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Patient-centred care characteristics reporting in osteopathic effectiveness clinical trials.

An innovative tool development and Scoping Review

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Abstract

Introduction: Osteopathy has been defined as a patient-centred healthcare profession and for some authors, this is one of the strengths of osteopathy as a clinical approach. To date there were no evidence regarding whether the studies evaluating the effectiveness of osteopathic care followed the characteristics of patient-centred care and a scoping review was proposed to evaluate that subject. As no measurement tools to assess the presence or absence of patient-centred, person-centred, or person-focused approaches in RCTs were available in the literature, it was firstly necessary to identify the characteristic elements of those approaches.

Objectives: to visualize whether previous research evaluating the effectiveness of osteopathy was conducted considering some of the characteristics deemed to be inherent of osteopathy. As a secondary objective, to inspect whether the existing research paradigm of osteopathic research needs to be reoriented.

Methods: A literature search was conducted at Pubmed, Cinahl and Science Direct to identify RCTs evaluating effectiveness of osteopathic care published in English or Spanish between 2007 and 2022. A key term search strategy was employed using "effectiveness", "osteopathic medicine", "osteopathic manipulation", "osteopathic manipulative treatment", "osteopathy", "osteopathic care", "osteopathic interventions" and "Randomized Controlled Trial" to identify relevant studies. After the initial identification of 547 articles, and after the screening and eligibility processes 38 trials were finally included in this ScR.

Results: A new measurement tool including 8 main elements and 40 items has been developed to assess the level of PCC, PeCC and PFC in RCTs. Only 30% of the evaluated items were found to be present at the RCT.

Conclusions: The use of PCC, PeCC and PFC elements at osteopathic effectiveness studies is low. Including those elements may not require significant changes in future study designs but provide a better insight into what happens in real clinical practice. Future research should evaluate to what extent PCC, PeCC or PFC remains as an apparent strength of osteopathy as a clinical approach, what is the level of theoretical knowledge of osteopaths in relation to patient or person-centred approaches and what is the actual level of implementation of such approaches in daily clinical practice. Finally, it would seem logical that the epistemological approaches evaluating osteopathic care should be coherent with the inherent characteristics of this type of approach and lead to research designs which in turn are coherent with them.

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Keywords | Osteopathy, patient-centred, person-centred, person-focused, effectiveness
List of abbreviations

BPS: Biopsychosocial
CEN: European Committee of Standardization
Cl: Complex Interventions
EBM: Evidence Based Medicine
MSK: Musculoskeletal
NICU: Neonatal Intensive Care Units
OIA: Osteopathic International Alliance
OMT: Osteopathic Manipulative Treatment
PCC: Patient-Centred care
PCM: Patient-Centred medicine
PCOS: Polycystic Ovarian Syndrome
PICO: Population, Intervention, Comparison, Outcomes
PROMs: Patient Reported Outcome Measures
PeCC: Person-Centred Care
PFC: Person-Focused Care
QoL: Quality of Life
RCT: Randomized Control Trial
RCTs: Randomized Control Trials
RoB: Risk of Bias
ScR: Scoping Review
SR: Systematic Review
TA: Therapeutic Alliance
TR: Therapeutic Relationship
VAS: Visual Analogue Scales
WHO: World Health Organisation
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Appendix 1. Letter to corresponding authors
1 Introduction

Osteopathy has been defined as a patient-centred rather than disease-centred healthcare profession (Butler 2010; CEN 2015; WHO 2010) and for some authors, it is one of the strengths of osteopathy as a clinical approach (Moran 2013:65). Although there may be some overlap in some of the interventions or techniques used, the practice of osteopathy is also defined as distinct from other health professions that also use manual techniques such as physiotherapy and chiropractic (WHO 2010; CEN 2015), however, patient centredness cannot be considered an exclusive feature of this therapeutic approach (Thomson, Petty & Moore 2013:25-28) nor seemed to mediate the effects of osteopathic medicine (Licciardone & Aryal 2021).

Studies evaluating the scope of osteopathic practice in United Kingdom, Switzerland, Spain, Australia, and Italy show that most patients consult an osteopath for musculoskeletal complaints and more specifically for spinal pain of mainly the neck and the lower back (Alvarez, López Plaza & Carvajal 2018:10; Cerritelli et al. 2020; Fawkes, Leach, Mathias & Moore 2010; Osteopathic International Alliance 2020:58; Vaucher, Macdonald & Carnes 2018:5).

Patients living with musculoskeletal (MSK) pain disorders often present comorbidities and share common biopsychosocial (BPS) risk profiles for pain and disability (Hartvigsen et al. 2018; Lewis & Sullivan 2018; Kittelson, George, Maluf & Stevens-Lapsey 2014; Lin et al. 2020). Those psychosocial factors need to be assessed and patients should be provided with information about their condition and management options (Hutting, Oswald, Staal & Heerkens 2020; Lin et al. 2020). While some guidelines on MSK pain recommend treatment packages including manual therapy, exercise and psychological therapy (NICE 2016), for some authors, on the management of MSK pain it is probably the time to move beyond ‘body region silos’ approaches to more critical thinking person-centred enactive approaches to care (Caneiro et al. 2020; Esteves, Cerritelli, Kim & Friston 2022). However, integrating person-centred care principles into clinical practice seemed to be difficult for some clinicians, due to lack of knowledge or skills to implement of this kind of care, or due to time limitations (Hutting et al. 2020; Unsgaard-Tøndel & Søderstrøm 2022; van den Heuvel, van der Horst, Winkelhorst, Roelofs & Hutting 2021). For that reason, a framework has been proposed to enable clinicians to incorporate person-centred principles in the management MSK pain (Hutting, Caneiro, Ong’wen, Miciak & Roberts 2022).
The biomedical model in osteopathic practice seems to have been predominant for decades (Penney 2013), and for some authors, the technical approach seems to be cornerstone of osteopathy (Lederman 2017). Today there seems to be a need to focus on the individuality of the patient as unique person and their idiosyncratic responses in relation to their environment and treatment. Patient-centred research in osteopathy might challenge the classical biomedical model of healthcare but is needed to enhance osteopathic practice by improving care and treatment outcomes (Thomson et al. 2013). On the same line, some authors highlight the importance of re-establishing the patient’s narrative at the centre of healthcare to allow a proper focus on the whole organic person rather than on the mechanisms operating within the body (Tyreman 2018:2).

On that line and despite its definition, to date there is no evidence regarding whether the studies evaluating the effectiveness of osteopathic care are really following the characteristics of patient-centred care. A scoping review is proposed to evaluate that subject.

## 2 Patient-centred, person-centred, and person-focused care and associated research paradigms

### 2.1 Patient-centred care (PCC):

A patient is a person seeking, needing or receiving health care (European Committee of Standardization CEN 2020). PCC is defined as care provision that is consistent with the values, needs, and desires of patients and is achieved when clinicians involve patients in healthcare discussions and decisions (Constand, Macdermid, Bello-haas & Law 2014; Mead & Bower 2000). The development of the concept of patient-centredness seemed to be intimately linked to perceived limitations in the conventional way of practicing healthcare, also defined as the biomedical model where patients' reports of illness are taken to indicate the existence of disease processes. That clinical model focuses on identifying and treating standard disease entities. To this end, the patient's illness is reduced to a set of signs and symptoms, which are investigated and interpreted within a positivist biomedical framework (Mead & Bower 2000).

For Mead & Bower (2000:1091-1093) there was no “gold standard” criterion for patient-centredness and gaps occur between that concept -put forward by theorists- and the measurement of it in empirical work mainly due to the fact that the development of valid
and reliable measures can be constrained by lack of theoretical clarity and the difficulties of measuring complex relationship processes.

2.2 Person-centred care (PeCC):

PeCC is similar to PCC but highlighting the fact that patients are persons and should not be reduced to their health status alone (European Committee of Standardization CEN 2020; Paul-Savoie, Bourgault, Potvin, Gosselin & Lafrenaye 2018). PeCC can be considered the practical application of the multidimensional BPS illness model and one of the three pillars of evidence-based medicine (EBM) (Langedoen 2004) while improving health related quality of life, reducing hospitalizations and being cost-effective (Brännström & Boman 2014; Sahlen, Boman & Brännström 2016). It’s also a shared understanding and agreement about what really matters to the patient and the professional assessment and guideline-driven care that incorporates evidence-based care and national/local routines (European Committee of Standardization CEN 2020).

Person or patient-centredness can be concepts whose interpretations are not always clear (Bensing 2000; Hutting et al. 2020) and this has already been highlighted by some authors in the field of osteopathy (Thomson et al. 2013). For that reason, researching PCC or PeCC represents a challenge for researchers attempting to understand or measure it, but at the same time, there seem to be many opportunities to explore the concept within osteopathic care (Thomson et al. 2013). However, it seems to be a priority to fully understand the meaning of the person-centred concept before planning which is the best or more accurate way to measure it (de Silva 2014).

With the aim to create favorable structural conditions for the practice of PeCC in Europe, to improve quality of care, and to be used as a guide for research purposes, the European Committee of Standardization CEN (2020) issued the European Standard EN17398 “Patient involvement in health care. Minimum requirements for person-centered care” providing the elements for patient involvement in health care and the development of therapeutic alliances. However, there seems to be no universally agreed definition of PeCC in the empirical literature (de Silva 2014), and although several valid and reliable tools are already available to measure that approach to care, no one covers all aspects of it. PeCC is complex and multifaceted, so measurement strategies need to reflect this.
The studies evaluating PeCC tend to focus on one of four main issues: the definition of its components, the type of care that patients want (preferences), the experience of PeCC and the results of it (outcomes) and included surveys for patients or clinicians, or observations of clinical encounters (Casu, Gremigni & Sommaruga 2019; de Silva 2014; Rokstad, Engedal, Edvardsson, & Selbaek 2012).

Beyond those four elements, there seem to be no studies analyzing the level of PeCC used (or not) at studies assessing effectiveness or efficacy of certain treatments.

2.3 Person-focused care (PFC):

PFC is an extension of PeCC that considers that patients' healthcare needs are better understood if complex concepts such as their life context and goals, economic situation or spirituality are taken into account (Bellows, Young & Chase 2014). Failure to consider the complexity of patients may result in care plans not being carried out, failure to achieve behavioral changes, or increased use of healthcare resources (Bellows et al. 2014).

2.4 Evidence Based Medicine and Person-Centred Medicine:

When presenting Evidence Based Medicine (EBM), patient centred clinical research was considered an important element of the best available external clinical evidence and particularly regarding clinically relevant research (Sackett, Rosenberg, Gray, Haynes & Richardson 1996)

However, EBM often focuses on the evaluation of medical interventions in average patients and in some cases, this can generate difficulties to obtain tangible benefits from the results of clinical research (Sackett et al. 1996) and probably, have propelled the recent and rapid development of patient-centred medicine (PCM) (Sagristán 2013). While EBM is sometimes characterized by "speaking the language of populations", the methods of PCM should "speak the language of individuals". Both approaches should not be seen as contradictory but complementary movements (Sagristán 2013:7).

The objective of PCM is to improve the health outcomes for individual patients, within the context of everyday clinical practice (Sagristán 2013:1). PCM gives higher priority to the personal relationship between clinician and patient to develop an alliance among them and is characterized by five key dimensions that differ from the biomedical model:
BPS perspective; “patient-as-person”; sharing power and responsibility; “doctor-as-person” and therapeutic alliance (TA) (Mead & Bower 2000:1088). A TA is a dynamic reciprocally influenced interaction between the person seeking care and the clinician, and it’s influenced by biological, social, and psychological contributing factors (Søndenå, Dalusio-King & Hebron 2020). Implementing a TA enables effective Person-Centred Care (PeCC) (Esteves et al 2022).

2.5 Randomized control trials, complex interventions, and person-centred care

Randomized control trials (RCTs) are widely recognized as the most reliable method for assessing the effect of therapeutic interventions (Berlin & Golub 2014). When classified according to the different aspects of the interventions they include explanatory and efficacy trials which are designed to assess whether and to what extent the interventions being tested work and pragmatic trials, which not only determine whether interventions work, but also attempt to describe the consequences of the interventions and its use in the clinical “real-live” practice scenario (Jadad 1998). Both approaches are complementary and RCT might combine elements of both (Stolberg, Norman & Trop 2004).

RCTs are also often described in terms of whether they evaluate the efficacy or effectiveness of an intervention. Efficacy refers to interventions carried out under ideal circumstances, whereas effectiveness evaluates the effects of an intervention under circumstances similar to those found in daily practice (Stolberg et al. 2004). However, RCTs seem to be problematic or even non-appropriate when used in non-pharmacological complex interventions (CI) like osteopathy (Alvarez Bustins 2022; Esteves et al. 2020). CI are characterized by the number of components involved, the range of objectives, their difficulty, or the level of flexibility allowed in the intervention (Skivington et al. 2018) and they are difficult to assess using standard methods (Minary et al. 2019; Alvarez Bustins G. 2022). Following this further, there seems to be a need to incorporate the same principles that rule a given intervention in the clinical environment, to the research studies seeking to assess its effectiveness or efficacy (Alvarez Bustins G. 2022).

Recent developments have been made to try to explain the osteopathic person-centred model of care from an enactive perspective (Bohlen, Shaw, Cerritelli & Esteves 2021; Esteves et al. 2022; Shaw, Abbey, Casals-Gutiérrez & Maretic 2022). From a research
methodology perspective, there’s also a claim to implement and promote more pragmatic clinical trials (Moran 2013:66) and a shift towards the use of qualitative research in that field (Consorti, Marchetti & De Marinis 2020; Thomson et al. 2013:30) as evidence-base practice can’t be restricted only to the evidence generated by RCT (Hawker, Payne, Kerr, Hardey & Powell 2002:1285).

That pragmatic attitude favours design choices that maximize applicability of the trial’s results to usual care settings and have been tested for many conditions (Zwarenstein et al. 2008:2). The specific extension of the CONSORT statement for reporting pragmatic trials aims to identify the information that should be included in those trials to determine applicability, feasibility and acceptance of the interventions provided and its use is recommended (Zwarenstein et al. 2008).

On the other hand, qualitative and/or mixed methods research methodologies have a considerable potential to generate evidence of effectiveness of treatment, can improve the external validity of trials and help researchers to be sensitive with the participants at trials (Cathain, Thomas, Drabble, Rudolph & Hewison 2013:12).

3 Purpose, aims and objectives

Osteopathy is defined as a patient-centred approach to healthcare but to date, there is no evidence regarding whether the studies evaluating the effectiveness of osteopathic care are really following the characteristics of patient-centred care.

Aim: to assess whether the studies evaluating the effectiveness of osteopathy follow the characteristics of patient-centred care.

Purpose: to analyze whether there is coherence between the used research methodologies and one of the main characteristics used at the definition of the osteopathic approach to health care. Also, to set up a first step towards a future mixed methods study including a Systematic Review (SR) plus a qualitative study on that field.

Objectives: to visualize whether previous research evaluating the effectiveness of osteopathy takes into account one of the characteristics considered to be inherent to that approach to health care. As a secondary objective, to inspect whether the existing research paradigm of osteopathic research needs to be reoriented.
Research questions: Are the studies evaluating the effectiveness of osteopathic care following the characteristics of patient-centred care? Can the osteopathic research paradigm be reoriented to incorporate more elements of patient-centred care?

4 Assessment methodology to evaluate PCC or PeCC in RCTs

To date, there are no measurement tools published in the literature to assess the presence or absence of patient-centred approaches in RCTs. Therefore, to measure these elements, it was firstly necessary to identify them, and then to create a measurement tool that would incorporate them. As a starting point, the four main areas described in the European Standard EN17398 (Committee of Standardization CEN 2020) were taken into consideration:

- The patient's narrative and experience of illness

- Partnership (of all involved experts, including the patient taking part in the care-related decisions)

- Documentation, care plan and information sharing

- Patient and public involvement in management, organisation and decision/policy-making.

A pilot literature review to identify potential characteristic elements of PCC, PeCC or PFC was then conducted by the author. Two research experts with publications in the field of person-centred osteopathy (Dr. Oliver Thomson PhD) and manual therapy methodological designs (Dr. Gerard Alvarez PhD) were contacted and presented with the elements identified in the review. Finally, the usability of the tool was discussed with them. As a result of this search, eight main features of PCC, PeCC and PFC were identified and then combined with several potentially identifiable methodological features or design properties that could be find in clinical trials.

Finally, the presence or absence of the following items was analyzed to determine whether each selected study adheres to the characteristics of PPC, PeCC or PFC:
1) BPS Perspective:

The intervention should not only target biological but also social and psychological determinants to health.

From that perspective, it would seem necessary to assess whether patient’s needs, preferences, values, family, or social situations or even lifestyle have been taken into consideration at the studies. Also, whether a holistic approach to healthcare was considered (adapted from Mead & Bower 2000) including a BPS understanding of the patient’s pain experience (Hutting et al. 2022:3).

2) Patient as Person (acknowledge the individual):

Patients should be considered as experts on their own health and have their own experience of illness which might be influenced by economical or cultural factors but also by beliefs (de Silva 2014; Mead & Bower 2000).

Elements to be analyzed: whether there are attempts to understand the whole person with factors like individuality and/or specificity or whether there is a tailoring of the examination and/or intervention (including participant’s attitudes and expectations, knowledge, personality, gender, age, ethnicity nature of problems or knowledge of the practitioner). Adapted from de Silva (2014), Hutting et al. (2022:3) and Mead & Bower (2000).

3) Partnership: Sharing Power & Responsibility (shared decision-making)

All involved experts (including the patient) should be involved on management and taking part on decisions (European Committee of Standardization CEN 2020). The clinician-patient relations shall incorporate mutual participation, were power and responsibility are shared enabling patient activation and involvement.

Elements to be analyzed: whether identification of potential problems that require a decision-making process and/or solutions, agreed courses of action taking into account patient’s preferred approaches and/or arrangements for follow-ups have been taken into consideration. Adapted from European Committee of Standardization CEN (2020), de Silva (2014), Hutting et al. 2022) and Mead & Bower (2000).
4) Therapeutic Alliance:

The environment and some individual qualities of the clinician might be factors influencing a therapeutic relationship (TR). Establishing meaningful connections, the context of care and a TR are important factors for the development of a Therapeutic Alliance (TA). (McCabe et al. 2021; Miciak, Mayan, Brown, Joyce & Gross 2019). Those connections, in other manual therapy approaches to care like physiotherapy, have been summarized in three categories: acknowledging the individual, giving-of-self, and using the body as a pivot point (Hutting et al. 2022:3; Miciak et al. 2019).

Elements to be analyzed: the use of touch and/or the focus on the patient’s body to establish connections through physical contact (Miciak et al. 2019) and to bridge a gap facilitating the patient’s connections to the body (Hutting et al. 2022:3). Also, whether strategies to monitor adherence to treatment, control for contextual factors, positive expectancy, therapeutic relationship, empathy, matching previous expectations and beliefs, have been taken into consideration (adapted from Mead & Bower 2000).

5) Practitioner as Person:

Clinicians and patients influence each other but there seem to be difficulties to operationalize the measurement of that complex and context-specific variable (Mead & Bower 2000).

Elements to be analyzed: whether clinicians communicate with patients in a validating, considerate, and non-judgmental manner and show to be aware of their limitations and explain pros and cons of the proposed options, had empathic attitude (including considering patient’s concerns, fears, or expectations), values, personality, gender, age, ethnicity, knowledge of patient, medical training and clinical experience. Adapted from Hutting et al. (2022), Mead & Bower (2000); Mercer, McConnachie, Maxwell, Heaney & Watt (2005).

6) The Patient Narrative & Experience of Illness:

That narrative might be an essential element when trying to identify the patients’ views of their objectives, needs, preferences, values, and resources, and it might include the
patients’ perception of their own role in their care (European Committee of Standardization CEN 2020). Clinicians should allow the patient to tell his/her “story” (Mercer et al 2005).

Patient Reported Outcome Measures (PROMs) are self-reported tools that can be used to assess how patients perceive, feel, and interpret their health status and treatment. They commonly evaluate domains such as symptom experiences, functional status, quality of life and satisfaction with care (Trujols et al. 2013: 558).

Elements to be analyzed: the use of PROMs and whether patients provided information regarding their everyday life, condition, symptoms, disease knowledge and perception, and about their motivation, experiences, or objectives with care (European Committee of Standardization CEN 2020).

7) Documentation, Care Plan, Information Sharing:

Any information about care should be produced and shared with the patient. Effective communication between care personnel and patients is a prerequisite for patient involvement. It needs to be recognized that e.g., sensory, or cognitive impairments, educational differences, differences in language, or culture can hamper communication between the patient and care personnel (European Committee of Standardization CEN 2020).

Elements to be analyzed: whether the information was shared (to challenge or make decisions about their care i.e., potential benefits, harms, or uncertainties), the plan of action was discussed with the participant, whether the participant was also involved in the decisions and its views were also considered at any point of the study.

8) Direction towards PCC, PeCC or PFC:

Health services shall ensure that the physical, cultural, and psychosocial environment of health care is conducive to person-centred care (de Silva 2014).

Elements to consider in the RCT's: communications barriers (i.e., checking that the patient has understood the information provided), safety, security where therapy occurs, no disturbances, physical barriers, presence of third parties, time limitations or workload pressures.
Table 1. Items to be analyzed to determine whether the studies follow any of the characteristics of PPC or PeCC or PFC.

<table>
<thead>
<tr>
<th>BPS Perspective</th>
<th>Patient Needs considered</th>
<th>Patient Preferences considered</th>
<th>Patient values considered</th>
<th>Social situation considered</th>
<th>Lifestyle considered</th>
<th>Use of holistic approach</th>
<th>BPS understanding of pain experience</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient as Person</td>
<td>Individually considered</td>
<td>Tailoring of examination</td>
<td>Tailoring of intervention</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Partnership</td>
<td>Information given</td>
<td>Identification of problems requiring decision-making</td>
<td>Agreed course of action considering patients preferences</td>
<td>Arrangements for follow-ups</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Therapeutic Alliance</td>
<td>Body as pivot. Use of touch to establish connections</td>
<td>Use of strategies to monitor adherence to treatment</td>
<td>Control of contextual factors considered</td>
<td>Use of positive expectancy elements (matching beliefs)</td>
<td>Use of elements of Therapeutic relationship</td>
<td>Empathic attitude</td>
<td></td>
</tr>
<tr>
<td>Practitioner as person</td>
<td>Use of validating and non-judgmental communicatio n</td>
<td>Awareness of own limitations</td>
<td>Explanation of pros and cons</td>
<td>Concerns, fears or expectations considered</td>
<td>Training or Clinical experience considered</td>
<td>Individuality of practitioner considered (age, gender, etc)</td>
<td></td>
</tr>
<tr>
<td>Patient's Narrative and Experience</td>
<td>Use of PROMS (PREMS?)</td>
<td>Patients providing info about their condition</td>
<td>Patients providing info about their motivation</td>
<td>Patient involved in decisions?</td>
<td>Patient's views considered?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Documentation, care plan &amp; info sharing</td>
<td>Was information shared?</td>
<td>Plan of action discussed?</td>
<td>Patient involved in decisions?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Directions towards PPC or PeCC</td>
<td>Reducing communications barriers (information understood?)</td>
<td>Safety and security elements considered</td>
<td>Control of disturbances</td>
<td>Control of physical barriers</td>
<td>Presence of third parties</td>
<td>Time limitations</td>
<td>Workload pressures taken into consideration</td>
</tr>
</tbody>
</table>

5 Methodology

This thesis is a Scoping Review (ScR) of the literature. ScRs are processes of systematized search of the available literature on a specific topic and can help to identify key concepts, theories, sources of evidence or gaps in the research (Canadian Institutes of Health Research 2009). Scoping studies might be perceived as a part of an ongoing process of reviewing (aiming to ultimately produce a systematic review) but also as a method in its own right that led to the publication and dissemination of research findings in a specific area (Arksey & O’Malley 2005).

Common reasons to perform/conduct a ScR include (Arksey & O’Malley 2005):

1. Examining the extent, range, and nature of research activity. ScRs are a useful way of mapping fields of study where it is difficult to visualize the range of material that might be available.
2. Determining the value of undertaking a full systematic review with a preliminary mapping to identify the extent of relevant literature, existing relevant reviews and/or potential costs.

3. Summarizing and disseminating research findings.

4. Identifying research gaps in the existing literature and aid planning and commissioning future research.

For the design of this study, the Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) Checklist was used as a guideline (Tricco et al. 2018). To select the period under revision it was considered that the conceptual framework for patient-centeredness was defined by Mead and Bower (2000), but the first elements to measure patient-centred communication were developed five years later (Epstein et al. 2005). For that reason, and in order to allow for some PCC development in the field of osteopathy it was determined to start this review two years after the later.

5.1 Search Protocol

The research question for this review was described with PICO acronym: Are the studies evaluating the effectiveness (P) of osteopathic care (I) following the characteristics (C) of patient-centred care (O)?


Intervention: osteopathic manipulative treatment, osteopathic medicine, osteopathy, osteopathic care, osteopathic interventions.

Context: health, healthcare, care

Outcomes: measurement of the presence or not of the principles of PCC, PeCC or PFC during the intervention.
Inclusion criteria: RCTs evaluating effectiveness of osteopathic care published in English or Spanish between 2007 and 2022. The period was limited to 15 years to include the drafting period of the WHO “Benchmarks for training in osteopathy” (2010).

Exclusion criteria: pilot studies, studies published in other languages, studies evaluating efficacy, feasibility and/or underlying mechanisms; studies with animals, conference abstracts, expert opinions.

Databases and publisher portals used at this review: Pubmed, Cinahl and Science Direct. The articles found at this review were filtered to detect those that directly relate to the research question. The relevance of them was assessed to determine whether to include in the review as "accepted" or not (rejected) based on three criteria (Hawker et al. 2002:1290-1291):

- Relevance to the research question
- Context of the study
- The type of study.

An assessment form (including the items described at Table 1) was produced for every article under revision in order to allow data extraction.

The risk of bias (RoB) was not assessed as this is a review that aims to assess whether aspects related to PCC, PeCC or PFC have been considered at the evaluated studies and not so much whether the studies assessed present high methodological rigor to determine effectiveness of osteopathic treatment.

Protocol Registration number: https://doi.org/10.17605/OSF.IO/8FM6H

5.2 Search terms (keywords) and search strategy:

Keywords: effectiveness, osteopathic manipulative treatment, osteopathic medicine, osteopathy, osteopathic care, osteopathic interventions, randomized controlled trial, RCT, pragmatic studies.
A key term search strategy was defined to identify relevant studies at databases and publisher portals (see Table 2).

Table 2: Key terms search strategy.

<table>
<thead>
<tr>
<th>Databases/ Publisher portals</th>
<th>Key terms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pubmed</td>
<td>(effectiveness) AND (((((((osteopathic medicine[MeSH Terms])) OR (&quot;manipulation, osteopathic&quot;[MeSH Terms])) OR (osteopathic manipulative treatment))) OR (&quot;osteopathy&quot;)) OR (&quot;osteopathic care&quot;)) OR (&quot;osteopathic interventions&quot;)) Filters: Randomized Controlled Trial</td>
</tr>
<tr>
<td>ScienceDirect</td>
<td>(&quot;osteopathic manipulative treatment&quot; OR &quot;osteopathic medicine&quot; OR &quot;osteopathy&quot; OR &quot;osteopathic care&quot; OR &quot;osteopathic interventions&quot;) AND effectiveness AND (rct OR &quot;randomized controlled trial&quot; OR &quot;pragmatic trial&quot;). Filters: &quot;Research articles&quot;, &quot;Medicine and dentistry&quot; and &quot;Nursing and health professions&quot;</td>
</tr>
<tr>
<td>Cinahl</td>
<td>TX ( (&quot;osteopathic manipulative treatment**&quot; OR &quot;osteopathic medicine&quot; OR osteopathy OR &quot;osteopathic care&quot; OR &quot;osteopathic intervention**&quot;) AND effectiveness AND (&quot;randomized control trial**&quot; OR RCT OR pragmatic) OR AB (&quot;osteopathic manipulative treatment**&quot; OR &quot;osteopathic medicine&quot; OR osteopathy OR &quot;osteopathic care&quot; OR &quot;osteopathic intervention**&quot;) AND effectiveness AND (&quot;randomized control trial**&quot; OR RCT OR pragmatic).</td>
</tr>
</tbody>
</table>

5.3 Selection of sources of evidence

The screening of the sources of evidence was carried out exclusively by the author of this thesis. After that process, RCT evaluating effectiveness of osteopathic care were selected to be included on the review. A flow diagram including the numbers of sources of evidence screened, assessed for eligibility, and finally included in the review with reasons for exclusions at each stage, was produced.
For logistical reasons related to the potential volume of studies to be evaluated, it was decided to limit this research to studies published over a 15-year period. In the selection of the articles in this ScR, the main criterion was that the trials evaluated the effectiveness of osteopathy. This selection considered the use of the word effectiveness in the title, in the abstract, or finally in the results obtained during the trial.

After the initial identification of 547 articles, and after the screening and eligibility processes based on their title and the information contained in the abstract or in the full text, 38 RCT were finally selected for further analysis and included in this ScR (see Figure 1).

Figure 1: PRISMA Flow diagram of the search strategy.
5.4 Data charting process

After selecting the studies to be evaluated, descriptive data of the studies and qualitative data regarding the presence or absence of the patient-centred items described at chapter 4.3, was extracted and analyzed individually.

Results were included on a table matching the selected studies and presence/absence of each of the eight items (see Table 3). In case of presence of any of the items, a description of the characteristics of that item was included on the table and analyzed afterwards. Where information relating to the study themes or to the items previously described was identified, this information was included in the PCC and PeCC individual study data chart in the corresponding sections, highlighting not only the presence or absence of these items, but also compiling those specific and relevant data that had been identified.

Table 3. PCC and PeCC data chart.

<table>
<thead>
<tr>
<th>Study reference</th>
<th>1 BPS Perspective</th>
<th>2 Patient as person</th>
<th>3 Partnership</th>
<th>4 Therapeutic Alliance</th>
<th>5 Practitioner as person</th>
<th>6 Patient’s narrative and experience</th>
<th>7 Documentation care plan &amp; info sharing</th>
<th>8 Directions towards PCC or PeCC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Needs considered</td>
<td>Individually considered</td>
<td>Information given</td>
<td>Body as pivot. Use of touch to establish connections</td>
<td>Use of validating and non-judgmental communication</td>
<td>Use of PROM (PREMs?)</td>
<td>Info was shared?</td>
<td>Reducing communications barriers (information understood?)</td>
<td></td>
</tr>
<tr>
<td>Patient Preferences considered</td>
<td>Tailoring of examination</td>
<td>Identification of problems requiring decision-making</td>
<td>Use of strategies to monitor adherence to treatment</td>
<td>Awareness of own limitations</td>
<td>Patients providing info about their condition</td>
<td>Plan of action discussed?</td>
<td>Safety and security elements considered</td>
<td></td>
</tr>
<tr>
<td>Patient values considered</td>
<td>Tailoring of intervention</td>
<td>Agreed course of action considering patients preferences</td>
<td>Control of contextual factors considered</td>
<td>Explanation of pros and cons</td>
<td>Patients providing info about their motivation</td>
<td>Patient involved in decisions?</td>
<td>Control of disturbances</td>
<td></td>
</tr>
<tr>
<td>Lifestyle considered</td>
<td>Arrangements for follow-ups</td>
<td>Use of positive expectancy elements (matching beliefs)</td>
<td>Concerns, fears or expectations considered</td>
<td>About experiences</td>
<td>Patient’s views considered?</td>
<td>Patient’s views considered?</td>
<td>Control of physical barriers</td>
<td></td>
</tr>
<tr>
<td>Use of holistic approach</td>
<td>Use of elements of Therapeutic relationship</td>
<td>Training or Clinical experience considered</td>
<td>About their objectives</td>
<td>Presence of third parties</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>BPS understanding of pain experience</td>
<td>Empathic attitude</td>
<td>Individuality of practitioner considered (age, gender, etc)</td>
<td>Time limitations</td>
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<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Workload pressures taken into consideration</td>
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</table>
During the charting process, the presence of the 41 items initially described was identified and after the analysis of the first 10 RCT it was observed that 2 items ("information given" and "was the information shared with patients?") evaluated the same element, so one of them was eliminated so that this duplicity would not distort the final results obtained. If any relevant information not previously included on the eight pre-defined categories (see chapter 4) was identified, it was also recorded and incorporated for further analysis.

After the review of all the studies, all corresponding authors of the selected studies were contacted via email to elucidate whether any type of patient-centred approach not described at the published paper was used during the trial process. In order potentially to increase the authors’ response rate (by making it easier to answer) a pre-arranged set of questions evaluating whether elements of any of the 8 above-mentioned items was taken into consideration, was produced. The authors were also asked to send a copy of the standard written consent that was used at their study including any information given to the participants before entering the study plus some specific questions (see Appendix 1). Only five of the corresponding authors answered the questions (13,16% response ratio) and provided additional information which was added to the corresponding data chart.

To facilitate, in a visual way, the handling of the data obtained, and also to facilitate their subsequent communication, a color system was used, where green represents the presence of a certain item, red the absence of it, and yellow the need for complementary information to determine one or the other.

Finally, the results obtained in each individual data chart were aggregated to form the General Results Chart using only the previously described colors to create a graphical representation of the result (see Table 4). Further analysis included the specific results obtained for each item.

6 Results

6.1 Characteristics of sources of evidence

From a general point of view, and considering all the PCC, PeCC and PFC items assessed in this review, nearly one third (n=29,7%) were present, nearly two thirds did
not (n=62.8%) and in 7.4% of the cases it was not possible to establish the presence or absence of such items (see Table 4 and Table 5).

### Table 4: General Results Chart.

<table>
<thead>
<tr>
<th>JCP</th>
<th>Perspectives</th>
<th>Patient needs consideration</th>
<th>Patient autonomy considered</th>
<th>Patient's views considered</th>
<th>Treatment or Clinical expectations considered</th>
<th>Concerns, fears or limitations aware of own experiences considered</th>
<th>Empathic attitude considered</th>
<th>Therapeutic relationship expected?</th>
<th>Presence of contextual barriers considered?</th>
<th>Use of positive expectancy elements?</th>
<th>Qualitative data on pain experience?</th>
<th>BPS understanding of patient values considered?</th>
<th>Patient Preferences considered?</th>
<th>Patient Needs considered?</th>
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<tbody>
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</tbody>
</table>

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References:
- Accorsi et al (2014)
- Albers et al (2017)
- Amatuzzi et al (2021)
- Auger et al (2021)
- Benjamin et al (2020)
- Carnevalli et al (2021)
- Cerritelli, Pizzolorusso et al (2013)
- Cholewicki et al (2022)
- Cuccia et al (2010)
- Dugailly et al (2014)
- Groisman et al (2020)
- Jones et al (2021)
- Jouhier et al (2021)
- Licciardone et al (2011)
- Lynen et al (2022)
- Mancini et al (2022)
- Manzotti et al (2020)
- Naci et al (2021)
- Piche et al (2014)
- Rotter et al (2022)
- Schwerla, Hinse et al (2020)
- Schwerla, Rother et al (2015)
- Schwerla, Wirthwein et al (2014)
- Swender et al (2013)
- Tamer et al (2017)
- Thomas et al (2022)
- Thomaz et al (2018)
- Voigt et al (2011)
- Wyatt et al (2011)
- Yosri et al (2022)
Table 5: Presence of the different characteristic elements of PCC, PeCC and PFC.

1) BPS Perspective: from the global analysis of the data, it is observed that the presence of this element is above the average (40% present vs. 53% absent) and very notably thanks to whether the patient’s needs were considered (an item that was found in 68.4% of the studies), whether lifestyle was considered (in 55% of the studies) or whether a BPS understanding of pain experience was considered (in 53% of the studies).
In this ScR, the patient's needs were taken into account when specific medication, medical care or training was required or when OMT techniques were applied accordingly to those needs. Also, in those cases where the intervention took place in Neonatal Intensive Care Units (NICU). Patient preferences were considered in 15% of the studies including those where certain techniques were modified to suit the patient's tolerance (Cholewicki et al. 2020), when individualized food plan were prepared for each patient based on personal preferences (Yosri et al. 2022) or when specific assent was obtained by child patients (Nemett et al. 2008).

Lifestyle was considered in more than half of the studies and included elements like health related quality of life (QoL) questionnaires in most of the cases, but also lifestyle advice in others.

The use of the holistic approach included whole body approaches and psychological considerations and was observed in 45% of the studies, but it was difficult to establish its presence in many cases (n=29%). Examples of the use of that approach included elements like: “dysfunctions can arise and be diagnosed in the whole body” (Schwerla et al. 2020) on a pragmatic RCT evaluating OMT on patients with shoulder pain, where they tried to “assess and threat the whole person” while “the location of dysfunction was not restricted to the area of the shoulder joint alone” at the same RCT.

A BPS understanding of pain experience was also found at more than 50% of the studies and included elements like: psychological interventions, mental health questionnaires or evaluation, affective disorders diagnosis, fear-avoidance beliefs, pain or disease specific education, or treatment including BPS approaches as part of management. In the other hand, patient values were only considered in one of the studies reviewed (2.6%).

2) Patient as person: from the overall analysis: 50% of the elements analyzed met the criteria established for PCC, PeC or PFC, 31% did not meet them, and it was not possible to establish such compliance in 19% of the elements analyzed. Patient individuality was considered in 61% of the studies analyzed, while tailoring in the examination or in the intervention was observed in 40% and 50% of the studies, respectively.

Individuality was considered in around 60% of the studies and included pragmatic approaches with individualized treatment or medication, “caring attention and listening” (Piche et al. 2014), techniques applied according to patient’s needs (Tamer et al. 2027)
or individualized plans. At that point, some authors did not want to compromise the potential effect of an “optimal osteopathic intervention” by standardising the intervention (Schwerla et al. 2014).

Tailoring of the examination was found on nearly 40% of RCT but in most of the cases, standardized examination forms were used to monitor changes. Included “manual assessment aims to identify any posture or mobility restriction areas” (Manzotti et al. 2020) or even “detailed history of birth, illness, accident or injury, daily patterns, analysis of posture and detailed evaluation of alignment and mobility” (Nemett et al. 2008).

The tailoring of the intervention was slightly more frequent (found on 50% of the studies) and included: choosing the OMT techniques according to each participant’s needs, physical condition, or age in some cases; or when the sequence, techniques or the dose was left to the discretion of the osteopaths and was not based on predetermined protocols (Accorsi et al. 2014; Carnevalli et al. 2021; Groisman et al. 2020)

3) Partnership: overall, 64% of the elements analyzed did not meet this criterion, 28% did, and it was not possible to establish compliance in 8% of the cases. An agreed course of action considering patient’s preferences was absent in 92% of the studies. On the other hand, arrangements for follow-ups were present in 68% of the evaluated studies and included elements like: queries to participants about signs and symptoms immediately after treatment, email, telephone, and in-person contacts; instructions to perform exercises at home, individualized action plans, treatment schedules to coincide with other clinic appointments or instructions about the treatment procedure to gain the patient’s confidence and cooperation. Those follow-up arrangements included in some cases clear information regarding the number of sessions and lead to lower numbers of drop-outs (Accorsi et al. 2014).

The identification of problems requiring decision-making was only found in 10% of the cases including elements like “patients received home instructions including an individualized asthma action plan” (Jones et al. 2021) or patients at NICU (Cerritelli et al. 2013; Cerritelli et al. 2015)

4) Therapeutic Alliance: globally, 59% of the elements analyzed do not meet the criteria of PCC or PeCC, while 32% do and in 9% it was not possible to establish such compliance. In this section, the use of touch to establish connections and the use of the body
as “pivot” was present in 100% of the studies analyzed, matching one of the main characteristics of osteopathy as a manual approach to healthcare. On the other hand, the use of positive expectancy elements (matching believes) was only observed in 8% of the studies analyzed and included elements like: “study conducted at the request of a parent-run charity in response to their members’ desire for evidence on which to base treatment choices” (Wyat et al. 2011) or “effects seen with this trial can give valid information of the extent of change associated with the decision to see an osteopath” and “having certain expectations was not controlled” (Lynen et al. 2020).

Empathic attitude elements were found in 5% of them including elements like: “the osteopath offers a caring attention and listening without any manipulation” (Piche et al. 2014), or “during the baseline period, the hands were placed in the incubator to match the skin temperature of the infant” (Manzotti et al. 2020).

The use of specific elements of a Therapeutic Relationship were found in 15% of the studies and included elements like: “Each osteopath was responsible for the same patient from enrollment to the end of the study” (Cerritelli et al. 2015), placing “one participant per room” (Mancini et al. 2022), or “caring attention and listening” (Piche et al. 2014). For Schwerla et al. (2014): “the lack of blinding allows for a personal therapeutic relationship to be established between patient and therapist” and “a positive therapeutic environment may be supportive in terms of trust and confidence”. Some authors considered those elements on the trial design with elements like: “potential placebo effects, such as deriving from establishing patient-practitioner relationships was not controlled” (Lynen et al. 2020) and others, after contacting them post initial analysis specifically did reply: “This was not part of the study and would have been written in the publication” (Rotter et al. 2022).

5) Practitioner as person: only 16% of the elements analyzed meet the criteria previously established for PCC, PeCC or PFC and in 79% of the cases they do not seem to be met. In this section, the absence of the use of validating and non-judgmental communication in all the studies analyzed stands out. Also, information on awareness of own limitations was only found in 2,6% and included elements like interventions performed by 2nd year students with limited clinical experience or when interventions were performed at NICU. Explanations of pros and cons were found at 5% of the studies and were mostly included at the consent form. In relation to that, the absence of information regarding the consent form content in many of the studies analyzed may have seriously conditioned the findings in relation to this particular item.
Regarding whether concerns, fears or expectations were considered, only 10% of the studies included information of that item. For Lynen et al. (2020) “having certain treatment expectations was not controlled” while in other cases, "waiting list designs may trigger nonspecific effects such as expectation" (Schwerla et al. 2015; Schwerla et al. 2014)

Training or clinical experience was considered in 68% of the studies and included elements like: osteopathic education, registration/certification, pre-study specific training or years of experience.

6) Patients’ narrative and experience: only 22% of the items analyzed as a whole met the previously established PCC, PeCC or PFC criteria, while 74% of the cases lacked them. In this section, the use of PROMS was observed in 68% of the studies and included elements like: specific and/or self-evaluation questionnaires, Visual Analogue Scales (VAS) measurement systems, sleep and fit diaries, or the assessment the level of patient’s satisfaction at the end of the study.

In 34% of the studies the patients provided information regarding their condition in a clear manner and included elements like: specific interviews, full medical screening, detailed history of birth, illness, accident or injury, or self-reported daily patterns, diary data, co-morbidities and concomitant treatments. In contrast, information regarding the patient's motivation, experiences or goals was only detailed in 2,6% of the studies.

7) Documentation care plan & info sharing: in general, only 26% of the elements analyzed seemed to comply with the established requirements, while in 67% of the cases no such compliance was observed. Interestingly, info was shared in 87% of the cases and this figure could have been higher if more information could have been obtained from the consent forms or from the selection process of the patients studied as most of the elements were found on that section and included written information and /or verbal explanation about the nature and purpose of the study by the research team, written informed consents by participants or legal guardians or clarifications regarding the procedures.

The plan of action was found to be discussed in 8% of the studies, and included: parental involvement in the design and choice of outcome measures (Wyatt et al. 2011) or individualized asthma action plans and “back to school kits” (Jones et al. 2021)
The patients seemed to be involved in decisions in 5% of the studies and that included elements like: changes in medication frequency or dose (Cerritelli et al. 2015), usual care on demand (Lynen et al. 2022) or parental involvement contributing to retention of children in the study. The patient's views were considered in 2.6% of the studies and again were mainly related to parental involvement.

8) Directions towards PCC, PeCC or PFC: in general, only 27% of the elements evaluated seem to meet the established criteria and their absence was observed in 63% of the cases. Safety and security were clearly considered in 92% of the studies and very particularly from the definition of the exclusion criteria that were considered during the selection process of the patients to be studied.

The control of disturbances was observed in 24% of the cases and included elements like selecting dark and quiet rooms (Auger et al. 2021), limiting the presence of one patient per room (Mancini et al. 2022), requesting the participant to seat with closed eyes to avoid environmental stimulations (Monaco et al. 2020) or when patients were at Intensive Care facilities.

The presence of third parties was found in 21% of the studies and included when patients received treatment at NICU or hospital facilities, students recording clinical findings and treatment delivered (Cholewicki et al. 2020) or dyads mother-child with unblinded pediatricians acting as observers (Jouhier et al. 2021).

Some information on the control of physical barriers was obtained in 13% of the studies analyzed and again was related to those cases were patients received treatment on hospital facilities. In 97% of the studies, workload pressures were not taken into consideration and that information was only found in one study but described as limitation (Jones et al. 2021).

In this section, special attention should be paid to time limitations and specifically to the time dedicated to the application of osteopathic treatment in the different studies analyzed. According to several studies from different countries the range of osteopathic consultations time is from 30 to 60min. (Osteopathic International Alliance OIA, 2020:55) (see Table 6). For that reason, a minimum treatment time of 30 min. was considered as a reference of no time limitations and therefore of PCC. In this review, in 61 % of the studies analyzed, the time dedicated to patient treatment was equal to or more than 30min, while in 39 % of the studies, this time was less than 30min.
Table 6: OIA Global Report (2020). Time spent with patients.

<table>
<thead>
<tr>
<th>Country</th>
<th>Author and Year</th>
<th>Patients/week - mean (#NP)</th>
<th>Time: minutes with patient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>Adams et al 2016</td>
<td>37</td>
<td></td>
</tr>
<tr>
<td>Belgium-Luxemburg</td>
<td>van Dun et al 2019</td>
<td>31-35</td>
<td>30 – 60 mins</td>
</tr>
<tr>
<td>Canada</td>
<td>Morin &amp; Aubin 2014</td>
<td></td>
<td>55 mins</td>
</tr>
<tr>
<td>Germany</td>
<td>Dornieden 2019</td>
<td>30 (1-5 NP/week 64%)</td>
<td>60 mins</td>
</tr>
<tr>
<td>Italy</td>
<td>Cerritelli et al 2020</td>
<td>25-50 (estimated mode)</td>
<td>46 – 60 mins</td>
</tr>
<tr>
<td>Netherlands</td>
<td>van Dun et al 2016</td>
<td>37</td>
<td>30-60 mins</td>
</tr>
<tr>
<td>New Zealand</td>
<td>Leach 2013</td>
<td></td>
<td></td>
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<tr>
<td>Spain</td>
<td>Alvarez et al 2020</td>
<td>21-30 (mode)</td>
<td>46 - 60 mins</td>
</tr>
<tr>
<td></td>
<td>Alvarez et al 2018</td>
<td></td>
<td>45 – 60 mins</td>
</tr>
<tr>
<td>Switzerland</td>
<td>Vaucher et al 2018</td>
<td>36 (5)</td>
<td>45 mins (median) 30-90 (range)</td>
</tr>
<tr>
<td>UK</td>
<td>Plunkett et al 2020</td>
<td>31 (7)</td>
<td>45 mins</td>
</tr>
</tbody>
</table>

6.2 Individual sources of evidence

After a general analysis of the data obtained and in order to obtain a clearer picture of the results obtained for each of the 38 articles reviewed in this ScR, individual data extracted from the General Results Chart were grouped on Table 7 which clearly shows that the use of the characteristic elements of the PCC, PeCC or PFC appears in approximately one third of the colored surface of that table (see table 7).
Table 7: Use of PCC, PeCC and FPC items in %. Individual results per RCT.

Wyatt et al. (2011) evaluated the results of cranial osteopathy treatments for children with cerebral palsy in the study showing the higher presence of the analyzed items. Around 68% of previously established PCC, PeCC or PFC items were found to be present, which represents more than 2 times above the average presence of these elements in the rest of the analysed articles (equivalent to 29.7%). Actually, all the items corresponding to the sections relating to BPS approach; patient as person; partnership; documentation, care plan and info sharing and almost all those relating to the therapeutic alliance and patients’ narrative were observed and this study.

It’s also one of the two examples where elements of empathic attitude were found at the published trial. This could be due to the fact that, from the initial study design, there was a close involvement of the patients’ parents at all stages. Such involvement makes the article itself a true exception among the total number of articles evaluated.
The RCT by Yosri et al. (2022) evaluated the effect of visceral manipulation on menstrual complaints in a convenient sample of Egyptian women with polycystic ovarian syndrome (PCOS). In their study, and exceptionally, we found the presence of more than half of the evaluated items.

In fifteen other studies, we found an above-average presence of the PCC, PeCC and PFC items (Cerritelli, Ginevri & Messi et al. 2015; Cerritelli, Pizzolorusso & Ciardelli et al. 2013; Cerritelli, Pizzolorusso & Cozzolino et al. 2015; Cholewicki et al. 2022; Lynen et al. 2022; Mancini et al. 2022; Manzotti et al. 2020; Nemett et al. 2008; Piche et al. 2014; Rotter et al. 2022; Schwerla et al. 2020; Schwerla et al. 2015; Schwerla et al. 2014; Swender et al. 2013; Voigt et al. 2011), while in the rest, the presence was below average.

The RCT by Monaco et al. (2008) evaluated the effects of OMT on mandibular kinetics in children with temporomandibular disorders and concluded that OMT could induce changes in the stomatognathic dynamics. In their study, we only found the presence of less than 10% of the elements evaluated, which represents the lowest presence of these elements in the entire review.

7 Discussion

7.1 Summary of evidence

This ScR aimed to assess whether the studies evaluating the effectiveness of osteopathy follow the characteristics of patient-centred care. To do so, it was necessary to initially establish the defining elements of the PPC, PeCC and PFC in the form of sections (n=8) and to identify the characteristic items of each of these elements (n=40) and then, to assess the presence or absence of those elements in RCT under review.

Measuring PCC, PeCC or PFC may help to assess the quality-of-service provision, to identify the benefit of a specific improvement initiative or help to identify whether individual needs and preferences are being addressed (de Silva 2014). Although this initial definition as a patient-centred approach (Butler 2010; CEN 2015; WHO 2010), in studies evaluating the effectiveness of osteopathy, we found little presence of the characteristic elements of this type of approach (n=29.7%).
The methodology used in the studies and the development of them were analysed within the study in search of those characteristic elements of PCC, PeCC and PFC that had been previously described. In order to do so, those 3 approaches were considered as a whole and not analyzed individually due to the lack of theoretical clarity of the definitions (Mead & Bower 2000:1091-1093).

It is necessary to point out that the absence of any of these items in the published study does not directly indicate that they could not have been present in the preparation and/or development of the research process as they could simple been non-reported on the published version and this will be further discussed on the limitations section of this ScR. It was therefore considered that after an initial analysis, all authors should be contacted for additional information.

De Silva (2014) produced an extensive review of evidence about commonly used approaches and tools used to help measure person-centred care summarizing themes from more than 23,000 studies about measuring PeCC or its components. They produced specific examples from 921 studies and to source the material, two reviewers independently screened more than 200,000 studies. At their review, the studies of PeCC tend to focus on one of four main issues: definitions, preferences, experiences or outcomes and the most researched measurement approaches and tools were described (see Table 8).

No previous examples of studies evaluating the level of PCC, PeCC or PFC on RCT have been found in the medical literature, so to assess those elements, it was firstly necessary to identify them by themes and then to group the items corresponding to each of these themes in a specific and innovative measurement tool (see Table 1). In this process, the European Standard in this field was taken as an initial reference (CEN 2020), but it was also necessary to complement the information contained therein with other research articles published before and after that Standard in order to create a tool that allowed to measure those elements from a broader perspective (Mead & Bower 2000; Mercer et al. 2005; Trujols et al. 2013; de Silva 2014; Miciak et al. 2019; McCabe et al. 2021; Hutting et al. 2022:3).
Table 8: Examples of approaches used to measure person-centred care and its components (de Silva 2014).

<table>
<thead>
<tr>
<th>Concept</th>
<th>Commonly researched measurement approaches</th>
<th>Most commonly researched structured tools</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Holistic concept of person-centred care</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Person-centred care / patient-centred care / individualised care / family-centred care</td>
<td>• Surveys with professionals</td>
<td>• Individualised Care Scale (ICS)</td>
</tr>
<tr>
<td></td>
<td>• Surveys with patients</td>
<td>• Measure of Processes of Care (MOPC)</td>
</tr>
<tr>
<td></td>
<td>• Interviews with patients</td>
<td>• Person-centred Care Assessment Tool (P-CAT)</td>
</tr>
<tr>
<td></td>
<td>• Interviews with professionals</td>
<td>• Person-centred Climate Questionnaire (PCCQ)</td>
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<td></td>
<td>• Focus groups</td>
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<tr>
<td></td>
<td>• Observation</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Interviews with family</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Review of patient notes</td>
<td></td>
</tr>
</tbody>
</table>

| 2. Examples of subcomponents of person-centred care | | |
| Patient satisfaction / experience of care | | |
| | • Surveys with patients | • Consumer Assessment of Healthcare Providers and Systems Hospital Survey (CAHPS) |
| | • Surveys with patients | | |
| | • Surveys with professionals | | |
| | • Interviews with patients | | |
| | • Focus groups | | |
| | • Surveys with family | | |
| | • Interviews with family | | |
| Patient engagement / activation | | |
| | • Surveys with patients | • Patient Activation Measure (PAM) |
| | • Surveys with professionals | | |
| Empathy / compassion / dignity | | |
| | • Surveys with patients | • Jefferson Scale of Physician Empathy (JSPE) |
| | • Surveys with professionals | | |
| | • Simulations / observation | | |
| | • Interviews | | |

| 3. Examples of behaviours supporting person-centred care | | |
| Person-centred communication | | |
| | • Observation | • Wide range of tools, including the Doctors’ Interpersonal Communication survey; no single tool most commonly researched |
| | • Surveys with patients | | |
| | • Surveys with professionals | | |
| Extent to which professionals support self-management | | |
| | • Surveys with patients | • Wide range of tools, including the Resources and Support for Chronic Illness Self-management Scale; no single tool most commonly researched |
| | • Surveys with professionals | | |
| Shared decision making | | |
| | • Surveys with patients | • Decisional Conflict Scale (DCS) |
| | • Surveys with professionals | • OPTION scale |
| | • Observation | | |

When analyzing RCT, clinicians and policymakers often distinguish between the efficacy and the effectiveness of an intervention, but both exist on a continuum that goes from the effects obtained under ideal circumstances (efficacy) to the effects under “real world” situations (effectiveness) (Gartlehner, Hansen, Nissman, et al. 2006:3).

Efficacy trials (explanatory trials) are often “disease orientated” (occurrence of a single disease or exacerbations of a single chronic condition) and can be poor predictors of the real-world effectiveness of the interventions they test (Treweek & Zwarenstein 2009). In manual treatments for some prevalent conditions like Low Back Pain (LBP)
they seem to be the most used (Maddox, Subialka, Young & Rhon 2022:538). On the other hand, effectiveness trials (pragmatic trials) measure the beneficial effects of an intervention performed in a situation similar to the typical clinical setting (i.e., how well a certain treatment works in practice) and include interventions that can affect simultaneously multiple conditions (Gartlehner et al. 2006:3). Pragmatic trials sacrifice internal validity to achieve generalizability and allow to measure elements like survival, functional status, costs, or health related quality of life (Ware & Hamel 2011:1687). Researchers shall somehow choose between standardized protocols and more individualized and clinically orientated ones (Hensel, Buchanan, Brown, Rodriguez & Cruser 2015:7), but within manual therapies, today there seems to be a need for more research emphasizing effectiveness (Maddox et al. 2022).

Within that continuum, a clear differentiation among those approaches is not always possible. Seven criteria have been proposed to distinguish effectiveness from efficacy trials: 1) populations in primary care, 2) less stringent eligibility criteria, 3) health outcomes, 4) long study duration; clinically relevant treatment modalities, 5) assessment of adverse events, 6) adequate sample size to assess a minimally important difference from a patient perspective and 7) intention-to-treat analysis (Gartlehner et al. 2006:5). Tools such as the PRagmatic Explanatory Continuum Indicator Summary (PRECIS-2) are also available to make the purpose of a given trial more explicit and to determine its applicability already from its initial design (Loudon, Treweek & Sullivan et al. 2015).

During the selection process of the RCTs to be analysed in this ScR, it was possible to objectify the difficulties in distinguishing between the two types of studies. In that sense, and as an example of that, although the initial objective of the RCT by Cholewicki et al. (2022) was to evaluate the efficacy of OMT in reducing pain and disability in patients with chronic neck pain (CNP), that trial was finally included on this ScR because they used a pragmatic research design, in which the efficacy of OMT was evaluated under “usual treatment” conditions, and using a intention-to-treat (ITT) analysis that included all participants who after randomization completed at least one post-baseline assessment. In the results, OMT was found to be safe and effective in reducing pain and disability in patients with CNP and participants showed significant improvements in sleep, fatigue, and depression scores immediately following treatment delivered over approximately 4 to 6 weeks.
This review did not aim to specifically evaluate the effectiveness of OMT in the studies analysed, and therefore, elements such as the evaluation of their Risk of Bias (RoB) have not been considered.

A priori, it would seem logical that the epistemological approaches in the field of osteopathy should be coherent with the inherent characteristics of this type of approach and that they should lead to research designs which in turn are coherent with them. In contrast, the results of this review show that the characteristic elements of PCC, PeCC or PFC are rarely present in the studies reviewed but it would not be surprising to find similar results if evaluations such as those presented here were carried out in other fields (such as in the evaluation of the effectiveness of physiotherapy, rehabilitation or chiropractic), but this is a hypothesis that has not yet been investigated yet, as this review is the first to evaluate the presence of these elements in RCTs. Interestingly, it would seem that certain of the elements evaluated (like tailoring of the examination and intervention, promoting a therapeutic alliance, or including patient’s narrative and experience elements) could be included in effectiveness RCTs without significant changes in the design of the studies, but probably allowing to provide a better insight into what happens in real clinical practice. It might seem, therefore, recommended to implement them in future studies.

Osteopathy is a manual approach to healthcare that generally uses the body as pivot and the use of touch to establish connections as clinical tools (Arcuri et al. 2022). OMT may provide “uncertain and surprising interoceptive information” that may allow to update maladaptive interoceptive predictions and therefore improve the ability to attend to (new) interoceptive information (Bohlen et al. 2021:14). Touch may also play a critical role in developing a robust therapeutic alliance and improve the biobehavioral synchrony between the patient and the practitioner, particularly with paediatric patients (Esteves, Cerritelli, Kim and Friston 2022) as it’s a primary modality for communication and interaction (Shaw et al. 2022:4). That robust alliance might assist patients in making sense of their experience of disease and develop new body narratives about their physical capacities (Gale 2011). However, although touch appears to be fundamental for osteopathic clinical practice, osteopathy should not be reduced to touch-only interventions (Paulus 2013; Thomson & MacMillan 2023) and should also include hands-off elements like patient education, lifestyle advice or certain psychological support (Bohlen et al. 2021:7).
Both clinical tools can be considered as (not exclusive) characteristics of osteopathic care and may not only help the clinician, but also facilitate patients’ connection to their bodies (Hutting et al. 2022:2). In addition to that, by acknowledging the individual (within the patient) and also by the give-of-self, clinicians can consciously form connections that align with PCC (Miciak et al. 2019). The establishment of meaningful connections is a characteristic element of a therapeutic relationship and should be promoted as better therapeutic relationships may lead to an improvement of clinical results and patient satisfaction, while relational ruptures may result in poor outcomes (Hutting et al. 2022:2; Shaw et al. 2022:3).

For Esteves et al. (2020) osteopathic practitioners have traditionally mainly focused on a biomedical approach to care, however, there are increasing frameworks available enabling a movement towards more person-centred approaches in osteopathy and focusing on the personhood of patients could be a more ethical and potentially more effective way to practice (Thomson & MacMillan 2023). At the review, we found a certain trend towards considering the patient as person, as interventions on that direction were found in half of the evaluated studies. In fact, recent publications regarding osteopathic care are also highlighting the importance of elements like fear avoidance behaviours, expectations and beliefs, coping strategies, or prior predictions within the persons’ “en-active-ecological” world (Esteves et al. 2022; Shaw et al. 2022). It would probably be worth incorporating those concepts not only at clinical practice but also at future studies (see Figure 2).

Osteopathic care should already benefit from moving from a PCC approach to a PeCC or a PFC one, as this might allow practitioners to better understand the whole person and not only “the patient within the person”, by focusing on individual interrelationships over time, view diseases as interrelated phenomena and also by observing the body systems as interrelated structures (Fahlgren, Nima, Archer & Garcia 2015).
Of all the 8 elements analyzed, “practitioner as person” is the one with the lowest performance in relation to the overall use of a patient/person centred approach. And this is despite the fact that the training and/or the clinical experience of the practitioners was considered in most of the studies. In some cases, considerable text space is devoted to highlighting the type of training received, whether general or specific to the study in question. Membership of some kind of regulatory or associative body is also noted at many studies. Although the need to highlight this is not clear, it is possible that the latter may be related to the lack of regulation of the practice of osteopathy in certain countries in an attempt to certify the type of practitioner who carried out the intervention. In contrast, there seems to be no tendency to describe elements such as the use of validating and non-judgmental communication as being present and very little in relation to the awareness of the practitioner’s own limitations, while explanations regarding pros and cons were found at only 5% of the studies and were mostly included at the consent form.
The need to inform patients before and during the development of any RCT may seem to be a mandatory element, given that patient consent is essential before participating in those studies. Such consent is (probably) given based on the information received in relation to the study protocol and/or development and can therefore be considered as proof of the information received. Interestingly, in four of the studies analyzed, no information regarding consent was found, while in most cases, the information was limited to the statement that the participants gave their consent to take part in the studies with no further explanation. That reduced information may, however, be also related to journal limitations regarding publication size and the reasons that led to it were not specifically investigated in the present study. In some cases, these limitations could be overcome by providing links to supplementary information (Racca et al. 2017).

The plan of action was rarely discussed with patients and at the reviewed studies, patients do not generally seem to be involved in decisions nor their views taken into consideration. That runs against the notion that health care providers should create favorable conditions to enhance partnership with patients, as optimal care may be influenced by effective inter-professional communication involving shared knowledge and a common understanding of objectives and care strategies (Committee of Standardization CEN 2020:4).

On a narrative medicine approach “patients and osteopaths engage through a shared focus on the body where meanings are created in the dyadic space” (Shaw et al. 2022:5). Creating co-constructed narratives, when patients are sharing their “journeys through uncertainty” will require a clear practitioners’ therapeutic attitude and specific efforts in terms of narrative competence and active listening (Shaw et al. 2022:5; Tyreman 2015).

Patients’ beliefs and objectives do not always fit with practitioners’ agendas, so strong, and potentially flexible therapeutic alliances may be needed when working towards shared sense-making (Shaw et al. 2022:5). Patient-centred approaches cannot be applied in the same way for every patient as this would be like “employing an un-patient-centred, patient-centred approach” (Thomson et al. 2013). A key factor may be the adjustment and flexibility of the practitioner to the individual patient.

It is possible to improve certain aspects such as patients’ narrative and experience by promoting, for example, the use of PROMS, but particularly by encouraging patients to provide information regarding their condition, their motivations, and their experiences or
objectives. Trujols et al. (2013) proposed that PROMS providing more patient-centred outcome assessment should use qualitative and participatory methods to capture and incorporate patient perspectives and values. In fact, it might even be advisable to incorporate them into the pre-post intervention questionnaires themselves, which would also allow the evaluation of the variation of those parameters as a result of the interventions. It is unlikely to improve the quality, effectiveness, and efficiency of healthcare without taking into account its primary consumers (Tinetti & Studenski 2011) however, information regarding the patient's motivation, experiences and/or goals was only detailed in 2.6% of the studies.

Except for "use of validating and non-judgmental communications" and "workloads pressures taken into consideration", the rest of the elements and items have been found to be present in this review to a greater or lesser extent and therefore could be used in other subsequent studies to the same or greater extent.

As a conclusion to this section, I would like to highlight the words of a professor I once had the privilege of knowing and who dedicated his life to philosophy and osteopathy: “The practitioner’s task is not merely to explain and treat, but to provide support and insight into the meaning of illness experiences in order to enable a patient to develop a better, life-enhancing narrative and become a more whole person" (Tyreman 2018).

7.2 Limitations

The results of this ScR have many limitations.

The measurement tool used as the basis for the development of this ScR was specifically designed to be able to carry out this review and has not been tested before. No previous analysis on the validity and/or reliability of the tool has been produced and that might limit the obtained results. On the other hand, this research was carried out individually by a supervised single Master student, and it was not possible to carry out a peer review of the analyses studies, which may also have conditioned the results obtained both in relation to the functioning of the measurement tool created, as well as in the analysis and data extraction of the studies evaluated. Future research including consensus studies to develop that tool should be implemented to define the measurable characteristics of PCC, PeCC and PFC.
The lack of access to certain information that may be present in the consent form and/or at the preliminary information given to participants of the studies evaluated, may have conditioned the results obtained in certain sections such as: whether explanations of the pros and cons in relation to a given intervention were given, whether the patient's concerns, fears and expectations were taken into account, whether the possible plan of actions was discussed with patients, or whether the patient's views were taken into account at any point in the process. As an example of this, in several cases where the corresponding authors responded to the request for additional information, the presence of some of those elements was found in the documentation provided after request. However, the low response ratio from the corresponding authors did not allow more solid data to be produced.

7.3 Conclusions

A new measurement tool has been developed to assess the level of PCC, PeCC and PFC in RCT. This tool can apparently be used in both explanatory or pragmatic studies and was used for the first time in studies evaluating effectiveness of osteopathic care, but its use is not restricted to osteopathic studies.

During the selection process of the RCTs that were analysed in this review, it was possible to identify difficulties in distinguishing between the two types of studies listed above, something that has been extensively discussed in previous studies.

Although osteopathy is defined as a patient-centred approach, the RCTs evaluating the effectiveness of osteopathy show a low level of PCC, PeCC or PFC. Interestingly, it would seem that some of the elements evaluated (like tailoring of the examination and intervention, promoting a therapeutic alliance, or including patient's narrative and experience elements) could be included in effectiveness RCTs without significant changes in the design of the studies, but probably allowing to provide a better insight into what happens in real clinical practice. It might seem, therefore, recommended to implement them in future studies.

Osteopathy is a manual approach to healthcare that uses “the body as pivot” and “the use of touch to establish connections” as clinical tools. The fact was found at all the reviewed trials and may lead to develop robust therapeutic alliances and/or to improve the biobehavioral synchrony between the patient and the practitioner. However, osteopathy should not be reduced to touch-only interventions and should also include
hands-off elements like patient education, lifestyle advice or certain psychological support.

The potential for practitioners to practice PCC, PeCC or PFC remains as an apparent strength of osteopathy as a clinical approach, but future research should evaluate to what extent this is the case, what is the level of theoretical knowledge of osteopaths in relation to patient or person-centred approaches and what is the actual level of implementation of such approaches in daily clinical practice. Additionally, moving from a PCC approach to a PeCC or a PFC one, may allow practitioners to better understand the whole person and not only “the patient within the person”.

Finally, it would seem logical that the epistemological approaches evaluating osteopathic care should be coherent with the inherent characteristics of this type of approach and lead to research designs which in turn are coherent with them.
Reviewed articles


References


Letter to corresponding authors

Dear Dr. (name of the corresponding author)

Thank you in advance for your time.

I’m conducting research regarding the use of patient-centred care approaches at studies evaluating the effectiveness of osteopathy as a part of my thesis at the Masters of Healthcare (Osteopathy) at the Metropolia University of Applied Sciences (Helsinki, Finland). I'm writting you as corresponding author of: “reference of the selected article”, which is one of the studies I already analized.

I would be very grateful if you can send me a copy of the standard written consent that was used at that study (please include any information given to the participants before entering the study, when possible) and if you can provide me any information regarding the following questions:

1) Were patients’ preferences, values or lifestyle considered at any point during the design or the development of the study?

2) Were patients’ views considered at any point regarding the care plan?

3) Were patients involved on any decisions during the study period?

4) During the intervention: was there presence of third parties?

5) Did you use any elements to promote a therapeutic relationship?

Looking forward to hear from you soon,

Best regards

Lluís M. Horta PT, DO, MSc student.