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Experience with Laser Therapy among Patients with Disc Degenerative Lower Back Pain in Nepal

A Qualitative Study

Master's thesis in Global Health Supervisor: Prof. Aslak Steinsbekk December 2020

echnology Master's thesis

NDU Norwegian University of Science and Technology Faculty of Medicine and Health Sciences Department of Public Health and Nursing



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> > by Shambhu Maharjan

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Abstract

Background: Low back pain has been the major health problem causing the most disability worldwide and in Nepal. Due to short term effect and side effects of pharmacological management of LBP, non-pharmacological treatments are also recommended. One such approach is low-level laser therapy (LLLT), despite conflicting results about its effect from studies. Still it is offered, and patients use it. Thus, patients' experiences are a highly valuable source to understand why it is used and how they experience the outcome. The objective was therefore to contribute with knowledge on this by exploring the experiences of patients diagnosed with disc degenerative disease suffering from lower back pain who were under treatment with low-level laser therapy in a clinic in Nepal.

Methods: A qualitative study with semi-structured individual face to face interviews was conducted in 2019. Patients were recruited in the waiting room of the clinic by combined effort of both the researcher and trained clinical staffs. The main question in the interview guide was 'how was your experiences about the treatment with laser therapy and how has it changed your previous condition related to back pain?'. The collected data was analysed using qualitative thematic analysis.

Results: Twenty participants, 14 females (mean age of 45 years) and 6 males (mean age of 54 years), who on averaged had attended two laser treatment sessions within last 12 months, were interviewed. The findings were categorised into five themes; History of low back pain and treatments used, Factors leading to use of LLLT, Experience with the organization of LLLT, Availability and affordability, and Outcome perception.

Conclusion: Our findings based on patients' experience showed some positive attitude towards the use and acceptance of low-laser laser therapy in low back pain from disc degenerative disease despite relieving pain completely. Explanations such as better compliance, less side effect, feeling of wellness and relaxation towards treatment, affordability and the positive relation between patients and service provider could be reasons for its acceptability.

Keywords: Low-level laser; low back pain; prolapsed intervertebral disc; degenerative disc disease; qualitative research.

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Abbreviations

LBP	Lower Back Pain
GBD	Global Burden of Disease
DALYs	Disability-Adjusted Life Years
YLDs	Years Lived with Disability
PIVD	Prolapsed Intervertebral Disc
MRI	Magnetic Resonance Imaging
CT-scan	Computed Tomography scan
TENS	Transcutaneous Electrical Nerve Stimulation
LLLT	Lower-Level Laser Therapy
LLLT LDH	Lower-Level Laser Therapy Lumber Disc Herniation
LDH	Lumber Disc Herniation

1. Background

1.1 Lower back pain and intervertebral disc degeneration

Lower back pain, one of a common musculoskeletal disorder, is one of the leading causes for long-term disability worldwide related to general well-being and a leading contributor to missed workdays [1]. Lower back pain is one of the most frequent reasons behind people visiting doctors for medical consultations. Estimations indicate that almost 80-95% of the people are suffered from back pain at some point in their lives [1,2]. According to the Global Burden of Disease (GBD) 2017 study, almost 577 million people globally are affected by activity-limiting lower back pain. Among all known communicable, non-communicable and accidental health problems, low back pain has been the top-most health problem causing the most disability according to 2019 ranking of diseases and injuries that accounts for the highest number of years lived with disability (YLDs) worldwide and increased to almost 581 million people globally [3].

Both se 2009 rank	exes, All ages, YLDs per 100,	.000 2019 rank
1 Low back pain		1 Low back pain
2 Migraine		2 Migraine
3 Age-related hearing loss		3 Age-related hearing loss
4 Major depression		4 Other musculoskeletal
5 Other musculoskeletal		5 Major depression
6 Dietary iron deficiency		6 Diabetes type 2
7 Anxiety disorders		7 Anxiety disorders
8 Diabetes type 2		8 Dietary iron deficiency
9 Neck pain		9 Neck pain
10 COPD		10 Falls
11 Falls		11 COPD

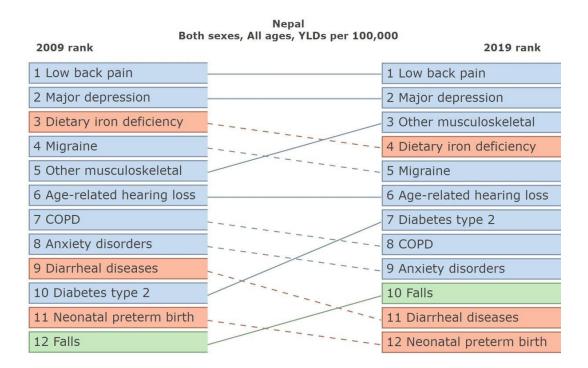
Global Both sexes, All ages, YLDs per 100,000

Communicable, maternal, neonatal, and nutritional diseases

Non-communicable diseases

Injuries

*Figure. 1, Top 10 causes of YLDs in 2019, 2009-2019, all ages, globally[3]. *Source: Institute of Health Metrics and Evaluation (IHME) Correspondingly, in Nepal, lower back pain had recently reached to the top ranking that accounts for the highest number of YLDs amongst all other condition [3]. Lower back pain is the leading cause of morbidity among adults. In developing country like Nepal where people are involved in manual labour work to lift heavy weights in the back is probably aggravator of degenerative process in Nepalese people [4,5]. Low literacy rate along with lack of health seeking behaviour and awareness as well as lack of access to medical services are some of unseen reasons behind the prevalence of low back pain [6]. Conversely, it is suggested that a passive job such as sitting at a desk or computer all day long may also lead to or contribute to back pain due to poor posture with inadequate back support [7]. Although there are evidence in western countries that identifies risk factors for back pain like smoking, obesity, driving, psychological stress, age and height [5] but it's hard to say how much it holds truth in country like Nepal due to lack of proper and systematic data.[4]



Communicable, maternal, neonatal, and nutritional diseases

Non-communicable diseases

Injuries

*Figure. 2, Top 10 causes of YLDs in 2019 and percent change, 2009-2019, all ages, in Nepal [3]. *Source: Institute of Health Metrics and Evaluation (IHME) Low back pain is not a particular disease on its own but rather it is a symptomatic and selflimiting condition of other underlying conditions or diseases [8]. Low back pain occurs in the lumber region of vertebral column due to tension and stiffness of muscles or nerves and bones [5]. Almost 90% of the reported back pain cases were found to be nonspecific back pain in which the underlying diseases or conditions are either unknown or unidentified [9]. Remaining 10% of the reported back pain is identified through different diagnostic methods [9]. Among many underlying diseases, degenerative disc like intervertebral disc degeneration or Prolapsed Intervertebral Disc (PIVD), is one of the most common mechanical causes of low back pain among other 10% of back pain [5, 9].

Low back pain can be acute pain (that lasts for less than 6 weeks) or subacute pain (last between 6 and 12 weeks) or chronic pain (lasts for longer than 12 weeks) based on duration of the pain persists [10].

Degenerative diseases are related to the changes in the normal structure and functioning of cells resulting in deterioration of tissues or organs over time due to continuous process or over-use.[5, 11] When the degenerated tissues are, discs between the vertebrae of vertebral column leading to pain, numbness, and weakness, it is termed as degenerative disc diseases.[5] And the disc between last thoracic vertebrae to first sacral vertebrae including lumber vertebra are involved that causes lower back pain. It often occurs when the usual rubbery discs lose integrity as a normal process of aging [5]. In a healthy back, intervertebral discs provide height and allow bending, flexion, and torsion of the lower back. As the discs deteriorate, they lose their cushioning ability and sometime the disc become too weak that their outer ring tears and bulges out which causes pressure on the nearby spinal nerves leading to severe back pain. Thus, this condition can lead to radiculopathy, myelopathy, spinal stenosis, degenerative spondylolisthesis, and herniations which are the main cause of maximum number of patients with severe low back pain [5].

1.2 Treatments available and Low-level laser therapy

With the first encounter of low back pain, most people with back pain do not seek medical consultations but rather self-manage to resolve the pain with some over the counter drugs and changing their lifestyles [12, 13].

Most acute back pains get better with complete rest, regular activities and avoiding heavy exercises or with pharmacological treatment [14]. However, more serious back pains can be treated with nonsurgical methods or surgery [5]. Available guidelines suggest combinations of pharmacological and nonpharmacological methods [15, 16]. Non-pharmacological treatment includes patient education programs, exercise programs, back schools, spinal manipulation, massage, acupuncture, physical therapy, and lumbar supports [15, 17].

Different guidelines are currently available for the management of back pain which seems to have variation among the physicians and clinicians [18]. Nowadays nonsteroidal antiinflammatory drugs (NSAIDs) are mostly used as effective pain killers. Due to short term effectivity with more side effects of pharmacological management of low back pain, nonpharmacological treatments are recommended by physicians [19]. When other traditional non-surgical therapies fail, surgery may be considered an option to relieve pain caused by serious musculoskeletal injuries or nerve compression, but outcomes are disappointing as surgical procedures are not always successful, and there is little evidence to show which procedures of surgery work best for their particular indication [20]. Moreover, there is still lack of evidence whether the spinal surgery is effective than placebo or the available evidence supports the clinical benefits compared to other non-surgical alternatives [21, 22]. Patients may suffer permanent loss of flexibility [5]. Moreover its quite expensive as well in context of country like Nepal.

After patients experienced the available conventional treatment to be inadequate or insufficient to treat their chronic disorder, they seek alternative treatments. Some studies have also found that, primary care physicians refer to complementary and alternative medical treatments for back pain [15]. Moreover, from the prospective of patients suffering from low back pain, the goals of any treatment adopted for lower back pain should reduce pain, allow patients to resume their normal activities, and to increase quality of life [15, 16]. From patient's perspective the results from alternative treatment are better with more lasting effects, have fewer or no side effect than those of conventional treatments, natural way of cure as non-invasive and non-pharmaceutical treatment [23, 24]. One such approach is low-level laser therapy (LLLT).

Though there are currently insufficient evidence for proven efficacy [25, 26], a wide variety of types of lasers, treatment schedules, and techniques have been used. Regardless of the current state of evidence for the effect of low-level laser therapy, it is offered by practitioners

and used by patients in many parts of the world for relieving pain in many musculoskeletal disorders, muscle relaxation, healing and repairing cells, tissues and ligaments, fibroblast proliferation, bio-stimulation in various conditions [27-32]. It has been used to relieve both acute and chronic pain, but the exact mechanism of pain relief is still unclear [27, 31]. Two types of pain nociceptive (caused by tissue damage) [33] and neuropathic pain (caused by nerve damage) [34] found to be responsive to low-level laser therapy clinically. However, it has not yet received Food and Drug Administration approval for any indication [15, 35]. Low-level laser therapy, also known as "cold" laser therapy, uses monochromatic (red beam or near infrared nonthermal) light emission from a low intensity laser diode (250 milli watts -2000 milli watt total optical power) [27, 36]. When applied, the focus laser light penetrates the surface of the skin without a heating (burning) effect, produce no sensation and do not damage the skin [37]. It is believed that due to the low skin absorption and no side effects, the laser light can penetrate deeply into tissues and can reach the site of damage or injury, where it interacts with various intracellular biomolecules resulting in the normalization of cellular components enhancing the body's natural healing processes [37]. The process is also called photo-biomodulation because the photon energy converted into bio-chemical energy which re-modulate to restore normal morphology and function of the cells. It increases oxygenation of tissues and allows injured or damaged cells to absorb photons of light, which speeds healing [38].

There is some evidence that supports the use of low-level laser therapy in reduction of pain and inflammation and enhances tissue healing both in hard and soft tissues, including muscles, ligaments, nerve cells and even bones [38, 39]. Consequently, apparently conflicting results from studies of low-intensity lasers may not be in conflict, and may represent fundamental, but poorly understood, differences in treatment approach [39]. Use of LLLT along with pharmacological treatment were reported to reduce pain and improve functional parameter. The researcher also concluded that the patients treated with laser therapy require lesser pharmacological medication with fewer side effects of the drug [40]. There are some studies which shows improvement in the treatment of discogenic back pain using LLLT [41]. The patients also reported no side effect and no heat generation during the treatment. The patient also reported the treatment being more pleasant with increased compliances [42]. Though the laser is believed to be non-invasive and non-ionising with no side effect [27], the North American Association for Laser Therapy conference in 2010 had contraindicated its use in eyes, in treatment of cancerous cells, in pregnancy and epilepsy.

A systemic literature search with meta-analyses on selected studies investigating the efficacy of low-level laser therapy for non-specific chronic low back pain found to be effective method for relieving pain but still a lack of evidence supporting its effect on function [38].

1.3 Patient experience

Patients' experiences are a highly valuable source to understand why it is used and what the results can be. It is important to explore aspects of the patient's perceptions and experiences related to treatment components [43]. It has been noted in a study that successful management and its outcome of back pain depends on patient's knowledge about the choice of treatment and its consequences [44]. Patient-experience is not only important component to look for health care quality, but it is also an important outcome in medical research. For hundreds of years many complementary and alternative medicine (CAM) has been adopted by the people worldwide [45]. Typically, after patients experienced the available conventional treatment or allopathic therapies to be inadequate or insufficient to treat their chronic disorder, they seek complementary (when used conjunction with conventional treatment) and alternative (when used instead of conventional treatment) treatments [46].

Based on searches in international medical databases, such as PubMed, MEDLINE, Scopus, EBSCOhost, PEDro, and Web of Science, it was not possible to identify publications that concerns exploring patient's experience with the use of low-level laser therapy for patient suffering from disc generative low back pain. Furthermore, no studies have been identified that have looked at the experience of using such treatment in Nepal. To get the complete picture, it is important to acquire more depth about the topic.

However, other studies on experience of patients regarding treatment with complementary and alternative modalities other than low-level laser treatment for back pain and other diseases, were identified. This section thus focuses on research investigating patient experiences of treatment with laser therapy in general or other complementary and alternative treatments for back pain [47]. In a qualitative study conducted for caries treatment with laser therapy, it was reported that the patients considered laser treatment as feasible and convenient. It was also reported of having positive impression due to absence of fear of needle and discomfort with the drill. Other related facilitator towards use of laser were reported as service provider role as initiator, safe feeling of laser and state of relaxation during treatment, and it was considered less painful [48].

A research conducted to provide insight into the full range of meaningful outcomes experienced by patients who participated in clinical trials of complementary and alternative medicine therapies (acupuncture, massage, yoga, chiropractic, *t'ai chi*, and/or mindfulness-based stress reduction) on back pain identified a range of positive outcomes such as 'increased options and hope, increased ability to relax, positive changes in emotional states, increased body awareness, changes in thinking that increased the ability to cope with back pain, increased sense of well-being, improvement in physical conditions unrelated to back pain, increased energy, increased patient activation, and dramatic improvements in health or well-being' [49].

Another qualitative study that concerned the changes in expectations over time among patients with chronic back pain seeking CAM therapies (yoga, chiropractic, acupuncture and massage) found out that the pre-expectation whether CAM therapy could relieve pain and improve in health condition changed to acceptance of chronic pain with increased awareness of the need for selfcare and maintenance for long term quality of life and well-being. Increased awareness and attention to the need of responsibility for their own health were considered as positive outcomes on basis of patients-reported outcome measures [50].

A qualitative sub-study conducted in United Kingdom, used patients' interviews following acupuncture treatment for back pain to explore patient's perception regarding the acceptability of the treatment and the study results suggested that the acceptability of the treatment is based on a complex and multifaceted appraisal of the treatment. The relation between the service provider and the patients were reported to be strong driver for the acceptability. Patients proper knowledge about the treatment modality was also noted to be important for the beneficial outcome and its maintenance. Moreover, in this study, patients reported a range of beneficial outcomes and some drawbacks of treatment like needle related discomfort and financial cost but the benefit of reduced back pain over the course of treatment outweighed negative experiences associated with treatment reactions [51].

In another similar qualitative study conducted in New York to explore the experience of patients from a low income, ethnically diverse medically underserved population receiving acupuncture for back and neck pain, the results were found to be similar. The patients reported of having physically, psychologically, socially sound health and well being with better personal control, calmness, and relaxation regarding the treatment modality. The role of expectancy and other psychological and emotional factors were also viewed as major factors in mediating the experience and outcome of acupuncture. However, in this study access and the cost were found to be major barrier [52].

In a study to explore the subjective experience of patients suffering from back pain and participating in a comprehensive spinal stabilizing exercise programme including education by experienced physiotherapist, the participants who had participated in focus group discussion reported positive effect of exercise on pain, functional disability, and quality of life. In addition, they also reported increased confidence of self-management and control over their low back pain [53].

1.4 Aim of the study

As stated above, knowledge about patients experience with different treatment modalities is important to understand its use. However, no study on experience of the patients suffering from lower back pain due to disc degenerative diseases who are under treatment with low level laser therapy in general and in Nepal specifically have been identified.

Therefore, the aim of this study was to explore the experience of patients diagnosed with disc degenerative diseases suffering from lower back pain who were under treatment with low-level laser therapy in a clinic in Nepal.

2. Methodology

To achieve the research objective, this study utilizes a descriptive qualitative design with semi-structured individual interviews. The data for study were collected in the fall 2019.

2.1 Setting

The study was conducted at Laser Therapy Clinic, Lalitpur, Nepal. The clinic is in the one of the districts of Kathmandu Valley. According to the medical doctor-in-charge/managing director of the clinic, there is only one clinic in entire Nepal that offers low level laser treatment for back pain. They reported that more than 10,000 cases have been consulted and treated the last decade. Typically, complaints among their patients have been back pain, neck pain, skin problems, arthritis, painful haemorrhoids.

The treatments have typically been scheduled as first course that consists of once-a-day laser treatment for 20 consecutive days then a resting period of 30 days followed by second course that consisted of one treatment per day for 10 consecutive days, again a gap of 30 days followed by 10 days third course. As reported by the medical practitioner the dose and time of laser treatment for individual patient, depends on the condition of the patients for example the number of intervertebral discs involved and nature of the condition like acute or chronic. Furthermore, maintenance courses were scheduled for 10 days course which can vary from 3 to 6 months resting period between two courses depending upon the severity of the condition. It was also reported that the once-a-day laser could be changed to intense treatment schedule which was consisted of two times a day laser treatment with 6 hours duration in between. Therefore, a 20 days (once-a-day) course into 5 days (2 times a day).

The clinic was opened for out-patient during day shift and it also offered in-patient service for patients traveling from outside the valley for the treatment.

2.2 Participants and recruitment

The inclusion criteria were patients diagnosed with disc degenerative (prolapsed disc and disc herniation) low back pain and under treatment with low-level laser treatment at the laser therapy who had attended at least two courses and agreed to take part in this study. In addition, to get variation in sampling, it was aimed to get variation in age, gender and length of low back pain.

To recruit participants, a purposive sampling strategy was used. Purposive sampling is one of the nonprobability strategies that gathers data from people who meet preselected narrow or specific criteria that are relevant to the objective of research [54]. Purposive sample sizes are often determined based on theoretical saturation which is the point in data collection when new data does not bring any additional information to the research object [55]. Purposive sampling ensures the variety in sample during data collection. Variation in demographic characteristics such as age (27 to 64 years), settlement from various part of the entire country, sexes, occupations as well as variety in duration of disease, causes and the treatment were some of the representational variation of the sample.

With the approval from the medical director of the centre and the help of clinical employee, the researcher searched for potential participants among patients under treatment. The primary researcher had a meeting with the manager and 3 clinical employees to discuss the recruitment. The manager gave access to the records of the patients attended the clinic. With the help of staff, the primary researched sorted out the patients who fitted the inclusion criteria of this study.

All the eligible participants who were attending laser clinic during the period of data collection were informed briefly about the study by the staff at the front desk. Out of all the eligible patients, those who were interested in taking part in the study, were requested to contact the researcher. The primary researcher was present at the clinic during opening hours. The participants were then approached by the researcher who gave more detailed information about the study, about the researchers himself and about formalities of inform consent and how their personal information will be maintained respecting their privacy. The researcher, who speaks both Nepalese and English, gave further oral information in the mother language of the patient and an informed consent either in English or Nepalese to be signed by those who agreed to take part in the study.

After all the paper related work, the researcher interviewed the participant in a comfortable peaceful environment in a room provided by the clinic, without interference from any third person. Since participants were attending the centre for10-20 days every day for treatment and some were inpatients staying at the centre, it was possible to schedule individual time for participants. The recruitment continued until what the last informant talked about was more or less similar to what was heard from other informants.

2.3 Data collection

The primary researcher conducted the face-to-face semi-structured interviews. All interviews took place at the centre in a closed room provided by the centre itself, without any disturbances and any influence from third person. As the primary researcher speaks Nepalese and Newari (local language of a community), the interviews were conducted in the mother language of the patient. Out of 20 interviews, 19 was in Nepalese language and one in Newari. The length of the interviews were 15 to 39 minutes with an average of 26 minutes and were audio recorded.

The process of transcription and translation should be considered as one of the key phases [56]. It is the phase from where the actual interpretative data are extracted for findings and conclusion is made within a research [57]. The researcher must have some previous knowledge about the topic to be used in the interviews [58]. Semi-structured interview guide is helpful tool that guides the interviewer during interviews to cover main topic regarding the research question [59, 60]. Semi-structured interview guide helps the investigator to explore similar information about the study topic from each informant [61]

The interviews were audio-recorded. Interviews were simultaneously translated and transcribed verbatim by the primary researcher to get the raw data. The interviews were conducted following a semi structured interview guide (the interview guide provided in the attachment section). The semi-structured interview guide (Appendix C) for the interview were developed before conducting actual interviews. The interview guide was formulated with consultation with the medical doctor (via online conversation) and the previous knowledge about the topic from available literatures. It was structured to cover the main topic for the study objective as well as for the discussion with the participants during interviews. It was reviewed by the thesis supervisor, the thesis advisory committee as well as the medical director of laser therapy centre in Nepal. In addition, this easy data collection method helped both the interviewer and interviewee providing guidance on next topic to talk about and the similar areas to be covered from all the interviewees.

Interviews were started with general information and participants were asked about their experiences about the treatment for their specific conditions. Participants were mostly asked open-ended questions like "how was your experiences about the treatment with laser therapy

and how has it changed your previous condition related to back pain?', 'how you developed your problem?' and what measures were taken regarding diagnosis, using other treatments before and during laser treatment, about other diseases if they have some, what effect or side-effect they experienced during treatment, about their expectation'. With open ended question informants were free to respond in their own words and more importantly in their mother language in convenient way [62]. Topics from the interview guide was introduced whenever the informants missed to share their views on specific topics themselves.

2.4 Data Analysis

Data analysis in qualitative research is complex and sometimes difficult to know what the researcher did during the analysis process and how their results or findings were produced [63]. In this section, the detailed process of the data analysis from raw data to final findings or result is described. Thematic analysis was employed to analyse this study. Thematic analysis method is a commonly used and flexible method of analysing qualitative data [64]. An inductive thematic analysis provides a rich description of the entire data set which is particularly useful when the topic under investigation is under researched [57].

This method of analysis was appropriate as no similar studies that matched this study, were found in any medical databases, and the data gathered are related to experiences of patients about the treatment and its components rather than any postulations, theories or assumption of researcher nor fitting the data into pre-existing frame [57].

Among various approaches in conducting step by step thematic analysis, this study used steps outlined by Braun & Clarke (2006). Thus, the analysis of this study was done in 6 phases: 1) familiarization 2) coding 3) generating themes 4) reviewing themes 5) defining and naming themes and finally 6) writing the report [56].

1) Familiarization

As described in the article by Braun & Clarke (2006), when the study is intended to reflect a rich description of the data sets like interviews, the researcher must immerse himself in the data to be familiar with the content [57]. Whether or not the interviews and its transcription is done by researchers themselves, they should have thorough knowledge about their collected

data information [65]. This first step thus involves reading and re-reading the data and noting down initial ideas [57].

The recorded face-to-face interviews in this study were collected in other language than English language. Conduction of interviews as well as the transcription and translation were done by the primary researcher himself. This close attention helped develop a far more thorough understanding of the data familiarizing with the actual meaning of the spoken sounds. After listening closely and repeatedly, and with the level of interpretive skill that the primary researcher possesses, the transcripts were prepared to retain rich and true original meaning of the information from the verbal meaning. The researcher included non-verbal clues and features than just words, to enrich the natural and accurate meaning of the text [57]. The prepared transcripts were read and reread to acquire more understanding of the meaning of the terms used in the interviews and to get initial comprehensive ideas.

2) Coding

In qualitative analysis, coding is the process of generating usable data from raw data set through the identification of codes that have some connection with each other" [66]. For Braun & Clarke, a code captures one (or more) insights about the data. These codes are usually shorthand labels which is generated by highlighting basic phrases or sentences within the text [57]. In this phase researcher must be aware during extraction of segment that no important content is lost [67].

In this study, initial codes were generated manually collating an idea or feeling expressed in phrases or sentence or paragraph of the individual transcript and individual codes was given various shorthand labels. During this process all the possible data or information were gathered that have some meaningful information related to the objective of the study from each individual interviews. All the data from individual transcript were then collated together into meaningful groups which is identified by relevant or potential code [57].

After generating all the possible codes from individual transcript, an overview of main points and common meanings that reoccurred were developed within or across the entire data set. The segments of the data from which codes were generated, they are extracted such that no context is lost. Numerous numbers of codes with its related segment from their respective text were arrange in a table.

3)Generating themes

A theme is some level of ideas, topic and patterns of response or meaning that reoccur in the data set which provide something important related to the research topic and its components [57]. For Braun & Clarke, a theme encompasses numerous insights organised around a central concept or idea. Along with emerging main overarching themes and sub-themes, it is good idea to keep everything such that nothing is lost at this stage whether it seems relevant to the research objective or not [57].

From the long list of initial codes, more broader themes were created by combining several codes into one context that identify pattern among them. All the data were analysed to provide structure to emerging candidate themes that could communicate some meaning among the group of codes with the help of mind mapping and Microsoft Excel Worksheet. At end of this stage, the researcher had collection of all the candidate themes and codes along with the extract of data that forms up the corresponding codes.

4) Reviewing themes

The emerging themes should have coherence data giving meaningful structure within the themes as well as distinction between themes. In addition, these themes should have useful and accurate representation of the data set [57]. The validity within themes and in relation to the data set is essential to develop a candidate thematic map that reflects the accurate representation to the entire data set [57].

The candidate themes were thus reviewed by comparing with the data set. In first level of review, the themes were compared against the codes and its data extract of the text. All the supporting information in the codes, missing information, overlapping information, relevant information regarding merging several themes or breaking down into more themes were reviewed within the themes. In the second level of review, the themes were compared against the entire data set. The thematic map at the end of this phase provided a clear picture that is used to interpret the finding of this research.

5) Defining and naming themes

When the final list of themes is ready, each of them need to be named and define accordingly such that the overall story the analysis tells about the topic under study portrays a clear and organised story with clear and defined names of the themes [57].

In this phase, the researcher came up with concise and easily understandable name representing each individual theme correspondingly so that they were not too complex and diverse. For each individual theme, a detailed analysis needed to be written. All the final themes were named and defined in detail that portrayed the story behind the theme themself and in context of data set in relation to the research objective. It was ensured that the data was not too much overlapped between the themes. Sub-themes were clearly identified and defined under corresponding themes.

At the end of this phase, the researcher had clear picture of the themes for final analysis and interpretation of the reports.

6) Writing the report

Final phase of the thematic analysis is writing the final report of the analysis of the themes that we have from phase 5. The researcher produced a complete research report following the IMRaD format structured by four main section: Introduction, Methods, Results and Discussion/Conclusion. In the article by Braun & Clarke (2006), it is stated that interpreting the findings for a given issue from any study is like telling a complex story of the data to the reader in concise and convincing way with evidence [57].

The report for this study was prepared describing exactly as it was done in the process of data collection, data analysis. The researcher presented all the demographic characteristics of the participants involved in the result section. The researcher described the themes individually with evidence from the extract of the data set in the result to support the themes. The findings were discussed comparing with other similar literature where applicable. The researcher tried to portray the issue of back pain in disc degenerative case and exploring patients views and experiences about the low-level laser therapy in management of the pain.

3. Ethics Approval, consent, and confidentiality

This study is conducted as a master thesis in Global Health at Norwegian University of Science and Technology (NTNU). It was reviewed and approved by NTNU on March 22, 2019 [Appendix A (1)]. Permission to conduct the study at the Laser Therapy Clinic in Nepal was approved from the medical director of the clinic herself on May 15, 2019 [Appendix A (2)]. The interviews were conducted in Nepal and was approved by the Nepal Health Research Council (NHRC) on June 30, 2019 [Appendix A (3)].

In the beginning of this study, it was proposed to be a mixed method study, both quantitative and qualitative and it was approved as such from NTNU, Laser Therapy Clinic and NHTC. After that the data collection was done. Due to unavailability of proper data for quantitative data, the researcher managed to get interviews only, so later we have to drop quantitative part and applied for REK approval. It was rejected for ethics approval from Regional Committees for Medical and Health Research Ethics (REK) on 14.04.2020 as the application for the approval was based on mixed method, and in addition, the data collection was already done before the application was approved by REK. Later the same project was applied for only qualitative research method and was approved by the Regional Committees for Medical and Health Research Ethics (REK) for mid-Norway region on June 23, 2020 as 'Approved with condition' and the condition were mentioned in the approval letter from REK [Appendix A (4)].

The participants were initially informed orally and in writing via an information letter before the interview at the clinic during their regular treatment schedule in Nepal. Consent for participation in the study was taken before real interview. The consent form in English and in Nepali are attached in appendix section of this report.

All the interviews were recorded (audio only) using Voice recorder device with permission of participants. The primary researcher is responsible for translation and verbatim transcription of the interviews. Confidentiality of patient information regarding personal data which can identify the participants are maintain to its highest extent possible. The patients were assigned number (for example male PT#01/female PT#02 and so on) instead of other identifiable information. All the names of people were replaced by their profession or other appropriate designation (for example, a doctor, a friend, a physiotherapist, etc) where the interviewee

talked about them during the interview. The recorded audio recordings were deleted from the device and stored in the researcher's hard disk with password protection. The transcripts and the consent forms and other related documents were kept safe with the primary researcher until November 2024 and will be destroyed afterwards. None of the documents in paper or electronic except this report were shared with other people.

4. **Results**

This section presents patient's experience with low-level laser therapy as complementary and alternative treatment approach for lower back pain in those patients diagnosed with disc degenerative cases in Nepal. Before presenting all the findings from the data analysis, general demographic characteristics of the sample population in the study is presented.

4.1 Demographic characteristics of participants

All 20 participants interviewed were diagnosed with prolapsed intervertebral disc lower back pain at the time of interview collection of this study. The age range of the population studied was 27 years to 64 years. The demographic characteristics of the participants collected were displayed in a Table 1 below.

Table 1. Demographic characteristics of the participants	
Demographic characteristics	Number
Age (Years)	
20-30	2
31-40	6
41-50	5
51-60	6
61-70	1
Sex	_
Female	14
Male	6
Residency	
Outside Kathmandu Valley	5
Inside Kathmandu Valley	
Kathmandu	10
Lalitpur	5
Marital status	
Married	17
Unmarried	3
Professions	
Health sector worker	4
Businessperson	3
Teaching	2
Office assistant	1
Kitchen assistant	1
Graphic designer	1
Housewife/Agricultural	8

Table #1. Demographic characteristics of all 20 participants in this study

At the time of this study, 15 participants were settled in capital city (Kathmandu Valley) and 5 were from outside Kathmandu valley. Regardless of the original residency of the participant, the participants were grouped according to the residency at the time of data collection which shows clustering of sample within Kathmandu Valley only as illustrated in the figure below.

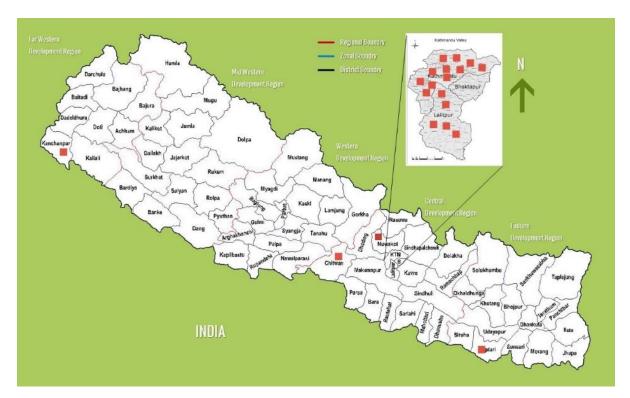


Figure 3. *Distribution of sample site*. The map depicts the detailed regions of Nepal and the coloured small square marker on the map represents approximate sample residency.

*Map Source: https://www.tibetdiscovery.com/nepal-tours/nepal-maps/

Beside diagnosed with PIVD or HD; 5 participants were having problem with thyroid disorder; one suffering from COPD; another was having problem of sinusitis and gastritis; one with hypertension along with thyroid disorder, gastritis and osteoarthritis; one with hypertension, high cholesterol and gout; One with hypertension.

Participants reported of suffering from back pain ranged from 1 year to 15 years whereas period of treatment with laser ranged from 2 months to 11 years. Regarding their treatment with laser, there was wide variation in the sessions the patients had attended, and all the participants had completed at least 2 courses which is presented in Table 2 below.

Low back pain occurrence & LLLT sessions	
Length of back pain	Numbers
Less than one year	-
One year to 5 years	9
Six years to 10 years	7
More than 10 years	4
Sessions of Laser attended	
Attendant only one course	-
Second course	8
Third course	4
Maintenance course	8

Table 2. Low back pain occurrence & Low-level laser treatment sessions attended by the participants for low back pain.

4.2 Findings

The findings were categorised into five major themes. The themes were 1) History of low back pain and treatments used, 2) Factors leading to use of LLLT, 3) Experience with the organization of LLLT, 4) Availability and Affordability of LLLT, and 5) Outcome perception. The themes were described in detail with relevant narrations from the corresponding interviews.

1. History of LBP and treatments used

This theme covers the participant's perceptions and experiences of their history of low back pain occurrence and different treatments they adopted previously before they came to know about low level laser therapy. Participants talked about their back pain as a minor health problem when they first experienced.

`.....I had this issue when I walked for a long time, and I really did not care for a long time. And though it would get better following day or a day after.....' (Female PT#19)

When they felt the need for treatment, the participants reported taking rest and using some over the counter medicine on their own rather than seeking a professional medical advice for diagnosis of their underlying condition that resulted in back pain.

"...That time I had intense pain but I thought that it was because of the heavy load I had carried. And it would go away on its own and after few days I got better too. But after then there was some pain not so intense but mild and I keep ignoring it for a long time. I took some painkillers and some massage on my own and it used to recover as well. But last time it got so worst that neither I could stand nor I could sit and lie down...'(Female PT#14)

After their self-managing efforts was insufficient in improving their condition, they reported of consulting medical doctors for diagnosis of their underlying condition and further treatment.

'Initially I was taking some medicine and some massaging gels from pharmacy. Later it was getting worse and one day it was worst and then I went to a hospital and after thorough check-ups they suspected that I might have PIVD at cervical as well as at back.' (Male PT#15)

Only those patients who had an accident reported of taking emergency treatment from hospitals. All the patients told that they mostly got pharmacological treatment from their doctors. Some patients reported using other treatment modalities like physiotherapy, acupuncture, acupressure, TENS, traction, massage therapy, some supportive lumbosacral corsets along with pharmacological ailments. They also told that these types of treatment were advised by either their physicians or their relatives and friends.

'Yes, after consulting an orthopaedic surgeon, I took lots of pain killer, took 3 injections which eased it for some period but the pain returns with more intensity and later lot of suggestion from doctors and relatives and friends I tried almost everything beside those medicine like acupuncture, TENS, tractions along with massage...' (Female PT#10)

Some participants reported of using herbal therapy, ayurvedic medicine and homeopathic medicine.

`.... I tried this ayurvedic medicine, massage, acupuncture and even I gave a try with this traditional Chinese traditional herbal medicine.....'(Male PT#03)

Some patients reported not using any other CAM treatment beside pharmacological treatment before laser therapy. A patient told that he already had back surgery for back pain before treatment with low level laser therapy.

'....my back pain started like 10 years ago. I had back surgery....... (Male PT#04)

2. Factors leading to use of LLLT

This theme covers the factors that lead the patients to look for alternative treatments like lowlevel laser therapy and why they decided to choose LLLT. The factors like unimproved condition with previous treatment modalities, adverse effects from other modalities, recommendation from different sources and getting actual knowledge about the treatment were reported.

The main factor the patients reported that the available conventional traditional treatments they had used previously other than LLLT, were not improving their back-pain condition. Patients reported that even after diagnosed with prolapsed disc, they were not getting any promising treatment modalities. They felt the treatment they were getting not the best one and some also commented as 'it was getting negative response' and 'getting even worse'.

'I visited an orthopractic doctor. He gave me some medicine and injection. I do not remember, but I felt better. After that, I started my work. But my pain returned, and it got more severe. It was so bad that it used to hurt even when I cough. Then I was suggested for acupuncture, physiotherapy, but it did not improve my condition...'(Male PT#04)

Some of them explained that they had wasted too much time in searching one suitable treatment modality which in course of time, their back pain developed from acute to chronic back pain.

Patients reported of suffering intense pain even after under treatment with other modalities. Moreover, they were concerned with their condition due to prolapsed disc and reported that they could not even able to stand and had to be carried by people when going for treatment. Beside the pain that was radiating to their lower limbs, participants also reported having tingling sensation in legs causing disability and affected even their daily activities.

'In past 9years, I had been to Delhi, Darbhanga, Siliguri, Dharan and Rajbiraj for treatment. But there was not any significant improvement. I consulted the lots of doctors, tried physiotherapy, acupuncture, tractions, and so onafter all efforts it left me pain 24/7. Difficulty sleeping, not able to perform my daily activities....wasted so many years with negative results.....' (Male PT#08)

'....my pain got worst. It was excruciating, I wish I could cut my nerves. I took hard pain killing medicine like opidol (opioid analgesic) and other NSAIDs but none of them works. My condition was so worst that 4 people had to carry me......'(Female PT#1)

Another factor that made patients search for new modalities was the adverse effects and side effects with the previously adopted treatment modalities. Patients shared their frustration taking too many painkillers which offer short term relief from pain but no improvement to their condition with prolapsed disc. In addition, some reported developing other diseases after replying on frequent usage of pharmacological treatments. Other factors related to adverse effects were the fear from other non-pharmacological treatment like pain from needle, fear with heavy instruments, having to perform hard exercises while suffering from intense pain and those who tried acupressure complained of getting some bruises and skin infection over the body. These unpleasant adverse effects were making them sought new more patients compliable treatment modalities.

'I have consulted many doctors and took many medicines which for sometimes relieved the pain but it was reoccurring and I was so frustrated as I could not quit my job and could not take medicine for ever. Then one of my friends suggested me about this therapy and I came here for the treatment and so I am taking it now...' (Male PT#15)

Furthermore, all patients reported of being advised by their orthopaedic surgeons undergoing surgery for back pain, but they did not choose the options because of unsatisfying and more serious adverse effects than those of pharmacological and non-pharmacological methods that they had heard about. Beside fear of being paralysed after surgery, they were also concerned about the financial burden they would suffer due to surgery. Some patients reported that they were familiar with the negative results from back surgery their relatives or friends had taken. A patient was continuing laser treatment for back pain even after having back surgery.

'At one hospital they recommended me to go for operation as looking at my MRI scanning, they said it was nerve compression.... [.....]Actually, I was afraid of surgery as my father had undergone operation for nerve compression before but the result was not satisfactory as well. He had one of his legs a bit loose like little paralyzed.' (Female PT#12)

Another leading factor was reported to be source of information. The participants reported that they were not recommended by any doctors especially orthopaedic surgeon, rather being advised by other relatives and friends while they were struggling with previous treatment modalities. The source of information was reported to be the driving factor towards choosing the laser therapy which was either from reliable relatives or friends. Some reported of choosing laser after seeing other getting improved results in their close surrounding while some patient visiting the clinic before for other reasons and later used it for their own back pain.

"...one of my cousin...[....] she suggested me to go to laser therapy clinic. She told me that if you had already tried so many things before you decide to go for operation just try laser once..." (Female PT#12) 'About this therapy....one of my brothers was treating for the same problem.....through him I came here.' (Female PT#5)

Though some informants explained of having prior knowledge about the treatment modality while other reported as being completely new treatment method to them. They also explained that they heard laser as harmful radiation for body cells and skin. Some patients reported of knowing about the laser priorly and choosing it over other available treatment modalities. Other reported that they had seen the promotional programs of laser therapy in some media, or news channels and decided to give it a try. Some also explained the intense painful conditions that they were facing, lead to use of laser without having enough knowledge.

'I had seen one of the interviews with the doctor on TV about laser therapy. While watching that, I feel that this might help...you know people try different unusual things to get better...' (Female PT#18)

'For me it was a totally new treatment method. Even though the doctor assured me for recovery, I was not sure or at that time you can say I did not trust her at all. I have no idea what they were going to do for 20 days with so called laser therapy. Previously I had heard that laser I harmful to skin but then I was about to be treated with those harmful radiations...' (Female PT#12)

Some participants, after advised by their friends and relatives, reported further seeking more information about laser therapy for back pain. Some of them reported searching some literatures and articles about laser on internet.

'before I came here, I had some homework about the laser therapy for pain on internet. I have read some articles about the laser and it's not so harmful as it is low level laser and I also read in one article that these types of laser will help reduce swelling and inflammation around the nerves and cells and something like that....' (Male participants#15)

While some chose LLLT because they already knew the doctor before they suffered from back pain. Some informants had expressed their belief and trust on the doctor and explained that they wanted to be treated by the hands they trusted.

'as I said I believed in her and I wanted to let myself treated by the hands that I trust...' (*Male PT#06*)

Even if they ended up wanting to try LLLT, they have few expectations towards LLLT in specific. Most expected or rather hoped that it would help. They reported that the expectation towards any new treatment was very less in the beginning due to the results they had from previous treatment modalities. Some took it as last hope as being frustrated with other options they adopted and saw no other option to be adopted.

".....I was so frustrated that I felt like 'so now what next' as none of the measures I adapted previously was not helping me at allthat time I got relief only when I was taking some medication...I could say at that time I took it as a last hope as laser was complete new for me......' (Female PT#09)

"... at that time I felt like if I needed to get recovery without doing nothing (laughing).... Like needed some magic or some potion that can instantly get rid of the pain.how many painkiller could I take....[...]....finally I agreed as I had to take one method....with a condition that if it would again hurt me with light and other things they probably would use as laser therapy then I would not go for the second day....and I came here.....' (Female PT#12)

3. Experience with the organization of the treatment

Patient's experience regarding organization of the treatment was covered by this theme. Regarding the usual schedule for treatment session, it was found to be variation among patients. The participants experienced the length of the treatment for first course was a problem having to come daily for 20 days. Conversely, participants living near the clinic reported to be no problem about the length of treatment. Those living outside the valley reported of taking intense course and stayed in the clinic for 10 days during first course as inpatients and later just 5 days intense one due to time constraint. Reduction in length with equal dose of treatment were reported to be convenient by the patient as they felt they saved time as well as avoid having to travel a lot which might worsen their painful conditions.

'I am taking 2 times a day laser for 5 days and this is my 3rd course, the first course was also 2 times a day.... you see the problem is... we have to be here for 10-20 days and you know how the condition is in villages.... we can barely take 2 days off from our daily routine, we have to look after our family, farm and animal farm and so on....' (Female PT#11)

'This is my third course of treatment. They told me to come for 20days but due to lack of time I took a intense course that is 2times a day for the first time for 10days and after 1month I had another 10day but that time I did it only once a day and after another one month this one.' (Male PT#03)

Patient were reported being curious and little scared about the laser as it was new to them before they had their first laser treatment, but they explained how the process of laser treatment helped overcoming the fear of treatment organisation they have previously experienced with other modalities of treatments. The participants described the laser machines and its components used to treat, were simpler and safer than they have expected. Terms like 'a pen connected to a small calculator like instrument', a torch light with its charger, 'a recorder in old days' were used for the actual laser machine.

'I think acupuncture is also useful but the use of so many needle is somehow inconvenient, and at the same time it is painful, but here in laser, no such thing just they have this one small calculator like machine with a torch that emits light, no fear of needles and blades and you know....' (Female PT#18)

The safety aspect of laser treatment is described by the participant in various factors. They discussed that the only thing they are getting as treatment is light without any external incision to skin and body, no external chemicals were introduced or injected inside their body, no extra pain from treatment modality and no extra heat.

"...it was just a torch light and they are pointing it on your body surface... no pain, no extra heat ...actually nothing......[...]... I got rid of fear of the treatment method but..... meanwhile I was also thinkingreally... just doing this will it really improve my condition?.....But you know when we take some treatment by just a look at those heavy and complicated machines will make it scary for taking the treatment......' (Female PT#12)

In addition to laser therapy, many participants reported of using some exercises, traction, TENS along with some pharmacological supplements like vitamins and calcium to strengthen the nerves and bones. Some still needed painkillers but in reduced frequency than before.

'She really worked hard for me. She started all the three-treatment therapy laser, traction, and TENS...'(Male PT#06)

'And now beside laser I am not on any kind of medicine like those painkillers except one vitamin B12 which the doctor prescribed me. I read it somewhere or may be heard that it strengthens your nerves. So, it's okay after all its just a vitamin.' (Male PT#15)

Moreover, the participants also related the organization of the treatment to be effective as they experienced even better relationship with the medical doctors, other medical staffs and non-medical staffs at the laser centre. They reported of being treated not as a patient but rather as friend or family member. Consultation with the medical doctor was expressed as a hope for recovery by many participants. Some also reported of relieving pain just by their friendly and warm behaviour and expressed their gratitude towards the whole service provider team.

"...but the support and the assurance I got from the doctors and the other staffs here, I managed to continue. Actually, you know in Nepal how the nurses and the staffs in a hospital behave, but I am so happy with all those staffs and always thanked them what they have done for me. They are always nice and supportive to patients....' (Female PT#12)

4. Availability and Affordability of LLLT

Participants are concerned with treatment availability as there is only one center that provides laser treatment. They explained facing problem in their back pain having to travel from different parts of the country especially those who live outside Kathmandu valley. Some participants living outside the valley stated that they must spend lot of time as well as money in traveling beside treatment time and cost. Even people living in Kathmandu valley reported having to travel a lot.

'It takes almost 1-2 hours even if I take flight otherwise by road it's almost a day....[...]....though I am getting better and laser itself is not so expensive but still it's all about the money. I have to travelled a lot and lots of expenses for traveling which almost equals to 10doses of laser.....' (Female PT#07)

Some of them compared the cost with other treatment modalities they used before and commented that the laser therapy being cost effective. While some felt that the laser was not itself costly but having to spend lots of money on travel was always somehow costly. They mostly compared cost effectiveness based on perceived result as well as risk of side effects from laser over other treatment modalities.

'I was suggested to go for surgery and it would cost like 200 thousand or may be more and still they said 'no guaranty' of recovery.....so what was the use of surgery then.....' (Male *PT#08*)

' look it's your health....even it will cost more and the result is satisfying then I don't have problem but I had used physiotherapy, other medicine and so on, and still it like same amount of money for laser. The only thing is I was not getting any improvement from previous treatment but now I am getting better...I had waste that money in previous treatment isn't it?....' (Female PT#02)

5. Outcome perception

Patient's experience and perception of the outcome after being exposed to low level treatment for back pain condition is presented in this theme. The participants treating with laser for their back pain diagnosed with PIVD and DH reported to have some change in their back pain. 'Pain is much reduced', 'getting much better', 'pain reduced by half fold', 'doing regular activities were much easier' were some of the terms used to describe their experience of improvement over pain from laser therapy. Even though participants after two courses of laser found their pain improving gradually but did not have confidence of complete absence of pain even after the longer treatment duration. Some reported that the pain was relieved but 'from 20 to 19', which was typical idioms used in Nepalese language as reduced by one point. Some participant reported of some change but nothing relating to pain.

'When I started to walk, I felt the pain, but now it's much better, and I fell pain only at this side. But it gets better after some time.' (Female PT#19)

Patients mostly compared their condition to the condition they had before low-level laser treatment and experienced improvement in their activities and movements. The participants responded their general condition and wellness is improved rather than pain. Some of the participants experience increased in pain severity on first few days of laser during their first course and after 20 doses of laser they felt some improvement.

'But I had those days also after 3days of treatment until 10-12days I almost wanted to discontinue but I was saying to myself that it had been long time struggling with the pain and I needed to stick to at least one treatment so I continued.....' (Female PT#12)

'Yes, there is difference. Before I came here 'I was unable to stand on my legs and ankle hurt and..... I don't know but there was pain in so many parts which make it difficult to walk for which I have to take taxi to visit here. And after the 4th day of treatment, I was able to walk easily...' (Female PT#10)

In addition, they also described that laser was comparatively better over other treatment methods they have used previously. Sense of relaxation during the laser treatment was reported by some informants. The participant experienced improvement from tingling sensation.

'it felt some improvement.....otherwise due to back problem, it was difficult stay without using lumber corset belt, its little easy now, also it was hard to stand for long time, needed to some kind of legs movement either move front/back or bend the legs or what so ever but I was moving my legs to ease the comfortability. In addition it was very difficult when I came here for the first time it's like the feeling of nerve deep inside was broken and had to drag my foot as it was like I had a paralysis to the legs. Then I came here for the treatment and it has some changes some improvements..' (Female PT#11)

5. Discussion

This section presents the discussion of methods and results and finally conclusion of this study at the end.

5.1 Discussion of the methods

This section is described by the concept of trustworthiness, which is crucial aspect in qualitative research. Trustworthiness ensures the quality and transparency in the methodology such that the research findings are worthy of attention [68]. Lincoln and Guba described the concept of trustworthiness by introducing criteria of credibility, transferability, dependability and confirmability [69]. In the following, credibility, transferability and confirmability were used to discuss the methodological strengths and limitations.

5.1.1 Credibility

Credibility is most important criteria that addresses the extent of trust or confident in researcher in the truth of the study's findings [69]. It depends on how true and accurate the informants view is represented. In this study, credibility was addressed by choosing purposive sampling techniques, a semi-structured interview guided interviews and following the step-by-step thematic analysis as documented by Braun and Clarke (2006) [69].

At the same time, the primary researcher was novice researcher and conducting his master level thesis, so it was challenging. Time constraint was one of the challenges that might affect the findings in detail and depth of the analysis as well as data collection. With limited experience in conducting qualitative interviews and the shorter length (an average of 26 min), the researcher might have left with the possibility of missing information in data collection.

In addition, *reflexivity* refers to researcher's conscious and deliberate effort and when a researcher clearly describes the contextual intersecting relationships (e.g., race, socio-economic status, age, cultural background) between the participants and themselves, it increases the credibility of the findings [70].

In this study, the researcher was involved in all stages in conducting this study and was not depending on third person that made it easier to accurately portray the representation of the information that the participant provided. Conduction of interviews in two local languages by the researcher himself made it further easier to provide the actual meaning of the participant's perception and experience into written form. Moreover, the interviewer was not involved in the treatment, informants could freely share their views without any external influences [62]. On the other hand, having to do all the process by researcher himself alone leaves the possibility of biasness. The primary researcher background and his prior knowledge about the issue and most of the intersecting relationship with participants has somehow affected the results. Moreover, the researcher had already been familiar with the laser therapy clinic before conduction of the study and there was some chance of reflecting some of his preconception about the patients' experiences towards the organisation of the treatment modality.

5.1.2 Transferability

The next criteria transferability ensures the extent to which the outcomes are valuable and useful to other setting than the context, location and people studied.[68] Transferability is supported by the rich and detailed description of the context and the background data as well as the detailed and diverse demographic characteristics of the people studied and transparent analysis of the data.

In this study, we have provided a clear and detailed description of the context, background information of the studied issue, demographic data of participants, step by step detailed procedures of methodology in this report. However, only the participants benefited with laser therapy and those who were continuing the treatment, attended the interviews. The researcher was unable to include variation in sample for example it missed patients who discontinued. The limited availability of the service at one place is another factor which could be affected the findings. Both out-patients and in-patients were interviewed and the relations between perception and experiences in those field could have resulted in other findings.

5.1.3 Confirmability

Confirmability is the degree that the findings are true representation of the information provided by the informant and therefore the interpretation.[68] It depends on data analysis of a research [69].

In this study, the researcher presented a short summary of the main topics that had been described by the informant at the end of the interviews to ensure the true meaning conveyed by the informant. Translation and transcription were conducted in detailed and checked against the records several times for accuracy. All the summary and field notes were stored in separate excel file for each interview. Every item in the data was given equal attention to form a corresponding code. The results were exact representation of the interviews without any assumption from the researcher. All the steps and processes were documented and checked against the guidelines documented in authentic sources.

Conversely, the data were processed and analysed by the researcher himself leaving some biasness. As the researcher was not a native English speaker and translated the interviews himself without prior experiences which could lead to some misinterpretation. The analysis was also conducted using only excel software which was challenging in generation of code, patterns and themes.

5.2 Discussion of the findings

Summary of the findings

The objective of this study was to explore the experience of patients regarding low back pain in disc degenerative case undergoing laser treatment. It was found that patients had used a range of treatment modalities before they sought out low-level laser treatment regarding their low back pain condition. The factors leading to use laser therapy was reported to be the unsatisfying responses in their back-pain condition from the treatments they had adopted. Furthermore, they had been recommended by their relatives and friends as they lack knowledge about laser. According to the participant's response, the treatment itself was experienced as simple, non-invasive, and safe with no side effects; cost effective compared to other modalities they previously used. Beside supportive behaviour from their service provider, they commented on its availability being a problem as it was available at only one clinic throughout the country. Regarding outcome perception, the general condition and wellbeing perception was improved and reduction in pain severity had reported to be some extent, but they were missing the feeling of complete absence of pain even after the longer treatment duration. As no studies on patients experience with low-level laser therapy for disc degenerative back pain was identified, this study is likely the first of its type. Thus, the findings will be compared to similar studies in other areas regarding why patient sought laser treatment, how they experienced the treatment itself and what were their perception of the outcome.

As described in the background of this study, the pattern of heath seeking in low back pain found to be similar as seen in other studies. This pattern is explained by the fact that the acute back pain is rather self-limiting in nature [12] and most acute pain gets better with complete rest, avoiding heavy exercises and some prefers medical treatment [5].

Most informants adopted combination of various treatment modalities like pharmacological treatment, non-pharmacological treatment like physiotherapy, acupuncture, acupressure, TENS, traction, herbal medicine, ayurvedic, homeopathy either prescribed by their physicians or suggested by their relatives and friends. Various studies and guidelines for management of back pain had also suggested some of these type of combination [5, 15, 17]. The advice the patients had been given about undergoing surgery during their consultation with an orthopaedic surgeon before they started laser treatment is similar to previous studies and guidelines [20]. Furthermore, rejection of the surgery options was reported by the patient because of knowledge they had and the negative consequences they had seen.

Prior knowledge and preconception about the laser therapy were found to inadequate before using low-level laser treatment. This lack of knowledge held true as little was known about low level laser therapy as suggested by studies available and the wide use of laser as surgical works instead of blades, repairing a damage retina in the eyes or cutting body tissues, and to heat or destroy small areas or cancer cells [71].

The acceptability of any treatment modalities is explained by various factors like the length of treatment, cost and accessibility as well as the patients- service provider relationship. [51,52, 72]. The treatment schedule for laser was presented to be longer duration by most of the patients which holds true with the results from studies that used laser therapy for various indication [72]. Several interviewees reported laser treatment being cost effective compared to other treatment modalities. Those who travelled longer distance for the laser treatment commented traveling cost was higher than the treatment itself. They also felt having the treatment available at one place to be problematic. It was noted from other study that access and the cost were found to be major barrier [52].

In addition, they expressed positive and supportive behaviour from the service providers which had a positive impact on their overall experience of the treatment. It has been noticed that a positive and effective relationship between patient and their care giver is essential for improving outcomes and quality of a treatment [72]. The relation between the service provider and the patients were reported to be strong driver for the acceptability of the treatment model itself as seen a study for back pain using acupuncture [51].

Furthermore, the informant also showed positive attitude towards its safety, simplicity, and affordability which further added acceptability of the treatment continuation. The informants felt safe in using laser due to non-invasiveness of laser, no side effects, no heat generation, no sound or vibration, simple instruments of treatment modality which is associated with motivation towards the treatment outcome. These outcome perceptions were matched with the study that used laser for caries treatment [48]. Similar results were found in various studies conducted using various complementary and alternative treatments [15, 23, 24]. Moreover, they commented that they were able to avoid the harmful side effects of pharmacological treatment, and inconvenient and uncompliant feeling from other form of complementary and alternative medicines which were seen in some of treatments like physiotherapy, acupuncture, and acupressure [15, 48].

The outcome perception of patients towards a treatment in low back pain is related to patientreported outcome such as improvement in functionality, pain and health-related quality of life [74]. In addition, patient-reported outcomes such as the motivation, active involvement and self-management skills of patients are crucial which can be seen in a study for low back pain using spinal stabilizing exercises [53]. These outcome perceptions are in lines with this study. The informant expressed positive response to low level laser treatment in reduction of pain severity, better functionality associated with physical activity and better health condition from underlying disease of disc degeneration of vertebra. A range of positive outcomes such as increased options and hope, increased ability to relax, increased sense of well-being, improvement in physical conditions unrelated to back pain, increased energy, increased patient activation, and dramatic improvements in health or well-being were also reported in a study conducted by Hsu, C., J. Bluespruce, K. Sherman and D. Cherkin (2010) [49]. As expected, since this study recruited patients continuing to use LLLT, reported to have at least some effect most notably pain relief. Although not directly comparable, as stated in the introduction, there are some reports on efficacy in treatment of discogenic back pain [40-42].

Meanwhile, in our study some patients experienced severe pain during first session of the treatment but improved gradually afterwards. In addition, few participants experienced lethargy during treatment session which were not described in studies previously.

The informants at the end of interviews were asked to comment on recommendation of this treatment, they emphasized it should have been the first line treatment and was recommendable which also did not describe previously by any studies.

5.3 Conclusion

Our findings based on patients' experience shows some positive attitude towards the use and acceptance of laser treatment associated with low back pain from disc degenerative disease. However, reduction in pain severity and feeling of wellness in general condition was unclear whether it was due to laser alone or other combination treatment. In addition, other explanations such as better compliance, less side effect, affordability and the positive relation between patients and service provider could be reasons for its acceptability. Altogether these findings can be useful for physicians, patients and researchers for further understanding about low-level laser treatment. Additional qualitative research exploring patients experiences towards use of low-level laser therapy for lower back pain from disc degenerative causes are important to know more about its outcome.

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Appendix A: Ethics Approvals

1. Approval from Norwegian University of Science and Technology, Norway

Fra: Veileder[jon.o.odland@ntnu.no]

Oppgavens tittel / Title of the thesis Laser Therapy for Lower Back Pain in Disc Degenerative Cases in Nepal: A Mixed Method Study Studenten(e)s navn / Student(s) name SHAMBHU MAHARJAN		
Dppgaven faller innenfor retningslinjene / The thesis meets the requirements	Ja / Yes	
Oppgaven er akseptabel fra et forskningsetisk synspunkt / The thesis is acceptable from a research- ethical perspective	Ja / Yes	
Kommentarer / Comments		
1. Forskningsmessig verdi av prosjektet / Significance of the research project	Tilfredsstillende / Satisfactory	
2. Valg av forskningsmetode / Choice of research method	Passende / Appropriate	
3. Omfanget av oppgaven / The scope of the thesis	Tilfredsstillende / Satisfactory	
4. Fremdriftsplan / Progress plan	Tilfredsstillende / Satisfactory	
5. Økonomisk overslag / Budget estimate	Rimelig / Reasonable	
6. Er formalitetene ovenfor REK, NSD, Biobank ivaretatt? / Have all the formalities regarding REK, NSD, Biobank etc. been considered?	Ja / Yes	
Kommentar / Comment The principle is that the candidate start the ethic	al process in Nepal, then we take it from here immediately.	
Konklusjon / Conclusion		
Konklusjon (til studenten) / Conclusion (for the student)	Aksepteres i nåværende form / Accepted as it is.	
Kommentar / Comment The candidate must be informed about the ethica	I process immediately. By experience, this will take some time in Nepal	
Skjemainnsender / Transmitter of form ID fra FEIDE / ID from FEIDE		
Navn innsender / Name transmitter	Jon Øyvind Odland	
E-post / E-mail	jon.o.odland@ntnu.no	

2. Approval from Laser Therapy Clinic, Nepal



Date: 15th May, 2019

TO WHOM IT MAY CONCERN

This is to inform you that LASER THERAPY CLINIC is the clinic with 18 years history of establishment, where daily more than 100 of patients comes for treatment. I approve Mr. Shambhu Maharjan for his research study in laser therapy clinic Nepal.

I wish him success.

Managing Director

Broad and the state of the stat

MD. General Physician, Gynecologist, Laser Therapist

3. Nepal Health Research Council (NHRC) Ethical Approval



Government of Nepal Nepal Health Research Council (NHRC) Estd. 1991

Ref. No.: 3344

30 June 2019

Mr. Shambhu Maharjan

Principal Investigator Norwegian University of Science and Technology Norway

Ref. Approval of thesis proposal entitled Laser therapy for lower back pain in disc degenerative cases in Nepal: A mixed method study

Dear Mr. Maharjan,

It is my pleasure to inform you that the above-mentioned proposal submitted on **19 April 2019** (Reg. no. 238/2019) has been approved by Nepal Health Research Council (NHRC) National Ethical Guidelines for Health Research in Nepal, Standard Operating Procedures Section 'C' point no. 6.3 through Expedited Review Procedures.

As per NHRC rules and regulations, the investigator has to strictly follow the protocol stipulated in the proposal. Any change in objective(s), problem statement, research question or hypothesis, methodology, implementation procedure, data management and budget that may be necessary in course of the implementation of the research proposal can only be made so and implemented after prior approval from this council. Thus, it is compulsory to submit the detail of such changes intended or desired with justification prior to actual change in the protocol. Expiration date of this proposal is **November 2019**.

If the researcher requires transfer of the bio samples to other countries, the investigator should apply to the NHRC for the permission. The researchers will not be allowed to ship any raw/crude human biomaterial outside the country; only extracted and amplified samples can be taken to labs outside of Nepal for further study, as per the protocol submitted and approved by the NHRC. The remaining samples of the lab should be destroyed as per standard operating procedure, the process documented, and the NHRC informed.

Further, the researchers are directed to strictly abide by the National Ethical Guidelines published by NHRC during the implementation of their research proposal and submit progress report in between and full or summary report upon completion.

As per your thesis proposal, the total research budget is **Rs 3,54,000** and accordingly the processing fee amounts to **Rs 10,000**. It is acknowledged that the above-mentioned processing fee has been received at NHRC.

If you have any questions, please contact the Ethical Review M & E Section at NHRC,

Thanking you,

Prof. Dr. Anjani Kumar Jha Executive Chairperson

Tel: +977 1 4254220, Fax: +977 1 4262469, Ramshah Path, PO Box: 7626, Kathmandu, Nepal Website: http://www.nhrc.gov.np, E-mail: nhrc@nhrc.gov.np

4. Norwegian Research Ethics Board Exception



Region: REK midt Saksbehandler: Ramunas Kazakauskas Vår dato: Telefon: 23.06.2020 Deres referanse:

Vår referanse: 140804

Aslak Steinsbekk

140804 Patient experience laser therapy Nepal

Forskningsansvarlig: Norges teknisk-naturvitenskapelige universitet

Søker: Aslak Steinsbekk

Søkers beskrivelse av formål:

Lower back pain (LBP), a musculoskeletal disorder, being one of the top health problem causing most disability accounting the highest number of years with disability in Nepal. One of the treatments offered is low-level laser therapy (LLLT), and a substantial number of patient has been treated with this therapy. However, no previous studies on the Nepalese patients experience with this type of treatment has been identified. Therefore, the this study explore the experiences of patients diagnosed with intervertebral disc degeneration treated for lower back pain with Low-level laser therapy in Nepal. A qualitative study with face-to-face individual qualitative interviews of patients attending one laser therapy clinic in Nepal will be conducted. The data will be analysed thematically, and the result published as a master thesis.

REKs vurdering

Vi viser til søknad om forhåndsgodkjenning av ovennevnte forskningsprosjekt. Søknaden ble behandlet av Regional komité for medisinsk og helsefaglig forskningsetikk Midt-Norge (REK midt) i møtet 03.06.2020. Vurderingen er gjort med hjemmel i helseforskningsloven § 10.

Denne søknaden er en revisjon av en tidligere innsendt søknad som har blitt avslått (vedtak datert 14.04.2020). I henhold til REKs praksis kan vi ikke behandle en søknad som er en revisjon av en tidligere innsendt søknad med samme formål, med mindre den er innsendt som en klage på et tidligere vedtak. Du sendte den nye søknaden innenfor tre ukers klagefrist. Vi behandlet derfor denne søknaden som en klage på forrige avslag.

Du har i den reviderte søknaden kommentert de punktene som var vår begrunnelse for avslaget:

- Utistrekkelig forskningsprotokoll: protokollen er nå revidert hvor den kvantitative delen av studien utgår. Prosjektet er nå kun en kvalitativ studie. Du har videre lagt ved en oversikt over tidlere gjennomført forskning på temaet samt revidert metodedelen til å omhandle kvalitative forskningsmetoder.
- Interessekonflikt: du opplyser om at rollen "supervisor" var uklart beskrevet i den opprinnelige søknaden. Du bekrefter at vedkommende ikke har hatt noen veiledningsansvar i forbindelse med prosjektet, men er en eier av klinikken hvor

REK midt

Besøksadresse: Øya Helsehus, 3. etasje, Mauritz Hansens gate 2, Trondheim

Telefon:73 59 75 11 | E-post:rek-midt@mh.ntnu.no Web:https://rekportalen.no

Norwegian Research Ethics Board Exception (continue)

prosjektet ble gjennomført. Studenten som gjennomførte prosjektet var heller ikke tilknyttet klinikken.

 Rekruttering av deltakerne: du bekrefter at alle deltakerne var informert både muntlig og skriftlig om prosjektet, på morsmål. Intervjuet var også gjennomført på det språket som deltakerne foretrakk.

Ettergodkjenning

Vi behandlet denne søknaden som en søknad om ettergodkjenning, fordi studien allerede er gjennomført. Vi vurderer at studien kan godkjennes. Du har i rollen som prosjektleder handlet i god tro. Det at søknaden ikke ble sendt i tide beror på en misforståelse i prosjektgruppen. Videre finner vi på grunnlaget av den reviderte forskningsprotokollen at prosjektet nå framstår som forsvarlig. Vi hadde godkjent den dersom søknaden hadde blitt sendt inn på forhånd.

Vilkår for godkjenning

- 1. Komiteen forutsetter at ingen personidentifiserbare opplysninger kan framkomme ved publisering eller annen offentliggjøring.
- Komiteen forutsetter at du og alle prosjektmedarbeiderne følger institusjonens bestemmelser for å ivareta informasjonssikkerhet og personvern ved innsamling, bruk, oppbevaring, deling og utlevering av personopplysninger.
- Av dokumentasjonshensyn må du oppbevare opplysningene i 5 år etter prosjektslutt. Opplysningene skal oppbevares avidentifisert, dvs. atskilt i en nøkkel- og en datafil. Opplysningene skal deretter slettes eller anonymiseres.

Vedtak

Godkjent med vilkår

Med vennlig hilsen

Vibeke Videm Dr. med. Leder, REK midt

Ramunas Kazakauskas Rådgiver

Sluttmelding

Søker skal sende sluttmelding til REK midt på eget skjema senest seks måneder etter godkjenningsperioden er utløpt, jf. hfl. § 12.

Søknad om å foreta vesentlige endringer

Dersom man ønsker å foreta vesentlige endringer i forhold til formål, metode, tidsløp eller organisering, skal søknad sendes til den regionale komiteen for medisinsk og helsefaglig

Norwegian Research Ethics Board Exception (continue)

forskningsetikk som har gitt forhåndsgodkjenning. Søknaden skal beskrive hvilke endringer som ønskes foretatt og begrunnelsen for disse, jf. hfl. § 11.

Klageadgang

Du kan klage på komiteens vedtak, jf. forvaltningsloven § 28 flg. Klagen sendes til REK midt. Klagefristen er tre uker fra du mottar dette brevet. Dersom vedtaket opprettholdes av REK midt, sendes klagen videre til Den nasjonale forskningsetiske komité for medisin og helsefag (NEM) for endelig vurdering.

Appendix B: Participant Information and Consent Sheet

i. English version

INVITATION TO PARTICIPATE IN A RESEARCH PROJECT

Laser Therapy for Lower Back Pain in Disc Degenerative Cases in Nepal: A Mixed Method Study

You are invited to participate in a research project to explore the experiences and perception of patients diagnosed with intervertebral disc degeneration treated for lower back pain with Low-level laser therapy in Nepal.

WHAT IS THE PROJECT ABOUT?

As part of the requirements for master's degree at NTNU, I must carry out a research study. The study is concerned with investigating effect of low-level laser therapy as an alternative treatment in lower back pain for patients diagnosed with intervertebral disc degeneration among people in Nepal.

The project will collect and record personal information about you. As you have been treating lower back pain for the intervertebral disc degenerative condition with laser, we have included you as a representative participant for our study. It will mainly involve interview for your experience and perception with this treatment and its outcome. The interview will take place in a private setting and the time frame will be from 15 to 30minutes only.

FORESEEABLE BENEFITS AND PREDICTABLE RISKS AND BURDENS OF TAKING PART

The study involves no additional intervention or any kind of tests. So, there will be no risks and burden of taking part in this study. The information about treatment you have been receiving could be useful to other population, so with participating in this study you are helping those patients.

VOLUNTARY PARTICIPATION AND THE POSSIBLITY TO WITHDRAW CONSENT

Participation in the project is voluntary. If you wish to take part, you will need to sign the declaration of consent on the last page. You can, at any given time and without reason withdraw your consent. This will not have any consequences for any future treatment. If you decide to withdraw participation in the project, you can demand that your tests and personal data concerning health be deleted, unless however, the personal data concerning health and tests have already been analysed or used in scientific publications. If you at a later point, wish to withdraw consent or have questions regarding the project, you can contact Shambhu Maharjan, +4746262360 and shambhum@stud.ntnu.no.

WHAT WILL HAPPEN TO YOUR PERSONAL DATA CONCERNING HEALTH?

Any personal data concerning health that has been recorded about you will only be used as described in the purpose of the project. You have the right to access information that has been recorded about you and the right to stipulate that any error(s) in the information that is recorded is/are corrected. You also have the right to know which security measures have been/will be taken when your personal data concerning health is processed.

All information will be processed and used without your name or personal identification number, or any other information that is directly identifiable to you. A code links you and your personal data concerning health via an identifier list. Only *Shambhu Maharjan as a researcher* will have access to this list.

Information about you will be anonymised or deleted five years after the project has ended.

SHARING OF PERSONAL DATA AND TRANSFER OF PERSONAL DATA ABROAD

By agreeing to participate in the study, you are also consenting to that your information for example age, diagnosis and comorbidity beside your main research interest can be transferred to another country as a part of research collaboration and publication. This can be a country where the laws do not meet the requirements of the European Data Protection Law. The researcher will therefore ensure that your personal data concerning health is kept safe.

The code that connects you and your personal data concerning health will not be released.

APPROVAL

This study is conducted as a master thesis in Global Health at Norwegian University of Science and Technology (NTNU). It was reviewed and approved by NTNU on March 22, 2019. Permission to conduct the study at the Laser Therapy Clinic in Nepal was approved from the medical director of the clinic herself on May 15, 2019. The interviews were conducted in Nepal and was approved by the Nepal Health Research Council on June 30, 2019. This study was approved by the Regional Committees for Medical and Health Research Ethics for mid-Norway region on June 23, 2020.

In accordance with the General Data Protection Regulation the controller NTNU and the researcher Shambhu Maharjan is independently responsible to ensure that the processing of your personal data concerning health has a legal basis. This project has legal basis in accordance with the EUs General Data Protection Regulation, article 6 no. 1a, article 9 no. 2a and your consent.

You have the right to submit a complaint on the processing of your personal health data concerning health to the Norwegian Data Inspectorate (Datatilsynet).

CONTACT INFORMATION

If you have any questions regarding the research project, you can get in touch with Shambhu Maharjan, +4746262360, email <u>shambhum@stud.ntnu.no</u>

I CONSENT TO PARTICIPATING IN THE RESEARCH PROJECT AND THAT MY PERSONAL DATA CONCERING HEALTH AND BIOLOGICAL MATERIAL CAN BE USED AS DESCRIBED ABOVE

City/Town and date	Participant's Signature
	Participant's Name (in BLOCK LETTERS)
	(Full name), we consent for him/her to participate
in the Research Project	
City/Town and date	Parent's/Guardian's Signature
	Parent's/Guardian's (in BLOCK LETTERS)
City/Town and date	Parent's/Guardian's Signature

Parent's/Guardian's (in BLOCK LETTERS)

Consent on behalf of a representative.

As next of kin for _____ (Full name) I hereby consent to that he/she can participate in the research project.

Place and date

Next of kin signature

Next of kin name (IN BLOCK LETTERS)

I confirm that I have given information about the research project.

.....

Place and date

Signature

Role in the research project

ii. In Nepali Language

अनुसन्धान प्रोजेक्टमा सहभागी हूने मन्जुरीनामा

तपाईंलाई एक अनुसन्धान परियोजनामा भाग लिन निमन्त्रणा दियिएको छ जुन हड्डी खिइने तथा नसा च्याप्ने रोगबाट हुने ढाड दुखाइको उपचारको लागी नेपालमा लेजर थेरेपीको प्रयोग गर्दाको अनुभवहरू र धारणा पत्ता लगाउन गरिएको हो।

NTNU मा मास्टर डिग्री को लागी आवश्यकता को भाग को रूपमा, मलाई एक अनुसन्धान अध्ययन को लागी हजुरको विचारको आवस्यकता भएको हो। नेपालमा हड्डी खिइने तथा नसा च्याप्ने रोगबाट हुने ढाड दुखाइको वैकल्पिक उपचारको रूपमा लेजर थेरेपी को प्रभाव को जांच संग यो अध्ययन सम्बन्धित छ।

परियोजना तपाईंको बारेमा व्यक्तिगत जानकारी सङ्कलन र रेकर्ड गर्नेछ। तपाईं लेजर संग हड्डी खिइने तथा नसा च्याप्ने रोगबाट हुने ढाड दुखाइको स्थितिको लागि उपचारको रूपमा, तपाईंलाई आफ्नो अध्ययनको लागि प्रतिनिधि भागीदारको रूपमा शामिल गरिएको छ। यसको उपचार र परिणामसँग तपाइँको अनुभव र धारणाको लागि मुख्य रूपमा अन्तर्वार्ता समावेश गर्नेछ। अन्तर्वार्ता एक निजी सेटिडमा हुनेछ र समय सीमा केवल 15 देखि 30 मिनेट सम्म हुनेछ।

अध्ययनमा कुनै अतिरिक्त हस्तक्षेप वा कुनै पनि प्रकारको परीक्षण समावेश छैन। तसर्थ, यो अध्ययनमा भाग लिन कुनै खतरा र बोझ हुनेछैन। तपाईंले प्राप्त गरेको उपचारको बारेमा जानकारी अन्य मानिसको लागि उपयोगी हुन सक्छ, त्यसैले यस अध्ययनमा भाग लिन तपाईंले तिनीहरूका (बिरामीहरूलाई) मद्दत गर्दै हुनुहुन्छ।

परियोजनामा सहभागिता स्वैच्छिक छ। यदि तपाइँ भाग लिन चाहानुहुन्छ भने, तपाईंलाई अन्तिम पृष्ठमा सहमतिको घोषणामा हस्ताक्षर गर्न आवश्यक छ। तपाईं कुनै पनि समयमा र कुनै कारणले तपाइँको सहमति फिर्ता लिन सक्नुहुन्छ। यो परिणाम भविष्यको कुनै पनि अन्य प्रयोजनको लागि प्रयोग हुने छैन। यदि तपाईंले यो परियोजनामा सहभागिता हटाउन निर्णय गर्नुहुन्छ भने, तपाइँ स्वास्थ्यको बारेमा आफ्नो परीक्षण र व्यक्तिगत डेटा मेटिने माग गर्न सक्नुहुनेछ, तथापि, स्वास्थ्य र परीक्षण सम्बन्धी व्यक्तिगत डेटा पहिले नै विश्लेषण गरिएको छ वा वैज्ञानिक प्रकाशनहरूमा प्रयोग गरिन्छ। यदि तपाईं पछिको बिन्दुमा, सहमति फिर्ता लिन वा यस परियोजनाको सम्बन्धमा प्रश्नहरू राख्न चाहनुहुन्छ भने, तपाईं शम्भु महर्जन, +4746262360 र shambhum@stud.ntnu.no मा सम्पर्क गर्न सक्नुहुन्छ।

तपाईंको बारेमा रेकर्ड गरिएको स्वास्थ्य सम्बन्धी कुनैपनि व्यक्तिगत डेटा मात्र परियोजनाको उद्देश्यमा वर्णन गरिएको रूपमा मात्र प्रयोग गरिनेछ। तपाईंसँग जानकारी र तपाईंको बारेमा दावी गर्ने अधिकारको पहुँच गर्न अधिकार छ कि रेकर्ड गरिएको जानकारीमा कुनै त्रुटि (हरू) सही छ। तपाईंसँग पनि जान्नको लागि अधिकार छ कि कुन सुरक्षा उपायहरू छन् / लैजानेछ जब तपाईंको व्यक्तिगत डेटा प्रसोधन गरिन्छ।

सम्पूर्ण जानकारीहरू प्रशोधन गरिनेछ र तपाईंको नाम वा व्यक्तिगत पहिचान नम्बर वा अन्य कुनै जानकारी जुन तपाइँसँग प्रत्यक्ष रूपमा पहिचानयोग्य बिना प्रयोग गरिन्छ। कोड एक पहिचानकर्ता सूची मार्फत स्वास्थ्य सम्बन्धी तपाइँ र तपाईंको व्यक्तिगत डेटा लिङ्क गर्दछ। शोधकर्ताको रूपमा मात्र शम्बु महर्जन यस सूचीमा पहुँच हुनेछ। तपाईंको परियोजना समाप्त भएको पाँच वर्ष पछि तपाईंको नाम हटाइनेछ। अध्ययनमा भाग लिन सहमत हुनाले, तपाइँले पनि तपाइँको जानकारीको लागि उदाहरणका लागि उमेर, निदान र अन्य रोग को आधारमा तपाईंको अनुसन्धान रुचि सम्बन्धी अर्को देशलाई अनुसन्धान सहयोग र प्रकाशनको भागको रूपमा हस्तान्तरण गर्न सकिन्छ। यो एक देश हुन सक्छ जहाँ कानुनहरूले युरोपेली डेटा संरक्षण कानूनको आवश्यकताहरू पूरा गर्दैनन्। यसैले अनुसन्धानकर्ताले यो सुनिश्चित गर्नेछ कि स्वास्थ्य सम्बन्धी तपाईंको व्यक्तिगत डेटा स्रक्षित राखिएको छ।

स्वास्थ्य सम्बन्धी कोड र तपाईंको व्यक्तिगत डेटा जोड्ने कोड जारी गरिने छैन। म अनुसन्धान प्रोजेक्टमा सहभागी हुन चाहन्छु र मेरो व्यक्तिगत जानकारी माथि उलेखित भए अनुसार स्वास्थ्यसंग सम्बन्ध राखेको छ।

हस्ताक्षर तथा मिति

Appendix C: Interview Guide

"Laser Therapy for Lower Back Pain in Disc Degenerative Cases in Nepal: A Mixed Method Study?"

I: Introduce Topic

- I: Who I am
- I: What the project is about
- I: Time/Duration of the Interview (30-60 minutes)
- I: Informed consent all information will be kept confidential and secure
- I: Permission for recording the conversation
- I: Possibility to withdraw participation
- I: Necessary data (Name, Age, Sex, Any Work/Job?)

I: Ask question: "What is your experience with the laser treatment at the clinic and how has this changed your current condition?

P: (Allow the participant to speak! Do not Interrupt!)

I: Choosing angle + 2 to 4 additional questions

Cover the following topics if not mentioned during the participant's response

- Main Diagnosis and comorbidities
- Length of low back pain
- Various treatment adopted
- difference in pain severity and general quality of life before and after treatment with laser)
- Expectation and knowledge about LLLT
- Recommendable as per their experiences
- I: End the interview and thank them for their participation

