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The Return-to-Work Assessment Study

Submission date
05/03/2013

Recruitment status
No longer recruiting

Registration date
19/03/2013

Overall study status
Completed

Last Edited
16/12/2015

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Return-to-work or employability assessments are commonly used to identify work abilities and to inform decisions about safety and readiness for return-to-work in injured workers. Decisions based on these assessments have important consequences for the individuals undergoing testing and their employers. Testing should therefore be accurate and trustworthy. In the realm of workers compensation, performance testing by a trained therapist (i.e. functional capacity evaluations where patients actually lift, carry, walk, etc. in the clinic) has traditionally been considered most useful and trustworthy for measuring work ability. However, such testing is time-consuming, expensive, frequently associated with pain reports, and only modestly predictive of sustained return-to-work. Self-report measures (i.e. paper-based questionnaires) are less frequently relied on but are typically less burdensome for both patients and clinicians. Whether performance testing is superior to self-report measures and actually worth the added burden and expense has not been evaluated. We plan to study whether performance testing enhances return-to-work assessment of injured workers beyond information gained from self-report measures.

Who can participate?
Workers compensation claimants with musculoskeletal injuries who have been assessed at Millard Health Centre in Edmonton, Canada.

What does the study involve?
Two groups of claimants will be formed, one group made of people who were assessed with a combination of performance-based and self-report functional measures and the second group made of people who were assessed with only self-report measures (i.e. interview and questionnaires). After the assessment, subjects will be contacted for one year to determine their work status and work level. Return-to-work outcomes will be compared between the two groups using appropriate statistical techniques.

What are the possible benefits and risks of participating?
Minimal risks are associated with this study. In fact, as participants in the intervention group will be completing only self-report as opposed to performance-based functional assessment, they will have lower risk of injury and pain than those in the regular care group. There will be no other direct benefits to participants, but we will be gaining knowledge related to the effectiveness of current return-to-work assessments to help improve these processes.

Where is the study run from?
The study will be undertaken at Millard Health in Edmonton, Alberta, Canada. Thousands of return-to-work assessments are conducted at this facility annually.

When is the study starting and how long is it expected to run for?
Participants were enrolled from October 2011 to June 2012. All follow-up interviews will be done in July 2013.

Who is funding the study?
WorkSafeBC

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
RS2009-0601

Study information

Scientific Title
The Return-to-Work Assessment Study: Evaluating Methods for Evaluating Ability

Study objectives

We hypothesize that workers undergoing performance testing will have comparable rates of return-to-work, sustainability and satisfaction ratings, but will return-to-work at higher work levels due to the systematic lower estimations obtained with self-report measures.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Alberta Health Research Ethics Panel, 28/08/2012, ref: Pro00008426, RES0003530

Study design
A cluster randomized controlled trial design will be used with analysis planned at the level of individual claimant

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Other

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Injured workers with musculoskeletal disorders.

Interventions
Within the WCB-Alberta system, claimants are referred to the rehabilitation facility for assessment when they have not returned to work within typical timeframes, additional barriers to recovery are suspected, or further medical/rehabilitative investigation is desired. Currently, all return-to-work assessments conducted at the facility contain a component of performance testing using the WorkWell (Duluth, MN) Functional Capacity Evaluation. To evaluate whether performance testing enhances the process, we will create a comparison group of claimants who undergo testing without performance testing.

Due to feasibility issues related to the current Millard Health admission process, instead of randomly allocating individual claimants to study groups we will randomize the clinicians administering work assessments. Claimants will therefore be considered to have entered clusters of individuals assessed by the same therapist. Clinicians who are trained and experienced in performing functional assessment from the facility will be enrolled. Typically approximately thirty clinicians work at the facility performing return-to-work assessments on a full-time basis. These clinicians will be randomly allocated to one of two groups, an intervention group or a standard assessment control group. To form the two groups, clinicians will be

assigned a number generated using a computerized random number generator, with odd numbers indicating intervention group membership.

Prior to beginning the trial, clinicians assigned to the intervention group will be trained regarding the details of the performance-less functional assessment battery described in the methods section below. Intervention group clinicians will then begin using this assessment while clinicians in the control group will continue current assessment procedures that include a component of performance testing (described below). Study researchers will be available to answer questions throughout the study, but clinicians will make all claimant level return-to-work decisions. Logistics of the regular admissions process at Millard Health will not be altered.

Due to the nature of work assessment, neither clinicians nor patients will be blinded to group allocation. However, claimants will not be aware of the study and will therefore be blind to group membership. Additionally, outcome evaluation will also be performed in a blinded fashion via obtaining information on claims outcomes from WCB administrative databases and through interviews by interviewers who are not aware of group allocation. Comparisons will be made on key outcomes between claimants seen by therapists within the two groups.

Intervention Variable
The primary comparison that will be made is between control (performance assessment) and intervention (self-report functional assessment only) groups. A dichotomous intervention variable will be created indicating group allocation. This will be done through identification of the assessing clinician in the facility database. Most aspects of the assessment process will be comparable across all subjects. Assessing clinicians will review workers files, take a history, and perform a musculoskeletal examination. Workers will complete the SF-36, Pain Disability Index, a 10-point Visual Analogue Pain Scale, and a physical job demands questionnaire. All of these procedures will continue as per usual routine. The only difference between groups will be in the form of functional assessment. Functional ability is currently assessed via the proprietary WorkWell (formerly Isernhagen) functional capacity evaluation.

Performance-Based Functional Assessment
As previously mentioned, we have performed extensive pilot testing and evaluation of the WorkWell functional capacity evaluation, which is the performance test used at the rehabilitation facility. This test involves a series of performance tests including manual handling, positional testing, and mobility and coordination tests. To make return-to-work decisions, clinicians compare claimant ability on the various items to required job demands. Claimants meeting or exceeding job demands are deemed suitable for return-to work. The protocol typically takes 4-8 hours and is administered over a two-day period. A kinesiophysical approach is used in which clinicians observe subjects physiological and biomechanical response to testing to determine when maximum physical ability has been reached.20 The measure has been shown to have acceptable reliability, construct validity as a measure of work-related ability, and modestly predicts future return-to-work.

Self-Report Functional Assessment
For this study, clinicians in the control group will be asked to stop using the WorkWell tool and begin assessing functional ability using self-report measures only. Numerous self-report measures are used for informing return-to-work decisions, however we will use a measure developed based on items in the WorkWell tool. In this questionnaire, subjects view pictures showing various functional tasks and predict to what level they would be able to perform the activity (i.e. lifting or carrying in kilograms, bending or standing in minutes). The manual handling component of this measure has been found to correlate moderately well (r = 0.50 0.73) with actual performance on the corresponding WorkWell items. To make return-to-work decisions,

clinicians will again compare results to physical job demands. Additional measures that will be implemented include the Patient Specific Functional Scale, and an expectation for recovery measure. Each of these has been found to be modestly predictive of future recovery within this specific Alberta context. Prior to study implementation and as part of training, the new assessment battery will be pilot tested and inter-rater reliability will be examined.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Our primary goal is to examine differences on level of sustained work following assessment (i.e. heavy, medium, light, sedentary or not working), with one group judged superior if they return to higher levels. Work levels are routinely used in standardized occupational descriptions. To determine work levels, telephone contacts will be made. An experienced polling firm who has previously done work with WCB-Alberta and our research group (Leger Marketing) will be contracted to perform the interviews. As work levels frequently transition over time (due to job changes, progression of modified duties, etc.) follow-up contacts will occur at multiple points in the subsequent year. Subjects will be contacted at one, three, six, and twelve months post-assessment. Questions will include whether subjects are working, and if not working for what reason. In those who are working, we will inquire about whether they are working full or part time hours and whether they are working full or modified duties. We will also ask them to rate their work level as sedentary (up to 5kg), light (5-10kg), medium (10-20kg), or heavy (>20kg) as per the National Occupational Classification.

Secondary outcome measures
Other relevant outcomes will include proxy indicators from the compensation database of timely and sustained return to work. Among subjects receiving time-loss benefits at admission, we will measure days to benefit suspension (censored at twelve months). This measure is commonly used as an indicator of return-to-work within compensation contexts. We will also analyze differences on time to claim closure. Lastly, we will extract information on subject satisfaction ratings routinely collected at the facility.

Overall study start date
01/11/2010

Completion date
01/10/2013

Eligibility

Key inclusion criteria
For the clinical trial, all male and female claimants over 18 years of age undergoing return-to-work assessment at Millard Health will be enrolled during the study time period (n = 480)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
480

Key exclusion criteria
1. Traumatic brain or psychological injury
2. Uncontrolled medical conditions

Date of first enrolment
01/11/2010

Date of final enrolment
01/10/2013

Locations

Countries of recruitment
Canada

Study participating centre
University of Alberta
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Funder(s)

Funder type
Government

Funder Name
WorkSafeBC (Canada)

Alternative Name(s)
WorkSafe British Columbia, Workers' Compensation Board of BC

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Canada

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Results article	results	01/12/2014	Yes	No