

SUPPLEMENTARY 1

TREND Statement Checklist

Paper Section/Topic	Item No.	Descriptor	Reported?	
			✓	Pg #
TITLE and ABSTRACT				
Title and Abstract	1	• Information on how units were allocated to interventions	X	1
		• Structured abstract recommended	X	1
		• Information on target population or study sample	X	1
INTRODUCTION				
Background	2	• Scientific background and explanation of rationale	X	1-2
		• Theories used in designing behavioral interventions		N/A
METHODS				
Participants	3	• Eligibility criteria for participants, including criteria at different levels in recruitment/sampling plan (e.g., cities, clinics, subjects)	X	3
		• Method of recruitment (e.g., referral, self-selection), including the sampling method if a systematic sampling plan was implemented	X	3
		• Recruitment setting	X	3
		• Settings and locations where the data were collected	X	3
Interventions	4	• Details of the interventions intended for each study condition and how and when they were actually administered, specifically including:	X	
		○ Content: what was given?	X	3-5
		○ Delivery method: how was the content given?	X	3-5
		○ Unit of delivery: how were subjects grouped during delivery?	X	4-5
		○ Deliverer: who delivered the intervention?	X	4-5
		○ Setting: where was the intervention delivered?	X	4-5
		○ Exposure quantity and duration: how many sessions or episodes or events were intended to be delivered? How long were they intended to last?	X	4-5
		○ Time span: how long was it intended to take to deliver the intervention to each unit?	X	4-5
○ Activities to increase compliance or adherence (e.g., incentives)	X	NA		
Objectives	5	• Specific objectives and hypotheses	X	1-2
Outcomes	6	• Clearly defined primary and secondary outcome measures	X	5-6
		• Methods used to collect data and any methods used to enhance the quality of measurements	X	5-6
		• Information on validated instruments such as psychometric and biometric properties	X	5-6
Sample size	7	• How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules	X	3
Assignment method	8	• Unit of assignment (the unit being assigned to study condition, e.g., individual, group, community)	X	3-4
		• Method used to assign units to study conditions, including details of any restriction (e.g., blocking, stratification, minimization)		4
		• Inclusion of aspects employed to help minimize potential bias induced due to non-randomization (e.g., matching)		
Blinding (masking)	9	• Whether or not participants, those administering the interventions, and those assessing the outcomes were blinded to study condition assignment; if so, statement regarding how the blinding was	X	6


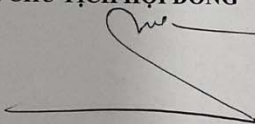
		accomplished and how it was assessed		
Unit of Analysis	10	• Description of the smallest unit that is being analysed to assess intervention effects (e.g., individual, group, or community)	X	6
		• If the unit of analysis differs from the unit of assignment, the analytical method used to account for this (e.g., adjusting the standard error estimates by the design effect or using multilevel analysis)		6
Statistical methods	11	• Statistical methods used to compare study groups for primary methods outcome(s), including complex methods for correlated data	X	6
		• Statistical methods used for additional analyses, such as subgroup analyses and adjusted analysis	X	6
		• Methods for imputing missing data, if used	X	6
		• Statistical software or programs used	X	6
RESULTS				
Participant flow	12	• Flow of participants through each stage of the study: enrollment, assignment, allocation and intervention exposure, follow-up, analysis (a diagram is strongly recommended)	X	6
		○ Enrollment: the numbers of participants screened for eligibility, found to be eligible or not eligible, declined to be enrolled, and enrolled in the study	X	6
		○ Assignment: the numbers of participants assigned to a study condition	X	6
		○ Allocation and intervention exposure: the number of participants assigned to each study condition and the number of participants who received each intervention	X	6
		○ Follow-up: the number of participants who completed the follow-up or did not complete the follow-up (i.e., lost to follow-up), by study condition		6
		○ Analysis: the number of participants included in or excluded from the main analysis, by study condition	X	6
		• Description of protocol deviations from study as planned, along with reasons		N/A
Recruitment	13	• Dates defining the periods of recruitment and follow-up	X	6
Baseline data	14	• Baseline demographic and clinical characteristics of participants in each study condition	X	6- 7
		• Baseline characteristics for each study condition relevant to specific disease prevention research	X	6- 7
		• Baseline comparisons of those lost to follow-up and those retained, overall and by study condition		N/A
		• Comparison between study population at baseline and target population of interest		
Baseline equivalence	15	• Data on study group equivalence at baseline and statistical methods used to control for baseline differences	X	8
Numbers analyzed	16	• Number of participants (denominator) included in each analysis for each study condition, particularly when the denominators change for different outcomes; statement of the results in absolute numbers when feasible	X	6- 7
		• Indication of whether the analysis strategy was “intention to treat” or, if not, description of how non-compliers were treated in the analyses		NA
Outcomes and estimation	17	• For each primary and secondary outcome, a summary of results for each estimation study condition, and the estimated effect size and a confidence interval to indicate the precision	X	6 -8
		• Inclusion of null and negative findings	X	6 -8
		• Inclusion of results from testing pre-specified causal pathways through which the intervention was intended to operate, if any	X	6 -8
Ancillary analyses	18	• Summary of other analyses performed, including subgroup or restricted analyses, indicating which are pre-specified or exploratory	X	6 -8

Adverse events	19	<ul style="list-style-type: none"> • Summary of all important adverse events or unintended effects in each study condition (including summary measures, effect size estimates, and confidence intervals) 	X	8
DISCUSSION				
Interpretation	20	<ul style="list-style-type: none"> • Interpretation of the results, taking into account study hypotheses, sources of potential bias, imprecision of measures, multiplicative analyses, and other limitations or weaknesses of the study 	X	8 -10
		<ul style="list-style-type: none"> • Discussion of results taking into account the mechanism by which the intervention was intended to work (causal pathways) or alternative mechanisms or explanations 	X	8 -10
		<ul style="list-style-type: none"> • Discussion of the success of and barriers to implementing the intervention, fidelity of implementation 	X	8 -10
		<ul style="list-style-type: none"> • Discussion of research, programmatic, or policy implications 	X	8 -10
Generalizability	21	<ul style="list-style-type: none"> • Generalizability (external validity) of the trial findings, taking into account the study population, the characteristics of the intervention, length of follow-up, incentives, compliance rates, specific sites/settings involved in the study, and other contextual issues 	X	10
Overall evidence	22	<ul style="list-style-type: none"> • General interpretation of the results in the context of current evidence and current theory 	X	8-10

From: Des Jarlais, D. C., Lyles, C., Crepaz, N., & the Trend Group (2004). Improving the reporting quality of nonrandomized evaluations of behavioral and public health interventions: The TREND statement. *American Journal of Public Health*, 94, 361-366.
For more information, visit: <http://www.cdc.gov/trendstatement/>

SUPPLEMENTARY 2

Supplementary 1. The Signed Ethical Approval

ĐẠI HỌC Y DƯỢC TP. HỒ CHÍ MINH HỘI ĐỒNG ĐẠO ĐỨC TRONG NCYSH	CỘNG HÒA XÃ HỘI CHỦ NGHĨA VIỆT NAM Độc lập – Tự do – Hạnh phúc
Số: <u>271</u> /HĐĐĐ-ĐHYD	TP. Hồ Chí Minh, ngày <u>01</u> tháng <u>02</u> năm <u>2024</u>
V/v chấp thuận các vấn đề đạo đức NCYSH	
CHẤP THUẬN CỦA HỘI ĐỒNG ĐẠO ĐỨC TRONG NGHIÊN CỨU Y SINH HỌC ĐẠI HỌC Y DƯỢC TP. HỒ CHÍ MINH	
IRB-VN01002/ORG0008603/FWA00023448	
Căn cứ Nghị quyết số 10/NQ-HĐT ngày 20/10/2020 của Hội đồng trường Đại học Y Dược TP. Hồ Chí Minh về việc ban hành Quy chế Tổ chức và hoạt động của Đại học Y Dược TP. Hồ Chí Minh;	
Căn cứ Nghị quyết số 26/NQ-HĐT ngày 20/10/2021 của Hội đồng Trường Đại học Y Dược TP. Hồ Chí Minh về việc điều chỉnh một số nội dung tại Nghị quyết số 10/NQ-HĐT ngày 20/10/2020 của Hội đồng Trường về việc ban hành Quy chế tổ chức và hoạt động của Đại học Y Dược TP. Hồ Chí Minh;	
Căn cứ Thông tư 04/TT-BYT ngày 5/3/2020 của Bộ trưởng Bộ Y tế quy định việc thành lập, chức năng, nhiệm vụ và quyền hạn của Hội đồng đạo đức trong nghiên cứu y sinh học;	
Căn cứ Quyết định số 3870/QĐ-ĐHYD ngày 6/10/2016 của Hiệu trưởng Đại học Y Dược TP. Hồ Chí Minh về việc ban hành Quy chế tổ chức và hoạt động của Hội đồng đạo đức trong nghiên cứu y sinh học;	
Căn cứ Quyết định số 939/QĐ-ĐHYD ngày 20/5/2021 của Hiệu trưởng Đại học Y Dược TP. Hồ Chí Minh về việc thành lập Hội đồng đạo đức trong nghiên cứu y sinh học, nhiệm kỳ 2021 - 2026;	
Trên cơ sở xem xét của thường trực Hội đồng Đạo đức trong nghiên cứu y sinh học Đại học Y Dược TP. Hồ Chí Minh ngày 01/02/2024.	
Hội đồng đạo đức trong nghiên cứu y sinh học chấp thuận về các khía cạnh đạo đức trong nghiên cứu đối với đề tài:	
<ul style="list-style-type: none">Tên đề tài: <i>Hiệu quả giảm đau và cải thiện tâm vận động của laser châm kết hợp vận động trị liệu trên người bệnh hội chứng tennis elbow</i>Mã số: 231100 - ĐHYDNgười thực hiện: <i>Dương Thị Thúy Duy – Sinh viên</i>Đơn vị chủ trì: <i>Đại học Y Dược thành phố Hồ Chí Minh</i>Địa điểm triển khai nghiên cứu: <i>Bệnh viện Lê Văn Thịnh</i>Thời gian tiến hành nghiên cứu: <i>từ tháng 02/2024 đến tháng 6/2024</i>Phương thức xét duyệt: <i>Quy trình rút gọn</i>	
Ngày chấp thuận: 01/02/2024	
Lưu ý: HĐĐĐ có thể kiểm tra ngẫu nhiên trong thời gian tiến hành nghiên cứu	
KT. HIỆU TRƯỞNG PHÓ HIỆU TRƯỞNG  <i>Nguyễn Hoàng Bắc</i>	TM. HỘI ĐỒNG P. CHỦ TỊCH HỘI ĐỒNG  Nguyễn Sào Trung

SUPPLEMENTARY 3

RESEARCH INFORMATION

1. Brief Information About the Study

Dear Sir/Madam,

I am Duong Thi Thuy Duy , Pre-medical student in the Traditional Medicine program at the Department of Traditional Medicine, University of Medicine and Pharmacy, Ho Chi Minh City. On behalf of the research team, I would like to invite you to participate in our study.

You have been diagnosed with Tennis Elbow Syndrome, and we would like to invite you to participate in our study on the treatment of this condition. Before you decide whether to participate or not, we kindly ask you to review the information provided below.

This information sheet contains some technical terms that may be difficult to understand.

Please feel free to ask any questions for further clarification or discussion. We are happy to answer any questions you may have.

Please take your time to carefully consider your decision. Thank you for reading this information sheet.

2. Purpose of the Study

The purpose of our study is to evaluate the effectiveness of laser acupuncture combined with therapeutic exercise for pain relief and improvement of the range of motion in patients with Tennis Elbow Syndrome.

The study period will be from February 2024 to September 2024.

This treatment method has the following advantages and disadvantages:

Treatment Method	Description	Advantages	Disadvantages	Treatment Cost
Laser Acupuncture Combined with Therapeutic Exercise	Therapeutic exercise + Laser acupuncture	Potential for higher success rates, no need for continuous manual handling by a technician	Possible side effects from laser acupuncture	Therapeutic exercise (50,000 VND per session); Laser acupuncture (50,000 VND per session). (All costs are waived for research participants.)

3. What You Will Be Asked to Do in the Study

The study will last for 4 weeks. After you agree to participate, you will complete a standard questionnaire (including information such as name, age, address, occupation, duration of illness, and some symptoms of Tennis Elbow Syndrome).

If you choose not to participate, you will still receive standard treatment as other patients.

Throughout the study, you will go through the following steps:

Step 1: Complete the questionnaire after agreeing to participate.

Step 2: Receive treatment.

Step 3: Every week for 4 consecutive weeks, you will return to the hospital for follow-up visits, and we will record the progress of your treatment through questionnaires.

For your safety, please report any discomfort or symptoms immediately to the research team so we can take appropriate measures.

4. Benefits

- You will not have to pay any costs during the study, including:
 - We will cover the costs of consultation, monitoring, and advice on your Tennis Elbow Syndrome.
 - We will provide free therapeutic exercise sessions.
 - We will cover all laser acupuncture costs.
 - In case of any adverse events, all treatment costs will be fully covered by us.
- You will have the opportunity to ask any questions about your condition and treatment at any time, and we will do our best to provide support.
- Spiritually, by participating in this study, you are contributing greatly to the medical field, particularly Traditional Medicine, and to future patients with similar conditions. This study aims to explore new treatment methods and integrate traditional and modern medical practices.

5. Risks and Inconveniences

During the study, you may experience some inconveniences, such as:

- An additional 10 minutes for each interview during follow-up visits. You will also need to arrange time for weekly follow-up visits and treatment.
- You will need about 15 minutes for each laser acupuncture session. We will schedule treatments at convenient times to minimize discomfort.

There may also be some risks of side effects from laser acupuncture. While the risks are low and typically mild, we have prepared a management plan for any adverse effects that may arise, including:

- **Post-treatment discomfort:** This is common and usually resolves on its own.
- **Local pain:** If severe, you will be advised to take common pain relievers.
- **Skin redness:** Usually resolves on its own; if severe, we will apply moisturizing Vaseline.
- **Skin burns:** In case of a burn, we will stop the study and refer you to a specialist.
- **Local itching or rash:** Usually resolves quickly; we may advise you to use over-the-counter antihistamines.
- **Fever:** You will be advised to take over-the-counter antipyretics, and the fever should subside. If the fever is high or prolonged, or accompanied by other severe symptoms, we will stop the study and refer you for further treatment.
- **Allergic reactions:** If a severe allergic reaction occurs, we will immediately follow the Ministry of Health's protocol and refer you to a specialist, halting the study.

If any symptoms persist, worsen, or cause significant discomfort, please visit the hospital for further evaluation and management. If the treating doctor determines that you are unable to tolerate the treatment, we will discontinue your participation in the study.

- **Hypotension:** If you experience low blood pressure during or after the laser acupuncture treatment, you may feel tired or dizzy. In such cases, we will have you lie down with your legs elevated to improve blood flow and ensure you are hydrated if it is safe to do so. We will closely monitor your blood pressure, and if necessary, arrange further medical care to address the issue promptly.
- **Dizziness:** If you feel dizzy during the procedure, we will immediately stop the treatment and assist you in sitting or lying down to rest. You will be guided to breathe slowly and deeply to help reduce the sensation of dizziness. We will monitor your condition closely and provide additional support if the dizziness persists.
- **Headaches:** In the event of a headache, we will ensure you rest in a quiet, comfortable space. If needed, we can provide mild pain relief options that are safe and appropriate for your condition. Additionally, we will evaluate whether the headache might be related to the laser acupuncture procedure.
- **Decreased vision:** If you notice any changes in your vision, such as blurriness or difficulty seeing, we will immediately halt the procedure and assess the situation carefully. If your vision does not improve quickly, we will consult an eye specialist to provide you with appropriate care and guidance.
- **Hemorrhage:** If bleeding occurs at the site of treatment, we will apply gentle pressure to stop it quickly. For any more significant bleeding, we will take appropriate measures to manage the situation and, if necessary, ensure you receive prompt medical attention at a healthcare facility.

We take every precaution to prevent adverse events by carefully screening participants, selecting reputable medical facilities, and ensuring that the procedures are performed by qualified and experienced Traditional Medicine specialists.

6. Costs of Participation

You will not incur any additional costs during the study.

We will cover the following costs:

- Consultation, monitoring, and advice regarding your Tennis Elbow Syndrome.
- Free therapeutic exercise sessions.
- Free laser acupuncture treatments.
- Any costs associated with managing adverse events, if they occur.
Payment will be made directly to the hospital.

7. Confidentiality

We plan to publish the results of this research but will not disclose any personal information about you. All data will be stored securely on password-protected computers, and paper records will be kept in locked cabinets to ensure confidentiality. Apart from the research team, some individuals, such as members of the Scientific and Ethics Committees at the University of Medicine and Pharmacy, Ho Chi Minh City, may have access to your data for research purposes.

8. Voluntary Participation

Your participation in this study is completely voluntary. You have the right to withdraw from the study at any time without any explanation or impact on your treatment at the hospital. Please notify us of your decision if you choose to withdraw.

9. Contact Information

If you have any questions or comments regarding this study, please contact:

- Dương Thị Thúy Duy – Mobile: 0924331242, Email: thuyduyyds@gmail.com
- Dr. Nguyễn Lê Việt Hùng – Mobile: 0909452324
- MSc. Dr. Nguyễn Thái Linh – Mobile: 0909979717

10. Commitment

By signing this consent form, you confirm that you understand the study and agree to participate. Participation is completely voluntary, and you can choose to withdraw at any time.

You must ensure that all your questions about this study have been answered and that you fully understand your responsibilities in this research.

CONSENT FORM FOR PARTICIPATION IN THE STUDY

I, _____, born in _____, gender: _____

After reading the information about the study: *Effectiveness of Pain Relief and Range of Motion Improvement from Laser Acupuncture Combined with Therapeutic Exercise in Patients with Tennis Elbow Syndrome*, I confirm that I have understood the details of the study. I have had the opportunity to ask questions, which were answered to my satisfaction.

I understand the purpose of the study, as well as my rights and responsibilities as a participant. I am aware that I can withdraw from the study without explanation, and I commit to informing the researcher if I choose to do so.

I also understand that my decision will be respected at all times for my health and safety.

I agree that only the doctor or relevant researcher, along with authorized health authorities, can access the data related to my participation, ensuring confidentiality.

I have received a copy of this information sheet and agree to participate in the study.

Signature of Participant:

Name: _____ Signature: _____

Date: _____

Signature of Researcher/Consent Taker:

I, the undersigned, confirm that the volunteer has read and understood this information sheet and has had all their questions answered. They understand the nature of the study, as well as the risks and benefits of participation.

Name: _____ Signature: _____

Date: _____