Abstract of thesis entitled

“Evidence-based guidelines of using auricular therapy in patients with chronic low back pain”

Submitted by

Tang Lai Fong

for the degree of Master of Nursing

at The University of Hong Kong

in July 2015

Low back pain is one of the most common health problem in adult and is the most prevalent musculoskeletal condition for medical consultation. It is the top 10 disease worldwide with prevalence of 39.7% in Hong Kong. Around 60% to 80% people reported recurrent back pain after their first episode. The pain would restrict patients’ daily life activities and their quality of life. This pain leads to lengthen hospitalization, repeated hospital admission and risen burden on healthcare professionals.

There are growing evidence demonstrated the effectiveness of auricular acupressure on managing chronic low back pain (CLBP). However, currently there is no systemic review conducted to support the translation of the research evidence into practice. Therefore, this dissertation aims to evaluate the current evidence on the application of auriculotherapy programme, to formulate an evidence-based guidelines, assess the implementation potential and to develop an implementation strategy and evaluation plan.
Five electronic databases, PubMed, China Journal Net, CINAHL Plus, Ovid Medline® and eKG, were searched. Six studies met the inclusion and exclusion criteria of this dissertation. Critical appraisal had been done to ensure the quality and validity of the selected studies by the Critical Appraisal Skill Programme (CASP) and the Scottish Intercollegiate Guidelines Network (SIGN). All the six included studies were graded as high quality studies and showed that the auriculotherapy effectively relieving the pain among the people with low back pain.

An evidence-based guidelines on using auricular therapy was developed, of which the implementation potential is assessed based on the similarity and the readiness of local setting of specialty of orthopedic and traumatology to the proposed environment. The proposed innovation was deemed to be feasible after the examination of approval method, staff competency and resources. The potential benefits to patients, frontline staff and the hospital were high while the risks to the patients were minimal.

A 12-month implementation program was scheduled including communication with stakeholders, training to nurses and a pilot of the guidelines. Evaluation plan of the effectiveness of the proposed innovation is developed, with the result generated to be used to provide recommendation for further adjustment on the protocol to give a better outcome. With little expenditure and expected input and the potential benefits to patients, healthcare providers and hospital, the implementation of the auriculotherapy innovation is suggested to be adopted in the clinical setting.
Evidence-based guidelines of using auricular therapy in patients with chronic low back pain

By

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BSN, RN

A dissertation submitted in partial fulfillment of the requirements
for the degree of Master of Nursing
at The University of Hong Kong

July 2015
Declaration

I declare that this thesis represents my own work, except where due acknowledgment is made, and that it has not been previously included in a thesis, dissertation or report submitted to this university or to any other institution for a degree, diploma or other qualification.

Signed .................................................................

Tang Lai Fong

July 2015
Acknowledgement

I would like to express my heartfelt gratitude to my supervisor Dr. Joyce Chung, who provides guidance and inspiration on this dissertation. Her encouragement and support throughout these two years enable me to complete this dissertation successfully. Thank you very much Dr. Chung!

I also like to express my sincere gratitude to my family who have supported and encouraged me since I was little and offer me a great environment to learn.

Finally, I deeply thank my friends, colleagues and classmates who have supported me to complete this master programme.
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## Abbreviations

<table>
<thead>
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<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>ADL</td>
<td>Activity of daily living</td>
</tr>
<tr>
<td>APN</td>
<td>Advanced practice nurse</td>
</tr>
<tr>
<td>BPI</td>
<td>Brief Pain Inventory Short Form</td>
</tr>
<tr>
<td>CASP</td>
<td>Critical Appraisal Skill Programme</td>
</tr>
<tr>
<td>CLBP</td>
<td>Chronic low back pain</td>
</tr>
<tr>
<td>COS</td>
<td>Chief of Service</td>
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<tr>
<td>DOM</td>
<td>Department Operation Manager</td>
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<tr>
<td>EBP</td>
<td>Evidence-based practice</td>
</tr>
<tr>
<td>EN</td>
<td>Enrolled nurse</td>
</tr>
<tr>
<td>HA</td>
<td>Hospital Authority</td>
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<tr>
<td>MBS</td>
<td>Modified Braden score</td>
</tr>
<tr>
<td>MPQ</td>
<td>McGill Pain Questionnaire</td>
</tr>
<tr>
<td>O&amp;T</td>
<td>Orthopedic and Traumatology</td>
</tr>
<tr>
<td>QOL</td>
<td>Quality of life</td>
</tr>
<tr>
<td>RCT</td>
<td>Randomized controlled trial</td>
</tr>
<tr>
<td>RN</td>
<td>Registered nurse</td>
</tr>
<tr>
<td>SPSS</td>
<td>Statistical Package for Social Science</td>
</tr>
<tr>
<td>TCM</td>
<td>Traditional Chinese Medicine</td>
</tr>
<tr>
<td>VRS-Chinese</td>
<td>Chinese Pain Intensity Verbal Rating Scale</td>
</tr>
<tr>
<td>VAS</td>
<td>Visual Analogue Scale</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organization</td>
</tr>
<tr>
<td>WN</td>
<td>Ward manager</td>
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**Symbols**

<table>
<thead>
<tr>
<th>Symbol</th>
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<tr>
<td>1++</td>
<td>High level of evidence</td>
</tr>
<tr>
<td>1+</td>
<td>Medium level of evidence</td>
</tr>
<tr>
<td>1-</td>
<td>Low level of evidence</td>
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</table>
CHAPTER 1

INTRODUCTION

1.1 BACKGROUND

1.1.1 Defining clinical terms

Auricular therapy, based on a set of anatomical maps located on auricle (Asher, et al, 2010), is to trigger ear acupoints to affect the gross anatomical organ related with that point by application of acupuncture-like stimulation to treat pain and medical conditions. Unlike acupuncture, auriculotherapy need small objects like botanical plant seeds or metal, magnet pellets, of size approximately 2mm, applied to patient’s acupoints of ear with a waterproof tape (Chiang, et al., 2012, Jorge, et al, 2014). Stimulation of auricular acupoints regulates Qi, of which a disease is considered to be caused by imbalance of a person’s energy Qi, is believed to activate the meridians and collateral systems; hence, to relieve pain and relax muscle (Huang, 2005, Oleson, 2003). Low back pain, according to Cheng (1999), is a result of deficiency of Qi in kidney which causes poor nourishment of meridians in the lumbar region, or trauma, e.g. sprain or contusion would lead to stagnation of Qi and blood; hence, producing the pain. Auricular acupressure is considered by World Health Organization, WHO (1990) be a form of microacupuncture that can influence the whole body. Once applied, participants can self-managed at home.

1.1.2 Background

Chronic low back pain (CLBP), often progressive and the cause be difficult to
determine, is measured by duration of pain which persists for more than three months (National Institute of Neurological Disorder and Stroke, 2013). The pain is localized below the 12th rib and above the inferior gluteal folds and classified as specific if suspected pathological cause and non-specific (90% of cases) (Anderson, 1986). CLBP places a huge burden on societies and healthcare systems worldwide in the areas of healthcare cost and work absenteeism, etc (Caro, Dagenais & Haldeman, 2008).

One of the most common health problems in adults is low back pain (Bell, et al., 2004, Briggs & Buchbinder, 2009, Chung, Wong & Zeng, 2013, Croft, Dionne & Dunn, 2006, World Health Organization, 2013) and the most prevalent musculoskeletal condition that people seek for medical advice for is CLBP (Agans, Freburger & Holmes, 2009, Caro, Dagenais & Haldeman, 2008, Hootman & Strine, 2007), which is one of the commonest problem in primary healthcare and is an epidemic concern (Shelerud, 1998), and it is the top 10 disease worldwide (Institute for Health Metrics and Evaluation, 2011). Around 60% to 80% people reported recurrent back pain after their first episode (Middleton, 2004). Low back pain is reported with most frequent in working population and with highest incidence for those aged 25 to 64 (Woolf & Pfleger, 2003). Hong Kong population is of no exception, with 39.7% prevalence (Coggon, et al, 1995). Hospital Authority, HA, (2014a) pointed out that 80% of adults experienced back pain at least once in their life time.

Prolonged sitting, standing and walking would worsen the pain. The pain would restrict patients’ mobility and affect their sleep, and, their strenuous activity and leisure pursuit would even be influenced by the pain episode and fear of recurrence.
(Woolf & Pfleger, 2003). Moreover, the longer the patient is absent from work the more unlikely he or she is to be back to job which constitutes a great impact on society.

The goal of CLBP treatment is to reduce the pain and maximize patients’ ability to function as a normal person so as to return to their normal daily activity and restore their quality of life (QOL).

1.2  AFFIRMING NEED

1.2.1  My local setting

I am working in Orthopedic and Traumatology (O&T) Ward in Pamela Youde Nethersole Eastern Hospital. Around one-tenth of patients admitted for low back pain accompanied with decreased mobility. Non-specific cases (pathological cause or fracture is ruled out) are started to be treated with Acetaminophen and Tramadol, and, plus or minus with nonsteroidal anti-inflammatory drug, in addition with acupuncture (for some cases) and physiotherapy for pain relief and walking exercise (to achieve pre-morbid status) and transfer technique.

1.2.2 Clinical issue

i. Degree of severity

The major cause of disability is low back pain, affecting people of all ages and is a frequent reason for medical consultation (WHO, 2013). Rasker (1995) showed that 10% to 20% physician consultation is for musculoskeletal complaint. Low back pain also leads to the most disability worldwide, and the condition would inhibit suffers
from performing various kind of work both inside and outside their home, imposing
the individuals, families, communities, industry and government a huge economic
burden in terms of direct treatment and additional economic result of loss of
productivity (Caro, Dagenais & Haldeman, 2008, Coggon, et al., 1995, Institute for
and would compromise their QOL (Moss, Lawton & Glicksman, 1991). According to
Ontario Health Survey, musculoskeletal complaints occupied 20% of healthcare
utilization (Badley, Rasooly & Webster, 1994). Worse, the condition is more
prevalent and constitutes a greater impact on elderly and especially on the foreseeable
aging population.

Hong Kong is one of the countries worldwide occupied with largest number of
people with low back pain (Leung, 1999). Study in 2005 showed that admission rate
of back pain in emergency medicine ward of Hong Kong public hospitals was 15.5%
and re-admission rate within 48 hour was 7.3% (Ho, 2008) and study in 2000 showed
that average length of stay owing to back pain is 2.5 days (Ho, 2008). Additionally,
patient, especially the elderly group, with CLBP always felt of losing control of their
pain problem and being a burden of their family. And it is showed that unmanaged
low back pain in elderly would lead to depression (Cohen-Mansfield & Marx, 1993,
Parmelee, Katz & Powell, 1991), functional disability and compromised QOL for
elderly group (Moss, Lawton & Glicksman, 1991). The condition of CLBP in Hong
Kong is on an alarming status which needs to attend to.

ii. What to improve

Currently, people with CLBP are mainly treated with analgesic (HA, 2012,
Mackintosh & Elson, 2008, WHO, 2013). However, a variety of adverse side effects
including drossiness, constipation, dry mouth and potential for addiction limits the use of analgesic (Benyamin, et al., 2008, Malanga & Woltf, 2008). Alternative treatments including physiotherapy, spinal manipulation, education, exercise, mobilization, massage are currently suggested to relieve CLBP but with limited efficacy (Dagenais & Haldeman, 2008, Hass, et al, 2011). When all other strategies have failed, disc surgery is the last option; however, the effect is disappointing (Andersson, Youssef & Phillips, 2013). Problems observed from my clinical setting include refusal of analgesic owing to side effect, and, frequent hospital visit for physiotherapy (some patients have to apply leave for attending the therapy which in turn affect their job stability and decrease the productivity of society).

Even though piles of new interventions have been conducted in the past decade, the magnitude of back pain related problems, especially those of CLBP, is still on increasing trend (Caro, Dagenais & Haldeman, 2008, Dagenais & Haldeman, 2008, Davis, Smith & Whedon, 2013). Therefore, the limitations of current pain management strategies are highlighted by the increasing prevalence of pain and ineffective CLBP management. Currently, there is no known cure for CLBP (Chung, et al, 2007); the goal of CLBP management remains the pain control and functional improvement and health-related QOL with avoidance, if possible, of therapeutic toxicity. Auriculotherapy, which has demonstrated promising effect on low back pain (Chung, et al., 2007, Suen & Wong, 2008), postoperative pain (Bi, et al., 1997, Felhendler & Lisander, 1996) and hip fracture pain management (Barker, Hoerauf & Kober, 2006), can be an alternative treatment for CLBP with less side effect and allow patients to self-managing pain at home or at work.

Public hospitals in Hong Kong are now promoting the combination of Western
medicine and Traditional Chinese Medicine (TCM) for the treatment for back pain. Auricular therapy, though, with promising analgesic effect shown, can be promoted to be an alternative for managing CLBP.

There are growing evidence demonstrated the effectiveness of auriculotherapy on managing CLBP. However, currently there is no systemic review conducted to support the translation of the research evidence into practice. Moreover, the knowledge of nurses to a specific area is important to the application of evidence-based practice, EBP (Kwekkeboom, 2008). Therefore, this thesis aims to generate an evidence-based guidelines of using auricular therapy in patient with CLBP in a safe and effective manner.

1.2.3 A potential innovation

It is observed from the clinical practice that analgesic and physiotherapy are the main measures to treating patient with CLBP. However, some patients, especially the elderly group, would refuse analgesic and rather concern the side effect of those analgesic including gastric discomfort and problem of addiction and believe that analgesic is harmful to their body health. Physiotherapy has shown to have a certain level for temporarily pain relief; however, most patients cannot afford time for frequent hospital visit for physiotherapy or pay for home physiotherapy after hospital discharge. With unmanaged back pain, patients would refuse walking, sitting out or even changing position on bed which would increase their risk of fall and developing complication including bed sore, pneumonia and even deep vein thrombosis, not to mention their daily living or work. There would be a problem of caring themselves if pain not managed well and the suffers would see themselves as a burden for their family.
An intervention for pain relief which is easily acceptable by patients (with less side-effect) and can be brought home is good so that patient can self-manage their pain at home, and auriculotherapy is an alternative as supported by growing evidence. Using auriculotherapy on CLBP management is a relatively new approach. After the completion of a translational research study, the intervention may be used to treat CLBP in local clinical setting. Moreover, there is currently no guidelines or protocol about using auriculotherapy on CLBP available in my clinical setting; hence, a guidelines is needed to be developed.

1.3 OBJECTIVE AND SIGNIFICANCE

Auriculotherapy may potentially benefit patient for relieving CLBP and promoting greatest functional improvement (Shirado, et al, 2005) so as to promote maximizing to their premorbid mobility level. With adequate pain control, patients regain their ability and confidence in resuming their activity and daily living (ADL), which in turn shorten the length of stay in hospital and reduce the re-admission rate and the risk of complication from immobility. Moreover, auricular therapy allows minimal interruption to ADL of patients with promotion of pain reduction. As the auricular instrument can stay in situ for a week, patients are allowed to self-treat at home which help to decrease their barriers to exercise. Additionally, this individual tailored approach may potentially enhance the patient to develop an active self-management strategy and as a long-term symptom management. However, there has not been systemic evaluation of the use of auriculotherapy on CLBP management. Therefore, the objectives of the proposed dissertation are as follow:
1. To systematically evaluate the effectiveness of auriculotherapy on managing CLBP.

2. To evaluate the quality of studies and to give a summary of all relevant studies selected.

3. To discuss the feasibility and implementation potential of applying auriculotherapy on managing CLBP in local Hong Kong hospital setting.

4. To develop an evidence-based guidelines of using auricular therapy in patients with CLBP.

5. To design an evaluation plan for testing and evaluating the effectiveness of the auriculotherapy programme.
CHAPTER 2

CRITICAL APPRAISAL

2.1 SEARCH AND APPRAISAL STRATEGIES

2.1.1 Identification of studies

i. Selection criteria

For the inclusion criteria, studies are chosen if subjects were (1) 18 years of age or above, (2) suffering back pain, (3) considered auriculotherapy as a treatment option, (4) had not received any prior treatment with auricular implants, (5) with study outcome regarding pain measurement, (6) literatures written in English, and, (7) randomized controlled trials (RCT) as RCT represents a highest level of evidence and is the gold standard for testing the effectiveness of a auriculotherapy within a patient population (Chalmers, et al, 1981).

For the exclusion criteria, studies are excluded if (1) intervention are not related to auriculotherapy or there was no comparison with auriculotherapy, (2) subjects have back pain caused by pathologies such as infection, metastasis, neoplasm, fracture or spinal deformity, and, (3) people with pacemaker or pregnancy.

ii. Search strategies

Manual and electronic search strategies were used.

Five electronic databases were searched by pre-defined keywords: auriculotherapy,
auriculopressure, auricular/ear acupressure, auricular/ear pressing therapy, back pain, lumbar pain and spinal pain, with keywords used both separately and in combination with each other for the search. Restriction criteria for the search are limited to RCTs.

Figure 1. PRISMA Flowchart Diagram
The databases searched include PubMed (1990 to August 2014), China Journal Net (1990 to August 2014), CINAHL Plus (1990 to August 2014) and Ovid Medline® (1948 to August 2014). Database from HA named eKG (earliest to August 2014) was also used. Literature search was conducted in each of the above database. After keyword search of each search engine, the titles of a piles of studies listed were screened for any potential studies. Abstracts of selected papers were then reviewed, which was then followed by reading the full papers and reference lists and elimination of paper duplication. Additionally, any relevant studies were attempted to be examined and extracted from the reference list of the selected papers. A flowchart is used to demonstrate the process of search and result, which is presented in Appendix I and a PRISMA flow diagram (Moher, et al, 2009), Figure 1.

iii. Data extraction

Six sampled studies were selected and data were extracted and translated into a table of evidence, which is presented in Appendix II and III.

iv. Appraisal strategies

Critical Appraisal Skill Programme (CASP), containing a critical appraisal checklist and 11 guiding questions, is used to assess the applicability, reliability and validity of published research (CASP, 2013). It was used here in this thesis to perform quality assessment of the selected studies. After the critical appraisal of the articles, Scottish Intercollegiate Guidelines Network (SIGN) (SIGN, 2014) was used to rate the level of evidence of the sampled articles.

2.2 RESULT
2.2.1 Date of search

Manual and electronic search strategies were used from July 11, 2014 to August 14, 2014.

2.2.2 Search result

Translational research starts with keyword searching from various databases. After the searching processes with restriction by pre-defined keywords, there were a total of 794 potential articles identified from the five databases: PubMed, China Journal Net, CINAHL, Ovid Medicine® and eKG. These yielded articles were then screened with title and abstract. 23 citations were found to be relevant and full texts were subsequently retrieved. Studies were excluded if they were (1) not RCT, (2) not meeting the selection criteria, and (3) duplicated studies. Reference lists of selected articles were further screened to look for any potential useful studies. No extra literature was extracted after elimination of duplication. Finally, a total of six studies were selected for this literature review. Please see Figure 1 and Appendix I. The six sampled studies were published between 2007 and 2014. Appendix III summarized the data of six studies in a table form. Appendix IV and VI showed the critical appraisal and quality assessment of the six sampled studies respectively, and, Appendix V and VII are the summaries respectively.

2.2.3 Summary of study characteristics

i. Type of study

in Spain (Vas, et al, 2014), four in Hong Kong (Yeh, et al, 2013, Suen, et al, 2007, Suen & Wong, 2008, Yeh, et al, 2010) and remaining one in Taiwan (Chung, et al, 2013,). Two of the studies were conducted in outpatient settings, two in elderly home and remaining two in orthopedic wards. All studies stated clearly their focused research questions.

ii. Sample size


iii. Patient characteristics

All the participants were 18 year-old or above. Three of the sampled studies investigated patient with CLBP (Yeh, et al, 2013, Suen, et al, 2007, Suen & Wong, 2008); one on chronic spinal pain (Vas, et al, 2014); two on pain control after lumbar spine surgery (Chung, et al, 2013, Yeh, et al, 2010). The demographic characteristics were insignificantly different including age, gender, education level, duration of back pain etc.

iv. Intervention


v. Time of data collection

Participants of four of the sampled studies were followed up and data was collected one to six months after the course of treatment (Yeh, et al, 2013, Vas, et al, 2014, Suen, et al, 2007, Suen & Wong, 2008); two were during treatment on a daily basis (Chung, et al, 2013, Yeh, et al, 2010).

vi. Outcome measurement tool


For QOL measurement, Yeh, et al (2013) used WHO Quality of Life-BREF while

vii. Dropout rate

Dropout rate among the six sampled studies varied from 5% to 30%. The most common reasons for withdrawal of studies were as follow: refusal of auriculotherapy (n = 10), home leave or outing (n = 13) and scheduling reason (n = 15).

2.2.4 Summary of methodological issues (Please see Appendix VI for details)

i. Treatment allocation

All the six sampled studies claimed that participants were randomized to the intervention or comparison group. However, two had not mentioned their method of randomization (Suen, et al, 2007 and Suen & Wong, 2008). The other four studies indicated the allocation method e.g. computer-generated number.

To ensure similarity of the group at the start of trial and to enhance the strength of causal relationship between the groups, all the six studies showed that the size of intervention and comparison groups were same or similar and that the baseline demographic characteristics were of no significant difference between the intervention and comparison groups.

For the treatment received, all the six sampled studies indicated that all the comparison groups got no intervention groups option and vice versa. Moreover, five studies (Yeh, et al, 2013, Vas, et al, 2014, Suen, et al, 2007, Suen & Wong, 2008, and Chung, et al, 2013) treated both the intervention and comparison groups equally. One
study (Yeh, et al, 2010) mentioned that additional pain relief treatment (muscle injection of Demerol) was given to 4 participants as per request. However, Yeh, et al (2010) had not mentioned whether the experimental or comparison group received the extra treatment; hence, the data was contaminated and risk of bias increased.

ii. Concealment method


iii. Blinding process

All, except the study of Vas, et al (2014), were single “blind” that the participants were unaware which treatment they were receiving. Vas, et al (2014) used double blinding method that both the participants and investigators were unaware which treatment received, hence, lowered the risk of bias in the study.

iv. Dropout rate

Dropout rate was ranged from 5% to 30%. The highest dropout rate was 30% (Suen, et al, 2007, and, Suen & Wong, 2008) with common reason of home leave or outing, death and hospitalization. Second high dropout rate was 21.28% (Yeh, et al, 2010) with common reason of incomplete information and refusal of intervention. The dropout rate, though high, were still considered acceptable as reason of high dropout
rate was mentioned as stated above and that they all demonstrated that there were no significant difference on characteristics between those who completed the study and those withdrew. However, level of evidence of these three studies was downgraded owing to the high dropout rate.

v. Sample size

Only three (Vas, et al, 2014, Chung, et al, 2013, Yeh, et al, 2010) out of the six sampled studies had the sample size calculation available. The statistical power of one study (Yeh, et al, 2013) was reduced because of small sample size.

vi. Data collection method

Data of both the intervention and comparison groups were collected in the same way in each of the six sampled studies and all of the group outcomes were determined by the same measurement tools in each of the six sampled studies. To analyze the overall result, statistical method of p-value, confidence interval, standard deviation and mean were used. The overall results of the six sampled studies were demonstrated to be precise as evidenced by the statistical method.

vii. Adverse event

No adverse events were reported except one study (Vas, et al, 2014) that 12 participants reported of implant induced pressure ulcer was noted on pinna, which was healed ten days after removal of implant, and, eight participants reported of worsen pain.

2.3 SUMMARY AND SYNTHESIS OF DATA
2.3.1 Level of evidence

All the six sampled studies were RCTs. All the studies were rated according to SIGN (high, medium or low level of evidence). Factors including probability of bias, significance, reliability and application potential would be taken into consideration for the rating. Quality assessment of the six sampled studies were listed on Appendix VI and summarized on Appendix VII and reference on Appendix VIII.

i. High level of evidence was rated in two studies (1++)

Vas, et al (2014) and Chung, et al (2013) were rated as high level of evidence. The focused questions were appropriately and clearly addressed in both studies. Sample sizes in their studies were enough to minimize the play of chance. Vas, et al (2014) used Software EpiDat V.3.1 while Chung, et al (2013) used computer-generated number to ensure randomization. Chung, et al (2013) used sealed and opaque envelops to ensure concealment while Vas, et al (2014) only mentioned that concealment method was used with no description of the method. Vas, et al (2014) had both the participants and investigation blind to the study to minimize participant bias and investigator bias. Chung, et al (2013) only had the participants blind. Demographic characteristics were similar in both the intervention and comparison group with the only differences between groups was the treatment under investigation in both studies. The intervention was beneficial to patient with back pain. The result was statistically significant with p value less than 0.05 with low dropout rate in both studies.

ii. Medium level of evidence was rated in three studies (1+)
Yeh, et al (2013), Suen, et al (2007), and, Suen and Wong (2008) were rated as medium level of evidence. All the three studies had their focused question clearly stated, with participant blind to minimize risk of participant bias and all with similar demographic characteristic with no significant difference showed. Experimental and comparison groups were treated the same except the treatment under investigation in all the three studies and the intervention result was significantly different with p value smaller than 0.05 in the three studies. However, concealment was mentioned but no detail was provided in the three studies. Moreover, Yeh, et al (2013) only had small sample size which would increase the chance of play but the dropout rate was small. Suen, et al (2007), and, Suen and Wong (2008) claimed having applied randomization but with no description which would increase the risk of selection bias. Additionally, dropout rate of Suen, et al (2007), and, Suen and Wong (2008) reached 30%. Although the dropout rate was high, they both demonstrated that there was no significant difference on the demographic variables at baseline between subjects dropped out and those continued to participate in the study.

iii. Low level of evidence was rated in one study (1-)

Yeh, et al (2010) was rated as low level of evidence. No concealment was mentioned in this study which would lead to potential risk for investigator to overestimate the effect of intervention. Muscle injection of Demerol, which was an additional treatment, was given to participants in this study but with no detail provided; hence, the data was contaminated and risk of bias increased.

2.3.2 Recommendation

Based on the finding from the sampled studies, several recommendations relating to
using auriculotherapy on back pain relief are listed below.


Studies were carried out in Western and Eastern countries, four (Yeh, et al, 2013, I+, Suen, et al, 2007, I+, Suen & Wong, 2008, I+, Yeh, et al, 2010, I-) of the six selected studies were even performed in Hong Kong and one performed in Taiwan (Chung, et al, 2013, I++); hence, the result was highly generalizable.


Informed consent before the auriculotherapy was stated in all the sampled studies. Therefore, it is suggested to include consent before initiation of course of auriculotherapy.

Participants had to be taught how to manage the implanted seed with return demonstration to ensure their understanding. Subsequently, they were encouraged to practice the pressing regularly at home as suggested. A handout is suggested to be provided for the participants to remind them the number and location of taped acupoints, and, when to press these taped acupoints.

Case of pressure ulcer was noted in study of Vas, et al (2014). However, the ulcer was healed after removal of implant. To minimize risk of pressure ulcer development, Modified Braden score, MBS, (Chan, Pang & Kwong, 2009, I+, Vas, et al, 2013, I++) is suggested to be assessed before the therapy and to provide appropriate measure when risk is high (cutoff score: 16/27).
CHAPTER 3

TRANSLATION AND APPLICATION

3.1 TARGET SETTING AND POPULATION

Auricular acupressure is proposed to be carried out in O&T Department of a public hospital under HA which serves a quarter of population in Hong Kong. There are four wards in O&T. One for female and male acute ward respectively; one is mixed ward for elective orthopaedic operation; one is day ward which served with both western and Chinese medicine. Each ward houses 46 beds, with totally 138 beds in O&T Department. O&T Department provides comprehensive care to its patients with support and collaboration by a multi-disciplinary team involving medical officers, nurses, TCM practitioners, physiotherapists, occupational therapists, dietitians and speech therapists, etc.

Auriculotherapy is intended to be used on patients suffering CLBP who aged 18 or above and are communicable.

3.2 TRANSFERABILITY

Transferability describes how to apply and fit a proposed innovation into a target local setting. Following is to assess the suitability of auriculotherapy protocol in local O&T wards.

3.2.1. Demographical characteristics
Basic characteristics of target population in local setting are similar to the population in reviewed studies (Appendix X). Mean age range of CLBP patients reported in reviewed papers was 45.4 to 82.13 years old with duration of pain from 2 to 10 years, whereas those admitted to my clinical setting was from 35 to 90 years old with duration of pain from 1 to 10 years. Both the groups had patients with CLBP dominant by female. Target population consists of Chinese exclusively, whereas those of reviewed studies were having one study from westerners and the others from Chinese (one from Taiwan and four from Hong Kong). Nonetheless, there is no evidence suggesting auriculotherapy works different in different ethnic groups.

### 3.2.2 Philosophy of care

HA (2014b) emphasizes “patient-centred care” as central philosophy and core value which stresses the importance of highest possible quality of health services to enhance the living standard and QOL of patients and to empower patients to regain their health and stay healthy. The proposed auriculotherapy, acts upon holistic care of an individual (Norton, 1995), is expected to meet the core value and to reduce pain which in turn regains their physical functioning and returns to ADL and improves sleeping quality as well as lessens the use of analgesic, and that patients can self-manage their pain at home, hence, regaining health and improving their QOL.

### 3.2.3 Benefiting sufficient clients

There is daily admission rate of 10 cases in average in each of the three admission wards by observation, with around 15% cases suffering CLBP; hence, approximately 1643 potential cases are likely to be benefited from the proposed intervention in a year, see Figure 2. Therefore, a considerable number of patients would be likely to be
benefited from the proposed intervention.

Figure 2. Estimated number of patients with CLBP/ year

3.2.4 Time for implementation and evaluation

Time to be taken from getting approval of the auriculotherapy program to actual implementation and evaluation in the O&T wards would be 12 months (Appendix XI). Upon approval by target hospital, two months are allocated for auriculotherapy team formation and material preparation, taking four days in four weeks would be provided to the frontline staff about the content of innovation, demonstration and evaluation (Appendix XII). Staff would be trained to screen for the potential cases, Figure 3, and to observe for any side effect that may resulted from auricular acupressure. All nurses are invited for the new implementation. Another two months are allocated for pilot testing of the auriculotherapy program. The pilot testing will be taken in one ward, followed by evaluation of pilot study finding, guidelines revision and modification where necessary. A total of six-month implementation and two-month evaluation are allocated. The program would be reviewed and modified simultaneously during the implementation with feedback collection. Finally, evaluation part will be taken place by completing a set of questionnaire by nurses and patients.
3.3 FEASIBILITY

Feasibility of implementing auriculotherapy for relieving CLBP in O&T wards will be discussed below.

3.3.1 Freedom of nurses to carry out implementation

“To put the patient into the best condition for nature to act upon him” is the goal of nursing of Florence Nightingale (Mantle, 1996). Auriculotherapy offers patients another treatment option for pain management and patients reserve the right to receive or terminate the innovation anytime. Auriculotherapy, which is an alternative therapy, can be initiated without physician’s order, hence, providing autonomy for nurses to implement.
3.3.2 Administrative support and resources

EBP has been well advocated in our hospital which is easily accessed on hospital website and regular journal sharing session. Our O&T Department emphasizes the importance of EBP and always welcomes any EBP benefiting to the patients. The Chief of Service (COS), Consultant, Department Operation Manager (DOM) and ward managers (WM) are the administrative stakeholders and they are open to any ideas and guidelines that improve the healthcare in O&T wards and they provide full autonomous support to frontline nurses on mutual sharing of up-to-date practices and research finding. This year, our O&T department launched an EBP gout program under the cooperation of multi-disciplinary team with promising result. The good clinical effectiveness set a significant foundation for further research utilization.

Equipment for implementing the auriculotherapy includes electric acupoint finder, magnetic pellet and micropore tape. Besides the manual that having information about auriculotherapy, handout is also provided for home practicing purpose.

Handout (Appendix XIII) including location of auricular acupoint and frequency of pressing would be prepared by auriculotherapy team member and revised by TCM physician. Currently, there is neither electric acupoint finder nor pellet available in my clinical setting, and funding would be applied for that.

3.3.3 Consensus

In my clinical setting, the atmosphere and culture encourages continuing professional development especially under the support and encouragement from training funding and study leave and compensatory off hours from our department.
Many nurses in my ward have already been taking up additional responsibilities e.g. infection control, wound care and medication safety.

The training session would introduce the clinical significance and potential benefits of the innovation to gain full support from health service providers. Hence, it is highly likely that the introduction of auriculotherapy will be welcome by nurses.

3.3.4 Interfering current staff function

Workload would be increased at beginning because assessment and education of auriculotherapy program take time. However, the overall workload would be decreased. Implementation of auriculotherapy actually brings pain relief for the patients. With better pain control, time can be saved from answering the call bell for analgesic and dealing with relative regarding the caring and discharge problem related to uncontrolled pain, workload of nurses and healthcare assistants can be reduced from lifting and positioning the patients as patient can better self-manage with their dressing, toileting and bathing, and, workload of physiotherapists would also decreased as fewer patients might require pain relief physiotherapy.

3.3.5 Availability of evaluation tool

Visual Analogue Scale (VAS) has been widely used in diverse adult population in assessment of pain intensity. VAS (Appendix XIV) is easy to administer and record and consists of a continuous scale of a horizontal line ranging from 0cm (no pain to 10cm (very severe pain) that provides a valid and reliable interval level data (Gould, 2001, Wewers & Lowe, 1990, Vas, et al, 2014 I++). Patient can mark on the point that they feel represents their perception of their current state of pain (Gillian, et al,
SF 12 health survey (Appendix XV) will be used to measure the quality of life (Vas, et al, 2014, ++). SF 12 health survey (Hospital for Special Surgery, 2014, 行政院衛生署台中醫院, 2005 年 10 月) uses 12 questions to measure functional health, in terms of physical and mental health, from patient’s view of point. The higher the score, the better the QOL of respondents (Ware, Kosinski & Keller, 1996, Vas, et al, 2014, ++).

3.4 COST/ BENEFIT RATIO OF THE INNOVATION

To implement the auriculotherapy innovation successfully, there must be a balance between the cost and benefit.

3.4.1 Potential risk

Auriculotherapy is considered as a safe practice and relatively low risk in implementing this innovation. Only one of the reviewed studies (Vas, et al, 2014) reported that implant induced pressure ulcer was noted on pinna of which only accounted for 4.5% and the ulcer was reported to be healed ten days after removal of implant. Auricular skin condition would be assessed by nurse beforehand to minimize the risk. Another potential risk is allergic to the material used for auriculotherapy. Patients would be assessed for allergy history beforehand and be educated to observe for their skin condition and to peel off the tape in case of any discomfort.

3.4.2 Risk of maintaining current practice

Analgesic, which is the dominant pain management, can lead to intolerance and can
cause exaggerative use of pain medication easily. Analgesic has side effects including nausea, drowsiness, gastric discomfort and constipation, etc. Besides the regular dose of analgesic, patients might use call bell frequently on requesting for extra analgesic. Moreover, analgesic only focuses on physical sensation of pain; psychological and social function of patient are often neglected. Impaired mobility due to pain intolerance would increase the risk of sore and extend the hospitalization and increase the readmission rate as well. Pain induced impaired physical mobility is most likely to lead to caring problem and hence discharge problem of which we spend a lot of time to deal with e.g. time to discuss to relative and delayed discharge.

3.4.3 Potential benefit

i. Patient

Auriculotherapy can relieve pain and relax muscle by regulating Qi (Huang, 2005, Oleson, 2003) and grant clients the feeling of self-controlling the pain. Better pain control and relaxation can help patients improve sleeping quality and their mood. Improved mood encourages patients to share feeling with their relative; hence, maintaining their normal social life. Additionally, improved pain control reduces analgesic consumption and regains their ability to self-care.

ii. Frontline staff

Nurses can enjoy a higher autonomy for the clinical practice as initiation of auriculotherapy without the need of physician’s order. And the overall workload for nurses and healthcare workers would be reduced as discussed above, hence, enhancing staff morale.
iii. Hospital

Auriculotherapy contributes to considerable savings in direct medical costs of medication and health services by decreasing the duration of hospitalization and readmission rate as discussed below, and, indirect cost by decreasing work absenteeism and increasing productivity (Yeh, et al, 2013). And the hospital reputation would be lived up by the effective and innovative EBP and be a good model to other hospitals.

3.5 Cost

All O&T nurses would be invited for training and implementation of the innovation. Approximately 1643 patients, as discussed before, are estimated to be eligible to take part in the auriculotherapy program per year. Each participant will have magnetic pellet taped on definite auricular acupoints by nurse and will be given a handout (Appendix XIII) for home practice purpose which will be approximately HK$10 per participant. Training room and equipment which is available in hospital as well as the computer, software, stationary, printing and papers will cost HK$100. Total estimated cost of training, manpower and material cost would be HK$54703.62 a year (Appendix XVI).

Medical saving from medication and health services due to shorten hospitalization and decreased readmission rate ranges from HK$9,529,400 to HK$1,510,032.01 a year (Appendix XVII) and it may outweigh the estimated cost. The potential benefit listed above in addition to the improvement in the QOL of patient is immeasurable and valuable.
3.6. EVIDENCE-BASED PRACTICE (EBP) GUIDELINES/PROTOCOL (SEE QUICK REFERENCE GUIDELINES BELOW, FIGURE 4)

The proposed nurse-led auriculotherapy program for patients with CLBP is transferable and feasible in my clinical setting. It is also safe and cost-effective. An EBP guidelines will be developed in this section to serve as guidance for implementing the new intervention.

3.6.1 Title

The title will be “evidence-based guidelines of using auricular therapy in patients with chronic low back pain”.

3.6.2 Aim

The purpose is to guide nurses on the use of auriculotherapy for relieving CLBP in adult patients.

3.6.3 Objective

The objective of evidence-based guidelines are:
1. To assist nurses to use auriculotherapy for better pain management of patient with CLBP.
2. To provide a guidelines to practice auriculotherapy in a safe and efficient way.
3. To encourage use of auriculotherapy through EBP.

3.6.4 Target population
Auriculotherapy will be provided to both male and female patient suffering from CLBP.

The inclusion criteria are:

1. Patient of age 18 or above
2. Persistent low back pain > 3 months
3. Considered auriculotherapy as a treatment option
4. Without cognitive impairment

The exclusion criteria are:

1. Not agree to use auriculotherapy as a treatment option
2. Impaired auricular skin integrity
3. Allergy to micropore tape
4. Allergy to alcohol swab

**Referral checklist**

<table>
<thead>
<tr>
<th><strong>Inclusion criteria</strong></th>
<th><strong>Exclusion criteria</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ Age 18 or above</td>
<td>☐ Not agree to use auriculotherapy as a treatment option</td>
</tr>
<tr>
<td>☐ Persistent low back pain &gt; 3 months</td>
<td>☐ Impaired auricular skin integrity</td>
</tr>
<tr>
<td>☐ Agreed to use auriculotherapy as a treatment option</td>
<td>☐ Allergy to micropore tape</td>
</tr>
<tr>
<td>☐ Without cognitive impairment</td>
<td>☐ Allergy to alcohol swab</td>
</tr>
</tbody>
</table>

*All exclusion criteria must be met.
#Excluded if any of the exclusion criterion
3.6.5 Guidelines/ protocol development process

The EBP guidelines is developed based on the evidence of reviewed studies and graded as according to the Level of Evidence (SIGN, 2014, Appendix VIII), and the recommendations suggested below are extracted from the reviewed literatures and graded according to the Grades of Recommendation (SIGN, 2014, Appendix XVIII). There were six studies for formulating the guidelines.

Recommendation 1

Use of auriculotherapy is highly encouraged to patient with CLBP. (A)


Recommendation 2

The skin condition and history of allergy should be assessed for eligibility of auriculotherapy. (A)

Patients with allergy history to micropore tape and alcohol is not candidate for auriculotherapy as the tape is used for attaching magnetic pellet on ear and alcohol swab for preparing the skin (Vas, et al, 2014, I++; Suen, et al, 2007, I+; Suen & Wong, 2008, I+).

Recommendation 3
Modified Braden Scale (MBS) is needed before the therapy to assess the risk of pressure ulcer (high risk: score <16). (A)

Auricular skin condition including sensation, integrity and circulation need to be assessed. Impaired skin condition would increase risk of pressure ulcer. Any patient with lesion on ear or high risk of pressure ulcer (*Appendix IX*) is not candidate for auriculotherapy (Vas, et al, 2014, 1++).

*Recommendation 4*

**Auriculotherapy is to start from the most sensitive ear and then switch to other ear alternatively. (A)**

A most sensitive ear has higher conductivity and hence leading to better effect of pain relief (Vas, et al, 2014, 1++).

*Recommendation 5*

**Electric acupoint finder is suggested to detect the auricular acupoint. (A)**


*Recommendation 6*

**For the duration of implant, it needs to be swapped to the other ear at least a week to let the ear and acupoints rest and relax. For the duration of the treatment course, the whole course of treatment is 3 to 4 weeks. (A)** (Yeh, et al, 2013, 1+; Vas, et al, 2014, 1++; Suen, et al, 2007, 1+; Suen & Wong, 2008, 1+)
Recommendation 7


Recommendation 8

Visual Analogue Scale (VAS) will be used for evaluation of pain. (A) (Vas, et al, 2014, I++, Yeh, et al, 2010, I-)

VAS consists of a continuous scale of a horizontal line ranging from 0cm (no pain) to 10cm (very severe pain) that provides a valid and reliable interval level data (Gould, 2001, Wewers & Lowe, 1990, Appendix XIV).

Recommendation 9


SF-12 health survey uses 12 questions to measure functional health and well-being in terms of physical and mental health from patient’s view of point. The higher the score, the better the quality of life of the respondents. (Appendix XV).
Figure 4: Quick Reference Guidelines

Screen by nurse
- Eligibility criteria fulfilled?
- MBS ok?

Yes

Initial assessment:
- pain: VAS (Recommendation 8)
- QOL: SF-12 Health Survey (Recommendation 9)

Assess sensitivity of pinna
- start from the most sensitive one (Recommendation 4)

No

-Skin preparation
- Locating acupoint by electric acupoint finder (Recommendation 5)
- Secure pellet on ear

Patient education
- Duration of treatment (Recommendation 6)
- Frequency (Recommendation 7)
- Observe auricular skin condition

No

Discomfort or s/s of sore?

Yes

Suitable to continue?

Follow up at 1, 2, 3, 4 week post application of pellet
- assess x skin condition (Recommendation 2)
- switch to other pinna alternatively (Recommendation 4)
- assess x VAS, SF-12 Health Survey

No

Yes

Excluded
CHAPTER 4

IMPLEMENTATION PLAN

Implementation plan, consisting a communication plan with the stakeholders and a pilot test for the trial of guideline, emphasizes the utilization of synthesized findings and recommendations for the practice (National Collaborating Centre for Methods and Tools, 2011) and would facilitate the EBP guidelines of pain management for patients with CLBP.

4.1 COMMUNICATION PLAN

The success in the change process depends on connection between the innovation, stakeholders and organizational structure (Johnson & Paton, 2007).

4.1.1 Identifying stakeholder

In current auriculotherapy program, there are several groups of stakeholders:

i. Project coordinator, also the author, is in-charge in literature review and drawing up evidence-based protocol for using auriculotherapy in pain management for CLBP patient.

ii. Administrators include the COS, DOM and three WMs of O&T Department.
They are responsible on department operation, resource allocation and manpower deployment within the department as well as authorized to reject or approve the implementation of an innovation. Moreover, WMs are responsible for daily ward operations and frontline staff duty arrangements.

iii. Opinion leaders are those who have the strongest influence on clinical practice and beliefs of other staff as well as monitor and evaluate the entire program. Among the staff in our ward, medical officers and advanced practice nurses (APN) are most experienced in managing CLBP and are the opinion leaders.

iv. Frontline staff, registered nurses (RN) and enrolled nurses (EN) in my ward, will be responsible in running the new protocol.

v. Other healthcare professionals including house officers of O&T department, physiotherapists and occupational therapists though may not directly take part in the program, they may have chance to answer questions regarding the innovation.

vi. TCM practitioner is responsible for training staff on the auriculotherapy skill.

vii. Ward clerks will be arranged a briefing on document arrangement and procedures of data collection and evaluation to facilitate a smooth workflow and clerical assistance.
viii. Patients will receive the auriculotherapy treatment.

4.1.2 Communication process

WM will be the first person to be contacted and presented with the clinical issue of CLBP and its severity in local setting, a brief summary of study evidences and detail of the proposed innovation including objectives, cost-benefit analysis, barrier and solution and timeline of implementation as well as the evaluation plan.

After approval from WM, a formal presentation would be given to COS, DOM and three ward representatives on regular O&T departmental meeting held every Monday morning. In the presentation, a detailed budget plan will be shown in addition to the information mentioned earlier. Presentation needs to be concise and clear to address the stakeholder query and concern regarding the necessity for change and implementation of innovation. Ongoing refinement will be adopted as according to the perspectives of WM to enhance the feasibility of innovation.

After approval from administrator, preparation phase is started. APN, three RNs and a TCM practitioner will be invited to form an auriculotherapy project team, with APN being the project leader who guides the team in material preparation, guideline refinement and evaluation, formation of communication plan and pilot testing. Other healthcare professions mentioned above will be notified regarding the proposed
innovation via intranet email.

Creating a “vision” on the urgency for change and benefit of the innovation can help winning nurses’ acceptance and cooperation (Claire, 2006 & Robert, 2008).

After approval from the administrators, frontline nurses will be presented with the proposed innovation, training schedule and workshop through intranet email, educational poster, case conference, nursing sharing session and monthly ward meeting. Identical briefing session consisting program introduction, literature review and Question & Answer session will be subsequently organized to clarify any skepticism identified from previous activity. To collect further feedback, evaluation form will be distributed after the activities so that any necessary modification can be determined.

After the pilot testing and training workshop, program outline and background information (Appendix XIX) will be posted up at education board at the corridor to give a snapshot to patient and relative. A well-illustrated information sheet in Chinese or English (Appendix XX), together with detailed program introduction, will be provided to those eligible cases after the initial assessment by ward nurses. If acceptance is confirmed, written informed consent will be obtained.

4.2 PILOT TESTING (SCHEDULE PLEASE SEE
Pilot testing needs to be conducted to test the feasibility of the auriculotherapy program before the full program implementation (Hodges & Videto, 2011).

### 4.2.1 Subject recruitment

Convenience sampling will be used to recruit eligible patients. About 43 patients will be recruited in four-week period. Patients will be screened according to the inclusion and exclusion criteria (Appendix XXII). After health assessment, nurses will explain the details of pilot test to the recruited participants and will obtain their written verbal consent. Problems or difficulty encountered during recruitment will be recorded.

### 4.2.2 Intervention

Workshop will be organized and divided into three identical lessons, with each lesson involving 30 frontline nurses. The workshop will introduce detail of the program (Appendix XII). Two-hour information workshop will be provided to accomplish empowerment of nurses in O&T department. Before application of auriculotherapy guidelines, team member will be trained professionally on correct location of auricular acupoint, technique on securing pellet, skin condition monitoring.
to prevent any adverse events and ensure the program safety. In the training workshop, instructors will demonstrate skill and technique on locating acupoints and how to anchor the pellet on pinna, with return demonstration by audience. Extra training session may be needed to ensure that all the team member perform return demonstration well. The entire training period will last about one month before the pilot testing.

4.2.3 Data collection and instrument

Before practicing auriculotherapy, information on demographic data, past health history and history of CLBP will be collected, together with the duration and intensity of pain will be assessed based on the VAS (as discussed earlier on Chapter 3).

Patients can comment on the evaluation part of assessment sheet about using auriculotherapy (Appendix XXVI). After a 4-week pilot test, satisfaction questionnaire will be distributed to nurses involved, on which they can reflect their perception and satisfaction regarding the program (Appendix XXIV & XXV).

Furthermore, the project team will hold a group meeting to discuss any difficulties or comments collected through the data assessment and collection processes.

4.2.4 Evaluation

In order to evaluate the practicability, effectiveness, safety and acceptance of the
program by staff, program team member will be met one week after the completion of treatment of all pilot participants. Logistics, staff acceptance, unexpected difficulties encountered as well as patients’ acceptance, refusal rate and dropout rate will be discussed and evaluated during the study period. After the evaluation, protocol and logistic arrangement will be fine-tuned in view of the findings of the pilot study before the full implementation of protocol.

4.3 EVALUATION PLAN

4.3.1 Outcome

Outcome for evaluating effectiveness of innovation can be categorized into three domains of patient, healthcare provider and system. Evaluation is an important stage to decide whether the innovation is worth future continuum.

4.3.1.1 Patient

Patient outcome is important on determining whether the innovation is effectively improving patient health, hence, weighing heavily in the evaluation.

Pain intensity level of patient with CLBP, which determines the clinical benefits and effectiveness of the proposed innovation, is the primary outcome of innovation. According to the table of evidence (Appendix II), the pain intensity level is measured
by VAS (Chung, et al, 2013, 1++ & Vas, et al, 2014, 1++, Appendix XIV). Details of VAS has been discussed in Chapter 3.

QOL of patient is the secondary outcome to be measured. According to table of evidence (Appendix II), QOL is measured by SF 12 health survey (Vas, et al, 2014, 1++, Yeh, et al, 2010, 1-, Appendix XV). Details of SF 12 health survey has been discussed in Chapter 3.

The participants will be invited to fill in questionnaire (Appendix XXVI) to before and after the program to determine their competence and satisfactory level of auriculotherapy program.

4.3.1.2 Healthcare provider

For a successful implementation of proposed program, frontline nurses are the key people. To evaluate the acceptability of proposed program, their performance and satisfaction levels about the innovation are significant indicators. Their attitudes and satisfaction level will be assessed by questionnaire (Appendix XXIV). The frontline nurses will be invited to fill in a 21-question survey before and after the completion of program to determine the effectiveness of the new protocol. Another 17-question survey (Appendix XXV) will be used to assess the skill acquired by the auriculotherapy team member in the training workshop. The scores for each questions
of both the survey range from 1 to 5 points, with 1 is the lowest and 5 is the highest satisfaction score respectively.

4.3.1.3 System

The aim of institution is to provide better care to our clients and better utilization of current resources; hence, reducing the cost and optimize the resources to provide the best care for the patients. Additionally, cost-effectiveness analysis is to compare the health outcomes with the resource costs of the intervention. The outcomes include reduction in prolonged hospitalization and reduction in the re-admission rate of patients with CLBP and improvement of QOL with controlled back pain. And most outcomes of the innovation can actually not easily be valued by money and impossible to be quantified.

4.3.2 Nature and number of clients to be involved

To ensure homogeneity of the patient group, eligible patients are those who have passed the health assessment with similar characteristics based on the identified evaluation studies (Appendix II) and are consistent with the developed clinical guidelines. The study is intended to be used on communicable patients, aged 18 or above, suffering CLBP for at least 3 months. Those who refuse to use auriculotherapy as a treatment option, with impaired auricular skin integrity and history of allergy to
micropore tape and alcohol swab would be excluded from the study (Appendix XXII).

Convenience sampling will be adopted to recruit target patients. The progress of all the recruited patients who have participated in the auriculotherapy program for treatment of CLBP would be monitored and evaluated until their completing or dropping out of the program.

The number of patient involved is calculated based on the primary outcome. The main outcome is to determine the change in VAS between the pre- and post-intervention. To calculate the sample size, an online program (Lenth, 2006) is used. Based on the power 80%, confidence interval of 95% and a maximum 5% chance of committing a false positive error by paired t-test, the online program require a minimum number of 33 patients. According to the literature (Vas, et al 2014), the assumed attrition rate is 30% and hence a total of 43 patients is required for the evaluation.

4.3.3 When and how often to take measurement

Demographic data will be collected during the initial assessment with the nursing assessment form as baseline. History of back pain such as nature, duration, location and pain intensity level will be assessed and documented in the assessment form.
Character of back pain including pain intensity level, pain reduction level and SF-12 will be followed and assessed every week after the commencement of auriculotherapy on Day 7, 14, 21 and 28 (Appendix XXIII). Patient’s acceptance question will be asked on Day 28. Individual interview will be arranged in a single room to ensure reliable answer and privacy.

4.3.4 Data analysis

To evaluate the effectiveness of the innovation, Statistical Package for Social Science (SPSS) version 22.0 will be used for statistical analysis by following intention-to-treat principle as discussed below under three domain: patient outcome, healthcare outcome and system outcome, with probability value less than 0.05 be considered as statistically significant. The demographic characteristics of patients will be used as descriptive statistics and will be analyzed with SPSS and be presented as mean, standard deviation and percentage.

4.3.4.1 Patient outcome

All subjects will receive the auriculotherapy for treating CLBP. The primary outcome is their pain intensity level, which will be assessed in terms of VAS on Day 0, 7, 14, 21 and 28. The evaluation objective is to determine whether the pain intensity level is reduced since the implementation of the innovation. To compare the pain
intensity level before and after the auriculotherapy, significance testing will be used, of which a two-tailed paired t-test for each follow-up visit will be used.

The secondary outcome is the QOL of the participants, which will be assessed in terms of SF-12 score on Day 0, 7, 14, 21 and 28. The evaluation objective is to determine if their QOL is changed since the implementation of the auriculotherapy. A significance testing will be adopted, of which a two-tailed paired t-test for each follow-up visit will be used.

With regard to satisfaction and competence of patient on using the auriculotherapy, a questionnaire (Appendix XXVI) will be used before and after the pilot test. One-group post-test design with a 95% confidence interval will be used to analyze their satisfaction score.

4.3.4.2 Healthcare provider outcome

With regard to perception of frontline staff on the new innovation, a questionnaire (Appendix XXIV) will be used before the pilot test and at the end of the program implementation. One-group post-test design with a 95% confidence interval will be used to analyze their satisfaction score.

With regard to the skills acquired by the auriculotherapy team members from the
workshop, the same approach will be used for the evaluation of the satisfaction score (Appendix XXV).

4.3.4.3 System outcome

Mean value of length of stay of all participants in the study will be analyzed and compared with that in the same period of time in 2014 by using a two-tailed independent t-test.

Project team leader will closely record and monitor the monetary expenditures and the total cost will be calculated after the completion of the program.

At regular ward meeting or group discussion session, any extra qualitative data related to the innovation from stakeholders will be collected and analyzed for further evaluation and refinement of protocol.

4.3.5 Criteria for the effectiveness of innovation

Only if the patient and healthcare provider outcomes fulfilled the required bases will the protocol be considered as effective.

4.3.5.1 Patient outcome

Innovation is regarded as effective if a significant decrease in pain score and a
significant improved SF-12 score after the intervention is observed. Such results are in comparison with the baseline score obtained among the recruited subjects. To achieve an optimal outcome, scores must reach a minimal clinically significant decrease of 10.00mm in VAS (Vas et al, 2014, ++) and clinically significant increase of 3.4 points in SF-12 score (Vas, et al, 2014, ++).

With more than 90% response rate and more than 60% of the items in the satisfactory questionnaire from patients achieving the grade of “3-neutral” or above, the program will be regarded as satisfactory.

4.3.5.2 Healthcare provider outcome

Innovation is regarded as beneficial when frontline nurses exhibit high satisfaction score, of which at least 60% of nurses satisfactorily execute the protocol and exhibit at least a 90% response rate, and, the frontline staff’s morale and job satisfaction would be increased with the successfully conducted innovation.

5.3.5.3 System outcome

To achieve an optimal outcome, length of stay owing to CLBP will be shortened and re-admission rate owing to CLBP will be decreased. Moreover, the cost spent on the program would be maintained below HK$54,000 a year and hospital would save
at least HK$9,529,400 a year by decreasing at least 1 day of hospitalization for each patient admitted for CLBP. *Details of expenditure of the innovation and the saving from shorten hospitalization and decreased readmission rate have been discussed in Chapter 3 (Appendix XVI & XVII).*
CHAPTER 5

CONCLUSION

Low back pain is one of the most common health problem in adult and is the most prevalent musculoskeletal condition for medical consultation. The current treatment for treating CLBP (even the disc surgery) is sub-optimal. Auricular therapy is an alternative treatment for CLBP. Nonetheless, there is not yet developed a conclusive high-level evidence on its effectiveness nor a well-established protocol, and most medical centers including the proposed setting has not yet practised the innovation. Therefore, a systematic, critical and evidence-based guidelines of using auricular therapy has been developed and it is proposed to be used in O&T department in local hospital.

Evidence-based studies were selected to generate a protocol for patients with CLBP in the proposed setting, and an implementation and evaluation plan were demonstrated. Evidence-based guidelines on using auriculotherapy was developed, which is transferable and feasible to the proposed setting. The potential benefit to patients, frontline staff and hospital are high while the risks to patients are minimal.
Appendix I: Flowchart for process of search

By keyword search:
1. Back pain OR lumbar pain OR spinal pain
2. Auriculotherapy OR auriculopressure OR auricular/ear acupressure OR auricular/ear pressing therapy

Reviewed by titles

Reviewed by abstract

Reviewed by full paper and reference list

Total articles for review after elimination of duplication: 6
### Bibliographic Citation

<table>
<thead>
<tr>
<th>Study Type</th>
<th>Patient Characteristics</th>
<th>Intervention</th>
<th>Comparison</th>
<th>Length of follow up</th>
<th>Outcome measures</th>
<th>Effect size</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prospective controlled study with randomization</td>
<td>- at least 18 years old - back pain of at least three months duration - non-specific back pain - willing to commit to all study visit and FU - pain intensity score 4 or more on 0-10 point numerical pain scale - no using concurrent adjunctive pain therapies - no allergy to tape -no skin disease to auricle</td>
<td>Auriculotherapy: True auricular point acupressure (APA) with taped seeds on correctly designated points (i.e., shenmen, lumbosacral vertebrae, sympathetic and nervous subcortex) (n=11)</td>
<td>Sham acupoints with taped seeds but on different acupoints than those designated for chronic low back pain (n=10)</td>
<td>1 month</td>
<td>Primary: (I) Effects of acupressure on pain, disability, psychological function &amp; quality of life (1) Pain intensity (worst) (2) Pain intensity (average) (3) Pain intensity (overall) (II) Clinically improvement difference(^1) in pain intensity and back specific disability (4) Pain intensity (worst) (5) Pain intensity (average) (6) Pain intensity (overall) (7) Back specific disability (8) Back specific disability (a) RMDQ(^2) (b) ODI(^3) (9) Psychological factors (10) Fear avoidance belief (a) physical activity (b) work (11) Health related quality of life (a) physical (b) psychological (c) social (d) environment</td>
<td>(1) -74% (p=0.00) (2) -76% (p=0.39) (3) -81% (p=0.02) (4) 10 (p=0.0108) (5) 10 (p=0.0108) (6) 10 (p=0.0108) (7) 6 (p=0.6563) (8) (a) -42% (p=0.82) (b) -28% (p=1.00) (9) -69% (p=0.25) (10)(a) -30% (p=0.37) (b) -44% (p=0.85) (11)(a) 1% (p=0.24) (b) -2% (p=0.74) (c) 0% (p=0.59) (d) -3% (p=0.33)</td>
</tr>
<tr>
<td>Bibliographic Citation</td>
<td>Study Type</td>
<td>Patient Characteristics</td>
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<tr>
<td>Vas, et al (2014)</td>
<td>Multicentre randomized controlled trial with two parallel arms, true &amp; placebo auriculopressure</td>
<td>- at least 18-year-old - with uncomplicated musculoskeletal spinal pain (cervical thoracic or lumbar) diagnosed by clinical history &amp; physical exam - no prior auricular implant - non-specific spinal pain &gt; 3 months - no previous spinal surgery - no skin disease to auricle - no pregnancy/ labour litigation by spinal pain</td>
<td>True auriculopressure (TAP) (applied according to standard practice &amp; individual diagnosis) Acupoint: shenmen, lumbosacral vertebrae, thalamus &amp; kidney (n=130)</td>
<td>Placebo auriculopressure (PAP) (n=135)</td>
<td>9 weeks &amp; 6 months</td>
<td>Primary: (1) Pain VAS(^5) T1(^6) (2) Pain VAS T2(^7) Secondary: (3) Patient’s quality of life – SF12(^8) T1 (4) Patient’s quality of life – SF12 T2 (5) Mental health – SF 12 T1 (6) Mental health – SF 12 T2 (7) Pain frequency T1 (8) Analgesic consumption T1 (9) Functional ability T1 (10) Hours of sleep T1 (11) Patients’ satisfaction with the outcome</td>
</tr>
<tr>
<td>Bibliographic Citation</td>
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</tbody>
</table>
| Suen et al (2007)      | Experimental study with pretest-posttest control group without randomization | - 60 year-old or above  
- nonspecific back pain > 3 months &/repeated episodes | - magnetic pellet  
- acupoint: shenmen, kidney, urinary bladder, lumbosacral vertebrae, liver & spleen (n = 30) | -Semen Vaccariae (assumed to have no therapeutic effect if no pressing on it (n = 30) | - 3, 5 & 7 weeks after starting treatment (full course of treatment: 3 weeks) | Chinese Pain Intensity Verbal Rating Scale – Difference (baseline – timepoint)  
(1) Baseline vs when therapy completed  
(2) Baseline vs 2-week follow-up  
(3) Baseline vs 4-week follow up | (1) 0.86 (p<0.001)  
(2) 0.66 (p<0.001)  
(3) 0.53 (p<0.001) |
<table>
<thead>
<tr>
<th>Bibliographic Citation</th>
<th>Study Type</th>
<th>Patient Characteristics</th>
<th>Intervention</th>
<th>Comparison</th>
<th>Length of follow up</th>
<th>Outcome measures</th>
<th>Effect size</th>
</tr>
</thead>
<tbody>
<tr>
<td>Suen &amp; Wong (2008)</td>
<td>Randomized control study</td>
<td>- at least 60 year-old</td>
<td>- magnetic pellet&lt;br&gt;- acupoint: shenmen, kidney, urinary bladder, lumbosacral vertebrae, buttoc, liver, spleen (n = 40)</td>
<td>- Semen vaccariae</td>
<td>- 1.5 weeks of treatment, 3 weeks of treatment, 2 weeks post-treatment &amp; 4 weeks post-treatment (n = 39)</td>
<td>- Aberdeen Score in 9% (Baseline – timepoint)&lt;br&gt;(1) 1.5 weeks of treatment&lt;br&gt;(2) 3 weeks of treatment&lt;br&gt;(3) 2 weeks post-tx (4) 4 weeks post-tx&lt;br&gt;- Mean score of pain and sensation in %&lt;br&gt;(Baseline – timepoint)&lt;br&gt;(5) 1.5 weeks of treatment&lt;br&gt;(6) 3 weeks of treatment&lt;br&gt;(7) 2 weeks post-tx (8) 4 weeks post-tx&lt;br&gt;- Mean score of physical activity in % (Baseline – timepoint)&lt;br&gt;(9) 1.5 weeks of treatment&lt;br&gt;(10) 3 weeks of treatment&lt;br&gt;(11) 2 weeks post-tx (12) 4 weeks post-tx&lt;br&gt;- Score of functional disability in % (Baseline – timepoint)&lt;br&gt;(13) 1.5 weeks of treatment&lt;br&gt;(14) 3 weeks of treatment&lt;br&gt;(15) 2 weeks post-tx (16) 4 weeks post-tx</td>
<td>(1) 8% (p&lt;0.001) (2) 11% (p&lt;0.001) (3) 11% (p&lt;0.001) (4) 10% (p&lt;0.001) (5) 5% (p&lt;0.001) (6) 7% (p&lt;0.001) (7) 7% (p&lt;0.001) (8) 6% (p&lt;0.001) (9) 2% (p&lt;0.001) (10) 3% (p&lt;0.001) (11) 3% (p&lt;0.001) (12) 2.5% (p&lt;0.001) (13) 1.3% (p&lt;0.001) (14) 1.7% (p&lt;0.001) (15) 1.7% (p&lt;0.001) (16) 1.6% (p&lt;0.001)</td>
</tr>
<tr>
<td>Bibliographic Citation</td>
<td>Study Type</td>
<td>Patient Characteristics</td>
<td>Intervention</td>
<td>Comparison</td>
<td>Length of follow up</td>
<td>Outcome measures</td>
<td>Effect size</td>
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</table>
| Chung et al (2013)     | Single blinded, sham controlled study with randomization | - at least 18 year-old - diagnosed with spinal stenosis, spondylolithesis & herniated intervertebral disc and underwent lumbar spine surgery - directly return to ward from anesthesia recovery room | PCA + auricular acupressure (Acupoint: shenmen, lumbasacral vertebrae, kidney, subcortex & stomach) + transcutaneous acupoint electric stimulation (n = 45) | - Sham group: acupressure to true acupoint but without embedding seed; TEA to sham acupoint (n = 45) - Control group: no acupoint stimulation (n = 45) | 24-, 48- & 72-hr after surgery | (1) Pain intensity VAS^10 score 24 hr after surgery: (a) AS, Sham, Control group (b) Scheffé post hoc test: AS vs Sham group (2) Pain interference score 24 hr after surgery: (a) AS, Sham, Control group (b) Scheffé post hoc: sham vs control group (3) GEE^12 result of pain intensity over time (a) AS vs control group (b) sham vs control group (c) time effect 24-48 hr after surgery (d) time effect 48-72 hr after surgery (4) GEE result of pain interference over time (a) sham vs control group (b) AS vs control group (c) time effect 24-48 hr after surgery (d) time effect 48-72 hr after surgery (5) Pain intensity score 72 hr after surgery (6) Satisfaction score 72 hr after surgery (7)(a) overall equianalgesic morphine consume (b) Scheffé post hoc test: AS vs control group | (1)(a) p=0.01
(1)(b) p=0.01
(2)(a) p=0.009
(2)(b) p=0.01
(3)(a) p=0.02
(3)(b) p=0.09
(3)(c) p<0.001
(3)(d) p<0.001
(4)(a) p=0.005
(4)(b) p=0.96
(4)(c) p<0.001
(4)(d) p<0.001
(5) p=0.96
(6) p=0.08
(7)(a) p=0.001
(7)(b) p=0.001 |
<table>
<thead>
<tr>
<th>Bibliographic Citation</th>
<th>Study Type</th>
<th>Patient Characteristics</th>
<th>Intervention</th>
<th>Comparison</th>
<th>Length of follow up</th>
<th>Outcome measures</th>
<th>Effect size</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yeh et al (2010)</td>
<td>Randomized control study</td>
<td>- at least 18 year-old -surgical regions involving 3 or fewer lumbar vertebrae - directly return to ward from anesthesia recovery room</td>
<td>True auricular acupressure (Acupoint: shenmen, occipital, lumbar-sacrum vertebrae, stomach, kidney, cardia &amp; endocrine) (n = 47)</td>
<td>Control group without acupressure (n = 47)</td>
<td>2, 24, 48 &amp; 72 hours after surgery</td>
<td>(1) trend to decrease pain intensity over time (a) pain level at present (b) worst pain in the past (c) average pain in the past (2) impact of pain (a) activities (b) walking ability (c) sleep (3) pain perception (4) analgesic satisfaction (5) postoperative morphine use over time (6) duration of patient controlled analgesic (PCA) use</td>
<td>(1) (a) (b) (c) significantly lighter pain in intervention group (2) (a) (c) no significant between-group differences except for (b) (3) no significant between-group differences (4) no significant between-group differences (5) no significant between-group differences (6) no significant between-group differences</td>
</tr>
</tbody>
</table>
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1. Minimum clinical important differences represent the smallest change considered by patient as an improvement.
2. RMDQ: Roland-Morris Disability Questionnaire
3. ODI: Modified Oswestry Low Back Pain Disability Index.
4. Non-specific spinal pain: spinal pain with no protrusion nor prolapse of intervertebral disc with concurrent neurological symptoms, and, causes not due to infection, malignant nor autoimmune disease or congenital deformity.
5. Pain intensity measured on an analogue visual scale from 0 to 100mm.
8. SF12: SF-12 health-related quality of life scale.
9. Aberdeen Score: use to assess the health status of people with LBP across 3 dimensions including pain, sensation and physical impairment affected by LBP; comprising items which are more culturally suitable for the local Chinese in Hong Kong.
10. VAS: Visual Analogue Score; use to assess pain intensity with a scale ranging from 0 (no pain) to 10 (very severe pain).
11. Post-tx: post-treatment

Reference


### Appendix III: Summary table of sampled studies

<table>
<thead>
<tr>
<th>Article</th>
<th>Level of evidence</th>
<th>Type of study</th>
<th>No. of Patients</th>
<th>Patient characteristics</th>
<th>Intervention</th>
<th>Comparison</th>
<th>Length of follow up</th>
<th>Outcome measure</th>
<th>Effect size</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yeh, et al (2013)</td>
<td>1+</td>
<td>RCT</td>
<td>21</td>
<td>Chronic low back pain</td>
<td>True auricular point acupressure</td>
<td>Sham acupoint</td>
<td>1 month after treatment</td>
<td>Effects of acupressure on pain, disability, psychological function &amp; quality of life</td>
<td>All with significant results except disability</td>
</tr>
<tr>
<td>Vas, et al (2014)</td>
<td>1++</td>
<td>RCT</td>
<td>265</td>
<td>Chronic spinal pain</td>
<td>True auriculopressure</td>
<td>Placebo auriculopressure</td>
<td>9 weeks &amp; 6 months after treatment</td>
<td>Effect on pain, quality of life, mental health, analgesic consumption, disability &amp; sleep</td>
<td>All with significant result except mental health and disability</td>
</tr>
<tr>
<td>Suen et al (2007)</td>
<td>1+</td>
<td>RCT</td>
<td>60</td>
<td>Chronic low back pain</td>
<td>True auriculotherapy</td>
<td>Sham auriculotherapy</td>
<td>3, 5 &amp; 7 weeks after starting treatment</td>
<td>Effect on pain</td>
<td>Significant result</td>
</tr>
<tr>
<td>Suen &amp; Wong (2008)</td>
<td>1+</td>
<td>RCT</td>
<td>79</td>
<td>Chronic low back pain</td>
<td>True auriculotherapy</td>
<td>Sham auriculotherapy</td>
<td>1.5 &amp; 3 week of treatment, 2 &amp; 4 week post-treatment</td>
<td>Effect on pain and disability</td>
<td>All with significant result</td>
</tr>
<tr>
<td>Chung et al (2013)</td>
<td>1++</td>
<td>RCT</td>
<td>135</td>
<td>Patient with lumbar spine surgery</td>
<td>PCA + acupoint stimulation</td>
<td>1. Sham acupoint stimulation</td>
<td>24-, 48- &amp; 72-hr after surgery</td>
<td>Effect on pain and analgesic consumption</td>
<td>All with significant result</td>
</tr>
<tr>
<td>Yeh et al (2010)</td>
<td>1-</td>
<td>RCT</td>
<td>94</td>
<td>Patient with lumbar spine surgery</td>
<td>PCA + true auricular acupressure</td>
<td>Control w/ no acupressure</td>
<td>2, 24, 48 &amp; 72 hours after surgery</td>
<td>Effect on pain, disability, sleep, analgesic consumption</td>
<td>Significant results only shown on pain intensity and disability</td>
</tr>
</tbody>
</table>
Appendix IV: CASP evaluation


<table>
<thead>
<tr>
<th>Screening Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Did the trial address a clearly focused issue?</td>
<td>Yes</td>
</tr>
<tr>
<td>2. Was the assignment of patients to treatments randomized?</td>
<td>Yes</td>
</tr>
<tr>
<td>3. Were all of the patients who entered the trial properly accounted for at its conclusion?</td>
<td>Yes -retention rate was 90% -all subjects were analyzed by the groups they originally designated.</td>
</tr>
<tr>
<td>4. Were patients, health workers and study personnel ‘blind’ to the treatment?</td>
<td>Yes -single “blind” -patients are “blind”</td>
</tr>
<tr>
<td>5. Were the groups similar at the start of the trial?</td>
<td>Yes -similar size of experimental group and sham group -the two group are not significantly different in demographic characteristics -randomization was mentioned but with no description</td>
</tr>
<tr>
<td>6. Aside from the experimental intervention, were the groups treated equally?</td>
<td>Yes -Both the experimental group and sham group were treated equally and data of both groups were collected in the same way.</td>
</tr>
<tr>
<td>7. How large was the treatment effect?</td>
<td>-Effects of auriculotherapy on pain, disability, psychological function &amp; quality of life were measured and were clearly specified - all with significant result except for the area of back specific disability</td>
</tr>
<tr>
<td>Question</td>
<td>Answer</td>
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<td>-------------------------------------------------------------------------</td>
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<tr>
<td>8. How precise was the estimate of the treatment effect?</td>
<td>-only p value was provided</td>
</tr>
<tr>
<td>9. Can the result be applied in your context?</td>
<td>Yes -they were suffering from same clinical problem</td>
</tr>
<tr>
<td>10. Were all clinically important outcomes considered?</td>
<td>Yes -the study mentioned the effectiveness on pain control and functional activity -the study didn’t mention the area about analgesic consumption but this didn’t affect the decision as pain intensity which is the primary outcome was shown to be significant improved with auriculotherapy</td>
</tr>
<tr>
<td>11. Are the benefits worth the harm and cost?</td>
<td>Yes -the study demonstrated a significantly great improvement on reduction on pain intensity and improvement in physical function but only with few adverse effects reported -for patient, auriculotherapy is non-invasive and well-accepted -for health worker, auriculotherapy is easy and safe to use -for policy maker, auriculotherapy is cost effective</td>
</tr>
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</table>

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<thead>
<tr>
<th>Screening Question</th>
<th>Answer</th>
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<tbody>
<tr>
<td>1. Did the trial address a clearly focused issue?</td>
<td>Yes</td>
</tr>
<tr>
<td>2. Was the assignment of patients to treatments randomized?</td>
<td>Yes</td>
</tr>
</tbody>
</table>
| 3. Were all of the patients who entered the trial properly accounted for at its conclusion? | Yes  
  -patient outcomes were analysed according to the group they were allocated  
  -no placebo group got an experimental group option or vice versa           |
| 4. Were patients, health workers and study personnel ‘blind’ to the treatment?   | Yes  
  -patients and investigators are “blind”                                                                                           |
| 5. Were the groups similar at the start of the trial?                            | Yes  
  -similar size of experimental group and placebo group  
  -the two group are not significantly different in demographic characteristics  
  -Software EpiDat V.3.1 was used for randomization, followed by stratification |
| 6. Aside from the experimental intervention, were the groups treated equally?     | Yes  
  -Both the experimental group and placebo group were treated equally and data of both groups were collected in the same way.     |
| 7. How large was the treatment effect?                                           | - Effects of auriculotherapy on pain, quality of life, quality of sleep, analgesic consumption, mental health, functional activity and patients’ satisfaction were measured and were clearly specified  
  - all with significant result except for the area of mental health and functional activity |
<table>
<thead>
<tr>
<th>Question</th>
<th>Response</th>
</tr>
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<tbody>
<tr>
<td>8. How precise was the estimate of the treatment effect?</td>
<td>-$P$ value and 95% confidence interval were shown</td>
</tr>
<tr>
<td>9. Can the result be applied in your context?</td>
<td>Yes - various demographic characteristics were discussed to exclude bias, hence, result was generalizable - they were suffering from the same clinical problem</td>
</tr>
<tr>
<td>10. Were all clinically important outcomes considered?</td>
<td>Yes - the study mention the effectiveness of auriculotherapy on pain control, functional activity and analgesic consumption</td>
</tr>
<tr>
<td>11. Are the benefits worth the harm and cost?</td>
<td>Yes - the study demonstrated a significantly great improvement on reduction on pain intensity and improvement in physical function but only with few adverse effects reported - for patient, auriculotherapy is non-invasive and well-accepted - for health worker, auriculotherapy is easy and safe to use - for policy maker, auriculotherapy is cost effective</td>
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<td>1. Did the trial address a clearly focused issue?</td>
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</tr>
<tr>
<td>2. Was the assignment of patients to treatments randomized?</td>
<td>Yes</td>
</tr>
</tbody>
</table>
| 3. Were all of the patients who entered the trial properly accounted for at its conclusion? | Yes  
-No control group got an experimental group option or vice versa  
-All participants were analyzed by the groups they originally allocated. |
| 4. Were patients, health workers and study personnel ‘blind’ to the treatment?     | Yes  
-single “blind”  
-patients were “blind”                                                                 |
| 5. Were the groups similar at the start of the trial?                             | Yes  
-similar size of experimental group and control group  
-the two group are not significantly different in demographic characteristics  
-randomization was mentioned but with no description |
| 6. Aside from the experimental intervention, were the groups treated equally?      | Yes  
-Both the experimental group and sham group were treated equally and data of both groups were collected in the same way. |
| 7. How large was the treatment effect?                                            | - Effects of auriculotherapy on pain was measured and was clearly specified  
- significant result was shown                                                                 |
| 8. How precise was the estimate of the treatment effect?                          | -p value was provided  
-Wilcoxon signed ranks test z-value was also provided |


<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>9. Can the result be applied in your context?</td>
<td>Yes</td>
<td>-they were suffering from same clinical problem</td>
</tr>
<tr>
<td></td>
<td></td>
<td>-the study was conducted in Hong Kong, the culture of participant was supposed to be similar to those of my clinical setting</td>
</tr>
<tr>
<td>10. Were all clinically important outcomes considered?</td>
<td>No</td>
<td>-the study mentioned the effectiveness on pain control</td>
</tr>
<tr>
<td></td>
<td></td>
<td>-the study didn’t mention the area about analgesic consumption and functional activity but this didn’t affect the decision as pain intensity which is the primary outcome was shown to be significant improved with auriculotherapy</td>
</tr>
<tr>
<td>11. Are the benefits worth the harm and cost?</td>
<td>Yes</td>
<td>-the study demonstrated a significantly great improvement on reduction on pain intensity but only with few adverse effects reported</td>
</tr>
<tr>
<td></td>
<td></td>
<td>-for patient, auriculotherapy is non-invasive and well-accepted</td>
</tr>
<tr>
<td></td>
<td></td>
<td>-for health worker, auriculotherapy is easy and safe to use</td>
</tr>
<tr>
<td></td>
<td></td>
<td>-for policy maker, auriculotherapy is cost effective</td>
</tr>
<tr>
<td></td>
<td></td>
<td>-as a holistic treatment approach, demonstrated a therapeutic effect on relieving LBP, some systemic symptom like headache, dizziness and sleep condition</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Screening Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Did the trial address a clearly focused issue?</td>
<td>Yes</td>
</tr>
<tr>
<td>2. Was the assignment of patients to treatments randomized?</td>
<td>Yes</td>
</tr>
<tr>
<td>3. Were all of the patients who entered the trial properly accounted for at its conclusion?</td>
<td>Yes -no participants lost to follow up -all subjects were analyzed by the groups they originally designated -no control group got an experimental group option or vice versa</td>
</tr>
<tr>
<td>4. Were patients, health workers and study personnel ‘blind’ to the treatment?</td>
<td>Yes -single “blind” -only participants were “blind”</td>
</tr>
<tr>
<td>5. Were the groups similar at the start of the trial?</td>
<td>Yes -same size of experimental group and sham group -the two group are not significantly different in demographic characteristics -randomization was mentioned but with no description -only small no. of male participants &amp; unable to determine gender differences in therapeutic effect; when excluded males from analyses, no significant differences of the result</td>
</tr>
<tr>
<td>6. Aside from the experimental intervention, were the groups treated equally?</td>
<td>Yes -Both the experimental group and sham group were treated equally and data of both groups were collected in the same way</td>
</tr>
</tbody>
</table>
7. How large was the treatment effect?  
- Effects of auriculotherapy on pain, disability, physical and functional outcomes were measured and were clearly specified  
- all with significant results

8. How precise was the estimate of the treatment effect?  
- only p value was provided

9. Can the result be applied in your context?  
Yes  
- they were suffering from same clinical problem  
- the study was conducted in Hong Kong, the culture of participant was supposed to be similar to those of my clinical setting

10. Were all clinically important outcomes considered?  
No  
- the study mentioned the effectiveness on pain control  
- the study didn’t mention the area about analgesic consumption but this didn’t affect the decision as pain intensity which is the primary outcome was shown to be significant improved with auriculotherapy

11. Are the benefits worth the harm and cost?  
Yes  
- the study demonstrated a significantly great improvement on reduction on pain intensity but only with few adverse effects reported  
- for patient, auriculotherapy is non-invasive and well-accepted  
- for health worker, auriculotherapy is easy and safe to use  
- for policy maker, auriculotherapy is cost effective

<table>
<thead>
<tr>
<th>Screening Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Did the trial address a clearly focused issue?</td>
<td>Yes</td>
</tr>
<tr>
<td>2. Was the assignment of patients to treatments randomized?</td>
<td>Yes</td>
</tr>
<tr>
<td>3. Were all of the patients who entered the trial properly accounted for at its conclusion?</td>
<td>Yes&lt;br&gt;- No control group got an experimental group option or vice versa&lt;br&gt;- All participants were analyzed by the groups they originally allocated</td>
</tr>
<tr>
<td>4. Were patients, health workers and study personnel ‘blind’ to the treatment?</td>
<td>Yes&lt;br&gt;- single “blind”&lt;br&gt;- patients were “blind”</td>
</tr>
<tr>
<td>5. Were the groups similar at the start of the trial?</td>
<td>Yes&lt;br&gt;- similar size of experimental group and control group&lt;br&gt;- the two group are not significantly different in demographic characteristics&lt;br&gt;- randomization: computer-generated number was used with opaque, sealed envelops for random allocation</td>
</tr>
<tr>
<td>6. Aside from the experimental intervention, were the groups treated equally?</td>
<td>Yes&lt;br&gt;- Both the experimental group and sham group were treated equally and data of both groups were collected in the same way.</td>
</tr>
<tr>
<td>7. How large was the treatment effect?</td>
<td>- Effects of auriculotherapy on change of pain and analgesic consumption was measured and was clearly specified&lt;br&gt;- significant result was shown</td>
</tr>
<tr>
<td>Question</td>
<td>Answer</td>
</tr>
<tr>
<td>------------------------------------------------------------------------</td>
<td>----------------------------------------------------------------------</td>
</tr>
<tr>
<td>8. How precise was the estimate of the treatment effect?</td>
<td>-p value was provided</td>
</tr>
<tr>
<td>9. Can the result be applied in your context?</td>
<td>-the study was conducted in Taiwan with the culture of participants was more or less the same as those to my clinical setting</td>
</tr>
<tr>
<td>10. Were all clinically important outcomes considered?</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>-the study mentioned the effectiveness on pain control and decrease in analgesic consumption</td>
</tr>
<tr>
<td></td>
<td>-the study didn’t mention the area about functional acitivity but this didn’t affect the decision as pain intensity analgesic consumption which are the primary outcome was shown to be significant improved with auriculotherapy</td>
</tr>
<tr>
<td>11. Are the benefits worth the harm and cost?</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>-the study demonstrated a significantly great improvement on reduction on pain intensity as well as improving analgesic quality but only with few adverse effects reported</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Screening Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Did the trial address a clearly focused issue?</td>
<td>Yes</td>
</tr>
<tr>
<td>2. Was the assignment of patients to treatments randomized?</td>
<td>Yes</td>
</tr>
<tr>
<td>3. Were all of the patients who entered the trial properly accounted for at its conclusion?</td>
<td>Yes -No control group got an experimental group option or vice versa -All participants were analyzed by the groups they originally allocated</td>
</tr>
<tr>
<td>4. Were patients, health workers and study personnel ‘blind’ to the treatment?</td>
<td>Yes -single “blind” -patients were “blind”</td>
</tr>
<tr>
<td>5. Were the groups similar at the start of the trial?</td>
<td>Yes -same size of experimental group and control group -the two group are not significantly different in demographic characteristics -randomization by use of a randomization list</td>
</tr>
<tr>
<td>6. Aside from the experimental intervention, were the groups treated equally?</td>
<td>Can’t say -muscle injection of Demerol was requested by 4 participants (10.8%) during the study, but no mention which group they were belonged to</td>
</tr>
<tr>
<td>7. How large was the treatment effect?</td>
<td>- Effects of auriculotherapy on change of pain, analgesic consumption, activity sleep and analgesic satisfaction were measured and were clearly specified - significant results were shown on reducing pain and walking ability but no between group differences were noted on other studied area</td>
</tr>
<tr>
<td>Question</td>
<td>Answer</td>
</tr>
<tr>
<td>------------------------------------------------------------------------</td>
<td>------------------------------------------------------------------------</td>
</tr>
<tr>
<td>8. How precise was the estimate of the treatment effect?</td>
<td>- <em>p value was provided</em></td>
</tr>
<tr>
<td>9. Can the result be applied in your context?</td>
<td><em>Yes</em></td>
</tr>
<tr>
<td>- they also suffering back pain</td>
<td></td>
</tr>
<tr>
<td>10. Were all clinically important outcomes considered?</td>
<td><em>Yes</em></td>
</tr>
<tr>
<td>- the effects of auriculotherapy on change of pain, analgesic consumption, activity sleep and analgesic satisfaction were all considered here</td>
<td></td>
</tr>
<tr>
<td>11. Are the benefits worth the harm and cost?</td>
<td><em>Yes</em></td>
</tr>
<tr>
<td>- the study demonstrated a significantly great improvement on reduction on pain intensity as well as improving analgesic quality but only with few adverse effects reported</td>
<td></td>
</tr>
</tbody>
</table>
### Appendix V: Summary table of critical appraisal of sampled studies

<table>
<thead>
<tr>
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<th></th>
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<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Did the trial address a clearly focussed issue?</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>2. Was the assignment of patients to treatments randomized?</td>
<td>Yes</td>
<td>Yes</td>
<td>Can’t say</td>
<td>Can’t say</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>3. Were all of the patients who entered the trial properly accounted for at its conclusion?</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>4. Were patients, health workers and study personnel ‘blind’ to the treatment?</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>5. Were the groups similar at the start of the trial?</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>6. Aside from the experimental intervention, were the groups treated equally?</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Can’t say</td>
</tr>
<tr>
<td>7. How large was the treatment effect?</td>
<td>Significant result except disability</td>
<td>Significant result except mental health and functional activity</td>
<td>Significant result</td>
<td>Significant result</td>
<td>Significant result</td>
<td>Significant result on pain and walking ability only</td>
</tr>
<tr>
<td>8. How precise was the estimate of the treatment effect?</td>
<td>p value</td>
<td>p value &amp; 95% CI</td>
<td>p value &amp; z value</td>
<td>p value</td>
<td>p value</td>
<td>p value</td>
</tr>
<tr>
<td>9. Can the result be applied in your context?</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>10. Were all clinically important outcomes considered?</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>11. Are the benefits worth the harm and cost?</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>
Appendix VI: Quality assessment of sampled studies

Methodology Checklist 2: Controlled Trials


<table>
<thead>
<tr>
<th>Guideline topic:</th>
<th>Key Question No:</th>
<th>Reviewer:</th>
</tr>
</thead>
</table>

Before completing this checklist, consider:

1. Is the paper a randomised controlled trial or a controlled clinical trial? If in doubt, check the study design algorithm available from SIGN and make sure you have the correct checklist. If it is a controlled clinical trial questions 1.2, 1.3, and 1.4 are not relevant, and the study cannot be rated higher than 1+

Is the paper relevant to key question? Analyse using PICO (Patient or Population Intervention Comparison Outcome). IF NO REJECT (give reason below). IF YES complete the checklist.

Reason for rejection: 1. Paper not relevant to key question ☐ 2. Other reason ☐ (please specify):

SECTION 1: INTERNAL VALIDITY

<table>
<thead>
<tr>
<th>In a well conducted RCT study...</th>
<th>Does this study do it?</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1 The study addresses an appropriate and clearly focused question.</td>
<td>Yes ☑ No ☐ Can’t say ☐</td>
</tr>
<tr>
<td>1.2 The assignment of subjects to treatment groups is randomised.</td>
<td>Yes ☑ No ☐ Can’t say ☐</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>1.3</td>
<td>An adequate concealment method is used.</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>1.4</td>
<td>Subjects and investigators are kept ‘blind’ about treatment allocation.</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>1.5</td>
<td>The treatment and control groups are similar at the start of the trial.</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>1.6</td>
<td>The only difference between groups is the treatment under investigation.</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>1.7</td>
<td>All relevant outcomes are measured in a standard, valid and reliable way.</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>1.8</td>
<td>What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed?</td>
</tr>
<tr>
<td>1.9</td>
<td>All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis).</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>1.10</td>
<td>Where the study is carried out at more than one site, results are comparable for all sites.</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**SECTION 2: OVERALL ASSESSMENT OF THE STUDY**

2.1 *How well was the study done to minimise bias?*

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>High quality (++)[ ]</td>
</tr>
<tr>
<td></td>
<td>Acceptable (+)[ ]</td>
</tr>
<tr>
<td></td>
<td>Unacceptable – reject 0 ☐</td>
</tr>
</tbody>
</table>

2.2 Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention?

*There was no information provided on how the effective size was calculated.*
| 2.3 | Are the results of this study directly applicable to the patient group targeted by this guideline? | Yes |
| 2.4 | **Notes.** Summarise the authors’ conclusions. Add any comments on your own assessment of the study, and the extent to which it answers your question and mention any areas of uncertainty raised above. |

Larger of the study group size can enhance level of evidence, and multi-sites studies can enhance confidence of result. Specific data from different participating centres and method of concealment are suggested to be provided to increase confidence of the result.

Foothnotes:

1.1 Element of research question is stated clear in the paper. P: patients suffering chronic low back pain for more than three months; I: True auricular acupressure; C: sham auricular acupressure; O: reduction in pain.
1.2 Computer-generated simple randomization was used.
1.3 Concealment was mentioned with no description.
1.4 Blinding level was single of which participants were kept blind to the treatment received.
1.5 The size of experimental and sham groups was similar. There was no significant difference on their demographic characteristics.
1.6 Both the experimental group and sham group were treated equally and data of both groups were collected in the same way.
1.7 The outcome of effect of auriculotherapy on pain, disability, psychological function & quality of life were measured and were clearly specified, all with significant result, with p value given, except for the area of back specific disability.
1.9 Intention to treat was mentioned in the text, with patient outcomes analysed according to the group they were designated and no control group got an experimental group option or vice versa.
1.10 No specific data was given.
# Methodology Checklist 2: Controlled Trials

**Study identification**  
*(Include author, title, year of publication, journal title, pages)*


**Guideline topic:**  
**Key Question No:**  
**Reviewer:**

---

**Before** completing this checklist, consider:

1. Is the paper a **randomised controlled trial** or a **controlled clinical trial**?  
   If in doubt, check the study design algorithm available from SIGN and make sure you have the correct checklist. If it is a **controlled clinical trial** questions 1.2, 1.3, and 1.4 are not relevant, and the study cannot be rated higher than 1+

Is the paper relevant to key question? Analyse using PICO (Patient or Population Intervention Comparison Outcome). IF NO REJECT (give reason below). IF YES complete the checklist.

**Reason for rejection:** 1. Paper not relevant to key question  
2. Other reason (please specify):

---

## SECTION 1: INTERNAL VALIDITY

**In a well conducted RCT study...**  
**Does this study do it?**

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1.1</strong></td>
<td>The study addresses an appropriate and clearly focused question.</td>
<td>Yes ☑ No □ Can’t say □</td>
</tr>
<tr>
<td><strong>1.2</strong></td>
<td>The assignment of subjects to treatment groups is randomised.</td>
<td>Yes ☑ No □ Can’t say □</td>
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</tr>
<tr>
<td>1.3</td>
<td>An adequate concealment method is used.</td>
<td>Yes ☑ No ☐ Can't say ☑</td>
</tr>
<tr>
<td>1.4</td>
<td>Subjects and investigators are kept ‘blind’ about treatment allocation.</td>
<td>Yes ☑ No ☐ Can't say ☐</td>
</tr>
<tr>
<td>1.5</td>
<td>The treatment and control groups are similar at the start of the trial.</td>
<td>Yes ☑ No ☐ Can't say ☐</td>
</tr>
<tr>
<td>1.6</td>
<td>The only difference between groups is the treatment under investigation.</td>
<td>Yes ☑ No ☐ Can't say ☐</td>
</tr>
<tr>
<td>1.7</td>
<td>All relevant outcomes are measured in a standard, valid and reliable way.</td>
<td>Yes ☑ No ☐ Can't say ☐</td>
</tr>
<tr>
<td>1.8</td>
<td>What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed?</td>
<td>5%</td>
</tr>
<tr>
<td>1.9</td>
<td>All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis).</td>
<td>Yes ☑ No ☐ Can't say ☐ Does not apply ☐</td>
</tr>
<tr>
<td>1.10</td>
<td>Where the study is carried out at more than one site, results are comparable for all sites.</td>
<td>Yes ☐ No ☐ Can't say ☑ Does not apply ☐</td>
</tr>
</tbody>
</table>

**SECTION 2: OVERALL ASSESSMENT OF THE STUDY**

<p>| | |</p>
<table>
<thead>
<tr>
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<th></th>
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</thead>
</table>
| 2.1 | *How well was the study done to minimise bias?*
   Code as follows:
   High quality (++): ☑
   Acceptable (+): ☐
   Unacceptable – reject 0: ☐
| 2.2 | Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention? | *The effective sample size was calculated at a 90% power at a 5% level of significance* |
| 2.3 | Are the results of this study directly | Yes |
| 2.4 | **Notes.** Summarise the authors’ conclusions. Add any comments on your own assessment of the study, and the extent to which it answers your question and mention any areas of uncertainty raised above. | Specific data from different participating centres are suggested to be provided to increase confidence of the result |

---

**Footnotes:**

1.1 Element of research question is stated clear in the paper. P: patients with chronic non-specific spinal pain; I: True auriculopressure; C: placebo auriculopressure; O: reduction in pain.

1.2 Software EpiDat V.3.1 was used for randomization, followed by stratification.

1.3 Concealment was mentioned with no description.

1.4 The blinding level was double blind with participants and investigators were “blind”.

1.5 The size of experimental and placebo groups was similar. There was no significant difference on their demographic characteristics.

1.6 Both the experimental group and placebo group were treated equally and data of both groups were collected in the same way.

1.7 The outcome of effect of auriculotherapy on pain, quality of life, quality of sleep, analgesic consumption, mental health, functional activity and patients’ satisfaction were measured and were clearly specified, all with significant result, with p value given, except for the area of functional activity and analgesic consumption.

1.9 ITT was mentioned in the text, with patient outcomes analysed according to the group they were designated and no placebo group got an experimental group option or vice versa.

1.10 No specific data was given.
Methodology Checklist 2: Controlled Trials

Studies identification  
*Include* author, title, year of publication, journal title, pages


Guideline topic: | Key Question No: | Reviewer:
---|---|---

Before completing this checklist, consider:

1. Is the paper a *randomised controlled trial* or a *controlled clinical trial*? If in doubt, check the study design algorithm available from SIGN and make sure you have the correct checklist. If it is a *controlled clinical trial* questions 1.2, 1.3, and 1.4 are not relevant, and the study cannot be rated higher than 1+

Is the paper relevant to key question? Analyse using PICO (Patient or Population Intervention Comparison Outcome). IF NO REJECT (give reason below). IF YES complete the checklist.

Reason for rejection: 1. Paper not relevant to key question 2. Other reason (please specify):

SECTION 1: INTERNAL VALIDITY

*In a well conducted RCT study...* | Does this study do it?
---|---
1.1 The study addresses an appropriate and clearly focused question. | Yes ☑ No ☐ Can’t say ☐
1.2 The assignment of subjects to treatment groups is randomised. | Yes ☐ No ☐ Can’t say ☑
1.3 An adequate concealment method is used. | Yes ☐ No ☐ Can’t say ☑
<p>| | | | |</p>
<table>
<thead>
<tr>
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<th></th>
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<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.4</td>
<td>Subjects and investigators are kept ‘blind’ about treatment allocation.</td>
<td>Yes ✓</td>
<td>No □</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Can’t say □</td>
<td></td>
</tr>
<tr>
<td>1.5</td>
<td>The treatment and control groups are similar at the start of the trial.</td>
<td>Yes ✓</td>
<td>No □</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Can’t say □</td>
<td></td>
</tr>
<tr>
<td>1.6</td>
<td>The only difference between groups is the treatment under investigation.</td>
<td>Yes ✓</td>
<td>No □</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Can’t say □</td>
<td></td>
</tr>
<tr>
<td>1.7</td>
<td>All relevant outcomes are measured in a standard, valid and reliable way.</td>
<td>Yes ✓</td>
<td>No □</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Can’t say □</td>
<td></td>
</tr>
<tr>
<td>1.8</td>
<td>What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed?</td>
<td>30%</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>- the demographic variables at baseline between subjects dropped out &amp; those continued to participate in the study was shown to be of no significant difference</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>- reason: home leave or outing, admission to hospital, somatic discomfort or death</td>
<td></td>
</tr>
<tr>
<td>1.9</td>
<td>All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis).</td>
<td>Yes □</td>
<td>No □</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Can’t say ✓ Does not apply □</td>
<td></td>
</tr>
<tr>
<td>1.10</td>
<td>Where the study is carried out at more than one site, results are comparable for all sites.</td>
<td>Yes □</td>
<td>No □</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Can’t say ✓ Does not apply □</td>
<td></td>
</tr>
</tbody>
</table>

**SECTION 2: OVERALL ASSESSMENT OF THE STUDY**

<p>| | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>2.1</td>
<td>How well was the study done to minimise bias?</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Code as follows:</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>High quality (++)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Acceptable (+)</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Unacceptable – reject 0 □</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.2</td>
<td>Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention?</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>There was no information provided on how the effective size was calculated.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
2.3 Are the results of this study directly applicable to the patient group targeted by this guideline?  
Yes

2.4 Notes. Summarise the authors’ conclusions. Add any comments on your own assessment of the study, and the extent to which it answers your question and mention any areas of uncertainty raised above.

Method of randomization and concealment are suggested to be provided to increase the confidence level. Specific data from different participating centres are suggested to be provided to increase confidence of the result.

Footnotes:
1.1 Element of research question is stated clear in the paper. P: patients with low back pain; I: true auriculotherapy; C: sham auriculotherapy; O: reduction in pain.
1.2 Randomization was mentioned but method not specific.
1.3 Concealment was mentioned with no description.
1.4 The blinding level was single blind with participants was “blind”.
1.5 The size of experimental and placebo groups was similar. There was no significant difference on their demographic characteristics.
1.6 Both the experimental group and placebo group were treated equally and data of both groups were collected in the same way.
1.7 The outcome of effect of auriculotherapy on pain was measured and was clearly specified, with significant result as with p value given for reference.
1.9 Intention to treat was mentioned in the text, with patient outcomes analysed according to the group they were designated and no control group got an experimental group option or vice versa.
1.10 No specific data was given.
# Methodology Checklist 2: Controlled Trials

**Study identification**  
*Include author, title, year of publication, journal title, pages*


<table>
<thead>
<tr>
<th>Guideline topic:</th>
<th>Key Question No:</th>
<th>Reviewer:</th>
</tr>
</thead>
</table>

**Before** completing this checklist, consider:

1. Is the paper a **randomised controlled trial** or a **controlled clinical trial**?
   If in doubt, check the study design algorithm available from SIGN and make sure you have the correct checklist. If it is a **controlled clinical trial** questions 1.2, 1.3, and 1.4 are not relevant, and the study cannot be rated higher than 1+

Is the paper relevant to key question? Analyse using PICO (Patient or Population Intervention Comparison Outcome). IF NO REJECT (give reason below). IF YES complete the checklist.

Reason for rejection: 1. Paper not relevant to key question ☐  2. Other reason ☐ (please specify):

### SECTION 1: INTERNAL VALIDITY

**In a well conducted RCT study…**

<table>
<thead>
<tr>
<th>Does this study do it?</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1.1</strong> The study addresses an appropriate and clearly focused question.</td>
</tr>
<tr>
<td><strong>1.2</strong> The assignment of subjects to treatment groups is randomised.</td>
</tr>
<tr>
<td><strong>1.3</strong> An adequate concealment method is used.</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>---</td>
</tr>
<tr>
<td>1.5</td>
</tr>
<tr>
<td>1.6</td>
</tr>
<tr>
<td>1.7</td>
</tr>
<tr>
<td>1.8</td>
</tr>
<tr>
<td>1.9</td>
</tr>
<tr>
<td>1.10</td>
</tr>
</tbody>
</table>

**SECTION 2: OVERALL ASSESSMENT OF THE STUDY**

<table>
<thead>
<tr>
<th></th>
<th>How well was the study done to minimise bias?</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.1</td>
<td>Code as follows:</td>
</tr>
<tr>
<td></td>
<td>High quality (++) ☐</td>
</tr>
<tr>
<td></td>
<td>Acceptable (+) ☑</td>
</tr>
<tr>
<td></td>
<td>Unacceptable – reject 0 □</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention?</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.2</td>
<td>There was no information provided on how the effective size was calculated.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Are the results of this study directly applicable to the patient group targeted by this guideline?</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.3</td>
<td>Yes</td>
</tr>
</tbody>
</table>

99
2.4 **Notes.** Summarise the authors’ conclusions. Add any comments on your own assessment of the study, and the extent to which it answers your question and mention any areas of uncertainty raised above.

Method of randomization and concealment are suggested to be provided to increase the confidence level. Specific data from different participating centres are suggested to be provided to increase confidence of the result.

---

**Footnotes:**

1.1 Element of research question is stated clear in the paper. P: patients with low back pain; I: true auriculotherapy; C: sham auriculotherapy; O: reduction in disability level and pain.

1.2 Randomization was mentioned but method not specific.

1.3 Concealment was mentioned with no description.

1.4 The blinding level was single blind with participants was “blind”.

1.5 The size of experimental and placebo groups was similar. There was no significant difference on their demographic characteristics. Only small number of male participants was noted in the study; hence, unable to determine gender differences in therapeutic effect. When males were excluded from analyses, no significant differences of the result was reported.

1.6 Both the experimental group and placebo group were treated equally and data of both groups were collected in the same way.

1.7 The outcome of effect of auriculotherapy on change of disability level and pain were measured and were clearly specified, with significant result as with p value given for reference.

1.9 All participants were accounted for and none are lost to follow-up.

1.10 No specific data was given.
Methodology Checklist 2: Controlled Trials

Study identification  
(Include author, title, year of publication, journal title, pages)


Guideline topic:  | Key Question No:  | Reviewer:
--- | --- | ---

**Before** completing this checklist, consider:

1. Is the paper a **randomised controlled trial** or a **controlled clinical trial**?  
   If in doubt, check the study design algorithm available from SIGN and make sure you have the correct checklist. If it is a **controlled clinical trial** questions 1.2, 1.3, and 1.4 are not relevant, and the study cannot be rated higher than 1+

Is the paper relevant to key question? Analyse using PICO (Patient or Population Intervention Comparison Outcome). IF NO REJECT (give reason below). IF YES complete the checklist.

Reason for rejection: 1. Paper not relevant to key question ☐  2. Other reason ☐  
(please specify):

**SECTION 1: INTERNAL VALIDITY**

<table>
<thead>
<tr>
<th>In a well conducted RCT study…</th>
<th>Does this study do it?</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1 The study addresses an appropriate and clearly focused question.</td>
<td>Yes ☑ No ☐ Can’t say ☐</td>
</tr>
<tr>
<td>1.2 The assignment of subjects to treatment groups is randomised.</td>
<td>Yes ☑ No ☐ Can’t say ☐</td>
</tr>
<tr>
<td>1.3 An adequate concealment method is used.</td>
<td>Yes ☑ No ☐ Can’t say ☐</td>
</tr>
<tr>
<td></td>
<td>Question</td>
</tr>
<tr>
<td>---</td>
<td>--------------------------------------------------------------------------</td>
</tr>
<tr>
<td>1.4</td>
<td>Subjects and investigators are kept ‘blind’ about treatment allocation.</td>
</tr>
<tr>
<td>1.5</td>
<td>The treatment and control groups are similar at the start of the trial.</td>
</tr>
<tr>
<td>1.6</td>
<td>The only difference between groups is the treatment under investigation.</td>
</tr>
<tr>
<td>1.7</td>
<td>All relevant outcomes are measured in a standard, valid and reliable way.</td>
</tr>
<tr>
<td>1.8</td>
<td>What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed?</td>
</tr>
<tr>
<td>1.9</td>
<td>All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis).</td>
</tr>
<tr>
<td>1.10</td>
<td>Where the study is carried out at more than one site, results are comparable for all sites.</td>
</tr>
</tbody>
</table>

### SECTION 2: OVERALL ASSESSMENT OF THE STUDY

<table>
<thead>
<tr>
<th></th>
<th>Question</th>
<th>Rating</th>
</tr>
</thead>
</table>
| 2.1 | How well was the study done to minimise bias? Code as follows:           | High quality (++)

- Acceptable (+)
- Unacceptable – reject

2.2 Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention? -80% power with 5% level of significance
- Effective size was 108, the population was oversampled by 25% in case of expected loss of follow-up

2.3 Are the results of this study directly applicable to the patient group targeted by this guideline? Yes
### 2.4 Notes

Summarise the authors’ conclusions. Add any comments on your own assessment of the study, and the extent to which it answers your question and mention any areas of uncertainty raised above.

Multi-sites study is suggested to enhance confidence of result.

---

**Footnotes:**

1.1 *Element of research question is stated clear in the paper.* P: lumbar spine surgical patients; I: true auriculotherapy combined with transcutaneous electric acupoint stimulation (TEAS) ; C: sham auriculotherapy and sham TEAS; O: reduction in analgesic consumption and pain intensity.

1.2 Randomization was used with computer-generated number for random allocation.

1.3 Concealment was used with opaque, sealed envelopes.

1.4 The blinding level was single blind with participants was “blind”.

1.5 The size of experimental and sham groups was similar. There was no significant difference on their demographic characteristics.

1.6 Both the experimental group and sham group were treated equally and data of both groups were collected in the same way.

1.7 The outcome of effect of auriculotherapy on change of analgesic consumption and pain was measured and was clearly specified, with significant result as with p value given for reference.

1.9 Intention to treat was mentioned in the text, with patient outcomes analysed according to the group they were designated and no control group got an experimental group option or vice versa

1.10 Not applicable.
### Methodology Checklist 2: Controlled Trials

**Study identification** *(Include author, title, year of publication, journal title, pages)*


**Guideline topic:** Key Question No: Reviewer:

**Before** completing this checklist, consider:

1. Is the paper a **randomised controlled trial** or a **controlled clinical trial**? If in doubt, check the study design algorithm available from SIGN and make sure you have the correct checklist. If it is a **controlled clinical trial** questions 1.2, 1.3, and 1.4 are not relevant, and the study cannot be rated higher than 1+

Is the paper relevant to key question? Analyse using PICO (Patient or Population Intervention Comparison Outcome). IF NO REJECT (give reason below). IF YES complete the checklist.

Reason for rejection: 1. Paper not relevant to key question □  2. Other reason □ (please specify):

### SECTION 1: INTERNAL VALIDITY

**In a well conducted RCT study...**

<table>
<thead>
<tr>
<th>Does this study do it?</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1.1</strong> The study addresses an appropriate and clearly focused question.</td>
</tr>
<tr>
<td><strong>1.2</strong> The assignment of subjects to treatment groups is randomised.</td>
</tr>
<tr>
<td><strong>1.3</strong> An adequate concealment method is used.</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>---</td>
</tr>
<tr>
<td>1.4</td>
</tr>
<tr>
<td>1.5</td>
</tr>
<tr>
<td>1.6</td>
</tr>
<tr>
<td>1.7</td>
</tr>
<tr>
<td>1.8</td>
</tr>
<tr>
<td>1.9</td>
</tr>
<tr>
<td>1.10</td>
</tr>
</tbody>
</table>

**SECTION 2: OVERALL ASSESSMENT OF THE STUDY**

<table>
<thead>
<tr>
<th></th>
<th>Question</th>
<th>Code as follows:</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.1</td>
<td>How well was the study done to minimise bias?</td>
<td>High quality (++), Acceptable (+)</td>
</tr>
<tr>
<td>2.2</td>
<td>Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention?</td>
<td>-80% power with 5% level of significance, -effective size was 94 and the study only recruited 94 participants</td>
</tr>
<tr>
<td>2.3</td>
<td>Are the results of this study directly applicable to the patient group targeted by this guideline?</td>
<td>Yes</td>
</tr>
</tbody>
</table>
### Notes
Summarise the authors’ conclusions. Add any comments on your own assessment of the study, and the extent to which it answers your question and mention any areas of uncertainty raised above.

*Multi-sites study is suggested to enhance confidence of result.*

*It is unethical to reject participants to request additional treatment for pain control.* Hence, the study is suggested to provide information on who requested extra treatment (muscle injection) to minimize the contamination of the finding.

*Method of concealment is suggested to be provided to enhance the confidence of result.*

*ITT or modified ITT is suggested to be provided to enhance the confidence of result.*

---

**Footnotes:**

1.1 Element of research question is stated clear in the paper. *P: lumbar spine surgical patients; I: true auricular acupressure; C: controlled group with no acupressure; O: reduction on pain intensity.*

1.2 Randomization by use of a randomization list.

1.3 No concealment method was reported.

1.4 The blinding level was single blind with participants was “blind”.

1.5 The size of experimental and placebo groups was same. There was no significant difference on their demographic characteristics.

1.6 Data of both groups were collected in the same way. Muscle injection of Demerol was requested by 4 participants (10.8%) during the study, but no mention which group they were belonged to.

1.7 The outcome of effect of auriculotherapy on change of analgesic consumption and pain was measured and was clearly specified, with significant result as with p value given for reference.

1.9 ITT was not mentioned in the text.

1.10 Not applicable.
Appendix VII: Summary table of quality assessment of sampled studies

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1 The study addresses an appropriate and clearly focused question.</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>1.2 The assignment of subjects to treatment groups is randomised.</td>
<td>Yes</td>
<td>Yes</td>
<td>Can’t say</td>
<td>Can’t say</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>1.3 An adequate concealment method is used.</td>
<td>Can’t say</td>
<td>Can’t say</td>
<td>Can’t say</td>
<td>Can’t say</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>1.4 Subjects and investigators are kept ‘blind’ about treatment allocation.</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>1.5 The treatment and control groups are similar at the start of the trial.</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>1.6 The only difference between groups is the treatment under investigation.</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Can’t say</td>
</tr>
<tr>
<td>1.7 All relevant outcomes are measured in a standard, valid and reliable way.</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>1.8 What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed?</td>
<td>10%</td>
<td>5%</td>
<td>30%</td>
<td>30%</td>
<td>6%</td>
<td>21.28%</td>
</tr>
<tr>
<td>1.9 All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis).</td>
<td>Yes</td>
<td>Yes</td>
<td>Can’t say</td>
<td>Does not apply</td>
<td>Can’t say</td>
<td>Can’t say</td>
</tr>
<tr>
<td>1.10 Where the study is carried out at more than one site, results are comparable for all sites.</td>
<td>Can’t say</td>
<td>Can’t say</td>
<td>Can’t say</td>
<td>Can’t say</td>
<td>Does not apply</td>
<td>Does not apply</td>
</tr>
<tr>
<td>2.1 Level of evidence</td>
<td>1+</td>
<td>1++</td>
<td>1+</td>
<td>1+</td>
<td>1++</td>
<td>1-</td>
</tr>
</tbody>
</table>
Appendix VIII: Key to evidence statements and forms of recommendations

**Level of evidence**

<table>
<thead>
<tr>
<th>Level</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1++</td>
<td>High quality meta-analyses, systematic reviews of RCTs, or RCTs with a very low risk of bias</td>
</tr>
<tr>
<td>1+</td>
<td>Well conducted meta-analyses, systematic reviews, or RCTs with a low risk of bias</td>
</tr>
<tr>
<td>1-</td>
<td>Meta-analyses, systematic reviews, or RCTs with a high risk of bias</td>
</tr>
</tbody>
</table>
| 2++   | High quality systematic reviews of case control or cohort studies  
High quality case control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is causal |
| 2+    | Well conducted case control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal |
| 2-    | Case control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal |
| 3     | Non-analytic studies, eg case reports, case series |
| 4     | Expert opinion |
## Appendix IX: Pressure Ulcer Risk Assessment

### MODIFIED BRADEN SCALE Cutoff Score: (Cutoff Score: 16/27)

<table>
<thead>
<tr>
<th>Risk Factors</th>
<th>Score</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sensory Perception</strong></td>
<td>1</td>
<td>Completely limited</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>Very limited</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>Slightly limited</td>
</tr>
<tr>
<td></td>
<td>4</td>
<td>No impairment</td>
</tr>
<tr>
<td><strong>Moisture</strong></td>
<td>1</td>
<td>Constantly moist</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>Often moist</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>Occasionally moist</td>
</tr>
<tr>
<td></td>
<td>4</td>
<td>Rarely moist</td>
</tr>
<tr>
<td><strong>Activity</strong></td>
<td>1</td>
<td>Bedfast</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>Chairfast</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>Walks Occasionally</td>
</tr>
<tr>
<td></td>
<td>4</td>
<td>Walks frequently</td>
</tr>
<tr>
<td><strong>Mobility</strong></td>
<td>1</td>
<td>Completely immobile</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>Very limited</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>Slightly limited</td>
</tr>
<tr>
<td></td>
<td>4</td>
<td>No limitation</td>
</tr>
<tr>
<td><strong>Friction &amp; Shear</strong></td>
<td>1</td>
<td>Problem</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>Potential problem</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>No apparent problem</td>
</tr>
<tr>
<td></td>
<td>4</td>
<td></td>
</tr>
<tr>
<td><strong>Body Built/ Height</strong></td>
<td>1</td>
<td>Obese</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>Emaciated</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>Above/below average</td>
</tr>
<tr>
<td></td>
<td>4</td>
<td>Average</td>
</tr>
<tr>
<td><strong>Skin Type</strong></td>
<td>1</td>
<td>Edematous</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>Tissue paper</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>Dry</td>
</tr>
<tr>
<td></td>
<td>4</td>
<td>Normal</td>
</tr>
</tbody>
</table>

**SUMMATIVE SCORE: ________________________________**
Appendix X: Comparison between the characteristics of the population in the reviewed studies and the target population in the new setting

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Target population (N)</td>
<td>1643</td>
<td>21</td>
<td>265</td>
<td>60</td>
<td>79</td>
<td>135</td>
<td>94</td>
</tr>
<tr>
<td>Gender</td>
<td>Male: 25% Female: 75%</td>
<td>Male: 20% Female: 80%</td>
<td>Male: 16.6% Female:83.4%</td>
<td>Male: Female:</td>
<td>Male: 3% Female: 97%</td>
<td>Male: 25% Female: 75%</td>
<td>Male: 27% Female: 73%</td>
</tr>
<tr>
<td>Age (years old)</td>
<td>35-90</td>
<td>22.4-67 Mean: 45.4</td>
<td>34-66 Mean: 51.1</td>
<td>75-89 Mean: 82.13</td>
<td>72-88 Mean: 81.66</td>
<td>47-74 Mean: 60.25</td>
<td>22-89 Mean: 63.7</td>
</tr>
<tr>
<td>Duration of CLBP</td>
<td>1-10 years</td>
<td>N/A</td>
<td>9.8 years</td>
<td>2-4 years</td>
<td>2-4 years</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Nationality</td>
<td>Mostly Chinese</td>
<td>Chinese</td>
<td>Spanish</td>
<td>Chinese</td>
<td>Chinese</td>
<td>Chinese</td>
<td>Chinese</td>
</tr>
<tr>
<td>Country</td>
<td>Hong Kong</td>
<td>Hong Kong</td>
<td>Spain</td>
<td>Hong Kong</td>
<td>Hong Kong</td>
<td>Taiwan</td>
<td>Hong Kong</td>
</tr>
</tbody>
</table>
## Appendix XI: Timetable for the program

<table>
<thead>
<tr>
<th>Event/ Month</th>
<th>Preparation and Pilot</th>
<th>Implementation</th>
<th>Evaluation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Jan</td>
<td>Feb</td>
<td>Mar</td>
</tr>
<tr>
<td>Get administrative approval</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Planning meeting</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Material preparation</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Staff training</td>
<td></td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Pilot testing</td>
<td></td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Pilot testing evaluation</td>
<td></td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Implementation</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Feedback collection</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Review &amp; report</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Overall evaluation</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## Appendix XII: Detail of auriculotherapy training workshop

<table>
<thead>
<tr>
<th>Information session (45 minutes)</th>
<th>Background</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Potential benefit &amp; clinical significance</td>
</tr>
<tr>
<td></td>
<td>Recruitment criteria</td>
</tr>
<tr>
<td></td>
<td>Video (locating for acupoint and securing pellet on ear)</td>
</tr>
<tr>
<td></td>
<td>Guideline</td>
</tr>
<tr>
<td>Sharing session (15 minutes)</td>
<td>Sharing</td>
</tr>
<tr>
<td></td>
<td>Q&amp;A</td>
</tr>
<tr>
<td>Training session (1 hour)</td>
<td>Demonstration on how to use electric acupoint finder and how to secure pellet on ear</td>
</tr>
<tr>
<td></td>
<td>Return demonstration</td>
</tr>
<tr>
<td></td>
<td>Evaluation</td>
</tr>
</tbody>
</table>
腰背痛
耳穴按壓幫到你

背景
慢性腰背痛全世界十大疾病之一，香港發生率為39.7%。在第一次腰背痛後，有約60%至80%人會復發。腰背痛會阻礙你的行動及影響睡眠，甚至至影響活動及休閒的追求。

什麼是耳穴按壓？
耳穴按壓，是指用大約2毫米大的磁粒，用防水膠帶固定在耳殼的穴位上，從而刺激對應的穴位。疾病的發生原於人體內氣的失衡，然而刺激耳穴有助於氣的調節，從而舒緩痛楚及讓肌肉放鬆。腰背痛正是由於腎經氣的不足所致。

耳穴按壓的位置
- 水門
- 腰骶
- 腎
- 丘腦

磁粒需要貼多久？
整個耳穴按壓的療程為三至四星期。為了讓你的耳朵受及耳穴能得到充分的休息和放鬆，在每星期的覆診，護士會將磁粒換到另一邊耳朵。

何時要按壓被貼的耳穴？
每天要按壓被貼的耳穴三至四次及當你感到痛時。每次要按壓每粒磁粒三分鐘。

觀察你的耳殼状况
如果發現被貼耳穴部位有不尋常如顏色轉變（紅、青、變黑）、腫、痛、有滲液、發熱或膠帶磁粒鬆脫，請立即移除膠帶及磁粒並聯絡你的醫生或護士。
Back pain?  
**Auriculotherapy is the solution**

**Background**

Chronic low back pain is the top 10 disease worldwide with prevalence of 39.7% in Hong Kong. Around 60% to 80% people reported recurrent back pain after their first episode. The pain would restrict patients’ mobility and affect their sleep, and, their strenuous activity and leisure pursuit would even be influenced by the pain episode and fear of recurrence.

**What is auriculotherapy?**

Unlike acupuncture, auriculotherapy need small magnet pellets of size approximately 2mm, applied to your acupoints of ear with a waterproof tape to trigger ear acupoints to affect the gross anatomical organ related with that point. Stimulation of auricular acupoints regulates Qi, of which a disease is considered to be caused by imbalance of a person’s energy Qi, is believed to activate the meridians and collateral systems; hence, to relieve pain and relax muscle. Low back pain is a result of deficiency of Qi in the kidney which causes poor nourishment of the meridians in the lumbar region, or trauma.

**Sites for target acupoint**

- Shenmen
- Lumbosacral vertebrae
- Kidney
- Thalamus

**Duration of implant**

The duration of the treatment course would last for three to four weeks. And the implant will be swapped to the other ear every week upon your follow up by the nurse to let the ear and acupoints rest and relax.

**When to press the taped acupoint?**

The taped acupoints needs to be pressed for three minutes each and three to four times a day and when you feel pain.

**Observe for your pinna condition**

If there is any abnormality of your taped acupoints noted on your pinna including abnormal color (red, pale, darken), swelling, pain, discharge, hotness or loosen of the taped pellets, remove the taped pellets and contact your doctor or nurse immediately.
Appendix XIV: Visual Analogue Scale

How severe is your pain today? Place a vertical mark on the line below to indicate how bad you feel your pain is today.

No pain ______________________________________________________________________ very severe pain
SF-12 questionnaire

This information will help your doctors keep track of how you feel and how well you are able to do your usual activities. Answer every question by placing a check mark on the line in front of the appropriate answer. It is not specific for arthritis. If you are unsure about how to answer a question, please give the best answer you can and make a written comment beside your answer.

1. In general, would you say your health is:
   ______ Excellent (1)
   ______ Very Good (2)
   ______ Good (3)
   ______ Fair (4)
   ______ Poor (5)

The following two questions are about activities you might do during a typical day. Does YOUR HEALTH NOW LIMIT YOU in these activities? If so, how much?

2. MODERATE ACTIVITIES, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf:
   ______ Yes, Limited A Lot (1)
   ______ Yes, Limited A Little (2)
   ______ No, Not Limited At All (3)

3. Climbing SEVERAL flights of stairs:
   ______ Yes, Limited A Lot (1)
   ______ Yes, Limited A Little (2)
   ______ No, Not Limited At All (3)
During the PAST 4 WEEKS have you had any of the following problems with your work or other regular activities AS A RESULT OF YOUR PHYSICAL HEALTH?

4. ACCOMPLISHED LESS than you would like:
   ____ Yes (1)
   ____ No (2)

5. Were limited in the KIND of work or other activities:
   ____ Yes (1)
   ____ No (2)

During the PAST 4 WEEKS, were you limited in the kind of work you do or other regular activities AS A RESULT OF ANY EMOTIONAL PROBLEMS (such as feeling depressed or anxious)?

6. ACCOMPLISHED LESS than you would like:
   ____ Yes (1)
   ____ No (2)

7. Didn’t do work or other activities as CAREFULLY as usual:
   ____ Yes (1)
   ____ No (2)

8. During the PAST 4 WEEKS, how much did PAIN interfere with your normal work (including both work outside the home and housework)?
   ____ Not At All (1)
   ____ A Little Bit (2)
The next three questions are about how you feel and how things have been DURING THE PAST 4 WEEKS. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the PAST 4 WEEKS –

9. Have you felt calm and peaceful?
   ______ All of the Time (1)
   ______ Most of the Time (2)
   ______ A Good Bit of the Time (3)
   ______ Some of the Time (4)
   ______ A Little of the Time (5)
   ______ None of the Time (6)

10. Did you have a lot of energy?
    ______ All of the Time (1)
    ______ Most of the Time (2)
    ______ A Good Bit of the Time (3)
    ______ Some of the Time (4)
    ______ A Little of the Time (5)
    ______ None of the Time (6)

11. Have you felt downhearted and blue?
    ______ All of the Time (1)
12. During the PAST 4 WEEKS, how much of the time has your PHYSICAL HEALTH OR EMOTIONAL PROBLEMS interfered with your social activities (like visiting with friends, relatives, etc.)?

_____ All of the Time (1)
_____ Most of the Time (2)
_____ A Good Bit of the Time (3)
_____ Some of the Time (4)
_____ A Little of the Time (5)
_____ None of the Time (6)

Total: ____________________
生活品質量表-SF-12

1. 一般而言，你對目前的健康狀況是？

<table>
<thead>
<tr>
<th></th>
<th>極好的</th>
<th>好的</th>
<th>好</th>
<th>普通</th>
<th>不好</th>
</tr>
</thead>
<tbody>
<tr>
<td>值</td>
<td>5</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
</tr>
</tbody>
</table>

2. 下面一些日常可能從事的活動，請問目前的健康狀況會不會限制您從事這些活動？

如果會限制多少？

<table>
<thead>
<tr>
<th>活動</th>
<th>受很多限制</th>
<th>受到一些限制</th>
<th>完全不受限</th>
</tr>
</thead>
<tbody>
<tr>
<td>中度程度活動，如搬桌子、拖地、打掃</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>走路10 鍾</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
</tbody>
</table>

3. 過去一個月內，您是否曾因為身體健康問題，而在工作上或日常生活活動有下列問題？

<table>
<thead>
<tr>
<th></th>
<th>是</th>
<th>否</th>
</tr>
</thead>
<tbody>
<tr>
<td>完成的工作量比您想完成的較少</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>可以做的工作或其他活動的種類受到限制</td>
<td>1</td>
<td>2</td>
</tr>
</tbody>
</table>

4. 過去一個月內，您是否曾因情緒問題，而在工作上或其他日常生活活動有下列問題

<table>
<thead>
<tr>
<th></th>
<th>是</th>
<th>否</th>
</tr>
</thead>
<tbody>
<tr>
<td>完成的工作量比您想要完成的較少</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>做工作或其他活動時不如以往小心</td>
<td>1</td>
<td>2</td>
</tr>
</tbody>
</table>

5. 在過去一個月內，您身體的疼痛程度有多嚴重？

<table>
<thead>
<tr>
<th></th>
<th>完全不痛</th>
<th>非常輕微的痛</th>
<th>輕微疼痛</th>
<th>嚴重的痛</th>
<th>非常非常嚴重的疼痛</th>
</tr>
</thead>
<tbody>
<tr>
<td>值</td>
<td>5</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
</tr>
</tbody>
</table>

6. 在過去一個月內，您的感覺及您對週遭生活感受為何？

<table>
<thead>
<tr>
<th></th>
<th>一直都是</th>
<th>大部分是</th>
<th>經常</th>
<th>有時</th>
<th>很少</th>
<th>從不</th>
</tr>
</thead>
<tbody>
<tr>
<td>您覺得心平氣和</td>
<td>6</td>
<td>5</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>您精力充沛</td>
<td>6</td>
<td>5</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>您覺得悶悶不樂和憂鬱</td>
<td>6</td>
<td>5</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
</tr>
</tbody>
</table>

7. 在過去一個月內，您的身體健康或情緒問題有多少時候妨礙到您的社交活動？

<table>
<thead>
<tr>
<th></th>
<th>一直都會</th>
<th>大部分時間</th>
<th>有時候會</th>
<th>很少會</th>
<th>從不會</th>
</tr>
</thead>
<tbody>
<tr>
<td>值</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>

總和：________________
### Total cost for auriculotherapy program (12 months)

<table>
<thead>
<tr>
<th>Training cost</th>
<th>Items</th>
<th>Cost/hour (HKD)</th>
<th>Total cost (HKD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Advanced practice nurse x 8</td>
<td>2-hour training session</td>
<td>$220</td>
<td>$3520</td>
</tr>
<tr>
<td>Registered nurse x 68</td>
<td></td>
<td>$180</td>
<td>$24480</td>
</tr>
<tr>
<td>Chinese Medicine Physician</td>
<td></td>
<td>$300</td>
<td>$600</td>
</tr>
</tbody>
</table>

Total training expense = HK$ 28600

<table>
<thead>
<tr>
<th>Personnel cost</th>
<th>Cost/hour (HKD)</th>
<th>Total cost (HKD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.1 hour/ patient x 100</td>
<td>$180</td>
<td>$1800</td>
</tr>
</tbody>
</table>

Total personnel cost = $1800

### Material cost (Every 100 patients)

<table>
<thead>
<tr>
<th>Items</th>
<th>Cost</th>
<th>Total cost (HKD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Venue &amp; equipment for training</td>
<td>Available on hospital</td>
<td>$100</td>
</tr>
<tr>
<td>Computer &amp; software (Power Point, video)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Printing, stationary &amp; poster</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Electric acupoint finder</td>
<td>$1500/ finder</td>
<td>$1500 x 4</td>
</tr>
<tr>
<td>Magnetic pellet</td>
<td>$7.95/100 patient</td>
<td>$7.95 x 16.43</td>
</tr>
<tr>
<td>Micropore tape</td>
<td>$1 x 1643</td>
<td>$1643</td>
</tr>
<tr>
<td>Alcohol swab</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Handout, assessment &amp; evaluation form</td>
<td>$10/patient</td>
<td>$10 x 1643</td>
</tr>
</tbody>
</table>

Total material cost = 24303.62

Total estimated cost for 12 months (for 100 patients) = HK$54703.62
### Appendix XVII: Saving from medical cost

<table>
<thead>
<tr>
<th>Service</th>
<th>Cost (HKD)/ day</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total cost for hospitalization</strong></td>
<td></td>
</tr>
<tr>
<td>General Ward</td>
<td>$4680</td>
</tr>
<tr>
<td>Physiotherapy</td>
<td>$1100</td>
</tr>
<tr>
<td>Medication</td>
<td>$20</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>$5800/ person</strong></td>
</tr>
</tbody>
</table>

**Total cost for readmission**

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>A&amp;E</td>
<td>$990</td>
</tr>
<tr>
<td>General Ward</td>
<td>4680 x 2*</td>
</tr>
<tr>
<td>Physiotherapy</td>
<td>$1100 x 2*</td>
</tr>
<tr>
<td>Medication</td>
<td>$20 x 2*</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>$12590/ person</strong></td>
</tr>
</tbody>
</table>

*By observation, clients from readmission of CLBP would hospitalize for at least 2 days*

### Total cost for hospitalization per year

\[
5,800 \times 1,643 = 9,529,400
\]

- Total cost of hospitalization / person
- Total no. of patient with CLBP

### Total cost for readmission per year

\[
12,590 \times 1,643 \times 7.3\% = 1,510,032.01
\]

- Total no. of patient with CLBP/year
- Total cost of readmission/ person
- Readmission rate

Total medical cost saving ranges from HK$9,529,400 to HK$1,510,032.01 a year.
## Appendix XVIII: Grades of recommendation

<table>
<thead>
<tr>
<th>Grade</th>
<th>Statements</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>At least one meta-analysis, systematic review, or RCT rated as 1++, and directly applicable to the target population; or A body of evidence consisting principally of studies rated as 1+, directly applicable to the target population, and demonstrating overall consistency of results</td>
</tr>
<tr>
<td>B</td>
<td>A body of evidence including studies rated as 2++, directly applicable to the target population, and demonstrating overall consistency of results; or Extrapolated evidence from studies rated as 1++ or 1+</td>
</tr>
<tr>
<td>C</td>
<td>A body of evidence including studies rated as 2+, directly applicable to the target population and demonstrating overall consistency of results; or Extrapolated evidence from studies rated as 2++</td>
</tr>
<tr>
<td>D</td>
<td>Evidence level 3 or 4; or Extrapolated evidence from studies rated as 2+</td>
</tr>
</tbody>
</table>
Appendix XIX: Poster of auriculotherapy workshop

Workshop

Back Pain? Auriculotherapy is the Solution

Chronic low back pain is the top 10 disease worldwide with prevalence of 39.7% in Hong Kong. Around 60% to 80% people reported recurrent back pain after their first episode. The pain would restrict patients’ mobility and affect their sleep, and, their strenuous activity and leisure pursuit would even be influenced by the pain episode and fear of recurrence.

Unlike acupuncture, auriculotherapy need small magnet pellets of size approximately 2mm, applied to your acupoint of ear with a waterproof tape to trigger ear acupoints to affect the gross anatomical organ related with that point. Stimulation of auricular acupoints regulates Qi, of which a disease is considered to be caused by imbalance of a person’s energy Qi, is believed to activate the meridians and collateral systems; hence, to relieve pain and relax muscle. Low back pain is a result of deficiency of Qi in the kidney which causes poor nourishment of the meridians in the lumbar region, or trauma.

<table>
<thead>
<tr>
<th>Information session (45 minutes)</th>
<th>Background</th>
</tr>
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<tbody>
<tr>
<td></td>
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<td>Guideline</td>
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<td></td>
<td>Return demonstration</td>
</tr>
<tr>
<td></td>
<td>Evaluation</td>
</tr>
</tbody>
</table>

腰痛
Back pain?
Auriculotherapy is the solution!

Chronic low back pain is the top 10 disease worldwide with prevalence of 39.7% in Hong Kong. Around 60% to 80% people reported recurrent back pain after their first episode. The pain would restrict patients’ mobility and affect their sleep, and, their strenuous activity and leisure pursuit would even be influenced by the pain episode and fear of recurrence.

Unlike acupuncture, auriculotherapy need small magnet pellets of size approximately 2mm, applied to your acupoint of ear with a waterproof tape to trigger ear acupoints to affect the gross anatomical organ related with that point. Stimulation of auricular acupoints regulates Qi, of which a disease is considered to be caused by imbalance of a person’s energy Qi, is believed to activate the meridians and collateral systems; hence, to relieve pain and relax muscle. Low back pain is a result of deficiency of Qi in the kidney which causes poor nourishment of the meridians in the lumbar region, or trauma.

✵ No side effect
✵ Simply pressing acupoints on ear to kill the back pain
✵ Can treat the back pain no matter you are in work or at home

Ask your Doctor of Nurse for Details!
慢性腰背痛全世界十大疾病之一，香港發生率為39.7%。在第一次腰背痛後，有約60%至80%人會復發。腰背痛會阻礙你的行動及影響睡眠，甚至影響活動及休閒的追求。

腰背痛？
耳穴按壓幫到你！

耳穴按壓，是指用大約2毫米大的磁粒，用防水膠帶固定在耳殼的穴位上，從而刺激對應的穴位。疾病的發生原於人體內氣的失衡，然而刺激耳穴有助於氣的調節，從而舒緩痛楚及讓肌肉放鬆。腰背痛正正是由於腎經氣的不足所致。

- 無副作用
- 輕鬆安壓耳穴便可鎮痛
- 可在家中/工作輕鬆處理背痛

向你的醫生或護士查詢更多資訊
## Appendix XXI: Timetable of pilot study plan

<table>
<thead>
<tr>
<th>Phase</th>
<th>Time (Week)</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
<th>11</th>
<th>12</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Preparatory period</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Training workshop</td>
<td></td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Evaluation and amendment of training workshop</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Pilot testing period</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Pilot testing for the innovation</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td><strong>Evaluation period</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Data collection and analysis</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Discussion and final review of the innovation</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>

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Appendix XXII: Patient referral form

Auriculotherapy Program – Referral

Please attach patient label here

Auriculotherapy Patient No.: ________________________________
Referral by: ________________________________
Date of Referral: ________________________________

Referral checklist

<table>
<thead>
<tr>
<th>Inclusion criteria*</th>
<th>Exclusion criteria#</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ Age 18 or above</td>
<td>□ Not agree to use</td>
</tr>
<tr>
<td>□ Persistent low back pain &gt; 3 months</td>
<td>auriculotherapy as a treatment option</td>
</tr>
<tr>
<td>□ Agreed to use auriculotherapy as a treatment option</td>
<td>□ Impaired auricular skin integrity</td>
</tr>
<tr>
<td>□ Without cognitive impairment</td>
<td>□ Allergy to micropore tape</td>
</tr>
<tr>
<td></td>
<td>□ Allergy to alcohol swab</td>
</tr>
</tbody>
</table>

*All inclusion criteria must be met.
#Excluded if any of the exclusion criterions is met.
Appendix XXIII: Nursing assessment form

**Nursing Assessment Form**

Please attach patient label here

Age: ____________________  Gender: *M/F

Body weight (kg): ________________  Body height (cm): ________________

Occupation: ____________________  Educational level: *primary/ secondary/ tertiary institution

Past medical history: ____________________

Allergy: ____________________

Alert: ____________________

Infectious status: ____________________

Modified Braden Scale (please refer to Appendix IX): ____________________

Pre-morbid status: *normal/ chair bound/ bedbound

Walking aid: *nil/ umbrella/ stick/ quadripod/ crutches/ frame

Treatment before admission (please prioritize in the box provided below as “1” is mostly used and “5” is least used if more than one option is chosen):

☐ Oral analgesic

☐ Injection

☐ Local application

☐ Physiotherapy/ Chiropractic

☐ Other (please indication): ____________________
History of back pain

Duration: ___________________________ Type: *Acute/Chronic

Pain location (please circle below): ________________________________

Pain intensity level (VAS):

How severe is your pain today? Place a vertical mark on the line below to indicate how bad you feel your pain is today.

No pain | very severe pain

SF-12 score (please refer to Appendix XV): ________________________

Evaluation:

Day 7

Pain intensity level (VAS):

How severe is your pain today? Place a vertical mark on the line below to indicate how bad you feel your pain is today.

No pain | very severe pain
Adverse/ undesirable events: *Yes/ No

Do you feel pain improved after auriculotherapy? Yes/ No

If yes, how much pain intensity level is reduced? *Low/ Medium/ High

SF-12 score (please refer to Appendix XV): ______________________

-------------------------------------------------------------------------------------------------------

Day 14

Pain intensity level (VAS):

*How severe is your pain today? Place a vertical mark on the line below to indicate how bad you feel your pain is today.*

No pain ___________________________ very severe pain

Adverse/ undesirable events: *Yes/ No

Do you feel pain improved after auriculotherapy? Yes/ No

If yes, how much pain intensity level is reduced? *Low/ Medium/ High

SF-12 score (please refer to Appendix XV): ______________________

-------------------------------------------------------------------------------------------------------

Day 21

Pain intensity level (VAS):

*How severe is your pain today? Place a vertical mark on the line below to indicate how bad you feel your pain is today.*

No pain ___________________________ very severe pain

Adverse/ undesirable events: *Yes/ No

Do you feel pain improved after auriculotherapy? Yes/ No

If yes, how much pain intensity level is reduced? *Low/ Medium/ High

SF-12 score (please refer to Appendix XV): ______________________
Day 28

Pain intensity level (VAS):

*How severe is your pain today? Place a vertical mark on the line below to indicate how bad you feel your pain is today.*

No pain [ ] very severe pain

Adverse/ undesirable events: *Yes/ No*

Do you feel pain improved after auriculotherapy? *Yes/ No*

If yes, how much pain intensity level is reduced? *Low/ Medium/ High*

SF-12 score (please refer to Appendix XV): __________________________

Do feel free to leave your comment here about this program:

_____________________________________________________________

- End -
Appendix XXIV: Staff satisfaction survey on auriculotherapy pilot testing for chronic low back pain

Staff Satisfaction Survey on Auriculotherapy Pilot Testing for Chronic Low Back Pain Patients

Date: ___________________________________________

Title of training: _______________________________________________

Trainer: _____________________________________________________

This questionnaire inquires about your satisfactory level about the auriculotherapy pilot testing. Please indicate your rating of the presentation in the categories below by circulating the appropriate umber, using a scale of 1 (least agree) through 5 (most agree).

<table>
<thead>
<tr>
<th>No</th>
<th>Statement</th>
<th>Least agree</th>
<th>Neutral</th>
<th>Most agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>The statement of the protocol is clear.</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>2</td>
<td>The content of the protocol is relevant.</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>3</td>
<td>The content was based on credible and up-to-date information.</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>4</td>
<td>The content was organized and easy to follow.</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>5</td>
<td>The content of the workshop is relevant.</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>6</td>
<td>The duration of the workshop is suitable.</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>7</td>
<td>The workshop guides me to use the protocol well.</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>8</td>
<td>This protocol is user-friendly.</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>9</td>
<td>The instructor used teaching methods appropriate for the content/audience.</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>10</td>
<td>The instructors was knowledgeable of the subject matter.</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>11</td>
<td>I receive adequate support to use the protocol.</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>12</td>
<td>The instruments used in the protocol are relevant.</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>13</td>
<td>The protocol is useful in relieving pain in chronic low back pain patient.</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>14</td>
<td>The content of the workshop is relevant.</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>15</td>
<td>In general, I am satisfied with the auriculotherapy program.</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
</tbody>
</table>
16. What knowledge/skills have you gained about the topics presented?

_____________________________________________________________________
_____________________________________________________________________

17. How will you apply what you have learned to your work?

_____________________________________________________________________
_____________________________________________________________________

18. What did you like best about the program?

_____________________________________________________________________
_____________________________________________________________________

19. What knowledge/skills have you gained about the topics presented?

_____________________________________________________________________
_____________________________________________________________________

20. What changes would make the presentation more effective?

_____________________________________________________________________
_____________________________________________________________________

21. Please feel free to write down your additional comments about the program below:

_____________________________________________________________________

End of the questionnaire.

Thank you for your participation.
Appendix XXV: Satisfaction questionnaire on auriculotherapy training program

**Staff Satisfaction Questionnaire on Auriculotherapy Training Program**

Date: ___________________________________________

Title of training: _______________________________________________

Trainer: _____________________________________________________

This questionnaire inquires about your satisfactory level about the auriculotherapy training workshop. Please indicate your rating of the presentation in the categories below by circulating the appropriate number, using a scale of 1 (least agree) through 5 (most agree).

<table>
<thead>
<tr>
<th>No.</th>
<th>Statement</th>
<th>Least agree</th>
<th>Neutral</th>
<th>Most agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>The objective of training is clearly defined.</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>2</td>
<td>The content of the training workshop is relevant.</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>3</td>
<td>Participation and interaction were encouraged.</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>4</td>
<td>The content is organized and easy to follow.</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>5</td>
<td>I had acquired the skills which enable me to conduct the auriculotherapy program.</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>6</td>
<td>I am confident in giving clear instructions and demonstrations to the patients.</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>7</td>
<td>I am able to identify the auricular acupoints of the patients by using the electric acupoint finder.</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>8</td>
<td>I could guide the patients to practice pressing the taped acupoint at home.</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>9</td>
<td>I achieved what the program expected.</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>10</td>
<td>I received adequate guidance to train the patients.</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>11</td>
<td>The duration of the training workshop is appropriate.</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>12</td>
<td>The teaching skill of the auriculotherapy instructors is appropriate.</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>13</td>
<td>The training experience will be useful in my work.</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>14</td>
<td>In general, I am satisfied with the auriculotherapy training workshop.</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
</tbody>
</table>
15. What did you like most about this training?

_____________________________________________________________________
_____________________________________________________________________

16. What aspect of training can be improved?

-  
_____________________________________________________________________

17. Please feel free to write down your additional comments about the program below:

_____________________________________________________________________

End of the questionnaire.

Thank you for your participation.
Appendix XXVI: Questionnaire for patient on competence of using auriculotherapy

**Client Questionnaire on Competence of Using Auriculotherapy**

Please attach patient label here

Date of filling questionnaire: ____________________

<table>
<thead>
<tr>
<th>No.</th>
<th>Statement</th>
<th>Least agree</th>
<th>Neutral</th>
<th>Most agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>I know the location of the taped acupoints.</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>2</td>
<td>I know how to press the taped acupoints.</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>3</td>
<td>I know when and how long to press the taped acupoints.</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>4</td>
<td>I know how to deal with when the tape is loosen.</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>5</td>
<td>I know how to deal with when abnormality (e.g. red, swelling, pain, hotness) is developed over the taped area.</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>6</td>
<td>I am confident in using auriculotherapy.</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>7</td>
<td>I am satisfied with the auriculotherapy programme.</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
</tbody>
</table>

Do feel free to leave any comment about using auriculotherapy here:

__________________________________________________________________________

End of the questionnaire.

Thank you for your participation.
Reference


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Pain), McGill Pain Questionnaire (MPQ), Short-Form McGill Pain
Questionnaire (SF-MPQ), Chronic Pain Grade Scale (CPGS), Short Form-36
Bodily Pain Scale (SF-36 BPS), and Measure of Intermittent and Constant
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