Effectiveness and efficacy of manual therapy for children and babies with respiratory, musculoskeletal, gastric, growth/development and behavioural conditions: Protocol for a systematic review

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Introduction

Osteopaths, chiropractors, physiotherapists and massage therapists treat babies and children using a variety of manual techniques and a consultation usually with a parent and or guardian of the child. The aim of therapy delivered manually (regardless of profession) is normally to promote healing, reduce symptoms and, or to optimise function.

Conditions that children and babies are treated for include: with difficulties feeding ('tongue tie'), sleeping, colic, distress, otitis media, plagiocephaly. It can be argued that these are common issues experienced by babies and their parents as part of normal growth and development and that most babies and children adjust and develop with time and thus are self-limiting. This presents particular difficulties when researching whether treatments are effective or not. Getting comparable comparison groups, blinding patients, parents and therapists is not always possible with complex interventions of this nature. Recruiting patients within specific short time frames also presents difficulties as effectiveness/efficacy studies often require large numbers of subjects so that there is enough data to ensure that bias between groups is minimised.

Many parents seek help and advice from those in complementary and alternative care to help them through these difficult periods because support and care for babies, children and their parents coping with these problems may not be accessible in main stream health care systems. Babies and children can also receive treatment for respiratory problems such as asthma, cerebral palsy, attention deficit hyperactivity disorder and autism. These are not necessarily self-limiting conditions and children may receive adjuvant care to allopathic medicine.

Treatment for babies is normally very gentle, manual therapists will often work using light palpation and the gentle encouragement of movement in the body to promote health and function.

There has been little rigorous research evaluating the effectiveness of manual techniques in the treatment of children and babies.

This lack of evidence has caused some controversy within the wider health care community, patients, sceptics and the advertising standards authority. There is a need to provide data about the value of the treatments to either the patient or the carer to validate its use, develop the therapeutic approach further, and/ or enhance its credibility. Previous reviews have shown evidence indicating high patient satisfaction rates and some improvements in outcomes but evidence is generally of low quality (Jaekel et al 2011). Others have concluded the evidence shows little or no effectiveness compared to controls (Podaski et al 2013). Jaekel studied osteopathy in the cranial field (all ages) and Podaski's review looked at osteopathy alone in babies, children and adolescents (up to 18 years

old). There are methodological issues studying effectiveness / efficacy in complex interventions and this also leads to problems meta-analysing data.

Case studies, case series and single cohort studies are limited in their value especially in children and babies as often conditions will resolve as the child grows and learns over time. There is potential to explore whether treatment reduces symptoms and/ or reduces duration of symptoms and or medication requirements.

Aim

The aim of this review is to synthesise data from primary research about effectiveness/efficacy of manual therapy treatments given to babies and children (0 – 5 years) for respiratory disorders, feeding difficulties, gastric conditions, musculoskeletal conditions, sleep and distress to help inform the osteopathic profession, parents/carers, and other healthcare professionals.

Method

Definitions

Manual therapists

We define manual therapists as statutory regulated or registered professionals who administer manual therapy. Manual therapists, include chiropractors, osteopaths, osteopathic physicians and physiotherapists who administer non-invasive therapeutic interventions that involve physical contact and which may or may not involve the use of mechanical and or electrical devices and or pharmaceutical agents.

We appreciate that statutory regulation varies between countries and that there are non-statutory regulated manual therapists administering other forms of manual therapeutic interventions such as Bowen technique, Rolfing, cranio-sacral therapy, vibration therapy and massage. These do not have statutory recognition and, or rarely, have a single registration body. Consequently, standards of training and practice may not be subject to the same degree of regulation, rigour and scrutiny as statutory regulated professions. We therefore will include only those studies where the therapist and/or therapy were clearly defined and stated, fitted our description of manual therapists and are recognised by a statutory regulated professional body.

Manual therapy

We will define manual therapy as practitioner-administered manual interventions that involve physical contact and do not include any mechanical devices. Where appropriate, we will categorise therapies using criteria proposed by Gross et al. (2002). They identified three types of intervention: manual therapy including but not limited to manipulation (high velocity, small or large amplitude techniques); mobilisation (low grade velocity, small or large amplitude techniques, neuromuscular techniques and cranio-sacral); and massage (other soft tissue techniques).

Typically manual treatments are multi-modal using combinations of techniques. Practitioners, depending on their analysis of the patient presentation, case history, medical history and contra-indications, will deploy a variety of individually appropriate techniques aimed to produce a therapeutic benefit. Techniques focus on improving health and function and may include passive articulation, springing, traction, harmonic oscillations and high or low velocity, high or low amplitude, short and/or long lever thrusts. Each of these approaches may be used in combination, with or without exercise prescription, and may be utilised with other therapeutic modalities such as acupuncture or various forms of electrotherapy, mechanically assisted manual therapies using equipment such as traction tables or employ mechanical devices such as the "activator instrument" used in chiropractic adjustments. In many cases manual therapy is administered concurrently with medication. All such approaches are deemed non-manual and are excluded from this review. However, we will include pragmatic studies where multi-modal/mixed interventions are administered, but only if it is clearly stated that the non-manual element was minimal (less than 90-95% of the overall intervention). Our search terms, and inclusion and exclusion criteria used for selecting articles for the systematic review will reflect this variety.

Children

We will only review studies of babies and children up to the age of 5 years old i.e. pre-school. We will split the studies according to the age of the child. Babies will be between 0 and 12 months old and will include pre-term births, Children will be from 13 months to 5 years old. Where these groups are mixed if there are over 85% of children in one of the age bands we will include them in that group. If there are less 85% then we will have a mixed age group. Studies of older children will not be included.

Searches

We will search the literature via type of therapist and child terms rather than by conditions so that we can review the range of conditions that may be treated. We will include studies about any condition.

('Osteopath*' or 'chiropract*' or 'physio*' or 'manual and therap*') and ('paed*' or 'bab*' or 'infant' or 'toddler' or 'child*')

We will search the following major scientific databases Cochrane central, MedlineOVID, Science Direct, Web of Science, EMBASE, CINAHL (Cumulative Index to Nursing and Allied Health Literature), and smaller profession-specific databases (PEDro (physiotherapy database), Index of chiropractic, OSTMED, and AMED (Allied and Complementary Medicine Database). Databases will be searched from inception to the current date of the search. We will also citation track from our selected full articles to ensure that our searches are inclusive. Reference lists will be examined also.

We include non-English language peer reviewed literature, specifically EU5 languages and Portuguese.

We will also citation track from our selected articles and use peer review networks to identify Masters and Doctoral level relevant dissertation and theses

Selection of articles

Due to the diverse nature of the subject area we propose the following inclusion and exclusion criteria. As there are many forms of manual therapy, types of treatment and therapists, the inclusion and exclusion criteria aim to create a more homogenous database of studies.

Selection criteria

Inclusion criteria

Statutory registered professional(s) or regulated professional(s) in a manual therapy.

Intervention or therapy must involve physical and/or manual contact to an individual with therapeutic intent, administered without the use of mechanical, automated, electronic, computer or pharmacological aides/products.

Babies (0-12 months includes pre-term) and Children (13 months- 4 years)

Patients must be conscious during the intervention.

Systematic reviews, RCTs, prospective cohort studies, observational studies, systematic reviews, case control studies, case series.

Peer reviewed literature only.

New/original data about efficacy/effectiveness of manual therapies.

Exclusion criteria

Non-peer reviewed literature: this includes reviews, letters and editorials.

Case studies.

Mixed interventions, multidisciplinary where response to manual therapy elements would be unclear/undeterminable.

Non-manual therapies including: the use of equipment, pharmaceutical, psychological, faith healing interventions.

Self-administered therapy, including exercise programmes.

Manual techniques applied to non- conscious patients (anaesthetised and cadavers).

Animal studies.

A PRISMA flow chart based on PRISMA guidance will be used in the selection and rejection of articles

Quality appraisal

Cochrane quality appraisal criteria will be used to assess the overall quality of the articles. We will grade the assessments from highest to lowest: High – majority of appropriate quality criteria were satisfied (80% plus); Medium – most of the appropriate quality criteria were satisfied (60 -79%); Low – below 60% of the appropriate quality criteria were not satisfied. Narrative comments will be recorded where there were quality issues with study methodology.

Each article will be categorised according to the methodological approach used to conduct the research. Graded as I to V depending on its place in the hierarchy of levels of evidence (Guyatt, Sackett et al1995). The hierarchy of evidence ranges from Level I, systematic reviews (SRs) with meta-analyses to Level V evidence based on authority, clinical experience i.e. descriptive studies, case histories and reviews. Level V literature will not be included in this review as the evidence is deemed too weak, the exception will be literature reviews that present some synthesis of data or original data.

All articles will be ranked in tables by level of evidence first followed by quality assessment ranking.

We will use a number of tools to evaluate quality. For example: the Cochrane risk of bias tool to assess SRs and RCTs, CASP qualitative study appraisal and cohort studies template.

Data extraction and analysis

Studies will be organised but type of research method, age of children and condition being treated.

A team of volunteers will select articles for inclusion into the review. Reviewers will independently select and reject articles blind to each other's choices. These will be checked against each other and any discrepancies will be reviewed by a third party for resolution and final decision. Quality will be appraised by one reviewer only. Data extraction will also be done by two reviewers using agreed data extraction criteria. Data will be extracted by one reviewer and checked by the second reviewer any discrepancies will be resolved by a third reviewer.

We will produce funnel plots to assess bias in publication and assess heterogeneity.

Randomised controlled trials and matched or paired cohort studies

We will extract final value scores for each group and convert them to standardised mean differences for comparison. Where change scores are presented we will either convert these back to final value scores (where possible) or ask the lead authors for final value data.

Prospective cohort studies

We will extract risk ratios data and where possible convert to relative risk ratios for comparison.

Questionnaire surveys

Narrative reviews will present descriptive data from these studies.

Qualitative studies

We will use a Framework approach to organise and synthesise findings from the qualitative data and identify emergent themes and sub themes.

Data will be meta-analysed where possible using REVMAN software.

The review will be reported using PRISMA guidelines (www.prisma-statement.org).

Dissemination

This review will be managed and coordinated by the National Council for Osteopathic Research (NCOR). The report will be drafted by NCOR and sent out for review and comment by the study team of volunteers. Volunteers will be recruited via the International Osteopathic Network (IORN).

Timeline

We hope to start the review in the mid 2015.

Acknowledgements and Funding

Everyone who donated money to NCOR to do this research will receive a PDF of the report. Papers will also be produced for publication in peer reviewed academic journals.

References

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Guyatt GH, Sackett DL, Sinclair JC, Hayward R, Cook DJ, Cook RJ (December 1995). "Users' guides to the medical literature. IX. A method for grading health care recommendations. Evidence-Based Medicine Working Group". *JAMA* **274** (22): 1800–4

PRISMA guidance: http://www.prisma-statement.org/ [accessed 16.1.15]

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