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TITLE: A Randomized Trial of Musculoskeletal Pain Treatment in a Military Population

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14. ABSTRACT Musculoskeletal system conditions are the leading cause of hospitalization and disability for the U.S. Armed Forces. The department of Defense pays over \$1.5 billion per year to disabled service members, and musculoskeletal conditions account for 40-50% of this amount. This study investigates the effectiveness of an interdisciplinary functional restoration approach to the treatment of Active Duty military from all 4 branches suffering from chronic musculoskeletal pain (CMP). The primary aims of this Functional and Occupational Rehabilitation Treatment (FORT) program include restoring physical function, retaining soldiers on active duty, and increasing the participants' abilities to effectively manage their pain. These outcomes, as well as socioeconomic variables, are evaluated immediately following treatment, and at 6, 12 and 18 months follow-up.					
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INTRODUCTION:

Musculoskeletal system conditions are the leading cause of hospitalization and disability for the U.S. Armed Forces. The Department of Defense pays over \$1.5 billion per year to disabled service members, and musculoskeletal conditions account for 40-50% of this amount. The medical discharge of one active duty U.S. military member in their twenties has been estimated to cost the government approximately \$250,000 in lifetime disability costs, excluding health-care costs. Despite continuous advances in military medicine, the rates of disability cases within the U.S. military have been increasing at an alarming rate, and nearly doubled between 1985 and 1994. Fortunately, numerous studies with civilian populations have demonstrated the efficacy of an interdisciplinary chronic pain rehabilitation program (ICPRP) at facilitating return-to-work in workers' compensation patients with occupational musculoskeletal disorders and work disability. Return-to-work rates with this population administered ICPRP often approach 80-85% at one year, compared to no-treatment or standard care comparison groups that demonstrate only a roughly 40% return-to-work.

Without changes in the current approach to the treatment of musculoskeletal conditions, recognized trends of increasing disability rates and tremendous associated costs will very likely continue in the future. Thus, there is a clear need for clinical research to develop evidence-based assessment and treatment approaches to decrease the enormous costs associated with chronic musculoskeletal conditions within the U.S. Armed Forces. The purpose of this study is to evaluate the effectiveness of an ICPRP designed to decrease chronic musculoskeletal pain, increase functioning, and retain military members on active duty. The major hypothesis is that the ICPRP will significantly increase the likelihood that active duty military personnel suffering from musculoskeletal disorders will remain on active duty and be fully qualified to perform all of their military duties, as well as positively impact other socioeconomic outcomes. All participants are active duty military members recruited from all four branches of the military and treated at Wilford Hall Medical Center at Lackland Air Force Base, Texas.

This is a pre-to post-treatment evaluation design, with evaluations conducted immediately before and after treatment, as well as at 6-, 12-, and 18-month follow-up periods in order to determine differential outcomes on variables such as return to full duty status, work retention, and additional health-care utilization. The specific aims of the study are to evaluate the efficacy of ICPRP in reducing patient-reported pain symptoms, unnecessary health-care utilization, health-care costs, and number of military members on medical profile, disability, or separated from active duty. Additional aims include improving functioning, increasing the number of military members remaining fit for duty and worldwide qualified, and increasing military members' ability to pass their physical fitness test for their respective military service. In summary, this research project addresses the clear need for clinical research to develop evidence-based assessment and treatment approaches to decrease the enormous cost associated with chronic musculoskeletal conditions within the U.S. Armed Forces.

BODY:

The following is an outline of progress pertinent to the tasks outlined in our statement of work:

Hire and train treatment team members – All grant-related personnel were hired as of December 2003 and trained by the Principal and Co-Investigators. Ongoing supervision of study personnel

is accomplished through weekly meetings with Dr. Peterson (PI), regular telephone contact with Dr. Gatchel (PI), and frequent site visits by Dr. Gatchel. Day-to-day project management is accomplished through the study coordinator, Dr. McGeary, who reports to the PIs. Protocol questions or concerns are brought up with the PIs for discussion as soon as possible.

Oversee the implementation of the interdisciplinary treatment program and guide any necessary changes to the treatment protocol – The interdisciplinary treatment program (dubbed the Functional Occupational Rehabilitation Treatment –FORT-- program) has been implemented at Wilford Hall Medical Center and has been running since January 2004. The program is overseen by Dr. McGeary and problems/required changes are addressed to the PIs. If Drs. Gatchel and Peterson deem a change necessary, it is addressed to the IRBs of record for consideration through amendments to the original protocol. To date, six amendments have been submitted, though none have been submitted in the past year.

Coordinate and oversee the development and maintenance of the study database, including quality assurance and database security in compliance with HIPAA and DoD regulations – The database for the FORT program was established in December 2003 with assistance from technical support personnel at the University of Texas Southwestern Medical Center at Dallas and Wilford Hall Medical Center. Presently, the database exists as a password-protected and encrypted Microsoft Access database. Access is only available to Dr. McGeary and his on-site study staff at Wilford Hall Medical Center (Christin Pasker, Karen LeRoy, Mysti Clifton). It is housed on a single computer located in a locked office on the fourth floor of Wilford Hall. Data coding sheets have been developed to minimize errors in data interpretation and all study staff have been trained in data coding. Data are entered by Ms. LeRoy and Ms. Clifton. Data quality is monitored bi-weekly by the study coordinator through a review of data coding sheets and the database. A formal data collection checklist was developed and implemented over the past year to ensure the completion of all records. This is further supported through monthly inter-rater reliability checks in which Dr. McGeary re-codes 5 to 10% of the records input for that month and compares his entries with those of the previous coder.

Enroll 90 patients as established by the study protocol – As of 2 February 2006, we have enrolled 73 participants in the study protocol. Twenty of those participants were enrolled in the past year. Study enrollment is ongoing and we expect to reach our final goal of 90 participants with a one-year no-cost extension. Recruitment was slower than originally anticipated due to widespread OIF/OEF deployments that strained manning throughout the Armed Services and made it difficult for Commanders to release soldiers for a 3-week pain treatment program (as was required for this study). Randomization checks confirm that we have managed to balance our enrolled participants between the Treatment-As-Usual (TAU) and FORT groups to ensure that they are comparable. This has been accomplished through the use of block randomization controlling for site of injury, length of disability, and gender. A summary of existing participant demographics is included below:

Variable	Level	
Group	FORT	20
	TAU	21
	Pending Randomization	11

Branch of Service	<i>Army</i>	16
	<i>Air Force</i>	54
	<i>Navy</i>	1
Gender	<i>Male</i>	44
	<i>Female</i>	27
Race	<i>Asian</i>	3
	<i>African American</i>	13
	<i>Caucasian, not Hispanic</i>	47
	<i>Hispanic</i>	7
	<i>Other</i>	1
Rank	<i>Enlisted (E1-E9)</i>	61
	<i>Officer (O1-O10)</i>	10
Site of Pain	<i>Lumbar</i>	54
	<i>Thoracic</i>	5
	<i>Cervical</i>	4
	<i>Multiple Spinal</i>	3
	<i>Upper Extremity</i>	2
	<i>Lower Extremity</i>	3

At the time of this report, two participants had been consented but had not yet completed assessment materials, so the total number of participants reviewed above is 71.

Demographics have been periodically analyzed after randomization to ensure equal distribution of participants across the two study groups. The following is the most recent analysis of the 66 participants who have been randomized and treated in this study (we currently have 7 participants awaiting randomization):

Demographic	Levels	FORT (% in grp)	TAU (% in grp)	Significance Level *
Branch of Service	<i>Army</i>	7 (23%)	9 (25%)	NS
	<i>Air Force</i>	23 (77%)	26 (72%)	
	<i>Navy</i>	0 (0%)	1 (3%)	
Gender	<i>Male</i>	21 (70%)	23 (64%)	NS
	<i>Female</i>	9 (30%)	13 (36%)	
Race	<i>Asian</i>	1 (3%)	2 (6%)	NS
	<i>African American</i>	5 (17%)	7 (19%)	
	<i>Caucasian, Non-Hispanic</i>	19 (63%)	24 (67%)	
	<i>Hispanic</i>	4 (13%)	3 (8%)	
	<i>Other</i>	1 (3%)	0 (0%)	
Rank	<i>Enlisted</i>	25 (83%)	31 (86%)	NS
	<i>Officer</i>	5 (17%)	5 (14%)	
Site of Pain	<i>Lumbar</i>	21 (70%)	27 (75%)	NS
	<i>Thoracic</i>	2 (7%)	3 (8%)	
	<i>Cervical</i>	3 (10%)	1 (3%)	
	<i>Multiple Spinal</i>	1 (3%)	2 (6%)	
	<i>Upper Extremity</i>	2 (7%)	0 (0%)	
	<i>Lower Extremity</i>	1 (3%)	3 (8%)	

* NS = no significant differences among variables based on Chi-square analyses

Problems and Set-backs: We had originally hoped to complete all of our initial recruitment, treatment, and assessment by the end of the third year as stated in our proposal. It should be noted that, because of the Iraqi war during the first part of 2003 and continuing to the present, there was a major deployment of personnel from Wilford Hall Medical Center. This interfered somewhat with the early implementation of all aspects of initial activities of YEAR 01, and continuing deployments also impacted some aspects of YEARS 02 through 04. Some potential participants found it difficult to leave their duty stations long enough to participate in a study of this magnitude, making it somewhat difficult to meet our recruitment goals as quickly as we hoped. However, we have recruited tirelessly through a variety of mechanisms with success, and we are totally confident that our final recruitment goal of 90 participants will ultimately be met if given an extension.

KEY RESEARCH ACCOMPLISHMENTS:

- Development of a comprehensive musculoskeletal pain database tapping over 100 variables
- Development and implementation of participant recruitment protocol
- Development and implementation of interdisciplinary chronic musculoskeletal pain treatment program at Wilford Hall Medical Center
- Development and implementation of treatment quality assurance protocol
- Development and implementation of data quality assurance protocol
- Development and training of comprehensive research team employing a Physical Therapist, Registered Nurse, and Clinical Psychologist
- Recruitment of 73 participants as of 2 February 2007
- At the time of this report, 24 participants have completed 1-year follow-up measures
- Data gathering is ongoing, so there have been no publications of note to date. However, the FORT program has been covered in news stories through the Wilford Hall Medical Center newsletter (Vital Signs), The Air Force and Army Times, and the Armed Forces Television Network
- Inter-rater reliability so far is at 97.8%, and inconsistent coding/scoring is discussed and rectified by Dr. McGeary, Ms. Clifton, and Ms. LeRoy.

REPORTABLE OUTCOMES:

In line with our Statement of Work, we have periodically examined our study data to determine the efficacy of the FORT treatment compared to the Treatment-As-Usual group. A summary of our outcomes is presented in the table below. Because our database allows us to examine over 200 variables, we have included just a handful of relevant outcomes for the purposes of this progress report. When examining the table below, please keep in mind the assessment intervals utilized for this project:

- **Pre-FORT:** assessment completed after the 4-week Anesthesiology follow-up, right before the FORT participants begin participation in the FORT program (this is a *pre-treatment* interval)
- **Post-FORT:** assessment completed after the 3-week FORT interval (this is a *post-treatment* interval)

- **One-Year:** psychosocial outcomes collected through pen-and-paper questionnaires and personal interviews one year after the Post-FORT assessment

Also, in preparation for data review, a list of the included measures is listed below with explanations of the domains assessed:

- **Pain VAS:** visual analog pain scale rating, ranging from 0 (no pain) to 10 (extreme pain)
- **MVAS:** a measure of self-reported physical disability. Score ranges include 0 (no disability), 1-40 (Mild disability), 41-70 (Moderate disability), 71-100 (Severe disability), 101-130 (Very Severe disability), 131-150 (Extreme disability)
- **BDI-2:** a measure of depressive symptomatology. Score ranges include 0-13 (Minimal depression), 14-19 (Mild depression), 20-28 (Moderate depression), 30+ (Severe depression)
- **Lift-FW:** floor-to-waist lifting capacity in pounds
- **Lift-WE:** waist-to-eye-level lifting capacity in pounds
- **SF-36 PCS:** a measure of health-related quality of life. The Physical Composite Score measures the impact of one's physical health on his or her life. The measure mean is 50, with a standard deviation of 10. Lower scores indicate worse quality of life.
- **SF-36 MCS:** same as above, but the Mental Composite Scale measures the impact of one's psychosocial functioning in his or her life.

Pre-FORT Measures: Summary of physical and psychosocial variables measured immediately before the 3-week intervention (FORT) interval.

Variable	Mean (SD)		Between Groups Significance*
	FORT	TAU	
Pain VAS	5.7	4.8	NS
MVAS	76.1	79.1	NS
BDI	11.3	13.8	NS
Lift-FW	49.4	40.9	NS
Lift-WE	40.6	32.5	NS
SF-36 PCS	32.5	35.6	NS
SF-36 MCS	51.6	48.3	NS

* NS = no significant differences between groups based on independent samples t-tests

Post-FORT Measures: Summary of physical and psychosocial variables measured immediately after the 3-week intervention interval.

Variable	Mean (SD)	Between Groups
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	FORT	TAU	Significance
Pain VAS	3.8	6.0	.002*
MVAS	54.3	76.6	<.001*
BDI	5.5	10.5	.004*
Lift-FW	79.2	52.5	.001*
Lift-WE	67.1	40.8	.001*
SF-36 PCS	43.5	34.3	.002*
SF-36 MCS	53.5	50.6	.098

* difference is statistically significant based on independent samples t-tests

Within-Groups Comparisons at Pre- and Post-Treatment: Summary of the extent of change in the physical and psychosocial variables within each group (FORT and TAU), between the initial and pre-intervention interval, and the pre- and post-intervention interval.

Variable	Within Groups Significance
	Pre-FORT → Post-FORT
Pain VAS FORT TAU	<.001* .377
MVAS FORT TAU	<.001* .353
BDI FORT TAU	.001* .045*
Lift-FW FORT TAU	<.001* .122
Lift-WE FORT TAU	<.001* .052
SF-36 PCS FORT TAU	<.001* .312
SF-36 MCS FORT TAU	.151 .439

* difference is statistically significant based on paired samples t-tests

One-Year Outcomes (N=24): Below is a summary of one-year outcomes for 24 of our participants. Due to the small size of groups (N=12 in each), comparisons are under-powered, so Odds Ratios are used to show outcomes so far.

Variable	OR	Conclusion
Met Medical Board within One Year after FORT	OR=1.8	Control patients were almost twice as likely to meet a medical board as FORT patients.
Continued Seeking Medical Care for Pain One Year after FORT	OR = 3.1	Control patients were over three times more likely to seek additional treatment for pain than were FORT patients.
Continued Taking Pain Medication One Year after FORT	OR = 2.5	Control patients are more than twice as likely to continue taking pain medications as FORT patients.

ONE-YEAR OUTCOMES (group means)

Variable	FORT	Control	Conclusion
Number of MD and/or ER visits for pain care in the last year after FORT (p=.18)	5.1	23.1	Control patients accounted for many more MD and ER visits for pain than FORT patients.
Number of different healthcare providers seen for pain treatment in the last year after FORT (p=.06)	1.8	2.8	Control patients sought out more healthcare options for their pain management.
Average pain VAS rating One-Year after FORT (p=.05)	3/10	5/10	Self-report pain intensity ratings indicate no drop-off in pain relief for FORT patients over the one-year follow-up.

CONCLUSION:

Data analysis to date shows a variety of desirable outcomes. Pre-treatment between-groups analysis revealed that the groups did not initially differ significantly on any of the variables assessed, suggesting that randomization has been successful in developing two similar groups for comparison. The FORT intervention resulted in significant lifting capacity increases for treatment participants, while the treatment-as-usual group showed no continued benefit for physical health-related quality of life during the intervention interval. A review of the pre- to post-treatment score changes between and within the two groups revealed significant beneficial changes in almost all domains for the FORT group compared to few beneficial changes for the TAU group. Based on these results, we can begin to conclude that the FORT intervention is of significant benefit for those who are treated. Certainly, a review of our one-year outcomes to date reveals that FORT participants are less likely to medically retire from service, less likely to seek ongoing care from multiple providers after treatment, and experience less pain even one-year after treatment than treatment-as-usual control patients. If these trends continue to hold up once more data are collected, then we can safely conclude that the amazing treatment gains of FORT program participation can be maintained for a period of at least 12 months. We look

forward to determining if this program can further contribute to military quality of life by helping our service members stay on active duty after developing a chronic musculoskeletal condition when they may have been otherwise medically retired.

REFERENCES

No new references included in this report.

APPENDICES

APPENDIX A: Summary of Pre-Treatment Outcomes

APPENDIX B: Summary of Post-Treatment Outcomes

APPENDIX C: Most Recently Approved Informed Consent Document

APPENDIX A

SUMMARY OF PRE-TREATMENT OUTCOMES

PRE-TREATMENT

Variable	FORT	Control	Finding	Conclusion
BDI	11.3	13.8	p=.198	No difference
SF-36 PCS	32.5	35.6	p=.123	No difference
MVAS	76.1	79.1	p=.268	No difference
OSW	17.8	19.0	p=.464	No difference
FABQ	15.2	17.0	p=.204	No difference
ISI	12.1	13.0	p=.490	No difference
Pain VAS	5.7	4.8	p=.375	No difference
MPI Interf	38.4	36.0	p=.018	FORT pts had more interference of pain on function
MPI Affect	40.5	40.4	p=.135	No difference

PRE-TREATMENT

Variable	FORT	Control	Finding	Conclusion
Lift Floor to Waist (lbs)	49.4	40.9	p=.396	No difference
Lift Waist to Eye-Level (lbs)	40.6	32.5	p=.243	No difference
Lumbar Flexion (deg)	40.1	41.7	p=.398	No difference
Lumbar Extend (deg)	14.6	15.2	p=.441	No difference
Lumbar Side Bend Rt (deg)	13.8	16.0	p=.060	No difference
Lumbar Side Bend Lt (deg)	16.2	15.6	p=.355	No difference
Lumbar Rotation Rt (deg)	5.1	4.9	p=.408	No difference
Lumbar Rotation Lt (deg)	3.8	4.7	p=.169	No difference
Treadmill Time (mm:ss)	6:15	5:48	p=.489	No difference

APPENDIX B

SUMMARY OF POST-TREATMENT OUTCOMES

POST-TREATMENT

Variable	FORT	Control	Finding	Conclusion
BDI	5.5	10.5	p=.004	FORT = less depression
SF-36 PCS	43.5	34.3	p=.002	FORT = better physical health-related quality of life
MVAS	54.3	76.6	p<.001	FORT = less self-report functional disability
OSW	11.2	16.5	p<.001	FORT = less self-report functional disability
FABQ	7.6	15.1	p<.001	FORT = less unrealistic fear of re-injury with activity
ISI	8.7	10.5	p=.018	FORT = less insomnia
Pain VAS	3.8	6.0	p=.002	FORT = less pain
MPI Interf	30.3	39.5	p=.004	FORT = less interference of pain on functioning
MPI Affect	34.5	44.2	p=.002	FORT = less impact of emotional distress on pain

PRE-POST TREATMENT CHANGE (FORT PATIENTS)

Variable	Pre-FORT	Post-FORT	Finding	Conclusion
BDI	11.3	5.5	p=.001	Significantly less depression
SF-36 PCS	32.5	43.5	p<.001	Significantly better physical health-related quality of life
MVAS	76.1	54.3	p<.001	Significantly less self-report functional disability
OSW	17.8	11.2	p<.001	Significantly less self-report functional disability
FABQ	15.2	7.6	p<.001	Significantly less unrealistic fear of re-injury with activity
ISI	12.1	8.7	p=.004	Significantly less insomnia
Pain VAS	5.7	3.8	p=.008	Significantly less pain
MPI Interf	38.4	30.3	p<.001	Significantly less interference of pain on functioning
MPI Affect	40.5	34.5	p=.009	Significantly less impact of emotional distress on pain

PRE-POST TREATMENT CHANGE (CONTROL PATIENTS)

Variable	Pre-FORT	Post-FORT	Finding	Conclusion
BDI	13.8	10.5	p=.045	Significant improvement
SF-36 PCS	35.6	34.3	p=.312	No significant difference
MVAS	79.1	76.6	p=.353	No significant difference
OSW	19.0	16.5	p=.078	No significant difference
FABQ	17.0	15.1	p=.113	No significant difference
ISI	13.0	10.5	p=.111	No significant difference

Pain VAS	4.8	6.0	p=.377	No significant difference
MPI Interf	36.0	39.5	p=.357	No significant difference
MPI Affect	40.4	44.2	p=.350	No significant difference

ONE-YEAR OUTCOMES (Odds Ratios)

Variable	OR	Conclusion
Met Medical Board within One Year after FORT	OR=1.8	Control patients were almost twice as likely to meet a medical board as FORT patients.
Continued Seeking Medical Care for Pain One Year after FORT	OR = 3.1	Control patients were over three times more likely to seek additional treatment for pain than were FORT patients.
Continued Taking Pain Medication One Year after FORT	OR = 2.5	Control patients are more than twice as likely to continue taking pain medications as FORT patients.

ONE-YEAR OUTCOMES (group means)

Variable	FORT	Control	Conclusion
Number of MD and/or ER visits for pain care in the last year after FORT (p=.18)	5.1	23.1	Control patients accounted for many more MD and ER visits for pain than FORT patients.
Number of different healthcare providers seen for pain treatment in the last year after FORT (p=.06)	1.8	2.8	Control patients sought out more healthcare options for their pain management.
Average pain VAS rating One-Year after FORT (p=.05)	3/10	5/10	Self-report pain intensity ratings indicate no drop-off in pain relief for FORT patients over the one-year follow-up.

Variable	FORT	Control	Finding	Conclusion
Lift Floor to Waist (lbs)	79.2	52.5	p<.001	FORT patients significantly stronger floor-to-waist
Lift Waist to Eye-Level (lbs)	67.1	40.8	p<.001	FORT patients significantly stronger waist-to-eye level
Lumbar Flexion (deg)	50.9	42.3	p=.030	FORT patients significantly better lumbar flexion
Lumbar Extend (deg)	18.0	12.2	p=.049	FORT patient significantly better lumbar extension
Lumbar Side Bend Rt (deg)	21.2	16.4	p=.031	FORT patients significantly better side-bend ROM to the right
Lumbar Side Bend Lt (deg)	19.7	15.8	p=.035	FORT patients significantly better side-bend ROM to the left
Lumbar Rotation Rt (deg)	7.2	3.6	p=.004	FORT patients significantly better right rotation of lumbar
Lumbar Rotation Lt (deg)	5.3	3.5	p=.053	FORT patients better rotation to the left, but not significant
Treadmill Time (mm:ss)	9:31	6:44	p<.001	FORT patients significantly better treadmill scores

PRE-POST TREATMENT CHANGE (FORT PATIENTS)

Variable	Pre-FORT	Post-FORT	Finding	Conclusion
Lift Floor to Waist (lbs)	49.4	79.2	p<.001	Significant strength increase
Lift Waist to Eye-Level (lbs)	40.6	67.1	p<.001	Significant strength increase
Lumbar Flexion (deg)	40.1	50.9	p=.042	Significant ROM increase
Lumbar Extend (deg)	14.6	18.0	p=.262	No significant difference, but increase noticeable
Lumbar Side Bend Rt (deg)	13.8	21.2	p=.001	Significant ROM increase
Lumbar Side Bend Lt (deg)	16.2	19.7	p=.053	No significant difference, but increase noticeable
Lumbar Rotation Rt (deg)	5.1	7.2	p=.041	Significant ROM increase
Lumbar Rotation Lt (deg)	3.8	5.3	p=.189	No significant difference, but increase noticeable
Treadmill Time (mm:ss)	6:15	9:31	p<.001	Significant improvement on treadmill test

PRE-POST TREATMENT CHANGE (CONTROL PATIENTS)

Variable	Pre-FORT	Post-FORT	Finding	Conclusion
Lift Floor to Waist (lbs)	40.9	52.5	p=.122	No difference
Lift Waist to Eye-Level (lbs)	32.5	40.8	p=.052	No difference
Lumbar Flexion (deg)	41.7	42.3	p=.019	Significant improvement (though clinically slight)
Lumbar Extend (deg)	15.2	12.2	p=.095	No difference
Lumbar Side Bend Rt (deg)	16.0	16.4	p=.152	No difference
Lumbar Side Bend Lt (deg)	15.6	15.8	p=.225	No difference
Lumbar Rotation Rt (deg)	4.9	3.6	p=.080	No difference
Lumbar Rotation Lt (deg)	4.7	3.5	p=.077	No difference
Treadmill Time (mm:ss)	5:48	6:44	p=.028	Significant improvement (though clinically slight)

APPENDIX C:

MOST RECENTLY APPROVED INFORMED CONSENT DOCUMENT

FWH20030036H
BROOKE ARMY MEDICAL CENTER/WILFORD HALL MEDICAL CENTER
INFORMED CONSENT DOCUMENT
(ICD Template Version 4. Feb 02)

A Randomized Trial of Musculoskeletal Pain Treatment in a Military Population

PRINCIPAL INVESTIGATOR – Lt Col Alan L. Peterson

If you choose not to participate in this research study, your decision will not affect your eligibility for care or any other benefits to which you are entitled.

DESCRIPTION/PURPOSE OF RESEARCH

You are being asked to consider participation in this research study. The purpose of this study is to evaluate the effectiveness of two different treatments designed to decrease chronic pain, increase functioning, and retain military members on active duty.

This study is being conducted at Wilford Hall Medical Center in San Antonio, Texas and Brooke Army Medical Center, San Antonio, Texas. The study will enroll approximately 90 active duty military personnel with musculoskeletal pain over a period of 18 months. The overall duration of the study will be about 4 years, but the time requirement for individual participants will be about four weeks with follow-up evaluations occurring at 6 months, 12 months, and 18 months.

The two approaches to pain management that will be evaluated in this study are as follows:

Group A, Standard Anesthesia Pain Clinic Medical Care: Participants in this group will be thoroughly evaluated by physicians trained in medical pain management techniques. Appropriate medical recommendations will be made and may include any of the following: pain medications, antidepressant medications, and nerve block and steroid injections. This treatment will include about 6 patient visits over a three-week period.

Group B, Standard Anesthesia Pain Clinic Medical Care AND Interdisciplinary Chronic Pain Rehabilitation Program: This group will receive all of the treatment as described in Group A above, as well as an interdisciplinary functional restoration treatment program, which consists of three major components. Each participant will be evaluated and treated by physical therapy, occupational therapy, and clinical health psychology in coordination with a supervising nurse-physician team. This group will include 3 weeks of full-time treatment including supervised physical exercise and learning pain management skills.

RANDOMIZATION OF STUDY PARTICIPANTS: As a participant, you will be randomly assigned to one of these two groups. Randomization is a process much like flipping a coin and means you will have the same chance of being assigned to either of these two groups.

PROCEDURES: As a participant, you will undergo the following procedures:

Meeting One: The first meeting with Clinical Health Psychology service will involve a full assessment of your pain condition. You will then receive an overview of the study, complete the

informed consent document, and be asked to complete several questionnaires about your functioning in many areas (estimated time 1 1/2 hours).

During the first session you will also be randomly assigned to one of the two groups. If you are assigned to Group A or B, you will be treated at the Anesthesia Pain Clinic at Wilford Hall or Brooke Army Medical Center as directed by your physicians. Should it be necessary for you to have a standard anesthesia pain clinic treatment requiring additional informed consent, a separate consent form will be completed at the time of the procedure. If you are selected for Group B, you will also be scheduled for inclusion in the Interdisciplinary Chronic Pain Rehabilitation Program. This three-week program will be offered at Wilford Hall Medical Center once each month.

Phone Contacts and Mailings: Participants in both Groups A and B will be contacted for follow-up information 3 weeks after the initiation of treatment and then at the 6 month, 12 month and 18 month point. Each of these follow-up contacts will involve gathering the same information on functioning as previously assessed. I understand that if I am no longer on active duty in the U.S. military at the time of one of my follow-up assessments, I will be contacted at my civilian address to request completion of the outcome questionnaires.

Should it be necessary for you to have a procedure requiring additional informed consent, a separate consent form will be completed at the time of the procedure.

RISKS OR DISCOMFORTS:

There is minimal psychological and/or physical risk from the early interventions to be used in this study. In past research, none of the subjects had any problems. You could experience stress from participating in this kind of research. Knowing that researchers have personal information about you may trouble you. There is a possibility that your low back pain may worsen if you are assigned to the early intervention; however, this is not anticipated.

For those in Group A and B, the risks and discomforts of participating are the same as those that would be expected when under the care of the Anesthesia Pain Clinic for any other patient. An additional informed consent for a standard anesthesia pain clinic treatment may be obtained at the time of treatment. These treatments include the use of medications and injections, and the potential adverse effects include infection, bleeding, nerve damage, allergic reactions and either no change or a worsening of your pain.

For those in Group B, there are some risks, which involve engaging in a functional restoration program although these are expected to be minimized since you will be following the recommendations of an interdisciplinary staff of healthcare providers (e.g., physician, nurse, psychologist, physical therapist, and occupational therapist). It is also possible that your pain could become somewhat worse during the course of treatment. There may also be unforeseen risks associated with this study. A previously unknown problem could result from your participation in this research. It is not possible to estimate the chances of such problems or how serious problems could be. Consequently, we ask that you inform the study doctor or any of the Investigators listed on this form of any problems that arise during this study, and also inform your physician. Finally, if you should ever report current or recent thoughts, plan or intent to harm or kill yourself or evidence of self-harm is ever indicated during the course of your participation in this study, your commander will be notified and appropriate action will be taken to

help ensure your safety, including assessment of risk by a credentialed Mental Health Provider and referral to an appropriate level of care (e.g., outpatient follow-up or inpatient hospitalization).

BENEFITS:

While there is no guarantee you will benefit from participating in this study, it is intended to reduce your pain, increase your functioning, and retain your active duty status. The treatments are believed to be beneficial, and how well they work is the focus on this study. The investigators have designed this study to learn if there is a difference and how they can better treat active duty members who often times are concerned about their ability to remain in the military until they decide to retire. There will also be a scientific benefit if this study can tell us which treatment for musculoskeletal pain is better.

PAYMENT (COMPENSATION):

You will not receive any compensation (payment) for participating in this study.

ALTERNATIVES TO PARTICIPATION: Alternatives may be available to you, including other pain management programs or individual consultations with Physical Therapy, Occupational Therapy, Mental Health, or Clinical Health Psychology available through your medical treatment facility. Other alternatives would be to seek follow-up care with your primary care manager or to participate in treatment at the Anesthesia Pain Clinic but to decline participation in the data collection or to decline any treatment at all.

CONFIDENTIALITY OF RECORDS OF STUDY PARTICIPATION:

Records of your participation in this study may only be disclosed in accordance with federal law, including the Federal Privacy Act, 5 U.S.C. 552a, and its implementing regulations. DD Form 2005, Privacy Act Statement- Military Health Records, contains the Privacy Act Statement for the records. By signing this consent document, you give your permission for information gained from your participation in this study to be published in medical literature, discussed for educational purposes, and used generally to further medical science. You will not be personally identified; all information will be presented as anonymous data.

Your records may be reviewed by the U.S. Food & Drug Administration (FDA), other government agencies, the BAMC/WHMC Institutional Review Boards, and by research staff. Further, representatives of the U.S. Army Medical Research and Materiel Command are eligible to review research records as a part of their responsibility to protect human subjects in research. Complete confidentiality cannot be promised, particularly for military personnel, because information regarding your health may be required to be reported to appropriate medical or command authorities.

ENTITLEMENT TO CARE:

In the event of injury resulting from this study, the extent of medical care provided is limited and will be within the scope authorized for Department of Defense (DoD) health care beneficiaries.

Your entitlement to medical and dental care and/or compensation in the event of injury is governed by federal laws and regulations, and if you have questions about your rights as a research subject or if you believe you have received a research-related injury, you may contact the Wilford Hall

Clinical Research Squadron Commander, (210) 292-7069 or Wilford Hall Medical Center Risk Manager, 210-292-6004. Brooke Army Medical Center Protocol Coordinators, 210-916-2598 or BAMC Judge Advocate, 210-916-2031.

Preparation in this study does not alter your ongoing medical benefits as a military beneficiary, and you will continue to receive any needed medical treatment should you experience illness or injury as a result of this study. In the event of injury resulting from the investigational procedures, the extent of medical care provided is limited and will be within the scope authorized for DoD health care beneficiaries.

BLOOD & TISSUE SAMPLES: “No blood or tissue samples will be taken as part of this study.”

STATEMENT OF GOOD FAITH: The investigator cannot guarantee or promise that you will receive benefits from this study; however, the investigator will keep you informed of any serious complications, which may result from your participation in this study.

VOLUNTARY PARTICIPATION:

The decision to participate in this study is completely voluntary on your part. No one has coerced or intimidated you into participating in this project. You are participating because you want to. Lt Col (Dr) Alan Peterson, (Wilford Hall Medical Center, DSN 554-5968, Commercial (210) 292-5968), Dr. Robert Gatchel, (University of Texas Southwest Medical Center, Dallas and the University of Texas at Arlington, (817) 272-1207), or one of their associates has adequately answered any and all questions you have about this study, your participation, and the procedures involved. Dr. Peterson, Dr. Gatchel, or a member of the Clinical Health Psychology staff at Wilford Hall Medical Center ((210) 292-5968) will be available to answer any questions concerning procedures throughout this study. If significant new findings develop during the course of this study that may relate to your decision to continue participation, you will be informed.

You may withdraw this consent at any time and discontinue further participation in this study without affecting your eligibility for care or any other benefits to which you are entitled. Should you choose to withdraw, you must inform one of the investigators. Your condition will continue to be treated in accordance with acceptable standards of medical treatment.

The investigator of this study may terminate your participation in this study at any time if he/she feels this to be in your best interest. Your consent to participate in this study is given on a voluntary basis. All oral and written information and discussions about this study have been in English, a language in which you are fluent.

CONTACT INFORMATION:

Principal Investigator (PI)

The principal investigator or a member of Clinical Health Psychology staff will be available to answer any questions concerning procedures throughout this study.

Principal Investigator: Lt Col Alan L. Peterson

Phone: (210) 292-5968

Institutional Review Board (IRB)

The WHMC Institutional Review Board (IRB), the hospital committee responsible for safeguarding your rights as a research subject, has assigned a member of the IRB, who is not part of the study team, to serve as an outside monitor for this study (this person is the Medical Monitor). If you have any questions about your rights as a research subject or any other concerns that cannot be addressed by the PI, you can contact the medical monitor, Joseph Schmelz, PhD, RN at (210) 292-5687. Or mail to: 59th Clinical Research Squadron/MSRP, 1255 Wilford Hall Loop, Lackland Air Force Base, Texas 78236.

In addition, if you have any comments, questions, concerns or complaints, you may also contact the Chairperson of the IRB, at (210) 292-7558. Or mail to: 59th Medical Wing/CM, 2200 Bergquist Drive, Lackland Air Force Base, Texas 78236.

A copy of this form has been given to you.

VOLUNTEER'S SIGNATURE

VOLUNTEER'S SSN

DATE

VOLUNTEER'S PRINTED NAME

FMP

SPONSOR'S SSN

DOB

VOLUNTEER'S ADDRESS (street, city, state, zip)

ADVISING INVESTIGATOR'S SIGNATURE

DATE

(PHONE NUMBER)

(can only be signed by an investigator whose name is listed in the protocol)

PRINTED NAME OF ADVISING INVESTIGATOR

WITNESS' SIGNATURE

DATE

(Must witness ALL signatures)

PRINTED NAME OF WITNESS

Subject's Stamp Plate

PRIVACY ACT OF 1974 APPLIES.

DD FORM 2005 FILED IN MILITARY HEALTH RECORDS