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Complete List of Authors:	Klussmann, Andre; Institute of Occupational Health, Safety and Ergonomics - ASER, Institute of Occupational Health, Safety and Ergonomics (ASER) Liebers, Falk; Federal Institute for Occupational Safety and Health (BAuA) Brandstädt, Felix; Federal Institute for Occupational Safety and Health (BAuA) Schust, Marianne; Federal Institute for Occupational Safety and Health (BAuA) Serafin, Patrick; Institute of Occupational Health, Safety and Ergonomics (ASER) Schäfer, Andreas; Institute of Occupational Health, Safety and Ergonomics (ASER) Gebhardt, Hansjürgen; Institute of Occupational Health, Safety and Ergonomics (ASER) Hartmann, Bernd; ArbMedErgo Consultant Steinberg, Ulf; Ergonomics Consultant Steinberg (ebus); Federal Institute for Occupational Safety and Health (BAuA)

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Title page

Validation of Newly Developed and Redesigned Key Indicator Methods (KIMs) for Assessment of Different Working Conditions with Physical Exposures based on Mixed Methods Design – A Study Protocol

Authors

Andre Klussmann[1#✉], Falk Liebers[2#], Felix Brandstädt[2], Marianne Schust[2], Patrick Serafin[1], Andreas Schäfer[1], Hansjürgen Gebhardt[1], Bernd Hartmann[3], Ulf Steinberg[2,4]

Address

[1] Institute of Occupational Health, Safety and Ergonomics (ASER), Corneliusstr. 31, 42329 Wuppertal, Germany.

[2] Federal Institute for Occupational Safety and Health (BAuA), Nöldnerstr. 40-42, 10317 Berlin, Germany.

[3] ArbMedErgo Consultant, Steinbeker Grenzdamm 30d, 22115 Hamburg, Germany

[4] Ergonomics Consultant Steinberg (ebus), Rügenwalder Weg 52, 12621 Berlin, Germany.

# These authors contributed equally to this work ✉ Corresponding author

✉ **Corresponding author**

Andre Klussmann, Dr.-Ing., M.Sc., Eur.Erg.

Institute of Occupational Health, Safety and Ergonomics (ASER), Corneliusstrasse 31, 42329 Wuppertal, Germany

Phone: +49 202 731000; Fax: +49 202 731184; Email: klussmann@institut-aser.de

Email

Andre Klussmann✉ – klussmann@institut-aser.de; Falk Liebers – liebers.falk@baua.bund.de; Felix Brandstädt – brandstaedt.felix@baua.bund.de; Marianne Schust – schust.marianne@baua.bund.de; Patrick Serafin – serafin@institut-aser.de; Andreas Schäfer – schaefer@institut-aser.de; Hansjürgen Gebhardt – gebhardt@institut-aser.de; Bernd Hartmann – HartmannBernd_Hamburg@web.de; Ulf Steinberg – ulf.steinberg@berlin.de

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Abstract

Introduction:

The impact of work-related musculoskeletal disorders (WRMSDs) is considerable. The assessment of work tasks with physical exposures is crucial to estimate the work-related health risks of exposed employees. Three Key Indicator Methods (KIMs) are available for risk assessment regarding manual lifting, holding and carrying of loads (LHC), manual pulling and pushing of loads (PP) and manual handling operations (MHO). Three further KIMs for risk assessment regarding whole-body forces (BF), awkward body postures (ABP), and body movement (BM) have been developed de novo. In addition, the development of a new combined method for mixed exposures (ME) is planned. All methods will be validated regarding face validity, reliability, convergent validity, criterion validity and further aspects of utility under practical conditions.

Methods and analysis:

As part of the joint project MEGAPHYS, a mixed methods study is being designed for the validation of KIMs and conducted in companies of different sizes and branches in Germany. Workplaces are documented and analysed by observations, applying KIMs, interviews and assessment of environmental conditions. Furthermore, a survey among the employees at the respective workplaces takes place with standardised questionnaires, interviews and physical examinations with special emphasis on musculoskeletal complaints and symptoms. It is intended to include 1,200 employees at 120 different workplaces. For the analysis of the quality criteria, the recommendations of the COSMIN checklist (COnsensus-based Standards for the selection of health Measurement INstruments) will be taken into account.

Ethics and dissemination:

The study was planned and conducted in accordance with the German medical professional code and the Helsinki Declaration as well as the German Federal Data Protection Act. The design of the study was approved by Ethics Committees. We intend to publish the validated KIMs in 2018. Results will be

published in peer-reviewed journals, presented at international meetings and disseminated to actual users for practical application.

Keywords

Risk assessment, Key Indicator Method, Work-related musculoskeletal disorders, Reliability, Criterion validity, Convergent validity

Strengths and limitations of this study

- This research project will provide a scientific substantiation and – if necessary according to the results of the study – modification of standardised methods to assess physical exposures at workplaces at a screening level.
- With the help of these KIMs, the full range of physical exposures (excluding exposures due to hand / arm and whole-body vibration) could be assessed by occupational health and safety stakeholders.
- Knowledge about the correlation between work-related factors and MSDs will be advanced.
- The study is limited by the cross-sectional design, which is not suitable to assess the causal relationship between variables but only associations.

Main text

INTRODUCTION

General background

Work-related musculoskeletal disorders (WRMSDs) have been recognised for many decades[1, 2]. Disorders often mentioned in the literature include low back pain and intervertebral disc diseases[3], epicondylitis[4] and carpal tunnel syndrome[5]. Hard physical work may also lead to high cardiovascular strain and may increase the mortality risk of ischaemic heart disease in individuals with a low or moderate fitness level[6].

According to the European Council Directive 89 / 391 / EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work, the employer must perform an assessment of the risks to safety and health at work, including those to which specific groups of workers are exposed[7]. One year later, a further European Council Directive 90 / 269 / EEC “manual handling of loads” of 29 May 1990 was published addressing the minimum health and safety requirements for the manual handling of loads where there is a risk particularly of back injury to workers[8]. To assess the risk of WRMSDs, a number of assessment methods have been developed[9].

Previous development and validation of the KIMs

In Germany, the release of the two European Council Directives triggered the development of “Key Indicator Methods” (KIMs), see Figure 1. The KIMs were developed for risk assessment at the screening level in the case of physical exposures. Potential users include occupational safety and health stakeholders and industrial engineers in companies, ergonomists, occupational health physicians, employers and employees associations, and insurance companies or research facilities. Three different KIM worksheets, one for Lifting, Holding, Carrying loads (KIM-LHC), one for Pulling and Pushing loads (KIM-PP) and one for Manual Handling Operations (KIM-MHO), are available so far. These methods were developed by the Federal Institute for Occupational Safety and

Health (BAuA) in close collaboration with practitioners, safety representatives, occupational health physicians, and the "Länderausschuss für Arbeitsschutz und Sicherheitstechnik" (Federal Committee of the States for Occupational Safety and Health)[10, 11, 12]. Briefly, work characteristics such as force, frequency and duration, and general working conditions are assessed by means of the KIM, and a score is calculated to summarise the work-associated risk for adverse health outcomes, e.g. musculoskeletal symptoms. To illustrate the result, the score is transformed into a traffic light scale indicating a low exposure situation where physical overload is unlikely to occur (= green), situations with slightly increased (= greenish yellow) and substantially increased (= yellow) exposure, up to a high exposure situation where physical overload is likely to occur and a redesign of the workplace is probably necessary (= red)[13]. The existing methods can be downloaded from the homepage of BAuA[14]. The three existing KIMs deal with manual handling of loads and repetitive manual handling operations. Further aspects of physical exposures, such as awkward body posture, whole-body forces and body movement have not or not sufficiently been included in this method inventory yet. To fill this gap, drafts of three supplemental methods were developed. Further developments are necessary and a revision of the three existing methods is required, so that all methods are compatible. In addition, the development of a method for the assessment of mixed physical exposures is planned.

Preliminary work – development of new KIM drafts

The preliminary work during the last decades mentioned above (see Figure 1), was complemented by an additional search of peer-reviewed articles and grey literature predominantly in German and English, and methods for the assessment of working conditions associated with physical exposures were analysed systematically. The various methods included on the one hand a large number of work characteristics considered to be related to health outcomes, and on the other hand a large number of different body regions, symptoms and diseases which could be affected by these work characteristics. There is only low evidence of a "cause and effect model" or even a "dose response relationship" with certainty between most physical exposures and MSDs. In the published studies or methods, the selection of the observed characteristics varied significantly. Unfortunately, details about the selection of the parameters were often not indicated in the publications available and many questions remain, e.g. questions about the deduction or the combination of the parameters to be assessed for description of work-related risks. In addition, only a small number of methods assessing biomechanical exposures in occupational settings have been tested in a systematic manner for validity, reliability, or other aspects related to their practical use[9].

The development of the new KIMs drafts was based on a comprehensive and critical literature review of the methods mentioned above. This knowledge was combined with interviews involving scientists, supervisors of state agencies and professional associations, occupational physicians, occupational health and safety officers, and managers from companies in various industries about typical kinds of exposures and exposure-structures of physical exposures. Finally, the drafts of three new KIMs (whole body forces, awkward postures, and body movement) were available for validation within the present study.

METHODS AND ANALYSIS

Aim, design and setting

In this study protocol, the concept for development and validation of the newly developed and redesigned KIMs is presented. It is part of a joint project (MEGAPHYS – Mehrstufige Gefährdungsanalyse physischer Belastungen am Arbeitsplatz [Multilevel risk assessment of physical exposures at work]). The distribution of the responsibility for the recruitment and documentation of the workplaces and the realization of the interviews of further partners in the joint project are described in the "Funding" and "Acknowledgements" sections. General aims, definition of the six archetypes of physical workload used and the background of the joint project MEGAPHYS have been described previously[15].

The aim of the study protocol presented here is to provide the concept of how to validate the revised versions of the three existing KIMs (KIM LHC, KIM PP, KIM MHO) and the draft versions of the three new KIMs for whole body forces, awkward postures, and body movement (KIM ABP, KIM BF, KIM BM) in order to provide validated risk assessment methods for these six types of physical exposures. Furthermore, a draft of a KIM for the assessment of mixed physical exposures, including relevant indicators of the six specific KIMs, is also planned (see Tables 1 and 2). The main objective to be considered is the association between physical exposures, as assessed by means of the scores of the KIMs, and the frequency of musculoskeletal symptoms and other outcomes within the exposed workers in terms of discriminative capacity of the KIMs or the combined KIM.

The validation of KIM uses a cross-sectional design and a mixed-method approach. For the determination of criterion validity, a cross-sectional study among 1,200 employees at approx. 120 different workplaces will be carried out. Workplace analyses will be done by direct observations and assessments using the KIMs, interviews of employees and managers, workplace measurements (e.g. noise, climate) and video recordings. These workplace analyses will also be used for the determination of face validity, reliability, convergent validity, criterion validity and further aspects of utility.

Setting of the study will be workplaces in voluntarily participating companies of different sizes and branches in Germany.

Characteristics of participants

For the analysis of criterion validity, male and female employees, 19 to 65 years of age, at workplaces with different types and levels of physical exposures are recruited, who have worked at the workplaces considered for at least three months and are proficient in the German language. For each type of physical exposure (total of six types: LHC, PP, MHO, BF, ABP, BM) and for each of four exposure levels as rated by experts beforehand (low, slightly increased, substantially increased, and high), approximately 40 to 50 employees will be recruited (assuming predominantly uniform exposures in each group). The aim is to cover all employees of the selected workplaces. If more than 20 employees are engaged in the same workplace, the participants will be selected randomly. The study population can be calculated as follows: 6 types of physical exposures x 4 exposure levels x 50 subjects per type of physical exposure and exposure level = 1,200 subjects. Assuming that at each workplace an average of 10 employees can be recruited, 120 workplaces need to be observed and documented. It is intended to analyse about 5 workplaces per type of physical exposure and exposure level. Approx. 10 employees per workplace will be interviewed by ergonomists, and interviewed and examined by physicians.

The data gathered during observation and documentation of the 120 workplaces will also be used for the determination of convergent validity, reliability and further aspects of utility. For the determination of interrater-reliability, 12 users of the KIMs are needed, to represent future users. Typical users of these kinds of assessment methods ideally are occupational health and safety stakeholders or industrial engineers in the companies. From these 12 users, six pairs will be formed (one pair per type of physical exposure), each observing 20 workplaces. This will result in 120 double ratings.

Research goals

The research goals (RG) include the examination of different quality criteria of the KIMs:

- RG 1: The KIMs are an adequate reflection of the construct to be measured (face validity).
- RG 2: At the completion of the KIMs, no relevant deviations occur between different users assessing the same workplaces (reliability).
- RG 3: Assessing workplaces using the KIMs and other screening methods measuring the same type of physical exposure will result in no relevant differences (convergent validity).
- RG 4: It is assumed, that employees at workplaces with high physical exposure show adverse health-related outcomes (e.g. musculoskeletal symptoms) more frequently than non-exposed workers. It is assumed,

that high risk scores derived in the assessment of workplaces with the KIMs are associated with a high prevalence of musculoskeletal symptoms and disorders (criterion validity or content validity regarding hypotheses testing).

The selection of the quality criteria described in the research goals are derived from a systematic evaluation of observational methods assessing biomechanical exposures at work[9]. For the analysis of the quality criteria, the recommendations of the COSMIN checklist (COnsensus-based Standards for the selection of health Measurement INstruments) will be taken into account[16]. The reporting of the results of this observational study will also consider the recommendations of STROBE (Strengthening The Reporting of OBservational studies in Epidemiology)[17].

Instruments and Methods

The instruments and methods for the assessment of exposures and outcomes (i.e. questionnaire, medical diagnostic tool, assessment of working conditions) used in this survey have been used in a similar form in other studies by several authors. Among them, the authors of the present study used them for the assessment of musculoskeletal symptoms in office workers[18] and in a former validation study of the KIM MHO[19, 20].

1) Assessment of exposures:

- Ergonomic work procedure analysis and assessment of technical procedures for the documentation of working conditions.

2) Application of the KIMs:

- Application of the six KIMs based on the exposure assessment.

3) Assessment of health outcomes:

- Standardised questionnaire for a survey among the employees.
- Medical diagnostic tool for the physical examination of the employees.

Ergonomic work procedure analysis for the assessment of exposures

The basis for the evaluation of the workplaces is an ergonomic work procedure analysis with detailed assessment of exposures during the shift. A workplace typically consists of a number of different work tasks. Duration and frequency of all work tasks are documented in a way that the KIMs, as well as further screening methods chosen for the testing of convergent validity, can be completed. The ergonomic work procedure analysis covers in principle all relevant objective characteristics that result from the type of work and the working conditions. Individual characteristics during work execution, random disruption of the workflow or unusual conditions will not be considered. Principal components of the work procedure analysis are:

1) Metadata of the workplace, such as: name and type of activity, precise list of work tasks, professional qualification requirements, position of employees, complexity of the activity, number of employees at the workplace, gender and age distribution, shift system, typical working time, predetermination of the work task;
2) Number and type of work task and for every work task detailed information, for example: about temporal distribution of this work task during the shift, determination of type of work (load handling, applying force, body posture, joint positions); and
3) Basic description of other relevant exposures, such as: noise level, lighting, vibration, hazardous materials.

Application of the Key Indicator Methods (KIMs)

The application and validation of the KIMs are the central goals of this research project and will be completed based on the ergonomic work procedure analysis. The KIMs contain an objective requirement and description of exposures and identify potential threats to physical overload. The KIMs include job characteristics and their interaction. The key indicators are classified in different scales. The scales correspond to conditions in practice and range from a minimum to maximum, or optimum to poor. The classification of these scales indicates bottlenecks for each category / indicator. By multiplying the scale value of the daily duration / frequency of activity with the sum of the other scale scores, a total value can be calculated. This calculated sum score can be allocated to an exposure level and one of four risk categories, an approach already used in existing KIMs[13]. The four risk categories reflect the increase of the probability of physical overload and correspondingly the increase in frequency of adverse health effect related to the given physical exposure from low (reference group) to high load situations (see above, section “Previous development and validation of the KIMs”).

An overview of the KIMs, including a brief description of the type of exposure, the key indicators considered and some examples of typical work tasks is provided for the already exisiting KIMs in Table 1 and for the KIMs under development in Table 2.

Table 1: Existing KIMs (to be revised)

Acronym	Focus of this Key Indicator Method (KIM)	Key Indicators to be considered in this KIM	Examples
KIM LHC	Manual Lifting, Holding and Carrying loads ≥ 3 kg	• Daily frequency • Effective load weight • Load handling conditions / location of the load • Body posture • Unfavourable working conditions • Work organisation / distribution of this exposure during the shift	Loading / unloading of bags, sorting packages, loading of equipment without lifting aids, picking
KIM PP	Manual Pushing and Pulling of loads with trucks and monorails	• Daily duration and distance • Load weight / transport device • Driveway conditions • Properties of transport device • Body posture • Unfavourable working conditions • Work organisation / distribution of this exposure during the shift	Postal service with cart, picking with containers, waste disposal
KIM MHO	Manual Handling Operations: Work tasks with uniform, repetitive motion and predominantly lower force expenses of the upper extremities during MHO	• Daily duration • Type, duration, and frequency of the executing force • Force transfer and gripping conditions • Hand-arm posture during manual work processes • Body posture • Unfavourable working conditions • Work organisation / distribution of this exposure during the shift	Assembly activities (e.g. installation of electrical appliances), sorting, cutting, cashiering, manually controlling, pipetting, microscopy, joining, turning, cutting, moving, wrapping

Table 2: New KIMs (to be developed)

Acronym	Focus of this Key Indicator Method (KIM)	Key Indicators to be considered in this KIM	Examples
KIM BF	Whole Body Forces with mostly stationary force application.	• Daily duration • Type, duration, and frequency of the executing force • Symmetry of the application of force • Body posture • Unfavourable working conditions • Work organisation / distribution of this exposure during the shift	Working with winches, work with levers, working with pneumatic hammers, working with chainsaws
KIM ABP	Awkward Body Postures including any strenuous postures, which are predestinated by the work process and are long lasting	• Duration and temporal distribution of different trunk postures • Duration and temporal distribution of sitting / walking / standing during the day • Duration and temporal distribution of hands above shoulder and far from body • Duration and temporal distribution of kneeling, squatting • Unfavourable working conditions	Steel fixing (concrete), manual welding, ceiling mounting, work at the microscope, working inside of tanks, microsurgery
KIM BM	Body Movements to a place of work or in a work area, which will be assessed independently of applying force	• Body movement and eventually carried load • Location of the load centre • Body movement when driving with transport device • Driveway conditions (if work task includes driving) • Unfavourable working conditions • Work organisation / distribution of this exposure during the shift	Climbing tower cranes, control inspections in channels, maintenance on furnaces
KIM ME	Mixed Exposures: combination of the exposures of a shift	• Covers the key indicators of the 6 KIMs mentioned above	Work places with different exposures during the shift

Standardised questionnaire for the assessment of health outcomes

The employees' questionnaire (conducted in interview) is divided into 4 parts:

1. Personal details including sociodemographic data (e.g. age, gender, years on the job, leisure time activities), general information about current and former occupational activities (e.g. type and amount of physical exposures, time pressure, shift work, working posture);
2. Subjective assessments of the exposure in the workplace (questionnaire of the subjective estimation of exposures – FEBA[21]);
3. Other psychosocial aspects (e.g. job satisfaction, social support, commitment; extract from the COpenhagen PSychOsocial Questionnaire - COPSOQ[22, 23]); and
4. Subjective perceived exertion of physical exposures (Borg RPE scale[24]).

Medical diagnostic tool for the assessment of health outcomes

The documentation of the medical interviews is based on the Standardised Nordic questionnaires for the analysis of musculoskeletal symptoms[25, 26]. To substantiate the statements of the employees about the musculoskeletal symptoms in the interviews, a physical examination is performed after the interview. To derive specific tentative medical diagnoses, a list of standard diagnoses of musculoskeletal disorders was considered. The medical diagnostic tool used in the present study was derived from a SALTSA study[27] and supplemented by a multi-stage diagnosis[28] and further examination techniques[29]. The diagnostic tool consists of a documentation sheet and a reference sheet. The documentation sheet is divided into three parts. Part A is a general survey to document painful or symptomatic body regions. Part B deals with specific examination techniques to be carried out if pain or symptoms in specific regions were documented in part A. According to these results and with assistance of a reference sheet, tentative diagnoses can be assigned using a list of diagnoses in part C.

These are:

Diseases of the upper extremities

- Cervical / cervicocephal syndrome
- Cervicobrachial syndrome
- Rotator cuff syndrome, adhesive capsulitis of shoulder
- Medial and lateral epicondylitis
- Flexor / extensor peritendinitis / tendosynovitis of forearm/wrist region
- Carpal tunnel syndrome
- Osteoarthritis of the joints of the distal upper extremities

Disorders of the lower back

- Low back pain / lumbago
- Lumbar facet syndrome – pseudo-radicular syndrome
- Lumbar radicular syndrome

Disease of the lower extremities

- Hip osteoarthritis
- Knee osteoarthritis (including chondromalacia patellae)
- Meniscus lesion
- Static insufficiency of foot
- Varicosis of the leg veins

Further relevant conditions not included in this list are also recorded.

Data Analysis Plan

Analysis of RG 1 (face validity)

For the determination of face validity, no statistic procedures are used. Face validity was derived from preliminary work and a feasibility study, which was done in preparation prior to the main study[30]. As mentioned above, the six KIMS were developed based on our own activities during the last decades including an extensive search of peer-reviewed scientific articles and other grey literature concerned with methods for the assessment of working conditions associated with physical exposures. In 2015, the feasibility of the six KIMs were field-tested among 114 workplaces in 40 different companies. At every workplace, the KIMs were completed and discussed with the respective occupational health and safety stakeholders in the companies, and developed further iteratively. Over-all, the KIM forms were completed 615 times during this process. According to these field-tests, the results seemed to be plausible to the stakeholders involved and all relevant aspects seemed to be implemented[28]. The results of this feasibility study were integrated in modified drafts of the KIMs which are basis for the scientific validation described in the following research goals and chapters.

Analysis of RG 2 (reliability)

It will be analysed, whether relevant deviations between different users assessing the same workplaces occur. The reliability will be determined by examining the independence of results assessed by different individuals (occupational health and safety stakeholders). Descriptive statistics (mean, median, variance, range) will be used to illustrate the distribution of different workplace assessments of the involved experts. Interrater-reliability for multiple raters will be analysed using standard video sequences of typical workplaces for risk assessment, and rating these videos by a group of selected experts under standardised conditions[31].

Analysis of RG 3 (convergent validity)

It will be analysed, whether relevant differences occur during assessment of workplaces with the KIMs and with other screening methods measuring the same type of physical exposure. Data basis for the determination of the convergent validity are descriptions of the 120 workplaces gathered in the cross-sectional study. During the selection of the workplaces to be included in the study, an equal distribution of the six types of physical exposures and the four exposure levels will be taken into account. It is assumed that an average of five work tasks can be analysed at any workplace. Thus, around 600 work task descriptions will be available, 100 descriptions per type of physical exposure. The KIM provides a score of 1 point to about 200 points (theoretically, point values > 1,000 are possible, however, these values are unlikely to appear under real conditions). If the respective comparison method also produces a score, correlation analyses will be performed[32]. The correlation coefficient and the mean value will be taken into account. If the comparison method does not produce a score (for example, differs only dichotomously between "green" and "red), Cohen's kappa[33] is calculated using the exposure levels of the KIMs. For the six types of physical exposures for the six KIMs, existing methods were selected for comparison which meet as many of the criteria as possible below:

- Description of quality criteria,
- Large degree of dissemination,
- Plausible and comprehensible model, and
- Pass ability with the concept presented here.

Analysis of RG 4 (criterion validity or content validity regarding hypotheses testing)

It will be analysed, whether employees at workplaces with high physical exposures show adverse health related outcomes (e.g. musculoskeletal symptoms) more frequently than non-exposed workers considering relevant confounders such as age, gender, constitution or disposition. It is assumed, that high scores derived in the assessment of workplaces with the KIMs are associated with a high frequency of musculoskeletal symptoms in exposed workers. Accordingly, low scores in the KIMs resulting at workplaces with low physical exposures are associated with a low frequency of musculoskeletal symptoms in workers. The considered (main) outcome region(s) for each type of physical exposure and each KIM vary. The approximate impact of physical exposures and outcomes is described schematically in Figure 2.

Effect estimates for dichotomous outcomes (prevalence of symptoms) are prevalence ratios with 95 % confidence intervals per type of physical exposure and exposure level, as determined by the KIMs. Effect estimates for continuous outcomes (perceived exertion, WAI) are beta-estimators (increment) with 95 % confidence intervals per type of physical exposure and exposure level, as determined by the KIMs. The lowest exposure level is regarded as the reference category (internal control group). The increments are estimated using linear regression models (IBM-SPSS-Statistics procedure Genlin) under consideration of confounders (at least: age, sex, BMI, and body height).

For each type of physical exposure (each KIM), the following models are calculated:

- Minimally adjusted models (age, gender),
- Moderately adjusted models (age, sex, BMI, body height and other types of physical exposures), and
- Maximally adjusted models (age, sex, BMI, body height, other types of physical exposures, other occupational exposures and other confounders).

Primarily, the moderately adjusted models wil be interpreted. As far as possible, based on the regression models, post hoc assessments of prevalences of the outcomes for each type of physical exposures will be conducted. Subjects are excluded from the analyses, if missing data in the different body region occur. Sensitivity analysis are intended regarding e.g. regional distribution of the workplaces, company characteristics (size, branche etc.) and gender.

Sample Size calculation

For power or sample size calculation the EpiManager-Software[34] and G*Power[35] were used.

Power for determination of reliability

For the determination of reliability (RG 2), 12 users of the KIMs are needed, to represent future potential users. From these 12 users six pairs will be formed, each observing 20 workplaces. This will result in 120 double ratings. As statistical measures, correlation coefficients are calculated and comparisons of mean values are carried out. The assessment of conformity is based on the following categories: values ≤ 0.3 = small; > 0.3 to < 0.5 = low; 0.5 to < 0.7 = good, ≥ 0.7 = high correlation.

In order to demonstrate a correlation (correlation coefficient, r) of 0.7 (alpha 0.05 and beta 0.8), about 15 double observations would be necessary. For a correlation of 0.8, 10 double observations would be necessary. The target of 20 double observations per type of physical exposure should ensure an adequate study power.

Power for determination of convergent validity

For the determination of convergent validity (RG 3) workplaces will be assessed by scientists experienced in ergonomics using the KIMs and further screening methods assessing the same type of physical exposures. A correlation coefficient between the KIM and an alternative screening method of r = 0.5 or higher is considered to be an adequate correlation[32]. To show that two methods correlate at least with an r of 0.5 or higher (H1: r > 0.5 vs. H0: r = 0), 56 records are required for each of the 6 KIMs. If only 30 records per process could be evaluated, it can be shown that the two methods correlate with an r of about 0.8 or higher (H1: r > 0.8 vs. H0: r = 0, alpha < 0.05, beta 0.8). If the comparison method does not produce a score but only categories, Cohen's kappa[33] is calculated. In this case, 100 data sets are needed to show statistically relevant correlations.

Power for determination of criterion validity

As described in RG 4, it is assumed, that employees at workplaces with high physical exposures show adverse health-related outcomes more frequently than non-exposed workers. The outcomes which will be considered in this study are (Table 3):

1) Prevalence of musculoskeletal symptoms (7-day and 12-month) in nine body regions (Figure 2),
2) Prevalence of tentative diagnoses, and
3) Perceived exertion (Borg RPE scale[24]).

Table 3: Expected outcomes according to exposure levels of the KIMs

Exposure levels of the KIMs	1) Prevalence of musculoskeletal symptoms	2) Prevalence of tentative diagnoses	3) Perceived exertion (Borg RPE scale)
Low	Reference group	Reference group	Very light
Slightly increased	7-day prevalence increased	12-month prevalence hardly increased	Light
Acceptance level			
Substantially increased	7-day prevalence significantly increased (at least double)	12-month prevalence slightly increased	Somewhat hard
Tolerance level			
High	7-day prevalence significantly increased (at least triple)	12-month prevalence substantially increased	Very hard

1) Power for the outcome "prevalence of musculoskeletal symptoms"

The minimum size of study population (at least 40 to 50 subjects per exposure level, targeted in "characteristics of the participants in the study") is based on the power calculation. The 7-day prevalence of MSDs among males and females without physical exposures (office workers) was assessed in preliminary studies[18]. The 7-day prevalence of MSDs for women was between 30 % (cervical spine) and 5 % (hip, ankles) and for men between 20 % (cervical spine) and 5 % (ankles) or 2 % (hip). The 12-month prevalence of MSDs in men and women without physical exposures was significantly higher, from 50 % to 65 % (cervical spine) to 10 % (hip, ankle). Assuming an alpha error of 5 % and a beta error of 80 %, in a group size of 40 persons exposed and 40 persons not exposed, and assuming a prevalence of 5 % in the reference group, a prevalence ratio of 6.5 is significantly increased. If the prevalence of MSDs in the reference group is 20 %, prevalence differences are detectable by a factor of 2.5. Prevalence differences of this amount between non-exposed (exposure level: low) and highly exposed employees (exposure level: high) were observed in the preliminary study mentioned above. It is therefore expected that variations in prevalence of factors of at least 2 to 6 will be detectable, when comparing the two highest exposure categories by KIM with the lowest exposure level (reference group).

2) Power for the outcome "prevalence of tentative diagnoses"

Due to the expected relatively low incidence of diagnoses in the working population, no statistically significant increase in the prevalence of tentative diagnoses is expected. However, an increasing trend with increasing physical exposure from exposure level "low" to exposure level "high" is expected.

3) Power for the outcome "perceived exertion (Borg RPE scale)"

The highest limitations in power calculation according to criterion variability result from dichotomous variables as described in the section above (power for the outcome "prevalence of musculoskeletal symptoms"). Therefore, the power of the study according to continuous variables (such as perceived exertion) is high due to the fact that 1,200 subjects will be included in this study. Considering the large number of subjects, small differences of continuous variables between risk category groups are detectable.

Quality control and assurance

The use of standardised and – if available and appropriate – already validated and/or evaluated screening methods as comparison or reference methods ensures high quality of work. All questionnaires will be completed during a face-to-face interview. The work-related physical examination will be performed by trained external physicians. A standardised procedure for physical examination is guaranteed by the specific standardised training of the physicians. Remembering earlier symptoms in a retrospective period could involve a recall bias. In order to minimize the bias and to get a more detailed overview, we ask for the past 7-days prevalence and the 12-month prevalence of symptoms. In addition, a physical examination is carried out. The observation of these three outcomes together might reduce the recall bias.

What this study adds

In this study, new KIMs for practical risk assessment of physical exposures are developed and these new KIMs, as well as the already existing KIMs, will be validated. The KIMs are a modular tool kit of practical screening methods for assessing the risk factors associated with work-related musculoskeletal disorders. In addition, the study will increase the knowledge concerning the correlation between specific MSDs and characteristics of physical exposures. With this knowledge, a better classification of occupational hazards with regard to MSDs will be available in future. This may lead to more specific prevention strategies.

ETHICS AND DISSEMINATION

Ethics approval and consent to participate

The study was planned and conducted in accordance with the German medical professional code and the Helsinki Declaration of 2013[36] as well as the German Federal Data Protection Act[37].

The design of the study was examined by the Ethics Committee of the Technical University Darmstadt. The protocol achieved a positive vote (approval no. EK15/2015 2015-09-22 as supplement to EK2/2013 2013-07-04) and the Ethics Committee of the Medical Faculty of the University of Tübingen (004/2016BO2). The study was started after the Ethics Committees gave their written and unrestricted approval.

Employees participate in the study voluntarily. They can end their participation at any time without reason and without negative consequences, e.g. for their job. Written informed consent for participation is obtained before the survey. Employees receive written and verbal information about the main features of the study as well as about potential benefits for their health and their contribution to the common public welfare. If they accept the conditions of the study and their participation, they document their consent with their signature. A copy of this statement is intended to be kept by the employee for later reference or cancellation of participation. All original documents are treated according to German Federal Data Protection Act. A comprehensive data protection concept was approved by the Data Protection Officer of the BAuA.

Timeframe of the study and dissemination of results

The study team started the planning of this project in 2012. The data collection for the cross-sectional study then started in spring of 2016 and will end in summer 2017. Description and analysis of the data will be done in 2017. It is intended to present the approved or revised KIMs to the public in 2018. Results will be published in peer-reviewed journals, presented at international meetings and disseminated to actual users for practical application. Potential users include occupational safety and health stakeholders and industrial engineers in companies, ergonomists, occupational health physicians, employers and employees associations, and insurance companies or research facilities.

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Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

All authors were involved in the conception and design of the study, and the preparation of this manuscript. US developed the first drafts of the KIMs and initiated this study. AK and FL concretised the salient content points of this protocol, such as selection of validation criteria and power calculation. AK had the lead management in preparation of the study protocol. US, AK, PS, HG, AS, BH, MS and FB form the development team of the new KIMs. All Authors were closely involved in the planning and development of the study design and preparing the study protocol. All authors read and approved the final manuscript.

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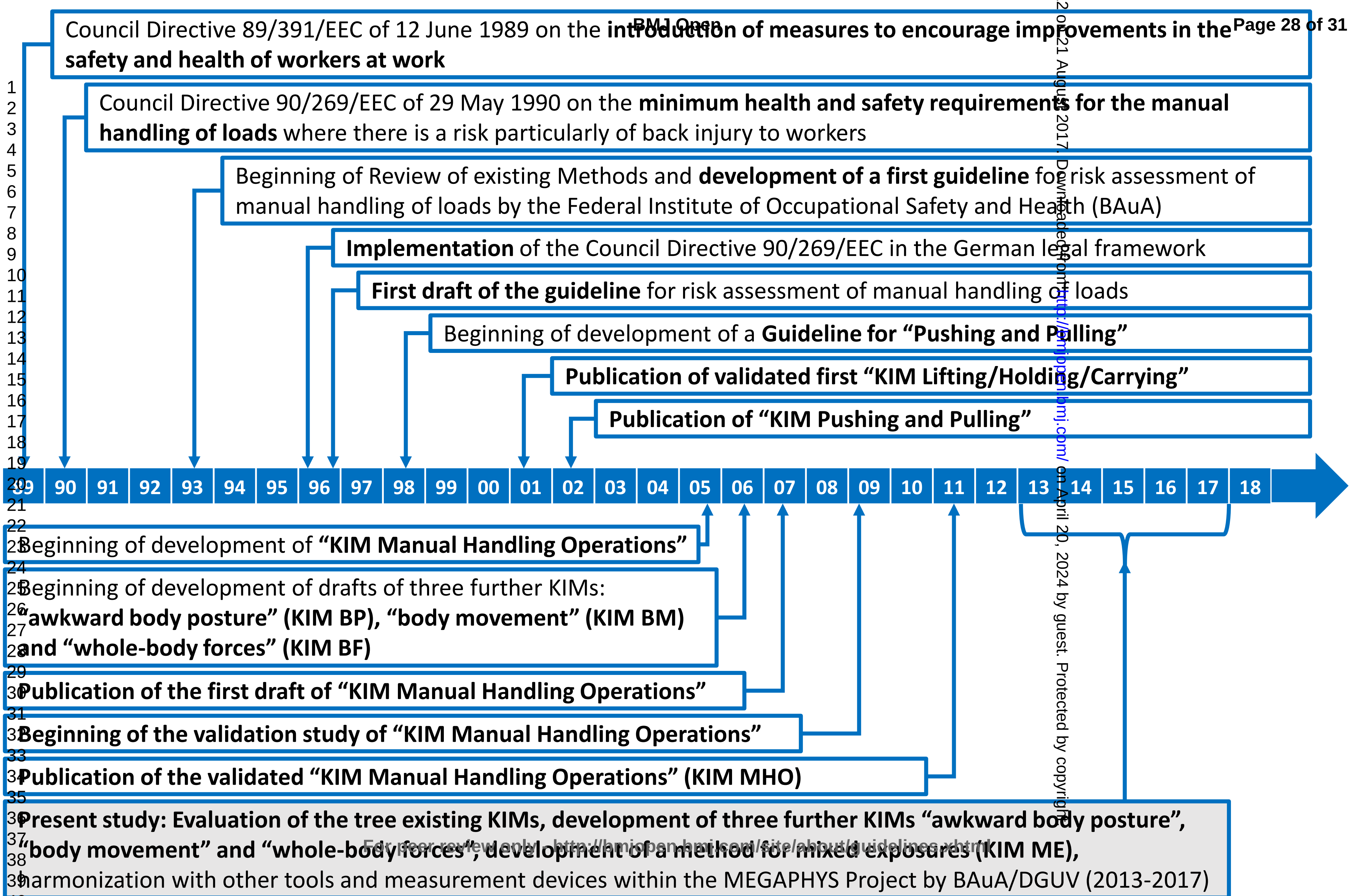
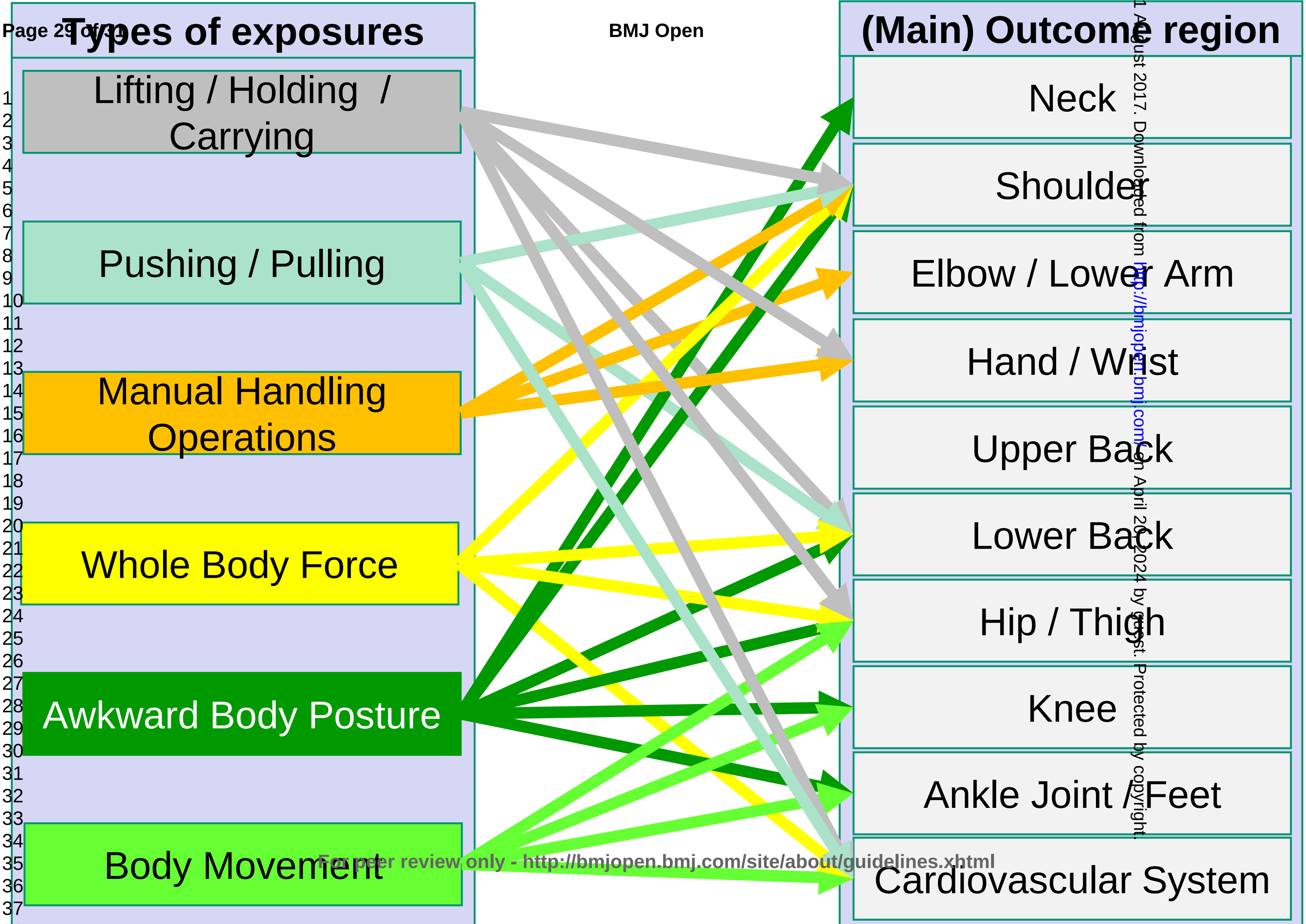
Figure 1: *Development of the Key Indicator Methods (KIMs) for the risk assessment of physical exposures since the year 1989. The horizontal arrow indicates the years of the development process.*

Figure 2: *Types of physical exposures and relation to the main outcome regions. For each type of physical exposure, one specific Key Indicator Method (KIM) is developed and validated*


Council Directive 89/391/EEC of 12 June 1989 on the **introduction of measures to encourage improvements in the safety and health of workers at work**
Council Directive 90/269/EEC of 29 May 1990 on the **minimum health and safety requirements for the manual handling of loads** where there is a risk particularly of back injury to workers
Beginning of Review of existing Methods and **development of a first guideline** for risk assessment of manual handling of loads by the Federal Institute of Occupational Safety and Health (BAuA)
Implementation of the Council Directive 90/269/EEC in the German legal framework
First draft of the guideline for risk assessment of manual handling of loads
Beginning of development of a **Guideline for "Pushing and Pulling"**
Publication of validated first "KIM Lifting/Holding/Carrying"
Publication of "KIM Pushing and Pulling"
89 90 91 92 93 94 95 96 97 98 99 00 01 02 03 04 05 06 07 08 09 10 11 12 13 14 15 16 17 18
Beginning of development of **"KIM Manual Handling Operations"**
Beginning of development of drafts of three further KIMs:
"awkward body posture" (KIM BP), "body movement" (KIM BM) and "whole-body forces" (KIM BF)
Publication of the first draft of "KIM Manual Handling Operations"
Beginning of the validation study of "KIM Manual Handling Operations"
Publication of the validated "KIM Manual Handling Operations" (KIM MHO)
Present study: Evaluation of the tree existing KIMs, development of three further KIMs "awkward body posture", "body movement" and "whole-body forces", development of a method for mixed exposures (KIM ME),
harmonization with other tools and measurement devices within the MEGAPHYS Project by BAuA/DGUV (2013-2017)


Types of exposures
Lifting / Holding / Carrying
Pushing / Pulling
Manual Handling Operations
Whole Body Force
Awkward Body Posture
Body Movement
(Main) Outcome region
Neck
Shoulder
Elbow / Lower Arm
Hand / Wrist
Upper Back
Lower Back
Hip / Thigh
Knee
Ankle Joint / Feet
Cardiovascular System

STROBE 2007 (v4) checklist of items to be included in reports of observational studies in epidemiology*
Checklist for cohort, case-control, and cross-sectional studies (combined)

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2-3
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4-6
Objectives	3	State specific objectives, including any pre-specified hypotheses	8
Methods			
Study design	4	Present key elements of study design early in the paper	6-7
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	6-8, 22-23
Participants	6	(*a*) ~~*Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up~~ ~~*Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls~~ *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	7
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	*9-15*
Bias	9	Describe any efforts to address potential sources of bias	21
Study size	10	Explain how the study size was arrived at	not applicable yet
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	15-21
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	15-21
		(*b*) Describe any methods used to examine subgroups and interactions	15-21
		(*c*) Explain how missing data were addressed	18
		(*d*) ~~*Cohort study*—If applicable, explain how loss to follow-up was addressed~~ ~~*Case-control study*—If applicable, explain how matching of cases and controls was addressed~~	not applicable

		Cross-sectional study—If applicable, describe analytical methods taking account of sampling strategy	
		(*e*) Describe any sensitivity analyses	not applicable yet
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	not applicable yet
		(b) Give reasons for non-participation at each stage	not applicable yet
		(c) Consider use of a flow diagram	not applicable yet
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	7
		(b) Indicate number of participants with missing data for each variable of interest	not applicable yet
		~~(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)~~	
Outcome data	15*	~~*Cohort study*—Report numbers of outcome events or summary measures over time~~	
		~~*Case-control study*—Report numbers in each exposure category, or summary measures of exposure~~	
		Cross-sectional study—Report numbers of outcome events or summary measures	15-21
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	not applicable yet
		(*b*) Report category boundaries when continuous variables were categorized	
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	
Discussion			not applicable yet
Key results	18	Summarise key results with reference to study objectives	
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	
Generalisability	21	Discuss the generalisability (external validity) of the study results	
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	24

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

BMJ Open

Validation of Newly Developed and Redesigned Key Indicator Methods (KIMs) for Assessment of Different Working Conditions with Physical Workloads based on Mixed Methods Design – A Study Protocol

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Manuscripts

Title page

Validation of Newly Developed and Redesigned Key Indicator Methods (KIMs) for Assessment of Different Working Conditions with Physical Workloads based on Mixed Methods Design – A Study Protocol

Authors

Andre Klussmann[1,4#✉], Falk Liebers[2#], Felix Brandstädt[2], Marianne Schust[2], Patrick Serafin[1], Andreas Schäfer[1], Hansjürgen Gebhardt[1], Bernd Hartmann[3], Ulf Steinberg[2]

Address

[1] Institute of Occupational Health, Safety and Ergonomics (ASER), Corneliusstr. 31, 42329 Wuppertal, Germany.

[2] Federal Institute for Occupational Safety and Health (BAuA), Nöldnerstr. 40-42, 10317 Berlin, Germany.

[3] ArbMedErgo Consultant, Steinbeker Grenzdamm 30d, 22115 Hamburg, Germany

[4] University of Wuppertal, School of Mechanical Engineering and Safety Engineering, Chair of Human Engineering, Gaussstr. 20, 42119 Wuppertal, Germany

# These authors contributed equally to this work ✉ Corresponding author

✉ Corresponding author

Andre Klussmann, Jun.-Prof. Dr.-Ing., M.Sc., Eur.Erg.

Institute of Occupational Health, Safety and Ergonomics (ASER), Corneliusstrasse 31, 42329 Wuppertal, Germany

Phone: +49 202 731000; Fax: +49 202 731184; Email: klussmann@institut-aser.de

Email

Andre Klussmann✉ – klussmann@institut-aser.de; Falk Liebers – liebers.falk@baua.bund.de; Felix Brandstädt – brandstaedt.felix@baua.bund.de; Marianne Schust – schust.marianne@baua.bund.de; Patrick Serafin – serafin@institut-aser.de; Andreas Schäfer – schaefer@institut-aser.de; Hansjürgen Gebhardt – gebhardt@institut-aser.de; Bernd Hartmann – HartmannBernd_Hamburg@web.de; Ulf Steinberg – ulf.steinberg@berlin.de

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Abstract

Introduction:

The impact of work-related musculoskeletal disorders (WRMSDs) is considerable. The assessment of work tasks with physical workloads is crucial to estimate the work-related health risks of exposed employees. Three Key Indicator Methods (KIMs) are available for risk assessment regarding manual lifting, holding and carrying of loads (LHC), manual pulling and pushing of loads (PP) and manual handling operations (MHO). Three further KIMs for risk assessment regarding whole-body forces (BF), awkward body postures (ABP), and body movement (BM) have been developed de novo. In addition, the development of a newly drafted combined method for mixed exposures (ME) is planned. All methods will be validated regarding face validity, reliability, convergent validity, criterion validity and further aspects of utility under practical conditions.

Methods and analysis:

As part of the joint project MEGAPHYS (Multilevel risk assessment of physical workloads), a mixed-methods study is being designed for the validation of KIMs and conducted in companies of different sizes and branches in Germany. Workplaces are documented and analysed by observations, applying KIMs, interviews and assessment of environmental conditions. Furthermore, a survey among the employees at the respective workplaces takes place with standardised questionnaires, interviews and physical examinations. It is intended to include 1,200 employees at 120 different workplaces. For analysis of the quality criteria, recommendations of the COSMIN checklist (COnsensus-based Standards for the selection of health Measurement INstruments) will be taken into account.

Ethics and dissemination:

The study was planned and conducted in accordance with the German Medical Professional Code and the Helsinki Declaration as well as the German Federal Data Protection Act. The design of the study was approved by Ethics Committees. We intend to publish the validated KIMs in 2018. Results will be

published in peer-reviewed journals, presented at international meetings and disseminated to actual users for practical application.

Keywords

Risk assessment, Key Indicator Method, Work-related musculoskeletal disorders, OCRA, NIOSH Lifting Equation, Strain Index

Strengths and limitations of this study

- This research project will provide a scientific substantiation and – if necessary according to the results of the study – modification of standardised methods to assess physical workloads at a screening level.
- With the help of these KIMs, the full range of physical workloads (excluding exposures due to hand-transmitted and whole-body vibration) could be assessed by occupational health and safety stakeholders.
- Knowledge about the correlation between work-related factors and MSDs will be advanced.
- The study is limited by the cross-sectional design, which is not suitable to assess the causal relationship between variables but only associations.

Main text

INTRODUCTION

General background

Work-related musculoskeletal disorders (WRMSDs) have been recognised for many decades[1, 2]. Disorders often mentioned in the literature include low back pain and intervertebral disc diseases[3], epicondylitis[4] and carpal tunnel syndrome[5]. Hard physical work may also lead to high cardiovascular strain and may increase the mortality risk of ischaemic heart disease in individuals with a low or moderate fitness level[6].

According to the European Council Directive 89 / 391 / EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work, the employer must perform an assessment of the risks to safety and health at work, including those to which specific groups of workers are exposed[7]. One year later, a further European Council Directive 90 / 269 / EEC “manual handling of loads” of 29 May 1990 was published addressing the minimum health and safety requirements for the manual handling of loads where there is a risk particularly of back injury to workers[8]. To assess the risk of WRMSDs, a number of assessment methods have been developed[9].

The risk assessment of physical workloads is a basic necessity to derive purposeful prevention measures. Beside the legal requirements mentioned above, ergonomic interventions usually have financial merits. Within a systematic review, from a company perspective strong evidence was found in support of the financial merits of ergonomic interventions in the manufacturing and warehousing sector, moderate evidence in the administrative support and health care sectors, and limited evidence in the transportation sector [10].

Previous development and validation of the KIMs

In Germany, the release of the two European Council Directives triggered the development of “Key Indicator Methods” (KIMs), see Figure 1. The KIMs were developed for risk assessment at the screening level in the case of physical workloads. Potential users include occupational safety and health stakeholders and industrial engineers in companies as well as ergonomists, occupational health physicians, employers and employees associations, and insurance companies or research facilities. Three different KIM worksheets, one for Lifting, Holding, Carrying loads (KIM-LHC), one for Pulling and Pushing loads (KIM-PP) and one for Manual Handling Operations (KIM-MHO), are available so far. These methods were developed by the Federal Institute for Occupational Safety and Health (BAuA) in close collaboration with practitioners, safety representatives, occupational health physicians, and the "Länderausschuss für Arbeitsschutz und Sicherheitstechnik" (Federal Committee of the States for Occupational Safety and Health)[11, 12, 13]. Briefly, work characteristics such as force, frequency and duration, and general working conditions are assessed by means of the KIM, and a score is calculated to summarise the work-associated risk for adverse health outcomes, e.g. musculoskeletal symptoms. To illustrate the result, the score is transformed into a traffic light scale indicating a low exposure situation where physical overload is unlikely to occur (= green), situations with slightly increased (= greenish yellow) and substantially increased (= yellow) exposure, up to a high exposure situation where physical overload is likely to occur and a redesign of the workplace is probably necessary (= red)[14]. The current existing methods can be downloaded from the homepage of BAuA[15]. The three existing KIMs deal with manual handling of loads and repetitive manual handling operations. Further aspects of physical workloads, such as awkward body posture, whole-body forces and body movement have not or not sufficiently been included in this method inventory yet. In order to fill this gap, drafts of three supplemental methods were developed. Further developments are necessary and a revision of the three existing methods is required, so that all six methods are compatible. In addition, the development of a method for the assessment of mixed physical workloads is planned.

Preliminary work – development of new KIM drafts

The preliminary work during the last decades mentioned above (see Figure 1), was complemented by an additional search of peer-reviewed articles and grey literature predominantly in German and English. Various other methods for the assessment of working conditions associated with physical workloads were analysed systematically. The various methods included on the one hand a large number of work characteristics considered to be related to health outcomes, and on the other hand a large number of different body regions, symptoms and diseases which could be affected by these work characteristics. There is only low evidence of a "cause and effect model" or even a "dose response relationship" with certainty between most physical workloads and MSDs. In the published studies or methods, the selection of the observed characteristics varied significantly. Unfortunately, details about the selection of the parameters were often not indicated in the publications available and many questions remain, e.g. questions about the deduction or the combination of the parameters to be assessed for description of work-related risks. In addition, only a small number of methods assessing biomechanical exposures in occupational settings have been tested in a systematic manner for validity, reliability, or other aspects related to their practical use[9].

The development of the new KIM-drafts was based on a comprehensive and critical literature review of the methods mentioned above. This knowledge was combined with interviews about typical kinds of exposures and exposure-structures of physical workloads, involving scientists, supervisors of state agencies and professional associations, occupational physicians, occupational health and safety officers, and managers from companies in various industries.. Finally, the drafts of three new KIMs (whole body forces, awkward postures, and body movement) were available for validation within the present study.

METHODS AND ANALYSIS

Aim, design and setting

In this study protocol, the concept for development and validation of the newly developed and redesigned KIMs is presented. It is part of a joint project

(MEGAPHYS – Mehrstufige Gefährdungsanalyse physischer Belastungen am Arbeitsplatz [Multilevel risk assessment of physical workloads]). The distribution of the responsibility for the recruitment and documentation of the workplaces and the realisation of the interviews of further partners in the joint project are described in the “Funding” and “Acknowledgements” sections. General aims, definition of the six types of physical workloads used and the background of the joint project MEGAPHYS have been described previously[16].

The aim of the study protocol presented here is to provide the concept of how to validate the revised versions of the three existing KIMs (KIM LHC, KIM PP, KIM MHO) and the draft versions of the three new KIMs for whole body forces, awkward postures, and body movement (KIM ABP, KIM BF, KIM BM) in order to provide validated risk assessment methods for these six types of physical workloads. Furthermore, a draft of an additional KIM for the assessment of mixed physical workloads, including relevant indicators of the six specific KIMs, is also planned (see Tables 1 and 2). The “combined KIM” will be developed during the study based on the Key Indicators of the six KIMs. Different mathematical models will be tested and enhanced iteratively. Since this method is not fixed at the beginning of the validation study, we will only be able to disseminate a draft of a combined method and not a fully validated method at the end of this project.

A number of methods for the risk assessment of physical workload already exist[9]. These methods are of very different extents and qualities, from simple checklists to comprehensive methods with extensive testing of different quality criteria (e.g. tested in several cross-sectional studies and longitudinal studies). A disadvantage of these methods is that they are often only "single solutions". That means, they focus on one type of physical workload (e.g. load handling) and the different methods have different risk scales. If someone wants to assess several different types of physical workload at a workplace, he or she must use different methods and obtain different results (e.g. a risk index at NIOSH Lifting Equation[17], or risk categories at Rapid Entire Body Assessment – REBA[18]). The reason for this project is to have one system with a uniform risk concept and cover all the main types of physical workloads. The division into the six different types of physical workloads presented here has mainly pragmatic reasons: These are distinguishable types of physical workloads which can be identified and assessed by the practical user.

The main objective to be considered is the association between physical workloads, as assessed by means of the scores of the KIMs, and the frequency of musculoskeletal symptoms and other outcomes within the exposed workers in terms of discriminative capacity of the six KIMs or the newly drafted combined KIM.

The validation of KIM uses a cross-sectional design and a mixed-method approach. For the determination of criterion validity, a cross-sectional study among 1,200 employees at approx. 120 different workplaces will be carried out. Workplace analyses will be done by direct observations and assessments using the KIMs, interviews of employees and managers, workplace measurements (e.g. noise, climate) and video recordings. Exposures are analysed and documented by members of the study team. The workplace analyses will also be used for the determination of face validity, reliability, convergent validity, criterion validity and further aspects of utility.

Setting of the study will be workplaces in voluntarily participating companies of different sizes and branches (including e.g. industry, handicraft, health care) in Germany.

Characteristics of participants

For the analysis of criterion validity, male and female employees, 19 to 65 years of age, at workplaces with different types and levels of physical workloads will be recruited, who have worked at the workplaces considered for at least three months and are proficient in the German language. For each type of physical workload (total of six types: LHC, PP, MHO, BF, ABP, BM) and for each of four exposure levels as rated by experts beforehand (low, slightly increased, substantially increased, and high), approximately 40 to 50 employees will be recruited (assuming predominantly uniform exposures in each group). The aim is to cover all employees of the selected workplaces. Employees participate in the study voluntarily. The employer makes participation in the study possible for the employees within the working time.

Only if more than 20 volunteers are engaged in the same workplace, the participants will be selected randomly. The study population can be calculated as follows: 6 types of physical workloads x 4 exposure levels x 50 subjects per type of physical workload and exposure level = 1,200 subjects. Assuming, that at each workplace an average of 10 employees can be recruited, 120 workplaces need to be observed and documented. It is intended to analyse about 5 workplaces per type of physical workload and exposure level. Approximately 10 employees per workplace will be interviewed by ergonomists, and interviewed and examined by physicians.

The data gathered during observation and documentation of the 120 workplaces will also be used for the determination of convergent validity, reliability and further aspects of utility. For the determination of interrater-reliability, 12 users of the KIMs are needed, to represent future users. Typical users of these kinds of assessment methods ideally are occupational health and safety stakeholders or industrial engineers in the companies. From these 12 users, six pairs will be formed (one pair per type of physical workload), each observing 20 workplaces. This will result in 120 double ratings. No specific skills will be required for this tests, but the users will get a standardised introduction in the methods. The content of this introduction will be used later as framework for a guideline which will be disseminated with the method.

Working hypotheses

The working hypotheses (WH) include the examination of different quality criteria of the KIMs:

- WH 1: The KIMs are an adequate reflection of the construct to be measured (face validity).
- WH 2: At the completion of the KIMs, no relevant deviations occur between different users assessing the same workplaces (reliability).
- WH 3: Assessing workplaces using the KIMs and other screening methods measuring the same type of physical workload will result in no relevant differences (convergent validity).

- WH 4: It is assumed, that employees at workplaces with high physical workloads show adverse health-related outcomes (e.g. musculoskeletal symptoms) more frequently than non-exposed workers. It is assumed, that high risk scores derived in the assessment of workplaces with the KIMs are associated with a high prevalence of musculoskeletal symptoms and disorders (criterion validity or content validity regarding hypotheses testing).

The selection of the quality criteria described in the working hypotheses are derived from a systematic evaluation of observational methods assessing biomechanical exposures at work[9]. For the analysis of the quality criteria, the recommendations of the COSMIN checklist (COnsensus-based Standards for the selection of health Measurement INstruments) will be taken into account[19]. The reporting of the results of this observational study will also consider the recommendations of STROBE (Strengthening The Reporting of OBservational studies in Epidemiology)[20].

Instruments and Methods

The instruments and methods for the assessment of exposures and outcomes (i.e. questionnaire, medical diagnostic tool, assessment of working conditions) used in this survey have been used in a similar form in other studies by several authors. The authors of the present study used them for the assessment of musculoskeletal symptoms in office workers[21] and in a former validation study of the KIM MHO[22, 23].

1) Assessment of exposures:

- Ergonomic work procedure analysis and assessment of technical procedures for the documentation of working conditions.

2) Application of the KIMs:

- Application of the six KIMs based on the exposure assessment.

3) Assessment of health outcomes:

- Standardised questionnaire for a survey among the employees.
- Medical diagnostic tool for the physical examination of the employees.

Ergonomic work procedure analysis for the assessment of exposures

The basis for the evaluation of the workplaces is an ergonomic work procedure analysis with detailed assessment of exposures during the shift. An a priori defined set of items of a complex workplace analysis was developed. Results are recorded in a large modular document for a detailed description of the work tasks and the workplace. A workplace typically consists of a number of different work tasks. Duration and frequency of all work tasks are documented in a way that the KIMs, as well as further screening methods chosen for the testing of convergent validity, can be completed. The ergonomic work procedure analysis covers in principle all relevant objective characteristics that result from the type of work and the working conditions. Individual characteristics during work execution, random disruption of the workflow or unusual conditions will not be considered. Principal components of the work procedure analysis are:

1) Metadata of the workplace, such as: name and type of activity, precise list of work tasks, professional qualification requirements, position of employees, complexity of the activity, number of employees at the workplace, gender and age distribution, shift system, typical working time, predetermination of the work task;
2) Number and type of work task and for every work task detailed information, for example: about temporal distribution of this work task during the shift, determination of type of work (e.g. load handling, applying force, body posture, joint positions); and
3) Basic description of other relevant exposures, such as: noise level, lighting, vibration, hazardous materials.

Application of the Key Indicator Methods (KIMs)

The application and validation of the KIMs are the central goals of this research project and will be completed based on the ergonomic work procedure analysis. The KIMs contain an objective requirement and description of exposures and identify potential threats to physical overload. The KIMs include job characteristics and their interaction. The key indicators are classified in different scales. The scales correspond to conditions in practice and range from a minimum to maximum, or optimum to poor. The classification of these scales indicates bottlenecks for each category and key indicator. By multiplying the scale value of the daily duration and frequency of activity with the sum of the other scale scores, a total value can be calculated. This calculated sum score can be allocated to an exposure level and one of four risk categories, an approach already used in existing KIMs[14]. The four risk categories reflect the increase in the probability of physical overload and correspondingly the increase in frequency of adverse health effects related to the given physical workload from low (reference group) to high load situations (see above, section "Previous development and validation of the KIMs").

An overview of the KIMs, including a brief description of the types of physical workloads, the key indicators considered and some examples of typical work tasks is provided for the already exisiting KIMs in Table 1 and for the KIMs under development in Table 2. The revisions of the already existing KIMs include small changes (e.g. wording) to harmonise the six KIMs and major changes, such as the modification of the time rating and the implementation of new aspects (e.g. load handling conditions and location of the load during LHC).

Table 1: Existing KIMs (to be revised)

Acronym	Focus of this Key Indicator Method (KIM)	Key Indicators to be considered in this KIM in the revised version	Examples
KIM LHC	Manual Lifting, Holding and Carrying loads ≥ 3 kg	• Daily frequency • Effective load weight* • Load handling conditions / location of the load** • Body posture • Unfavourable working conditions* • Work organisation / distribution of this type of physical workload during the shift**	Loading / unloading of bags, sorting packages, loading of equipment without lifting aids, picking
KIM PP	Manual Pushing and Pulling of loads with trucks and monorails	• Daily duration and distance* • Load weight / transport device* • Driveway conditions** • Properties of transport device** • Body posture • Unfavourable working conditions • Work organisation / distribution of this type of physical workload during the shift*	Postal service with cart, picking with containers, waste disposal
KIM MHO	Manual Handling Operations: Work tasks with uniform, repetitive motion and predominantly lower force expenses of the upper extremities during MHO	• Daily duration* • Type, duration, and frequency of the executing force* • Force transfer and gripping conditions • Hand-arm posture during manual work processes • Body posture • Unfavourable working conditions • Work organisation / distribution of this type of physical workload during the shift	Assembly activities (e.g. installation of electrical appliances), sorting, cutting, cashiering, manually controlling, pipetting, microscopy, joining, turning, cutting, moving, wrapping

* Compared to the existing KIM, this Key Indicator is modified considerably in the revised version
** Compared to the existing KIM, this Key Indicator is added in the revised version

Table 2: New KIMs (to be developed)

Acronym	Focus of this Key Indicator Method (KIM)	Key Indicators to be considered in this KIM	Examples
KIM BF	Whole Body Forces with mostly stationary force application.	• Daily duration • Type, duration, and frequency of the executing force • Symmetry of the application of force • Body posture • Unfavourable working conditions • Work organisation / distribution of this type of physical workload during the shift	Working with winches, work with levers, working with pneumatic hammers, working with chainsaws
KIM ABP	Awkward Body Postures including any strenuous postures, which are predestinated by the work process and are long lasting	• Duration and temporal distribution of different trunk postures • Duration and temporal distribution of sitting / walking / standing during the day • Duration and temporal distribution of hands above shoulder and far from body • Duration and temporal distribution of kneeling, squatting • Unfavourable working conditions	Steel fixing (concrete), manual welding, ceiling mounting, work at the microscope, working inside of tanks, microsurgery
KIM BM	Body Movements to a place of work or in a work area, which will be assessed independently of applying force	• Body movement and eventually carried load • Location of the load centre • Body movement when driving with transport device • Driveway conditions (if work task includes driving) • Unfavourable working conditions • Work organisation / distribution of this type of physical workload during the shift	Climbing tower cranes, control inspections in channels, maintenance on furnaces
KIM ME	Mixed Exposures: combination of the exposures of a shift	• Covers the key indicators of the 6 KIMs mentioned above	Work places with different exposures during the shift

Standardised questionnaire for the assessment of health outcomes

The employees' questionnaire (conducted in interview) is divided into 4 parts:

1. Personal details including sociodemographic data (e.g. age, gender, years on the job, leisure time activities), general information about current and former occupational activities (e.g. type and amount of physical workload, time pressure, shift work, working posture);
2. Subjective assessments of the exposure in the workplace (questionnaire of the subjective estimation of exposures – FEBA[24]);
3. Other psychosocial aspects (e.g. job satisfaction, social support, commitment; extract from the COpenhagen PSychOsocial Questionnaire - COPSOQ[25, 26]); and
4. Subjective perceived exertion of physical workload (Borg RPE scale[27]).

Medical diagnostic tool for the assessment of health outcomes

The documentation of the medical interviews is based on the Standardised Nordic questionnaires for the analysis of musculoskeletal symptoms[28, 29]. To substantiate the statements of the employees about the musculoskeletal symptoms in the interviews, a physical examination is performed after the interview. In order to derive specific tentative medical diagnoses, a list of standard diagnoses of musculoskeletal disorders is considered. The medical diagnostic tool used in the present study was derived from a SALTSA study[30] and supplemented by a multi-stage diagnosis[31] and further examination techniques[32]. The diagnostic tool consists of a documentation sheet and a reference sheet. The documentation sheet is divided into three parts. Part A is a general survey to document painful or symptomatic body regions. Part B deals with specific examination techniques to be carried out if pain or symptoms in specific regions were documented in part A. According to these results and with assistance of a reference sheet, tentative diagnoses can be assigned using a list of diagnoses in part C.

These are:

Diseases of the upper extremities

- Cervical / cervicocephal syndrome
- Cervicobrachial syndrome
- Rotator cuff syndrome, adhesive capsulitis of shoulder
- Medial and lateral epicondylitis
- Flexor / extensor peritendinitis / tendosynovitis of forearm/wrist region
- Carpal tunnel syndrome
- Osteoarthritis of the joints of the distal upper extremities

Disorders of the lower back

- Low back pain / lumbago
- Lumbar facet syndrome – pseudo-radicular syndrome
- Lumbar radicular syndrome

Disease of the lower extremities

- Hip osteoarthritis
- Knee osteoarthritis (including chondromalacia patellae)
- Meniscus lesion
- Static insufficiency of foot
- Varicosis of the leg veins

Further relevant conditions not included in this list are also recorded.

Data Analysis Plan

Analysis of WH 1 (face validity)

Face validity was derived from preliminary work and a feasibility study, which was done in preparation prior to the main study[33]. For the determination of face validity, no statistic procedures are used. As mentioned above, the six KIMs were developed based on our own experiences and research during the last decades, including an extensive search of peer-reviewed scientific articles and other grey literature concerned with methods for the assessment of working conditions associated with physical workloads. In 2015, the feasibility of the six KIMs were field-tested at 114 workplaces in 40 different companies. At each workplace, the KIMs were completed and discussed with the respective occupational health and safety stakeholders in the companies, and developed further iteratively. Over-all, the KIM forms were completed 615 times during this process. According to these field-tests, the results seemed to be plausible to the stakeholders involved and all relevant aspects seemed to be implemented[33]. The results of this feasibility study were integrated in modified drafts of the KIMs which are basis for the scientific validation described in the following research goals and chapters.

Analysis of WH 2 (reliability)

It will be analysed, whether relevant deviations between different users assessing the same workplaces occur. The reliability will be determined by examining the independence of results assessed by different individuals (occupational health and safety stakeholders). Descriptive statistics (mean, median, variance, range) will be used to illustrate the distribution of different workplace assessments of the involved experts. Interrater-reliability for multiple raters will be analysed using standard video sequences of typical workplaces for risk assessment, and rating these videos by a group of selected experts under standardised conditions[34].

Analysis of WH 3 (convergent validity)

It will be analysed, whether relevant differences occur during assessment of workplaces with the KIMs and with other screening methods measuring the same type of physical workload. Data basis for the determination of the convergent validity are descriptions of the 120 workplaces gathered in the cross-sectional study. During the selection of the workplaces to be included in the study, an equal distribution of the six types of physical workloads and the four exposure levels will be taken into account. It is assumed that an average of five work tasks can be analysed at any workplace. Thus, around 600 work task descriptions will be available, 100 descriptions per type of physical workload. Each KIM provides a score of 1 point to about 200 points (theoretically, point values > 1,000 are possible, however, these values are unlikely to appear under real conditions). If the respective comparison method also produces a score, correlation analyses will be performed[35]. The correlation coefficient and the mean value will be taken into account. If the comparison method does not produce a score (for example, differs only dichotomously between "green" and "red), Cohen's kappa[36] is calculated using the exposure levels of the KIMs. For the six KIMs expressing six types of physical workloads, other existing methods were selected for comparison which meet as many of the criteria as possible below:

- Description of quality criteria,
- Large degree of dissemination,
- Plausible and comprehensible model, and
- Matching ability with the concept presented here.

At the time of the adoption of this study protocol, among others the following methods are suggested for the examination of convergent validity: Rapid Entire Body Assessment – REBA[18], Assessment technique for postural loading on the upper body – LUBA[37], Assessment of Exposure to Occupational Repetitive Actions of the Upper Limbs – OCRA[38], Threshold Limit Value for Mono-Tasks Handwork Hand Activity Level – HAL[39], Strain-Index[40], NIOSH Lifting Equation[17], Group-Evaluation-Tables[41], Garg-Procedure[42], Procedure for the assessment of workloads – BAB[43] and the former versions of the KIMs[11,12,13], as these fit more or less with one or more of the six types of physical workload (LHC, PP, MHO, BF, ABP or BM) and therefore to one or more of the six newly developed and redesigned KIMs.

Analysis of WH 4 (criterion validity or content validity regarding hypotheses testing)

It will be analysed, whether employees at workplaces with high physical workloads show adverse health-related outcomes (e.g. musculoskeletal symptoms) more frequently than non-exposed workers considering relevant confounders such as age, gender, constitution or disposition. It is assumed, that high scores derived in the assessment of workplaces with the KIMs are associated with a high frequency of musculoskeletal symptoms in exposed workers. Accordingly, low scores in the KIMs resulting at workplaces with low physical workloads are associated with a low frequency of musculoskeletal symptoms in workers. For each type of physical workload and each KIM the (main) outcome region(s) considered vary. The approximate impact of physical workloads and outcomes is described schematically in Figure 2.

Effect estimates for dichotomous outcomes (prevalence of symptoms) are prevalence ratios with 95 % confidence intervals per type of physical workload and exposure level, as determined by the KIMs. Effect estimates for continuous outcomes (e.g perceived exertion) are beta-estimators (increment) with 95 % confidence intervals per type of physical workload and exposure level, as determined by the KIMs. The lowest exposure level is regarded as the reference category (internal control group). The increments are estimated using linear regression models (IBM-SPSS-Statistics procedure Genlin) under consideration of confounders (at least: age, sex, BMI, and body height). For each type of physical workload (each KIM), the following models are calculated:

- Minimally adjusted models (age, gender),
- Moderately adjusted models (age, sex, BMI, body height and other types of physical exposures), and
- Maximally adjusted models (age, sex, BMI, body height, other types of physical workloads, other occupational exposures and other confounders, see Table 3).

Primarily, the moderately adjusted models wil be interpreted. As far as possible, based on the regression models, post hoc assessments of prevalences of the outcomes for each type of physical workload will be conducted. Subjects are excluded from the analyses, if missing data in the different body regions occur. Sensitivity analyses are intended regarding regional distribution of the workplaces, company characteristics (size, branche etc.) and gender. For an overview of the outcomes, exposures, predictors and potential confounders, see Table 3. The analysis of effect modifiers is not included in this study.

Table 3: Description of outcomes, exposures, predictors and potential confounders

Outcomes	Exposures	Predictors	Potential confounders
1) Prevalence of musculoskeletal symptoms (7-day and 12-month prevalence) in the following body regions: • Neck • Shoulder • Elbow / Lower arm • Hand / Wrist • Upper Back • Lower Back • Hip / Thigh • Knee • Ankle joint / Feet 2) Tentative medical diagnoses 3) Exposure reaction of the cardiovascular system described by perceived exertion (Borg RPE scale)	Six types of physical workload: • Manual lifting, holding and carrying of loads (LHC) • Manual pulling and pushing of loads (PP) • Manual handling operations (MHO) • Whole body forces (BF) • Awkward body postures (ABP) • Body movement (BM)	Predictors are the exposure levels of the KIMs: • Level 1 (reference category): low exposure, physical overload is unlikely to occur • Level 2: slightly increased exposure, physical overload possible for particular groups of employees • Level 3: substantially increased exposure, physical overload possible • Level 4: high exposure, physical overload is likely to occur	• Sex (split variable) • Age • Body-Mass-Index (BMI) • Body height • Other types of physical workload* • Other occupational exposures (e.g. noise, vibrations) • Job satisfaction • Quantitative demands • Cognitive demands • Workplace insecurity • Influence at work • Social support • Social relations
* If e.g. tested for the exposure LHC, the other exposures, which might occur during the shift (PP, MHO, BF, ABP, BM) are considered as confounders. For a rough overview, see Figure 2.			

Sample Size calculation

For power or sample size calculation the EpiManager-Software[44] and G*Power[45] were used.

Power for determination of reliability

For the determination of reliability (WH 2), 12 users of the KIMs are needed, in order to represent future potential users. From these 12 users six pairs will be formed, each observing 20 workplaces. This will result in 120 double ratings. As statistical measures, correlation coefficients are calculated and comparisons of mean values are carried out. The assessment of conformity is based on the following categories: values ≤ 0.3 = small; > 0.3 to < 0.5 = low; 0.5 to < 0.7 = good; ≥ 0.7 = high correlation.

In order to demonstrate a correlation (correlation coefficient, r) of 0.7 (alpha 0.05 and beta 0.8), about 15 double observations would be necessary. For a correlation of 0.8, 10 double observations would be necessary. The target of 20 double observations per type of physical workload should ensure an adequate study power.

Power for determination of convergent validity

For the determination of convergent validity (WH 3) workplaces will be assessed by scientists experienced in ergonomics using the KIMs and further screening methods assessing the same type of physical workload. A correlation coefficient between the KIM and an alternative screening method of r = 0.5 or higher is considered to be an adequate correlation[35]. To show that two methods correlate at least with an r of 0.5 or higher (H1: r > 0.5 vs. H0: r = 0), 56 sets of recorded data are required for each of the six KIMs. If only 30 sets of recorded data per process could be evaluated, it can be shown that the two methods correlate with an r of about 0.8 or higher (H1: r > 0.8 vs. H0: r = 0, alpha < 0.05, beta 0.8). If the comparison method does not produce a score but only categories, Cohen's kappa[36] is calculated. In this case, 100 data sets are needed to show statistically relevant correlations.

Power for determination of criterion validity

As described in WH 4, it is assumed, that employees at workplaces with high physical workloads show adverse health-related outcomes more frequently than non-exposed workers. The outcomes to be considered in this study are (Table 4):

1) Prevalence of musculoskeletal symptoms (7-day and 12-month) in nine body regions (Figure 2),
2) Prevalence of tentative diagnoses, and
3) Perceived exertion (Borg RPE scale[27]).

Table 4: Expected outcomes according to exposure levels of the KIMs

Exposure levels of the KIMs	1) Prevalence of musculoskeletal symptoms	2) Prevalence of tentative diagnoses	3) Perceived exertion (Borg RPE scale)
Low	Reference group	Reference group	Very light
Slightly increased	7-day prevalence increased	12-month prevalence hardly increased	Light
Acceptance level			
Substantially increased	7-day prevalence significantly increased (at least double)	12-month prevalence slightly increased	Somewhat hard
Tolerance level			
High	7-day prevalence significantly increased (at least triple)	12-month prevalence substantially increased	Very hard

1) Power for the outcome "prevalence of musculoskeletal symptoms"

The minimum size of study population (at least 40 to 50 subjects per exposure level, targeted in "characteristics of the participants in the study") is based on the power calculation. The 7-day prevalence of MSDs among males and females without physical workloads (office workers) was assessed in preliminary studies[21]. The 7-day prevalence of MSDs for women was between 30 % (cervical spine) and 5 % (hip, ankles) and for men between 20 % (cervical spine) and 5 % (ankles) or 2 % (hip). The 12-month prevalence of MSDs in men and women without physical workloads was significantly higher, from 50 % to 65 % (cervical spine) to 10 % (hip, ankle). Assuming an alpha error of 5 % and a beta error of 80 %, in a group size of 40 persons exposed and 40 persons not exposed, and assuming a prevalence of 5 % in the reference group, a prevalence ratio of 6.5 is significantly increased. If the prevalence of MSDs in the reference group is 20 %, prevalence differences are detectable by a factor of 2.5. Prevalence differences of this amount between non-exposed (exposure level: low) and highly exposed employees (exposure level: high) were observed in the preliminary study mentioned above. It is therefore expected that variations in prevalence of factors of at least 2 to 6 will be detectable, when comparing the two highest exposure categories by KIM with the lowest exposure level (reference group).

2) Power for the outcome "prevalence of tentative diagnoses"

Due to the expected relatively low incidence of diagnoses in the working population, no statistically significant increase in the prevalence of tentative diagnoses is expected. However, an increasing trend with increasing physical workloads from exposure level "low" to exposure level "high" is expected.

3) Power for the outcome "perceived exertion (Borg RPE scale)"

The highest limitations in power calculation according to criterion variability result from dichotomous variables as described in the section above (power for the outcome "prevalence of musculoskeletal symptoms"). Therefore, the power of the study according to continuous variables (such as perceived exertion) is high due to the fact that 1,200 subjects will be included in this study. Considering the large number of subjects, small differences of continuous variables between risk category groups are detectable.

Quality control and assurance

The use of standardised and – if available and appropriate – already validated and/or evaluated screening methods as comparison or reference methods ensures high quality of work. All questionnaires will be completed during a face-to-face interview. The work-related physical examination will be performed by trained external physicians. A standardised procedure for physical examination is guaranteed by the specific standardised training of the physicians.

Remembering earlier symptoms in a retrospective period could involve a recall bias. In order to minimize the bias and to get a more detailed overview, we ask for the past 7-days prevalence and the 12-month prevalence of symptoms. In addition, a physical examination is carried out. The observation of these three outcomes together might reduce the recall bias. According to the selection criteria, only workers are included who are actually working at the workplaces. Workers with sickness absence cannot be considered in the recruitment. This could imply a healthy worker effect. The total number of workers at a workplace is requested of the companies and the number of sick leave days in the last 12 months is enquired of the volunteers. The information is considered in sub-analyses to get an impression of the extent of this issue.

What this study adds

In this study, new KIMs for practical risk assessment of physical workloads are developed and these new KIMs, as well as the already existing KIMs, will be validated. The KIMs are a modular tool kit of practical screening methods for assessing the risk factors associated with work-related musculoskeletal disorders. In addition, the study will increase the knowledge concerning the correlation between specific MSDs and characteristics of physical workloads. With this knowledge, a better classification of occupational hazards with regard to MSDs will be available in future. This may lead to more specific prevention strategies.

ETHICS AND DISSEMINATION

Ethics approval and consent to participate

The study was planned and conducted in accordance with the German Medical Professional Code and the Helsinki Declaration of 2013[46], as well as the German Federal Data Protection Act[47].

The design of the study was examined by the Ethics Committee of the Technical University Darmstadt. The protocol achieved a positive vote (approval no. EK15/2015 2015-09-22 as supplement to EK2/2013 2013-07-04) and the Ethics Committee of the Medical Faculty of the University of Tübingen

(004/2016BO2). The study was started after the Ethics Committees gave their written and unrestricted approval.

Employees participate in the study voluntarily. They can end their participation at any time without reason and without negative consequences, e.g. for their job. Written informed consent for participation is obtained before the survey. Employees receive written and verbal information about the main features of the study as well as about potential benefits for their health and their contribution to the common public welfare. If they accept the conditions of the study and their participation, they document their consent with their signature. A copy of this statement is intended to be kept by the employee for later reference or cancellation of participation. All original documents are treated according to the German Federal Data Protection Act. A comprehensive data protection concept was approved by the Data Protection Officer of the BAuA.

Timeframe of the study and dissemination of results

The study team started the planning of this project in 2012. The data collection for the cross-sectional study then started in spring of 2016 and will end in summer 2017. Description and analysis of the data will be done in 2017. It is intended to present the approved or revised KIMs to the public in 2018. Results will be published in peer-reviewed journals, presented at international meetings and disseminated to actual users for practical application. Potential users include occupational safety and health stakeholders in companies, industrial engineers, ergonomists, occupational health physicians, employers and employees associations, and insurance companies or research facilities.

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(IAD) and the Leibniz Research Centre for Working Environment and Human Factors (IfADo). BAuA and IFA are responsible for the recruitment of 50 % of the workplaces each. IFA contributes to the documentation of all 120 workplaces. ASER with BAuA, and IAD are each responsible for the documentation of 50 % of the workplaces and the execution of 50 % of the described interviews. The physical examinations of the employees are performed by trained physicians of the Kern Medical Engieering GmbH (KME), Frankfurt, in cooperation with Prof. Rieger, head of the Institute of Occupational and Social Medicine and Health Services Research, University Hospital of Tuebingen. The authors thank Dr. Paul Kahle for the English language check.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

All authors were involved in the conception and design of the study, and the preparation of this manuscript. US developed the first drafts of the KIMs and initiated this study. AK and FL concretized the salient content points of this protocol, such as selection of validation criteria and power calculation. AK had the lead management in preparation of the study protocol. US, AK, PS, HG, AS, BH, MS and FB form the development team of the new KIMs. All Authors were closely involved in the planning and development of the study design and preparing the study protocol. All authors read and approved the final manuscript.

List of abbreviations

ABP – Awkward Body Posture; BAB – Beurteilung arbeitsbedingter Belastungen [Procedure for the assessment of workloads]; BAuA – Bundesanstalt für Arbeitsschutz und Arbeitsmedizin [Federal Institute for Occupational Safety and Health] in Germany; BF – Whole-Body Force; BMI – Body Mass Index; BM – Body Movement; COPSOQ – Copenhagen Psychosocial Questionnaire; COSMIN – Consensus-based Standards for the selection of health Measurement Instruments; DGUV – Deutsche Gesetzliche Unfallversicherung [German Accident Insurance]; EEC – European Council Directive; FEBA – Fragebogen zur subjektiven Einschätzung der Belastungen am Arbeitsplatz [Questionnaire of the subjective estimation of exposures]; HAL – Threshold Limit Value for Mono-Tasks Handwork Hand Activity Level; IBM-SPSS-Statistics – Software package used for statistical analysis; KIM – Key Indicator Method [Leitmerkmalmethode]; LASI – Landerausschuss für Arbeitsschutz und Sicherheitstechnik [Committee of the Laender for Occupational Safety and Health] in Germany; LHC – Lifting/Holding/Carrying; LUBA – Assessment technique for postural loading on the upper body; MEGAPHYS – Mehrstufige Gefährdungsanalyse physischer Belastungen am Arbeitsplatz [Multilevel risk assessment of physical workload]; MHO – Manual Handling Operations; MSDs – Musculoskeletal Disorders; NIOSH – National Institute for Occupational Safety and Health; OCRA – Assessment of Exposure to Occupational Repetitive Actions of the Upper Limbs; PP – Pulling/Pushing; REBA – Rapid Upper Limb Assessment; WH – Working Hypotheses; WRMSDs – Work Related Musculo-Skeletal Disorders

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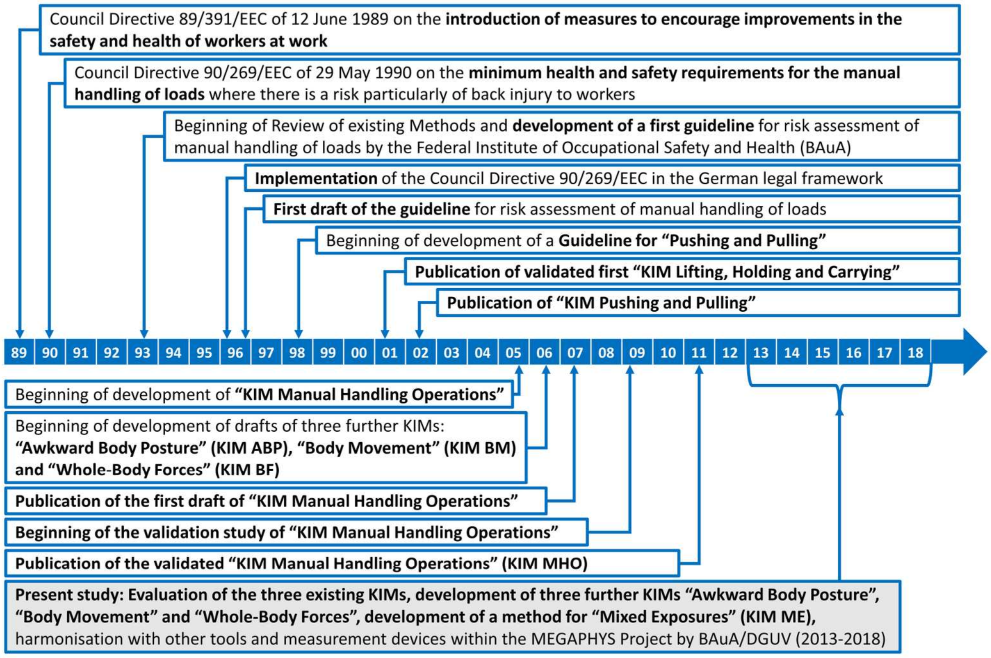
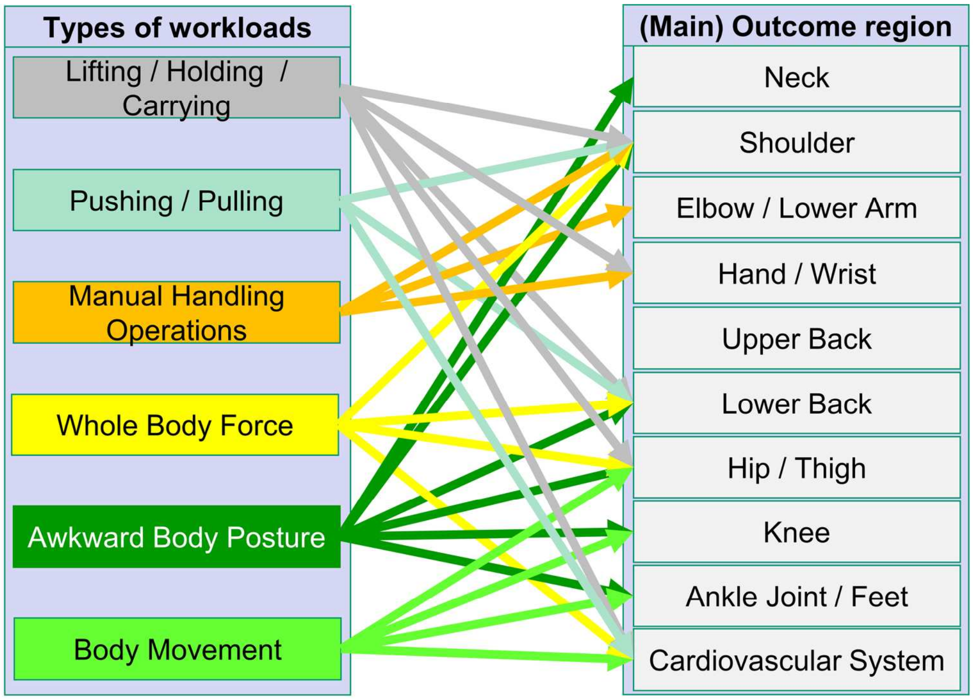
Figure 1: *Development of the Key Indicator Methods (KIMs) for the risk assessment of physical workloads since the year 1989. The horizontal arrow indicates the years of the development process.*

Figure 2: *Types of physical workloads and relation to the main outcome regions. For each type of physical workload, one specific Key Indicator Method (KIM) is developed and validated.*



Development of the Key Indicator Methods (KIMs) for the risk assessment of physical workloads since the year 1989.

180x119mm (300 x 300 DPI)



Types of physical workloads and relation to the main outcome regions.

170x117mm (300 x 300 DPI)

STROBE 2007 (v4) checklist of items to be included in reports of observational studies in epidemiology*
Checklist for cohort, case-control, and cross-sectional studies (combined)

Section/Topic	Item #	Recommendation	Reported on page # in the Document "Manuskript-KIMs-withTC-2017.04.13.docx"
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2-3
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4-6
Objectives	3	State specific objectives, including any pre-specified hypotheses	9-10
Methods			
Study design	4	Present key elements of study design early in the paper	6-8
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	6-8, 24-25
Participants	6	(*a*) ~~*Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up~~ ~~*Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls~~ *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	8-9
		~~(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed~~ ~~*Case-control study*—For matched studies, give matching criteria and the number of controls per case~~	Not applicable
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	10-16, see esp. Table 3, p13
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	10-16
Bias	9	Describe any efforts to address potential sources of bias	23-24
Study size	10	Explain how the study size was arrived at	not applicable yet
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	16-24
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	16-24
		(*b*) Describe any methods used to examine subgroups and interactions	16-24
		(*c*) Explain how missing data were addressed	19
		(*d*) ~~*Cohort study*—If applicable, explain how loss to follow-up was addressed~~ ~~*Case-control study*—If applicable, explain how matching of cases and controls was addressed~~ *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy	not applicable
		(*e*) Describe any sensitivity analyses	not applicable yet

Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	not applicable yet
		(b) Give reasons for non-participation at each stage	not applicable yet
		(c) Consider use of a flow diagram	not applicable yet
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	8-9
		(b) Indicate number of participants with missing data for each variable of interest	not applicable yet
		~~(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)~~	
Outcome data	15*	~~*Cohort study*—Report numbers of outcome events or summary measures over time~~	
		~~*Case-control study*—Report numbers in each exposure category, or summary measures of exposure~~	
		Cross-sectional study—Report numbers of outcome events or summary measures	16-24
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	18-21
		(*b*) Report category boundaries when continuous variables were categorized	12 (4 categories for considered physical workload, see also Table 3, page 13)
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	19
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	19
Discussion			Planned, not applicable yet
Key results	18	Summarise key results with reference to study objectives	
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	
Generalisability	21	Discuss the generalisability (external validity) of the study results	
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	26

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.