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Neck balance system in the treatment of chronic mechanical neck pain: a prospective randomized controlled study

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Background. **Chronic mechanical neck pain (MNP) is a very common condition, that may occur in general population. There is a lack of evidence for most therapies except for exercise therapy with combining methods, whose effectiveness is still moderate.**
Aim. **The aim of this study was to determine the effect of a novel neck balance system-Dal Monte 2(NBS-DM2) incorporated into a special cap on pain in sufferers of MNP after treatment and at three months follow-up.**
Design. **Prospective randomized controlled trial.**
Setting. **Outpatient clinic of the University of Rome "Foro Italico".**
Population. **Forty-five volunteers of both sexes affected by grade II MNP were enrolled.**
Methods. **NBS-DM2/RW (regular weight), NBS-DM2/NW (negligible weight) and Pulsed Electromagnetic Fields (PEMF) have been used for 8 weeks. Neck Disability Index (NDI), Neck Pain and Disability Scale (NDPS) questionnaires and Visual Analogic Scale (VAS) score were evaluated before, after the treatment period and 3 months after the end of treatment.**
Results. **NBS-DM2/RW compared with NBS-DM2/NW and PEMF group performed better in the reduction of the three measures at the end and at short term run ($p \leq 0.05$).**
Conclusion and clinical rehabilitation impact. **When applied to grade II MNP patients, NBS-DM2/RW leads to pain relief and reduction of disability. These effects persist over a short term follow-up period. PEMF therapy was found to have no significant effect on reduction of pain and disability in this study**

KEY WORDS: Cervical vertebrae - Postural balance - Neck pain, therapy - Physical therapy modalities.

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Mechanical neck pain (MNP) is a non specific common disorder in the general population. It is characteristically aggravated with movements of the neck and is resistant to common therapeutic intervention.[1] MNP affects from 45% to 54% of the general population at some time during their lives and can result in severe pain and disability.[2, 3] Further, the economic expense caused by neck muscular-skeletal diseases is extremely high, second only to low back pain costs in the United States.[4] The source of symptoms in MNP is not completely understood, but has been purported to be related to various anatomical structures as muscles, ligaments and uncovertebral joints of the cervical spine even in the absence of radiographic signs of degenerative disease.[5] Several etiologic factors have been advocated to be related to MNP as postural abnormalities, traumas, psychoemotional stresses, altered neuromuscular control of the cervical muscles.[2] Impairment in muscle function is a feature of MNP and has been implicated as a significant factor in the maintenance of this disorder.[6,

[7] The treatments that patients receive for MNP are varied, of multimodal nature including pharmacological medications, orthoses, physical modalities, spinal manipulation, mobilization or combined methods of exercises therapy.[8-11] There is a lack of evidence for most therapies except for exercise therapy, whose effectiveness is still moderate.[11] In particular, in a recent review Kroeling *et al.* have emphasized that there is little information available from trials to support the use of physical medicine modalities for MNP, with some support provided by the use of electromagnetic therapy with respect to pain reduction.[12] Recently, a special cap which included a thin padding mass of variable weights in the occipital region was proposed for therapeutic purposes.[13] The idea was that a slight load applied to the back of the head may reduce the tension of the neck muscles required to sustain the head weight. With the belief that such support could alleviate symptoms and disability, we aimed the study to evaluate the hypothetical beneficial effect of Neck Balance System (NBS- DM2) in the treatment of patients affected by MNP in a prospective randomized controlled study.

Materials and methods

The study was carried out in the outpatient Clinics of the University of Rome Foro Italico (IUSM) in the period between July 2010 and December 2011 and was conducted in accordance with the Helsinki declaration on Human Research. Forty-five volunteers of both sexes practicing non professional sport activities aged between 25 and 55 years reporting presence of mechanical neck symptoms of at least 3 months and no more than two years (average 7.86±4.08 months) were enrolled in the study, after provided informed consent (Table I). For the purpose of this study, MNP was defined as generalized neck pain with mechanical characteristics including symptoms provoked by maintained neck postures, neck movements, or by palpation of the cervical muscles. In particular patients with grade II MNP (no signs or symptoms of major pathology and major interference with activity of daily living), with painful reactivity to palpation according to Task Force on Neck Pain and associated disorders Classification [14] were recruited. Patients were excluded if they exhibited any previous history of a whiplash injury, history of cervical spine surgery, herniation, diagnosis of cervical radiculopathy or mielopathy, osteoporosis or any rheumatic diseases, or if they underwent physical treatment within 5 weeks prior to the trial. All patients were equally randomized in three groups using a randomization list generated by a random number generator and provided with a computer program by one of the research assistant. Treatment assignments were placed in sealed, opaque, consecutively numbered envelopes and were concealed from the investigators involved with the screening and randomization process. Group (A) included 15 patients that wore NBS-DM2/RW system, whose balancing weights, according to sex and BMI, were 0.3 kg or 0.4 kg for female and 0.5 kg for male, as provided by manufacturer, four hours a day (two hours in the morning, two hours in the afternoon), five times a week for 8 weeks. Group B included 15 patients that wore the same device NBS-DM2/NW but with negligible balancing weights of approximately 0.04 kg with the same treatment modalities of Group A. Group C included 15 patients that underwent electromagnetic therapy with PEMF device (MRS 2000+ designo electromeds home [USA]) with a range frequency between 5 and 25 Hz sinusoidal wave and intensity of 5-70 μT. PEMF was administered to the whole body using a mat 1.8×0.6 min size. The mat produced a pulsating electromag-

TABLE I.—*Baseline characteristics of DM2, DM2-sham, PEMF groups mean (standard deviation) at baseline, P-values.*

	DM2	DM2-sham	PEMF	p-value
Sex	7 females; 8 males	11 females; 4 males	13 females; 2 males	.017
Weight	67.9±11.5	64.73±9.2	63.1±8.4	.188
Height	171.1±9.4	167.4±9.0	167.1±6.7	.199
Age	40.5±7.4	43.0±9.4	44.0±9.6	.284
VAS	5.9±1.3	6.2±1.0	6.2±1.1	.556
NDI	34.9±14.7	32.9±11.7	30.9±9.8	.365
NDPS	45.4±16.5	41.1±14.8	48.6±10.3	.546

netic field with a mean intensity of 40 μT. During the treatment the patients were lying on the mat for 4 hours a day (2 hours in the morning 2 hours in the afternoon) five times a week for 8 weeks. During the 8 week intervention period, participants were asked not to change their dose or type of analgesic/FANS medication, if they were prescribed. If none was prescribed, participants were urged not to begin taking any new analgesic/FANS medication during the intervention period. The NBS-DM2 device (N.B.S. Srl. Busto Arsizio VA Italy) is composed by variously shaped hats of different size; in this trial a baseball type cap was used for both sexes, with the given size selected according to skull girth. The cap is easy to apply and contains counterweights applied in the rear zone (Figure 1). The balancing masses are perfectly inserted and masked into two appropriate posterior pockets of the medical device, with their sharp end oriented towards the top of the skull and their labeled part facing the external side of the head. The softer surface of the balancing mass is the one close to the head while the rounded sides of the balancing masses are positioned outward. The two baseball type caps used for group A and B were absolutely identical in their shape, indistinguishable from each other, except for the different masses placed in the posterior pockets. Before starting the trial, each of the participants randomized to group A and B were adequately instructed by a video and a subsequent practical demonstration on how to apply and properly fix the cap. Outcome measures: following inclusion into the study, participants completed self reported measurements of neck pain and disability. The primary outcome measures were: the Neck Disability Index (NDI) to measure perceived disability. The NDI is a validated 10-item questionnaire relating to daily activity and cervical spine related pain. Each item is scored from 0 to 5 and the total score out of 50 points is summated [15] with higher scores corresponding to greater disability. The NDI has been demonstrated to be a reliable and valid assessment of disability in patients with neck pain.[16] Neck Pain and Disability Scale (NPDS) is a composite index including 20 items which measure the intensity of pain, its interference with vocational, recreational, social and functional aspect of living and the presence and extent of associated emotional factors in patients with neck pain. Patients respond to each item by marking along 10 cm Visual Analogue Scale (VAS). Items score range from 0 to 5 and the total score is a total score of the items score.[17] Participants were asked to record their average current neck pain intensity, by placing a mark on a 100 mm line bordered at one end by the words "no pain" and the other end by the words "worst pain ever".[18] All these outcomes were assessed by masked independent assessors at 0 (baseline), 8 (end of treatment, and 12 weeks after the end of treatment), with the 8-week assessment being the primary decision time.

Figure 1.—The external shape of the baseball type cap (A), the inside posterior pockets containing the masses (arrow) (B).

Statistical analysis

An *a priori* power analysis was conducted to determine the size of the three groups using a repeated measure between-within factors Anova test. A total sample of 45 partecipants (15 for each group) was required to achieve a significance at 0.05 α and a power of 0.9, with a small effect size (0.2). Baseline values for demographic and clinical data were calculated as mean values at the first visit. Given the design of the study the analysis was based on the comparison of the end of treatment (after 8 weeks) and follow-up (12 weeks from the last treatment) with the baseline outcomes. An intention to treat approach was used (a per-protocol analysis was, however, performed– results not shown). We then

TABLE II.—*VAS, NDI, NDPS, mean values (SD), difference pre-post and pre-follow-up and P-values between groups*

	Dm2 group	DM2-sham group	PEMF group	DM2-DM2-sham P-value (between groups)	DM2-PEMF P-value (between groups)	PEMF-DM2-sham P-value (between groups)
VAS						
Pre-post	-2.50 (1.47)	-0.29 (.65)	-0.77 (0.87)	<0.01	<0.01	0.108
Pre-follow	-2.15 (1.26)	-0.47 (0.72)	-0.78 (0.53)			
NDI						
Pre-post	-13.33 (10.51)	-1.03 (4.45)	-2.57 (1.08)	<0.01	<0.01	0.268
Pre-follow	-10.73 (9.90)	-1.13 (5.68)	-2.23 (1.78)			
NDPS						
Pre-post	-8.93 (7.16)	-3.07 (2.90)	-3.80 (2.91)	<0.01	<0.01	0.564
Pre-follow	-14.83 (11.27)	-2.20 (11.03)	-3.63 (2.39)			

assigned a constant outcome based on the last observed available response to the dropout patients. The baseline outcome was afterwards assigned to the end-of-treatment and follow-up outcomes if the patient dropped-out during the treatment period, while the end-of-treatment outcome was assigned to the follow-up outcome if the patient dropped out before the follow-up control. An ANOVA was performed to check for differences between the three groups at baseline (for the demographic and the three outcome scores). To determine differences at post and follow-up between each pair of groups an ANOVA for repeated measure was performed on the change in the pre-post treatment outcome and pre-follow-up treatment outcome between each two groups (NBS-DM2/RW and - NBS-DM2/NW, NBS-DM2/RW and PEMF, NBS-DM2/NW and PEMF). A Shapiro-Wilk test was performed to check for normality of each outcome at baseline, 2-months follow-up, and 5-months follow-up, together with graphical evaluation of Q-Q plot. A p level of ≤0.05 was considered to be statistically significant (see note to Table II for Bonferroni adjustment). The analysis was performed with R2.14.0.

Results

During a 17 month period, 70 potential subjects were assessed for eligibility; of them, 45 were allocated at random and entered into the trial (Figure 2). The remaining 25 volunteers who were not randomized were excluded for the following reasons: 19 did not meet the inclusion criteria; 6, despite their eligibility, declined to participate, because time constrains would not allow them to attend 5 sessions per week. The average demographic and clinical data and SD were calculated for all subjects at baseline (Table I). No differences were found between the three groups regarding the demographic variables – weight, height, and age - at baseline. A significant difference was, however, found for the sex distribution between the three groups (P≤0.05). At the baseline, no significant differences were detected between the three groups in relation to the outcome measures examined, pain intensity (VAS) and disability scales (NDI and NDPS scales). The Shapiro-Wilk test for normality performed on the three outcomes (W-values close to 1 and P-values >0.05) and the Q-Q plot evaluation confirm that the outcomes are normally distributed (results not shown). Results for the repeated measure ANOVA are shown in Table II (mean values for each outcome and each group at baseline, 2-months, and 5-months follow up are shown in Figure 3).

Comparison between the NBS-DM2/RW - NBS-DM2/NW *groups*

The comparison between the outcomes for the NBS-DM2/RW group with the NBS-DM2/NW group shows a significant effect of the group for the three outcome measures examined - VAS (P<0.01), NDI (P<0.01), NDPS (P<0.01). Additionally neither significant time effect for VAS (P>0.05) and NDPS (P>0.05 nor a significant group-time effect –VAS P<0.01) and NDPS (P<0.01) is observed (Figure 2). NBS-DM2/RW compared with the NBS-DM2/NW group performed better in the reduction of the three measures at the end of treatment and at short term run.

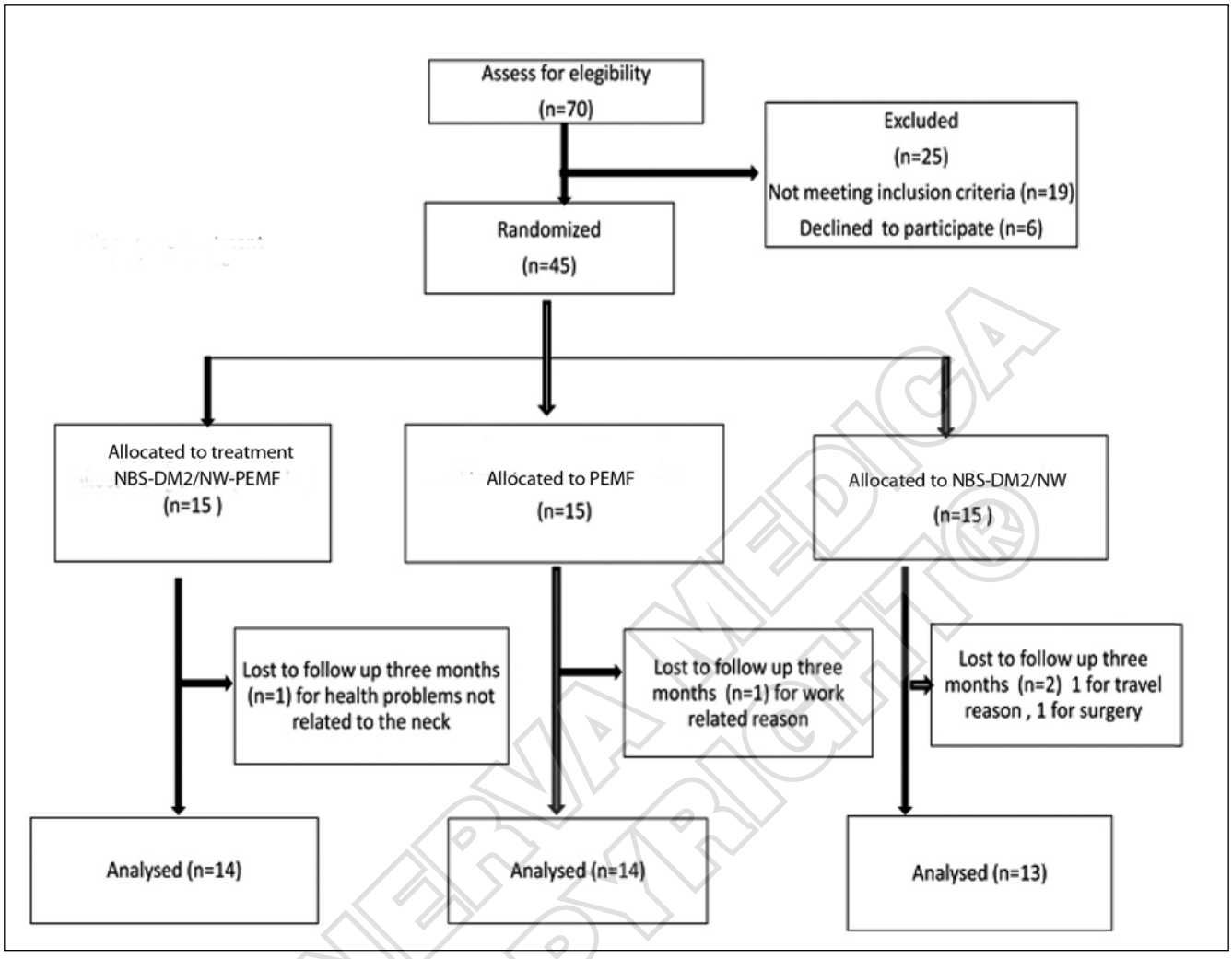

Figure 2.—Flow diagram of the study.

Comparison between the NBS-DM2/RW *-PEMF groups*

The analysis of the DM2 group and the PEMF group shows a statistically significant effect of the group for VAS (P<0.01), NDI (P<0.01), and NDPS (P<0.01). Except for VAS (for which the shape of the curves are similar between groups and over time), the NDI and NDPS also show a statistically significant time - VAS (P<0.01) and NDPS (P<0.01) - and time-group - VAS (P<0.01) and NDPS (P<0.01) NBS-DM2/RW compared with the PEMF group performed better in the reduction of the three measures at the end of treatment and short term run.

Comparison between the DM2/-NW-PEMF groups

The between-group analysis indicate no significant effect of the group variable - VAS (P>0.05), NDI (P>0.05), NDPS (P>0.05). Similarly, no statistically significant effects of time and time-group interaction have been detected. This result confirms that do not exist any statistically significant improvement in outcome measures between the PEMF and the NBS-DM2/NW groups. None of the participants reported any study related adverse effects. None of the participants from the NBS-DM2/RW group reported any severe effect on health during the treatment period, except for one patient who reported a transient sen-

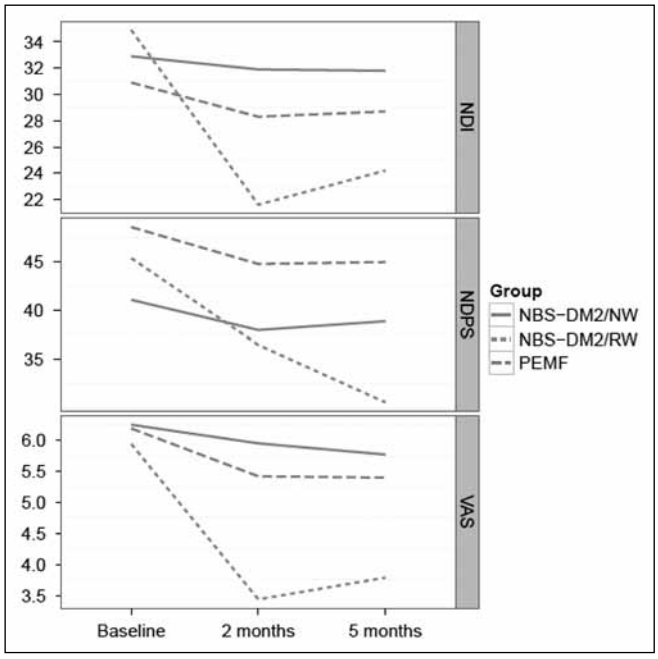

Figure 3.—Mean VAS, NDI, and NDPS score at baseline, 2 months, and 5 months by group.

sation of heaviness of the head between the second and third application, which, however, disappeared at the end of the first week of treatment. One participant from the NBS-DM2/RW group dropped out for health problems not related to neck pain, one from the PEMF group for work related reason and two from NBS-DM2/NW group declined to continue the trial, due to lack of interest. Thus, the 91,1 % of the randomized sample completed the study.

Discussion

The results of this preliminary study demonstrated that participants receiving NBS-DM2/RW had statistically significant reduction in NDI, NDS and VAS score. These scores reduced at the end of the 8 weeks treatment and were maintained at 12 weeks after the end of treatment. On contrary, the subjects assigned to NBS-DM2/NW did not show any statistically significant improvement in all of self reported questionnaires. This is the first study analyzing the effect of balancing masses inserted in the back of a special device in patients affected by MNP, where no kind of particular exercises is requested.. Cervical collars, are the only passive neck supports that are typically recommended for whiplash injury or to relieve pain in subjects with neck pain, even if the research evidence does not support their use.[19, 20] Even if Sutbeyaz *et al.* demonstrated in randomized double blind placebo study significant reduction of

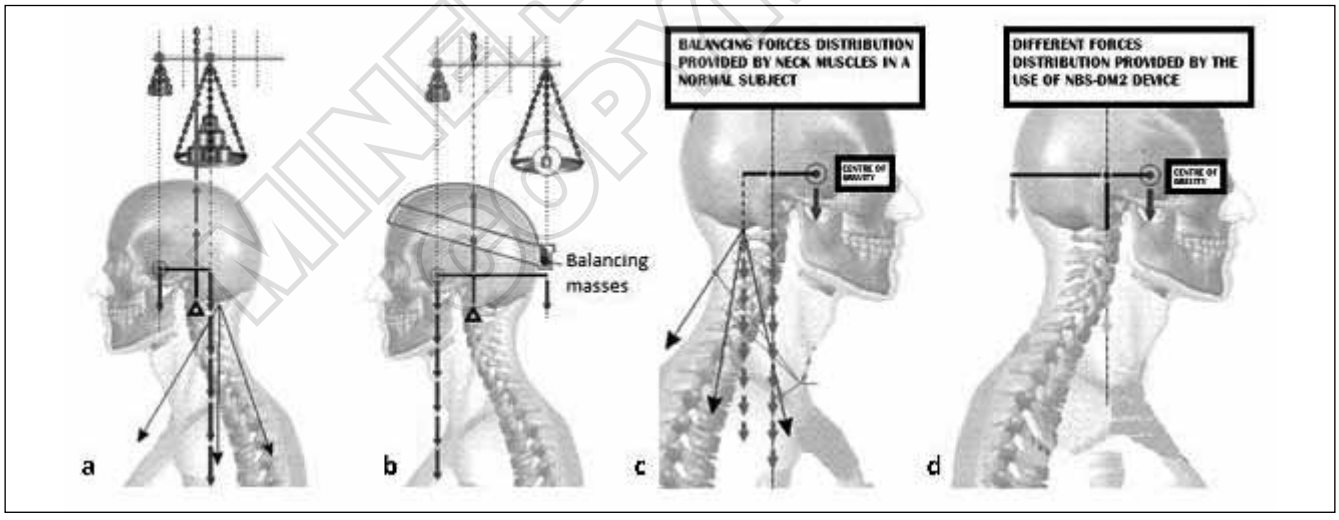

Figure 4.—A) The action of neck muscles to counterbalance the head is accomplished by a short lever arm system; B) the application of small masses posteriorly in the occipital side of the head generates a mechanical advantage, prolonging the lever arm of neck muscles; C) direction and distribution of balancing forces exerted by neck muscles in a normal subject; D) change in force's vector distribution with the incorporation of NBS-DM2 device.

pain with PEMF therapy administered twice a day for three weeks in patients affected with cervical osteoarthritis, no change in pain score was conversely observed in our group treated with PEMF,[22] even with a longer application. The major strength of our study lies in its scientific stringency. We were extremely careful in the randomization process, the three groups showed no statistically difference at baseline regarding their demographic variables and in the use, as outcome measures, of two of the most widely used and strongly validated tools for assessing self related disability in patients with neck pain.[16, 23] Our design was moreover important, all the participants received treatment for 8 weeks and the final evaluation was performed after 12 more weeks to ascertain whether improvements lasted over time. The data for the statistical analysis were processed by a statistician who was unaware of the treatment allocation. In the present study the two neck balance systems, the effective with regular weights and that one used as a control with negligible weights were absolutely identical except for the different masses placed in the posterior pockets. The neurophysiologic mechanism by which the NBS-DM2 is effective in reducing pain is not completely understood. One possible explanation of this mechanism could rely on its action that is simply accomplished by modifying the levers of the muscular system that balance, together with cervical vertebrae, the head on the neck in a cantilever like structure.[13, 24] From a biomechanical stand point, the centre of the head is positioned quite ahead of the balance point of the skull on the spine;[24] this advanced centre of gravity is counterbalanced by the action of the neck muscles, especially the extensors, which implement their action through a mechanically unfavorable levers system, since they have an extremely short lever arm.[25] Impairments of the deep sleeve of muscles that envelope the cervical vertebral column (both anterior and posterior) have been, in fact, identified in patients with MNP disorders.[26] The application of small weights located posteriorly in the occipital side of the head, has merely the effect of prolonging the lever arm, which counteracts the falling down of the head, neutralizing the neck muscles effort (Figure 4A-D).[13] Another possible explanation could be that NBS-DM2 might contribute to improve the performance of the postural head control system components.[26, 27] Pavan *et al.* conducted a biomechanical, non invasive study of head neck complex in seated subjects, either asymptomatic or reporting neck pain, applying NBS-DM2 for a certain time, to study the variations of head neck posture. In relation to the initial head position, after removing NBS-DM2 the head of subjects complaining of neck pain, stayed retracted by -3.8±2.7 mm (P<0.01), apparently acquiring a new postural strategy able to reduce the contraction of neck extensor muscles. The responses preliminarly obtained by these authors, suggest that head posture during and after wearing the cap is surely conditioned by complex neural mechanism and could reflect a change in the neural strategy, by redistributing loads between synergists and antagonistic muscles.[28]

Limitations

There were some limitations to our study that need to be recognized. The first limitation is the modest sample size of 45 participants, with a prevalence of females in the sample. Despite this, the authors present real and statistically significant positive trends relating to NBS-DM2 in treating people with mechanical neck pain. As this was a preliminary study, discussion of these results in a wider context of MNP, should be limited to the focused sample size investigated. The second limitations was that the participants in this study suffered from grade II MNP, therefore, our results might not apply to patients with more severe (grade III and IV). The potential value of a longer follow-up for this kind of therapeutic support was not investigated during this trial, it was interesting to find significant short term pain reduction and improvement in the other outcomes measures utilized. Finally, the lack of blinding of the researchers who delivered the NBS- DM2 support (RW and NW) to patients after the randomization process. Much of the treatment rendered by practitioners is pharmacologic, manual, physical agents oriented, exercise of multimodal in nature,[29, 30] future studies should consider the role of NBS DM2 as an alternative or in combination with these more traditional therapies. Even if this device was associated with an high level of treatment compliance, further studies are needed with a larger sample, more severe grade of MNP and a longer follow-up to confirm the validity and compliance of this support.

Conclusions

In this preliminary trial, participants who received the effective NBS-DM2/RW experienced significant reduction in the intensity of neck pain and disability, compared with participants receiving either sham NBS or PEMF.

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