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Impact of a non-return-to-work prognostic model (WORRK) on allocation to rehabilitation clinical pathways : A single centre parallel group randomised trial

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Impact of a non-return-to-work prognostic model (WORRK) on allocation to rehabilitation clinical pathways : A single centre parallel group randomised trial

THESE

préparée sous la direction du Docteur François Luthi

et présentée à la Faculté de biologie et de médecine de l'Université de Lausanne pour l'obtention du grade de

DOCTEUR EN MEDECINE

par

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pour Le Doyen
de la Faculté de Biologie et de Médecine

Monsieur le Professeur John Prior
Vice-Directeur de l'Ecole doctorale

RESEARCH ARTICLE

Impact of a non-return-to-work prognostic model (WORRK) on allocation to rehabilitation clinical pathways: A single centre parallel group randomised trial

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Abstract

Introduction

Stratified medicine might allow improvement of patient outcomes while keeping costs stable or even diminishing them. Our objective was to measure if a prediction model, developed to predict non-return to work (nRTW) after orthopaedic trauma, improves the allocation to various vocational pathways for use in clinical practice.

Material and methods

Randomised-controlled trial on vocational inpatients after orthopaedic trauma (n = 280). In the intervention group, nRTW risk (estimated using the WORRK tool) was given to the clinician team before allocation of vocational pathways, while in the control group it was not. Three pathways were available: simple, coaching and evaluation (EP). Accompanying indications for interpretation of the nRTW risk were given. The primary outcome was the proportion of patients allocated to the EP. The secondary outcome was patients' and clinicians' satisfaction.

Results

450 patients were assessed for eligibility, 280 included, 139 randomized to the control group (mean age 42.3years) and 141 to the intervention group (43.2years). The two groups had a similar risk profile. The patients in the intervention group were more often referred to the EP compared to the control group, but not statistically significantly more (risk ratio 1.31 [95% CI 0.70–2.46]). The number needed to treat was 30. When considering patients transferred to different pathways during rehabilitation, more patients from the intervention group were transferred to the EP over the course of the rehabilitation, increasing the risk ratio to 1.57 [95% CI 0.89 to 2.74].

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Data Availability Statement: Not all data are available, due to the confidentiality policy of the rehabilitation clinic. Data for the calculation of the primary outcome are available as Supporting Information file. For requests for additional data, please contact: Patrick Antonin (Chef du service informatiquel, Clinique romande de réadaptation) email: Patrick.Antonin@crr-suva.ch, Tél. +41 27 603 2030.

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Discussion

The knowledge of the risk of nRTW has an influence, that is not however statistically significant and is without clinical importance as previously defined by our own power calculations (based on a 15% increase in referral to EP in the intervention group compared to the control group), on clinical decision making with regards to the allocation of patients to different physical and vocational rehabilitation programs after orthopaedic trauma. This influence is less than what was expected, possibly due to insufficient directive guidelines accompanying the WORRK model, or because clinicians associate less hours of therapy (as with certain rehabilitation programs) to disadvantaging the patient. These findings do, however, support the multi-factorial aspect of clinician decision-making.

Introduction

Work disability, defined as cessation of work due to illness, injury or any other medical cause, constitutes a vast economic and social burden, with more than 40 million disabled people of working age in the European Union, largely due to psychiatric illnesses and musculoskeletal disorders, and in particular, non-fatal, minor to moderate professional and non-professional orthopaedic traumas [1–5]. In addition to the financial load, work disability and more specifically orthopaedic trauma has a variety of consequences on patients, often leading to substantial psychosocial strain, affecting quality of life, reducing physical activity, causing chronic pain and leading to prolonged absence from work, a factor which can again have a negative effect on health (physical and psychological) as well as social integration [5–8]. Orthopaedic and vocational rehabilitation plays an important role not only in the costs incurred by musculoskeletal trauma, but also in determining patient outcomes [9, 10]. There is therefore room for development in the functioning of rehabilitation centres, particularly in their attribution of resources, in order to alleviate not only economic, but also patient-related physical, psychological and social strains.

Research is currently being directed towards what is called stratified medicine: treatment decisions are made according to the biological or risk characteristics of a patient, and therefore their likely response to the treatment in question [11]. This ideally allows for the improvement of patient outcomes while keeping costs stable, if not diminishing them. In order to attain this type of practice, prognostic research must follow a certain framework. Firstly, prognostic factors must be identified. These are characteristics, whether they be biomarkers, symptoms or behavioural and psychosocial factors, that among people with a given start point, are associated with, whether directly or indirectly, a subsequent endpoint [12]. These factors can not only already give clues towards modifiable targets, but can then also be combined within a prognostic model in order to predict individuals' risk of a specific endpoint [13]. After development (and therefore internal validation), prognostic models should then be externally validated and ideally analysed for their impact in clinical practice; however, despite many models being elaborated, few are studied for their external validation and even less for their utility and influence on decision making and patient outcomes [13].

An objective and reproducible prognostic model, which includes 1 occupational, 6 biomedical, and 12 psychosocial factors, has been developed and externally temporally validated at 3 different follow-up time points, to predict RTW status: the Wallis Occupational Rehabilitation Risk (WORRK) model [14, 15]; the formula is accessible by following the link beside the reference). This model, applied at admission to rehabilitation, predicts non-return to work status following discharge from the rehabilitation centre at 3, 12 and 24 months and is applicable to a wide range of musculoskeletal injuries and patients, including those with poor health literacy or language fluency. Such a tool may aid clinicians working in physical and vocational rehabilitation centres in order to stratify patients, allowing them to be more rapidly screened and put into programmes best suited to their likely return to work outcome and therefore improving the efficiency of vocational rehabilitation. The purpose of this study was therefore to evaluate the clinical impact on decision making of the WORRK prognostic model, by analysing if the knowledge of the risk of non-return to work (estimated by the means of the WORRK model), influences the decision to allocate patients to different physical and vocational rehabilitation programs, without jeopardizing their satisfaction regarding their rehabilitation stay.

Materials and methods

Design

This was a single centre, parallel group, randomised controlled trial with stratified block randomisation.

Amendments to the protocol: The non-return to work follow up at 3, 12 and 24 months, as described in the protocol for the secondary outcomes, is still ongoing and has not been included in this publication. Similarly, only participant's socio-demographic data is included in this publication, and not data concerning the other questionnaires and function tests mentioned in the protocol. With regards to patient satisfaction, because we were more interested in outcome satisfaction and not process satisfaction, it was decided to deviate from the originally proposed satisfaction scale, and instead use the Global Impression of Change Scale (at discharge compared to at admission). The CONSORT checklist (S1 File), the Project protocol (S2 File) and the data for the primary analyses (S3 File) are provided as supporting information.

Participants

The setting of this trial was the "Clinique Romande de Réadaptation" (CRR), a Swiss rehabilitation medical centre financed by the main accident insurance in Switzerland (SUVA). Patients, mostly blue collar workers, half of whom are immigrant workers, are referred by insurance medical advisors, orthopaedic surgeons or general practitioners, predominantly between 9 to 12 months after mostly traffic and work accidents with orthopaedic trauma of the back, upper or lower limb as well as multiple traumas, if they exhibit persistent pain and functional limitations. Multidisciplinary therapeutic programs are put in place in order to improve functional status, quality of life, and the chance of returning to work. We included patients that had no severe traumatic brain injury at time of accident (Glasgow coma Scale >8), had no spinal cord injury, were capable of judgment, were not under legal custody and were not younger than 18 or older than 60 years of age at the time of rehabilitation. Most of the patients were blue collar workers and were injured after traffic, work or leisure accidents [8, 16].

Description of the clinical pathways

Each patient admitted to the CRR is during his or her first week, allocated to one of three rehabilitation pathways. Patients can be transferred from one pathway to another over the course of the rehabilitation.

The Simple Pathway (for patients with a low risk of not returning to work) provides individual and group physiotherapy for reduction of impairments and physical conditioning (16–18 hours/week on average) of which there are 4–6 hours/week of training in vocational workshops with an average duration of 5 weeks rehabilitation. There are generally no psychosocial interventions.

The Coaching Pathway (for intermediate risk profiles) is composed of a similar schedule to the previous Pathway (in terms of type and number of hours/day of therapy and average stay), but integrates cognitive and behavioural therapies (individual and/or in groups by means of four sessions throughout the rehabilitation) and often assessment of social conditions (including insurance aspects and social advice) by social workers and occupational psychologists.

The Evaluation Pathway (for high risk profiles) comprises mainly grou6p physiotherapy sessions and vocational workshops are two hours long at most (total of 12–14 hours/week) with rehabilitation being on average 3 weeks. The main goal is to clarify the medical situation and the residual functional capacities. Psychological and social assessments are only planned if needed.

Intervention: The WORRK model

The WORRK model was completed for all patients (control and intervention), by a team of trained nurses, giving an individual probability (expressed in %) of non-return to work. Clear instructions as to how investigators should answer the different items are available, and the predictive formula is programmed on electronic devices (reference already mentioned in the introduction). This score was then revealed, for only the intervention group, to the medical doctors before their decision as to which clinical pathway the patient should be allocated. Guidelines where provided for interpretation, including the study's objectives and recommendations for use (probability score under 50% of nRTW, "Simple" or "Complex pathway" are probably most suitable, 50–69% of nRTW the "Evaluation Pathway" should be considered, over 70% of nRTW, the "Evaluation Pathway" is probably the most suitable choice). Several specifications were also given: the probability score was for not returning to work and therefore the higher the score, the lower the chances are of returning to work, the score was only a prediction and did not represent the exact future of the patient, and the clinical pathway choice remained the clinician's taking into account his or her impressions and the context of the patient.

Control

The only difference for the patients in the control group was that the corresponding medical doctor and the rehabilitation team did not receive the information from the WORRK model.

Outcomes

The primary outcome was the proportion of patients allocated to the Evaluation Pathway. The number of patients allocated to the three different pathways was be gathered by the administrative planning unit. Furthermore, we analysed the number of transfers of pathway allocation during the course of each rehabilitation stay.

The secondary outcome was the patient's satisfaction, measured by the Global Impression of Change Scale at discharge (compared to at admission). This scale shows patients' beliefs concerning the importance of their improvement or worsening, and thus the efficacy of the treatment, and is recommended by the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials, for use in chronic pain clinical trials as an outcome measure [17].

Sample size

This randomised controlled trial was designed as a parallel group, superiority trial with one primary outcome, the proportion of patients allocated by the team to the Evaluation Pathway. Today, only 10% of all patients are allocated to the Evaluation Pathway, therefore we assumed that the proportion allocated to this pathway in the control group would be 0.1. We assumed that an improvement of the allocation rate of 15% was the minimally clinically important difference (from 10 to 25% on the Evaluation Pathway). Setting the type-I error rate at 5% and the statistical power to 80% and using a two-sided Z-Test, we needed to include 112 patients per group (for details see: [18]). In order to allow for the estimated attrition rate of 25%, we included 280 patients.

Randomisation

Once a patient was admitted to the clinic, a study nurse checked the eligibility criteria, informed the patient about the study (orally and in writing). All participants signed an informed consent form. The WORRK model was completed for all included patients.

The sequence list was generated with a stratified block-randomization technique (stratified for the risk score (five strata, with cut-offs at 0.2, 0.4. 0.6. 0.8 risk)). We performed the stratified block randomization with block length of random order from 2 to 8– unknown to the staff— with the user written ad-on programme *ralloc* within Stata 14.1.

The allocation list was kept at an external office. The included patients' unique numbers were sent over a secure e-mail server to the external randomisation office and the allocated intervention was received in the same manner.

Blinding

Patients were considered as blinded; the rehabilitation team did not communicate the score predicted by the WORRK tool. The assessors of the primary and secondary outcomes (the administrative planning unit and the patient his- or herself, respectively) were blinded to the group allocation. The statistical team was blinded during the data-cleaning period.

Statistical methods

Descriptive statistics: Baseline characteristics of the patients for all known and potential prognostic variables were described overall and per intervention group with mean and standard deviation. Differences between groups in baseline values were described and interpreted based on clinical knowledge as well as with effect sizes (Cohen's d for continuous outcomes; Phi for binary data, Cramers' Phi for categorical outcomes). Effects sizes of 0.2 can be considered as small differences, 0.5 as moderate and 0.8 as large differences [19].

Primary outcome: The difference of the proportion of patients allocated to the evaluation pathway between the intervention and the control group was expressed with the risk ratio and the absolute risk difference (ARR), both with corresponding 95% confidence intervals, calculated with the cs command within Stata (Stata version 14.1, StataCorp, Texas). The cs command is a standard Stata command to calculate the ratio of two risks (i.e. intervention group and control group in our case) with exact confidence intervals. The number needed to treat (NNT) was calculated from the absolute risk difference (1/ARR). We did a sensitivity analysis where the changes in the rehabilitation pathways was taken into consideration. We did a sensitivity analysis taking into account the patients transferred to a different pathway during the rehabilitation.

Secondary outcomes: We calculated the risk ratio for the patients' satisfaction, assessed with the evaluation of their impression of change over the course of the rehabilitation. We additionally made an analysis of the clinicians' satisfaction with the WORRK tool after the end of the study. All statistical tests were two-sided.

Results

We assessed 450 patients for eligibility and included 280 patients between March and November 2015, 139 being attributed to the control group (mean age 42.3 years) and 141 to the intervention group (mean age 43.2 years), with no lost data concerning the primary and secondary outcomes (see Fig 1). The two groups were very similar in regards to age, gender, pain, quality of life, probability score (estimated by the WORRK tool), education, certification, and type of accident (see Table 1).

Primary outcome

In the control group, 15 patients were allocated to the "Evaluation Pathway" while there were 20 allocated to this pathway in the intervention group (see Table 2). The patients in the intervention group were therefore more often referred to the "Evaluation Pathway", having a 31% higher chance, but this difference was not statistically significant (RR 1.31 [95% CI 0.7–2.46]) (see Fig 2). The absolute risk reduction was calculated to be 3.4%, giving a NNT of 30. When taking into account the patients transferred to a different pathway during the rehabilitation, more patients from the intervention group were transferred into the "Evaluation Pathway" over the course of the rehabilitation (7 patients) than from the control group (2 patient). This increases the chances of being referred to the "Evaluation Pathway" to 57% (RR 1.57 [95% CI 0.89 to 2.74]) but again this difference was not statistically significant (see Fig 2).

Secondary outcome

There was no decrease in the patients' satisfaction (via the evaluation of their impression of change over the course of the rehabilitation) between the control and intervention group, with

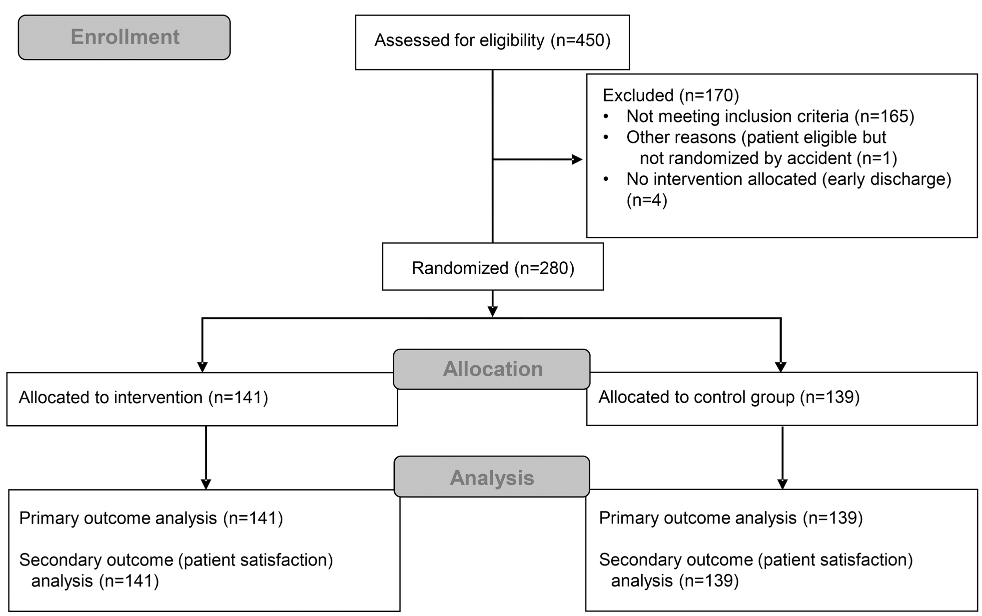

Fig 1. CONSORT flow diagram of the study.

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Table 1. Characteristics of study participants.

	All		Intervention		Control		Between-Group
Variables	n	mean (sd) or n(%)	n	mean (sd) or n(%)	n	mean (sd) or n(%)	Effect Size
Women	280	38 (14%)	141	19 (13%)	139	19 (14%)	-0.006
Age (years)	280	42.71 (10.54)	141	43.16 (10.26)	139	42.26 (10.83)	-0.09
Pain (0 to 100)	280	50.52 (25.93)	141	49.2 (26.09)	139	51.87 (25.79)	0.10
Quality of life (0 to 100)	280	45.1 (23.27)	141	44 (23.48)	139	46.21 (23.09)	0.10
Risk not to return to work (in %)	280	60.6 (19.23)	141	60.53 (19.05)	139	60.66 (19.49)	0.01
Higher education (> 9 years)	280	115 (41%)	141	60 (43%)	139	55 (40%)	0.06
Having a professional certification	280	84 (30%)	141	43 (30%)	139	41 (29%)	0.02
Working full time	279	243 (87%)	141	125 (89%)	138	118 (86%)	0.09
Injury was declared as work injury	280	165 (59%)	141	84 (60%)	139	81 (58%)	0.03
Local language was native language	280	86 (31%)	141	41 (29%)	139	45 (32%)	-0.07

Effect size: 0.2 can be considered as a small difference, 0.5 a moderate difference and 0.8 a large difference. sd = standard deviation, n = number of participants.

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even a 17% increase in satisfied patients in the intervention group, but this difference was not statistically significant (RR 1.17 [095% CI 0.812 to 1.678]) (see Fig 3).

With regards to clinicians' satisfaction with the WORRK tool, the qualitative analysis showed that the decision makers were mostly satisfied with the decisions they took using the WORRK score, as well as with the decision-making process it generated, and would use the tool more often if given the choice. Three of the four clinicians did not regret any decisions taken with the help of the WORRK score, and agreed that it facilitated their decision-making process. Half of the clinicians felt the WORRK score strongly influenced their decisions and that the score was came with sufficient guidelines, while the other half did not. They all strongly agreed that the WORRK score was not the only indicator they took into consideration before making their decision, and one of the four clinicians felt unsure that decisions taken using the tool were in the best interest of the patient. Additionally, it was shown that the clinicians have varying opinions concerning the "Evaluation pathway". For example, one clinician states "there should be the possibility of having individual physiotherapy sessions for patients in the EP", and half of the clinicians believe that by using the EP, patients are at risk of being disadvantaged while the other half do not.

Discussion

In this randomized controlled trial evaluating the clinical impact of the WORRK model on clinicians' decisions regarding rehabilitation program allocation, the knowledge of patient's risk profile increased clinicians' initial attribution to the shorter and more resource-efficient program by 31%, a result that was not, however, statistically significant or considered clinically important (according to our own power calculations). Regarding clinicians' decision changes

Table 2. Allocation to the different treatment pathways.

	All			Intervention			Control		
Programme	N Allocated (%)	N End Rehab (%)	Changed (%)	N Allocated (%)	N End Rehab (%)	Changed (%)	N Allocated (%)	N End Rehab (%)	Changed (%)
Complex Pathway	208 (74.3)	199 (71.1)	-9 (-4.3)	103 (73)	96 (68.1)	-7 (-6.8)	105 (75.5)	103 (74.1)	-2 (-1.9)
Simple Pathway	37 (13.2)	37 (13.2)	0 (0)	18 (12.8)	18 (12.8)	0 (0)	19 (13.7)	19 (13.7)	0 (0)
Evaluation-Pathway	35 (12.5)	44 (15.7)	9 (25.7)	20 (14.2)	27 (19.1)	7 (35)	15 (10.8)	17 (12.2)	2 (13.3)

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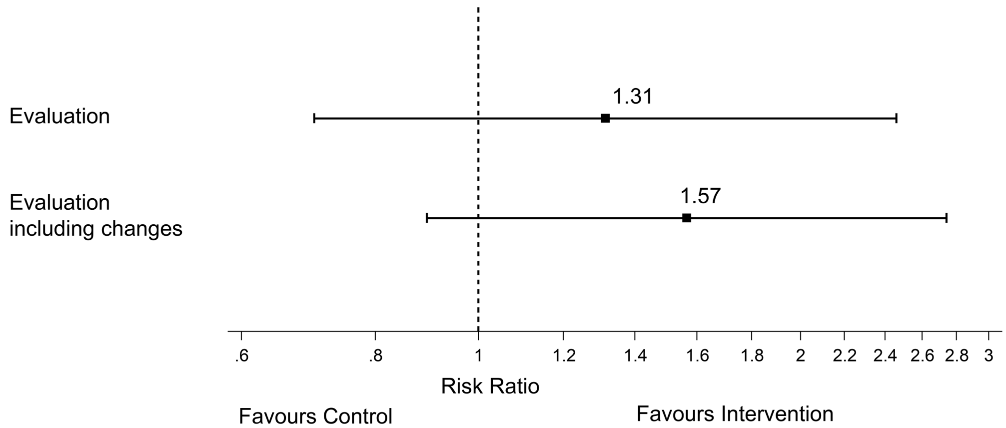

Fig 2. Point estimate and 95% confidence interval for the risk ratio for the referral to the "Evaluation Pathway" in the intervention group compared to the control group. The upper part shows the risk ratio for the primary analysis; the lower part shows the analysis taking into account the patients who were transferred into the "Evaluation Pathway over the course of the stay.

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during hospitalization (transfer of patients to an alternate rehabilitation program), this impact is increased to 57%, still however not attaining statistical significance, with 19% of patients from the intervention group being in the "Evaluation pathway" compared with 12% in the control group. Additionally, these changes did not negatively influence patient satisfaction, with even 17% more satisfied patients in the intervention group.

The effect of the WORRK model on clinician's behaviour is smaller than what was expected; instead of seeing a 15% increase in allocation to the "Evaluation pathway", there was only a 3% increase when considering clinician's initial decision and a 7% increase when taking into account decision changes during rehabilitation. Very few studies have analyzed the impact of prognostic models on clinician's decision, and it is therefore difficult to know what effect can be judged as significant, especially considering that prognostic models vary greatly not only in their application and possible consequences on decisions, but also in the structure and guidelines accompanying them. For example, a study analyzing the impact of social interventions, which are simply suggestive, on clinician's decisions, shows a similarly low impact (decrease in x ray prescription in chronic back pain patients (OR 1.6 [95% CI 1.1–2.3]) and decrease in rest prescription in the same population (OR 1.6 [95% CI 1.2–2.3])) [20]. However, a study analyzing a more directive intervention with specific guidelines as to the application of the information received, demonstrated a much higher impact (back pain patients referred for further physiotherapy according to their prognosis was increased by 17%) [21]. In a more acute pathology (pulmonary embolism), risk stratification showed a high impact on allocation to greater acuity units (14% increase in patients admitted to ICU) while a lower impact was found with decisions concerning invasive interventions (3% increase in patients receiving thrombolysis, 4.5% more mechanical ventilation, 3% more vasopressor use and 7% increase in

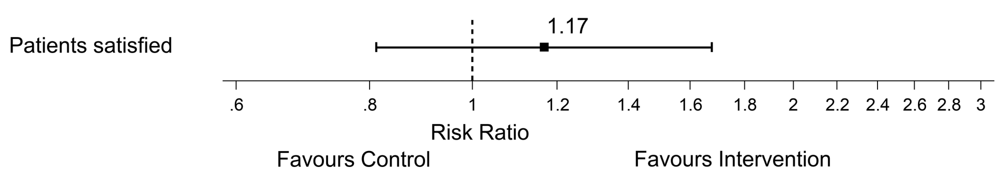

Fig 3. Point estimate and 95% confidence interval for the risk ratio for the patients being satisfied with the rehabilitation in the intervention group compared to the control group.

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inferior vena cava filter indications) [22]. This suggests that clinician's decision making is multi-factorial, and that risk stratification can be helpful but has varying impacts depending not only on the accompanying directives, but also on the context in which the decision is taken and the potential consequences on the patient: there is a greater impact on decisions that could be regarded as being easier, taken in a calmer setting and having less consequences on patient's immediate health such as which unit to send the patient to, while the impact is lesser when regarding urgent decisions with consequences on patient's immediate health status.

Knowing this, it can be argued that the WORRK prognostic model was not accompanied by sufficient guidelines: indeed, the score was given with only suggestions for decisional modifications, and perhaps if these suggestions had been more directive, a more important impact may have been seen.

As our clinician satisfaction qualitative analysis showed, however, the choice of allocation of patients to the diverse rehabilitation programs is a multi-factorial one, and the WORRK model is only a small aspect that clinician's take into account during the decision-making process. This is also supported by the findings of Stamm *et al*, [22] as discussed in the previous paragraph.

Moreover, after evaluating the clinician's satisfaction with the WORRK model, it has been shown that clinicians are afraid to negatively influence patient's potential outcomes by allocating them to a rehabilitation program that provides less physical and vocational interventions, as they think more therapies will increase patient satisfaction and outcome. This leads us to the conclusion that clinician education is also important for future interventions. It is known that inpatient physical and vocational rehabilitation requires a lot of resources: not only economic, but also from a patient's perspective, with heavy physical and psychological demands coming with an intensive and inpatient program that lasts several weeks [9, 10]. This study attempted to identify high-risk patients that should be included in rehabilitation programs using fewer resources, while leaving the opportunity for revision of the decision. Although going against health care professional's desire to improve outcomes by providing more care may seem counterintuitive, it has been shown in numerous domains that reduced interventions in high-risk populations reduce psychological and physical stress as well as health care costs, and that these decisions can be ethically and legally just [23–27]. In chronic pain following musculoskeletal injuries, investigation and management plans (especially biomedical) are often repeated despite lack of improvement, possibly submitting patients to repetitive deception, failure and reinforcing their perceived disability, causing additional physical and psychosocial strain. Additionally, in the light of ever tightening budgets, Daniels and Sabin proposed the "accountability for reasonableness" framework in order to ensure that priority setting and decisions for the distribution of healthcare resources are fair and legitimate; in order for them to seem acceptable to stakeholders (especially to those concerned by and those making the decisions), a fair process involving sustainable practices is key, with transparency, and possibility for appeals and revisions [28–30]. The procedure used in this study seems to respect these various recommendations, encouraging further investigations into the use of the WORRK model in clinical settings.

Yet another consideration to make is the role played by the cohort of patients itself and the variability of the rehabilitation programs used on the multi-factorial nature of clinician decision-making. Indeed, it is known that the type of patient analysed in this study is at risk of having psychosocial factors impeding physical recovery [7], which the clinician will give important consideration to before choosing a clinical pathway. As psychosocial interventions and therapies are integrated into the Complex Pathway, this approach will be preferred for this type of patient, and explains why the majority of patients in this centre are allocated to it, especially when considering clinicians' fear of disadvantaging them.

In regards to patient satisfaction, the increase in satisfaction in the intervention group compared with the control group was found to be due to patients in the simple and complex programs, while patients in the evaluation program showed no change in satisfaction. We can imagine that due to the intervention of the WORRK model, clinicians were able to better identify patients who would not respond positively to the simple and complex programs, and therefore the satisfaction of patients remaining in these programs was less diluted by non-responders. The WORRK model may therefore help to better identify non-responders to programs with many hours of physical and vocational therapies.

The first strength of this study is its design, being a randomised controlled trial. Secondly, this study analyses the clinical impact of a prognostic model, which, as already mentioned, is rare, with most prognostic models being applied without impact studies to support them [13]. Thirdly, patients were not excluded depending on their health literacy or language fluency, allowing the inclusion of a diverse and representative population of orthopaedic trauma patients, reducing selection bias due to cultural criteria [31].

The principal limitation of this study is the limited generalisation, due to the specific population that was analysed with the RCT; it would be interesting to analyse the impact of the model in a different setting and health care system (for example where compensation bodies are not available). It must be noted that the WORRK model has already been externally temporally validated, and a study is currently underway for external geographical validation. An additional limitation, as already mentioned, is that the WORRK tool was not accompanied by sufficiently directive guidelines. Further limitations include factors that could jeopardise the internal validity, including events and changes that could have occurred between the start and end of a patients' hospital stay or of the study itself (leakage, history, maturation). These include, for example, the WORRK score becoming known concerning a patient that was originally in the control group leading to a program transfer, the evolution of a patients' health status during hospitalisation leading to transfer to an alternate rehabilitation program regardless of the WORRK score, or a medical doctor increasing his or her experience and therefore changing his or her behaviour throughout the study regardless of the WORRK score.

Future perspectives could see the WORRK model modified in its presentation, comprising more directive guidelines for facilitated use and application. Moreover, clinician education is necessary to counter beliefs that shorter and more resource-efficient rehabilitation programs potentially disadvantage patients. In order to give weight to these arguments we put forward, a study could be carried out to prove that "less is more", analysing functional and psychological outcomes in high risk patients (estimated by the WORRK model), half of which are in a longer and more resourceful program, the other half being in a shorter and more resource-efficient program.

Conclusion

In conclusion, the knowledge of the risk of non-return to work, estimated by the means of a prognostic model (WORRK), has an influence but that is not statistically significant and does not attain what was previously defined by our own power calculations as clinically important (15%), on clinical decision making with regards to the allocation of patients to different physical and vocational rehabilitation programs after orthopaedic trauma, without jeopardizing their satisfaction regarding their rehabilitation stay, and in a more important manner when taking into account decision changes during rehabilitation. These findings support the multifactorial aspect of clinician decision-making.

Other information

The protocol was registered at ClinicalTrials.gov (NCT02396173) and this study was approved by the local ethical committee (Commission cantonale valaisanne d'éthique medical–CCVEM 047/14).

Supporting information

S1 File. CONSORT checklist.
(DOC)

S2 File. Project protocol.
(PDF)

S3 File. Data file.
(CSV)

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A Return-to-Work Prognostic Model for Orthopaedic Trauma Patients (WORRK) Updated for Use at 3, 12 and 24 Months

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Abstract *Purpose* Updating the Wallis Occupational Rehabilitation Risk (WORRK) model formula, predicting non-return to work (nRTW) at different time points (3 and 12 months) than in the validation study (2 years). *Methods* Secondary analysis of two samples was carried out (following orthopaedic trauma), including work status, the first at 3 months (428 patients) and the second at 12 months (431 patients) after discharge from rehabilitation. We used calibration (agreement between predicted probabilities and observed frequencies) and discrimination (area under the receiver operating characteristics curve) to assess performance of the model after fitting it in the new sample, then calculated the probabilities of nRTW based on the coefficients from the 2-year prediction. Finally, the intercepts were updated for both 3- and 12-month prediction models (re-calibration was necessary for the adjustment of these probabilities) and performance re-evaluated. *Results* Patient characteristics were similar in all samples (mean age 43 in both groups; 86% male at 3 months, 84% male at 12 months). The proportion of nRTW at 3 months was 63.8% and 53.4% at 12 months (50.36% at 2 years). Performance of the original WORRK for both 3- and 12-month prediction showed an AUC of 0.73, while statistically significant miscalibration was found for both time points ($p < 0.001$). After the updating of the intercept, calibration was improved and did not show significant miscalibration ($p = 0.458$ and 0.341). The AUC stayed at 0.73. *Conclusion* The WORRK model was successfully adapted by changing the intercept for 3- and 12-month prediction of nRTW, now available for use in clinical practice.

Keywords Rehabilitation · Vocational · Decision support techniques · Return to Work

Introduction

Work related and non-work related orthopaedic trauma constitutes a very important economic and social burden. In Switzerland alone, a country with 8 million inhabitants, the expenditure on direct costs, which involve all acute medical care and hospitalisation, rehabilitation and additional health care management, attains 1.23 billion US$, and indirect costs amount to an astounding 1.81 billion US$ (loss of earning and productivity as well as medical and worker compensation) [1–5]. On top of the financial load, orthopaedic trauma also leads to substantial disability and psychosocial strain, affecting quality of life, causing chronic pain and leading to prolonged inability to work, a factor which can have a negative effect on health (physical and psychological) as well as social integration [1, 3, 4, 6]. At first, as research was focused on major injuries, these effects were thought to be primarily as a consequence of life-threatening traumas. However, follow-up studies using the Abbreviated Injury Score (AIS) [7] scale to examine

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the efficacy of trauma centres made it clear that moderate and minor traumas contributed significantly or even more so than major traumas to the health burden [8].

It is now known that work is beneficial to health, and that return to work (RTW) can be used as an indicator of post-injury functioning and therefore the success of not only the acute-phase medical management but also long-term medical care such as rehabilitation and vocational programmes [1, 9, 10]. When considering what factors predict return to work, research shows that injury severity and medical factors alone cannot, especially as time passes and the injury becomes chronic. RTW prediction models for routine cases of low back pain (LBP) have supported the importance of these non-medical factors [11–14]. Other factors involved in predicting RTW are therefore being explored, with importance now being given to bio-psycho-social determinants such as job-related and socio-economic factors, patients' psychological state and compensation and/or legal involvement; these factors are essentially the same when comparing LBP and orthopaedic trauma patients [1, 3, 10, 13, 15–19]. By recognising these variables, measurable early in recovery as they are mostly independent of the injury itself, it may be possible to adjust clinical decision making once out of the acute phase, with regards to physical and vocational rehabilitation programmes as well as compensation, in order to better distribute the resources available [1, 3].

In order to most accurately predict RTW status, it is important to identify an objective and reproducible screening method, applicable to a wide range of injuries and patients, including those with poor health literacy or language fluency. A model has already been developed and externally temporally validated by Luthi et al. [4], which applied at admission to rehabilitation, predicts non-return to work status at 2 years post-rehabilitation: the Wallis Occupational Rehabilitation Risk (WORRK) model (the formula is accessible by following the link beside the reference). This model includes 1 occupational, 6 biomedical and 12 psychosocial factors, and can be applied after orthopaedic trauma and for LBP patients; its difference and advantage over existing LBP prognostic models however is that it does not discriminate against non-native speakers, who make up a large proportion of the target population, therefore being applicable in patients that would otherwise be excluded because of this factor. Having access to this tool for prediction of work status at 3 and 12 months post-rehabilitation, however, could assist in decision-making earlier on in the rehabilitation process. The purpose of this study was therefore to externally temporally validate the already existing WORRK model, applied at admission to a rehabilitation centre, for 3- and 12-month prediction of non-return to work post-rehabilitation, after moderate and minor orthopaedic injury, allowing patients to be more rapidly screened and put into programmes best suited to their likely return to work outcome.

Methods

The study took place at the "Clinique Romande de Réadaptation" (CRR), a Swiss accident insurance fund (SUVA—the main injury insurance in Switzerland) medical centre, where patients are sent on average 9 months after mostly traffic and work accidents if they exhibit persistent pain and functional limitations. Multidisciplinary therapeutic programs are put in place in order to improve functional status, quality of life, and the chance of returning to work. Using existing data from previous patient cohorts drawn from the CRR, we included patients with acute orthopaedic injuries (including all musculoskeletal localisations and AIS classifications [7]), admitted on average 9 months following the initial injury, and with information concerning their 3- and 12-month work status after discharge from the rehabilitation centre (representing their work status at, on average, 12 and 21 months following the initial injury), as well as information necessary for the predictors included in the WORRK prediction tool. We included patients that had no severe traumatic brain injury at time of accident (Glasgow coma Scale > 8), had no spinal cord injury, were capable of judgment, were not under legal custody and were not older than 62 years of age at the moment of hospitalization (to omit those who might opt for retirement rather than to RTW). Most of the patients were blue collar workers and were injured after traffic, work or leisure accidents [20, 21].

The Swiss Insurance Framework

Health and accident insurances are compulsory in Switzerland; health insurance is financed by the individual, whereas each worker is insured against occupational and non-occupational accidents (as well as their consequences) by his/her employer and financed by monthly salary deductions. All construction and manual workers (i.e. blue collar workers) are insured by the Swiss National Accident Insurance Fund (Suva), which is the main accident insurer in the country. The accident and occupational disease insurances are in charge of providing daily financial allowances until there is a possibility of returning to work or until a disability pension is allocated. Disability insurance has set up specific structures to analyse the state of health and residual occupational capacity of the impaired workers. State of health is determined by a general practitioner and, if in doubt, by an acknowledged expert whereas vocational evaluation and rehabilitation are mainly carried out by specialised clinics [22].

The accident insurer must pay for medical treatment as long as a significant improvement in the state of health can be anticipated, without limit in terms of time or cost. The insured persons have a legal right to integration measures, but they are obliged to cooperate and do everything possible to return to an occupational activity, avoiding the need for pension allocation. If this is impossible, the disability insurance will help the worker in finding work, or look into the possibility of occupational reclassification and permit the insured person to obtain new occupational qualifications. With the intercession of the insurance institutions at an early stage in the form of vocational rehabilitation measures, the chances of work resumption and long-term reintegration are considerably increased, but if these measures fail, the disability insurance will have to pay a disability pension. Thus, reintegration measures are in the interests of the individual having had the accident, but also in the financial interests of the insurance company itself [23, 24].

Transportability of the Published WORRK Model to Different Follow-up Intervals; Model Performance

We wanted to evaluate whether the WORRK prediction formula, which was developed for the prediction of non-return to work at 24 months after discharge from rehabilitation, could be used to predict non-return to work at 3 or 12 months in the same setting and with similar patients as used in the validation study of the original WORRK prediction model. These time points were chosen close to the end of rehabilitation treatment (3 months) and at 1 year because it is know that there is a steady increase in RTW in these patients during the first year, with then a plateau after 2 years, making this period potentially the most important in the recovery process [24]. To assess this, we evaluated the model performance of the published WORRK prediction tool with indices for discrimination and calibration. For discrimination, we calculated the area under the receiver operating characteristic (ROC) curve, as well as sensitivity, specificity, and positive and negative predictive values. For testing the calibration we used the Hosmer–Lemeshow test [25] and plotted the observed proportions of non-return to work against the predicted probabilities for groups defined by ranges (10%) of predicted risk as well as the slopes and calibration intercepts [26]. The calibration intercept is called calibration in the large and is calculated with a logistic regression with the slope fixed at one. If the coefficient is negative, the model will overestimate the probability of non-return to work; if the coefficient is positive, the model will underestimate the probability of non-return to work. Because the prevalence of non-return to work at 3 and 12 months is higher than at 24 months, we expected that this coefficient would be greater than zero. Because this sample comes from the same population as the samples for the development and validation of the original WORRK formula, we expected that the model would only need an update of the intercept, without revision of the model itself.

Updating of the Prediction Model

Because the prevalence of non-return to work is different at 24, 12 and 3 months, we decided to update the intercept, as proposed by Steyerberg et al. [27]. After analysis of the calibration plot, we updated the intercept of the model for 3- and 12-month prediction separately. For this we fitted a logistic regression model in the new samples with the intercept as the only free parameter and using the linear predictor based on the previously published coefficients of the predictors as an offset variable (i.e. fixing the slope at unity). We did not update the prediction coefficients.

With the two new prediction formulae with the updated intercepts for the 3-month and 12-month follow-up, we re-evaluated the model performance (i.e. discrimination and calibration).

All analyses were done with Stata version 13.0 (College Station, Texas 77845 USA) and with R statistical software version 2.15.3 [28] with the packages PresenceAbsence (version 1.1.9).

Results

From the different cohort studies, we included 428 patients with a 3-month follow-up and 431 patients with a 12-month follow-up. When analysing the overlap of the samples, 94 patients (17.9%) with a 3-month follow-up did not have a 12-month follow-up and 97 (18.5%) with a 12 month follow-up did not have a 3 month follow-up. The basic characteristics are quite similar for both follow-up time points (see Table 1). The non-return to work rate was, as expected, higher at 3 months (64%) than at the 12-month follow-up (53%).

Model Performance for 3- and 12-Month Prediction Using the Formula Developed for Prediction at the 2-Year Follow-up

The calibration plot showed that there was significant miscalibration for both the 3-month ($p<0.001$) (Fig. 1) and 12-month ($p<0.001$) (Fig. 2) prediction.

The discrimination for 3- and 12-month prediction of non-return to work was moderate with an AUC of 0.73,

Table 1 Characteristics of the patients for both follow-up time points

Variable	3 months, n = 428	12 months, n = 431	Difference between 3-month and 12-month samples (95% CI); p value
Men, n (%)	368 (86%)	364 (84%)	1.5% (−3.2 to 6.3%); p = 0.529
Age, mean (sd)	43 (10.9)	43 (10.5)	
Native speakers—French (%)	287 (67%)	270 (63%)	4.4% (−2.0 to 10.8%); p = 0.1758
Higher education (%)	268 (63%)	255 (59%)	3.5% (−3.1 to 10.0%); p = 0.300
Not returned to work at follow-up, n (%)	273 (64%)	229 (53%)	10.7% (4.1 to 17.2%); p = 0.002
Location: lower limb (%)	183 (43%)	182 (42%)	0.5% (−6.1 to 7.1%)
Location: back (%)	89 (21%)	99 (23%)	−2.2% (−7.7 to 3.3%)
Location: upper limb (%)	134 (31%)	132 (31%)	0.6% (−5.5 to 6.9%)
Location: multiple injuries (%)	22 (5%)	18 (4%)	1.0% (−1.9 to 3.8%)

CI confidence interval

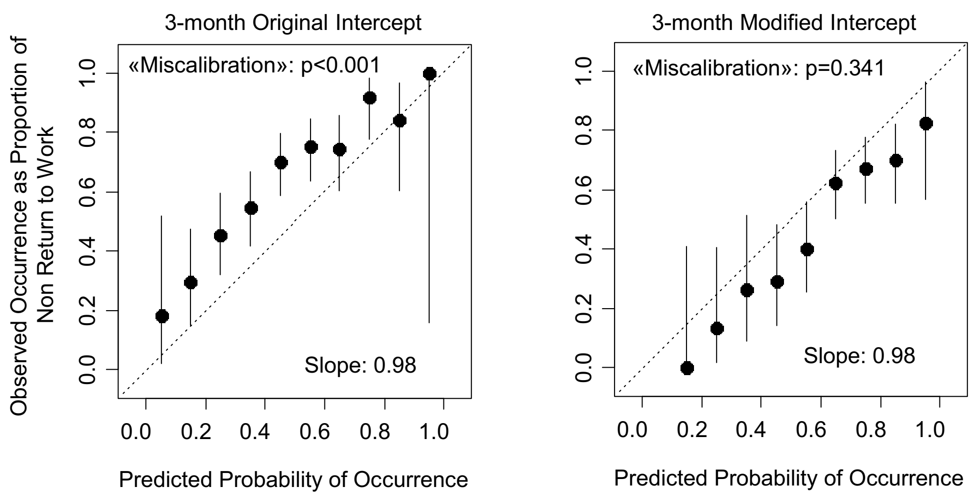

Fig. 1 Calibration plots for the 3-month prediction with the original (*left*) and modified intercept (*right*)

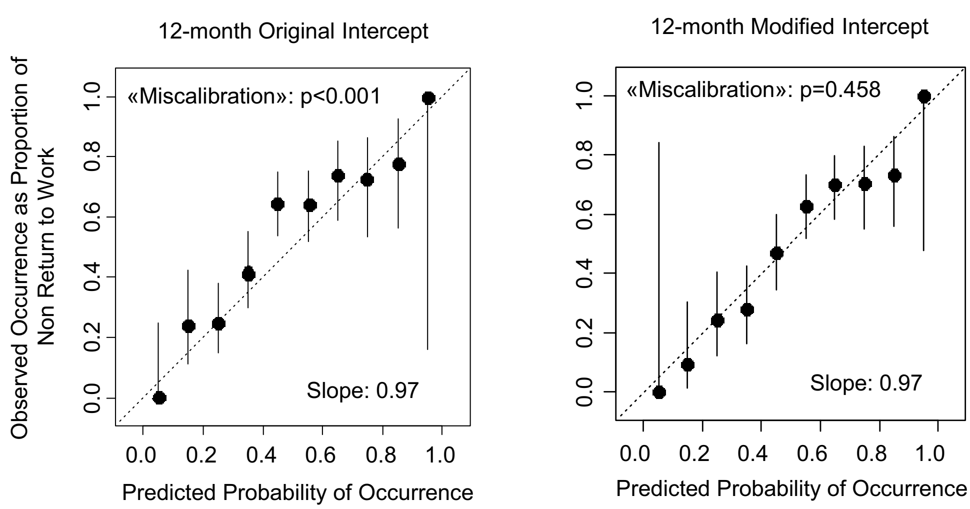

Fig. 2 Calibration plots for the 12-month prediction with the original (*left*) and modified intercept (*right*)

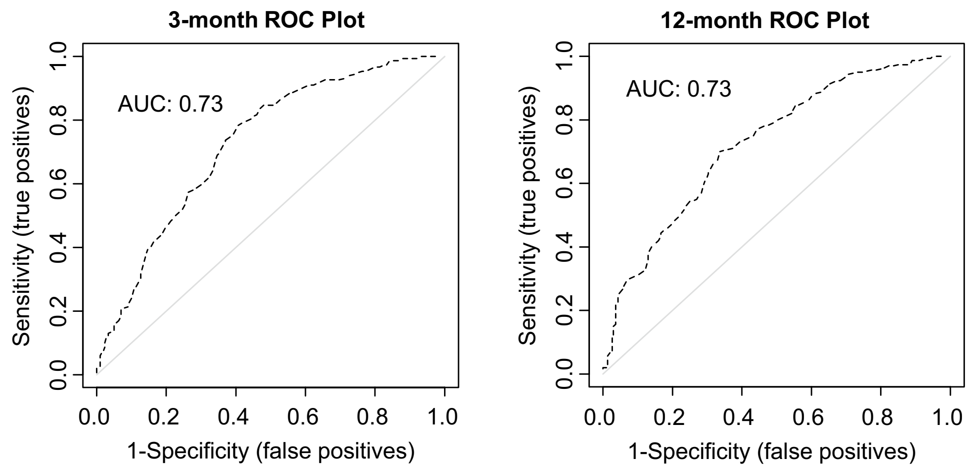

Fig. 3 Receiver operating characteristic curves for the 3-month (*left*) and the 12-month prediction (only modified intercept shown). *AUC* area under the curve. *N* total number of participants with complete data for the variables in the model

which is equal to the published 2-year prediction [4]. See Fig. 3.

Model Performance for 3- and 12-Month Prediction After Adaptation of the Intercepts

The original intercept as published by Luthi et al. in 2014 was −2.649848. This was adapted to −1.7850574 for the 3-month analysis, and to −2.978829 for the 12-month analysis.

After the modification of the intercepts, the calibration was better and with a non-significant test for deviation from perfect calibration ($p=0.341$ for the 3-month prediction and $p=0.458$ for the 12-month prediction). See Figs. 1 and 2.

The discrimination remained the same with an AUC of 0.73.

The sensitivity, specificity, as well as the positive and negative predictive values for different cut-off points of the predicted probability of non-return to work based on the adapted prediction formulas are presented in Table 2. For example, if a threshold of 0.5 is used, of 100 patients predicted to not return to work, at 3 months 28 will have returned to work (PPV 72) while at 12 months 31 will have returned to work (PPV 69).

Discussion

In this evaluation of the Wallis occupational rehabilitation risk (WORRK) model, applied to a cohort of patients at admission to an occupational rehabilitation programme following minor or moderate orthopaedic trauma, it can be concluded that the WORRK model, originally built for the prediction of non-return to work status at 2 years post rehabilitation, can be used for the prediction of 3- and 12-month work status, by changing simply the intercept of the model, as the baseline risk for non-return to work is not the same at 3 and 12 months in comparison to 2 years.

Table 2 Sensitivity (SN), specificity (SP), as well as the positive (PPV) and negative (NPV) predictive values for different cut-off points of the predicted probability of non-return to work based on the adapted prediction formulas

Threshold	3-Month prediction non-return to work						12-Month prediction non-return to work					
	n predicted positive	SN	SP	PPV	NPV	% c.cl	n predicted positive	SN	SP	PPV	NPV	% c.cl
≥0.1	428	100	0	64	0	64	429	100	1	53	100	54
≥0.2	421	100	5	65	100	65	408	99	10	56	91	58
≥0.3	403	97	12	66	72	66	367	95	26	59	81	62
≥0.4	376	95	25	69	75	70	317	89	44	64	77	68
≥0.5	333	88	39	72	64	70	251	75	61	69	68	68
≥0.6	268	74	58	76	56	68	165	52	77	72	58	63
≥0.7	181	53	76	80	48	61	89	28	88	73	52	56
≥0.8	92	30	93	88	43	53	42	14	95	76	49	52
≥0.9	22	7	97	82	37	39	5	2	100	100	47	48

c.cl correct classified

The effect of rehabilitation on chronic low back pain is known to influence very little RTW [29]. Though the rates of nRTW after rehabilitation found in our acute orthopaedic trauma patients may seem low, they fall within the rates found in similar populations (Clay et al. [1] report rates ranging between 15 and 58%).

The strength of this study is the systematic approach, the large sample size and the application of the model at two different follow-up time points. The strengths of the WORRK model are first of all that it is one of the only systematic tools that is an improvement on an existing model, having used recalibration in order to apply it to different follow-up time points [30]. This is advantageous over other models that are validated at a certain follow-up time point, and then arbitrarily applied to different time points without recalibration. Additionally, it allows the inclusion of patients with poor health literacy or language fluency. Incorporating this population into the analysis is important as they are an increasing presence in the work force of industrialised countries, are at risk of adverse work conditions, and may have cultural expectations or representations hindering return to work [4, 8, 31–34]. Moreover, the WORRK model includes twelve psychosocial factors (including language, education and profession, but also social vulnerability, mental health threat and coping) making it applicable in a wide range of socio-economic environments.

The three main limitations are first that the calibration at 3 months is slightly inaccurate and the model might benefit from a recalculation of the coefficients or the addition of new predictors. However, this would need a larger sample size, and it was therefore decided not to carry out this recalculation. The second limitation is that this study only provides a temporal external validation [35]; in order to be able to recommend the WORRK model in other settings and health systems (for example where compensation bodies are not available), an external validation (applicable in other centres) is necessary. Thirdly, it must be noted that certain important notions with regards to RTW such as self-efficacy and information about the workplace environment, are not measured by the model, as they were not available in a standardised manner at the time [36]. A revision of the model should address this issue.

When comparing this model to other available prediction models, there are, to the best of our knowledge, no other prediction tools that are clinician rated. However, there are prediction models using a workers compensation-claims database [3], performance-based measures [37], performance-based measures combined with self-reported ability [38] and purely self-reported questionnaires via the OMPSQ (Orebro Musculoskeletal Pain Questionnaire) [39]. These models may be difficult to apply in an acute rehabilitation setting for the following reasons, respectively: where compensation bodies may not yet be involved or not available at all (for example as is the case in the UK), where performance may still be suboptimal due to injury, and in a chronic rehabilitation setting where self-reported ability can be biased by long-term sick leave as well as poor health literacy or language fluency [31]. Moreover, although using purely insurance-based data provides excellent prediction, this type of model is not pertinent in different socio-economic or insurance settings. The WORRK model is therefore an innovative applicable tool for the acute and chronic rehabilitation setting, providing an objective and accessible prediction of work status at 3, 12 and 24 months.

Moreover, the WORRK model might be useful in clinical practice with regards to the decision making process. For example, in situations where the duration and program of the rehabilitation depends on the prognosis, our model might inform clinicians earlier in the chronology of the patient. This could be particularly useful as 1 year post-rehabilitation seems to potentially be the most important period in the recovery process [24]. These decisions may also improve the efficient allocation of scarce resources. However, the effectiveness of the application of this tool is still to be evaluated in a randomized controlled trial, a study which is currently underway (NCT02396173).

With regards to use in research, the results of this study suggest that the WORRK model can be used, with a modified intercept, for the prediction of shorter follow-up time points. This is important, for example, in randomized controlled trials for the inclusion or stratification of patients, as well as in observational studies where it is important to control for confounding [40]. With our update of the intercepts at 3 and 12 months, this is now possible for studies with follow-up time points of 3, 12, or 24 months.

In conclusion, the Wallis Occupational Rehabilitation Risk Model (WORRK), which until now has been validated for the prediction of work status at 2 years post rehabilitation following minor or moderate orthopaedic trauma, has now been temporally externally validated for the prediction of work status at 3 and 12 months by changing the intercept of the model. Use of this model in clinical and research settings may then be used to screen patients, particularly at 12 months, assisting in decision-making and allocation of appropriate rehabilitation programmes and funds.

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Compliance with Ethical Standards

Conflict of interest Chantal Plomb-Holmes, François Lüthi, Philippe Vuistiner, Bertrand Leger and Roger Hilfiker declare that they have no conflict of interest.

Ethical Standards All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2000. Informed consent was obtained from all patients for being included in the study.

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