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Evaluation of "I-Preventive": a digital preventive tool for musculoskeletal disorders in computer workers; a randomized controlled trial

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Abstract

Objectives: I-Preventive is a digital preventive tool for musculoskeletal disorders (MSDs) in computer workers. We sought to determine its impact on pain in computer workers with upper-limb MSDs and visual discomfort.

Methods: We conducted a prospective feasibility study in two different sites of a Michelin tire factory in France. We randomized 200 employees to either an intervention group (I-preventive) or control group, each comprising symptomatic and asymptomatic employees. The workers were followed-up for 5 months. The main outcome was overall recovery from complaints following one month's intervention based on Nordic-style and eyestrain questionnaires.

Results: We included 185/200 workers: 96 in the intervention group (mean age: 41.8±1.4 years old; 88.5% males) and 79 in the control group (mean age: 42.9±12.0 years old; 94.5% males). The most painful areas (numerical scale ≥2) were the neck (40.0%), upper back (18.8%), and shoulders (15.7%). For the most painful anatomical area, the Nordic score significantly decreased after 1 month in the intervention group (p=0.038); no change was observed in the control group (p=0.59). After 1 month's use, the intervention group reported less pain in the painful area and less visual discomfort symptoms (p=0.02). Adherence to the I-preventive program was 60%.

Conclusion: I-Preventive is effective in the short-term on MSD pain and visual discomfort by promoting active breaks and eyestrain treatment. This easy-to-use digital tool allows each worker to focus on areas of their choice *via* personalized, easy exercises that can be performed in the workplace.

Key Words: musculoskeletal diseases, eyestrain, work, visual display units, stretching, exercise, software

Strengths and limitations of this study

- Some software programs were built to promote frequent breaks at work for visual display unit users but only very few tools were evaluated with a high level of proof.
- The novelty of the I-Preventive strategy is its implementation of frequent short daily active breaks promoted by a software program, which can only be achieved within a prevention-oriented organizational culture.
- The I-Preventive software program is particularly effective in the short-term due to its individualized and personalized form, allowing workers to focus on areas of their choice by offering exercises that are easily performed in the workplace.
- Despite this digital tool being easy to use, adherence decreased over time, and its favorable impact was not maintained over the long term.
- Future studies should comprise objective measures of physical performance and effectiveness at work in order to establish cost-effectiveness benefits based on economic analyses.

Introduction

Musculoskeletal disorders (MSDs) in the working population currently represent one of the most worrying work-related health issues[1], with considerable economic burden on society.[2] There is, however, still no consensus on their precise definition. MSD is a broad term encompassing a range of degenerative, dysfunctional, and inflammatory conditions affecting the musculoskeletal system.[1] Moreover, the majority of available data is focused on MSD defined by anatomical site. For example, upper-limb MSD covers both well-defined diseases like epicondylitis and non-specific pain syndromes with no clear clinical definition.[1] These heterogeneous definitions can make drawing comparisons between studies difficult. Although the prevalence rates of MSD vary widely depending on the body part considered and tools used for symptom assessment, they can exceed 30%.[3] Recent studies have encouraged a more global approach to MSD by analyzing the extent of musculoskeletal symptoms, particularly the number of symptomatic anatomical sites, either in the general population or working population.[4] When considering a global approach, multisite symptoms were predominant (33-66% of workers) over those strictly confined to a specific anatomical site (15-30% of workers).[4]

The major risk factors for MSD are repetitive movements, high muscular strength demands, awkward or extreme positions, rapid work pace, extreme temperatures, insufficient recovery time, mechanical pressure, and segmental vibrations.[5] Additional workplace-related risk factors include psychosocial factors, such as high demands and low decision latitude.[6] Work-related risk factors are, in fact, unequally distributed across occupational groups depending on the specific nature of the work tasks and production processes, the ergonomic and psychosocial characteristics of the workplace, and the organization's occupational health policies.[7] In particular, MSDs are the most prevalent disorders among sedentary workers, especially those using visual display units (VDU).[8] Over the last two decades, the number of

VDU workers has increased dramatically, with even managers now considered computer office workers. The most frequent musculoskeletal symptoms occur in the neck and shoulder area, with a prevalence of up to 62% reported in VDU workers.[9]

Musculoskeletal symptoms of VDU users have multi-factorial etiologies, such as non-neutral wrist, arm, and neck postures, work station design, and duration of VDU exposure, as well as perceived job strain with low decision latitude and high workload.[10] VDU workers' musculoskeletal discomfort most commonly affects the neck, shoulders, back, and eyes.[11] Long-duration computer work without breaks has also been related to eye injury, as duration of mouse use has been to neck and upper extremity symptoms.[12]

We are therefore convinced that appropriate MSD-preventive tools for VDU workers are urgently required. These tools must be clinically evaluated by providing evidence-based medical data. Interventions aimed at reducing MSDs in VDU workers should be aimed at both physical/ergonomic and organizational/psychosocial work factors, and must be supported by managers in order to ensure worker adhesion to the intervention.[9] The majority of strategies have focused on new workstation design [13], yet their effectiveness remains highly questionable. Strategies could be more effective if they were to implement changes in the temporal pattern of the work task, such as supplementary rest breaks allowing for periods of recovery from the monotonous load.[14] The effect of exercise on MSD symptoms has recently been demonstrated in workers.[15] In addition to exercise, rest breaks, and especially frequent "microbreak",[16] have been shown to reduce discomfort, eyestrain, fatigue, and mood disturbances, in addition to improving keystroke speed and accuracy. Some software programs were built to promote frequent breaks at work for VDU users. These breaks can be active, with stretching exercises during working days. However, only very few tools were evaluated with a high level of proof (Wellnomics® Breaks).[17] Within a large French tire factory (Michelin), a taskforce was convened including physicians, nurses, prevention engineers, and

a sports teacher, aiming to evaluate an online tool called "I-Preventive", which promotes active breaks with stretching exercises.

Our principal aim was thus to estimate the effects of I-preventive on MSDs and visual discomfort.

Methods

Design

A quasi-experimental design was proposed within a tire factory in France. This feasibility study aimed to measure the impact of I-Preventive on MSD symptoms and therefore define the optimal effect sizes for calculating the sample size required for a larger cluster-randomized controlled trial. While we did not focus on a putative cluster effect, in order to maintain a suitable methodology, an independent statistician conducted the randomization of four participating departments. The workers were randomized into an intervention group (I-Preventive) and control group, with each containing participants with MSDs. This study was conducted from June to October, 2014. Measurements were made with repeated data requests (Figure 1). The study was approved by the Sud-Est 6 medical ethics committee of the University Hospital of Clermont-Ferrand, France (ClinicalTrial.gov identifier: NCT02350244). All employees corresponding to the inclusion criteria received a summary of the study, which was considered a non-opposition form. This non-pharmacological trial was designed in accordance with the Consolidated Standards of Reporting Trials statement (CONSORT).[18]

Participants

The participating workers were recruited from a potential 200 employees of the Michelin research departments. The inclusion criteria required participants to be employees aged 18-65 years old, completing at least 5 hours of VDU work per day, receiving no treatment for rheumatic or neurological diseases, undergoing no changes in VDU/workstation apparatus,

having taken no sick leave in the previous month, and exhibiting no behavioral/learning disorders. Only administrative staff and no blue-collar workers were thus included.

Intervention

Workers in the intervention group received an activation code to download the software program (I-Preventive, *www.i-prentive.com*) on their VDU. I-Preventive promoted active breaks *via* an individualized computer application. It allowed workers to focus on body regions of their choice, offering high flexibility. After selecting the body part, I-Preventive asked about symptoms and suggested appropriate exercises. Workers could follow the suggested personalized exercises or use the random mode. At regular intervals, a visual signal on the screen prompted VDU workers to take active breaks. The visual signal described short individualized exercises of no more than one and a half minutes. The exercises were easy to perform and most could be carried out while seated without needing specific equipment (Figure 2). Users could program one to four active breaks daily. The computers were not locked during the breaks, thus workers could postpone the active break by clicking on "later". The software offered worksheets that could be downloaded and used as information tools. The intervention lasted 4 months.

The control group received usual healthcare with the occupational physician.

Baseline assessments

All participants (intervention and control groups) completed the same questionnaires.

MSDs were evaluated by the Nordic-style questionnaire, validated in 2007 as a useful tool for monitoring work-related MSDs, especially if respondents included a numerical rating scale pertaining to symptom severity.[19] It is derived from the original Nordic questionnaire published in 1987 that was then translated into French in 1994.[20] The Nordic questionnaire included a numerical pain scale ranging from 0-10 for each anatomical region.

Eyestrain assessment covered various symptoms like headache, blurred vision or eye stinging, by means of a horizontal numerical scale from 0-10,[21] commonly used by the French national institute of research and prevention (INRS).

Global psychological status was evaluated on the hospital anxiety and depression scale (HAD).[22] Psychosocial work characteristics were measured using a horizontal visual analog scale (VAS) for both stress and satisfaction at work.

Physical activity and sedentary behavior were measured by means of the international physical activity questionnaire (IPAQ).[23]

Sociodemographic characteristics (gender, age, work position, etc.) were also recorded.

Follow-up assessments

All baseline assessments were repeated at 1 month (M1), 2 months (M2), 3 months (M3), and 4 months (M4), with the exception of VAS stress/satisfaction and HAD, which were not measured at M2 and M3 (Figure 2). Sociodemographic characteristics were only compiled at baseline.

To verify whether the participants performed the exercises or not (adherence), we had to rely on their monthly individual reports at M1, M2, M3, and M4.

At M4, the intervention group was asked to give feedback on the software, recommended breaks, and exercises.

Outcomes

The main outcome was the overall decrease in complaints at M1, assessed by means of the Nordic-style and eyestrain questionnaires, in addition to the change in number of asymptomatic workers (numerical value <2 on the Nordic-style questionnaire).

Secondary outcomes included long-term follow-up of the Nordic-style and eyestrain questionnaires at M2, M3, and M4; changes in global psychological status (HAD, VAS of

stress/satisfaction at work) between M0 and M4; evolution of physical activity and sedentary behavior; number of sick-leave days. Adherence to the program was assessed at M1, M2, M3, and M4 in order to investigate a dose-response relationship, using a self-reported questionnaire indicating a frequency of use from the following options: less than once a week, a few times a week, once every day, and several times every day.

Statistical considerations

In line with the literature, it appeared difficult to estimate an optimal sample size for assessing software promoting active breaks using exercises with the aim of treating MSD and visual discomfort in VDU workers. In addition, the sample size was set considering this study to be a feasibility pilot study.

For this reason, we calculated that 64 workers per group would enable an effect size equal to 0.5 for a Type I error α=0.05 (two-tailed) and statistical power of 80%.

Considering possible loss to follow-up (rate fixed at 25%), we finally chose to include a minimum of 80 VDU workers per group. Statistical analysis was performed using Stata software, Version 13 (StataCorp, College Station, TX, U.S.). The tests were two-sided, with a Type I error set at α=0.05. Baseline characteristics were presented as mean±standard deviation (SD) or median [interquartile range] according to statistical distribution for continuous data, and the number of workers and associated percentages for categorical parameters. Comparisons among independent groups (workers accessing I-Preventive or not) were performed by Student's t-test, or by the Mann-Whitney U test if t-test conditions could not be respected (homoscedasticity analyzed by the Fisher-Snedecor distribution). Comparisons between qualitative parameters of the independent groups were performed by Chi-squared test or, if necessary, Fisher's exact test. For the evolution of the longitudinal NORDIC study (and visual discomfort score), mixed models (the linear models for the NORDIC score considered a quantitative or generalized linear for the proportion of VDU

workers with NORDIC scores above a given threshold, in line with the literature) were proposed in order to take into account the difference between and within individual variability (random effect) while studying the fixed group effects, time, and interaction. The normality of residuals was assessed and gender, age, site, and original pain or discomfort were studied in previous models as covariates (fixed effects). Workers' frequency of I-Preventive use (before or after holidays) was also recorded, particularly in the context of a specific intra-group analysis of workers who had access to the I-Preventive software. Finally, this was complemented by analyses that were situation-matched to the parameters collected at only two time points (M0 and M4 for HAD and VAS of stress/satisfaction), with the usual tests applied: Student's paired t-test or the Wilcoxon signed-rank test for quantitative parameters and Stuart-Maxwell test for categorical variables.

Results

Participants

Among the 200 employees invited, 185 (93%) agreed to participate. Of these, 11 (6%) were excluded from the analysis due to disease, maternity leave, interim status, retirement, and change in job. We thus included 175 employees, 96 assigned to the intervention group and 79 to the control group (Figure 2). Workers located on the same floor or in the same building were assigned to the same group in order to avoid contamination bias and enhance adherence to the program within the intervention group, as well as to implement the study in a regular work environment. The two groups did not differ at baseline, with the exception of the percentage of females and sedentary time (Supplementary Table 1 and Supplementary Table 2), with the control group including less females (n=2, 2.5% *vs.,* 11.5%, p=0.04) and exhibiting a lower level of sedentary lifestyle (530.6±0.8 *vs.*, 610.2±0.9 minutes/day, p=0.04).

Digital tool acceptability

Exercises were carried out by 58% of participants in random mode and by 42% following the individualized software suggestions. The primary anatomical parts exercised were the neck (74.4%), eyes (51.3%), hands (41.9%), elbows (37.8%), lower back (36.5%), and shoulders (35.1%). At M4, overall satisfaction with the digital tool was 43%, with 90% of participants reporting the tool was simple to use or the exercises easy to perform. However, 35% of employees had some technical difficulties in using the tool, 39% experiencing concentration problems and 64% problems coordinating the active breaks with their work. Adherence decreased throughout the intervention, from 60% of employees using I-preventive every day (once or several times) at M1 to 37% at M4 ($p < .01$). Overall, 40% of participants declared feeling better with active breaks when working on the computer.

Primary outcomes

At *baseline*, the groups did not differ in terms of the percentage of workers suffering from each painful anatomical part ($p=0.62$), nor for the maximal pain assessed by the NORDIC questionnaire (3.3 ± 0.3 for the intervention group *vs.*, 3.0 ± 0.3 for the control group; $p=0.2$). The most painful anatomical parts (numerical value ≥ 2) were the neck (40.1%), lower back (35.7%), upper back (18.8%), and shoulder (11.7%). The majority reported one or two painful locations (62.7%), 17.9% reported three locations, and 8.9% reported four.

In *longitudinal follow-up* with *quantitative analysis*, the maximum NORDIC score did not differ between groups at M1 using analysis of covariance (ANCOVA) ($p=0.44$). In a complete multivariate model and after adjustment for NORDIC score at baseline, sedentary time, memorizing, and maximum NORDIC score tended to decrease, though not significantly so ($p=0.18$). However, on studying the fixed-group effects based on a longitudinal evolution of maximum NORDIC score, we observed a significant difference at M1 for the intervention group ($p=0.038$) *vs.* baseline and no difference for the control group ($p=0.59$) (Figure 3).

In *longitudinal follow-up* with *qualitative analysis*, the percentage of body parts with a NORDIC score ≥2 did not differ at M1 using random-effect logistic model analysis, compared with the control group (p=0.18). For longitudinal analysis in intra-groups, this parameter had significantly decreased at M1 in the intervention group (p=0.02), *versus* the control group (p=0.57) (Figure 4).

For both the quantitative and qualitative analyses, no significant difference was found between the groups at the end of the study, even though a trend of decrease at M2 was observed (p <.01).

Secondary outcomes

At baseline, eyestrain did not differ between groups. The symptoms were loss of eyesight (55.2% of participants), eye stinging (48.8%), glare (48.8%), blurred vision (44.2%), headache (34.8%), and eye irritation (23.2%). At M1, visual discomfort significantly decreased for both the quantitative (maximum visual score) and qualitative longitudinal analyses (visual symptoms ≥2) in the intervention group (p=0.025 and p=0.02, respectively), with no change observed in the control group (p=0.65 and p=1.0, respectively). No significant difference was found at the end of the study.

The intervention program did not exhibit significant impact on work stress, work satisfaction, anxiety, or depression symptoms, and no links were established between stress, anxiety or depression and MSD or ocular symptoms.

We recorded four sick leaves in the intervention group corresponding to psychiatric or surgical diseases, with none linked with MSD. There were no sick leaves within the control group.

Sub-group analysis

On analyzing the sub-groups, the longitudinal evolution of the NORDIC score was more effective for employees using the individualized software form (p=0.009). Those who were

happy to use I-Preventive tended to have less painful localizations, reporting a pain score <2 (p=0.12). Baseline NORDIC scores (< or ≥2) did not influence the benefits of intervention. Adherence to I-Preventive was not linked to greater benefits in MSD symptoms, evaluated by the NORDIC questionnaire, even following adjustment for age and gender.

Discussion

Main findings

Our pilot feasibility study demonstrated the potential of active breaks to prevent MSD symptoms and eyestrain. The I-preventive software program was shown to be particularly effective in the short-term in its individualized and personalized form, allowing workers to focus on areas of their choice by offering exercises that are easy to perform at the workplace. However, despite this digital tool being easy to use, adherence decreased over time, so that this favorable impact was not maintained over the long term.

Validated methods for the prevention of MSD

Prevention of MSD should be based on an integrative approach combining ergonomics and physical activity interventions.[13] In ergonomics, no clear positive impact has been demonstrated by single intervention programs, such as work station adjustments (technical), rest breaks (organizational) or ergonomic training (behavioral) on work-related MSD. However, when these specific interventions were included in a combined approach, they became more effective.[13] Physical activity interventions at the workplace demonstrated benefits on computer-worker MSDs, consisting of either 20-30-min training sessions two or three times a week[24] or short daily active breaks,[25] in addition to either stretching and joint mobilization exercises or strength training and dynamic endurance training.[26] Training sessions appear to have more pronounced long-term effects than short daily active breaks, in

accordance with our study findings. These studies involved a coach or physical therapist to motivate the participants.[26] Conflicting results reported in the literature could be explained by the high risk of bias from the studies due to an unknown random allocation procedure, as well as insufficient motivation to exercise or lack of intention-to-treat analyses.[27] The novelty of the I-Preventive strategy is its implementation of frequent short daily active breaks promoted by a software program, which can only be achieved within a prevention-oriented organizational culture.

A novel digital tool for the prevention of MSD

Computer usage and sedentary behavior at the workplace has increased dramatically over the past decade,[28] with emails emerging as a new communicative tool. Office workers thus remain in the same posture for longer, accompanied by long periods of keyboard usage, which can cause and aggravate MSDs. Paradoxically, several software programs have been implemented to promote exercise at the workplace and prevent MSD. Despite the promotion of exercise through software, however, programs have been largely developed for chronic diseases like type two diabetes,[29] and these digital strategies were rarely implemented at the workplace for health outcomes in general[30] and especially not for preventing MSD.[14] As for the use of a computerized decision support system for primary and secondary prevention of work-related MSD disability, only one study tried to improve MSD prevention by analyzing the ergonomic process through self-reported questionnaires from a software tool.[31] Moreover, only two studies used a software program to specifically prevent MSD. The results from the short-term pilot study conducted on a low sample size supported the theory that this type of exercise reminder software programs may help to reduce perceived pain among office workers.[32] In accordance with our findings, the use of a software program encouraging workers to take regular breaks has been reported elsewhere to contribute to perceived recovery from neck and upper-limb complaints.[17] Nevertheless, our study was not designed to

assess the specificity of breaks or exercise in MSD prevention[17], and long-term studies involving more subjects should now be conducted so as to describe the effects of these programs and underlying mechanisms.

General health effects of our intervention

Overall, the neck, shoulders, and upper and lower back were the most affected regions among our computer users, in line with the literature.[32] Moreover, computer-related visual and ocular symptoms are the most frequently occurring health problems in people who spend a large proportion of their working day looking at a computer screen.[33] Given the high prevalence of these symptoms,[34] it is likely that all VDU workers will at some point need eye examinations in order to assess symptoms associated with VDU use. Furthermore, visual and musculoskeletal discomfort have been intrinsically linked together.[35] To our knowledge, our study was the first to simultaneously evaluate and prevent MSDs in combination with ocular symptoms. Satisfaction at work was also found to be related to both outcomes in the literature,[35] therefore demonstrating that implementation strategies targeting both MSDs and ocular symptoms should be further investigated in relation with perception of work. For example, shoulder symptoms were reported to occur more frequently in workers with passive (low demand and low control) or high-strain jobs (high demand and low control).[36] Similar conclusions were demonstrated for elbow disorders.[37] However, no link was established between psychosocial risk factors and carpal tunnel syndrome.[38] In our study, the levels of anxiety and depression were low, and no link was found between them and MSDs or ocular symptoms. Finally, as patients with MSDs often report perceived physical activity barriers, any preventive intervention should address the specific concerns of each individual.[39]

Limitations

Our study had some limitations. One could argue that the inclusion number was low, yet the sample size was relatively large compared with that of other pilot studies, and the percentage of participants who agreed to participate was exceptional (>90%),[40] with none lost to follow-up. This good representation of computer workers thus reduced potential bias and allowed us to generalize results for other services. The protocol was carried out in a high-demand working environment, and thus may easily be translated to other areas. Secondly, even though we implemented a run-in period with a control group and repeated measures, the study was not blinded for the participants, and the principal resulting outcome was for upper-limb MSD. Further studies should thus compare an intervention group combining lower- and upper-limb exercises to a placebo control group focusing, for example, on lower-limb exercises. Also, the decreasing adherence throughout the study could have been caused by the summer holidays falling between M1 and M2, or a decrease in job demand for those who did not go on holiday, which may have lowered the impact of our intervention on MSD. In addition, some found it impossible to adapt active breaks to their specific working schedules, which, along with software defects, also likely contributed to the decreasing adherence. Finally, the software was not designed to evaluate the objective measure of adherence to the program, such as number of connections or amount of time spent on the tool. Furthermore, physical symptoms were not clinically assessed by a physician however, subjective scales have been validated and are commonly used both in routine practice and research.[19] Future studies should comprise objective measures of physical performance and effectiveness at work in order to establish cost-effectiveness benefits based on economic analyses.

Conclusion

Our pilot feasibility study demonstrated the potential of active breaks for preventing MSDs and ocular symptoms. The I-Preventive software program is particularly effective in the short-term due to its individualized and personalized form, allowing workers to focus on areas of their choice by offering exercises that are easily performed in the workplace. However, despite this digital tool being easy to use, adherence decreased over time, and its favorable impact was not maintained over the long term. A strong preventive culture requires a particular organizational strategy in order to manage the health and safety of the workforce, as the willingness of employers to implement innovative strategies in their organizations and personnel development is paramount for the tool's effectiveness.

Abbreviations HAD, hospital anxiety and depression; IPAQ, international physical activity questionnaire; MSDs, musculoskeletal disorders; VAS, visual analog scale; VDU, visual display units

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Competing interests

The authors declare that they have no competing interests.

Data sharing statement

No additional data are available.

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S 1: Characteristics of employees at baseline

Characteristics of employees	Intervention group (n=96)	Control group (n=79)	*p*-value
Age (year) – mean+/-SE	41.8±11.4	42.9±12.0	0.53
Male – number (%)	85 (88.5%)	77 (97.5%)	**0.04**
Body Mass Index (kg/m^{-2}) – mean+/-SE	24.6±0.3	24.6±0.3	0.9
Correctives lenses – number (%)			
Contact lenses	10 (10.42%)	18 (22.8%)	0.12
Multifocal lenses	28 (29.2%)	15 (19.0%)	
Other	20 (20.8%)	17 (21.5%)	
None	37 (38.5)	29 (36.7)	
Medical history of musculoskeletal disorders – number of workers (%)	15 (15.6%)	9 (11.4%)	0.51
Medications for musculoskeletal disorders – number of workers (%)	20 (20.8%)	11 (13.9%)	0.32
Physical activity level (IPAQ) – number (%)			
Intense	57 (58.8%)	53 (66.3%)	0.31
Moderate	33 (34.0%)	19 (23.8%)	
Low	7 (7.2%)	8 (10.0%)	

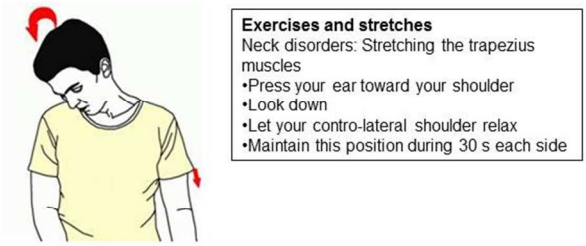
SE: standard error; IPAQ: international physical activity questionnaire

S 2: Characteristics of occupation at baseline

Characteristics of occupation	Intervention group (n=96)	Control group (n=79)	*p*-value
Hierarchy – number (%)			
Senior executive	14 (14.6%)	11 (13.9%)	1.0
Collaborator	82 (85.4%)	68 (86.1%)	
Duration of employment (year) – mean+/-SE	5.5±0.04	6.5±0.04	0.3
Work schedule – number (%)			
Full-time	92 (96.8%)	78 (98.7%)	0.6
Part-time	3 (3.2%)	1 (1.3%)	
Business travel (day/month) – mean+/-SE	2.0±0.01	2.8±0.02	0.08
Main task – number (%)			
Creative	51 (53.7%)	27 (35.1%)	0.16
Communications	12 (12.6%)	16 (20.8%)	
Word processing	16 (16.8%)	19 (24.7%)	
Data acquisition	6 (6.3%)	5 (6.5%)	
Data entry	10 (10.5%)	10 (13.0%)	
Screen time – number (%)			
0-2 hours/day	1 (1.1%)	3 (3.8%)	0.2
2-4 hours/day	12 (12.8%)	16 (20.3%)	
4-6 hours/day	31 (33.0%)	24 (30.4%)	
6-8 hours/day	36 (38.3%)	31 (39.2%)	
>8 hours/day	14 (14.9%	5 (6.3%)	
Workstation – number (%)			
Stationary computer	19 (20.0%)	11 (13.9%)	0.06
Laptop computer	66 (69.5%)	66 (83.5%)	
Both	10 (10.5%)	2 (2.5%)	
Sedentary time (minutes /day) – mean+/-SE	610.2±0.9	530.6±0.8	**0.0004**
Hospital and anxiety depression scale – mean+/-SE			
Anxiety (/21)	5.7±0.3	5.2±0.3	0.2
Depression (/21)	2.8±0.3	2.9±0.2	0.7
Stress at work (visual analog scale) – mean+/-SE	3.7±0.3	3.5±0.2	0.6
Number (%) of workers having to:			
Concentrate at work	89 (93.7%)	74 (93.7%)	0.6
Memorize at work	81 (85.3%)	66 (83.5%)	0.8

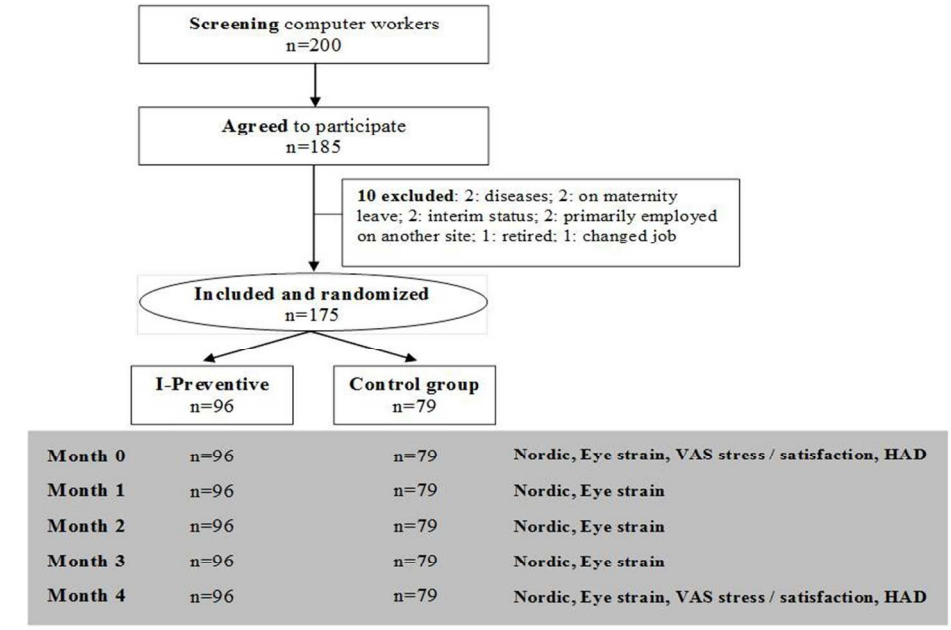
SE: standard error

Figure 1: Example of an exercise presented on the screen during prompted rest break (from I-Preventive)



254x190mm (96 x 96 DPI)

Figure 2: Flow Chart



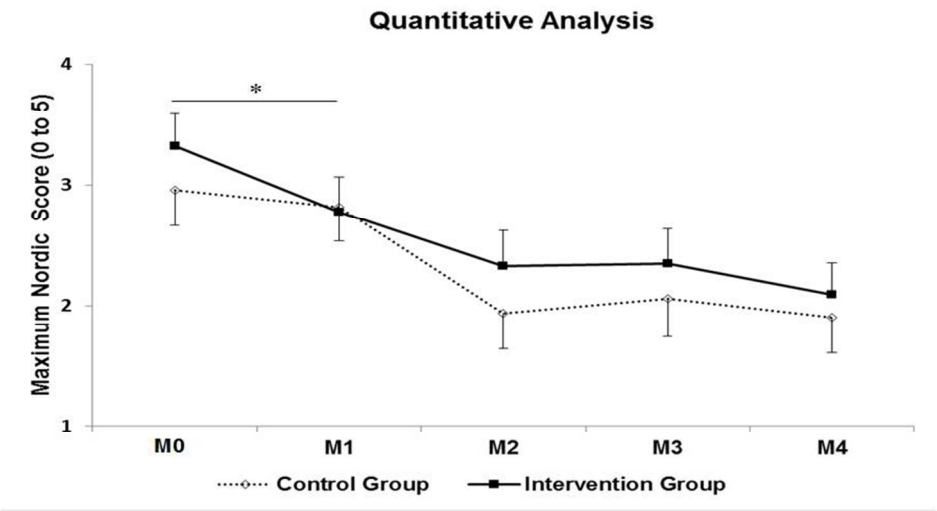
VAS: visual analog scale; HAD: hospital anxiety and depression scale

Flow Chart

254x190mm (96 x 96 DPI)

Figure 3: Longitudinal evolutions of maximum NORDIC score

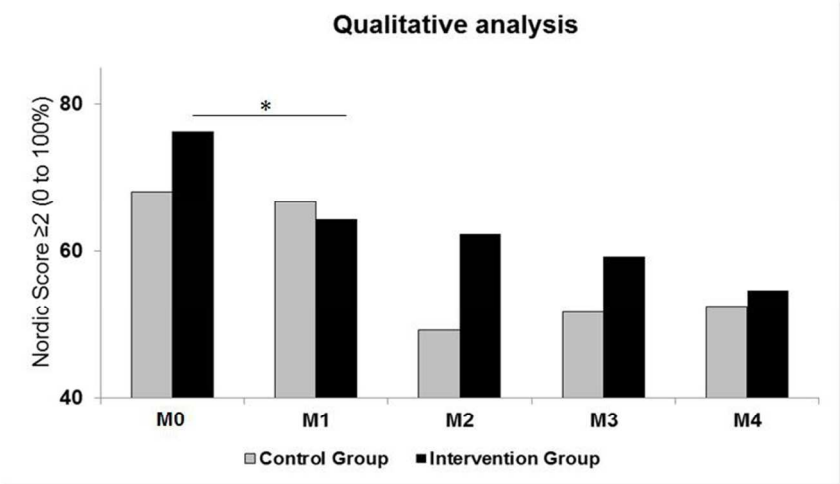
*: p <.05. The fixed group effects with longitudinal evolution of maximum NORDIC score emphasized a significant difference at Month 1 (M1) for the intervention group (p=0.038) and no difference for the control group (p=0.59)



254x190mm (96 x 96 DPI)

Figure 4: Percentage of body areas with a NORDIC score ≥2

*: p <.05. The fixed group effects with longitudinal evolution of NORDIC score ≥2 emphasized a significant difference at Month 1 (M1) for the intervention group (p=0.02) and no difference for the control group (p=0.57)



254x190mm (96 x 96 DPI)

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2
Background and objectives	2a	Scientific background and explanation of rationale	4
	2b	Specific objectives or hypotheses	5-6
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	6
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	NA
Participants	4a	Eligibility criteria for participants	6-7
	4b	Settings and locations where the data were collected	6
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	7
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	7-9
	6b	Any changes to trial outcomes after the trial commenced, with reasons	NA
Sample size	7a	How sample size was determined	9
	7b	When applicable, explanation of any interim analyses and stopping guidelines	NA
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	6
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	6
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	6
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	6
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	NA

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	NA
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	9-10
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	9-10
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	Figure 2-10
	13b	For each group, losses and exclusions after randomisation, together with reasons	Figure 2-10
Recruitment	14a	Dates defining the periods of recruitment and follow-up	6 and 8
	14b	Why the trial ended or was stopped	6
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	10 S1 and S2
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	10
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	11-12 Figure 3
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	11-12 Figure 4
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	12-13
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	NA
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	16
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	13-15
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	13-15
Other information			
Registration	23	Registration number and name of trial registry	6
Protocol	24	Where the full trial protocol can be accessed, if available	6
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	17

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

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Evaluation of "I-Preventive": a digital preventive tool for musculoskeletal disorders in computer workers; a pilot cluster randomized trial

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Evaluation of "I-Preventive": a digital preventive tool for musculoskeletal disorders in computer workers; a pilot cluster randomized trial

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Abstract

Objectives: I-Preventive is a digital preventive tool for musculoskeletal disorders (MSDs) in computer workers. We sought to determine its impact on pain in computer workers with upper-limb MSDs and visual discomfort.

Methods: We conducted a pilot cluster randomized trial in two different sites of a tire factory in France. We randomized 200 employees to either an intervention group (I-preventive) or control group, each comprising symptomatic and asymptomatic employees. The workers were followed-up for 5 months. The main outcome was overall recovery from complaints following one month's intervention based on Nordic-style and eyestrain questionnaires.

Results: We included 185/200 workers: 96 in the intervention group (mean age: 41.8±1.4 years old; 88.5% males) and 79 in the control group (mean age: 42.9±12.0 years old; 94.5% males). The most painful areas (numerical scale ≥2) were the neck (40.0%), upper back (18.8%), and shoulders (15.7%). For the most painful anatomical area, the Nordic score significantly decreased after 1 month in the intervention group (p=0.038); no change was observed in the control group (p=0.59). After 1 month's use, the intervention group reported less pain in the painful area and less visual discomfort symptoms (p=0.02). Adherence to the I-preventive program was 60%.

Conclusion: I-Preventive is effective in the short-term on MSD pain and visual discomfort by promoting active breaks and eyestrain treatment. This easy-to-use digital tool allows each worker to focus on areas of their choice *via* personalized, easy exercises that can be performed in the workplace.

Key Words: musculoskeletal diseases, eyestrain, work, visual display units, stretching, exercise, software

Strengths and limitations of this study

- Some software programs were built to promote frequent breaks at work for visual display unit users but only very few tools were evaluated with a high level of proof.
- The novelty of the I-Preventive strategy is its implementation of frequent short daily active breaks promoted by a software program, which can only be achieved within a prevention-oriented organizational culture.
- The I-Preventive software program is particularly effective in the short-term due to its individualized and personalized form, allowing workers to focus on areas of their choice by offering exercises that are easily performed in the workplace.
- Despite this digital tool being easy to use, adherence decreased over time, and its favorable impact was not maintained over the long term.
- Future studies should comprise objective measures of physical performance and effectiveness at work in order to establish cost-effectiveness benefits based on economic analyses.

Introduction

Musculoskeletal disorders (MSDs) in the working population currently represent one of the most worrying work-related health issues[1], with considerable economic burden on society.[2] There is, however, still no consensus on their precise definition. MSD is a broad term encompassing a range of degenerative, dysfunctional, and inflammatory conditions affecting the musculoskeletal system.[1.1] These heterogeneous definitions can make drawing comparisons between studies difficult. Although the prevalence rates of MSD vary widely depending on the body part considered and tools used for symptom assessment, they can exceed 30%.[3 4] When considering a global approach, multisite symptoms were predominant (33-66% of workers) over those strictly confined to a specific anatomical site (15-30% of workers).[4]

The major risk factors for MSD are repetitive movements, high muscular strength demands, awkward or extreme positions, rapid work pace, extreme temperatures, insufficient recovery time, mechanical pressure, and segmental vibrations.[5] Additional workplace-related risk factors include psychosocial factors, such as high demands and low decision latitude.[6.7] In particular, MSDs are the most prevalent disorders among sedentary workers, especially those using visual display units (VDU).[8] The most frequent musculoskeletal symptoms occur in the neck and shoulder area, with a prevalence of up to 62% reported in VDU workers.[9]

Musculoskeletal symptoms of VDU users have multi-factorial etiologies, such as non-neutral wrist, arm, and neck postures, work station design, and duration of VDU exposure, as well as perceived job strain with low decision latitude and high workload.[10 11] Long-duration computer work without breaks has also been related to eye injury, as duration of mouse use has been to neck and upper extremity symptoms.[12]

We are therefore convinced that appropriate MSD-preventive tools for VDU workers are urgently required. These tools must be clinically evaluated by providing evidence-based

medical data. Interventions aimed at reducing MSDs in VDU workers should be aimed at both physical/ergonomic and organizational/psychosocial work factors, and must be supported by managers in order to ensure worker adhesion to the intervention.[9] The majority of strategies have focused on new workstation design [13], yet their effectiveness remains highly questionable. Strategies could be more effective if they were to implement changes in the temporal pattern of the work task, such as supplementary rest breaks allowing for periods of recovery from the monotonous load.[14] The effect of exercise on MSD symptoms has recently been demonstrated in workers.[15] In addition to exercise, rest breaks, and especially frequent "microbreak",[16] have been shown to reduce discomfort, eyestrain, fatigue, and mood disturbances, in addition to improving keystroke speed and accuracy. Some software programs were built to promote frequent breaks at work for VDU users. These breaks can be active, with stretching exercises during working days. However, only very few tools were evaluated with a high level of proof (Wellnomics® Breaks).[17] Within a large French tire factory, a taskforce was convened including physicians, nurses, prevention engineers, and a sports teacher, aiming to evaluate an online tool called "I-Preventive", which promotes active breaks with stretching exercises.

Our principal aim was thus to estimate the effects of I-preventive on MSDs and visual discomfort.

Methods

Design

A pilot cluster randomized trial was proposed within a tire factory in France. This study aimed to measure the impact of I-Preventive on MSD symptoms and therefore define the optimal effect sizes for calculating the sample size required for a larger cluster-randomized controlled trial. While we did not focus on a putative cluster effect, in order to maintain a suitable methodology, an independent statistician conducted the randomization of four

participating departments using table random. The workers were randomized into an intervention group (I-Preventive) and control group, with each containing participants with MSDs. Workers located on the same floor or in the same building were assigned to the same group in order to avoid contamination bias, to maintain blinding and enhance adherence to the program within the intervention group, as well as to implement the study in a regular work environment. Researchers were composed of two occupational physicians (CL, GG). GG was in charge of selection and inclusion. CL was in charge of the data treatment under blind conditions to the treatment group. This study was conducted from June to October, 2014. Measurements were made with repeated data requests (Figure 1). The study was approved by the Sud-Est 6 medical ethics committee of the University Hospital of Clermont-Ferrand, France (ClinicalTrial.gov identifier: NCT02350244). All employees corresponding to the inclusion criteria received a summary of the study, which was considered a non-opposition form. This non-pharmacological trial was designed in accordance with the Consolidated Standards of Reporting Trials statement (CONSORT).[18]

Participants

The participating workers were recruited from a potential 200 employees of the research departments. The inclusion criteria required participants to be employees aged 18-65 years old, completing at least 5 hours of VDU work per day, receiving no treatment for rheumatic or neurological diseases, undergoing no changes in VDU/workstation apparatus, having taken no sick leave in the previous month, and exhibiting no behavioral/learning disorders. Only administrative staff and no blue-collar workers were thus included.

Intervention

Workers in the intervention group received an activation code to download the software program (I-Preventive, *www.i-prentive.com*) on their VDU. I-Preventive promoted active breaks *via* an individualized computer application. It allowed workers to focus on body

regions of their choice, offering high flexibility. After selecting the body part, I-Preventive asked about symptoms and suggested appropriate exercises. Workers could follow the suggested personalized exercises or use the random mode. At regular intervals, a visual signal on the screen prompted VDU workers to take active breaks. The visual signal described short individualized exercises of no more than one and a half minutes. The exercises were easy to perform and most could be carried out while seated without needing specific equipment (Figure 2).

Step 1: Select the body part, the system asks the operator to associate a symptom and suggests the appropriate exercises.

Step 2: Select the usage either by following the individualized default form or using the random mode.

Step 3: Participants are prompted by a signal on the screen also called « the health bar » to take a rest break every two hours. They are stimulated to perform physical exercises (lasting 30 seconds to one and a half minute each) at the start of each rest break. Users can program one to four active breaks daily.

During the remaining period of the rest break the computer was not blocked, and the subjects could delay active break later by clicking on the button « later ». Generally, workers postponed breaks when they were in meetings on average once or twice a day. The software offered worksheets that could be downloaded, printed at the workplace and used as information tools. These worksheets were composed of physical exercises for each body part. Then, employees could realize exercises out of daily breaks proposed by the computer and out of the office. The intervention lasted 4 months.

The control group received usual healthcare with the occupational physician.

Baseline assessments

All participants (intervention and control groups) completed the same questionnaires.

MSDs were evaluated by the Nordic-style questionnaire, validated in 2007 as a useful tool for monitoring work-related MSDs, especially if respondents included a numerical rating scale pertaining to symptom severity.[19] It is derived from the original Nordic questionnaire published in 1987 that was then translated into French in 1994.[20] The Nordic questionnaire included a numerical pain scale ranging from 0-10 for each anatomical region.

Eyestrain assessment covered various symptoms like headache, blurred vision or eye stinging, by means of a horizontal numerical scale from 0-10,[21] commonly used by the French national institute of research and prevention (INRS).

Global psychological status was evaluated on the hospital anxiety and depression scale (HAD).[22] The HAD is a 14-item self-report measure that was specifically developed to assess anxiety and depression. It is considered to be an effective means of screening for anxiety and depression and is widely used. It has two subscales, one assessing anxiety (HAD-A) and the other assessing depression (HAD-D). The scores for each subscale range from 0 to 21. Psychosocial work characteristics were measured using a horizontal visual analog scale (VAS) for both stress [23,24] and satisfaction at work [25]. This test assesses the perceived stress level of individuals at work, on a horizontal, non-calibrated line of 100 mm, ranging from very low (0) to very high (100).

Physical activity and sedentary behavior were measured by means of the international physical activity questionnaire (IPAQ).[26,27]

Sociodemographic characteristics (gender, age, work position, etc.) were also recorded.

Follow-up assessments

All baseline assessments were repeated at 1 month (M1), 2 months (M2), 3 months (M3), and 4 months (M4), with the exception of VAS stress/satisfaction and HAD, which were not measured at M2 and M3 (Figure 2). Sociodemographic characteristics were only compiled at baseline.

To verify whether the participants performed the exercises or not (adherence), we had to rely on their monthly individual reports at M1, M2, M3, and M4.

At M4, the intervention group was asked to give feedback on the software, recommended breaks, and exercises.

Outcomes

The main outcome was the overall decrease in complaints at M1, assessed by means of the Nordic-style and eyestrain questionnaires, in addition to the change in number of asymptomatic workers (numerical value <2 on the Nordic-style questionnaire).

Secondary outcomes included long-term follow-up of the Nordic-style and eyestrain questionnaires at M2, M3, and M4; changes in global psychological status (HAD) between M0 and M4; evolution of physical activity and sedentary behavior; number of sick-leave days.

Adherence to the program was assessed at M1, M2, M3, and M4 in order to investigate a dose-response relationship, using a self-reported questionnaire indicating a frequency of use from the following options: less than once a week, a few times a week, once every day, and several times every day.

Statistical considerations

According to literature, it appeared difficult to estimate an optimal sample size for the main endpoint of this study to assess software promoting active breaks using exercises with the aim

of treating MSD and visual discomfort in VDU workers. Sample size has been estimated according to Cohen's recommendations [28] who has defined effect-size bounds as: small (ES: 0.2), medium (ES: 0.5) and large (ES: 0.8, "grossly perceptible and therefore large"). We calculated that 64 workers per group would enable an effect size equal to 0.5 for a type I error α=0.05 (two-tailed) and statistical power of 80%, which corresponds to a minimal difference in terms of primary endpoint NORDIC score equals 1.5 points (for a standard-deviation at 3). Considering possible loss to follow-up (rate fixed at 25%), we finally chose to include a minimum of 80 VDU workers per group. Statistical analysis was performed using Stata software, Version 13 (StataCorp, College Station, TX, U.S.). The tests were two-sided, with a Type I error set at α=0.05. Baseline characteristics were presented as mean±standard error (SE)or median [interquartile range] according to statistical distribution for continuous data, and the number of workers and associated percentages for categorical parameters. Comparisons among independent groups (workers accessing I-Preventive or not) were performed by Student's t-test, or by the Mann-Whitney U test if t-test conditions could not be respected (homoscedasticity analyzed by the Fisher-Snedecor distribution). Comparisons between qualitative parameters of the independent groups were performed by Chi-squared test or, if necessary, Fisher's exact test. For the evolution of the longitudinal NORDIC study (and visual discomfort score), mixed models (the linear models for the NORDIC score considered a quantitative or generalized linear for the proportion of VDU workers with NORDIC scores above a given threshold, in line with the literature [19]) were proposed in order to take into account the difference between and within individual variability (random effect) while studying the fixed group effects, time, and interaction. The normality of residuals was assessed and gender, age, site, and original pain or discomfort were studied in previous models as covariates (fixed effects). Workers' frequency of I-Preventive use (before or after holidays) was also recorded, particularly in the context of a specific intra-group analysis of

workers who had access to the I-Preventive software. Finally, this was complemented by analyses that were situation-matched to the parameters collected at only two time points (M0 and M4 for HAD, with the usual tests applied: Student's paired t-test or the Wilcoxon signed-rank test for quantitative parameters and Stuart-Maxwell test for categorical variables.

Results

Participants

Among the 200 employees invited, 185 (93%) agreed to participate. Of these, 11 (6%) were excluded from the analysis due to disease, maternity leave, interim status, retirement, and change in job. We thus included 175 employees, 96 assigned to the intervention group and 79 to the control group (Figure 2). At *baseline*, the groups did not differ in terms of the percentage of workers suffering from each painful anatomical part (p=0.62), nor for the maximal pain assessed by the NORDIC questionnaire (p=0.2). They differ at baseline, with the percentage of females and sedentary time, with the control group including less females (n=2, 2.5% *vs.,* 11.5%, p=0.04) and exhibiting a lower level of sedentary lifestyle (530.6±0.8 *vs.*, 610.2±0.9 minutes/day, p=0.04) (Supplementary Table 1 and Supplementary Table 2).

Digital tool acceptability

Exercises were carried out by 58% of participants in random mode and by 42% following the individualized software suggestions. The primary anatomical parts exercised were the neck (74.4%), eyes (51.3%), hands (41.9%), elbows (37.8%), lower back (36.5%), and shoulders (35.1%). At M4, overall satisfaction with the digital tool was 43%, with 90% of participants reporting the tool was simple to use or the exercises easy to perform. However, 35% of employees had some technical difficulties in using the tool, 39% experiencing concentration problems and 64% problems coordinating the active breaks with their work. We consider that less than 25% of the employees post-poned the breaks. Adherence decreased throughout the intervention, from 60% of employees using I-preventive every day (once or several times) at M1 to 37% at M4 ($p < .01$). Overall, 40% of participants declared feeling better with active breaks when working on the computer.

Primary outcomes

The most painful anatomical parts (numerical value ≥2) were the neck (40.1%), lower back (35.7%), upper back (18.8%), and shoulder (11.7%). The majority reported one or two painful locations (62.7%), 17.9% reported three locations, and 8.9% reported four.

In *longitudinal follow-up* with *quantitative analysis*, the maximum NORDIC score did not differ between groups at M1 using analysis of covariance (ANCOVA) ($p=0.44$). In a complete multivariate model and after adjustment for NORDIC score at baseline, sedentary time, memorizing, and maximum NORDIC score tended to decrease, though not significantly so ($p=0.18$). However, on studying the fixed-group effects based on a longitudinal evolution of maximum NORDIC score, we observed a significant difference at M1 for the intervention group ($p=0.038$) *vs.* baseline and no difference for the control group ($p=0.59$) (Figure 3).

In *longitudinal follow-up* with *qualitative analysis*, the percentage of body parts with a NORDIC score ≥2 did not differ at M1 using random-effect logistic model analysis,

compared with the control group (p=0.18). For longitudinal analysis in intra-groups, this parameter had significantly decreased at M1 in the intervention group (p=0.02), *versus* the control group (p=0.57) (Figure 4).

For both the quantitative and qualitative analyses, no significant difference was found between the groups at the end of the study, even though a trend of decrease at M2 was observed (p <.01).

Secondary outcomes

At baseline, eyestrain did not differ between groups. The symptoms were loss of eyesight (55.2% of participants), eye stinging (48.8%), glare (48.8%), blurred vision (44.2%), headache (34.8%), and eye irritation (23.2%). At M1, visual discomfort significantly decreased for both the quantitative (maximum visual score) and qualitative longitudinal analyses (visual symptoms ≥2) in the intervention group (p=0.025 and p=0.02, respectively), with no change observed in the control group (p=0.65 and p=1.0, respectively). No significant difference was found at the end of the study.

The intervention program did not exhibit significant impact on work stress, work satisfaction, anxiety, or depression symptoms, and no links were established between stress, anxiety or depression and MSD or ocular symptoms.

We recorded four sick leaves in the intervention group corresponding to psychiatric or surgical diseases, with none linked with MSD. There were no sick leaves within the control group.

Sub-group analysis

On analyzing the sub-groups, the longitudinal evolution of the NORDIC score was more effective for employees using the individualized software form (p=0.009). Those who were happy to use I-Preventive tended to have less painful localizations, reporting a pain score <2 (p=0.12). Baseline NORDIC scores (< or ≥2) did not influence the benefits of intervention.

Adherence to I-Preventive was not linked to greater benefits in MSD symptoms, evaluated by the NORDIC questionnaire, even following adjustment for age and gender.

Discussion

Main findings

Our pilot cluster randomized trial demonstrated the potential of active breaks to reduce MSD symptoms and eyestrain. The I-preventive software program was shown to be particularly effective in the short-term in its individualized and personalized form, allowing workers to focus on areas of their choice by offering exercises that are easy to perform at the workplace. However, despite this digital tool being easy to use, adherence decreased over time, so that this favorable impact was not maintained over the long term.

Validated methods for the prevention of MSD

Prevention of MSD should be based on an integrative approach combining ergonomics and physical activity interventions.[13] In ergonomics, no clear positive impact has been demonstrated by single intervention programs, such as work station adjustments (technical), rest breaks (organizational) or ergonomic training (behavioral) on work-related MSD. However, when these specific interventions were included in a combined approach, they became more effective.[13] Physical activity interventions at the workplace demonstrated benefits on computer-worker MSDs, consisting of either 20-30-min training sessions two or three times a week[29] or short daily active breaks,[30] in addition to either stretching and joint mobilization exercises or strength training and dynamic endurance training.[31] These studies involved a coach or physical therapist to motivate the participants.[31] Training sessions appear to have more pronounced long-term effects than short daily active breaks, in accordance with our study findings[31]. Ipreventive software program is particularly effective at one month but

has no long-term effects. Conflicting results reported in the literature could be explained by the high risk of bias from the studies due to an unknown random allocation procedure, as well as insufficient motivation to exercise or lack of intention-to-treat analyses.[32] The novelty of the I-Preventive strategy is its implementation of frequent short daily active breaks promoted by a software program

A novel digital tool for the prevention of MSD

Computer usage and sedentary behavior at the workplace has increased dramatically over the past decade[33]. Office workers thus remain in the same posture for longer, accompanied by long periods of keyboard usage, which can cause and aggravate MSDs. Paradoxically, several software programs have been implemented to promote exercise at the workplace and reduce MSD. Despite the promotion of exercise through software, however, programs have been largely developed for chronic diseases like type two diabetes,[34] and these digital strategies were rarely implemented at the workplace for health outcomes in general[35] and especially not for preventing MSD.[14] As for the use of a computerized decision support system for primary and secondary prevention of work-related MSD disability, only one study tried to improve MSD prevention by analyzing the ergonomic process through self-reported questionnaires from a software tool.[36] Moreover, only two studies used a software program to specifically reduce MSD. The results from the short-term pilot study conducted on a low sample size supported the theory that this type of exercise reminder software programs may help to reduce perceived pain among office workers.[37] In accordance with our findings, the use of a software program encouraging workers to take regular breaks has been reported elsewhere to contribute to perceived recovery from neck and upper-limb complaints.[17] Nevertheless, our study was not designed to assess the specificity of breaks or exercise in MSD prevention[17], and long-term studies involving more subjects should now be conducted so as to describe the effects of these programs and underlying mechanisms.

General health effects of our intervention

Overall, the neck, shoulders, and upper and lower back were the most affected regions among our computer users, in line with the literature.[32] Moreover, computer-related visual and ocular symptoms are the most frequently occurring health problems in people who spend a large proportion of their working day looking at a computer screen.[38] Given the high prevalence of these symptoms,[39] it is likely that all VDU workers will at some point need eye examinations in order to assess symptoms associated with VDU use. Furthermore, visual and musculoskeletal discomfort have been intrinsically linked together.[40] To our knowledge, our study was the first to simultaneously evaluate and reduce MSDs in combination with ocular symptoms. [4142]

Limitations

Our study had some limitations. One could argue that the inclusion number was low, yet the sample size was relatively large compared with that of other pilot studies, and the percentage of participants who agreed to participate was exceptional (>90%),[43] with none lost to follow-up. This good representation of computer workers thus reduced potential bias and allowed us to generalize results for other services. The protocol was carried out in a high-demand working environment, and thus may easily be translated to other areas.. Also, the decreasing adherence throughout the study could have been caused by the summer holidays falling between M1 and M2, or a decrease in job demand for those who did not go on holiday, which may have lowered the impact of our intervention on MSD. In addition, some found it impossible to adapt active breaks to their specific working schedules, which, along with software defects, also likely contributed to the decreasing adherence. Finally, the software was not designed to evaluate the objective measure of adherence to the program, such as number of connections or amount of time spent on the tool. Furthermore, physical symptoms were not clinically assessed by a physician however, subjective scales have been validated and are commonly used both in routine practice and research.[19] Future studies should comprise objective measures of physical performance and effectiveness at work in order to establish cost-effectiveness benefits based on economic analyses.

Conclusion

Our pilot feasibility study demonstrated the potential of active breaks for preventing MSDs and ocular symptoms. The I-Preventive software program is particularly effective in the short-term due to its individualized and personalized form, allowing workers to focus on areas of their choice by offering exercises that are easily performed in the workplace. However, despite this digital tool being easy to use, adherence decreased over time, and its favorable impact was not maintained over the long term.

Abbreviations HAD, hospital anxiety and depression; IPAQ, international physical activity questionnaire; MSDs, musculoskeletal disorders; VAS, visual analog scale; VDU, visual display units

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Contributors BP performed the majority of the statistical analysis and contributed to the interpretation of data and writing the support. EC, GG, CM, CL supervised the conduct of the control study. CL, GG, CM, contributed to data collection. CL, EC and FD contributed to interpretation of data and writing the report. All authors have contributed to the revision of the manuscript and have approved the final version.

Competing interests

There is no conflict of interest.

Data sharing statement

No additional data are available.

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Figure 1: Example of an exercise presented on the screen during prompted rest break (from I-Preventive)

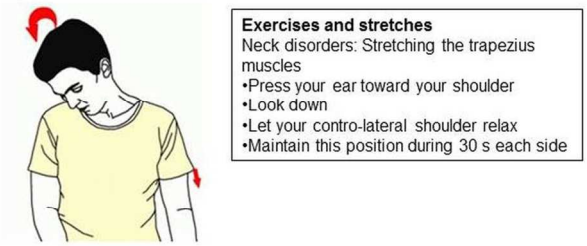

Figure 1

119x90mm (300 x 300 DPI)

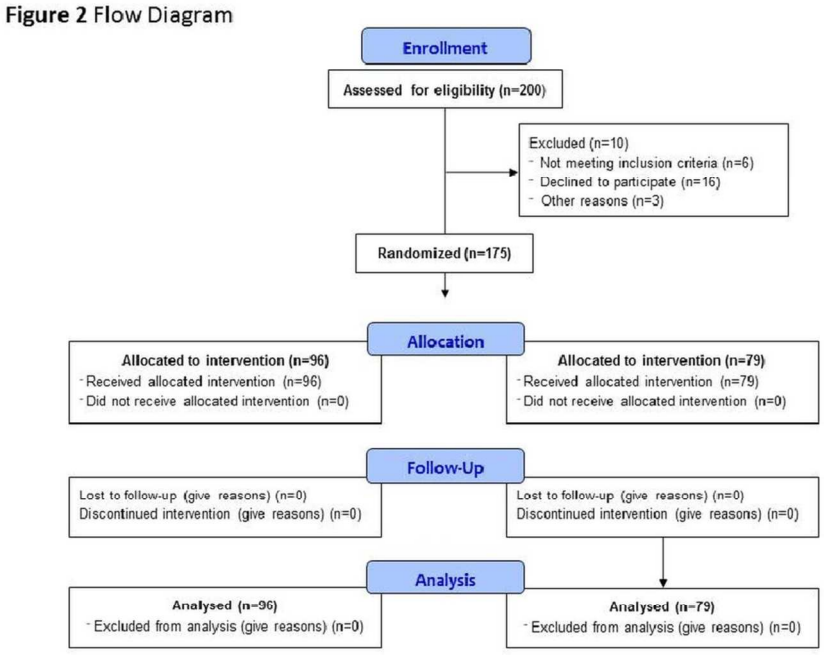

Figure 2

119x90mm (300 x 300 DPI)

Figure 3: Longitudinal evolutions of maximum NORDIC score

*: p <.05. The fixed group effects with longitudinal evolution of maximum NORDIC score emphasized a significant difference at Month 1 (M1) for the intervention group (p=0.038) and no difference for the control group (p=0.59).

The covariates were chosen according to univariate results and clinical relevance: age, site, and baseline pain or discomfort.

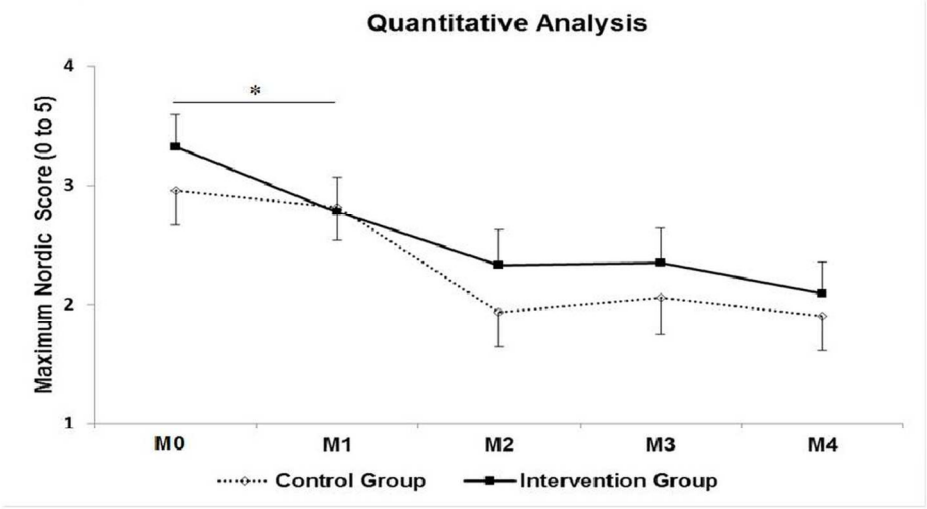

Figure 3

119x90mm (300 x 300 DPI)

Figure 4: Percentage of body areas with a NORDIC score ≥2

*: p <.05. The fixed group effects with longitudinal evolution of NORDIC score ≥2 emphasized a significant difference at Month 1 (M1) for the intervention group (p=0.02) and no difference for the control group (p=0.57).

The covariates were chosen according to univariate results and clinical relevance: age, site, and baseline pain or discomfort.

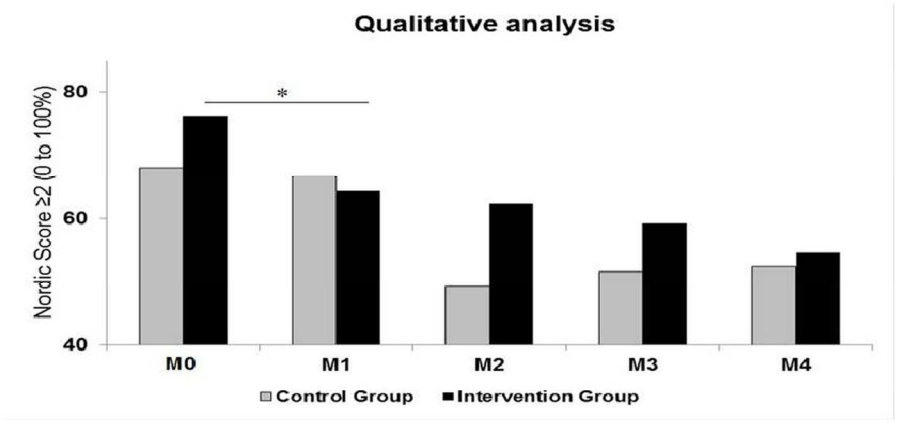

Figure 4

119x90mm (300 x 300 DPI)

Supplementary Table 1: Characteristics of employees at baseline

Characteristics of employees	Intervention group (n=96)	Control group (n=79)	*p*-value
Age (year) – mean+/-SE	41.8±11.4	42.9±12.0	0.53
Male – number (%)	85 (88.5%)	77 (97.5%)	**0.04**
Body Mass Index (kg/m^{-2}) – mean+/-SE	24.6±0.3	24.6±0.3	0.9
Correctives lenses – number (%)			
Contact lenses	10 (10.42%)	18 (22.8%)	0.12
Multifocal lenses	28 (29.2%)	15 (19.0%)	
Other	20 (20.8%)	17 (21.5%)	
None	37 (38.5)	29 (36.7)	
Medical history of musculoskeletal disorders – number of workers (%)	15 (15.6%)	9 (11.4%)	0.51
Medications for musculoskeletal disorders – number of workers (%)	20 (20.8%)	11 (13.9%)	0.32
NORDIC Questionnaire	3.3±0.3	3.0±0.3	0.2
Hospital and anxiety depression scale mean+/-SE			
Anxiety (/21)	5.7±0.3	5.2±0.3	0.2
Depression (/21)	2.8±0.3	2.9±0.2	0.7
Stress at work (visual analog scale) mean+/-SE	3.7±0.3	3.5±0.2	0.6
Satisfaction at work (visual analog scale) mean+/-SE	6.7±0.3	6.5±0.2	0.4
Physical activity level (IPAQ) – number (%)			
Intense	57 (58.8%)	53 (66.3%)	0.31
Moderate	33 (34.0%)	19 (23.8%)	
Low	7 (7.2%)	8 (10.0%)	

SE: standard error; IPAQ: international physical activity questionnaire

Supplementary Table 2: Characteristics of occupation at baseline

Characteristics of occupation	Intervention group (n=96)	Control group (n=79)	*p*-value
Hierarchy – number (%)			
Senior executive	14 (14.6%)	11 (13.9%)	1.0
Collaborator	82 (85.4%)	68 (86.1%)	
Duration of employment (year) – mean+/-SE	5.5±0.04	6.5±0.04	0.3
Work schedule – number (%)			
Full-time	92 (96.8%)	78 (98.7%)	0.6
Part-time	3 (3.2%)	1 (1.3%)	
Business travel (day/month) – mean+/-SE	2.0±0.01	2.8±0.02	0.08
Main task – number (%)			
Creative	51 (53.7%)	27 (35.1%)	0.16
Communications	12 (12.6%)	16 (20.8%)	
Word processing	16 (16.8%)	19 (24.7%)	
Data acquisition	6 (6.3%)	5 (6.5%)	
Data entry	10 (10.5%)	10 (13.0%)	
Screen time – number (%)			
0-2 hours/day	1 (1.1%)	3 (3.8%)	0.2
2-4 hours/day	12 (12.8%)	16 (20.3%)	
4-6 hours/day	31 (33.0%)	24 (30.4%)	
6-8 hours/day	36 (38.3%)	31 (39.2%)	
>8 hours/day	14 (14.9%	5 (6.3%)	
Workstation – number (%)			
Stationary computer	19 (20.0%)	11 (13.9%)	0.06
Laptop computer	66 (69.5%)	66 (83.5%)	
Both	10 (10.5%)	2 (2.5%)	
Sedentary time (minutes /day) – mean+/-SE	610.2±0.9	530.6±0.8	**0.0004**
Number (%) of workers having to:			
Concentrate at work	89 (93.7%)	74 (93.7%)	0.6
Memorize at work	81 (85.3%)	66 (83.5%)	0.8

SE: standard error

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2
Background and objectives	2a	Scientific background and explanation of rationale	4
	2b	Specific objectives or hypotheses	5-6
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	6
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	NA
Participants	4a	Eligibility criteria for participants	6-7
	4b	Settings and locations where the data were collected	6
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	7
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	7-9
	6b	Any changes to trial outcomes after the trial commenced, with reasons	NA
Sample size	7a	How sample size was determined	9
	7b	When applicable, explanation of any interim analyses and stopping guidelines	NA
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	6
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	6
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	6
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	6
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	NA

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	NA
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	9-10
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	9-10
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	Figure 2-10
	13b	For each group, losses and exclusions after randomisation, together with reasons	Figure 2-10
Recruitment	14a	Dates defining the periods of recruitment and follow-up	6 and 8
	14b	Why the trial ended or was stopped	6
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	10 S1 and S2
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	10
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	11-12 Figure 3
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	11-12 Figure 4
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	12-13
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	NA
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	16
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	13-15
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	13-15
Other information			
Registration	23	Registration number and name of trial registry	6
Protocol	24	Where the full trial protocol can be accessed, if available	6
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	17

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

BMJ Open

Evaluation of "I-Preventive": a digital preventive tool for musculoskeletal disorders in computer workers; a pilot cluster randomized trial

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Evaluation of "I-Preventive": a digital preventive tool for musculoskeletal disorders in computer workers; a pilot cluster randomized trial

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Abstract

Objectives: I-Preventive is a digital preventive tool for musculoskeletal disorders (MSDs) in computer workers. We sought to determine its impact on pain in computer workers with upper-limb MSDs and visual discomfort.

Methods: We conducted a pilot cluster randomized trial in two different sites of a tire factory in France. We randomized 200 employees to either an intervention group (I-preventive) or control group, each comprising symptomatic and asymptomatic employees. The workers were followed-up for 5 months. The main outcome was overall recovery from complaints following one month's intervention based on Nordic-style and eyestrain questionnaires.

Results: We included 185/200 workers: 96 in the intervention group (mean age: 41.8±1.4 years old; 88.5% males) and 79 in the control group (mean age: 42.9±12.0 years old; 94.5% males). The most painful areas (numerical scale ≥2) were the neck (40.0%), upper back (18.8%), and shoulders (15.7%). For the most painful anatomical area, the Nordic score significantly decreased after 1 month in the intervention group (p=0.038); no change was observed in the control group (p=0.59). After 1 month's use, the intervention group reported less pain in the painful area and less visual discomfort symptoms (p=0.02). Adherence to the I-preventive program was 60%.

Conclusion: I-Preventive is effective in the short-term on musculoskeletal complaints and visual discomfort by promoting active breaks and eyestrain treatment. This easy-to-use digital tool allows each worker to focus on areas of their choice *via* personalized, easy exercises that can be performed in the workplace.

Key Words: musculoskeletal diseases, eyestrain, work, visual display units, stretching, exercise, software

Strengths and limitations of this study

- Some software programs were built to promote frequent breaks at work for visual display unit users but only very few tools were evaluated with a high level of proof.
- The novelty of the I-Preventive strategy is its implementation of frequent short daily active breaks promoted by a software program, which can only be achieved within a prevention-oriented organizational culture.
- The I-Preventive software program is particularly effective in the short-term due to its individualized and personalized form, allowing workers to focus on areas of their choice by offering exercises that are easily performed in the workplace.
- Despite this digital tool being easy to use, adherence decreased over time, and its favorable impact was not maintained over the long term.
- Future studies should comprise objective measures of physical performance and effectiveness at work in order to establish cost-effectiveness benefits based on economic analyses.

Introduction

Musculoskeletal disorders (MSDs) in the working population currently represent one of the most worrying work-related health issues[1], with considerable economic burden on society.[2] There is, however, still no consensus on their precise definition. MSD is a broad term encompassing a range of degenerative, dysfunctional, and inflammatory conditions affecting the musculoskeletal system.[1].[1] These heterogeneous definitions can make drawing comparisons between studies difficult. Although the prevalence rates of MSD vary widely depending on the body part considered and tools used for symptom assessment, they can exceed 30%.[3] [4] When considering a global approach, multisite symptoms were predominant (33-66% of workers) over those strictly confined to a specific anatomical site (15-30% of workers).[4]

The major risk factors for MSD are repetitive movements, high muscular strength demands, awkward or extreme positions, rapid work pace, extreme temperatures, insufficient recovery time, mechanical pressure, and segmental vibrations.[5] Additional workplace-related risk factors include psychosocial factors, such as high demands and low decision latitude.[6].[7] In particular, MSDs are the most prevalent disorders among sedentary workers, especially those using visual display units (VDU).[8] The most frequent musculoskeletal symptoms occur in the neck and shoulder area, with a prevalence of up to 62% reported in VDU workers.[9]

Musculoskeletal symptoms of VDU users have multi-factorial etiologies, such as non-neutral wrist, arm, and neck postures, work station design, and duration of VDU exposure, as well as perceived job strain with low decision latitude and high workload.[10] [11] Long-duration computer work without breaks has also been related to eye injury, as duration of mouse use has been to neck and upper extremity symptoms.[12]

We are therefore convinced that appropriate MSD-preventive tools for VDU workers are urgently required. These tools must be clinically evaluated by providing evidence-based

medical data. Interventions aimed at reducing MSDs in VDU workers should be aimed at both physical/ergonomic and organizational/psychosocial work factors, and must be supported by managers in order to ensure worker adhesion to the intervention.[9] The majority of strategies have focused on new workstation design [13], yet their effectiveness remains highly questionable. Strategies could be more effective if they were to implement changes in the temporal pattern of the work task, such as supplementary rest breaks allowing for periods of recovery from the monotonous load.[14] The effect of exercise on MSD symptoms has recently been demonstrated in workers.[15] In addition to exercise, rest breaks, and especially frequent "microbreak",[16] have been shown to reduce discomfort, eyestrain, fatigue, and mood disturbances, in addition to improving keystroke speed and accuracy. Some software programs were built to promote frequent breaks at work for VDU users. These breaks can be active, with stretching exercises during working days. However, only very few tools were evaluated with a high level of proof (Wellnomics® Breaks).[17] Within a large French tire factory, a taskforce was convened including physicians, nurses, prevention engineers, and a sports teacher, aiming to evaluate an online tool called "I-Preventive", which promotes active breaks with stretching exercises.

Our principal aim was thus to estimate the effects of I-preventive on MSDs and visual discomfort.

Methods

Design

A pilot cluster randomized trial was proposed within a tire factory in France. This study aimed to measure the impact of I-Preventive on MSD symptoms and therefore define the optimal effect sizes for calculating the sample size required for a larger cluster-randomized controlled trial. While we did not focus on a putative cluster effect, in order to maintain a

suitable methodology, an independent statistician conducted the randomization of four participating departments using table random. The workers were randomized into an intervention group (I-Preventive) and control group, with each containing participants with MSDs. Workers located on the same floor or in the same building were assigned to the same group in order to avoid contamination bias, to maintain blinding and enhance adherence to the program within the intervention group, as well as to implement the study in a regular work environment. Researchers were composed of two occupational physicians (CL, GG). GG was in charge of selection and inclusion. CL was in charge of the data treatment under blind conditions to the treatment group. This study was conducted from June to October, 2014. Measurements were made with repeated data requests . The study was approved by the Sud-Est 6 medical ethics committee of the University Hospital of Clermont-Ferrand, France (IRB00008526, ClinicalTrial.gov identifier: NCT02350244). All employees corresponding to the inclusion criteria received a summary of the study, which was considered a non-opposition form. This non-pharmacological trial was designed in accordance with the Consolidated Standards of Reporting Trials statement (CONSORT).[18]

Participants

The participating workers were recruited from a potential 200 employees of the research departments. The inclusion criteria required participants to be employees aged 18-65 years old, completing at least 5 hours of VDU work per day, receiving no treatment for rheumatic or neurological diseases, undergoing no changes in VDU/workstation apparatus, having taken no sick leave in the previous month, and exhibiting no behavioral/learning disorders. Only administrative staff and no blue-collar workers were thus included.

Intervention

Workers in the intervention group received an activation code to download the software program (I-Preventive, *www.i-prentive.com*) on their VDU. I-Preventive promoted active breaks *via* an individualized computer application. It allowed workers to focus on body regions of their choice, offering high flexibility. After selecting the body part, I-Preventive asked about symptoms and suggested appropriate exercises. Workers could follow the suggested personalized exercises or use the random mode. At regular intervals, a visual signal on the screen prompted VDU workers to take active breaks. The visual signal described short individualized exercises of no more than one and a half minutes. The exercises were easy to perform and most could be carried out while seated without needing specific equipment (Figure 1). The following steps for the use of I-Preventive were:

Step 1: Select the body part, the system asks the operator to associate a symptom and suggests the appropriate exercises.

Step 2: Select the usage either by following the individualized default form or using the random mode.

Step 3: Participants are prompted by a signal on the screen also called « the health bar » to take a rest break every two hours. They are stimulated to perform physical exercises (lasting 30 seconds to one and a half minute each) at the start of each rest break. Users can program one to four active breaks daily.

During the remaining period of the rest break the computer was not blocked, and the subjects could delay active break later by clicking on the button « later ». Generally, workers postponed breaks when they were in meetings on average once or twice a day. The software offered worksheets that could be downloaded, printed at the workplace and used as information tools. These worksheets were composed of physical exercises for each body part.

Then, employees could realize exercises out of daily breaks proposed by the computer and out of the office. The intervention lasted 4 months.

The control group received usual healthcare with the occupational physician.

Baseline assessments

All participants (intervention and control groups) completed the same questionnaires.

MSDs were evaluated by the Nordic-style questionnaire, validated in 2007 as a useful tool for monitoring work-related MSDs, especially if respondents included a numerical rating scale pertaining to symptom severity.[19] It is derived from the original Nordic questionnaire published in 1987 that was then translated into French in 1994.[20] The Nordic questionnaire included a numerical pain scale ranging from 0-10 for each anatomical region.

Eyestrain assessment covered various symptoms like headache, blurred vision or eye stinging, by means of a horizontal numerical scale from 0-10,[21] commonly used by the French national institute of research and prevention (INRS).

Global psychological status was evaluated on the hospital anxiety and depression scale (HAD).[22] The HAD is a 14-item self-report measure that was specifically developed to assess anxiety and depression. It is considered to be an effective means of screening for anxiety and depression and is widely used. It has two subscales, one assessing anxiety (HAD-A) and the other assessing depression (HAD-D). The scores for each subscale range from 0 to 21. Psychosocial work characteristics were measured using a horizontal visual analog scale (VAS) for both stress [23,24] and satisfaction at work [25]. This test assesses the perceived stress level of individuals at work, on a horizontal, non-calibrated line of 100 mm, ranging from very low (0) to very high (100).

Physical activity and sedentary behavior were measured by means of the international physical activity questionnaire (IPAQ).[26,27]The IPAQ instruments have acceptable measurement properties for monitoring population levels of physical activity among 18 to 65-year-old adults in diverse settings, at least as good as other established self-reported questionnaires.

Sociodemographic characteristics (gender, age, work position, etc.) were also recorded.

Follow-up assessments

All baseline assessments were repeated at 1 month (M1), 2 months (M2), 3 months (M3), and 4 months (M4), with the exception of VAS stress/satisfaction and HAD, which were not measured at M2 and M3. Sociodemographic characteristics were only compiled at baseline.

To verify whether the participants performed the exercises or not (adherence), we had to rely on their monthly individual reports at M1, M2, M3, and M4.

At M4, the intervention group was asked to give feedback on the software, recommended breaks, and exercises.

Outcomes

The main outcome was the overall decrease in musculoskeletal complaints at M1, assessed by means of the Nordic-style and eyestrain questionnaires, in addition to the change in number of asymptomatic workers (numerical value <2 on the Nordic-style questionnaire).

Secondary outcomes included long-term follow-up of the Nordic-style and eyestrain questionnaires at M2, M3, and M4; changes in global psychological status (HAD) between M0 and M4; evolution of physical activity and sedentary behavior; number of sick-leave days.

Adherence to the program was assessed at M1, M2, M3, and M4 in order to investigate a dose-response relationship, using a self-reported questionnaire indicating a frequency of use from the following options: less than once a week, a few times a week, once every day, and several times every day.

Statistical considerations

According to the novelty of our research, it appeared difficult to estimate an optimal sample size for the main endpoint of this study to assess software promoting active breaks using exercises with the aim of treating MSD and visual discomfort in VDU workers. Sample size has been estimated according to Cohen's recommendations [28] who has defined effect-size bounds as: small (ES: 0.2), medium (ES: 0.5) and large (ES: 0.8, "grossly perceptible and therefore large"). We calculated that 64 workers per group would enable an effect size equal to 0.5 for a type I error α=0.05 (two-tailed) and statistical power of 80%, which corresponds to a minimal difference in terms of primary endpoint NORDIC score equals 1.5 points (for a standard-deviation at 3).

Considering possible loss to follow-up (rate fixed at 25%), we finally chose to include a minimum of 80 VDU workers per group. Statistical analysis was performed using Stata software, Version 13 (StataCorp, College Station, TX, U.S.). The tests were two-sided, with a Type I error set at α=0.05. Baseline characteristics were presented as mean±standard error (SE)or median [interquartile range] according to statistical distribution for continuous data, and the number of workers and associated percentages for categorical parameters. Comparisons among independent groups (workers accessing I-Preventive or not) were performed by Student's t-test, or by the Mann-Whitney U test if t-test conditions could not be respected (homoscedasticity analyzed by the Fisher-Snedecor distribution). Comparisons between qualitative parameters of the independent groups were performed by Chi-squared test or, if necessary, Fisher's exact test. For the evolution of the longitudinal NORDIC study (and visual discomfort score), mixed models (the linear models for the NORDIC score considered a quantitative or generalized linear for the proportion of VDU workers with NORDIC scores above a given threshold, in line with the literature [19]) were proposed in order to take into account the difference between and within individual variability (random effect) while

studying the fixed group effects, time, and interaction. The normality of residuals was assessed and gender, age, site, and original pain or discomfort were studied in previous models as covariates (fixed effects). Workers' frequency of I-Preventive use (before or after holidays) was also recorded, particularly in the context of a specific intra-group analysis of workers who had access to the I-Preventive software. Finally, this was complemented by analyses that were situation-matched to the parameters collected at only two time points (M0 and M4 for HAD, with the usual tests applied: Student's paired t-test or the Wilcoxon signed-rank test for quantitative parameters and Stuart-Maxwell test for categorical variables.

Results

Participants

Among the 200 employees invited, 185 (93%) agreed to participate. Of these, 11 (6%) were excluded from the analysis due to disease, maternity leave, interim status, retirement, and change in job. We thus included 175 employees, 96 assigned to the intervention group and 79 to the control group (Figure 2). At *baseline*, the groups did not differ in terms of the percentage of workers suffering from each painful anatomical part (p=0.62), nor for the maximal pain assessed by the NORDIC questionnaire (p=0.2). They differ at baseline, with the percentage of females and sedentary time, with the control group including less females (n=2, 2.5% *vs.,* 11.5%, p=0.04) and exhibiting a lower level of sedentary lifestyle (530.6±0.8 *vs.*, 610.2±0.9 minutes/day, p=0.04) (Supplementary Table 1 and Supplementary Table 2).

Digital tool acceptability

Exercises were carried out by 58% of participants in random mode and by 42% following the individualized software suggestions. The primary anatomical parts exercised were the neck

(74.4%), eyes (51.3%), hands (41.9%), elbows (37.8%), lower back (36.5%), and shoulders (35.1%). At M4, overall satisfaction with the digital tool was 43%, with 90% of participants reporting the tool was simple to use or the exercises easy to perform. However, 35% of employees had some technical difficulties in using the tool, 39% experiencing concentration problems and 64% problems coordinating the active breaks with their work. We consider that less than 25% of the employees post-poned the breaks. Adherence decreased throughout the intervention, from 60% of employees using I-preventive every day (once or several times) at M1 to 37% at M4 ($p < .01$). Overall, 40% of participants declared feeling better with active breaks when working on the computer.

Primary outcomes

The most painful anatomical parts (numerical value ≥2) were the neck (40.1%), lower back (35.7%), upper back (18.8%), and shoulder (11.7%). The majority reported one or two painful locations (62.7%), 17.9% reported three locations, and 8.9% reported four.

In *longitudinal follow-up* with *quantitative analysis*, the maximum NORDIC score did not differ between groups at M1 using analysis of covariance (ANCOVA) (p=0.44). In a complete multivariate model and after adjustment for NORDIC score at baseline, sedentary time, memorizing, and maximum NORDIC score tended to decrease, though not significantly so (p=0.18). However, on studying the fixed-group effects based on a longitudinal evolution of maximum NORDIC score, we observed a significant difference at M1 for the intervention group (p=0.038) *vs.* baseline and no difference for the control group (p=0.59) (Figure 3).

In *longitudinal follow-up* with *qualitative analysis*, the percentage of body parts with a NORDIC score ≥2 did not differ at M1 using random-effect logistic model analysis, compared with the control group (p=0.18). For longitudinal analysis in intra-groups, this

parameter had significantly decreased at M1 in the intervention group (p=0.02), *versus* the control group (p=0.57) (Figure 4).

For both the quantitative and qualitative analyses, no significant difference was found between the groups at the end of the study, even though a trend of decrease at M2 was observed (p <.01).

Secondary outcomes

At baseline, eyestrain did not differ between groups. The symptoms were loss of eyesight (55.2% of participants), eye stinging (48.8%), glare (48.8%), blurred vision (44.2%), headache (34.8%), and eye irritation (23.2%). At M1, visual discomfort significantly decreased for both the quantitative (maximum visual score) and qualitative longitudinal analyses (visual symptoms ≥2) in the intervention group (p=0.025 and p=0.02, respectively), with no change observed in the control group (p=0.65 and p=1.0, respectively). No significant difference was found at the end of the study.

The intervention program did not exhibit significant impact on work stress, work satisfaction, anxiety, or depression symptoms, and no links were established between stress, anxiety or depression and MSD or ocular symptoms.

We recorded four sick leaves in the intervention group corresponding to psychiatric or surgical diseases, with none linked with MSD. There were no sick leaves within the control group.

Sub-group analysis

On analyzing the sub-groups, the longitudinal evolution of the NORDIC score was more effective for employees using the individualized software form (p=0.009). Those who were happy to use I-Preventive tended to have less painful localizations, reporting a pain score <2

(p=0.12). Baseline NORDIC scores (< or ≥2) did not influence the benefits of intervention. Adherence to I-Preventive was not linked to greater benefits in MSD symptoms, evaluated by the NORDIC questionnaire, even following adjustment for age and gender.

Discussion

Main findings

Our pilot cluster randomized trial demonstrated the potential of active breaks to reduce MSD symptoms and eyestrain. The I-preventive software program was shown to be particularly effective in the short-term in its individualized and personalized form, allowing workers to focus on areas of their choice by offering exercises that are easy to perform at the workplace. However, despite this digital tool being easy to use, adherence decreased over time, so that this favorable impact was not maintained over the long term.

Validated methods for the prevention of MSD

Prevention of MSD should be based on an integrative approach combining ergonomics and physical activity interventions.[13] In ergonomics, no clear positive impact has been demonstrated by single intervention programs, such as work station adjustments (technical), rest breaks (organizational) or ergonomic training (behavioral) on work-related MSD. However, when these specific interventions were included in a combined approach, they became more effective.[13] Physical activity interventions at the workplace demonstrated benefits on computer-worker MSDs, consisting of either 20-30-min training sessions two or three times a week[29] or short daily active breaks,[30] in addition to either stretching and joint mobilization exercises or strength training and dynamic endurance training.[31] These studies involved a coach or physical therapist to motivate the participants.[31] Training sessions appear

to have more pronounced long-term effects than short daily active breaks, in accordance with our study findings[31]. Ipreventive software program is particularly effective at one month but has no long-term effects. Conflicting results reported in the literature could be explained by the high risk of bias from the studies due to an unknown random allocation procedure, as well as insufficient motivation to exercise or lack of intention-to-treat analyses.[32] The novelty of the I-Preventive strategy is its implementation of frequent short daily active breaks promoted by a software program

A novel digital tool for the prevention of MSD

Computer usage and sedentary behavior at the workplace has increased dramatically over the past decade[33]. Office workers thus remain in the same posture for longer, accompanied by long periods of keyboard usage, which can cause and aggravate MSDs. Paradoxically, several software programs have been implemented to promote exercise at the workplace and reduce MSD. Despite the promotion of exercise through software, however, programs have been largely developed for chronic diseases like type two diabetes,[34] and these digital strategies were rarely implemented at the workplace for health outcomes in general[35] and especially not for preventing MSD.[14] As for the use of a computerized decision support system for primary and secondary prevention of work-related MSD disability, only one study tried to improve MSD prevention by analyzing the ergonomic process through self-reported questionnaires from a software tool.[36] Moreover, only two studies used a software program to specifically reduce MSD. The results from the short-term pilot study conducted on a low sample size supported the theory that this type of exercise reminder software programs may help to reduce perceived pain among office workers.[37] In accordance with our findings, the use of a software program encouraging workers to take regular breaks has been reported elsewhere to contribute to perceived recovery from neck and upper-limb complaints.[17] Nevertheless, our study was not designed to assess the specificity of breaks or exercise in MSD prevention[17],

and long-term studies involving more subjects should now be conducted so as to describe the effects of these programs and underlying mechanisms.

General health effects of our intervention

Overall, the neck, shoulders, and upper and lower back were the most affected regions among our computer users, in line with the literature.[32] Moreover, computer-related visual and ocular symptoms are the most frequently occurring health problems in people who spend a large proportion of their working day looking at a computer screen.[38] Given the high prevalence of these symptoms,[39] it is likely that all VDU workers will at some point need eye examinations in order to assess symptoms associated with VDU use. Furthermore, visual and musculoskeletal discomfort have been intrinsically linked together.[40] To our knowledge, our study was the first to simultaneously evaluate and reduce MSDs in combination with ocular symptoms. [4142]

Limitations

Our study had some limitations. One could argue that the inclusion number was low, yet the sample size was relatively large compared with that of other pilot studies, and the percentage of participants who agreed to participate was exceptional (>90%),[43] with none lost to follow-up. This good representation of computer workers thus reduced potential bias and allowed us to generalize results for other services. The protocol was carried out in a high-demand working environment, and thus may easily be translated to other areas.. Also, the decreasing adherence throughout the study could have been caused by the summer holidays falling between M1 and M2, or a decrease in job demand for those who did not go on holiday, which may have lowered the impact of our intervention on MSD. In addition, some found it impossible to adapt active breaks to their specific working schedules, which, along with

software defects, also likely contributed to the decreasing adherence. Finally, the software was not designed to evaluate the objective measure of adherence to the program, such as number of connections or amount of time spent on the tool. Furthermore, physical symptoms were not clinically assessed by a physician however, subjective scales have been validated and are commonly used both in routine practice and research.[19] Future studies should comprise objective measures of physical performance and effectiveness at work in order to establish cost-effectiveness benefits based on economic analyses.

Conclusion

Our pilot feasibility study demonstrated the potential of active breaks for preventing MSDs and ocular symptoms. The I-Preventive software program is particularly effective in the short-term due to its individualized and personalized form, allowing workers to focus on areas of their choice by offering exercises that are easily performed in the workplace. However, despite this digital tool being easy to use, adherence decreased over time, and its favorable impact was not maintained over the long term.

Abbreviations HAD, hospital anxiety and depression; IPAQ, international physical activity questionnaire; MSDs, musculoskeletal disorders; VAS, visual analog scale; VDU, visual display units

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Competing interests

There is no conflict of interest.

Data sharing statement

No additional data are available.

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Figure 1: Example of an exercise presented on the screen during prompted rest break (from I-Preventive)

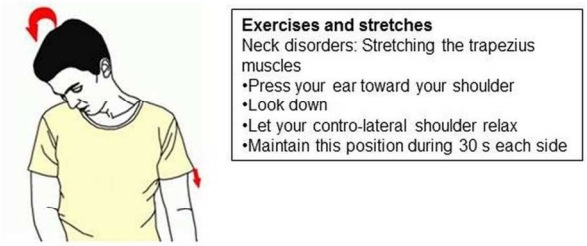

Figure 1

119x90mm (300 x 300 DPI)

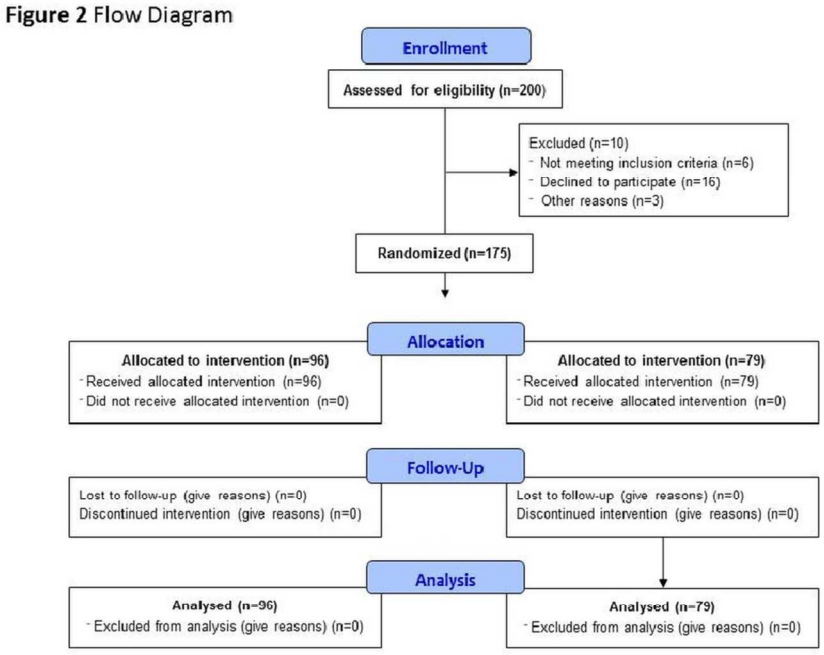

Figure 2

119x90mm (300 x 300 DPI)

Figure 3: Longitudinal evolutions of maximum NORDIC score

*: p <.05. The fixed group effects with longitudinal evolution of maximum NORDIC score emphasized a significant difference at Month 1 (M1) for the intervention group (p=0.038) and no difference for the control group (p=0.59).

The covariates were chosen according to univariate results and clinical relevance: age, site, and baseline pain or discomfort.

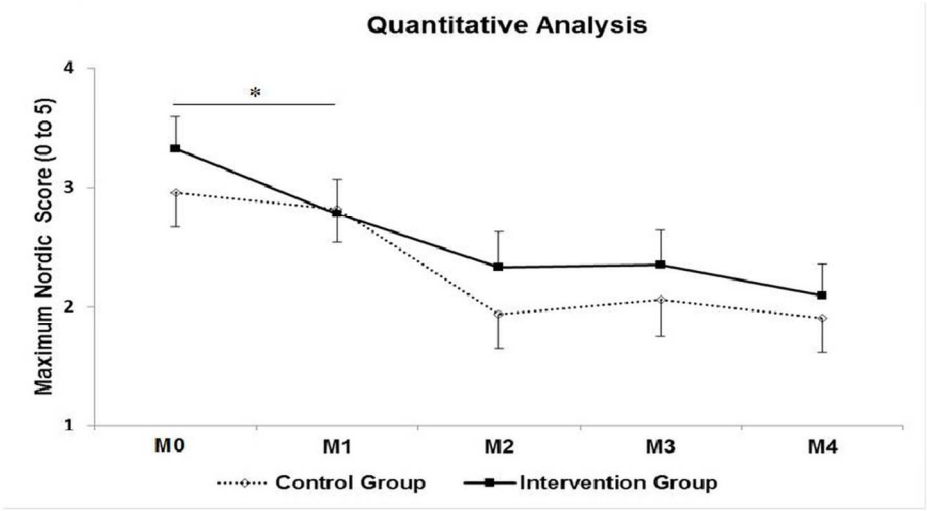

Figure 3

119x90mm (300 x 300 DPI)

Figure 4: Percentage of body areas with a NORDIC score ≥2

*: p <.05. The fixed group effects with longitudinal evolution of NORDIC score ≥2 emphasized a significant difference at Month 1 (M1) for the intervention group (p=0.02) and no difference for the control group (p=0.57).

The covariates were chosen according to univariate results and clinical relevance: age, site, and baseline pain or discomfort.

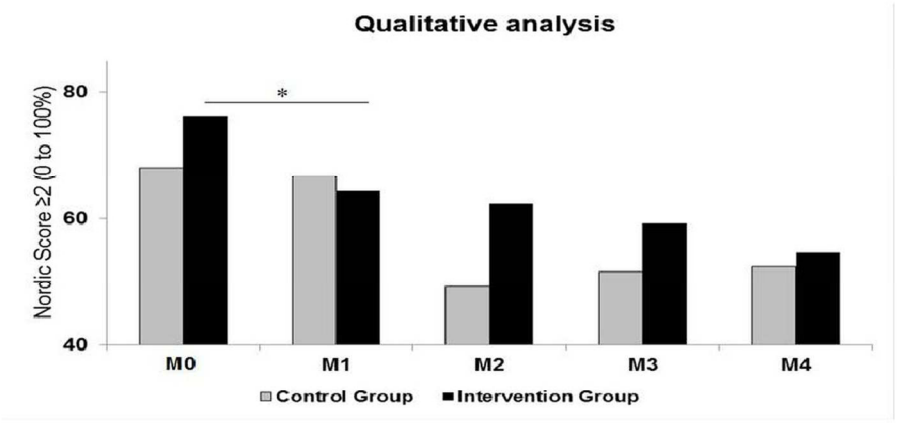

Figure 4

119x90mm (300 x 300 DPI)

Supplementary Table 1: Characteristics of employees at baseline

Characteristics of employees	Intervention group (n=96)	Control group (n=79)	*p*-value
Age (year) – mean+/-SE	41.8±11.4	42.9±12.0	0.53
Male – number (%)	85 (88.5%)	77 (97.5%)	**0.04**
Body Mass Index (kg/m^{-2}) – mean+/-SE	24.6±0.3	24.6±0.3	0.9
Correctives lenses – number (%)			
Contact lenses	10 (10.42%)	18 (22.8%)	0.12
Multifocal lenses	28 (29.2%)	15 (19.0%)	
Other	20 (20.8%)	17 (21.5%)	
None	37 (38.5)	29 (36.7)	
Medical history of musculoskeletal disorders – number of workers (%)	15 (15.6%)	9 (11.4%)	0.51
Medications for musculoskeletal disorders – number of workers (%)	20 (20.8%)	11 (13.9%)	0.32
NORDIC Questionnaire	3.3±0.3	3.0±0.3	0.2
Hospital and anxiety depression scale mean+/-SE			
Anxiety (/21)	5.7±0.3	5.2±0.3	0.2
Depression (/21)	2.8±0.3	2.9±0.2	0.7
Stress at work (visual analog scale) mean+/-SE	3.7±0.3	3.5±0.2	0.6
Satisfaction at work (visual analog scale) mean+/-SE	6.7±0.3	6.5±0.2	0.4
Physical activity level (IPAQ) – number (%)			
Intense	57 (58.8%)	53 (66.3%)	0.31
Moderate	33 (34.0%)	19 (23.8%)	
Low	7 (7.2%)	8 (10.0%)	

SE: standard error; IPAQ: international physical activity questionnaire

Supplementary Table 2: Characteristics of occupation at baseline

Characteristics of occupation	Intervention group (n=96)	Control group (n=79)	*p*-value
Hierarchy – number (%)			
Senior executive	14 (14.6%)	11 (13.9%)	1.0
Collaborator	82 (85.4%)	68 (86.1%)	
Duration of employment (year) – mean+/-SE	5.5±0.04	6.5±0.04	0.3
Work schedule – number (%)			
Full-time	92 (96.8%)	78 (98.7%)	0.6
Part-time	3 (3.2%)	1 (1.3%)	
Business travel (day/month) – mean+/-SE	2.0±0.01	2.8±0.02	0.08
Main task – number (%)			
Creative	51 (53.7%)	27 (35.1%)	0.16
Communications	12 (12.6%)	16 (20.8%)	
Word processing	16 (16.8%)	19 (24.7%)	
Data acquisition	6 (6.3%)	5 (6.5%)	
Data entry	10 (10.5%)	10 (13.0%)	
Screen time – number (%)			
0-2 hours/day	1 (1.1%)	3 (3.8%)	0.2
2-4 hours/day	12 (12.8%)	16 (20.3%)	
4-6 hours/day	31 (33.0%)	24 (30.4%)	
6-8 hours/day	36 (38.3%)	31 (39.2%)	
>8 hours/day	14 (14.9%	5 (6.3%)	
Workstation – number (%)			
Stationary computer	19 (20.0%)	11 (13.9%)	0.06
Laptop computer	66 (69.5%)	66 (83.5%)	
Both	10 (10.5%)	2 (2.5%)	
Sedentary time (minutes /day) – mean+/-SE	610.2±0.9	530.6±0.8	**0.0004**
Number (%) of workers having to:			
Concentrate at work	89 (93.7%)	74 (93.7%)	0.6
Memorize at work	81 (85.3%)	66 (83.5%)	0.8

SE: standard error

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2
Background and objectives	2a	Scientific background and explanation of rationale	4
	2b	Specific objectives or hypotheses	5-6
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	6
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	NA
Participants	4a	Eligibility criteria for participants	6-7
	4b	Settings and locations where the data were collected	6
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	7
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	7-9
	6b	Any changes to trial outcomes after the trial commenced, with reasons	NA
Sample size	7a	How sample size was determined	9
	7b	When applicable, explanation of any interim analyses and stopping guidelines	NA
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	6
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	6
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	6
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	6
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	NA

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	NA
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	9-10
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	9-10
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	Figure 2-10
	13b	For each group, losses and exclusions after randomisation, together with reasons	Figure 2-10
Recruitment	14a	Dates defining the periods of recruitment and follow-up	6 and 8
	14b	Why the trial ended or was stopped	6
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	10 S1 and S2
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	10
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	11-12 Figure 3
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	11-12 Figure 4
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	12-13
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	NA
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	16
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	13-15
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	13-15
Other information			
Registration	23	Registration number and name of trial registry	6
Protocol	24	Where the full trial protocol can be accessed, if available	6
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	17

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.