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Treatment for Central Sensitization and Shoulder Pain Using Systemic Manual Therapy (SMT)

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Abstract

Objective: The purpose of this study is to test a hypothesized treatment for the central sensitization component of shoulder pain, which is based on Halili's proposed temporal model for central sensitization.

Design: Cohort retrospective multivariate analysis.

Methods: This study uses The Halili physical therapy statistical analysis tool (HPTSAT) to evaluate the average rate of improvement in shoulder pain and overall associated symptoms in 734 patients after provision of 552 protocol combinations of Systemic Manual Therapy.

Results: Among the 734 patients in the study 429 (58%) reported improved specific changes related to shoulder pain. The average improvement in shoulder pain was 1.51 points ($p<0.001$). Forty-one combinations containing 16 distinct protocols passed the HPTSAT criteria to demonstrate better treatment effect than optimal standard of care (oSOC) including 5 of the protocols proposed to treat the central sensitization component.

Discussion and Conclusion: This study supports the treatment approach for central sensitization (CS) hypothesized in the temporal model for central sensitization (TMCS) when treating shoulder pain.

Keywords: Shoulder pain, Temporal model for central sensitization, Systemic manual therapy, Barral, Fascial counterstrain, Integrative manual therapy

Introduction

The purpose of this study is to continue to evaluate CS and the proposed treatment for it in musculoskeletal and neuromuscular conditions. This study replicates similar investigations looking at the CS components in knee pain [1], trigeminal neuralgia [2], chronic low back pain [3] and hip pain [4]. The TMCS [5] outlines the basis for the mechanisms and treatment of CS. It defines CS as a dysfunctional state of the central and autonomic nervous systems where several self-reinforcing neurological loops trap the body in a state of CS. One of the several elements considered when testing the treatment hypothesis discussed in the TMCS is that the treatment protocols predicted by the TMCS to address CS should be effective in treating a body region regardless of the anatomical proximity to it. While the previous investigations [1–4] had already demonstrated all the elements required to reject the TMCS null hypothesis, further replicating these findings when treating shoulder pain would be a step closer to validating the TMCS hypothesis.

Shoulder pain is the third most common musculoskeletal disorder worldwide, with annual prevalence rates ranging from 10.8% to 55.2% [6,7]. Shoulder pain tends to have a generally unfavorable prognosis, and accurately predicting clinical outcomes presents substantial difficulties [8]. It encompasses several diagnostic categories, including adhesive capsulitis, rotator cuff injury, supraspinatus impingement syndrome, acromioclavicular dysfunction, fractures, nerve-related injuries, and instability [9,10]. Additionally, various conditions such as

obesity, diabetes, cancer, stroke, and post-cardiac surgery can contribute to shoulder pain and restriction, resulting in functional loss, work limitations, and socioeconomic problems [11–16]. An additional common challenge in diagnosing and treating shoulder pain arises from overlapping with pain pathways associated with cervical dysfunction [17].

Some authors have suggested that central sensitization may play an important role in musculoskeletal disorders [5,18–21]. In 1983, Woolf [22] introduced the term "central sensitization" to describe the connection between the central nervous system and hypersensitivity to pain, along with other symptoms associated with the autonomic nervous system, such as poor sleep, fatigue, and cognitive impairment [23,24]. Halili [5] proposed the TMCS. According to this model, CS occurs due to the confluence of metabolic stress and the continued propagation of that stress over time. In addition, the temporal model contains a template that can test hypothetical mechanisms for pathophysiology as well as for the efficacy of a proposed intervention. The pathophysiology component of Halili's TMCS describes five progressive stages of autonomic and Central nervous systems (CNS) function where CS is maintained at the fourth stage due to repeated trauma and/or self-reinforcing neurological loops. The TMCS further contains a proposed intervention for using systemic manual therapy (SMT) [25] to stabilize CS. The proposed treatment entails disruption of those self-reinforcing neurological loops using specific SMT protocols.

SMT protocols [25] are a group of about 50 protocols that have been developed and standardized over couple of decades by incorporating individual techniques from several osteopathic and physical therapy methods such as fascial counterstrain (FCS) [26], Barral [27], integrative manual therapy (IMT) [28] and muscle energy techniques (MET) [29]. A protocol refers to a specific group of techniques that are performed in one treatment session.

Halili [5] postulates that if the proposed protocols to disrupt the loops that maintains the state of CS (Urinary drainage (UD), Diaphragm cranial sinus (DCS), Cardiac cervical cranial vascular (CCCV) and at least one of the following: Lower abdominal urogenital (LAUG), Barral abdominal motility (Barral), and Gastro urinary ovarian uterine (GUOU) are: (1) effective in treating both the treated area and overall symptoms, (2) do so regardless of the anatomical proximity to the treated region, and (3) effect sustained improvement over episode of care, then the null hypothesis can be rejected.

The rejection of this null hypothesis was previously demonstrated, by meeting these conditions, when treating the central sensitization component of knee pain [1], Trigeminal neuralgia [2], Chronic low back pain [3], and hip pain [4] and as discussed, this study attempts to replicate these findings when treating mostly sensitized patients with shoulder pain complaints.

Methodology

This study was approved by Argus independent Review Board (www.argusirb.com) on July 21, 2021.

The specific outcome measure used for this study was the Patient Identified Problem (PIP) scale [30].

The PIP scale is a 1 to 10 (half point permitted) scale. The patient can score between 1 (which denotes that the problem is not currently active) and 10 (which indicates maximal intensity). Problems were examined both individually and as a cumulative score. The cumulative score was calculated according to the following formula: PIP = SUM (individual score/number of problems) × 10 (adding the scores of all individual problems, dividing the total by the number of individual problems, and then multiplying by 10). Symptoms were graded by the patient whenever possible to decrease the examiner's bias. Scoring was always performed at the next visit and not immediately after the treatment. The PIP scale had a specificity and sensitivity of 91.46% and 64.45%, respectively, and an ICC score of 0.96. Minimal clinically important change (MCID) for change observed in the whole scale is 3.8 (95% CI 1.4 to 8.2), and for an individual problem, score change is 0.89 (95% CI 0.33 to 1.5).

To identify which SMT protocols or protocol combinations were more effective than the oSOC, the HPTSAT [31] was used.

The HPTSAT is a software tool designed to control for a number of internal validity threats, such as repeated measurements error, when retrospective clinical data is analyzed as well as a placebo effect. One of the key functions of the tool is to measure the average rate of change (ARC5) during multiple treatment sessions. The tool then compares the rate during the period a specific protocol or protocol sequence was done and compares it to the rate during times other treatments were done. The tool identifies all protocols or sequences that met a specific quantitative differentiation criterion. The criterion uses both parametric and non-parametric tests as well as sample and effect size.

The HPTSAT analyzed 44,915 blinded visit records of 2,710 patients from the Halili Physical Therapy EMR (electronic medical records) system v. 2021, Tucson, AZ (HPT2021) between the dates of 4/2/2015 and 11/29/2022.

The exclusion criteria were the absence of more than one treatment session. Because the main intent of the study was to evaluate the CS component, there was no differentiation between different types of shoulder pathology when creating the study sample.

In the HPTSAT analysis, a study sample was created using the search terms "shoulder," "scapula," and "scapular" in the PIP list [30]. The resulting sample included 741 patients (511

female, 230 male, average age 61.18, range (10 to 95). The evaluating physical therapist identified central sensitization as one of the differential diagnoses in 551 patients (74%). This determination was done using a methodology similar to the one outlined by Lluch *et al.* [32]. Seven patients were excluded from the study since they had less than 2 visits.

Among the remaining 734 patients there were 993 episodes of care (if 90 days have passed since the last visit, then the next visit is considered a new episode of care).

The HPTSAT located and analyzed 552 SMT protocols or protocol combinations (having a frequency >5). The tool identified, among this group, the protocols and protocol sequences that met or exceeded the differentiation criteria established by the HPTSAT to denote that they are better than the oSOC. The established HPTSAT criteria for differentiation include sample size larger than 20, ARC_5 larger than MCID low value of 95% CI, Welch's, Mann-Whitney (MW), ANOVA $p < .05$, and Hodges' $g > 0.2$. Further qualitative demographic and comorbidity information as well as episode of care data was compiled and analyzed using the HPTSAT [30] and MedCalc software [33].

Results

Qualitative observations

To gain some qualitative understanding of the sample, we noted the following: The average time period a patient was followed in this study was 394 days. The average length of episode of care was 159 days (95% CI 143 to 174), average visits per episode were 15 (95% CI 14 to 17); average days between treatments was 10. For a list of comorbidities and additional information, refer to the accompanying dataset [34].

Episode of care data

Changes in overall PIP scale scores over the study period were as follows: 511 patients (70%) reported improvement in overall PIP complaints; 58 patients (8%) either reported no change or did not record; and 165 patients (23%) reported worsening of overall PIP scores. On average, overall PIP scale score improved by 9.63 points (p, SD and 95% CI were < 0.001, ± 20.08, 11.08 to 8.18 respectively). This change exceeded the MCID of 3.8 including its 95% CI upper limits of 8.2 points. The average improvement at end of episode of care was nearly identical to the average improvement noted at the end of the study period (9.63 vs 9.36, p=0.75).

Specific changes related to shoulder pain complaints were: 429 patients (58%) reported improvement; 178 patients (24%) either did not record or reported no change; and 127 patients (17%) reported worsening of shoulder pain score. On average, individual complaint of shoulder pain improved by 1.51 points (p, SD and 95% CI were < 0.001, ±2.69, 1.70 to 1.32 respectively). This change exceeded the upper limit of the MCID CI of 1.4. It is worth noting that the average improvement over the study period (which included multiple episodes of care), was significantly higher than the average improvement noted after a single episode of care (1.51 vs. 1.09 p<0.001).

Response to specific SMT protocol and protocol sequences

The 16 individual protocols passing the HPTSAT criteria were: Cardiac Cervical Cranial Vascular (CCCV), Lower Abdominal Urogenital (LAUG), Cardiovascular Venous Thoracic (CVVT), Upper Extremity Drainage Jones (UEDJ), Upper Extremity Nerves (UEN), Muscle Energy Technique sacroiliac combined with Vascular protocol variations (METVAS), Side-Lying Modified Glides (Top) (SLMG or SLMGT), Urinary Drainage (UD), Diaphragm Cranial Sinus (DCS), Sympathetic Nerve (SYMPN), Upper Extremity Periosteum (UEOST), Lower Extremity Drainage Jones (LEDJ) (all variations), Venous Thoracic Cardiopulmonary (VTCP), Barral abdominal motility (Barral), Spinal Drainage Jones (lumbar or cervical variations (SPDJL or SPDJC) and harmonic mobilizations techniques [35]. All but two of the protocols (UEOST and SYMPN) that passed the HPTSAT criteria for shoulder pain were also found in the combinations that passed the criteria for effectiveness on overall change. In accordance with the TMCS [5], five of the 16 passing protocols (CCCV, DCS, UD, Barral, LAUG) were performed because of their hypothesized general effect on central sensitization. The passing combinations are listed in **Table 1**.

Table 1. Passing combinations.

Protocol/combinations	n	freq, control	ARC5	Rx, oSOC	SD (95% CI)	Welch	MW	ANOVA	Hedges'
DCS Barral CCCV VTCP UEDJ	20	20, 61462	1.18	1.32, 0.14	2.37 (3.41 to 1.33)	0.037	0.023	< .001	0.88
BARRAL CCCV VTCP UEDJ	25	72, 61410	1.03	1.16, 0.13	2.02 (2.49 to 1.55)	< .001	< .001	< .001	0.76
UD DCS LAUG CCCV MET	25	26, 61456	0.82	0.96, 0.14	1.81 (2.5 to 1.11)	0.028	0.008	0.002	0.61
UD METVAS SPDJ	20	111, 61371	0.81	0.94, 0.13	1.69 (2 to 1.37)	< .001	< .001	< .001	0.59
DCS Barral CCCV VTCP	38	111, 61371	0.76	0.89, 0.13	1.95 (2.32 to 1.59)	< .001	< .001	< .001	0.56
DCS LAUG CCCV METVAS	27	80, 61402	0.71	0.85, 0.14	1.89 (2.3 to 1.47)	0.001	< .001	< .001	0.53
SLMG UD DCS	22	130, 61352	0.7	0.83, 0.13	1.94 (2.28 to 1.61)	< .001	< .001	< .001	0.52

UD DCS VTCP	26	137, 61345	0.7	0.83, 0.13	2.17 (2.53 to 1.81)	< .001	0.003	< .001	0.51
Barral CCCV VTCP	47	267, 61215	0.69	0.82, 0.13	1.79 (2.01 to 1.58)	< .001	< .001	< .001	0.51
CCCV Barral	22	197, 61285	0.66	0.79, 0.13	1.6 (1.82 to 1.37)	< .001	< .001	< .001	0.49
METVAS CVVT	36	251, 61231	0.61	0.74, 0.13	2.21 (2.48 to 1.93)	< .001	< .001	< .001	0.45
UEDJ UEN UEOST	29	170, 61312	0.61	0.74, 0.13	1.52 (1.75 to 1.29)	< .001	< .001	< .001	0.45
LAUG LEDJ UD DCS BARRAL	54	54, 61428	0.57	0.71, 0.14	1.56 (1.97 to 1.14)	0.009	< .001	0.002	0.43
CCCV METVAS SLMG	22	123, 61359	0.51	0.65, 0.14	1.34 (1.58 to 1.1)	< .001	< .001	< .001	0.38
UD METVAS SLMG	27	181, 61301	0.51	0.64, 0.13	1.21 (1.39 to 1.03)	< .001	< .001	< .001	0.37
LAUG CCCV METVAS	35	203, 61279	0.49	0.62, 0.13	1.83 (2.08 to 1.58)	< .001	< .001	< .001	0.36
UEDUEOUENUD	26	76, 61406	0.48	0.62, 0.14	1.92 (2.36 to 1.49)	0.03	< .001	0.002	0.36
METVAS UEDJ	35	273, 61209	0.48	0.61, 0.13	1.92 (2.15 to 1.69)	< .001	< .001	< .001	0.36
VTCP METVAS	38	316, 61166	0.45	0.58, 0.13	1.36 (1.5 to 1.21)	< .001	< .001	< .001	0.33
UD DCS LAUG CCCV	120	323, 61159	0.43	0.56, 0.13	1.54 (1.71 to 1.37)	< .001	< .001	< .001	0.32
CCCV VTCP UEDJ	52	294, 61188	0.41	0.54, 0.13	1.84 (2.05 to 1.63)	< .001	0.011	< .001	0.3
METVAS LEDJ	20	171, 61311	0.41	0.54, 0.13	1.57 (1.8 to 1.33)	< .001	< .001	< .001	0.3
UEN UEOST	30	285, 61197	0.39	0.52, 0.13	1.46 (1.63 to 1.29)	< .001	< .001	< .001	0.29
UEDJ UEOST UEN	34	193, 61289	0.39	0.52, 0.13	1.65 (1.88 to 1.42)	0.001	< .001	< .001	0.29
CCCV UEDJ	27	256, 61226	0.38	0.51, 0.13	1.64 (1.85 to 1.44)	< .001	< .001	< .001	0.28
KW Harmonic mobilizations	34	357, 61144	0.38	0.51, 0.13	1.9 (2.1 to 1.7)	< .001	< .001	< .001	0.28
CCCV CVVT UEDJ	30	168, 61314	0.37	0.51, 0.14	1.68 (1.94 to 1.43)	0.005	< .001	< .001	0.27
CVVT UD	25	214, 61268	0.37	0.5, 0.13	1.61 (1.83 to 1.39)	< .001	< .001	< .001	0.27
DCS LAUG CCCV	148	790, 60692	0.37	0.5, 0.13	1.55 (1.66 to 1.44)	< .001	< .001	< .001	0.27
CVVT UEDJ UEN	21	119, 61363	0.37	0.51, 0.14	1.57 (1.86 to 1.29)	0.011	0.005	0.003	0.28
DCS UD DCS	29	151, 61331	0.37	0.51, 0.14	1.34 (1.55 to 1.13)	< .001	0.006	< .001	0.28
LEDJ UD DCS BARRAL	63	184, 61298	0.36	0.49, 0.13	1.63 (1.87 to 1.4)	0.004	< .001	< .001	0.26
VTCP UEDJ UD	83	440, 61042	0.35	0.48, 0.13	1.65 (1.8 to 1.5)	< .001	< .001	< .001	0.26
LAUG LEDJ UD VTCP	31	86, 61396	0.35	0.49, 0.14	1.55 (1.88 to 1.23)	0.035	0.054	0.014	0.27
DCS SLMG	20	188, 61294	0.33	0.47, 0.14	2.31 (2.64 to 1.98)	0.052	0.023	< .001	0.24
MET SLMG UD	22	125, 61357	0.33	0.47, 0.14	1.38 (1.63 to 1.14)	0.008	0.005	0.005	0.25
METVAS SPDJ	39	334, 61148	0.33	0.46, 0.13	1.33 (1.47 to 1.18)	< .001	0.001	< .001	0.24
UD SYMPN	22	201, 61281	0.32	0.45, 0.13	1.92 (2.18 to 1.65)	0.02	< .001	< .001	0.24
METVAS LAUG LEDJ	48	242, 61240	0.32	0.45, 0.13	2.01 (2.27 to 1.76)	0.016	0.016	< .001	0.23
REV VAS	21	288, 61194	0.32	0.45, 0.13	1.19 (1.33 to 1.05)	< .001	0.001	< .001	0.23
SLMG UD	53	461, 61021	0.32	0.45, 0.13	1.63 (1.78 to 1.48)	< .001	0.003	< .001	0.23

Key: n: Number of Times Combination was Done; freq: Number of 1-5 Measurements Including This Combination; control: Number of 1-5 Measurements Not Including This Combination; ARC5: Average Rate of Change Over Five Measurements; Rx: ARC5 of freq; oSOC: ARC5 of Optimal Standard of Care (control frequency); SD: Standard Deviation; CI: Confidence Interval; Welch: p of Welch's t Test; MW: p of Mann-Whitney Test; ANOVA: p of Analysis of Variance; Hedges' g: Hedges's Effect Size; IAUG: Lower Abdominal Urogenital; Barral: Barral Abdominal Motility; UD: Urinary Drainage; DCS: Diaphragm Cranial Sinus; CCCV: Cardiac Cervical Cranial Vascular; WCP: Venous Thoracic Cardiopulmonary; CVVT: Cardiovascular Venous Thoracic; SLMG: Side-Lying Modified Glides; SPDJ: Spinal Drainage Jones (all versions); SYMPN: Sympathetic Nerve; METVAS: Muscle Energy to SI Joint and Vascular Combination; UEDJ: Upper Extremity Drainage Jones; UEOST: Upper-Extremity-Periosteum; UEN: Upper Extremity Nerves; LEDJ: Lower Extremity Drainage Jones; Harmonic: Harmonic Shoulder Mobilizations; KW: Keyword

Seven protocols (VTCP, CVVT, UEDJ, UEOST, UEN, SYMPN, and harmonic mobilizations) are proposed to have a direct effect because of the anatomical proximity of the techniques to the shoulder area.

Two protocols (SPDJ and SLMG) which are performed on spinal structures could have either regional or desensitization effects.

LEDJ, which has neither regional nor direct proximity to the shoulder, is proposed to have a distant decongestive effect because of its focus on venous and lymph circulation.

The METVAS protocols have portions that are done directly on the shoulder in addition to spinal and pelvic techniques, hence could affect symptoms via number of different mechanisms.

REVVAS, which is one common component of the METVAS combination, has also been shown to pass the HPTSAT criteria as a stand-alone protocol. This could be because of either a regional or a desensitization mechanism.

Additional observations

Exercises performed during the therapy session, whether alone or in combination with other techniques (the HPTSAT controls for the effects of home exercises), produced a small but significantly better effect than the oSOC. The ARC5 for exercises was 0.36 vs 0.13 for oSOC ($p<0.001$ and effect size of 0.17).

Unlike harmonic mobilizations, more conventional glenohumeral mobilizations were not statistically better than the oSOC. The ARC5 for mobilizations was 0.22 vs 0.14 ($p=0.3$, effect size=0.06)

Counterstrain techniques, either the original Jones strain-counterstrain (SCS) [36] or FCS [26] were done using the pragmatic approach of seeking tender points and then treating them, were statistically virtually identical to the oSOC. The ARC5 for SCS was 0.14 vs 0.13, ($p=0.9$, effect size=0.00). We need to be cautious interpreting the effect observed after doing individual counterstrain techniques because unlike when protocols were used, different techniques were done based on the clinician judgment in a given day.

The complete performance of the remaining protocol combinations, the effects of comorbidities, additional post-hoc tests, and raw data tables are available in the accompanying dataset [34].

Discussion

The results of this research successfully reject the null hypothesis for the temporal model since all conditions specified to meet the null rejection criteria were met. Out of the original sixteen protocols found by this study to be better than oSOC, five protocols that were proposed to disrupt neurological loops that maintain central sensitization (UD, DCS, Barral, LAUG, CCCV) had shown to be effective in treating both shoulder pain and overall symptoms, regardless of their anatomical proximity to the treated region; and the results demonstrate sustained improvement over episode of care.

The results of this study replicate the findings that the protocols proposed by the TMCS to address CS (UD, DCS, Barral, LAUG, CCCV) are effective regardless of their anatomical proximity to the area treated [1–4]. Furthermore, this study supports the TMCS hypothesis for treatment and pathology since none of these protocols provide direct intervention over the shoulder joint and yet provide statistically significant reduction in shoulder pain.

The remaining 11 protocols that were included in the combinations shown to be better than the oSOC are hypothesized to do so by more direct or regional effects on the shoulder area.

The prognosis for shoulder pain is generally poor, and predicting clinical outcomes poses significant challenges. Previous randomized controlled trials (RCTs) have demonstrated short-term improvements with various interventions for shoulder pain, but evidence of effective interventions specifically for chronic shoulder pain remains limited [8,37]. Thus, understanding the CS status of patients and implementing a treatment model that addresses the autonomic nervous system may play a crucial role in effectively managing chronic shoulder pain and other chronic conditions. Our study suggests, in line with existing evidence, that shoulder pain can be improved through exercises and mobilization of the shoulder and then goes beyond this to demonstrate that interventions specifically targeting CS can lead to further improvement in shoulder pain. The positive outcomes of treatments using the five protocols that target CS suggest their potential effectiveness in improving shoulder pain. It is important to note that while this study does not provide the exact physiological mechanism to explain results, it does indicate that the treatment effect of these protocols surpasses that of the oSOC.

Overall, these findings highlight both the potential of protocols designed to address CS, and their effectiveness in managing chronic shoulder pain. Further research is needed to elucidate the physiological mechanisms that underlie this common condition, and to establish the long-term effects of the interventions investigated in this study. By incorporating a comprehensive approach that recognizes and addresses CS, and by utilizing targeted interventions, clinicians may enhance treatment outcomes for patients with chronic shoulder pain.

Key Points

- This study demonstrates the benefits of using a standardized form of therapy called SMT in treating complex problems such as CS in shoulder pain.
- The findings of this study support the TMCS implicating CS as a functional rather than structural neurophysiological adaptation.
- This study also provides targeted interventions to effectively treat other elements of chronic shoulder pain such as circulatory congestion.

Limitations

- We need to consider that most patients seek help with multiple problems, not just for shoulder pain. Therefore, until we have data outcome multiple other problems that are similar to those of this study and until we understand how each problem interacts with any other problems present, the treating physical therapist must still rely on the basic HOAC qualitative model when developing an individual plan of care.
- Because this study focused on the CS component and not on specific pathologies that can generate shoulder pain, it is not possible to tell if the interventions that were having direct effects on the shoulder region would be effective for all shoulder associated pathology.
- The study sample did not show sufficient variability in the order in which the sequence of protocols was performed. Therefore, we cannot make statistical inferences regarding the optimal order of protocols in a sequence.
- Performing SCS and FCS in the more traditional pragmatic manner is dependent on the decision-making skills of the clinician. As such, their limited efficacy observed needs to be interpreted with caution.
- The absence of randomization when selecting patients or protocols introduces bias, considering confounding variables such as differences in age, gender, duration of symptoms, or concurrent conditions were not adequately accounted for. This might limit the generalizability of the findings, making it difficult to conclude that the observed effects were due to SMT alone.

Future Implications

This study's findings can be generalized in two ways. First, clinicians who use SMT, fascial counterstrain, IMT or Barral techniques can immediately implement the SMT protocols suggested in this study. The episode of the care outcome is the second generalization that can be made. This outcome can be considered by any professional who treats shoulder pain and is used as a benchmark against which all other interventions can be measured.

Recommendation for Future Research

To overcome the limitations of this current study, future research should be structured as a randomized controlled trial (RCT) with a prospective study design, where data is collected in real-time allowing for better control of variables and more reliable data collection.

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There were no external funding sources for this study.

Study Approval

This study was approved by Argus independent Review Board (www.argusirb.com) on July 21, 2021. There were no human subjects in this study.

Conflicts of Interest

There are no conflicts of interest to report in this study.

Author's Contribution Statement

AH contributed to concept, design, data collection and interpretation and writing of this manuscript. GS contributed to concept, design, writing, data interpretation and writing of this manuscript.

Patient Involvement Statement

There were no patients involved in this study.

Data Sharing

Sata is publicly available in Mendeley Data, V1, doi: 10.17632/7j6cmhzzx9.1.

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