

STUDY TITLE:

The Effects of Mindfulness Practice with Tao Art (“Love Peace Harmony” Calligraphy and Song) on Wellbeing – Controlled Randomized Study

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RELATED STUDIES:

Mindfulness practice using Tao art (Calligraphy and Song) and drinking energized water in Various Illnesses– prospective follow-up study.

Effect of Tao calligraphy Meditation and Energized Water on Depression
Randomized Controlled Cross-over Study
Phase 1

1.0 Purpose and rationale of the study:

Objectives

The goal of this study is to measure the positive effects of a unique form of mindfulness practice that involves engaging with Tao art (tracing Tao Calligraphy of Love Peace Harmony while listening to or singing the Tao Music or Tao Song, “Love, Peace and Harmony”). We will study the impact of this Tao art mindfulness practice on three aspects of well-being: Perceived Stress (PSS), the Social Connectedness Scale (SCS), and Peace of Mind Scale (PoMS).

In previous studies that explored the effects of Tao art mindfulness practice on various health conditions, participants that regularly practiced with Tao art reported a decrease in the symptoms of their illness (as perceived subjectively), an improvement in laboratory results or other tests, observed signs of progress as reported by the treating clinician, and an increase in well-being as measured by standardized scientific questionnaires. However, it should be noted that, with exception of our German study into Depression [32], the Tao art mindfulness practices were also combined with other Tao Technologies, such as Subtle Energy Transmissions for each subject for their condition.

The current research aims to 1) study the effects of Tao art mindfulness practices (tracing the Tao Calligraphy of Love Peace Harmony and chanting or listening to the Tao Song and Tao Music, “Love, Peace and Harmony”) without any other Tao Technologies in play and 2) expand the focus to the general (non-clinical) population, looking at specific indices of wellbeing so that we can begin to determine how useful Tao art mindfulness practices may be in enhancing people’s daily lives.

Hypotheses

The research null hypothesis is that individuals who will engage in daily mindfulness practice with Tao art will report NO significant improvement of various aspects of well-being as measured by standardized scientific questionnaires; specifically, no significant reduction of Perceived Stress and no significant increase in Social Connectedness and Peace of Mind.

For statistical analysis of scores obtained from questionnaires, Anova and regression analysis will be used to evaluate the null hypothesis. The p value will represent how unlikely the observed data would be if the null hypothesis were actually true and we will use them to reach conclusions. We set the confidence level at 95% and if we receive $p < 0.05$, then H_0 is rejected. The correlation coefficient will be used to determine any correlation between various factors (e.g. effects of age, sex, length and frequency of mindfulness practices, and other) on outcome and regression analysis to

determine the relation of independent and dependent variables.

Background and Theoretical Framework

A large and growing body of research shows that mindfulness and meditation practices are beneficial to our physical and mental health and well-being [1] [2] [3]. Mindfulness refers to a state of awareness that arises from paying attention to the present moment, without judgment, whereas meditation refers to a practice or technique that can cultivate mindfulness, inner peace, and more. Mindfulness practices are often synonymous with meditation, and the terms are often used interchangeably.

Research has demonstrated the positive effects of mindfulness-based meditation on brain function, immune system, diabetes, hypertension, fibromyalgia, cholesterol levels, blood pressure, heart rate, and cortisol levels [2]. Likewise, mindfulness and meditation practices have been shown to increase self-compassion and improve memory and emotional regulation [3]. In a comprehensive meta-analysis of 209 studies, the authors concluded that mindfulness-based therapy was effective for many types of psychological problems, while being especially good for reducing anxiety, depression, and stress [4]. In another overall review of mindfulness-based interventions, they were found to be effective for many common and diverse mental, physical, and social conditions [5].

In recent decades, mindfulness and meditation practices and programs have become increasingly commonplace for stress management and reduction because they are effective. It's no wonder that mindfulness-based meditation practices lead to greater mental, physical, and psychological well-being, with one of the key mechanisms for such outcomes being their effect on the regulation or reduction of stress [3] [6].

In recent years, there is also a growing interest in the application of the arts for public health and wellbeing [7]. Self-expression through art or engaging with different forms of art has been found to be helpful for many health conditions [8], and doctors in the United Kingdom have started prescribing "the arts" to treat or positively influence many kinds of health conditions [9] [10].

Some forms of art are also meditative and contemplative, and many can be readily transformed into such a process. The mindfulness-based meditation being explored in this research rests in part on the benefits of music, singing or chanting, and calligraphy tracing (in particular, tracing a unique form of Chinese calligraphy).

Through our own experience, we know that music can transform or uplift our mood and research supports this, suggesting that engagement with music plays a role in mood regulation [11]. Harvard Health shares how music enhances our health and performance, claiming that music has "major effects on many aspects of health ranging from memory and mood to cardiovascular function and athletic performance" [12]. A recent systematic review and meta-analysis of "music interventions" found that they are associated with significant clinical improvements in Health-Related Quality of Life indices (especially

the mental components), and interestingly, they found that whether people sang, played, or listened to music, the results were similar [13]. A slightly earlier systematic review and meta-analysis of music therapy for stress reduction found overall large to medium large effects on stress-related outcomes. [14] Likewise, though research is limited in this area, chanting meditations have documented effects on stress and well-being [15] [16].

Chinese calligraphic writing is a dynamic process that uses an ink-laden brush to create defined configurations of characters. Revered as one of the most important artforms in China, it has also been shown, as a mindfulness practice, to help reduce stress and improve mental wellbeing [17]. The practice of Chinese calligraphy writing facilitates the development of concentration, creativity, and relaxation, which can lead to a more peaceful mental state [18]. Studies in the medical field have confirmed its significant effects on psychosomatic conditions, post-traumatic hyper-arousal symptoms, hypertension, and type 2 diabetes [19] [20] [21]. Other research publications have shown how it can improve cognitive function of the elderly [22], improve neuropsychiatric symptoms [23], reduce stress [17], and help children with ADHD [24]. In one case, a man who was in a coma for two years awakened and continued to improve after his medical team took his hand and helped him to trace calligraphy daily with his finger [25].

This research will explore the effects of a unique mindfulness-based meditation that combines tracing the Tao Calligraphy Love Peace Harmony while listening to, singing, or chanting with the Tao Song, "Love, Peace and Harmony." We will study its effect upon selected aspects of well-being.

Tao Calligraphy is based on a unique branch of Chinese calligraphy known as Yi Bi Zi, which applies one-stroke writing. Every character is written with one continuous stroke of the brush, with the brush always in contact with the paper.

In a unique style of moving meditation, practitioners focus on a work of Tao Calligraphy art, tracing the characters with their fingers while simultaneously listening to or singing/chanting (silently or aloud) the Tao Music or Song, which enables them to achieve deep concentration and relaxation during wakefulness.

This unique practice was developed by Dr. Zhi Gang Sha, who learned Yi Bi Zi Calligraphy from the Professor Li Qiuyun and connected the calligraphy writing with health-improving practices.

The Tao Song, "Love, Peace and Harmony" consists of short, inspiring verses that are repeated, and is a beautiful way to lift and inspire peoples' hearts and help them to experience peace and calm. The song was professionally recorded and is available on the Love Peace Harmony Foundation website as a free distribution.

The aspects of well-being we will measure are perceived stress, peace of mind, and social connectedness. We have already discussed the value of mindfulness meditations for reducing or regulating stress and how this appears to contribute to numerous beneficial outcomes related to well-being. In this study we will look at the impact of the

Tao art mindfulness practice on psychological stress as measured by the Perceived Stress Scale, which is a popular tool for measuring the degree to which situations in one's life are appraised as stressful [34].

Peace of mind is also a great asset in today's world. The Peace of Mind Scale was developed to capture an internal state of peacefulness and harmony that is said to be a more valued aspect of subjective well-being in the east [35], however it has recently begun to receive attention cross-culturally [36] and has also been studied in conjunction with calligraphy writing and stress [37]. The Tao Calligraphy tracing and Tao Music and Song applied in this study both focus on the message of love, peace, and harmony, which closely aligns with the Peace of Mind Scale content, in addition to the practices general meditative value.

Social connectedness is the experience of belonging through different types of supportive relationships [38]. The Social Connectedness Scale measures the extent to which one feels connected to others in their social environment. It is easy to imagine how social support and connection can buffer potential negative effects of stress. Among other things, it has been measured in studies of mindfulness involving on-line chanting meditations [39] and in conjunction with yogic breathing and perceived stress [40].

For the list of Research Presentations please refer to Appendix A.

METHOD

This study will determine the effects of mindfulness practice with Tao art (tracing the Tao Calligraphy Love Peace Harmony and singing / listening to the Tao Song "Love, Peace and Harmony") for 6 months, as measured through subjective and objective evaluations of participants.

Design of the Study

The study will be performed as a 6-month randomized waitlist control study.

The subjects will be adults (19 years and older), that are interested in participating in this study. They will express their interest by filling a simple expression of interest form on www.Sharesearchfoundation.com.

New subjects may enter the study at any time. After new subjects are admitted into the study, they will be randomized into the practice or waitlist control group.

The practice group will start practices at baseline time point T0 and will stop practices

after 3 months at time point T1. The waitlist control group will start practices at time point T1 at 3 months and will stop practices after 3 months at time point T2 (at 6 months).

The study will evaluate the effects of mindfulness practice using these standardized questionnaires:

- . Perceived Stress Scale (PSS)
- . Social Connectedness Scale (SCS)
- . Peace of Mind Scale.

All participants will complete the set of 3 questionnaires upon entry into the study - Baseline time point (T0); at 3-months interval (T1), and at six-months timepoint (T2).

Screenshots of online versions of questionnaires are submitted for review alongside of the protocol.

Allocation of responsibilities:

Instruction of subjects on how to do mindfulness practice with Tao art and organization of regular weekly practices for 12 weeks will be the sole responsibility of Love Peace Harmony Foundation.

All Research related issues: Admission to the study (Screening and Consenting), collection, handling, and evaluation of questionnaires and presentation of the research results will be the sole responsibility of Sha Research Foundation.

Study Execution

The study will be performed by collecting application data from the subjects personally or, if applicable, remotely by email or by fax.

The research Questionnaires will be filled on line using personal ID Codes – to ensure confidentiality.

Love Peace Harmony Foundation team will be responsible for teaching subjects the mindfulness practice with Tao art, providing a Tao calligraphy Love Peace Harmony card for tracing practice and offering weekly group practices.

The practice sessions with Tao art will be done for the participants for free by Love Peace Harmony Foundation. There will be no fees for the teaching on how to practice nor for any other aspect of participation in the study.

Conversely, participants will receive no remuneration for participating in the study.

Data collection, data handling, and data assessment will be the responsibility of Sha Research Foundation's research team members who have a scientific background, and will be performed by email and online collection. Members of the research team may help with teaching on occasion.

Participants of the study will also be required to do mindfulness practice with Tao art for thirty minutes every day, to record the length of practice, and responses during and after each practice.

Sha Research Foundation will clearly inform participants that the teaching and research teams will not be offering any medical diagnosis, guidance, evaluation, or treatment and that participation in the study is not a replacement for any conventional allopathic medical diagnosis or treatments.

Subjects in the study should continue to follow their physicians' advice and recommendations during their participation in the study and should continue to receive any and all conventional allopathic or Integrative treatments in which they have been participating prior to entry into this study.

Participants are also encouraged to continue their usual spiritual practices in which they have been participating prior to the study.

The study will commence in 2025 and will last for about 5 years. We plan to accept new subjects into the study at any time from its commencement in 2025 up to June of 2030 – with expected conclusion in December of 2030.

There is no limit to the number of subjects enrolled to this study during the study years. Subjects can withdraw from the study with no penalty at any time for whatever reasons they may have.

2.0 Enrollment Criteria (who can be in your study and who would not be eligible to participate in your study):

Patient Population

Inclusion criteria

- Age 19 and over
- Resident of USA or Canada
- Willingness and ability to comply with data collection requirements
- Submission of required documentation before entering into the study, including informed consent and consent to release of information
- Willingness to allow their data to be used for research purposes and published as deemed fit (while conforming to all applicable privacy laws) by Sha Research Foundation
- Willingness to practice the daily meditations and follow the study protocol

Exclusion criteria

- Not meeting any of the inclusion criteria

- Resident of any country outside Canada or USA
- Unwillingness to participate in data gathering
- Unable to follow the practice regimen, including the daily individual mindfulness practices for at least 30 minutes
- Pregnant or nursing. Participants who become pregnant during the study will be required to end their participation.
- Serious mental disorders (e.g. bipolar mania-depression, schizophrenia)
- There are no exclusion criteria placed upon potential subjects related to national origin, culture, ethnicity, race, sex, physical disability, sexual orientation, religion, or spiritual practices.

3.0 Sample Size:

A/ Sample Size:

The study will be conducted as randomized waitlist-controlled study. It will include subjects who are 19 years old and over at the time of the examination, fulfilling inclusion criteria. We will enroll minimum of 30 subjects. There is no upper limit to the number of subjects enrolled into the study.

The evaluation of questionnaires will be done using SPSS program using appropriate parametric and non-parametric tests: For statistical analysis of scores obtained from questionnaires we will use Anova and regression analysis; we set confidence level at 95%.

The results of the study will be published on the Sha Research Foundation website and on the scientific meetings and journals. The audience is expected to be the healthcare, scientific, and integrative, complementary, and alternative medicine communities.

The data and results of the study remain the intellectual property of Sha Research Foundation.

Authorship of the data of this study will be (following ICMJE Recommendations) based on:

1. degree of contribution to the conception or design of the study
2. degree of creating any important intellectual content of the study
3. degree of participation on creating final report
4. an agreed role in the conduct of the study.

4.0 Recruitment and Screening Methods:

Recruitment announcement will be placed at:

Sha Research Foundation website: www.ShaResearchFoundation.com

Sha Research Foundation Twitter and Facebook

and also on Love Peace Harmony Foundation website: <https://lovepeaceharmony.org/>

Love Peace Harmony Twitter and Facebook
In Newspapers, magazines, and Journals

5.0 Research Locations:

The registered location of Sha Research Foundation is:
1517 North Point St., #417 San Francisco, California 94123-1711 USA

Location (Education) of this study is:
Master Sha Tao Wellness Centre,
1333 Kennedy Rd, Scarborough, ON M1P 2L6

6.0 Multi-site Research (research that involves external collaborating institutions and individuals):

N/A

7.0 International Research (where data collection will occur outside the United States and U.S. territories, including online activities)

The research will take place in the U.S.A and Canada only.

8.0 Procedures Involved:

The study includes:

- A personal or telephone discussion (clarification of inclusion / exclusion criteria)
signing of the consent /Information
- Randomization into practice and waitlist control groups
- instruction in the study design and practicing the Tao Calligraphy art mindfulness practice to practice group
- first data collection questionnaires at Time point T0 – before start of mindfulness practice with Tao Art. This is done for both practice and control group
- regular Zoom practices with practice group participants (or pre-recorded mindfulness practices with Love Peace Harmony coaches as a back-up)
- Second data collection of the questionnaires at Time point T1 (3 months) by both practice and control group participants.
- At this point, the practice group stops practices and the waitlist control group participants start practices for 3 months
- Time point T2 (6 months) – again both practice and control group participants fill questionnaires
- Completion of assessments by a Study principal co-investigator

9.0 Research with Vulnerable Populations (if children are the ONLY vulnerable population you plan to enroll, do NOT complete this section -- instead fill out Appendix A)

N/A

10.0 Incomplete Disclosure or Deception:

N/A

11.0 Consent Process:

Trained research team member(s) will follow SRF Consent process V1 Aug 6 2024. After obtaining the name and contact of potential participant from the PI, research team, member will connect with the potential subjects for screening using inclusion and exclusion criteria of the study. This will be done either in person, over the phone, or in a Zoom meeting. If the consent is done by the phone-call or Zoom, signature will be issued on behalf of the participant by the consenting research team member and witnessed by a second person. Participant will be given a copy of the consent form and a study information letter for the participants, explaining the study in more detail. For consent form see Main ICF. The signed consent will be sent to and stored at Sha Research Foundation for 7 years.

12.0 Waiver of Participant Signature on Consent Form:

We would like to apply for a waiver of documentation of consent for verbal consent so that consent can be obtained remotely.

13.0 Waivers and Alterations of Consent Information:

N/A

14.0 Financial Compensation:

There will be no compensation of research participants. Participants will receive free instructions and weekly mindfulness practices with instructor/coach. Research involves Minimal Risk to the participants; therefore, no compensation will be available to the participants.

15.0 Audio/Video Recording/Photography

We will not be performing any video, audio or photography recording of subjects.

16.0 Potential Benefits of this Research:

There has been growing empirical studies of Chinese calligraphic handwriting that resulted in improvements in visual attention and span, increased mental concentration, confirming as an effective treatment for psychosomatic conditions and post-traumatic hyper-arousal symptoms, and exhibited significant effects on hypertension and type 2 diabetes. Leisure activities occurring later in life that includes calligraphy may inhibit cognitive decline. Our own studies clearly documented improvement in Wellbeing Scores (Rand SF-36 questionnaire, EORTC QLQ 30 questionnaire), improvement in pain scores (McGill pain questionnaire) in subject suffering from chronic pain, and improvement in depression scores (BDI, PHQ9 and HAM questionnaires) in patient with depression. Wellbeing, pain study, and Depression study (from Germany) have been already presented at various conferences. This current study aims to go beyond helping people with illness, we wish to document improvement of quality of life of general population, specifically – how less stressed and more peaceful they feel, and how better connected to others they become.

17.0 Potential Risks to Participants:

No risks or negative side effects to human participants to the Tao calligraphy meditation with Tao song have been observed in our pilot projects and formal studies.

18.0 Provisions to Protect Participant Privacy and Data Confidentiality:

All scientific data will be stored in the external hard drive in the spreadsheet under ID code numbers according to Tri Council Policy Statement: Ethical Conduct for Research Involving Humans (2005).

A unique ID code number will be assigned to each participant for entry for internal tracking. Once the unique ID number is assigned, no personal identity information is kept with research spreadsheets.

The data collected via website will have only confidential ID assigned and never any names or personal identifiers. As there are no names associated with participants' responses in their electronic research files, it would be impossible to know which subject these responses

belong to.

When client provides personal information in paper form, these are scanned and forwarded to research team by email. Paper original documents are returned to participant who provided them in person, or burned if sent by mail. Once the email with documents is received by research team, downloaded to research external hard drive, and confirmed receipt, the emails with files are deleted from email inbox.

All collected personal information is stored on external hard drive that can be accessed only through a password-protected computer.

There will be no hard copies of data printed out, although the results of statistical tests and actual papers for presentation will be in paper form.

19.0 Data Monitoring Plan to Ensure the Safety of Participants:

The collected data will remain the property of Sha Research Foundation and only members of the research team will have the access to the research data collected.

Each participant will complete an Application Form. The signed consent forms will be faxed to the Foundation. Data collection during the study will be executed at baseline, 3 months and 6 months.

Research Data

1) Participants will complete following research questionnaires prior to the incept of mindfulness practice with Tao art:

- . Perceived Stress Scale (PSS)
- . Social Connectedness Scale (SCS)
- . Peace of Mind Scale (PoMS).

2) During the time of the study, participants will complete following research questionnaires:

- . Perceived Stress Scale (PSS)
- . Social Connectedness Scale (SCS)
- . Peace of Mind Scale (PoMS).

C) Data Processes

There will a Consent Process form filled after consenting procedure, this will be reviewed.

All applications are audited for completion.

The log of adverse events will be maintained (this would include data issues also).

The other logs would be: Protocol deviation Log, Subject withdrawal and termination log, Subject visit log spreadsheet, Telephone log.

Application and consent will be scanned and stored on large (not flash drive) external drive by principal investigator. After he confirms receipt, any person obtaining these documents will delete them from their computers and from email inbox. Once principal investigator downloads the data from inbox to a hard drive, any email containing data will be deleted from the inbox.

Research Data collected on password-protected entry on the website, will have only first

name and confidential ID as identifiers, and so even in unlikely event of breach to website, no research data could be attributable to a particular person.

All data will be stored for 7 years and will be safely deleted afterwards. Any retiring hard drive will be not only erased, but also physically damaged so could not be read from anymore (in accordance to Canadian Medical Protective Association guidelines).

20.0 Long-term Data and Specimen Storage and Sharing:

All scientific data will be stored on external hard drive at least 7 years under ID code numbers according to Tri Council Policy Statement: Ethical Conduct for Research Involving Humans (2005) and HIPAA. All data will be deleted after 7 years.

No personal or attributable medical data will be shared outside of Sha Research Foundation.

21.0 Qualifications of Research Team to Conduct the Research:

Peter Hudoba, MD, FRCS, Physician, affiliated as researcher with, and prior CEO of Sha Research Foundation. Previously Asst. Professor of Neurosurgery, University of Saskatchewan. Cynthia Hamilton, PhD, Clinical Researcher, former Assistant Research Director Vancouver Coastal Health Research Institute, North Vancouver, BC, Canada. Marsha Valutis, BA, MA, PhD, Applied Psychology, U.S.A. Jaime Chow, Epidemiologist with over 15 years of applied public health. London, UK Amy Yamashiro, Management and Program Analyst. Washington DC, U.S.A.

Appendices and additional documents:

Appendix A: SRF Research Conferences Presentations 2001-2024
Appendix B: References
Informed Consent Form
Information Letter to Subjects
Perceived Stress Scale (PSS)
Social Connectedness Scale (SCS)
Peace of Mind Scale (PoMS)

Allan Chuck November 24, 2024

Allan Chuck
President and CEO
Sha Research Foundation

Peter Hudoba November 25, 2024

Peter Hudoba
Principal Research Investigator