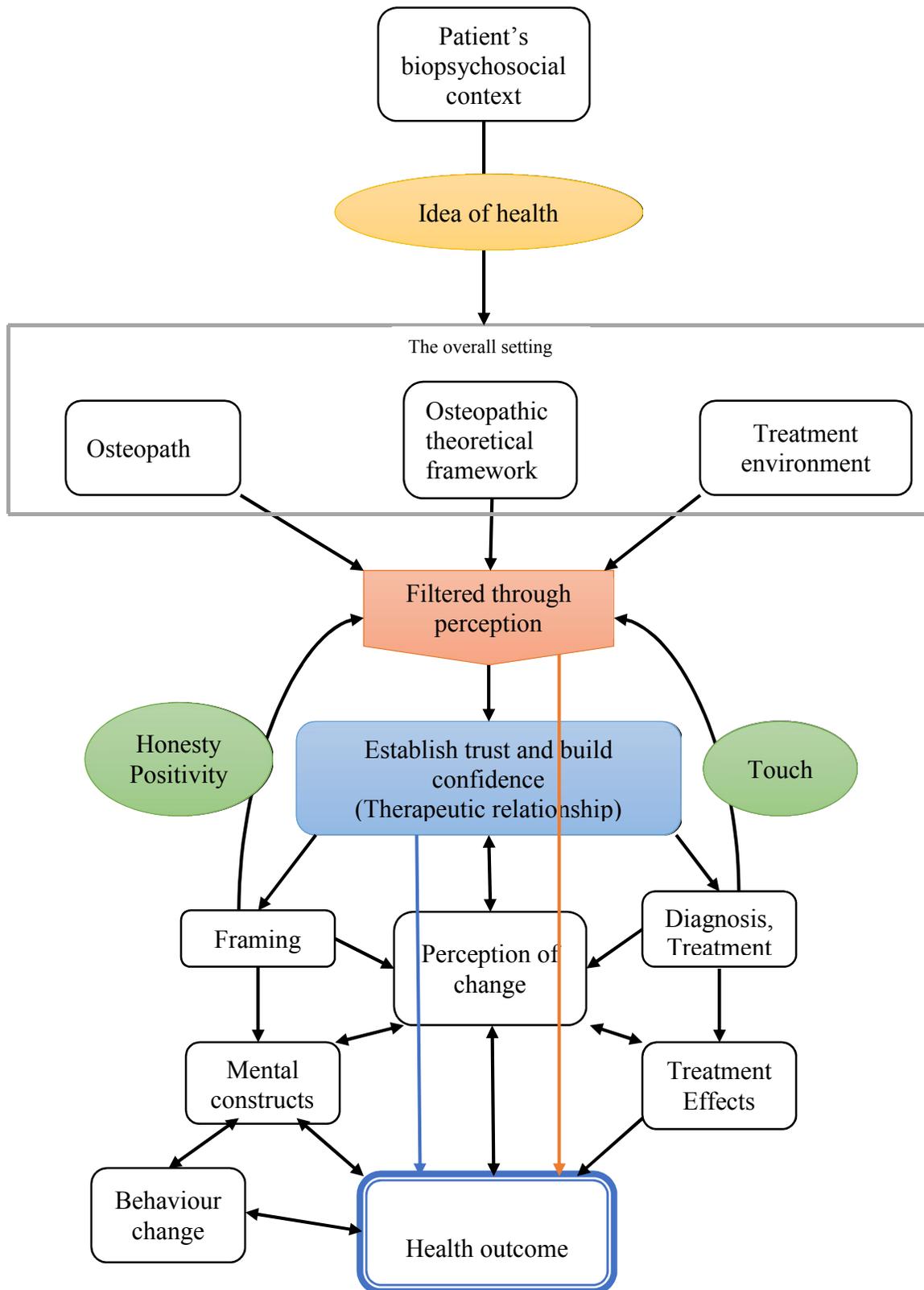


## Theoretical Framework of Placebo Effects in Osteopathic Practice

<p><b>Definition</b></p>	<p>Placebo effects are the psycho-neuro-bio-behavioural effects resulting from a patient's perception, interpretation and response to a therapeutic (psychosocial and environmental) context.</p>
<p><b>Treatment elements: Defining, Incidental and Preliminary</b></p>	<p>All treatments have defining, incidental, and preliminary elements which interact to influence treatment outcome (Caspi and Bootzin, 2002).</p> <p><u>Defining elements</u> are the interventions that are derived from the theoretical framework guiding the therapy and are intentionally applied.</p> <p><u>Incidental elements</u> are the variables that accompany the defining elements of the therapy, and are necessary but not sufficient components of the specific kind of therapy.</p> <p><u>Preliminary elements</u> are those that precede the intervention such as the process of making an appointment.</p> <p>The elements of therapy that are considered defining, incidental, or preliminary is dependent on the <b>theoretical paradigm</b> (e.g. biomedical vs. osteopathic), <b>context</b> (e.g. research vs. practice), and <b>situation</b> (e.g. the nature of the illness/condition) and can be re-classified as necessary.</p> <p><b>Placebo effects are typically viewed as being caused by 'incidental' elements, but can be caused by 'defining' elements depending on the therapeutic framework, context, and situation.</b></p>
<p><b>Determinants</b></p>	<p>Placebo effects are determined by environmental factors, individual patient and practitioner factors, the patient-practitioner interaction and communication, the process of providing a framework, and the nature of the illness.</p> <p>Central to the formation of placebo effects is the intersection between the perceptions of the patient, the development of trust, and pre-existing expectations, hope, and beliefs.</p> <p>Placebos ('inert' treatments) and deception are not necessary for placebo effects to occur. Placebo effects can subsequently be intentionally derived in an ethical manner.</p>
<p><b>Mechanisms</b></p>	<p>Placebo effects are an observation and manifestation of inherent adaptability and resiliency mechanisms.</p> <p>Specific mechanisms underlying placebo effects include:</p> <ol style="list-style-type: none"> <li>a) Activation of endogenous opioid and dopamine networks</li> <li>b) Psychoneuroimmunological processes</li> <li>c) Classical conditioning processes</li> <li>d) Specific modulation of autonomic nervous system activity</li> </ol>

<b>Effect on healing processes</b>	<p>Placebo effects are most likely to be observed in subjective measures of health, but can also be observed in neurological, functional and biochemical outcomes.</p> <p>Placebo effects have the greatest influence on healing processes occurring on psychological/emotional levels (i.e., subjective experiences of illness), but can also influence physical manifestations of healing processes through alterations in function (physiology).</p>
<b>Evidence-based method promoting health</b>	<p>Placebo effect mechanisms and determinants are supported by a strong evidence base that can be applied ethically in osteopathic practice as an adjunct tool to potentiate inherent health-restorative processes.</p>
<b>Defining element of osteopathic practice</b>	<p>Intentional use of these (evidence based) tools in clinical practice argues for classification of these elements of treatment as one of the defining elements of osteopathic practice. (Figure 1)</p>



**Figure 1: Process of Health Promotion in Osteopathic Practice.** Generated from content from informant interviews.

## Practical guidelines for engaging ‘placebo’ mechanisms in Osteopathic practice

### 1. Build trusting partnerships

What it does

- enables osteopathic diagnosis and treatment to proceed

- enables patients to share sensitive information that may be influencing health

- amplifies placebo effect mechanisms (i.e. - enhances the neurophysiological effect of providing a framework for understanding on the patient’s hope, beliefs, and expectations)

What it is

▪ Partnership = patient has an active role

How to do it

- Build partnerships by:
  - Providing information and encouraging questions
  - Working towards a shared understanding of the cause and nature of the illness
  - Sharing in decisions regarding treatment options
  - Empowering the patient with strategies and tools for self-care
- Build trust by:
  - Adapting (assess patient’s affective state and needs → interpret what kind of interaction would be beneficial → adapt behaviour accordingly)
  - Honesty
  - Confidence
  - Competence
  - Demonstrating knowledge of osteopathy and the human body

Key behaviours: listening, acknowledging, adapting, communicating effectively

### 2. Utilize strategies of effective communication

What it does

- central role in forming trusting partnerships

- role in providing a framework for understanding

- helps to identify patient factors in placebo responding (personality, beliefs, values)

What it is

- Communication = content + style (process) of conveying information
- Verbal and non-verbal (behavioural, tactile) dimensions

How to do it:

- Ask appropriate questions to gain an understanding of the whole person
- Utilize active listening strategies to convey interest and understanding
- Encourage active participation (partnership, enablement)
- Frame information positively and communicate clearly in a way the patient can understand
- Use an empathetic and emotionally supportive style
- Figure 2

<b>3. Provide a framework</b>	
<p><u>What it does</u></p> <ul style="list-style-type: none"> <li>- directs behaviour</li> <li>- hones focus</li> <li>- shapes the patient's expectations, hopes and beliefs → neurophysiological and behavioural effects</li> <li>- open-ended framing + reevaluation preserves hope, encourages health-promoting behaviours, and provides the opportunity to redirect hope/expectations in the future</li> <li>- positive guarantees of outcome → future nocebo effects if expectations are not met</li> <li>- negative guarantees of outcome → nocebo effects and diminishes health promoting behaviours</li> </ul>	<p><u>What it is:</u></p> <ul style="list-style-type: none"> <li>▪ Framing is embedded in the process of educating patients about:               <ul style="list-style-type: none"> <li>○ The nature of osteopathic assessment and treatment</li> <li>○ Assessment findings and/or diagnosis</li> <li>○ The rationale for the treatment plan</li> <li>○ The expected outcomes of treatment</li> <li>○ How to interpret the meaning of body sensations before/during/after treatment</li> </ul> </li> <li>▪ Honest, positive &amp; realistic</li> </ul> <hr/> <p><u>How to do it:</u></p> <ul style="list-style-type: none"> <li>▪ DO:               <ul style="list-style-type: none"> <li>○ combine positive open-ended expectations of prognoses/outcomes with process of re-evaluation</li> <li>○ use re-evaluation to frame improvements → bolster hope and trust</li> <li>○ use framing to redirect hope/expectations if treatment is ineffective or if progress plateaus (refer to other modality and/or modify plan)</li> </ul> </li> <li>▪ DON'T:               <ul style="list-style-type: none"> <li>○ provide positive OR negative <i>guarantees</i> of outcome</li> </ul> </li> </ul>
<b>4. Create a unique and comfortable environment</b>	
<p><u>What it does:</u></p> <ul style="list-style-type: none"> <li>- minimizes cues that elicit negative conditioned responses acquired from other settings (eg: conditioned nausea from chemotherapy provided in hospital settings)</li> <li>- patient's perceptions of environmental factors can have cognitive and affective (neurophysiological) responses</li> </ul>	<p><u>What it is:</u></p> <ul style="list-style-type: none"> <li>▪ Environment = treatment room → clinic/hospital → geographical location/neighbourhood</li> </ul> <hr/> <p><u>How to do it:</u></p> <ul style="list-style-type: none"> <li>▪ Create an environment that is clean and professional but not overly 'sterile' or impersonal</li> <li>▪ Create environments that have unique:               <ul style="list-style-type: none"> <li>○ Objects in the treatment room (plants, art, furniture)</li> <li>○ Colour of treatment room walls</li> <li>○ Views of nature/outside environment</li> </ul> </li> <li>▪ Promote a feeling of warmth, positivity, and comfort in the environment by:               <ul style="list-style-type: none"> <li>○ Ensuring interactions with other individuals in the treatment setting (eg: administrative staff) are positive and equitable</li> <li>○ Maintaining passion about your work as an osteopath</li> </ul> </li> </ul>

## 5. Recognize placebo-sensitive conditions and individuals

### What it does

- informs practitioner adaptation to each individual

- enables practitioner to select individualized placebo determinants to amplify placebo effect mechanisms

### What it is

#### ▪ Placebo sensitive conditions & functions:

- Pain
- Parkinson's Disease
- irritable bowel syndrome
- cardiovascular diseases
- depression
- asthma
- psoriasis
- common cold
- autonomic regulation of blood pressure, airway resistance, and gastric activity

#### ▪ Individual placebo sensitivity is related to:

- disposition-situation interactions
  - optimism + positively framed rationale conveyed with certainty (but not when outcome is framed as 'uncertain')
  - agreeableness or reclusiveness + warm, supportive patient-practitioner interaction (but not 'limited' interactions)
- personality traits with similar neurobiological underpinnings as placebo effects
  - stress resiliency, interpersonal function, prosocial motivation, novelty seeking, behavioural drive, and fun seeking
- concordance between intrinsic values and the therapeutic ritual/rationale
  - spirituality when the treatment is contextualized as a spiritual therapy

### How to do it:

- Gain familiarity with the patient's belief systems, values, and dispositional tendencies by:
  - Utilizing methods of effective communication (Figure 2)
  - Interacting from a place of neutrality and non-judgement

Maintain honesty, authenticity and genuineness while slightly altering content and style of communication to facilitate dispositional-situational interactions

## 6. Engage in personal development and self-care

### What it does

- creates positive psychosocial contexts for patients (biopsychosocial health in a practitioner's broader context translates into clinical encounters)

- patient's perceptions of subtle cues from the practitioner can make significant differences in placebo effects

- practitioner's beliefs will influence placebo mechanisms

### What it is

- Personal rituals and efforts to maintain/promote your own biopsychosocial health
- Psychosocial dimensions involve:
  - Value placed on relationships
  - Enjoyment from interpersonal interactions
  - Love, compassion, empathy, humility, vulnerability, emotional intelligence, personality, outlook on life, general disposition → enters the patient-practitioner interaction
  - Authenticity, genuineness, honesty: if practitioners clinical context = broader context

### How to do it

- Take care of yourself!
- There are many ways to promote your own psychosocial health, find what works for you.
- Promote biological dimensions by:
  - Maintaining adequate nutrition, rest, and exercise
  - Avoiding deleterious habits such as smoking and excessive drinking,
  - Reducing your own somatic dysfunction

## 7. Recognize the role of ritual and meaning

### What it does

- engagement with therapeutic rituals outside the treatment setting may repeatedly engage placebo mechanisms

- rituals concordant with a patient's intrinsic values may promote adherence to the treatment plan and may have positive psychoneuroimmunological effects

### What it is:

- Treatment ritual includes:
  - Characteristics/processes of treatment
  - Therapeutic relationships
  - Environments
  - Frameworks
- The patient's perceptions and interpretations are the filtering and organizing systems that influence physiological and behavioural responses

### How to do it:

- Highlight aspects of treatment that are concordant with a patient's values/beliefs
- Provide suggestions of self-care rituals
  - Self-care rituals with recognized health benefits have placebo effects embedded within them

### **8. Maintain honesty and ethics**

- Duty for clinicians to provide ethical and honest care
- Concealment or deceit is unacceptable clinician behaviour, and is not necessary for placebo effects to occur
- Placebo mechanisms are engaged by honest, transparent, and ethical approaches via:
  - o Effective trusting relationships
  - o The process of honest framing
  - o Creation of positive treatment environments
  - o The treatment characteristics and rituals that hold positive meanings for a patient
  - o The biopsychosocial health and beliefs of the practitioner

### **9. Recognize the potential and know the limits**

- These guidelines have the potential to influence subjective, neurological, functional, and biochemical measures of health
- These guidelines are not a substitute for a proven therapy, rather they are a complement to existing treatments

### **10. Use these strategies as an adjunct tool in the provision of comprehensive patient care**

- These guidelines outline a therapeutic method of potentiating a patient's inherent self-restorative processes
- Apply these guidelines within the context of providing treatment informed by established osteopathic principles of practice

Ask questions to gain an understanding of the whole person, addressing:

- primary complaint - allowing patient to discuss symptoms fully
- general health and other symptoms and concerns
- the patient's understanding of the cause/effect/meaning of their symptoms on their function and their health
- the patient's expectations of treatment

Actively listen and paraphrase by:

- pausing to give time for the patient to speak
- allowing the patient to 'tell their story'
- paraphrase to communicate understanding and check accuracy

Enable the patient and encourage active participation by:

- encouraging questions
- working towards a mutual agreement regarding cause and nature of the illness
- providing verbal and written information
- sharing in decision making about treatment options

Provide emotional support through:

- reassurance
- warmth
- empathy
- acceptance, non-judgement, validation
- demonstrating interest
- conveying care, compassion, and confidence
- appropriate use of humour

Utilize positive non-verbal communication through:

- eye contact
- orienting body to face the patient
- appropriate use of touch (conveyed confidently)
- maintaining presence
- interacting from a place of love, compassion, humility, and vulnerability

Provide information (a framework) about:

- the nature of osteopathic assessment and treatment
- the findings of the assessment and/or diagnosis and prognosis
- the rationale for the treatment plan
- the meaning of body signs and symptoms
- expectations of treatment outcomes

**Figure 2: Strategies of Effective Communication.** Adapted from Derksen et al., 2013; Griffin et al., 2004; Hojat et al., 2011; Kaptchuk, Kelley, Conboy, et al., 2008; Rakel et al., 2011; Stewart, 1995; and content from informant interviews.

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