

Greater Manchester EUR Policy Statement

Title/Topic: Complementary and Alternative Therapies

Reference: GM030

Date: September 2015

Last Reviewed: September 2016



VERSION CONTROL

Version	Date	Details	Page number
0.1	05/11/2014	Initial draft	N/A
0.2	21/11/2014	<p>Following discussion at the Greater Manchester EUR Steering Group on 19/11/2014 the paragraph around Hypnotherapy for severe and intractable Irritable Bowel Syndrome removed from Policy Exclusions.</p> <p>Policy approved by the GM EUR Steering Group on 19/11/14 to go out to Consultation following the above amendment.</p>	<p>8</p> <p>N/A</p>
1.0	25/06/2015	<p>Changes made following the GM EUR Steering Group meeting on 20/05/2015 post Consultation:</p> <p><u>Section 1 - Introduction</u> Second paragraph, second sentence amended to read:-</p> <p>The evidence search was carried out using the same search strategies and looking for the same types and level of evidence as for the policies relating to western (scientific) medicine.</p> <p>Under Section 2 - Definition & Section 4 - Commissioning Criteria Policy Exclusions added that acupuncture will be covered by a separate policy for acupuncture alone.</p> <p>Policy approved by the GM EUR Steering Group meeting on 20/5/2015 subject to the above amendments.</p>	<p>7</p> <p>7 & 8</p>
1.1	05/04/2016	<p>Under Section 8 - Adherence to NICE Guidance - the section on Chiropractic corrected to Chiropractic - can be offered as part of the care pathway for low back pain rather than Osteopathy.</p> <p>List of diagnostic and procedure codes in relation to this policy added as Appendix 3.</p> <p>Policy changed to Greater Manchester Shared Services template and references to North West Commissioning Support Unit changed to Greater Manchester Shared Services.</p> <p>Wording for date of review amended to read “<i>One year from the date of approval by Greater Manchester Association Governing Group thereafter at a date agreed by the Greater Manchester EUR Steering Group (unless stated this will be every 2 years)</i>” on ‘Policy Statement’ and section ‘13. Date of Review’.</p>	<p>9</p> <p>30</p> <p>N/A</p> <p>3 & 12</p>
2.0	21/09/2016	<p>The policy was reviewed in August 2016 and two new papers were found, an updated version of a review and a new review, however these did not affect the criteria in the existing policy. Following GM EUR Steering Group on 21 September 2016 it was agreed that the following updates be made:</p>	

		<ul style="list-style-type: none"> • Review date added to cover page and ‘Policy Statement’ • The ‘Date of Review’ on ‘Policy Statement’ and in body of report changed to <i>“Three years from the date of last review unless new evidence warrants earlier review”</i> <p>The following has been added to the funding mechanism for clarity:-</p> <p>Hypnotherapy for adults with Irritable Bowel Syndrome (IBS) - Prior Approval via the EUR route (if compliant with NICE CG61 can be approved by clinical triage all other cases will go to the relevant IFR panel).</p> <p>Hypnotherapy for children with IBS is only commissioned in exceptional cases of IBS or chronic abdominal pain and requires an IFR application.</p> <p>Addition of the following under ‘Mandatory Criteria’ in ‘Section 4 – Criteria for Commissioning’:</p> <p><i>“Hypnotherapy for adults with Irritable Bowel Syndrome (IBS) is commissioned in line with NICE CG61 this requires an application for prior approval via the EUR route and if compliant with NICE CG61 can be approved by clinical triage all other cases will go to the relevant IFR panel.</i></p> <p><i>Hypnotherapy for children with IBS is only commissioned in exceptional cases of IBS or chronic abdominal pain and requires an IFR application.”</i></p> <p>Removal of <i>“*Dealt with in a separate policy”</i> in relation to ‘Acupuncture’ under ‘Section 2 – Definition’ and <i>“Acupuncture which will be covered by a separate policy for acupuncture alone.”</i> under Policy Exclusions in ‘Section 4 – Criteria for Commissioning’.</p> <p>Addition of the following to ‘Section 11 - Documents which have informed this Policy’:</p> <ul style="list-style-type: none"> • <i>“NICE CG23: Depression: management of depression in primary and secondary care</i> • <i>NICE CG53: Chronic fatigue syndrome / myalgic encephalomyelitis (or encephalopathy): diagnosis and management</i> • <i>NICE CG59: Osteoarthritis: the care and management of osteoarthritis in adults</i> • <i>NICE CG79: Rheumatoid arthritis in adults: management</i> • <i>NICE CG171: Urinary incontinence in women: management”</i> 	<p>1 & 4</p> <p>4 & 14</p> <p>5 & 13</p> <p>4 & 9-10</p> <p>13</p>
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POLICY STATEMENT

Title/Topic:	Complementary and Alternative Therapies
Issue Date:	September 2015
Reviewed:	September 2016
Commissioning Recommendation:	<p>These therapies are not commissioned as stand-alone treatments.</p> <p>Hypnotherapy for adults with Irritable Bowel Syndrome (IBS) is commissioned in line with NICE CG61 this requires an application for prior approval via the EUR route and if compliant with NICE CG61 can be approved by clinical triage all other cases will go to the relevant IFR panel.</p> <p>Hypnotherapy for children with IBS is only commissioned in exceptional cases of IBS or chronic abdominal pain and requires an IFR application.</p> <p>Those complementary and alternative therapies which are an integral part of an agreed care pathway within existing contracts (supported by a service specification) are excluded from this policy.</p> <p>See Section 4: Criteria for Commissioning</p>
Date of Review:	Three years from the date of last review unless new evidence warrants earlier review.
Prepared By:	Greater Manchester Shared Services Effective Use of Resources Policy Team

Approved By	Date Approved	Funding Mechanism
Greater Manchester Effective Use of Resources Steering Group	20/05/2015	<p>GM EUR Steering Group recommended funding mechanism:</p> <p>Funding will be made available on an individual patient basis for patients where clinical exceptionality has been demonstrated and funding approval should be sought from Greater Manchester Shared Services EUR Team.</p> <p>Hypnotherapy for adults with Irritable Bowel Syndrome (IBS) - Prior Approval via the EUR route (if compliant with NICE CG61 can be approved by clinical triage all other cases will go to the relevant IFR panel).</p> <p>Hypnotherapy for children with IBS is only commissioned in exceptional cases of IBS or chronic abdominal pain and requires an IFR application.</p>
Greater Manchester Chief Finance Officers/Greater Manchester Heads of Commissioning	11/08/2015	N/A
Greater Manchester Association Governing Group	15/09/2015	N/A
Bury Clinical Commissioning Group	07/10/2015	Recommended mechanism above
Bolton Clinical Commissioning Group	23/10/2015	Recommended mechanism above
Heywood, Middleton & Rochdale Clinical Commissioning Group	20/11/2015	Recommended mechanism above
Central Manchester Clinical Commissioning Group	16/12/2015	Recommended mechanism above
North Manchester Clinical Commissioning Group	21/10/2015	Recommended mechanism above
Oldham Clinical Commissioning Group	15/09/2015	Recommended mechanism above
Salford Clinical Commissioning Group	15/09/2015	Recommended mechanism above
South Manchester Clinical Commissioning Group	01/10/2015	Recommended mechanism above
Stockport Clinical Commissioning Group	23/09/2015	Recommended mechanism above
Tameside & Glossop Clinical Commissioning Group	25/10/2015	Recommended mechanism above

Trafford Clinical Commissioning Group	17/11/2015	Recommended mechanism above
Wigan Borough Clinical Commissioning Group	07/10/2015	Recommended mechanism above

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Policy Statement

The Greater Manchester Shared Services (GMSS) has developed this policy on behalf of Clinical Commissioning Groups (CCGs) within Greater Manchester, who will commission complementary and alternative therapies in accordance with the criteria outlined in this document.

In creating this policy the GMSS has reviewed this clinical condition and the options for its treatment. It has considered the place of this treatment in current clinical practice, whether scientific research has shown the treatment to be of benefit to patients, (including how any benefit is balanced against possible risks) and whether its use represents the best use of NHS resources.

This policy document outlines the arrangements for funding of this treatment for the population of Greater Manchester.

Equality & Equity Statement

The GMSS/CCG has a duty to have regard to the need to reduce health inequalities in access to health services and health outcomes achieved, as enshrined in the Health and Social Care Act 2012. The GMSS/CCG is committed to ensuring equality of access and non-discrimination, irrespective of age, gender, disability (including learning disability), gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, gender or sexual orientation. In carrying out its functions, the GMSS/CCG will have due regard to the different needs of protected characteristic groups, in line with the Equality Act 2010. This document is compliant with the NHS Constitution and the Human Rights Act 1998. This applies to all activities for which they are responsible, including policy development, review and implementation.

In developing policy the GMSS policy team will ensure that equity is considered as well as equality. Equity means providing greater resource for those groups of the population with greater needs without disadvantage to any vulnerable group.

The Equality Act 2010 states that we must treat disabled people as *more equal* than any other protected characteristic group. This is because their 'starting point' is considered to be further back than any other group. This will be reflected in GMSS evidencing taking 'due regard' for fair access to healthcare information, services and premises.

An Equality Analysis has been carried out on the policy. For more information about the Equality Analysis, please contact policyfeedback.gmscu@nhs.net.

Governance Arrangements

Greater Manchester EUR policy statements will be ratified by the Greater Manchester Association Governing Group (AGG) prior to formal ratification through CCG Governing Bodies. Further details of the governance arrangements can be found in the Greater Manchester EUR Operational Policy.

1. Introduction

This commissioning policy has been produced in order to provide and ensure equity, consistency and clarity in the commissioning of complementary and alternative therapies by Clinical Commissioning Groups in Greater Manchester. When this policy is reviewed all available additional data on outcomes will be included in the review and the policy updated accordingly.

This policy has been developed in response to the increasing popularity of complementary and alternative therapies. The evidence search was carried out using the same search strategies and looking for the same types and level of evidence as for the policies relating to western (scientific) medicine. The

policy reflects the relative lack of high quality research data available to support the use of these therapies.

2. Definition

Complementary and alternative therapies are those therapies not considered to be part of mainstream “western” or “scientific” medicine. It includes, but is not exclusive to:

- Acupuncture
- Aromatherapy
- Alexander Technique
- Applied Kinesiology
- Aromatherapy
- Autogenic Training
- Ayurveda
- Chiropractic
- Craniosacral therapy
- Environmental Medicine
- Osteopathy
- Healing
- Herbal Medicine (all forms)
- Hypnosis / hypnotherapy
- Homeopathy
- Massage
- Meditation
- Naturopathy
- Nutritional Therapy
- Reflexology
- Reiki
- Shiatsu
- Yoga therapy

The evidence base for most of the above list is limited and good quality research is required before these can be fully evaluated.

3. Aims and Objectives

Aim

This policy document aims to specify the conditions under which complementary and alternative therapies will be routinely commissioned by Clinical Commissioning Groups in Greater Manchester.

Objectives

- To reduce the variation in access to complementary and alternative therapies
- To ensure that complementary and alternative therapies are commissioned where there is acceptable evidence of clinical benefit and cost-effectiveness.
- To reduce unacceptable variation in the commissioning of complementary and alternative therapies across Greater Manchester.
- To promote the cost-effective use of healthcare resources.

4. Criteria for Commissioning

Mandatory Criteria

These therapies are not commissioned as stand-alone treatments.

Hypnotherapy for adults with Irritable Bowel Syndrome (IBS) is commissioned in line with NICE CG61 this requires an application for prior approval via the EUR route and if compliant with NICE CG61 can be approved by clinical triage all other cases will go to the relevant IFR panel.

Hypnotherapy for children with IBS is only commissioned in exceptional cases of IBS or chronic abdominal pain and requires an IFR application.

Policy Exclusions

Those complementary and alternative therapies which are an integral part of an agreed care pathway or are covered within existing contracts (supported by a service specification) are excluded from this policy. This includes, but is not limited to, the care pathways for low back pain, musculoskeletal, headache, Parkinson's disease and Multiple Sclerosis.

Clinicians can submit an Individual Funding Request (IFR) if they feel there is a good case for exceptionality.

Exceptionality means 'a person to which the general rule is not applicable'. Greater Manchester sets out the following guidance in terms of determining exceptionality; however the over-riding question which the IFR process must answer is whether each patient applying for exceptional funding has demonstrated that his/her circumstances are exceptional. A patient may be able to demonstrate exceptionality by showing that s/he is:

- Significantly different to the general population of patients with the condition in question.

and as a result of that difference

- They are likely to gain significantly more benefit from the intervention than might be expected from the average patient with the condition.

5. Description of Epidemiology and Need

Complementary and alternative techniques are becoming increasingly popular; however, there is no accurate data on the numbers using these therapies at present.

6. Evidence Summary

The evidence base for complementary and alternative therapies is increasing but is still mainly composed of low level poor quality evidence and good quality research is still required before these therapies can be considered for routine commissioning.

In view of the number of individual funding requests received the following therapies and conditions were reviewed in more detail.

Chiropractic in Treating Back Pain

The evidence reviews, appraisals and technology assessment for the use of chiropractic in treating back pain all agree that the studies available for review are not ideal. However, their findings are consistent in that chiropractic appears no better or worse in terms of short, medium and long term outcomes than more conventional treatments. Patients appear to have a higher level of satisfaction with chiropractic than with other interventions. It appears to be a cost-effective part of the management of back pain in certain circumstances. All reviews called for higher quality outcome studies to be carried out.

Complementary and Alternative therapies

The evidence base for complementary and alternative therapies is increasing but is still mainly composed of low level poor quality evidence. Individual therapies have been evaluated by NICE and for the majority there is no – or insufficient evidence of their effectiveness.

Full details of the Evidence Reviews are contained with Appendix 1.

7. Rationale behind the Policy Statement

Complementary and alternative therapies are becoming increasingly popular; however, there is little evidence available for their use as stand-alone therapies and as a result they are only commissioned in Greater Manchester as part of specific pathways of care.

8. Adherence to NICE Guidance

This policy adheres fully to the recommendations made in the following NICE documents:

Alexander Technique

NICE CG35: Parkinson's disease The Alexander Technique may be offered to benefit people with Parkinson's Disease by helping them to make lifestyle adjustments that affect both the physical nature of the condition and the person's attitudes to having Parkinson's Disease.

Applied Kinesiology

NICE CG116: Food allergy in children and young people: Food allergy in children and young people - Do not use applied kinesiology in the diagnosis of food allergy.

Aromatherapy

NICE CG42: Dementia: Aromatherapy can be considered as part of a pathway of care for dementia.

NICE CG132: Caesarean section: the effects on the likelihood of caesarean section of complementary therapies used during labour (such as acupuncture, aromatherapy, hypnosis, herbal products, nutritional supplements, homeopathic medicines, and Chinese medicines) have not been properly assessed.

Chiropractic

NICE CG88: Low back pain and NICE IPG451: Peripheral nerve-field stimulation for chronic low back pain: Chiropractic - can be offered as part of the care pathway for low back pain.

Osteopathy

NICE CG60: Surgical management of otitis media with effusion in children: Cranial osteopathy is not recommended for the management of otitis media with effusion (OME).

NICE CG88: Low back pain and NICE IPG451: Peripheral nerve-field stimulation for chronic low back pain: Osteopathy - can be offered as part of the care pathway for low back pain.

Herbal Medicine

NICE CG132: Caesarean section: Therapies used during labour (such as acupuncture, aromatherapy, hypnosis, herbal products, nutritional supplements, homeopathic medicines, and Chinese medicines) have not been properly evaluated and further research is needed.

Hypnosis / Hypnotherapy

NICE CG26: Post-traumatic stress disorder (PTSD): PTSD sufferers request other forms of psychological treatment (for example, supportive therapy/non-directive therapy, hypnotherapy, psychodynamic therapy or systemic psychotherapy), they should be informed that there is as yet no convincing evidence to support this.

NICE CG61: Irritable bowel syndrome in adults and NICE ESNM16: Irritable bowel syndrome with constipation in adults: linaclotide: 1.2.3.1 Referral for psychological interventions (cognitive behavioural therapy [CBT], hypnotherapy and/or psychological therapy) should be considered for people with IBS

who do not respond to pharmacological treatments after 12 months and who develop a continuing symptom profile (described as refractory IBS)

NICE PH10: Smoking cessation services: Hypnotherapy for smoking cessation – there is evidence that these techniques do not improve long-term abstinence rates more than a placebo.

Homeopathy

NICE CG57: Atopic eczema in children: Children with atopic eczema and their parents or carers should be informed that the effectiveness and safety of complementary therapies such as homeopathy, herbal medicine, massage and food supplements for the management of atopic eczema have not yet been adequately assessed.

NICE CG60: Surgical management of otitis media with effusion in children: Homeopathy is not recommended for the management of otitis media with effusion (OME).

NICE CG70: Induction of labour: Healthcare professionals should inform women that the available evidence does not support homeopathy for induction of labour.

NICE CG97: Lower urinary tract symptoms: Do not offer homeopathy for treating lower urinary tract symptoms (LUTS) in men.

Massage

NICE CG55: Intrapartum care: Perineal massage should not be performed by healthcare professionals in the second stage of labour.

NICE CG60: Surgical management of otitis media with effusion in children: Massage is not recommended for the management of otitis media with effusion (OME).

NICE CG179: Pressure ulcers: Prevention and management of pressure ulcers: Do not offer skin massage or rubbing to adults, neonates, infants, children and young people to prevent a pressure ulcer.

NICE PH40: Social and emotional wellbeing: early years: Health visitors or midwives should consider evidence-based interventions such as baby massage and video interaction guidance to improve maternal sensitivity and mother-infant attachment.

Reflexology

NICE CG61: Irritable bowel syndrome in adults: The use of reflexology should not be encouraged for the treatment of irritable bowel syndrome (IBS).

Yoga therapy

NICE CG186: Multiple sclerosis: Stretching exercises including yoga may be helpful in treating MS.

9. Mechanism for Funding

Clinical Commissioning Group	Funding Mechanism
Bolton Bury Heywood, Middleton & Rochdale Manchester Central Manchester North	Funding will be made available on an individual patient basis for patients where clinical exceptionality has been demonstrated and funding approval should be sought from Greater Manchester Shared Services EUR Team.

<p>Manchester South Oldham Salford Stockport Tameside & Glossop Trafford Wigan</p>	<p>Hypnotherapy for adults with Irritable Bowel Syndrome (IBS) - Prior Approval via the EUR route (if compliant with NICE CG61 can be approved by clinical triage all other cases will go to the relevant IFR panel).</p> <p>Hypnotherapy for children with IBS is only commissioned in exceptional cases of IBS or chronic abdominal pain and requires an IFR application</p>
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10. Audit Requirements

There is currently no national database. Service providers will be expected to collect and provide audit data on request.

11. Documents which have informed this Policy

- Greater Manchester EUR Operational Policy
- NICE CG26: Post-traumatic stress disorder (PTSD)
- NICE CG35: Parkinson's disease
- NICE CG42: Dementia
- NICE CG55: Intrapartum care
- NICE CG57: Atopic eczema in children
- NICE CG60: Surgical management of otitis media with effusion in children
- NICE CG61: Irritable bowel syndrome in adults
- NICE CG70: Induction of labour
- NICE CG88: Low back pain
- NICE CG97: Lower urinary tract symptoms
- NICE CG98: Neonatal jaundice
- NICE CG116: Food allergy in children and young people
- NICE CG126: Management of stable angina
- NICE CG132: Caesarean section
- NICE CG150: Headaches
- NICE CG177: Osteoarthritis
- NICE CG179: Pressure ulcers: prevention and management of pressure ulcers
- NICE CG186: Multiple sclerosis
- NICE ESNM16: Irritable bowel syndrome with constipation in adults: linaclotide
- NICE ESUOM27: Chronic pain: oral ketamine
- NICE IPG451: Peripheral nerve-field stimulation for chronic low back pain
- NICE PH10: Smoking cessation services
- NICE PH40: Social and emotional wellbeing: early years
- NICE CG23: Depression: management of depression in primary and secondary care
- NICE CG53: Chronic fatigue syndrome / myalgic encephalomyelitis (or encephalopathy): diagnosis and management
- NICE CG59: Osteoarthritis: the care and management of osteoarthritis in adults
- NICE CG79: Rheumatoid arthritis in adults: management
- NICE CG171: Urinary incontinence in women: management

12. Links to other Policies

This policy follows the principles set out in the ethical framework that govern the commissioning of NHS healthcare and those policies dealing with the approach to experimental treatments and processes for the management of individual funding requests (IFR).

13. Date of Review

Three years from the date of last review unless new evidence warrants earlier review.

14. Glossary

Term	Meaning
Acupuncture	An ancient eastern medicine which is increasingly popular in this country. It involves placing needles at strategic points around the body. Some forms involve a low electric current passing through the needles.
Alexander Technique	A system designed to promote well-being by retraining one's awareness and habits of posture to ensure minimum effort and strain.
Applied Kinesiology	A technique claimed to be able to diagnose illness or choose treatment by testing muscles for strength and weakness.
Aromatherapy	The use of aromatic plant extracts and essential oils for healing and cosmetic purposes
Autogenic Training	A form of relaxation therapy involving auto-suggestion
Ayurveda	The traditional Hindu system of medicine (incorporated in Atharva Veda, the last of the four Vedas), which is based on the idea of balance in bodily systems and uses diet, herbal treatment, and yogic breathing
Chiropracty	A system of complementary medicine based on the diagnosis and manipulative treatment of misalignments of the joints, especially those of the spinal column, which are believed to cause other disorders by affecting the nerves, muscles, and organs.
Craniosacral Therapy	A system of alternative medicine intended to relieve pain and tension by gentle manipulations of the skull regarded as harmonizing with a natural rhythm in the central nervous system
Environmental Medicine	A multidisciplinary field involving medicine, environmental science, chemistry and others, overlapping with environmental pathology. It may be viewed as the medical branch of the broader field of environmental health.
Healing	The flow of beneficial energy between the Healer and the recipient that deals with the "dis-ease" at its deepest level and frees the recipients natural resources to work in the most effective way for them.
Herbal Medicine (all forms)	The study or practice of the medicinal and therapeutic use of plants; herbalism
Hypnosis / Hypnotherapy	The use of hypnosis (the induction of a state of consciousness in which a person apparently loses the power of voluntary action and is highly responsive to suggestion or direction)as a therapeutic technique

Homeopathy	A system in which ailments are treated by minute doses of natural substances that in larger amounts would produce symptoms of the ailment
Massage	A range of techniques to manipulate the soft tissues and joints of the body
Meditation	A method of achieving relaxation and consciousness expansion by focusing on a mantra or a key word, sound, or image while eliminating outside stimuli from one's awareness
Migraine	<p>A complex condition with a wide variety of symptoms. For many people the main feature is a painful headache. Other symptoms include disturbed vision, sensitivity to light, sound and smells, feeling sick and vomiting. Migraines can be very frightening.</p> <p>The symptoms vary from person to person and individuals may have different symptoms during different attacks. The attacks may differ in length and frequency, usually lasting from 4 to 72 hours and most sufferers are free from symptoms between attacks. Migraines often impact on a sufferers work, family and social life.</p>
Naturopathy	a system based on the theory that diseases can be successfully treated or prevented without the use of drugs, by techniques such as control of diet, exercise, and massage
NICE	National Institute for Health and Care Excellence
NICE CG	Clinical Guidance
NICE ESNM	Evidence summaries: new medicines
NICE ESUOM	Evidence summaries: unlicensed or off-label medicines
NICE IPG	Interventional procedure guidance
NICE PH	Public health guidance
Nutritional Therapy	The application of nutrition and health science that seeks to enable individuals to maximise their health potential.
Reflexology	A system of massage used to relieve tension and treat illness, based on the theory that there are reflex points on the feet, hands, and head linked to every part of the body
Reiki	A healing technique based on the principle that the therapist can channel energy into the patient by means of touch, to activate the natural healing processes of the patient's body and restore physical and emotional well-being
Shiatsu	Shiatsu is a Japanese form of bodywork. The word shiatsu means "finger pressure", and shiatsu is sometimes described as a finger pressure massage
Yoga Therapy	A self-empowering process, where the care-seeker, with the help of the Yoga therapist, implements a personalized and evolving Yoga practice, that not only addresses the illness in a multi-dimensional manner, but also aims to alleviate his/her suffering in a progressive, non-invasive way.

References

N/A

Appendix 1 – Evidence Review

Title/Topic: Complementary and Alternative Therapies
Ref: GM030

SECTION 1: GENERAL

Search Strategy

Database	Result
NICE	See documents which have informed this policy – Section 11
NHS Evidence and NICE CKS	<ul style="list-style-type: none"> • Cochrane review for pain management in labour (see below) • Complementary and alternative therapies and dementia - Alzheimer's Society fact sheet (not cited here) • A systematic review of evidence for the effectiveness of practitioner-based complementary and alternative therapies in the management of rheumatic diseases: rheumatoid arthritis Gary J. Macfarlane, Priya Paudyal, Michael Doherty, Edzard Ernst, George Lewith, Hugh MacPherson, Julius Sim and Gareth T. Jones on behalf of the Arthritis Research UK Working Group on Complementary and Alternative Therapies for the Management of the Rheumatic Diseases Rheumatology (Oxford). 2012 Sep;51(9):1707-13. Epub 2012 Jun 1. • Complementary and Alternative Therapies for Back Pain II Agency for Healthcare Research and Quality U.S. Department of Health and Human Services Evidence Report/Technology Assessment Number 194 • Complementary and alternative therapies for treating multiple sclerosis symptoms: a systematic review Huntley A, Ernst E Complement Ther Med. 2000 Jun;8(2):97-105. • Efficacy of complementary and alternative medicine therapies in relieving cancer pain: a systematic review Bardia A, Barton D L, Prokop L J, Bauer B A, Moynihan T J J Clin Oncol. 2006 Dec 1;24(34):5457-64. • The evidence base of complementary and alternative therapies in depression Thachil AF, Mohan R, Bhugra D. J Affect Disord. 2007 Jan;97(1-3):23-35. Epub 2006 Aug 22
SIGN	No specific studies but included in a number of treatment reviews (not cited here)
Cochrane	<p>Complementary and alternative therapies for pain management in labour (Review) Smith CA, Collins CT, Cyna AM, Crowther CA Cochrane Database of Systematic Reviews 2006, Issue 4</p>
York	<ul style="list-style-type: none"> • York (DARE) Review: Complementary and alternative therapies for the management of menopause-related symptoms: a

	<p>systematic evidence review Nedrow A, Miller J, Walker M, Nygren P, Huffman L H, Nelson H D</p> <ul style="list-style-type: none"> • York (DARE) Review: Complementary / alternative therapies for premenstrual syndrome: a systematic review of randomized controlled trials Stevinson C, Ernst E
BMJ Clinical Evidence	BMJ Clinical Evidence review – Headache (chronic tension-type)
BMJ Best Practice	Not included in search
General Search (Google)	<p>Homeopathy for Cancer Integrative therapies for oncology; Current Oncology—Volume 14, Number 4 Ernst MD PhD</p>
Medline / Open Athens	Not carried out due to number of review articles already found
Other	No further search carried out due to the number of review articles already found

Summary of the evidence

The evidence suggests that a number of these therapies are effective within the context of an overall pathway of care. There is insufficient high quality evidence available for their use as stand-alone therapies.

The evidence

Levels of evidence	
Level 1	Meta-analyses, systematic reviews of randomised controlled trials
Level 2	Randomised controlled trials
Level 3	Case-control or cohort studies
Level 4	Non-analytic studies e.g. case reports, case series
Level 5	Expert opinion

1. LEVEL 1: SYSTEMATIC REVIEW

A systematic review of evidence for the effectiveness of practitioner-based complementary and alternative therapies in the management of rheumatic diseases: rheumatoid arthritis

Gary J. Macfarlane, Priya Paudyal, Michael Doherty, Edzard Ernst, George Lewith, Hugh MacPherson, Julius Sim and Gareth T. Jones on behalf of the Arthritis Research UK Working Group on Complementary and Alternative Therapies for the Management of the Rheumatic Diseases

Rheumatology (Oxford). 2012 Sep;51(9):1707-13. Epub 2012 Jun 1.

ABSTRACT

Objective: To critically review the evidence on the effectiveness of complementary therapies for patients with RA.

Methods: Randomized controlled trials, published in English up to May 2011, were identified using systematic searches of bibliographic databases and searching of reference lists. Information was extracted on outcomes and statistical significance in comparison with alternative treatments and reported side effects. The methodological quality of the identified studies was determined using the Jadad scoring system. All outcomes were considered but with a focus on patient global assessment and pain reporting.

Results: Eleven eligible trials were identified covering seven therapies. Three trials that compared acupuncture with sham acupuncture reported no significant difference in pain reduction between the groups but one out of two reported an improvement in patient global assessment. Except for reduction in physician's global assessment of treatment and disease activity reported in one trial, no other comparative benefit of acupuncture was seen. There were two studies on meditation and one each on autogenic training, healing therapy, progressive muscle relaxation, static magnets and tai chi. None of these trials reported positive comparative effects on pain but some positive effects on patient global assessment were noted at individual time points in the healing therapy and magnet therapy studies. A small number of other outcomes showed comparative improvement in individual trials. There were no reports of major adverse events.

Conclusion: The very limited evidence available indicates that for none of the practitioner-based complementary therapies considered here is there good evidence of efficacy or effectiveness in the management of RA.

2. LEVEL 1: HEALTH TECHNOLOGY ASSESSMENT

Complementary and Alternative Therapies for Back Pain II

Agency for Healthcare Research and Quality U.S. Department of Health and Human Services
Evidence Report/Technology Assessment Number 194

Background: Back and neck pain are important health problems with serious societal and economic implications. Conventional treatments have been shown to have limited benefit in improving patient outcomes. Complementary and Alternative Medicine (CAM) therapies offer additional options in the management of low back and neck pain. Many trials evaluating CAM therapies have poor quality and inconsistent results.

Objectives: To systematically review the efficacy, effectiveness, cost-effectiveness, and harms of acupuncture, spinal manipulation, mobilization, and massage techniques in management of back, neck, and/or thoracic pain.

Data Sources: MEDLINE, Cochrane Central, Cochrane Database of Systematic Reviews, CINAHL, and EMBASE were searched up to 2010; unpublished literature and reference lists of relevant articles were also searched.

Study Selection: All records were screened by two independent reviewers. Primary reports of comparative efficacy, effectiveness, harms, and/or economic evaluations from randomized controlled trials (RCTs) of the CAM therapies in adults (age ≥ 18 years) with back, neck, or thoracic pain were eligible. Non-randomized controlled trials and observational studies (case control, cohort, cross-sectional) comparing harms were also included. Reviews, case reports, editorials, commentaries or letters were excluded.

Data Extraction: Two independent reviewers using a predefined form extracted data on study, participants, treatments, and outcome characteristics.

Data Analysis: Included studies were stratified by the region, cause, and duration of pain. Evidence was summarized qualitatively and RCTs were pooled according to the post-treatment follow-up at which the

outcomes were measured. Subgroup and sensitivity analyses were planned a priori. Publication bias was examined through visual inspection of funnel plot and a regression-based method.

Results: 265 RCTs and 5 non-RCTs were included. Acupuncture for chronic nonspecific low back pain was associated with significantly lower pain intensity than placebo but only immediately post-treatment (VAS: -0.59, 95 percent CI: -0.93, -0.25). However, acupuncture was not different from placebo in post-treatment disability, pain medication intake, or global improvement in chronic nonspecific low back pain. Acupuncture did not differ from sham-acupuncture in reducing chronic non-specific neck pain immediately after treatment (VAS: 0.24, 95 percent CI: -1.20, 0.73). Acupuncture was superior to no treatment in improving pain intensity (VAS: -1.19, 95 percent CI: -2.17, -0.21), disability (PDI), functioning (HFAQ), well-being (SF-36), and range of mobility (extension, flexion), immediately after the treatment. In general, trials that applied sham-acupuncture tended to produce negative results (i.e., statistically non-significant) compared to trials that applied other types of placebo (e.g., TENS, medication, laser). Results regarding comparisons with other active treatments (pain medication, mobilization, laser therapy) were less consistent. Acupuncture was more cost-effective compared to usual care or no treatment for patients with chronic back pain.

For both low back and neck pain, manipulation was significantly better than placebo or no treatment in reducing pain immediately or short-term after the end of treatment. Manipulation was also better than acupuncture in improving pain and function in chronic nonspecific low back pain. Results from studies comparing manipulation to massage, medication, or physiotherapy were inconsistent, either in favor of manipulation or indicating no significant difference between the two treatments. Findings of studies regarding costs of manipulation relative to other therapies were inconsistent.

Mobilization was superior to no treatment but not different from placebo in reducing low back pain or spinal flexibility after the treatment. Mobilization was better than physiotherapy in reducing low back pain (VAS: -0.50, 95 percent CI: -0.70, -0.30) and disability (Oswestry: -4.93, 95 percent CI: -5.91, -3.96). In subjects with acute or subacute neck pain, mobilization compared to placebo significantly reduced neck pain. Mobilization and placebo did not differ in subjects with chronic neck pain.

Massage was superior to placebo or no treatment in reducing pain and disability only amongst subjects with acute/sub-acute low back pain. Massage was also significantly better than physical therapy in improving back pain (VAS: -2.11, 95 percent CI: -3.15, -1.07) or disability. For subjects with neck pain, massage was better than no treatment, placebo, or exercise in improving pain or disability, but not neck flexibility. Some evidence indicated higher costs for massage use compared to general practitioner care for low back pain.

Reporting of harms in RCTs was poor and inconsistent. Subjects receiving CAM therapies reported soreness or bleeding on the site of application after acupuncture and worsening of pain after manipulation or massage. In two case-control studies cervical manipulation was shown to be significantly associated with vertebral artery dissection or vertebrobasilar vascular accident.

Conclusions: Evidence was of poor to moderate grade and most of it pertained to chronic nonspecific pain, making it difficult to draw more definitive conclusions regarding benefits and harms of CAM therapies in subjects with acute/subacute, mixed, or unknown duration of pain. The benefit of CAM treatments was mostly evident immediately or shortly after the end of the treatment and then faded with time. Very few studies reported long-term outcomes. There was insufficient data to explore subgroup effects. The trial results were inconsistent due probably to methodological and clinical diversity, thereby limiting the extent of quantitative synthesis and complicating interpretation of trial results. Strong efforts are warranted to improve the conduct methodology and reporting quality of primary studies of CAM therapies. Future well powered head to head comparisons of CAM treatments and trials comparing CAM to widely used active treatments that report on all clinically relevant outcomes are needed to draw better conclusions.

3. LEVEL 1: SYSTEMATIC REVIEW

Complementary and alternative therapies for treating multiple sclerosis symptoms: a systematic review

Huntley A, Ernst E

Complement Ther Med. 2000 Jun;8(2):97-105.

The authors state that rigorous research on the complementary treatments of MS symptoms is scarce. There are no CATs that have been shown to be unequivocally effective. There is some evidence that dietary linoleic acid may be of long-term benefit for the physical symptoms of MS patients. Magnetic field therapy and neural therapy appear to have a short-term ameliorative effect on the physical MS symptoms. Massage, bodywork and psychological counselling seem to improve depression, anxiety and self-esteem felt by the patient. All require further investigation in large-scale RCTs.

4. LEVEL 1: SYSTEMATIC REVIEW

Efficacy of complementary and alternative medicine therapies in relieving cancer pain: a systematic review

Bardia A, Barton D L, Prokop L J, Bauer B A, Moynihan T J

J Clin Oncol. 2006 Dec 1;24(34):5457-64.

Authors' conclusions

There was some evidence of short term benefit for the relief of cancer pain with hypnosis, imagery, support groups, acupuncture and healing touch but, due to the paucity of rigorous trials, no interventions can be recommended due to short duration and lack of power and sham control.

5. LEVEL 1: SYSTEMATIC REVIEW

The evidence base of complementary and alternative therapies in depression

Thachil AF, Mohan R, Bhugra D.

J Affect Disord. 2007 Jan;97(1-3):23-35. Epub 2006 Aug 22

ABSTRACT

Background: Depression is one of the leading indications for using Complementary and Alternative Medicine (CAM). This paper reviews the evidence of efficacy of different types of CAM in depression with the aim of identifying the highest level of evidence.

Methods: We conducted literature searches restricted to the English language for studies on CAM as monotherapy in depression. All papers were reviewed by two researchers and the evidence was ranked according to a widely referenced hierarchy of evidence.

Results: 19 papers formed the final review. We found Grade 1 evidence on the use of St. John's wort, Tryptophan/5-Hydroxytryptophan, S-adenosyl methionine, Folate, Inositol, Acupuncture and Exercise in Depressive disorders, none of which was conclusively positive. We found RCTs at the Grade 2 level on the use of Saffron (Herbal medicine), Complex Homoeopathy and Relaxation training in Depressive disorders, all of which showed inconclusive results. Other RCTs yielded unequivocally negative results. Studies below this level yielded inconclusive or negative results.

Limitations: Searches were restricted to the English language. Our list of CAM approaches may not have been comprehensive. We excluded studies on the use of CAM as an adjunctive treatment and this review aimed to identify only the highest level of evidence.

Conclusions: None of the CAM studies show evidence of efficacy in depression according to the hierarchy of evidence. The RCT model and the principles underlying many types of CAM are dissonant,

making its application in the evaluation of those types of CAM difficult. The hierarchy of evidence we used has limited utility in grading trials of CAM.

6. LEVEL 1: CLINICAL EVIDENCE REVIEW

BMJ Clinical Evidence review – Headache (chronic tension-type)

ABSTRACT

Introduction: Chronic tension-type headache (CTTH) is a disorder that evolves from episodic tension-type headache, with daily or very frequent episodes of headache lasting minutes to days. It affects 4.1% of the general population in the USA, and is more prevalent in women (up to 65% of cases).

Methods and Outcomes: We conducted a systematic review and aimed to answer the following clinical questions: What are the effects of drug treatments for chronic tension-type headache? What are the effects of non-drug treatments for chronic tension-type headache? We searched: Medline, Embase, The Cochrane Library, and other important databases up to March 2007 (Clinical Evidence reviews are updated periodically; please check our website for the most up-to-date version of this review). We included harms alerts from relevant organisations such as the US Food and Drug Administration (FDA) and the UK Medicines and Healthcare products Regulatory Agency (MHRA). **RESULTS:** We found 50 systematic reviews, RCTs, or observational studies that met our inclusion criteria. We performed a GRADE evaluation of the quality of evidence for interventions.

Conclusions: In this systematic review, we present information relating to the effectiveness and safety of the following interventions: acupuncture; amitriptyline; analgesics; anticonvulsant drugs; benzodiazepines; botulinum toxin; chiropractic and osteopathic manipulations; cognitive behavioural therapy (CBT); Indian head massage; mirtazapine; relaxation and electromyographic biofeedback; selective serotonin reuptake inhibitor antidepressants (SSRIs); and tricyclic antidepressants (other than amitriptyline).

Key Points

Chronic tension-type headache (CTTH) is a disorder that evolves from episodic tension-type headache, with daily or very frequent episodes, lasting minutes to days.

- It affects 4.1% of the general population in the USA, and is more prevalent in women (up to 65% of cases).

We found only limited evidence about the treatment of CTTH.

- Regular analgesics may lead to chronic headache symptoms and reduce the effectiveness of prophylactic treatment.
- Amitriptyline and mirtazapine may be equally effective in reducing the duration and frequency of CTTH, although amitriptyline may be associated with a less favourable adverse-effect profile.
- We don't know whether tricyclic antidepressants other than amitriptyline are effective in treating CTTH.
- We found no evidence examining the effectiveness of noradrenergic and specific serotonergic antidepressants, other than mirtazapine, in CTTH.
- We don't know whether SSRIs are effective in treating CTTH.
- We don't know whether benzodiazepines are effective in treating CTTH, and they are commonly associated with significant adverse effects.
- We found no evidence examining the effectiveness of anticonvulsants, such as sodium valproate, topiramate, and gabapentin, in CTTH.

- Botulinum toxin does not seem to be a useful treatment for CTTH. It may be associated with several adverse effects, including facial weakness, difficulty in swallowing, and disturbed local sensation.

We don't know whether non-drug treatments, such as CBT, relaxation or electromyographic biofeedback, or acupuncture, are effective in treating CTTH.

- We don't know whether chiropractic and osteopathic manipulations are effective in treating CTTH. These treatments have been associated with rare, but very serious, adverse effects; for example, arterial dissection causing stroke, other stroke syndromes, and cerebellar and spinal cord injuries.

7. LEVEL 5: EXPERT OPINION

Homeopathy for Cancer

Integrative therapies for oncology; Current Oncology—Volume 14, Number 4

E Ernst MD PhD

Homeopathy is again popular—also with cancer patients. Observational data suggesting effectiveness have to be interpreted with great caution. Randomized controlled trials are scarce, and those currently available are burdened with significant methodologic limitations. All of the existing RCTs are in the realm of cancer palliation and supportive care. Independent replication of these data are not currently available. Few experts would argue that low-potency homeopathic remedies (preparations that contain pharmacologically active molecules) may generate clinical effects. The dispute centres mainly on the issue of whether high potency remedies (preparations diluted beyond the Avogadro number) can be effective. Potencies (dilutions) of botanic substances beyond 7C (meaning 7 dilutions, each 1:100) do not contain a sufficiently significant number of molecules of the original material to be pharmacologically active.

8. LEVEL 1: REVIEW

Complementary and alternative therapies for pain management in labour (Review)

Smith CA, Collins CT, Cyna AM, Crowther CA

Cochrane Database of Systematic Reviews 2006, Issue 4.

Acupuncture and hypnosis may help relieve pain during labour, but more research is needed on these and other complementary therapies. The pain of labour can be intense, with tension, anxiety and fear making it worse. Many women would like to labour without using drugs, and turn to alternatives to manage pain. Many alternative methods are tried in order to help manage pain and include acupuncture, mind body techniques, massage, reflexology, herbal medicines or homoeopathy, hypnosis and music. We found evidence that acupuncture and hypnosis may help relieve labour pain. There is insufficient evidence about the benefits of music, massage, relaxation, white noise, acupressure, aromatherapy, and no evidence about the effectiveness of massage or other complementary therapies.

9. LEVEL 1: SYSTEMATIC REVIEW

York (DARE) Review: Complementary and alternative therapies for the management of menopause-related symptoms: a systematic evidence review

Nedrow A, Miller J, Walker M, Nygren P, Huffman L H, Nelson H D

Authors' conclusions

There are insufficient data to support the effectiveness of any complementary and alternative therapy for the management of menopausal symptoms.

10. LEVEL 1: SYSTEMATIC REVIEW

York (DARE) Review: Complementary/alternative therapies for premenstrual syndrome: a systematic review of randomized controlled trials

Stevinson C, Ernst E

Authors' conclusions

On the basis of the current evidence, no complementary or alternative therapy may be recommended as a treatment for PMS.

SECTION 2: CHIROPRACTY FOR THE TREATMENT OF BACK PAIN

What is it?

Chiropractic is a system of complementary medicine based on the diagnosis and manipulative treatment of misalignments of the joints, especially those of the spinal column, which are believed to cause other disorders by affecting the nerves, muscles, and organs. In this case its use in the treatment of back pain is being reviewed.

Search Strategy

Database	Result
NICE	Nil found
NHS Evidence	<ul style="list-style-type: none"> • Cochrane review - cited below • York cost effectiveness review - cited below • Well-being outcomes of chiropractic intervention for lower back pain: a systematic review Parkinson L, Sibbritt D, Bolton P, van Rotterdam J, Villadsen I. Clin Rheumatol. 2013 Feb;32(2):167-80. doi: 10.1007/s10067-012-2116-z. Epub 2012 Nov 14.
SIGN	Nil found
Cochrane	<p>Cochrane Intervention Review: Combined chiropractic interventions for low-back pain Walker BF, French SD, Grant W, Green S. Assessed as up-to-date: 27 November 2009. <i>Cochrane Database of Systematic Reviews</i> 2010, Issue 4. Art. No.: CD005427. DOI: 10.1002/14651858.CD005427.pub2</p>
York	<ul style="list-style-type: none"> • University of York CRD Review: Cost-effectiveness of medical and chiropractic care for acute and chronic low back pain Haas M, Sharma R, Stano M • Effective Health Care Bulletin: Acute and Chronic Low Back Pain, Nov 2000 – not cited as did not review chiropractic and needs updating
BMJ Clinical Evidence	Nil found
BMJ Best Practice	Nil specific to chiropractic
General Search (Google)	<ul style="list-style-type: none"> • Provider and self-help sites – not cited here • Cost-effectiveness studies of medical and chiropractic care for occupational low back pain: a critical review of the literature Marjorie L. Baldwin, PhDa, Pierre Côté, DC, MScb, John W. Frank, MD, MScd, William G. Johnson, PhD The Spine Journal 1 (2001) 138–147 • Costs and outcomes of chiropractic treatment for low back pain, July 2005 This summary is based on a comprehensive health technology assessment available from CCOHTA's web site (www.ccohta.ca): Brown A, Angus D, Chen S, Tang Z, Milne S, Pfaff J, Li H,

	Mensinkai S. The Canadian Agency for Drugs and Technologies in Health (CADTH) Health Technology Assessment
Medline / Open Athens	Not done

Summary of the evidence

The evidence reviews, appraisals and technology assessment for the use of chiropractic in treating back pain all agree that the studies available for review are not ideal. However their findings are consistent in that chiropractic appears no better or worse in terms of short medium and long term outcomes than more conventional treatments. Patients appear to have a higher level of satisfaction with chiropractic than with other interventions.

It appears to be cost-effective.

All reviews called for higher quality outcome studies to be carried out.

The evidence

Levels of evidence	
Level 1	Meta-analyses, systematic reviews of randomised controlled trials
Level 2	Randomised controlled trials
Level 3	Case-control or cohort studies
Level 4	Non-analytic studies e.g. case reports, case series
Level 5	Expert opinion

1. LEVEL 1: SYSTEMATIC REVIEW

Cochrane Intervention Review: Combined chiropractic interventions for low-back pain

Walker BF, French SD, Grant W, Green S.

Assessed as up-to-date: 27 November 2009.

Cochrane Database of Systematic Reviews 2010, Issue 4. Art. No.: CD005427.

DOI: 10.1002/14651858.CD005427.pub2

ABSTRACT

Background: Chiropractors commonly use a combination of interventions to treat people with low-back pain (LBP).

Objectives: To determine the effects of combined chiropractic interventions (that is, a combination of therapies, other than spinal manipulation alone) on pain, disability, back-related function, overall improvement, and patient satisfaction in adults with LBP, aged 18 and older.

Search methods: We searched: The Cochrane Back Review Group Trials Register (May 2009), CENTRAL (*The Cochrane Library* 2009, Issue 2), and MEDLINE (from January 1966), EMBASE (from January 1980), CINAHL (from January 1982), MANTIS (from Inception) and the Index to Chiropractic Literature (from Inception) to May 2009. We also screened references of identified articles and contacted chiropractic researchers.

Selection criteria: All randomised trials comparing the use of combined chiropractic interventions (rather than spinal manipulation alone) with no treatment or other therapies.

Data collection and analysis: At least two review authors selected studies, assessed the risk of bias, and extracted the data using standardised forms. Both descriptive synthesis and meta-analyses were performed.

Main results: We included 12 studies involving 2887 participants with LBP. Three studies had low risk of bias. Included studies evaluated a range of chiropractic procedures in a variety of sub-populations of people with LBP. No trials were located of combined chiropractic interventions compared to no treatment. For acute and subacute LBP, chiropractic interventions improved short- and medium-term pain (SMD -0.25 (95% CI -0.46 to -0.04) and MD -0.89 (95%CI -1.60 to -0.18)) compared to other treatments, but there was no significant difference in long-term pain (MD -0.46 (95% CI -1.18 to 0.26)). Short- term improvement in disability was greater in the chiropractic group compared to other therapies (SMD -0.36 (95% CI -0.70 to - 0.02)). However, the effect was small and all studies contributing to these results had high risk of bias. There was no difference in medium- and long-term disability. No difference was demonstrated for combined chiropractic interventions for chronic LBP and for studies that had a mixed population of LBP.

Authors' conclusions: Combined chiropractic interventions slightly improved pain and disability in the short-term and pain in the medium-term for acute and subacute LBP. However, there is currently no evidence that supports or refutes that these interventions provide a clinically meaningful difference for pain or disability in people with LBP when compared to other interventions. Future research is very likely to change the estimate of effect and our confidence in the results.

2. LEVEL 1: COST EFFECTIVENESS REVIEW

University of York CRD Review: Cost-effectiveness of medical and chiropractic care for acute and chronic low back pain

Haas M, Sharma R, Stano M

DOI: 10.1016/j.jmpt.2005.08.006

Record Status: This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED.

Health technology: Two treatments for patients with acute and chronic low-back pain (LBP) were examined. Chiropractic care consisted of spinal manipulation, physical modalities, an exercise plan and self-care education. Medical care included prescription drugs, an exercise plan and self-care advice, with some patients being also referred for physical therapy. Chronic LBP was defined as an episode of at least 7 weeks' duration.

Economic study type: Cost-effectiveness analysis.

Study population: The study population comprised patients with the primary complaint of acute or chronic LBP. The patients had to be at least 18 years old and ambulatory. Pain had to be of mechanical origin (i.e. not due to tumours, inflammatory disease, or organic referred pain). Patients were excluded if they were pregnant or had contraindications to spinal manipulation.

Setting: The setting was primary and secondary care. The economic study was carried out in the USA.

Dates to which data relate: The effectiveness and resource use data were gathered from 1994 to 1996. The price year was 1995.

Source of effectiveness data: The effectiveness evidence was derived from a single study.

Link between effectiveness and cost data: The costing was carried out prospectively on the same sample of patients as that included in the effectiveness study.

Study sample: A sample of 2,780 patients was identified from the practices of 60 chiropractic doctors (CD) and 111 primary-care medical doctors (MD) in 51 CD and 14 general practice community clinics. Patients were excluded if they had received care from a provider of the same type as the enrolling clinician in the previous 6 weeks, or if they did not understand English. The patients were divided between chronic and acute LBP groups. Among patients with chronic LBP, there were 527 individuals (55.4% women) in the CD group and 310 (52.6% women) in the MD group. The mean ages of these patients were 42.2 (+/- 14.4) years (CD group) and 39.4 (+/- 12.7) years (MD group), respectively. Among patients with acute LBP, there were 1,328 individuals (47.7% women) in the CD group and 615 (46.7% women) in the MD group. The mean ages were 42.1 (+/- 12.9) years (CD group) and 38.5 (+/- 12.1) years (MD group), respectively

Study design: This was a prospective, multi-centre, longitudinal, practice-based, non-randomised comparative study. With the exception of one medical clinic, which was located in Vancouver (Washington), all medical and chiropractic clinics were located in Oregon. The length of follow-up was one year, and the outcomes were assessed at baseline and at 3 and 12 months. The response rates for the clinical outcomes were 66% at 3 months and 62.6% at 12 months. These were uniform across the groups.

Analysis of effectiveness: Only patients with complete follow-up data appear to have been included in the analysis of the clinical outcomes. The clinical outcomes used in the analysis were pain, disability, physical and mental health, and satisfaction. Clinical and satisfaction outcomes were evaluated on 100-point scales. Pain severity, a primary clinical outcome, was measured on a 100-mm visual analogue scale (VAS) that ranged from "no pain" (0) to "excruciating pain" (100). Functional disability was measured with the Revised Oswestry Disability Questionnaire, a 10-item, 100-point scale assessing pain and daily activities. A higher score indicated greater disability. Physical and mental health was evaluated with subscales of the Short Form (SF)-12 questionnaire. A 3-item depression questionnaire appended to the SF-12 was used to screen for major depression or dysthymia. Two questions measured trust of the provider types, and one question evaluated confidence in treatment success. These three were measured on 6-point Likert scales dichotomised for the analysis.

Patient data were obtained using self-administered questionnaires. Several differences between the MD and CD cohorts were statistically significant at baseline, although the authors stated that only a few of them were clinically relevant. For example, for chronic patients, MD patients had greater disability, poorer physical health, and a greater prevalence of pain radiating below the knee. Regression analyses were carried out to adjust clinical outcomes for baseline characteristics. Statistical significance was set at a p-value of $p < 0.01$, and a clinically important difference between groups for the primary outcomes was set at 10 points.

Effectiveness results: In the chronic LBP cohort, the adjusted mean difference between the CD and MD groups after one year (positive value represents outcome improvement for CD compared with MD) was:

- for pain, 7.3 (+/- 2.1), ($p=0.000$);
- for disability, 5.4 (+/- 1.7), ($p=0.001$);
- for physical health, 3.0 (+/- 3.6), ($p=0.396$);
- for mental health, 1.2 (+/- 3.7), ($p=0.757$); and
- for satisfaction, 18.1 (+/- 4.9), ($p=0.000$).
- In the acute LBP cohort, the adjusted mean difference between the CD and MD groups after one year (positive value represents outcome improvement for CD compared with MD) was:
- for pain, 3.6 (+/- 1.3), ($p=0.007$);
- for disability, 2.7 (+/- 1.1), ($p=0.012$);

- for physical health, 9.2 (+/- 2.5), (p=0.000);
- for mental health, 5.4 (+/- 2.5), (p=0.032); and
- for satisfaction, 14.0 (+/- 3.1), (p=0.000).

Clinical conclusions: The effectiveness analysis showed that acute and chronic chiropractic patients experienced statistically significant better outcomes in pain, functional disability and patient satisfaction; no significant difference was found for mental and physical health in chronic patients. Clinically relevant differences were found for patient satisfaction (using a 10-point difference as threshold for clinically relevant improvement).

Measure of benefits used in the economic analysis: All clinical outcomes used in the effectiveness analysis were used as summary benefit measures in the economic evaluation. These included pain, disability, mental and physical health, and patient satisfaction.

Direct costs: The perspective adopted in the study was unclear. However, the analysis took office-based costs (including X-ray and prescribed medication), the costs of advanced imaging, surgical consultation, and referral to physician therapists into consideration. The unit costs were not presented separately from the quantities of resources used. The costs came from Medicare/ChiroCode relative value units and Medicare conversion factors in order to use a standardised measure of costs. The resource use data were derived from the sample of patients included in the effectiveness analysis. Discounting was not relevant as the costs were incurred during a 12-month period. The price year was 1995.

Statistical analysis of costs: A multiple regression model was used to adjust the total costs for baseline differences in clinical and economic data. Statistical tests were also carried out to test the significance of differences in the costs.

Indirect Costs: The indirect costs were not considered in the cost analysis.

Currency: US dollars (\$)

Sensitivity analysis: Sensitivity analyses were not carried out.

Cost results: The adjusted mean difference in office costs between the CD and MD groups after one year was \$158 (+/- 60) among patients with chronic LBP, (p=0.009) and \$112 (+/- 38) among patients with acute LBP, (p=0.003).

However, the adjusted mean difference in total costs between the CD and MD groups after one year was \$1 (+/- 80) among patients with chronic LBP and \$43 (+/- 47) among patients with acute LBP. Differences in the total costs did not reach statistical significance in chronic and acute patients.

Log-transformations of the costs confirmed the untransformed results.

Synthesis of costs and benefits: Incremental cost-effectiveness ratios were calculated by dividing the difference in cost between CD and MD by the difference in each benefit measure over a one-year timeframe.

In the chronic cohort, the incremental cost per unit of improvement in the benefit measures ranged from \$0 to \$0.7 when the total costs were considered and from \$8.7 to \$136.4 when only office costs were considered.

In the acute cohort, the incremental cost per unit of improvement in the benefit measures ranged from \$3.1 to \$16.1 when the total costs were considered and from \$8.0 to \$41.7 when only office costs were included.

The lowest ratios were found when patient satisfaction was used as the benefit measure, while the highest values were obtained when mental health was used as the benefit measure. Similar results were found when differences in benefits found after 3 months were used instead of those found after one year.

Authors' conclusions: Chiropractic care was relatively cost-effective in the treatment of chronic low-back pain (LBP). The results were less clear for acute patients, where only small improvements were found in clinical outcomes at additional, but not statistically significant, costs.

CRD COMMENTARY

Implications of the study: The study results suggested that chiropractic care may be at least as effective as traditional medical care for the treatment of patients with LBP. Under some circumstances, chiropractic care may be more effective, especially among chronic LBP patients.

3. LEVEL 1: SYSTEMATIC REVIEW

Well-being outcomes of chiropractic intervention for lower back pain: a systematic review

Parkinson L, Sibbritt D, Bolton P, van Rotterdam J, Villadsen I.

Clin Rheumatol. 2013 Feb;32(2):167-80. doi: 10.1007/s10067-012-2116-z. Epub 2012 Nov 14.

Abstract

The usefulness of chiropractic for treatment of low back pain is a contentious issue. Chiropractors advocate holism and general well-being as a key principle on which they base their clinical practice, yet the quality of life, lifestyle, health and economic impacts of chiropractic intervention for back pain in adults have rarely been investigated. This article provides an overview of chiropractic principles and practices, together with the results of a systematic review of peer-reviewed publications between 2000 and 2010 retrieved from MEDLINE, CINAHL, EMBASE, AMED and Cochrane Database of Systematic Reviews. This review sought to determine the benefits of chiropractic treatment and care to well-being, and to what extent chiropractic treatment and care improve quality of life. Of 1,165 articles, 12 articles were retained, representing six studies (four randomised controlled trial, two observational) of varying quality. There was a high degree of inconsistency and lack of standardisation in measurement instruments and outcome measures. Three studies reported reduced use of other/extra treatments as a positive outcome; two studies reported a positive effect of chiropractic intervention on pain, and two studies reported a positive effect on disability. The six studies reviewed concentrated on the impact of chiropractic care on physical health and disability, rather than the wider holistic view which was the focus of this study. It is difficult, therefore, to defend any conclusion about the impact of chiropractic intervention on the quality of life, lifestyle, health and economic impact on chiropractic patients presenting with back pain.

4. LEVEL 1: REVIEW

Cost-effectiveness studies of medical and chiropractic care for occupational low back pain: a critical review of the literature

Marjorie L. Baldwin, PhDa, Pierre Côté, DC, MScb, John W. Frank, MD, MScd, William G. Johnson, PhD

The Spine Journal 1 (2001) 138–147

Background context: Back pain is the single most costly work-related injury. Chiropractors and physicians are the main primary care providers for occupational low back pain (OLBP), but there is no consensus regarding the relative cost-effectiveness of these two modes of care.

Purpose: To critically appraise and synthesize recent literature on the cost-effectiveness of medical and chiropractic care for OLBP, and to propose a cost-effectiveness methodology that integrates epidemiologic and economic methods for future studies.

Study design: Literature review. MEDLINE was searched from 1990 through 1999. Nine articles that met the inclusion criteria were reviewed. The methodological quality of the articles was critically appraised independently by two epidemiologists using standardized review criteria. Two health economists reviewed the studies on cost-effectiveness.

Results: The current literature suggests that chiropractors and physicians provide equally effective care for OLBP but that chiropractic patients are more satisfied with their care. Evidence on the relative costs of medical and chiropractic care is conflicting. Several methodological deficiencies limit the validity of the reviewed studies. No studies combine high-quality cost data with adequate sample sizes and controls for confounding factors.

Conclusion: Existing studies fail to clarify whether medical or chiropractic care is more cost effective. We suggest that future studies must combine epidemiologic and economic methods to answer the question adequately.

5. LEVEL 1: HEALTH TECHNOLOGY APPRAISAL

Costs and outcomes of chiropractic treatment for low back pain, July 2005

This summary is based on a comprehensive health technology assessment available from CCOHTA's web site (www.ccohta.ca): Brown A, Angus D, Chen S, Tang Z, Milne S, Pfaff J, Li H, Mensinkai S.

The Canadian Agency for Drugs and Technologies in Health (CADTH) Health Technology Assessment

Technology: Chiropractic treatment

Disease: Low back pain (LBP) is tiredness, discomfort or pain in the low back. It is experienced by 70% to 80% of adults at some time during their lives. In Canada, it is estimated that medical expenditure on LBP costs \$6 billion to \$12 billion annually. In addition, there are societal costs due to lost productivity from days off work and disability payments.

Issue: Chiropractic care is a common treatment for LBP. Public funding support for chiropractic care varies across the provinces and territories in Canada. A clinical and economic review of chiropractic care for LBP was done because there is uncertainty about clinical and cost effectiveness compared with standard medical treatment or physical therapy; and there is variability in public funding for this treatment across Canada.

Methods and Results: Chiropractic care was compared with physical therapy and standard medical care for effectiveness and costs of treatment for LBP. Effectiveness was primarily determined by examining evidence from existing systematic reviews. Eighteen review articles were identified after screening available literature. Four trials published after the reviews were completed, were also identified. Relative costs were examined from 10 identified economic studies (four cost comparisons and six cost-consequence studies). Nine of the included economic studies were from the US and one was from Australia. None of the included studies were full cost-effectiveness studies.

Implications for Decision Making

- There is no clear clinical advantage to chiropractic treatment for LBP versus standard medical care or physical therapy. Studies show that the three treatment methods have similar effects on pain relief and functional improvement. The higher quality reviews did not find significant differences in effectiveness.

- There is no clear cost advantage for any of the three methods studied. One of the included economic studies compared chiropractic care with physical therapy; and found costs to be similar. Cost results varied among the studies comparing chiropractic care with standard medical care. In terms of improving lost time from work, chiropractic care was similar to physical therapy; and as effective as or better than standard medical care.
- Regional costs will require consideration. The impact on regional health care budgets will need to be considered when decisions on the funding of chiropractic care for LBP are being made. A well-designed Canadian study that compares the cost-effectiveness of LBP care provided by chiropractors, physical therapists and primary care physicians would be of benefit.

Appendix 2 – Diagnostic and Procedure Codes

(All codes have been verified by Mersey Internal Audit's Clinical Coding Academy)

GM030 - Complementary & Alternative Therapies Policy	
Functional therapy session	X61.1
Relaxation therapy session	X61.2
Body massage	X61.3
Movement therapy NEC	X61.4
Other specified complementary therapy	X61,8
Unspecified complementary therapy	X61.9
With the following ICD-10 diagnosis code(s); nothing specified in the policy, but often associated with:	
Radiculopathy	M54.1
Cervicalgia	M54.2
Sciatica	M54.3
Lumbago with sciatica	M54.4
Low back pain	M54.5
Pain in thoracic spine	M54.6
Other dorsalgia	M54.8
Dorsalgia, unspecified	M54.9
Chronic intractable pain	R52.1
Other chronic pain	R52.2