Comparison of randomized and nonrandomized controlled trials evidence regarding the effectiveness of workplace exercise on musculoskeletal pain control

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Abstract. Evidence synthesized based on randomized controlled trials (RCT) results are recognized as the pinnacle of research excellence; however, the conduction of RCT in workplace environment is not always possible. This study comparatively reviewed evidence from RCT and non-RCT studies in which participants performed workplace exercise for musculoskeletal pain control. Up to February 2011, PubMed, MEDLINE, Embase, Cochrane, PEDro and Web of Science databases were searched. All trials that evaluated workplace exercise interventions for controlling musculoskeletal pain were included. The PEDro scale was used to rate the studies' quality, PRISMA and Cochrane recommendations were applied, and association between frequencies of effect size categories (small, moderate, large) from various outcomes by study type was tested (2x3 contingency table). The search yielded 10239 references in English, from which 21 RCT and 12 non-RCT were selected. Both groups of studies presented methodological flaws including descriptions of randomization, blinding of examiners and absence of intention-to-treat analysis for the RCT, and further absence of controls and blind assessor for the non-RCTs. RCTs had significantly more moderate and large effect size reported in their results compared to non-RCTs (p=0.04). Considering the difficulties in randomizing participants in occupational settings, all studies would benefit from better describing pertinent methodological information.

Keywords: physical education and training; workers; prevention, musculoskeletal diseases, evaluation

1. Introduction

Musculoskeletal disorders have been recognized as a worldwide health problem. One of the measures for controlling these disorders is workplace exercise practice. However, besides being frequently used for musculoskeletal pain and disorders control, there is controversy regarding effectiveness and the means of implementation of such intervention.

In spite of representing the pinnacle of research excellence, randomized clinical trial designs are not

always possible, adequate or ethical [6,34,39] and its implementation in natural settings, as the occupational ones, is not simple. Several authors have described practical factors that substantially limit the opportunities for conducting RCTs to foster occupational safety and health promotion programs [4,6,39,50]. Among them, employees usually work in groups making it impossible to change work conditions or behavior individually.

Considering these difficulties, quasi-experimental designs involving comparison groups and pre-post

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studies are often conducted in occupational settings. However, according to Silverstein and Clark [39] these studies can only be considered effective when they adequately measure exposure, health outcomes and potential confounders or effect modifiers.

External validity is also important to be evaluated as it can threat the possibility of the results to be generalized to other groups, time and settings [14].

Taking into account the advantages and difficulties of conducting RCT in the workplaces, the present study comparatively reviewed evidence from randomized and non-randomized controlled trials (non RCT) in which participants had performed exercise at worksites for musculoskeletal pain control. So, the current review aims to evaluate the methodological aspects and results from systematically reviewed RCT and non RCT in order to verify their potential problems and contributions to improve workplace preventive interventions based on exercises. Besides the specific context of the present review, the methodological criteria adopted here tried to follow whenever possible the recommendations proposed by PRISMA [29] and Cochrane [21] collaborations for systematic review conduction.

2. Materials and methods

2.1. Literature search strategy

Up to February, 2011 a search on PubMed, MED-LINE, Embase, Cochrane, PEDro, and Web of Science databases was conducted using the following keywords: workplace, musculoskeletal diseases, occupational diseases, musculoskeletal complaints, symptoms, exercise, preventive exercise, worksite physical activity, warming up, stretching, break rest, work pause, ergonomic intervention, ergonomic training, ergonomic program, efficacy, effectiveness, evaluation. Each electronic database was searched from the earliest year available to identify relevant studies published in the English language. Two independent reviewers (RFCM and FAF) selected the studies based on 3 consecutive phases: 1. title selection; 2. abstract review and 3. full paper retrieval and review to identify those which match the inclusion criteria regarding type of study design, participants, intervention and outcomes. Reviewers independently selected the trials to be included in the review using a standard form adapted from the Cochrane Collaboration. Disagreements during the whole process were solved by consensus.

2.2. Eligibility criteria for initial study selection

2.2.1. Type of study

Randomized controlled trials and quasiexperimental designs with comparison groups, and pre-post type prospective studies were eligible to be included in this study.

2.2.2. Participants

Only studies reporting results from active working population at their current occupational activities were analyzed.

2.2.3. Types of interventions

Trials either investigating or comparing workplace interventions including exercise for musculoskeletal symptoms prevention were selected.

2.2.4. Outcome measures

Studies investigating musculoskeletal symptoms, particularly pain, as one of the main outcome measures were included.

2.3. Methodological quality assessment of the included studies

The PEDro scale [49] was used to rate the quality of both groups of studies included in this review: RCT and non RCT. PEDro scale was the eligible methodological evaluation tool as it covers the four main types of bias pointed by the Cochrane Collaboration (the more important agency for providing recommendations for health care interventions): 1. selection bias; 2. performance bias; 3. attrition bias and 4. detection bias[21], which may threat the internal validity of both RCT and non RCT studies.

Each PEDRo's criterion is scored according to its presence or absence in the evaluated study. The criteria assessed are related to: 1. Specification of eligibility criteria; 2. Random allocation of the subjects to groups; 3. Concealment of allocation; 4. Similarity of the groups at baseline regarding the most important prognostic indicators; 5. Blinding of all subjects; 6. Blinding of all therapists who administered the therapy; 7. Blinding of all assessors who measured at least one key outcome; 8. Measurement of key outcomes for more than 85% of the subjects initially allocated to groups; 9. Inclusion of "intention to treat" analysis for at least one key outcome; 10. Report of between-group statistical comparisons for at least one key outcome; 11. Report of both point measures and measures of variability for at least one

key outcome. Each satisfied item (except the first) contributes one point to the total score (range=0-10 points).

The external validity was independently evaluated based on 4 criteria previously adopted by van Poppel et al [48]: 1. Homogeneity of participants; 2. Adequate control group; 3. Relevant outcome measures; 4. Follow up longer than 6 months.

2.4. Data extraction

All authors independently extracted data regarding study design, study participants, comparison groups, intervention performed (sample sizes, type of exercise performed, frequency and duration of each session), outcome measures, evaluation tools and outcomes using a standardized form. Information from group(s) mean(s) and standard deviation(s) for each outcome was obtained from RCT and non RCT studies.

2.5. Effect size calculation

Effect sizes (ES) from studies that provided the required information were calculated using the software G*Power 3.1®. Studies that conducted both within-group and between-group comparisons, had effect sizes calculated only for the between-group comparison from post-intervention measurement(s). ES were further classified as small, moderate or large, according to Cohen's criteria [8] for standardized differences in means, using the thresholds 0.20, 0.50 and 0.80, respectively.

2.6. Data analysis

The data collected through the standardized form were descriptively analyzed. After this, nominal data for each PEDro scale criteria, external validity, items related to exercise protocols reproducibility, number and type of pain evaluation tools were categorized as sufficient or not sufficient according to its description and compared by the Exact Fisher test. Also, 2 (RCT, non RCT) x 3 (ES category) contingency table tested association between frequency of ES and study type. Total PEDro score for RCT and non RCT studies were compared by Mann Whitney U test. These analyses were conducted with the SPSS 19.0 package SPSS, Chicago, IL) with level of significance α =0.05.

3. Results

The electronic search yielded a total of 10239 references published in English. At the end of the selection process, 21 RCT and 12 non RCT satisfied the inclusion criteria and were included in the present review. From the 12 non RCT retrieved, two studies were classified as double publication for musculoskeletal pain outcomes [35,38] lasting 11 studies for drawing conclusions (Table 1). From the 21 RCTs, one was a double publication [2,7] lasting 20 RCTs for the final analysis (Table 2). Overall, 50 ES were calculated, from those, 40 ES were from 17 RCT [1,3,15,18-20,22,24,25,30,33,41,42,44-47],and 10 ES from 4 non RCT studies [17,35,36,43]. The remaining 3 RCT [2,27,37] and 7 non RCT [5,12,13,16,28,31,40] did not provide information necessary for ES calculation.

3.1. Internal validity

The results of internal validity scores for non RCT and RCT studies are shown in Tables 1 and 2, respectively. Taking into account the maximum score possible for the PEDro scale (10 points), the non randomized studies group achieved a mean score of 2.09±0.92 points (min1; max4), while the RCT group achieved a mean value of 4.65±1.18 points (min3; max8). However, according to Maher [32], due to the impossibility of achieving conditions such as blinding of therapist (criterion 5) or subjects (criterion 6) in clinical trials conducted in the workplace, the maximum score that can be reached by these clinical trials is 8/10. For the non RCT studies, another two criteria are not possible to be achieved due to the own nature of this study group: random allocation (criterion 2) and concealed allocation (criterion 3). In this case, the maximum score that can be reached by the non RCT group is 6/10. These limitations suggested the need for a data adjustment according to the maximum possible score for each group, i.e, 6 for non RCT and 8 for the RCT group. When considering the adjusted analyses, a mean relative score of 0.35±0.19 (min0.17; max0.67) was achieved for the non RCT group, while a mean relative value of 0.58±0.15 (min0.37; max1) was reached for the RCT group. These results represented a mean percentage of 35% of the maximum score possible for the non RCT group and 58% for the RCT group.

Significant difference were identified between RCT and non RCT groups for both PEDro total (p<0.001) and PEDro relative (p=0.003) scores.

The comparison between RCT and non RCT studies for each PEDro criterion analysis showed significant differences between groups for four PEDro scale criteria assessed. Fisher test identified significant differences for the following criteria: (1) Specification of eligibility criteria (p=0.001); (2) Random allocation of subjects to groups (p<0.001); (4) Similarity of the groups at baseline (p=0.047) and; (11) Report of point and variability measures for at least one key outcome (p=0.042). Besides Fisher test having not identified significant difference for both criteria 8 - Measurement of at least one key outcome for more than 85% of subjects initially allocated to groups, and criteria 9 - Description of an intention to treat analysis; both of them were observed in 40% of the RCT and only in 18% of the non RCT studies. Despite these discrepancies, Fisher test did not revealed significant difference, probably due to the small number of non RCT studies included.

Table 1
Assessment of methodological quality of non RCT studies by PEDro scale

	PEDro Scale												
Study	01	02	03	04	05	06	07	08	09	10	11	PEDro Score	Relative PEDro score*
Genaidy et al. [17]	-	-	-	-	-	-	-	-	-	+	+	2	0.33
Balci & Aghazadeh [5]	-	-	-	-	-	-	-	-	-	+	-	1	0.17
Mongini et al [35]	-	-	-	-	-	-	-	+	+	+	+	4	0.67
Mongini et al [36]	-	-	-	-	-	-	+	-	+	+	+	4	0.67
Macedo et al [31]	-	-	-	-	-	-	-	-	-	+	+	2	0.33
Fenety and Walker [16]	+	-	-	-	-	-	-	+	-	-	+	2	0.33
Dehlin et al. [13]	-	-	-	-	-	-	-	-	-	+	-	1	0.17
Dehlin et al. [12]	-	-	-	-	-	-	-	-	-	+	-	1	0.17
Shinozaki [40]	-	-	-	-	-	-	-	-	-	+	-	1	0.17
Skargren and Oberg [43]	+	-	-	+	-	-	-	-	-	+	-	2	0.50
Leclerc et al . [28]	+	-	-	-	-	-	-	-	-	+	+	2	0.33
Number of studies which satisfied the PEDro criteria	3	0	0	1	0	0	1	2	2	10	7		

*Values calculated in function of the maximum score possible for non randomized controlled trials group: 6 points.

The index used was: relative PEDro score=total PEDro score/6

Table 2 Assessment of methodological quality of RCT studies by PEDro scale

							PEI	Dro Sc	ale				
Study	01	02	03	04	05	06	07	08	09	10	11	PEDro Score	Relative PEDro score**
Donchin et al. [15]	+	+	-	+	-	-	-	-	+	+	-	4	0.5
Kellett et al. [24], 1991	+	+	-	+	-	-	-	-	-	+	+	4	0.5
Groningsater et al [19]	+	+	-	+	-	-	-	+	-	+	+	5	0.6
Gundewall et al. [20]	-	+	-	-	-	-	-	+	-	+	+	4	0.5
Takala et al [44]	+	+	-	+	-	-	+	+	-	+	+	6	0.8
Gerdle et al. [18]	+	+	-	-	-	-	+	-	-	+	+	4	0.5

Number of studies which satisfied the PEDro crite ria		19	3	10	0	0	5	8	8	20	19		
Pedersen et al. [37]	+	+	-	-	-	-	+	-	+	+	+	5	0.6
Tveito and Eriksen [46]	+	+	+	+	-	-	-	-	-	+	+	5	0.6
Andersen et al [3]	+	+	-	+	-	-	-	-	-	+	+	4	0.5
Andersen et al. [2]	+	+	-	-	-	-	+	+	+	+	+	6	0.8
Kietrys et al. [25]	+	+	-	-	-	-	-	+	+	+	+	5	0.6
Sjogren et al. [42]	+	+	-	-	-	-	-	+	+	+	+	5	0.6
Sjogren et al. [41]	+	+	+	+	-	-	+	+	+	+	+	8	1.0
Maul et al. [33]	+	+	-	+	-	-	-	-	-	+	+	4	0.5
Tsauo et al. [45]	-	+	-	-	-	-	-	-	-	+	+	3	0.4
van den Heuvel et al. [47]	+	+	-	-	-	-	-	-	-	+	+	3	0.4
Larsen et al. [27]	+	+	-	+	-	-	-	+	+	+	+	6	0.8
Horneij et al. [22]	+	+	-	-	-	-	-	-	+	+	+	4	0.5
Ahlgren et al. [1]	+	-	+	-	-	-	-	-	-	+	+	4	0.5
Lundblad, et al. [30]	+	+	-	+	-	-	-	-	-	+	+	4	0.5

**Values calculated in function of the maximum score possible for randomized controlled trials group: 8 points.

The index used was: relative PEDro score = total PEDro score/8.

3.2. External validity

The comparison between groups through the Fisher test showed significant differences for the homogeneity (p<0.001) and adequate control group (p<0.001) criteria. These two criteria were satisfied by 90% of the RCT studies, but were met by only 18% of the non RCT ones. Regarding the report of relevant results (criteria 3), 35% of RCTs and 45% of the non RCT satisfied this criteria (p=0.705). Regarding the last validity criteria evaluated (follow up longer than 6 months) the groups presented very similar results: 25% of RCT and 27% of non RCT met the criteria (p>0.9).

3.3. Training protocol description

Significant differences were identified for type of exercise applied and for the frequency and duration of exercise sessions. Each item was classified either as insufficient or sufficient, according to its in/adequate description. Table 3 present the descriptive and statistics results related to the protocols adopted in both groups.

	Absolute number and percentage of studies with sufficient description of exercise protocol items							
Study Type	Body region	Type of exercise	Frequency and dura- tion of the session					
RCT	16 (80%)	20 (100%)	20 (100%)					
Non RCT p value	7 (63%)	8 (72%)	7 (63%)					
(Fisher test)	0.405	0.037*	0.01*					

Table 3 Comparison of protocol characteristics

* Statistical significant difference (p<0.05)

3.4. Symptoms evaluation

The effects of exercise intervention on pain results were mainly assessed by questionnaires in both groups. However, while 65% of the RCT studies used two or more pain evaluation tool to assess variables related to pain, only 27% of the non RCT study group has performed a more comprehensive analysis of this symptom using 2 or more objective evaluation tools (p=0.066).

3.5. Effect size by study type

A significant association between ES category and study type was found (p=0.0400), with RCTs reporting greater frequencies of moderate and large ES and non RCTs reporting small ES (Table 4).

Table 4 Frequency distribution of Effect Size category by Study type

Study	Ef	fect Size (ES) Cate	gory
Туре	Small	Moderate	Large
RCT	16	15	9
Non RCT	8	0	2

4. Discussion

The great heterogeneity regarding methodological quality of the primary studies in RCT and non RCT studies could be identified as the main reason that precluded clinical evidence synthesis and comparison between the RCT and non RCT groups. On the other hand important scientific recommendations could be synthesized regarding future research on exercise workplace exercise interventions.

The assessment of internal validity by the PEDro scale revealed low methodological quality of non randomized studies performed in the workplace for musculoskeletal pain prevention. After adjusting the data to the maximum score per group, the non randomized studies presented a low mean score (less than 50% of the maximum score possible), while the RCT group achieved a mean value of 58% of the total maximum score possible. Thus, comparatively, both groups presented expressive methodological problems indicating the need for improvements, in order to provide their contribution for interventions aiming at controlling pain in occupational settings. This is particularly valid for the non RCT that, despite the absence of randomization, have presented extra deficiencies, as the common absence of control groups and blind assessor, which threat the internal validity of the studies and contribute to biased results [23]. Regarding the RCT studies, the main deficiencies identified were inadequate descriptions of randomization procedures, blinding of examiners and absence of intention-to-treat analysis. The absence of examiners' blinding has been pointed out as one of most important features to increase the potential for biases [26]. Thus, despite the fact that randomized controlled trials have been often cited as the most

powerful design in research evidence for evaluating health care effectiveness [11], they can also present considerable methodological limitations.

In general, the external validity was low for both groups of studies. However, the RCT showed better results for homogeneity and adequate control of group. Both groups of studies would benefit from better reporting relevant results and performing longer follow ups. Comparatively, the non RCT studies presented poorer descriptions of the exercise protocols. This insufficient description reduces the possibilities of evaluating these protocols, their results and reproducibility Furthermore, the RCT studies included more tools for evaluating the main outcome. Considering the challenge still involved in the evaluation of pain in occupational settings, and absence of a consensual methodology for this task [10], the RCT studies seems to have more chances of fulfilling a comprehensive evaluation.

This argument might also be related to the fact that while the RCTs provided strong evidence about the effectiveness of workplace exercise in controlling neck pain among workers who performed sedentary tasks, and moderate evidence for low back pain relief among workers who performed heavy physical tasks, as previously evaluated by Coury et al. [9]; the non RCT analyses did not allow drawing any substantial clinical conclusion. As reported earlier, stronger methodological flaws than just the lack of an adequate random allocation of the subjects between groups were presented. Furthermore, in addition to weaknesses in method procedures, non RCT tend not to report necessary information for effect size calculation. In fact, while 85% of the selected RCT provided information such as study groups means and standard deviations, only 36.4% of the non RCT provided such information. Also, the frequency of methodological flaws observed in non RCTs seems to be followed by results with effect sizes of smaller magnitudes, compared to RCTs.

The above-mentioned characteristics of non RCT studies clearly minimize their potential for contributing with practical workplace exercise evidence synthesis. The stronger methodological control of RCT studies may yield appropriate conditions for minimizing threats to internal validity and, consequently, offer conditions such that reports of intervention effects may be optimized.

5. Limitations

The current review presents some weakness that need to be considered. The search strategy, restricted to English-language publications, could have contributed to reduce the number of potential studies included in each group. The low number of non RCTs studies identified and included here generated an unbalanced comparison between groups. Another point to be mentioned is the lack of standardized pain evaluation tool which jeopardized the studies comparability. However, this condition is related to the multidimensional nature of pain evaluation and, thus, beyond the scope of this review.

6. Conclusion

It would be expected that non-randomized trials would lead to lower methodological quality evaluation than randomized trials, particularly when the studies are assessed by protocols addressed to evaluate aspects related to randomization. However, the non-randomized trials included in this review have presented flaws greater than the ones related to the randomization process itself. Thus, considering the difficulties in applying the randomization design in interventions intended for collective situations in occupational settings, the programs would benefit from the authors providing detailed methodological information. The RCTs would be improved by the inclusion of better descriptions of randomization procedures, blinding of examiners and the intention-totreat analysis, while the non-RCTs would be improved by the inclusion of a control group and blind assessors.

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