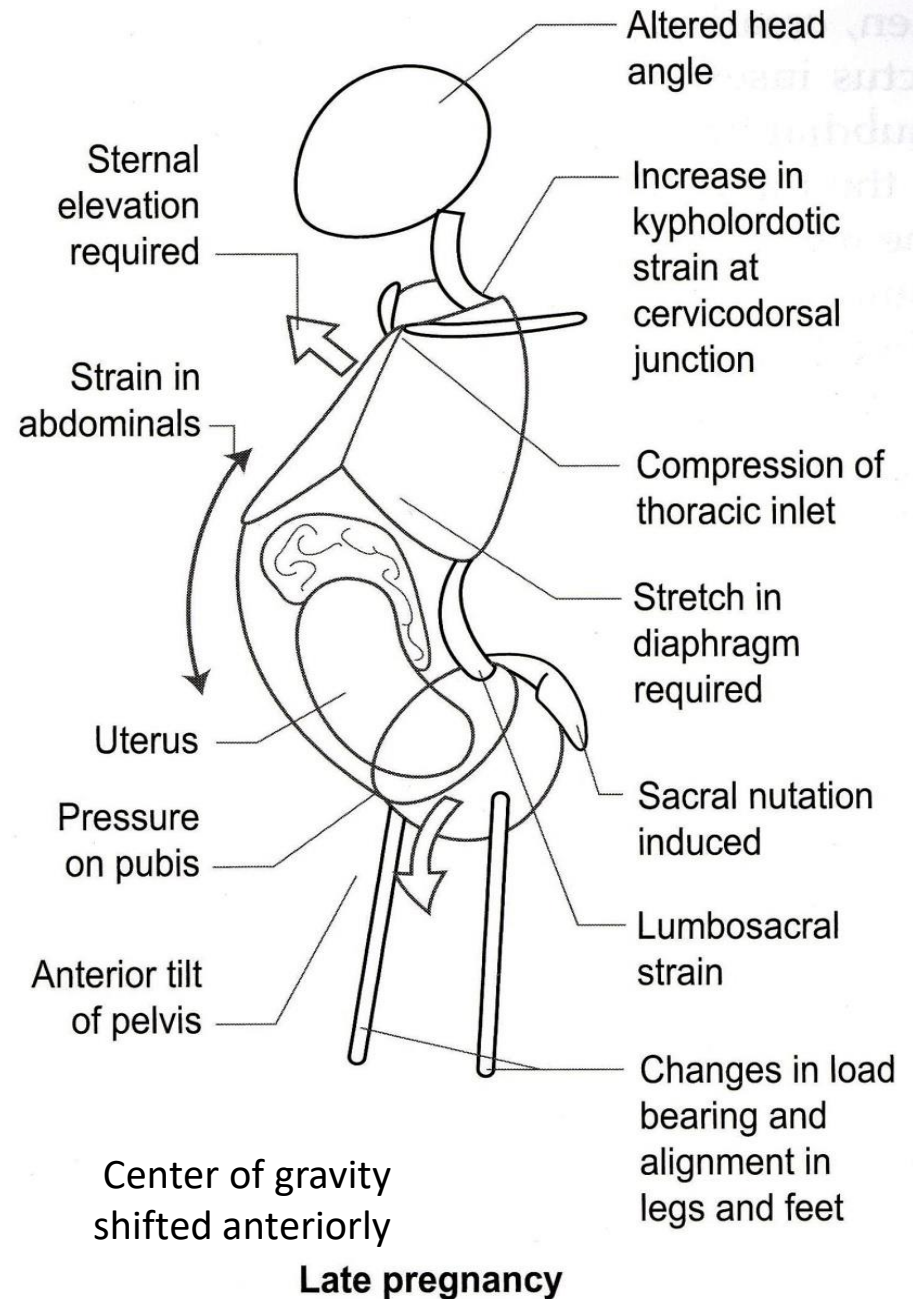


Pregnancy
Research in Osteopathic
Manipulation Optimizing
Treatment
Effects: The PROMOTE Study

Kendi Hensel, DO, PhD

Kendi.hensel@unthsc.edu

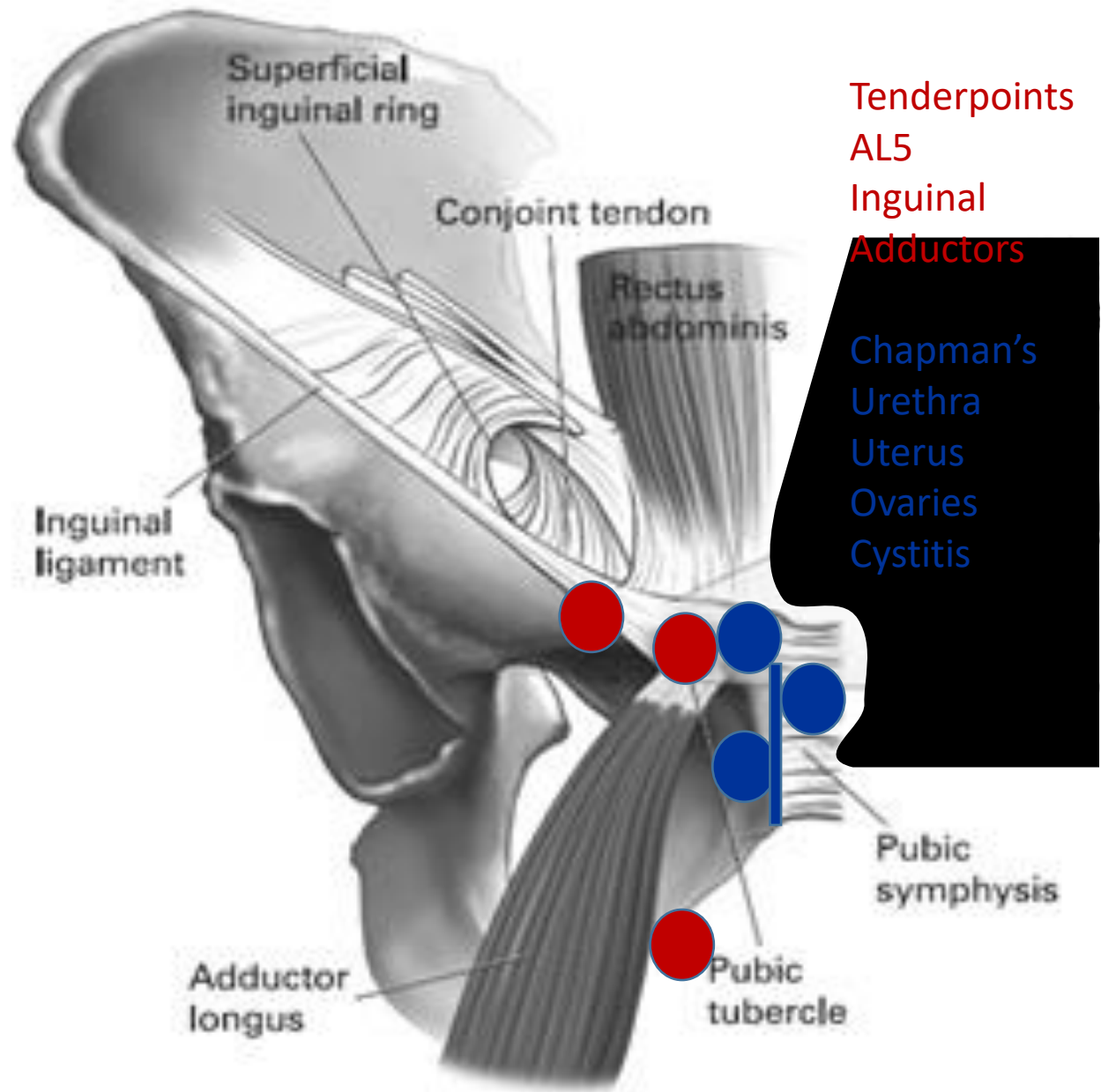
Musculoskeletal Changes in Late Pregnancy



Common Conditions in Pregnancy

- **Low back pain**
 - Compensatory lordosis
 - Stress across vertebral facets of lumbar spine
 - Increases shear forces across intervertebral disc spaces
 - Shortened paraspinal muscles
- **Sacroiliac joint pain**
 - Excessive connective tissue stretch & microtrauma
 - Increased mobility at SI joint due to distention of pelvis (relaxin)
- **Posterior pelvic pain**
 - Radiation of pain in posterior part of thigh, extends down below knee*
- **Muscle cramps**
- **Sluggish venous return**
 - Lower extremity edema & congestion
 - Hemorrhoids , Varicosities
 - Breast soreness
 - Fluid retention (progesterone)
 - Carpal tunnel syndrome
 - De Quervain's
- **Joint pains**
- **CNS congestion:**
 - Nausea
 - Headaches
- **Vomiting**
- **Progesterone**
 - Constipation (decreased peristalsis)
 - Reflux esophagitis (decreased esophageal sphincter tone)
- **Expanding uterus**
 - Urinary frequency
 - Various paresthesias or radicular symptoms
 - Direct pressure on nerve roots/plexi by gravid uterus or lumbar lordosis
 - Ilioinguinal & iliofemoral nerve distribution
 - Round ligament pain

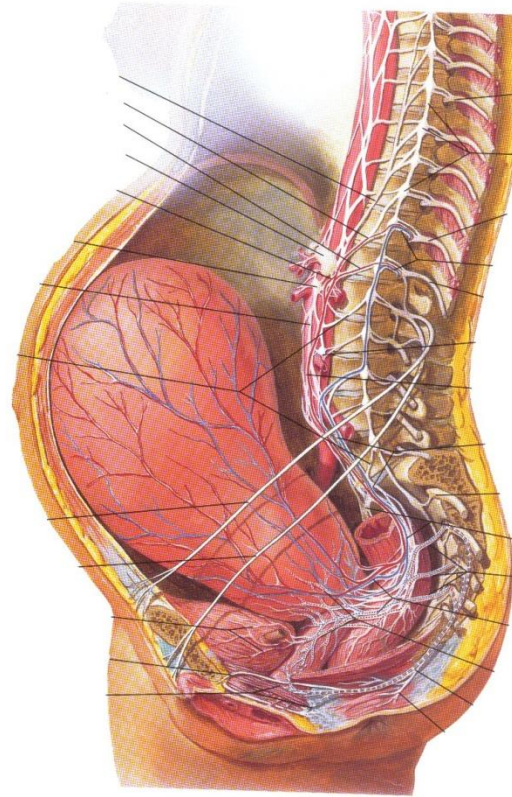
Pubic pain



OMM Considerations

- SNS T10-L2

- ↑ vasoconstriction
→ poor nutrition & O₂ exchange
- ↑ uterine contraction
- ↓ threshold for pain for the uterus



- PNS S2-4

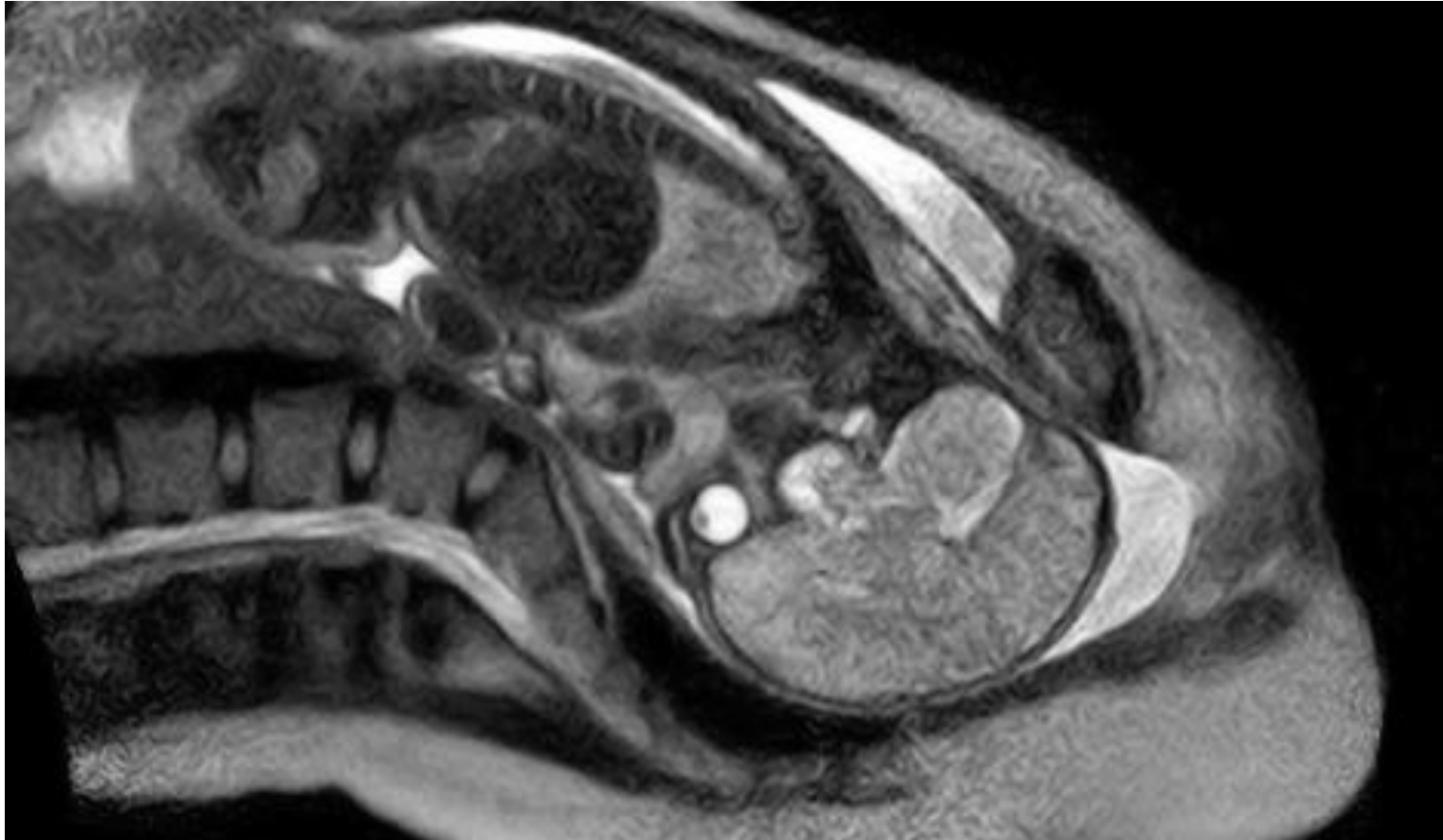
- ↑ stimulation:
- ↑ relaxation of uterine muscle
- ↑ vasodilation
- ↓ threshold for pain for the cervix

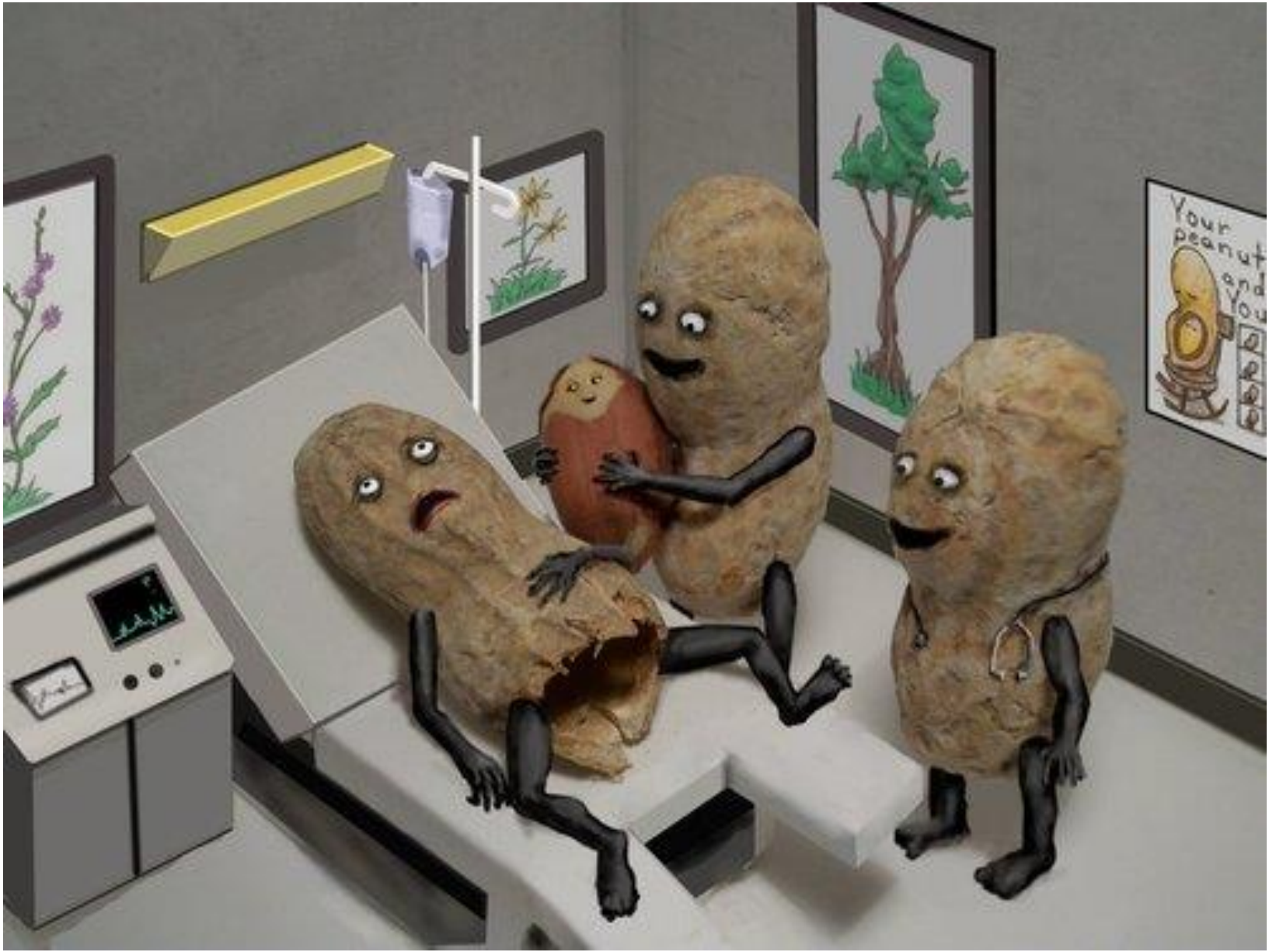
- Lymphatic:

- Impaired lymphatic flow

- ↑ tissue congestion
- Bloating and discomfort

Why treat the sacrum and pelvis?





Research on OMT's effects on pregnancy, labor & delivery

- Decreased labor time
- Decreased pain medication use during delivery
- Decreased nausea/vomiting of pregnancy
- Decreased use of forceps
- Decreased incidence of meconium-staining of the amniotic fluid
- Decreased preterm delivery

OMT & Pregnancy

- King et al, “Osteopathic Manipulative Treatment in Prenatal Care: A Retrospective Case Control Design Study”, *JAOA*, 103(12): 577, December 2003.
- 160 women from 4 cities who received prenatal OMT vs 161 from same cities who did not receive prenatal OMT
- In pregnant patients who received prenatal OMT, there were lower rates of:
 - Occurrence of meconium-stained amniotic fluid (6% vs 26%)
 - Preterm delivery (4% vs 12%)
 - Lower use of forceps (0% vs 2%)
- **Prospective study was recommended**

Pilot study design

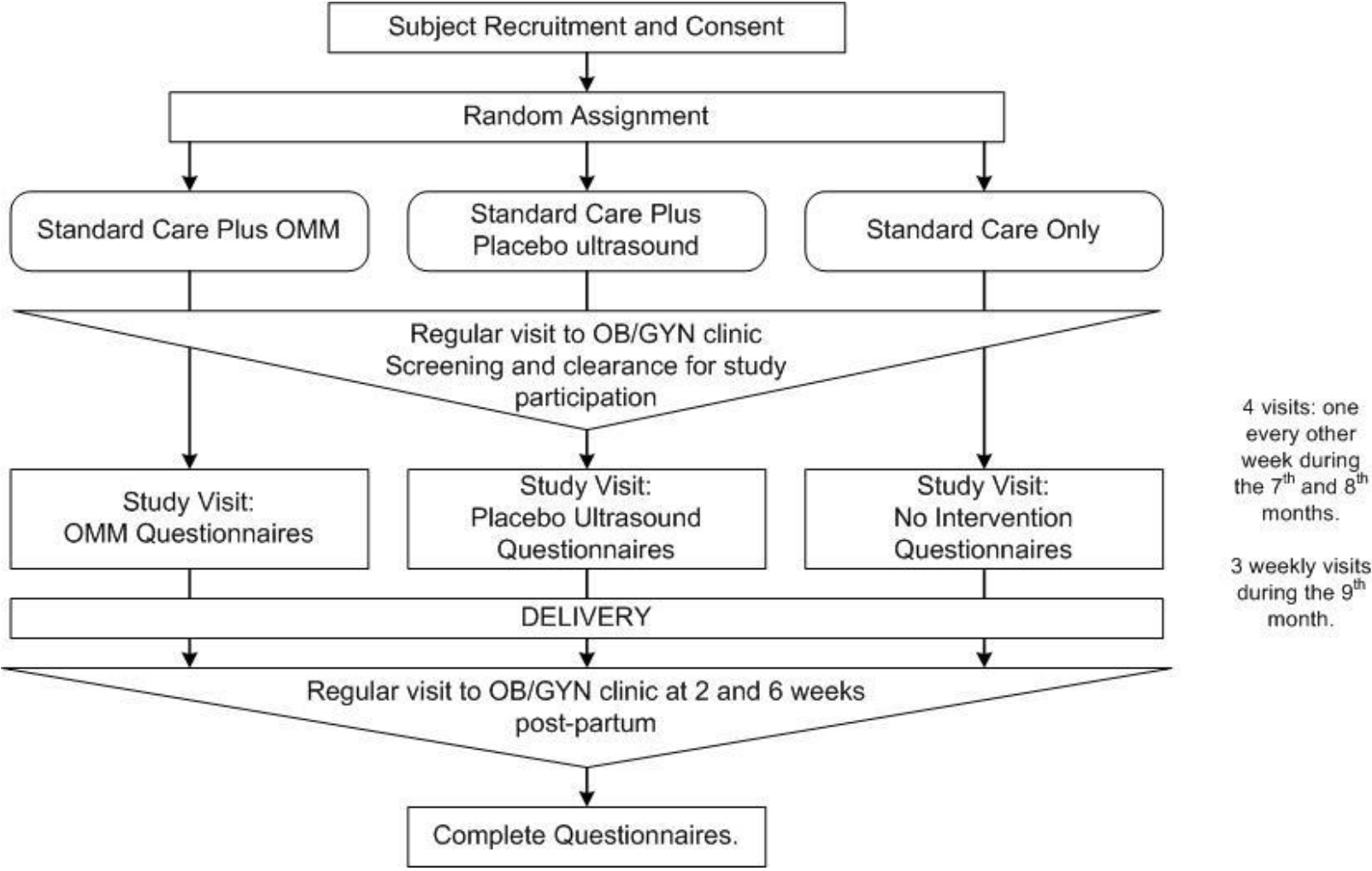
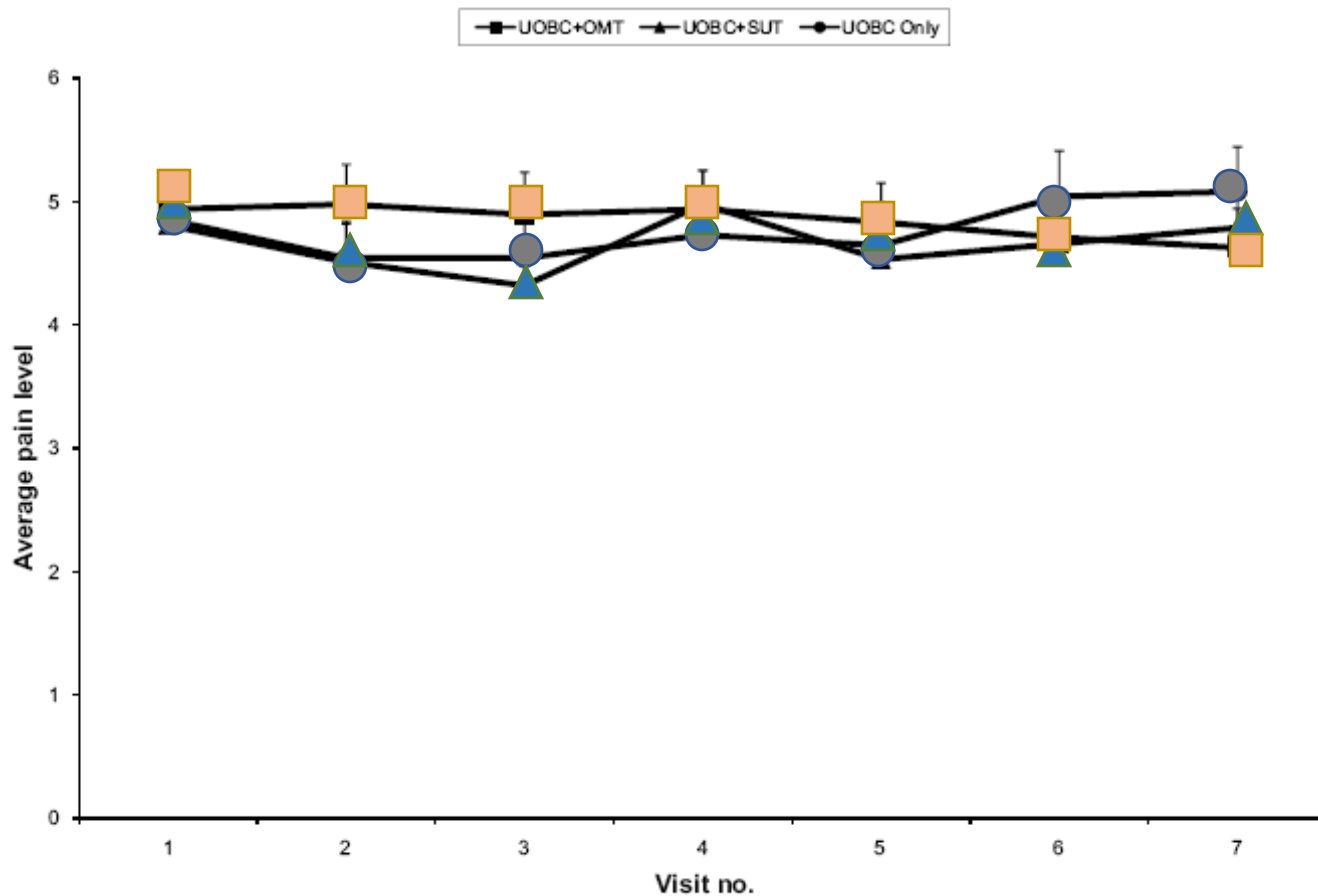


FIGURE 3
Average back pain levels over time

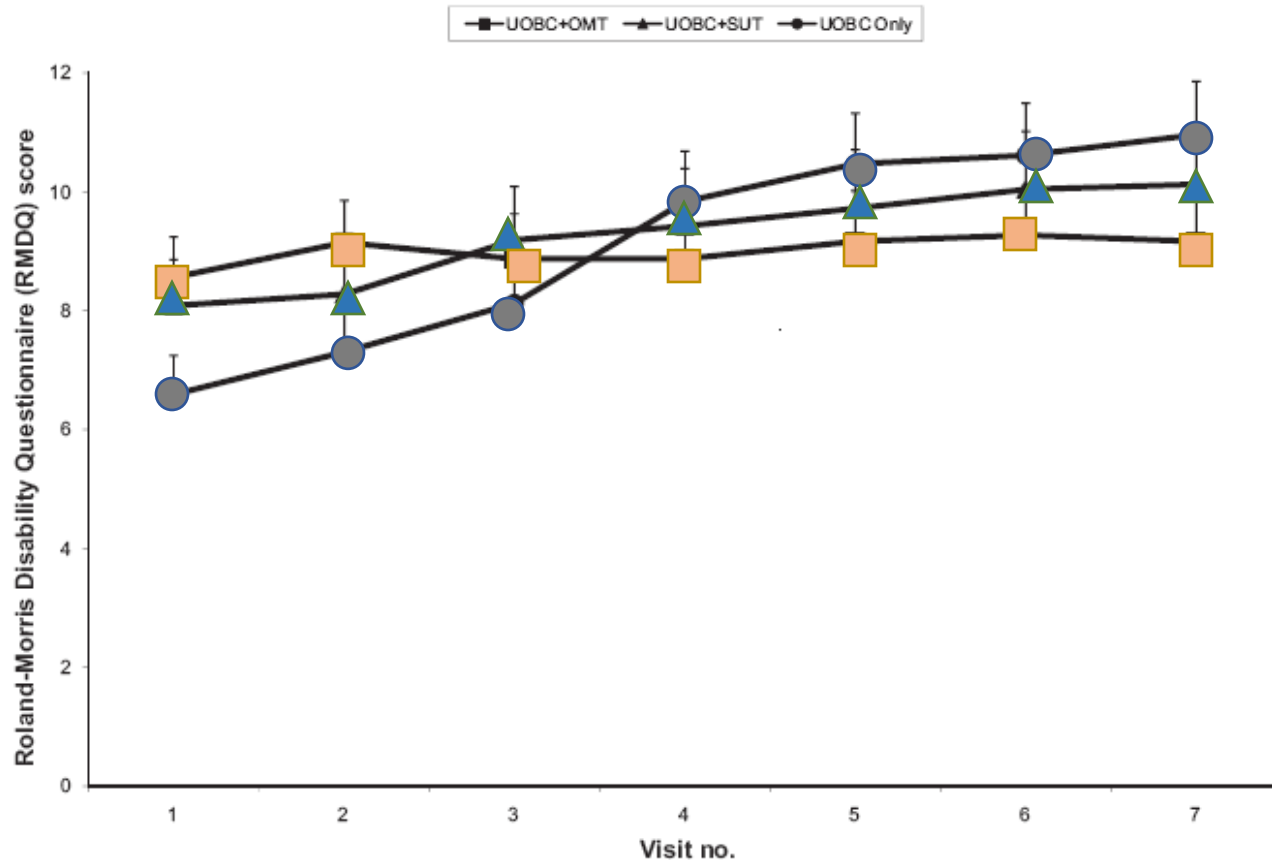


Results are presented as mean and standard error. There were no statistically significant differences in pain levels among treatment groups.

OMT, osteopathic manipulative treatment; *SUT*, sham ultrasound treatment; *UOBC*, usual obstetric care.

Licciardone. OMT of back pain and related symptoms. Am J Obstet Gynecol 2010.

FIGURE 4
Roland-Morris Disability Questionnaire (RMDQ) scores over time



Results are presented as mean and standard error. The treatment group ($P = .02$) and time ($P = .01$) main effects and the treatment group \times time interaction effect ($P < .001$) were all statistically significant.

OMT, osteopathic manipulative treatment; SUT, sham ultrasound treatment; UOBC, usual obstetric care.

Licciardone. OMT of back pain and related symptoms. *Am J Obstet Gynecol* 2010.

Summary- pilot study

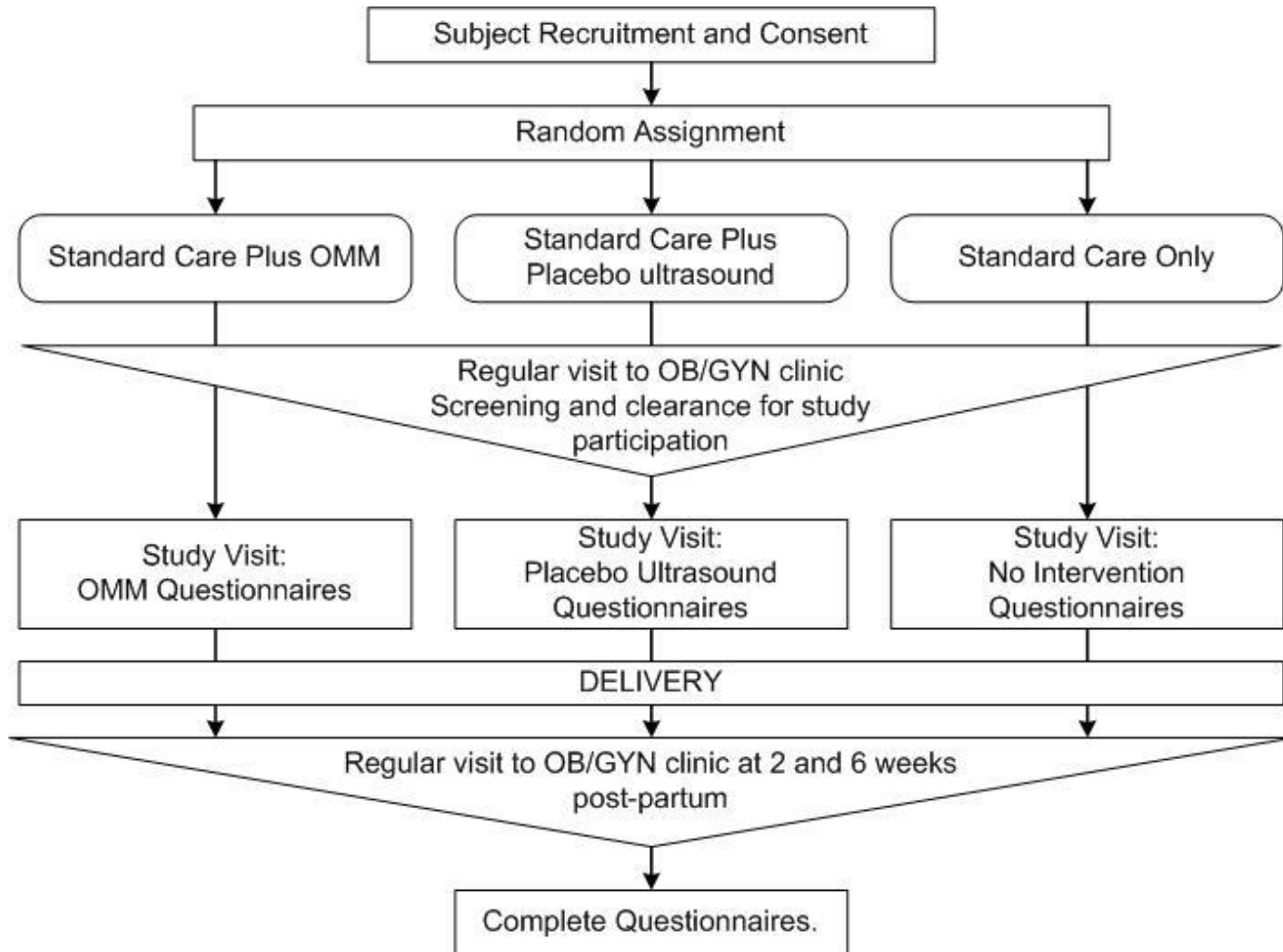
- N=144
- Pre-delivery outcomes
 - Substantially favorable findings with respect to functional disability
 - Some trends in favorable findings with respect to VAS pain scores
- Labor and delivery outcomes
 - Some trends in favorable findings at delivery (MSAF)
 - No trends in obstetrical complications (sample size too small to assess relatively rare events)
- **Larger study needed to evaluate rarer clinical outcomes**

PROMOTE study



Pregnancy
Research in
Osteopathic
Manipulation
Optimizing
Treatment
Effects

NIH (NCCAM) study design (part of K23 grant)



4 visits: one every other week during the 7th and 8th months.

3 weekly visits during the 9th month.





Acute improvement in hemodynamic control after osteopathic manipulative treatment in the third trimester of pregnancy^{*}



Kendi L. Hensel^{a,*}, Christina F. Pacchia^b, Michael L. Smith^{b,c}

^a Department of Osteopathic Manipulative Medicine, University of North Texas Health Science Center, Fort Worth, TX, United States

^b Department of Integrative Physiology, University of North Texas Health Science Center, Fort Worth, TX, United States

^c Osteopathic Research Center, University of North Texas Health Science Center, Fort Worth, TX, United States

Available online 30 August 2013

KEYWORDS

Blood pressure;
Hypotension;
Tilt;
Muscle pump;
Osteopathic
manipulation

Summary

Objectives: The physiological changes that occur during pregnancy, including increased blood volume and cardiac output, can affect hemodynamic control, most profoundly with positional changes that affect venous return to the heart. By using Osteopathic Manipulative Treatment (OMT), a body-based modality theorized to affect somatic structures related to nervous and circulatory systems, we hypothesized that OMT acutely improves both autonomic and hemodynamic control during head-up tilt and heel raise in women at 30 weeks gestation.

Design: One hundred subjects were recruited at 30 weeks gestation.

Setting: The obstetric clinics of UNTHHealth in Fort Worth, TX.

Intervention: Subjects were randomized into one of three treatment groups: OMT, placebo ultrasound, or time control. Ninety subjects had complete data ($N = 25, 31$ and 34 in each group respectively).

Main outcome measures: Blood pressure and heart rate were recorded during 5 min of head-up tilt followed by 4 min of intermittent heel raising.

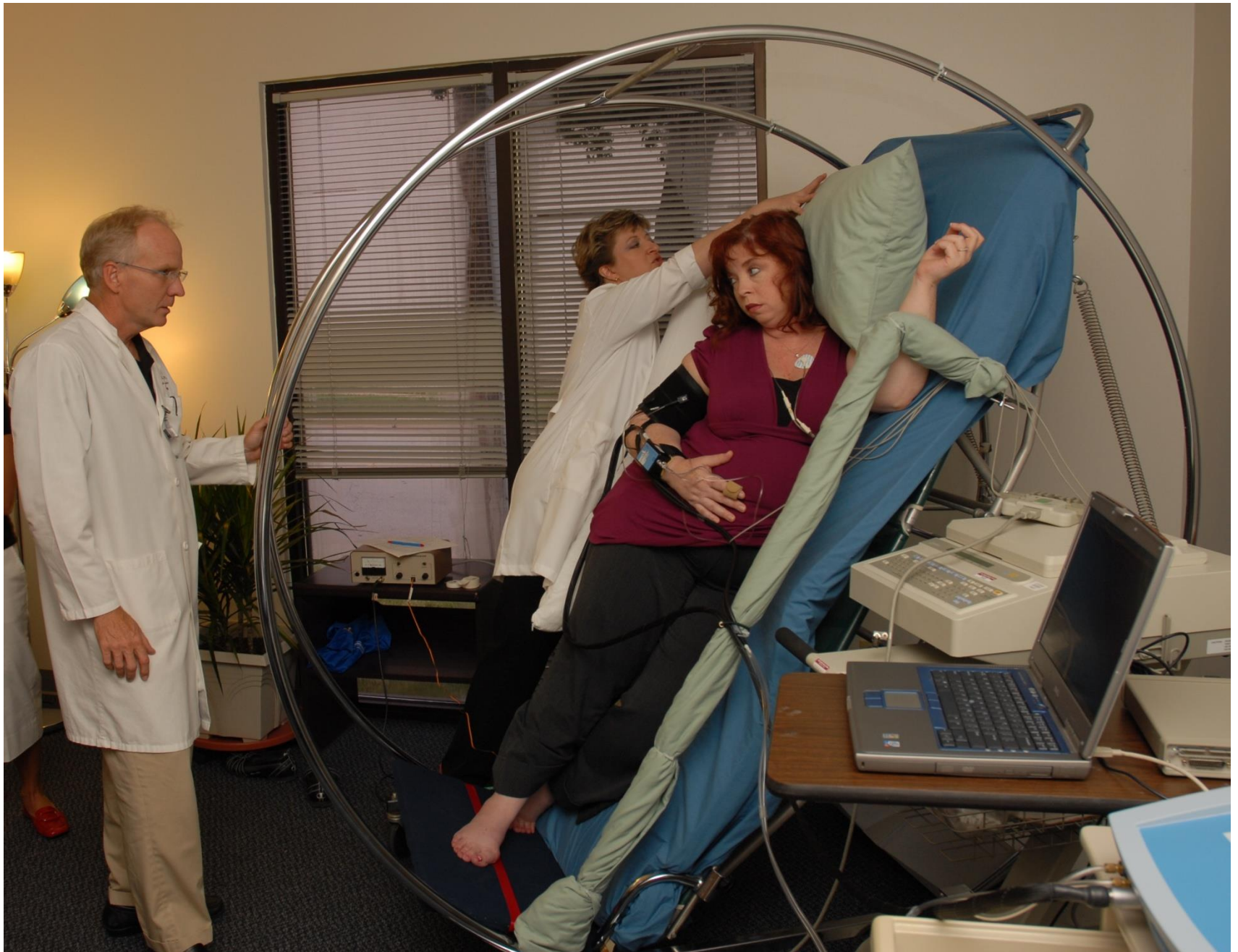
Results: No significant differences in blood pressure, heart rate or heart rate variability were observed between groups with tilt before or after treatment ($p > 0.36$), and heart rate variability was not different between treatment groups ($p > 0.55$). However, blood pressure increased significantly ($p = 0.02$) and heart rate decreased ($p < 0.01$) during heel raise after OMT compared to placebo or time control.

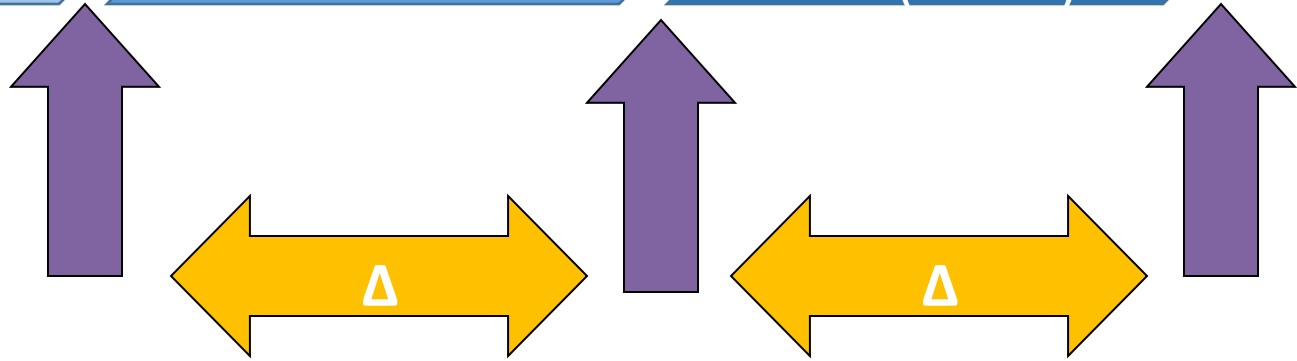
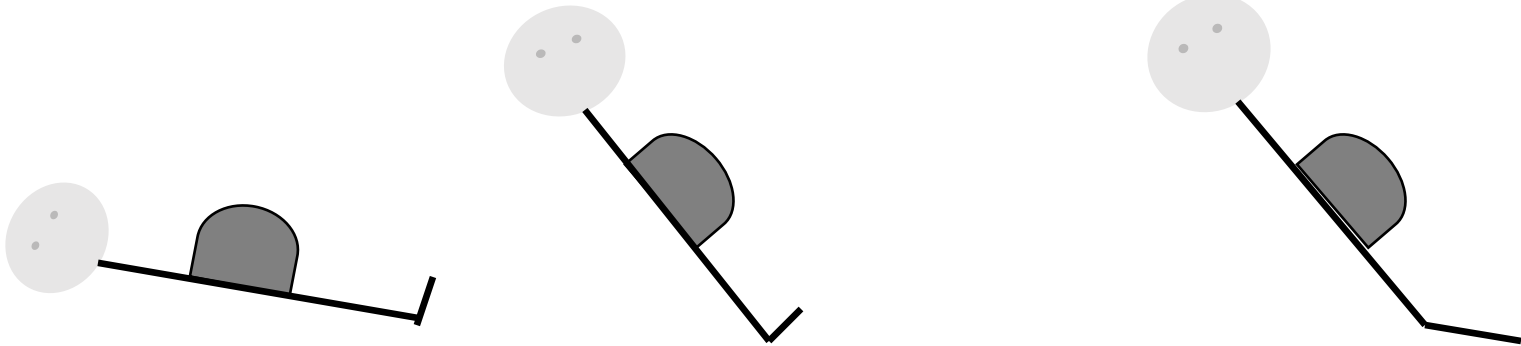
NIH/AOA Physiology Substudy

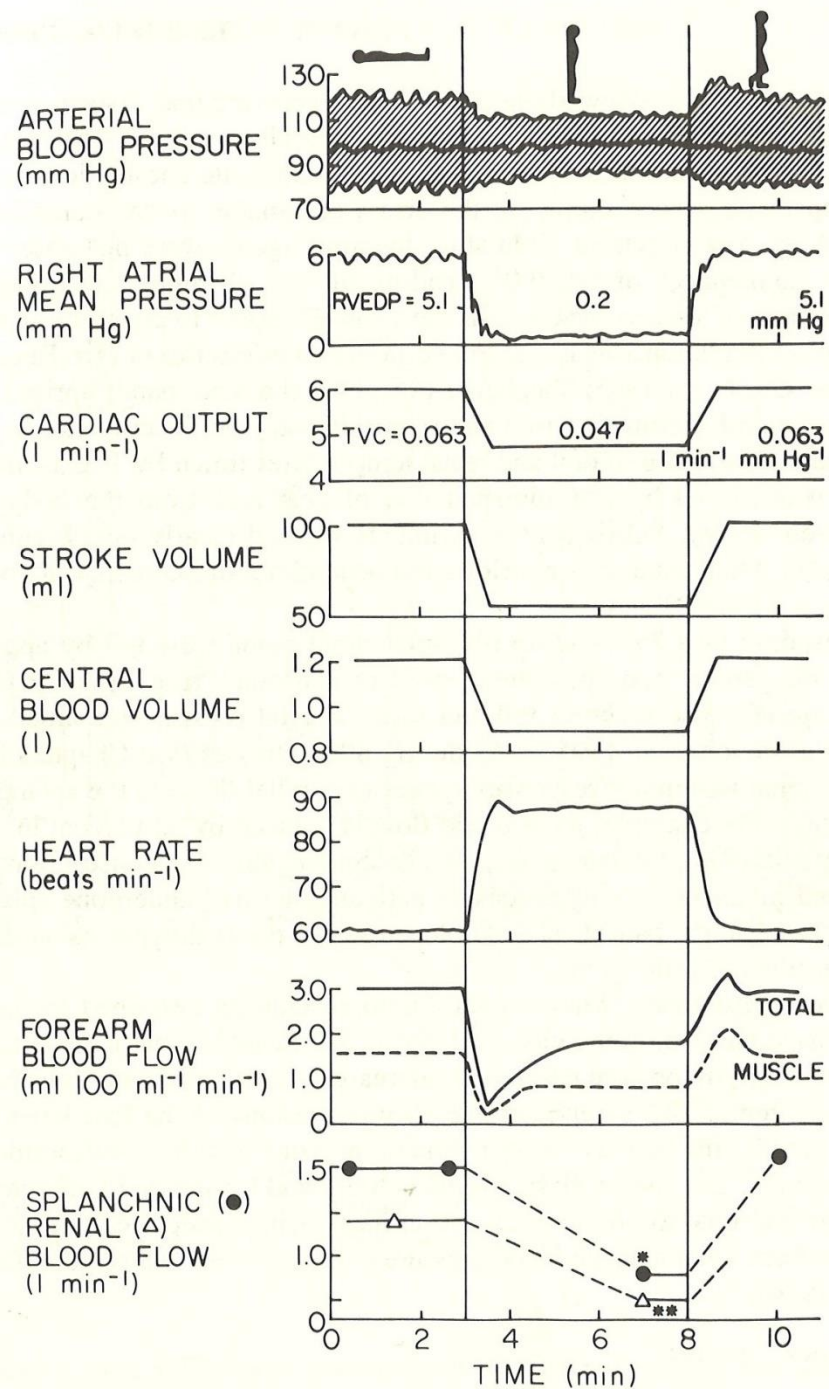
- **Before and after treatment**
 - **30 weeks gestation**
 - **36 weeks gestation**
- **Autonomic and hemodynamic measures**
 - **Heart rate variability**
 - **Blood pressure variability**
 - **Leg volume**
 - **Supine venous flow rate**
 - **Orthostatic challenge and skeletal muscle pump as physiologic stimuli**

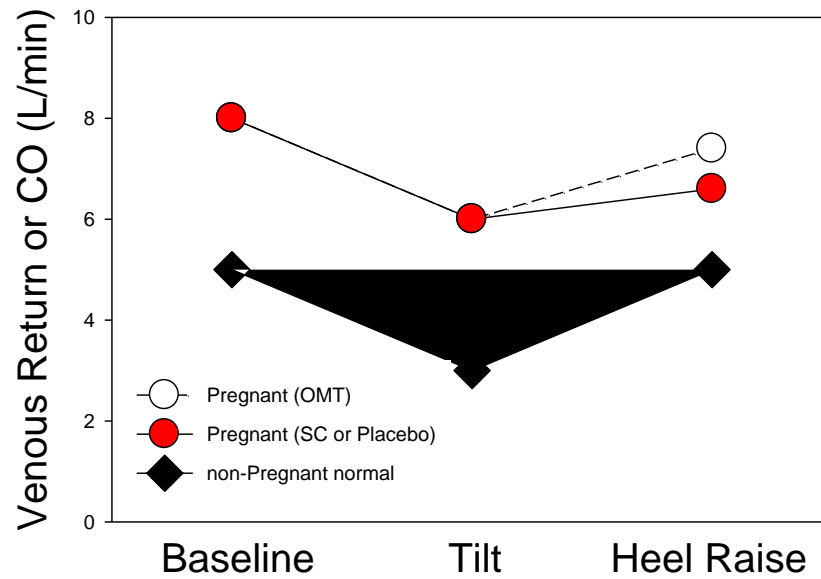
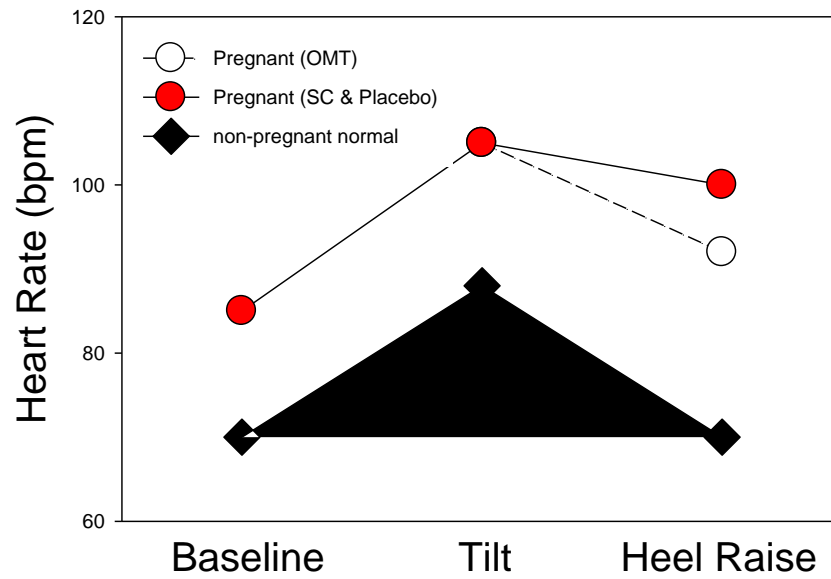












OBSTETRICS

Pregnancy Research on Osteopathic Manipulation Optimizing Treatment Effects: the PROMOTE study

Kendi L. Hensel, DO, PhD; Steve Buchanan, DO, FACOOG (Dist);
Sarah K. Brown, DrPH; Mayra Rodriguez, MPH; des Anges Crusier, PhD

OBJECTIVE: The purpose of this study was to evaluate the efficacy of osteopathic manipulative treatment (OMT) to reduce low back pain and improve functioning during the third trimester in pregnancy and to improve selected outcomes of labor and delivery.

STUDY DESIGN: Pregnancy research on osteopathic manipulation optimizing treatment effects was a randomized, placebo-controlled trial of 400 women in their third trimester. Women were assigned randomly to usual care only (UCO), usual care plus OMT (OMT), or usual care plus placebo ultrasound treatment (PUT). The study included 7 treatments over 9 weeks. The OMT protocol included specific techniques that were administered by board-certified OMT specialists. Outcomes were assessed with the use of self-report measures for pain and back-related functioning and medical records for delivery outcomes.

RESULTS: There were 136 women in the OMT group; 131 women in the PUT group and 133 women in the UCO group. Characteristics at

baseline were similar across groups. Findings indicate significant treatment effects for pain and back-related functioning ($P < .001$ for both groups), with outcomes for the OMT group similar to that of the PUT group; however, both groups were significantly improved compared with the UCO group. For secondary outcome of meconium-stained amniotic fluid, there were no differences among the groups.

CONCLUSION: OMT was effective for mitigating pain and functional deterioration compared with UCO; however, OMT did not differ significantly from PUT. This may be attributed to PUT being a more active treatment than intended. There was no higher likelihood of conversion to high-risk status based on treatment group. Therefore, OMT is a safe, effective adjunctive modality to improve pain and functioning during the third trimester.

Key words: low back pain, osteopathic manipulation, pregnancy

Table 4. Primary Outcomes Estimated in a Linear Mixed Effects Model

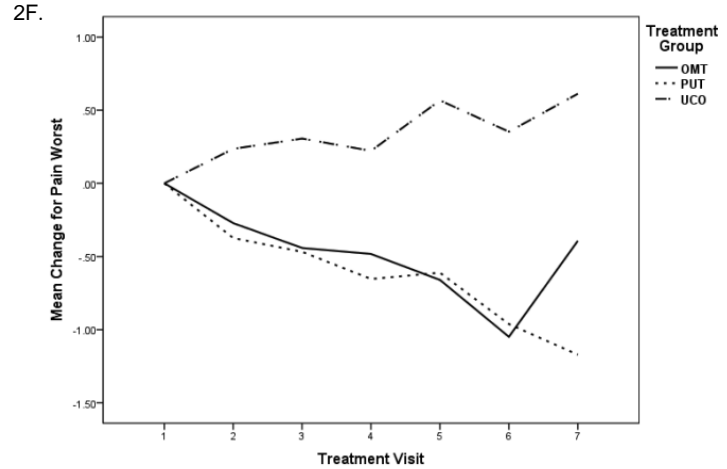
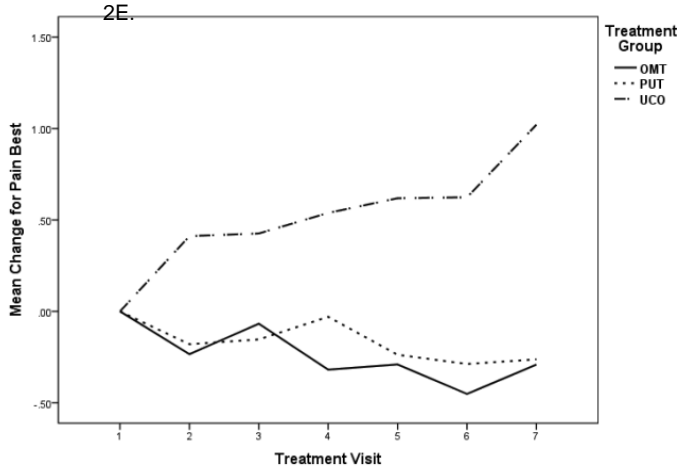
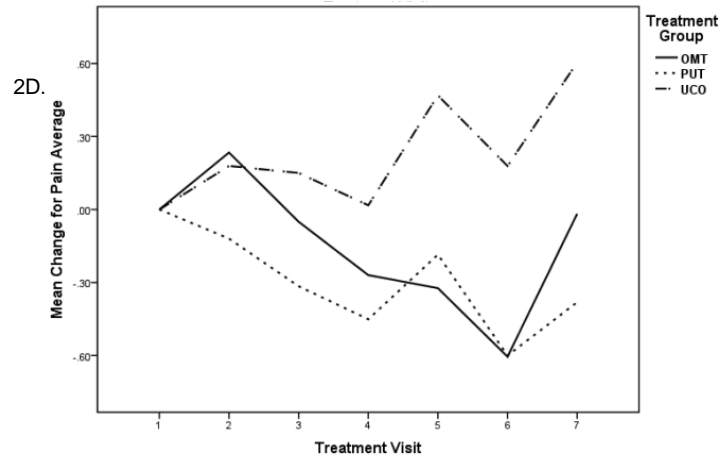
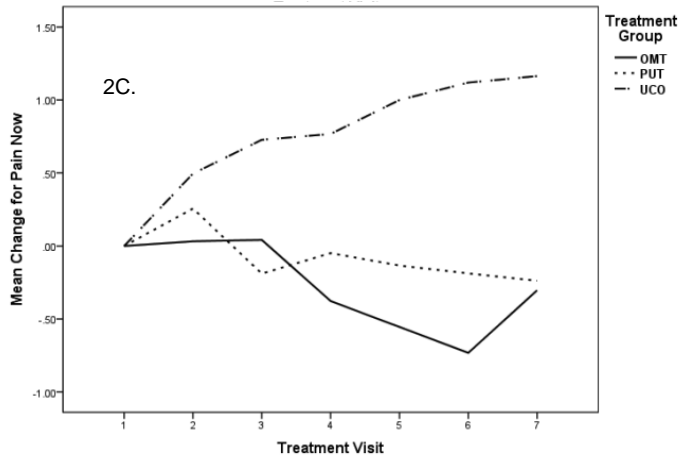
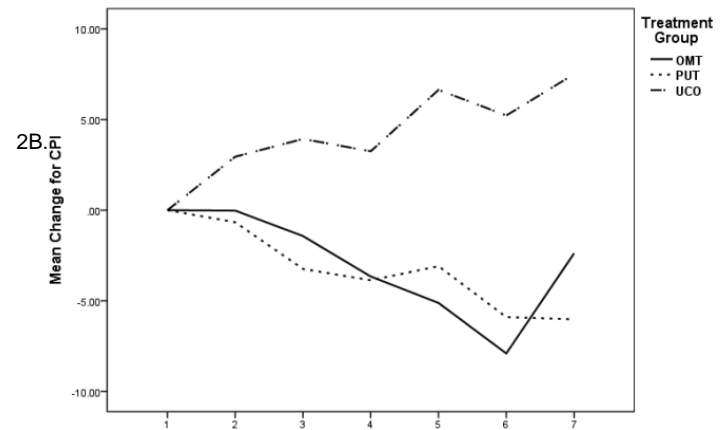
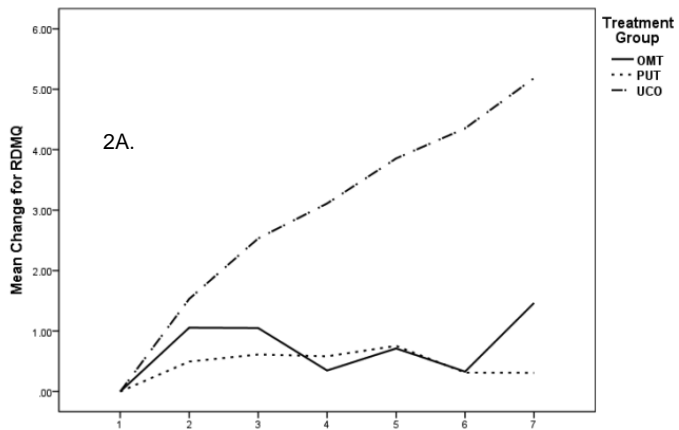
	OMT (n=136)	USP (n=131)	SCO (n=133)	Difference Between OMT and SCO Groups		Difference Between OMT and USP Groups	
				Mean (95%CI)	P value	Mean (95%CI)	P value
Pain Now	-.299	-.034	.707	-1.01 (-1.44 to -0.57)	<.001	-0.26 (-0.7 to 0.17)	.438
Pain Average	-.205	-.364	.175	-0.38 (-0.77 to 0.02)	.065	0.16 (-0.24 to 0.56)	>.999
Pain Best	-.202	-.154	.478	-0.68 (-1 to -0.36)	<.001	-0.05 (-0.38 to 0.28)	>.999
Pain Worst	-.482	-.641	.296	-0.78 (-1.15 to -0.4)	<.001	0.16 (-0.22 to 0.54)	.942
RMDQ	.676	.469	2.926	-2.25 (-3.18 to -1.32)	<.001	0.21 (-0.73 to 1.14)	>.999

CI, confidence interval; OMT, Osteopathic Manipulative Treatment; RMDQ, Roland Morris Disability Questionnaire; SCO, Standard Care Only; USP, Ultrasound Placebo.

Values are estimates for mean change in pain and P values are pairwise comparisons using Bonferonni adjustment.

Hensel, KL et al. *AJOG* 2015;212:108.e1-9.





Hensel, KL
 et al.
AJOG
 2015;212:
 108.e1-9.



Placebo potency and effect

- Light-moderate massage
 - Less pain
 - Shorter labor times
 - Lower rates of prematurity
 - *Expert Rev Obstet Gynecol*. 2010 Mar;5(2):177-181.
- Placebo effect
 - Assessment and observation
 - Therapeutic ritual (placebo)
 - Supportive patient-practitioner relationship
 - Kaptchuk Ted J, Kelley John M, Conboy Lisa M et al. *BMJ* 3.April 2008, published online
 - Harvard's *Program in Placebo Studies and the Therapeutic Encounter*

Growing APAP controversy

- Wheezing and asthma
- Cryptorchidism
- Neurodevelopment
 - Gross motor development
 - Communication
 - Internalizing and externalizing behavior
 - Activity levels
- Systematic Reviews and Meta-analysis
 - Clinical & Experimental Allergy, 2011
 - 93,039 subjects
 - Chest, 2009
 - 425,140 subjects
- FDA Drug Safety Communication 1-9-15
 - Quotes study on APAP and ADD
 - Liew, Z. *JAMA Pediatr* 2014;168:313-20.

Incidence of High-risk Status

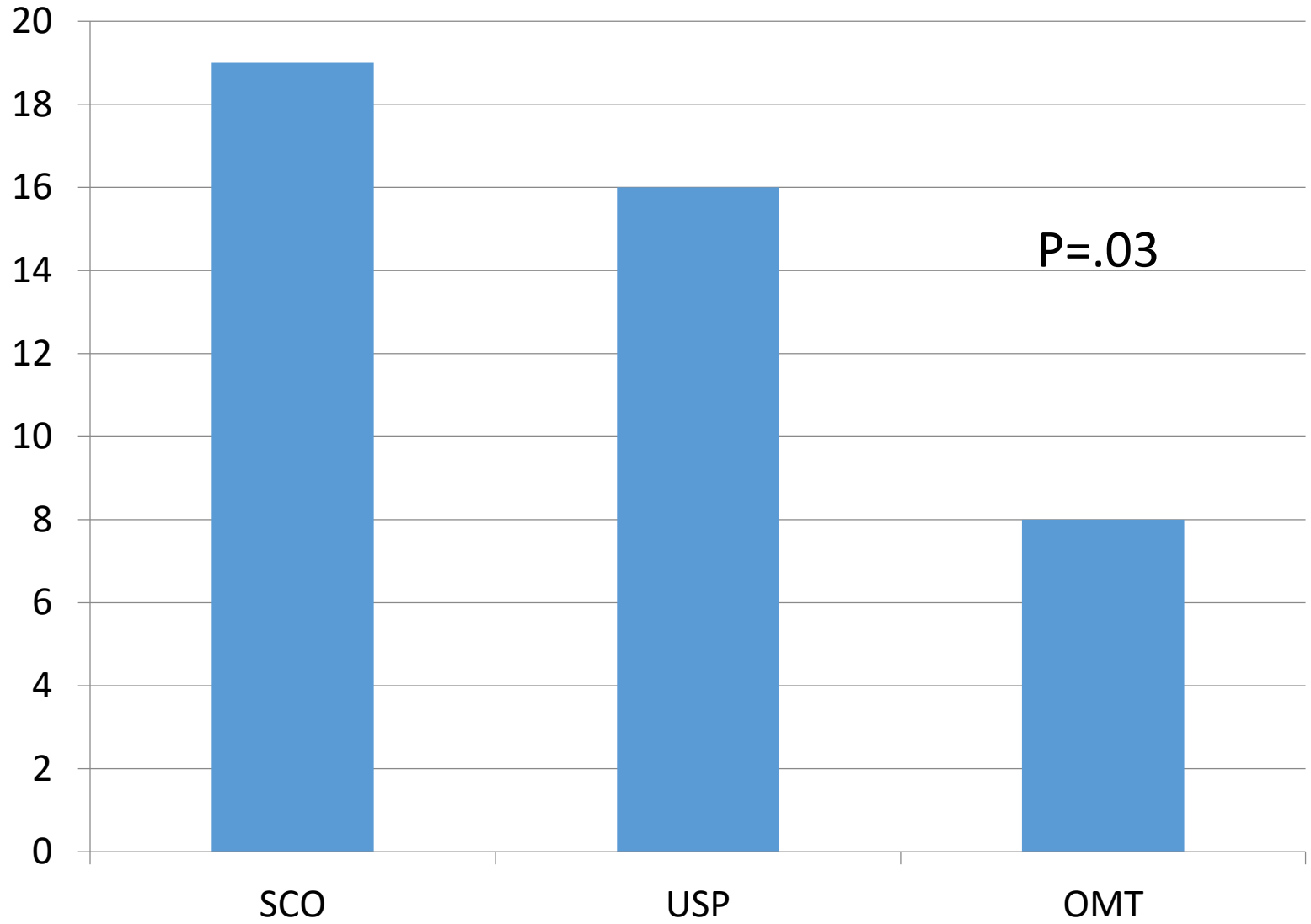


TABLE 1
Participant Characteristics by Treatment Group

	All	Usual Care Only	Placebo Ultrasound Treatment	OMT	P value
	380	129 (33.9%)	122 (32.1%)	129 (33.9%)	
Age, y ^a (n = 380)	24.3 (4.2)	24.8 (4.5)	24.1 (4)	24.1 (4.1)	0.299
Nulliparous (n = 380)	131 (34.5%)	45 (34.4%)	42 (32.1%)	44 (33.6%)	0.991
High risk (n = 380)	43 (11.3%)	19 (14.7%)	16 (13.1%)	8 (6.2%)	0.030
Episiotomy or Perineal Laceration (n = 372)	152 (40%)	57 (37.5%)	44 (28.9%)	51 (33.6%)	0.487
Converted to C-section (n = 379)	38 (10%)	14 (36.8%)	10 (26.3%)	14 (36.8%)	0.714
Assistive Device used (n = 338)	10 (3%)	5 (50%)	1 (10%)	4 (40%)	0.235
Meconium Stain (n = 377)	68 (18%)	21 (30.9%)	24 (35.3%)	23 (33.8%)	0.786
Precipitous Labor (n = 321)	10 (2.6%)	5 (50%)	2 (20%)	3 (30%)	0.537
Prolonged Labor (n = 320)	47 (12.4%)	14 (29.8%)	8 (17%)	25 (53.2%)	0.003
Complications (n = 375)	48 (12.6%)	18 (37.5%)	15 (31.2%)	15 (31.2%)	0.835
APGARs Score @ 1 min ^a (n = 373)	8.5 (1.1)	8.4 (1.2)	8.4 (1)	8.6 (1)	0.158
APGARs Score @ 5 min ^a (n = 374)	8.9 (0.5)	8.9 (0.3)	8.9 (0.6)	8.9 (0.6)	0.702

^aData are given in mean (standard deviation).

So what does this mean for my practice?

- Data from this study showed that the application of the OMT protocol does not result in increased risk of high-risk status, in fact, women who received OMT were less likely to develop high risk status.
- The OMT protocol also did not increase risk of precipitous labor, conversion to caesarian section, perineal laceration, meconium-stained amniotic fluid, or requiring the use of forceps or a vacuum device.
- In all the maternal outcomes examined, no difference was reported among the three study groups with the exception of incidence of prolonged labor. Women receiving OMT were able to successfully labor longer and vaginally deliver with no increased incidence of complications, including perineal laceration, episiotomy, and use of forceps or vacuum device.
- The addition of body-based therapies, such as OMT or massage, appears to be a safe intervention to reduce the progression of back pain and decreasing functional status throughout the third trimester.

Bottom line

- These results suggest that the OMT protocol as applied in PROMOTE is a safe intervention during the third trimester, and is effective at slowing the progression of back pain and disability through the end of pregnancy.

PROMOTE Study OMT Protocol

- Sitting
 - Forward-leaning articulatory T-spine
- Supine
 - Cervical ST/MFR
 - OA decompression
 - Thoracic Inlet MFR
- Lateral Recumbent (R and L)
 - Scapulothoracic MFR
 - Lumbosacral ST
- Supine
 - Ab diaphragm MFR
 - Pelvis
 - AP pelvic diaphragm MFR
 - SI articulation
 - Frogleg sacral articulation
 - Innominate rotations
 - Pubic decompression
 - CV4

Video available

http://web.unthsc.edu/info/200677/osteopathic_manipulative_medicine/1490/research

Billing and coding for OMT

- After evaluating a patient and arriving at a diagnosis (which may include somatic dysfunction), it is appropriate to report an evaluation and management (E/M) code to describe the service.
 - Document the following for E/M service code:
 - Chief Complaint • History • Examination • Medical Decision Making
- Append Modifier-25 to the E/M service code
 - (E/M) service is separate and separately identifiable service from the OMT procedure and should be reported separately.
 - The decision to use or not to use OMT is made at each visit, based on the patient's presentation at that time.
- Document the procedure of OMT
 - Somatic dysfunctions
 - Techniques
 - Response to treatment

Billing and coding for OMT

- Document somatic dysfunction diagnoses
 - **M99.00** Segmental and somatic dysfunction of head region
 - **M99.01** Segmental and somatic dysfunction of cervical region
 - **M99.02** Segmental and somatic dysfunction of thoracic region
 - **M99.03** Segmental and somatic dysfunction of lumbar region
 - **M99.04** Segmental and somatic dysfunction of sacral region
 - **M99.05** Segmental and somatic dysfunction of pelvic region
 - **M99.06** Segmental and somatic dysfunction of lower extremity
 - **M99.07** Segmental and somatic dysfunction of upper extremity
 - **M99.08** Segmental and somatic dysfunction of rib cage
 - **M99.09** Segmental and somatic dysfunction of abdomen and other regions
- OMT billed by number of regions treated
 - 98925 1-2 body regions
 - 98926 3-4 body regions
 - 98927 5-6 body regions
 - 98928 7-8 body regions
 - 98929 9-10 body regions

–**PROMOTE Protocol**

- Forward-leaning articulatory T-spine
- Cervical ST/MFR
- OA decompression
- Thoracic Inlet MFR
- Scapulothoracic MFR
- Lumbosacral ST
- Ab diaphragm MFR
- AP pelvic diaphragm MFR
- SI articulation
- Innominate rotations
- Pubic decompression
- CV4

• **Billable regions**

- Thoracic region (may also be rib if rib S/D diagnosed)
- Cervical region
- Head region
- Thoracic region
- Upper extremity
- Lumbar region
- Abdominal region
- Pelvic region
- Sacral region
- Pelvic region
- Pelvic region
- Head region
- **7-8, or 9-10 regions billable**

Protocol video

- <http://jaoa.org/article.aspx?articleid=2578872&resultClick=1>
- Pregnancy Research on Osteopathic Manipulation Optimizing Treatment Effects: The PROMOTE Study Protocol. Hensel KL, Carnes MS, Stoll, ST. *JAOA*, November 2016, Vol. 116, 716-724. doi:10.7556/jaoa.2016.142



With many thanks:

- Research Coordinators Extraordinaire
Mayra Rodriguez, MPH
Lauren Hamlett
- Treatment Providers
Dave Mason, DO
Mo-Ping Tham, DO
Lesley Schmitz, DO
Claudia McCarty, DO, FAAO
Russ Gamber, DO, MPH
Dennis Minotti, DO



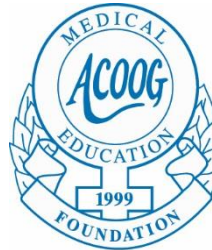
- des Anges Cruser, PhD
- Michael Smith, PhD
- Steve Buchanan, DO, FACOOG
- Models Krista Gordon, MPH and Katy Kemp
- UNTHHealth OB/Gyn Department
- Dennis Dowling, DO, FAAO
- Michael Carnes, DO, FAAO, and Scott Stoll, DO, PhD



Acknowledgments



AMERICAN OSTEOPATHIC ASSOCIATION
TREATING OUR FAMILY AND YOURS



HDI
5000

MAT-FETAL MED AT KMH

02/04/17:104600

C5-2 OB/kd

17 Apr 02

10:49:35 am

Tib0.5 MI 1.1

Fr #226 8.4 cm

ATL

Map 3
150dB/C 2
Persist Med
2D Opt:Res

BW 0 Pg 0
Col 0 Pg 0



-U
.
- 1
.
- 2
.
- 3
.
- 4
.
- 5
.
- 6
.
- 7
.
- 8



Protocol video

- <http://jaoa.org/article.aspx?articleid=2578872&resultClick=1>
- Pregnancy Research on Osteopathic Manipulation Optimizing Treatment Effects: The PROMOTE Study Protocol. Hensel KL, Carnes MS, Stoll, ST. *JAOA*, November 2016, Vol. 116, 716-724. doi:10.7556/jaoa.2016.142

References

- Kimberly PE. (2000). The Kimberly Manual. Millennium edition. Walsworth Publishing Co.
- DiGiovanna, EL. (2005). An Osteopathic Approach to Diagnosis and Treatment, 3rd Edition. Lippincott Williams & Wilkins.
- O'Connell JA. (1998). Bioelectric Fascial Activation and Release. AAO Publishing.
- Nicholas, AS. (2012). Atlas of Osteopathic Techniques. 2nd Edition. Lippincott Williams & Wilkins.
- Radjieski, JM. (1998). Effect of Osteopathic Manipulative Treatment on Length of Stay for Pancreatitis: A Randomized Pilot Study. JAOA 98:5, p264-272.

- Channell MK, Mason DC. *The 5-Minute Osteopathic Manipulative Medicine Consult*. LWW, 2009.
- Nelson KE, Glonek T. *Somatic Dysfunction in Osteopathic Family Medicine*. LWW, 2007.
- Licciardone JC, Buchanan S, Hensel KL, et al. Osteopathic manipulative treatment of back pain and related symptoms during pregnancy: a randomized controlled trial. *Am J Obstet Gynecol* Vol.202:1. January 2010, pp43.e1-43.e8.
- Hensel, KL, Pacchia, CF, Smith, ML. Acute Improvement In Hemodynamic Control After Osteopathic Manipulative Treatment In The Third Trimester Of Pregnancy. *Comp Therapies in Medicine* (2013) 21, 618—626.

- Hensel KL, Buchanan S, Brown SK, et al. Pregnancy Research on Osteopathic Manipulation Optimizing Treatment Effects: the PROMOTE study. *Am J Obstet Gynecol* 2015;212:108.e1-9. DOI: <http://dx.doi.org/10.1016/j.ajog.2014.07.043>
- Hensel KL, Carnes MS, Stoll ST. Pregnancy Research on Osteopathic Manipulation Optimizing Treatment Effects: The PROMOTE Study Protocol. *J Am Osteopath Assoc* 2016; 116(11):716-724. doi:10.7556/jaoa.2016.142
- Hensel KL, Roane BM, Chaphekar AV, Smith-Barbaro P. PROMOTE Study: Safety of Osteopathic Manipulative Treatment During the Third Trimester by Labor and Delivery Outcomes. *J Am Osteopath Assoc* 2016; 116(11):698-703. Doi:10.7556/jaoa.2016.140

- King HH. (2000). OMT in prenatal care: Evidence supporting improved outcomes and health policy implications. AAO Journal (Summer), 25-33.
- Taylor GW. (1949). Osteopathic management of nausea and vomiting of pregnancy. JAOA 48(11), 581-582.
- King HH. Osteopathic manipulative treatment in prenatal care: a retrospective case control design study. JAOA;103:577-582.
- Whiting LM. (1911). Can the length of labor be shortened by Osteopathic treatment? JAOA (11),917-921.
- Guthrie RA (1982). Effect of pressure applied to the upper thoracic vs lumbar areas for inhibition of lumbar myalgia during labor. JAOA 82(4), 247-251.
- Guthrie RA (1980). Lumbar inhibitory pressure for lumbar myalgia during contractions of the gravid uterus at term. JAOA 80(4), 246-266.