More Than Words: An investigation into the patient experience of informed consent in Osteopathy

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Declaration

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This Thesis/Dissertation/Research Project entitled *More Than Words: An Investigation into the patient experience of informed consent in Osteopathy* is submitted in partial fulfilment for the requirements for the Unitec degree of Master of Osteopathy.

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Candidate’s declaration

I confirm that:

- This Thesis/Dissertation/Research Project represents my own work;
- Research for this work has been conducted in accordance with the Unitec Research Ethics Committee Policy and Procedures, and has fulfilled any requirements set for this project by the Unitec Research Ethics Committee.

Research Ethics Committee Approval Number: 2016:1048

Candidate Signature: [Signature] Date: 30/01/2018

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Preface
Informed consent in healthcare has evolved markedly throughout history through legislative rulings, regulations, and research. Significant recent evolution has occurred in surgical, medical and nursing professions for which there exists a wealth of research. This disciplinary experience and knowledge has also altered the way informed consent is now understood and obtained within other allied primary health professions, such as osteopathy. However, unlike these professions, there is limited research into informed consent within an osteopathy context.

The aim of this study is to investigate the nature of patients’ lived experience of informed consent within an osteopathic consultation. Participants of this study were interviewed and their responses analysed, using an Interpretative Phenomenological Interpretation methodology, in order to gain a depth of knowledge about this lived experience. This has the potential to provide an insight into how patients perceive the informed consent process. The information from this research could help osteopaths can create an environment rich in information exchange, patient autonomy and mutually agreed treatment processes.

This thesis is presented in four sections. Section one is a literature review about communication, information exchange, and informed consent in healthcare, with an emphasis on New Zealand and osteopathic contexts. Section two outlines a comprehensive description of the phenomenological methodology and the application of this approach to the research methods. Section three contains a manuscript that is formatted in accordance with the International Journal of Osteopathic Medicine (IJOM) submission requirements (see Appendix K). This manuscript reports the investigation into the patient experience of informed consent in osteopathy and includes the results and a discussion. Section four is the Appendices which contains supplementary documentation such as ethical approval, participant information and consent forms, and examples of the data analysis process.
Section 1: Literature Review
Introduction

Healthcare practitioners have an ethical, administrative, and legal obligation to provide the information which allows patients to give informed consent (1-4). Yet, a definition of “adequate” informed consent, especially in applied clinical settings, continues to be a point of contention among medical disciplines (2, 5). It is generally viewed as the patient giving their permission for the practitioner to perform mutually agreed upon treatments after understanding risks and benefits of possible treatment options and therapeutic interventions (6, 7). In its narrow and self-interested sense, gaining consent may be construed by practitioners as mitigating their own risk in the face of adverse events (8). However, the ethical duty of practitioners stretches beyond professional self-protection or preservation. Broadening the view of consent beyond a legal requirement, to one that encourages the exchange of information to inform patients, creates the basis for patient autonomy, empowerment, therapeutic engagement and successful treatment outcomes (3, 4, 8, 9).

History of Informed Consent

Historically, consent was described as a patient’s “right to determine what shall be done with his (sic) body” (10). The evolution of consent though, has become more complex over time. Conceptually, it is the patient providing their consent for the practitioner to treat after a mutual understanding of the risks and benefits, and alternative therapeutic interventions, is reached (2, 6, 7, 11, 12). However, within this general view, a significant point of contention is recognizing how true informed consent is best obtained within a clinical setting.

Within a New Zealand context, the evolution of informed consent is especially pertinent. In 1988, The Cartwright Inquiry (13) was instrumental in the move of New Zealand practitioners and researchers towards the inclusion of informed consent processes in their work’s ethical protocols. The inquiry began after Professor Herbert Green performed a longitudinal experiment on 948 women undergoing gynaecological examinations. The experiment involved intentionally undertreating cervical cancer, without any form of informed consent from the participants (13). The Cartwright Inquiry and subsequent report made detailed recommendations about improving communication and informed consent practices. The main elements recommended in
the report included the right of patients to personal autonomy, receiving adequate information about treatments, risks, and benefits, providing multiple appropriate treatment options, and the choice to decline proposed treatments, or withdraw or decline treatments being administered (13-15). The report and its recommendations triggered widespread changes to informed consent processes in a wide variety of practitioner and research-oriented environments (15) and have framed the subsequent legislative reforms and regulations around informed consent with healthcare practitioners across New Zealand (14).

**Communication and Informed Consent**

Communication is defined as “the process of creating shared understanding” (16). In a clinical setting, it consists of verbal and non-verbal cues acting dynamically to reach this shared understanding (17-20). Research has noted that non-verbal communication has directly affected the quality of patient-centred communication and levels of patient satisfaction (17-20). Non-verbal cues such as images, colours, body language, eye contact, and environment work dynamically with verbal cues to mould the patient’s experiences of informed consent messages (20-22) and influence the extent to which the patient is engaged and participating actively in clinical discussions (17). Nonverbal communication is therefore a key element of communicating and understanding the informed consent process within a wider successful clinician-patient consultation experience.

**Relevance to Osteopathy Treatment**

As osteopathy is a primary healthcare profession regularly dealing with patients in a vulnerable state, it is inevitable that concerns and complaints will arise. A two-year exploratory study undertaken by Carnes (23) reviewed all reported concerns and complaints about osteopaths in the United Kingdom. A significant portion of concerns was categorised as ‘conduct of osteopath’. These concerns mainly related to inappropriate or ineffective communication, and failure to gain valid consent. A second significant category of concerns related to perceived inappropriate or unjustified treatments. It is widely recognised that the effects of consent malpractice can result in patient harm and legal action (14, 15, 24). This is especially pertinent to osteopathy and manual therapy as any touching of another human being that is unauthorised or
unconsented is considered assault in the eyes of the law (25). The medico-legal implications for osteopaths also extend beyond this to the risk of professional negligence. Health practitioners are exposed to accusations of negligent behaviour if they fail to completely advise the patient of inherent risks, efficacy, and nature of the proposed treatment (25). The findings from Carnes’ (23) study re-affirm that effective communication with patients and gaining informed consent should always be a professional priority and area of continual development and refinement, to ensure consistently high standards of ethical practice.

The Cartwright Inquiry has also underpinned informed consent protocols in New Zealand osteopathic settings. Obtaining informed consent is a requirement of the osteopathic practice standards enforced by the Osteopathic Council of New Zealand (26). However, despite this national standard and continuing professional guidance, practitioner compliance to these standards needs on-going support. Recent cases of sub-par informed consent processes in osteopathy were initiated by patient complaints to the New Zealand Health and Disability Commissioner (27, 28). The investigations into these complaints concluded that clear communication of the patient’s diagnosis, and risks and benefits of treatment were inadequate and affected carers as well as the patient (28). These investigations highlight the need for improved professional guidance and practice, which may emerge from greater understandings of the patient experience of granting informed consent.

**Giving Information**

Informed consent is implicitly related to practitioners giving information about clinical reasoning (5, 8, 29). Yet, the consent processes patients will experience in their consultation continually risk being de-prioritised, condensed into overly-simplistic forms, or fully omitted (7, 29) despite the post-Cartwright recommended pathways towards ethically sound practice and research. Inadequate or ineffective communication reduces the consent process for treatment to levels where the practitioner assumes or infers consent, or the patient implies their consent through attendance and passive participation. In either situation little is strategically done to gather the patients’ valid and active informed consent (4, 30).
It is commonly recognized that patients remember approximately half of the information disclosed throughout the informed consent process (31-35). This varies depending on the effects of age, education, cognitive function, and anxiety about their presenting complaint (12, 33, 35, 36). A combination of good verbal plain language explanations, visual aids and models, and audience appropriate written information is regarded as highly preferable by patients (37-39). Personalised multimedia resources and structuring information into concise summaries of essential information could increase information retention (40-42) as it overcomes the problem of generically written information contributing to reduced information retention (40-43). Arnold et al., (43) suggests that making informed consent processes patient-specific and an educational opportunity, enables the patient to participate more actively in their care because there is a greater depth to their understanding.

On the other hand, some studies have shown that providing comprehensive information around informed consent in combined oral, written, and video formats produce mixed effects on patient anxiety, comprehension, or satisfaction. Some researchers suggest that the form of presentation is clinically insignificant or has no impact on these factors (44, 45), while others (7, 12, 29, 37, 39, 46-48) challenge this view. Over 75% of patients in Daniels & Vogel’s (37) osteopathic study about what, when, and how information should be provided to patients, believed that written consent forms inadequately serve the purpose of informed consent, preferring verbal consent processes instead. A further aspect complicating the situation is the practitioner’s preferred mode of communication. While these findings show patients endorse the process of informed consent and highly rate information about current diagnosis and treatment risks (2, 29, 39, 46, 49-51), that endorsement is mediated by the verbal, visual and written modes of communication preferred by the practitioner (37). That is, practitioners can use conversation to successfully gain consent, however patients may gain more from a combination of oral, visual, and written resources.

**Benefits of Informed Consent**

There are a number of advantages for both patient and practitioner from gaining informed consent that leads to enhanced clinical experiences and improved therapeutic relationships. Patients who are informed have more opportunities to actively
participate and follow treatment plans because they reach common understandings with their clinician through the consent processes (46, 52, 53). This can include information about their illness, prognosis, and treatment options. Improved therapeutic relationship and effective communication act reflexively upon one another, which can strengthen patient trust and orientate the consultation towards a patient-centred approach (4, 29, 46, 48, 53, 54). Practicing consistent informed consent benefits the patient, the practitioner, and the relationship between the two (29, 53, 55).

**Risks associated with Manual Therapy**

Although informed consent in osteopathy is required, and the benefits from consistently practising it have been evidenced and are significant, there are few studies about informed consent in osteopathy that focus on the experience of the patient or approach the issue from a patient’s perspective. A small pilot study in the United Kingdom used focus groups of patients and osteopaths to discuss the communication of risks, benefits and shared decision-making in an osteopathic setting (6). A small part of this research asked patients about their perception of information about risk. They found it odd that osteopaths were expected to provide information about treatment risks when their General Practitioner did not routinely discuss the risks of prescribed medication. Some respondents mentioned that no one discussed risks or, if they were mentioned, they took no notice anyway. A survey of Australian physiotherapists found that only 33% of respondents consistently sought informed consent for cervical manipulations (56).

Spinal manipulations have been linked to mild adverse reactions such as headaches, discomfort, and fatigue (57). There have been causal links to more severe adverse reactions such as vertebral artery dissections (58), disc herniations, strokes, fractures, and even death (57, 59, 60). There is significant debate about the frequency of these more severe occurrences however because, as the literature notes there is a lack of inter-professional reporting or under-reporting of incidents (61-64). Osteopaths, however, should be wary about these treatment reaction risks. It is interesting to note that patients felt it was necessary to be informed about the likely risks and benefits of their possible treatment options and to share the decision making, leading the patient to be more active and engaged in the consultation (3, 6, 29).

**Implied and Tacit Consent**
Seeking and delivering consent in serial consultations is potentially troublesome. Repeatedly following ethical procedures for consensual treatment can seem monotonous or unnecessary for a patient who visits an osteopath regularly for the same treatment (37). In this scenario, the patient may appear to be tacitly placing their trust in the practitioners’ choice of treatment. Research has identified the patients’ conduct, conversational statements, following instructions, the absence of dissenting, or their voluntary regular attendance at a clinic as forms of implied or tacit consent (25, 29, 65). Also, both parties may feel that making a free, voluntary, and declared informed decision is unnecessary, beyond the first consultation as the practitioner is assumed to be acting in the patient’s best interest (3, 66). However, in the case of serial treatments, where the patient’s circumstances or management changes, the practitioner is obliged to repeat the informed consent process and discuss inherent risks and benefits of different treatment plans (32). In general, even if the patient thinks it is unnecessary or tedious (24, 29), obtaining on-going consent over time for numerous treatments is an ethical imperative, a legal obligation and a vital competency that should be consistently sustained for practitioners (26, 65).

**Conclusion**

The literature review has shown that the process of communicating informed consent and indicating patient preference have been topics of research for many years and have largely focused on conceptual ethico-legal and litigious contexts within the context of doctors, surgeries, and hospitals (7, 12, 24, 43). It has also revealed a number of contentious issues with respect to how information about treatment information, including the use of purposed and personalized multimedia options, should be presented, and how regularly practitioners should actively seek consent from the regular patients. Current investigations in an osteopathic context, for example, include the use of a patient information leaflet (6). There is a gap in the research that analyses the subjective perceptual factors that constitute a patient’s lived experiences of informed consent beyond the preferred process of information exchange (37). The aim of this study is to initiate an investigation that has the potential to provide new insights into patient–practitioner communication using semi-structured interviews and phenomenological analysis methodology. By looking at consent through the patient experience, the study hopes to identify adaptations and adjustments practitioners could
implement to improve patient autonomy, ensure complete patient and practitioner safety, comfort and trust and reduce the number of complaints or concerns made against osteopaths.
References:


Section 2: Methodology to Method

Note: This section provides a comprehensive review of the methods reported in Section 3 (Manuscript). Some of this content overlaps with Section 3, but is provided to give a more comprehensive overview.
Methodology

The following chapter describes the research methodology and methods used to explore patients’ experiences of informed consent in osteopathic consultations. It briefly describes the two dominant research paradigms and then explains in more detail the rationale for choosing Interpretative Phenomenological Analysis (IPA) with which to design, conduct the research and subsequent data analysis.

The study of informed consent in osteopathy has been negligible and therefore there is limited understanding of the patient experience of informed consent in an osteopathic setting. In order to gain an insight into the patient experience of informed consent, 1 osteopathic practitioner and 6 patients were investigated using interpretative phenomenological inquiry.

Qualitative Research

The aim of research is to describe, explain, or answer specific research questions. Two dominant paradigms – quantitative and qualitative – shape the methodological decisions contemporary researchers make. These paradigms have distinctive philosophical underpinnings (1). Qualitative research aims to achieve a close-up, multifaceted view of a single phenomena or experience (3). The data collected in a qualitative paradigm is rich in personal emotion, expression, and detail to the point of saturation (1). Qualitative research does not aim to provide generalisable results across the population but focuses on deeply exploring a single phenomena or experience instead. Researcher biases and assumptions are made clear and suspended to allow for complete immersion and engagement to understand the data collected (1, 3). The results of a qualitative study provide the foundation upon further knowledge can be built upon and, in clinical settings, may contribute toward a more patient-focused practice, sensitive to their needs and experiences (3). It is within this qualitative paradigm that this phenomenological study of the patient experience of informed consent in an osteopathic setting in contextualised.

Interpretative Phenomenological Analysis

For this exploratory study, Interpretative Phenomenology Analysis (IPA) was chosen to answer the research question ‘What are the experiences of informed consent in a New
Zealand clinical osteopathic consultation for six patients?’. IPA was chosen because it aims to make sense of another person's interpretation of a given phenomena in a given context (4). It allows the researcher to not only create a relevant, detailed coding system but also interpret the meaning of the themes and claims that are extrapolated from the data. IPA captures not only the participants' experience, but also explores the meanings assigned to the experiences and describes how the researcher interprets these experiences (5-7). IPA has been successful in earlier osteopathic research contexts (7) including investigating the views and experiences of informed consent (5, 6). For this study, IPA aligns methodologically with the aim of the researcher to understand the patient's experience and interpretation of informed consent and how to make sense of these. The researcher is simultaneously a trainee osteopath and osteopathic patient. These dual roles have developed some preconceptions about informed consent processes in osteopathy. These preconceptions include the importance of informed consent as an ethical and legal requirement. All preconception were identified in full and suspended in order to focus on the experiences of the research participants.

**Phenomenology**

Where little is known about a phenomenon, phenomenological inquiry gives the researcher an opportunity to seek an understanding of the phenomenon (8, 9). Phenomenology questions the nature of phenomena (9) and guides the interpretative process towards mean-making (8) (9). As a research approach it is distinguished by three philosophical features: a belief in the importance of subjective consciousness; that consciousness is active and bestows meaning; and that knowledge can be gained by understanding the essential structures of consciousness (10). Therefore, phenomenological inquiry is a valuable tool for gaining an understanding of the human experience. Specifically, the researcher conducted individual semi-structured interviews of six patients to gain an understanding of their experiential perceptions of the informed consent process in osteopathy. Interviews allowed the inquiry to capture and compare the participants' experiences as naturalistic phenomena to a depth and richness sufficient to inform a methodologically sound and verifiable analysis (11).
**Hermeneutics**

The work of Schleiermacher, Heidegger, and Gadamer (12) primarily inform our understanding of hermeneutics, the second major influence on IPA. Essentially, hermeneutics is premised on the view that reality is socially constructed and focuses on interpreting social interaction and language. Hermeneutics is concerned more with the meanings of a phenomenon than the phenomenon itself. In the qualitative sciences, hermeneutics is about meanings and intentions: capturing the meanings of situated human interaction and revealing the underlying intentions of these interactions. It involves the analysis of meaning in a social context (10). Importantly, hermeneutic research explicitly acknowledges the researcher’s subjectivity in their attempts to examine phenomena, interpret data, and make analytical sense of the participant’s world (4) and is therefore an integral part of the IPA methodology,

**Idiography**

The third major influence of IPA is idiography. This emphasizes explaining and understanding the unique and the particular of individual cases, in order to understand wider principles of individual behaviour. In other words, idiographic research focuses on a particular subjective, relativistic social world rather than a prescribed, ordered and external reality (10). To achieve this, the researcher positions participants in a particular context and explores their particular individual experiences, seeking to uncover how each participant represents and conceptualises their personal experience of the context. This study follows the key principles of idiographic research by thoroughly examining the particulars of each case individually before moving on to interpreting behavioural patterns of the group. Idiographically researching the patients’ lived experience of informed consent in osteopathic consultations has the potential to reveal, at their deepest level, patterns of behaviour that may be hidden, or present quite differently at surface levels (12).
Methods

This section discusses project details including participant recruitment and ethical considerations. Data collection, data management, and data analysis are discussed in the conclusion of this sub-section.

Sample Selection and Recruitment

The involvement of both an osteopath and patients required two separate recruitment processes for this research investigation. The sample selection and recruitment methods were:

1. Purposive sampling was used to find an osteopath who values informed consent as a tool to improve collaboration between practitioner and patient. The researcher asked registered, practising osteopaths and the Osteopathic Council of New Zealand if they knew of someone that matched the description. All recommendations were approached and their eligibility was determined. Following recruitment, the researcher provided a detailed explanation of the research investigation, which included a description of what was entailed and the commitment they were making (see Appendix A). A signed written consent form was completed before data collection began (see Appendix B).

2. The researcher recruited a total of six patients using convenience sampling through telephone conversations from the database of a single tertiary osteopathic teaching clinic, where the researcher worked, in New Zealand. The researcher discussed the research process and eligibility criteria with interested candidates. An appointment time was established where participants were briefed further with a written information sheet and given the opportunity to have questions answered by the researcher (see Appendix C). Participants then gave written consent to the researcher and were enrolled in the study (see Appendix D), at which stage they were introduced to the osteopath.

Inclusion, Exclusion and Withdrawal Criteria

Osteopath Criteria

Inclusion Criteria:
The osteopathic practitioner must be registered in New Zealand and hold an Annual Practising Certificate.

The osteopathic practitioner must understand the research process and consent to the audio recording of their consent in a clinical consultation.

The osteopathic practitioner must value informed consent as a tool to improve collaboration between practitioner and patient.

The osteopathic practitioner must collaborate with the creation of a brief guided written reflection and complete one at the conclusion of each consultation with participating patients.

The osteopathic practitioner agrees to collaborate with the researcher to create a structured checklist of items that are required for establishing informed consent. This checklist must be used in the studied consultations.

Withdrawal Criteria

The osteopath may withdraw their own data (six recorded consultations and guided written reflections) from the study up to five working days after their final consultation and accompanied recording and reflection is completed.

Patient Criteria

Inclusion Criteria:

- Six patients of any gender above the age of 16. The age of consent criteria has been put in place to ensure that informed consent for the research can be provided as an adult in New Zealand.

- The patients must understand the research process and be able to give informed consent to voice recording throughout the consultation and interview.

Exclusion Criteria:

- Any friend or relative of the osteopath who treats them, or the researcher.

- A returning or regular patient for the osteopath.

- Participants who are unable to provide their consent in order to participate.

- Participants who do not consent to, or withdraw their consent for, audio recordings of the interviews.

- Participants who do not meet the inclusion criteria.
• Participants who have red flags including sudden onset of a severe headache, vomiting, disturbed consciousness, severe and debilitating pain.

Withdrawal Criteria:
• All patient participants may withdraw their interview data and involvement from the study up to five working days after their recorded consultation and interview.

Ethical Considerations
The research was granted ethical approval by the Unitec Research Ethics Committee, Approval Number: 2016:1048 (see Appendix E). The areas of ethical considerations are outlined below:

Informed consent
Prior to data collection, a written informed consent was obtained from all participants in the research. The consent form outlined the research process and intended use of the collected data. The contents of the written consent form was verbalised to each participant to ensure complete comprehension.

Confidentiality
Each patient participant was assigned a number throughout the transcription process and research to protect their identity and information. The osteopath’s name or location was not mentioned throughout research process to avoid a breach of confidentiality. An external transcriber, with no association to the research project or participants, was used to transcribe the interviews. A Transcribers Confidentiality Agreement (see Appendix F) was signed prior to transcription.

Data Security
All data were stored in an encrypted file on the researcher’s personal computer and flash-drive. All original files were immediately disposed of. The only people who had access to this information was the researcher and supervisors, upon request. All data will be retained for 10 years following the date of the consultation and securely stored in a locked filing cabinet at the researcher’s residence. During this period, only the
researcher and supervisors will have access unless express permission is granted from the involved participants. Following this, the data will be destroyed to ensure confidentiality is maintained.

*Personal Psychosocial or Emotional Harm*
Because informed consent can be considered a sensitive topic, the possibility of psychosocial or emotional harm was outlined when ethical approval for the study was sought. A subsequent action plan was made to offer details of a free counselling service. There were no instances where the action plan had to be carried out. The participants were provided with the contact details of the researcher and supervisor in the event of any follow-up questions or complaints.

*Data Collection*
Before data collection began, the osteopath collaborated with the researcher to create a checklist of the components of consent that needed to be covered in each consultation to ensure that the studied phenomenon was similar for each participant (see Appendix G). Three methods were used to collect data. Firstly, the studied consultations and the informed consent processes were recorded in their entirety. Secondly, the osteopath wrote a short, guided reflection following each studied consultation. Thirdly, semi-structured face-to-face interviews were used to gather the patient participants’ experiences of the consultation.

*Guided Written Reflections*
After each consultation with a participating patient, the osteopath completed a guided reflection (see Appendix H). The reflection had open-ended questions for the osteopath to provide as much or as little information as they like. The questions were mutually agreed upon and created with both the osteopath and researcher prior to data collection. The guiding questions allowed for consistency between reflections. The opportunity was given to the osteopath to add or remove any information in the reflection up to 48 hours after the consultation. The reflection was estimated to take 10 minutes to complete and provided an insight into how the osteopath believed the informed consent process went. They also aided the researcher in contextualising the phenomenon by understanding the osteopath’s intentions of what consent was gained.
for. However, these reflections were not included in the analysed data because they did not provide further insight on the patient experience.

**Semi-Structured Interviews**

Individual semi-structured interviews were held with the six patient participants. Each interview lasted approximately 30 minutes in length; however, there was flexibility in the length depending on the participants’ needs. The interviews took place, over the telephone, within 48 hours following the osteopathic consultation. Interviewer bias and influence was limited by using clean language and no leading questions (13). Participants were allowed to answer the questions with as much or as little information as they wanted. An interview guide outlined the process of the interviews and topics of questions asked (see Appendix I).

The data collection method of semi-structured interviews with a small group of participants who have a certain experience in common with each other is suitable for IPA (14). This common experience in the proposed research is the process of establishing informed consent by the same osteopath. The interviews were approached in a curious and facilitative manner to allow the richness of accounts consistent with phenomenological inquiry (9). As mentioned in the background literature, there have been no studies similar to the investigation proposed. Therefore no pre-existing theories will be used and assumptions will be avoided to generate the codes or themes when analysing the data. This is ideal as IPA explores topics where little is known (14).

**Data Transcription**

For convenience, an external party was paid to type transcripts of each interview and consultation. The transcriber completed a confidentiality agreement. The researcher listened to each recording while checking what the transcriptionist wrote to check for accuracy in the transcript. Patient participants were asked to check their interview transcript immediately afterwards to see whether they wish to add or delete anything. No participants used this opportunity.

**Data Analysis**
Smith, Flowers (12) outline of IPA guided the data analysis and interpretation process of the interviews:
1. Reading and re-reading
2. Initial noting
3. Developing emergent themes
4. Searching for connections across emergent themes
5. Moving on to the next case
6. Looking for patterns across cases.

Data analysis and interpretation aimed to consider the participants’ experiences and their attempts to make sense of these experiences.

To assist in the final step of data analysis across all cases, an electronically built mind map was created using the website Debategraph. The map was created by the researcher applying thought to the type and strength of relationship between each code, from the researcher applying subjective meaning to the participants’ perspectives. Debategraph used this coding to create mindmaps, which represented of the analysed data (see Appendix J). This rigorous analysis of the intricacies and connections between the themes were reviewed to ensure they reflected the researcher's understanding of the collected data.

The last step was to categorise and name the final themes. Secondary thematic analysis was undertaken at a meeting of the researcher and one of the supervisors team. In this phase, the initial themes were defined, refined and renamed to determine the story of each theme and its link to data. An informative name for each theme that resonated with the researcher’s experiences interviewing the participant was added. This naming process also enlisted the help of a patient safety and quality specialist at a local hospital to bring an external and expert eye to the data and therefore enhance the face validity and credibility of the names assigned to themes (15, 16).
References:


Section 3: Manuscript

Note: The manuscript presented here is intended for submission to the *International Journal of Osteopathic Medicine* (IJOM). The manuscript is presented together with a COREQ checklist (see Supplementary Material) to ensure it is consistent with the standards being reported in IJOM.
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ABSTRACT

More Than Words: An Investigation into the patient experience of informed consent in Osteopathy

Medical informed consent is described as permission to perform mutually agreed upon examination and treatment after understanding the risks and benefits of multiple options. The informed consent process is at the heart of patient centred care and ethical practice in all health professions, yet there is a limited research base about patients’ lived experience of informed consent in an osteopathic context. Using semi-structured interviews, this study explored how six patients experience the informed consent process in a single New Zealand osteopathic clinical setting. Interpretative Phenomenological Analysis (IPA) was used to analyse these experiences. The results show that information exchange and active patient engagement play significant roles. The patients in this study have little recollection of an initial and explicit consent process but instead, describe the ongoing process of consent as their treatment progresses. Information from this research can be used to help osteopaths understand the patient experience of consent which could lead a greater collaboration between patient and practitioner.

Keywords: Consent, informed, osteopath, clinical, information exchange, active engagement
INTRODUCTION

Communication of treatment pathways, and of their associated risks and benefits in order to obtain truly informed consent is a key feature of ethical health professional practice and an administrative and legal obligation for healthcare practitioners (1-4). Yet, a definition of “adequate” informed consent, especially in applied clinical settings, continues to be a point of contention among health practitioners (2, 5). Historically, consent was described as a patient’s “right to determine what shall be done with his body” (6). In a more modern context, it has become more complex and nuanced (4). Conceptually, it is generally viewed as the patient giving their permission for the practitioner to perform mutually agreed upon treatments after understanding risks and benefits of possible treatment options and therapeutic interventions (2, 4, 7-10). A significant point of interest is recognising when and how consent is given or retracted within a clinical setting.

Although informed consent for osteopathic treatment is required and significantly rewarding for the therapeutic relationship (11), sub-par informed consent continues to be a significant contributor to patient complaints both internationally and within New Zealand (12-14). The investigations of complaints typically note that clear communication of the patient’s diagnosis, and risks and benefits of treatment, were lacking. The quality of practitioner communication directly affects patients’ decisions to give or withdraw their consent (5, 15, 16). While in areas, such as medicine, consent is a process driven by legislative and administrative protocol, patient education, and the explicit signing of a consent form (2, 17); in osteopathy consent procedures vary between practitioners and are often verbal or indirectly communicated within the course of a conversation. This highlights a need for improved practitioner understanding about how to interpret those unspoken forms of communication that may signal consent or otherwise. A greater understanding of the patient experience of granting informed consent may provide guidance for practitioners about the informed consent process.

Research into informed consent has been extensively conducted within the context of general practitioners and hospitals (4). However, there have been few investigations within the context of osteopathy. Current investigations only extend as far as
ascertaining the usefulness of a patient information leaflet (7) and preferred process of information exchange (18). Findings from these studies suggest that patients felt it was necessary to be informed about their possible treatment options and to share the decision making; however it can seem monotonous or unnecessary for a patient who visits an osteopath regularly for the same treatment. The patients’ lived experience of informed consent within an osteopathic setting has yet to be investigated. The aim of this study is to begin this investigation using semi-structured interviews and phenomenological analysis methodology.
METHODOLOGY AND METHODS

Study design
A qualitative research method of semi-structured interviews was used to investigate the patients’ lived experience of informed consent in their osteopathic treatments in New Zealand. Interviews provide an account of an experience that is rich in personal emotion, expression, and detail (19). A rigorous analysis of the data was done using an Interpretative Phenomenological Analysis (IPA) framework. IPA aims to understand and make sense of another person’s interpretation of a given phenomena in a given context (20). IPA was used in this study to capture not only the participant’s experience, but also to allow exploration of the meanings assigned to the experiences and the researcher’s interpretations (21-23). This study follows the reporting requirements outlined in the consolidated criteria for reporting qualitative research (COREQ) (24) – see supplementary material.

Participants
Participants were an osteopath and 6 patients who had received treatment at an Osteopathy teaching clinic in New Zealand in the past.

Inclusion criteria
To be included in this study, the osteopath was required to hold active registration with the Osteopathic Council of New Zealand, and a current Annual Practising Certificate.

For inclusion, patients were required to meet the following criteria:
1. be aged above 16 years to ensure that informed consent for the research can be provided as an adult in New Zealand;
2. had not received treatment from the participating osteopath in the past;
3. exhibited no ‘red flags’ at the time of consultation, including sudden onset of a severe headache, vomiting, disturbed consciousness, severe and debilitating pain.

Recruitment
Purposive sampling was used to find an osteopath who values informed consent as a tool to improve collaboration between practitioner and patient.
After eligibility was determined, the osteopath received a detailed explanation of the research investigation, which included a description of what was involved and the commitment they were making. A signed written consent form was completed by the osteopath before data collection began.

The researcher recruited a total of six patients through telephone conversations from the database of a single tertiary teaching clinic in New Zealand, where the researcher worked. Interested candidates were formally interviewed to discuss the research process and eligibility criteria. The first 6 eligible candidates were accepted. An appointment time was established where participants were further briefed with an information sheet and given the opportunity to have questions answered. Participants then gave written consent for the research and were enrolled in the study, at which stage they were introduced to the osteopath.

**Ethical considerations**

The study was approved by the Unitec Research Ethics Committee (UREC Approval No: 2016:1048). All participants gave written informed consent for their involvement in the research, prior to the consultations commencing. Participant privacy is protected by the use of a secure location to store physical material, and password encryption for electronic data. All participants were offered the opportunity to withdraw their involvement and their interview data, from the study up to five working days after their recorded consultation.

**Procedures**

The procedure to undertake this research investigation involved: (1) the patient and osteopath were introduced to one another and directed to the consultation room by the researcher; (2) the researcher turned on the audio recorder and left the room; (3) the osteopath was provided with a pro forma case history form to take notes throughout the consultation and a checklist of aspects of informed consent to be covered in each consultation; (4) the osteopath left the room to signal to the researcher the consultation had been completed; (5) the researcher entered the consultation room to stop recording the consultation and begin recording the semi-structured interview; (6) at
the interview’s conclusion the patients were offered a booking with a senior student osteopath in the tertiary clinic for ongoing care; (7) the osteopath was asked to write a brief guided reflection after each consultation.

The consultations were completed at a tertiary teaching institute in New Zealand. Audio recordings of the consultation and patient interviews were completed using the Voice Memos application on an iPhone 6. All data were downloaded and stored on an encrypted flash-drive. All original files were immediately disposed of. Access to the information was given to the researcher and supervisors, upon request. All data will be retained for 10 years following the date of the consultation and securely stored in a locked filing cabinet at the researcher’s residence.

After each consultation, the osteopath completed a 10 minute guided reflection to provide an insight into how they believed the informed consent process went. This aided the researcher in contextualising the phenomenon by understanding the osteopath’s intentions. However, this data was not included in analysis as it did not provide further insight in the patient experience.

At the conclusion of the consultation, five of the six participating patients completed their interview. In one case, the interview was undertaken within 24 hours.

Data Analysis
All patient interviews were transcribed verbatim and anonymised prior to analysis. Each transcript was read through once initially while listening to the interview audio to ensure transcription reliability. An Interpretative Phenomenological Analysis framework was used to analyse this data (25). Each transcript was analysed individually with full immersion through reading and re-reading. Initial noting and developing of emergent themes were completed using a colour-coding system. Connections between these themes were sought before moving on to the next transcript. An electronic mind map was created using Debategraph to identify the type, and strength, of the relationship between the themes in each transcript. This rigorous analysis of the intricacies and connections between the themes were reviewed to ensure they reflected the true meaning of the collected data.
The last step was to categorise and name the final themes. Secondary thematic analysis was undertaken at a meeting of the researcher and one of the supervisory team. In this phase, the initial themes were defined, refined and renamed to determine the story of each theme and its link to data. An informative name for each theme that resonated with the researcher's experiences interviewing the participant was added. This naming process also enlisted the help of a patient safety and quality specialist at a local hospital to bring an external and expert eye to the data and therefore enhance the face validity and credibility of the names assigned to themes (26, 27).
RESULTS

The following comment by one respondent sums up the patient experiences of consent:

“The word "consent" was not used at any stage.” (P1)

Despite all participants describing their ongoing approval of treatment, none could recall any explicit use of the word consent. Their consent to osteopathic treatment appeared to take the form of ongoing permission throughout conversations in the consultation. The participants described multiple ways beyond the use of words, that they had provided consent. Five participants reported that their previous experiences as an osteopathic patient had already set their expectations about what would occur in the consultation. Four of these participants also suggested that volunteering to be physically present in an osteopathic consultation implied their consent. Two participants mentioned an ‘end justifies the means’ perspective which in their view, explained why giving consent was neither expected nor an explicit part of the consultation process. Feelings of comfort, being at ease, and having confidence in the osteopath’s clinical skills also emerged as key components of the patient experience of providing consent. Within this dynamic ongoing and interactive process, three significant themes emerged: the conversational nature of ongoing permission; Information processing and prioritisation; [and] Participatory nature of consent.

Theme 1: Conversational nature of ongoing permission

There were a variety of patient descriptions of how they delivered their permission for treatment. Firstly, a clear theme emerged from all six participants’ accounts that permission was giving in a relaxed and conversational manner throughout the entire consultation. This manner included both verbal and non-verbal elements.

Secondly, all participants mentioned that the osteopath used descriptions and clinical justifications to gain consent for their approach to treatment. Five participants reported that the osteopath provided clinical justification for the diagnosis and use of treatment. Three participants felt the osteopath adjusted their explanations to suit their levels of understanding. These changes made information easier to understand because it was non-technical and concise. Most participants noted the close time proximity between
what the osteopath said they were about to do, and what was actually done. This increased patients’ levels of confidence as the relevance of the treatment became more immediately obvious.

### Table 1: Conversational nature of ongoing permission

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<thead>
<tr>
<th>Example</th>
<th>Interpretation</th>
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<tbody>
<tr>
<td>“I’m focused on whether or not I can see the rationale for what they’re going to do, and then I’m happy for them to proceed.” (P2)</td>
<td>Clinical approach described and justified</td>
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<td>“Well, it was clear, he explained to me what he was gonna do and I understood what was gonna happen. It was very good... Oh, just enough to let me know what was gonna happen... Didn’t go on for hours.” (P6)</td>
<td>Expectations established Concise information</td>
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<td>“It (consent) was kind of like normal conversation, basically.” (P1)</td>
<td>Consent through ongoing conversation</td>
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<td>“He got my hand and got my thumb and put it in the same place and found the same thing and said, &quot;Now you press,&quot; so I could experience that.&quot; (P2)</td>
<td>Consent given after technique modeled</td>
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<td>“He asked me if I was feeling discomfort and I know that I was clenching my teeth at spots.” (P5)</td>
<td>Non-verbal cues successfully communicating state of consent.</td>
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<td>“He guided me through the whole treatment with regard to how I would feel and kept saying, if anything was too much, I could stop it. He was kinda telling me I’m part of the deal here. Yeah, so I was quite happy with all of that.” (P5)</td>
<td>Comfortable with withdrawing consent</td>
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<td>“As he was doing each part of the treatment, he was explaining it to me, all the way through.” (P1)</td>
<td>Steady flow of information provided</td>
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<td>“It just kind of happens quick, you don’t really realize that it’s happening. It’s just basically explaining what’s wrong and saying, “This is what I’m gonna do,” and then if you want that... If you feel comfortable with that, then that’s what happens.” (P5)</td>
<td>Consent within casual conversation. Comfort as component of consent.</td>
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<tr>
<td>“As a patient, you’re not focused on allowing this person to do... You don’t have the concept of permission in your mind.” (P2)</td>
<td>Patient focus</td>
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Thirdly, participants identified a number of non-verbal cues such as nodding, grimacing, and following the osteopaths’ instructions as ways to successfully communicate their
permission. Five participants felt they were continuously reaffirming their consent for treatment by responding to the osteopath’s regular questions about levels of pain and being asked if everything was ‘OK’?. This continuous cycle of revisiting the patient’s verbal consent and communication assured two participants that they could withdraw permission at any time. Two participants reported that the osteopath used non-verbal communication such as modelling in less vulnerable areas of the body, such as the arm, to indicate what a technique will feel like, and help gain permission.

**Theme 2: Information processing and prioritisation**

The second significant theme that emerged encompassed how patients experienced information exchange and processing throughout the consultations. Two participants reported that processing the clinician’s information was in itself a positive form of treatment. Receiving and processing information about their presenting complaint, treatment, prognosis, and their suggested self-care strategies made five participants feel more empowered, reduced their stress, and challenged their own pre-set expectations around their behaviours, current self-care regime, and presenting complaint. This increased their confidence in themselves and the osteopath’s clinical skills, which in turn deprioritised the need, in their view, for an explicit consent procedure to be enacted.

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<tr>
<td>“Yeah, except for when he got some of the technical body parts, 'Cause, not having a medical background, I don’t know any of them.” (P1)</td>
<td>Terminology as barrier to understanding.</td>
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<td>“I’d rather they just focus on the job... I do have further questions, but I sort of just focus on the main points 'cause it really becomes information overload, actually.” (P2)</td>
<td>Pain relief prioritised above clinical knowledge. Perceived relevance of information affects memory. Questions as a distraction from treatment.</td>
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<td>“There are some things I can recall quite easily, other things I can’t. The fact that he made me feel better was okay.” (P1)</td>
<td>Memory and recall difficulty. Vulnerability.</td>
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<tr>
<td>“Risks, risks? I didn’t identify ’em or didn’t lock into my head anyways.” (P5)</td>
<td>Risk perception is patient specific.</td>
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“Well, for me, I’m an analytical type, so when he gives me the explanation I think of about 20 questions, but I don’t wanna ask them... I’d rather they just focus on the job. I do have further questions, but I sort of just focus on the main points ’cause it really becomes information overload, actually.” (P2)

Pain relief prioritised above clinical knowledge. Questions as a distraction from treatment.

“I thought his explanations were probably the most clearest I’ve received... I think his articulate explanations engendered confidence... and makes you feel that this person knows what they’re doing.”. (P2)

Patient empowerment through information. Clarity of information engendered confidence in practitioner.

“He mostly gave me information, and I don’t really need anymore at that point. “ (P3)

Expansion of knowledge around condition

“Everything that was happening was all being explained as we were going through the procedure.” (P4)

Ongoing information throughout consultation

“When you get to my age and you get so many aches and pains, it’s nice to have it in your mind that you understand it. Now, if you don’t understand it, your brain drifts. It drifts with problems. So, you get up in the morning and you feel that thing and you say, "Oh, when is that gonna go away?" Now, if you can get a little bit more confidence boost, it takes a lot of the stress out." (P6)

Processing information as treatment.

Five participants rated gaining pain relief from the consultation a higher priority than being made aware of, or informed about the clinical context. Three of these patients perceived themselves as damaged, vulnerable, or broken. This hindered their memory and recall of information as they did not feel adequately equipped to process information about their complaint. The speed of information delivery and use of technical terms were also mentioned as factors that reduced their processing and retention of information. This suggested that patients deprioritised clinical justification for the treatment they were about to receive, whether it was paced carefully or hurriedly completed, in favour immediate pain relief.

Four participants mentioned they were given opportunities to ask questions. However, this was rarely used as it was perceived as a distraction from treatment or they felt that enough information had already been provided.
Despite the osteopath providing clear information about the potential risks and benefits of treatment, of interest is that one particular participant mentioned that they did not perceive these as risks, due to their previous positive experience receiving osteopathic treatment from other practitioners.

**Theme 3: Participatory nature of consent**

Engagement levels throughout the consultation was a common theme among participants. When asked about how they gave their consent, participants identified *engagement* and described it in a number of ways. Actively engaged participants acknowledged that they needed to involve themselves throughout the consultation through participation, shared decision-making, and a desire to understand what was happening to them. Four participants manifested this active engagement through the importance they ascribed to their self-care exercises, practitioner advice and knowing what their bodies needed. Many participants who were actively engaged felt their treatment was a collaborative experience with the osteopath. This experience of an interactive way of working acted as its own generator of consent.

**Table 3 Participatory nature of consent**

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<th>Example</th>
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<tr>
<td>“I like being participatory. I like hearing what things they’re doing and how it’s going to feel for me and that I can actually say, “Gee, that hurts,” and he’ll stop.” (P3)</td>
<td>Acknowledged need to involve self throughout consultation.</td>
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<td>“With the flow of information... My feeling is that I was involved” (P3)</td>
<td>Actively involved in decision making through conversation. Consultation is a collaborative partnership with osteopath.</td>
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<td>“He's given me some exercise to take away, which I like. Quite like to do that myself.” (P3)</td>
<td>Actively engaged in self-care.</td>
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<td>“I could understand why some people would feel the desire to... To give in to do what they're told by a professional, I don't have that.” (P5)</td>
<td>Appreciates importance of active participation throughout consultation</td>
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<td>“I figured that I’m sufficiently assertive that if something would bother me that I'd speak up, so I didn't really consciously pay a lot of attention. I know that he did say, “Hey, you're in charge.””</td>
<td>Increased awareness of self improves patient autonomy.</td>
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On the other hand, passive engagement in the consultation was manifested in only one participant's responses in which they revealed that they felt overwhelmed at times by the level of communication. This cognitive overload decreased their cognitive awareness of their physical self and their desire to take responsibility for their own personal healthcare. Informed consent, in this case, was centred on trust in the practitioner's skills in the absence of any sound appreciation of chosen treatment strategies.

<table>
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<th>(P5)</th>
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<td>&quot;No, it just kind of happens quick, you don’t really realize that it’s happening kind of. So it’s just basically explaining what’s kind of wrong and saying, &quot;This is what I’m gonna and do,&quot; and then you kind of... Obviously, you want that... If you feel comfortable with that, that’s what you wanna do, then that’s what happens.&quot; (P4)</td>
<td>Overwhelmed with speed of information delivery. Trust in practitioner decisions.</td>
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DISCUSSION

The study has first and foremost affirmed that consent in osteopathy is an active and on-going process, one that is dynamically different to consent for other healthcare disciplines such as surgeries (8, 10, 28-30). In addition, the study has identified three themes related to patient consent and ongoing permission that expand our understanding of what constitutes “informed” consent from the perspective of the patient. These are: ‘Conversational nature of ongoing permission’, ‘Information processing and prioritisation’, ‘Participatory nature of consent’. Each theme identifies a different aspect of patients’ experience of informed consent.

The first identified theme ‘Conversational nature of ongoing permission’ describes the types of verbal and non-verbal communication that occurred throughout the consultation. Communication is defined as “the process of creating shared understanding” (31). Although gaining pre-treatment consent was deliberately attempted for each patient, the experience more commonly recalled was that of a conversation delivering ongoing agreement. The osteopath’s conversational approach used throughout the consultation created a shared understanding of permission being requested and granted by the patients. This corresponds with research suggesting that this is the preferred method of obtaining consent in osteopathy for patients (18). However, the participants did not consistently attribute to this conversation, as the granting of explicit verbal consent. This is possibly related to the absence of any standardised procedure to be followed that will comprehensively capture each patient’s informed consent (5).

Gaining informed consent in osteopathy is an ethical and legal obligation as set out by the New Zealand Health and Disability Commissioner (HDC) and Osteopathic Council (OCNZ). According to the HDC, written consent for a healthcare procedure is only required if their risk for adverse effects is significant (32). When these significant risks are not present, consent can be obtained in any form, such as the conversational form experienced in this study, as long as the expected risks and benefits of treatment have been discussed (32, 33). However, if patients do not believe that explicit consent has been granted, this could cause potential ethico-legal issues to arise where the
practitioner has assumed consent because the patient was actively engaged in conversation.

Despite the potential for misinterpretation, in this study, the continual provision of consent through the conversation did reassure patients that they could withdraw their consent at any time. Participants felt guided through the consultation and their responses to the osteopath’s communication constituted ongoing agreement for the treatment to continue. Specifically, these conversational interactions made participants feel they were consenting to the case history, examination, treatment, and post-treatment care in real time, as required. This reiterates two important points: first that consent is not a one-time event, but a continual process of specific re-evaluation and re-consenting (2, 4, 34). Second, that maintaining open communication about clinical reasoning is both desirable and important (5, 16, 35). Open communication impacts the comfort levels of patients, which in turn relates to them consenting to particular treatments or procedures (16, 36). The more relaxed a patient is about treatment processes, the more likely they will understand and consent to that procedure being done, even if, as some participants suggested, such reasoning was ostensibly of little relevance or value to them.

The open continual communication participants experienced throughout the consultation consisted of both non-verbal and verbal cues. The non-verbal cues mentioned by participants included the osteopath’s open and confident posture, the patients’ own facial expressions, eye contact, and the environment of the clinical setting. These non-verbal cues worked to inform the osteopath what level of pain or discomfort the patient was experiencing with a movement or technique, or if they had misunderstood some information or instruction, and might withdraw consent to continue. Participants recalled that this was a successful form of communication because as the osteopath readily picked up on these cues, they responded appropriately by questioning if it was fine to continue, and if consent to treat was maintained. The dynamic interaction of non-verbal and verbal cues in a clinical setting have been found in previous research to help create patient-practitioner shared understanding (16, 37-39) and shape and maintain informed consent (16, 34, 36, 40, 41). These findings also align with those in the research literature that shows that non-verbal communication
directly affects the quality of patient-centred communicative interaction and levels of patient satisfaction (37-39). In this study, the non-verbal cues worked dynamically with the verbal communication to ensure patients continued their active consenting through the entire consultation period.

In terms of the content being verbally communicated, participants regarded having the clinical approach described and justified as the most important information upon which to base their consent. This suggests a robust link between the exchange of information about clinical reasoning and the provision of informed consent (16, 42, 43). The clinical information established their expectations for the imminent examination, treatment, and prognosis. Participants in this study who experienced and understood the clinical reasoning behind techniques felt more trust in the osteopath’s skills. This is a phenomenon that Fiscella et al. also identified (35). The importance of communicating clinical reasoning to patients also aligns with Carnes’ (12) findings that the absence of a communication around clinical justification was one of the main reasons for patient complaints. Therefore, communicating clear clinical justifications about prognosis and treatment is a vital constituent element of the ‘informed’ part of informed consent.

The second theme identified in this research was ‘Information processing and prioritisation’. Participants were visiting the osteopath because they perceived themselves as broken or injured, and in a vulnerable state. Despite clinical reasoning being identified as an important aspect of gaining consent, they reported that knowing why a technique was being performed was less important than the potential it offered to relieve pain. A related factor was levels of trust participants felt based on their prior knowledge from previous experiences (34, 44). When participants were asked, many could not recall the risks explained by the osteopath, because they did not perceive the information provided as risks and trusted the practitioner’s clinical expertise. In turn, this meant that they retained less knowledge about the treatment process. This professional trust reduced the patients’ need for explicit consent.

It is common for patients to remember approximately half of the information disclosed throughout the informed consent process (29, 30, 45-47). Prioritising pain relief and naive trust attribution over information processing create medico-legal implications for
the informed consent process. If risks and benefits of possible treatment options fail to be explicit enough for patient comprehension, there is a risk that the informed consent hasn’t been gained (2, 4, 32, 33, 43, 48-51). This emphasizes the point that although patients may believe that the information provided has been sufficient, it may not necessarily be understood (4, 43). As Leach et al (7) has noted in their study, participants mentioned that no one had discussed risks or if they did, they didn’t take any notice of them. Yet patients do feel it was necessary to be informed about likely risks and benefits of their possible treatment options (7, 15, 52, 53). Even where pain relief is a priority, or prior experience has created a high trust environment, it is incumbent upon the practitioner to ensure patient comfort and clear communication is maintained throughout the consultation. Thereby reducing the feeling of vulnerability and patient unease, from which possible complaints or concerns may result (12-14, 51).

Participants’ consenting behaviours, and what information they retained, misunderstood, or assumed were also influenced by the terminology the osteopath used and the speed with which they presented the information. The anatomical terms used by the osteopath was regarded as unnecessary academic background and contributed to difficulties retaining information for consent purposes. The speed with which the osteopath explained the treatment processes was satisfactory for most participants. However, one comment highlighted the need for osteopaths to judge if their speed of information delivery and type of content prevents rather than facilitates clear understanding and informed consent. Further, the information exchange was almost entirely verbal. It has been recognised that for information to be learned effectively, information should be presented in three different ways (54). Research within osteopathy has shown that a combination of good verbal explanations, anatomical models, images and written information is preferred by patients (18, 50). Skillfully combining multiple verbal and visual modes to inform and educate patients can enhance memory recall of information provided for the consent process (2). In addition, to ensure that the effect extends well beyond a slight increase in information retention (55), the volume and relevance of information given must be considered, especially when that information is generically presented in writing (15, 56, 57). Personalised multimedia resources and structuring information into concise summaries of essential information could help minimise barriers to information retention and shift the focus
away from the dominant of oral delivery of the osteopath (15, 56, 57). Such steps will help practitioners and patients reach a robustly consented, understanding of treatment pathways through a more balanced use of verbal, visual and written communication strategies.

The study identified a variety of effects participants experienced after receiving information in their consultations. The information the osteopath provided them with was a working diagnosis, clinical reasoning and rationale, risks and benefits of treatment, prognosis, and self-care advice. There was a significant affective consequence from patients receiving this information. Participants felt confident, empowered, and comfortable with their broadened knowledge of their condition. These findings identified that the comfort and confidence that participants experienced as a result of the quality of practitioner communication, play a significant role in the ongoing affirming of their consent. This reinforces that the ‘informed’ part is equally, if not more, important than the ‘consent’ itself. The research literature links this ‘informed’ point strongly with the ethos of patient-centred approaches to care, which benefits the therapeutic relationship, and makes patients’ participation in following treatment plans more likely (11, 43, 58, 59). Conversely, providing inadequate information risks negating the patients’ right to autonomy and consent, and could be viewed as failing to adhere to the ethico-legal duties of a healthcare practitioner (32, 33, 42). Consistently providing relevant information not only promotes patient-centred care but creates the conditions for patients to give consent which is informed by accurately explained and understood clinical reasoning (34).

The third theme that emerged was the Participatory nature of consent. This means that patient perceptions of how informed consent was delivered and received depended upon how engaged they felt in the consultation process. Patient engagement and active participation in clinical discussions are linked to how open the communication is between the two parties (38). There were clear differences between participants who were actively engaged and those who were passively engaged in their consultation and care. The actively engaged participants often referred to having an increased awareness of self and a desire to participate in decision making throughout the consultation, which in turn made consent easier to give. This could indicate that these participants had
higher health literacy than others. This varies from a phenomenon often found in the literature where patients wish to be informed but not involved (2, 60, 61). Conversely, a participant who was more inclined to be passive throughout the consultation mentioned that they felt no collaborative partnership with the osteopath. This manifested as a feeling of being overwhelmed, decreased awareness and interest of their physical body. This could have implications for providing consent for treatment as the patient does not feel informed and could feel pressured into consenting. Therefore, participation and engagement levels of patients can inform the degree to which consent was readily provided. For participants who passively engaged throughout the consultation, patient-centred care was very low, the osteopath was put in charge of all decision-making and consent was given without a desire for information, a situation considered harmful to patient autonomy and shared-decision making (2, 3, 48, 49). It also carries a risk that these patients did not always recognise when they were providing permission for treatment, which could potentially lead to a complaint if any adverse event were to occur. On the other hand, engaged patients in the consultation expressed a sense of control around their condition and took personal responsibility for their own health and care. Informed consent was easier for these patients to give and recall.

Participants felt that they engaged when the osteopath invited them to participate in demonstrating self-care exercises, such as stretches or encouraged responses within their conversation. For example, when the osteopath provided them with a decision to make, or information about alternative treatment options. One notable form of patient engagement was when the osteopath demonstrated a technique on a less vulnerable area of their body to set expectations and gain consent to apply the technique to the affected area. This allowed patients to experience and feel what a technique would be like to determine whether they would consent to the same technique being applied to the sensitive area, such as the front of the neck. Modeling techniques in a less vulnerable area beforehand set patient expectations about what they will experience with the technique. Although the study did not directly address cultural issues of treatment it is worth noting that within a multicultural population, or with patients who have experienced domestic violence in New Zealand (62), certain body areas could have increased emotional and physical sensitivity or cultural significance. This respects their
personal and cultural background and allows them to consent safely or withdraw consent should they feel uncomfortable or culturally unsafe.

For participants in this research, previous positive experiences of osteopathic care were identified as an important variable leading to implicit consent as these patients entered the consultation with pre-established expectations. This meant that a number of patients already felt an automatic level of comfort and safety throughout the consultation, and implied their consent by allowing the consultation to proceed without dissent or complaint. Although forms of implied consent was a common feature for these participants, it should not be the only form of consent obtained. However, this accounts for explicit consent, particularly verbal consent, being largely absent from participants' focus or responses. Other expressions of implied consent manifested as patients' expression of confidence in the osteopath, active participation, and being physically present in an osteopathic consultation.
CONCLUSION

This study provides an insight into the patient experience of informed consent in osteopathy. This study suggests that the patient experience of consent is more than an explicit verbal confirmation of comfort and safety or a prescriptive protocol applied uniformly across all consultations. The significant variables that influence the consent process are the quality of verbal and non-verbal, communication between the osteopath and their patient. The study reaffirms that gaining consent throughout each subsequent treatment is not just a medico-ethical imperative, but builds a sense of treatment partnership; even if it at times it may feel arduous, repetitive or considered unnecessary for both the osteopath and patient. In essence, omitting some form of on-going strategic consent process could constitute a risk to the therapeutic relationship.

The study has indicated that when patients feel involved, informed, and invested in their personal healthcare, they are likely to give truly informed consent, be it explicit or implied for the treatment process. Greater understanding of the patient’s perspective of the consent experience can lead to improved professional development in the way osteopaths communicate with their patients to gain their consent for treatment. The findings from this study are clinically relevant for all manual therapists and could be implemented immediately to encourage mutually safe patient-centred care and have implications for the number and frequency of concerns voiced, or complaints laid against osteopaths.

Limitations of this study include patient variability of informed consent experiences, small sample size, and that the osteopath works in a New Zealand osteopathic teaching clinic which could provide a consent process that is not necessarily generalisable to the osteopathic population in New Zealand or internationally. Another limitation that has been identified is that the patients had different responses to the treatment, which could be a result of the osteopath’s behaviour changing towards each patient. However, these limitations do not affect the findings significantly as the patient experience of informed consent has been rigorously analysed and is valid for the context within which it was researched.
Previous research around informed consent has primarily focused on hospitals, doctors, and surgeries (8, 10, 28, 48). This study has highlighted a potential difference in the very nature of informed consent as it relates to ongoing treatment especially in manual therapies, rehabilitation and complementary medicine contexts.

This study opens a new area of potential future research within a complementary medicine context. Potential research questions relate to what may prove to be an evolving and dynamic process of consent: one that changes and develops as treatment progresses. For example, does pain override considerations of risk on early visits and once pain is reduced or better managed does the consideration of risk or new pain effect the consent process. Do evolving goal setting and assessment processes in collaboration with the patient become an integral part of informed consent as the treatment timeline advances and does a meaningful consent process change and evolve

The limitation of transferability is noted. Similar studies could be replicated to include more osteopaths from different areas, to gain an understanding of the patient experience that could be more transferability to a population. The osteopath's experience of informed consent could be researched to see if it aligns with that of their patients. The impact and importance of ongoing consent and communication research for both osteopaths and patients could generate useful findings and conclusions that give more informed guidance to practising osteopaths, their regulatory environment, and national governance bodies. Research into strategies that minimize the effects of age, education, cognitive function, and anxiety (10, 45, 47, 63) on information retention could be of use.
REFERENCES:


Supplementary Material:
Consolidated criteria for reporting qualitative studies (COREQ): 32-item checklist


The criteria has been formatted as: Item number – Guide questions/description

DOMAIN 1: RESEARCH TEAM AND REFLEXIVITY
Personal Characteristics
1. Interviewer/facilitator – Which author/s conducted the interview or focus group?
Principal researcher (Caitlin Kilpin)

2. Credentials – What were the researcher’s credentials? E.g. PhD, MD
BAAppSc (Human Biology), Master of Osteopathy student.

3. Occupation – What was their occupation at the time of the study?
Student

4. Gender – Was the researcher male or female?
Female

5. Experience and training – What experience or training did the researcher have?
Two years of clinical experience in an osteopathic tertiary teaching clinic; no previous research training

Relationship with participants
6. Relationship established – Was a relationship established prior to study commencement?
The researcher had spent time with the participating osteopath during time in the tertiary teaching clinic. There was no relationship with the patient participants of this study prior to its commencement.
7. Participant knowledge of the interviewer – What did the participants know about the researcher? e.g. personal goals, reasons for doing the research.
All participants recruited understood that the researcher was completing this study to partially fulfill the requirements for the Master of Osteopathy degree.

8. Interviewer characteristics – What characteristics were reported about the interviewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic
The researcher developed an interest in the topic of informed consent during the practical component of her undergraduate and masters degree.

DOMAIN 2: STUDY DESIGN

Theoretical framework
9. Methodological orientation and Theory – What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis
Interpretative phenomenology analysis

Participant selection
10. Sampling – How were participants selected? e.g. purposive, convenience, consecutive, snowball
Purposive sampling for osteopath and convenience sampling for patients.

11. Method of approach – How were participants approached? e.g. face-to-face, telephone, mail, email
Osteopath: Email invitation
Patients: Formal telephone conversation.

12. Sample size – How many participants were in the study?
Osteopath: n=1
Patients: n=6
Total: n=7 participants
13. **Non-participation – How many people refused to participate or dropped out? Reasons?**

No participants refused to participate or dropped out throughout the study.

**Setting**

14. **Setting of data collection – Where was the data collected? e.g. home, clinic, workplace**

A single tertiary osteopathic teaching clinic

15. **Presence of non-participants – Was anyone else present besides the participants and researchers?**

No

16. **Description of sample – What are the important characteristics of the sample? e.g. demographic data, date**

No demographic or age data was collected. All participants were above the age of 16 years old as a requirement to participate.

**Data collection**

17. **Interview guide – Were questions, prompts, guides provided by the authors? Was it pilot tested?**

The interview questions were piloted prior to data collection using two people not related to osteopathy or the study.

18. **Repeat interviews – Were repeat interviews carried out? If yes, how many?**

No repeat interviews were carried out.

19. **Audio/visual recording – Did the research use audio or visual recording to collect the data?**

Audio recording was used to collect the data.

20. **Field notes – Were field notes made during and/or after the interview or focus group?**

Brief field notes were made with timestamps throughout the interview. Further field notes were made after the interview.
21. Duration – What was the duration of the interviews or focus group?
Audio recorded interviews lasted between 15 and 25 minutes.

22. Data saturation – Was data saturation discussed?
Following the conclusion of the patient interviews, the researcher and primary supervisor discussed data saturation. It was decided that the richness of the data obtained from 6 patient interviews was sufficient to achieve the research aim.

23. Transcripts returned – Were transcripts returned to participants for comment and/or correction? Yes – Transcripts were returned to the participants. No comments or corrections were made.

DOMAIN 3: ANALYSIS AND FINDINGS

Data analysis

24. Number of data coders – How many data coders coded the data?
One data coder- the principal researcher (Caitlin Kilpin)

25. Description of the coding tree – Did authors provide a description of the coding tree?
A description of the coding tree is not present in the manuscript.

26. Derivation of themes – Were themes identified in advance or derived from the data?
All themes were derived from the data.

27. Software – What software, if applicable, was used to manage the data?
DebateGraph

28. Participant checking – Did participants provide feedback on the findings?
No participants provided feedback on the findings.

Reporting

29. Quotations presented – Were participant quotations presented to illustrate the themes / findings? Was each quotation identified? e.g. participant number
Yes- Quotations were extracted from the data and referenced to each participant e.g. P1, P2

30. Data and findings consistent – Was there consistency between the data presented and the findings?
Yes.

31. Clarity of major themes – Were major themes clearly presented in the findings?
Yes.

32. Clarity of minor themes – Is there a description of diverse cases or discussion of minor themes?
Yes, three major themes were discussed and no minor themes were identified.
Section 4: Appendices
Appendix A: Practitioner Information Sheet
Information sheet for osteopaths
An explorative phenomenological study of six patients’ lived experiences of informed consent in an osteopathic clinical consultation.
Start date: 24/08/2016
Finish date: 24/08/2017

About this research
You are invited to participate in a research project investigating the informed consent process used in an osteopathic consultation. Consent is a key constituent of any consultation with a health professional. You have been invited to participate because it is believed that you value informed consent as a tool to improve collaboration between practitioner and patient. It is important to understand the lived experiences in this context to ensure the processes used are adequate to fit yours and the patient’s needs.

What will happen in this research?
You are invited to take part in a research study involving six patients. The events will be as follows:

- The researcher will explain the purpose of the research and discuss any questions or concerns you may have. You will then be asked to read and sign a written consent form.
- You will work with the researcher to create an informed consent checklist and guided written reflection template.
- You will approach six patients who are new to your practice and inform them about the study prior to their appointment time. Information sheets will be given to you for this reason. You will ask the patient if there are interested in participating. If yes, you will let them know that you will pass their contact details onto the researcher. The researcher will then determine the patient’s eligibility and explain the research process. Written consent will be gained at this point.
- At the scheduled appointment time, you will be asked to use a voice recorder to record the entirety of the consultation with the patient. The checklist that was created at the beginning will be used throughout these consultations.
- At the conclusion of the consultation, you will be asked to complete the written reflection. The opportunity to edit these reflections will remain until 48 hours after the consultation.
- This process will be repeated six times.

What do I need to do?
You will be asked to:

- Invite six new patients participants to participate.
• Collaborate with the researcher to create a checklist of items that need to be addressed in an informed consent process. This checklist must be used with each patient participant.

• Collaborate with the researcher to create a guided written reflection that will be used at the conclusion of each studied consultation.

• Agree to audio record the entirety of your initial consultation with the six patients.

You will have the opportunity to review and edit any of the six written reflections up to 48 hours after the consultation.

**How will the data be stored?**
All research data will be saved to the researcher’s personal computer hard-drive in a password-protected file. A copy of the password-protected file will be made to a flash-drive to be used as a back-up. You will have the opportunity to keep a copy of the written reflections and audio from the consultations. This may be used within a professional development reflective framework. All research data will be retained for 10 years following the date of the consultation and securely stored in a locked filing cabinet at the lead researcher’s residence. After which, it will be disposed of.

**Information about withdrawing from the study**
You may withdraw your data and subsequent participation from the study up to five working days after your final reflection.

**Personal information confidentially and security**
Your confidentiality in this research cannot be guaranteed. The research party and patient participants will know that you are participating. If a patient participant mentions your name or clinic throughout data collection, a pseudonym will be assigned throughout transcription. There will be no identifiable features of your identity or clinic in the final script. At the conclusion of the study, you will have the opportunity to utilise the guided reflections, recorded consultations, and published interview data for their individual professional development. However, this would limit your confidentiality and anonymity.

You will have the opportunity to receive an electronic copy of the research findings at the conclusion of the study. The results from this study may be published in a journal.

If you have any further questions about this research please don’t hesitate to contact the following:

*Researcher:*
Caitlin Kilpin
Tel: 027 847 4223
Email: caitlinkilpin@gmail.com

*Research Supervisor:*
Principal Supervisor:
Dale Sheehan
dsheehan@unitec.ac.nz
Appendix B: Practitioner Consent Form
An explorative phenomenological study of six patients’ lived experiences of informed consent in an osteopathic clinical consultation.
Start date: 24/08/2016
Finish date: 24/08/2017

Participant name: ______________________________________________

I have reviewed the information sheet about this research project. I have read and understood the information sheet presented to me. I have had the opportunity to discuss any queries or concerns regarding this research with the researcher, Caitlin Kilpin, and am satisfied with the explanations given.

I understand that participating in this project is my own choice. I consent to collaborating with the researcher to design an ideal informed consent checklist and guided written reflection template. I consent to approaching six new patients in my private practice to participate, audio recording their initial consultations, and completing six written reflections afterward. I recognise that I may withdraw my own data (audio from six consultations and six written reflections) from the study up to five working days after the final reflection. I understand that pseudonyms will be used to disguise my identity and any information reported will not identify me, or my clinic, in any way. I acknowledge that I will have the opportunity to review and edit my six written reflections, and the researcher will be in contact within 48 hours of the accompanying consultation to make this opportunity available. I have been provided with the researcher’s contact details as well.

I understand that anything I say in six written reflections will remain confidential and that only the researcher (Caitlin Kilpin) and her supervisors will have access to these. I acknowledge that I may keep a copy of the guided written reflections and audio from the consultations to use within a reflective professional development framework.

I understand the six written reflections will be securely stored on the researcher’s hard-drive and an encrypted back-up will be stored in safe and separate locations. I acknowledge that all data will be retained for a period of 10 years, and kept at the researcher’s secure residence. At the conclusion of this time, all data will be destroyed. I give permission for the analysed findings published from this research project to be drawn upon and utilised to inform future research projects. I also give permission for anonymised data to be utilised in future publications of this research project.

I acknowledge that I can see the finished research document and that the results from this study may be published in a journal.

I have had adequate time to consider everything and I give my informed consent to be a part of this research project.

I know whom to contact to discuss any questions or concerns about this project.
The researcher is: Caitlin Kilpin
Caitlinkilpin@gmail.com
Tel: 027 847 4223

Participant Signature: ................................ Date: ................................

Project explained by: ........................... Signature: ........................... Date: .................

Thank you for participating in this research.
Appendix C: Patient Information Sheet
Information sheet for patients

An explorative phenomenological study of six patients’ lived experiences of informed consent in an osteopathic clinical consultation.

About this research
You are invited to participate in a research project exploring the informed consent processes that your osteopath uses. Consent is giving your permission to the osteopath to examine and treat you. Consent and the patient experience in an osteopathic setting has not been well researched. This research will guide further research which hopes to provide an insight in how consent can be improved to fit your needs as a patient. Please note that participation in this research will not impact on your osteopathic treatment or management.

What do I need to do?
If you are expressing interest in the research project, your osteopath will provide the researcher with your contact details. The researcher will contact you to discuss whether you are eligible to participate. You will have the opportunity to discuss any questions or concerns with the researcher. You will then be asked to read and sign a written consent form to demonstrate your understanding and willingness to participate. This study involves recording the audio from your initial appointment and participating in an interview (approximately 30 minutes) afterward. You will be asked to a series of questions about the appointment and the audio from this interview will be recorded. The interview may be conducted by phone or face-to-face up to 48 hours after your appointment.

Data Transcription
An external party with no association to the research project will be asked to transcribe the interview audio. This external party has signed a written confidentiality agreement. You will have the opportunity to review your interview transcript and you may use this opportunity to add or remove any information and check for accuracy. The researcher will contact you for this reason. The only people who will have access to your individual interview data after transcription will be the researcher and research supervisors. The researcher will transcribe the data specifically related to informed consent that was recorded throughout the appointment. The osteopath and research team will have access to this data.

Information about withdrawing from the study
You may withdraw your own data (interview and appointment audio recordings) from the study up to five working days after your interview.

Personal information confidentially and security
Your real name and information will be kept strictly confidential. All information will be stored in an encrypted file on the researcher's personal computer and flash drive. All original files will be deleted. The only people who will have access to your interview data and personal information will be Caitlin Kilpin and her research supervisors. All data will be retained for 10 years following the date of the consultation and securely stored in a locked filing cabinet at the researcher’s residence. All efforts will be made to anonymise your identity. Throughout the transcription process pseudonyms will be used and any identifying features such as description of clothing, treatment, and area of pain will be removed before
publication. Due to the small sample size, there is a possibility that your data may be identifiable to the osteopath. This will not effect the treatment or management that you receive from the osteopath. However, the opportunity to review your interview transcripts will be given to highlight parts of the interview you believe could be used to identify you. As the results from this study may be published in a journal, the option will be given to remove these parts from the transcript completely or make them unpublishable.

You will have the opportunity to receive an electronic copy of the research findings at the conclusion of the study. The researcher will contact you to make these opportunities available.

If you have any further questions about this research please don’t hesitate to contact the following:

**Researcher:**
Caitlin Kilpin
Tel: 027 847 4223
Email: caitlinkilpin@gmail.com

**Research Supervisor:**
Principal Supervisor:
Dale Sheehan
dsheehan@unitec.ac.nz
Appendix D: Patient Consent Form
An explorative phenomenological study of six patients’ lived experiences of informed consent in an osteopathic clinical consultation.

Start date: 24/08/2016  
Finish date: 24/08/2017

**Participant name:** ________________________________

I have reviewed the information sheet about this study. I have read and understand the information sheet presented to me. I have had the opportunity to discuss any queries or concerns regarding this research with the researcher, Caitlin Kilpin, and am satisfied with the explanations given.

I understand that participating in this project is my own choice. I consent to one audio throughout an initial osteopathic appointment and one audio recording during an interview. I recognise that I may withdraw my own data (audio recordings from appointment and interview) from the study up to five working days after the interview. I understand that pseudonyms will be used to disguise my identity and any information reported will not identify me in any way to people outside of the research project.

I understand that anything I say or do during the interview recordings will remain confidential and that only the researcher (Caitlin Kilpin), her supervisors, and a transcriber will have access to these transcripts. I understand that due to the small sample size, the osteopath may be able to identify what I said in the interview, however, this will not disadvantage or affect my ongoing treatment with the osteopath. I acknowledge that I will have the opportunity to review and edit a copy of the interview transcript to ensure that I am comfortable with what may be published, and the researcher will be in contact to make this opportunity available. I have been provided with the researcher’s contact details as well.

I understand the audio recordings will be securely stored on the researcher’s hard-drive and an encrypted back-up will be stored in safe and separate locations. I acknowledge that all data will be retained for a period of 10 years, and kept at the researcher’s secure residence. At the conclusion of this time, all data will be destroyed. I give permission for the analysed findings published from this research project to be drawn upon and utilised to inform future research projects. I also give permission for anonymised data to be utilised in future publications of this research project.

I acknowledge that I can see the finished research document and that the results from this study may be published in a journal.

I have had adequate time to consider everything and I give my informed consent to be a part of this research project.

I know whom to contact to discuss any questions or concerns about this project.
The researcher is: Caitlin Kilpin
caitlinkilpin@gmail.com
Tel: 027 847 4223

Participant Signature: ................................ Date: ................................

Project explained by: ................................ Signature: .......................... Date: ........................

Thank you for participating in this research.
Appendix E: Ethics Approval Letter
Caitlin Kilpin  
21A Neats Place  
Blockhouse Bay  
Auckland 0600

21.9.16

Dear Caitlin,

Your IIE number for this application: 2016-1048  
Title: An explorative phenomenological study of six patients’ lived experiences of informed consent in an osteopathic clinical consultation.

Your application for ethics approval has been reviewed by the Unitec Research Ethics Committee (UREC) and has been approved for the following period:

Start date: 25.8.16  
Finish date: 25.8.17

Please note that:

1. The above dates must be referred to on the information AND consent forms given to all participants.

2. You must inform UREC, in advance, of any ethically-relevant deviation in the project. This may require additional approval.

You may now commence your research according to the protocols approved by UREC. We wish you every success with your project.

Yours sincerely,

[Signature]

Nigel Adams  
Deputy Chair, UREC

cc: Dale Sheehan  
Cynthia Almeida
Appendix F: Transcribers Agreement
**Research Title:** An explorative phenomenological study of six patients’ lived experiences of informed consent in an osteopathic clinical consultation.

**Researcher Name:** Caitlin Kilpin

**Address:** Unitec Osteopathy Clinic 41, 139 Carrington Road, Mount Albert, Auckland, 1025

**Phone number:** 027 847 4223

**Email:** caitlinkilpin@gmail.com

I ________________________________ (full name - please print) agree to treat in absolute confidence all information that I become aware of in the course of transcribing the interviews or other material connected with the above research topic. I agree to respect the privacy of the individuals mentioned in the interviews that I am transcribing. I will not pass on in any form information regarding those interviews to any person or institution. On completion of transcription I will not retain or copy any information involving the above project.

I am aware that I can be held legally liable for any breach of this confidentiality agreement, and for any harm incurred by individuals if we disclose identifiable information contained in the audiotapes and/or files to which we will have access.

Signature: …………………………………………………………. Date: ……………………………………………………..

**UREC REGISTRATION NUMBER:** 2016:1048

This study has been approved by the UNITEC Research Ethics Committee from 24/08/2016 to 24/08/2017. If you have any complaints or reservations about the ethical conduct of this research, you may contact the Committee through the UREC Secretary (ph: 09 815-4321 ext 8551). Any issues you raise will be treated in confidence and investigated fully, and you will be informed of the outcome.
Appendix G: Informed Consent Checklist
## Informed Consent Checklist

<table>
<thead>
<tr>
<th>Attribute</th>
<th>Completed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consent gained for observation and examination</td>
<td></td>
</tr>
<tr>
<td>Working diagnosis explained</td>
<td></td>
</tr>
<tr>
<td>Treatment option one explained:</td>
<td></td>
</tr>
<tr>
<td>• Risks</td>
<td></td>
</tr>
<tr>
<td>• Benefits</td>
<td></td>
</tr>
<tr>
<td>• Expected outcome</td>
<td></td>
</tr>
<tr>
<td>Treatment option two explained:</td>
<td></td>
</tr>
<tr>
<td>• Risks</td>
<td></td>
</tr>
<tr>
<td>• Benefits</td>
<td></td>
</tr>
<tr>
<td>• Expected outcome</td>
<td></td>
</tr>
<tr>
<td>Patient involvement in decision-making</td>
<td></td>
</tr>
<tr>
<td>Opportunity for patient questions</td>
<td></td>
</tr>
</tbody>
</table>
Appendix H: Guided Written Reflection
Guided Written Reflection

Please answer the following questions while reflecting on your recent consultation.

Questions:
1. Describe how you gained informed consent from the patient for examination and treatment.

2. Describe any positive or negative aspects during the process of informed consent.

3. Tell me about the information you provided about their examination and treatment.
   a. How much information did you provide about treatment risks and benefits?
   b. Tell me how this information was presented.
   c. Did the patient understand the information? If yes, how did you know?

4. Tell me how much information you provided about subsequent or alternative treatment options.

5. Describe how you involved the patient in decision-making throughout the consultation?

6. Was the patient given the opportunity to ask questions throughout the entire process?

7. Is there anything else you would like to add or reflect on?
Appendix I: Interview Guide
Interview Guide for Semi-structured Interviews

Prior to osteopathic appointment:

- Thank the participant for their involvement in this research.
- Introduction – Begin with introducing myself and ask the participant to do the same.
- Read through and explain information sheet and consent form. Ensure the patient understands their role in the research.
- Ensure the participant understands the audio from the appointments and interviews will be recorded.
- Ask the participant if they have any queries or concerns.
- Confirm/sign the consent form.
- Schedule a time to complete the interview within 48 hours of the consultation.

At the time of the interview, ask the participant if they would like to begin the interview in a particular way (i.e. Karakia, prayer).

Throughout the interview, participants will be asked to reflect on their recent experience as a patient in an osteopathic clinic.

Questions:
1. Describe how you gave the osteopath permission to examine and treat you.
2. Describe any positive or negative aspects during the process of giving permission.
3. Tell me about the information you received about your examination and treatments.
   a. How much information were you given about your treatment?
   b. Tell me how this information was presented.
   c. Was the information easily understood? How was this understanding expressed to the osteopath?
   d. Did anything happen throughout the appointment that you weren’t expecting?
4. Tell me how much information you were given about subsequent or alternative treatment options.
5. Describe how the osteopath involved you in decision-making throughout the consultation?
6. Were you given the opportunity to ask questions throughout the entire process?
7. Is there anything else you would like to add or reflect on?
• Thank the participant for their involvement in the study
• Ask if there are any concerns and reaffirm the confidentiality of data.
• Remind the participant of subsequent processes and the ability to withdraw within five working days.
• Ensure contact information of researcher, and supervisor is given.
Appendix J: DebateGraph Maps

Note: These maps are optimally viewed on a computer screen and are available for public viewing. Each node provides an interactive opportunity to see how it is related to other nodes. The lines connected to the central node are colour co-ordinated depending on the type of the relationship they represent. The thickness of these relationships relates to the rating of the relationship strength on a scale of 1-9.
Map 1 – Full Map
Available to view at: https://debategraph.org/informedconsent
Map 2 – Conversational Nature of Informed Consent
Available to view at: https://debategraph.org/conversational
Map 3 – Information Processing and Prioritisation
Available to view at: https://debategraph.org/informationprocessing
Map 4 – Participatory Nature of Consent
Available to view at: https://debategraph.org/patientcentred
Appendix K: International Journal of Osteopathic Medicine: Guidelines for Authors
INTRODUCTION

The Editors of the Journal welcome contributions for publication from the following categories: Letters to the Editor and Editorials, Reviews and Original Research articles, Protocols, Commentaries, Education, Clinical and Practice articles (Case Studies).

The Guidelines are separated into the following sections:

A Online Submission
B Types of Contributions
C General Guidance
D Preparation of the Manuscript
E Specific Guidance for Original Research Articles
F Specific Guidance for Protocols
G Post Acceptance

Types of contributions

For all the following types of contributions authors are requested to consider the international readership of the journal and to be aware of the need to explain local contexts or define terminology where these are likely not to be commonly understood internationally. Word limits exclude tables, figures and reference list.

Letters to the Editor (up to 1,000 words)

As is common in biomedical journals the Editorial Board welcomes critical responses to any aspect of the journal. In particular, letters that point out deficiencies and that add to, or further clarify points made in a recently published work, are welcomed. The Editorial Board reserves the right to offer authors of papers the right of rebuttal, which may be published alongside the letter.

Reviews and Original Articles (2,000 - 5,000 words)

Authors should select "Review Article" or "Full Length Article" at the submission stage when submitting either a Review or an Original Research article. These should be either (i) reports of new findings related to osteopathic medicine that are supported by research evidence. These should be original, previously unpublished works; or (ii) a critical or systematic review that seeks to summarise or draw conclusions from the established literature on a topic relevant to osteopathic medicine.
Please see specific guidance below for original research articles and the requirement to submit a checklist from the appropriate reporting guideline together with your paper as a guide to the editors and reviewers of your paper. The checklists for each reporting guideline can be found on the EQUATOR website. Checklists should be uploaded at submission as "Checklist" file types.

Short review (1,500-3,000 words)
The drawing together of present knowledge in a subject area, in order to provide a background for the reader not currently versed in the literature of a particular topic. Shorter in length than and not intended to be as comprehensive as that of the critical or systematic review paper. These papers typically place more emphasis on outlining areas of deficit in the current literature that warrant further investigation.

Research Note (up to 1,500 words)
Authors should select "Research Paper" at submission stage when submitting a Research Note. Findings of interest arising from a larger study but not the primary aim of the research endeavour, for example short experiments aimed at establishing the reliability of new equipment used in the primary experiment or other incidental findings of interest, arising from, but not the topic of the primary research. Includes further clarification of an experimental protocol after addition of further controls, or statistical reassessment of raw data.

Preliminary Findings (1,500-2,500 words)
Authors should select "Preliminary Report" at submission stage when submitting a Preliminary Findings paper.
Presentation of results from pilot studies which may establish a solid basis for further investigations. Format similar to original research report but with more emphasis in discussion of future studies and hypotheses arising from pilot study.

Professional Commentaries (up to 2,000 words)
Includes articles that do not fit into the above criteria as original research. Includes commentaries and essays especially in regards to history, professional identity, clinical scope and development, and political and legal aspects of osteopathic medicine.

Clinical Practice
Authors should select the article type "Clinical Commentary" when submitting a Clinical Practice paper - there will be an option within the submission process to further select the type of format as below. Authors are encouraged to submit papers in one of the following formats: Case Report, Case Problem, and Evidence in Practice.

i. Case Reports - usually document the management of one patient, with an emphasis on presentations that are unusual, rare or where there was an unexpected response to treatment (e.g. an unexpected side effect or adverse reaction). Authors may also wish to present a case series where multiple occurrences of a similar phenomenon are documented. Preference will be given to reports that are prospective in their planning and utilise Single System Designs, including objective measures.

ii. The aim of the Case Problem is to provide a more thorough discussion of the differential diagnosis of a clinical problem. The emphasis is on the clinical reasoning and logic employed in the diagnostic process.

iii. The purpose of the Evidence in Practice report is to provide an account of the application of the recognised Evidence Based Medicine process to a real clinical problem. The paper should be written with reference to each of the following five steps:
1. Developing an answerable clinical question. 2. The processes employed in searching the literature for evidence. 3. The appraisal of evidence for usefulness and applicability. 4. Integrating the critical appraisal with existing clinical expertise and with the patient’s unique biology, values, and circumstances. 5. Reflect on the process (steps 1-4), evaluating effectiveness, and identifying deficiencies.

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The editors are looking for studies that will appeal to a wide general readership. The question being addressed and the planned design and analysis will need to be as original as possible, topical, and valid. All protocols will be subject to the journal's usual peer review process.

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• The article should be between 3500-4000 words in length excluding references.
• A short summary should precede the main body of the article overviewing the contents.
• The introduction should review the relevant literature and put the subject matter into context.
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This new section of the *International Journal of Osteopathic Medicine* provides accounts of new teaching and learning methods, curriculum development and implementation, and assessment strategies in undergraduate and post-qualifying osteopathic education, and continuous professional development initiatives. It also serves as a forum for communication between osteopathic educators, policy developers and those involved in clinical practice. Papers which focus on osteopathic education in both classroom and clinical/practice environments are welcomed for this new section of the journal. It is essential that the evidence-base to osteopathic education is developed and this is reflected in papers submitted for publication. In alignment with the journal's overall Aims and Scope, papers submitted for consideration of publication should be relevant to an international audience, even if they are national in scale of study. The editorial team wish to encourage submission of papers that demonstrate:

- Innovation and development of education
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The text of original research for a quantitative or qualitative study is typically subdivided into the following sections:

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Present results in a logical sequence in the text, tables and illustrations. Do not repeat in the text all the data in the tables or illustrations. Emphasise or summarise only important observations.

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Qualitative researchers might wish to consult the guideline listed below:
Qualitative studies - COREQ - Consolidated criteria for reporting qualitative research.

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