

Putting Patient-reported Functional health status instruments into Occupational health services practice: A Controlled trial of the Worker-based outcomes assessment system (WBOAS)

Robert H. Ross, Ph.D., Jesse Q. Sargent, B.A., Peter W. Callas, Ph.D., K. Celeste Gaspari, Ph.D.

18 December 2003

Authors: Robert H. Ross, Special Assistant for Development, Health and Human Development Programs, Education Development Center, Newton MA 02458. Jesse Q. Sargent, Research Associate, Clinical Neuroscience Research Unit, Fletcher Allen Health Care, Burlington VT 05401. Peter W. Callas, Research Associate Professor, Medical Biostatistics, University of Vermont, Burlington VT 05405. K. Celeste Gaspari, Ph.D., Quality Improvement Consultant, Quality Monitoring and Improvement, Fletcher Allen Health Care, Burlington VT 05401.

Please direct correspondence to Robert H. Ross, Ph.D., HHD/EDC, 55 Chapel Street, Newton MA 02458-1060, tel. 617-618-2466, email ross@edc.org.

Acknowledgements: The lead author gratefully acknowledges support in conducting this research from **CDC/NIOSH grant 5 R21 OH07339** and from Diane Aja, M.S., Benjamin C. Amick, Ph.D., Richard A. Galbraith, M.D., Ph.D., Ashley K. Hardesty, A.S., Krystal Jenness, P.T., Ted Rooney, R.N., M.P.H., Jill Zhou, P.T., and Thomas J. Zweber, M.D.

Table of contents

Abstract	3
Summary	5
Background		
Methods		
Results		
Conclusions		
1. Background	9
Injury burden		
Injury management		
Outcomes assessment		
2. Methods	11
Subjects and sites		
Instrument and intervention		
Protocol		
Data collection		
Study measures		
Data analysis		
3. Results	18
Pre-intervention period		
Site effectiveness		
Intervention period		
Subject characteristics (Pre-treatment)		
Primary Predictions		
Clinical		
Functional		
Process		
Cost		
Secondary predictions		
Worksite evaluation, redesign		
Behavioral health care		
4. Comments	38
Site effectiveness (Pre-intervention period)		
Subject characteristics (Pre-treatment)		
Outcomes (Intervention period)		
Clinical		
Functional		
Process		
Cost		
Referrals		
5. Conclusions	43
References	45
Glossary of Acronyms	49
Glossary of Tables	50
Endnotes	51

Abstract. The Intervention tested the effects of incorporating the Worker-based outcomes assessment system (WBOAS) into Occupational health services (OHS) practice at Fletcher Allen Health Care (FAHC, Burlington VT). The WBOAS is a Work-related musculoskeletal disorders (WRMSD) treatment and secondary prevention improvement protocol designed to inform treatment by putting same-session (a) touchscreen-generated patient-reported outcomes trends graphics (contrasting initial, previous, and current visits on Physical and Behavioral health status, Pain symptoms and related attitudes, and Work role limitations) and (b) trends-based auxiliary treatment referral guidelines (for work site evaluation and redesign and for behavioral health care) into the hands of physical and occupational therapists (PT/OTs) and their patients. The study employed a prospective, parallel cohort, external control design--the strongest controlled trial frame possible given the impossibility, when the provider is integral to the intervention, of randomizing subjects same-site to test and control arms--and featured one Test and two Control site clinics. Subjects were FAHC employees with WRMSDs including strain/sprain, cumulative trauma (upper extremity, lower extremity, lower back), tendonitis, and carpal tunnel syndrome. Test site PT/OTs delivered Standard plus (WBOAS) care, i.e. Standard care augmented by same-session outcomes trends graphics (to set and re-set injury treatment and return-to-work goals) and trends-based referral guidelines (to initiate auxiliary worksite evaluation and redesign and/or behavioral health care). Control site PT/OTs delivered Standard care alone.

Primary predictions were that, controlling for covariates such as patient-reported demographics, co-morbidities, injury severity, physical and behavioral health, work limitations, psychosocial profile, and work conditions, Test site subjects would exhibit higher rates of (1) clinical outcome: treatment period Injury recovery (IR) and post-treatment period Re-injury avoidance (RA), (2) functional outcome: treatment period Return-to-work (RTW) and post-treatment period Stay-at-work (SAW) success, and (3) process outcome: post-treatment period evaluated Provider performance (PP) and Overall satisfaction (OS) with care, at no lower rate of (4) cost outcome: treatment or post-treatment period Cost-adjusted outcome (CaO). Secondary predictions were that Test site subjects likewise would exhibit higher rates of (5) auxiliary care: treatment period referrals to Worksite evaluation and redesign (WSE, WSR) and to Behavioral health care (BHC). Results were that, compared to Standard care alone, Standard plus (WBOAS) care was found:

(1) clinical outcome: with prediction to significantly improve (a) subjects' IR and RA on patient-reported Physical functioning (SF-36 PF-10 difference in mean improvement at discharge [1 mo post-treatment follow-up] 0.22 vs 0.12 p=0.01, difference in mean improvement at 3 mo post-treatment follow-up 0.23 vs 0.15 p=0.05, difference in mean improvement at 6 mo post-treatment follow-up 0.24 vs 0.16 p=0.07) and on expert-rated New injury/re-injury avoidance (baseline [pre-treatment] through 6 mo post-treatment follow-up incidence 4/0.05:14/0.15 p=0.04), (b) male subjects' IR on expert-rated Injury recovery status at discharge (1 mo post-treatment follow-up continuous: mean 2.0 vs 2.6 p=0.05), and (c) male subjects' who smoke IR on expert-rated Injury recovery status at discharge (1 mo post-treatment follow-up dichotomous: percent scored 1&2 vs 3&4 81 vs 40 p=0.05); but against prediction not to improve (a) subjects' IR and RA on patient-reported Behavioral health status or Pain symptoms, Life control/personal efficacy, and Fear/avoidance at discharge (1 mo post-treatment follow-up) or at 3 and 6 mo post-treatment follow-up or (b) female subjects' IR on patient-reported Injury recovery status at discharge (1 mo post-treatment follow-up).

(2) functional outcome: against prediction not to improve subjects' RTW or SAW success, patient-reported or expert-rated, though men did trend in the predicted direction on RTW.

(3) process outcome: with prediction to significantly improve (a) subjects' evaluated PP at discharge (1 mo post-treatment follow-up) on PCAS Physical examination (difference in mean evaluation 0.87 vs 0.81 $p=0.05$) and (b) male subjects' evaluated PP at discharge (1 mo post-treatment follow-up) on PCAS Contextual knowledge (difference in mean evaluation 0.80 vs 0.59 $p=0.01$) and nearly on Interpersonal treatment and Communication; but against prediction not to improve (a) male subjects' evaluated PP at discharge (1 mo post-treatment follow-up) on PCAS Longitudinal continuity (difference in mean evaluation 0.44 vs 0.52 $p=0.05$), (b) female subject's evaluated PP at discharge (1 mo post-treatment follow-up) on PCAS Contextual knowledge, Interpersonal treatment, Communication or Longitudinal continuity (LoC difference in mean evaluation 0.44 vs 0.52 $p=0.05$), (c) subjects' evaluated PP at discharge (1 mo post-treatment follow-up) on PCAS Visit-based continuity, Integration of care, Interpersonal treatment, or Trust, or (d) subjects' OS with care at discharge (1 mo post-treatment follow-up).

(4) cost outcome: with prediction to measurably improve CaO on two dimensions of IR and RA, patient-reported Physical functioning (CaO=1.83:1.10=1.66 or 66 percent higher at discharge [1 mo post-treatment follow-up], CaO=1.53:1.10=1.39 or 39 percent higher at 3 mo post-treatment follow-up) and expert-rated New injury/re-injury avoidance (baseline [pre-treatment] through 6 mo post-treatment follow-up incidence CaO=1.12/1.10=1.018 or 2 percent higher at 6 mo post-treatment follow-up); but against prediction not to improve CaO on other dimensions of IR and RA such as patient-reported Behavioral health status or Pain symptoms, Life control/personal efficacy, and Fear/avoidance at discharge (1 mo post-treatment follow-up) or at 3 and 6 mo post-treatment follow-up.

(5) auxiliary care: against prediction not to improve subjects' PT/OT-initiated WSE and WSR or BHC referral rates.

Any future study involving WBOAS-type Interventions should bolster capacity to attribute effects to the Intervention by instituting a pre-Intervention period adequate to garnering reliable baseline (pre-treatment) measures of outcomes and controls; adopting a staggered Intervention whereby Intervention period 1 Control site become Intervention period 2 Test site clinics; blinding Control site to Test site clinic protocol so as to minimize the cross-site contamination that can lead to Hawthorn effect distortions; and stratifying subjects by gender so as to reliably chart Intervention effect similarities and differences between men and women. The importance of securing the Pre-intervention period buy-in of administrators, providers, and staff essential to the study cannot be underestimated. Employers, especially those in the health services or like sectors (e.g. human services), should consider sponsoring WBOAS-type Interventions so as to advance the WRMSD treatment and secondary prevention outcomes research base; calculating per patient net savings (outcome-to-cost) represented by any observed greater effectiveness of WBOAS-type WRMSD care on, for example, Injury recovery or Re-injury avoidance, Return to work or Stay at work success measures; and modifying OHS treatment accordingly.

Summary

Background. Patient-reported functional health status measures have emerged to complement provider-reported clinical assessment as means to gauging treatment success (output) across a range of conditions and practice settings. Incorporated as diagnostic instruments directly into treatment, these measures have also been used as intervention components per se (input) and as such been observed to affect treatment outcomes. Their use on both counts was aided by a dramatic drop over the 1990s in outcomes information gathering and processing costs. The Intervention reported here tests the effects of incorporating the Worker-based outcomes assessment system (WBOAS), based on a battery of functional health status measures, directly into Occupational health services (OHS) practice. The WBOAS is a Work-related musculoskeletal disorders (WRMSD) treatment and secondary prevention improvement protocol developed over the mid-1990s at the New England Medical Center (Boston MA), rolled out 1998-99 at LL.Bean (Freeport ME), and now piloted 2000-03 in a first controlled trial at Fletcher Allen Health Care (FAHC, Burlington VT). The WBOAS informs treatment by putting same-session (a) touchscreen-generated patient-reported outcomes trends graphics (contrasting initial, previous, and current visits on Physical and Behavioral health, Pain symptoms and related attitudes, and Work role limitations) and (b) trends-based auxiliary treatment referral guidelines (for work site evaluation and redesign and for behavioral health care) into the hands of physical and occupational therapists (PT/OTs) and their patients.

Methods. The WBOAS/FAHC pilot study employed a prospective, parallel cohort, external control design--the strongest controlled trial frame possible given the impossibility, when the provider is integral to the intervention, of randomizing subjects same-site to test and control arms--and featured one Test and two Control site clinics. Subjects were FAHC employees with WRMSDs including strain/sprain, cumulative trauma (upper extremity, lower extremity, lower back), tendonitis, and carpal tunnel syndrome. Sites, one test and two controls, were geographically separate FAHC-managed OHS clinics. Test site PT/OTs delivered Standard plus (WBOAS) care, i.e. Standard care augmented by same-session outcomes trends graphics (to set and re-set injury treatment and return-to-work goals) and trends-based referral guidelines (to initiate auxiliary worksite evaluation and redesign and/or behavioral health care). Control site PT/OTs delivered Standard care alone. Primary predictions were that, controlling for covariates such as patient-reported demographics, co-morbidities, injury severity, physical and behavioral health, work limitations, psychosocial profile, and work conditions, Test site subjects would exhibit higher rates of (1) clinical outcome: treatment period Injury recovery (IR) and post-treatment period Re-injury avoidance (RA), (2) functional outcome: treatment period Return-to-work (RTW) and post-treatment period Stay-at-work (SAW) success, and (3) process outcome: post-treatment period evaluated Provider performance (PP) and Overall satisfaction (OS) with care, at no lower rate of (4) cost outcome: treatment or post-treatment period Cost-adjusted outcome (CaO). Secondary predictions were that Test site subjects likewise would exhibit higher rates of (5) auxiliary care: treatment period referrals to Worksite evaluation and redesign (WSE, WSR) and to Behavioral health care (BHC).

Results. In the Pre-intervention period Test and Control sites were equally effective on all measures of clinical, functional, and process outcome, except on the Behavioral health dimension

of IR and the Life control/personal efficacy dimension of RA. The two differences were immaterial however, since the Intervention was not subsequently observed to affect either dimension. In the Intervention period, Test and Control site subjects at baseline (pre-treatment) were comparable on all of the same measures, except on the Physical functioning dimension of Injury severity, where Test site subjects were observed to be more severely impaired. As Test and Control sites were subsequently observed to differ significantly on Physical functioning at discharge (1 mo post-treatment follow-up) (IR) and at 3 mo (and near significantly at 6 mo) post-treatment follow-up (RA), the baseline (pre-treatment) difference thereon was material and was examined as, but not found to be, a confounder of observed Intervention effects. Intervention results were that, compared to Standard care alone, Standard plus (WBOAS) care was found:

(1) clinical outcome: with prediction to significantly improve (a) subjects' IR and RA on patient-reported Physical functioning (SF-36 PF-10 difference in mean improvement at discharge [1 mo post-treatment follow-up] 0.22 vs 0.12 $p=0.01$, difference in mean improvement at 3 mo post-treatment follow-up 0.23 vs 0.15 $p=0.05$, difference in mean improvement at 6 mo post-treatment follow-up 0.24 vs 0.16 $p=0.07$) and on expert-rated New injury/re-injury avoidance (baseline [pre-treatment] through 6 mo post-treatment follow-up incidence 4/0.05:14/0.15 $p=0.04$), (b) male subjects' IR on expert-rated Injury recovery status at discharge (1 mo post-treatment follow-up continuous: mean 2.0 vs 2.6 $p=0.05$), and (c) male subjects' who smoke IR on expert-rated Injury recovery status at discharge (1 mo post-treatment follow-up dichotomous: percent scored 1&2 vs 3&4 81 vs 40 $p=0.05$); but against prediction not to improve (a) subjects' IR and RA on patient-reported Behavioral health status or Pain symptoms, Life control/personal efficacy, and Fear/avoidance at discharge (1 mo post-treatment follow-up) or at 3 and 6 mo post-treatment follow-up or (b) female subjects' IR on patient-reported Injury recovery status at discharge (1 mo post-treatment follow-up).

(2) functional outcome: against prediction not to improve subjects' RTW or SAW success, patient-reported or expert-rated, though men did trend in the predicted direction on RTW.

(3) process outcome: with prediction to significantly improve (a) subjects' evaluated PP at discharge (1 mo post-treatment follow-up) on PCAS Physical examination (difference in mean evaluation 0.87 vs 0.81 $p=0.05$) and (b) male subjects' evaluated PP at discharge (1 mo post-treatment follow-up) on PCAS Contextual knowledge (difference in mean evaluation 0.80 vs 0.59 $p=0.01$) and nearly on Interpersonal treatment and Communication; but against prediction not to improve (a) male subjects' evaluated PP at discharge (1 mo post-treatment follow-up) on PCAS Longitudinal continuity (difference in mean evaluation 0.44 vs 0.52 $p=0.05$), (b) female subject's evaluated PP at discharge (1 mo post-treatment follow-up) on PCAS Contextual knowledge, Interpersonal treatment, Communication or Longitudinal continuity (LoC difference in mean evaluation 0.44 vs 0.52 $p=0.05$), (c) subjects' evaluated PP at discharge (1 mo post-treatment follow-up) on PCAS Visit-based continuity, Integration of care, Interpersonal treatment, or Trust, or (d) subjects' OS with care at discharge (1 mo post-treatment follow-up).

(4) cost outcome: with prediction to measurably improve CaO on two dimensions of IR and RA, patient-reported Physical functioning (CaO=1.83:1.10=1.66 or 66 percent higher at discharge [1 mo post-treatment follow-up], CaO=1.53:1.10=1.39 or 39 percent higher at 3 mo post-treatment

follow-up) and expert-rated New injury/re-injury avoidance (baseline [pre-treatment] through 6 mo post-treatment follow-up incidence CaO=1.12/1.10=1.018 or 2 percent higher at 6 mo post-treatment follow-up); but against prediction not to improve CaO on other dimensions of IR and RA such as patient-reported Behavioral health status or Pain symptoms, Life control/personal efficacy, and Fear/avoidance at discharge (1 mo post-treatment follow-up) or at 3 and 6 mo post-treatment follow-up.

(5) auxiliary care: against prediction not to improve subjects' PT/OT-initiated WSE and WSR or BHC referral rates.

Conclusions. The WBOAS/FAHC pilot study, and this is its principal strength, constitutes the first controlled trial of the Worker-based outcomes assessment system, a Work-related musculoskeletal disorders (WRMSD) treatment and secondary prevention improvement protocol that informs treatment by putting same-session touchscreen-generated patient-reported outcomes trends graphics and trends-based auxiliary treatment referral guidelines into the hands of physical and occupational therapists (PT/OTs) and their patients. Given that the provider was integral to the Intervention, the study could not randomize subjects at baseline (pre-treatment), and this is its principal weakness. Only those Intervention effect confounders anticipated in advance and measured, pertaining to study site and study subject characteristics, could thus be controlled for. These though were tested for and discounted as needed throughout this report and no effect reported left any measured confounder unexamined.

Characteristic of a pilot, the study was of limited duration and accrual. It featured a logistically complex protocol that required the consent and cooperation of dozens of personnel, including medical center administrators and staff (human relations, employee health, employee accounts, patient records, IRB), OHS study site providers and staff (RNCMs, MDs, PT/OTs, clinic staff), and patients (study subjects through 6 mo post-treatment follow-up). The effort required to conduct patient-oriented, practice-based research of the sort should not be underestimated. Future studies involving WBOAS-type controlled Interventions should complement the effort, and bolster capacity to attribute effects to the Intervention, by instituting a pre-Intervention period adequate to garnering reliable baseline (pre-treatment) measures of outcomes and controls; adopting a staggered Intervention whereby the Intervention period 1 Control clinic itself becomes an Intervention period 2 Test clinic; blinding Control sites to Test site protocol so as to minimize the cross-site contamination that leads to possible Hawthorn effect distortions; and stratifying subjects by gender so as to reliably chart Intervention effect similarities and differences between men and women. The importance of securing the Pre-intervention period buy-in of administrators, providers, and staff essential to the study likewise cannot be underestimated.

The relevance for both research and practice of the study lies in Intervention effects that were observed to improve, and not to improve, the primary and secondary outcomes measured. Thus, in trial, and compared to Standard care alone, Standard plus (WBOAS) care was observed

(1) clinical outcome: to significantly improve subjects' Physical functioning at discharge (1 mo post-treatment follow-up) and at 3 (and near significantly at 6 mo) post-treatment follow-up, men's Injury recovery status at discharge (1 mo post-treatment follow-up), and subjects' New

injury/re-injury incidence (baseline [pre-treatment] through 6 mo post-treatment follow-up); but not to improve subjects' Behavioral health status or Pain symptoms, Life control/personal efficacy, and Fear/avoidance at discharge (1 mo post-treatment follow-up) or at 3 and 6 mo post-treatment follow-up or women's Injury recovery status at discharge (1 mo post-treatment follow-up).

- (2) **functional outcome:** not to improve subjects' RTW or SAW success, though men did trend in the predicted direction.
- (3) **process outcome:** to significantly improve subjects' evaluated PP on Physical examination and men's evaluated PP on Contextual knowledge (and near significantly so on Interpersonal treatment and Communication); but not to improve women's evaluated PP on Contextual knowledge, Interpersonal treatment, Communication or Longitudinal continuity or subjects' evaluation of Provider performance on Visit-based continuity, Integration of care, Interpersonal treatment, or Trust; and not to improve subjects' OS with care.
- (4) **cost outcome:** to measurably improve treatment period CaO on Physical functioning at discharge (1 mo post-treatment follow-up) and at 3 mo post-treatment follow-up, respectively 66 percent and 39 percent again more effective on this outcome *for these subjects*, and on New injury/re-injury avoidance rate baseline (pre-treatment) through 6 mo post-treatment follow-up, 2 percent again more effective on this outcome *for these subjects*; but not to improve treatment period CaO on other clinically-relevant outcomes such as Behavioral health status or Pain symptoms, Life control/personal efficacy, and Fear/avoidance at discharge (1 mo post-treatment follow-up) or at 3 and 6 mo post-treatment follow-up;
- (5) **auxiliary care referrals:** not to improve either WSE and WSR or BHC referral rates.

Employers, especially those in the health services or like sectors (e.g. human services), should consider sponsoring WBOAS-type Interventions so as to advance the WRMSD treatment and secondary prevention outcomes research base; calculating per patient net savings (outcome-to-cost) represented by any observed greater effectiveness of WBOAS-type WRMSD care on, for example, Injury recovery or Re-injury avoidance, Return to work or Stay at work success measures; and modifying OHS treatment accordingly.

1. Background

Injury burden. Repetitive motion injuries, mostly upper extremity and back disorders, are the fastest growing source of disability in the U.S. workplace, with incidence increasing fourteen-fold 1974-96 (Bernard 1997). In Washington State 1990-97, six in 1000 full time employees a year made accepted compensation claims for carpal tunnel syndrome, rotator cuff disorders, and epicondylitis, resulting in \$500 million total cost and five million lost work days. Extrapolated nationally, these three problems would amount to \$32 billion in total cost and 320 million lost workdays a year (Silverstein and Kalat 1998). Back problems constitute 25% of all disabling occupational injuries in the U.S. and cause a loss of 1400 work days per 1000 employees a year (Wiesel et al. 1984). Lower back pain is responsible for 20 million sick days a year, and 12.9 million physician visits a year are made for chronic back pain (Nachemson 1992). The direct medical cost of spinal disorders is estimated at \$23.5 billion a year, with a total cost of from \$25-\$85 billion (Frymoyer 1996). The longer return-to-work takes the lower the probability an employee will return at all, falling to below 50% in six months (Waddell 1992).

Small wonder then that the National Institute for Occupational Safety and Health's *National Occupational Research Agenda* (NORA) (National Institute for Occupational Safety and Health, 1996)¹ and the Institute of Medicine (IOM) Panel on Musculoskeletal Disorders and the Workplace's *Musculoskeletal Disorders and the Workplace* (Institute of Medicine 2001)² should signal how heavy the social and economic burden of WRMSD is in the U.S. And no less wonder that related recommendations might be made, 1) the IOM Panel's that well-designed workplace interventions should serve to "reduce the incidence and impact of musculoskeletal injuries, illnesses, and disorders [variously] by reducing or eliminating the external loads, changing organizational factors, altering the social environment, improving individual stress-coping skills, or matching the physical demands of the job with the employee's physical capacities" (pp. 301-02); and 2) the NORA Agenda's that OHS should be a locus of workplace intervention, that OHS research, "a young discipline [focused] on the organization, financing, and management of occupational health care services to assess their impact on occupational health care delivery, quality, cost, access, and outcomes," can provide "the quantitative and qualitative methodology to examine the impact" of these services. (Executive summary, National Institute for Occupational Safety and Health 1996).

Injury management. Though WRMSD treatment and prevention efforts to date have operated largely independently of one another, the present day aging workforce and rising emphasis on worker productivity call for combining elements of each into a more integrated approach to WRMSD management (Rudolph and Deitchman 1999). On the prevention side, primary prevention centers on hazardous work exposures, which includes exposure to poor work stations, and on appropriate employee training and has been the principal approach taken in the U.S. to reducing WRMSD incidence (Cohen and Colligan 1999). A recent National Academy of Sciences review concluded accordingly that "successful interventions require attention to individual, organizational, and job characteristics" (National Academy of Sciences 1999) and consensus is emerging on the value of multidimensional approaches from lab-based interventions to field studies of injured and healthy employees (Smith et al. 1998). Secondary prevention centers on workplace application of the "illness management" model, one that targets the value of

health care and measures it using patient-reported functional health status and work role performance instruments comparable to industry's Total Quality Management (TQM) measures.

On the treatment side, though physical and occupational therapists (PT/OTs) provide the better part of WRMSD care, and that care has been linked to treatment success, i.e. to positive clinical (injury recovery) and functional (return to work) outcomes (Jette and Jette 1996, LaRosa 1988), no controlled intervention has yet been conducted to gauge the effectiveness of the sorts of care these providers deliver. The low reliability, and limited utility in predicting treatment outcomes, of the physical assessment data PT/OTs and other OHS providers report, moreover, points to the need for incorporating patient-reported measures in such interventions (Beaton et al. 1996, Loisel et al. 1998). Relatedly, an emerging treatment matter concerns when to address behavioral health problems, i.e. when to refer employees to behavioral health care. Research has demonstrated the effect of behavioral health status on injury incidence and return to work success (Armenian et al. 1998, Broadhead et al. 1990, Bromet et al. 1992, Burton et al. 1995, Phelan et al. 1996, Katz et al. 1997). Depression, for example, is associated with lower rates of return to work in employees with back injuries (Hasenbring 1994, Waddell et al. 1993).

Outcomes assessment. Of patient-reported functional health status instruments, two types are now widely used, generic ones like the SF-36 (Ware et al. 1993) used to measure outcomes both within one disease or condition or class thereof and across two or more such, and specific ones applied just to one illness or condition or class thereof, WRMSDs for instance (Levine et al. 1993). If the latter are more sensitive to clinically important differences (Beaton and Richards 1996, Besette et al. 1998, Bombardier et al. 1995), the former permit standard comparison across diseases and conditions and may also be more sensitive to contextual effects. Both types are now commonly used in outcomes assessment (Bergner 1989, Bergner and Rothman 1987, Deyo et al. 1991, Patrick and Bergner 1990, Martin et al. 1997). Recent clinical trials report that care improves when the pre/post outcomes information generated by these instruments is directly incorporated into clinical decision-making (Calkins et al. 1994, Rubenstein et al. 1989, 1995). Work role performance instruments in turn have been developed that link health status to specific work demands and thus operationalize return to work success over and above the mere the "fact" of return to work (Pransky and Himmelstein 1996). If an injured employee is returned to work too quickly and does not perform well, or is soon re-injured, then return to work per se misses the more significant and costly outcome (Higgs et al. 1995). A study of Ontario employees where 85% returned to work but 61% soon left because of re-injury (Baldwin et al. 1996) underscores the need for controlled Interventions that link outcomes-based injury treatment and guidelines-based re-injury prevention (e.g. involving referral to worksite evaluation and redesign and to behavioral health care). Yet even with the emergence of employers as value-conscious primary purchasers of health care, such linked approaches in OHS settings remains more recommended than practiced (Jette and Jette 1996, Pransky and Himmelstein 1996) and no study yet has tested the utility of any such Worker-based outcomes assessment system (Pransky et al. 1999).

2. Methods

Subjects and sites. Eligible subjects were FAHC employees (regular full-time, regular part-time, temporary part-time) with WRMSDs including strain/sprain, cumulative trauma (upper extremity, lower extremity, lower back), tendonitis, and carpal tunnel syndrome who, for that injury, were subsequently scheduled for PT/OT at one of the three FAHC-managed geographically separate OHS clinic study sites.

(1) Invited by EH	(2) Pre- Consented by EH	(3) Made eligible by Referral for PT/OT	(4) Eligibles Consented Baseline (pre- treatment) Interview	(5) 1 mo. (post- treatment) follow-up Interview	(6) 3 mo. (post- treatment) follow-up Interview	(7) 6 mo. (post- treatment) follow-up Interview	(a) Accrual Rate (4) / (3)	(b) Retention Rate (7) / (4)
362	302	223	179	158	151	138	0.80	0.77

All eligible employees were invited to join the study, conditional upon their subsequent referral to PT/OT, by FAHC Employee Health (EH), where all WRMSDs are first seen by one of three R.N. Case Managers (RNCMs). RNCMs were charged to provide initial injury assessment and care and to refer as needed for medical treatment to a FAHC or other medical care provider (M.D., P.A., N.P.). Of 362 thus invited, 302 gave permission and were “pre-consented.” Medical care providers in turn were charged to treat injured employees and refer them as needed for PT/OT to a FAHC and other PT/OT site. Of 302 pre-consented employees, 223 became eligible to join the study by being referred for PT/OT to a study site. Of these, 179 (0.80 accrual) gave permission and were consented, then baseline (pre-treatment) interviewed, always before the first treatment visit to PT/OT. Of 179 consented subjects, 158 completed the study through discharge (1 mo post-treatment follow-up) (0.88), 151 through 3 month post-treatment follow-up (.84), 138 through 6 month post-treatment follow-up (0.77 retention) (**Table 1**). From intake, the RNCMs served as manager-communicator among patients, medical care providers and PT/OTs, work supervisors and insurers, and study personnel. Under Workers Comp, employers have the right to assign employees to providers and employees have the right to see a provider of choice. The matter is usually resolved amicably.

The study employed a prospective, parallel cohort, external control, Standard vs Standard plus research design, the strongest possible controlled trial frame given the impossibility, when the provider is integral to the intervention, of randomizing study subjects same-site to test and control arms. The Sports and Orthopaedic Rehabilitation Center (SORC) served as Test site, the Work Enhancement and Rehabilitation Center (WERC) and the Hand, Upper Extremity, and Microsurgery Center (Hand) as Control site clinics (**Table 2**). Altogether, the three sites accounted for 0.95 of total FAHC WRMSDs referred to PT/OT. Due to the nature of EH-to-Medical Care referral criteria (ex. efficient distribution, employee preference), unrelated as they were to WRMSD type or severity, little variation was expected or observed (**Table 5**) in Test and Control site subject characteristics measured at baseline (pre-treatment).

Table 2. Subject accrual by referral to PT/OT site (SORC, WERC, Hand)
--

EH-to-Medical Care. RNCMs use distribution criteria (e.g. efficient allocation among treatment sites) and employee preference (e.g. travel-to-clinic logistics) to refer employees to one of four medical care sites/types:

- Emergency Room (FAHC ER) if indicated by the injury, where patients are first seen by an ER physician, resident, nurse, or physician assistant.
- Walk In Clinic (FAHC WIC) where sub-emergency patients but with have high levels of pain are first seen by a physician who could then refer them back to EH for post-treatment follow-up PT/OT.
- Occupational Health (FAHC OH) where patients are first seen by a MD, PA, or NP.
- Primary care physicians (PCMD) for patients who prefer to be seen by their own primary care provider and staff.

Medical Care-to-PT/OT. Medical care providers refer injured employees indirectly (back through EH) or directly to PT/OT at:

- Sports and Orthopaedic Rehabilitation Center (FAHC SORC), c. 45% WRMSDs at study start.
- Work Enhancement and Rehabilitation Center (FAHC WERC), c. 50% WRMSDs at study start.
- The Hand, Upper Extremity, Microsurgery Center (FAHC Hand), c. 5% WRMSDs at study start.

Instrument and intervention. The WBOAS/FAHC pilot study instrument was constituted by parts or all of three functional health status measures: the SF-36 Health Survey, the Treatment Outcomes in Pain Survey (TOPS), and the Work Limitations Questionnaire (WLQ-27). The SF-36 Health Survey (Ware 1993), is a validated condition-generic measure composed of eight multi-item sub-scales, two of which, the ten-item PF-10 (Physical functioning) and the five-item MH-5 (behavioral health), were incorporated into the study instrument.³ The TOPS (Rogers et al. 2000; Rogers et al. 2000) is a validated condition-specific (pain) measure composed of fourteen domain sub-scales, three of which, pain symptoms, fear/avoidance, and life control/personal efficacy, were likewise incorporated.⁴ The WLQ-27 (Amick et al. 1999, 2000) is a validated condition-specific (work role performance) measure composed of four domain sub-scales (scheduling, physical, psychosocial, output demands), each of which incorporated into the study instrument. The WLQ captures an injured employee's performance comprehensively, across four types of work activity, and in a way that condition-generic measures cannot.⁵

The WBOAS/FAHC pilot study intervention combined information and action. Information side, at PT/OT in-take (pre-treatment) and at 10-14 day intervals throughout treatment, Test site subjects were asked to use a touch screen monitor to report (five to ten minutes) their current Physical function and Behavioral health (SF-36 PF-10, MH-5), Pain symptoms and related attitudes (TOPS), and Work role performance (WLQ-27 scheduling, physical, psychosocial, and output demands). Input was then instantly analyzed (by algorithm) and printed out on one page of nine corresponding bar graphs, which, by the second and third visits, contrasted trends (initial, previous, current visit). Action side, Test site PT/OTs employed (a) trends graphics to set and re-set injury recovery and return-to-work goals and (b) trends-based referral guidelines to initiate auxiliary Worksite evaluation (WSE) and Redesign (WSR) and Behavioral health care (BHC). PT/OTs were instructed by study personnel, and regularly re-instructed, on how to use trends graphics and trends-based auxiliary treatment referral guidelines. In this way, all Test site subjects received information-based PT/OT over the course of treatment, while some received trends-based WSE and WSR and/or BHC as well. WSEs checked problems related to the workstation, armrests, work surface, keyboard/mouse/monitor, document holder, footrest, workstation set-up, environment, lighting, ventilation, noise, work posture, and stretching. WSRs remedied identified problems. Remedies involved changing equipment (e.g. a new keyboard to minimize keying forces and improve working posture in patient billing, or a new lift assist or

storage area design to reduce lifting hazards in the warehouse) and/or work organization (e.g. light duty made available in shipping and receiving, or a modified work/rest schedule).⁶ For BHC, PT/OTs employed trends-based guidelines to refer employees to an OHS staff psychologist. Referral guidelines, based on published population norms, encouraged PT/OTs to refer (a) to WSE and WSR when the SF-36 PF10 trended < 50%, when TOPS Pain symptoms, Life control/personal efficacy, and Fear/avoidance trended > 50%, or when WLQ physical, scheduling, or outputs trended > 50% and (b) to BHC when SF-36 MH-5 trended < 50%, when TOPS Fear/avoidance or Life control/personal efficacy trended > 50%, or when WLQ psychosocial trended > 50%. Within 25% of these cut-offs, PT/OTs were asked to consider the respective referrals. In each instance, they were asked to discuss possible referral with the patient.

Protocol. In the WBOAS/FAHC pilot pre-study phase (30 Sept 2000-11 Feb 2001) study personnel (a) buy-in: presented the project and protocol to FAHC leadership and OHS administrators (whose approval was essential), EH RNCMs (responsible for pre-consenting eligible employees and, in the post-study phase, for assessing RTW outcomes), study site PT/OTs (responsible for recording treatment data, for treating Test site subjects according to protocol, and, in the post-study phase, for assessing IR outcomes) and staff (responsible for transmitting treatment data); (b) site preparation: trained Test and Control site providers and staff in their study roles and installed Test site touch screen, computer, and printer technology; (c) database: established subject-, therapist-, and administration-reported data collection and storage modalities and engaged and trained personnel responsible for data entry and management; (d) forms: finalized study forms, including questionnaires and data sheets; (e) logistics: settled study logistics with management, cost centers, human resources, and clinic providers and staff.

In the study phase (12 Feb 2001-24 Jan 2003), (a) pre-consent, RNCMs presented the study to prospective subjects, invited them to participate conditional upon their subsequent enrollment in PT/OT at a study site,⁷ secured the signatures of those who agreed, and transmitted the contact information of the ones of these subsequently so enrolled to the Study coordinator; (b) consent, before the first PT/OT treatment visit, the Study coordinator then contacted these, and met with those who concurred, to conduct the consent and baseline (pre-treatment) interview (consenting subjects agreed to complete baseline (pre-treatment), discharge (1 mo post-treatment follow-up), and 3 and 6 mo post-treatment follow-up questionnaires, for which they were paid \$30); (c) in-treatment, Test site subjects received Standard plus (WBOAS) care, Control site subjects Standard care alone.

In the post-study phase (25 Jan-29 May 2003) data collected throughout the study period were analyzed for the purpose of testing study hypotheses, findings were reported, and study close-out documents were drafted.

Table 3. Study measures, measurement timing	Pre-Treatment Period	Treatment Period (Intake and Treatment Visits)	Post-Treatment Period			Continuous (Pre-Post Treatment)
			One Month follow-up	Three-Month follow-up	Six Month follow-up	
Patient-reported						
1. Physical & Behavioral health: SF-12	X	X	X	X	X	
Subject psychosocial						
2. Behavioral health: SF-36 MH-5	X	X	X	X	X	
3. Fear/Avoidance: TOPS	X	X	X	X	X	
4. Life control/personal efficacy: TOPS	X	X	X	X	X	
Injury severity and co-morbidity						
5. Physical Functioning: SF-36 PF-10	X	X	X	X	X	
6. Pain: TOPS Pain symptoms, SF-36 BP-2	X	X	X	X	X	
7. Work limitations: WLQ-27	X	X	X	X	X	
8. UpperExFunction:Brigham	X		X	X	X	
9. BackFunction:Roland-Morris	X		X	X	X	
10. LowerExFunction:WOMAC	X		X	X	X	
11. UpperExSymptom:Levine-Besette	X		X	X	X	
12. BackSymptom:Modems	X		X	X	X	
13. LowerExSymptom:Modems	X		X	X	X	
14. Co-Morbidities: TIBI	X					
Subject demographics						
15. Age	X					
16. Sex	X					
17. Ethnicity	X					
18. Number of people in household	X					
19. Martial status	X					
20. Education	X					
21. Household income	X					
22. Smoking, drinking	X					
23. Length of time in job	X					
24. Get along with co-workers, supervise	X		X	X	X	
Treatment variation, performance						
25. Medications			X			
26. Non-FAHC provider visits, ex. BHC			X			
27. PCAS			X			
28. Satisfaction			X	X	X	
Work conditions						
29. JobDemands (psychsoc): JCQ	X		X	X	X	
30. Coworker/Supervisor support	X		X	X	X	
31. Job control	X		X	X	X	
Provider-reported						
Treatment variation						
32. Number of clinic visits		X				
33. PT/OT procedures		X				
34. Behavioral health referrals by PT/OT		X				
35. Other referrals by PT/OT		X				
36. Treatment other providers, NP MD		X				
37. Worksite evaluation requests		X				
38. Worksite redesign requests		X				
39. Worksite evaluations made		X				
40. Worksite redesigns made		X				
Administration-reported						
41. Study costs (direct, indirect)						X
42. Treatment costs (direct, indirect)						X

Data collection. Altogether, patient-reported, provider-reported, and administration-reported data were collected (**Table 3**). Study subjects completed baseline (pre-treatment), discharge (1 mo post-treatment follow-up), and 3 and 6 mo post-treatment follow-up questionnaires variously reporting demographics, injury severity, co-morbidities, treatment variation, psychosocial factors, and work conditions data. At 1 mo post-treatment follow-up, with treatment still fresh in mind, subjects evaluated Provider performance (PCAS). PT/OTs (and site staff) reported data on number of clinic visits, PT/OT procedures conducted over the course of treatment, WSEs and WSRs requested and made and BHC and other referrals made. And administrative systems reported WBOAS/FAHC pilot study and Test and Control site WRMSD treatment costs.

Study measures. Primary and secondary outcomes and control variables were measured, the latter to ascertain whether unmeasured differences in covariates might confound observed Intervention effects. Primary outcomes included (1) clinical: treatment period Injury recovery (IR) and post-treatment period Re-injury avoidance (RA), (2) functional: treatment period Return-to-work (RTW) and post-treatment period Stay-at-work (SAW) success, and (3) process: post-treatment period evaluated Provider performance (PP) and Overall satisfaction (OS) with care, and (4) cost: treatment or post-treatment period Cost-adjusted outcome (CaO). Secondary outcomes included treatment period (5) auxiliary care: referrals to Worksite evaluation and redesign (WSE, WSR) and to Behavioral health care (BHC). Control variables included patient-reported demographics, injury severity, co-morbidities, treatment variation, and psychosocial factors.

For clinical outcomes, IR at discharge (1 mo post-treatment follow-up) was measured by (a) appraisal of an expert panel of four OHS PT/OT and M.D. raters⁸ and (b) change in patient-reported symptom severity (SF-36 PF-10, MH-5, BP-2, TOPS Pain symptoms and related attitudes) from baseline (pre-treatment) to discharge (1 mo post-treatment follow-up); RA was measured by (a) OHS RNCM reports of patients' re-injury incidence within six months of discharge (data compiled by the Study coordinator) and (b) change in patient-reported symptom severity at discharge (1 mo post-treatment follow-up) and 3 and 6 mo post-treatment follow-up.

For functional outcomes, RTW success was measured by (a) appraisal of an expert panel of three OHS RNCM raters⁹ and (b) change in patient-reported work limitations WLQ-27 Physical, Schedule, Psychosocial, Outputs demands) from baseline (pre-treatment) to 1 mo post-treatment follow-up; SAW success was measured by (a) OHS RNCM reports of patients' Work restriction incidence within six months of discharge (data compiled by the Study coordinator) and (b) change in patient-reported work limitations at discharge (1 mo post-treatment follow-up) and 3 and 6 mo post-treatment follow-up.

For process outcomes, evaluated PP was measured at 1 mo post-treatment follow-up by the Primary Care Assessment Survey (PCAS);¹⁰ OS with care likewise by a single item satisfaction with care measure.

For cost outcomes, CaO was measured by Test subject incremental treatment outcome adjusted for incremental treatment cost. Thus were Test site compared to Control site treatment to quadruple outcome (on Physical functioning, for example) and only double cost per patient, then

cost-adjusted (CaO=4:2=2.0) it could be considered 2.0 or two times more effective *on that outcome for those subjects studied*.

For secondary outcomes, WSEs and WSRs requested and conducted and BHC referrals were measured by a simple count based on RNCM and PT/OT written reports.

For control variables, demographic data were patient-reported at baseline (pre-treatment) on age, sex, ethnicity, number of people in household, marital status, education, occupation, household income, behaviors such as drinking and smoking,¹¹ time in the job, and getting along with supervisors and co-workers; injury severity was patient-reported at baseline (pre-treatment) and post-treatment follow-up using the SF-36 PF-10 and BP-2, TOPS Pain symptoms, and WLQ-27;¹² co-morbidities were patient-reported at baseline (pre-treatment) using the Total Illness Burden Inventory (TIBI, Stier et al. 1999); treatment variation was patient-reported at post-treatment follow-up by means of patient-reported check-lists of medications, non-FAHC provider visits, evaluated Provider performance, and Overall satisfaction; psychosocial factors by using the SF-36 MH-5 and TOPS life control/personal efficacy and fear/avoidance sub-scales. Overall physical and behavioral health status was measured using the SF-12 (Ware et al. 1996).

Data analysis. Primary predictions were that, controlling for covariates such as patient-reported demographics, co-morbidities, injury severity, physical and behavioral health, work limitations, psychosocial profile, and work conditions, Test site subjects would exhibit higher rates of (1) clinical outcome: treatment period Injury recovery (IR) and post-treatment period Re-injury avoidance (RA), (2) functional outcome: treatment period Return-to-work (RTW) and post-treatment period Stay-at-work (SAW) success, and (3) process outcome: post-treatment period evaluated Provider performance (PP) and Overall satisfaction (OS) with care, at no lower rate of (4) cost outcome: treatment or post-treatment period Cost-adjusted outcome (CaO). Secondary predictions were that Test site subjects likewise would exhibit higher rates of (5) auxiliary care: treatment period referrals to Worksite evaluation and redesign (WSE, WSR) and to Behavioral health care (BHC).

Results for predictions (1)–(3) and (5) were examined descriptively to detect any unusual values or other anomalies. Baseline (pre-treatment) characteristics of Test and Control site subjects were compared using two-sample t tests for continuous variables and Fisher exact test for categorical variables. For age and income, which had too many categories for Fisher exact test, a Pearson's chi-square test was used instead. Analyses were conducted comparing Pre-intervention period Test and Control sites, when few differences were expected, and Intervention period Test and Control sites. Test and Control sites subjects were compared on the aforementioned primary and secondary outcomes and control variables. Comparison of Test and Control site subjects for expert-rated IR and RTW success, for example, was done using two-sample t tests and nonparametric Wilcoxon rank-sum tests. Because these outcomes were scaled 1-4, consistency of findings with categorical analysis was examined by dichotomizing the scales into scores of 1 and 2 (complete and near complete IR and RTW) versus 3 and 4 (partial and little or no IR and RTW). Fisher exact test was used for this analysis. Changes in outcomes from baseline (pre-treatment) to at discharge (1 mo post-treatment follow-up) and at 3 and 6 month post-treatment follow-up were compared by using two-sample t tests and Wilcoxon rank-sum tests on the

change scores. Potential confounding and interaction were assessed using stratified analysis and linear or logistic regression, respectively, for continuous and dichotomous outcomes. The Breslow-Day test for homogeneity was used to test for interaction in the stratified analysis. The Wald statistic for the interaction term was used in the regression analyses. Confounding was evaluated by examining consistency of stratified results with the un-stratified findings and by examining changes in parameter estimates in regression. Because the study had a non-randomized control, baseline (pre-treatment) group equivalence was carefully assessed. FAHC has a stable working population, thus consistent employee demographics.

Results for prediction (4) were derived by assembling data on the costs of conducting the study, of the Standard care afforded all study subjects, and of the Standard plus (WBOAS) care component of care afforded Test site subjects only. Cost estimates were used for equipment and supplies that were donated, in place already, or had multiple uses only one of which was study related. Prevailing market values were used to calculate rents (for space), project-related percentage use of an item (for equipment), and the wage value of time spent with the protocol (for personnel).

3. Results

Pre-intervention period

Site effectiveness. Due to the comparability of care offered across the three FAHC-managed OHS clinic study sites, differences in treatment effectiveness were not expected or observed between Test and Control sites in the Pre-intervention period as measured by Injury recovery (IR) or Re-injury avoidance (RA), Return to work (RTW) or Stay at work (SAW) success, evaluated Provider performance (PP) or Overall satisfaction (OS), or referrals to Worksite evaluation and Redesign (WSE and WSR) or Behavioral health care BHC) (**Table 4**). Only on the behavioral health dimension of patient-reported IR ($p=0.03$ for difference in improvement at discharge [1 mo post-treatment follow-up]), the life control/personal efficacy dimension of patient-reported RA ($p=0.05$ for difference in improvement at 6 mo post-treatment follow-up),¹³ and for provider-reported WSR requests, were significant differences observed (all in favor of Test site subjects). Considering the low numbers involved ($n=12, 20$) (for WSR requests, for example, if Test site requests had fallen just one point, from 4 to 3, the Fisher p value would have risen to 0.14) no one of these differences may be considered reliable.

Table 4. Site effectiveness (Pre-intervention period)					
	Test site		Control site		
Injury recovery: Expert-rated, baseline (pre-treatment) to discharge (1 mo post-treatment follow-up)	SORC (n=12)		WERC (n=20)		t test p value
Continuous measure	mean (sd)	2.1 (0.7)	mean (sd)	2.1 (1.1)	0.92
Dichotomous measure	no (%) 1&2	9(75%)	no (%) 1&2	13 (65%)	0.55
Injury recovery: Patient-reported, baseline (pre-treatment) to discharge (1 mo post-treatment follow-up)	SORC (n=11)		WERC (n=19)		
SF-36 physical functioning	mean (sd)	6 (23)	mean (sd)	14 (22)	0.37
SF-36 behavioral health		14 (14)		4 (11)	0.03
TOPS life control/personal efficacy		19 (22)		11 (20)	0.29
TOPS fear/avoidance		-20 (24)		-18 (29)	0.83
TOPS pain symptoms		-20 (20)		-27 (23)	0.37
Re-injury avoidance: Expert-rated	SORC (n=12)		WERC (n=20)		
New injury/re-injury baseline (pre-treatment) through 6 mo post-treatment follow-up	no (%)	4 (33%)	no (%)	2 (10%)	0.17
New injury during 6 mo post-treatment follow-up		3 (25%)		1 (5%)	0.14
Re-injury avoidance: Patient-reported, baseline (pre-treatment) to 6mo post-treatment follow-up	SORC (n=11)		WERC (n=19)		

SF-36 physical functioning	mean (sd)	14 (11)	mean (sd)	19 (18)	0.37
SF-36 behavioral health		12 (18)		4 (15)	0.19
TOPS life control/personal efficacy		33 (23)		13 (26)	0.05
TOPS fear/avoidance		-38 (31)		-27 (27)	0.31
TOPS pain symptoms		-28 (27)		-33 (28)	0.65
Return to work success: Expert-rated, baseline (pre-treatment) to 6mo post-treatment follow-up		SORC (n=11)		WERC (n=19)	
Continuous measure	mean (sd)	0.8 (1.1)	mean (sd)	1.7 (0.9)	0.72
Dichotomous measure	no (%) 1&2	8 (73%)	no (%) 1&2	14 (74%)	1.00
Return to work success: Subject-reported, baseline (pre-treatment) to discharge (1 mo post-treatment follow-up)	mean (sd)	SORC (n=11)	mean (sd)	WERC (n=19)	
WLQ physical		-17 (29)		-28 (27)	0.31
WLQ schedule		-10 (39)		-13 (48)	0.88
WLQ psychosocial		-23 (19)		-14 (39)	0.41
WLQ output		-17 (32)		-16 (42)	0.96
Stay at work success: Expert-rated		SORC (n=11)		WERC (n=20)	
Work restriction during treatment (absence, reduced hours, modified work)	no (%)	2 (18%)	no (%)	8 (40%)	0.26
Work restriction during 6 mo post-treatment follow-up (absence, reduced hours, modified work)		3 (27%)		5 (25%)	1.00
Stay at work success: Patient-reported, baseline (pre-treatment) to 6mo post-treatment follow-up	mean (sd)	SORC (n=11)	mean (sd)	WERC (n=19)	
WLQ physical		-27 (21)		-33 (26)	0.50
WLQ schedule		-9 (39)		-31 (40)	0.14
WLQ psychosocial		-20 (20)		-25 (28)	0.63
WLQ output		-10 (39)		-32 (33)	0.11
Provider performance: Patient-reported at 1mo post-treatment follow-up	mean (sd)	SORC (n=12)	mean (sd)	WERC (n=20)	
Longitudinal continuity 1 question		68 (24)		56 (24)	0.21
Visit-based continuity, 1 question		92 (10)		86 (17)	0.28
Knowledge of patient, 4 questions		73 (12)		69 (19)	0.51
Integration of care, 6 questions		79 (13)		70 (0)	0.56
Physical exam, 1 question		82 (20)		78 (19)	0.59
Interpersonal treatment 5 questions		87 (11)		82 (17)	0.44
Communication, 6 questions		88 (10)		79 (19)	0.09

Trust 8, questions	79 (11)	80 (17)	0.86
Overall satisfaction 1=best, 7=worst	1.7 (0.5)	1.9 (1.1)	0.53
PT/OT-initiated auxiliary care	no (%)	no (%)	Fisher p value
Provider-reported	SORC (n=12)	WERC (n=20)	
Behavioral health referral	2 (17%)	1 (5%)	0.54
Other referral	3 (25%)	3 (15%)	0.65
Worksite evaluation requested	4 (33%)	3 (15%)	0.38
Worksite evaluation implemented	3 (25%)	3 (15%)	0.65
Worksite redesign requested	4 (33%)	1 (5%)	0.05
Worksite redesign implemented	1 (8%)	1 (5%)	1.00
Worksite restriction requested	5 (42%)	8 (40%)	1.00
Worksite restriction implemented	5 (42%)	3 (15%)	0.12
Patient-reported	SORC (n=10)	WERC (n=18)	
Behavioral health referral	1 (10%)	1 (6%)	1.00
Other referral	2 (20%)	1 (6%)	0.28
Worksite redesign referral	2 (20%)	3 (17%)	1.00
Worksite equipment purchase	1 (10%)	3 (17%)	1.00

Intervention period

Subject characteristics (Pre-treatment). Because WBOAS/FAHC pilot study Test and Control sites served the same employee population, and clinic assignment occurred by convenience, little variation was expected or found in study subjects' characteristics at baseline (pre-treatment) (Table 5). Making the largest sample size comparison—that between the Test site in the Intervention period (SORC) and all Non-intervention sites (SORC in the Pre-intervention period plus WERC and Hand in the Intervention period)—few differences were observed on patient-reported demographics, injury severity, co-morbidities, treatment variation, psychosocial factors, physical and behavioral health status. Only on injury severity (SF-36 PF-10 Physical functioning, $p < 0.01$, to the detriment of Test site subjects) and just four of sixty-four measured co-morbid states were significant differences observed.

	Test site	Control site	
Intervention period test site vs all Non-intervention sites	SORC (n=83)	SORC/WERC/Hand (n=95)	t test p value
Demographics	no (%)	no (%)	
Age			

<35	29 (35%)	27 (29%)	0.72
35-39	11 (13%)	13 (14%)	
40-44	10 (12%)	19 (20%)	
45-49	11 (13%)	10 (11%)	
50-54	16 (19%)	15 (16%)	
55-59	5 (6%)	6 (6%)	
60-64	1 (1%)	3 (3%)	
Sex (female)	61 (73%)	79 (84%)	0.10
Race (white)	76 (92%)	90 (97%)	0.59
Persons in household (including self)			
1	15 (18%)	12 (13%)	0.70
2	23 (28%)	32 (34%)	
3-5	41 (49%)	44 (47%)	
>5	4 (5%)	5 (5%)	
Marital status			
Married	40 (48%)	53 (57%)	0.45
Living together	9 (11%)	13 (14%)	
Separated	3 (4%)	1 (1%)	
Divorced	15 (18%)	12 (13%)	
Widowed	1 (1%)	3 (3%)	
Never married	15 (18%)	11 (12%)	
Household income last year			
Less than \$10,000	2 (2%)	1 (1%)	0.50
\$10,000-\$19,999	6 (7%)	5 (5%)	
\$20,000-\$29,999	14 (17%)	18 (20%)	
\$30,000-\$39,999	15 (19%)	19 (21%)	
\$40,000-\$49,999	10 (12%)	12 (13%)	
\$50,000-\$59,999	6 (7%)	13 (14%)	
\$60,000-\$69,999	15 (19%)	7 (8%)	
\$70,000-\$79,999	4 (5%)	7 (8%)	
\$80,000 or more	9 (11%)	9 (10%)	
Smoking habits			
Never	33 (40%)	40 (43%)	0.56
Former	29 (35%)	32 (34%)	
<1 pack/day	11 (13%)	16 (17%)	
1 to <2 packs/day	10 (12%)	6 (6%)	
2+ packs/day	0 (0%)	0 (0%)	
Alcohol consumption			
Never	20 (24%)	18 (19%)	0.30
Occasional social drink	59 (71%)	66 (70%)	
1-3 drinks/day	4 (5%)	10 (11%)	

4+ drinks/day	0 (0%)	0 (0%)	
Get along with coworkers			
Poorly	0 (0%)	0 (0%)	0.27
Fairly	2 (2%)	1 (1%)	
Well	6 (7%)	15 (16%)	
Very well	46 (55%)	51 (54%)	
Excellently	29 (35%)	27 (29%)	
Get along with team leader			
Poorly	1 (1%)	1 (1%)	0.32
Fairly	2 (2%)	6 (6%)	
Well	9 (11%)	17 (18%)	
Very well	42 (51%)	46 (49%)	
Excellently	29 (35%)	24 (26%)	
	mean(sd)	mean(sd)	p value
Highest grade completed	13.7 (1.8)	13.5 (1.7)	0.47
Years employed at FAHC	5.8 (6.1)	5.4 (6.1)	0.63
Injury severity	mean (sd)	mean (sd)	
SF-36 physical functioning	59 (29)	70 (21)	<0.01
SF-36 BP-2	41 (22)	41 (22)	0.72
TOPS pain symptoms	56 (18)	57 (18)	0.49
Co-morbidities	no (%)	no (%)	
WRMSD in 6 mo prior to “study” injury	7 (8%)	10 (11%)	0.80
TIBI: No significant differences across 64 TIBI items but for:			
Tingling/burning feet (none of time)	65 (79%)	82 (87%)	0.03
Rapid heart beat past 4 wks, none of time	61 (74%)	80 (85%)	0.02
Seasonal allergy past 4 wks, none of time	42 (51%)	67 (71%)	0.04
Blood pressure medication, yes	14 (17%)	6 (6%)	0.03
Psychosocial			
TOPS life control/personal efficacy	67 (24)	67 (18)	0.90
TOPS fear/avoidance	60 (22)	61 (19)	0.89
Physical/behavioral health status			
SF-12 physical health	37 (9)	38 (9)	0.57
SF-12 behavioral health	52 (11)	53 (9)	0.36
Work limitations			
WLQ physical	43 (30)	41 (25)	0.67
WLQ schedule	32 (31)	34 (29)	0.79
WLQ psychosocial	21 (25)	23 (26)	0.56
WLQ output	31 (29)	38 (30)	0.12

Primary Predictions

Clinical outcomes

H:1.1. Compared to Standard care, Standard plus (WBOAS) subjects will exhibit higher rates of treatment period **Injury recovery (IR)**.

Expert-rated, the Intervention does not appear to have affected (with prediction) baseline (pre-treatment) to discharge (1 mo post-treatment follow-up) IR assessed either as a continuous (1-4) or a dichotomous (percent scored 1&2 vs 3&4) variable (**Table 6**, and endnote 8). Thus there was no significant difference found between Intervention period Test and Control site IR (continuous: mean 2.1 vs 2.2 $p=0.71$; dichotomous: percent scored 1&2 vs 3&4 69 vs 70 $p=1.00$) or between the Test site in the Intervention period and all Non-intervention study sites (continuous: mean 2.1 vs 2.1 $p=0.86$; dichotomous: percent scored 1&2 vs 3&4 69 vs 70 $p=1.00$).

Table 6. Injury recovery, expert-rated: Baseline (pre-treatment) to Discharge (1 mo post-treatment follow-up)			
	Test site	Control site	
Continuous score (1-4)	mean (sd)	mean (sd)	t test p value
Intervention period test vs control sites	SORC (n=83)	WERC (n=60)	
	2.1 (0.8)	2.2 (0.8)	0.71
Intervention period test site vs all Non-intervention sites	SORC (n=83)	SORC/WERC/Hand (n=92)	
	2.1 (0.8)	2.1 (0.9)	0.86
Dichotomous score (1&2 vs 3&4)	no (%) 1&2	no (%) 1&2	
Intervention period test vs control sites	SORC (n=83)	WERC (n=60)	
	57 (69%)	42 (70%)	1.00
Intervention period test site vs all Non-intervention sites	SORC (n=83)	SORC/WERC/Hand (n=92)	
	57 (69%)	64 (70%)	1.00

But the Intervention does appear to have affected (with prediction) baseline (pre-treatment) to discharge (1 mo post-treatment follow-up) IR for men. Stratifying by sex, and comparing the Intervention period Test site to all Non-intervention sites, Test site men do exhibit significantly higher IR than Control site men (continuous: mean 2.0 vs 2.6 [n=22, 15] $p=0.05$; dichotomous: percent scored 1&2 vs 3&4 77 vs 47 $p=0.08$), though for the women there is no such contrast (continuous: mean 2.1 vs 2.0 [n=61, 76] $p=0.47$; dichotomous: percent scored 1&2 vs 3&4 66 vs 74 $p=0.35$) (see endnote 8). The p value (0.03) for the different Intervention effect for men and women is likewise significant. That men were under-enrolled in the study may explain the lack of an overall Intervention effect, as results disproportionately reflect women's outcomes.

That Intervention period Test site subjects exhibited lower baseline (pre-treatment) Physical functioning (SF-36 PF-10) than all Non-intervention Control site subjects raises the possibility that their greater improvement post-treatment may have been due to that lower starting point, not to treatment modality. But secondary analysis revealed no evidence of such confounding or interaction between IR and baseline (pre-treatment) Physical functioning for men or for women. The Intervention effect observed for men did not change when controlling either for baseline (pre-treatment) SF-36 PF-10--there is no differential effect for those with low versus high baseline (pre-treatment) Physical functioning--or for demographics including age, number in household, marital status, education, income, or years employed at FAHC. Race had a distribution too skewed for stratified analysis.

Only for smoking was a differential effect observed, such that the Intervention appears more effective for smokers, less effective for non-smokers. Thus though numbers fall within cells, a positive Intervention effect was found, comparing the Intervention period Test site to all Non-intervention sites, in men who smoke. Significantly more Test site men who smoked than Control site men who smoked were rated as 1 or 2 on IR (13/16 0.81 vs 4/10 0.40 p=0.05). Conversely, a negative Intervention effect was found for nonsmoking Test and Control site women (17/27 0.63 vs. 29/33 0.88 p=0.03). For male nonsmokers and female smokers, Test and Control sites subjects barely differed by percent scored 1 or 2. It could be hypothesized that the Intervention is particularly effective in men who smoke because this is the sub-group that least looks after its health, thus the one the Intervention prompts most to do so, contrariwise for female nonsmokers.

Patient-reported, the Intervention does appear to have affected (with prediction) baseline (pre-treatment) to discharge (1 mo post-treatment follow-up) IR as assessed by the SF-36 PF-10 (Physical functioning) and the TOPS life control/personal efficacy sub-scale, in each instance favoring Test site subjects, though not as assessed by the SF-36 BP-2 (bodily pain) and MH-5 (behavioral health) and TOPS pain symptoms and fear/avoidance sub-scales (**Table 7**). Thus significant or near significant differences were found between Intervention period Test and Control site IR in Physical functioning (p=0.01 for difference in mean improvement at discharge [1 mo post-treatment follow-up]) and in life control/personal efficacy (p=0.08 for difference in mean improvement at discharge [1 mo post-treatment follow-up]). A significant difference was likewise found between the Test site in the Intervention period and all Non-intervention study sites in Physical functioning (p=0.01 for difference in mean improvement at discharge [1 mo post-treatment follow-up]).

Table 7. Injury recovery, patient-reported: Baseline (pre-treatment) to Discharge (1 mo post-treatment follow-up) *			
	Test site	Control site	
	mean (sd)	mean (sd)	t test p value
Intervention period test vs control sites	SORC (n=75)	WERC (n=53)	
SF-36 physical functioning	22 (27)	12 (19)	0.01

SF-36 behavioral health	3 (16)	0 (16)	0.35
TOPS life control/personal efficacy	11 (23)	4 (22)	0.08
TOPS fear/avoidance	-24 (29)	-20 (25)	0.52
TOPS pain symptoms	-22 (25)	-25 (24)	0.51
Intervention period test site vs all Non-intervention sites	SORC (n=75)	SORC/WERC/Hand (n=83)	
SF-36 physical functioning	22 (27)	11 (20)	0.01
SF-36 behavioral health	3 (16)	3 (15)	0.95
TOPS life control/personal efficacy	11 (23)	8 (22)	0.29
TOPS fear/avoidance	-24 (29)	-20 (26)	0.40
TOPS pain symptoms	-22 (25)	-24 (23)	0.47
* Means are [X month] - [baseline (pre-treatment)], where X=1 mo post-treatment follow-up			

Again, that Intervention period Test site subjects exhibited lower baseline (pre-treatment) Physical functioning (SF-36 PF-10) than Control site subjects raises the possibility that their greater improvement post-treatment may have been due to that lower starting point. If lower functioning subjects were to improve more than higher functioning subjects regardless of treatment modality, then the Intervention could not be deemed the agent of that greater improvement. And in fact, across all study sites, subjects with baseline (pre-treatment) SF-36 PF-10 scores below 70 were observed to improve more than those with baseline (pre-treatment) scores of 70 or above (mean improvement of 29 vs 6 at discharge [1 mo post-treatment follow-up], 32 vs 8 at 3 mo and 33 vs 9 at 6 mo post-treatment follow-up, all $p < 0.0001$). And yet multiple linear regression reveals a significant interaction between study site (test and control) and baseline (pre-treatment) SF-36 PF-10 score on improvement seen at discharge (1 mo post-treatment follow-up) and 3 and 6 mo post-treatment follow-up (interaction p values=0.08, 0.05, 0.01 respectively). Thus especially for patients with low baseline (pre-treatment) Physical functioning the Intervention is an agent of greater improvement.

According to the 1 mo “interaction” model (Table 8), considering subjects with baseline (pre-treatment) SF-36 PF-10 values of 25, 50, and 75, those at the Test site “out-improved” those at Control sites, respectively, by 13, 8, and 3 points, at discharge (1 mo post-treatment follow-up). At each level of baseline (pre-treatment) Physical functioning, i.e. controlling for differences in injury severity, Test site subjects show greater improvement post-treatment. And the lower the level of baseline (pre-treatment) Physical functioning, the greater the difference in improvement is between Test and Control site subjects, i.e. the more the Intervention is effective. Stratifying by sex, the effect is somewhat stronger for men than women, but the difference is not statistically significant. Findings at 3 and 6 month post-treatment follow-up are consistent with this. Again, the Intervention effect did not change when controlling for the aforementioned demographics.

Pre-treatment PF-10 score	Test site subjects at discharge (1 mo post-treatment follow-up)	Control site subjects at discharge (1 mo post-treatment follow-up)	Improvement difference
25	44	31	13

50	28	20	8
75	12	9	3

H:1.2. Compared to Standard care, Standard plus (WBOAS) subjects will exhibit higher rates of post-treatment period **Re-injury avoidance (RA)**.

Expert-rated, the Intervention does appear to have affected (with prediction) 1 to 6 mo post-treatment follow-up RA as assessed by New injury/re-injury incidence baseline (pre-treatment) through 6 mo post-treatment follow-up and by New injury during 6 mo post-treatment follow-up (**Table 9**). Thus between the Test site in the Intervention period and all Non-intervention study sites a significant difference was found for New injury/re-injury incidence baseline (pre-treatment) through 6 mo post-treatment follow-up period (0.05 vs 0.15 $p=0.04$) as well as a near significant difference for New injury incidence during the 6 mo post-treatment follow-up period (0.04 vs 0.12 $p=0.06$), in each instance in favor of Test site subjects. That no such difference was found in these same subjects' WRMSD incidence in the 6 mo prior to their "study" WRMSD (**Table 5**, Co-morbidities) bolsters the view that the Intervention contributed to the difference in observed RA.

	Test site	Control site	Fisher p value
	no (%)	no (%)	
Intervention period test site vs all Non-intervention sites	SORC (n=83)	SORC/WERC/Hand (n=95)	
New injury/re-injury baseline (pre-treatment) through 6 mo post-treatment follow-up	4 (5%)	14 (15%)	0.04
New injury during 6 mo post-treatment follow-up	3 (4%)	11 (12%)	0.06

Stratified analysis and logistic regression were used to investigate whether higher Test site RA might be due to confounding by differences observed in baseline (pre-treatment) Physical functioning, sex, pre-study WRMSD, or work restrictions, where differences between groups, albeit non-significant, were observed. There was no evidence for such individual confounding. Not only did the Intervention effect not disappear, it became stronger when controlling for all these variables simultaneously ($p=0.02$ for Intervention effect for New injury during the 6 mo post-treatment follow-up period per se, $p=0.01$ for New injury/re-injury baseline [pre-treatment] to 6 mo post-treatment follow-up). And, though across sites men were found more likely than women to be injured/re-injured during treatment through 6 mo post-treatment follow-up (**Table 10**), between sites male and female Test site subjects alike were injured/re-injured less than male and female Control site subjects, likewise bolstering the view that the Intervention contributed to the difference in observed RA.

	Males (n=37)	Females (n=140)	t test
--	--------------	-----------------	--------

	no (%)	no (%)	p value
New injury/re-injury treatment through 6 mo post-treatment follow-up	8 (22%)	10 (7%)	0.03
New injury during 6 mo post-treatment follow-up	6 (16%)	8 (6%)	0.08

Neither effect, moreover, appears to be a time period artifact. In the Pre-intervention period, though numbers are small, the Test site (SORC) does not have a lower Re-injury rate than the Control site (WERC). But in the Intervention period, the magnitude of the difference between the Intervention period test (SORC) and control (WERC/HAND) sites is virtually the same—0.04 vs 0.11 ($p=0.10$) for New injury during 6 mo post-treatment follow-up and 0.05 vs 0.13 ($p=0.13$) for New/re-injury baseline (pre-treatment) through 6 mo post-treatment follow-up—as that between the Intervention period Test site (SORC) and all Non-intervention sites (which include Pre-intervention period Test site subjects) reported in **Table 9**.

Finally, for the Intervention to have a) reduced the incidence of New injury/re-injury baseline (pre-treatment) through 6 mo post-treatment follow-up and of New injury during 6 mo post-treatment and b) improved Physical functioning (especially for those with low Physical functioning at baseline (pre-treatment), but (at least for women) c) not improved IR (or RTW success, as below, for men and women) would seem anomalous (when co-variation might be expected) were it not for the fact that IR (and RTW success) was judged at the end of treatment, while most of the injuries occurred during 6 mo post-treatment follow-up, not during treatment. Thus three of four Test site and eleven of fourteen Control site subject injuries were new injuries during that follow-up period.

Patient-reported, the Intervention likewise appears to have affected (with prediction) post-treatment (through 6 mo post-treatment follow-up) RA as assessed by the SF-36 PF-10 (Physical functioning), though not as assessed by the SF-36 BP-2 (bodily pain) and MH-5 (behavioral health) and the TOPS pain, life control/personal efficacy, and fear/avoidance sub-scales (**Table 10**). Thus near significant or significant differences were found between Intervention period Test and Control site RA in Physical functioning ($p=0.10$ and 0.12 for difference in mean improvement at 3 and 6 mo) and between the Test site in the Intervention period and all Non-intervention study sites ($p=0.05$ and 0.07 for difference in mean improvement at 3 and 6 mo), in each instance in favor of Test site subjects. Stratifying by sex, the effect is again somewhat stronger for men than women, though the difference is not statistically significant.

	Test site	Control site	t test p value
	mean (sd)	mean (sd)	
Intervention period test vs control sites	SORC (n 3 mo=71 n 6 mo=68)	WERC (n 3 mo=50 n 6 mo=40)	
SF-36 physical functioning 3 mo	23 (26)	15 (22)	0.10
SF-36 physical functioning 6 mo	24 (28)	15 (22)	0.12

SF-36 behavioral health 3 mo	6 (20)	2 (13)	0.13
SF-36 behavioral health 6 mo	5 (21)	3 (15)	0.71
TOPS life control/personal effic'y 3 mo	14 (25)	9 (21)	0.22
TOPS life control/personal effic'y 6 mo	14 (19)	8 (24)	0.24
TOPS fear/avoidance 3 mo	-28 (30)	-30 (26)	0.73
TOPS fear/avoidance 6 mo	-32 (27)	-25 (30)	0.20
TOPS pain symptoms 3 mo	-29 (24)	-33 (26)	0.41
TOPS pain symptoms 6 mo	-29 (24)	-33 (27)	0.44
Intervention period test site vs all Non-intervention sites	SORC (n 3 mo=71 n 6 mo=68)	SORC/WERC/Hand (n 3 mo=80 n 6 mo=70)	
SF-36 physical functioning 3 mo	23 (26)	15 (20)	0.05
SF-36 physical functioning 6 mo	24 (28)	16 (20)	0.07
SF-36 behavioral health 3 mo	6 (20)	3 (14)	0.22
SF-36 behavioral health 6 mo	5 (21)	5 (16)	0.97
TOPS life control/personal effic'y 3 mo	14 (25)	13 (22)	0.68
TOPS life control/personal effic'y 6 mo	14 (19)	13 (26)	0.93
TOPS fear/avoidance 3 mo	-28 (30)	-31 (25)	0.64
TOPS fear/avoidance 6 mo	-32 (27)	-27 (29)	0.34
TOPS pain symptoms 3 mo	-29 (24)	-30 (26)	0.74
TOPS pain symptoms 6 mo	-29 (24)	-32 (27)	0.49
* Means are [X month] - [baseline (pre-treatment)], where X=3 or 6 mo post-treatment follow-up			

Functional outcomes

H:2.1. Compared to Standard care, Standard plus (WBOAS) subjects will exhibit higher rates of treatment period **Return to work (RTW)** success.

Expert-rated, the Intervention does not appear to have affected (with prediction) baseline (pre-treatment) to discharge (1 mo post-treatment follow-up) RTW success assessed either as a continuous (1-4) or as a dichotomous (1&2 vs 3&4) variable (**Table 12** and endnote 9). In fact by the former assessment a near significant difference was found between Intervention period Test and Control site RTW success (continuous: mean 1.8 vs 1.5 p=0.06) to the detriment of Test site subjects. The same trend by the same assessment was found in RTW success between the Test site in the Intervention period and all Non-intervention study sites (continuous: mean 1.8 vs 1.6 p=0.16) to the same detriment.

	Test site	Control site	T test p value
Continuous score	mean (sd)	mean (sd)	
Intervention period test vs control sites	SORC (n=78)	WERC (n=60)	

	1.8 (1.0)	1.5 (0.8)	0.06
Intervention period test site vs all Non-intervention sites	SORC (n=78)	SORC/WERC/Hand (n=90)	
	1.8 (1.0)	1.6 (0.8)	0.16
Dichotomous score	no (%) scored 1&2	no (%) scored 1&2	
Intervention period test vs control sites	SORC (n=78)	WERC (n=60)	
	60 (77%)	50 (83%)	0.40
Intervention period test site vs all Non-intervention sites	SORC (n=78)	SORC/WERC/Hand (n=90)	
	60 (77%)	72 (80%)	0.71

But again, as for IR, the Intervention may have affected (with prediction) baseline (pre-treatment) to discharge (1 mo post-treatment follow-up) RTW success for men, though the finding is not statistically significant as it was for IR, and thus there is only a trend. Stratifying by sex, and comparing the Intervention period Test site to all Non-intervention sites, Test site men do exhibit RTW success higher than Control site men (dichotomous: percent scored 1&2 vs 3&4 86 vs 71 $p=0.41$; continuous: mean 1.57 vs 1.64 $p=0.80$), though for the women there is no such contrast (dichotomous: percent scored 1&2 vs 3&4 74 vs 81 $p=0.30$, continuous: mean 1.8 vs 1.6 $p=0.10$) (see endnote 9). The p value ($p=0.16$) for the different Intervention effect for men and women admits the same trend. That men were under-enrolled in the study may again explain the lack of an overall Intervention effect, as results disproportionately reflect women's outcomes. Again, the Intervention effect observed for men did not change when controlling either for baseline (pre-treatment) SF-36 PF-10--there is no differential effect for those with low versus high baseline (pre-treatment) Physical functioning--or for demographics including age, number in household, marital status, education, income, or years employed at FAHC. Race had a distribution too skewed for stratified analysis.

And again, only for smoking was a differential effect observed, such that the Intervention appears more effective for smokers, less effective for non-smokers. Thus though numbers fall within cells, a positive Intervention effect was found, comparing Intervention period Test and Control sites, in men who smoke. More Test site men who smoked than Control site men who smoked were rated 1 or 2 on RTW (13/15 0.87 vs 5/9 0.56 $p=0.15$). Conversely, a negative Intervention effect was found for nonsmoking Test and Control site women (20/25 0.80 vs 33/35 0.94 $p=0.12$). For male nonsmokers and female smokers, Test and Control sites subjects barely differed by percent scored 1 or 2. It could be hypothesized again that the Intervention is particularly effective in men who smoke because this is the sub-group that least looks after its health, thus the one the Intervention prompts most to do so; and contrariwise for female nonsmokers.

Patient-reported, the Intervention does not appear either to have affected (with prediction) baseline (pre-treatment) to discharge (1 mo post-treatment follow-up) RTW success as assessed by the WLQ scheduling, physical, psychosocial, and output sub-scales (**Table 13**). Uniformly there were no significant differences found in RTW success between Intervention period Test

and Control sites or between the Test site in the Intervention period and all Non-intervention study sites.

Table 13. Return to work success, patient-reported: Baseline (pre-treatment) to Discharge (1 mo post-treatment follow-up)*

	Test site	Control site	
	mean (sd)	mean (sd)	t test p value
Intervention period test vs control sites	SORC (n=75)	WERC (n=53)	
WLQ physical	-22 (28)	-20 (24)	0.66
WLQ schedule	-16 (30)	-17 (26)	0.79
WLQ psychosocial	-13 (25)	-12 (26)	0.82
WLQ output	-15 (29)	-17 (31)	0.82
Intervention period test site vs all Non-intervention sites	SORC (n=75)	SORC/WERC/Hand (n=83)	
WLQ physical	-22 (28)	-21 (25)	0.85
WLQ schedule	-16 (30)	-15 (34)	0.93
WLQ psychosocial	-13 (25)	-14 (29)	0.84
WLQ output	-15 (29)	-17 (34)	0.81

* Means are [X month] - [baseline (pre-treatment)], where X=1 mo post-treatment follow-up

H:2.2. Compared to Standard care, Standard plus (WBOAS) subjects will exhibit higher rates of treatment period **Stay at work (SAW)** success.

Expert-rated, the Intervention does not appear to have affected (with prediction) 1 to 6 mo post-treatment follow-up SAW success as assessed by the incidence of any Work restriction during 6 mo post-treatment follow-up (**Table 14**). In fact between the Test site in the Intervention period and all Non-intervention study sites a near significant difference was found for Work restriction (absence, reduced hours, work modification) in the 1 to 6 mo post-treatment follow-up period (0.60 vs 0.48 p=0.16) to the detriment of Test site subjects.

Table 14. Stay at work success, expert-rated: Baseline (pre-treatment) to 6 mo post-treatment follow-up

	Test site	Control site	
	no (%)	no (%)	Fisher p value
Intervention period test site vs all Non-intervention sites	SORC (n=83)	SORC/WERC/Hand (n=95)	
Any work restriction during treatment (Absent, reduced hours, or modified work)	59 (74%)	51 (57%)	0.02
Any work restriction* during 6 mo post-treatment follow-up	43 (60%)	42 (48%)	0.16

* Absence, reduced hours, or modified work.

And yet the effect (against prediction) appears to be a time period artifact. If instead of the Intervention period test site vs all Non-intervention sites (including the Pre-intervention period Test site) comparison, the “Intervention period only” comparison is made, the difference disappears. The reason is that there were proportionately more work restrictions during the Intervention than during the Pre-intervention period for both the Test and Control sites (Table 15). Indeed, the Pre-intervention vs Intervention period increase from 27 percent to 60 percent for the Test site (SORC vs SORC) is near significant ($p=0.06$) and that from 25 percent to 61 percent for the Control site (WERC vs WERC/HAND) is significant ($p=0.01$). A similar trend is seen for work restrictions during treatment. The Intervention period increase in work restrictions at both Test and Control sites may well be explained by an Intervention-induced improvement in record keeping on the part of RNCMs rather than by any increase in actual restrictions.

	Test site	Control site	t test p value
	no (%)	no (%)	
Pre-intervention period	SORC (n=11)	WERC (n=20)	
Any work restriction due to injury* during 6 mo post-treatment follow-up	3 (27%)	5 (25%)	$p=1.00$
Intervention period	SORC (n=72)	WERC/HAND (n=56)	
Any work restriction due to injury* during 6 mo post-treatment follow-up	43 (60%)	34 (61%)	$p=1.00$
Absence from work, reduced hours, or modified work			

Looking just at Days absent from work due to injury 1 to 6 mo post-treatment follow-up (Table 16) and (because only 14 percent of all study subjects had one or more such days absent) scoring 0 vs 1 or more days absent, significantly more Test site subjects had one or more days absent due to injury comparing both Intervention period Test vs Control sites and Intervention period Test site vs all Non-intervention sites (because there is a significant difference also for Intervention period Test vs Control sites, the effect is not a time period artifact). Contrary to expectation therefore—that if there were significantly fewer New injuries/re-injuries in Test site subjects there would also be fewer with Days absent from work due to injury—there is actually little relationship between the two. Of those with New injury/re-injury, 3 (0.17) had 1 or more days absent, while of those without New injury/re-injury, 20 (0.14) had 1 or more days absent ($p=0.71$). The difference between Test and Control site subjects appears to be at least partly due to the baseline (pre-treatment) difference in SF-36 PF-10, since when controlling for this difference, the p value changes from 0.04 to 0.40. But the direction of the effect after controlling is still the same. The Intervention appears not to have lead to a reduced number of Days absent due to injury during 6 mo post-treatment follow-up. Test site subjects may have been made more conscious of resting their injuries by the information component (touchscreen-generated outcomes trends graphics contrasting initial, previous, and current visits on Physical and Behavioral health status, Pain symptoms and related attitudes, and Work role limitations) of Standard plus (WBOAS) care, leading to more Days absent from work.

	Test site	Control site	
	no (%)	no (%)	t test p value
1+ days absent due to injury			
Pre-intervention sites	SORC	WERC	
	3 (27%)	1 (5%)	0.12
Intervention period test vs control sites	SORC	WERC/Hand	
	15 (21%)	4 (7%)	0.04
Intervention period test site vs all Non-intervention sites	SORC	SORC/WERC/Hand	0.04
	15 (21%)	8 (9%)	

Patient-reported, the Intervention does not appear either to have affected post-treatment (through 6 mo post-treatment follow-up) follow-up SAW success as assessed by the WLQ scheduling, physical, psychosocial, and output sub-scales (Table 17). Uniformly there were no significant differences found in SAW success between Intervention period Test and Control sites or between the Test site in the Intervention period and all Non-intervention study sites.

	Test site	Control site	
	mean (sd)	mean (sd)	t test p value
Intervention period test vs control sites	SORC (n 3 mo=71 n 6 mo=68)	WERC (n 3 mo=50 n 6 mo=40)	
WLQ physical 3 mo	-27 (27)	-23 (25)	0.41
WLQ physical 6 mo	-27 (28)	-26 (27)	0.74
WLQ schedule 3 mo	-19 (30)	-21 (28)	0.79
WLQ schedule 6 mo	-22 (27)	-24 (32)	0.75
WLQ psychosocial 3 mo	-14 (25)	-11 (23)	0.52
WLQ psychosocial 6 mo	-13 (24)	-17 (27)	0.51
WLQ output 3 mo	-18 (30)	-21 (32)	0.63
WLQ output 6 mo	-20 (27)	-28 (32)	0.19
Intervention period test site vs all Non-intervention sites	SORC (n 3 mo=71 n 6 mo=68)	SORC/WERC/Hand (n 3 mo=80 n 6 mo=70)	
WLQ physical 3 mo	-27 (27)	-26 (25)	0.81
WLQ physical 6 mo	-27 (28)	-28 (26)	0.93
WLQ schedule 3 mo	-19 (30)	-22 (36)	0.60
WLQ schedule 6 mo	-22 (27)	-24 (32)	0.81
WLQ psychosocial 3 mo	-14 (25)	-14 (25)	0.95
WLQ psychosocial 6 mo	-13 (24)	-19 (26)	0.15

WLQ output 3 mo	-18 (30)	-23 (32)	0.35
WLQ output 6 mo	-20 (27)	-26 (34)	0.25
* Means are [X month] - [baseline (pre-treatment)], where X=3 or 6 mo post-treatment follow-up			

Process outcomes

H:3.1. Compared to Standard care, Standard plus (WBOAS) subjects will exhibit higher rates of evaluated **Provider performance (PP)** at 1 mo post-treatment follow-up.

Patient-reported, the Intervention does appear to have affected (with prediction) evaluated PP at discharge (1 mo post-treatment follow-up) as assessed by several of the eight PCAS sub-scales (**Table 18**). Thus though no significant differences were found between Intervention period Test and Control site evaluated PP, the differences that were observed were all (except for Longitudinal continuity) in favor of Test site subjects, though this was also the case in the Pre-intervention period. Comparing the Test site in the Intervention period and all Non-intervention study sites, observed differences again all favor Test site subjects (significantly so for Physical exam: mean improvement of 0.87 vs 0.81 p=0.05), except for Longitudinal continuity (mean improvement of 0.44 vs 0.52 p=0.05, to the detriment of Test site subjects).

	Test site	Control site	
	Mean (sd)	mean (sd)	t test p value
Intervention period test vs control sites	SORC (n=82)	WERC (n=61)	
Longitudinal continuity (1 question)	44 (23)	48 (28)	0.43
Visit-based continuity (1 question)	85 (27)	82 (33)	0.59
Knowledge of patient (4 questions)	72 (18)	66 (21)	0.11
Integration of care (6 questions)	78 (19)	76 (23)	0.78
Physical exam (1 question)	87 (18)	81 (23)	0.16
Interpersonal treatment (5 questions)	89 (13)	86 (16)	0.30
Communication (6 questions)	86 (18)	83 (20)	0.36
Trust (8 questions)	81 (15)	78 (17)	0.26
Intervention period test site vs all Non-intervention sites	SORC (n=82)	SORC/WERC/Hand (n=93)	
Longitudinal continuity (1 question)	44 (23)	52 (27)	0.05
Visit-based continuity (1 question)	85 (27)	84 (28)	0.85
Knowledge of patient (4 questions)	72 (18)	68 (19)	0.17
Integration of care (6 questions)	78 (19)	76 (21)	0.80
Physical exam (1 question)	87 (18)	81 (22)	0.05
Interpersonal treatment (5 questions)	89 (13)	85 (15)	0.13

Communication (6 questions)	86 (18)	82 (19)	0.26
Trust (8 questions)	81 (15)	78 (17)	0.29

And the Intervention appears to have affected (with prediction) evaluated PP for men. Comparing the Test site in the Intervention period and all Non-intervention study sites, significant or near significant differences were found not only on Physical exam but also on Knowledge of patient (mean improvement of 0.80 vs 0.59 p=0.01), Interpersonal treatment (mean improvement of 0.90 vs 0.80 p=0.10), and Communication (mean improvement of 0.90 vs 0.78 p=0.10).

These effects, for all subjects and for subjects by sex, do not appear to be time period artifacts. In the Pre-intervention period, though numbers are small, Test and Control site subjects have Physical exam means (82 for SORC and 78 for WERC p=0.59) comparable to those they have in the Intervention period. And in the Intervention period the same comparability on Physical exam obtains between Intervention period Test and Control sites (87 vs 81 p=0.05) and the Intervention period Test site and all Non-intervention sites (87 vs 81 p=0.16). For the effects by sex, though numbers are even smaller in the Pre-Intervention period, results in the Intervention period are essentially the same as those for all subjects.

Stratifying PCAS results by baseline (pre-treatment) Physical functioning (SF-36 PF-10), a counter-trend was found to the Intervention's observed effect to increase Physical functioning more in subjects with low (than high) baseline (pre-treatment) SF-36 PF-10 scores. Thus there were PCAS differences more for those with high (than low) baseline (pre-treatment) Physical functioning. Why those who experienced less rather than more relative improvement in physical function would more positively evaluate PP is not clear. Perhaps those less severely limited are less troubled by their injury and thus easier to please.

H:3.2. Compared to Standard care, Standard plus (WBOAS) subjects will exhibit higher rates of **Overall satisfaction** with care (OS) at discharge (1 mo post-treatment) follow-up).

Patient-reported, the Intervention does not appear to have affected OS with care at discharge (1 mo post-treatment follow-up) as assessed by the single-item Satisfaction with care question (Table 19). No significant differences were found between Intervention period Test and Control site OS, though differences went in the predicted direction. As for evaluated PP, so for OS with care the same counter-trend obtained, such that there were OS with care differences more for those with high (than low) baseline (pre-treatment) SF-36 PF-10 scores.

	Test site	Control site	
Satisfaction (1=best -- 7=worst)	mean (sd)	Mean (sd)	t test p value
Pre-intervention period	SORC (n=12)	WERC (n=20)	
	1.7 (0.5)	1.9 (1.1)	0.53
Intervention period test vs control	SORC	WERC	

sites	(n=8)	(n=61)	
	1.6 (1.0)	1.8 (1.0)	0.22
Intervention period test site vs all Non-intervention sites	SORC (n=82)	SORC/WERC/Hand (n=93)	
	1.6 (1.0)	1.8 (1.0)	0.20

Cost outcomes

H:4. Standard plus (WBOAS) subjects will exhibit **Cost-adjusted outcome** (CaO) rates that are no lower than those of Standard care subjects.

Cost-adjusted outcome (CaO) is incremental treatment outcome adjusted for incremental treatment cost. In a controlled trial, for example, were Test site compared to Control site treatment to double outcome but double cost as well per patient, then cost-adjusted ($CaO=2:2=1.0$) there would be no net gain. But if it were to quadruple outcome and only double cost per patient, then cost-adjusted ($CaO=4:2=2.0$) it could be considered 2.00 (two times) or 100 percent more effective. In the present instance, were Test site (Standard plus) compared to Control site (Standard) WRMSD treatment to nearly double outcome (1.83 on Physical functioning, for example) but cost just a tenth more (1.10) per patient, then cost-adjusted ($CaO=1.83:1.10=1.66$) it could be considered 1.66 or 66 percent (two-thirds) again more effective *on that outcome for those subjects studied*. The employer, and like employers, might then wish to calculate the actual cost-saving represented by that 66 percent greater effectiveness per patient and consider adopting Standard plus (WBOAS) care as a sound investment in secondary prevention.

Outcome. Based on reported findings (Tables 7, 9, 10, 11) it is IR and RA (on the dimensions of patient-reported Physical functioning and expert-rated New injury/re-injury incidence baseline [pre-treatment] through 6 mo post-treatment follow-up) that most warrant attention. If the significant differences reported thereon—between Test and Control site subjects' mean improvement on patient-reported Physical functioning (SF-36 PF-10) at 1 mo and at 3 mo post-treatment follow-up and on expert-rated New injury/re-injury incidence baseline (pre-treatment) through 6 mo post-treatment follow-up—were translated into increments, then Test site subjects appear a) to have improved 83 percent ($0.22:0.12=1.83$) and 53 percent ($0.23:0.15=1.53$) more than Control site subjects on Physical functioning, respectively, at 1 mo and 3 mo post-treatment follow-up and b) to have avoided new injuries and re-injuries from baseline (pre-treatment) through 6 mo post-treatment follow-up 12 percent ($79/83:81/95$ [Test:Control site uninjured/unre-injured]=1.12) more than Control site subjects.

Cost. Data were assembled for the costs a) of conducting the study, b) of the Standard care afforded Test and Control site subjects alike, and b) of the plus (WBOAS) component afforded Test site subjects alone. Conducting the study cost \$190,095.99, the sum of the total cash grant (\$187,548.00) and the estimated value of donated items (\$2,547.99), or \$1062 per subject (n=179). The cost of Standard care alone came to \$1918.33 per subject, which is the weighted average of the principal Test and Control sites, SORC and WERC, calculated in order to be used

as the base figure for estimating percentage increase in cost associated with Standard plus (WBOAS) care. The reported average was based on the fact that 47% of subjects visited the site with a per-patient Standard treatment cost of \$1711.86 per patient (SORC) while 53% of them visited the site with a per-patient Standard treatment cost of \$2101.44 (WERC). The cost of the plus (WBOAS) component added to the Standard care of Test site subjects came to \$189.87 per subject. It was calculated using the dollar value of PT/OTs', staff's, Study coordinator's, and subjects' time as well as the same session use-in-treatment Touchscreen instrumentation associated with this added component. Subjects, for example, spent time completing the Touchscreen questionnaire and therapists incorporating results of graphic print-outs so generated into treatment. Standard plus (WBOAS) care thus cost about ten percent more ($\$2108.20:\$1918.33=1.099$) than Standard care alone.

Cost-adjusted outcome. If, as observed, Standard plus (WBOAS) care did cost 1.10 or 10 percent more than Standard care alone but improved patient-reported Physical functioning (SF-36 PF-10) 1.83 or 83 percent and 1.53 or 53 percent more, respectively, at 1 mo and 3 mo post-treatment follow-up, then cost-adjusted ($CaO=1.83:1.10=1.66$ and $1.53:1.10=1.39$) it can be considered 1.66 or 66 percent and 1.39 or 39 percent again more effective, respectively, *on these outcomes for those subjects studied*.¹⁴ Similarly, if, as observed, Standard plus (WBOAS) care did produce a New injury/re-injury avoidance rate (baseline [pre-treatment] through 6 mo post-treatment follow-up) 12 percent more ($79/83:81/95=1.12$) than that of Standard care alone, then cost-adjusted ($CaO=1.12/1.10=1.018$) it can be considered 1.8 or just shy of 2 percent again more effective *on this outcome for those subjects studied*.

Secondary predictions

Auxiliary care referrals

H:5. Compared to Standard care, Standard plus (WBOAS) subjects will exhibit higher rates of treatment period **Worksite evaluation** (WSE) and **Worksite redesign** (WSR) referral.

Provider-reported, the Intervention does not appear to have affected (with prediction) PT/OT-initiated referral to either WSE or WSE auxiliary to treatment (**Table 20**). In fact significant differences were found (against prediction), therefore to the detriment of Test site subjects, in WSEs requested and implemented both between the Intervention period Test and Control sites (requested 6/0.07:19/0.30 $p<0.01$, implemented 7/0.08:17/0.27 $p<0.01$) and between the Test site in the Intervention period and all Non-intervention study sites (requested 6/0.07:26/0.27 $p<0.01$, implemented 7/0.08:23/0.24 $p=0.01$). Work restrictions requested and implemented followed the same pattern (against prediction), as did patient-reported WSR referrals and worksite equipment purchases.

H:6. Compared to Standard care, Standard plus (WBOAS) subjects will exhibit higher rates of treatment period **Behavioral health care** (BHC) referral.

Provider-reported, the Intervention does not appear to have affected (with prediction) PT/OT-initiated referral to BHC auxiliary to treatment (**Table 20**). Thus neither between the Intervention period Test and Control sites (7/0.08 vs 4/0.06 p=0.76) nor between the Test site in the Intervention period and all Non-intervention study sites (7/0.08 vs 7/0.07 p=1.00) were significant differences found for such referrals. Patient-reported, the same finding obtained.

Table 20. PT/OT-initiated auxiliary care, therapist- and subject- reported			
	Test site	Control site	Fisher
	no (%)	no (%)	p value
Provider-reported			
Intervention period test vs control sites	SORC (n=83)	WERC/Hand (n=63)	
Behavioral health referral	7 (8%)	4 (6%)	0.76
Other referral *	9 (11%)	7 (11%)	1.00
Worksite evaluation requested	6 (7%)	19 (30%)	<0.01
Worksite evaluation implemented	7 (8%)	17 (27%)	<0.01
Worksite redesign requested	6 (7%)	5 (8%)	1.00
Worksite redesign implemented	1 (1%)	3 (5%)	0.32
Worksite restriction requested	10 (12%)	20 (32%)	0.01
Worksite restriction implemented	9 (11%)	16 (25%)	0.01
Intervention period test site vs all Non-intervention sites	SORC (n=83)	SORC/WERC/Hand (n=95)	
Behavioral health referral	7 (8%)	7 (7%)	1.00
Other referral *	9 (11%)	13 (14%)	0.65
Worksite evaluation requested	6 (7%)	26 (27%)	<0.01
Worksite evaluation implemented	7 (8%)	23 (24%)	0.01
Worksite redesign requested	6 (7%)	10 (11%)	0.60
Worksite redesign implemented	1 (1%)	5 (5%)	0.22
Worksite restriction requested	10 (12%)	33 (35%)	<0.01
Worksite restriction implemented	9 (11%)	24 (25%)	0.02
Patient-reported			
Intervention period test vs control sites	SORC (n=75)	WERC/Hand (n=52)	p value
Behavioral health referral	4 (5%)	2 (4%)	1.00
Other referral *	15 (20%)	13 (26%)	0.51
Worksite redesign referral	10 (14%)	19 (38%)	<0.01
Worksite equipment purchase	11 (15%)	23 (44%)	<0.01
Intervention period test site vs all Non-intervention sites	SORC (n=75)	SORC/WERC/Hand (n=79)	
Behavioral health referral	4 (5%)	4 (5%)	1.00
Other referral *	15 (20%)	16 (21%)	1.00
Worksite redesign referral	10 (14%)	24 (31%)	0.01
Worksite equipment purchase	11 (15%)	27 (34%)	0.01

* Orthopaedics, Hand/wrist speciality, Neurologic, other PT/OT, Acquatic, Chiropractic, or Massage.

4. Comments

WBOAS/FAHC pilot study findings—covering Pre-intervention period site effectiveness and Intervention period subject characteristics (pre-treatment) as well as primary and secondary outcomes—are summarized in **Table 21**.

Site effectiveness (Pre-intervention period). Study sites were equally effective on all measures of clinical, functional, and process outcome, except on the Behavioral health dimension of IR, the Life control/personal efficacy dimension of RA, and WSR requests. The differences were immaterial, however, because the low numbers involved (n=12, 20 by site) make each unreliable, and the Intervention was subsequently observed to affect neither dimension of IR or RA.

Subject characteristics (Pre-treatment). Intervention period Test and Control site subjects at baseline (pre-treatment) were comparable on all of the same measures, except on the Physical functioning dimension of Injury severity, where Test site subjects were observed to be more severely impaired. As Test and Control sites were subsequently observed to differ significantly on Physical functioning at discharge (1 mo post-treatment follow-up) (IR) and at 3 mo (and near significantly at 6 mo) post-treatment follow-up (RA), the baseline (pre-treatment) difference thereon was material and was examined as, but not found to be, a confounder of observed Intervention effects.

Pre-intervention period	Sites comparable on balance	Sites incomparable for	
Site effectiveness	IR,RA,RTW,SAW,PP,OS	SF-36 MH-5 (IR), TOPS LC (RA), WSR requests	
Intervention period			
Subject characteristics (pre-treatment)	IR,RA,RTW,SAW,PP,OS	SF-36 PF-10 (IR)	
Prediction	With prediction (p < or = 0.05)	No difference (p > 0.05)	Against prediction (p < or = 0.05)
H:1.1. > IR expert-rated	Men IR status (continuous: mean 2.0 vs 2.6 p=0.05). Men who smoke IR status (dichotomous: percent scored 1&2 vs 3&4 81 vs 40 p=0.05) (IPTvCS)	Women	Women who do not smoke IR status (dichotomous: percent scored 1&2 vs 3&4 63 vs 88 p=0.03)
H:1.1. > IR patient-reported	All subjects SF-36 PF-10 (difference in mean improvement 0.22 vs 0.12 p=0.01)	SF-36: MH-5, BP-2; TOPS: LC, FA, PS	No
H:1.2. > RA expert-rated	All subjects New injury/re-injury incidence baseline (pre-treatment) through 6 mo post-treatment follow-up (4 vs 14 p=0.04)	No	No
H:1.2. > RA patient-reported	All subjects SF-36 PF-10 (difference in mean improvement at 3 mo post-treatment follow-up 0.23 vs 0.15 p=0.05)	SF-36: MH-5, BP-2; TOPS: LC, FA, PS	No
H:2.1. > RTW expert-rated	No	Yes	No
H:2.1. > RTW patient-	No	WLQ: SD,	No

reported		PHD, PSD, OD	
H:2.2. > SAW expert-rated	No	Yes	No
H:2.2. > SAW patient-reported	No	WLQ: SD, PHD, PSD, OD	No
H:3.1. > PP patient-reported	All subjects PCAS PE (difference in mean evaluation 0.87 vs 0.81 p=0.05). Men PCAS KP (difference in mean evaluation 0.80 vs 0.59 p=0.01)	PCAS VBC, IC, CPC, IP, TR	Women PCAS LoC (difference in mean evaluation 0.44 vs 0.52 p=0.05)
H:3.2. > GS patient-reported	No	Yes	No
H.4. Test site subjects CaO=> Control site subjects CaO	All subjects SF-36 PF-10: CaO 1.83:1.10=1.66 or 66% again more effective at discharge (1 mo post-treatment follow-up) CaO 1.53:1.10=1.39 or 39% again more effective at 3 mo post-treatment follow-up. All subjects New injury/re-injury avoidance through 6 mo post-treatment follow-up: CaO=1.12:1.10=1.018 or 2% more effective.	NA	NA
H.5. > PT/OT-initiated referral to WSE or WSR auxiliary to treatment, either therapist- or patient-reported	No	No	WSE requested (6/0.07:19/0.30 p=<0.01) implemented (7/0.08:17/0.27 p=<0.01) IPT WSR requested (6/0.07:26/0.27 p=<0.01), implemented (7/0.08:23/0.24 p=0.01)
H.6. > PT/OT-initiated referral to BHC auxiliary to treatment, either therapist- or patient-reported	No	Yes	No
* Except in the one instance labeled "IPTvCS"=Intervention period Test vs Control sites. Abbreviations: IR Injury recovery, RA Re-injury avoidance, RTW Return to work success, SAW Stay at work success, PP evaluated Provider performance, OS Overall satisfaction with care, CaO Outcome-adjusted Outcome, BHC Behavioral health care, WSE Worksite evaluation, WSR Worksite redesign. SF-36 PF physical functioning, MH mental health, BP bodily pain. TOPS PS pain symptoms, LC life control/personal efficacy, FA fear/avoidance. WLQ SD scheduling demands, PHD physical demands, PSD psychosocial demands, OD output demands). PCAS LoC longitudinal continuity, VBC visit-based continuity, KP knowledge of patient, IC integration of care, CPC clinician-patient communication, PE thoroughness of physical examinations, IP interpersonal treatment, TR trust.			

Outcomes (Intervention period)

Clinical outcome (H:1.1 and 1.2, IR and RA). With prediction, Test site subjects exhibited higher rates of patient-reported treatment period IR and post-treatment period RA on Physical functioning (SF-36 PF-10 difference in mean improvement at discharge [1 mo post-treatment follow-up] 0.22 vs 0.12 p=0.01, difference in mean improvement at 3 mo post-treatment follow-up 0.23 vs 0.15 p=0.05, difference in mean improvement at 6 mo post-treatment follow-up 0.24 vs 0.16 p=0.07); against prediction, they exhibited no higher rates on Behavioral health status or

Bodily pain (SF-36 MH-5 and BP-2) or on Pain symptoms, Life control/personal efficacy, and Fear/avoidance (TOPS) at discharge (1 mo post-treatment follow-up) or at 3 and 6 mo post-treatment follow-up. With prediction, Test site subjects exhibited higher rates of expert-rated post-treatment period RA measured by New injury/re-injury incidence (baseline [pre-treatment] through 6 mo post-treatment follow-up 4/0.05:14/0.15 p=0.04). And male Test site subjects exhibited higher rates of expert-rated treatment period IR measured by Injury recovery status at discharge (1 mo post-treatment follow-up continuous: mean 2.0 vs 2.6 p=0.05), as did male Test site subjects who smoked (dichotomous: percent scored 1&2 vs 3&4 81 vs 40 p=0.05).

- that no significant difference was observed in subjects' WRMSD incidence in the 6 mo prior to their "study" WRMSD (**Table 4**, Co-morbidities) bolsters the view that the Intervention contributed to the difference in observed IR and RA.
- that significant differences were found in Physical functioning at 1 and 3 mo (and near significant at 6 mo) post-treatment follow-up, but not in Behavioral health status or Pain symptoms, Life control/personal efficacy, and Fear/avoidance, suggests that, at least as implemented in this study, the Standard plus (WBOAS) "information" component (same-session outcomes trends graphics to set and re-set injury treatment and return-to-work goals) was more effective than the "action" component (trends-based referral guidelines to initiate auxiliary worksite evaluation and redesign and/or behavioral health care); indeed the Intervention did not affect PT/OT-initiated referral to BHC, and a significantly higher percentage of Control than Test site subjects had PT/OT-initiated WSE's (as well as worksite restrictions) requested and implemented.
- that men who smoke were the only sub-group to see a significant (positive) difference in expert-rated IR may be due to the fact that these are the subjects who least look after their health and whom the Intervention might thus most prompt to do so.
- that between the Test site in the Intervention period and all Non-intervention study sites a significant difference was found in treatment period Work restriction to the detriment of Test site subjects (**Table 14**, 59/0.74:51/0.57 p=0.02 Any work restriction during treatment) suggests a price paid for the higher IR rates observed in their favor, inasmuch as Test site PT/OTs, induced by referral guidelines to auxiliary WSE and WSR, may have lowered New injury/re-injury in part by raising Work restriction incidence.

Functional outcome (H:2.1 and 2.2, RTW and SAW success). Against prediction, Test and Control site subjects exhibited no significant differences in rates of patient-reported or expert-rated treatment period RTW or post-treatment period SAW success, though male subjects did trend in the predicted direction on RTW success. In fact a near significant difference was found (**Table 12**, mean 1.8 vs 1.5 p=0.06) against the prediction (to the detriment of Test site subjects).

- that men trend in the predicted direction in expert-rated RTW success suggests that Standard plus (WBOAS) care was more effective for them than for women; possibly, men are more temperamentally inclined to the same-session outcomes trends graphics, its "high tech" information component.

Process outcome (H:3.1 and 3.2, evaluated PP and OS with care). With prediction, Test site subjects exhibited higher rates of evaluated PP at discharge (1 mo post-treatment follow-up) on

the Physical exam dimension (PE difference in mean evaluation 0.87 vs 0.81 $p=0.05$) of the PCAS; against prediction, they exhibited no higher rates on Visit-based continuity, Knowledge of patient, Integration of care, Clinician-patient communication, Interpersonal treatment, or Trust dimensions, and a significantly lower rate on Longitudinal continuity (0.44 vs 0.52 $p=0.05$), of the PCAS. Male Test site subjects exhibited higher rates of evaluated PP at discharge (1 mo post-treatment follow-up) on the Knowledge of patient dimension (KP difference in mean evaluation 0.80 vs 0.59 $p=0.01$, and near significantly on Interpersonal treatment and Communication) of the PCAS. But female Control site subjects exhibited higher rates of evaluated PP at discharge (1 mo post-treatment follow-up) on the Longitudinal continuity dimension (LoC difference in mean evaluation 0.44 vs 0.52 $p=0.05$). Against prediction, Test and Control site subjects exhibited no significant differences in rates of patient-reported OS with care.

- that men evaluate PP so may, again, be due to their being more temperamentally inclined than women to the knowledge or “high tech” component (same-session outcomes trends graphics) of Standard plus (WBOAS) care, hence more likely to feel that it adds significantly to the knowledge, interpersonal, and communicative dimensions of their treatment.
- that no differences were observed on the global measure, OS with care, is not surprising given that just three of eight PCAS sub-scales discriminated Test from Control site subjects.

Cost outcome (H:4, CaO). With prediction, Test sites subjects exhibited no lower (indeed they exhibited higher) rate of treatment period and post-treatment period CaO on two dimensions of IR and RA, patient-reported Physical functioning (CaO=1.83:1.10=1.66 or 66 percent higher at discharge [1 mo post-treatment follow-up], CaO=1.53:1.10=1.39 or 39 percent higher at 3 mo post-treatment follow-up) and expert-rated New injury/re-injury avoidance (baseline [pre-treatment] through 6 mo post-treatment follow-up) (CaO=1.12/1.10=1.018 or 2 percent higher at 6 mo post-treatment follow-up).

- were Standard plus (WBOAS) compared to Standard care to a) nearly double outcome (1.83) on patient-reported Physical functioning at discharge (1 mo post-treatment follow-up) and cost just a tenth more (1.10) per patient, thus b) cost-adjusted (CaO=1.83:1.10=1.66) be 1.66 or 66 percent (two-thirds) again more effective *on that outcome for those subjects studied*, then c) the employer, and like employers, might wish to calculate the actual cost-saving represented by that 66 percent greater effectiveness per patient and consider adopting Standard plus (WBOAS) care as a sound investment in secondary prevention; likewise for calculating and comparing the cost-savings represented by any greater effectiveness per patient observed on other IR or RA, not to mention RTW or SAW success, measures.

Auxiliary care (H:5 and H:6, WSE and WSR, and BHC). Against prediction, Test site subjects exhibited lower rates of provider-reported referral to WSE (requested 6/0.07:19/0.30 $p<0.01$, implemented 7/0.08:17/0.27 $p<0.01$ for Intervention period Test vs Control sites; requested 6/0.07:26/0.27 $p<0.01$, implemented 7/0.08:23/0.24 $p=0.01$ for the Test site in the Intervention period vs all Non-intervention study sites) and of Work restriction (requested 10/0.12:20/0.32 $p<0.01$, implemented 9/0.11:16/0.25 $p<0.01$ for Intervention period Test vs Control sites; requested 10/0.12:33/0.35 $p<0.01$, implemented 9/0.11:24/0.25 $p=0.01$ for the Test site in the

Intervention period vs all Non-intervention study sites). Test and Control site subjects exhibited no significant differences in rates of provider-reported referral to WSR or BHC.

- that Control site providers “out-referred” the Test site for both WSEs and WSRs—something that cannot be explained by baseline (pre-treatment) difference in site effectiveness (see **Table 5**, where the trend favors the Test site)—may have resulted from a Hawthorn effect whereby Control site therapists, aware they were “just” the Standard care site, ramped up referrals, though no post-Intervention interviews were conducted to explore this possibility; a study involving Test and Control clinics situated in a single organization setting can experience such site “contamination.”
- there is also the possibility that the Pre-intervention period was not of sufficient duration to show the true direction or magnitude of study site differences in referral rates.

5. Conclusions

The WBOAS/FAHC pilot study, and this is its principal strength, constitutes the first controlled trial of the Worker-based outcomes assessment system (WBOAS), a Work-related musculoskeletal disorders (WRMSD) treatment and secondary prevention improvement protocol that informs treatment by putting same-session touchscreen-generated patient-reported outcomes trends graphics and trends-based auxiliary treatment referral guidelines into the hands of physical and occupational therapists (PT/OTs) and their patients. Given that the provider was integral to the Intervention, the study could not randomize subjects at baseline (pre-treatment), and this is its principal weakness. Only those Intervention effect confounders anticipated in advance and measured, pertaining to study site and study subject characteristics, could thus be controlled for. These though were tested for and discounted as needed throughout this report and no effect reported left any measured confounder unexamined.

Characteristic of a pilot, the study was of limited duration and accrual. It featured a logistically complex protocol that required the consent and cooperation of dozens of personnel, including medical center administrators and staff (human relations, employee health, employee accounts, patient records, IRB), OHS study site providers and staff (RNCMs, MDs, PT/OTs, clinic staff), and patients (study subjects through 6 mo post-treatment follow-up). The effort required to conduct patient-oriented, practice-based research of the sort should not be underestimated.

Any future study involving WBOAS-type Interventions should bolster capacity to attribute effects to the Intervention by

- instituting a pre-Intervention period adequate to garnering reliable baseline (pre-treatment) measures of outcomes and controls;
- adopting a staggered Intervention whereby Intervention period 1 Control site become Intervention period 2 Test site clinics (**Table 22**);¹⁵
- blinding Control site to Test site clinic protocol so as to minimize the cross-site contamination that can lead to Hawthorn effect distortions; and
- stratifying subjects by gender so as to reliably chart Intervention effect similarities and differences between men and women.

The importance of securing the Pre-intervention period buy-in of administrators, providers, and staff essential to the study likewise cannot be underestimated.

Study period	Test clinic	Control clinic	Hypotheses/outcomes
Pre-intervention period	No-Intervention	No Intervention	Test=Control
Intervention 1 period	Intervention	No Intervention	Test > Control
Intervention 2 period	Intervention	Intervention	Control=Test

The relevance for both research and practice of the study lies in Intervention effects that were observed to improve, and not to improve, the primary and secondary outcomes measured. Thus, in trial, and compared to Standard care alone, Standard plus (WBOAS) care was observed

(1) clinical outcome: with prediction to significantly improve (a) subjects' IR and RA on patient-reported Physical functioning and on expert-rated New injury/re-injury avoidance, (b) male subjects' IR on expert-rated Injury recovery status at discharge, and (c) male subjects' who smoke IR on expert-rated Injury recovery status at discharge; but against prediction not to improve (a) subjects' IR and RA on patient-reported Behavioral health status or Pain symptoms, Life control/personal efficacy, and Fear/avoidance at discharge or at 3 and 6 mo post-treatment follow-up or (b) female subjects' IR on patient-reported Injury recovery status at discharge.

(2) functional outcome: against prediction not to improve subjects' RTW or SAW success, patient-reported or expert-rated, though men did trend in the predicted direction on RTW.

(3) process outcome: with prediction to significantly improve (a) subjects' evaluated PP at discharge on PCAS Physical examination and (b) male subjects' evaluated PP at discharge on PCAS Contextual knowledge and nearly on Interpersonal treatment and Communication; but against prediction not to improve (a) male subjects' evaluated PP at discharge on PCAS Longitudinal continuity, (b) female subject's evaluated PP at discharge on PCAS Contextual knowledge, Interpersonal treatment, Communication or Longitudinal continuity, (c) subjects' evaluated PP at discharge on PCAS Visit-based continuity, Integration of care, Interpersonal treatment, or Trust, or (d) subjects' OS with care at discharge.

(4) cost outcome: with prediction to measurably improve CaO on two dimensions of IR and RA, patient-reported Physical functioning and expert-rated New injury/re-injury avoidance; but against prediction not to improve CaO on other dimensions of IR and RA such as patient-reported Behavioral health status or Pain symptoms, Life control/personal efficacy, and Fear/avoidance at discharge or at 3 and 6 mo post-treatment follow-up.

(5) auxiliary care: against prediction not to improve subjects' PT/OT-initiated WSE and WSR or BHC referral rates.

Employers, especially those in the health services or like sectors (e.g. human services), should consider sponsoring WBOAS-type Interventions so as to advance the WRMSD treatment and secondary prevention outcomes research base; calculating per patient net savings (outcome-to-cost) represented by any observed greater effectiveness of WBOAS-type WRMSD care on, for example, Injury recovery or Re-injury avoidance, Return to work or Stay at work success measures; and modifying OHS treatment accordingly.

References

- Amick, Benjamin C., Swanson Naomi G., Chang Hong. Office Technology and Musculoskeletal Disorders. Building an Ecological Model for the Origins of Musculoskeletal Injuries and Their Consequences. *Occupational Medicine: State of the Art Reviews* 1999; 14(1).
- Amick, Benjamin C., Lerner Deborah, Rogers William H, Rooney Ted, Katz Jeffrey N. A review of health-related work outcome measures and their uses, and recommended measures. *Spine* 2000; 25: 3152-60.
- Armenian HK, Pratt LA, Gallo J, Eaton WW. Psychopathology as a predictor of disability: a population-based follow-up study in Baltimore, Maryland. *American Journal of Epidemiology* 1998; 148: 269-275.
- Atlas SJ, Deyo RA, Keller RB, et al. The Maine Lumbar Spine Study, Part II. 1-year outcomes of surgical and non-surgical management of sciatica. *Spine* 1996; 21:1777-86.
- Baldwin M, Johnson WG, Butler R. The Error of Using Returns-to-Work to Measure the Outcomes of Health Care. *American Journal of Industrial Medicine* 1996; 29: 632-641.
- Beaton DE, Bombardier C, Hogg-Johnson SA. Measuring health in injured workers: a cross-sectional comparison of five generic health status instruments in workers with musculoskeletal injuries. *American Journal of Industrial Medicine* 1996; 29: 618-631.
- Beaton DE, Richards RR. Measuring function of the shoulder. A cross-sectional comparison of five questionnaires. *Journal of Bone & Joint Surgery - American Volume* 1996; 78-A (6): 882-890.
- Bessette L, Sangha O, Kuntz KM, et al. Comparative responsiveness of generic versus disease-specific and weighted versus unweighted health status measures in carpal tunnel syndrome. *Medical Care* 1998; 36: 491-502.
- Bombardier C, Melfi CA, Paul J, et al. Comparison of a generic and a disease-specific measure of pain and physical function after knee replacement surgery. *Medical Care* 1995; 33: AS131-AS144.
- Bernard BP, ed. *Cincinnati: National Institute for Occupational Safety and Health, DHHS, 1997, in which Anonymous, Musculoskeletal disorders and workplace factors.*
- Bergner M. Quality of life, health status, and clinical research. *Medical Care* 1989; 27: S148-S156
- Bergner M, Rothman ML. Health status measures: an overview and guide for selection. *Annual Review of Public Health* 1987; 8: 191-210.
- Broadhead WE, Blazer DG, George LK, Tse CK. Depression, disability days and days lost from work in a prospective epidemiologic survey. *JAMA* 1990; 264: 2524-2528.
- Bromet EJ, Dew MA, Parkinson DK, Cohen S, Schwartz JE. Effects of occupational stress on the physical and psychological health of women in a microelectronics plant. *Social Science & Medicine* 1992; 34: 1377-1383.
- Burton AK, Tillotson KM, Main CJ, Hollis S. Psychosocial predictors of outcome in acute and subchronic low back trouble. *Spine* 1995; 20: 722-728.
- Burton AK, Tillotson KM, Symonds TL, Burke C, Mathewson T. Occupational risk factors for the first-onset and subsequent course of low back trouble. A study of serving police officers. *Spine* 1996; 21: 2612-2620.

- Calkins DR, Rubenstein LV, Cleary PD, et al. Functional disability screening of ambulatory patients: a randomized controlled trial in a hospital-based group practice. *Journal of General Internal Medicine* 1994; 9: 590-592.
- Cohen, A and Colligan M. Assessing Occupational Safety and Health Training: A Literature Review. *National Institute for Occupational Safety and Health* 98-145. 1999. Cincinnati.
- Deyo RA, Diehr P, Patrick DL. Reproducibility and responsiveness of health status measures. Statistics and strategies for evaluation. *Controlled Clinical Trials* 1991; 12: 142S-158S.
- Frymoyer J, Pope M, Clements J, Wilder D, MacPherson B and Ashikaga T. Risk factors in low back pain. *J Bone and Joint* vol 65A, no 2, Feb 1983 p 213-218
- Frymoyer JW. Magnitude of the problem. In Wiesel SW, Weinstein JN, Herkowitz HN, Dvorak J, Bell GR (eds). *The Lumbar Spine*, 2nd edition Vol 1 WB Saunders Co, Philadelphia, 1996, page 8
- Hasenbring M, Marienfeld G, Kuhlendahl D, Soyka D. Risk Factors for Chronicity in Lumbar Disk Patients. *Spine* 1994; 19: 2759-2765.
- Higgs PE, Edwards D, Martin DS, Weeks PM. Carpal Tunnel Surgery Outcomes in Workers: Effect of Workers' Compensation Status. *The Journal of Hand Surgery* 1995; 20A: 354-360.
- Institute of Medicine. Committee on the Future of Primary Care. *Primary Care: America's Health in a New Era*. Washington DC: National Academy Press, 1996.
- Institute of Medicine. Panel on Musculoskeletal Disorders and the Workplace. *Musculoskeletal Disorders and the Workplace: Low Back and Upper Extremities*. Washington DC: National Academy Press, 2001.
- Jette DU, Jette AM. Physical therapy and health outcomes in patients with knee impairments. *Physical Therapy* 1996; 76: 1178-1187.
- Jette DU, Jette AM. Physical therapy and health outcomes in patients with spinal impairments. Published erratum appears in *Phys Ther* 1997 Jan;77(1): 113. *Physical Therapy* 1996; 76: 930-941.
- Keller, S. Quantifying social consequences of occupational injury and illnesses: State of the art and research agenda. *Functional, Economic, and Social Outcomes of Occupational Injuries and Illnesses: Integrating Social, Economic, and Health Services Research Discussion Papers*. National Institute for Occupational Safety and Health. June 13-15, 1999. Denver Colorado.
- Katz, Jeffrey N. Worker Self-Report in Assessing the Quality and Outcome of Work-Associated Musculoskeletal Disease. 2-25. 1997.
- LaRosa JH. Women, Work, and Health: Employment as a Risk Factor for Coronary Heart Disease. *American Journal of Obstetrics and Gynecology* 1988; 158: 1597-1602.
- Levine DW, Simmons BP, Koris MJ, et al. A Self-Administered Instrument for the Assessment of Symptom Severity and Functional Status in Carpal Tunnel Syndrome. *J Bone Joint Surg* 1993; 75A: 1585-1592.
- Loisel P, Poitras S, Lemaire J, Durand P, Southiere A, Abenhaim L. Is work status of low back pain patients best described by an automated device or by a questionnaire? *Spine* 1998; 23: 1588-1594.

- Martin DP, Engelberg R, Agel J, Swiontkowski MF. Comparison of the Musculoskeletal Function Assessment questionnaire with the Short Form-36, the Western Ontario and McMaster Universities Osteoarthritis Index, and the Sickness Impact Profile health-status measures.
- Mathiowetz, N and Wunderlich, G. eds. Survey Measurement of Work Disability: Summary of a Workshop. National Academy Press. Washington, DC 2000.
- Nachemson AL. Newest knowledge of low back pain: a critical look. *Clin Ortop.*, 279 (1992) 8-20
- National Academy of Sciences. Steering Committee for the Workshop on Work Related Musculoskeletal Disorders. *Work-Related Musculoskeletal Disorders: Report, Workshop Summary, Workshop Papers.* 1999. Washington DC.
- National Institute for Occupational Safety and Health. National Occupational Research Agenda. NIOSH CDC PHS U.S. Department of Health and Human Services. April 1996.
- Nunnally, J. *Psychometric Theory*, Second Edition. New York: McGraw-Hill 1978.
- Patrick DL, Bergner M. Measurement of health status in the 1990s. *Annual Review of Public Health* 1990; 11: 165-183.
- Pransky G, Benjamin K, and Dembe, A. Performance and Quality Measurement in Occupational Health Services: Current Status and Agenda for Further Research. 1999. National Institute for Occupational Safety and Health.
- Pransky G, Himmelstein J. Outcomes research: implications for occupational health. *American Journal of Industrial Medicine* 1996; 29: 573-583.
- Phelan J, Schwartz JE, Bromet EJ, et al. Work stress, family stress and depression in professional and managerial employees. *Psychological Medicine* 1991; 21: 999-1012.
- Rogers WH, Wittink HM, Ashburn MA, Cynn D, Carr DB. (2000) Using the "TOPS," an Outcomes Instrument for Multidisciplinary Outpatient Pain Treatment. *Pain Medicine* 1: 1, 55-67.
- Rogers WH, Wittink H, Wagner A, Cynn D, Carr DB. Assessing individual outcomes during outpatient multidisciplinary chronic pain treatment by means of an augmented Sf-36. *Pain Med.* 2000 Mar;1(1): 44-54.
- Rubenstein LV, Calkins DR, Young RT, et al. Improving patient function: a randomized trial of functional disability screening. *Annals of Internal Medicine* 1989; 111: 836-842.
- Rubenstein LV, McCoy JM, Cope DW, et al. Improving patient quality of life with feedback to physicians about functional status. *Journal of General Internal Medicine* 1995; 10: 607-614.
- Rudolph, L and Deitchman, S. Integrating Occupational Health Services and Occupational Prevention Services. 1999. National Institute for Occupational Safety and Health. 99.
- Safran, Dana Gelb, Kosinski, Mark, Taira, Deborah A., Rogers, William H., Ware, John, Lieberman, Naomi, and Tarlov, Alvin R. The Primary Care Assessment Survey: Tests of Data Quality and Measurement Performance. 1996.
- Safran DG et al. The Primary Care Assessment Survey: Tests of data quality and measurement performance. *Medical Care* 1998; 35: 728-739.
- Safran DG, Taira DA, Rogers WH, Kosinski M, Ware JE, Tarlov AR. Linking Primary Care Performance to Outcomes of Care. *Journal of Family Practice* 1998; 47: 213-220.
- Shutty, M.S., DeGood, D.E., Tuttle, D.H., Chronic pain patients' beliefs about their pain and treatment outcomes. *Arch Phys Med Rehabil*, 71(1990)128-132.

- Silverstein, Barbara and Kalat, J. Work related disorders of the back and upper extremity in Washington State: 1989-96. 40-1-1997. 1998. Olympia, WA, State of Washington Department of Labor and Industries.
- Sinclair SJ, Hogg-Johnson SH, Mondloch MV, Shields SA. The effectiveness of an early active intervention program for workers with soft-tissue injuries. The Early Claimant Cohort Study. *Spine* 22(24): 2919-31.
- Smith, M, Karsh, BT, and Moro, F. A Review of Research on Interventions to Control Musculoskeletal Disorders. Working Paper prepared for the National Academy of Sciences. 1998. University of Washington at Madison.
- Stier DM, Greenfield S, Lubeck DP, Dukes K, Flanders SC, Henning JM, Weir J & Kaplan SH. Quantifying Co-morbidity in a Disease-Specific Cohort: The Adaptation of the Total Illness Burden Index to Prostate Cancer. *Urology*. 1999; 154(3): 424-49.
- Waddell G, Newton M, Henderson I, Somerville D, Main CJ. A Fear-Avoidance Beliefs Questionnaire (FABQ) and the role of fear-avoidance beliefs in chronic low back pain and disability. *Pain* 1993; 52: 157-168.
- Waddell G. Biopsychosocial analysis of low back pain. *Ballieres Clin Rheumatol* 6 (1992) 523-557
- Wells KB. The Functioning and Well-Being of Depressed Patients: Results from the Medical Outcomes Study. *Journal of American Medical Association* 1989; 262: 914-919.
- Wells KB, Stewart A, Hays RD, et al. The Functioning and Well-being of Depressed Patients. *JAMA* 1989; 262: 914-919.
- Ware JE, Snow KK, and Kosinski M, Gandek BG. SF-36 Health Survey Manual and Interpretation Guide. 1993. Boston, The Health Institute, New England Medical Center.
- Ware JE, Jr., Kosinski M, Keller SD. A 12 Item Short Form Health Survey: Construction of scales and preliminary tests of reliability and validity. *Med Care* 1996; 34: 220-233.
- Wiesel SW, Tsourmas N, Feffer HL et al. A study of computer associated tomography: the incidence of positive CAT scans in asymptomatic group of patients. *Spine* 9 (6) 549, 1984

Glossary of Acronyms

BHC	Behavioral health care
BP-2	Bodily Pain sub-scale (2-item) of the SF-36
CaO	Cost-adjusted outcome
EH	Employee Health (Office of)
FAHC	Fletcher Allen Health Care (Burlington VT)
Hand	Hand, Upper Extremity, and Microsurgery Center (FAHC)
IR	Injury recovery
MH-5	Mental health index sub-scale (5-item) of the SF-36
NORA	National Occupational Research Agenda
OHS	Occupational health services
OS	Overall satisfaction
PF-10	Physical functioning sub-scale (10-item) of the SF-36
PP	Provider performance
PCAS	Primary Care Assessment System
PT/OT	Physical/occupational therapist
RA	Re-injury avoidance
RNCM	Registered nurse case manager
RTW	Return-to-work
SAW	Stay-at-work
SF-36	SF-36 Health Survey
SORC	Sports and Orthopaedic Rehabilitation Center (FAHC)
TIBI	Total Illness Burden Inventory
TOPS	Treatment of Pain Survey
WBOAS	Worker-based outcomes assessment system
WERC	Work Enhancement and Rehabilitation Center (FAHC)
WLQ	Work Limitations Questionnaire (27-item)
WRMSD	Work-related musculoskeletal disorder
WSE	Worksite evaluation
WSR	Worksite redesign

Glossary of Tables

- Table 1. Study accrual and retention (figures and rates)
- Table 2. Subject accrual by referral to PT/OT site (SORC, WERC, Hand)
- Table 3. Study measures, measurement timing
- Table 4. Site effectiveness (Pre-intervention period)
- Table 5. Subject characteristics (Intervention period, pre-treatment)
- Table 6. Injury recovery, expert-rated: Baseline (pre-treatment) to Discharge (1 mo post-treatment follow-up)
- Table 7. Injury recovery, patient-reported: Baseline (pre-treatment) to Discharge (1 mo post-treatment follow-up) *
- Table 8. Mean values SF-36 PF-10: [discharge (1 mo post-treatment follow-up) - baseline (pre-treatment)]
- Table 9. Re-injury avoidance, expert-rated: Post-treatment (through 6 mo post-treatment follow-up) period
- Table 10. New injury/re-injury rate by Sex: Intervention period, all sites
- Table 11. Re-injury avoidance, patient-reported: Post-treatment (through 6 mo follow-up) period
- Table 12. Return to work success, expert-rated: Baseline (pre-treatment) to Discharge (1 mo post-treatment follow-up)
- Table 13. Return to work success, patient-reported: Baseline (pre-treatment) to Discharge (1 mo post-treatment follow-up)
- Table 14. Stay at work success, expert-rated: Baseline (pre-treatment) to 6 mo post-treatment follow-up
- Table 15. Number and percent of Work restrictions by study site: Pre-Intervention and Intervention periods
- Table 16. Days absent due to injury during 6 mo post-treatment follow-up
- Table 17. Stay at work success, patient-reported: Post-treatment (through 6 mo follow-up) period
- Table 18. Evaluated Provider performance at Discharge (1 mo post-treatment follow-up)
- Table 19. Overall satisfaction with care at Discharge (1 mo post-treatment follow-up)
- Table 20. PT/OT-initiated auxiliary care, therapist- and subject- reported
- Table 21. Principal study findings, Intervention period test site vs all Non-intervention sites
- Table 22. Staggered Intervention design to bolster Effects attribution capacity

¹ "Employers reported 6.3 million work injuries and 515,000 cases of occupational illnesses in 1994. That same year, occupational injuries alone cost \$121 billion in lost wages and lost productivity, administrative expenses, health care, and other costs. This figure does not include the costs of occupational diseases. Despite the continuing need for occupational safety and health research, both public and private sector efforts are facing increasing fiscal constraints. These financial challenges, in the face of the large burden of work-related disease, injury, and death, led NIOSH to work with the occupational safety and health community to develop a National Occupational Research Agenda." (Executive summary, National Institute for Occupational Safety and Health, 1996)

² "In 1999, nearly 1 million people took time away from work to treat and recover from work-related musculoskeletal pain or impairment of function in the lower back or upper extremities. Conservative estimates of the economic burden imposed, as measured by compensation costs, lost wages, and lost productivity, are between \$45 and \$54 billion annually. ... The size and complexity of the problem and the diversity of interests and perspectives [involved is what led] Congress [to request] a study by the National Research Council and the Institute of Medicine covering the scientific literature on the causation and prevention of these disorders [funded] by the National Institute for Occupational Safety and Health (NIOSH) and by the National Institutes of Health (NIH)." (Institute of Medicine 2001, pp. 1-2)

³ The SF-36 PF-10 sub-scale, which has been used in a range of outcome studies for work-related low back injuries (Atlas et al. 1996), measures ability to perform ten lower limb and back ADLs ($r=0.85$, $\alpha=0.90$) (Ware et al., 1993): 1. vigorous activities, such as running, lifting heavy objects, participating in strenuous sports; 2. moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf; 3. lifting or carrying groceries; 4. climbing several flights of stairs; 5. climbing one flight of stairs; 6. bending, kneeling, or stooping; 7. walking more than a mile; 8. walking several blocks; 9. walking one block; 10. bathing or dressing yourself. The SF-36 MH-5, which Katz found was a strong predictor of return to work success, measures anxiety, depression, loss of control, and positive well-being (Ware 1993). A score of 52 points or less on the MH-5 is a cutoff for clinical depression (Wells 1989, Wells et al. 1989).

⁴ The Pain symptoms scale contains five items developed across a sample of 437 chronic pain patients ($\alpha=0.91$, scaling success 100%) and validated by comparison to chart reviews for physician documentation of the patient's best, worst, and average pain ratings 0-10 ($r=0.81$ with Pain symptoms scale, 0.93 when completed same day patients reported pain ratings to physicians). In responsiveness tests the pain scale changed an average 7 points between the initial and 5-week (post-treatment) follow-up visit in response to treatment ($p<.001$). The Fear/avoidance scale contains ten items—five worded negative, five positive, for balance (Waddell et al. 1993, Nunnally, 1978)—reduced for the WBOAS/FAHC pilot study to the five that focus on beliefs about how present work may affect pain ($\alpha=0.70$, scaling success 100%). The Life control/personal efficacy scale contains five items, gauges control over pain and stress and problem solving ability, and exhibits comparable reliability ($\alpha=0.83$) (Shutty et al. 1990).

⁵ Notably, the Sickness Impact Profile (SIP), which specifically focuses on how a person accommodates work to illness (e.g. shorter hours, lighter work) and to illness at work (e.g. irritability, endurance), does not present a comprehensive set of work activities, thus misses the range of ways health and work may interact (Mathiowetz and Wunderlich 2000). A five sub-scale version of the WLQ-27, which separated out 4-item "mental" and 3-item "social" sub-scales from the 7-item "psychosocial demands" sub-scale, yielded Chronbach alphas of 0.88 (scheduling, physical), 0.92 (mental), 0.80 (social) and 0.90 (output) and scaling success score from 91 to 100%. The WLQ was normed using a survey administered three times in 1998 at LL.Bean (73% response rate), result of which included that average healthy employees have some work limitation, that average scores vary by sub-scale (as low as 10, as high as 15), and that the a behavioral health problem considerably exacerbates any WRMSD.

⁶ Worksite evaluations, requested either by PT/OTs or by OHS medical care providers, were conducted by trained PT/OT evaluators. Evaluators' recommendations, including those for equipment, had in turn to be supported by the patient's EH RNCM and medical care provider before being implemented.

⁷ From the IRB-approved pre-consent form, “In an effort to improve the outcomes of treatment received by ... employees with work-related musculoskeletal injuries like yours, a team of researchers is conducting a research study [which] tests whether patients like you get better treatment when ... therapists (PT/OTs) incorporate graphic results from patient-reported questionnaires into their treatment plans. Using a ‘touch screen’ display similar to a bank’s ATM, some patients will spend about fifteen minutes just before certain treatment visits answering questions about their health and work limitations. ... Were you to be referred for PT/OT by Employee Health or by your medical care provider ... would you consider being contacted [by the Study coordinator] concerning your possible participation in the study?”

⁸ Subjects were scored 1 to 4, a score produced by averaging across four components of IR success at discharge relative to pre-injury—Pain status, Return to work, Functionality/ADLs, and Strength/range of motion at discharge--each component itself scored 1 to 4 (complete recovery, near complete recovery, partial recovery, little or no recovery). For Pain status, for example, ratings were 1. Complete recovery=Pain resolved, 2. Near complete recovery=Pain not interfering with ADLs or work tasks, 3. Partial recovery=Pain partially interfering with ADLs or work tasks, 4. Little or no recovery=Pain severely interfering with ADLs or work tasks.

⁹ Subjects were scored 1 to 4, a score produced by averaging across four components of RTW success at discharge relative to pre-injury--Work status, MMI/impairment status, Injury treatment post-discharge, and patient’s Subjective health status--each component itself scored 1 to 4 (complete success, near complete success, partial success, little or no success. For work status, for example, ratings were 1. Complete success=patient at pre-injury work status: full duty (same or equivalent job, unrestricted), 2. Near complete success=patient at near pre-injury work status: modified duty (same or equivalent job, restricted, ex. lower performance requirements and/or hours worked), 3. Partial success=patient is discharged with improvement but measurably short of pre-injury work status: modified duty (lesser job, i.e. lower performance requirements and/or hours worked), 4. Little or no RTW success=patient is discharged with little or no improvement and far short of pre-injury work status: total disability (out of work, injury related).

¹⁰ The PCAS is a validated, patient-reported measure primary care Provider performance evaluation instrument designed to assess seven dimensions of care identified by the Institute of Medicine’s Committee on the Future of Primary Care (1996). The measure contains eleven scales--Accessibility (organizational, financial), Continuity (longitudinal, visit-based), Comprehensiveness (knowledge of patient, preventive counseling), Integration of care, Clinical interaction (clinician-patient communication, thoroughness of physical examinations), Interpersonal treatment, and Trust--which taken altogether comprehend the entire clinician-patient primary care relationship. Evidence from cross-sectional studies suggests that PCAS scales are substantially linked to important outcomes of care, including patients’ adherence to medical advice, satisfaction, and changes in health status (Safran et al. 1998, Safran et al. 1998). The direction and sequencing of these linkages is the focus of on-going longitudinal and intervention studies. Psychometric testing reveals that the PCAS has excellent measurement properties and performs consistently well across varied sectors of the population defined according to demographic, socioeconomic, and health characteristics (Safran et al. 1998, Safran et al. 1998, Safran et al. 1996). Because study PT/OTs had no responsibility for accessibility, preventive counseling, or integration of care, the measure was modified for use in the WBOAS/FAHC pilot study by replacing the word “provider” with “therapist” where necessary and by including only the remaining eight scales which bore directly on PT/OT performance: Continuity (longitudinal, visit-based), Comprehensiveness (knowledge of patient), Integration of care, Clinical interaction (clinician-patient communication, thoroughness of physical examinations), Interpersonal treatment, and Trust.

¹¹ Smoking has been shown to be related to back pain, though the causal process has not been identified (Frymoyer 1983).

¹² Though measured, study N proved too small to meaningfully employ the controls (for function and for symptom) by injury locus (upper-extremity, upper and lower back, lower extremity) listed on **Table 3** (rows 8-13)

¹³ That the direction of the matched Test to Control site scores reported on **Tables 4, 7, and 11** for the three validated TOPS sub-scales (Life control/personal efficacy/LC, Fear/avoidance/FA, Pain symptoms/PS) should be, alternately, positive, negative, and negative would seem anomalous (considering that each measures a co-variant of living with pain) were it not for the facts that a) per standard scale construction procedure, response directionality on constituent Likert-scaled items was reversed both between the four-item LC and five-item PS sub-scales (LC: 0-No control/6-Extreme control, PS: 0-No pain/6-Worst pain possible) and within the five-item FA sub-scale (two items: fearful-to-not fearful, three items: not fearful-to-fearful) and b) per study logistics, while baseline (pre-treatment) questionnaires, being novel to the subject, were generally administered in a guided interview format by the Study coordinator, most follow-up (post-treatment) questionnaires were mailed and therefore subject-administered. It is likely therefore that, on the latter, subjects just “mowed through” the three TOPS sub-scales without heeding the change in directionalities following the first sub-scale.

¹⁴ This is essentially to take the relative risk (ratio of outcome in Test group to outcome in Control group) and reduce it by 10% in order to adjust for the fact that the intervention cost 10 percent more. Thus 1.83 adjusts to 1.66, 1.53 to 1.39.

¹⁵ The present study intended but was prevented—by an unforeseeable transportation-to-Control site problem that emerged mid-study due to construction of a very large parking facility at FAHC’s Medical center hospital—from implementing this staggered model whereby the Intervention period 1 Control site (WERC) was to have become an Intervention period 2 Test site. As WERC was located five miles from the Medical center hospital (where the majority of study subjects were employed) and was not accessible by intercampus bus, the Test site (SORC, which was accessible by Intercampus bus) thus became the more convenient site, and study subjects seen at WERC diminished proportionally.

Title: Outcomes Of Injured Employee Health Status Assessment
Investigator: Robert H. Ross
Affiliation: Vermont University
City & State: Burlington, VT
Telephone: 802-847-4874
Award Number: R21OH7339
Start & End Date: 9/30/2000-5/29/2003
Total Project Cost: 187548
Program Area:
Key Words: health care workers, intervention, musculoskeletal disorders

Final Report Abstract:

The Intervention tested the effects of incorporating the Worker-based outcomes assessment system (WBOAS) into Occupational health services (OHS) practice at Fletcher Allen Health Care (FAHC, Burlington VT). The WBOAS is a Work-related musculoskeletal disorders (WRMSD) treatment and secondary prevention improvement protocol designed to inform treatment by putting same-session (a) touchscreen-generated patient-reported outcomes trends graphics (contrasting initial, previous, and current visits on Physical and Behavioral health status, Pain symptoms and related attitudes, and Work role limitations) and (b) trends-based auxiliary treatment referral guidelines (for work site evaluation and redesign and for behavioral health care) into the hands of physical and occupational therapists (PT/OTs) and their patients. The study employed a prospective, parallel cohort, external control design--the strongest controlled trial frame possible given the impossibility, when the provider is integral to the intervention, of randomizing subjects same-site to test and control arms--and featured one Test and two Control site clinics. Subjects were FAHC employees with WRMSDs including strain/sprain, cumulative trauma (upper extremity, lower extremity, lower back), tendonitis, and carpal tunnel syndrome. Test site PT/OTs delivered Standard plus (WBOAS) care, i.e. Standard care augmented by same-session outcomes trends graphics (to set and re-set injury treatment and return-to-work goals) and trends-based referral guidelines (to initiate auxiliary worksite evaluation and redesign and/or behavioral health care). Control site PT/OTs delivered Standard care alone.

Primary predictions were that, controlling for covariates such as patient-reported demographics, co-morbidities, injury severity, physical and behavioral health, work limitations, psychosocial profile, and work conditions, Test site subjects would exhibit higher rates of (1) clinical outcome: treatment period Injury recovery (IR) and post-treatment period Re-injury avoidance (RA), (2) functional outcome: treatment period Return-to-work (RTW) and post-treatment period Stay-at-work (SA W) success, and (3) Process outcome: post-treatment period evaluated Provider performance (PP) and Overall satisfaction (OS) with care, at no lower rate of (4) .cost outcome: treatment or post-treatment period Cost-adjusted outcome (CaO). Second~ Predictions were that Test site subjects likewise would exhibit higher rates of (5) auxili~ care: treatment period referrals to Worksite evaluation and redesign (WSE, WSR) and to Behavioral health care (BHC). Results were that, compared to Standard care alone, Standard plus (WBOAS) care was found:

(I) clinical outcome: with prediction to significantly improve (a) subjects' IR and RA on patient-reported Physical functioning (SF-36 PF-10 difference in mean improvement at discharge [1 mo post-treatment follow-up] 0.22 vs 0.12 $p=0.01$, difference in mean improvement at 3 mo post-treatment follow-up 0.23 vs 0.15 $p=0.05$, difference in mean improvement at 6 mo post-treatment follow-up 0.24 vs 0.16 $p=0.07$) and on expert-rated New injury/re-injury avoidance (baseline [pre-treatment] through 6 mo post-treatment follow-up incidence 4/0.05:14/0.15 $p=0.04$), (b) male subjects' IR on expert-rated Injury recovery status at discharge (1 mo post-treatment follow-up continuous: mean 2.0 vs 2.6 $p=0.05$), and (c) male subjects' who smoke IR on expert-rated Injury recovery status at discharge (1 mo post-treatment follow-up dichotomous: percent scored 1&2 vs 3&4 481 vs 40 $p=0.05$); but against prediction not to improve (a) subjects' IR and RA on patient-reported Behavioral health status or Pain symptoms, Life control/personal efficacy, and Fear/avoidance at discharge (1 mo post-treatment follow-up) or at 3 and 6 mo post-treatment follow-up or (b) female subjects' IR on patient-reported Injury recovery status at discharge (1 mo post-treatment follow-up).

Publications: