ABSTRACT

REDUCING PAIN AND DISABILITY FOR WHIPLASH VICTIMS: A DOUBLE-BLIND RANDOMISED CONTROLLED TRIAL

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Study design

Double-blind Randomised Controlled Trial

Objectives:

The object of this research is to compare the strength and endurance versions of progressive resistance exercise for patients with neck pain.

Summary of Background Data

In the Australian Capital Territory the most frequent accident type is the rear end collision which constitutes around 46% of all crashes [1]. Three percent of people involved in rear end collisions are injured [1]. Up to 84% of victims of rear end collision who are hospitalised report acute neck pain [2], of whom 10% progress to chronic pain [3]. Treatment for these patients constitutes a considerable financial burden for society [4]. Most patients with chronic neck pain resume driving, but because they have restricted neck mobility they are more likely to be involved in further motor vehicle accidents. Therefore, it is important to ascertain which treatment is most effective for reducing the pain and functional limitations that accompany chronic neck pain. In March 1996 the Australian Transport Safety Bureau and the NRMA Road Safety Trust jointly funded a randomised controlled trial to compared therapeutic exercise for chronic neck pain. The trial was conducted in the ACT and is now complete.

Methods:

103 patients with chronic neck pain were randomised to either strength or endurance training. Primary outcomes were pain and functional limitations. Secondary outcomes were muscular strength and endurance and range of movement.

Results and Conclusions:

The trial is a world first in terms of methodology and results.

- It is the first randomised controlled trial to find that strength training is significantly more effective than endurance training for reducing pain and functional limitations, and increasing muscle strength in patients with chronic neck pain.
- It is the first trial to develop a sensitive and valid measure of patients' and therapists' adherence to exercise protocol, by comparing performance over subsequent sessions

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REDUCING PAIN AND DISABILITY FOR WHIPLASH VICTIMS: A DOUBLE-BLIND RANDOMISED CONTROLLED TRIAL

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INTRODUCTION

Injury, resulting from a motor vehicle accident is a common cause of acute neck pain. Whiplash, defined as sudden extension, flexion, torsion or lateral flexion with subsequent recoil motion [1] is identified by acute pain and accompanying restricted movement and protective behavior. If restricted movement and protective behaviour persist, joint immobility progresses and the cervical muscles atrophy [2]. Weakened cervical muscles are associated with chronic continuous or recurrent pain of more than three months duration [3]. Twenty-five percent (± 10%)of whiplash victims progress to chronic pain [1]. Most of them are still able to drive, but due to restricted movement are at added risk of being involved in further accidents. Therefore, it is important to ascertain the safest and most effective methods of strengthening the neck muscles of patients with CNP. Progressive resistance training (PRT) is the recognised method of increasing muscle strength in the limbs. However, most physical medicine modalities for neck pain consist of gentle stretching and isometric exercises, or at most aerobic or work hardening exercises [4]. The reason for the under utilisation of PRT, particularly the strength version is twofold. First, it is only within the last decade that equipment, such as the MedX Neck Rotator (see Figure 1), that is capable of isolating the affect of PRT to the cervical musculature has become available. Second, despite evidence to the contrary [3, 5-7], Highland reports that many clinicians believe that strength training of the cervical spine is unsafe and may even aggravate patients' symptoms [8].
Endurance training is prescribed because it is thought to increase muscle strength, [9, 10]and be effective in reducing pain [9, 11]. However, single-blind trials have found that, while endurance training seems to reduce pain over time, it is no more effective than more passive treatments such as physiotherapy or chiropractic treatment [11]. A methodological problem with single-blind trials is that patients are always aware of whether they receive the intervention or control treatment. For this reason significant pain reductions over time may be influenced by the Hawthorne[1] effect and should not necessarily be taken at face value. The most rigorous test is to compare the strength and endurance versions of PRT under double-blind conditions. The hypotheses of this paper are that the strength version of PRT is more effective than the endurance version in, (1) reducing pain intensity and affective pain[2], and the functional limitations associated with CNP, and (2) increasing the strength of the cervical musculature. The third hypothesis is that in terms of muscle function a dose-response relationship exists for strength training, but not for endurance training.

MATERIALS AND METHODS

The trial was conducted in a rehabilitation clinic in Canberra in the Australian Capital Territory, Australia. The sample was drawn from the predominately public service and mixed business city of Canberra, and the industrial city of Queanbeyan, located nearby in New South Wales.

The Australian National University ethics committee approved the project in 1997. The accrual period of the trial ran for two years from April 1998 to May 2000. Consecutive patients who attended the clinic complaining of neck pain were considered for the trial. Strength training was the intervention and endurance-training the alternative treatment. Both treatment protocols were comprised of 2 half-hour individual sessions per week on the MedX Neck Rotator for a period of eight to twelve weeks.

The Strength-Training Protocol

In the strength version of PRT the exerciser moves slowly with a heavy weight. Therefore, in a strength-training session, patients were required to perform one set of rotations with a weight load estimated to allow for 10-12 repetitions to volitional fatigue, or repetition maximum (RM)[3]. However, the patient was permitted to perform as many repetitions as they could in that one set. The initial weight loaded into the MedX was typically ≥60% of measured strength by the 2nd or 3rd training session. After that, subject to patient tolerance, the goal was to increase the weight by approximately 2-4lbs at each of the subsequent sessions while endeavouring to maintain a 10-12RM.

The Endurance-Training Protocol

In the endurance version of PRT the exerciser moves as quickly as is comfortable with a light weight. Therefore, in an endurance-training session the patient was required to perform one set of 20 repetitions with a minimal weight. If 30% of the participants measured strength was less than 20lb no weight at all was loaded into the MedX at the first session. The patient was permitted to perform as many repetitions as they could. The goal of the treatment thereafter was to

[1] The Hawthorne affect is the positive effect on a person's behaviour when they know they are being observed. In a double-blind trial it is balanced, but not eliminated.

[2] The affective dimension of pain includes the negative emotions, such as anxiety, depression and fear that that are contextually related to pain intensity

[3] Repetition Maximum (RM) is the number of repetitions a person can perform with a given weight before volitional fatigue occurs.

increase the repetitions by 2-4 each session until the patient reached 30-35 repetitions before increasing the weight. Therefore, patients should not incur more than one or two small increases in weight during the program

Blinding

Participants were informed that two slightly different forms of therapeutic exercise were being compared. They were naive as to which was the preferred treatment, and as they were individually trained on the MedX they could not compare their treatment with that of any other patient. All pre-treatment questionnaires and measures of muscle strength and endurance were administered prior to randomisation. The measurement therapist and the principal investigator were still blinded at the time of administering the post-treatment questionnaires and measures. The treatment therapist/s could not be blinded to group allocation. Therefore, to ascertain whether the therapist/s inadvertently indicated any treatment preference a post-hoc analysis was performed on patients' perceptions of the therapists' commitment to the treatment.

Outcomes

The primary outcomes of pain intensity and affective pain were measured by visual analogue scale (VAS) [12]. The VAS is a 15cm line anchored at one end by a descriptor such as no pain, and at the other end by a descriptor such as worst pain possible. The participant pens a slash through the line to indicate the intensity of the sensation. The Role-Emotional sub-scale of the SF-36 General Health Survey[13] was used to measure the impact of emotional distress on daily activities. The SF-36 Physical-Function and Role Physical sub-scales were used to measure functional limitations. Muscle strength was measured on the MedX.

Statistical Analysis

The Statistical Package for Social Sciences (SPSS) [14] was used for data entry and analysis. The primary analysis was by intention to treat (ITT) [4]. Paired t tests were conducted to determine the reliability of the physical measures. Significance of difference between means for normally distributed variables was determined by ANOVA. Chi squared and logistic regression analysis was used to assess differences in non-parametric outcomes. Of the sixteen tests[5] conducted on the measures of pain and functional limitations there was one significant, and one marginally significant time*group interaction. We are aware that the Type I error rate is slightly inflated. The weight pushed and number of repetitions performed was recorded at every session for every participant. A post-hoc analysis, which compared these two variables over subsequent sessions, was conducted to measure adherence to protocol at the level of individual sessions. A post-hoc blinded rating of the exercise records was also performed to measure adherence to allocated protocol at the level of the individual patient.

Separate regression analyses were conducted on the whole sample to ascertain which variables predicted positive outcomes. We then conducted multiple regression analyses for those predicting variables with p values less than .15. Possible predictive variables for an increase in muscle strength were the total weight pushed, or total number of repetitions performed over the duration of the treatment, and the number of sessions attended. Possible predictors of a reduction in pain intensity, depression and functional limitations were total weight pushed, or total number of repetitions performed, increase in muscle strength, and number of sessions attended. Dependent variables were (1) pain intensity and (2) depression measured by VAS, (3) the influence of emotional problems on everyday activities measured by the SF-36 Role-Emotional scale, and (4) functional limitations measured by the SF-36 Physical-Functioning scale.

To measure adherence to allocated protocol we developed a method of awarding bonus, or penalty, points depending on the quality of each training session. A good quality session was defined as one where the indicated variable, being weight pushed in strength training and repetitions performed in endurance training, was either equal or greater than the previous session, while the contra-indicated variable was either equal or less than the previous session. This analysis yielded a list of all participants for each group, ranked in order of adherence to protocol. We compared the ranked lists to the blinded classification of the exercise sheets to ascertain their validity. We then compared them to the ranked group lists of total weight for strength training and total number of repetitions performed for endurance training, to ascertain their sensitivity in identifying the most valid [6]measures. We then compared the top 17 participants from each group as defined by the ranked adherence lists, to the other participants in their group in terms of number of good quality sessions, and increase in muscle strength. We sought to ascertain whether there was a dose-response relationship between adherence to either strength or endurance training and increase in muscle strength.

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[4] Intention to treat analysis is based on the original treatment assignment regardless of whether some particpants did not receive their assigned treatment.

[5] For reasons of brevity this paper discusses only the six major measures.

[6] As both groups were balanced for demographic and baseline measures, those measures taken from participants who adhered most closely to their allocated protocol will be the most valid.

We conducted ITT analysis on the sub-set of top adherers from each group. We are aware that this analysis contravenes the principles of randomisation, because the participants have self-selected themselves into the top adherers and there may be different factors driving the selection process in each group. However, the goal of the analysis was to ascertain whether, the measures of the top adherers would yield greater changes over time, and possibly, more significant inter-group differences by comparison to the whole group analysis.

RESULTS

One hundred and thirty-four patients attended the clinic during the accrual period complaining of neck pain. Thirty-one patients did not participate in the trial. Non-participants were not demographically or etiologically different from the participants. The strength and endurance groups were not demographically different at baseline. Seventy-five percent of the sample was victims of motor vehicle accidents and a further twenty percent incurred their injury at work. Twelve patients, six from each group, did not complete the post-treatment measures for pain or functional limitations. Sixteen participants from the strength-training group and thirteen from the endurance-training group did not complete post-treatment measures for muscle strength and endurance.

The post-hoc analysis of patients' perceptions indicated that the blinding of patients had been successfully maintained throughout the duration of treatment χ^2 (1) = .271, p = .60). Therefore, the Hawthorne effect is balanced, and there are no negative or positive placebo effects associated with the trial.

Pain

As can be seen from Table 1 there were no significant differences between groups for the measures of pain intensity and affective pain at baseline. The VAS for pain intensity indicates a significant and clinically meaningful[15, 16] reduction in pain intensity for both groups, with a large treatment effect, η^2 .228. However, there is no significant time by group interaction. The VAS for depression also measured a significant and clinically meaningful reduction over time (η^2 .155), but there was no time by group interaction. The SF-36 Role-Emotional scale indicates a marginally significant intergroup difference (p = .076, η^2 = .046) favouring the strength-training group (see Table 1). The impact of emotional distress on daily activities actually increased over time for the endurance group whereas it decreased over time for the strength group. Changes over time for both groups were statistically significant and clinically meaningful.

Functional limitations

As can be seen from Table 1 the SF-36 Physical-Functioning scale indicates a significant time by group interaction favouring strength training (p = .04) with a small attached estimated treatment effect, η^2 =. 048. This result is supported by the trend of the SF-36 Role-Physical scale.

Muscle Strength

As can be seen from Table 1 both groups made statistically significant gains in isometric strength of 63% for strength training and 46% for endurance training. The attached estimated treatment effect is very large, η^2 =. 388. However, there is no significant time by group interaction, although, the trend favours strength training. The data indicate that an increase in muscle strength of at least 20% is related to a small, but significant reduction in pain. As there is no literature on the clinical value of increases in cervical muscle strength in the rotational plane we maintain that on average both groups experienced gains in muscle strength that equate to limited clinical value.

Blinded Rating and Ranked Adherence Lists

The blinded rating of the exercise records indicates that five participants allocated to endurance training actually received strength training of moderate to excellent quality, and one participant allocated to strength training received moderate quality endurance training. Further, the analysis of performance over subsequent sessions indicated that fifteen percent of the total numbers of sessions were therapist driven deviations from protocol, while nine percent were patient driven. Only 26 of the 197 therapist driven deviations from protocol occurred in the six incorrect protocols. The remaining 171 deviations occurred at different treatment sessions with other participants.

The correlation between the ranked adherence lists and the ranked lists of total weight pushed for strength training and total number of repetitions performed for endurance training was very good (r = .744). In terms of sensitivity in identifying the most valid measures, i.e., of those who adhered most closely to allocated protocol, the points-based ranked adherence system was clearly superior to the ranked lists of total weight and total number of repetitions. This was evidenced by it ranking those participants identified by the blinded rating as receiving the incorrect protocol lower by comparison to the ranked lists.

Regression Analysis

The separate regression analyses indicated that number of sessions attended (p =.14) and total weight pushed throughout the duration of the treatment (p = .001) were the only predictors of increased muscle strength with p values less than .15. Total number of repetitions performed was non-significantly inversely associated with strength gains. The multiple regression indicated that only total weight pushed was a predictor of increase in strength (p =. 002, R^2 = .18). Increase in muscle strength (p = .04, R^2 .06) was the only predictor of a reduction in pain intensity. While the R^2 value is small it is similar to those reported in other research into the relationship between pain and physical movement [17].

Increase in muscle strength was the only marginally significant predictor of a reduction in depression measured by VAS (p = .059, R^2 = .06). Regression analysis indicated that total weight pushed (p = .02) and the numbers of sessions attended (p = .11) were predictors of a reduction in the impact of emotional distress on daily activities with p values less than .15). Multiple regression indicated that only total weight pushed was a significant predictor of a reduction in emotional distress (p = .02, R^2= .08). Total weight pushed (p = .001) and the numbers of sessions attended (p =.004) were the only predictors of a reduction in functional limitations with p values less than .15. Multiple regression indicated that only total weight pushed predicted a reduction in functional limitations (p = .001, R^2= .15 The R^2 values for the regression analysis of functional limitations are similar to those found in other studies investigating the relationship between muscle strength and functional limitations [18].

Analysis of Top Adherers

Inter-group differences of the Top Adherers for body mass index, age at first presentation, duration of pain, medication use, work satisfaction, the desire to give the most socially accepted response, number of sessions attended, and duration of treatment were very small. However, with regard to age, and the proportion of males in each group the sample size is too small to detect what might be significant inter-group differences.

As a group, the strength and endurance-trained top adherers are demographically and etiologically different from the other participants. Not unexpectedly, they had significantly more treatment sessions. However, by comparison to the other participants, significantly less of the top adherers had only secondary level education. Further, a significantly higher proportion of the top adherers reported their pain as distinctly episodic rather than continuous. If they reported continuous pain it was of considerably less duration than the other participants (p = .06). The proportion of males is also significantly higher in the sub-groups of top adherers by comparison to the other participants.

As can be seen from Table 1 despite considerably reduced power, the marginally significant result favouring strength training for a reduction in emotional distress becomes significant at p = .03 with the more valid measures of the top adherers. The trend for non-significant findings for pain intensity and depression in the whole group analysis reverses to favour strength training. Results for an increase in muscle strength (which was a trend in the whole group analysis) now indicates that strength training elicited a significantly greater increase in muscle strength (p = .04). The significantly greater reduction in functional limitations experienced by the strength-trained participants in the whole group analysis almost retains its significance (p = .051).

Ten out of the fifteen sessions for the strength trained top adherers were of good quality. They pushed around 540($\pm$ 93) newton meters of weight throughout the duration of the treatment, which is 75% more than the 308($\pm$110) newton meters pushed by the other participants. Top adherers increased their muscle strength by 84% compared to 40% for the other strength-trained participants. Twelve out of fifteen sessions for the endurance-trained top adherers were of good quality. Top adherers performed 645($\pm$ 39) repetitions during the treatment, which is 88% more than the 348($\pm$ 184) repetitions performed by the other participants in their group. However, endurance-trained top adherers increased their strength by 42%, essentially the same as the 43% experienced by the other endurance-trained participants.

Discussion and Conclusions

The results for the primary analysis indicate statistically significant and clinically meaningful reductions in pain intensity over time for both groups, but no significant inter-group difference. The SF-36 Role-Emotional scale detected a strong trend favouring strength training, which, as discussed previously, can be partly attributed to an increase in the influence of emotional distress on daily activities over time for the endurance trained participants. The post-hoc analysis of patients' perceptions confirms that this was not a negative placebo effect; therefore, it possibly reflects participants' genuine disillusionment with endurance training. The SF-36 Physical-Functioning scale indicates that strength trained participants reduced their functional limitations significantly more than the endurance trained participants.

It is difficult to compare the results for change over time for pain intensity, affective pain, or functional limitations reported in this trial to others in the literature. With the exception of one trial, which was methodologically flawed [19] all trials evaluating exercise therapy for neck pain in the literature are single-blind trials. Therefore, it is impossible to determine the degree of the Hawthorne effect in their reported reductions over time. The increase in muscle strength for the strength trained participants in this trial are the largest yet recorded in a CNP population. Fifty-six to sixty-one percent increases in muscle strength have been recoded for the rotational plane in uncontrolled studies [7, 20]. Therapist driven deviations from protocol appear to partly explain the non-significant inter-group difference for increase in muscle strength in the primary analysis. As the blinded classification of exercise records indicates, substantially more participants in the endurance group, by comparison to the strength group, were administered the incorrect protocol. Deviations from protocol also partially explain the lack of a significant inter-group difference for reductions in pain intensity in the whole group analysis. As the results of the regression analysis clearly show that total weight pushed is the only significant predictor of an increase in muscle strength, which in turn is the only significant predictor of a reduction in pain intensity. Some, but not all of the deviations from protocol can be attributed to a miscommunication between therapists.

The analysis of top adherers indicates that if patients are able to adhere to an intensive exercise program strength training elicits clinically meaningful greater gains in muscle strength. We do not regard participants' self-selection into the top adherers as a limitation of the research design. We believe that it is a useful adjunct analysis for the following reasons: -

1) It provides data for eligibility criteria and sample size calculations for future trials.
2) It yields demographic and etiologic characteristics that may be useful for predicting which patients are most likely to be able to adhere to an intensive exercise program.

A dose-response relationship for both the intervention and alternative treatments can be calculated.

The comparison of the strength gains for top adherers to those of the other participants in their groups provides compelling evidence for the absence of a dose-response relationship in endurance training, and its presence in strength training. The top and lower adherers in the endurance-training group only increased their muscle strength by less than forty-five percent, the same as the lower adherers in the strength-training group. By contrast the 84% increase in strength experience by the top adherers to strength training is more than twice the magnitude of the other strength-trained participants, and is accompanied by a reversal of the trend for a reduction in pain intensity.

The bonus and penalty point system that yielded the ranked adherence lists was developed for this trial. It was tailored to reduce the impact of therapist-driven deviations from protocol. A systematic method of ranking adherence to protocol has not been used in trials evaluating therapeutic exercise for neck pain before, because previous trials have been single-blind, therefore, it was not feasible to develop such a system.

The trial has confirmed that both strength training and testing in the rotational plane with iso-technology are safe, effective and reliable. The trial has also demonstrated that methodologically sound double-blind trials comparing different versions of therapeutic exercise can be conducted. Therapist and patient driven deviations from protocol can be identified and distinguished from each other. Future research should be in the form of double-blind trials where therapist driven deviations from protocol are measured and managed. The possible causal link between increasing muscle strength and decreasing pain intensity, affective pain and functional limitations warrants further rigorous analysis.

Figure 1 MedX Rotary Neck Machine

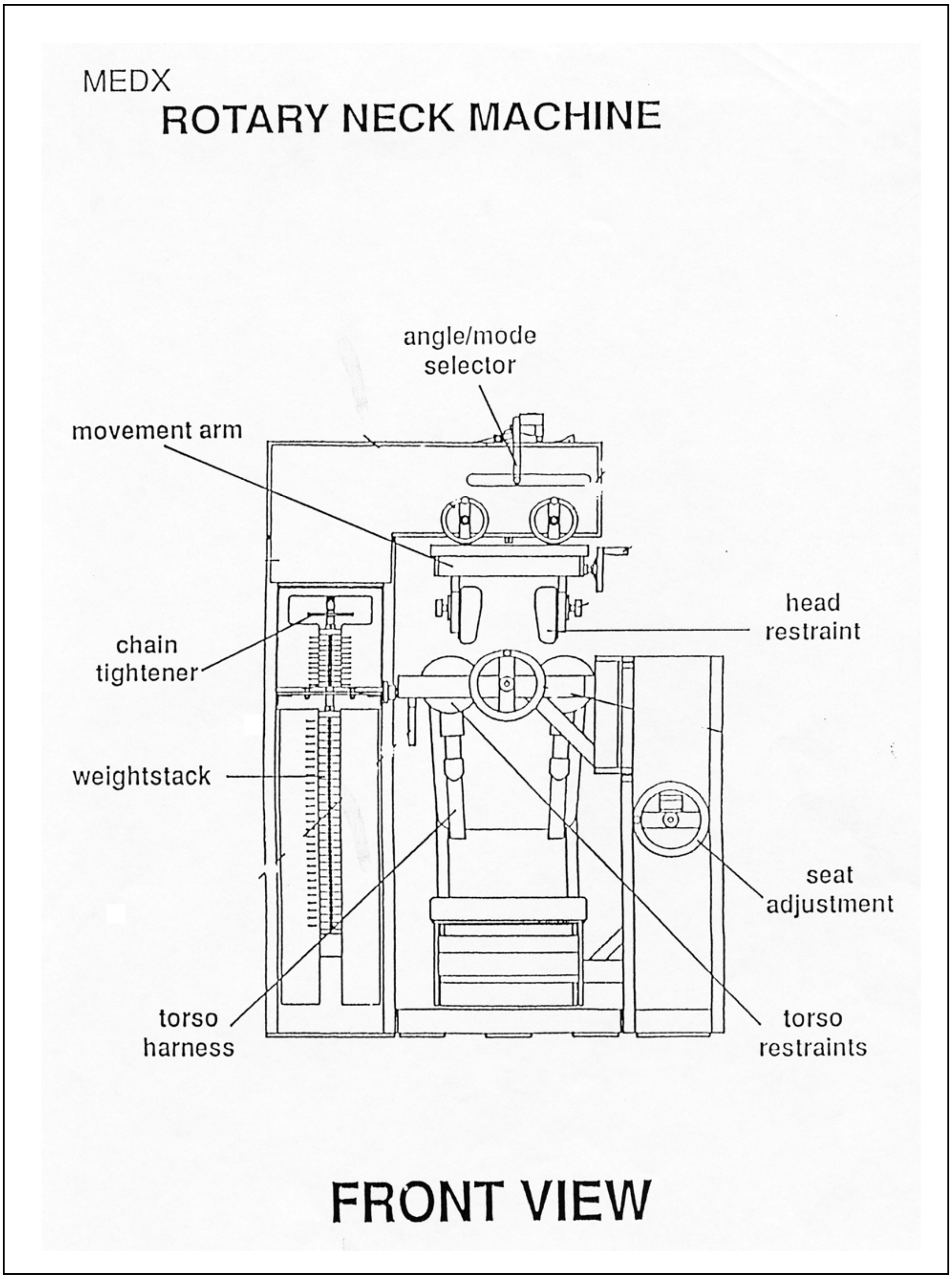

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Table 1 Results for Primary and Top Adherer's Analyses

Variable	Group	No	Pre-Treat	Post Treat	X over time	% change	η^2 X over time	F, p values for change over time	η^2 time Xgroup	F, p values for time^{x}group interaction
WG Intensity	ST	45	57 (19)	45 (21)	12	21	.228	F (1,89) = 26.27, (p< .0001)	.002	F (1,89) = .190, (p = .66)
	ET	46	54 (22)	40(24)	14	26				
TA Intensity	ST	16	56(23)	36(20)	20	36	.351	F (1,31) = 16.76, (p<.0001)	.026	F (1,31) = .831, (p = .37)
	ET	17	51(24)	38(23)	13	25				
WG Depression	ST	42	43(31)	33(27)	10	23	.155	F (1,83) = 15.22, (p< .0001)	.004	F (1,83) = .34, (p = .56)
	ET	43	42(29)	29(25)	13	31				
TA Depression	ST	15	37(35)	19(23)	18	49	.193	F (1,30) = 7.19, (p =. 01)	.030	F (1,30) = .93, (p =. 34)
	ET	17	40(28)	32(28)	8	20				
WG SF-36 Role Emot	ST	40	56 (44)	48 (43)	8	14	.000	F (1,78) = .032, (p = .86)	.040	F (1,78) = 3.22, (p = .076)
	ET	40	59 (40)	68 (44)	-9	-15				
TA SF-36 Role-Emot	ST	15	51 (50)	31 (40)	20	39	.024	F (1,29) = .713 (p = .41)	.127	F (1,29) = 4.20, (p = .050)
	ET	16	60 (39)	69 (41)	-9	-15				
WG SF-36 Physical Function	ST	43	48 (25)	40 (23)	8	17%	.077	F (1,84) = 7.01, (p = .01)	.048	F (1,84) = 4.19, (p = .04)
	ET	43	43 (20)	42 (21)	1	2%				
TA SF-36 Physical Function	ST	16	49 (28)	32 (23)	17	35%	.295	F (1,31) = 12.98, (p = .001)	.122	F (1,31) = 4.31, (p = .05)
	ET	17	46 (25)	42 (25)	4	9%				
WG SF-36-Role Physic	ST	43	87 (25)	79 (35)	8	9%	.032	F (1,83) = 2.71, (p = .10)	.003	F (1,83) = .305, (p = .59)
	ET	43	90 (19)	86 (30)	4	4%				
TA SF-36-Role Physic	ST	16	84 (21)	66 (41)	18	21%	.090	F (1,31) = 3.08, (p = .09)	.034	F (1,31) = 1.07, (p = .30)
	ET	17	88 (20)	84 (34)	4	5%				
Strength*	ST	34	3.22(1.84)	5.24(3.4)	2.02	63%	.388	F (1,71) = 45.00, (p <.0001)	.013	F (1,71) = .91, (p = .34)
	ET	39	3.53(2.1)	5.05(3.25)	1.52	43%				
TA Strength	ST	15	3.77(1.94)	6.94(4.05)	3.17	84%	.479	F (1,29) = 26.61, (p < .0001)	.135	F (1,29) = 4.52, (p =.04)
	ET	16	3.17(1.81)	4.49(2.41)	1.32	42%				

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