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The effectiveness of a cognitive behavioral exercise approach (CBEA) compared to usual care in patients with a Whiplash associated disorder: A quasi-experimental clinical trial

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Abstract.
BACKGROUND: Whiplash Associated Disorders (WAD) is a biopsychosocial problem, education may be an essential part in the treatment and the prevention of chronic WAD. However, it is still unclear which type of educative intervention has already been used in WAD patients and how effective such interventions are.
OBJECTIVE: To examine the effectiveness of a cognitive behavioral exercises approach (CBEA) for self-training of the neck relative to usual care in individuals with WAD in acute phase.
METHODS: Forty-one patients, 65.9% female (mean ± SD age: 41 ±11 years), with WAD were recruited immediately after the accident (within 48 hours) and assigned according to patient choice to receive a CBEA self-training of the neck or usual care for 15 days. The primary outcome measure was pain intensity and disability as measured with the Neck Disability Index (NDI). Secondary outcome measures included the presence of headaches, dizziness, nausea, and difficulties with concentration and memory. Measurements were taken at pre-treatment, 2 weeks post-treatment and 4- and 12- weeks after the injury.
RESULTS: Patients receiving the CBEA intervention experienced a greater reduction in pain as compared to those receiving the usual care at the end as well as 4 and 12 weeks after the intervention ($P < 0.001$), for the Neck Disability Index (NDI) decreased more in the CBEA than controls over the 15 days and ($F_{[3.0]} = 552.383$; $P = 0.001$), and in both groups at all follow-up periods (all, $P = 0.001$).
CONCLUSIONS: This quasi-experimental clinical trial provides evidence that a CBEA for self-training of the neck may be more beneficial in treating pain than usual care in patients with WAD. However, the CBEA had limited value in improving NDI. Future studies should include several therapists, a measure of a long-term outcomes and randomize patients to groups.

Keywords: Whiplash, cognitive-behavioural exercises, neck

1. Introduction

Whiplash associated disorders (WAD) consist a soft tissue or bony injury as a result of a swift acceleration and deceleration of the head and neck [1]. Whiplash associated disorders are a disabling condition and the patients symptoms may include neck pain, arm pain and headaches [1]. It has been reported that WAD continues to rise and the incidence has been reported to be approximately 300 per 100.000 individuals [2]. Although it has been reported that the majority of patients with WAD will experience a full recovery within a few

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months, it is estimated that approximately 50% will continue to experience pain and disability at a 1-year follow-up [3]. The yearly cost associated with WAD is estimated to $3.9 billion dollars in the United States an 13.4 billion dollars in Europe resulting in a substantial economic burden [4] Furthermore, it should also be recognized patients with WAD may experience signs of abnormal sensory processing and central sensitization leading to the development of chronic symptoms at long-term follow-up [1,6].

In Italy, patients with WAD were commonly subjected to soft neck collar and painkillers as the first method of treatment following injury. Clinical practice guidelines have recommended rapid return to usual activity, education, manual therapy and therapeutic exercise as viable treatment approaches for reducing disability [5]. It has also been shown that patients with high baseline pain scores and disability have a poor prognosis [7]. Although number of interventions including exercise have been suggested as effective treatment options for the management of WAD [7,8], a recent systematic review suggested that there is inconclusive evidence that neck exercises are beneficial in the management of patients with WAD [9].

Patients with WAD often experience symptoms beyond physical impairments as a result of inappropriate pain behaviours and high levels of stress. It has been suggested that it is essential to address both cognitive and behavioural manifestations in patients with WAD in an attempt to maximize recovery [10]. A case series of patients with WAD demonstrated that patients managed with a cognitive-behavioral approach experienced a reduction of symptoms and full return of function [11]. A clinical trial comparing a CBT approach to a group receiving just the exercises [12] demonstrated those recivieing CBT experienced significantly less pain at follow-up. The authors suggested that future studies should continue to examine the impact of CBT in patients with WAD and include larger sample sizes. The acute phase of WAD is relatively different from the chronic phase, since it includes either patients experiencing a full recovery in short time and patients prone to chronicity); one can wonder if a preventive approach combining the two best evidence based rehabilitation practices (exercises, within a cognitive-behavioural approach) can improve results in the short and long term of patients with WAD. Before proceeding to a randomised controlled trial, this hypothesis needs to be examined through observational data. Therefore the purpose of the current clinical trial was to examine the effects of exercises and a cognitive behavioural exercise approach (CBEA) compared to usual care for reducing pain and disability in a population with WAD in the acute phase (within 48 hours from injury).

2. Methods

2.1. Design

We conducted a quasi-experimental clinical trial. Informed consent was obtained from all participants and the protocol was approved by the Ethical Committee of IRCCS Don Gnocchi Foundation, Milan, Italy.

2.2. Assignment of patients

Forty-one patients, 65.9% female (mean ± SD age: 41 ± 12 years) and 34.1% male (mean ± SD age: 40 ± 11 years), with a WAD as a result of a motor vehicle accident were consecutively recruited within 48 hours of the injury from March 2013 to October 2013 at the Emergency Unit of Istituto Clinico Città di Brescia, Brescia, Italy. To be included in the study, the participants had to be 18–70 years of age and needed to have a diagnosis WAD grades 1 and 2 according to the clinical classification of the Quebec Task Force of 1995 [1] as determined by an emergency room physician, had to have a score greater than 4 points at the Visual Analogue Scale (VAS) [13] without clinical signs of nerve root compression [14] and simultaneous concussion or other head trauma [15]. All patients underwent radiographic examination to exclude vertebral fractures [16].

According to usual care practices in Italy, each participating patient was prescribed a soft neck collar and painkillers to be used for a period between 7 and 14 days. Patients selectively chose to participate in one of 2 groups: an experimental group who received CBEA for self-training of the neck or a control group who received usual care intervention for 15 days. All outcome measures were collected at baseline, immediately following the intervention period, and 1- and 2-months following the end of the intervention.

2.3. Sample size calculation

The sample size and power calculations were performed with the ENE 3.0 software (GlaxoSmithKline©, Universidad Autónoma, Barcelona). The calculations were based on detecting a mean difference of 2 cm on

a 10 cm visual analogue scale (VAS) assuming a standard deviation of 2 cm, a 2-tailed test, an alpha level of 0.05, and a desired power of 80%. The estimated desired sample size was 16 individuals per group.

2.4. Outcome measures

2.4.1. Current pain

The primary outcome measure was neck pain intensity which was assessed with a VAS. The VAS is a 10 cm line anchored with a "0" at one end representing no pain and "10" at the other end representing the worst pain imaginable [9]. Pain was assessed at rest. The VAS was selected as the primary outcome measure based on its ability to detect changes and has a reported minimal clinically important difference (MCID) of 2.0 cm [17,18].

2.4.2. Neck disability index

Disability was assessed using the Italian version of Neck Disability Index (NDI) [19], a 10-item self-administered questionnaire. There are four items that relate to subjective symptomatology (pain intensity, headache, concentration, sleeping) and six items that relate to activities of daily living (lifting, work, driving, recreation, personal care, reading). Each question is scored on a 6-point scale ranging from 0 (no disability) to 5 (full disability), and these are added together to make a total score ranging from 0 to 50, which is interpreted as follows: 0 to 4 = no disability, 5 to 14 = mild disability, 15 to 24 = moderate disability, 25 to 34 = severe disability, and greater than 34 = complete disability. A blind assessor converted these scores to a percentage.

2.4.3. Common symptoms

The patients were asked about the symptoms that they related to the whiplash injury. The symptoms assessed included neck pain, headache, dizziness, stiffness, nausea, shoulder and spine pain, anxiety, irritability, concentration problems and sleeplessness. We assessed the presence or absence of these symptoms (yes/no).

All outcomes measures were assessed pre-treatment, at 2 weeks post-treatment and 4- and 12-weeks after the accident. The sequence of testing for the outcome measures was randomized among participants. The trial was designed according to the STROBE publishing guidelines [20].

2.5. Intervention

Guidelines for the management of whiplash [21] recommend that patients be provided educational material about WAD so all patients were provided with an educational booklet. The booklet was specifically created to improve the patient's beliefs about whiplash injuries and management strategies. The booklet provided information about the mechanism of injury, advice on suitable activities and reassurance about recovery, suggesting patients quickly get back to their normal activities of daily living and work, avoiding rest and prolonged immobilization [22].

2.5.1. CBEA group

Patients in this group received information about whiplash, reassurance about recovery and instructions about the importance of active self-training of the neck and a rapid return to activities of daily living after a whiplash injury. All patients were prescribed a 15-day protocol of active exercises beginning on the first day of treatment under the supervision of a physiotherapist which were to be continued at home; first while wearing a neck collar according to the physician's prescription (that precluded end-of-range movement, and offered a gentle resistance to exercises), then without the collar. The protocol consisted in 7 neck movement exercises (rotation, side bending, bending and extension, neck retraction), 4 neck strengthening exercises (isometric, no movement exercise – bending, side bending and extension) and 3 shoulder movement exercises (flexion, rotation, extension). Patients were instructed to perform these exercises in the sitting position once a day. Movement exercises were designed to improve ROM of the neck. Patients were instructed to perform gentle and active movements up to a maximum range within their pain tolerance. The movements were repeated 10 times in each direction.

Neck strengthening exercises were designed to improve neck stability. Patients were instructed to perform a muscle contraction with the resistance of one hand for 10 seconds in each direction without feeling pain. Shoulder exercises were designed to improve ROM and strength of shoulder muscles. Patients were instructed to begin these exercises when they were no longer wearing the neck collar [5,7].

2.5.2. Usual care group

Patients in this group received usual care consisting of immobilization in a soft collar, the use of painkillers and a sick leave for a period between 7 and 14 days.

In the case of persisting symptoms the general practitioner determined if the patient was to receive further treatment/medical examination. Patients were interviewed at pre-treatment and during follow-up periods.

2.6. Statistical analysis

Data were analyzed using SPSS version 19.0 (SPSS Inc, Chicago, IL), and conducted following an intention-to-treat analysis using the last value forward method. The results are expressed as means, standard deviations, and/or 95% confidence intervals. The Kolmogorov-Smirnov test showed a normal distribution of the data. Potential differences in baseline demographic and clinical variables between groups were analyzed using independent Student t-tests for continuous data and chi-square of independence for categorical data. For the main outcome of the study, a 2 × 3 repeat measures analysis of variance ANOVA was used to examine the effects of treatment on pain intensity and disability index at each measurement occasion as the dependent variable with group (CBEA, usual care) as the between-subjects variable and time (pre-treatment, 2 weeks post-treatment and 4- and 12-weeks after the accident) as the within-subjects variable. The main hypothesis of interest was Group × Time interaction. Post-hoc comparisons were conducted with Bonferroni correction Between-groups effect sizes were calculated by using Cohen's d coefficient. An effect size greater than 0.8 was considered large, around 0.5 moderate, and less than 0.2 small. The statistical analysis was conducted at a 95% confidence level and a $P < 0.05$ was considered statistically significant.

3. Results

3.1. Demographic data

Fifty ($n = 50$) consecutive subjects with WAD were screened for eligibility criteria. Forty-one patients (mean ± SD age: 41 ±11 years; 65.9% female) satisfied all eligibility criteria, agreed to participate, and were assigned according to patient choice to the experimental ($n = 25$) or control ($n = 16$) group. The reasons for ineligibility included head trauma ($n = 5$), vertebral fractures, ($n = 1$), and clinical signs of nerve root compression ($n = 3$). Baseline features of both groups were similar for all variables (Table 1). There were no statistically significant differences in the reported frequency of symptoms after the accident, for any demographics or outcomes at baseline. No adverse events were reported during or after the application of the treatment, and none of the patients started taking new medications during the study.

Table 1
Baseline demographics for both groups*

	CBEA group [no. (%)] ($n = 25$)	Usual care group [no. (%)] ($n = 16$)
Age (yrs) (mean ± SD)	40 ± 12	43 ± 11
Gender		
Men	7 (28.0)	7 (43.8)
Female	18 (72.0)	9 (56.2)
Neck pain intensity (VAS, 0–10)	6.7 (1.1)	6.2 (1.0)
Neck disability index (NDI, 0–100)	60.5 (11.3)	58.1 (8.4)
Pain killer		
Yes	22 (88)	21 (81.3)
No	3 (12)	4 (18.8)

*Data are expressed as means ± standard deviation (SD); CBEA: cognitive behavioral exercise approach.

Table 2
Common symptoms pre-treatment and 12 weeks later for both groups

	Pre-treatment ($n = 41$)		12 weeks after the Accident ($n = 41$)	
	Symptoms		Symptoms	
	Yes(%)	No(%)	Yes(%)	No(%)
Headache				
CBEA	100	0	0	100
Usual care	56.3	43.8	46.2	53.8
Dizziness				
CBEA	60	40	4.3	97.5
Usual care	68.8	31.3	0	100
Nausea				
CBEA	60	40	0	100
Usual care	62.5	37.5	0	100
Difficulty with concentration				
CBEA	0	100	0	100
Usual care	6.3	93.8	0	100
Insomnia				
CBEA	64.0	39.0	0	100
Usual care	68.8	31.3	7.7	92.3
Neck stiffness				
CBEA	100	0	0	100
Usual care	100	0	23.1	76.9
Neck pain				
CBEA	100	0	2.8	95.7
Usual care	100	0	38.4	61.5
Back pain				
CBEA	56.0	54.0	0	100
Usual care	50.0	50.0	7.7	92.3
Shoulder pain				
CBEA	76.0	24.0	8.7	91.3
Usual care	68.8	31.2	7.7	92.3

CBEA: cognitive behavioral exercise approach.

Table 3
Treatment type post-treatment and 12 weeks later for both groups

	Post-treatment ($n = 41$)		12 weeks after the Accident ($n = 41$)	
	Treatment		Treatment	
	Yes (%)	No (%)	Yes (%)	No (%)
Sick leave				
CBEA	0	100	0	100
Usual care	12.5	87.5	0	100
Exercises				
CBEA	88.0	12.0	8.7	91.3
Usual care	0	100	0	100
Neck collar				
CBEA	56.0	44.0	0	100
Usual care	75.0	25.0	0	100
Painkiller				
CBEA	88.0	12.0	4.30	95.7
Usual care	81.3	18.8	30.8	69.2

CBEA: cognitive behavioral exercise approach.

3.2. Common symptoms

Pre-treatment, 82.9% of the total patients reported severe headache, 63.4% reported severe dizziness, 61.0% reported severe nausea, 100% reported severe neck pain and 100% reported severe neck stiffness. After 12 weeks, 16.7% of the patients reported severe headache, 2.8% reported severe dizziness, 0% reported severe nausea, 16.7% reported severe neck pain and 8.3% reported severe neck stiffness (Table 2).

3.3. Frequency of additional treatment

At two weeks after the injury, 53.7% of the patients used painkiller and 36.6% of the patients used a neck collar. 34.1% of the patients used sick leave and 56.4% of the patients used exercises (Table 3).

3.4. Neck pain intensity (VAS)

For the VAS, the ANOVA revealed a significant effect of time ($F_{[3.0]} = 181.335$; $P = 0.001$, partial eta $= 0.842$) and for the group–by-time interaction ($F_{[3.0]} = 13.188$; $P = 0.001$, partial eta $= 0.279$) for pain intensity. The post hoc analysis revealed significant within group differences for the CBEA ($P = 0.001$), but not for the usual care group ($P = 1.0$). We found significant differences between the pretreatment and follow-up periods in the CBEA and Usual care group (all, $P = 0.001$) (Table 4). Between-groups mean differences post-intervention was -2.5 (95%CI; -3.9, -1.1), the 4 week follow-up was -2.7 (95%CI; -4.0, -1.5) and the 12 week follow-up was -1.1 (95%CI; -1.9, -0.4) for VAS. Between-groups effect sizes were small at post-treatment and follow-up periods (all, $d < 0.2$).

3.5. Neck disability index

For the NDI there was a significant effect of time ($F_{[3.0]} = 552.383$; $P = 0.001$, partial eta $= 0.942$)

and group-by-time ($F_{[3.0]} = 13.409$; $P = 0.001$, partial eta = 0.283), interactions (Table 4). All participants in both groups demonstrated changes (decreases) over the 15 days and follow-up periods (all, $P = 0.001$). There was significant difference between the groups at post-treatment and follow-up periods (all, $P = 0.001$). Between-groups effect sizes were small at post-treatment period and follow-up periods (all, $d < 0.2$).

4. Discussion

This quasi-experimental trial examined the effects of a CBEA program including patient education and self-training of the neck musculature in a patient population with WAD. The results demonstrated that those patients who received the CBEA experienced significantly greater improvements in pain and disability compared to those who received usual care. It is interesting to note that the between group differences for pain improvements and the lower bound estimate of the 95% confidence interval exceeded the reported MCID of 2.0 cm for the VAS [17,18]. We believe this provides preliminary evidence to support the use of a CBEA in the management of patients with WAD, supporting the importance of a future randomized controlled trial, and providing preliminary results which may assist with a future power analysis.

The current results support the hypothesis of Soderlund et al. [10] who has suggested that a multimodal approach including biopsychosocial components may be beneficial in reducing pain and disability as well as preventing chronicity in a patient population with WAD. Furthermore the current results support those of Adams et al. [23] and Sullivan et al. [24] who both found that a multimodal physical therapy program that included a psychosocial intervention resulted in greater function and a more rapid return to work. However, these 2 studies were not experimental and hence a cause and effect relationship could not be. Additionally, our results support those of Schnabel et al. [25] who randomly assigned a group of patients to wear a collar or participate in an exercise program. At the end of 6-weeks patients in the exercise group experienced significantly greater improvements in both pain and disability. Perhaps immobilization with a soft-collar should not be prescribed to patients after a WAD unless it is medically necessary (cervical instability).

It should also be noted that we started treatment of the patients in the study within 48 hours of their injury.

Table 4
Mean (SD) for pain intensity and NDI at all study visits for each group, mean (SD) difference within groups, and mean (95% CI) difference between groups

Outcome	Groups								Difference within groups						Difference between groups		
	Week 0		Week 2		Week 4		Week 12		Week 2 minus Week 0		Week 4 minus Week 0		Week 12 minus Week 0		Week 2 minus Week 0	Week 4 minus Week 0	Week 12 minus Week 0
	CBEA	U.C	CBEA	U.C	CBEA	U.C	CBEA	U.C	CBEA	U.C	CBEA	U.C	CBEA	U.C	Exp minus Con	Exp minus Con	Exp minus Con
	($n = 25$)	($n = 16$)	($n = 25$)	($n = 16$)	($n = 25$)	($n = 16$)	($n = 25$)	($n = 16$)									
VAS	6.9	6.1	2.8	5.3	1.1	3.9	0.1	1.2	4.0*	0.8	5.7*	2.2*	6.8*	4.9*	−2.5#	−2.7#	−1.1#
	(1.1)	(0.9)	(2.1)	(1.6)	(1.6)	(2.1)	(0.4)	(1.7)	(0.3)	(0.5)	(0.4)	(0.5)	(0.3)	(0.4)	(−3.9 to −1.1)	(−4.0 to −1.5)	(−1.9 to −0.4)
NDI	61.5	56.8	16.4	32.3	5.5	16.8	0.1	4.0	45.0*	24.5	56.0*	40.0*	61.4*	52.8*	−15.9#	−11.3#	−3.9#
	(10.6)	(7.9)	(9.8)	(14.2)	(5.1)	(12.0)	(0.4)	(4.5)	(2.4)	(3.2)	(2.0)	(2.7)	(2.0)	(2.6)	(−24 to −7.7)	(−17.1 to −5.5)	(−5.8 to −2.0)

CBEA: cognitive behavioral exercise approach, U.C = Usual care, VAS = Visual Analog Scale, NDI = Neck disability index. # Significant difference between-group, $P < 0.05$ (95% confidence. *Significantly different within-group, $P < 0.05$ (95% confidence interval).

So it is possible that the early initiation of exercise might have assisted with reducing the patient's symptoms in the CBEA group. Rosenfeld et al. [26] randomly assigned patients to receive an active intervention or usual care. Additionally, individuals in both groups started treatment either quickly after the WAD or more than 2 weeks after the injury. The results demonstrated that if the active group started treatment quickly (less than 96 hours) then they experienced significantly greater reductions in pain. Furthermore, in an additional analysis, these same authors [4] demonstrated that the early initiation of active treatment reduced the overall costs associated with the WAD. Perhaps this is the reason why patients in the current study exhibited improvement. Future studies should further examine the timing of treatment.

It is also possible that some would argue that it might not be the specific exercises we prescribed that resulted in reductions in pain but it could also be that education to stay active might be just as beneficial. However, Gwendolijine et al. [27] randomly assigned patients with a WAD to receive exercise prescribed by a physical therapists or treatment provided by a general practitioner which consisted of education on graded activity. Similar to our study, the results demonstrated that both groups got better but the group that received exercise under the direction of a physical therapists experienced significantly greater pain reductions at the one year follow-up period.

There are a number of limitations to this study that must be considered. Only 1 therapist performed all interventions so the generalizability of the results may be limited. The follow-up period was limited to 12-weeks and therefore we cannot be certain if the pain reduction lasted beyond that time. Additionally, patients self-selected which group they wanted to participate in. It might have been that there are other characteristics associated with individuals who selected the exercise group that might have been responsible for the reductions in pain. We also did not have a true control group. Future randomized clinical trials should include a control group, include multiple therapists, randomize patients to treatment groups, and collect data at a long-term follow-up.

5. Conclusion

This quasi-experimental clinical trial provides the first evidence that the CBEA approach was more beneficial in reducing pain than usual care in this population of patients with WAD. However, the CBEA had limited value in improving disability. Patients in the CBEA also experienced significantly better for most secondary outcomes compared to usual care. Future studies are needed to further examine the effectiveness of the CBEA for the management of patients with WAD.

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Conflicts of interest

No conflicts of interest.

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