Complementary and Alternative Medicine in Nervous System Conditions

Edited by
James D. Adams

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Special Issue Editors

James D. Adams
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About the Special Issue Editors

James David Adams, Jr. is an associate professor of pharmacology and pharmaceutical sciences at the University of Southern California School of Pharmacy. Jim has written over 260 articles and has authored, co-authored or edited over 10 books on pharmacology and traditional medicine. He is author of Healing with Medicinal Plants of the West – Cultural and Scientific Basis for their Use, which is in its third revised edition. Jim’s scholarly interests include California Indian medicine, medicinal plants, pain and chronic pain. His research on Parkinson’s disease, Alzheimer’s disease, stroke, oxidative stress and California medicinal plants has been cited and quoted in many journals.

Jim has served as editor for more than 20 influential journals in the fields of pharmacology, medicinal chemistry and traditional healing practices. He is currently Editor-in-Chief for J Multidisciplinary Scientific Journal. He has been the editor for several books including books published by the Royal Society of Chemistry.

Jim teaches the public, pharmacy and medical students about California Indian medicine. He is very active in teaching the public how to treat pain and chronic pain with California plant medicines. He also teaches a course in medical marijuana to pharmacy students.

Prior to coming to the University of Southern California School of Pharmacy, he was on the faculty at Washington State University College of Pharmacy. He earned his doctoral degree at the University of California San Francisco and had postdoctoral positions at Baylor College of Medicine and the National Institutes of Health.

Professional Development Areas of Expertise
- Oxidative Stress and Mechanisms of Oxygen Radical Production
- Parkinson’s Disease
- Stroke
- Nicotinamide (Vitamin B3) Pharmacology
- California Indian Medicine and Plant Medicines
Preface to “Complementary and Alternative Medicine in Nervous System Conditions”

Highlights of Complementary and Alternative Medicine in Nervous System Conditions: An Interview with Dr. James David Adams, Jr.

James David Adams, Jr. *

School of Pharmacy, University of Southern California, Los Angeles, USA; E-Mail: jadams@usc.edu

1. What is the importance of Complementary and Alternative Medicine in community settings? Currently, there are many scholars who have reservations about this subject. As an expert in this field for over 20 years, could you please introduce the topic of “Complementary and Alternative Medicine in Nervous System Conditions”?

**Dr. Adams:** The peripheral and central nervous systems are involved in many conditions, such as pain, hypertension, stroke and neurodegenerative diseases. Standard medicine does not adequately treat many of these conditions. Traditional medicine can offer complementary and alternative treatments that may be helpful. Pain is usually treated with dangerous oral medications such as nonsteroidal anti-inflammatory drugs and opioids. These drugs have major adverse reactions and kill many patients. Acupuncture and other skin centered therapies are more effective at treating pain, with fewer adverse reactions. Hypertension is, in part, caused by excessive sympathetic activity that can be blocked with sympathetic antagonists. These drugs all have major adverse reactions and do not cure hypertension. Patients must stay on these drugs for the rest of their lives, like an addiction. The chances of patients suffering drug toxicity are probably 100% over their lifetimes. Traditional medicine offers the concept of balance that can help prevent and cure hypertension through avoiding toxic lifestyles. Stroke results in paralysis of the limbs in many patients. Standard medicine is inadequate at helping with stroke recovery and paralysis. Traditional medicine offers medicines and physical therapy techniques that can greatly aid stroke patients. The current book will help expose the standard healthcare community to traditional medicines that can be helpful in treating nervous system conditions. Patient centered healthcare should emphasize prevention through avoiding toxic lifestyles and avoiding the use of standard drugs as much as possible.

2. What is the relationship between medicinal plants and “Complementary and Alternative Medicine in Nervous System Conditions”? Are medicinal plants...
important for this topic?

Dr. Adams: The most important aspect of alternative medicine is prevention. Standard medicine is very poor at helping patients alter their toxic lifestyles and live healthy lifestyles. Simply by getting rid of toxic lifestyles a number of diseases can be prevented or delayed including heart disease, type 2 diabetes, arthritis and perhaps Alzheimer’s disease and Parkinson’s disease.

Plant medicines are very important in helping patients find safer and less expensive ways to treat themselves and support healthy lifestyles. Topical plant medicines can be potent pain relievers that are more rapid acting and safer than oral medicines. These topical plant medicines inhibit pain by interacting with skin sensory neurons and are also anti-inflammatory by inhibiting neurogenic inflammation. In other words, by treating pain in the skin, the sensory neurons cease to secrete inflammatory proteins that promote inflammation throughout the body.

3. Have you ever been treated with Complementary and Alternative Medicine? Can you share your feelings about the research in this field over recent years?

Dr. Adams: Most of my personal healthcare comes from prevention and plant medicines. I live a balanced lifestyle that involves keeping myself thin and strong. I run an hour every day. I keep my body fat content at about 4% of my body weight.

When I contract a cold or flu, I use California plant medicines, such as elderberry Sambucus nigra, to treat myself for free. When I am in pain, I use sagebrush Artemisia californica liniment to treat myself for free. When I have skin problems, I use a balm made from chamise Adenostoma fasciculatum to treat myself for free.

I am one of a few Scientists engaged in research on California plant medicines. There is no funding to work on this subject. The FDA does not allow clinical trials of California plant medicines because of fears that these medicines are not safe. Both of the clinical trials that I proposed to the FDA were rejected based on safety issues. The medicines I had proposed to use are traditional California Indian medicines that have been used for many centuries and are known to be safe. I have treated hundreds of patients with these medicines with very few safety issues.

4. What are the current challenges in this area? Is it possible to allay public concerns about complementary and alternative medicine? Are there any other indications, where you could confirm its effectiveness?

Dr. Adams: Healthcare professionals and the public are taught that complementary and alternative medicine is either fraud or dangerous, in other words not effective or not safe. There is a very strong belief among many people that plant medicines are all placebos. This implies that if a patient does not believe in a plant medicine (placebo), it will not work. I have offered to treat many pain patients with topical plant medicines and have been refused. These patients believe that plant medicines are ineffective placebos. However, those patients who actually try the medicines find rapid, powerful pain relief with anti-inflammatory effects.
In order to allay public concerns about these medicines, I teach the public in lectures and on hikes. Those people who make the medicines themselves for free and try them, teach their friends. This is a long, slow process. I must contend with television shows and press articles that insist plant medicines are placebos. There are many effective plant medicines. Tea and coffee are plant medicines that are used daily by millions of people to stay alert. Chocolate is an effective medicine for the heart, especially in patients who are magnesium deficient. Many prescription drugs come from plants including scopolamine, digoxin, many antibiotics and many anti-cancer agents. Marijuana is a very effective drug for several conditions.

5. **What are the future aspects of this research field, or do you have any suggestions for future work of researchers in this field? Will you encourage more researchers to participate in research in the field of complementary medicine?**

**Dr. Adams:** Cancer therapy and antibiotic therapy are very involved in plant medicines. There is even one medicine, paclitaxel, which originally came from a California plant. Currently, since there is no funding for plant medicines, Scientists are encouraged to be closed minded about the subject. Scientists are directed by funding availability to work on other areas. Science must be approached with an open mind. We are currently in a situation where many thousands of people die in the USA every year from oral pain killers. This is caused entirely by the closed minded approach that teaches there is no other way to treat pain other than oral medications. An open minded approach to topical pain relievers, acupuncture and other topical therapies can save the lives of thousands of people every year.

6. **Were there any particular studies that impressed you or inspired you, or interesting things that have happened in your research, would you like to share with us?**

**Dr. Adams:** The people of the USA have decided to allow the use of medical marijuana in many parts of the country. This has been a real benefit to many people suffering from epilepsy, multiple sclerosis, anxiety, cancer pain and nausea, chronic fatigue syndrome, traumatic brain injury and other conditions. Marijuana had been banned in the USA due to the perception that it was from either Mexico or India and was not fit for Americans. This closed minded approach has been replaced with a more open minded attitude. Americans now should learn the proper use of medical marijuana, which is sometimes topical use.

7. **What distinguishes this special issue from others in the field, why should researchers subscribe this special issue book?**

**Dr. Adams:** This book provides a unique, open minded approach. The chapters have not been chosen based on the availability of research funding for the topics. This provides a different and perhaps ground breaking approach to therapeutics.
Miraculous Healings of Chronic Lyme disease, Fibromyalgia and Sarcoidosis without the Use of Pharmaceuticals or Antibiotics

Richard Sarnat, MD

Chief Medical Officer, Advanced Medicine Integration, L.L.C, Highland Park, Illinois 60035, USA; E-Mail: rsarnat@amibestmed.com

* Correspondence: Richard L. Sarnat, MD; E-Mail: rsarnat@amibestmed.com

Academic Editor: James D. Adams

Special Issue: Complementary and Alternative Medicine in Nervous System Conditions

Abstract

While “miraculous healings” of various disease states have been scientifically reported previously, the exact mechanism, which allow for these seeming miracles or spontaneous remissions is poorly understood. [1-15] By contrast, the mechanism of action underlying the “miraculous healings” in the three case studies reported herein: Sarcoidosis, Chronic Lyme disease and Fibromyalgia seems to be understood with greater clarity, as these case reports are representative of the many hundreds of case studies I have documented over a ten-year period while observing the work of Master John Douglas and the graduates of his Elite Development course.

While certainly inspiring, admittedly all of these discoveries must ultimately be subjected to more rigorous scientific methodology. Yet, the sheer number of miraculous healings I have observed and the fact that this body of knowledge can be taught to others who obtain similarly effective results is very exciting, given the rising worldwide prevalence of idiopathic chronic diseases and the growing microbial resistance to antibiotics.

Keywords

Miraculous healing; energy medicine; sarcoidosis; fibromyalgia; Lyme disease
1. Sarcoidosis – Case Study #1 (CS #1)

CS #1 is a 53 year-old white female who was diagnosed with the rare and “incurable” disease Sarcoidosis in August of 2012. She was inflicted with generalized signs of Sarcoidosis inflammation - pain and swelling in her bones, ankles, and nerves, including her left optic nerve and the larger involuntary nerves of the heart.

The first presentation of her Sarcoidosis was extreme bilateral swelling of her ankles and lower legs without antecedent trauma. She said, “My legs looked like I had elephantiasis.”

She progressed to having trouble breathing even at rest, when formerly she was a very active and athletic person. “The pain was intense, ranging from pressure in the chest, to deep bone ache, to throbbing unrelenting pain in the swollen areas.”

By six months after the onset of her first symptoms, the nerve pain had progressed to a dull ache in the internal organs and a tingling and burning pain on her skin that felt like, “I was constantly being bitten by red ants.”

Two years after the onset of her symptoms she manifested signs that the autonomic nervous system was involved, with irregular heart arrhythmias which were clinically disconcerting, creating dizziness and chest pressure.

Vision was also affected with severe retro-orbital pain, tearing and loss of significant vision in the left eye. CS #1 was also seen by numerous ophthalmologists, who confirmed the diagnosis of granulomas within the left optic nerve.

As of August 2012, bilateral hilar lymphadenopathy was present on the chest x-ray, as well as a high normal ACE level of 56 (range 9-67 U/L). Protein electrophoresis showed decreased albumin and mildly elevated acute phase Alpha-1 and Alpha-2 globulins, suggesting acute inflammation. ANA EIA was moderately positive at 30 Hfunits (range 0-19)

She was prescribed high doses of prednisone and Norco for the pain over a duration of 13 months. Yet despite this treatment, her pain did not abate and clinically her disease progressed with increasingly more severe symptoms. Her daily average pain scale score was reported as, “7/10, typically progressing to 10/10 at night and disrupting her sleep.”

CS #1 began an extensive information search, and joined an online Sarcoidosis support group. She traveled to Cleveland Clinic to see a prominent neurologist specializing in Sarcoidosis, where she was told that should the disease continue to progress that she would be facing cardiac corrective surgical procedures.

CS #1 became convinced over time that nothing in the conventional medical world would cure her. Faced with this realization, she felt herself spiritually guided to take matters into her own hands, and arrived at the following conclusions:

“During my inner and outer search for knowledge, I came to the conclusion that my Sarcoidosis was caused by an underlying disturbance in three areas: physical, mental and spiritual.

1) Hidden bacteria, stress and fatigue plagued the physical arena;
2) Unresolved karma and alienation from my Higher Self plagued the spiritual arena;
3) Resentments, lower level behavior and anger plagued the mental arena.
Quite a nasty combination, and a sobering call to action for me.”

CS #1 first encountered Master John Douglas, an Australian Clairvoyant with a successful track record of miraculous healings (both local and non-localized) in the spring of 2013 at a seminar in California. Master John Douglas prescribed a healing regimen of trace minerals, tourmaline detox
foot patches and the daily use of his audio CD repair tools called Location Repair, Subconscious Repair and Spirit Repair. These audio CD Repair tools are a set of guided meditations and healing requests that according to Master John Douglas, “invoke the Celestial Angelic realm in a very focused, demonstrable and predictable manner.”

As CS #1 was so debilitated by this time she could hardly be active. Her daily routine primarily consisted of long hourly Jacuzzi-type baths, while listening to the various audio phonic CD Repair tools.

Within one month after seeing Master John Douglas and using the audio CD Repair tools CS #1 reports that, “she was able for the first time to stop using alcohol, Norco and marijuana to numb her pain.”

She then weaned herself off of prednisone, under her doctor’s supervision, and began what she describes as “an anti-inflammatory, heavy metal free diet,” which was essentially a vegan diet.

In preparation for her second upcoming session with Master John Douglas, she incorporated the regular use of an additional four audio CD Repair tools to facilitate her healing: Subconscious Repair, Faith and Sensory Repair, Climate Crisis and Relationship Repair.

The second time she saw Master John Douglas in December of 2014, she describes herself, as “drug free, physically prepared, and spiritually ready to be healed.” She was guided by her intuition to ask a specific request when she saw Master John Douglas: “please kill any and all bacteria causing my granulomas and Sarcoidosis.”

Within seconds of uttering this request, Master John Douglas clairvoyantly found and killed two forms of hidden bacteria located within her white blood cells.

She reports that, “within a two minute timeframe of having Master John Douglas kill the underlying bacteria in her body, her pain level went down to zero, and her spirit was lifted to new heights of faith and gratitude.”

Since December of 2014 and the day of this transformative healing, she reports no reoccurrence of her symptoms and a return to her formerly vibrant life.

As of January 2018, her most recent ANA IFA screen is completely negative and her chest x-ray is now normal.

1.1 Discussion

In the conventional medical world, Sarcoidosis is considered an incurable disease, whose pathology can affect any organ, as granulomas, a form of scar tissue, continue to be formed, unchecked by any effective known treatment.

These granulomas cause inflammation and affect each patient differently. They can occur in any part of the body, causing damage and loss of function in the affected area.

Master John Douglas clairvoyantly discovered that the root cause of Sarcoidosis is the presence of two Nano-sized bacteria living within the white blood cells. These infectious agents then cause the white blood cells to rupture their cell membranes and explode into a granuloma, creating secondary pain and dysfunction.

Master John Douglas relates his subjective memories of CS #1’s healing session, “The insight of this new discovery was known as soon as I looked into her cellular level with my enhanced sensory mechanisms and saw two Nano-sized bacteria within a single white blood cell. There would be no other normal situation in which this presentation of dual intracellular bacterium would occur,
other than a pathological situation. Sometimes the easiest way to diagnose and discover something new is by seeing what shouldn’t be present - being aware of the anomaly.”

Since 2014, this discovery and eradication of the root cause of Sarcoidosis has been duplicated numerous times by both Master John Douglas and graduates of his Elite Development training course, suggesting a cause and effect relationship which deserves more rigorous clinical trials.

2. Chronic Lyme disease – Case Study #2

CS #2 is a 51 year old white female whose primary care physician estimates that she first contracted Lyme disease almost twenty years before it was officially diagnosed. By 2008 the patient’s symptoms included progressive flu-like symptoms, constant dull aches, brain fog and complete loss of energy. “Just to get the kids off to school and pick them up was a heroic effort.” The rest of the day she spent in bed, trying to revitalize.

In 2008 her parents brought her two of Master John Douglas’s audio CD Repair tools - Spirit Repair and Health Repair, which she now feels intuitively “paved the way for her eventual healing.”

On May 12th, 2012 the patient first met Master John Douglas at a seminar in Portland. Even during the initial group healing, she was aware of a total transformation in her body, as it changed “from a constant background hum, which she believes was created by the large numbers of infectious agents, to instant silence as all of the infectious agents were killed.”

The patient’s blood tests were unknown to Master John Douglas, yet as soon as he saw her he said, “you are 1000% Babesia infected, you got bit by the tick that drank from the sewer.” In fact, he was correct; the patient’s lab tests were negative for Borrelia and positive for Babesia.

CS #2 intuitively knew within seconds that, “she was fully healed and her suffering was over. She reports that Master John Douglas told her that all of her symptoms would disappear within five weeks if she followed his detox protocol exactly.”

CS #2 religiously followed the prescribed detox protocol, which utilized daily salt baths, foot patches, trace minerals, using body Repair discs and listening to the audio CD Repair tools. As predicted, after five weeks of the protocol the patient’s symptoms completely disappeared and she has had no return of symptoms since that time. She “feels better now than she did in her twenties or thirties”.

2.1 Discussion

Graduates of Master John Douglas’s Elite Development course are taught to verify the presence or absence of active Lyme disease not by blood tests, which are known to have many false positive and false negative results.

Master John believes a more accurate assessment is made by measuring the presence or absence of the pathognomonic electromagnetic signal emanating from a variety of tick bites, including Borrelia bacteria, as well as measuring for the presence or absence of signature toxins circulating in the brain, joints, or internal organs. [16, 17]

Using Master John’s techniques, Lyme disease is rarely found as an isolated Borrelia infection and typically has multiple co-infections, including parasitic animals that lay residual eggs.

While Elite Development course graduates can use electromagnetic frequencies to kill all the various co-infectious organisms, the eggs are resistant to being eradicated by this technique. To
kill the eggs one must use an herbal combination of black walnut, wormwood and cloves. Anti-parasitic pharmaceuticals are also effective in killing the eggs but have a much higher potential for more severe side effects.

In my observations of many Lyme disease patients treated by this technique, recovery from chronic Lyme disease is complicated by the fact that many Lyme disease patients also have difficulty clearing the Lyme specific toxins, even after all the organisms are dead. Clairvoyantly, Lyme toxins are observed to be sticky, like tar in the physiology, which is why the healing phase of detoxification can take a year or more in chronic long-term cases.

Many patients have an additional difficulty detoxifying due to a glutathione enzyme malfunction. This malfunction can be discovered by the absence or weakness of the electromagnetic signal associated with this physiologic process as well as correlation with confirmatory lab work. Supplementation with a glutathione spray applied to the back of the throat helps alleviate this problem and accelerates the healing detoxification process.

3. Fibromyalgia - Case Study #3

CS #3 is 62 year-old Japanese American female who first presented with Fibromyalgia symptoms in 2004. During this same timeframe the patient was being treated for breast cancer with surgery, chemo and radiation. Given the close proximity of the onset of fibromyalgia symptoms to her cancer related treatments, originally the patient was confused as to whether these were separate or related disease processes.

However, following the completion of her cancer treatments, as the hallmark symptoms of Fibromyalgia began to manifest without abatement, the patient’s primary care physician referred her to a rheumatologist. By that time, the patient had developed chronic severe pain worse in the morning, “which was destroying her quality of life.” CS #3 was officially diagnosed with Fibromyalgia by her rheumatologist, who prescribed a number of conventional medical pharmaceutical treatment trials, all of which failed to alleviate her symptoms.

The only pain relief she was able to achieve was by pushing herself through her early morning pain, by doing exercise first thing in the morning. She reports that, “her pain level was 10/10 every day, just attempting to move out of bed.” She describes her pain as, “having something strapped around her body which was sharp and constant, as if pins penetrated your body with every movement.”

Close friends, just on the chance that it could help, invited her to a seminar with Master John Douglas. She had already listened to a few of his audio CD Repair tools in preparation and was hopeful.

She remembers that, “Master John Douglas opened the lecture talking about folks in the audience who were there to relieve their Fibromyalgia pain and about universal energy and how it could effect all things in life. The more he talked, the more intuitively the patient knew she was about to be healed.”

According to the patient’s awareness, “the actual healing took place during the group seminar and was transformative, even before my individual five minute personal session”, which typically follows the group healing/seminar.

During a segment of the group seminar, Master John Douglas had the audience participate in a breathing exercise. At the conclusion of the breathing exercise she recalls feeling “immediate
relief emanating from the site of her former “Porto catheter”, which had been used as her previous chemotherapy infusion site.” She remembers that she complained of pain emanating from the Porto catheter site from the moment it was put in and intuitively felt it was the source of the original infection causing her Fibromyalgia.

During the personal session, the patient reports that, “Master John Douglas was able to clairvoyantly go back through time and confirm that the original infection occurred during the insertion of the Porto catheter and that after the initial healing took place in the group seminar/healing that the body was entirely free from that infection.”

Since the healing that took place at this seminar, no Fibromyalgia symptoms have reoccurred, although the patient does have chronic neck and structural arthritis per her physician.

The patient is delighted, “that she no longer wakes up crying first thing in the morning and that she no longer has excruciating pain.” She currently takes no medicines.

After the healing, the biometric markers on her osteoporosis labs, which formerly had been getting worse suddenly improved and have remained stable, as did her bone scan.

She has not attended any additional Master John Douglas related seminars since this healing event. Although she does report that, “she listens to the audio CD Health Repair tool a minimum of three times per week.” She remains physically active without restriction since her miraculous healing.

3.1 Discussion

Master John Douglas reports, “that he discovered that the etiology of Fibromyalgia is a Nano-sized inflammatory negative animal living within the bone marrow (negative animals are a discrete category different from bacteria, viruses, molds, fungus, yeast or parasites).

Master John believes this Nano-sized inflammatory animal is the cause of the deep bone pain and the chronic fatigue that Fibromyalgia patients report. Clairvoyantly, he can “see” that the bone marrow is poorly perfused and that lethal concentrations of conventional antibiotics fail to achieve the required concentrations needed to eradicate this infectious agent. Master John asserts, “that this infectious agent is only able to be killed by an Angelic electromagnetic pulse tuned to the resonance of this animal, much like an opera singer shatters a crystal glass.”

Furthermore, it is his contention that all autoimmune diseases are actually a misnomer and that each disease in this category has an unknown infectious etiology, which when properly identified and killed results in a resolution of symptoms. [18]

4. Conclusion

These three case studies are representative of the many hundreds of case studies I have documented over a ten-year period while observing the work of Master John Douglas and the graduates of his Elite Development course.

While certainly inspiring, all of these discoveries must ultimately be subjected to more rigorous scientific methodology. Yet, the sheer number of miraculous healings I have observed and the fact that this body of knowledge can be taught to others who obtain similarly effective results is very exciting, given the rising worldwide prevalence of idiopathic chronic diseases and the growing microbial resistance to antibiotics.
Acknowledgments

I would like to acknowledge Master John Douglas for his tireless work ethic and his passion to save humanity from the unseen dangers, which threaten life on this planet and to the real people in our anonymous case studies who were willing to share their intimate medical experiences for the benefit of science.

Author Contributions

All work was done by the primary author.

Competing Interests

The author declares that no competing interests exist.

References


Literature Review

How Can Acupuncture Be Used in Treating Dementia?

Fung Kei Cheng, PhD

Hong Kong

* Correspondence: Fung Kei Cheng; E-Mail: oasischeng@yahoo.com

Academic Editor: James D. Adams

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Abstract:

(1) **Background**: Dementia erodes the quality of life of patients and their caregivers, and the growing dementia population threatens public finance in the health and social services. In addition to formal medical treatments, complementary and alternative medicine is applicable to dementia, in which acupuncture has become an option for prevention, remedy, and rehabilitation. Acupuncture is a traditional Chinese medical method that uses needle penetration at acupoints (specific points throughout the body which will be stimulated for therapeutic achievements), resulting in alleviating dementia symptoms; for example, enhancements in cognition, memory, language, behaviour, emotion, and self-care.

(2) **Methods**: This narrative review analyses 44 clinical human-based studies conducted 1998-2017, pertaining to 3078 participants who were 45-100 years old in Austria, China, Hong Kong, Japan, and the USA.

(3) **Results**: This review offers an overview of various methods of acupuncture (using acupuncture alone or combined with other therapies), and how they can be conducive to people inflicted by dementia.

(4) **Conclusions**: This study also reveals future research directions to develop acupuncture, which offers a novel approach to health care practitioners and patients.

**Keywords**

Alzheimer’s disease; traditional Chinese medicine; complementary and alternative therapy; dementia; narrative review; neuro-degenerative syndrome; rehabilitation
1. Introduction

Statistical data warn that 7.7 million new cases each year worldwide have been added on top of the existing 47.5 million people with dementia [1]. Dementia is a neuro-degenerative syndrome [2] caused by a reduction in the number of neurons, resulting in a deterioration of neuronal structure and functions, which incurs a progressive or chronic decline in cognition, thinking, memory, comprehension, language, learning, judgement, behaviour, emotion, and self-care [3]. These impairments demand about 1% of the global gross domestic product [4] to serve patients and their families, and deplete the workforce in cases where young-onset dementia begins before 65 years old [5].

The aetiological mechanism of dementia has not yet been well-identified [6], but this disease stems from a variety of heterogeneous factors [7], yielding various types such as senile dementia (Alzheimer’s disease) [8], vascular dementia [9], Lewy bodies dementia, frontotemporal dementia, and primary progressive aphasia [10]. Additionally, in 12-20% of patients [11, 12], the disease is induced by reversible causes [13]; for example, depression induced cognitive impairment, surgical brain lesions, tumours and chronic subdural hematomas, structural brain abnormalities, metabolic disorders, alcohol and medication related dementia, toxicants, infection, and nutritional deficiencies [14], which are all likely treatable.

Apart from formal medical treatments for dementia, including medication, behavioural-oriented therapies, and psychosocial interventions [15-17], complementary and alternative medicine has been adopted with positive outcomes [18], for instance, aerobic exercise [19], art therapy [20], creative therapy [21], dancing therapy [22], music therapy [23], gardening [24], and Ginkgo biloba [25], together with traditional Chinese methods [26].

Many ancient Chinese medicinal records [27], such as the Emperor’s Inner Canon [28] (also known as Huangdi Neijing or the Inner Canon of Huangdi), documented the effectiveness of acupuncture on syndromes or symptoms that are similar to dementia. Acupuncture is a Chinese medical method that has been practised for over 3,000 years. Its objective is to restore the flow of qi (energy) within the body [29] through the stimulation of nerve endings, which consequently enhances brain function [30], attaining healthy, balanced life energy [31]. It normally uses 5-15 needles penetrating at specific points (namely, acupoints) from 365 acupoints located along 14 meridians [32] throughout the body.

Acupuncture has become an option for treating Parkinson’s disease [33], Alzheimer’s disease [34, 35] and dementia [36, 37], as supported by Chinese projects since the 1980s [38]. In particular, its effects on vascular dementia have shown improvements in memory, cerebral ischemia, hippocampus function, and synaptic plasticity, in the regulation of vasoactive substances and blood flow in the brain, in the prevention of excessive free radicals, the facilitation of angiogenesis, the inhibition of neuronal apoptosis, and in the modulation of neurotransmitter production, as well as increases in glucose metabolism [39-44], and the amelioration of cognitive impairment [45]: albeit Lee and colleagues [46] are hesitant regarding these outcomes.

Diverse acupuncture methods have been utilised for dementia, such as body acupuncture, scalp acupuncture, ophthalmic acupuncture, tongue acupuncture, and acupoint injection [47-50]. Moreover, acupuncture may combine with other approaches [51-53]; for example, Chinese herbs
[54], pharmaceutical drugs [55], and moxibustion [56]. Benefiting from modern technology, it has also developed further into different modes, including electro-acupuncture, and laser acupuncture.

This narrative review analyses how acupuncture can alleviate dementia symptoms, through either acupuncture alone or through combined therapies. The findings of the reviewed clinical research potentially supply alternatives to medical practitioners and patients for preventive, curative, and rehabilitative purposes.

2. Research Methods

This review adopted 27 major digital databases in ProQuest; for instance, Biological Sciences, British Nursing Index, MEDLINE, ProQuest Medical Library, PsycARTICLES, and PsycINFO. The keywords “acupuncture”, “dementia” and “Alzheimer’s disease” were input; 114 studies were listed. Additionally, two significant Chinese databases – China National Knowledge Infrastructure (CNKI) and Taiwan Electronic Periodical Services (TEPS) – were employed, in which the keywords included “針灸” and “失智症 OR 癡呆症 OR 腦退化症 OR 認知障礙症 OR 阿茲海默症 OR 阿爾茨海默氏症”, resulting in 451 potential projects.

![Figure 1 Selection process](image)

The retrieved clinical human-based research which was published in peer-reviewed scholarly journals prior to 2018 was selected. Duplicated works, non-resultant trials, literature reviews, book reviews, dissertations, letters to the editor, and commentaries were excluded. According to the eligibility criteria, 44 projects (n=12 in English, n=32 in Chinese) were reviewed (Figure 1),
which included 3078 participants who were 45-100 years old in Austria (n=1), China (n=40), Hong Kong (n=1), Japan (n=1) and the USA (n=1), and were carried out from 1998 to 2017.

3. Results and Discussion

This narrative review (refer to Table 1) delves into the effects of acupuncture on dementia from the perspectives of being used singly, or in combination with other therapies, impacting neurological effects and reducing dementia-induced mental problems. Also, comparison studies analyse the effectiveness of different combined approaches. The research outcomes unveil decreases in dementia symptoms following both acupuncture used alone and combined methods; however, the latter yields a higher effectiveness rate.

3.1 Acupuncture Used Alone

This narrative review investigates the effects of using acupuncture alone on neurological, cognitive, and mental improvements [57, 58]. It also exhibits comparison studies which have compared the effectiveness of acupuncture and medication, as well as different acupuncture techniques.

Neurological changes. Acupuncture has remarkable benefits for cognition in dementia rehabilitation [59], likely due to the following discoveries. When stimulating points at Taichong (LR3) and Hegu (LI4), it increases connectivity in most of the hippocampus-related regions in patients affected by Alzheimer’s disease, particularly the connection between the right middle front lobe and the left hippocampus [60]. This path activates the cognitive-associated regions [61], especially those that contribute to early dementia [62].

Randomly assigned to two groups [63], ten participants with vascular dementia and stroke experience each underwent 20-minute sessions but at different acupoints for these two groups. Assessments were carried out using positron emission tomography (PET), which indicated cerebral metabolism in the lentiform nucleus of the affected hemisphere, and the temporal lobe of the non-affected hemisphere. One case study reported that a 77-year-old woman with cerebral-vascular dementia intensified both cerebral oxygen saturation and cerebral blood flow velocity after seven 10-minute acupuncture sessions (by needle and laser), improving cognitive function, motor speech function, short memory, sleeping, and headaches [64], along with quality of life [65].

Lowering cognitive symptoms. Shi [66] evaluated the effects of acupuncture among 36 participants with vascular dementia who joined an intervention, reporting enhancements in cognition, memory, and language 14 days after treatment, and in visual and spatial skills 28 days after treatment. However, there was a lack of intervention details. Another research programme with 54 patients received 30 13-minute sessions for scalp acupuncture, resulting in improved cognitive function, including gains in orientation, calculation, and behaviour [67], which was supported by a Japanese project [68] and a randomised controlled trial [69] showing significant improvements in cognitive ability and daily life activities.

Weakening dementia-related mental problems. Apart from neuro-refinement, acupuncture can also treat dementia-led mental illnesses through the amelioration of outside symptoms: such as sleep problems, which worsen dementia symptoms [70]. In a within-subjects designed project, 19 participants were observed in the control stage for six weeks, after which they took part in 12
30-minute sessions for another six weeks [71]. Despite the absence of significant indicators of sleep efficiency on the pre- and pro-tests, improvements in resting and sleeping times were apparent after treatment.

Depression is common in the dementia population [72], which in turn increases risks for dementia as well [73]. Lombardo and colleagues [74] investigated 11 patients who were given three 30-minute sessions in the first week and 2-3 sessions per week in weeks 7-10. Although they reported slight amelioration in depression and anxiety, they experienced significant enhancements in energy.

**Comparison studies.** Zhu and colleagues [75] randomly allocated 30 patients to receive 30-minute daily acupuncture treatments for 8 weeks, and another 30 patients to take 30mg of nimodipine, thrice a day for 8 weeks. Improved scores were reported in the Mini-Mental State Examination and Montreal Cognitive Assessment, and lower levels of high sensitivity C-reactive protein (hs-CRP) and interleukin-6 (IL-6) levels were apparent in both groups. Moreover, better indicators in the Syndrome Differentiation Scale of Vascular Dementia and in the above tests were exhibited in the acupuncture group than in the medication group, implying better enhancements in cognition. This was further supported by Liu and team [76], Jia [77], Tan and colleagues [78], and Zheng and Zhang [79]. Another similar study compared acupuncture and piracetam, showing more positive signals on P300 (an endogenous potential) in the acupuncture group, implying better improvements in their memory, cognition, and emotions [80]. Zhu [81], as a supplement to his research, reported that 95% of patients in the acupuncture group revealed improvements in cognition, compared to 75% in the piracetam group.

Aside from the basic one-needle-one-acupoint technique, point-through-point acupuncture has also been utilised. This special technique reaches more than one acupoint by means of a single needle. Thirty patients were randomly distributed to the basic technique group and another 30 to the point-through-point group. They underwent 30-minute daily sessions over a period of 30 days. Results showed that 83.3% of patients in the latter group yielded improvements in their dementia symptoms, compared to 60% in the former [82].

### 3.2 Combined Methods

In addition to the confident results from acupuncture treatments used alone to treat dementia, researchers have examined combined interventions that present even greater effectiveness [83].

**With neuro-developmental therapy.** One project assigned 39 patients to a Bobath therapy group, and another 39 to an experimental group that combined acupuncture and the Bobath technique [84]. Bobath therapy is a multidisciplinary neuro-developmental approach for neurological rehabilitation to improve motor control, body alignment, and movement coordination. 91.4% of patients in the experimental group indicated improvements in neurological impairment, cognitive function, and daily activities, compared to 85.3% in the Bobath therapy group.

**With medications.** Studies comparing the combination of acupuncture and drugs reveal positive signs as well. One study spelled out improvements in cognition, memory, and language, following 14 days of treatment using acupuncture and medication, and in visual spatial skills after 28 days of treatment [85]. This was supported by other research [86]. However, no information about the medication was provided in these projects.
Liu and team [87] randomly assigned 168 patients to two groups equally for a 56-day examination period. The control group took 5mg of donepezil hydrochloride once a day; the treatment group took the same dose along with acupuncture. The results presented more noticeable improvements in cognitive functions in the latter than in the former. In another project, both the experiment and control groups were offered identical therapy: acupuncture and medication (antiplatelet agents, antihypertensive, diuretics and nimodipine) [88], and the experimental group was given additional acupuncture treatments at different acupoints. They improved in cognitive function, memory, and self-care, but the effectiveness rates differed: 80% for the former, and 46.7% for the latter. Therapy combining acupuncture and piracetam tablets produced similar outcomes [89, 90].

Three equal groups were randomly distributed [91]: Group 1 was given 30 minutes of acupuncture and moxibustion; Group 2 was given 20mg huperzine A tablets, thrice per day for 30 days; and Group 3 was assigned acupuncture, moxibustion, and tablets. Improvements were reported related to cognitive functions: 83.3% in Group 1, 66.7% in Group 2, and 93.3% in Group 3, reflecting the effectiveness of combined Chinese and Western methods.

Comparison has also been applied to Chinese medicine with encouraging results in recent studies; for instance, Guo [92], He and colleagues [93], Huang [94], Li and members [95], Ni [96], Niu [97], and Yang and team [98]. One project with 68 participants randomly allocated between an acupuncture group and an acupuncture with Six Flavour Rehmanni (Chinese medicine) group [99]. Improvements were apparent in 88.2% of the patients in the combined group, but only 67.6% in the single treatment group. Nevertheless, participants underwent differing treatment periods: 30 days (n=24), 40 days (n=22), 50 days (n=12), and 60 days (n=10). Further analyses became difficult owing to insufficient details on research design and results.

Looking into the effects of different combinations, 60 patients were randomly, equally assigned to an acupuncture with Chinese medicine group, an acupuncture with Western drugs group (folic acid 10mg, vitamin B6 30mg, huperzone A tablet 0.1mg, twice a day), and a non-treatment group [100]. According to the three measurements at pre-treatment, and at the 3rd and 6th months, the acupuncture with Chinese medicine group exhibited better outcomes than the acupuncture with Western drugs, and no changes were presented in the non-treatment group.

Moreover, Wu and Guo [101] recruited 56 patients who undertook a daily programme, including acupuncture, Chinese medicine, and drugs (donepezil and nicergoline). The findings showed 83% success rate and low side effect rate (10%). They also indicated significant improvements in self care and quality of life. Other research substantiated these outcomes [101-103].
Table 1 Analysis of the 44 reviewed studies

<table>
<thead>
<tr>
<th>Source</th>
<th>Research objective</th>
<th>Sample size</th>
<th>Intervention</th>
<th>Results</th>
<th>Research location</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guo [92]</td>
<td>To compare the effects of acupuncture and Chinese medicine on vascular dementia.</td>
<td>98 patients (n=56 males, n=42 females), aged 51-77</td>
<td>Randomly allocated to the acupuncture with Chinese medicine (n=49; n=29 males, n=20 females; aged 52-76), and Chinese medicine (n=49; n=27 males, n=22 females; aged 51-77) groups. No details of treatment.</td>
<td>Improvements in hemodynamic index in acupuncture with Chinese medicine group.</td>
<td>China.</td>
</tr>
<tr>
<td>Huang [94]</td>
<td>To compare the effects of acupuncture with medicine and drug alone on Alzheimer’s disease.</td>
<td>170 patients, aged 60-85. Unspecified sex ratio</td>
<td>Randomly distributed to acupuncture with medicine (n=100; aged 60-85), and drug (selegiline, piracetam, donepezil, and Chinese medicine) (n=70; aged 60-83) groups. Acupuncture: 20-30 minutes session, total 20-30 sessions.</td>
<td>Effect rate: 98% in acupuncture with medicine group, 89% in drug group. Better scores in Mini-Mental State Examination (MMSE) and Activity Daily Living (ADL) in acupuncture and Chinese medicine group.</td>
<td>China.</td>
</tr>
<tr>
<td>Jia, Zhang [77]</td>
<td>To compare the effects of acupuncture and drug on Alzheimer’s disease.</td>
<td>87 patients (n=29 males, n=58 females). Unspecified age range</td>
<td>Distributed to the acupuncture (n=43; n=13 males, n=30 females), and drug (n=44; n=16 males, n=28 females) groups. Acupuncture: 30-minute session, 3 times a week, total 36 sessions. Drug: donepezil 5mg daily.</td>
<td>Better improvements in acupuncture group than in drug group. Side effect rate: 12% in acupuncture group, 16% in drug group.</td>
<td>China.</td>
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<tr>
<td>Li, Feng [95]</td>
<td>To compare the effects of Chinese and Western medicine and drug alone on dementia.</td>
<td>90 patients (n=41 males, n=49 females), aged 60-81</td>
<td>Randomly assigned to the Chinese and Western medicine (n=45; n=21 males, n=24 females; aged 61-80), and drug (n=45; n=20 males, n=25 females; aged 60-81) groups. No details of acupuncture intervention.</td>
<td>Effect rate: 98% in Chinese and Western medicine group, 87% in drug group. Side effect rate: 2% in Chinese and Western medicine group, 4% in drug group.</td>
<td>China.</td>
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<td>Li and Li [57]</td>
<td>To compare the effects of acupuncture at neck and bodily acupuncture on vascular dementia.</td>
<td>60 patients (n=38 males, n=22 females), aged 55-76.</td>
<td>Randomly distributed to the acupuncture at neck (n=30; n=20 males, n=10 females; aged 55-75), and acupuncture (n=30; n=18 males, =12 females; aged 55-76) groups. Acupuncture: 40-minute session, total 56 sessions.</td>
<td>Effect rate: 80% in acupuncture at neck group, 57% in acupuncture group.</td>
<td>China.</td>
</tr>
<tr>
<td>Liu, Zhao [102]</td>
<td>To compare the effects of Chinese and Western medicine on vascular dementia.</td>
<td>120 patients (n=71 males, n=49 females), aged 60-89.</td>
<td>Randomly allocated to the Western medicine (n=40; n=24 males, n=16 females), Chinese and Western medicine (n=40; n=22 males, n=18 females) and Chinese medicine (n=40; n=25 males, n=15 females) groups. No details of acupuncture treatment.</td>
<td>Effect rate: 78% in Western medicine group, 98% in Chinese and Western medicine group, 83% in Chinese medicine group.</td>
<td>China.</td>
</tr>
<tr>
<td>Nakamura, Huodo [68]</td>
<td>To evaluate the effects of acupuncture on vascular dementia.</td>
<td>56 patients (n=17 males, n=39 females), aged 60-100.</td>
<td>12 sessions. Unspecified session duration.</td>
<td>Significant improvements in physical, behavioural, and psychological activities.</td>
<td>Japan.</td>
</tr>
<tr>
<td>Ni [96]</td>
<td>To compare the effects of acupuncture with Chinese medicine and drug on Alzheimer’s disease.</td>
<td>65 patients (n=36 males, n=29 females); aged 65-80.</td>
<td>Allocated to the acupuncture with Chinese medicine (n=33; n=18 males, n=15 females; aged 65-79), and drug (n=32; n=18 males, n=14 females; aged 66-80) groups. Acupuncture: 30-40 minutes daily sessions, total 60 sessions. Drug: donepezil hydrochloride tablets 5mg daily.</td>
<td>Effect rate: 82% in acupuncture with Chinese medicine group, 59% in drug group.</td>
<td>China.</td>
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<td>Niu [97]</td>
<td>To compare the effects of acupuncture with Chinese medicine and drug on vascular dementia.</td>
<td>100 patients (n=56 males, n=44 females), aged 64-77.</td>
<td>Randomly assigned to the acupuncture with Chinese medicine (n=50), and drug (n=50) groups. No details of acupuncture treatment. Drug: donepezil 5mg daily.</td>
<td>Effect rate: 96% in acupuncture with Chinese medicine group, 78% in drug group. Significant improvements in memory, attention, calculation, recollection, and language ability in acupuncture with Chinese medicine group than in drug group.</td>
<td>China.</td>
</tr>
<tr>
<td>Tan, Ren [78]</td>
<td>To compare the effects of acupuncture and drug on vascular dementia.</td>
<td>60 patients (n=36 males, n=24 females). Unspecified age range.</td>
<td>Randomly allocated to the acupuncture (n=30; n=17 males, n=13 females), and drug (n=30; n=19 males, n=11 females) groups. Acupuncture: 30-minute daily session, total 30 sessions. Drug: nicergoline 20mg, 3 times a day, 30 days.</td>
<td>Effect rate: 93% in acupuncture group, 73% in drug group.</td>
<td>China.</td>
</tr>
<tr>
<td>Wu and Guo [101]</td>
<td>To compare the effect of combined treatment (acupuncture, Chinese medicine, drug) and drug on dementia.</td>
<td>56 patients (n=26 males, n=30 females). Unspecified age range.</td>
<td>Randomly distributed to the combined treatment (acupuncture, Chinese medicine, drug) (n=30; n=16 males, n=14 females), and drug (n=26; n=10 males, n=16 females) groups. Acupuncture: 1-minute session, twice a day, unspecified total sessions. Drug: donepezil 5mg daily; nicergoline 30mg, 3 times a day.</td>
<td>Effect rate: 83% in combined treatment group, 54% in drug group. Side effect rate: 10% in combined treatment group, 54% in drug group. Better improvements in self care and quality of life in combined treatment group than drug group.</td>
<td>China.</td>
</tr>
<tr>
<td>Yang, Yin [98]</td>
<td>To compare the effects of acupuncture with Chinese medicine</td>
<td>106 patients (n=55 males, n=51 females), aged 54-73.</td>
<td>Randomly allocated to acupuncture with Chinese medicine (n=53; n=27 males, n=26 females; aged 54-73), and drug (n=53; n=28 males, n=25 females; aged 54-71) groups.</td>
<td>Effect rate: 93% in acupuncture with Chinese medicine group, 74% in drug group.</td>
<td>China.</td>
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<td>Zhu [83]</td>
<td>To compare the effects of warming acupuncture and standard care on senile dementia.</td>
<td>92 patients (n=60 males, n=32 females), aged 58-82.</td>
<td>Acupuncture: unspecified session duration, total 30 sessions.</td>
<td>Effect rate: 91% in warming acupuncture group, 65% in standard care group.</td>
<td>China.</td>
</tr>
<tr>
<td>Cui, Li [58]</td>
<td>To compare the effects of various kinds of acupuncture on dementia.</td>
<td>226 patients (n=119 males, n=107 females), aged 58-79.</td>
<td>Randomly assigned to the warming acupuncture (n=46; n=28 males, n=18 females; aged 58-82), and standard care (n=46; n=32 males, n=14 females; aged 59-80) groups.</td>
<td>Effect rate: 12% in acupuncture on head group, 15% in bodily acupuncture group, 27% in acupuncture with Chinese acupuncture, 34% in multiple therapy group.</td>
<td>China.</td>
</tr>
<tr>
<td>Feng [103]</td>
<td>To compare the effects of combined treatment and drug on vascular dementia.</td>
<td>50 patients. Unspecified sex ratio and age range.</td>
<td>Distributed to the acupuncture on head (n=26), bodily acupuncture (n=34), hydro-acupuncture (n=29), acupuncture with Chinese medicine (n=61), and multiple therapy (n=76) groups. Acupuncture: 30-minute session, total 75 sessions.</td>
<td>Better improvements in the combined treatment group.</td>
<td>China.</td>
</tr>
<tr>
<td>He, Li [93]</td>
<td>To compare the effects of electro-acupuncture and manual acupuncture on</td>
<td>60 patients (n=34 males, n=26 females), aged 49-76.</td>
<td>Randomly assigned to the electro-acupuncture with Chinese medicine (n=30; n=18 males, n=12 females; aged 51-71), and acupuncture with Chinese medicine and rehabilitation programme</td>
<td>Better results in electro-acupuncture with Chinese medicine group.</td>
<td>China.</td>
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<td>vascular dementia.</td>
<td>(n=30; n=16 males, n=14 females; aged 49-76) groups. Acupuncture: 1-hour session, total 24 sessions.</td>
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<td>Liang [89]</td>
<td>To compare the effects of warming acupuncture and drug on senile dementia.</td>
<td>74 patients (n=52 males, n=22 females). Unspecified age range.</td>
<td>Randomly allocated to the warming acupuncture (n=37; n=27 males, n=10 females), and drug (n=; n=25 males, n=12 females) 37groups. Acupuncture: unspecified session duration, total 90 sessions. Drug: piracetam 0.8g, 3 times per day, 3 months.</td>
<td>Effect rate: 95% in warming acupuncture group, 70% in drug group.</td>
<td>China.</td>
</tr>
<tr>
<td>Liu, Wang</td>
<td>To evaluate the protective effect of acupuncture with donepezil hydrochloride for treating vascular dementia after stroke.</td>
<td>168 patients (n=106 male, n=62 female), aged 45-75.</td>
<td>Randomly assigned to 2 groups: taking donepezil hydrochloride (n=84; n=52 male, n=32 female), and taking donepezil hydrochloride with acupuncture (n=84; n=54 male, n=30 female). Donepezil hydrochloride: 5mg/day, once a day, 7 days a course, 8 courses.</td>
<td>Noticeable improvements in cognitive functions</td>
<td>China.</td>
</tr>
<tr>
<td>Shao [86]</td>
<td>To compare the effects of acupuncture with drug and drug only on dementia.</td>
<td>86 patients (n=44 males, n=42 females); unspecified age range.</td>
<td>Randomly distributed to the acupuncture and drug (n=43; n=24 males, n=19 females), and drug only (n=43; n=20 males, n=23 females) groups. Acupuncture: 30-minute daily session, unspecified total sessions.</td>
<td>Effect rate: 81% in acupuncture and drug group, 56% in drug only group.</td>
<td>China.</td>
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<tr>
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<td>Shi [66]</td>
<td>To assess the effects of acupuncture on vascular dementia.</td>
<td>36 patients (n=24 male, n=12 female). Unspecified age range.</td>
<td>Unspecified session duration and total sessions.</td>
<td>Improvements in cognition, memory, and language 14 days after treatment. Improvements in visual and spatial skills 28 days after treatment.</td>
<td>China.</td>
</tr>
<tr>
<td>Zheng and Zhang [79]</td>
<td>To compare the effects of acupuncture with Chinese medicine and drug on C-reactive protein among the elderly with dementia.</td>
<td>80 patients (n=47 males, n=33 females). Unspecified age range.</td>
<td>Randomly distributed to the acupuncture with Chinese medicine (n=40; n=24 males, n=16 females), and drug (n=40; n=23 males, n=17 females) groups. Acupuncture: 30-minute daily session, total 28 sessions. Drug: alprazolam 0.4mg, twice a day; paroxetine 40-60mg daily.</td>
<td>A greater decrease in C-reactive protein in acupuncture with Chinese medicine group than in drug group. Better improvements in self-care, self-esteem, language, and emotional control in acupuncture with Chinese medicine group.</td>
<td>China.</td>
</tr>
<tr>
<td>Guan [99]</td>
<td>To compare the effects of acupuncture and acupuncture with Chinese medicine on senile dementia.</td>
<td>68 patients (n=36 males, n=32 females), aged 60-85.</td>
<td>Randomly assigned to the acupuncture (n=34; n=17 male, n=17 female) and acupuncture with Chinese medicine (Six Flavour Rehmanni) (n=34; n=19 male, n=15 female) groups. 10 sessions a course, 3 course a cycle. Number of treatment courses: 3 (n=24), 4 (n=22), 5 (n=12), 6 (n=10).</td>
<td>88% (n=30) and 68% (n=24) showed significant improvements in acupuncture with Chinese medicine and acupuncture groups respectively.</td>
<td>China.</td>
</tr>
<tr>
<td>Li, Wang [82]</td>
<td>To compare the effects of scalp acupuncture point-through-point and general</td>
<td>60 patients (n=35 male, n=25 female), aged 50-77.</td>
<td>Randomly assigned to scalp acupuncture point-through-point (n=30; n=16 male, n=14 female), and general acupuncture (n=30; n=19 male, n=11 female) groups. Both groups: 60-minute per session, once a</td>
<td>83% in the scalp acupuncture point-through-point group showed improvements, while 60% in the general acupuncture group.</td>
<td>China.</td>
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<td>Re and Chen [67]</td>
<td>To look into the effects of scalp acupuncture on dementia.</td>
<td>54 patients (n=34 male, n=20 female), aged 66-84.</td>
<td>13-minute daily session, 10 times a course, 3 courses.</td>
<td>Improved cognitive functions, including orientation, calculation, and behaviour.</td>
<td>China.</td>
</tr>
<tr>
<td>Shi, Li [69]</td>
<td>To examine the effects of acupuncture on vascular dementia.</td>
<td>63 patients with routine care (n=29 male, n=34 female).</td>
<td>Randomised controlled trial. 3 groups: randomised acupuncture (n=22; n=12 male, n=10 female), non-randomised acupuncture (n=19; n=6 male, n=13 female), and control (n=22; n=11 male, n=11 female) groups. 1 30-minute session every alternate day, 6 weeks, maximum 21 sessions. Measurements: baseline, after 6-week treatment, and after 4-week follow-up.</td>
<td>Significant improvements in cognitive status and activities of daily life. Limited effects on health-related quality of life.</td>
<td>China.</td>
</tr>
<tr>
<td>Zhu, Cai [75]</td>
<td>To compare the effects of acupuncture and medication on dementia.</td>
<td>60 patients (n=33 males, n=27 females).</td>
<td>Randomly assigned to the acupuncture (n=30; n=17 male, n=13 female) and medication (n=30; n=16 male, n=14 female) groups. Acupuncture: 30-minute once a day, 6 times per week, 4 weeks a course, 2 courses. Medication: nimodipine 30mg, 3 times a day, 8 weeks.</td>
<td>The acupuncture group shows better improvements in cognition measured by Mini-Mental State Examination and Montreal Cognitive Assessment, high sensitivity C-reactive protein (hs-CRP) and interleukin-6 (IL-6).</td>
<td>China.</td>
</tr>
<tr>
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<tr>
<td>Liang, Wang [62]</td>
<td>To examine the effects of acupuncture on vascular dementia.</td>
<td>28 participants (n=14 patients with Alzheimer' disease, n=14 normal elders). Unspecified sex ratio and age range.</td>
<td>3-minute session, unspecified total sessions.</td>
<td>Effective on early dementia.</td>
<td>China.</td>
</tr>
<tr>
<td>Pan, Ge [80]</td>
<td>To compare the effects of acupuncture and medication on vascular dementia by measuring P300.</td>
<td>116 patients, aged 48-80. Unspecified sex ratio.</td>
<td>Randomly assigned to the acupuncture (n=58) and medication (n=58) groups. Intervention group: 30-minute daily session, 15 sessions a course, 3 courses. Control group: piracetam 0.8g, 3 times a day, 6 weeks a course.</td>
<td>Positive signs on P300, implying potential improvements in memory, cognition, and emotion.</td>
<td>China.</td>
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<tr>
<td>Shi [85]</td>
<td>To investigate the effects of acupuncture and medication on vascular dementia.</td>
<td>21 patients (n=14 males, n=7 females). Unspecified age range.</td>
<td>No details of treatment.</td>
<td>Improvements in cognition, memory, and language after 14-day treatment. Improvements in visual spatial skills after 28-day treatment.</td>
<td>China.</td>
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<tr>
<td>Wang, Liang [60]</td>
<td>To examine the effects of acupuncture on hippocampal connectivity in patients with Alzheimer’s disease using functional magnetic resonance imaging (fMRI).</td>
<td>28 participants (n=14 patients with Alzheimer’s disease, n=14 healthy elders). Unspecified sex ratio and age range.</td>
<td>3 minutes acupuncture. Unspecified total sessions.</td>
<td>Increased connectivity in most of the hippocampus related regions in Alzheimer patients (particularly the connectivity between the right middle front lobe and the left hippocampus) after acupuncture, but no evident connectivity in the right or left hippocampus. Tai Chong (LR3) and He Gu (LI4) affect the connectivity. The bilateral thalamus showed significantly higher connectivity with the left hippocampus, while the medial prefrontal cortex showed significantly lower connectivity with the left hippocampus. In addition, the left thalamus, middle frontal lobe, and insula showed significantly higher connectivity with the right hippocampus following acupuncture in the control group.</td>
<td>China.</td>
</tr>
<tr>
<td>Zhu [81]</td>
<td>To compare the effects of acupuncture and medication on dementia.</td>
<td>80 patients (n=35 male, n=45 female), aged 55-91.</td>
<td>Randomly assigned to the acupuncture (n=40; n=18 male, n=22 female) and medication (piracetam) (n=40; n=17 male, n=23 female) groups. Acupuncture: once a day, 10 days a course, 3 months; unspecified session duration. Medication: piracetam 1.4g, 3 times a day, 10 95% of the acupuncture group showed improvements in cognition, comparing to 75% in the medication group.</td>
<td>95% of the acupuncture group showed improvements in cognition, comparing to 75% in the medication group.</td>
<td>China.</td>
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<tr>
<td>Kwok, Leung [71]</td>
<td>To examine the effects of acupuncture on sleep problems of patients with dementia.</td>
<td>19 patients, aged 55-90. Unspecified sex ratio.</td>
<td>12 weeks: first 6 weeks for control stage, and the next 6 weeks for treatment. 12 30-minute sessions in 6 weeks.</td>
<td>Improvements in resting and sleeping time. No significant indicators of sleep efficiency and cognition.</td>
<td>Hong Kong.</td>
</tr>
<tr>
<td>Wang, Nie [61]</td>
<td>To inquire into the effects on acupuncture on mild cognitive impairment and Alzheimer disease.</td>
<td>36 patients (n=13 male, n=23 female; n=8 mild cognitive impairment, n=14 Alzheimer disease, n=14 healthy people). Unspecified age range.</td>
<td>3-minute session; unspecified total sessions.</td>
<td>Positively activate cognitive-related regions.</td>
<td>China.</td>
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<tr>
<td>Liu and Wang [100]</td>
<td>To compare the effects of acupuncture with Chinese medicine and Western medicine on vascular dementia.</td>
<td>60 patients (n=44 males, n=16 females), aged 45 years old.</td>
<td>Randomly assigned to the acupuncture with Chinese medicine (n=20; n=14 male, n=6 female), Western medicine (n=20; n=16 male, n=4 female), and control (non-treatment) (n=20; n=14 male, n=6 female) groups. Acupuncture with Chinese medicine: medicine 2 times a day, and acupuncture once a day. Unspecified session duration and total sessions of acupuncture. Western medicine: folic acid 10mg, vitamin B6 30mg, huperzine A tablet 0.1mg, twice a day. Measurements: pre-treatment, 3 months, and 6 months.</td>
<td>The acupuncture with Chinese medicine group showed more significant improvements than that in the Western medicine group. No improved signs showed in the control group.</td>
<td>China.</td>
</tr>
<tr>
<td>Ye, Ma [84]</td>
<td>To evaluate the effects of acupuncture (warming needle) on vascular dementia.</td>
<td>78 patients (n=56 males, n=22 females), aged 49-76.</td>
<td>Randomly assigned to 2 groups: intervention (routine treatment + acupuncture; n=39, n=27 male, n=12 female) and control (routine treatment; n=39, n=29 male, n=10 female) groups. Acupuncture: once a day, 5 days a course, 8 courses; unspecified session duration. Routine treatment: Bobath therapy. Measurements: baseline, 8-week, 3-month.</td>
<td>Improvements in neurological impairment, cognitive function, and daily activities; 91% in the intervention group, and 85% in the Bobath group.</td>
<td>China.</td>
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<td>Liu, Zhang [76]</td>
<td>To assess the effects of scalp acupuncture on vascular dementia.</td>
<td>92 patients. Unspecified sex ratio and age range.</td>
<td>Randomly assigned to the acupuncture (n=47) and medication (n=45) groups. Scalp acupuncture: 30-minute daily session, 6 times a course, 5 courses. Medication: nimodipine tablets, 40mg, 3 times a day, 30 days.</td>
<td>Improvements in cognitive function, and daily activities in the acupuncture group.</td>
<td>China.</td>
</tr>
<tr>
<td>Huang, Chen [63]</td>
<td>To investigate the effects of acupuncture on cerebral metabolism for rehabilitation of vascular dementia.</td>
<td>10 patients with vascular dementia and stroke experience, aged 62-75 years old (n=5) male, (n=5) female.</td>
<td>Randomly assigned to 2 groups with 20-minute acupuncture: Group A with acupuncture on Jianyu (LI15), Waiguan (SJ5), Hegu (LI4), Xuehai (SP10), Zusanli (ST36), Sanyinjiao (SP6) and Taichong (LR3), Group B with acupuncture on Jianyu (LI15), Waiguan (SJ5), Hegu (LI4), Xuehai (SP10), Zusanli (ST36), Sanyinjiao (SP6), Taichong (LR3), Baihui (DU20), Shuigou (DU26), and Shenmen (HT7). Unscheduled total sessions.</td>
<td>In group A (routinely treated patients) glucose metabolism was higher after treatment than before in the lentiform nucleus of the affected hemisphere and the temporal lobe of the non-affected hemisphere (p &lt; .05). In group B (VaD-specific needling), metabolism increased bilaterally in frontal lobes and thalami, as well as in the temporal lobe and the lentiform nucleus of the non-affected hemisphere (p &lt; .05).</td>
<td>China.</td>
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</table>
| Yu, Zhang [88]  | To examine the effects of acupuncture with medicine on vascular dementia.           | 60 patients (n=45 male, n=15 female). Unspecified age range.                  | Randomly assigned to treatment (horizontal insertion acupuncture, acupuncture + routine medication) (n=30; n=22 male, n=8 female) and control (acupuncture and routine medication) (n=30; n=23 male, n=7 female) groups.  
30-minute daily sessions for 6 weeks. Routine medication: antiplatelet agents (aspirin or ticlopidine), antihypertensive, diuretics and nimodipine. | Improved cognitive function, memory, and self care; 80% in the treatment group and 47% in the control group.                                                                                      | China.                                                        |
| Jin and Jin [90]| To compare the results of acupuncture and acupuncture with medicine for vascular dementia treatment. | 56 patients (n=31 male, n=25 female), aged 58-72.                           | Randomly assigned to the acupuncture (n=26) and combined treatment (n=30) groups.  
Acupuncture: 30-minute daily session, 2 months; unspecified total sessions. Medication: piracetam tablet, 3 tablets per dose, 3 doses a day, 2 months. | Both groups showed improvements, and the combined group showed more significant enhancements; 90% in the combined group and 84.1% in the acupuncture group.                  | China.                                                        |
<p>| Schwarz, Litscher [64]| To look into the effects of acupuncture on vascular dementia by increasing both cerebral oxygen saturation and cerebral blood flow velocity. | One (n=1) 77-year-old woman with cerebral-vascular dementia.                  | 7 10-minute sessions of acupuncture within 13 weeks, 10 with needles and 1 with a laser.                                                                                                                     | Improved cognitive function. Motor speech function, short memory, sleeping, and headaches were improved after the second treatment.                                                                      | Austria.                                                      |</p>
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<tr>
<td>Huang and Yu [65]</td>
<td>To inquire into the effects of acupuncture on vascular dementia.</td>
<td>17 patients. Unspecified sex ratio and age range.</td>
<td>30-minute daily sessions, 10 times per course, 2 courses.</td>
<td>Significant improvements in cognition and quality of life.</td>
<td>China.</td>
</tr>
<tr>
<td>Lombardo, Dresser [74]</td>
<td>To investigate the effects of acupuncture on anxiety and depression in persons with Alzheimer’s disease or vascular dementia.</td>
<td>11 patients. Unspecified sex ratio and age range.</td>
<td>30-minute times per week in the first week, 2-3 times a week in the 7th-10th weeks.</td>
<td>Improvements in anxiety and depression, but not significantly. Great improvements in energy.</td>
<td>USA.</td>
</tr>
<tr>
<td>Shen, Zhi [91]</td>
<td>To assess the effects of acupuncture with moxibustion on dementia.</td>
<td>90 patients, aged 53-86. Unspecified sex ratio.</td>
<td>Randomly assigned to 3 groups: Group 1, acupuncture and moxibustion (n=30); Group 2, medicine (n=30); and Group 3, acupuncture, moxibustion and medicine (n=30) groups. Acupuncture: 30-minute once a day, 15 days per course, 2 courses. Medicine: huperzine A tablets, 20mg, 3 times a day, 30 days.</td>
<td>Improved cognitive functions; 83% in Group 1, 67% in Group 2, and 93% in Group 3.</td>
<td>China.</td>
</tr>
<tr>
<td>Li, Zhuang [59]</td>
<td>To examine the effects of acupuncture on dementia.</td>
<td>30 patients (n=23 male, n=7 female), aged 54-80.</td>
<td>30-minute daily session, unspecified total sessions.</td>
<td>90% of patients showed improvements in cognition.</td>
<td>China.</td>
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4. Recommendation

Recommendations are discussed here regarding research and practical implications. Despite the results in this review which reported that dementia symptoms are mitigated by acupuncture or combined treatments, the sample sizes were usually less than 80 participants (n=29 projects). This lowers data reliability and negatively affects the representation and generalisation of the research outcomes. A larger sample size is suggested to gather robust data [104].

The effects of acupuncture on dementia have been demonstrated through this review. However, there is an absence of follow-up investigations [105], which causes difficulties in judging effect duration. Follow-up or longitudinal studies are therefore proposed to inquire into whether the effects of acupuncture are valid over the long-term.

Although there are randomised controlled trials in the reviewed projects (n=29), most of them did not detail their randomisation process or research design. It is justifiable to carry out well-designed randomised examinations to produce scientific and reliable data.

In light of Chinese medicinal theories, treatments are designed to meet individual needs. Thus, there is no protocol for acupuncture therapy [106] with different numbers of acupoints. If more elaboration on patterns of acupoint penetration had been presented, researchers could have studied in a more systematic manner.

Chinese medicine aims to strengthen life energy, focusing on prevention. Further study is therefore recommended on how acupuncture can delay the onset of dementia [107], which would optimise the advantages of acupuncture from the preventive perspective.

5. Conclusion

This narrative review analyses 44 clinical, human-based research projects conducted in Asia Pacific and North America with 3078 participants, aged 45-100. It offers an overview of how acupuncture can contribute to dementia by using acupuncture either singly or combined with other approaches. Acupuncture is comparatively safe and cost-effective when treatment is performed by a qualified, trained practitioner. According to this analysis, acupuncture is potentially effective in improving the cognition, memory, language, behaviour, emotions, and self-care of patients with dementia symptoms. It also proves that its combination with medications or other therapies can maximise these consequences. In short, acupuncture is suggested for preventive, remedial, and rehabilitative purposes; however, it does need further well-designed scientific research with more reliable data sets.

Author Contributions

The author is responsible for the entire process of writing up, revising, and approving the final version of this manuscript.

Competing Interests

There is no conflict of interest to declare with respect to the present manuscript submitted for publication.
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Review

Healthcare Clowning: Use of Specific Complementary and Alternative Medicine for Hospitalized Children

Alberto Dionigi *

Federazione Nazionale Clowndottori, Cesena, Italy; E-Mail: presidenza@fnc-italia.org

* Correspondence: Alberto Dionigi; E-Mail: presidenza@fnc-italia.org

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Abstract:
Clowning has a varied tradition and a long history. Recently, clowns have been adopted in the medical setting with the aim of decreasing the negative emotions that can be experienced during hospitalization and medical procedures, as well as inducing positive feelings in patients, their relatives, and the hospital staff. Due to an increase in the number of clowns working in hospitals and the large amount of interest shown in utilizing this approach, an increasing number of studies have focused on testing the efficacy of this complementary and alternative strategy. Here, we provide an overview of the concept of healthcare clowning followed by a literature review of 28 randomized controlled trials (RCTs) drawn from two databases (PubMed and Google Scholar), with the aim of investigating and discussing evidence for the effects of healthcare clowning on children. The search revealed the different settings in which RCTs have been conducted: preoperative areas, during medical procedures, and during hospitalization. The search also revealed the different outcomes that were measured. In general, the results show that clown interventions are effective in decreasing negative emotions and psychological symptoms and in enhancing the well-being of patients and their relatives. Appreciation of clown interventions by healthcare staff has also increased in recent years.

Keywords
Clown; clown doctor; children; humor; positive emotions; complementary medicine
1. Introduction

Clowns have entertained people for centuries and, for a considerable period of time, they have also been involved in the healing process. In fact, it is believed that clowns were present in ancient Greece during the time of Hippocrates because doctors were aware that humor affected health positively [1]. At the end of the 19th Century, the Fratellini Brothers, a famous clown trio, started visiting pediatric patients admitted to hospitals in France. However, interest in the field of healthcare clowning has grown only during the last 30 years [2]. This increase in public interest is attributable to the work of Michael Christensen, a professional clown who worked in the Big Apple Circus in New York. In 1986, this circus established the first Clown Care Unit that was active in a pediatric department and following this example, several associations were shortly established worldwide. More recently, the influence of the American medical doctor, Hunter “Patch” Adams, expanded this movement to include volunteers. The art of clowning in healthcare settings now includes varied practitioners, ranging from well-intentioned volunteers to professional clowns [1]. These practitioners are required to undergo comprehensive training through which they learn the artistic skills and the strategies for dealing with psychological issues in the healthcare system [3]. Healthcare clowning is an interdisciplinary art that involves a wide variety of skills, such as humor, magic, and music, that exert a therapeutic effect on patients and relatives [2]. Thus, it represents a complementary and alternative medicine (CAM) approach aimed at providing humor-based distraction for improving the mood of hospitalized pediatric patients [3]. Here, we provide an overview of the current knowledge regarding the effectiveness of clown interventions in reducing the psychological distress of hospitalized pediatric patients.

2. Literature Review

Limited research has been conducted in the field of healthcare clowning; to our knowledge, the first study that evaluated the efficacy of clown interventions in decreasing anxiety among pediatric patients was published in 2005 [4]. Thus, we first conducted a literature search of the PubMed database for reports published from January 2005 to February 2018 to identify empirical studies involving pediatric patients. We used the search terms “clown”, “clown doctor”, “medical clown”, and “children”. The search terms were used for all fields (including the title, abstract, keywords, and full text). In the first search, we did not limit the search by the language used. A total of 95 reports were identified in this search.

Among the papers screened, we included those that: (a) provided empirical evidence about the impacts and outcomes of clown interventions on hospitalized pediatric patients, (b) included a pediatric population, and (c) included only randomized controlled trials (RCTs) or quasi-RCTs. Meta-analyses, case studies, and studies published in a language other than English were excluded. The titles, abstracts, and full texts of the included manuscripts were examined. A total of 23 papers were identified. Thereafter, we screened the Google Scholar database to identify additional research papers. Using the same selection criteria described for the initial search, we identified five additional research papers in this second search. Thus, a total of 28 papers that met the inclusion criteria were identified as being relevant to the current literature review.
3. Results

As a result of the literature review, we identified 28 reports involving studies that: (a) assessed the effects of clown interventions on pediatric patients (and their parents) in the preoperative area, (b) were conducted on pediatric patients undergoing medical procedures, or (c) were conducted during the hospital stay of pediatric patients.

3.1 Effects of Clown Interventions on Children and Parents in the Preoperative Area

Hospitalization and surgery have always been considered negative experiences that can exert considerable health effects on adults and children [5]. Even minor pediatric surgery may have negative consequences on the emotional, behavioral, cognitive, and educational development of a child, and it is estimated that approximately 50% of children experience anxiety while undergoing surgery [6]. Several studies have focused on the ability of healthcare clown interventions to decrease the negative emotions experienced by pediatric patients during the preoperative period. To the best of our knowledge, the first study in this field was performed in Italy in 2005 [7] with the aim of investigating the effects exerted by the presence of a clown on a pediatric patient’s preoperative anxiety during anesthesia induction for minor surgery. In this study, 40 children (aged 5–12 years) were randomly allocated to the experimental group (n = 20) and the control group. Two professional clown doctors interacted with the experimental group patients (accompanied by one parent) during the move from the ward room (WR) to the operating room (OR), while the control group patients received standard care (accompanied by one parent with no other distractions). Preoperative anxiety was assessed by two psychologists using the Modified Yale Preoperative Anxiety Scale (m-YPAS), which is an observational behavioral checklist. Parental anxiety was assessed using the State–Trait Anxiety Inventory. The assessment was carried out both in the WR and in the OR during the induction of anesthesia. The results showed that, during the induction of anesthesia, the anxiety of the patients in the experimental group was significantly lower than that of those in the control group. However, there was no significant difference between the scores of the parents in the two groups, although the parents of the experimental group patients had lower levels of anxiety.

A Portuguese study conducted in 2010 [8] evaluated the ability of clown interventions to reduce the preoperative anxiety of 70 children (aged 5–12 years) scheduled to undergo minor surgery, while also considering parental anxiety. In contrast to the first study, self-reporting measures were used instead of the evaluations of an external observer in this study; both the children and the parents in the clown group showed a reduction in preoperative anxiety and emotional responses. In contrast, an Italian study conducted in 2014 on 77 children (aged 3–11 years) showed that clowns helped reduce anxiety even when they were present only in the preoperative room and were not involved in the medical procedure in the OR [9].

An Israeli study conducted in 2009 [10] divided pediatric patients (aged 3–8 years) into the following three groups: Group 1 (no premedication; no clown); Group 2 (midazolam administered 15–30 min before surgery); Group 3 (two clowns present in the preoperative holding area and accompanied the patient to the OR until anesthesia-induction). Video recordings were made of the patients for later use in grading. The study showed that clowns alleviated preoperative anxiety, although there were no significant differences among the three groups during the anesthesia mask induction. Furthermore, the clown group had the largest increase in the m-YPAS score. The
main limitation of this study was that the interventions were identifiable owing to the occasional appearance of the clowns in the videos of the EG patients.

In a more recent trial conducted in Italy in 2010 [11], a total of 75 patients (aged 5–12 years) patients were also randomly assigned to one of three groups to determine differences in the effects of parental presence, clowns, or sedative premedication on preoperative anxiety. The results showed that the anxiety of children in the clown group was significantly lower than that of those in the premedication and control groups, with no significant differences found between the latter two groups.

A later study aimed at evaluating the potential of psychological interventions (clowns, dog interaction, and music) to reduce anxiety and fear levels was conducted in a sample of Italian patients [12]. One hundred-five children (aged 4–11 years) enrolled for MRI examinations, were assigned to the experimental group (15 children interacted with a clown, 12 with dogs and 13 with musicians) and 65 children were assigned to the control group. The results confirmed the high effectiveness of the three interventions in reducing the level of anxiety and fear and decreasing the need for sedation in the experimental groups compared to the control group.

Although the majority of the results are positive, some studies show methodological limitations that can affect the results. A study of the efficacy of clown interventions in lowering preoperative anxiety compared to the effect of toys and video games in a large sample of Italian children (aged 5–12 years) had various limitations. [13]. The study involved an experimental group of 444 children, and a control group of 441 children who were not accompanied by clowns in the waiting room and were free to play with toys and video games. Patients assigned to the experimental group experienced less anxiety during anesthesia-induction than those in the control group. However, the study design was unclear because the authors did not specify the number of children who used toys or video games.

A RCT conducted in Portugal in 2016 [14] aimed to test the effectiveness of clown doctors in reducing anxiety among children undergoing general surgery and in their parents who accompanied them. The sample consisted of 88 children (n = 44 per group) aged 4–12 years. The results confirmed that clown interventions reduced the anxiety in the children’s caregivers; however, the results did not support the hypothesis related to the ability of clown interventions to reduce anxiety in children. One possible reason for the lack of effectiveness in children may be the combination of setting and sedation that may have regulated anxiety.

In recent years, some studies have focused not only on decreasing anxiety, but also on evaluating other interesting outcomes. One RCT evaluated the effect of healthcare clowning on a sample of 80 children (aged 2–16 years) scheduled to undergo outpatient penile surgery (meatotomy) [15]. In addition to having lower anxiety levels, the children accompanied by clowns required a reduced anesthesia-induction time, spent less time in the , and were discharged earlier.

A recent German study [16] investigated the ability of clown interventions to induce positive psychological and physiological effects in hospitalized pediatric patients. Thirty-one children (aged 4–13 years) were randomly assigned to a clown group (n = 17) or a control group (n = 14). Both physiological (saliva samples for oxytocin measurement) and psychological parameters (children’s anxiety, worries, and well-being) were assessed. Children in the intervention group showed lower levels of anxiety and higher oxytocin concentrations at T2 than at T1, while the control group showed no changes.
Finally, a combined intervention of art therapy and clown visits was shown to enhance the efficacy of oral medication in reducing preoperative anxiety in pediatric patients [17]. Seventy-eight children (aged 3–11 years) who were administered general anesthesia for surgery were divided into the standard practice (n = 41) and intervention (n = 37) groups; the intervention group received both art therapy and clown visits. The combination of the two different CAMs significantly reduced the anxiety of the children in the intervention group; however, it was not possible to define the efficacy of each CAM approach.

3.2 Presence of Clown Doctors during Medical Procedures

Recently, the efficacy of clown doctor interventions has been investigated in children undergoing painful medical procedures. In fact, children often experience anxiety when undergoing medical treatment, and learn to associate these treatments with anxiety. Anxiety occurs when an individual’s well-being is threatened or endangered in any manner [18]. Patient anxiety reduction is categorized as behavioral, cognitive, physical, emotional, or pharmacological [19], and clown interventions provide the benefit of humor and positive emotions, encompassing all the categories mentioned, except pharmacological [20]. Therefore, clown interventions can be defined as a CAM approach.

One of the first studies in this area was conducted in Denmark [21] on 60 pediatric patients with spastic cerebral palsy. It assessed the effectiveness of the performance of a female clown in reducing a child’s crying during the administration of botulinum toxin. The research showed mixed results, with positive results in girls, while boys under the age of 8 years showed negative effects, and no effect observed in children treated for the first time. Only a female clown was involved in the intervention; therefore, it is reasonable to conclude that a sex-related correlation may be established.

Several other studies yielded mixed results. A quasi-experimental study was conducted to assess the role of a clown in reducing negative emotions during anogenital examination in 30 children (aged 1–17 years) who were allegedly abused [22]. Results indicated that children who were visited by a clown (n = 24) showed significantly lower levels of fear and pain and had a less severe perception of the invasiveness of the procedure, while there was no difference in hyperarousal and avoidance behavior. One limitation of the study was that there was no evaluation before the intervention, although the authors attempted to bridge this gap by performing a retrospective survey among the children about their level of fear before the evaluation.

The effect of clown interventions on the pain experienced by 47 pediatric emergency patients (aged 3–16 years) during intravenous administration was also evaluated [23]. Clown interventions were found to be effective only in those aged 4–7 years, while no significant differences were observed in those aged 8 years and older. It is noteworthy that the clown intervention reduced the lower levels of anxiety only among the parents of older children. This lack of a “clown effect” in the parents of younger children may be attributed to the fact that they were more involved in reassuring their children and were therefore not so focused on the clown’s performance. Thus, this group of parents were less able to benefit from the “calming” effect of the clown’s intervention.
Two recent Israeli studies showed that clown interventions were helpful in reducing pain perception in pediatric patients with juvenile idiopathic arthritis during the administration of intra-articular corticosteroids [24]. The researchers evaluated procedural pain during the injection of nitrous oxide (NO2), asking the patient, parents, physicians, healthcare clowns, and nurses to rate their pain by completing a visual analog scale (VAS) ranging from 0 to 10. Thirty-two children (23 girls and 9 boys) participated in the study of 46 procedures. The presence of the clown helped reduce pain and stress in patients, although five patients had increased heart rate and experienced increased pain. The main limitation of this study was the lack of a control group; however, data were compared to the findings from a similar study that did not involve the use of a clown.

Another study confirmed that clowns were effective in decreasing anxiety and pain in children undergoing allergy skin prick tests [25]. In this blinded RCT, 91 children (aged 2–17 years) were randomly assigned to either the control group or the experimental group. Anxiety was assessed using the m-YPAS, and pain was assessed using the Face, Legs, Activity, Cry, Consolability (FLACC) scale. One of the main limitations of this study was that an external observer made the evaluations.

Clowns were effective in reducing the duration of crying as a subjective assessment of pain level in 100 Israeli children (aged 2–10 years) during withdrawal of venous blood [26]. However, the lowest level of pain was experienced by a child in the group that received local anesthetic cream, and the levels were not significantly altered by the clown intervention. The control group had the shortest pain duration for the entire process compared to that of the other two groups. A similar study was conducted to investigate the ability of healthcare clown interventions to reduce a child’s distress during venipuncture [27]. A total of 53 Israeli children (aged 2–15 years) were randomly assigned to the healthcare clown group (n = 29) or the control group (n = 24). The healthcare clown intervention reduced the distress caused by venipuncture in children, although there was no effect on the cortisol levels, indicating that clown intervention was more helpful in decreasing the psychological symptoms than the physiological symptoms.

These results were in accordance with those of a quasi-RCT conducted in Italy that evaluated the effectiveness of clown visits in 40 children (aged 4–11 years) undergoing painful procedures in an emergency department [28]. The outcome measures were the clown’s influence on the patient’s procedural pain and anxiety. The study showed that the pain levels in the two groups remained unchanged; however, the anxiety levels were significantly lower in the clown group. A recent study [29] on 142 Israeli patients (aged 0–5 years) investigated the ability of clown interventions to prevent the need for sedation in young children. The main aim of the clowns was to encourage the child to cooperate during the procedure. Only five children (3.2%) required pharmacologic sedation after the intervention compared to 100% before it, indicating the potential of clown interventions as a good alternative to sedation in cases where the procedure does not involve pain and only requires the child’s cooperation.

One study investigated the impact of clown interventions on pain during recurrent botulinum toxin injections in children with cerebral palsy [30]. A total of 45 children (aged 1.5–18 years) were randomized to receive either clown (n = 20) or standard care (n = 25). Assessment of pain VAS before and after the procedures showed lower levels of pain experienced during the procedure among the children receiving clown care compared with those receiving standard care. In another Israeli study, 93 children (aged 2–6 years) who required physical examination in the pediatric
emergency department were recruited and randomly assigned to one group that underwent physical examination conducted by a pediatrician in the presence of caregivers (n = 49) or another examined with the assistance of a healthcare clown (n = 44) [31]. Results showed that the duration of discomfort was shorter in the clown group. Moreover, 94% of pediatricians reported that the healthcare clown improved their ability to perform a complete physical examination.

3.3 Studies Conducted on Hospitalized Children Receiving Visits from Clown

In healthcare settings, clown doctors often conduct “clown rounds”. In this parody of medical rounds, clowns ask permission before entering the patient’s room to improvise a visit with the aim of distracting the patient and his/her relatives from boredom and reducing the stress and anxiety caused by hospitalization [32].

Few studies have been conducted to evaluate the effect of clowns in reducing negative emotions during medical rounds. An Italian RCT [33] assessed the role of clowns in decreasing symptoms in 43 pediatric patients hospitalized for respiratory pathologies. During their hospital stay, 21 patients in the experimental group received clown visits lasting almost three hours, while 22 children assigned to the control group received no clown visits. The experimental group showed earlier disappearance of pathological symptoms and significant lowering of diastolic blood pressure, respiratory frequency, and temperature than that in the control group.

A Canadian study assessed 10 individuals (aged 4–21 years) with differing levels of disability [34] over a period of four days after receiving alternating the control (days 1 and 3) or intervention (days 2 and 4). On the day of the intervention, the children engaged in an interactive performance lasting 15 minutes with a pair of clowns. On the control day, the children watched a television (TV) comedy show of the same duration. The outcomes measured on each day consisted of physiological, behavioral, emotional, and verbal responses. The clown intervention led to significantly positive changes in all the responses (physiological, behavioral, emotional, and verbal) compared to those recorded in the control group. The limitations of this study were the small sample size and the large age range of participants.

Recently, a Turkish study investigated the effect of hospital clowns on anxiety and depression levels of pediatric patients and their mothers during their hospital stay [35]. A total of 99 children (aged 7–13 years) and their mothers were randomly divided into the clown group (n = 50) and the control group (n = 49). The presence of clowns during the hospital stay was found useful for managing the patient’s anxiety and depression; however, it was not efficient for lowering the anxiety of their mothers.

A Brazilian study on 36 children (aged 6–7 years) diagnosed with any acute pathology [36] aimed to evaluate the role of clown doctors in reducing stress by assessing the children’s responses using physiologic (salivary cortisol level) and psychological measures (VAS score). The clowns performed at lunchtime and at dinnertime; 18 children were randomly assigned to the lunchtime performance and 18 to the dinnertime performance. Each child served as his/her own control. Assessment of the outcome measures before and after the clown doctor activities revealed a reduction in salivary cortisol levels after the clown doctor intervention in both groups. Furthermore, a significant difference was observed in the VAS scores of the lunch group.

A recent and innovative study assessed the influence of culture on the effects of healthcare clowning interventions on anxiety and pain among a group of 89 children (39 Jewish and 50
Bedouin) aged 7.5–12 years [37]. Although the clown visits reduced the pain and anxiety in both cultural groups, anxiety levels were reduced more significantly among the Bedouin children. Furthermore, the anxiety reduction in this sample was mediated by verbal components.

Finally, we report one of the few studies assessing positive emotions due to clown interventions [38]. A total of 100 patients (aged 6–14 years) were randomized to a clown visit group (n = 50) or a no-visit control group (n = 50). Positive emotions were assessed using a modified version of the KINDer Lebensqualitätsfragebogen questionnaire at three time points; before the clown visit (pre-test), immediately after the clown visit (post-test), and four hours after the visit (follow-up). Clown visits induced positive emotions at the second assessment in both the children and their parents; however, the effects were not maintained at follow-up. Moreover, the clown visits did not alter the perceived physical well-being. These results confirmed that although clown visits improve the psychological well-being of pediatric patients and their relatives, the effects are short-lived, and there is no effect on the physiological symptoms.

4. Discussion

One of the main goals of clowning is to bring smiles and laughter to an audience of people of all ages. Today, healthcare clowning is an integral part of the healthcare system. In the previous 30 years, the number of clown doctors has increased significantly both in the US and Europe [39]. They use humor, empathy, and sensitivity to support, divert, and help patients, their relatives, and hospital staff in dealing with concerns over healthcare and medical treatment. Clown interventions have several aims including seeking to parody the medical routine to distract pediatric patients during medical procedures and to induce positive emotions while reducing negative emotions in patients and caregivers. This approach also aims to stimulate humor and playfulness, support relationships, and provide a safe and positive environment where the patient can undergo medical procedures; thus, it can be considered a CAM approach [3].

This area of research is relatively new; to our knowledge, the first study was published in 2005. However, since then, the effect of clowning interventions in several clinical settings has received increasing attention [3]. The literature review presented here demonstrates how most controlled trials of the impact of clown doctor interventions on children have highlighted the positive effects, although the results are conflicting. The most significant efforts to promote controlled trials of the efficacy of clown interventions in children are being made in Israel (12 studies) and Italy (8 studies). Reports of two studies in Germany and Portugal have been also been published, while there are reports of only one study each from Brazil, Denmark, Canada, and Turkey.

This review of the RCTs conducted on children (and in some cases on parents as well) has highlighted the fact that most studies have focused on decreasing the negative emotions (such as anxiety, pain, and stress) experienced by children. Only a few aimed to study the increase in positive emotions, such as improving the hospital atmosphere and bringing something positive, unexpected, and unconventional to the experience. Moreover, some studies showed no significant effect on the outcomes and concluded that clown interventions did not help parents cope with their anxiety [7, 10]. There are various problematic issues associated with the investigation of evidence regarding the efficacy of clown interventions. Nevertheless, the evidence available to date suggests that there is a wide variety of possible applications for the activity of clown doctors.
Rigorous evaluation of the therapeutic effect of clowning is complex. This complexity is due to several factors:

1) Clowning is a complex multi-modal intervention established according to medical conditions, procedures, family functioning, and healthcare teams [40]. Separating each aspect may be an area for further research.

2) During their performance, clown doctors are required to adapt their techniques for each patient, remembering that their goal is to improve the emotional state of the patient [2]. This means that a standard intervention among different patients with various conditions may not always be possible. It is important that clown doctors have the ability to improvise according to the current situation, based on the patient’s medical and psychological condition. This, inevitably, makes it challenging to implement a standardized approach, as would be required in a RCT.

3) The studies reviewed here involve both professional and volunteer clowns. Some RCTs involved one clown, while others involved two clowns, and very few reports [9, 27] include details of the training or expertise of the clowns. This aspect requires clarification in future research because a single clown and a pair of clowns may have a different relational impact on the intervention recipients.

4) The majority of the published studies have focused on the presence of clown doctors in the anesthetics area, replicating the study design first established by Vagnoli and colleagues [7]. Moreover, in some cases, the outcome measures were different. Further studies in other settings, such as oncology, emergency, and pediatric departments, using different study designs are warranted.

5) The studies also differed in the manner of outcome evaluation (self-evaluated or evaluated by others, such as trained psychologists). Several studies assessed the anxiety experienced by children using the m-YPAS and noted that while attempts were made to blind the observers, achieving a true blind observation is challenging because children may talk about their experience with the clowns. In the case of studies that used video recordings, the clowns may rapidly appear in a video or children may directly focus their attention on the clown, and therefore, be easily identified as a member of the experimental group. Moreover, several studies of children’s anxiety and pain showed no significant reduction in pain perception. Further studies should focus on the effects of the non-pharmacological techniques (e.g., distraction, storytelling, music, and soap bubbles) used by clown doctors.

6) Although a healthcare clown’s purpose is to bring joy and laughter in healthcare settings, with positive psychology as the theoretical background, the majority of the studies have focused on the ability of clowning to decrease negative emotions. Only a few studies have investigated the nature of the positive emotions elicited. This information gap should be addressed in future research.

Despite these limitations, research shows that clowns generally play a positive role in reducing the negative emotions both in hospitalized children and their parents, although rigorous research is warranted to confirm these results.

Author Contributions

The author is responsible for the entire process of writing up, revising, and approving the final version of this manuscript.
Competing Interests

The authors have declared that no competing interests exist.

References

A Multi-modal Intervention after Stroke: The Caregiver Experience

Katie M. Hinsey, MS, OTR/L \(^{1,2,†,‡}\), Karen E. Atler, PhD, OTR/L \(^{1,†}\), Christine A. Fruhauf, PhD \(^{3,†}\), Ruby A. Boster, MS, OTR/L \(^{1,4,†,‡}\), Marieke Van Puymbroeck, PhD, CTRS, FDRT, RYT-200 \(^{5,†}\), Arlene A. Schmid, PhD, OTR/L, FAOTA, RYT-200 \(^{1,†}\)

1. Colorado State University, Department of Occupational Therapy, Fort Collins, CO, US; E-mails: katie.hinsey@rmktherapy.com; karen.atler@colostate.edu; Rbolster@craighospital.org; arlene.schmid@colostate.edu
2. Rocky Mountain Kid Therapy, Northglenn, CO, US; E-mail: katie.hinsey@rmktherapy.com
3. Colorado State University, Department of Human Development and Family Studies, Fort Collins, CO, US; E-mail: Christine.fruhauf@colostate.edu
4. Craig Hospital, Department of Occupational Therapy, Englewood, CO, US; E-mail: Rbolster@craighospital.org
5. Clemson University, Department of Parks, Recreation, and Tourism Management, Clemson, SC, US; E-mail: mvp@clemson.edu

‡ Current Affiliation: if any

† These authors contributed equally to this work.

* Correspondence: Arlene A. Schmid, PhD, OTR; E-Mail: Arlene.schmid@colostate.edu

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Abstract:

**Background:** A fall prevention intervention was delivered to people with chronic stroke (Merged Yoga and Occupational Therapy intervention-MY-OT). All caregivers were invited to also attend the 8-week intervention and were included in these analyses.

**Methods:** The aim of this study was to examine changes in caregiver burden, positive aspects of caring, and caregiver’s experiences after participating in the MY-OT intervention. This was a secondary data analyses and the purpose of this mixed-methods study was to
quantitatively assess changes in caregiver burden (Zarit Burden Interview) and positive aspects of caregiving (Positive Aspects of Caregiving scale) and qualitatively explore the experience of the caregivers who attended the intervention. Focus groups and individual interviews with the caregivers were completed, transcribed, and reviewed. Qualitative data were analysed to identify emergent themes that described the caregiver experience.

**Results:** The average age of nine caregivers was 64.86 years old and most caregivers were female (66%). Caregivers who attended the MY-OT intervention (n=6) demonstrated less caregiver burden (47% decrease) and more positive aspects of caregiving (26% increase) than those who did not attend (n=3). Four qualitative themes emerged and included: positive changes in daily life; being in the present; new learning opportunities for the dyad and individual; and building a sense of community.

**Conclusions:** In this small sample of caregivers, yoga and occupational therapy appeared helpful in reducing caregiver burden, increasing positive aspects of caregiving, and contributing to positive experiences over all. Future research studies should be developed to include the caregiver and address the caregiver dyad.

**Keywords**
Caregiver; dyad; yoga; occupational therapy; self-management; stroke

### 1. Introduction

In the United States, informal caregivers provide the equivalent of $470 billion dollars of care annually, fulfilling an integral role within the healthcare system [1]. Informal caregivers are the unpaid helpers of those who are unable to fully care for themselves, usually individuals with complex medical needs and chronic conditions. Currently, 39.8 million Americans are informal caregivers, and of that, 59% are caring for someone with a chronic condition [2], such as stroke. Stroke results from a disruption of blood flow to the brain that affects 6.6 million Americans [3] and may lead to significant physical, cognitive, and functional deficits. Caregiving for people with stroke often requires providing assistance with daily living, self-care, medication management, community access, and socialization [2].

Together, the caregiver and the care recipient become a caregiver dyad. This is a close, interconnected dyadic relationship where the outcomes of one person wholly affect the other [2, 4]. Due to the intensity of the caregiving role, caregivers often experience negative effects, which is known as caregiver burden. Significant burden is experienced by 25-54% of informal caregivers [5] and can result in: decreased mental health including high levels of stress and emotional distress; restricted social participation; and increased risk for health conditions [6, 7]. In contrast, Mackenzie and Greenwood (8) found that positive aspects of caregiving also exist and may include: a sense of purpose; closer relationships; inner strength; and skill acquisition. Caregivers with higher levels of positive aspects of caregiving report greater life satisfaction despite higher levels of burden [9]. As such, it is necessary to provide interventions for caregivers that increase these positive aspects of caregiving in order to mediate the burden and negative aspects of caregiving.
Current caregiver interventions for caregivers of people with chronic stroke fall within one of three types: psychoeducational; creating support; and skill building [10]. Specific interventions for caregivers include mentoring; self-management; support groups; and respite [11, 12]. However, there are a lack of evidence-based interventions for caregivers that are multimodal or target the dyad together [13]. Furthermore, there is a significant need for interventions that address the caregivers’ mental, physical, emotional, and cognitive health as a result of lifestyle changes within their caregiving role.

Considering this need, yoga has been found to positively affect caregivers’ mental, physical, emotional, and cognitive health. Measured outcomes show yoga leads to improved: stress; anxiety; depression; lower body strength; coping abilities; and quality of life [14-16]. However, yoga alone may not be enough to address ways in which caregivers can manage their health effects and organize their daily lives to optimize positive health outcomes. Therefore, Lambert, Duncan (17) recommend taking a multi-modal approach and combining physical activity with self-management to holistically address caregiver’s needs.

Self-management interventions build skills in individuals with chronic conditions to manage their health within their daily lives [18]. Preliminary research shows that within the caregiver dyad, self-management can contribute to both the caregiver and care recipient’s sense of self-efficacy, improved quality of life, and engagement in daily activities [19, 20]. Occupational therapy (OT) has been shown to improve caregivers’ management of their multiple roles and participation in valued activities [21, 22] through self-management and group therapy interventions across environments [23]. Specifically, an OT-led group format can provide group cohesiveness, instil hope, and promote interpersonal learning [24]. This group format has also been found to be effective for community dwelling older adults in addressing physical function, social function, role limitations, and general mental health [25]. Thus, combining yoga and group OT may be an effective way to address caregiver’s psychosocial and physical needs.

To date, no research has been conducted examining yoga and group OT together as an intervention for caregivers of people who have had a stroke. However, results of studies using yoga and OT with other populations are encouraging [26, 27]. Yoga and group OT together could likely address multiple caregiver needs. The purpose of this multi-methods study was to assess the impact of the Merging Yoga and Occupational Therapy (MY-OT) intervention on caregivers of people living with chronic stroke.

Ethics Statement

Institutional Review Board approval was received for the full study. All caregiving participants provided written informed consent prior to participating in the study.

2. Materials and Methods

2.1 Design

This was a secondary data analysis, as the primary research intervention and questions were related to fall prevention in people with chronic stroke [27]. All caregivers were invited to also attend the MY-OT fall prevention intervention; this current study was a mixed-methods study exploring the experience of the informal caregivers who attended the intervention. We included
two quantitative measures, assessing caregiver burden and positive aspects of caregiving, and completed focus groups or interviews after the intervention.

2.2 Recruitment and participants

People with stroke were recruited to the study via local stroke support groups, flyers, and contact lists. Thirteen people with stroke participated in the MY-OT study, individuals had to be six months post stroke, have a fear of falling, and have impaired balance [27]. The majority of stroke survivors (77%) had the stroke more than five years ago. Nine study participants identified an informal caregiver; all nine caregivers were contacted to be recruited to attend the MY-OT intervention. Caregivers then self-selected between attending the MY-OT intervention with their care recipient (n=6) or not attending the intervention (n=3). Regardless of attending MY-OT, all nine caregivers were asked to engage in data collection; seven completed assessments, eight attended the focus group, and seven completed the interview, therefore each provided written informed consent prior to participating in the study.

2.3 Intervention

The MY-OT intervention included yoga and group OT twice a week for eight weeks and was developed to address fall prevention for people with stroke. The intervention was not designed to address caregiver outcomes, however we invited caregivers to attend the intervention and complete caregiver related outcome assessments as there is evidence that including the caregiver may be beneficial to both members of the caregiving dyad [28, 29].

Hatha yoga was led by a registered yoga teacher (RYT). The yoga protocol was a standardized progression of physical poses (asana) in sitting, standing, and supine. The yoga protocol was developed to improve balance, strength, and range of motion in lower extremities for people who have had a stroke. Yoga also included breath work (pranayama) and mantras related to stroke recovery. Guided meditation (dhyana) with relaxation was also completed at the end of each yoga each session. The OT sessions were approximately 45-50 minutes and consisted group OT focusing on managing fall risks and preventing falls. The OT was led by a registered and licensed occupational therapist (OTR/L). OT sessions included education, training, and self-management techniques to mitigate future fall risks for participants. Additional MY-OT intervention details were previously published [27].

2.4 Procedures

All caregivers, regardless of attending MY-OT were asked to complete the quantitative assessments and qualitative data collection in focus groups and interviews.

2.4.1 Quantitative data collection

Data were collected by a trained researcher using standardized assessments. Caregiver demographics such as age, race, gender, education level, and time since the care recipient’s stroke were collected. Variables of interest were caregiver burden (CGB) and positive aspects of caregiving (PAoC). These were measured using the Zarit Burden Interview (ZBI) and the Positive Aspects of Caregiving (PAoC) scale, respectively.
Caregiver Burden. The ZBI is a 22-item questionnaire on which caregivers provide ratings (0-4, “never” to “almost always”) about their perceptions of burden in their caregiving relationship. Total potential scores range from 0-88, with the following interpretations: little or no burden (0-20), mild to moderate burden (21-40), moderate to severe burden (41-60), severe burden (61-88). Items generally address the ideas of personal strain and role strain related to the impact of caregiving in the caregiver’s daily life [30]. The ZBI has been found to be a valid and reliable measure for caregivers of people who have had a stroke [31].

Positive Aspects of Caregiving. The PAoC is an 11-item questionnaire that uses a 1-5 rating scale (“I disagree a lot” to “I agree a lot”) where potential scores range from 1-45, with higher scores indicating greater PAoC. Caregivers rate phrases that address their mental and emotional state in relation to their caregiving role. An example of one such question is: “Providing care for my care recipient makes me feel more valued”. The phrases are constructed to represent two main constructs, ‘self-affirmation’ and ‘outlook on life’.

2.4.2 Qualitative data collection

Focus group and individual interview questions were developed to explore the experience of caregivers after participating in the MY-OT intervention with their care recipients. All caregiver participants were invited to participate in both focus groups and individual interviews. This interview process allowed for further understanding of the caregiver’s experience [32]. Through interviewing the participants as a group and individually, nuanced elements of each caregiver’s experience were revealed. Caregivers answered questions relating to perceived mental, physical, emotional, and social changes for both caregiver and care recipient as well as any impact these results may have had in their daily lives (See Table 1). Both focus groups and individual interviews were conducted to address group and individual dynamics resulting from the intervention.

<table>
<thead>
<tr>
<th>Focus Group Questions</th>
<th>Individual Interviews</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. What changed over the last 8 weeks? Possible probes: physical, emotional, social, stress</td>
<td>1. Have you seen any changes in your relationships since participating in this study?</td>
</tr>
<tr>
<td>2. Would you recommend this program to other people with stroke? Why?</td>
<td>2. Has this study had any impact on your own activities or your shared activities?</td>
</tr>
<tr>
<td>3. What are the benefits of participating in this intervention in a group setting?</td>
<td>3. Tell me about how this program has impacted your care recipient? And how has it impacted you?</td>
</tr>
</tbody>
</table>

Focus group interviews were approximately one hour and followed the final MY-OT intervention session. The focus group was led by a trained researcher to facilitate rich, group discussion and understand the group impact of the intervention [33]. Individual interviews were scheduled within two weeks of the last intervention session and lasted between 30 to 60 minutes. Questions focused on eliciting the experience of the caregivers after participating in MY-OT.
2.5 Data analysis

2.5.1 Quantitative data

Quantitative data were analyzed using SPSS 23 software (SPSS Inc, Chicago, IL). Descriptive statistics using the mean, standard deviations, frequencies, and proportions were used to describe the sample. Due to the small sample size, percent change for each outcome score was calculated (Time 1-Time 2/Time 1x100). Additionally, we examined the caregivers by groups (i.e. people who chose to attend the MY-OT intervention and people who chose not to attend).

2.5.2 Qualitative data

All interviews and focus groups were audio recorded and transcribed by trained researchers. Each interview was then analyzed and coded by at least two researchers using an inductive process occurring at two levels: “In vivo” identification of codes and the generation of larger themes that represent the caregiver’s experience. “In vivo” coding was completed using direct quotes from the participants to identify codes [34]. To do this, researchers familiarized themselves with the interviews by thoroughly reading each transcript line-by-line, making notes of ‘chunks’ of meaning and generating tentative themes within interviews (open coding). Afterwards, the researchers met for multiple consensus meetings to compare codes and discuss emerging themes.

Following “In vivo” coding, the data were categorized into larger themes [34]. To begin identifying larger themes, sub-themes were generated and organized across interviews. Researchers continued meeting to interpret findings, discuss potential final themes, and ground themes in the data. Finally, researchers collaborated until consensus was reached regarding final themes. Nvivo 11 software (QSR International, Melbourne, Australia) was used to support qualitative analyses.

To provide trustworthiness and credibility, further methods for rigor include research triangulation and individual researcher positioning [35]. The method for triangulation occurred through individual coding, meetings to discuss the evolution of coding schemes, and the end-result of consensus regarding coding each unit of meaning. Throughout the analyzation process, an audit trail was recorded by each researcher.

3. Results

3.1 Findings

The average age of caregivers was 64.86 years old and most caregivers were female (66%). See Table 2 for additional demographic data. Three caregivers chose not to participate in the intervention for the following reasons: chose to use the time to run errands; chose to use the time to read or other leisure activity; and wanted the husband with stroke to have an independent activity where she (caregiver) was not attending to him. On average, the remaining six caregivers attended 12±2.8 of the MY-OT sessions. All nine caregivers were invited to participate in data collection, eight caregivers participated in the focus group and 7 individual interviews were conducted.
Table 2 Caregiver characteristics (n=9).

<table>
<thead>
<tr>
<th>Variable</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (mean (SD)) (n=7)*</td>
<td>64.86 (4.59)</td>
</tr>
<tr>
<td>Gender (female)</td>
<td>6 (66%)</td>
</tr>
<tr>
<td>Race (Caucasian)</td>
<td>9 (100%)</td>
</tr>
<tr>
<td>Married/Part of Couple</td>
<td>8 (89%)</td>
</tr>
<tr>
<td>Relationship to Care Recipient (spouse)</td>
<td>7 (78%)</td>
</tr>
<tr>
<td>Years Caregiving (greater than 5 years)</td>
<td>6 (66%)</td>
</tr>
<tr>
<td>Education (‘some college’ and above) (n=7)*</td>
<td>5 (71%)</td>
</tr>
</tbody>
</table>

*Data unknown for two caregivers who did not complete quantitative assessments

For caregivers who attended the MY-OT sessions, caregiver burden decreased by 47%. In contrast, for those who did not attend, caregiver burden decreased by 2%. Caregivers who attended MY-OT demonstrated an increase of 26% in positive aspects of caregiving, while caregivers who did not attend saw a decrease of 4%. See Table 3. Caregivers who did not attend MY-OT stated that they used the four hours a week for various activities, such as: shopping, reading, and running errands.

Table 3 Change for CBG and PAoC.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Pre: Mean (SD)</th>
<th>Post: Mean (SD)</th>
<th>Percent Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>CGB: MY-OT (n=4)</td>
<td>32.23 (18.75)</td>
<td>17.00 (12.49)</td>
<td>↓47%</td>
</tr>
<tr>
<td>CGB: Respite (n=3)</td>
<td>32.00 (12.36)</td>
<td>31.25 (12.31)</td>
<td>↓2%</td>
</tr>
<tr>
<td>PAoC: MY-OT (n=4)</td>
<td>28.33 (4.62)</td>
<td>35.67 (3.78)</td>
<td>↑26%</td>
</tr>
<tr>
<td>PAoC: Respite (n=3)</td>
<td>34.67 (7.10)</td>
<td>33.25 (6.34)</td>
<td>↓4%</td>
</tr>
</tbody>
</table>

*CGB = Caregiver Burden; PAoC = Positive Aspects of Caregiving

3.2 Major themes

3.2.1 “A huge change”

Caregivers who did not attend MY-OT reflected no specific changes in their relationships. However, caregivers who did attend noted multiple changes within their daily lives, for both the caregiver and the care recipient. Caregivers who attended MY-OT found themselves feeling less stressed, laughing more, and spending greater quality time with their care recipient. They also found the dedicated time together contributed to shared, positive experiences. Several caregivers felt as if they were ‘nagging’ less because they did not have to provide as much one-on-one care after the intervention. For example, a caregiver stated:

You know, yesterday we did my husband’s shower, which is, I have to help him, we have a tub in the shower and so he can’t get in and out. And usually it seems like
that’s a chore. So I thought “Shower today…” But we had fun! I mean we talked and visited and laughed and he teases me and squirts me. I mean I realized, I said ‘This was fun!’ This is fun! He said, “Yeah!” [laughs] He thought it was fun all along. But maybe, maybe that’s where that perspective came from because it never had occurred to me that that was fun before. It always was a chore. But it wasn’t. We did, we had a good time, like we usually do. So, that might have come from the yoga…introspection…I don’t know…”

Many caregivers noted that attending the intervention two times a week provided them with a new activity to engage in together. One participant said “It did change our activity level because we were kind of in a rut…” Frequently, the caregiver and care recipient would extend this time by going out to eat or running errands together after the MY-OT intervention. Caregivers who attended MY-OT also said that their care recipients would initiate more activities, such as taking walks or attending social events and that the dyad felt inspired to try more new things (e.g. going on vacation, attending yoga in the community). Caregivers stated that these changes added a new, positive dimension to their daily life. Participating in the intervention did appear to increase the caregiver’s responsibility in some areas, such as driving. For example, caregivers who chose not to participate in the intervention noted an increase in burden through driving their care recipient to the intervention which sometimes interfered with their own planned activities. Supporting this finding, a caregiver made the following statement:

“So, that has added a real positive dimension to our relationship and in my life because I still have to drive her, I still have to do things, but you know, she does more on her own than she used to, so it’s not like I’ve gained 20% more free time. In fact, I drive her more places and you know, I have to do more things and the driving her around more is one of those physical time consuming things. In terms of my emotional state, I don’t think I have to worry about what is she thinking about today. And that gives, that does give me more mental free time to pursue some of the things that I want to do.”

While physical and cognitive changes were mainly seen in care recipients, these changes likely influenced the type and quality of care the caregivers provided outside of the intervention. Several caregivers reported observing care recipient improvements in balance, endurance, alertness, vision, and speech. Caregivers indicated that these changes allowed the care recipients to engage in more activities for longer periods of time, raised spirits, and provided the caregiving dyad with options to participate in activities in the future. One caregiver who attended MY-OT reported feeling less pain due to rheumatoid arthritis. These experiences suggest that participating in MY-OT contributed to changes that allowed caregivers and care recipients to participate more fully in their daily lives.

3.2.2 I’m in the present

Caregivers who did not attend MY-OT reported observing their care recipients having more self-confidence, but reported no personal changes related to this theme. Caregivers who chose to attend MY-OT reported multiple ways in which they garnered positive feelings and greater
self-awareness. They reported feeling hopeful about their current and future situation, feeling better physically and mentally, changing their perspective about their conditions, and using breathing as a positive coping tool in everyday life. They reported feeling hopeful about the future and wanting to engage in more new activities.

Caregivers also report their own reduced stress levels, less worry, raised spirits, and enjoyment in having something new to do. This likely relates to participating in yoga which taught awareness of being in the present moment. For example, one caregiver stated:

>What I think is so miraculous is that when I get to participate in the yoga, I’m not thinking about her. ... I’m not worried about the future so much as, you know well, what if, what if. I mean, I’m in the present, and isn’t that wonderful? To just be in the present, be grateful for where you are, grateful for what you have and not worry about either the past or the future. So, that’s been my experience, has just been absolutely fantastic.

Caregivers frequently mentioned seeing what they once thought of as negative experience as now positive. One caregiver mentioned seeing her care recipient as strong instead of fragile and feeling more grateful for the gifts they have been given in life. This was illustrated when she states:

> I mean it happened, and it’s like, ‘ok, we’ll roll with the punches’. So, we’ve had to change our routines and things that have happened in our lives. But this has added a dimension of hope and/or ‘ok, we’re not in a stasis’. My wife, I think, is realizing that yeah, things can change. And that she can, that it won’t happen without her effort. That, more than anything, you don’t have to sit and just wait to die.

Caregivers also reported that the confidence and motivation their care recipients’ gained positively influenced their interactions with each other. After participating in the MY-OT intervention, the dyad experienced changes in perspective which positively influenced the choices they make in their daily life.

### 3.2.3 I learned so much

For caregivers who attended MY-OT, observing interactions between the participants and between participants and staff was invaluable. Being able to ‘sit back’ and ‘give space’ appeared to be an important aspect of this theme. Caregivers learned more about the care recipients’ perspective as well as new information by listening to the care recipients’ answers and observing them interact with other people. This carried over into daily life as is illustrated by the following statement:

> Because initially, after her stroke, I looked at her as being so fragile. And um, I didn’t want to do anything that was going to tax her strength or anything like that. Well, as I’ve looked at the participants in this study, none of them are fragile. They wouldn’t be here today if they were fragile because they have strength, they have stamina, that have determination ... You know, I’m a manager, I take control,
manipulate, mother, all those little things that are really an unhealthy thing and I have found that simply due to the information [OT], I am much more relaxed.

This information suggests that including caregivers in the intervention provides opportunities to learn new information about the care recipient through observation.

All caregivers reported learning new information regarding fall prevention management and how to engage in yoga. However, caregivers who did not attend the intervention learned the information second-hand through their care recipients. Caregivers who attended MY-OT reported more robust gains in knowledge, specifically about fall prevention, stroke and fatigue, and increasing awareness in daily activities. For example,

I, for me, the discussion, around the table, was really good. And I think maybe that’s really why I am much easier with my husband, much less likely to get stressed. Just hearing everyone else’s comments and, the fatigue, for example, the doctors have acted like that’s unusual for so long, we need to change the medicine but everybody at that table talked about fatigue even years into stroke, ... so it was really beneficial for me to hear how people worked around those situations [uh huh] and how they’re stroke symptoms affected them...

All caregivers also learned that physical change is possible even years after stroke and many commented that they were frustrated they had been initially told that ‘what is gained after six months is all you can expect to gain’. Caregivers who attended MY-OT reported that by learning how to safely participate in yoga, they were given a new coping tool that they could integrate into the dyad’s daily life. By learning this new information, caregivers stated they felt relief at understanding the bigger picture of living with stroke. Learning new information, even years after the onset of stroke, was a valuable experience for caregivers. For caregivers who attended the MY-OT intervention, they learned new strategies, how to apply those strategies, and were able to make sense of the ‘bigger picture’ of living with stroke.

3.2.4 There are other people out there

All caregivers in the study acknowledged the value of the social aspect of the intervention. Being able to interact with other people who understand the experience of living with stroke provided support and opportunities to meet new people. Caregivers who attended MY-OT reported feeling positive about the new relationships they built while participating in the intervention. Caregivers found support in each other and observed their care recipients forming new friendships as well. For example, one caregiver stated:

And so the right people came to that study and the people that needed to see each other came to that study and I think that we now have been given so many gifts as a result of that study. Not only individual and personal gifts but a networking...and knowing that we’re ok and knowing that we all are ok.

The social aspect provided an open and relaxed environment for caregivers and care recipients alike to grow personally and socially. Caregivers were able to ‘step back’, form relationships with each other and give their care recipients the space to do the same.
Caregivers who attended the intervention reported that the supportive atmosphere and the experience of the professionals involved was very important. Those who attended were provided with materials, given coffee, and were invited to sit in the fall prevention OT group. They reported feeling welcome and included in the study. They also stated that learning therapeutic information in a community setting provided a supportive learning environment. This was discussed by a caregiver:

“It’s real because the lead researcher is a teacher. So, she wants to impart that information to you. When you go to a medical person, you have an exam and they tell you this and then it’s over. And I think to be able to have a teacher tell you all of these aspects and then, of course, you have wonderful helpers too, I think was just phenomenal! Because it’s not controversial, you’re not competing with another medical person over here, but you’re being told, for the very first time for me, that these things exist with stroke effects. I didn’t know that.

Thus, by providing a supportive social environment, caregiver’s reported greater feelings of well-being, social growth and opportunities for learning.

4. Discussion

The aim of this study was to examine changes in caregiver burden, positive aspects of caring, and caregiver’s experiences after participating in the MY-OT intervention. Like in previous studies, we found that the caregiving role leads to high levels of caregiver burden [36, 37]. When reflecting on the time prior to the intervention, caregivers demonstrated strained relationships, decreased participation in valued activities and reduced physical activity [21]. Interestingly, caregivers who did not attend the MY-OT intervention saw little to no change in caregiver burden or positive aspects of caregiving. However, those who participated, saw a marked improvement in both areas. Our findings were consistent with the Mackenzie and Greenwood (8) systematic review of positive experiences of caregiving in stroke, where positive coping skills, in this case learned through yoga and self-management, were linked to increased positive experiences in caregiving. This suggests that multimodal interventions, such as MY-OT, can be used to target changes in caregiver burden and positive aspects of caring.

By qualitatively examining caregiver’s experiences, we showed that positive experiences for caregivers can be garnered through specific interventions. After participating in MY-OT, caregivers reported many positive changes related to information gathering, a change in perspective, coping skills, and supportive environments. While all caregivers reported learning new, pragmatic information, those who attended MY-OT reported experiencing more complex and robust modes of learning. For example, learning through observation or implementing what was learned at home, which likely impacted other areas of their lives. Caregivers also reported multiple advantages of sharing the experience with their care receiver, including increased quality of time together and observation of the care recipient in a new setting. We also found that caregivers experienced a change in perspective potentially leading to greater feelings of hope and gratitude. Additionally, after MY-OT, caregivers reported improved coping strategies, feeling less stress, more flexibility, and a shift in awareness; this is consistent with outcomes found in yoga research [16, 38, 39]. These positive outcomes are possibly due to the multi-modal approach of using yoga...
and OT together to address individual and group needs. Consistent with previous research, our findings also show that skill-building, education and training, supportive social environments, a collaborative health care team and positive lifestyle changes were of value to caregivers [40, 41]. Furthermore, a sense of community was important to build trust between healthcare professionals and the caregiving dyad, potentially leading to greater learning opportunities. These findings suggest that interventions targeting the caregiving dyad may provide an opportunity to meet multiple needs for both individuals across their continuum of care.

Multiple researchers recommend providing interventions for caregivers throughout the continuum of care [42] as needs change based on severity of the care recipients’ stroke symptoms and ability to engage in daily activities. MY-OT, a program that could someday be provided in a community setting, may provide social supports, provide access to health professionals and teach techniques for self-management in the caregiving dyad’s daily life [13]. Perhaps it is most relevant to develop and test interventions that simultaneously address the needs of both individuals in the caregiving dyad. Limited dyad intervention research has been completed, and is mostly limited to care recipients with dementia, but dyad-based interventions appear to be feasible and beneficial to both members of the dyad [28, 29]. A dyadic may have greater effects than other interventions due to a focus on dyadic interactions. Outcomes may be greater in dyad interventions, because care recipients’ adherence increases when individuals engage in an intervention together [28] and when both members provide social support to each other [43, 44]. Our study provides preliminary evidence that using yoga in conjunction with OT led self-management groups creates positive experiences by addressing psychosocial, physical, and learning needs for both members in the dyad. Additionally, we learned the importance of providing a venue for increased socialization through a group intervention, likely to be an important piece of future intervention development. These experiences may mitigate the effects of caregiver burden and provide opportunities for positive change in daily life for both the caregiver and the care recipient many years after the stroke occurs.

4.1 Limitations

As with all studies, limitations exist. The primary limitation in this study is that the intervention was initially created as a fall prevention program for people with stroke, and not the caregivers. However, the data collected shows that involving caregivers in the intervention was still greatly informative and beneficial for caregivers. Future studies should focus on creating interventions targeting both the caregiver and the care recipient together [4]. Another limitation is that we cannot say what part of the intervention specifically affected change in this study. Both the group OT and the yoga target different needs, and it is possible that their combination together provided greater opportunities for growth. Other limitations include a non-blinded assessor and no control group, limited sample, homogeneity of race, education levels, and gender. The very small sample size does not allow for true conclusions to be made; however appears to provide a first glimpse into the caregiver experience for this type of merged intervention. Also, the study was conducted in a small, college town, which does not provide a representative sample of caregivers of people with stroke throughout the country.

4.2 Future research
As previously mentioned, future studies should look at group OT and yoga for caregivers and care recipients together across populations. This may allow for a wider range of assessments and data collection as well as adapting the intervention to the needs of the individuals. Likewise, a continued focus on programs for caregiving dyads are still needed [45]. Caregivers and care recipients require different types of information and instruction beyond information provided in the acute phase of stroke. It is possible that OT led education and self-management groups combined with yoga may be beneficial following completion of stroke related outpatient therapies. We also recommend that the caregiver and care recipient both participate in the study, as caregivers report learning through observation of their care recipients and participating in the yoga and group OT together. Future studies may want to provide opportunities for the caregivers to meet separately throughout the study, as this would allow for further socialization, support, and networking, as was suggested by caregivers in their interviews. Providing the dyad with this information sooner in their recovery process, such as during the outpatient phase of recovery, may prevent unwarranted difficulties later in the process (information about falls and fatigue, reduction of isolation, opportunities for health and wellness). Additionally, it will be necessary to complete a larger randomized controlled trial to better understand the impact of the yoga and occupational therapy intervention versus a social group or other controlled intervention.

4.3 Clinical implications

Professionals working with caregiver dyads are advised to provide client- and family-centered interventions, which involve the caregiver, to best address the needs of the dyad and improve quality of care. We recommend professionals take a strengths-based approach to build positive experiences for the caregiver which can bolster feelings of hope, improve quality of life, change negative perceptions, and affect positive change within the caregiving relationship. There continues to be a need for targeted intervention and education with this population. Specifically, OT led groups and yoga together may be a powerful tool for affecting positive physical and emotional change, providing stress relief, teaching management skills, and providing coping tools for the dyad.

5. Conclusions

Researchers continue to recommend the creation of interventions that address both the caregiver and care recipient’s needs. The experiences of caregivers after participating in MY-OT mirror outcomes found for care recipients in previous studies. Thus, merging group occupational therapy and yoga is a powerful, multimodal intervention that is capable of addressing a variety of needs for both individuals. Caregivers provide a great service within our healthcare service and are often overlooked. By providing targeted interventions, such as MY-OT, we can support our caregivers in living long and healthy lives while fulfilling their caregiving roles.

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Author Contributions
Schmid, Hinsey, Bolster were all involved in the intervention and in data collection. All authors were involved in development of focus groups questions and choice of assessments. Hinsey, Atler, Fruhauf, and Schmid were all involved in qualitative data analyses. Schmid, Hinsey, and Van Puymbroeck were involved in quantitative analyses. All authors were involved in writing and reviewing the manuscript.

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Competing Interests

The authors have declared that no competing interests exist.

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Auricular Interventions in Neurology: the Vascular Autonomic Signal Challenge

Im Quah-Smith, MD, PhD 1, 2, *

1. Roseville Wellness Group, 3/30-32 Barcoo Street, Roseville NSW 2069, Australia; E-Mail: quahsmith@gmail.com
2. Conjoint Lecturer, Women’s and Children’s Health, UNSW Medicine, The University of New South Wales, Randwick NSW 2031, Australia; E-Mail: quahsmith@gmail.com

* Correspondence: Im Quah-Smith; E-Mail: quahsmith@gmail.com

Abstract

The Auricular approach to diagnostics and therapeutics has gained momentum over the last 15 years. Battlefield Acupuncture has taken on a life of its own and has been adopted into NATO and even been introduced into neonatal intensive care. It is time to take on the challenge of Auricular Medicine - the application of the neurophysiological phenomenon referred to as the Vascular Autonomic Signal or VAS to identify active ear sites in Auricular interventions. It is time to utilize the VAS in therapeutics, recognizing its potential for recording the healing process.

Keywords

Auricular medicine; neurology; public health

1. Background

The escalating costs of health care delivery has become a major issue for many countries and there is an urgent need to seek new approaches which can be taught to clinicians world wide and
applied to patient care effectively and more economically. This is our challenge as a world community. Currently of major concern is the opioid crisis. The devastation to the affected individuals and their communities, as well the cost to society in general, has now reached critical status. In 2017, the opioid crisis has been declared a health emergency in the United States. In Australia medications containing opioids are no longer available over the counter as of February 2018. There is no doubt many more countries will adopt stricter policies in the future. Let us all rise to the challenge and work together to implementing affordable health strategies. In this communication, Auricular Medicine is explored for its potential in delivering affordable diagnostics and therapeutics.

2. The Vascular Autonomic Signal

Auricular Medicine is the system of auricular clinical diagnostics and therapeutics that utilizes the neurophysiological phenomenon commonly referred to as the Vasculo-Autonomic Signal or VAS. [1-3]. The VAS is also known as the RAC or Reflex Auricular Cardiac. The VAS is underutilized today. Documented half a century ago by a French physician Dr Paul Nogier, it has been neglected or ignored by many clinicians. Today the time has come for more clinicians to explore the VAS and seek its relevance in diagnostics and therapeutics. The changes in the VAS (best identified at the radial pulse as amplitude changes) is linked to changes in the body’s autonomic status and also the integrity of the body’s interior and exterior functionality.

In 2017, the VAS was clearly identified as a dynamic representation of the interplay between the Vagal and Sympathetic response with the former recording the subtlety of short duration effects and the latter recording the longer duration effects [4, 5]. It is important to note that Moser et al described the interactions not only between the high frequency vagal response and the low frequency sympathetic response, but how these interactions had an effect on the electrical field of the individual.

This was recognition of the presence of every individual’s electrical field or electromagnetic field and the possibility of field changes with environmental shifts.

It can be used to identify auricular (and body acupuncture) sites requiring attention or treatment. Currently the VAS is located using one’s thumb or other digit at the radial pulse seeking an increased or change in pulse amplitude when the auricular site being screened or tested is dysfunctional. It is a sign indicating that particular auricular site requires intervention. [1-3] Many clinicians use a pressure device to induce pressure pain to identify these auricular dysfunctional sites. It has to be considered that a non-pain inducing approach in identifying these dysfunctional sites may be advantageous as it avoids stimulation or over activation of the pain pathways. The VAS is also known as the Nogier Reflex in some countries such as Germany. Currently, new methods are under development for identification and utilization of the VAS. [6]

3. Neuroimaging Evidence

Auricular point specificity has been studied [7] as has the anatomical and functional aspects of stimulating auricular knee points [8]. The central pain control regions of the anterior cingulate and the thalamus were also shown to be involved in BFA [9]. More neuroimaging studies especially functional magnetic resonance imaging are required to better document the dynamic relationships between auricular stimulation, cranial nerves activation and access to relevant brain
regions and their feedback responses or their top down effects. Low level laser acupuncture to depression specific acupuncture points regulates at the default mode network as part of its central mechanisms [10, 11]. This may be part of the central mechanisms for auricular medicine.

### 4. Auricular Neurological Access to the Brain

The foundation of auricular interventions has been its innervation and access to the central nervous system. [12] Clinically Auricular Medicine has been used world wide for many decades due to its empirical effectiveness without strong biological evidence. It has only been in recent years that the central mechanisms have finally been identified. The connectivity of the auricular branches of the trigeminal (Cranial Nerve 5 or CN5) and the vagus nerve (Cranial Nerve 10 or CN10) to the cortical, subcortical brain regions and the rest of the nervous system networks has finally been revealed. [11, 13-15]

The auricular branch of the superior cervical ganglion has direct access to the sleep control or circadian rhythm brain regions at the supra-chiasma centre for melatonin regulation. [16, 17]

The Vagal regulatory capabilities of auricular medicine has an important part to play in the reducing the inflammatory effects in many of today’s diseases. Vagal afferents in body tissue have inflammatory receptors for cytokines. Auricular Medicine’s vagal access for homeostatic re-regulation holds the key to down-regulating this inflammation response by reducing cytokine production via nicotinergic acetylcholine receptors as found on macrophages. [18, 19]

With these recent findings, the role of Auricular Medicine in the brain to body’s psycho-neuro-endocrin-immunological regulation has finally been made clearer.

### 5. Clinical Applications

Acupuncture has been useful in the fight against the opioid crisis for the management of pain conditions. [20] Leading the advance has been the remarkable growth in interest and subsequent increase internationally in the clinical application of an auricular intervention referred to as Battlefield Acupuncture or BFA. [9] Although its architect, retired United States Air Force Colonel Richard Niemtzow, developed it for acute pain management in the battlefield, its principals and mechanisms for controlling central pain has been implemented in other clinical settings including in neonatal intensive care units to reduce pain and suffering and preserve the cellular integrity of the developing cortex and sub-cortex [21-27]. Acupuncture in paediatrics has long been established [28, 29] and it is of even greater interest to implement Auricular Medicine at the neonatal stage in life. It may well be protective of good health to start at this neonatal stage and much remains to be done with further investigations.

The National Acupuncture Detoxification Association (NADA) has also developed an auricular protocol for the treatment of addictions and related psychological change [30]. Low intensity laser as a modality for auricular acupuncture in patient care has also been helpful.*- [31] Auricular intervention for cancer pain has been found to be effective [32].

At the 9th International Symposium on Auriculotherapy in 2017 [33], it was clear that Auricular Medicine has an overwhelming evidence base for successful implementation clinically in many fields of medicine. The most outstanding current research projects studied how auricular stimulation helped: 1) to reduce amyloid deposits in the dementia brain by improving glymphatic clearance rates, 2) how auricular stimulation re-regulated functional connectivity at the brain to
successfully treat depression, and finally, 3) by identifying active ear foci in neonates one is able to predict the illness rate or negative health events rate by the number of active foci at the ear.

6. DOSAGE: How Much Is Enough?

Currently, when applying auricular needles, ear pressure seeds or magnets, there is no quantifiable measure for how long they need to be left in place nor how frequently the intervention has to be repeated and at what intervals. Moving forward, the challenge is to use modalities such as low level laser as the intervention of choice. Using the VAS to detect how much is enough laser, it will be possible to, at each time point, upload the correct quantity of laser energy to effect a positive shift in neurophysiological change for each patient.

These energy uploads can be recorded and has been shown to reduce (as the patient condition requires less energy transfer for the healing process as it gets better) over time with patient recovery. [34]

7. Conclusion

As health care systems approach overload, the realization that there has to be better solutions to rein in health dollars, still deliver effective and affordable care, is high on the list of priorities for every government. Today Auricular Medicine has strong biological and clinical evidence for its application within health care delivery. The next challenge is to validate the Vascular Autonomic Signal to better predict durations of treatments required for the restoration of good health.

Author Contributions

The author is responsible for the entire process of writing up, revising, and approving the final version of this manuscript.

Competing Interests

The authors have declared that no competing interests exist.

References

Review

What is the Current Evidence to Support the Use of Herbs and Supplements to Treat Mood and Anxiety Disorders?

Megan Berberich † and Bettina Bernstein †,‡,*

Philadelphia College of Osteopathic Medicine (PCOM), Philadelphia Campus, 4170 City Avenue, Philadelphia, PA 19131, USA; E-Mails: MeganBe@pcom.edu; BettinaBe@pcom.edu

‡ Additional Affiliation: Children’s Hospital of Philadelphia

† These authors contributed equally to this work.

* Correspondence: Dr. Bettina Bernstein, D.O.; E-Mail: BettinaBe@pcom.edu

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Abstract:

Background: Treatment of mood and anxiety disorders with supplements, herbs and nutraceuticals (dietary supplements) is at this point viewed as an integrative or alternative treatment, however these substances have been around for quite some time and are regarded as basic to the understanding of human biochemistry, physiology, health and illness in medicine.

Methods: This review article was done using a literature search utilizing the National Library of Medicine online data base and the PCOM electronic library data base of 1,707,669 academic journals to include studies utilizing herbs and supplements for depression and anxiety published in the past 10 years. Studies of a positive and negative type were both included in this review article.

Results: Step wise approach to depression and anxiety should first address insomnia. Reduction of the risk of self-harm should be addressed and reduction of oxidative stress is desirable especially for young adults and adolescents. Effect size differs between supplements.
Conclusions: Side effect profile should be taken into consideration when choosing supplements or herbal preparations.
Gender may impact response to different herbs and supplements.
Future research trials are needed to confirm best practices.

Keywords
Depression; anxiety; sleep; insomnia; probiotics; vitamin C; vitamin D; vitamin B1; vitamin B6; Zinc; Magnesium; saffron (C. Sativus); curcumin; crocin; fatty acids; rhodiola; walnuts, SAMe; Tryptophan; Theanine; camomile; lavender; inositol; N-Acetyl Cysteine; St. Johns Wort; passiflora incarnata L. (Passifloraceae); valeriana officinalis L.; personalized treatment

1. Introduction

Treatment of mood and anxiety disorders with supplements, herbs and nutraceuticals (dietary supplements) is at this point viewed as an integrative or alternative treatment, however these substances have been around for quite some time and are regarded as basic to the understanding of human biochemistry, physiology, health and illness in medicine. Multivitamins and mineral supplementation have been found to have a favorable safety ratio. [1]

It is important to keep in mind that many accepted psychiatric treatments (for example, cognitive behavioral therapy (CBT) took years to be regarded as an evidence based treatment due to the lack of sufficiently powered studies because of the challenges to getting these types of studies funded. [2] Treatments to facilitate healthy sleep may prevent as well as to intervene in depression and anxiety; this is important due to the recent research that has found that impaired sleep has a deleterious impact on the default mode network, which may be a root cause of both depression and anxiety [3].

2. Materials and Methods

No human, animal, plant subjects were involved as this article is a review article. The authors do not have any conflicts of interest to report for this review article.

This review article was done using a literature search utilizing the National Library of Medicine online data base and the PCOM electronic library data base of 1,707,669 academic journals to include studies utilizing herbs and supplements for depression and anxiety published in the past 10 years. Studies of a positive and negative type were both included in this review article.

The studies included in this review used scales and checklists to assess level of severity and remission in response to treatment interventions for major depressive disorder: the Beck Depression Inventory (BDI), Hamilton Depression Rating Scale (HDRS or HAM-D), and Patient Health Questionnaire-9 (PHQ-9). The BDI quantifies characteristic aspects of depression. It asks participants to scale twenty-one aspects of depression from zero to three, and adding each grade for a total score. The total score is then categorized into different severity levels of depression. A sample BDI is found in the Index. The HDRS also quantifies the severity of depression, but uses a seventeen factor measurement. Each aspect is ranked from either zero to two or zero to four. The total summation gives a patient a score, which is then categorized into severity of depression. The
PHQ-9 is a nine item questionnaire that was created from the 20 item short form general health survey to measure increase in depression severity; a score greater than or equal to 10 had a sensitivity of 88 percent and a specificity of 88 percent for major depression, scores of 5, 10, 15, and 20 represented mild, moderate, moderately severe and severe depression [3].

3. Results

3.1 Probiotics

Probiotics are microorganisms naturally found within the human digestive tract, aiding in digestion, protection against harmful microorganisms, and vitamin production [4]. Akkasheh et al. (2016) performed a study analyzing the effects of probiotic administration on major depressive disorder (MDD). After 8 weeks of supplementation with a probiotic capsule containing Lactobacillus acidophilus, Lactobacillus casei and Bifidobacterium bifidum, researchers noticed a decrease in Beck Depression Inventory (BDI) total scores compared to the placebo. Metabolic parameters also improved with probiotics as a decrease in inflammatory marker, high-sensitivity C-reactive protein (hs-CRP), was found as well as a decrease in insulin resistance. Unfortunately the study results might not be valid as the study did not tease out possible confounding factors that might have played a role in reduction of inflammation, the study was short in duration (8 weeks), did not provide guidance on whether the type of probiotic makes a difference even though the P value was at the level of 0.05 showing a significant difference between the probiotic and placebo groups as the BDI Score was -5.7 ± 6.4 vs -1.5 ±4.8 for probiotic group vs. placebo, respectively, and p = 0.001. After adjustments, BDI score decreased -5.3 ±1.2 and -1.8 ± 1.2 for probiotic and placebo group respectively, where p* = 0.05 [5].

Further support for the use of probiotics in decreasing the risk of mood disorders was demonstrated by Huang et al. in a meta-analysis of randomized controlled trials. They found that regular intake of probiotics, whether through diet or as a supplement, had a beneficial effect on mental health biomarkers, MDD, and overall mood. This specifically applied to patient populations less than 60 years old, and in populations with and without depression. Therefore, both depressed and non-depressed people may benefit from probiotics [6].

3.2 Vitamins and Micronutrients

Vitamin C. Vitamin C (ascorbic acid) is involved in various functions of the human body. Despite being a vital requirement, humans are unable to synthesize it. Therefore, it is obtained through the diet naturally in foods, as a supplement in other foods, and as a supplement on its own. It is hypothesized that Vitamin C can adjust catecholamine activity, thereby decreasing reactions to stress. [7].

Oliviera et al. [8] studied the effect of Vitamin C supplementation on blood pressure and possible improvement in anxiety. Anxiety can have a pathophysiological tie to oxidative stress, where decreased levels of ascorbic acid are associated with increased levels of anxiety. Vitamin C, being an antioxidant, should prevent oxidative stress, thus improving anxiety. In this study, high school students received a 14-day supply of either 500 mg of Vitamin C or a placebo. The results demonstrated a significant decrease in the Beck Anxiety Inventory (BAI) in the Vitamin C group compared to the placebo group. While there was no effect on blood pressure, there was a
significant decrease in the mean heart rate of the Vitamin C group compared to the placebo group, thus Vitamin C supplementation may be helpful to reduce anxiety.

Vitamin D. Vitamin D is a vitamin found in few foods, but can be produced within the body as a response to ultraviolet rays from the sun coming into contact with the human skin. This activates Vitamin D synthesis within the kidneys. Vitamin D appears to be a relatively cheap and safe supplement [9, 10].

There has been long standing interest in the use of vitamin D for depression and anxiety as well as in the treatment of ADHD as a clear association has been found for low vitamin D levels and depression [11, 12, 13, 14] and several research studies attempted to answer the question whether Vitamin D supplementation hastens rates of recovery from major depression, as it has been known that lower levels of Vitamin D correlate with symptoms of depression especially in middle aged [15, 16, 17] and elderly individuals [18].

Belzeaux confirmed what Vidgren et al. had determined that decreased vitamin D levels are associated with a major depressive episodes, and also that low vitamin D levels can result in cognitive impairment. [19] Belzeau et al. performed a study including patients with a major depressive episode not currently on medication. Using the Stroop Color Test, they found during a major depressive episode, those patients with hypovitaminosis had impaired cognitive inhibition [20].

Several studies of vitamin D supplementation were negative studies, where no improvement was observed with supplementation [21].

A review article found that of 7 studies reviewed that were without flaws, only one study found Vitamin D supplementation to be beneficial for depression however overall all-cause mortality was reduced for older adults taking vitamin D [22].

These negative findings could be attributed to weaknesses in the design of the studies: dosage too low for effect, short duration, use of a non-standard measure of depression, lack of agreement on what is the cut off score to indicate remission unfortunately were present in these studies [22, 23, 24, 25].

Frandsen et al. in a 2014 study, focused on seasonal affective disorder (SAD) in healthcare professionals and measured outcome using a self-reported questionnaire: the Structured Interview Guide for the Hamilton Depression Rating Scale, Seasonal Affective Disorders (SIGH-SAD). Treating for longer than the usual length of time (12 weeks instead of 8 weeks), they showed no significant difference in SIGH-SAD scores between the Vitamin D-supplemented group and the placebo group [26].

Shaffer et al (2014) found that a subgroup analysis of adults with clinically significant depressive symptoms to gain moderate benefit of Vitamin D supplementation for depression [24].

An older study done by Kjaergaard et al. in 2012 found that patients with lower serum 25-hydroxyvitamin D (25(OH)D) levels demonstrated worse depression symptoms than patients with higher (25(OH)D) levels; the study did not find significant improvement in severity of depression with supplementation of 40,000 IU of Vitamin D₃ a week for 6 months [27].

Sepehrmanesh, et al. performed a double-blinded, randomized, placebo-controlled 8-week clinical trial looking at Vitamin D supplementation and its effect on BDI, insulin resistance, and biomarkers of oxidative stress in patients with MDD. Supplementation with Vitamin D resulted in a greater decrease in BDI than the placebo group, as well as decreased insulin resistance in the Vitamin D-supplemented group despite the lack of improvement in serum hs-CRP levels [28].
Focker et al. are currently in the midst of a study looking at the possible relationship between mood and Vitamin D supplementation in children and adolescents with Vitamin D deficiency. The future findings may provide a deeper insight into the relationship between pediatric psychiatry and Vitamin D supplementation, as well as a more definitive approach to treatment with supplementation [29]. In conclusion, additional studies are needed to validate the connection between hypovitaminosis and cognitive impairment.

**Thiamine.** Thiamine (or thiamin), also known as Vitamin B1 is involved in multiple functions within the human body, including growth, development, and cell functioning. Most importantly, thiamine is a cofactor involved in obtaining energy from nutrients in food [30]. Ghaleiha et al. performed a study looking at the effects of thiamine supplementation on MDD. Although the overall impact of supplementation was not greater than placebo at the 12 week mark, as measured by the Hamilton Depression rating scale, at 6 weeks, there was significant improvement in HDRS scores in the thiamine-supplemented group compared to the placebo group. Thus, thiamine might be effective for immediate improvement in mood despite the lack of effect after 12 weeks, and may be helpful as an adjunctive bridge therapy during the antidepressant lag time for a faster effect on MDD [31].

**B vitamins.** Vitamin B6 is obtained through the diet and is a cofactor in many enzymatic reactions, primarily for protein metabolism [32].

Folate (or folic acid) is involved as a coenzyme in DNA and RNA production, as well as the metabolism of amino acids [33].

Vitamin B12 is also a cofactor for enzymatic reactions, especially the conversion of homocysteine to methionine, as methionine is required to make S-adenosylmethionine, an important methyl donor for various biological reactions [34].

Using the Montgomery-Asberg Depression Rating Scale (MADRS), Almeida et al. researched the impact of B vitamin supplementation along with standard antidepressant treatment utilizing citalopram over a one year time period for the treatment of MDD. This study also used the Mini-International Neuropsychiatric Interview (MINI) to allocate participants into diagnostic groupings. The results demonstrated that the group receiving vitamin B supplementation in addition to citalopram did not experience a positive response after 12 weeks of treatment, but had an enhanced response after 52 weeks. When looking at the participants who relapsed, those who received vitamin B supplementation experienced relapse less frequently than those treated with the placebo. Future studies that show replication of the Almeida study findings is needed to support a recommendation to provide B vitamin supplementation when treating MDD [35].

**Zinc.** Zinc is a mineral found in foods and dietary supplements and is required for numerous enzymatic reactions within the human body. Because the body is unable to store zinc, its level is managed daily to participate in the “immune system, protein synthesis, wound healing, DNA synthesis, and cell division” [36].

Salari et al. researched the effects of zinc supplementation on MDD in patients with multiple sclerosis (MS). MDD was rated using the Beck questionnaire, and after 12 weeks of zinc supplementation, there was a significant decrease in Beck questionnaire scores even though Zinc, did not affect any neurological signs of MS [37].

**Magnesium.** Magnesium, like many other vitamins and minerals within the body, is involved as a cofactor in various enzymatic reactions. It is especially important in ion transportation, an important aspect of nerve impulse conduction, muscle contraction, and heart rhythm [38].
Tarleton et al. performed a randomized clinical trial assessing the effects of 6 weeks of magnesium supplementation in patients with mild-moderate depression. Depression was graded using a PHQ-9 scale, with mild-moderate depressed patients scoring between 5 and 19.

Participants either had magnesium supplementation during the first 6 weeks or during weeks 7-12 of the study, and the supplements contained 248 mg of elemental magnesium (in a 500 mg MgCl$_2$ tablet). During the period of treatment with magnesium, there was significant improvement in pHQ-9 scores. Secondarily, there was also improvement in anxiety with magnesium supplementation based off of GAD-7 scores. Additional positive side effects included some decrease in severity of both headaches and muscle cramps. Unfortunately, this study has limitations, including the lack of a placebo group and it was not double-blinded, thus, additional research is necessary on magnesium supplementation [39].

### 3.3 Saffron

Saffron is produced from the dried stigmas of the *Crocus sativus* plant. While it is well known in the realm of cooking, it also contains some medicinal properties [40].

Kashani et al. [41] compared saffron to fluoxetine in the treatment of postpartum depression. The diagnosis of postpartum depression was made using DSM-IV-TR (text revision) criteria, and the treatment options contained either 15 mg of saffron extract or a fluoxetine capsule. Depression was graded using the Hamilton Depression Rating Scale (HDRS), and after 6 weeks, the study found “no significant difference between the 2 groups in terms of reduction in HDRS score from baseline to each time”, as well as almost equal remission rates between the two groups. Saffron had similar efficacy in treating depression when compared to fluoxetine, and had a lower incidence of side effects. Fluoxetine was associated with more side effects, such as headache, dry mouth, drowsiness and constipation.

A review article of 12 randomized control trial studies from the University of Florida and Jacksonville University found that saffron improves depressive symptoms, premenstrual syndrome, sexual dysfunction and reduced snacking behaviors similar to Fluoxetine without significant negative effects [42].

More studies are needed to confirm saffron as an effective depression treatment, as Kashani’s study lacked a placebo group and was a relatively small size study for a short time period [43, 44].

### 3.4 Curcumin

Curcumin is derived from turmeric, and has been known for its anti-inflammatory properties, as well as aiding in the treatment of metabolic syndrome, pain and degenerative eye conditions [45].

Yu et al. performed a study analyzing curcumin supplementation in combination with escitalopram and its effects on various aspects of depression. The Chinese versions of HDRS-17 and MADRS scores were used for assessment of depression. The study also measured inflammatory cytokines, IL-1B and TNF-a, substances that other studies have found to be elevated in depressed patients. Both the placebo and curcumin groups were being treated with escitalopram. After 6 weeks of curcumin supplementation, patients had decreased HDRS-17 and MADRS scores compared to those in the placebo group, demonstrating a significant antidepressant behavioral response. Those supplemented with curcumin also had significantly
decreased inflammatory markers, IL-1B and TNF-a, compared to the placebo group. This study demonstrated enhanced efficacy of escitalopram with curcumin supplementation [46].

Lopresti et al. analyzed the effect of curcumin on major depression and atypical depression using the Inventory of Depressive Symptomatology self-rated version (IDS-SR30) and Spielberger State-Trait Anxiety Inventory (STAI), both alone and in conjunction with antidepressant treatment. Improvement with curcumin supplementation was more beneficial after the first 4 weeks. Although the IDS-SR30 scores in both the placebo and supplementation groups improved in the first 4 weeks, in weeks 4 to 8, improvement continued only in the curcumin group.

Anxiety also decreased with curcumin, paralleling the improvement found for depressive symptoms as STAI anxiety scores improved more during weeks 4 to 8, despite seeing improvement within the first 4 weeks of treatment. As the study by Lopresti et al. was a small size, larger scale studies should be performed [47].

Another study performed by Lopresti and Drummond found continued improvement with curcumin treatment in major depressive disorder, but there was no significant improvement with the addition of saffron to a low-dose curcumin supplement [48].

3.5 Crocin

Crocin has a long history of use in herbal medicine; Crocin is derived from *Crocus sativus*, and is what gives saffron its color. Talaei et al. analyzed the efficacy of Crocin in the treatment of major depression in addition to an SSRI (fluoxetine, sertraline, or escitalopram) for 4 weeks. The effects were measured using the Beck Depression inventory (BDI), Back Anxiety Inventory (BAI), and Mood Disorder Questionnaire (MDQ).

Safety and tolerability were demonstrated as crocin did not result in side effects, and efficacy was shown as depressive symptoms in the group treated with crocin improved compared to the placebo group. As the study had a small sample size and was performed over a short time, additional research is necessary with a larger sample size and over a longer time frame [49].

3.6 Fatty Acids

There have been various studies of polyunsaturated fats and their effects on depression, and Park et al. analyzed the effect of eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) on depressed patients. Using the Center for Epidemiological Studies Depression Scale Korean version (CED-D-K), the Hamilton Depression Rating Scale 17-item version, the Clinical Global Impression Scale (CGI-S) and Clinical Global Impression Improvement (CGI-I), they looked at the effects of fatty acid on depression. Results showed a significant improvement in CGI-I scores with n-3 polyunsaturated fatty acid (PUFA) supplementation, but no effects on HAM-D-17, CGI-S scores compared to the placebo group. It should be known that the placebo group had an initial higher intake of fish, a source of n-3 PUFAs, compared to the supplement group. This shows n-3 PUFAs may be a beneficial adjuvant to treatment, rather than as monotherapy in the treatment of depression. This study was performed in Asia. Because diets vary geographically, this study should be reproduced with various populations and diets, and with a larger population [50].

A meta-analysis performed by Mocking et al. provided additional insight into whether PUFAs actually had a beneficial impact on the treatment of depression. Various issues were address from previous meta-analyses, such as the ratio of eicosapentaenoic acid (EPA) to docosahexaenoic acid
(DHA), publication bias, effect size, duplicate publication, and lack of focus on MDD only. Ultimately, this current meta-analysis found support for the use of omega-3 PUFAs in the treatment of MDD, with higher doses of EPA having a greater effect. The improvement in MDD was greater in studies where supplementation was in addition to concurrent use of antidepressants [51]. Looking beyond the scope of MDD, Wozniak et al. conducted a 12-week study analyzing the effects of high EPA/DHA omega-3 fatty acids and inositol on children with bipolar spectrum disorder. The study was broken down into three treatment arms: inositol and placebo, omega-3 fatty acids with placebo, and omega-3 fatty acids with inositol. They found the treatment group receiving the omega-3 fatty acids plus inositol demonstrated the greatest improvement in bipolar spectrum disorder, in regards to the Young Mania Rating Scale, the Children’s Depression Rating Scale, and the Brief Psychiatric Rating Scale. This study does have limitations, such as a 54% completion rate, a small sample size, and the lack of inclusion of severely ill patients [52].

A review by Schneider et al. further endorsed the beneficial aspects of PUFAs. Treatments with DHA were found to increase the serotonin concentrations in multiple studies. Additional studies also found a similar trend of decreased DHA and increased n-6:n-3 ratios of fatty acids in patients with depression and anxiety. Those who committed suicide from depression had lower levels of DHA. Bipolar patients also had a similar pattern of lower DHA levels. The meta-analyses found efficacy of PUFAs in the treatment of depression, especially with EPA or EPA and DHA combination therapy [53].

Further research should be performed with a focus on potential side effects of EPA supplementation and any possible biochemical interactions between EPA and antidepressants [53].

3.7 *Rhodiola rosea*

*Rhodiola rosea* also known as rose root has been used in folk medicine and has been considered an adaptogen to improve health status and to treat a variety of health conditions, including depression. A review of eleven randomized placebo controlled trials [54] found that although few adverse effects were reported it was unclear if there was a definite benefit as far as general mental functioning was concerned as would be hoped from an adaptogen [55].

Limited research has kept its exact mechanism unknown, but has been found to have effects on serotonin, dopamine, and acetylcholine, all important components in mood regulation. Mao et al. performed the first study looking at *R. rosea* and its effects on major depressive disorder compared with sertraline and a placebo group. Depression was scored using HAM-D. The findings demonstrated a clinically meaningful reduction in HAM-D scores between *R. rosea* and sertraline. There was no overall significant difference in improvement between all groups, but the *R. rosea* group experienced less side effects compared to treatment with sertraline. This suggests possible use for *R. rosea* in patients unable to tolerate the side effects of other antidepressant medications [54].

3.8 *Walnuts*

Walnuts contain various neuroprotective compounds including Vitamin E, folate, melatonin, and polyphenols. Pribis performed a trial looking at the effect of walnut intake on mood in healthy
college students. Mood was assessed using the Profiles of Mood States (POMS) in non-depressed participants. Walnut intake appeared to improve the mood of males but not females. The reason for the differential outcome was not elucidated, thus further research and study replication should be done to confirm these results [56].

3.9 S-Adenosyl-L-Methionine (SAMe)

S-adenosyl-L-methionine (SAMe) is produced naturally within the body, made from L-methionine, an amino acid, and adenosine triphosphate. It is involved in donating methyl groups to neurotransmitters in the brain [57].

Multiple trials have demonstrated the positive effect of SAMe and its use as an antidepressant when compared to placebo and other tricyclic antidepressants.

Mischoulon et al. researched the effect of SAMe on depression compared to the effect of selective serotonin reuptake inhibitors (SSRIs) and serotonin-norepinephrine reuptake inhibitors (SNRIs). HAM-D-17 was used to assess antidepressant efficacy. Inventory of Depressive Symptomatology – Clinician Rated (IDS-C) and CGI-I were used to assess secondary improvement. Results showed a decrease in HAM-D-17 scores in all groups (SAMe, escitalopram, and placebo) however the trial was considered a failed trial due to the lack of clinical significant effects of SAMe on depression after 12 weeks of supplementation and a lack of significant difference between supplemental, escitalopram and placebo groups [58]. This trial, however, was one of many looking at the efficacy of SAMe as an antidepressant.

A review of research conducted in 2017 found in double-blind, randomized controlled trials, SAMe was as effective or better than tricyclic antidepressants. SAMe was found to have a positive effect in depression treatment, demonstrating to be as effective, if not more beneficial, than anti-depressant medications. Additional studies found a beneficial effect of SAMe as adjunctive treatment with antidepressants as well [59].

3.10 Tryptophan

5-Hydroxy-L-tryptophan (5-HTP) is the precursor of serotonin. It has been taken as a treatment for depression, insomnia, and fibromyalgia. Many studies have been conducted looking at the use of 5-HTP in the treatment of depression, but only few have held statistical significance. Overall, it has been shown that 5-HTP is beneficial as adjuvant treatment for depression when used in conjunction with nialamide, clomipramide, and nomifensine, but limited data is available for the use of 5-HTP as an adjuvant with anti-depressant medication. Reported side effects associated with the use of 5-HTP include nausea, vomiting, and diarrhea, and no adverse effects have been found when used with monoamine oxidase inhibitors [60].

3.11 Theanine

*Camellia sinensis*, or theanine, is an amino acid found in the green tea herb. While the exact mechanism is unknown, it is thought the calming effect of green tea is due to inhibition of cortical excitation. It is important to consider possible antioxidant and antiproliferative effects as well. More research must be done to determine the efficacy of the antianxiolytic properties of theanine [61]. A recent review article found that phytochemicals including carbatrol found in oregano and
thyme as well as Lavandula may have antidepressant effects without the hepatotoxicity concerns that exist for other agents such as kava kava [63, 71].

3.12 Camomile

Although over the counter product teas advertised to encourage sleepiness may contain chamomile (as well as other ingredients such as Passiflora), the amount of active ingredient may not be enough to promote sleep. Gerbarg and Brown discuss the limited amount of research on the effects of chamomile. It can be used to treat anxiety and insomnia, as it has been shown to act on GABA-metabolizing enzymes in rat brain homogenates. Specifically, spigenin, a component of chamomile, “has high affinity for benzodiazepine GABA receptors... but causes minimal sedation”.

Chamomile demonstrated a significant improvement in anxiety compared to the placebo group after 8 weeks of supplementation in patients with generalized anxiety disorder. The effects were mild, and therefore, it is thought that chamomile can be used in addition to other sedatives and herbs [61].

3.13 Passiflora and Valeriana

Basic neuroscience research done by Guerrero and Medina found that Passiflora incarnata had sleep induction effects on rats. Administration of the extracts of Passiflora incarnate induced a significant decrease in the total time spent in a state of wakefulness (p<0.05; statistical power=0.85); concomitantly, an important increase in the amount of slow wave sleep (p<0.05; statistical power=0.98) however there was no overall change in rapid eye movement sleep for rats.

Valeriana officinalis L. has been utilized for treatment of insomniac patients. Subjective analysis indicates a shortening of the sleep latency, a decrease in number of awakenings through the night, self-perception of having a repairing sleep after administration of the extracts of this plant [62].

3.14 Lavendula

Lavender has been used for many years for its sleep-inducing and anxiolytic effects. Lavender oil aromatherapy and massages have been shown to ease some symptoms of anxiety in patients. Fißler, and Quante performed a retrospective study on eight patients to determine the effects of Lasea (a brand of lavender oil capsule) on MDD, symptoms of anxiety, insomnia, and psychomotor agitation. They found six out of eight patients had a decrease in HAMD-17 scores after treatment with Lasea. Three patients experienced decreased time falling asleep with treatment, and six patients experienced a decrease in agitation as well. This retrospective analysis demonstrates positive benefits for the use of lavender oil capsules for patients with MDD. Because this was a retrospective case study, more research is necessary, including randomized, double-blinded, placebo-controlled studies [63].

3.15 Inositol

Inositol is produced by the body as a precursor of phosphatylinositol, which is a component of neurological membranes. Phosphatylinositol is important in the regulation of signaling in multiple pathways.
A literature review by Akhondzadeh et al. concluded that inositol had a greater positive effect in the treatment of depression, panic and obsessive compulsive disorder compared to the placebo group. Inositol was also effective when combined with fluvoxamine, and less side effects were reported with inositol than with fluvoxamine alone. Inositol shows promise as an adjuvant treatment for multiple psychiatric conditions, including depression, panic, OCD, bipolar depression, binge eating, and bulimia nervosa [60].

3.16 N-Acetylcysteine

As a precursor to the essential amino acid, cysteine, N-Acetylcysteine (NAC) has many potential benefits. NAC can cross the blood-brain barrier secondary to oral intake, whereas cysteine cannot. NAC can increase the amount of cysteine in the brain, thus modulating glutaminergic and dopaminergic pathways. N-acetylcysteine and methylcobalamin (discussed earlier in this article) target the problem of oxidative stress. NAC is available over the counter, and is both an antioxidant and a prodrug for cysteine as well as glutathione. [61] NAC can scavenge reactive oxygen species, protecting the brain. The anti-inflammatory effects of NAC could potentially protect the brain, preventing aging due to inflammatory cytokines. [62] The role of NAC in these metabolic pathways sets the foundation for its use in various psychiatric conditions. One hypothesis is that increased oxidative stress is thought to contribute to the development of bipolar disorder. [63] NAC may potentially play a role as an anti-inflammatory and as a dopamine modulator [64].

A recent study by Cullen et al. of thirty five adolescents and young adults found a reduction in non-suicidal self harm (NSSI) and depression scores using the Beck Depression Inventory with oral NAC twice daily even though no decrease in impulsivity was found [65].

3.17 St. John’s Wort

St. John’s Wort contains extracts from hypericum, an herb that has been used to treat depression for hundreds of years. Hypericum has many undesired drug interactions as it induces cytochrome P450 isoenzymes CYP3A4m 2C19, and 2C9 as well as the P-glycoprotein transporter. The drug interactions with St. John’s Wort make it less desirable in the treatment for females of childbearing age, as hypericum increases the clearance of estradiol, and in turn, can change the efficacy of oral contraceptives. Hypericum also has a variety of neurological effects, acting on serotonin, norepinephrine, dopamine, and other neurotransmitters, in addition to its neuroendocrinologic and neuroimmunologic properties [66].

A review article looking at eleven randomized controlled trials found an overall lack of efficacy of St. John’s Wort in the treatment of depression and anxiety as compared to standard treatments and troublesome side effects of St. John’s Wort that parallel the typical side effects of SSRIs (sexual side effects, serotonin syndrome and discontinuation syndrome, as well as changes in appetite, diarrhea, constipation, nausea, dyspepsia) led to a conclusion that St. John’s Wort does not offer a significant benefit over treatment with conventional SSRIs for depression or anxiety [67].
4. Discussion

Principles of personalized medical care such as population health considerations help with the choice of a supplement whether it be a single micronutrient or a broad-spectrum micronutrient blend to be used adjunctively with conventional treatments or as a stand-alone option. When comparing the potential benefits, broad-spectrum micronutrient formulas have shown promise for use to reduce anxiety especially traumatic anxiety [68, 69]. The use of herbs was found to have more significant potential adverse side effects in a case study that found psychotic symptoms from herbal supplementation [70].

5. Conclusions

A first step approach should include addressing insomnia, especially as recent studies have shown promising basic science research with a constituent of Lavender, Lavendula, active agent, linalool [71] a potentially safe alternative to conventional treatment of insomnia that may not worsen depressive symptoms, result in daytime grogginess or cause rebound anxiety and other agents such as Valeriana, and Chamomile may also be helpful. Inositol’s ability to reduce repetitive worry and associated agitation which can disturb sleep especially when given with omega-3 fatty acids may provide a more health promoting alternative that is appropriate for youth with bipolar depression for whom typical mood stabilizers can cause problematic adverse metabolic consequences, especially due to the long duration of treatment.

Reduction of the risk of self-harm should also be a high priority when determining effective treatment; supplements that reduce oxidative stress such as vitamin C, NAC, B12 and Zinc are especially attractive for use with young adults and adolescents with a favorable side effect profile which includes possible reduction of cold sores (as cold sores may be a contributor to low self-esteem).

SAMe may have a higher effect size than some other supplements such as 5-HTP without the side effects that 5-HTP can have such as nausea, vomiting and diarrhea.

Magnesium supplementation for depression may be a more appropriate choice in persons who also suffer headaches due to the side effect profile.

Gender may also be an important consideration when picking a supplement. Walnuts may be helpful for males but not for females to improve mood. Women of childbearing age should avoid include St. John’s wort due to the potential to reduce efficacy of oral contraceptives due to drug interactions; saffron and crocin may be more desirable choices. Older individuals who may be more prone to vitamin D deficiency and cognitive impairment may benefit more from vitamin D supplementation, although youth may also benefit from supplementation.

Future research trials are needed with larger numbers of individuals of varied gender and age as well as cultural background to further elucidate what person is more likely to benefit from a particular treatment.

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Additional Materials


References


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Abstract

**Background:** People suffering from multiple sclerosis (MS) commonly use complementary and alternative medicine due to the partial efficacy of conventional treatments, the chronic aspect of MS, the impact of pain and the side-effects of medication. An exploratory descriptive study of three cases was performed to document and analyse the experience patients treated for MS with applied kinesiology.

**Methods:** Qualitative interviews were conducted with three patients who had been diagnosed with MS at the Neurology Department and who had sought concurrent applied kinesiological treatment from a kinesiologist. The interviews were open-ended and semi-structured. A second interview was conducted for validation. The interviews produced texts that were subjected to phenomenological-hermeneutic text analysis. The three case studies were synthesized for a cross-case analysis.

**Results:** The following themes emerged from the interviews: “having hope”, “trusting the kinesiologist”, “diet changes essential”, “losing trust in the healthcare system”, “feeling confused” and “getting better”. Patients who underwent applied kinesiology treatment reported a sense of hope, trust and increased health. Comprehensive analysis of the survey results revealed that the patients felt able to “make changes for life”, “get past their diagnosis of multiple sclerosis” and “experience increased health” through applied kinesiology treatment.
Conclusion: The interviews provide phenomenological-hermeneutic narratives of health well-being among patients treated with applied kinesiology for MS. The treatment assisted the patients in achieving a sense of well-being and health rather than invalidity. In parallel, the patients exhibited stabilization of their magnetic resonance imaging results during the applied kinesiology treatment period. The patients also reported a feeling that they could transcend their diagnosis of MS.

Keywords
Complementary and alternative medicine; CAM-treatment; applied kinesiology; case study; multiple sclerosis

1. Introduction

People suffering from multiple sclerosis (MS) commonly use complementary and alternative medicine (CAM) due to the partial efficacy of conventional treatment [1], the chronic nature of the condition [2, 3], the impact of pain [4], and the side-effects of several medications [5, 6]. Here, applied kinesiological treatment of MS was evaluated in an exploratory descriptive study consisting of three cases, as a means of enhancing scientific assessment [7]. Interviews were conducted to describe the personal experiences of patients receiving kinesiological treatment for MS.

2. Background

2.1 Multiple Sclerosis

Autoimmune diseases affect between 5% and 7% of the adult population in Europe and North America [8]. Included among these diseases is MS, an inflammatory demyelinating condition of the central nervous system caused by abnormal immune mechanisms [9]. The resulting injury to the myelin in the central nervous system, and to the nerve fibers themselves, interferes with the transmission of signals between the brain and spinal cord and other parts of the body (National MS Society 2017). The onset is primarily within the age range of 20–40 years and twice as many women are affected compared with the incidence in men [10]. Symptoms may be mild, such as numbness in the limbs, or severe, such as paralysis or loss of vision. The progress, severity, and specific symptoms of MS are unpredictable and vary from one person to another. While the etiology of MS is still unknown, a combination of several factors are thought to be involved. Studies are ongoing in the areas of immunology, epidemiology and genetics to find the cause of the condition. Since MS is more common in northern latitudes and less common in areas closer to the equator, the possible protective effects of increased exposure to the sun and the vitamin D it provides on those living nearer the equator are under investigations. MS occurs in most ethnic groups, including African-Americans, Asians and the Hispanic/Latino population, but is more common in Caucasians of northern European ancestry (National MS Society 2017). Less visible subjective symptoms of pain, fatigue and depression are common and burdensome and adversely affect the patient’s quality of life [11-13].
2.2 Multiple Sclerosis and Conventional Medicine (CM)

People with MS can experience one of four disease courses, each of which might be mild, moderate, or severe. A number of disease-modifying agents are currently available, including Avonex and Betaseron (interferon beta [IFN β]-1b), Copaxone®(glatiramer acetate[GA]) and Tysabri (natalizumab), which can reduce disease activity and progression for many individuals with relapsing forms of MS, including those with secondary progressive disease who continue to have relapses [14]. Treatment of relapsing-remitting MS (RRMS) is currently being based on immunomodulatory drugs, such as recombinant IFN β-1a and IFN β-1b or GA, although these therapies have been shown to be only modestly effective. Recently, it has been suggested that the nerve damage, supported by the inflammatory processes, is an early event in MS evolution, which immunomodulatory drugs can only partially prevent. In clinical trials, IFN and GA demonstrated only partial efficacy that could be ascribed to the fact that the studies that have led to their approval have been initiated in patients with a disease history of several years. Early IFN β-1a treatment has been shown to be effective in preventing the conversion of the first isolated demyelinating episodes into clinically definite MS both after 1 year and 2 years of follow-up. Side-effects and the occurrence of adverse event were the same as those reported in the many studies on IFN β treatments administered to patients with different levels of MS [14, 15]. MS damages several parts of the nerves, not only the myelin sheath. GA (Copaxone®) is a synthetic amino acid polymer empirically shown to suppress experimental allergic encephalomyelitis (EAE), an animal model of MS. In this review, we found that the available data do not support a beneficial effect of GA in preventing both disease progression, measured as a sustained worsening in disability, and clinical relapses. With regard to adverse events, no major toxicity was observed, although local injection-site reactions were observed in up to 50% of treated patients [16].

2.3 Multiple Sclerosis and CAM

CAM use is widely spread among patients with MS; 57% to 81 % of patients use CAM at some point during the course of their disease [3, 5, 7, 17-19]. An internet search for information using the search words “CAM and MS” rendered 689 000 hits, indicating a vast interest. Many factors influence the utilization of CAM, such as socio-demographic variables of age, aspects of illness, and the severity of MS [7, 17]. Common CAM therapies are dietary modification, nutritional and herbal supplementation, mind-body therapies, low-fat diet, and essential fatty acid supplementation [20]. The efficacy of specific vitamin supplementation remains unclear [21]. Recently, cannabis, yoga and meditation have been evaluated in controlled studies that have provided evidence of some benefits [22]. Healthcare professionals require knowledge of CAM therapies, their interactions with conventional treatments, and related research to safely facilitate patients’ exploration and utilization of CAM [23]. Naturopaths use both a multiple, broad-ranging CAM therapies for treating MS and report treatment effectiveness on the following outcomes: quality of life, symptom severity, relapse rates, and disease progression [24]. Increased odds of using CAM in females and the more highly educated individuals have been reported in four studies [25].
2.4 Applied Kinesiology

Applied kinesiology (AK) was first developed in 1964 by the American chiropractor George Goodheart and is now used by chiropractors, osteopaths, medical doctors, dentists and others with a license to practice. Dr. Goodheart found that evaluation of normal and abnormal body function could be accomplished using muscle tests. A body of basic and clinical evidence has been generated on the manual muscle test (MMT) since its first reviewed publication in 1915. Rosner and Cuthbert define AK as a system designed to evaluate structural, chemical and mental aspects of health by MMT together with other methods of diagnosis leading to a variety of non-invasive treatments which involve “joint manipulations or mobilizations, myofascial therapies, cranial techniques, meridian and acupuncture skills, clinical nutrition and dietary management, counseling skills, evaluating environmental irritants, and various reflex techniques” [26]. While performing the kinesiology MMT, the tester is evaluating the patients’ ability to maintain a flexed position in a selected joint. The therapist subjectively monitors the resistance created by the patient against the tester’s pressure or tension. External conditions, such as being in touch with chemical substances, healthy or unhealthy, may increase or decrease this resistance [27]. Single case studies using AK techniques have been performed [28, 29], one concerning a boy with ADHD and the other concerning a boy suffering from Lyme disease. Both studies utilized AK as a diagnostic tool. AK can be combined with numerous other CAM treatments and is utilized in many variations.

Holographic kinesiological treatment (HKT) was used by the practicing kinesiologist in this study. HKT is a system developed to strengthen the immune system and combines medical knowledge from areas of neurology, metabolism, anatomy, nutrition, oxygenation, and pH-value and uses the nervous system to identify different weaknesses in the body. Depending on the results - how the body reacts - the therapist treats the client with different techniques, such as nutrition (vitamins and minerals), acupuncture, osteopathy, homeopathy and craniosacral treatments as well as addressing the patient’s thoughts and feelings. When the developers of the system first started using the treatments, they achieved an understanding of how the body works, and to be able to help their clients the practitioners had to develop nutrition and supplements of their own brand to make sure it helped every process in the body. Therefore, the treatments include a unique combination of one or several of the following: herbal medication, vitamins, supplements, and dietary and physical training recommendations. The treatments are classified as integrative medicine, meaning that they are both alternative and complementary to conventional medicine. The three cases described here, and particularly Case 3, illustrate that there are no competitive interactions between CM and HKT treatments.

2.5 Health Narratives

Kleinman makes distinctions between the perspectives of the patients and their family’s on the disease. Recognition of the structural or functional perspective and sickness as the macro social perspective is essential for a medical holism [30]. The philosopher Toombs, who suffered from MS from her late twenties, describes in detail the process of the decline of her body resulting in alienation [31] and states that “in health the body is taken for granted and ignored”. She experiences her body as damaged and diseased rather than whole, hindering her ability to live her
life. This rift between the body as lived and the biological body, and between the complex perceptions of reality, is also defined by Carel [32] as alienation. Svenaeus goes on to describe illness as an un-home-likeness of being-in-the-world and consequently, health as a home-likeness of being-in-the-world [33].

As a concept, health is defined by the World Health Organization (2017) “as a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity”. The Cochrane Collaboration defines CAM as “a domain of healing resources... other than those intrinsic to the politically dominant health system of a particular society or culture”[34]. In a broader sense, the concept of life vitality, that is itself a holistic term, is more inclusive of individual variations and experiences of health. Holism is central to CAM theories and practices, involving “all aspects of lifestyle, including environment, diet, physical fitness, emotional stability, emotional awareness, sense of faith”[35]. CAM is further defined as complementary: a non-mainstream practice used together with conventional medicine, and alternative: as a non-mainstream practice used in place of conventional medicine (NCCIH, 2016). Integrative medicine is the convergence of conventional and complementary medicine in a coordinated manner [36].

2.6 Problem Area

The etiology of MS is still unknown and patients suffering from MS commonly seek CAM treatments. Due to the scarcity of studies on AK treatment in general and of AK treatment of MS in particular, it is important to conduct an exploratory descriptive case study of patient experiences of AK treatment of MS.

3. Aim

The objective of the case study is to document and analyze the experience of applied kinesiological treatment of patients suffering from multiple sclerosis.

4. Methods

To map out an area that previously has not been the topic of academic research, a qualitative approach is adequate to obtain an overall picture of a new phenomenon, and through interviews, a phenomenon is highlighted, analyzed and described [37, 38]. Qualitative methods are useful for the study of human and social experience, communication, thoughts, expectations, meaning and attitudes [38].

4.1 Case Study

We conducted an exploratory descriptive case study into a field that is currently undocumented. This method is suitable for analyzing the etiology and mechanisms of a contemporary subject over which the investigator has little or no control [39]. Furthermore, Yin proposes that a case study can be used to investigate a phenomenon in depth in its real-life context and is especially applicable when the boundaries between a phenomenon and its context are not evident. This is a multi-case study and its strength is the rationalization of literal and theoretical replication, making it more robust than a single case study [39].
4.2 Context

Inclusion criteria: purposive sampling was used to select patients who had been diagnosed with, and treated for, MS at a neurology department in Stockholm and simultaneously and individually sought CAM-treatment from a specific kinesiologist. Exclusion criteria: patients who sought only one form of treatment. The kinesiologist practiced at an AK treatment center outside Stockholm and established in 1995. The number of informants was based on the number of patients referred by the kinesiologist and who agreed to participate in the study. More patients could have been selected, but due to time limitations, the selection process stopped after consent to participate was received from three patients. The case study design rendered the need for more cases superfluous. The treating kinesiologist contacted the patients by telephone during September and October 2016, requested their participation, and following acceptance, forwarded contact information to the first and corresponding author. Two patients declined to participate in the study. According to the kinesiologist, the three patients were selected because they were the first he encountered who met the inclusion criteria of having been diagnosed as suffering from MS by a MD and who also sought AK treatment. The patients had no prior and/or present knowledge of each other. No relationship was established between patients and researchers prior to study commencement. Two separate interviews were conducted, a primary interview and a second follow-up interview performed during October and November 2017.

4.3 Data and Data Collection

The sample comprised three patients who had been diagnosed with MS by a MD and who were receiving AK treatment for the condition (Table 1). The patients were all referred by the kinesiologist who first requested permission to disclose personal contact information concerning participation in interviews about their experience of AK treatment, and their thoughts on health and trust. The interviews were open-ended, semi-structured without probing since prior knowledge of the outcome of the interviews was low. The interview guide was developed based on Kleinman’s Illness Explanatory Models [40] (Appendix 1). There were two individual meetings with each participant. The first meeting was the interview itself and lasted for 30–45 minutes, whereas the second meeting took place when the patient had received and validated a copy of the transcribed interview. The first interviews were conducted in the participant’s home; although in one case, a telephone interview was conducted. One follow-up interview was conducted in a café, one in the participant’s home and one over the telephone.

Table 1 Case study sample.

<table>
<thead>
<tr>
<th></th>
<th>Case 1</th>
<th>Case 2</th>
<th>Case 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex</td>
<td>Female</td>
<td>Female</td>
<td>Female</td>
</tr>
<tr>
<td>Age</td>
<td>46</td>
<td>52</td>
<td>44</td>
</tr>
<tr>
<td>Marital status</td>
<td>Divorced</td>
<td>Divorced</td>
<td>Married</td>
</tr>
<tr>
<td>Children</td>
<td>Two children, shared custody</td>
<td>Two children, one at home</td>
<td>Two children at home</td>
</tr>
<tr>
<td>Occupation</td>
<td>Accountant</td>
<td>Tailor and saddler</td>
<td>Economist</td>
</tr>
</tbody>
</table>
The interview questions concerned the patient’s personal experience of AK treatment and what the treatment has meant to them [41]. To counterbalance selection bias and possible preconceptions, fieldnotes were taken prior to, during and after each meeting with the participants [42]. The fieldnotes were utilized as an instrument to prepare the researcher for the process of interviewing and enabling the conscious process of separating the personal from the professional aspects of their role. The three participants shared their medical records of the MS diagnosis, the documentation of the progression of the disease and/or the progression of their MRI status. These medical records create a source of data separate from the interviews and were used with the recommendation from the local Ethics Committee. To create validity in an exploratory case study, Yin (2009) suggests several tactics, such as the use of multiple sources of evidence and allowing participants to review the data.

4.4 Data Analysis

Data were evaluated through phenomenological-hermeneutic text analysis. This method is frequently applied in qualitative humanistic studies in which the main body of data consists of narrative interviews that are recorded and transcribed producing a text for analysis [43]. Ricoeur [44] stated that “interpretation of the text constitutes a movement from understanding to explanation and from explanation to comprehension.” On the same note, Lindseth and Norberg (2004) explained their phenomenological-hermeneutic methodology as consisting of three working phases: naïve reading, structural analysis and comprehensive understanding. The goal of phenomenology is the collection and full description of vast bodies of data without reducing the richness of life or life experiences. Considering the exploratory aspect of the study, this method of analysis appeared suitable, encompassing an open-ended design for gathering data. The analysis consisted of an individual report of each case, followed by a cross-case analysis (Table 2) and the drawing of conclusions [39]. The validity of the analysis was confirmed by a co-researcher involved in the study, who held a PhD and whose research was based on qualitative methodology [37]. This retrospective study was approved by the regional research Ethics Committee in Stockholm, Sweden (2014/373-31/1). All participants were guaranteed full confidentiality, and all gave informed consent to participate. The informants will have access to the analysis when finalized by receiving a personal copy of the study.

In this study, patients are at risk of re-living some of the hardships of their disease while providing their accounts, which might have psychological and emotional implications [37, 45]. In such cases referral to professional counseling was prepared for.

Table 2 Cross-case synthesis.

<table>
<thead>
<tr>
<th></th>
<th>Case 1</th>
<th>Case 2</th>
<th>Case 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical tests</td>
<td>MRI, LP</td>
<td>MRI, LP</td>
<td>MRI, LP</td>
</tr>
<tr>
<td>medical doctor</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physical symptoms at onset of MS</td>
<td>Right body numbness</td>
<td>Right body numbness</td>
<td>Right body numbness</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Headaches</td>
<td>Right leg problem</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Loss of speech</td>
</tr>
<tr>
<td>diagnosis</td>
<td>Double vision Dizziness</td>
<td>Double vision Balance problem</td>
<td></td>
</tr>
<tr>
<td>-----------</td>
<td>-------------------------</td>
<td>-----------------------------</td>
<td></td>
</tr>
<tr>
<td>Mental symptoms at onset of MS</td>
<td>Depressed</td>
<td>Frightened</td>
<td>Depressed</td>
</tr>
<tr>
<td>Treatment</td>
<td>Applied kinesiology</td>
<td>Applied kinesiology</td>
<td>Conventional medicine/applied kinesiology</td>
</tr>
<tr>
<td>Medical treatment</td>
<td>Interferon injections for 4 weeks</td>
<td>Interferon injections for 3 months</td>
<td>Interferon injections for 2 years, Tysabri for 6 years, Mabthera since 2016</td>
</tr>
<tr>
<td>Start of kinesiology treatment</td>
<td>One month prior to diagnosis</td>
<td>Six months prior to diagnosis</td>
<td>11 years after first incidence, 8 years after diagnosis</td>
</tr>
<tr>
<td>Dietary changes recommended by kinesiologist</td>
<td>Stop eating wheat, rye, and dairy products</td>
<td>Stop eating wheat and dairy products</td>
<td>Stop eating wheat most of the time except while on vacation</td>
</tr>
<tr>
<td>Relapse</td>
<td>No relapse</td>
<td>No relapse</td>
<td>One relapse (prior to AK treatment)</td>
</tr>
<tr>
<td>Physical symptoms at interview</td>
<td>None</td>
<td>None</td>
<td>Right leg weakness Balance problem</td>
</tr>
<tr>
<td>Mental symptoms at interview</td>
<td>Feeling healthy Mentally robust</td>
<td>Feeling healthy Mentally robust</td>
<td>Feeling healthy Mentally robust</td>
</tr>
<tr>
<td>Outcome</td>
<td>EDSS level 0 No increase in cervical spinal cord or brain damage MRI: no new lesions found</td>
<td>EDSS level 0 No increase in cervical spinal cord or brain damage MRI: no new lesions found</td>
<td>EDSS decreased from level 3 to level 2 No increase in cervical spinal cord or brain damage MRI: no new lesions found</td>
</tr>
</tbody>
</table>

5. Findings

5.1 Case Presentation and Naïve Understanding

Case 1. The woman interviewed in Case 1 was referred to the kinesiologist by family prior to having an incident of right body numbness and a loss of control over the right side of the body. During this incident, she sought hospital care and underwent a magnetic resonance imaging (MRI) scan as well as a lumbar puncture (LP). A few months later, she was diagnosed with MS. The patient received interferon injections for four weeks but the treatment was stopped due to severe side-effects, including influenza-like symptoms. The patient sought AK treatment from the kinesiologist and after 1 year, she adopted the specific recommendation of the kinesiologist to exclude wheat, wheat starch and rye from her diet. Diet changes were essential and improved her sense of health and well-being. The hospital stated that they would perform follow-up MRIs 1 year after diagnosis; however, she was not contacted until 5 or 6 years later, which caused her to lose trust in the medical system. During this period, she had experienced improved health and gained trust in the kinesiologist.
Case 2. Case 2 was also a woman who sought treatment from the kinesiologist prior to being diagnosed with MS. The patient experienced episodes of dizziness, headaches, right body numbness and double vision, whereupon she sought medical care. The MS diagnosis was given quite quickly after an MRI and LP were performed, and she started medical treatment with interferon injections. Due to severe side-effects, including influenza-like symptoms, the injections were stopped after three months and she sought AK treatment from the kinesiologist. In this case too, the kinesiologist was recommended by a friend. The patient experienced having hope, which increased immediately following the primary AK treatment and enabled her to trust the kinesiologist. She made dietary changes instantly and stopped eating wheat and dairy products directly after being diagnosed with MS, thus causing her to realize that the diet changes were essential. The patient had been back to the hospital for MRIs a few times; however, at the time of the interview, she had not been contacted by the hospital for 5 years. The participant had not felt the need for medical consultations and experienced a loss of trust in the medical system.

Case 3. Case 3 was a woman who experienced loss of speech, right leg numbness, and double vision. After a month, most of the problems had subsided. The hospital continued to monitor her health status without providing a diagnosis for a further 4 years. The participant had two children before commencing any medical treatment. Nine years after the first MS episode, the patient reacted very strongly to analgesic injections during surgery to correct a hallux valgus. The patient described her own reaction as hysterical. Following this experience, the first relapse of MS occurred and the expanded disability status scale (EDSS) level escalated to 3. The patient was first treated with interferon injections, which she continued for 2 years in spite of severe side-effects, including influenza-like symptoms. At this time, she was referred to the kinesiologist through friends and sought treatment. At the time of interview, she had been receiving medical treatment and AK treatment in parallel for the previous 6 years, and the EDSS level had come down to 2, where it had remained for the previous 5 years. The patient had realized that diet changes were essential and had excluded wheat from her diet some years previously, although she made exceptions to the diet during vacations. She currently has remnants of right leg numbness and recurring balance problems, goes to a personal trainer (PT) and engages in physical training. She reported feeling confused facing the conundrum as to the cause of the symptoms and effects of her fitness regimen considering the restrictions of motherhood resulted in her being physically unfit. At the same time, she felt frightened by recurring falls and stumbling caused by right leg weakness and was uncertain as to what improvements were due to her medical and AK treatments. Due to her complex set of simultaneous lifestyle modifications and different treatments, she reported trusting the medical system, and trusting the kinesiologist as well as having hope.

5.2 Structural Analysis

During the first naïve reading and the subsequent structural analysis, different themes emerged from the interviews. The analysis of the transcribed interviews will be presented, highlighting the complexity of the individual cases as well as apparent similarities.

Having hope. In the quest for a healthy life, the patients in all three cases reported having hope in relation to having been diagnosed with MS. Having foresight is an important ingredient in coping with a serious ailment and participating in a process aimed at improving health. All three
cases showed this aspect of experiencing hope when depression or darker feelings could have been expected considering the chronic aspect of MS.

“When I received this new diagnosis of MS, the kinesiologist could immediately remove the worst symptoms and then we could all go on vacation, the whole family actually.”

**Trusting the kinesiologist.** All three patients recollected how they felt able to trust the kinesiologist immediately on commencing treatment. This sense of trust had remained throughout years of receiving AK treatment. The ability to trust was referred to by all as a vital element of their treatment, motivating them to comply with the kinesiologist’s advice to avoid wheat and/or rye and/or dairy products, taking the prescribed herbal medication and vitamin supplements, and continuing treatment.

“When you go for AK treatment, you get a lot of confidence in the kinesiologist because if you have a problem, you do not have to say it, he finds it and it's quite fascinating but very hard to tell others who have not met him.”

And:

“Yes, I do trust him, because I've had results so many times, indicating he knows what he's doing. You will get help when you go there.”

**Diet changes essential.** Excluding wheat from a diet while living in a Western country requires a distinct effort, since one has to read all labels on all food and be interrogative at all times in restaurants and public places that serve food and beverages. All three cases made major dietary changes and found this essential to the improvement of their health.

“So I do think that I am allergic to wheat flour more than that I have MS basically, or maybe that I have the tendency towards MS in the body.”

The patient in Case 3 stated that she made exceptions to the dietary restriction during vacations, and said that she refused to feel guilty about this, meaning that she had to live her life.

**Losing trust in the healthcare system.** The patients in both Case 1 and Case 2 lost their trust in the healthcare system during the process of commencing AK treatment. Both women had not been contacted by the healthcare system for a period of 5 years; however, the feeling that they had been forgotten was not directly linked to their loss of trust in the healthcare system. Rather the loss of trust was due to various reasons and conditions appearing as a result of, and including, the overall aspect of experiencing a sense of health.

“Yes, I have confidence in the kinesiologist. But then, I do not have the same confidence in the healthcare service, no.”

Both patients stated feeling that changes of diet and the effects it has on ailments and chronic conditions were not a consideration of the healthcare system. Based on the changes in lifestyle made by all three patients, they further claimed feeling that the medical system would only consider aspects of lifestyle such as physical training.

“I have no confidence at all in regular medical care, I do not go to the doctor unless I've broken my leg or something like that. So no, I do not trust what they are saying.”

**Feeling confused.** The patient in Case 3 reported trusting both the kinesiologist and the healthcare system and received treatment from both simultaneously. She recollected that the kinesiologist had told her that she could refrain from medical treatment; however, she stated that even though she trusted the kinesiologist, her trust was not blind, so she did not want to stop medical treatment. She was feeling confused as to what was helping to improve her health, since
she was working with a PT, had made dietary changes, received medical and AK treatment and was advancing in her professional position.

“The question is, the body is not so logical, or well, maybe it is, but it's hard for a normal person to know what's what.”

Getting better. All participants experiencing positive results rapidly following AK treatment, which all described as having been a great motivator for continuing with the treatment. They all recollected experiencing improved health immediately following a treatment, some even at the point of leaving the consultation room.

“The stomach is better. I was really in pain after the hallux valgus surgery, and then I got other problems in my foot. I do not know if this often happens, but I got Morton syndrome, with pain in your nerves. That completely disappeared when I got AK treatment and I need much less sleep.”

5.3 Comprehensive Understanding

The naïve reading was validated by the structural analysis. This process entailed referring to both the naïve reading and the structural analysis based on condensed descriptions [43]. A comprehensive synthesis of the structural analysis is shown in Table 3.

<table>
<thead>
<tr>
<th>Case 1</th>
<th>Case 2</th>
<th>Case 3</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Making lifestyle changes</strong></td>
<td>Diet essential</td>
<td>Diet essential</td>
</tr>
<tr>
<td>Losing trust in the medical system</td>
<td>Losing trust in the medical system</td>
<td></td>
</tr>
<tr>
<td><strong>Getting past the diagnosis of MS</strong></td>
<td>Having hope</td>
<td>Having hope</td>
</tr>
<tr>
<td>Trusting the kinesiologist</td>
<td>Trusting the kinesiologist</td>
<td>Trusting the medical system</td>
</tr>
<tr>
<td><strong>Experiencing health through AK treatment</strong></td>
<td>Improved health</td>
<td>Improved health</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Feeling confused</td>
</tr>
</tbody>
</table>

Making changes for life. In all three cases, the patients made substantial dietary changes recommended by the kinesiologist and all were convinced of the benefits that accompanied these sacrifices and changes. They experienced a sense of increased control over the risk of a MS relapse. The two women who had been following the kinesiologist’s recommendations were well. The health of the patient who was following the kinesiologist’s recommendations and simultaneously receiving conventional medical treatment had stabilized. She also experienced improved health immediately after each AK treatment although the improvements may not have happened exactly as she had hoped; for example, although she first sought treatment for right leg weakness, the most significant positive change she experienced was improvements in her stomach condition. Furthermore, the patient was continually concerned about maintaining this condition that had improved her life.
Getting past the diagnosis of MS. All participants shared their medical records showing a diagnosis of MS by an MD. The patients in Cases 1 and 2 trusted the CAM practitioner and were feeling healthy. Neither of them identified themselves by their condition and had medical records showing that their MRIs did not indicate an increasing severity of MS. However, their medical records did not state that they were MS-free, which is to be expected since the medical world considers MS to be incurable. Following the primary medical treatment with interferon, all the patients had almost identical experiences of an influenza-like syndrome lasting for a day or two after the injection. All the patients explained how they were able to live beyond the MS diagnosis, with the patients in Cases 1 and 2 not identifying with the MS diagnosis at all. The patient in Case 2 said that she usually told people that she had recovered from MS, despite being acutely aware that this is highly improbable. The patient in Case 3 said she had MS but that there were much worse things in the world and she did not feel impaired by the condition, nor was she afflicted by relapses.

Experiencing health through AK treatment. The AK treatment had given the participants a sense of hope, trust and increased health. All the participants had been able to create a bridge traversing fear and despair, not to mention hopelessness, and had found the courage and bravery necessary to try new treatments and make way for experiencing health. That illustrates a concept of health as a holistically defined sense based on the individual and specific experiences of each person receiving AK treatment involving herbal medication, vitamin supplements, dietary changes, physical exercise and in one case, combining all of these elements with conventional medical treatments.

6. Discussion

The apparent serendipity and outstanding coincidence surrounding the circumstances by which the patients in Case 1 and Case 2 found the kinesiologist prior to having been diagnosed with MS was an extraordinary ingredient in their individual treatment and its success. The ramifications of this remain unclear, since it was not the subject of study, but rather an aspect revealed during the study. All three cases have reported unconditionally seeking AK treatment, implying that they had been prepared to make life changes and “take the leap of faith” required to bridge the gap. Such action requires bravery considering the biomedical paradigm in conjunction with the limitations of evidence for the effectiveness of CAM treatments. Rather, it relies heavily on the individual’s courage and quest for a healthier life, displaying self-awareness and self-care [46].

This cross-case synthesis shows that AK treatments warrant further investigation (Table 2). A comprehensive understanding of AK is necessary considering the absence of a cure for the chronic condition of MS, in addition to the absence of conclusive evidence for the etiology and effects of medication [6]. This study indicates the potential scientific relevance of AK treatment based on the parallel stabilization of the MRI scans during the treatment periods in all three cases combined with the real-life experience of increased health; therefore, these findings urgently need further investigation. Hope and trust were shown to be important factors in the complex relationship between doctor/practitioner and patient. The content of AK treatments cannot be evaluated in this present study; it was not subject of this research. The present study aimed to describe the patients’ experiences of AK treatment for MS. Two of the participants appeared so well that they did not feel impaired, struck by illness, or in need of medical treatment, despite apparently being
lost to the medical system. In Case 3, the EDSS level decreased from level 3 to level 2 and had remained stable for the 5 years prior to the study, also indicating stability and recovery. This indicates that AK treatments have improved the patient’s experience of health.

All three women were happy and were not afflicted by depression [47] caused by the loss of health, their mental robustness having improved with their physical health. They were content with the kinesiologist and their AK treatments. The patients in Cases 1 and 2 clearly stated that trusting the practitioner was of the utmost importance and neither patient trusted the medical system; in contrast, the patient in Case 3 trusted both the kinesiologist and the medical system. The main conclusion from this is that trust contributed the experience of AK treatment, resulting in a “no fear” existence for all three patients. In all three cases, the patients had, to some degree, received treatment from the medical system, changed their diets, experienced improved health, trusted the kinesiologist, and practiced physical exercise; all of which were indicative of an underlying broader definition of health. All three patients had a holistic health experience that allowed them to transcend their diagnosis of MS.

6.1 Methodological Considerations

The validation of the interviews was uncomplicated; while reading the transcribed interviews, all participants made only minor corrections, with no factual errors, just minor misunderstandings. This study is a best-case scenario with a certain amount of bias and selection bias considering that patients were referred by the treating kinesiologist [38, 45]. Malterud [38] claims that the retrospective casuistry in medical research is usually based on a so-called “Eureka moment” that one later wants to relate to others. External validity is not considered the stronghold or the purpose of qualitative studies [45], although Malterud reminds us that the English physician Edward Jenner discovered the principle of smallpox vaccination in the year 1796 based on a single case study. Kvale further opines that “to validate is to investigate”, suggesting that validation should be conducted throughout the research. For the same reasons, Yin (2009) also suggests using replication logic in the design of multi-case studies. To generate validity in this exploratory case study, multiple sources of evidence were utilized [39] [48], and Malterud [49] similarly states that “the validity of clinical evidence can be strengthened when qualitative and quantitative methods complement each other”.

Future studies are needed to examine patient experiences of AK treatments and to assess whether AK treatments are experienced as transformative as they were in the present study. The participants should be enrolled on the basis of open exit selection. Future studies on AK treatment, both as a diagnostic and a therapeutic tool, are of importance for furthering our scientific understanding of this method. Future rigorous research with the capacity to produce reliable evidence regarding CAM theories and practices are of importance for the safety of patients.

7. Conclusion

In this case study of three women who sought AK treatment for MS, all three patients reported being able to make changes for life, getting past their diagnosis of MS and being able to experience increased health through AK treatment. In relation to the phenomenological narratives in illness studies, our findings suggest that the interviews in this study are phenomenological-hermeneutic narratives of health, as well as describing experiences of
becoming at one with the body. The interviews also assess the value of AK treatments as a holistic approach assisting patients in sculpting the living body [50] into the home-likeness of being-in-the-world [33], experiencing becoming whole, and experiencing health. In each of the cases reported here, the MRI results were stabilized during the AK treatment period and all three patients felt able to transcend their diagnosis of MS.

Acknowledgments

The authors are grateful to all three patients for sharing their lived experiences of seeking AK treatment for the affliction of MS, to the kinesiologist for sharing patient referral contact information and for having sought primary consent from the patients to participate in the research.

Author Contributions

The authors have contributed in all stages, from formulation the project, development, reading, analysing, discussing, and writing. Katarina has been the initiative-taker, and coordinator and was responsible for manuscript editing. Data and material are available upon request with respect to the integrity of the participants.

Competing Interests

The authors have declared that no competing interests exist.

List of Abbreviations

AK Applied Kinesiology  
CAM Complementary and Alternative Medicine  
EDSS Expanded Disability Status Scale  
LP Lumbar puncture  
MD Medical Doctor  
MMT Manual Muscle Testing  
MS Multiple Sclerosis  
MRI Magnetic resonance imaging  
PT Personal trainer

Appendix 1: Interview Guide

CAM & MS 2017-10-10
1. Can you tell me what it was like to get MS and what it has meant for you?
2. The treatment you received with kinesiology, what has it meant for you? How did you experience kinesiological treatment?
3. How do you experience your health today?
4. Can you give me personal information about your age, family situation, education and occupation?
5. How do you look at the future?
6. Do you have medical data showing that you have been diagnosed with MS and how your test questions (MR and LP) have looked like, can I see them?

Follow-up Interview:
1. Have you read the transcribed interview and do you think it is correct, as it has been transcribed?
2. What is health, how does it occur and how is it maintained?
3. Is trust important to you in your relationship to health?

References
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Case Report

**Chronic Pain Two Cures**

James David Adams, Jr *

University of Southern California, School of Pharmacy, Los Angeles, CA, USA; E-Mail: jadams@usc.edu

* Correspondence: James David Adams; E-Mail: jadams@usc.edu

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**Abstract:**

**Background:** This study presents several case reports of chronic pain patients treated with two different plant medicines from the Chumash Indian tradition.

**Methods:** Patients suffering from self-reported fibromyalgia, chronic back pain, chronic bursitis, chronic tendinitis and other conditions were treated. California sagebrush (Artemisia californica) was grown by the author and made into a liniment. The liniment was applied to painful sites on the skin. Black sage (Salvia mellifera) was made into a sun tea. Chronic pain and other pain patients soaked their feet in the preparation.

**Results:** The liniment provided relief from even severe pain within a minute or so. After daily use for several days, chronic pain was resolved in several patients. The sun tea provided pain relief throughout the body within 20 minutes. After 1 – 7 days of once daily use, several chronic pain patients had improved conditions.

**Conclusions:** Both A. californica liniment and S. mellifera sun tea provide pain medicines that according to patients, can cure chronic pain. Cure means the pain does not return.

**Keywords**  
Chronic pain; cure; California sagebrush; black sage; monoterpenoids; sesquiterpenoids; pain chemokine cycle
1. Introduction

Chronic pain affects 11% of US adults and increases with age [1]. There is no FDA approved cure for chronic pain. Chronic pain patients are treated with oral non-steroidal anti-inflammatory agents and oral opioids that kill over 100,000 patients every year from ulcers, heart attacks, strokes, seizures and respiratory depression [2].

Pain is sensed in the skin and is best treated in the skin [3, 4]. Transient receptor potential cation channels are abundant on sensory afferent neurons of the skin. These channels are the main pain receptors in the body. There are 28 different transient receptor potential cation channels that exist on nonoverlapping populations of skin sensory afferent neurons. These channels can be inhibited by plant derived monoterpenoids. It is critical to use a mixture of several different monoterpenoids to inhibit as many types of transient receptor potential cation channels as possible.

Chronic pain is caused by a cyclic, self-perpetuating mechanism in which stressed or damaged skin cells release chemokines that stimulate production of prostaglandins and IL-17 [2, 5]. Prostaglandins and IL-17 then stimulate chemokine production. Prostaglandins come from cyclo-oxygenase-2 that is present in macrophages attracted into the skin by chemokines. Prostaglandins cause pain by interacting with prostaglandin receptors and enhance pain by inducing the phosphorylation of transient receptor potential cation channels. Skin resident T cells produce IL-17. This is the pain chemokine cycle. Oral medications do not adequately penetrate into the skin to inhibit these mechanisms and stop chronic pain.

The A. californica liniment has been successfully used on patients suffering from broken bones, pain from large abrasions, bruises, sprains, strains, spinal stenosis, osteoarthritis, rheumatoid arthritis, cancer pain, bursitis, muscle pain from over exertion, gout, hip replacement, knee replacement, headaches, migraine headaches, basilar migraines, diabetic neuropathy, shingles, bee stings, a gunshot wound to the abdomen and other conditions [6-8]. The S. mellifera sun tea has been successfully used to treat pain from abrasions, bruises, sprains, strains, osteoarthritis, rheumatoid arthritis, bursitis, muscle pain from over exertion, headaches and other conditions [6, 9].

2. Materials and Methods

The liniment was made as follows: 86 g of leaves and branches of A. californica, 1 leaf of Salvia apiana, one Persea americana seed and 500 ml of 70% isopropanol were put into a brown glass jar for 6 weeks [7]. The plant material was removed leaving a dark green liniment. Sun tea was made from S. mellifera: 115 g of leaves and stems, 1 leaf of Salvia apiana, 2 liters of water were combined and placed in the sun for 4 – 6 hours [6]. The plant material was removed leaving a red-brown sun tea.

The author is not a medical doctor and did not perform any diagnostics tests or examinations on any patient. The diagnoses provided to the patients by other medical professionals were used in this work. Many patients declined to provide information on family history, medications, other medical conditions, psychosocial history, or genetics. The data that was provided by patients is presented in the results. The author did not perform examinations or diagnoses after treatment, but relied on the ability of each patient to rate their pain. Many patients were treated once, reported pain relief, but were lost to follow up. These patients are not included in this work.
Chronic pain patients were given the liniment and instructed to apply it liberally to the skin at painful sites with a cotton ball or by spray. They were instructed to continue using the liniment once or twice daily for 5 – 7 days. Other chronic pain patients were asked to soak their feet in the sun tea for 20 minutes or more. They were instructed to soak their feet in the sun tea once daily for 5 – 7 days. All chronic pain patients were asked to stop all oral pain medications, including opioids.

Before and after the initial treatment, patients were asked to rate their pain on a scale of 0 – 10. They were asked to report their pain levels after 5 – 7 days of treatment. Patients were recruited from the general population around Southern California. These were people who attended talks about Chumash Healing given by the author. Some of the patients attended because they were willing to try anything to treat their chronic pain, others attended in order to prove that the chronic pain treatments were ineffective. The patients did not share common beliefs or opinions. All patient personal information is protected and will not be published. The author is a recognized traditional healer in the Chumash Indian tradition. He is allowed to practice traditional healing and is protected by California State Law.

3. Results

Chronic pain has been successfully treated in many patients, at least 31, with the liniment and/or the sun tea. It was noted with several patients that in order to improve chronic pain, all opioids had to be stopped, including fentanyl patches. This involved cutting opioid doses in half every week until all opioids were no longer used. Opioid induced hyperalgesia was noted in several patients. Chronic pain was resolved in many patients with back, neck and other pain.

A Caucasian man, 58 years old, suffered from chronic back pain and had a diagnosis of slipped disks. He began using the liniment and reported that he was cured of his chronic pain within 3 weeks. He no longer needed any pain medication and returned to a normal life. He had no other illnesses, was not using any medications and had no family history of chronic pain.

Another Caucasian man, 55 years old, suffered from chronic back pain and found that the liniment relieved his pain. He was reluctant to stop his oral opioids and struggled with his opioids for several weeks until he was able to stop them, while continuing the liniment. He then reported he was cured of his chronic pain. He did not recall if there was a family history of chronic pain and declined to discuss other medications or conditions he had.

A Caucasian woman, 48 years old, suffered from chronic back pain for many years. After using the liniment for three weeks and gradually stopping her opioids, she reported that her pain was much better and she no longer needed pain medicines. She had no family history of chronic pain and did not discuss other medications or conditions she had.

A Caucasian man, 34 years old, suffered from chronic back pain for many years. He began using the liniment while gradually stopping his opioids and reported that he was cured of his pain after a month. He declined to discuss other details of his history or conditions.

A Caucasian woman, 36 years old, suffered from chronic back pain, started using the liniment, gradually stopped using oral opioids and reported that she was cured after four weeks. She did not want to discuss other details of her history or medications.

A Latino man, 48 years old, suffered from a herniated disc since he was a child. He used the liniment for four weeks, gradually stopped his opioids and reported that he was cured of his pain.
He did not suffer from other conditions, did not discuss other medications and had no family history of chronic pain.

A Caucasian man, 49 years old, suffered from chronic back pain due to spinal stenosis and reported pain relief when he used the liniment. After using the liniment for five weeks while gradually stopping oral opioids, he reported that he was cured of his chronic pain. He declined to discuss other details of his history or medications.

A young Caucasian woman, 25 years old, suffered from chronic back pain for several months after excessive gym exercises. She used the liniment while gradually stopping oral opioids over a three week period and reported that she was cured of her chronic pain. She had no family history of chronic pain, was not using other medications and was otherwise healthy.

A young Caucasian woman, 26 years old, suffered from chronic back pain after a car accident. She used the liniment for four weeks while gradually stopping oral opioids and reported she was cured of her pain. She had no family history of chronic pain, did not suffer from other conditions and was not using other medications.

A Caucasian man, 28 years old, suffered from chronic back pain after a car accident. He treated his pain daily with six tablets of oxycodone. He reported that the liniment relieved his pain. He slowly weaned himself off of oxycodone and continued the liniment. One week after stopping the oxycodone, he reported that he was cured of his chronic pain and no longer needed pain medication. He was otherwise healthy, had no family history of chronic pain and used no other medications.

A pregnant woman 32 years old, suffered from chronic back pain. She used the liniment for one week and reported that her back pain was gone and did not return. She was otherwise healthy, had no family history of chronic pain and was not taking other medications.

A young Asian man, 72 years old, had suffered from chronic back pain for several years. He used the liniment for one week and reported that he was cured of his pain. He declined to discuss other details of his history or health.

A 62 year old Caucasian man had suffered from chronic back pain for several years. He tried the liniment and said it did not relieve his pain. He tried the liniment a few more times over the next few days and said he got no relief from his pain. This patient declined to say if he was using opioids and declined to discuss other details of his condition or history.

A male Asian, 72 years old, had suffered from chronic back pain for several years. He used the sun tea for one week and reported that he was cured of his pain. He declined to discuss other details of his history or health.

A Caucasian woman, 73 years old, suffered from postsurgical chronic back pain, used the sun tea and the liniment for one week and reported she was cured of her pain. She suffered from no other conditions, was not using other medications and did not report her family history.
A Caucasian woman, 75 years old, suffered from chronic back pain for 15 years. She used the sun tea and the liniment for one week and reported she was cured of her pain. She did not suffer from any other condition and declined to report her history or other medications.

A Caucasian woman, 63 years old, suffered from fibromyalgia for many years. Her fibromyalgia limited her ability to do her job. She used the sun tea for one week and the liniment for one month, while stopping all other pain medications, and reported she was cured of her fibromyalgia pain. She was otherwise healthy, did not use other medications and had no family history of chronic pain.

A Caucasian woman, 75 years old, suffered from chronic shoulder pain for many years. She used the liniment for one week and reported she was cured of her chronic pain. She was in the practice of using marijuana regularly, did not use other medications, had no family history of chronic pain and suffered from hip arthritis.

A Caucasian woman, 64 years old, suffered from chronic shoulder pain for several months. She used the liniment for five days and reported that she was cured of her pain. She did not suffer from other conditions, had no family history of chronic pain and did not discuss the use of other medications.

A Caucasian man, 61 years old, suffered from chronic bursitis of the neck, shoulders and back for several months. He used the liniment for one week and reported he was cured of his bursitis pain. He was otherwise healthy, used no other medications and had a family history of chronic pain in his mother.

A Caucasian man, 55 years old, suffered for several years from bursitis in the right shoulder that interfered with sleep. He was addicted to oxycodone that was used to treat his pain. The liniment cured his bursitis pain temporarily, only as long as he could avoid taking oxycodone. Oxycodone induced hyperalgesia was a prominent problem in this patient. When he started oxycodone again, the pain returned. He eventually stopped taking oxycodone and reported the liniment cured his chronic pain. He declined to discuss other details of his health or history.

A Caucasian woman, 64 years old suffered from chronic shoulder pain for several months. She used the liniment for one week and reported she was cured of her pain. She was otherwise healthy and declined to discuss the use of other medications or details of her health or history.

A Caucasian man, 60 years old, suffered from tendinitis in his right leg for several months. He reported that his pain was cured after using the liniment for one week. He was otherwise healthy and declined to report other details of his history or health.

A Latino woman, 78 years old, suffered from tendinitis in her right leg for several years. She used the liniment for one week and reported that she was cured of her pain. She declined to discuss other details of her health or history.

A Caucasian man, 42 years old, suffered from chronic knee pain for several months. He used the liniment for one week and reported that he was cured of his pain. He was otherwise healthy and did not discuss other details of his health or history.

A Caucasian woman, 28 years old, suffered from chronic foot pain. She used the liniment for one week and reported that she was cured of her pain. She did not suffer from other conditions, did not use other medications and had no family history of chronic pain.

A young Caucasian man, 26 years old, suffered from chronic knee pain. He used the liniment and reported he was cured of his pain after one week. He was otherwise healthy and did not discuss other details of his health or history.
A Caucasian man, 32 years old, suffered from chronic knee and shoulder pain. He used the liniment for one week and reported he was cured of his pain. He was otherwise healthy, did not use any medications and had no family history of chronic pain.

A Caucasian man, 27 years old, suffered from chronic knee pain for 3 months. He used the liniment one time and reported that he was cured of his chronic pain. He was healthy in every other way, did not use any medications and had no family history of chronic pain.

A Latino woman 58 years old suffered from chronic pain in her left hip for several months. She applied the liniment to her hip and received rapid relief of her pain. She continued to use the liniment daily for one week and reported that the pain did not return. She did not discuss other details of her health or history.

Many chronic pain patients were treated once with the liniment or the sun tea, reported relief of their pain but did not respond to requests for follow up information. It is not known if their chronic pain improved more than one day.

### 3.1 Limitations of the Study

The current work was conducted by a Pharmacologist who is a Traditional Healer, not a medical doctor. Therefore, medical records were not available. Many patients declined to state the cause of their pain or their family histories. Few patients were willing to discuss their drug therapy or other illnesses. The study was not placebo controlled. The investigator and the patients were not blinded to the identity of the drug used.

### 4. Discussion

The author applied for an Investigational New Drug application to the Food and Drug Administration in 2011 in order to perform a clinical trial with the liniment. The application was denied because the reviewing officials were not convinced of the safety of the liniment. The liniment is a traditional Chumash Indian remedy that has been used by the author and other practitioners of Chumash Healing in several hundred patients with no safety concerns or reports of tolerance, addiction or adverse drug events. In July of 2018, the Food and Drug Administration denied the New Drug application from the author for black sage sun tea, stating that more treatment data and safety data must be provided. The sun tea is a traditional medicine used by the Chumash Indians of California. The author has used black sage sun tea in many patients. None of the patients in the current study reported tolerance, addiction or adverse effects from the liniment or sun tea.

Several patients reported that they were able to stop using opioids because they found pain relief from the liniment or sun tea. Some of the patients were addicted to opioids and struggled to overcome their addictions. Most of the patients using opioids said that the liniment or sun tea helped them overcome their addiction and in some cases, opioid induced hyperalgesia.

One of the great fallacies in medicine is that pain comes from the brain and other internal sites. Therefore, pain must be treated in the brain with oral or injected medicines. The current report treated pain only in the skin, and provides evidence of improvements in chronic pain. The current report confirms that the safest and most effective way to treat pain is in the skin (2-8). Of course, the brain and brain stem are involved in processing pain.
Is the pain relief reported here due to the placebo effect? It is possible that some of the pain relief was due to the placebo effect, or perhaps due to the charisma of the author. However, in the author’s experience, chronic pain patients tend to be hostile toward charismatic people who offer placebos. It may be possible that a placebo controlled clinical trial could elucidate the placebo effects of the medicines used in this study. As stated before, the author has applied to the FDA to perform placebo controlled, double blind, randomized clinical trials of the medicines described in this work. The FDA has declined to approve the clinical trials.

Chronic pain patients were taught how to make the liniment and sun tea themselves for free. Many patients make the liniment for themselves and their acquaintances. The plants used to make the medicines are common, not endangered and can be grown in gardens to make harvesting easier.

The liniment and the sun tea contain several monoterpenoids that stop pain by inhibiting transient receptor potential cation channels and cure chronic pain by inhibiting the synthesis of IL-17 (2). This stops the pain chemokine cycle. Monoterpenoids are largely cleared from the skin by evaporation, only a small percentage passes through the skin and is cleared by the liver and kidneys.

The liniment contains sesquiterpenoids that penetrate into the skin and down regulate cyclooxygenase-2 (5). This shuts down the synthesis of prostaglandins and stops the pain chemokine cycle of chronic pain. Oral medications do not penetrate adequately into the skin to stop chronic pain. Sesquiterpenoids are largely cleared from the skin by evaporation. Only a small percentage is cleared by the liver and kidneys.

5. Conclusions

The Chumash Indians of California teach us how to cure chronic pain. The current case study provides the reason to perform randomized, double blind, placebo controlled clinical trials of the liniment and the sun tea. In the meantime, practitioners of Chumash Healing will continue to treat and resolve chronic pain.

Acknowledgements

The author gratefully acknowledges the Chumash Indians of California for teaching him how to treat pain and resolve chronic pain.

Author Contributions

The author performed all the duties described and wrote the manuscript.

Funding Source

The author has not been able to get any funding from any source to perform this work.

Competing Interests

The author has no competing interests.

Additional Materials
Table 1 Summary of chronic pain patients treated in this study. DTS – declined to state.

<table>
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<th>Duration of pain</th>
<th>Duration of pain relief</th>
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References

Review

Healthcare Provider’s Guide to Kratom: Succinct Introduction to the Basics and the Questions

Joseph V. Pergolizzi, Jr 1,2, Robert Taylor, Jr 1, Robert B. Raffa 2,3, 4, *, Jo Anne LeQuang 1

1. NEMA Research, Naples, FL, USA; E-Mails: jpergolizzi@adminnemaresearchcom.onmicrosoft.com; rtaylor@adminnemaresearchcom.onmicrosoft.com; joann@leqmedical.com
2. Neumentum, Palo Alto, CA, USA; E-Mail: robert.raffa@temple.edu
3. Temple University (Emeritus), Philadelphia, PA, USA
4. University of Arizona (Adjunct), Tucson, AZ, USA

* Correspondence: Robert B. Raffa; E-Mail: robert.raffa@temple.edu

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Abstract

Background: The leaves of Mitragyna speciosa (kratom), a tropical tree that is indigenous to Southeast Asia, have been used traditionally to increase stamina, as a digestive aid, and as an analgesic. Kratom use is now increasingly popular in the rest of the world because of easy availability through the Internet and real, or perceived, views of efficacy and safety.

Methods: PubMed and MedLine searches were conducted of published articles available in English.

Results: Mitragynine and 7-hydroxymitragynine are the primary psychoactive compounds of the over 25 alkaloids in kratom. Subjective effects are dose dependent: a mild stimulation at lower doses, sedative effects at intermediate doses, and mild opioid-like effects at higher doses. Toxicity is rare and may be due instead to polypharmacy. Abrupt discontinuation after extensive use can produce withdrawal symptoms, but use does not imply overt dysfunction or decreased quality of life. In fact, Kratom has been used by opioid substance abusers as a means of easing withdrawal. Indeed, the use of kratom as a safer choice than opioids is an argument against overzealous regulatory control. Potential therapeutic utility
as a mixed-acting analgesic agent, anti-inflammatory, and possibly anticancer agent are currently being investigated.

**Conclusions:** Kratom or one or more of its constituent substances likely have important therapeutic potential – or as drug-discovery leads – as analgesics, treatment or prevention of opioid use disorder, and possibly other medical conditions. Since its use as a recreational drug is also on the rise, it is imperative that healthcare providers and regulators maintain an open mind and support the need for more basic and clinical research to help elucidate the actual potential medical benefits and potential adverse effects of this simultaneously old, yet new, pharmacologic agent.

**Keywords**
Kratom; pharmacology; therapy; opioid-abuse treatment

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### 1. Introduction

*Mitragyna speciosa* (kratom) is a tropical tree of the Rubiaceae family (of which coffee is also a member) that is indigenous to Southeast Asia. Leaves from the tree (see Figure 1) are traditionally used (chewed) by laborers to increase energy and stamina [1], or for medicinal purposes such as pain relief, digestive disorders, and even to attenuate morphine withdrawal [2].

![Figure 1 Kratom plant (photo credit: Wikimedia Commons).](image)

Kratom has become increasingly popular and visible in the rest of the world in recent years [3]. As a natural substance with a long history, this ethnodrug known variously as ‘kratom’, ‘ketum’, ‘biak’ (Malaysia), or ‘krathom’ (Thailand) among others, is both scientifically interesting and a potential concern to healthcare providers and regulatory agencies because not enough is understood about its pharmacologic or adverse effects. Complicating things, as an unregulated natural product, the exact composition of a given commercial product is often unknown.

### 2. Materials and Methods

Online sources such as PubMed, MedLine, and news media were searched for publications and articles available in English with titles or search terms relevant to the topic. Search terms included
kratom (and regional synonyms such as biak, etc.), *mitragyna*, mitragynine, 7-hydroxymitragynine, plus terms related to specific pharmacology (e.g., mu- delta- and kappa-opioid receptors, affinity, efficacy, biased ligand, etc.). References within each citation were also searched. To the best of our ability the pertinent information, or at least the essence of the information, has been distilled herein from the several hundred ‘hits’.

3. Results

3.1 From Traditional to Contemporary Use

Kratom has been used for centuries by manual laborers in Southeast Asia countries to enhance mental-alertness and increase stamina. In some communities, kratom leaves have also been part of traditional folk medicine, and as such it has been used to treat a variety of medical conditions, including diabetes, fever, and diarrhea. Its efficacy for pain-relief (analgesic agent) is well known to traditional practitioners [4]. It is sometimes also used as part of religious ceremonies and at social and community gatherings [5]. Until recently, Malaysia and Thailand were the main geographical areas of kratom use. Surveys reported lifetime prevalence of use of about 2% [6] to 5% [7].

However, although kratom is legal in parts of the world, including much of the United States, it is not devoid of potential problems. For example, kratom is the most frequently used illegal drug in Thailand [8]. It is also illegal in Malaysia, but it may be more openly available from suppliers and coffee shops [9]. Thailand very recently approved the use of kratom plants for medicinal use. In the West, kratom can be obtained from online sources and from specialty shops and bars [10]. Some Internet sources of kratom market it as a supplement or herbal product, which may lead certain purchasers into thinking that the product is completely harmless because it is a “natural” substance [10, 11]. The legal status of the drug in the United States allows people to use the drug without exposure to legal risks. It has even been promoted as a “safe, legal high.” [3, 11].

Multiple sources provide kratom powder made from dried leaves [12]. Consumption patterns can vary by location (with much overlap): chewing kratom is common in Thailand, drinking kratom-infused beverages is more common in Malaysia, and powders and capsules are more popular in the West [13]. Historically, kratom leaves (fresh or dried) have been brewed into a tea, smoked or chewed [14], which is how manual laborers in rural Southeast Asia came to be known as “kratom eaters” for the habit of chewing fresh leaves throughout the day [1]. The leaves have a bitter and unpleasant taste, so some users prefer to make it more palatable by infusing it into tea, coffee, or other beverages and adding milk, sugar, or other flavorings. Recently, “4 x 100” cocktails are being used by young people in countries that prohibit alcohol (the name from the four main ingredients of a sweet caffeine-containing beverage, kratom, codeine, and variably some antidepressant or anxiolytic drug, served over ice, yielding a drink that reportedly mimics the effects of liquor) [6, 15].

Although Malaysia strictly regulates kratom and penalizes possession [3], rural communities do not look down on its use by laborers, provided that the use is for work to support their families [1]. There is little discrimination or disrespect for kratom users, although some family members may rebuke regular users for spending too much money on their ‘habit’ [2]. In fact, Southeast Asia kratom users may be viewed by their peers as particularly diligent people, taking advantage of the drug’s energizing effects in order to work longer hours and earn more money for their families [1].
And in contrast to individuals who use other substances, habitual kratom users in Southeast Asia tend to be older, married, and living together with the families that they support [1, 7, 9].

In the West, kratom has historically been viewed as something of a novelty, a natural herbal product with possible therapeutic benefits, or even as a legal high. Many in the West still view kratom as mild and completely harmless, partly because it is considered a natural substance and partly because there are few laws restricting its use.

It is not known if long-term excessive use of kratom leads to social, physical, or psychological problems [3]. Kratom use can lead to the development of physical dependence and withdrawal symptoms upon too abrupt discontinuation [16]. However, the assumption by some that these are definitive signs of ‘addiction’ is outdated and inaccurate, since they are physical phenomena that result from basic pharmacologic principles and apply to almost all drugs.

3.2 Kratom and the Law

The laws regarding kratom can be convoluted, complex, or altogether confusing. For example, kratom has been technically outlawed in Thailand since 1943 [3], where it is illegal to plant, grow, possess, import, or export kratom leaves [7]. Nevertheless, kratom is widely used in Thailand and users do not experience particular social stigma. Now, Thailand has very recently approved the use of kratom plants for medicinal use. Kratom is a controlled substance in Australia, Bhutan, Malaysia, Myanmar, and other countries [17], but it is legal to cultivate kratom in Malaysia as long as it is not consumed, distributed, or prepared for distribution (leaving one to wonder what else is there) [9].

Only a few European nations have regulations specifically addressing kratom [18], and kratom is largely uncontrolled in the United States (but there is currently a very intense debate on this subject) [13]. This may also make it particularly appealing to risk-averse recreational users [19].

While the United States and United Kingdom do not regulate kratom, the United States Food and Drug Administration (FDA) has issued an import-alert warning about possible side effects [20]. And the United States Drug Enforcement Administration (DEA) has added kratom to its list of “Drugs and Chemicals of Concern.” [21, 22]. The FDA has seized certain products containing kratom, but typically only in products where kratom is used in dietary supplements. The import-alert of 2014 allows officials to interdict such products when the agency believes that the product is adulterated [20]; the United States Department of Justice has ruled that kratom is a dietary ingredient for which there is not sufficient reasonable assurance that it does not present risk of illness or injury. Large seizures of imported dietary supplements containing kratom have occurred [23, 24].

3.3 Pharmacologically Active Compounds in Kratom

The main active compounds in kratom leaves are the alkaloids mitragynine and 7-hydroxymitragynine, plus speciogynine, paynantheine, and speciociliatine [6]. It contains dozens of different but structurally related alkaloids along with flavonoids, terpenoid saponins, polyphenols, and glycosides [3].

The alkaloid content of kratom is about 0.5% to 1.5% [25, 26], which varies from plant to plant, and depends upon the strain, its location of cultivation and the season [27]. Mitragynine is lipophilic, with poor solubility in water [28]. The alkaloid fraction of mitragynine can be as high as 66% for kratom from Thailand or as low as 12% for kratom from Malaysia [29]. Although
structurally dissimilar to morphine and other opioids, mitragynine has some affinity for opioid receptors [30]. All of the mitragynine analogs in kratom (e.g., speciogynine, paynantheine, and speciociliatine) are indole alkaloids with a monoterpene moiety [29]. 7-Hydroxymitragynine is more potent than mitragynine in in vitro and in vivo tests [29, 31, 32].

Botanically, there are three main strains of kratom. The red variety originated in Bali and is known in folk medicine as an effective pain reliever. The green and white varieties originated in Malaysia and have a reputation for their stimulating effects [33]. Buyers who shop online may find “brand names” such as Bali kratom, Malaysian kratom, Thai kratom, Maeng Da kratom, white-veined Borneo kratom, Java kratom, Sumatra red, and so on [27]. Online sellers have attempted to rank kratom by grade in terms of potency with “organic commercial grade” the least and “super” or “super enhanced” the most potent forms [33]. However, these grades are marketing terms used by those selling kratom and have not been subjected to any form of scientific scrutiny or objective analysis.

3.4 Pharmacology

The exact pharmacological mechanism(s) responsible for producing kratom’s characteristic effects have yet to be established [34-37]. Some of the earliest work on the basic science of kratom was done by Macko et al. [38], who reported among other things the antinociceptive effects of mitragynine in mice (hot-plate test), rats (tail-flick and paw-pressure tests), and dogs (hindleg flick). The pharmacologic response to kratom [3] varies among individuals, which might result from kratom’s hydrophobicity, poor solubility in water, variable drug release in body fluids, and variable acid degradation properties. Kratom’s subjective effects depend on dose: stimulation is characteristic of low doses, analgesia and sedative effects of higher doses [39]. Interesting recent studies suggest that the differences from traditional poppy-derived opioids might be attributable to the G protein ‘biased signaling’ nature of interaction at the mu-opioid receptor [40, 41].

Kratom is mainly metabolized in the liver [42, 43]. In a study on human recombinant cytochrome P450 (CYP450) enzymes, mitragynine produced a strong inhibitory effect on CYP3A4 and CYP2D6, moderate inhibition of CYP1A2, and weak inhibition of CYP2C19. This suggests that concomitant use of kratom and other drugs that act as substrates of these enzymes might result in potential drug interactions [6, 25, 44]. In a pharmacokinetic study of healthy subjects who regularly used kratom, mitragynine levels declined exponentially, suggesting a two-compartment model [45]. About 0.14% of mitragynine was excreted unchanged in the urine [45].

3.5 Adverse Effects and Toxicity

Oral doses of total alkaloid extract of *Mitragyna speciosa* at 200 mg/kg were lethal to rats [46]. The lethal dose 50% (LD50) for mice was 477 mg/kg for mitragynine and 591 mg/kg for alkaloid extract [39]. The therapeutic index for the alkaloid extract compared to mitragynine was 3:1 and 20:1, respectively [28].

The literature contains a few reports of putative kratom-related fatalities, but most involve poly-substance use, so it is difficult to attribute causality [47]. Preclinical reports or individual case reports of excess kratom use have suggested adverse effects, but more well-validated clinical research is clearly needed [17, 48-53].
Those who used kratom regularly over extended periods of time have reported weight loss, dehydration, constipation, hyperpigmentation, lethargy, and fatigue [9]. Other adverse effects, including trembling hands and headaches, have also been reported [7].

### 3.6 Abuse Potential

Kratom appears to have some potential for abuse [1, 7, 8]. And abrupt discontinuation of regular kratom use can produce mild withdrawal symptoms (e.g., irritability, lethargy, yawning, rhinitis, muscular aches and pains, cramps, and diarrhea) [1, 8]. ‘Psychological’ withdrawal symptoms are reported also (tension, restlessness, aggression, sadness, delusions, hallucinations, moodiness, anxiety, and cravings) [8, 16]. Other reports add insomnia and pruritus [54]. The withdrawal symptoms may persist for a few days [16], but compared to withdrawal from other substances, the kratom experience has been described as generally shorter and not as distressing [16]. Regular kratom users in Malaysia did not exhibit social dysfunction compared to non-users, and none were involved in criminal activities to support their habit [55].

Concern of potential abuse is expressed because low doses act as a stimulant and therefore might pose the risk of a milder version of the stimulation produced by amphetamines or cocaine, and higher doses produce more sedative effects, possibly posing the risk of a milder version of opioids [56-58]. In some preclinical studies, mitragynine has been reported to be mildly rewarding, or to impair learning and memory [51, 59, 60]. But recent studies have shown that mitragynine is not self-administered by rats [61, 62].

Dose-dependent stimulatory and sedative effects of kratom, potentially attractive to some users, suggests that a small subset will abuse it, as occurs in locations where the plant grows indigenously [1]. Ready Internet access, and low price also suggest that it will become increasingly popular among recreational users [9]. On the other hand, the use of kratom instead of dangerous drugs of abuse would represent a net plus to individuals and society. Hence the on-going regulatory debate.

Kratom constituents are not currently detectable in conventional urine drug screening assays, but chromatography-tandem or ion-mass spectrometry instruments can detect kratom [3, 10, 13]. Kratom was added to the Monitoring List of the World Anti-Doping Agency in sports in 2014. There are currently no standardized screens for mitragynine other than liquid chromatography-mass spectrometry [25].

### 3.7 Clinical Response to Kratom Toxicity

Kratom toxicity has been reported, but mainly in the form of case reports – and almost always involving polysubstance use – making it difficult to draw conclusions. The symptoms of kratom toxicity have been reported to include heart palpitations, seizures, and coma [63, 64]. One case of intrahepatic cholestasis has been described in a young male who used kratom for two weeks [49]. The literature reports fatalities associated with the use of kratom, but polydrug use is almost always involved [41, 44, 63, 65]. The relative toxicity of mitragynine and 7-hydroxymitragynine remains to be elucidated. Reports almost never include the relative concentrations, which may or may not be an important consideration [66].

Patients with kratom overdose should be considered for detoxification, which should be undertaken in clinic. The clinical team should ascertain what the patient took and if multiple
substances might be involved – which is highly likely. Patients undergoing withdrawal should receive supportive care and should be treated in accordance with detoxification protocols.

### 3.8 Clinical Response to Kratom Dependence/Abuse

The literature reports a case of “addiction” and detoxification in a 37-yr Caucasian woman who was introduced to kratom by a colleague for pain control. She soon began buying kratom online because in addition to analgesic benefits, it gave her the added energy that helped her manage her busy schedule [67]. She presented in kratom withdrawal and was initiated on an opioid withdrawal protocol in the hospital using symptom-triggered clonidine at a dose of from 0.1 to 0.2 mg/kg every two hours based on her Clinical Opioid Withdrawal Scale (COWS) score; she also was administered 50 mg oral hydroxyzine every six hours and 0.1 mg/day clonidine via a transdermal patch. She experienced severe withdrawal symptoms on the COWS scale which improved rapidly by the third day. Following detoxification, she experienced symptoms of depression and was discharged from hospital with counseling and oral naltrexone 50 mg [67]. There is no current consensus as to the best way to manage kratom withdrawal. It has been suggested that combination therapy including alpha-2 agonists and hydroxyzine may be efficacious in relieving the physical and mental symptoms [67]. Once the patient has successfully discontinued kratom, maintenance strategies are also unclear. While it has been suggested that buprenorphine or methadone be used as maintenance therapy, kratom is not of the opioid class and this raises regulatory issues regarding the appropriateness of using opioids for kratom maintenance [67]. Naltrexone (an opioid antagonist) may be helpful in that it may attenuate cravings, as it does for alcohol [67].

### 4. Discussion

As kratom use increases in the United States, people will seek advice from clinicians about it, because they have used it, want to try it, or because they are concerned about another person using it. Some patients may believe or assume that it is a safe herbal supplement or some kind of natural pain reliever. Others think it should be outlawed entirely. Clinicians should know the legal status of kratom in their state and municipality and remind patients that although it is a natural (and often legal) substance, it can still have as yet unknown potential adverse effects.

#### 4.1 Kratom’s Potential Role for the Treatment of Opioid Withdrawal

Kratom is sometimes used as a safer, legal alternative to other substances [9, 13]. It has also been used to help relieve opioid withdrawal symptoms and as an aid for those seeking to discontinue opioid use [9]. Migration from opioid use to kratom use has been documented in Southeast Asia [5]. Clinical trials of the value of kratom for treatment of opioid abuse and of alleviating withdrawal symptoms is a topic worthy of further study.

#### 4.2 Therapeutic Potential of Kratom

The components of kratom have been studied in a variety of preclinical in vitro and in vivo tests [10, 25, 56, 68, 69]. Methanolic and alkaloid extracts significantly prolonged response latency in the hot-plate test, indicative of analgesic activity [70, 71]. Mitragynine had antinociceptive
properties when administered either orally or intraperitoneally to rats [72]. Oral or subcutaneous mitragynine produced potent antinociceptive effect in the tail-flick and hot-plate tests in mice [73].

Kratom is sometimes marketed—openly—as an herbal supplement for pain control [53, 74, 75]. The analgesic properties of kratom and those of its major active principal mitragynine are subjects worthy of study in clinical trials.

Mitragynine may also exert an anti-inflammatory effect [29, 30] by suppressing prostaglandin E2 (PGE-2) in the cyclooxygenase (COX) 2 pathway [32]. It has also been suggested that mitragynine may possess anticancer properties [76]. Kratom extracts and mitragynine have displayed cytotoxicity to certain human cancer cell lines (e.g., SH-SY5Y) [77]. Mitragynine may modulate muscle neurogenic contraction [78-80], and gastric secretion [81], consistent with traditional use. There are also anecdotal reports that it has aphrodisiac properties [9].

5. Conclusions

Kratom, long used in Southeast Asia as a work-enhancing energizer and traditional remedy, is rapidly growing in use in the West as a result of availability through the Internet, aided in part by its current non-scheduled status and perception by some that it offers a safe all-natural high. In low doses users experience a pleasant stimulation, sedation and analgesia at moderate doses, and mild opioid-like effects at high doses. There are reports of withdrawal symptoms if the drug is abruptly discontinued after long-term use. Kratom components— or analogs of them—might have therapeutic potential for several conditions, including pain relief and opioid use disorder. Its use as a recreational drug is very likely to increase, raising a dilemma for healthcare providers and regulators: should it be tightly regulated, or should it be viewed as a better option than ‘hard’ drugs — and therefore controlled more like ethanol. It is important that clinicians familiarize themselves with this substance and how to counsel patients with respect to its use. It is also important that they be proactive in the debate and the decision process regarding scheduling kratom as a controlled substance. It is either the next drug of abuse or a panacea to the opioid crisis — or, most likely, something in between that requires mature, informed decision-making.

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Author Contributions

These authors contributed equally to this work

Competing Interests

The authors have declared that no competing interests exist.

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Case Report

Chronic Pain after Reported Whiplash Injury – A Patient Case Report

Gunnel Berry *

Private Practitioner, Hunter's Moon Cottage Preston Candover, Basingstoke, UK; E-Mail: gunnel.berry1@gmail.com

* Correspondence: Gunnel Berry; E-Mail: gunnel.berry1@gmail.com

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Abstract

Chronic pain is notoriously multifactorial, multifaceted and difficult to manage. Twenty per cent of reported whiplash-injured persons go on to develop a Whiplash Associated Disorder (WAD) where persistent pain becomes chronic with no prospect of change [1]. Paucity of effective therapies to address the effect of WAD enforces new approaches. This case report, with a patient’s perspective, illustrates a novel therapy, Adapted Reflextherapy (AdRx), which is akin to reflexology and has been used, developed and revised by the author for two decades, to address the physical and psychological aspects of chronic WAD. While there is no reported single therapy recommended to treat chronic WAD there is evidence that cognitive processes [2] and patient centredness [3] are strongly related to positive outcomes in the treatment of patients with chronic low back pain. Similarly, exploratory [4] and experimental [5] studies suggest that reflexology has an anti-nociceptive effect and may reduce anxiety and stress in conjunction with reducing hyperalgesia. The patient in this case report developed chronic symptoms after a double, opposite-directional car crash 3.5 years prior to commencing AdRx treatment. The patient was encouraged to write a self-reporting pain diary where she describes her predicament and experience of receiving treatment. Her symptoms shifted from a ‘stalemate’ position to one of improved quality of life (QoL) and reduced pain levels. This case report offers a hypothesis that ongoing pain may be a ‘paper trail’ of compromised neural plasticity as an effect from not only one injury but that of an array of incidents from which pain-producing peptides have accumulated in the nervous system.
system. As AdRx is applied on nerve endings at the periphery, it is suggested that it acts as a ‘counter-irritant’ in a neural sense producing an array of descending (inhibitory) signals at spinal and central levels. The case report aspires to illustrate changes in a chronic WAD patient and perhaps offer an opportunity for change in others.

Keywords
Whiplash injury; whiplash associated disorder; chronic pain; quality of life; pain diary; adapted reflextherapy; reflexology; neural plasticity.

1. Introduction

‘Whiplash injury’ is a controversial diagnosis in today’s medical and insurance policy climate. Existence, or non-existence, of whiplash injury after a road traffic accident (RTA) has been reported and discussed in literature with various opinions. Dishonest claims of a whiplash injury affect insurance premiums and call into question the plausibility of those who really do suffer after a motor vehicle accident. Some sceptics consider the diagnosis to be untrue or at least doubtful [6].

Whiplash injury arises from an ‘acceleration/deceleration mechanism of transfer of energy to the neck arising from a motor vehicle accident or other setting such as work or sport’ [7-8].

Whiplash Associated Disorder (WAD) arises and describes people with ongoing symptoms affecting the whole body as a sequela from the whiplash injury [9]. WAD is associated with chronic pain, anxiety, depression, catastrophising and comorbid health issues [10]. In the UK, 300,000 people were diagnosed with ‘whiplash injury’ in 2003 [11] with a falling trend for light reported injuries up to 2016. Although there is still no known treatment recommended for WAD or chronic pain perse [12], clinical practices still receive referrals for WAD [9]. There is an abundance of literature supporting biopsychosocial approaches to treat WAD (Sterner Gerdle 2004; Soderlund Lindberg 1999; Jull Vicenzino et al. 2005) and physical therapy has its role to play whereby ‘stabilising exercises, low velocity mobilising techniques and ergonomic advice was proven to be superior over a self-management programme’ [13]. In addition, while Bogduk [14] supports the notion of zygapophysial joint injury as source for chronic neck pain after a whiplash advocating radiofrequency neurotomy to relieve symptoms, Michaleff, Maher, Christine Lin et al. [15], conclude from their meta-analysis data that radiofrequency neurotomy is a complex procedure and may only be effective in selected patients. They advocate that ‘simple advice’ is as effective as comprehensive physiotherapy programmes. Concomitantly, AdRx emerged as a treatment for chronic persistent pain after whiplash and WAD [16-18].

This case report presents a patient who, having sustained a double, opposite-directional whiplash injury in a motor vehicle collision gained appreciative, self-reported, enduring improvement after AdRx intervention. It is suggested that by touching the skin, an action potential arises which initiates a neural response which has an effect on central and spinal mechanisms (ascending) as well as peripheral structures (descending) to change a persistent pain state. It is hypothesised that alterations in neural plasticity play an active role in the measurable changes.
2. Adapted Reflextherapy (AdRx)

Adapted Reflextherapy (AdRx), akin to reflexology, is a therapeutic intervention applied to the feet (hands may also be used) in musculo-skeletal pain patients as a primary assessment and treatment tool. The therapy has been used for over two decades by the author and has been found to facilitate change in patients with chronic pain conditions associated with WAD [18] and persistent pain [18-19].

Reflexology [20-27] states that the medial arches of the foot relate in anatomical terms to the spine (see Figure 1 and 2), and, metaphorically, the anatomical body is ‘superimposed’ on the foot like a ‘pedal homunculus’ (Figure 3). AdRx evolved from this theory but was adapted as a therapeutic treatment technique with a supporting working hypothesis during a clinical research episode in a GP practice [28]. It was found to be effective in patients with severe whiplash injury from motor vehicle accidents as well as those who suffered injuries in a serious train crash in London in 1999 [29]. A teaching programme was set up to share the AdRx hypothesis and treatment practice in 2002.

![Medial arch right foot](image)

**Figure 1** Medial arch right foot.

Spinal segments: Cervical, thoracic, lumbar, sacral, coccygeal (Reprinted with permission: Pru Hughes School of Reflexology).

Colour key: Yellow = cervical, 1-7; Red = thoracic, 1-12; Blue = lumbar, 1-5; Green = sacral, 1-4 fused; Pink = coccygeal fused.

Albeit empirical, the AdRx hypothesis is based on retrospective observations of patients in the clinic which include clinical reasoning in relation to the patient presenting symptoms, past history, anatomy, neurophysiology, neuroplasticity and effect of injury in terms of hypersensitivity, chronicity and centralisation. In addition, AdRx originates from a convergence of theory of reflexology, neurophysiology, chronic pain theories, concept of ‘memory of pain’, and effect of trauma, and coinciding with two colleagues, one physiotherapist and one reflexologist, independently demonstrating pressure on one spot on the foot to relieve pain in a corresponding somatic area. For instance, in accordance with Saab & Haynes [30], by touching the skin, an action potential arises within the axon which initiates a neural response at spinal and higher centres.
(thalamus) which initiates a counteractive response affecting central and peripheral neural mechanisms supported by the notion that ‘massage has an hypoalgesic effect on experimental pain’.

![Figure 2: Dorsal aspect - right foot.](image)

Vertebral segments: Cervical (C1-7), Thoracic (T12), Lumbar (L5), Sacral (S4) and Coccygeal (Cx).

![Figure 3: ‘Pedal homunculus’.](image)

Spine superimposed on left foot according to Robert St John. (1996) [44] and Ann Gillanders (2002) [45]. Note anatomical position, i.e. plantar aspect of foot represents anterior aspect of body.

Reflexology has earned recognition to reduce pain in cancer [31-32] in lower limb amputees and phantom limb pains [33]. It has been reported as helpful in conditions including multiple
sclerosis, anxiety [34], and childbirth [35]. However, Poole, et al. [36], found insufficient evidence for using reflexology in low back pain sufferers and White AR (2000) and White AR, Williamson, and Ernst (2000) disputed claims for health promotion [37-38] considering ‘diagnoses’ no better than chance in identifying medical conditions in one blinded study [39].

Nevertheless, using a pseudo-medical phenomenology, AdRx has been found to reduce pain and restore function in patients suffering from persistent pain after injuries. The physiological effects from an acceleration/deceleration mechanism during a car accident, or a fall while skiing or skating or falling off a ladder and slipping on ice or wet floor, however long ago, should be considered as a source of chronic pain. AdRx hypothesises that past injuries could be responsible, or at least, play a role in the present pain patterns. Clinical findings of hypersensitive areas and reduced mobility in the feet, introduces possibilities of understanding the origin of a painful state. It is also hypothesised that in addition to the mechanical compromises after injury, the neural plasticity has also altered to an extent beyond the normal which we call a compromised neural plasticity (CNP) state. It describes a state of the neural plasticity which is not quite normal yet functional and without apparent severe damage. It is a term used for patients who present with ‘non-specific’, persistent pain patterns interpreted as a ‘legacy’ of a disturbed neural plasticity rather than a response to disease or inflammatory processes. Based on documentation that pain-producing peptides remain in the neural system even after the main pain issues have gone [40], Guez, Hildingsson, Rosengren et al., found nerve tissue markers indicating damage after whiplash trauma [41]. AdRx hypothesis assumes a legacy of peptidal change in the axonal flow after a whiplash injury which increases after each repeated acceleration/deceleration episode. A simple stumble may set the pain-producing peptides in motion and increase adverse neural plasticity activity. This peptidal ‘echo’ becomes part of the neurophysiological response in the next injury resulting in a CNP, presenting as hypersensitivity, centralisation and continued pain and dysfunction [42]. Although it is not simple to identify nociceptive receptor fields without ambiguity [43], AdRx hypothesises that by tactile exploration of the feet, a reasoned suggestion can be drawn to the causes of a painful state. The great advantage of AdRx is its simplicity and easy access to assess and treat the patient. Areas that are painful during touch are not necessarily painful during fully weight bearing.

2.1 AdRx Examination

As part of an otherwise orthodox physiotherapy assessment, the feet of the patient are examined in supine in the context of a possible spinal injury and sensitivity reflecting the neural elements of pain patterns. The examination detects, reflects and interprets the foot/joint stiffness as stiffness and sensitivity at spinal joint levels including costo-vertebral junctions, symphysis pubis and sacro-iliac joints. Comparisons are made with anatomical pain sites regarding the relevant pain and the anatomical assessment already carried out. The patient is asked questions such as: ‘Does this reasoning make sense to you? Does the explanation relate to your symptoms? How do the symptoms not relate to your previous understanding and belief systems you may have learnt from other health professional?’ Anatomical models are used to explain clinical reasoning to the patient.

As part of the assessment and treatment, a ‘review’ process and ‘goal-setting’ is included at each visit. This highlights signs and symptoms to be assessed at the next visit. A goal may be as
simple as walking upstairs without aid, or just being able to stand and sit on a chair without pain.
The ultimate aim may be to live a life without taking painkillers. In cases where people do not
tolerate having their feet touched the hand can be used. Complete refusal to have the feet
touched has occurred on 3 occasions, based on religious grounds.

The feet are examined to detect painful areas with particular focus on the medial arches and
crural joints with the patient lying supine (Figure 1 and 2). Degrees of inversion and eversion
mobility at the medial arches are noted as well as dorsi- and plantarflexion at the crural joint
which are interpreted in relation to the patient’s pain presentation. Reduced inversion/eversion
mobility indicates reduced thoracic spine mobility. Reduced dorsi/plantarflexion at the crural joint
is interpreted as compromised mobility of the symphysis pubis joint indicating reduced pelvic tilt
mechanism. Reduced mobility at the 1st metatarsal-phalangeal joint indicates reduced cervical
spine mobility, etc.

The depth of manual pressure on the dermis varies depending on the sensitivity of the skin in
relevant areas. Areas of chronic nature are frequently found to be less sensitive. Acute areas are
often highly sensitive to such a degree that the skin is too sensitive to touch at all in which case
the therapist merely ‘hovers’ over the intended area for a second or two to obtain information, in
which case it may be advisable to address the hand instead. It has been found that, as treatment
progresses the skin accommodates and reduces sensitivity to allow direct contact. This is
interpreted as reduced hyperalgesia and sensitivity.

2.2 AdRx Treatment

The AdRx treatment has high specificity and task purpose in its application, meaning that only
areas which are deemed interconnected with the patient’s symptoms are treated. Treatment
consists of direct pressure on the dermis at 90° direction as much as possible (see Figure 4).

Depth of pressure varies depending on the severity of the patient’s symptoms. In acute cases,
including high sensitivity on touch, ‘light touch’ (1-3mm) is used. Deep pressure (3-6mm) is applied
in chronic and less sensitive cases.

Duration of continued pressure on one single area depends on chronicity. ‘Short’ duration in
acute cases (30 secs) and ‘long’ duration in chronic situations (60 secs – 120 secs).

Foot therapy application like AdRx frequently increases pain issues for 24 hours post-treatment.
This can be interpreted as exacerbated symptoms and hence a disadvantage to the patient.
Conversely, it could be seen as an ‘effect’ from the treatment, hence, an advantage. Anecdotally,
the first treatment causes most ‘effect’. Subsequent treatments may increase pain but with
reduced intensity. Improvements are not always linear especially in patients with a history of
decades of pain. Improvement in these cases is usually slow, interrupted by episodes of pain
exacerbation, yet with improvement in mobility, function, moods and quality of life. Even those
with complex pain issues are known to achieve change. While a reflexology treatment may require
one hour’s treatment using reflex zones [46-47], on the whole foot, AdRx is task specific and
selects one or two relevant areas for treatment each time. As effective treatment time is
approximately 10–20 minutes at each visit, AdRx procedure fits in well in the physiotherapy
department.
2.3 Whiplash Injury and Chronicity

A whiplash injury may occur at any time that the body is subjected to a sudden acceleration/deceleration mechanism. Whiplash injuries are graded 0 – IV depending on severity of symptoms at time of impact.

Briefly, WAD Grades include [9]:
0 No neck complaint
   No physical sign (s)
1 Neck complaint of pain, stiffness or merely tenderness
   No physical sign (s)
2 Neck complaint and musculoskeletal sign (s)
3 Neck complaint and neurological sign (s)
4 Neck complaint and fracture or dislocation

The effect on the human body at time of deceleration can only be estimated but even small injuries to nerves may set off a cascade of compromises in the neural plasticity which ultimately leads to pain [48]. 20% of whiplash injured patients go on to develop chronic symptoms [49] and women are more affected than men suffering more headaches in the case of vehicle impacts [50-51]. The ultimate effect of the deceleration forces may depend partially on the individual’s anatomical build and strength to resist kinetic energies during the impact. Hypersensitivity, hyperalgesia, catastrophising, depression and bizarre pain patterns are commonly considered to be symptoms of ‘central sensitisation’ which are the effect from a whiplash injury and commonly called Whiplash Associated Disorders (WAD), to describe the overall involvement of psyche and soma simultaneously. Widespread hypersensitivity is associated with poor recovery [52] and caused by continuous bombardment of adverse action potentials from the periphery to brain and central structures. It is suggested that patients should be assessed for ‘intensity of pain, depression and catastrophizing when planning a rehabilitation programme’ [10]. In terms of AdRx hypothesis, applying touch and topical pressure facilitates an action potential which appears to affect the whole of the nervous system including the limbic system. Full recovery is not always achievable, and in cases of chronic pain it may take years to fulfil its full potential. Dutiful care should be taken during the history taking to establish whether a patient has ever had an injury or mishap which could be held ‘responsible’ for the ultimate symptoms as it may have compromised...
neural plasticity. The incident may have happened as a child, may seem irrelevant, happened a long time ago and may simply have been forgotten. However, the physical impact on the body may set in motion the adverse neurophysiological responses, as discussed, resulting in a compromised neural plasticity process. This process affects the somatosensory system as well as the limbic system involving the autonomic nervous system resulting in symptoms which are bizarre and may be misinterpreted by patient and health professional alike.

3. Case Report

A 32-year-old female postgraduate researcher, Tina (not her real name), had a motor vehicle accident 3.5 years earlier resulting in Grade 2 l whiplash injuries [9]. At the time of impact, Tina’s car was hit at the rear (1st whiplash) during a stationary holdup on the motorway pushing her forward into a crash barrier (2nd whiplash). She felt no pain at time of accident (-s). However, neck pain commenced 3 hours later (Grade I). Tina claimed that the car accident 3.5 years ago still affected her daily life with a variety of symptoms such as headaches, peripheral numbness, shoulder pain, upper and lower back pain, tinnitus, tension in the leg and knee muscles, achy feet and hands, sciatica, carpal tunnel syndrome and, finally, an underactive thyroid which was diagnosed 4 months post-accident. Whether this was coincidental or a product of injury is not known. She described her symptoms as ‘achy limbs, felt heavy and painful all over from general use with pain radiating around the body even into nails and teeth’. Joints felt ‘sticky’ and she had to keep moving around continuously to ‘free up’. Some of the original symptoms eased one year after the injury but had now returned.

Working at a university establishment, Tina followed up an invitation to pursue a research project in the usefulness of AdRx for chronic neck pain sufferers [53] carried out by a physiotherapy MSc student. The research project included four weekly treatments @ 10 minutes each session, and aimed to assess efficacy to reduce pain in chronic neck pain patients using AdRx as a method of treatment. Tina was, by chance, allocated to the sham group and received a ‘pretend’ treatment which included a mild foot massage on the lateral aspect of the foot (away from the ‘spinal’ areas). The sham treatment had nevertheless a mild positive effect and reduced Tina’s neck pain a little. She became curious to possible further effects of treatment and wished to continue with the AdRx treatment after completion of the research project. The 10 volunteers included in the project were invited to continue with further treatment offered by the therapist at a reduced commercial rate. Tina self-funded her treatment.

3.1 Previous Therapies and Present Status

By the time Tina started her AdRx treatments 3.5 years after the original injury, she had received, and benefitted from, 43 treatments of physiotherapy and chiropractor treatments. A rheumatologist offered advice and analgesic medication, such as amitriptyline, and magnesium (Mg).

Tina suffered from daily symptoms of persistent pain and reduced ‘quality of life’ since the car accident. Her pain was under control but ‘quality of life’ issues were still 30% away from being fully recovered. She had daily severe headaches, neck pain, low back pain, all-body sensory unexplained pains increasing with sudden fast movements and any kind of lifting even light bags. Sleeping was partially disturbed depending on positioning, work increased backache from
prolonged sitting at a desk working on the computer with muscle tension and joint stiffness to protect her from the pain which in turn increased tiredness and affected mental concentration. To relieve symptoms, Tina stood up every 20 minutes to do gentle stretching exercises. Her daily routine included 1.5 hours of yoga, cycling, Pilates and swimming in various combinations to keep the worst symptoms away.

Previous Medical History: Fractured wrist age 7, under-active thyroid developed post-injury

Social: Tina lived with her parents at the time of the accident and travelled by car to work. She was a normal young lady enjoying her research work which took her abroad from time to time. She enjoyed outdoor life and would do much more in the form of exercise and outdoor activities if only the persistent pains would ease.

3.2 Assessment

3.2.1 In Standing

Posture
Tina was tall, slim with an erect posture.

3.2.2 Mobility

Spinal mobility:
Hypermobile tendency [54].
Lumbar Spine: Forward flexion – touch floor
  Extension - beyond 15° with degree of discomfort
  Side-flexion - unremarkable
Thoracic spine: Unremarkable
Cervical spine: Unremarkable
Shoulder mobility: Full range

3.2.3 In High Sitting

SLUMP [55] tested positive (+ve) on both legs increasing tension posterior-knee and down the leg at full knee extension. Posterior leg symptoms were reduced with neck extension.

3.2.4 In Lying

SLR (Straight Leg Raising) was equal at 85°, limited by posterior knee stiffness but no pain.
Hip and knee mobility: No abnormality detected

3.2.5 Pain

Self-reported pain areas and quality of pain 3.5 years post-injury as described in Figure 5.
Figure 5 Pain September 2013 (1st Assessment) (revised for printing purposes).

Pain Chart Legend: **Front** (+ = ‘stabbing’ pain (R) hip; x = ‘aching’ pain elbows, thighs, knees; /// = ‘other symptoms’ medial thighs, anterior (L) hip, anterior (R) knee.), **Back** (+ = ‘stabbing’ pain back neck, lower back; x = ‘aching’ pain neck, shoulders, spine and posterior knees; /// = ‘other symptoms’ back of head, (R) shoulder, thoracic & lumbar spine, sacrum, bilateral posterior hips and full legs including soles of feet.).

3.3 Foot Examination as Per AdRx

General impression of feet: flexible and mobile.
Skin condition of feet: unremarkable.

3.3.1 Tenderness on Palpation

Bilateral areas: Symphysis Pubis joints (SPJ), Lumbar segments 1-5 (L) > (R), and Cervical C6/7 level.

Mobility of medial arches was restricted at Lumbar areas and rotation of 1st phalanx at meta-tarsal/phalangeal joint.

Outcome Considerations
- Anatomical build
- Gender
- Hypermobility
- Chronicity since time of accident
- Personal profile
- Motivation
- Diagnostic challenges and reasoning

**Anatomical Build:** ‘The slender female neck is more vulnerable to injury than the average male neck’ [56] supporting the opinion that females are more likely to develop chronic neck symptoms associated with an acceleration-deceleration mechanism to the neck [56].
Gender: Tina is vulnerable due to her slender build and gender, following a trend that women have more persistent neck pain and headaches than men do by a ratio of 7:3 [50]

Hypermobility: Hypermobility is a generic ability of soft tissues to extend beyond normal joint flexibility resulting in poor joint stability. In severe cases, the heart muscle may be affected. Anecdotally, the author has found that patients have persistent pain in conjunction with hypermobile joints. Even small degrees of excessive joint flexibility have been found to cause excessive pain during joint movement. The question arises, is it possible that hyperflexibility is, in part, responsible for ongoing pain states? The patient has to continuously keep on stretching tissues and joints to achieve comfort and pain-free movements as observed in Tina’s case. No literature has been noted to date to support this observation in cases of whiplash injury and chronicity.

Chronicity: 3.5 years post injury, chronicity is well established. Prognosis and predicted outcomes can only be speculative. The general consensus is that biopsychological approaches may offer coping strategies but no specific treatment approach has proved superior to another. From this rather bleak baseline, no prognosis was made.

Personal Profile: Tina was a highly intelligent young lady with a good job at a higher education establishment. She worked conscientiously with her daily diary to produce a clear picture of her reactions after each treatment and attainment targets she had set herself. Her prediction of constant pain put her under strain and made her understandably mildly anxious. After 3.5 years of continuous symptoms her endurance waned from time to time.

Motivation: Tina was highly motivated to improve her quality of life situation. She wanted to increase her outdoor activities and do more travelling.

Diagnostic Challenges and Reasoning: Central hypersensitivity to peripheral stimulation was found in whiplash patients by Curatolo, Petersen-Felix, Arendt-Nielsen et al. [57], and is associated with poor recovery [58] which in this case was prevalent and demonstrated by the self-reported diagrams. Experience using AdRx in hypersensitive patients has determined that caution has to be observed in response to the magnitude of reactions which may occur in patients having suffered a neck injury. The treatment has to commence in areas relating to the base of the spine at the first visit and finally, on the 3rd visit possibly, include the neck area. Adverse reactions have been observed in two female patients aged 22 and 25, by applying too much pressure on the feet resulting in, temporarily, syncope and fainting. The outcomes from the treatments are always discussed and negotiated between therapist and patient.

3.4 Outcome Measures

3.4.1 Principle of Outcomes

Tina had achieved good progress from physiotherapy and osteopathic interventions during the 1st year post-injury. She had adopted a self-managing approach using exercises, stretching and swimming to cope and manage her ongoing symptoms. Starting AdRx as a method of treatment, it was agreed to use a ‘phenomenological’ approach to assess progress by using a reflective pain diary [59] recording variations in quality and quantity of pains in different part of her body by drawing body charts and writing verbal annotations. The body charts were compared weekly comparing changes in pain patterns over time. Straight leg raise (SLR) is a neurodynamic test. It
has reasonable validity and Charnely stated in 1951 that ‘the straight leg raise was more important than all of the other clinical and radiological signs put together’ (Butler 2000) [60].

- **JOINT MOBILITY**
- SLR [60] (Straight Leg Raise)
- SLUMP – (a SLR test in sitting) [60].
- **PAIN DIARY**

**Joint Mobility:** Spinal mobility was never an issue due to hyperflexible joint mechanisms compared to normal joint mobility. However, in relation to hypermobility, Tina had reduced hip flexion with 90° flexion at 1st assessment. The expectations of her joint mobility were adjusted to accommodate this anomaly.

- **SLR 85° bilateral**
- **SLUMP [61] + ve bilateral**

**Pain Diary:** The aim of Tina’s treatment was to reduce persistent pain and improve quality of life (QoL), both of which are ‘individual’ interpretations. Huskinsson states that ‘pain is a personal psychological experience’ [62]. Using a pain diary Tina had an opportunity to identify, interpret and express her own moods and variations in the variations of pain patterns. She drew ‘quality’ and ‘quantity’ pain changes on the body chart and also narrated the effects from the treatment. Comparisons between drawings and writing week by week helped to identify changes. This approach worked well.

She described her symptoms in Figure 5, 6 & 7:
- ‘achy pain’ (x)
- ‘stabbing pain’ (+) on two occasions in description under figures
- ‘other pains or symptoms’ (///)

![Figure 6 Pain February 2014 – 6 months after starting treatment (revised for printing purposes).](image)

**Front** (x = (achy pain) at anterior (R) hip and both thighs; /// = (other pains or symptoms) medial upper thighs.), **Back** (/// = (other pains or symptoms) at base of skull, thoracic and lumbar spine, soles of feet; ‘achy pain’ (x); ‘stabbing pain’ (+); ‘other pains or symptoms’ (///)).
Figure 7 Pain December 2014 - 16 months after starting treatment (revised for printing purposes).

Front (x = Medial and lateral knees.), Back (R) /// = ‘other symptoms’ at back of head, (R)side of neck, T1 area, bilateral hips and medial aspect of top of thighs.)

3.5 Summary from the 1st Assessment

A rear shunt (injury 1) forced a frontal crash (injury 2) resulting in a double, opposite-directional, blow to spinal structures 3.5 years ago resulting in a grade 2 WAD. Ongoing symptoms are considered to be CNP-producing severe hyperalgesia, allodynia and maladaptive changes affecting mood and quality of life in accordance with ‘central sensitisation’. Mild to moderate arthrogenic involvement in association with hypermobility was noted.

3.6 Prognosis at 1st Assessment

A prognosis was not made in this case because of the unpredictability of the case in terms of chronicity, uncertainty of widespread symptoms in conjunction with hypermobile joints. A question mark was raised whether the thyroid gland had responded adversely due to the incident or may have been an ‘in the making’ already prior to the road traffic incident.

3.6.1 Goal Setting

It was decided to carry out 4 initial, consecutive treatments and review overall outcomes in view of satisfaction and changes. It was decided to complete another 6 treatments. Minor goal setting was completed at each treatment episode.

3.6.2 Timeline

Tina received 10 AdRx treatments spaced over 6 months. After finishing all treatments, she got in touch after 10 months and submitted a ‘body-chart’, Figure 7, finalising the overall outcome.
3.6.3 Treatment

Each visit lasted 30 minutes including 10 minutes assessment with a review, 10 minutes active treatment and 10 minutes to organise a follow-up with review to reflect on quality of life changes and pain patterns. Treatment was carried out in supine with two pillows under the knees to create a mild flexion position of the lumbar spine. The treatment focused on the symphysis pubis/sacro-iliac joint areas including the plantar and dorsiflexion at the crural joint of each foot but included the whole of the lumbar spine with emphasis on ‘stretching’ and ‘linking’ upper and lower ends of the autonomic chain. Treatment outcomes were noted after each treatment. Except for a sensation of dizziness, she did not experience any other adverse effect from the treatment(s). All treatments were carried out by the author in her private rooms.

3.6.4 Results

**Joint Mobility:** Spinal mobility was not an issue but did nevertheless increase mildly beyond normal range of movement in accordance with a tendency to hypermobility.

- **SLR:** 100°+ on the 9th treatment
- **Slump:** 7th visit showed full knee extension with full dorsiflexion of the ankle on both sides. Asymptomatic progress was maintained at the 10th visit

**Pain:** Self-reported pain charts and conscientious and expressive narratives of her experiences after AdRx treatments demonstrated the changes in quality and quantity of pain in the whole body. Tina was able to differentiate the outcomes as she became increasingly aware of changes in her symptoms. This qualitative approach offered a chance to measure changes in pain using ‘size of pain areas’ to describe quantity rather than a more orthodox Visual Analogue Scale (VAS) [63], which in terms of chronic pain is unsatisfactory [64-65].

3.7 Conclusion at End of Treatment (6 Months)

Figure 5, 6 & 7 show changes in both *quality* and *quantity* of pain on the body charts. The +ve outcomes in both QoL and pain, interspersed with a few short-lived ups and downs of pain, were maintained 1 year after stopping the treatment. Tina was able to manage her ‘downs’ by self-management over time.

Tina was able to endure and enjoy more outdoor activities, travel widely and was able to sit for longer periods without fear of complete exhaustion and increased pain. She was satisfied that the AdRx treatment made a big difference to facilitate improvement in her condition and felt a strong sense of empowerment overcoming her symptoms. Although there were still episodes of discomfort and low back pain from time to time, they were of shorter duration and easier to overcome. No other treatment intervention was used. After 10 treatments it was decided that sufficient progress had been achieved for Tina to ‘go solo’. The overall impression of using AdRx in WAD patients with chronic pain is that even with persistent pain and associated symptoms it is possible to achieve altered somatosensory conditions.

3.7.1 +ve Aspects of Tina’s Treatment

- Long-lasting benefits from treatment compared with other treatments.
- Despite chronic symptoms, lasting improvement was achieved.
✓ Activity, exercise endurance, quality of life improved.
✓ Hope at the end of the tunnel.
✓ Progressive improvement.
✓ Tina pointed out to the therapist to ‘target most effective areas’ as far as she was concerned. This helped to make relevant choices in relation to the painful spots on the feet (which in turn would affect the anatomical areas).
✓ Tina thought this was the most positive and effective treatment out of all treatments she had received.
✓ After a few treatments, Tina suggested that she was less sensitive to touch – this was interpreted as change in the hyperalgesic condition of nerve endings.
✓ Tina gained confidence to be more active and has now the duration to fulfil those ambitions.
✓ Tina had increased strength to carry out household tasks.
✓ Felt she had more energy in general.

3.7.2 -ve Aspects of the Treatment

✓ Increase of pain after treatment; worst after 1st session; interesting that “I felt like my worse symptoms from several years before had returned”.
✓ Persistent pain still there albeit much reduced.
✓ Dizziness: a new symptom.

3.8 Patient Perspective

3.8.1 Experience of Adapted Reflextherapy Described by the Patient

18th February 2018:
Three and a half years before I started Adapted Reflextherapy, I was involved in a car accident having been hit at an angle from the rear and pushed into a crash barrier on a motorway. The classic symptoms of whiplash started after four hours, with new symptoms emerging up to two years post-accident. These included pains or aches in my head, shoulders, upper back, lower back, spine, legs, knees, feet, hands, plus widespread stiffness and achiness, sciatica, tinnitus, hypothyroidism and concentration problems. Most severe was the pain in my lower back and neck. Some of these I still have today but are now very much reduced.

Before I had Adapted Reflextherapy, the effects of whiplash were reduced through five months of physio, three years of chiropractic treatment, six months of magnesium, a treatment of amitriptyline, aromatherapy, Pilates and yoga. The most effective of these was magnesium, but Adapted Reflextherapy changed the game again.

Prior to the treatment I was in constant pain. Each morning I would wake up extremely stiff and needed to stretch or undertake gentle exercise for 45 minutes each morning to relieve the pain. I could sit for about 1 hour at a time in the morning, maybe two hours in the afternoon before the stiffness and pain became too much. Being active was important. I had built up my walking and cycling to about 2 hours (with lots of rests), but this was at times challenging and often resulted in achiness, stiffness, and tiredness, all of which could only be relieved by stretching. Resting made the symptoms worse. My neck and back pain meant housework, in particular bending, was challenging and had to be broken down into smaller
chunks. I struggled to cook a simple meal after work. Lifting heavy objects was impossible, I struggled to carry a handbag and could not live an independent life. In addition to my morning exercise, I exercised 45 minutes each evening, plus as I spent much of my day working on a computer, hourly short walks and/or stretches were essential to reduce pain.

In the days after my first Adapted Reflextherapy treatment, my legs felt tight, I had heightened pain in my neck and head, was dizzy and felt very achy and heavy. I was tense and often jittery with tingling nerves all over my body. It felt like my worse symptoms from several years before had returned, in addition to the new symptom of dizziness. After a few days these subsided, and the pain in my back was reduced.

Over 5.5 months, I had ten treatments. Each targeted a different part of my body so that the extent and type of pain was substantially reduced, particularly in my head, neck, lower back and legs. As with other treatments or exercise programmes, some treatments were more effective than others. I talked with Gunnel to target the most effective areas of pain, and this helped.

Overall, this treatment was the most positive and effective one I received: I could reduce the amount of my daily exercises and stretches and became less reliant on them. I can now do a greater range of exercises and undertake exercise by choice rather than as a means to reduce pain. Immediately after my final treatment, I was able to sit for several hours at a time and I really enjoyed watching my first film which I didn’t need to exercise through! Three months after finishing the treatment I was able to walk for 5 hours carrying a small handbag, with less problems than before. Generally, I had more energy and also was less sensitive to touch. I was also able to do housework and cook for longer. Gradually as I gained more strength and confidence, the range of activities I could do increased in number, difficulty and duration.

Importantly, unlike other treatments, apart from the occasion wobble, the benefits have been long-lasting, and this was a step-change in my prognosis. The only long-lasting negative effects of the treatment I received was dizziness on lifting heavy objects which subsided after a couple of years and an involuntary jitter of my limbs a few times a day which still persists. Although I still have some pain, this is very much less than before, is less widespread and is variable in intensity, and I have much more control of it. At times, I have hours now which I am pain free and importantly have achieved activities that I never thought I would be able to do again if it was not for the Adapted Reflextherapy treatment.

4. Discussion

WAD is the result of ongoing symptoms from a whiplash injury including ‘central sensitisation’ where pain is modulated and controlled by higher centres which also control moods [66]. There is no single therapeutic intervention which is recommended in chronic and persistent pain states apart from pain management programmes, tailored to the individual [13], and emphasising psychological aspects of pain [67]. Here, we give a case report of a lady described as suffering from WAD for 3.5 years. She was selected to represent a novel approach in treating WAD, whereby it is hypothesized that sensory input from the periphery produces a neural activation which encompasses higher centres thereby including the psyche as well as the soma. The patient was advised to express her treatment experience using a self-reporting (narrative) diary including
drawing body chart images to describe areas of pain and adverse sensations. This was considered a suitable tool to describe physical and mental changes in the patient. The role of the therapist was to focus on measurable somatic alterations as has been praxis of the author throughout her clinical practice. The importance of incorporating teaching of pain mechanisms during a course of treatment is acknowledged. In this case, the patient had had plenty of opportunity to learn about pain management and causes of pain from a series of other therapists. It was not necessary to repeat these psychosocial aspects of pain. The research methodology chosen in this presentation aims to combine the quantitative changes and qualitative impressions to give the patient a voice in order to encourage improved clinical practice. Ong and Coady write that ‘…. qualitative approaches ... provide insights into the way people live with pain and disability, how patients and clinicians interact, and how professional education can be improved’ [68].

Pain is an enigma with many variables and there is a call for further insight into chronic pain [69]. It is nevertheless my opinion, based on observations and clinical experience, that chronic pain conditions are frequently associated with a past history of sudden deceleration mechanisms of the body whereby minor injuries occur, invisible to the eye or examination, leaving a trail of compromised neural activity. It is as if the nervous system has accommodated itself to a ‘siege’ mentality via reactions in its neural plasticity and cannot re-set itself to normal workings. It reacts like a diesel engine filled with petrol – it coughs and splutters and stops. Similarly, the chemistry does not gel and the body aches and hurts and finally gives up to pain. Patient choices are limited in terms of how they can help themselves, let alone understand ‘why’ they have pain. In orthodox musculoskeletal pain management, ‘pain’ is considered an inflammatory, or disease, process yet seldom as an ongoing neurophysiological reaction per se after a deceleration mechanism and blow to the soma. Non-steroidal anti-inflammatory medication is the ‘first aid’ intervention to combat the pain, but, it does not solve ongoing persistent pain. It is of interest to note that Olausson et al. [70] propose a particular hypothesis including CT (connective tissue) afferent coding property and pathways in gentle skin-to-skin contact which they name ‘the social touch hypothesis’. This hypothesis applies to unmyelinated tactile afferents in non-glabrous skin (in rats). Maybe there is an explanation waiting to be discovered (in humans) which could justify and explain the sometimes drastic and enigmatic changes observed during and after a foot treatment? The AdRx hypothesis states that touch on the feet is able to moderate acute and chronic pain states acting as a neuro-plasticity counter irritant.

With regards to the overall importance of the central mechanisms involved in pain production, AdRx offers a hypothesis that ‘touch’ initiates a sensory afferent impulse signalling and affecting ongoing neural plasticity. This in turn will affect pre-existing neural compromises from previously injured areas. Ongoing pain may potentially originate from the content of the axonal flow from another injury, including quality and quantity peptides, in the autonomic as well as the somatosensory nervous systems. Peptidal changes vary depending on demand in normal and abnormal circumstance, such as after injury [48, 71] and will affect, and are dependent on, synaptic integrity as well as the axonal transport [30]. Peptidal changes vary depending on demand in normal and abnormal circumstance, such as after injury [48, 71]. It is not possible to determine nor differentiate the origin of pain due to, as discussed, its transient behaviour and intermittent occurrence. See more in Khalsa (2004) [72]. Hypothetically, the spinal cord area, medulla, autonomic chain and peripheral connections are all implicated to a greater or lesser degree in their role to conduct information and may be a source of pain. There is not one source
of pain but a widespread effect and reaction in psychoneuroimmune (PNI) responses throughout, including in the autonomic nervous system chain which links closely to the limbic system [73]. Treede, Jensen, Campbell et al. call for more integrative research into the spinal segments that are part of pain-producing structures [74]. AdRx is known to have facilitated change in hyperalgesic and hypersensitive persons with persistent pain. It has been a first choice of treatment to reduce hypersensitivity and hyperalgesia in acute and chronic pain after whiplash including WAD. Once ‘hypersensitivity’ in tissues has been reduced, orthodox methods of physical therapies may be applied as necessary which hitherto have been impossible to implement due to the hyperalgesia of the tissue matrix [19].

AdRx intervention appears to have had a favourable effect on hypersensitive symptoms in the context of injury and WAD. Although Tina still suffers episodes of pain, they are less frequent and less severe. Pain no longer dominates her life and QoL has much improved. To date, the improvements have persisted beyond 18 months. Tina had tried various coping strategies during 3.5 years to overcome her dysfunctional existence. As per her body charts, she found that the AdRx treatment assisted in reducing her uncomfortable symptoms. Six months after her first treatment, hypersensitive areas had reduced in size and intensity. Ten months later, during which no treatment was carried out, minor low backache symptoms seem to have recurred but without interference to daily activities.

Tina experienced reduced neck pain after having had a sham treatment in the research project. This may be suggestive thinking like a placebo effect, i.e. a positive effect without a real neurological link. Placebo is a powerful usage of suggestive thinking in the treatment of pain. In a postal questionnaire of 100 members of the Association of Chartered Physiotherapists in Reflex Therapy (ACPIRT), it was considered by the majority of the respondents that ‘placebo’ played a 25% part in the outcome of the patient. In other words, the effect of the treatment played a 75% part in changes that could be observed and self-reported by the patient [75]. Does this support or negate the treatment philosophy, i.e. by stopping treatment, you stop incoming action potentials into the nervous system hence symptoms have a tendency to return albeit with lessened power and strength.

Hypermobility was a comorbidity in Tina’s case. This has been found to be a common feature in individuals who do not recover fully from injury. The reason for this is not known but should be considered in cases of ‘non-recovery’.

5. Takeaway Message

While AdRx remains an enigma, in terms of chronic pain and unresolved WAD, patients have responded well to a foot application regardless of the origin of their pain and chronicity of symptoms. After 20 years of clinical experience in using AdRx, it is not considered a fanciful notion but aims to convey the capacity for the neural plasticity to self-regulate. Chronicity leads to comorbidities and unfortunately, in some cases, to suicide [76]. We have to dare to rethink how pain is maintained with concomitant physiological responses in order to overcome the challenge of persistent pain. The world is desperate to find a way to combat chronic pain. This case report aims to raise awareness of an alternative approach to chronic pain in WAD. It suggests a coherent interconnective neural signalling system which can be utilised to change pain behaviour.
Informed Consent

Patient provided informed consent – yes.

Author Contributions

Gunnel Berry did all the research work of this study.

Competing Interests

The author runs courses in AdRx. A book is for sale on the AdRx website.

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The nervous system is everywhere in the body, especially in the skin. Ancient Chinese acupuncture charts show us that the nerves are all connected and can work together to promote health. This connection occurs through the brain and brain stem. It is clear that acupuncture is analgesic by inhibition of transient receptor potential cation channels in the skin [1]. The role of chemokines in pain is becoming understood. Chemokines promote pain in the skin and activate ascending neural pathways that regulate chemokine production in nerves throughout the body [2]. Chronic pain is a whole body experience.

The use of herbal medicines is supported by thousands of years of experience. Our ancestors survived in part by using herbal medicines. In traditional societies, a supportive family and community environment were also crucial to healthcare, including healthcare for mood, anxiety and depression [3]. Religious practices can play an important role in healthcare. Medical marijuana has come to us due to the use of ganja in religious practices in India. The careful selection of CNS active strains of Cannabis sativa by ancient religious practitioners in India has led us to the medical marijuana we use today. For instance, cannabidiol lotion can be rubbed on the cheeks to quickly relieve anxiety [4].

Herbs are complex mixtures of active ingredients that work together to promote health. Human bodies have evolved over the last 200,000 years to use these complex mixtures as medicines. Some active ingredients may improve the bioavailability of other ingredients. Some
chemicals may potentiate or synergize the actions of active chemicals. The hunt for single active ingredients in herbal medicines has produced many drugs that are used today. However, the use of complex herbal drugs may be important for conditions that modern medicine and single active ingredients cannot adequately treat, such as chronic pain.

The most powerful medicine we have is the human body. Drugs only help the body heal itself. This is why seemingly miraculous cures have been documented, since the body heals itself. We must relearn the traditional concept of living in balance [5]. When the body is in balance, the body heals itself. Balance involves keeping the body thin and strong. Daily exercise is critical. The most important muscle is the heart. The heart requires gentle endurance exercise. Myokines released by exercising muscles help maintain health.

We are currently in a period where standard healthcare has not progressed as quickly as in the past. In fact, the quality of health for most people has decreased significantly due to obesity, type 2 diabetes, cardiovascular disease and other lifestyle diseases [6]. Healthcare providers have started to supply excuses for the lifestyle diseases of their patients. We must learn from Traditional Healers that a healthy lifestyle is essential to good health.

Author Contributions

James David Adams did all the research work of this study.

Competing Interests

The authors have declared that no competing interests exist.

References

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