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Early Intervention with Low Back Injured Workers who are at Risk for Work Disability

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Early Intervention With Low Back Injured Workers
Who Are At Risk For Work Disability

Final Report

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Background

Low back pain (LBP) is the leading cause of occupational disability in workers under age 45, and is a recurrent problem in workers of all ages [1,2]. Fortunately, LBP typically resolves rapidly: 60% in 1 week, 90% in 6 weeks and 95% in 12 weeks [3]. However, LBP that does not resolve [4-6] is costly: in the US alone, protracted debilitating LBP currently results in \$100 billion in treatment costs per annum [7]. Both economic and health-outcome considerations fuel growing interest in identifying the risk factors of protracted LBP-mediated disability and in early intervention focusing on the risk factors [8,9].

Risk factors for disabling LBP tend to follow a biopsychosocial predictive model [10-15]. In a workers' compensation setting, these risk factors include the individual (micro-level) demographic and psychosocial characteristics of injured workers; the system-related (meso-level) characteristics of the worksites employing and indemnifying workers when injured, the medical and occupational services treating work-related injury, the insurers authorizing the healthcare and wage loss benefits the injured workers receive; and the provincial and national (macro-level) political and regulatory structures that define disability [12,15-19].

Depression and anxiety have been documented as being among the individual psychosocial factors that are associated with recurrent LBP [20-24], and treatment is compromised when comorbid conditions are not addressed [25,26]. In addition, fear of re-injury and distress elicited by pain are often more disabling and predictive of delayed return to work (RTW) than severity of injury [18,27-32]. Furthermore, a worker's pain

beliefs are influenced by the perception of pain held by the worker's families, coworkers, and others on whom the worker relies, including their healthcare providers [33-38].

A review of the extant literature reveals several common tenets of early interventions (EI) designed to prevent occupational disability in musculoskeletal disorders. One significant tenet is that multimodal and multidisciplinary EI, combining clinical, educational and occupational RTW components, is more effective than care comprised of single elements [9,39-44]. Another tenet identifies the need for coordinated communication among disability stakeholders, i.e., the injured workers, their employer(s), their unions, other designated advocates and legal representatives, and their compensation, healthcare, and vocational providers [39,45]. A focus on RTW, appropriate and timely determination of required services, and reliance on evidence-supported care are also recurrent tenets [42,46].

Key EI components for back-injured workers include case management [47-51]; recovery and RTW planning between the primary physician and workers' compensation clinical team [52-54]; workplace assessment; job-specific task modification and work schedule accommodations [55,56]; return to pre-injury activities [8,57]; exercise and physical restoration [58,59]; cognitive-behavioral and problem solving therapies [28,48,60-64] and ongoing phone call support and print or on-line information that address re-injury fears and encourage self-efficacy [65].

The literature identifies multiple barriers to the transfer of current EI-related empirical evidence to research-informed practice guidelines [54]. Those barriers include the heterogeneity of participant and control groups, including mixed clusters of disability risk factors [24,66]; the limited degree of intervention standardization and diversity of

outcomes measured, including length of time monitored [67], and; the breadth of differences among healthcare and compensation systems overseeing expedited recovery and RTW interventions [44,46,68]. Receipt of workers' compensation benefits has also been identified in the literature as a complicating factor in EI [69]. Very few studies have utilized a workers' compensation setting as an intervention site [70-72], and even fewer have focused on workers with disabling back pain [43,45].

Evidence indicates that interdisciplinary biopsychosocial rehabilitation applied at the sub-acute stage (typically defined as between two and ten weeks after the injury) with occupational and clinical components, facilitates positive RTW outcomes [39,43,58]. Some studies into the effectiveness of EI investigated a single component or "a package" of multiple modalities implemented serially or simultaneously. Very few studies offered an integrated approach and, if so, did not focus on high-risk workers [39]. In a recent prognostic study of low back injured workers 4-6 weeks post-injury [15], a wide range of outcomes was experienced by workers whose injuries initially appeared similar [73]. As a consequence, prognostic stratification of workers was considered important to this scientific inquiry into occupational disability.

In the few EI studies conducted in workers' compensation settings, outcomes indicated that time loss from work and transition from modified to regular job duties were reduced for workers in the acute phase of their LBP [74]. These outcomes resulted from cognitive-behavioral therapies exploring the biopsychosocial processes of pain, the benefit of remaining on the job, and/or the benefit of returning to pre-injury shifts and tasks as soon as medically able. Pioneering research on interdisciplinary workers' compensation-based case management was initiated in studies on upper limb disorders

which involved the examination of case management for ergonomic problem solving and usual care [71,72]. A study by Gatchel et al. [48] also demonstrated the effectiveness of an interdisciplinary clinical team approach together with case management for general care patients at elevated risk of protracted disability.

A recent systematic review of the literature indicated that early timing of interventions during the course of disability offers an additional advantage since most clinicians become concerned about patient risk of intransigent disability (considered established by three months) at 4 weeks post-injury [75]. Whereas intervention has been found to be most effective at the sub-acute stage of LBP [76], the effect of EI is often not observed immediately, but rather becomes more prominent with time in longer term and multi-year studies [39,48,77]. In general, therefore, [46,78] large-scale trials of the influence of case management on symptom resolution, re-injury prevention, and restoration of worker sense of well being and satisfaction with their recovery and RTW are largely absent [8].

The paucity of workers' compensation-based EI studies can be explained by a number of factors, including the barriers created by the compensation system's reliance on narrowly defined biomedical or forensic models [79]; uninformed use of empirically validated flagging of "at risk" workers within 4 to 10 weeks post-injury [46,68]; the traditionally passive role of workers in recovery and RTW [79]; initiation of interdisciplinary case management only where there has been protracted time loss or reduced productivity at work, and insufficient stakeholder interaction, which also increases the likelihood of adversarial relationships and decreases the likelihood of worker participation in empirical research [46]. A review of occupational health

guidelines [80], however, found that educational approaches to removing the psychosocial barriers to recovery and enhancing worker self-management of musculoskeletal pain, while innovative, have not yet fully addressed the impact of workplace organizational factors on RTW.

The purpose of this study was to evaluate the effectiveness of early intervention, within the workers' compensation setting, for high- and moderate-risk workers who had sustained a back injury and had remained off work for 4 to 10 weeks following injury. The EI under study was based on the most current evidence-based research on interdisciplinary management of acute and sub-acute back pain [46,52,74,80,81].

The current EI intervention comprised integrated clinical, occupational and case management components. To identify those at elevated risk for continued work disability, to select a study population, and to prognostically stratify high and medium risk sub-groups from the original cohort of injured workers who had not returned to work 4 to 10 weeks post-injury, the study utilized the recently validated Risk for Disability Questionnaire [82], which has been used in earlier research.

In a precursor to this research, a pilot study was conducted, the results and recommendations of which were used to inform the current EI study. The pilot study empirically demonstrated the effectiveness of EI in time loss reduction in the workers' compensation setting. In addition, statistically significant differences were recorded at six months post intervention for workers at the highest risk of protracted disability [83]. These results are consistent with other EI studies undertaken during the acute and sub-acute phases of back pain.

Analysis of the content of the current intervention and the results of other studies suggest that the improved outcomes observed may have been linked to reduced fear and catastrophizing, increased awareness of the benign nature of non-specific back pain, the benefit of self-efficacy, positive expectations of recovery and RTW, and other coping skills provided by the EI [17]. Enhanced employer support for RTW, brought about by workplace intervention, was also a likely facilitator [84].

The current study built on the recommendations of the pilot EI study, utilizing a randomized approach and exploring cost-benefits of the intervention. The literature stipulates that, following injury, early intervention enhances recovery and return to work, and decreases costs [17,31,32,43,63,85-88]. Despite a paucity of research and diverse outcomes, there is emerging empirically derived evidence and clinical consensus that motivational interviewing and negotiation as intervention techniques may bring about constructive change in pain management [89,90] and reduce perceived obstacles to recovery and RTW for workers with LBP who are at risk of protracted disability [80,91]. Therefore, motivational interviewing, negotiation and collaborative problem solving involving all key disability stakeholders: the injured worker, workers' compensation system representatives (nurse advisor, medical advisor and case manager), employer and family physician were conceived as central cognitive-behavioral approaches to this EI study. Other interdisciplinary advisers were also available, on an as needed basis, throughout recovery and RTW.

Methods

Study Objectives

The main objective of this study was to evaluate the effectiveness of proactive, interdisciplinary EI within a workers' compensation interdisciplinary case management setting. The study focused on workers at risk of protracted disability following back injury who remained off work 4 to 10 weeks post-injury. The specific objectives were threefold: 1) to evaluate EI for sub-acute back-injured workers at elevated risk for protracted work disability, 2) to evaluate the recovery and RTW outcomes, and 3) to provide EI improvement recommendations. To achieve these objectives, the study incorporated the following components derived from current evidence-informed RTW guidelines and studies [46,89,92-95]: case management-based secondary disability prevention; multidisciplinary, multimodal intervention combining clinical, occupational and case management approaches; ongoing, timely communication among stakeholders; an early workplace visit involving stakeholders and focused on medically-indicated, productive job accommodations; motivational interviewing, negotiation and RTW coaching by an occupational health trained nurse to reduce fears of re-injury and RTW and other negative expectations held by the workers, and; joint development and implementation of a cost effective recovery and RTW plan, in conjunction with the worker and multi-disciplinary case management team.

Design of the Study

In this randomized controlled study, conventional workers' compensation case management was compared with interdisciplinary, multimodal, clinical, occupational and case management-based early intervention for back injured workers at two different levels of risk for disability: moderate and high.

The study received Ethics approval from the University of British Columbia. Workers with non-specific back injury claims 4-10 weeks post injury received a letter from the research team inviting their voluntary participation, together with the consent forms and questionnaire packages. The information obtained from the questionnaire, including the workers' risk for disability level, was kept confidential. The occupational health nurse from the workers' compensation case management team received the names of the workers who agreed to participate and who met the admission criteria, and initiated the EI.

Participant Selection

Participants were selected, according to study admission criteria, from workers' compensation (WorkSafeBC) Service Delivery Locations (SDLs) in large, urban centres in British Columbia, Canada. The Risk for Disability Questionnaire [15,82] was mailed to all workers who had sustained a compensable back injury and were 4 to 10 weeks post-injury. Workers were identified as having elevated risk for disability (moderate or high) on the basis of their summary score from the questionnaire. Baseline measures within the questionnaire gathered information on participant demographics and responses to questions from the Short Form (SF)-36 Health Survey [96], Expectations of Recovery, Workers' Compensation System's and Employer's Response to Claim, Perception of Severity of Disability, Waddell Symptoms [97] and Karasek Job Content Questionnaire [98].

To be admitted to the study, workers had to be at high risk (defined as less than a 33% probability of RTW within three months of assessment) or moderate risk (defined as those with a 34 to 65% probability of RTW within three months of assessment) of

disability. Risk levels were determined on the basis of previous research using the RDQ [15,82]. Participants also had to be between ages 19 and 65 inclusive. As well, the participants could not be working more than 20 hours per week, and had to be in receipt of workers' compensation temporary partial or total disability benefits. In order to participate in the study, workers also had to be able read and respond in English. Workers with a knee, hip, head, or neck injury, workers who were pregnant, and/or those with previous back surgery were excluded.

Consenting injured workers who qualified for the study were randomly assigned to either the Early Intervention or Control groups. The Control group received case management in the usual manner of the workers' compensation system in British Columbia. The Early Intervention group, in contrast, received proactive, multimodal EI.

Workers' Compensation Case Management Teams

In both the Intervention and Control groups, the case management teams were comprised of a physician, nurse advisor, registered psychologist, vocational rehabilitation consultant, case manager and team administrative assistant.

Experimental procedures

The EI was informed by the evidence-based management model advocated in the literature [80]: it comprised an integrated occupational, clinical and case management approach within a biopsychosocial rehabilitation context. More specifically, the intervention was comprised of the following key elements:

- 1) **Multi-System Interaction:** to ensure and facilitate communication and coordination of RTW activities between the worker and his or her primary care

- physician and specialists, employer(s), other service providers, unions, advocates and representatives, and the case management team;
- 2) Multi-Method Approach: to encourage workers' realistic and positive expectations of recovery and to remove or reduce barriers to RTW;
 - 3) Enhancement of Capabilities: to provide referral services, support, education and reassurance to assist workers in achieving recovery and RTW goals, including workplace support and advice to stay active; to aid the case management team in resolving RTW issues, and; to offer consultation to other stakeholders;
 - 4) Resource Use and Coordination: to ensure appropriate referrals and resources to support injured workers; to identify and take action to address gaps in and barriers to services, and; to maintain provider consistency, issues resolution and goal-directedness.

The intervention focused on individual workers and on three critical systems within which workers interacted during the course of recovery from a back injury recovery: the workplace (employer, coworkers and unions), the workers' compensation system (case manager and advisors), and the primary health care providers (family physician).

To implement the EI within the workers' compensation setting, the following was undertaken:

- Training: the case management team at the intervention site was provided training in evidence-focused clinical and occupational guidelines, and in "soft" clinical skills including problem-solving, motivational interviewing and negotiation;

- Early referrals: referrals to the case management team at the intervention site were made once workers consented to participate;
- One-to-one session: a session with the worker was conducted by a nurse advisor on the case management team to identify the worker's expectations of recovery, perception of disability and RTW barriers, and to provide education, reassurance, encouragement to stay active, and back pain management advice [81]. The case manager was available to answer worker claim-related questions and to participate in the development of the RTW plan;
- Workplace visit: the nurse advisor was available for a workplace visit to participants, and;
- Interaction with family physician: communication between a workers' compensation physician and the worker's primary healthcare practitioner with respect to recovery and RTW issues.

Measures

A previously developed and validated Risk for Disability Questionnaire [82] was utilized. Cut-off scores were determined to separate the participants into thirds, establishing stratification of the injured worker sample into low, moderate and high risk for disability levels.

The binary outcome of Return to Work was measured at three, six and twelve months for both the intervention and control groups. Duration of disability, costs of health care and wage loss were also measured at six and twelve months for both groups, using workers' compensation claim data administrative databases.

Results

Sample

A total of 2943 questionnaires were mailed to workers (see Figure 1). Of the 747 (25%) respondents, 239 met the eligibility criteria for participation in the study. Of these 239 eligible individuals, 76 workers were assessed to be at elevated risk for disability: 31 at high risk and 45 at moderate risk. These 76 individuals were randomly assigned to Intervention and Control groups. Due to participant attrition, the final intervention group comprised 29 workers: 13 high risk and 16 moderate risk.

A total of 63 participants comprised the final study: 29 participants in the Intervention group and 34 participants in the Control group.

Figure 1. Early Intervention Study Sampling Frame

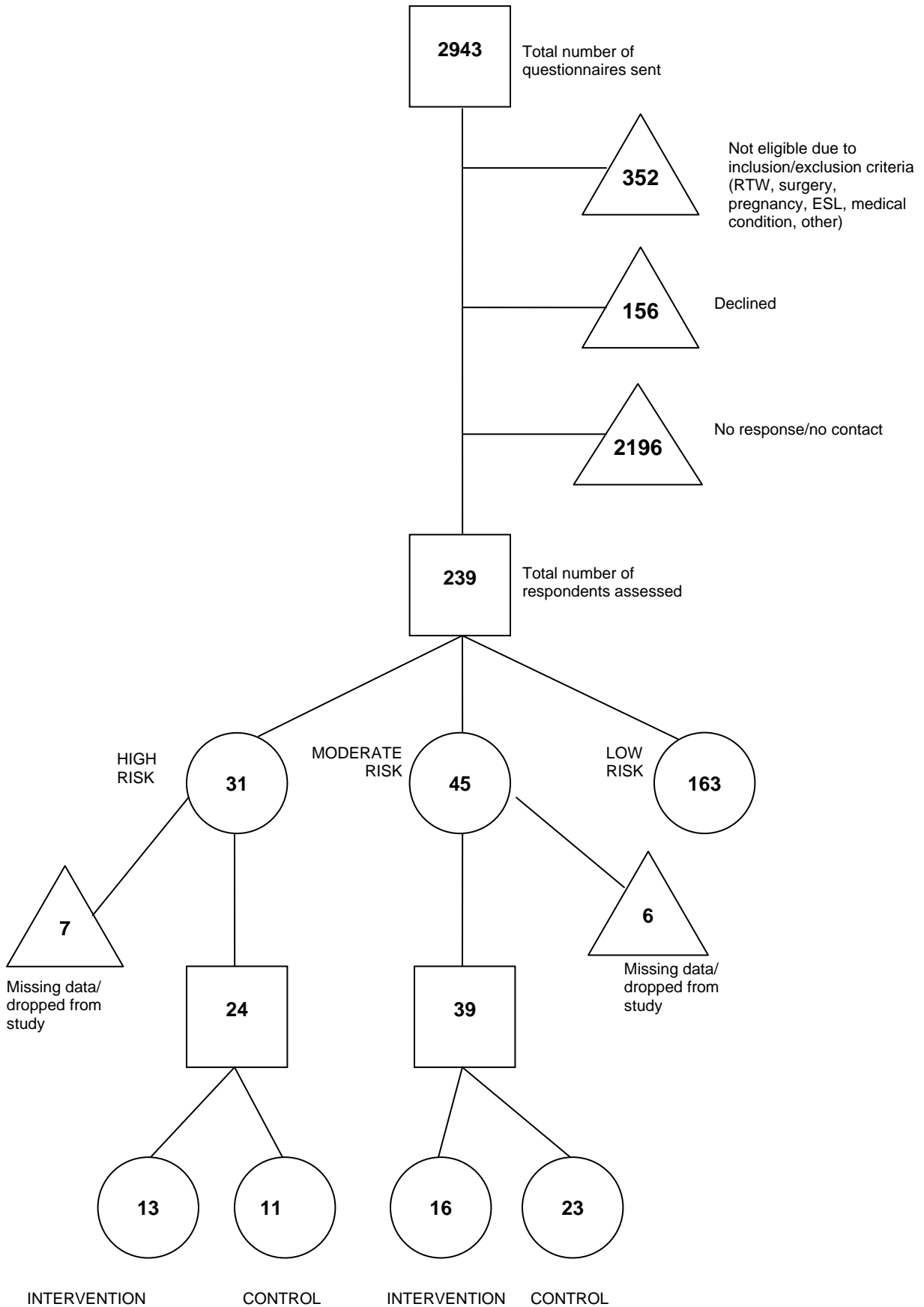


Table 1 shows the number (and percent) of respondents in each risk category, for the two study groups. The difference between groups with respect to percentage of high risk participants was not statistically significant ($P=.31$).

Table 1. Number (and percent) of participants in each risk category, by study group

Risk Category	Study Group		Total
	Intervention	Control	
Moderate	16 (55%)	23 (68%)	39 (62%)
High	13 (45%)	11 (32%)	24 (38%)
Total	29	34	63

Comparison of Study Groups by Demographic Characteristics

Since the two groups were similar with respect to percentage in each risk category, participants from both risk categories were combined in order to assess the comparability of the two study groups with respect to demographic variables (see Table 2).

Table 2 shows that the Intervention and Control groups were similar with respect to age, sex, education, marital status, size of household, union membership, years at current job, and hours of work prior to injury.

Table 2. Comparison of study groups by demographic variables

Characteristic	Study Group		P-value (1)
	Intervention (N=29) Count (Percent)	Control (N=34) Count (Percent)	
<i>Sex:</i>			
Male	19 (66%)	21 (62%)	.76
Female	10 (34%)	13 (38%)	
<i>Marital Status:</i>			
Married/Common-Law	21 (73%)	21 (62%)	.62
Single (Never Married)	5 (17%)	7 (21%)	
Widowed/Separated/Divorced	3 (10%)	5 (17%)	
<i>Percent total income worker provided:</i>			
Over 75%	87 (58%)	54 (57%)	.83
50% to 75%	37 (25%)	27 (28%)	
25% to 50%	19 (13%)	9 (10%)	
Under 25%	7 (5%)	5 (5%)	
<i>Highest education:</i>			
Grade School (0-8 yrs)	2 (7%)	0 (0%)	.27
High School (9-12 yrs)	11 (38%)	12 (35%)	
College/University/Technical School	16 (55%)	22 (65%)	
<i>Number of people in household</i>			
1	5 (17%)	6 (18%)	.81
2	7 (24%)	7 (21%)	
3	7 (24%)	9 (26%)	
4	5 (17%)	9 (26%)	
5	5 (17%)	3 (9%)	
<i>Union member?</i>			
Yes	22 (76%)	22 (65%)	.34
No	7 (24%)	12 (35%)	
Characteristic			
	Intervention (N=29) Mean (SD)	Control (N=34) Mean (SD)	P-value (2)
<i>Age (at injury)</i>	43.4 (9.5)	39.8 (9.7)	.14
<i>Number of people in household</i>	2.9 (1.4)	2.9 (1.38)	.88
<i>Number of months held current job</i>	105.3 (97.7)	80.1 (78.5)	.27
<i>Number of hours working when injured</i>	34.3 (17.0)	35.5 (18.2)	.80

Notes:

(1) P-values are based on chi-square tests of independence

(2) P-values are based on two-sample t-tests of means

Comparison of Study Groups by Biopsychosocial Measures

The comparability of the two study groups with respect to biopsychosocial measures at baseline was also assessed using participants from both risk categories combined (see Table 3). The Intervention and Control groups were not significantly different with respect to any of the SF-36 scales, except Mental Health, nor with respect to Perception of Severity of Disability, Waddell Symptoms, Employer Response to Claim, Expectations of Recovery, or any of the workplace scales based on Organizational Policies and Practices. Although the Intervention group had a higher mean score on the SF-36 Mental Health subscale, this result is likely spurious and due to the fact that nearly 20 tests were performed here, thus inflating the probability of a Type I error.

Table 3. Comparison of study groups by biopsychosocial measures at baseline

Biopsychosocial Measures	Study Group		P-value (1)
	Intervention (N=29)	Control (N=34)	
	Mean (SD)	Mean (SD)	
Expectations of Recovery (Range: 7-21)	16.7 (2.5)	15.9 (2.7)	.22
Response to Claim (Range: 0-4)	2.2 (1.2)	2.6 (1.3)	.22
SF-36: Physical Functioning	30.5 (16.9)	33.1 (19.2)	.58
SF-36: Role-Physical	0.9 (4.6)	0.7 (4.3)	.91
SF-36: Bodily Pain	26.4 (9.2)	28.5 (14.9)	.52
SF-36: General Health	58.8 (21.8)	62.5 (15.9)	.44
SF-36: Vitality	25.7 (14.3)	25.0 (16.1)	.86
SF-36: Social Functioning	41.4 (16.7)	33.5 (19.4)	.090
SF-36: Role-Emotional	23.0 (34.6)	11.8 (25.8)	.15
SF-36: Mental Health	52.7 (16.5)	44.6 (14.1)	.040
SF-36: Health Transition	3.0 (0.5)	2.9 (0.8)	.63
SF-36: Physical Component Scale	28.9 (4.1)	29.1 (4.1)	.80
SF-36: Mental Component Scale	38.2 (6.7)	35.9 (5.1)	.13
Perception of Severity of Disability	2.2 (0.8)	2.4 (0.9)	.35
Waddell Symptoms	3.0 (1.4)	2.6 (1.3)	.31
OPP People-oriented Culture (2)	2.6 (1.0)	2.6 (0.9)	.91
OPP Safety Climate (2)	2.9 (1.0)	3.1 (0.8)	.49
OPP Ergonomic Practices (2)	2.2 (1.0)	2.2 (1.1)	.88
OPP Disability Management (2)	2.6 (0.8)	2.7 (0.9)	.72

Notes:

(1) P-values are based on two-sample t-tests of means

(2) The reference for this scale on Organizational Policies and Practices (OPP) is: Amick & Habeck (2000)[99].

Other Baseline Comparisons

There was no significant association between either the return to work or risk categories and any of the following variables: sex, marital status, highest education level, union membership, number of people in household, number of hours working when injured, number of hours working now, or total months employed by this employer. The only differences identified were that those who did not return to work were younger, and those with high risk for disability had held their current jobs longer.

Comparison of Study Groups by Return to Work Outcome Measures

The two study groups were compared with respect to the primary outcome of Return to Work (RTW), first using the total sample and then separately for each risk category. If RTW had not occurred by 12 months a participant was classified as Did Not RTW (NRTW; see Table 4).

There was no evidence of a difference between Intervention and Control groups in RTW status either for the total sample or for either risk category. For moderate risk, a higher percentage of the Control group returned to work by 3 months while for high risk, a higher percentage of the Intervention group returned to work by 3 months; however, neither difference was statistically significant. Overall, 93% of the Intervention group and 85% of the Control group returned to work.

Table 4. Comparison of study groups by Return to Work (RTW) outcome measures

Total Sample	Study Group		P-value
	Intervention (N=29)	Control (N=33)	
RTW at 3 months	17 (59%)	21 (64%)	.14
RTW at 6 months	6 (21%)	1 (3%)	
RTW at 12 months	4 (14%)	6 (18%)	
Did not RTW (NRTW)	2 (7%)	5 (15%)	

Moderate Risk	Study Group		P-value
	Intervention (N=16)	Control (N=23)	
RTW at 3 months	9 (56%)	18 (78%)	.073
RTW at 6 months	4 (25%)	0 (0%)	
RTW at 12 months	1 (6%)	3 (13%)	
NRTW	2 (13%)	2 (9%)	

High Risk	Study Group		P-value
	Intervention (N=13)	Control (N=10)	
RTW at 3 months	8 (62%)	3 (30%)	.15
RTW at 6 months	2 (15%)	1 (10%)	
RTW at 12 months	3 (23%)	3 (30%)	
NRTW	0 (0%)	3 (30%)	

Note: (1) P-values are based on chi-square tests of independence

Analysis of Number of Interventions

The Intervention and Control groups were compared with respect to the number of “encounters” or “interventions” received, classified into the following categories:

- nurse advisor involvements
- workplace visits or assessments
- case management involvements
- communications between WorkSafe’s medical advisor/nurse advisor and the worker’s primary physician
- other interventions

- total interventions

Since the distributions of the number of interventions were highly skewed, two analyses were carried out: two-sample t-tests and Mann-Whitney rank tests (see Table 5). The conclusions from both were the same: the Intervention group had significantly more interventions in each category and overall. In fact, the total number of interventions in the Intervention group was about double the number in the Control group.

Table 5. Comparison of study groups by numbers of interventions

Number of...	Intervention (N=29)			Control (N=32)			t-test	Mann-Whitney
	Mean	Median	Range	Mean	Median	Range	P-value	P-value
Nurse Advisor Involvements	9.2	7	0-26	1.4	0	0-14	<.001	<.001
Workplace Visits or Assessments	0.7	1	0-2	0.3	0	0-2	.013	.013
Case Management Involvements	23.4	16	0-141	13.6	12	0-53	.070	.045
Communications between MA/NA and Physician	0.6	0	0-2	0.4	0	0-3	.27	.14
Other Interventions	3.8	3	0-18	2.3	2	1-9	.034	.042
Total Interventions	37.7	30	0-187	17.9	16	1-64	.006	.002

In addition, the association between number of interventions and return to work status was analyzed in both the Intervention and Control Groups (see Table 6).

Table 6: Association between number of interventions and RTW in the Intervention and Control groups

Moderate Risk	RTW status	Mean	N	SD	
Intervention	RTW at 3 mos	26.4	9	18.0	
	RTW at 6 mos	31.8	4	24.9	
	RTW at 12 mos	187.0	1	-	
	Did not RTW	51.5	2	17.7	
	TOTAL	40.9	16	43.6	P-value = .001
Control	RTW at 3 mos	15.8	16	14.8	
	RTW at 12 mos	17.7	3	16.5	
	TOTAL	15.6	21	14.0	P-value = .90
High Risk					
Intervention	RTW at 3 mos	22.9	8	10.8	
	RTW at 6 mos	70.0	2	46.7	
	RTW at 12 mos	38.0	3	18.0	
	TOTAL	33.6	13	24.6	P-value = .032
Control	RTW at 3 mos	16.0	3	4.6	
	RTW at 6 mos	13.0	1	-	
	RTW at 12 mos	23.7	3	5.5	
	Did not RTW	37.3	3	17.7	
	TOTAL	24.4	10	13.2	P-value = .18

The results of the analysis showed that the number of interventions was significantly associated with return to work in the Intervention group, for workers with moderate and high risk for disability. No such association was found in the Control group.

Comparison of Study Groups by Cost and Days Lost Outcome Measures

The two study groups were compared for moderate and high risk categories combined and then again separately, using outcome measures of Work Days Lost, Total Costs, STD Costs, and Health Care Costs, each within windows of 6 and 12 months (see Table 7). Vocational Rehabilitation Costs are included in the Total Costs, but not split out here since they occurred very rarely.

For the total sample there was no statistically significant difference between the Intervention and Control groups with respect to days paid or costs. Although the cost data

exhibited considerable variability throughout, reducing the power to detect differences between groups, the Intervention group showed consistently higher mean levels than the Control group for all the cost variables.

For moderate risk participants, Work Days Lost, Total Costs and STD Costs, within six months were significantly higher for the Intervention group than the Control group. For example the Intervention group had a mean Total Cost within six months of approximately \$13,000, compared with the Control group which had a mean of approximately \$8,900. Further, the mean Days Paid within six months was 95 for the Intervention group compared with 73 for the Control group.

There were no statistically significant differences between study groups for the high risk participants. An examination of the means shows very similar levels for the two groups.

Table 7. Comparison of study groups by Cost (\$) and Days Lost outcome variables

Total Sample	Study Group		P-value (1)
	Intervention (N=29)	Control (N=34)	
	Mean (SD)	Mean (SD)	
Work Days Lost within 6 mos	94 (43)	79 (38)	.13
Work Days Lost within 12 mos	108 (68)	86 (48)	.13
Total Costs within 6 mos	12302 (6897)	9687 (5134)	.090
Total Costs within 12 mos	15028 (11808)	11184 (8384)	.14
STD Costs within 6 mos	8964 (4801)	7091 (4065)	.10
STD Costs within 12 mos	10337 (7477)	7894 (5694)	.15
Health Care Costs within 6 mos	3278 (2809)	2595 (1564)	.23
Health Care Costs within 12 mos	4630 (4875)	3289 (3019)	.19

Moderate Risk	Study Group		P-value (1)
	Intervention (N=16)	Control (N=23)	
	Mean (SD)	Mean (SD)	
Work Days Lost within 6 mos	95 (39)	73 (38)	.093
Work Days Lost within 12 mos	112 (68)	83 (51)	.14
Total Costs within 6 mos	12940 (7715)	8907 (4122)	.041
Total Costs within 12 mos	16042 (13626)	10899 (8808)	.16
STD Costs within 6 mos	9399 (4962)	6634 (3338)	.044
STD Costs within 12 mos	11275 (8758)	7731 (5723)	.13
Health Care Costs within 6 mos	3541 (3428)	2273 (1319)	.11
Health Care Costs within 12 mos	4767 (5139)	3168 (3376)	.25

High Risk	Study Group		P-value (1)
	Intervention (N=13)	Control (N=11)	
	Mean (SD)	Mean (SD)	
Work Days Lost within 6 mos	94 (48)	90 (37)	.82
Work Days Lost within 12 mos	104 (70)	91 (41)	.61
Total Costs within 6 mos	11517 (5949)	11316 (6731)	.94
Total Costs within 12 mos	13780 (9496)	11778 (7791)	.58
STD Costs within 6 mos	8428 (4737)	8046 (5343)	.86
STD Costs within 12 mos	9183 (5653)	8234 (5894)	.69
Health Care Costs within 6 mos	2955 (1874)	3270 (1872)	.69
Health Care Costs within 12 mos	4462 (4732)	3544 (2216)	.56

Note: (1) P-values are based on two-sample t-tests of means

To address concern that the study host introduced a form of early intervention in the Control group instead of conventional case management, an extended comparative

outcome analysis using a comparison group that included conventional case management without early intervention (the comparison group from a previous, pilot [non-randomized] study) was utilized. Participants in the pilot study group met the same entry, demographic and biopsychosocial criteria as participants in the randomized study and were therefore considered an appropriate comparator. The results of the comparison are shown in Table 8.

Table 8. Comparison between EI Pilot Project Conventional Case Management group and EI Current Project Intervention and Control Groups

	Pilot Study Conventional Case Management Comparison Group	Current Study Early Intervention Group	Current Study Control Group	
Moderate Risk	n = 20	n = 16	n = 23	
	Count (percent)	Count (percent)	Count (percent)	P-value (1)
RTW at 3 months	17 (85%)	9 (56%)	18 (78%)	.13
RTW at 6 months	16 (80%)	13 (81%)	18 (78%)	.97
	Mean (SD)	Mean (SD)	Mean (SD)	P-value (2)
Days lost	77 (45)	112 (68)	83 (51)	.073
	Pilot Study Conventional Case Management Comparison Group	Current Study Early Intervention Group	Current Study Control Group	
High Risk	n = 17	n = 13	n = 11	
	Count (percent)	Count (percent)	(Count percent)	P-value (1)
RTW at 3 months	6 (35%)	8 (61%)	3 (30%)	.23
RTW at 6 months	5 (29%)	10 (77%)	4 (40%)	.031
	Mean (SD)	Mean (SD)	Mean (SD)	P-value (2)
Days lost	120 (44)	104 (70)	91 (41)	.45

(1) Chi-square tests to compare percentages across all three groups

(2) One-way ANOVA F-tests to compare means across all three groups

Notably, for the high risk for disability subgroup, a significantly higher percentage of the Early Intervention study group returned to work by 6 months (using cumulative totals) than for the two comparison groups, including the Control group and the Conventional Case Management Comparison group from the pilot study [83]. No other return to work differences were significant.

In addition, Days Lost were higher in the current study for the moderate risk subgroup but lower in the high risk subgroup; however, the latter difference was not significant.

Summary of Return to Work Over Time

RTW at Three Months.

At the 3 month follow-up, data on Return to Work were obtained for 58 of the 63 total participants at baseline. Of these, two-thirds (66%, 38 of 58 participants) reported that they were currently working. Of those currently working, 79% (30 of 38) were working full-time; 68% (26 of 38) had returned to their former job, 17% (6 of 38) to a modified former job and 17% (6 of 38) to a different job. Most (92%, 35 of 38) had the same employer as prior to the injury.

Of the one-third (34%, 20 of 58) who were not currently working, 6 (30%) had made attempts at return to work; 3 had not returned to work for reasons other than the injury.

RTW at Six Months.

At the 6 month follow-up, data on Return to Work were obtained for 52 of the 63 total participants at baseline. Of these, over two-thirds (71%, 37 of 52 participants) reported that they were currently working. Of those currently working, 78% (29 of 37) were working full-time; 73% (27 of 37) had returned to their former job, 5% (2 of 37) to a modified former job, 3% (1 of 37) to a similar job, and 19% (7 of 37) to a different job. Most (87%, 32 of 37) had the same employer as prior to the injury.

Of the one-third (29%, 15 of 52) who were not currently working, 10 (67%) had made attempts at return to work; and 5 had not returned to work for reasons other than the injury.

RTW at Twelve Months.

At the 12 month follow-up, data on Return to Work were obtained for 48 of the 63 total participants at baseline. Of these, four in five (79%, 38 of 48 participants) reported that they were currently working. Of those currently working, 90% (34 of 38) were working full-time; 76% (29 of 38) had returned to their former job, 8% (3 of 38) to a modified former job, and 16% (6 of 38) to a different job. Most (84%, 32 of 38) had the same employer as prior to the injury.

Of the one-fifth (21%, 10 of 48) who were not currently working, 8 (80%) had made attempts at return to work; 4 had not returned to work for reasons other than the injury.

Table 9 presents Return to Work Accommodations made for the 38 participants who had returned to work by the 3-month, 6-month and 12-month points.

Table 9: Three-month, Six-month, and Twelve-month RTW Accommodations

Type of Work Accommodation	Three-month (N=38)		Six-month (N=37)		Twelve-month (N=38)	
	Number	Pct of Cases	Number	Pct of Cases	Number	Pct of Cases
No accommodations made	12	32%	14	38%	13	34%
Accommodations not necessary	0	0%	0	0%	0	0%
Another job (temporary)	1	3%	2	5%	0	0%
Another job (permanent)	1	3%	0	0%	0	0%
Graduated Return to Work	20	53%	21	57%	25	66%
Light or modified duties	15	40%	16	43%	15	40%
Flexible scheduling	7	18%	8	22%	5	13%
Special equipment	1	3%	0	0%	1	3%
Modification of machinery	0	0%	1	3%	0	0%
Modification of work environment	3	8%	0	0%	1	3%
Reduced amount of work	7	18%	9	24%	9	24%
Longer breaks	5	13%	4	11%	3	8%
Change in shifts	4	11%	4	11%	3	8%
Other accommodation	6	16%	5	14%	9	24%

Note: The total percentages exceed 100% since multiple work accommodations were possible.

Notably, the most commonly used Work Accommodations at all data collection times measured were: Graduated Return to Work, Light or Modified duties, Flexible Scheduling, and Reduced Amount of Work. About one third of the participants did not receive any accommodations.

The relationship between job accommodations and RTW was also analyzed for the total sample of participants using three variables which categorized cases by whether or not any accommodations were made at the 3 month, 6 month and 12 month time points. Subsequently, these variables were cross-tabulated by return to work status (see Table 10).

Table 10. Relationship between job accommodations and RTW

A3 = Any accommodations made at 3 months, by RTW status					
A3	RTW at 3 mo	RTW at 6 mo	RTW at 12 mo	Did not RTW	Row Total
No	10 26.3%	7 100.0%	9 90.0%	7 100.0%	33 53.2%
Yes	28 73.7%	0 .0%	1 10.0%	0 .0%	29 46.8%
Total	38	7	10	7	62
Chi-square = 28.8; P-value < .001					
A6 = Any accommodations made at 6 months, by RTW status					
A6	RTW at 3 mo	RTW at 6 mo	RTW at 12 mo	Did not RTW	Row Total
No	20 52.6%	2 28.6%	8 80.0%	6 85.7%	36 58.1%
Yes	18 47.4%	5 71.4%	2 20.0%	1 14.3%	26 41.9%
Total	38	7	10	7	62
Chi-square = 7.14; P-value = .068					
A12 = Any accommodations made at 12 months, by RTW status					
A12	RTW at 3 mo	RTW at 6 mo	RTW at 12 mo	Did not RTW	Row Total
No	20 52.6%	4 57.1%	5 50.0%	6 85.7%	35 56.5%
Yes	18 47.4%	3 42.9%	5 50.0%	1 14.3%	27 43.5%
Total	38	7	10	7	62
Chi-square = 2.83; P-value = .42					

A review of Table 10 showed that at three months, participants who had received any job accommodation were more likely to have returned to work. However, this relationship appeared to have diminished by six months and disappeared at twelve months.

Comparison of Return to Work by biopsychosocial measures at 6 and 12 months

At 6 months, the group that had returned to work and the group that had not were not significantly different on any of the SF-36 subscales or Waddell Symptoms scale (see Table 11). However, at 12 months, the group that had returned to work had significantly more positive scores on most of the SF-36 subscales and the Waddell Symptoms scale than the group that had not returned to work (see Table 12). Among SF-36 subscales

predictive of RTW, the following were most significant: Physical Functioning, Role Emotional, Mental Health, and Physical Component.

Table 11. Comparison of RTW (Yes/No) by biopsychosocial measures at 6 Months

	RTW = Yes (N=37)	RTW = No (N=15)	
Biopsychosocial Measures	Mean (SD)	Mean (SD)	P-value (1)
SF-36: Physical Functioning	65.3 (22.1)	61.7 (28.0)	.62
SF-36: Role-Physical	37.8 (41.1)	35.0 (42.1)	.82
SF-36: Bodily Pain	47.8 (23.6)	50.4 (28.1)	.74
SF-36: General Health	57.7 (24.5)	64.4 (20.5)	.35
SF-36: Vitality	45.3 (24.1)	57.0 (22.3)	.11
SF-36: Social Functioning	66.2 (26.7)	62.5 (26.7)	.65
SF-36: Role-Emotional	60.4 (42.2)	60.0 (40.2)	.98
SF-36: Mental Health	66.0 (22.6)	64.3 (23.6)	.81
SF-36: Health Transition	3.0 (0.6)	2.7 (0.8)	.17
SF-36: Physical Component Scale	40.0 (9.5)	38.2 (11.9)	.57
SF-36: Mental Component Scale	44.3 (11.0)	47.5 (10.0)	.33
Waddell Symptoms	1.9 (1.5)	2.3 (2.3)	.49

Note: (1) P-values are based on two-sample t-tests of means

Table 12. Comparison of RTW (Yes/No) by biopsychosocial measures at 12 Months

	RTW = Yes (N=38)	RTW = No (N=10)	
Biopsychosocial Measures	Mean (SD)	Mean (SD)	P-value (1)
SF-36: Physical Functioning	71.1 (23.3)	50.5 (21.4)	.015
SF-36: Role-Physical	51.3 (44.3)	25.0 (40.8)	.096
SF-36: Bodily Pain	57.1 (23.4)	43.5 (13.3)	.085
SF-36: General Health	63.3 (25.1)	48.3 (25.8)	.10
SF-36: Vitality	52.0 (24.4)	37.5 (23.7)	.10
SF-36: Social Functioning	70.4 (31.2)	58.8 (29.5)	.29
SF-36: Role-Emotional	74.6 (35.9)	46.7 (39.1)	.037
SF-36: Mental Health	72.4 (18.6)	56.4 (24.5)	.028
SF-36: Health Transition	3.0 (0.3)	2.9 (0.6)	.57
SF-36: Physical Component Scale	43.7 (8.7)	35.4 (8.4)	.010
SF-36: Mental Component Scale	46.9 (10.6)	41.0 (12.1)	.14
Waddell Symptoms	1.6 (1.6)	3.2 (2.3)	.014

Note: (1) P-values are based on two-sample t-tests of means

Repeated Measures Analysis of Variance

Repeated measures analysis of variance revealed that none of the scales showed significant differences with respect to study group or risk category. Change over time was strongly significant for all subscales except the SF-36 General Health and SF-36 Health Transition subscales (see Table 13). It also appears that the major gains in all cases occurred between baseline and 6 months. Mean differences between 6 and 12 months are usually comparatively smaller and sometimes no gains are indicated (for example, in general health and vitality).

Table 13: Comparison of Mean Scores on SF-36 and Waddell Symptoms, by Study Group and Risk Category, across time (Baseline, Six months, Twelve Months)

Physical Functioning	Experimental			Control			Full Sample		
	Mod	High	Total	Mod	High	Total	Mod	High	Total
Baseline	27.5	34.0	30.8	33.7	28.1	31.7	31.2	31.4	31.3
Six Months	61.5	70.0	65.8	62.0	65.0	63.0	61.8	67.8	64.3
Twelve Months	58.5	70.5	64.5	70.7	66.9	69.4	65.8	68.9	67.1
Role-Physical	Experimental			Control			Full Sample		
	Mod	High	Total	Mod	High	Total	Mod	High	Total
Baseline	0.0	2.5	1.3	1.7	0.0	1.1	1.0	1.4	1.2
Six Months	20.0	40.0	30.0	36.7	34.4	35.9	30.0	37.5	33.1
Twelve Months	32.5	50.0	41.3	46.7	50.0	47.8	41.0	50.0	44.8
Bodily Pain	Experimental			Control			Full Sample		
	Mod	High	Total	Mod	High	Total	Mod	High	Total
Baseline	26.5	28.5	27.5	32.1	14.9	26.1	29.9	22.4	26.8
Six Months	39.9	54.0	47.0	47.7	50.0	48.5	44.6	52.2	47.8
Twelve Months	48.0	56.3	52.2	53.6	57.5	55.0	51.4	56.8	53.7
General Health	Experimental			Control			Full Sample		
	Mod	High	Total	Mod	High	Total	Mod	High	Total
Baseline	60.2	55.1	57.7	61.6	58.8	60.6	61.0	56.7	59.2
Six Months	69.5	62.6	66.1	52.5	65.4	57.0	59.3	63.8	61.2
Twelve Months	60.5	52.7	56.6	54.7	69.5	59.8	57.0	60.2	58.3
Vitality	Experimental			Control			Full Sample		
	Mod	High	Total	Mod	High	Total	Mod	High	Total
Baseline	33.0	15.0	24.0	28.0	18.8	24.8	30.0	16.7	24.4
Six Months	60.0	49.5	54.8	43.0	46.3	44.1	49.8	48.1	49.1
Twelve Months	48.0	39.5	43.8	50.7	55.0	52.2	49.6	46.4	48.3

Social Functioning	Experimental			Control			Full Sample		
	Mod	High	Total	Mod	High	Total	Mod	High	Total
Baseline	48.8	37.5	43.1	37.5	18.8	31.0	42.0	29.2	36.6
Six Months	68.8	63.8	66.3	60.0	64.1	61.4	63.5	63.9	63.7
Twelve Months	58.8	73.8	66.3	73.3	65.6	70.7	67.5	70.1	68.6

Role-Emotional	Experimental			Control			Full Sample		
	Mod	High	Total	Mod	High	Total	Mod	High	Total
Baseline	30.0	30.0	30.0	11.1	4.2	8.7	18.7	18.5	18.6
Six Months	80.0	46.7	63.3	55.6	54.2	55.1	65.3	50.0	58.9
Twelve Months	53.3	73.3	63.3	75.6	75.0	75.4	66.7	74.1	69.8

Mental Health	Experimental			Control			Full Sample		
	Mod	High	Total	Mod	High	Total	Mod	High	Total
Baseline	64.4	45.2	54.8	46.9	35.0	42.8	53.9	40.7	48.4

Six Months	76.0	65.2	70.6	62.1	59.0	61.0	67.7	62.4	65.5
Twelve Months	66.0	61.2	63.6	76.0	68.0	73.2	72.0	64.2	68.7
Health Transition	Experimental			Control			Full Sample		
	Mod	High	Total	Mod	High	Total	Mod	High	Total
Baseline	3.1	2.8	3.0	2.6	3.6	3.0	2.8	3.2	3.0
Six Months	3.1	2.8	3.0	2.8	2.6	2.7	2.9	2.7	2.8
Twelve Months	3.2	3.0	3.1	2.8	2.9	2.8	3.0	2.9	3.0
Physical Component	Experimental			Control			Full Sample		
	Mod	High	Total	Mod	High	Total	Mod	High	Total
Baseline	28.5	30.5	29.5	29.5	26.9	28.6	29.1	28.9	29.0
Six Months	36.1	41.5	38.8	39.5	38.9	39.3	38.1	40.3	39.1
Twelve Months	38.5	42.8	40.7	43.1	42.3	42.8	41.2	42.6	41.8
Mental Component	Experimental			Control			Full Sample		
	Mod	High	Total	Mod	High	Total	Mod	High	Total
Baseline	42.3	34.6	38.4	37.0	31.8	35.2	39.1	33.3	36.7
Six Months	52.4	43.7	48.0	41.9	44.8	42.9	46.1	44.2	45.3
Twelve Months	44.2	43.4	43.8	46.4	48.0	47.0	45.5	45.4	45.5
Waddell Symptoms	Experimental			Control			Full Sample		
	Mod	High	Total	Mod	High	Total	Mod	High	Total
Baseline	2.8	3.2	3.0	2.2	3.6	2.6	2.4	3.4	2.8
Six Months	1.8	1.2	1.5	1.4	2.7	1.8	1.5	1.9	1.7
Twelve Months	1.3	1.2	1.3	1.3	2.5	1.7	1.3	1.8	1.5

Logistic Regression Modeling

Logistic Regression models were fit in an attempt to predict Return to Work. The Return to Work variable reported on previously (RTW at 3, 6, 12 months or Did Not RTW) was collapsed into a binary variable: Returned to Work (RTW) or Did Not Return to Work (NRTW).

Independent variables were selected from bivariate analyses that showed significant differences between RTW and NRTW. Potential predictors were:

- Risk category (Moderate or High)
- Number of hours working when injured

- Response to Claim
- Baseline SF-36 Bodily Pain
- Baseline SF-36 Social Functioning.

To assess the predictive value, the classification rate was compared with the baseline classification rate that would be achieved by using the majority category; 70% of cases could be correctly classified by predicting all participants would return to work.

Backward stepwise regression retained only two variables: SF-36 Bodily Pain and Number of hours working when injured, and resulted in a correct classification rate of 77%.

To further assess any differences between the Intervention and Control groups, Study Group was then included in the pool of predictor variables. It did not turn out to be a significant predictor.

Discussion

The results of the current EI study should be considered in the context of significant changes in the conventional case management at the site of our study, which WorkSafeBC implemented shortly after its initiation. Substantial service delivery changes affected interventions offered within the control group of our study. Based on information obtained from WorkSafeBC, the interdisciplinary case management units across the province of British Columbia introduced a new early intervention approach to injured workers in the subacute stage post-injury. This new EI approach was largely based on the pilot model developed earlier by the authors of the current study [83] and replaced the previous conventional treatment which was in place at the inception of this study. As a result, our control group ceased to act as a true control group and is more properly conceived as a comparison group. Thus, in further interpretation of the data, the term “comparison group” is more appropriate. It is difficult to discuss our data without understanding the nature of the treatment provided for the comparison group and without understanding the differences between both interventions. For ease of reference, the study intervention will now be called EI-1 and the newly system-introduced comparison intervention will be called EI-2.

The newly introduced EI intervention, EI-2, adopted key objectives of the study intervention (EI-1), namely: (1) multi-system interaction among the key RTW stakeholders and the injured worker; (2) a multi-method approach to encouraging workers’ positive expectations of recovery and to remove or ameliorate RTW barriers; (3) enhancement of capabilities by early referrals, support and reassurance to assist workers in achieving recovery and RTW and by team-based resolution of RTW issues

and (4) resource use and coordination to ensure appropriate and timely referrals; to identify and take action to address gaps in, and barriers to, services, and to maintain provider consistency, issues resolution and goal-directedness. Moreover, the EI-2 adopted the following intervention components of the EI-1: injured workers' access to an early problem solving, health education and planning individual session with a Nurse Advisor; enhanced communication among the workers and the RTW stakeholders, including health care providers and employer; and case-management-based collaborative problem-solving and planning. The EI-2 intervention was also introduced at the same, subacute stage of recovery from LB injury.

The key differences between the EI-1 and EI-2 were:

1. the EI-2 but not EI-1 covered all workers with musculoskeletal pain claims and included those workers who were deemed by WorkSafeBC as in need for it, rather than being restricted to volunteers from elevated risk groups, like in the EI-1
2. the EI-2 was applied flexibly, with respect to timing, intervention protocol, and number and types of interventions, in a way that was deemed to be suitable to individual clinical and RTW needs of the workers. In contrast, the study EI-1 intervention was inflexible (“fixed”) with respect to protocols, number and type of intervention components and their timing, and was standardized for all workers.

As a result of the evolution of the control group and introduction of a flexible (EI-2) in comparison to an inflexible, standardized protocol (EI-1), the results of the study are best reconceptualized and interpreted in this new context.

The most significant finding from our current study, in contrast to the non-randomized pilot study conducted with a regular conventional intervention-based control group [83] was a significant narrowing of the outcome gap between EI-1 and EI-2 and the absence of statistically significant differences between the two, despite EI-1 providing about twice as many interventions as EI-2. Notably, smaller than expected sample sizes (secondary to significant accrual problems throughout the study) made demonstration of statistical significance particularly difficult. In addition, both moderate and high risk workers were included in the intervention although it is now known from the previous study [83] that the pilot EI benefited only high risk workers.

Keeping these caveats in mind, there were some outcome findings that closely approached significance levels and warrant attention. For moderate risk workers, a higher percentage of the EI-2 group than the EI-1 group returned to work by 3 months. This result is consistent with previous findings that the EI-1 pilot version (very similar to current version) was not a suitable and effective intervention for moderate risk workers, possibly being redundant or even interfering with the natural course of recovery [83]. Notably, there has been significant empirical support for the notion that non-specific LBP usually remits without intervention [100,101]. Thus, it appears that for workers at moderate risk for disability, the flexible, need-based, individual and low intensity (as measured by the number of interventions) EI-2 produced a trend towards better outcomes than the intensive and fixed EI-1 intervention.

In addition, studies in other fields of health psychology, for example, in the area of psychological interventions in hypertension, have demonstrated the superiority of flexible, individual intervention approaches, over fixed type of interventions [102]. Also,

consistent with previous EI pilot study findings [83], a higher percentage of high risk workers, for whom the intervention was actually designed, returned to work, by three months, as compared to those in the EI-2 group. Interestingly, it has been documented in other areas of health psychology that the clinical outcomes of cognitive-behavioural interventions are often most significant in individuals with the highest level of clinical impairment at the outset (e.g., review of literature on behavioural treatments for hypertension by Linden and Moseley, 2006 [102]).

When the cumulative return to work by six months from the current study was compared to the conventional case management group from the pilot study [83], for high risk workers a significantly higher percentage of EI-1 returned to work than for the two comparison groups: EI-2 and Conventional Case Management. This finding is consistent with the outcomes of the Pilot Study, which showed improved RTW outcomes of EI intervention in the high risk group at six months as compared to case management [83].

The review of cost outcomes in our current study indicated a lack of statistically significant differences between EI-1 and EI-2 in the total sample, with respect to days paid or disability costs. However, for moderate risk workers, days paid, total costs and short term disability costs within six months were significantly lower for EI-2 in comparison to EI-1. This finding lends more credence to the earlier conclusion based on RTW outcomes that for moderate risk workers, a low intensity, flexible and unscripted intervention coordinated by the workers' compensation case management team provided superior results to a fixed, protocol-driven, standardized intervention. In addition, despite a trend towards better RTW outcomes at 3 months in the EI-1 group, long term cost differences between EI-1 and EI-2 were not statistically significant. This finding may be

related to the absence of further interventions beyond the 3 month follow-up point that could have assisted with the maintenance of gains. The need for ongoing efforts to support safe and sustained work has recently been emphasized in the literature [51,103,104]. Also, the lack of flexibility in responding to clinical and occupational needs of injured workers, more inherent in EI-1 than in EI-2, might have contributed to this discrepancy.

The findings from our current study, in the context of other literature on interventions to prevent low back disability [46,83], indicate that workers with LBP who are at high risk for occupational disability constitute a special subset of injured workers with LBP. They require a goal-oriented, individualized and intensive interdisciplinary intervention involving the key RTW stakeholders and an ongoing monitoring-type intervention after the initial return to work, to improve their RTW status.

To achieve improved outcomes, significant system-wide screening efforts need to be implemented in order to identify this small group of workers to whom most of the negative RTW and cost outcomes are attributed [91]. Such efforts are often labour intensive and costly for the workers' compensation system and result in varying rates of false positives and negatives. The best correct classification rates of workers as high risk range from high 70% to low 80% depending on the method used [15,82,91,105]. Our current study showed 77% prediction of RTW rate for participating workers with subacute LBP, consistent with previous data.

In addition, based on our experience, most injured workers at high risk for disability do not volunteer to participate in research studies conducted in the workers' compensation environment. It is unclear how different are those who volunteer for

intervention studies from those who do not and it is likely that volunteer bias is present. These workers who volunteer may have more complex clinical needs, may have higher education, may be more open towards new interventions and health-oriented, and/or may feel more comfortable dealing with the workers' compensation system. In each case, some form of sample bias could be introduced, which could be magnified by a small intervention sample size. In the case of our study, the relative advantage of the EI-2 intervention, other than its flexibility, was its ability to engage, by virtue of the compensation and rehabilitation policy of the workers' compensation system, all injured workers who were deemed to be in need of EI, rather than to engage only volunteers, like in EI-1.

The review of changes in the RTW rates for both EI groups cumulatively showed that at 3 and 6 month follow ups, about two-thirds of the participants were working. Most of them returned to work full time and worked for the pre-injury employer. At the 12 month follow up, four in five participants were working; 90% of them full time. Of those not working, most of them made attempts at RTW. Four of ten NTRW workers had not returned to work for reasons other than injury. Thus, there was a clear improvement in RTW rates over the 12 month period of time, which is not normally expected to occur in NTRW back injured workers in the absence of intervention. By six months to one year, without intervention, RTW rates in back pain are expected to reach plateau and not improve further [106].

It is often not known to what degree job accommodations facilitate RTW in musculoskeletal disorders. Our study explored job accommodations provided to study participants (total sample) who returned to work, over time. The graduated return to

work (GRTW) was provided to about 50% of participants at 3, 6 and 12 months; light duties were offered to about 40% of workers at 3, 6 and 12 months and a reduced amount of work to about 24% at 3, 6 and 12 months. Non-accommodation rates were in the 30% range over time. Flexible scheduling ranged from 18% at 3 months, through 22% at 6 months to 13% at 12 months. Longer breaks were decreasing over time, from 13 % at 3 months, through 11% at 6 months to 8% at 12 months. It appears that the key accommodation rates including GRTW, light duties and reduced amount of work remained steady over time whereas flexible scheduling and longer breaks were decreasing over time, likely with improved worker function. Due to lack of baseline data on the rates of job accommodation for workers with LBP by their employers, it is difficult to discern if seemingly high rates of job accommodation among workers participating in both types of EI are actually secondary outcomes of EI, or they represent some other phenomenon. Notably, availability of job accommodations, particularly in the form of lighter duties, has been identified as one of the predictors of RTW among workers with LBP [12,15].

Our study also demonstrated a positive association between job accommodations for all participants and return to work, at the three month point. This relationship decreased in significance as the time since injury and RTW elapsed. At 12 months, the relationship was nonexistent. This finding underscores the importance of early accommodations but further research is required due to the small N and the finding that about 30% of workers did not receive any accommodation.

In addition, biopsychosocial factors associated with RTW versus NRTW among study participants, regardless of the EI type, were analyzed. Although there were no

differences identified on the biopsychosocial measures at 6 months, interesting findings emerged at 12 months. At that point, the RTW group demonstrated significantly higher levels of Mental Health, Role-Emotional and Physical Component dimensions on the SF-36 and improved performance on Waddell symptoms as compared to NRTW group. One may speculate that by 12 months, in the NRTW group, back pain disability became chronically associated with psychological distress and physical limitation factors that might have served to perpetuate it. This finding is consistent with evidence of the prominent role of psychosocial factors in maintenance of back pain disability over time [12,23,82,107,108].

Change in the biopsychosocial characteristics of injured workers participating in the study as measured by SF-36 and Waddell symptoms was found to be a more significant factor than the study group or risk category, except for the SF-36 dimensions of General Health and Health Transition, which remained stable over time among study participants. This finding underscores the importance of developing multivariate RTW models in LBP for different times post injury, and associated interventions targeting different identified time-based risk factors [28,68,104,109]. In the case of our study, most, if not all, identified factors were actually modifiable by clinical and occupational interventions. No demographic (and thus non-modifiable) factors were found to be predictors of RTW in our study, consistent with our previous research [15,82,105]. When the RTW variable reported on at 3, 6 and 12 months was collapsed into the binary variable RTW and NRTW, two key predictors emerged: SF-36 Bodily Pain and Number of Hours Working, producing a correct classification rate of 77%. Although no purely psychosocial predictors were identified in this analysis, one may suggest that perception

of bodily pain is affected by psychosocial factors, as indicated in accepted conceptualizations of pain as a biopsychosocial construct (IASP, 1994)[110-114].

Conclusions

The current EI study was unexpectedly affected by the change in the conventional case management intervention group which was originally intended as a control group. As a result, the study had to be refocused as a comparison between two types of EI for workers with subacute back pain guided by the same key principles; EI-1 which was standardized, protocol-driven and “fixed” in terms of modalities, sequencing and number of interventions applied and EI-2 which was non-standardized, need-driven, flexibly applied and thus not controlled systematically by the research team. Although due to small sample sizes only trends approaching statistical significance were discovered, it appears that workers at moderate risk for disability did better with flexible intervention with respect to early RTW; moreover, statistically significantly lower disability costs in this intervention group as compared to the fixed intervention group were evident. In contrast, it appears that workers at high risk for disability who received the fixed intervention that was specifically designed for this group, showed a trend towards better RTW early outcomes than those who received the flexible intervention. Importantly, at six months, the cumulative return to work rates of high risk workers in the fixed intervention group were significantly higher than for high risk workers in the flexible intervention group and in the conventional intervention group from the pilot study [83]. These findings are consistent with the results of an earlier pilot study by the current authors [83]. The intensity of the intervention (number of interventions applied) was not associated with the outcomes of the study participants.

The RTW rates of both EI groups have been high compared to literature data and somewhat unexpectedly improved in the longer term, at the 12 month follow up. It was noted that a significant number of successful RTW participants received various job accommodations, with GRTW, light duties and reduced volume of work being most prevalent. The most significant factors associated with RTW at 12 months were physical functioning, role-emotional factors, mental health and Waddell symptoms. When time-based RTW outcomes were collapsed into binary RTW and NRTW variables, two key predictors were identified: bodily pain and number of hours working when injured. The correct classification rate was 77%, consistent with previous studies [82,91,105].

Study Limitations and Recommendations for Future Research

In addition to changes in the intervention provided in a group intended as a control group, other unexpected study limitations have arisen from small sample sizes. The accrual rate of the workers for the study was extremely low and averaged between one and two workers per month despite intensive screening efforts. The low participation rate may have adversely affected the representativeness of the sample. However, this problem was partly offset by the randomized design.

The design and logistic challenges encountered by the researchers in this study underscore the need to be prepared for the unexpected in naturalistic research settings such as the workers' compensation system. Future studies should ensure ahead of time that no significant changes take place in control groups which are part of the workers' compensation delivery system. Researchers need to control all aspects of interventions, including those in the comparison group, which was not possible to accomplish in our study, except for post-hoc analyses. Longer data collection time needs to be built into the

design given the low participant accrual rates. Also, longer term monitoring of workers' RTW maintenance and provision of interventions on an as-needed basis following the formal conclusion of the EI, may be beneficial and could be explored. In addition, workers at moderate risk for disability should not participate in EI designed for workers at high risk for disability as they are unlikely to benefit from it. The so-called flexible intervention should be more systematically compared to fixed intervention and their differential effectiveness and utility carefully analyzed from the outset of the study.

It is also suggested that future studies should incorporate the measurement of job accommodations provided to injured workers in the course of RTW as part of the outcome evaluation process in interventions. Likewise, recurring patterns of disability, typical in LBP, should be captured rather than singular RTW events [115,116].

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