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The Work-It Study for people with arthritis: Study protocol and baseline sample characteristics

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Abstract.
BACKGROUND: People with arthritis are at risk of work disability. Job accommodation and educational programs delivered before imminent work loss can minimize work disability, yet are not currently being widely implemented. The Work-It Study is a randomized controlled trial testing the efficacy of a problem solving program delivered by physical and occupational therapy practitioners to prevent work loss over a two-year period among people with arthritis and rheumatological conditions.
OBJECTIVE: The purpose of this paper is to describe the protocol of the randomized controlled trial, and describe the baseline characteristics of the subjects and their work outcomes.
METHODS: 287 participants were recruited from the Boston area in Massachusetts, USA. Eligible participants were aged between 21–65, self-reported a physicians' diagnosis of arthritis, rheumatic condition, or chronic back pain, reported a concern about working now or in the near future due to your health, worked at least 15 hours a week, had plans to continue working, and worked or lived in Massachusetts. Subjects were recruited through community sources and rheumatology offices. Participants in the experimental group received a structured interview and an education and resource packet, while participants in the control received the resource packet only. The baseline characteristics and work related outcomes of the participants were analyzed.
CONCLUSIONS: To our knowledge, the Work-It Study is the largest and most diverse randomized controlled trial to date aiming to identify and problem solve work-related barriers, promote advocacy, and foster work disability knowledge among people with chronic disabling musculoskeletal conditions. Despite advances in medical management of arthritis and other rheumatological and musculoskeletal conditions, many people still have concerns about their ability to remain employed and are seeking strategies to help them sustain employment.

Keywords: Work disability, arthritis, randomized controlled trial, occupational therapy, physical therapy

1. Introduction

Preventing work disability, operationalized as employment loss or work activity limitations due to health [1], is important for people with various forms of arthritis, other rheumatic conditions such as scleroderma, lupus, and fibromyalgia, and chronic back

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pain. Twenty three to forty five percent (23–45%) of people with rheumatic conditions are estimated to be unemployed within 10 years of diagnosis; this includes diagnoses of rheumatoid arthritis [2], psoriatic arthritis [3], and lupus [4]. Work activity limitation—i.e., impairment in the ability to meet expected daily work tasks or activities—is also common among people with chronic musculoskeletal or rheumatic conditions. Thirty one percent of people with arthritis or related rheumatic conditions reported a work limitation related, at least in part, to their chronic conditions [5]. Workplace activity limitations and employment cessation have substantial monetary impacts on the individual, family and society, with estimates of the financial impact of work disability and productivity losses among persons with rheumatic conditions two to four times greater than direct healthcare costs [6, 7].

Intervening on work factors *prior* to health-related employment cessation can sustain employment and improve the performance of work-related activities and tasks among people with arthritis and rheumatological conditions [8, 9]. Allaire et al. demonstrated that people receiving an experimental intervention comprised of work-related barrier reduction, promotion of disability self-advocacy, and career guidance had nearly 40% lower odds of employment cessation over four years compared to the control group [8]. However, this approach is not widely available. Public vocational rehabilitation programs could provide a similar approach, yet these programs typically serve people who are unemployed and often those with the most severe level of disability are eligible. Individuals with arthritis, and other chronic conditions, are unlikely to be eligible for the program at the time when services could be delivered on a preventive basis. Other approaches aimed at intervening prior to employment cessation include offering comprehensive occupational therapy services to address work related issues [10], or ergonomic assessment and recommendation [11], or a combination of work-related barrier reduction, promotion of disability self-advocacy, and career guidance [8]. Other studies explored the effectiveness of a combination of group sessions addressing self-management of arthritis, ergonomic testing by an occupational therapist, and use of vocational rehabilitation services [12]. What were these studies findings that you mentioned in the previous sentence?

Occupational therapy practitioners (OTs), physical therapy practitioners (PTs), and rehabilitation health professionals, may have the expertise to deliver work disability prevention programs. In a number of studies, OTs and PTs have improved work functioning among people with arthritis, and believe intervening with people with arthritis to prevent work disability is within their scope of practice [10–12]. In a small feasibility study, OTs and PTs utilized a structured interview tool, the Work Experience Survey for People with Rheumatic Conditions (WES-RC), and were able to generate solutions to common work related problems among people with arthritis and work limitations [13]. The WES-RC is based on the Work Experience Survey (WES), an evidence based approach to address work barriers among people with chronic conditions including arthritis [8], and multiple sclerosis [14, 15]. Trained vocational rehabilitation counselors using the WES to address job barriers and accommodation, as well as vocational counseling, have effectively maintained employment among people at risk of employment cessation. The efficacy of such an intervention delivered by OTs and PTs has not been evaluated in a clinical trial. To address this need, we developed the "Efficacy of a Modified Vocational Rehabilitation Intervention (also known as the Work-It Study)." To our knowledge the Work-It Study is the first study to examine the effects of an intervention designed to reduce work-related barriers and provide basic education on disability rights, responsibilities, and resources delivered by physical and occupational therapists.

The objectives of this paper are to 1) describe the study protocol of the Work-It Study and 2) describe baseline demographics, disease, and work characteristics of the Work-It Study sample.

2. Methods

The Work-It Study is a randomized controlled trial of people with self-reported physician diagnosed rheumatic conditions at risk of work loss. Study participants were enrolled between October 2011 and January 2014. Participants were recruited from the community, rheumatologists' patient practices, and persons listed on medical registries, newspapers, Craigslist postings, flyers, professional organizations, and social support groups.

The inclusion criteria were: a) age 21–65 years, b) currently employed at least 15 hours per week, c) living or working in Massachusetts, d) self-report of doctor-diagnosed arthritis, other rheumatological condition, or chronic low back pain, and e) self-report

a concern about their ability to stay employed either now or in the next few years due to their health. Exclusion criteria were: a) on worker's compensation or disability leave at the time of the telephone screening (unless also working 15 hours or more per week for pay), b) plans to leave work or retire in the next two years, c) participation in other research intervention studies related to employment, d) subjects with back pain from a work-related injury or non-specific acute back pain, or e) unable to speak or understand English.

Interested participants contacted the study staff by telephone or email, and were screened over the phone. Eligible subjects who agreed to participate in the study were mailed consent forms approved by the Institutional Review Board of Boston University, and were subsequently enrolled when the Work-It Study staff received their written consent by mail.

2.1. Randomization and blinding

Randomization of participants to be enrolled occurred prior to recruitment. Treatment assignments were randomly generated with equal probability of assignment to the intervention or control arms using statistical software, and were placed in sealed and opaque envelopes in numerical order maintained in a locked file by the study coordinator. The study investigators and research assistants (data collectors) have been kept blinded to the treatment assignments.

2.2. Intervention

2.2.1. Materials

The Work Experience Survey for–Rheumatic Conditions (WES-RC) was used to deliver the job barrier reduction portion of the intervention. The WES-RC is modified from the Work Experience Survey (WES). The WES consists of a background section, which assesses demographics, job and health information, checklists of a wide range of potential workplace barriers, and barrier prioritization mechanisms, including identification of the three most problematic barriers. The validity of the WES has been demonstrated through studies that confirm its theoretical base and show that barriers vary according to disabilities' unique effects [14]. In addition to these domains on the WES, the WES-RC includes items that could be barriers to work, but are not workplace-based, e.g., commuting problems, stairs at home, and family responsibilities, as well as items that related specifically to rheumatic conditions such as lighting [13]. These types of items can be problematic for people with rheumatological and musculoskeletal conditions and could impact work abilities [16, 17].

In addition to the WES-RC, a previously developed companion manual containing solution suggestions for barrier in the WES-RC checklist was used. The suggestions were elicited from OTs and PTs practicing in rheumatology, and then adjudicated by a panel of experts (JK, SA and an OT in academic practice).

2.2.2. Procedures

Participants in the experimental group received the WES-RC structured interview and an education and resource packet, which included information about job accommodation/ergonomic organizations (e.g. Job Accommodation Network), disability and employment legal resources (e.g. Americans with Disabilities Act), local vocational rehabilitation programs, local disability advocacy centers, voluntary health agencies (e.g. Arthritis Foundation), and chronic disease management websites. The intervention was delivered in a 1.5-hour meeting with a trained, licensed occupational therapy practitioner or physical therapy practitioner at a location that was convenient for the participant. The therapists had received a formal 8-hour training by the principal investigator, which included a detailed background and overview of the study intervention. The training also focused on using the WES-RC, and the solution manual, to assist in identifying and problem solving work-related barriers by utilizing resources to promote advocacy, and disability knowledge. Case study applications were used to ensure comprehension of the study intervention procedures.

The intervention consisted of a meeting with the participant, and two follow-up phone calls. During the meeting, the therapists used the WES-RC to assess a participant's health and vocational background and work barriers (problems). Therapists used the manual of solutions to suggest solutions to barriers indicated on the WES-RC when needed. Specific referrals to resources or other providers were given as needed. After the meeting, the therapists called the participants two times: three weeks, and three months after the first meeting. The average phone call lasted approximately 20 minutes.

2.3. Control

Participants in the control group received the same education and resource packet that experimental group participants received, but had no contact

with the therapists. The resource packet was mailed to these participants.

2.4. Measures and assessments

Participants were interviewed at baseline, 6-, 12-, and 24-months. Interviews consisted of self-report measures administered over the telephone by trained interviewers.

The primary outcome of this study was work limitation ascertained by the Output Job Demand scale of the Work Limitations Questionnaire (WLQ). This instrument assesses limitations in the persons' ability to perform work activities due to a health condition and consists of four separate scales. To limit respondent burden, only the Output Demand scale was used. Items in this subscale pertain to difficulty performing specific job tasks over the past two weeks due to a physical or emotional health condition or problem (e.g., "in the past two weeks, how much of the time did your physical health or any emotional problems make it difficult for you to finish your work on time?"). The responses for the proportion of time with difficulty range from none of the time (0%), to all of the time (100%). This WLQ has established validity and reliability in assessing work limitation for people with arthritis [18, 19].

Work limitation was also measured using the World Health Organization Health and Work Performance Questionnaire (HPQ). The HPQ consists of three subscales: absenteeism, work performance (similar to work limitation), and job-related accidents. For this study, the work performance subscale will be used only. This subscale consists of three items. The first item reads: "On a scale from 0–10, where 0 is the worst job performance and 10 is the performance of a top worker, how would you rate the usual performance of most workers in a job similar to yours? The second and third item use the same 0–10 scale but asks the participants to rate their usual performance over the past year or two, and in the past four weeks. Two scores can be generated from these items, the absolute and the relative scores. The absolute score is a percentage (0–100%, where 0 is the worst performance) obtained from the individual's perception of how they performed at work during the last four weeks, while the relative score is a ratio of how the person performed in the last week compared to how they rate other workers' performance in a job similar to theirs. The relative score has a restricted range between 0.25 and 2.0 (0.25 is the worst relative performance or 25% less of other workers' performance). The question pertaining to the participant's work performance over the past 1-2 years is not used in generating scores. Rather, the item is used as a synthetic bounded recall question, designed to prime the respondent to give a more accurate answer for the following one. The HPQ has established validity and reliability in measuring work performance for employed individuals [20, 21].

Job Self-efficacy: Five items were used to assess job self-efficacy using questions developed in previous studies of vocational rehabilitation job retention programs [8, 22]. These items specifically ask the participants about their confidence in both deciding to tell, and talking with employers and coworkers, about their health condition at work (e.g., "how confident are you about deciding whether or not to tell an employer about your health related work problems?"). Scores range from 1 (not confident) to 4 (very confident).

Pain, job satisfaction, fatigue and stress: Pain is commonly assessed using a 100 mm visual analogue scale (where 0 is the least pain and 10 is the most pain), a method that is reliable and valid [23]. In this study, pain was measured using the same approach in the context of work (e.g., "on a scale from 0 to 10 where 0 is the least pain and 10 is the most pain imaginable, how severe has your pain been, on average, at the end of your work day during the past week?"). Job satisfaction, fatigue, and stress were assessed using the same approach.

Health Assessment Questionnaire (HAQ): The HAQ was used to measure participants' functional status. The HAQ has 41 items (e.g., "Are you able to shampoo your hair?"), and response options range from 0–3 (0 is without any difficulty and 3 is unable to do). Total scores range from 0 to 3, where increasing scores indicate worse functioning. This instrument has established reliability and validity in assessing functional status for samples of people with arthritis [23, 24].

Job type: Job titles were classified according to the U.S. Department of Labor jobs classification. The participants were grouped into two main job categories: the first group worked in managerial and professional jobs, and the second group worked in sales, services, natural resources, construction and maintenance, production, transportation and moving, and military specific occupations.

The number of jobs a person is working, hours worked per week, and numbers of days missed in the past three months because of their health condition were also collected.

Arthritis type and demographic variables including age, sex, marital status, ethnicity, and educational attainment were also collected.

2.5. Data analysis

Based on previous studies using the output demand scale of the WLQ, a standard deviation of 24.5 was expected for this outcome. A pre-specified sample size of 350 was selected for the study (175 per group) in order to achieve 80% power to detect a difference of 7.5 units on the WLQ output demand scale using a two-sided two-sample t-test at the 0.05 significance level.

Summary statistics, such as means, standard deviations, and frequencies were calculated for all the baseline demographic, health and work-related variables. Job titles were classified using the United States Bureau of labor – Standard Occupational Classification. Comparisons between characteristics of different subgroups of subjects were done using either two-sample t-tests or Pearson chi-square tests depending on the outcome type. A significance level of 0.05 was used for statistical significance in all tests, and all analyses were performed using the SAS statistical computing software, version 9.3.

3. Results

3.1. Description of sample

Over a two-year enrollment period, six-hundred and fifty-two people were screened, and 493 were found to be eligible to participate in the study. 317 people returned informed consent forms and, of these, 17 were unable to be contacted for their baseline phone call, and 13 were found to be ineligible due to a change in job hours or job status since screening. Two-hundred and eighty-seven participants completed the baseline visit, and were enrolled in the Work-It Study (82% of the targeted enrollment was achieved). These 287 enrolled participants comprise the study sample reported on below.

Median age of the participants was 50.4 years, 73% of whom were female ($n = 209$). Nearly 70% of the sample was White, 21% were Black or African American, and 10% were Asian, Latino, or Native American/Alaskan. The majority reported having a college degree or having attended graduate school ($n = 168$). About a third of the sample were married (34.8%), less than half were single (44.3%), and the remaining 20.9% were divorced, widowed, or separated. About a third of participants reported living alone (33.8%) (Table 1).

Table 1
Demographic and health characteristics of the work-it Study participants

Variable	Value (N = 287)
Age	50.4 years (SD = 10.6)
Age group	
21–29	5.9% ($n = 17$)
30–39	11.2% ($n = 32$)
40–49	19.9% ($n = 57$)
50–59	42.5% ($n = 122$)
60+	20.6% ($n = 59$)
Gender	
Female	72.8% ($n = 209$)
Male	27.2% ($n = 78$)
Race	
White	69.2% ($n = 198$)
Black or African American	21.3% ($n = 61$)
Other	9.5% ($n = 27$)
Ethnicity	
Hispanic/Latino	6.6% ($n = 19$)
Non-Hispanic/Latino	93.4% ($n = 267$)
Education	
Some high school	2.4% ($n = 7$)
High school	11.2% ($n = 32$)
Some college	27.9% ($n = 80$)
College	28.9% ($n = 83$)
Some graduate school	4.9% ($n = 14$)
Graduate school	24.7% ($n = 71$)
Education groups	
High school or less	13.6% ($n = 39$)
Some college or college graduate	56.8% ($n = 163$)
Some graduate school or more	29.6% ($n = 85$)
Marital Status	
Married	34.8% ($n = 100$)
Widowed	1.7% ($n = 5$)
Separated	3.5% ($n = 10$)
Divorced	15.0% ($n = 43$)
Single	44.3% ($n = 127$)
Other	0.35% ($n = 1$)
No answer	0.35% ($n = 1$)
Live alone	
Yes	33.8% ($n = 97$)
No	66.2% ($n = 190$)
Diagnosis	
Inflammatory arthritis	33.2% ($n = 95$)
OA and Back pain	66.8% ($n = 191$)
Health Assessment Questionnaire	1.22 (SD: 0.56)

Nearly 80% of participants had one job, and the mean number of hours worked per week was 36.2. Nearly half (44.6%) of the participants worked in management, professional or related occupations. On average, participants missed 3.2 days of work in the past three months because of their health condition. The sample reported being limited in their work activities more than a third of the time (35.3%) in the past two weeks. As measured by the self-efficacy

items, confidence was moderately high in deciding to tell other people, (employers and coworkers) or speaking with others about their health condition at work. Additionally, the participants reported that their overall work performance during the past four weeks was slightly lower than others who perform the same job. Pain, fatigue, stress and job satisfaction over the preceding week were scored as moderate on average, between 6 and 7 on the visual analogue scale (Table 2). Fifty-one participants were recruited from the clinic (17.8%), while the remainder of the sample was recruited from the community. Subjects recruited from the clinic worked significantly more hours per week ($p = 0.03$) than subjects recruited from the community, 40 versus 35 hours, respectively. No other significant differences were found between samples from the community and the clinic (Table 3).

Work outcomes were further explored to see if there were any differences in levels of work limitation between different demographic variables. There was a significant difference in the WLQ output demands score between participants who were married, and participants who were not married (31.76 vs. 37.1, $p = 0.04$), pain (5.6 vs. 6.4, $p = 0.003$), and fatigue (6.3 vs. 6.8, $p = 0.03$). Educational attainment also showed differences in work limitations; participants who had some college or less were significantly more limited in the workplace in the last two weeks compared to people with a college degree or higher (38.5 vs. 32.9, $p = 0.03$).

Table 2
Work characteristics of the Work-It Study participants

Variable	N = 287 (%)
Number of jobs ($n = 287$)	
1	78.8%
2	17.1%
3 or more	4.2%
Hours per week	36.2 (SD = 14.3)
Days missed in the past 3 months	3.2 (SD = 7.15)
Job Classification (6 categories)	
Management, professional, and related occupations	44.6%
Service occupations	22.7%
Sales and office occupations	22.0%
Natural resources, construction and maintenance occupations	5.9%
Production, transportation and material moving occupations	4.9%
Job classification (2 categories) ($n = 287$)	
Management, professional, and related occupations	44.6%
Combined Category*	55.4%
Work Limitations Questionnaire (WLQ) (n)	35.3 (SD = 21.4)
Self-efficacy	2.6 (SD = 0.81)
World Health Organization Health and Work Performance Questionnaire (HPQ)	
Relative score	1.02 (SD = 0.33)
Absolute score	74.1 (SD = 18.3)
Pain	6.2 (SD = 2.2)
Fatigue	6.7 (SD = 2.0)
Stress	6.3 (SD = 2.5)
Job satisfaction	6.5 (SD = 2.7)

4. Discussion

The Work-It Study is a clinical trial of people with self-reported arthritis, other rheumatic, or musculoskeletal conditions who are concerned about their ability to continue working now or in the next few years due to their health. To our knowledge, this is the largest study examining the effects of a work-related barrier reduction and disability education intervention delivered by occupational and physical therapy practitioners. The experimental intervention that was evaluated on two-year work functioning outcomes, was designed to help participants identify and problem solve work-related barriers, promote advocacy, and foster work disability knowledge. With more than 8 million people in the United States reporting a work limitation due to their arthritis and estimated losses up to $100 billion of lost earnings and productivity limitations due to musculoskeletal conditions [7, 25], effective approaches to minimize work disability outcomes are critical.

We compared participants who were recruited from clinical versus community settings. Our findings illustrate that people recruited from the community, work on average five hours less than people recruited from clinical settings. However, individuals recruited from the community report similar levels of work limitations, pain, fatigue and stress, potentially indicating that there is a need to intervene at the community level to reach those individuals and improve work related outcomes among people with chronic painful musculoskeletal conditions [8, 11, 26]. In addition, it is noteworthy that we recruited almost 300 people with arthritis and work limitations over a two-year period from one geographical area, suggesting that there is a demand for effective supports to help people with chronic musculoskeletal pain conditions address work-related challenges.

While the Work- It Study sample demographics pertaining to age, sex, and functional level are similar to other work disability intervention studies among people with arthritis [27], educational attainment and ethnic aspects are different. Nearly 60%

Table 3
Differences in work outcomes by clinic and community samples

Variable	Clinical ($n = 51$) Mean (SD)	Community ($n = 233$) Mean (SD)	P-value
Hours per week	40.14 (21.98)	35.38 (11.87)	0.03*
Days missed in the past three months	4.10 (9.05)	3.04 (6.67)	0.34
Work Limitations Questionnaire (WLQ)	34.56 (17.22)	35.41 (22.26)	0.80
Self-efficacy	2.48 (0.84)	2.65 (0.80)	0.19
World Health Organization Health and Work Performance Questionnaire (HPQ)			
Relative score	1.03 (0.30)	1.02 (0.33)	0.83
Absolute score	74.71 (15.67)	73.94 (18.82)	0.76
Pain	5.92 (2.21)	6.27 (2.19)	0.31
Fatigue	6.80 (1.93)	6.67 (2.02)	0.67
Stress	6.29 (2.33)	6.31 (2.51)	0.95
Job satisfaction	6.59 (2.61)	6.46 (2.69)	0.74
Health Assessment Questionnaire (HAQ)	1.36 (0.55)	1.19 (0.56)	0.047*

of the Work-It participants had a college degree or more. Work disability is believed to be higher among people with lower levels of educational attainment and in jobs where workers have less control and more physically active jobs such as construction, sales, telecommunications, and the service industry [27]. The higher representation of educational attainment in our sample may reflect the academic, health, and industry jobs in Massachusetts; however, it also highlights a potential need for employment related supports for people with higher educational attainment who are working in professionals and managerial jobs. In addition, the Work-It Study has nearly a third of the participants reporting non-white ethnicities making it the most diverse randomized controlled trial to date in work disability.

Occupational and physical therapists engage in work disability educational and treatment approaches, but do not utilize the structured interview approach that we used in this study. The structured approach may provide an efficient and effective way to bridge the gap between the clinic and the work environment. Since physical and occupational therapists are health professionals that strive to prevent disability and promote participation, these professions may be well positioned to provide this type of intervention.

In this paper, we report on the baseline characteristics of the Work-It Study participants. Because of the nature of randomized control trials, we are limited in drawing direct comparisons with factors associated with baseline work functioning and employment status variables. As with all randomized controlled trials, the sample has inherent limitations in terms of people being motivated and willing to participate in a clinical trial, and the sample may not be generalizable to a broader population of people with chronic painful conditions who are at risk of work disability.

The Work-It Study is the first of its kind to be delivered by occupational and physical therapy practitioners. To our knowledge, the Work-It Study is largest and most diverse to date aiming to identify and problem solve work-related barriers, promote advocacy, and foster work disability knowledge among people with chronic disabling musculoskeletal conditions. Despite advances in medical management of arthritis, and other rheumatological and musculoskeletal conditions, many people still have concerns about their ability to remain employed and are seeking strategies to help them sustain employment.

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Conflict of interest

The authors have no conflict of interest to report.

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