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Minimal important difference for anxiety and depression surveys after intervention to increase daily physical activity in smokers

Diferença mínima importante para questionários de ansiedade e depressão após intervenção para o aumento da atividade física diária em tabagistas

Diferencia mínima importante para cuestionarios a cerca de ansiedad y depresión después de intervención para un aumento de la actividad física diaria en tabaquistas

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ORIGINAL RESEARCH

ABSTRACT | Nicotine dependence is associated with the presence of anxiety and depression. Several instruments (questionnaires) are used to quantify these symptoms; however, it has not been known yet which magnitude of change quantified by these instruments better reflects relevant alterations in these symptoms after an intervention in smokers. The objective of this study was to determine the value of the minimal important difference for questionnaires about anxiety and depression after an intervention aimed at increasing daily physical activity in smokers. Fifty-seven smokers with normal spirometry underwent a program to increase daily physical activity. During the two-month period, they used a pedometer (step counter) and received an informative booklet, both as incentives to increase daily physical activity. Participants were assessed pre- and post-program and, in each assessment, questionnaires that quantify anxiety and depression were applied (Hospital Anxiety and Depression Scale - HADS A and D; State-Trait Anxiety Inventory - STAI, and Beck Depression Inventory - BDI). There was a significant increase in daily physical activity (steps/day) and an improvement in the scores of all questionnaires. Minimal important difference values for this population were eight points for the HADS A, six for HADS D, ten for STAI and 11 for BDI. The present study allowed to determine the minimal important difference values for reduction of anxiety and depression after a support program to increase daily physical activity in

smokers. These results indicate a potentially significant change, beyond any measurement error.

Keywords | Anxiety; Depression; Smoking; Questionnaires.

RESUMO | A dependência nicotínica está associada à presença de ansiedade e depressão. Vários instrumentos (questionários) são utilizados para quantificar tais sintomas; porém, não se sabe qual magnitude de melhora avaliada por meio deles reflete mudanças relevantes destes sintomas após uma intervenção em tabagistas. O objetivo deste estudo foi determinar o valor da diferença mínima importante para questionários de ansiedade e depressão após uma intervenção que visa o aumento da atividade física diária em tabagistas. Cinquenta e sete tabagistas com espirometria normal foram submetidos a um programa para o aumento de atividade física diária. Durante um período de dois meses, os participantes utilizaram um pedômetro (contador de passos) e receberam uma cartilha informativa, ambos como incentivo para aumentar a atividade física diária. Os tabagistas foram avaliados antes e após o programa e, em cada avaliação, aplicaram-se questionários que quantificam ansiedade e depressão (Escala Hospitalar de Ansiedade e Depressão - HADS A e D; Inventário de Ansiedade Traço-Estado de Spielberger - STAI e Inventário de Depressão de Beck - BDI). Houve aumento significativo da atividade física diária (passos/dia) e melhora da pontuação de todos os questionários aplicados. Os valores da diferença mínima importante para esta população foram de oito pontos para

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HADS A, seis para HADS D, dez para STAI e 11 para BDI. O presente estudo possibilitou determinar os valores da diferença mínima importante para redução da ansiedade e depressão após um programa de incentivo à atividade física em tabagistas. Esses resultados indicam uma mudança potencialmente significativa, além de qualquer erro de medida.

Descritores | Ansiedade; Depressão; Hábito de Fumar; Questionários.

RESUMEN | La dependencia nicotínica es asociada a la presencia de ansiedad y depresión. Diversos instrumentos (cuestionarios) son usados para cuantificar tales síntomas, pero no se sabe cuál magnitud de mejoría evaluada por medio de ellos refleje cambios relevantes de los síntomas después de una intervención en tabaquistas. El objetivo de ese estudio fue determinar el valor de la diferencia mínima importante para cuestionarios a cerca de ansiedad y depresión después de una intervención que intenta aumentar la actividad física diaria en tabaquistas. Cincuenta y siete tabaquistas con espirometría normal fueron sometidos al programa para aumentar la

actividad física diaria. Por un período de dos meses, los participantes utilizaron un podómetro (contador de pasos) y recibieron una cartilla informativa como incentivos para aumentar la actividad física diaria. Los tabaquistas fueron evaluados antes y después del programa y a cada evaluación se aplicaron cuestionarios que cuantifican ansiedad y depresión (Escala Hospitalaria de Ansiedad y Depresión – HADS A y D; Inventario de Ansiedad Tracio-Estadío de Spielberger – STAI y Inventario de Depresión de Beck – BDI). Se observó aumento significativo de la actividad física diaria (pasos por día) y mejora de la puntuación de todos los cuestionarios aplicados. Los valores de la diferencia mínima importante para esa población fueron de ocho puntos para HADS A, seis para HADS D, diez para STAI y 11 para BDI. Con el presente estudio, se puso determinar los valores de la diferencia mínima importante para reducción de ansiedad y depresión después de un programa de incentivo a la actividad física en tabaquistas. Esos resultados indican un cambio potencialmente significativo, además de cualquier error de mensuración.

Palabras clave | Ansiedad; Depresión; Hábito de Fumar; Cuestionarios.

INTRODUCTION

Nicotine dependence is an addiction caused by the consumption of nicotine through smoking tobacco, and is considered by the World Health Organization (WHO) as the leading cause of preventable death in the world. It is estimated that there are approximately six million deaths every year due to smoking-related diseases¹.

Previous studies²⁻⁴ report that nicotine dependence is associated with anxiety disorders and depression, since the greater the degree of nicotine dependence associated with high consumption of cigarettes, the greater the severity of these symptoms.

Cigarette smoking and physical inactivity also play an important role in the development of high morbidity and mortality, and the association between them generates deleterious health effects⁵. The use of pedometers (small devices that count steps) and motivational interventions (e.g., informative booklets) as an incentive to increase the level of physical activity in daily life has been widely used in various populations⁶, including in smokers^{5,7,8}.

Prior literature suggests that physical activity and smoking are inversely related through psychological conditions, such as anxiety and depression⁹. Due to the range of instruments available for the quantification of anxiety and depression¹⁰⁻¹², it is difficult to choose one that best evaluates improvement in symptoms after an intervention aimed at smokers. When the instruments

in use are questionnaires, they should be considered sensitive, reliable, valid, and especially responsive¹³.

Responsiveness can be defined as the ability of an instrument to accurately detect the change in the symptoms of the individuals, and is usually quantified by a numeric score¹³. There is a minimum level of change that can be identified by an instrument, also called minimal important difference (MID). This can be defined as the smallest change that the instrument can detect, which makes it possible to interpret whether this observed change represents improvement or worsening of symptoms to the individual^{13,14}.

The determination of MID for an instrument is extremely important in understanding the distinction between statistical and clinical significance. However, the current literature does not indicate what is the magnitude of change that truly represents the value of MID for changes in anxiety and depression of smokers after an intervention. Thus, the aim of this study was to determine the value of MID for anxiety and depression questionnaires after an intervention aimed at increasing daily physical activity in smokers.

METHODOLOGY

This study was conducted at the Research Laboratory in Pulmonary Rehabilitation (LFIP), located at the

University Hospital of Universidade Estadual de Londrina (HU-UEL). This study was approved by the Research Ethics Committee With Human Subjects of the HU-UEL under No. 173/10. For participation in the study, all subjects signed a free and informed consent form.

Sample and study design

In a convenience sample, participants were smokers with normal spirometry, age above 18 years old, of both genders, without severe or unstable pathological conditions that would influence the performance of physical activities in daily life. In addition, the subjects could not be using antidepressants or anxiolytics. Were excluded from this study smokers who had any events that differed from their normal daily routine during the study period (e.g., disease) as well as those who had no understanding and/or non-cooperation regarding the research procedures and methods or who gave up on participating in the study.

In a longitudinal and prospective design, participants were evaluated at two times: at baseline (EV1), held before the two-month protocol to encourage physical activity, and at the final evaluation (EV2), after the protocol. In these two instances, individuals responded to questionnaires on personal data and smoking habits, in addition to those specific to anxiety and depression symptoms. Additionally, they were evaluated for lung function (spirometry) and remained for six days with a pedometer, in order to determine their level of physical activity in daily life (PADL).

Evaluation of the level of physical activity in daily life

To assess the level of PADL, smokers carried, for six days, the pedometer (step counter) by Yamax Digiwalker SW-200 (YAMAX, Tokyo, Japan). They were instructed to use the apparatus according to the recommendations described in the study by Kovelis et al.⁵, as well as to use for at least eight hours per day. The level of PADL was determined by the mean number of steps in the six days of pedometer use, before and after the intervention protocol.

Assessment of the levels of anxiety and depression

The level of anxiety of smokers was quantified using two questionnaires: Hospital Anxiety and Depression Scale, Anxiety item (HADS-A) and Spielberger's State-Trait Anxiety Inventory (STAI).

HADS consists of 14 multiple-choice items, seven of which are related to anxiety (HADS-A), while the other seven items are related to depression (HADS-D). These have a score of 0 to 3 points, where 0 means no symptoms, and 3, the maximum degree of symptoms, totaling 21 points in each domain, that is, anxiety and depression. In this study, we used the validated version of the questionnaire for the Portuguese language¹⁰.

The other instrument used to quantify levels of anxiety was the STAI, which consists of 20 items and requires that individuals report how they generally feel. In the present study, we used the validated version of the questionnaire for the Portuguese language¹¹.

The level of depression of smokers was quantified using two questionnaires: HADS, Depression item (HADS-D), and the Beck Depression Inventory (BDI). The latter consists of 21 items and has four alternatives that reflect the levels of increasing symptom severity. As with other questionnaires, this study used the version validated for the Portuguese language¹². The HADS-D instrument was applied as previously described in this section.

Intervention protocol

Upon completion of the EV1, smokers underwent a two-month intervention protocol, in which they received a pedometer and an informative booklet. The pedometer was intended to encourage smokers to achieve the goal of 10,000 steps/day, value suggested as a minimum to be considered as a physically active individual¹⁵. The informative booklet contained information about the benefits of a daily walk and practical guidelines, which encouraged individuals to include as much walking as possible in their routine.

Statistical analysis

Statistical analysis was performed using GraphPad Prism 5.0 software (GraphPad Software Inc., La Jolla, CA, USA). The normal distribution of data was assessed using the Shapiro-Wilk test and description of the results is given depending on the normal distribution of data. Comparisons pre- versus post-intervention of the variables studied were performed by Student's *t* paired test or Wilcoxon's test, and the correlations between changes in these variables were analyzed by Pearson's or Spearman's correlation coefficient, also depending on the normality of the data. The statistical significance considered was $p \leq 0.05$.

For the determination of MID, calculations were performed for the effect size (ES), standardized response mean (SRM) and standard error of measurement (SEM), as will be described below.

In order to quantify the responsiveness of the anxiety and depression questionnaires, the indexes for the ES and SRM were used¹⁶. The ES is the difference between the average score of the instruments in EV1 (x_1) and EV2 (x_2), divided by the standard deviation of the baseline (s_1), as seen in Equation 1:

$$ES = \bar{x}_2 - \bar{x}_1 / s_1 \tag{1}$$

SRM is another method used to quantify the response capacity of an instrument, which can be calculated from the difference between the average score of the instruments in EV1 (x_1) and EV2 (x_2), divided by that of the standard deviation of the baseline (s_1) and final (s_2) scores:

$$SRM = \bar{x}_2 - \bar{x}_1 / s_2 - s_1 \tag{2}$$

To sort the instrument's ability to detect changes, the following criteria¹⁶ are applied: results from ES and SRM of 0.2, 0.5 and 0.8 points represent a small, moderate or large amount of responsiveness, respectively¹⁷.

After assessing the responsiveness of the instruments, the value of MID can be measured based on the calculation of the SEM index, which is a measure of the precision or accuracy of the instrument. This can be calculated by the product of the baseline standard deviation with the square root of (1-r), where r is the reliability coefficient (Cronbach's alpha) or intraclass correlation¹³:

$$SEM = s_1 \times \sqrt{1-r} \tag{3}$$

When determining the values of SEM, MID can be calculated by the product of SEM with the square root of two (due to the variance of error measurement of each instrument) and by the cut-off value of 1.96, representing a normal standard curve associated with a 95% confidence interval¹⁸:

$$MID = 1.96 \times \sqrt{2} \times SEM \tag{4}$$

RESULTS

The study included 57 smokers, aged 51 ± 10 years, with an average body mass index (BMI) indicating slight

overweight, and normal lung function. The average consumption of cigarettes was 39 ± 23 years-pack. Table 1 shows the baseline characteristics of the sample (EV1) and the results after the intervention (EV2). There was no significant change in BMI and spirometric variables after the protocol, but there was a significant decrease in the amount of cigarettes smoked per day after the intervention.

There was a significant increase in the number of steps per day after the intervention (Table 2). Of all the study participants, 30 (53%) of them reached the goal of 10,000 steps/day at the end of the protocol. Moreover, there was a statistically significant improvement (i.e., decrease) in the score of all questionnaires (Table 2). There was no correlation between the change post-pre intervention (delta) in the number of steps/day with those in any of the questionnaires and the number of cigarettes/day ($-0,17 < r < 0,15$; $p > 0,05$ for all of them).

Table 3 shows the values of responsiveness indices of the instruments used, in addition to those of MID of each instrument. It can be observed that the questionnaires used in this study had a small or moderate capacity for change, and that STAI showed the highest values in the responsiveness index.

Of the 57 study participants, 19 (33%) decreased the score of at least one anxiety or depression questionnaire to values equal to or greater than the MID established for that instrument. When looking at the level of PADL and the number of cigarettes smoked per day of these 19 subjects, 14 (74%) of them increased the number of steps/day

Table 1. Characteristics of the sample of smokers (n=57) before and after the incentive program to increase physical activity in daily life

	Pre-Program (EV1)	Post-Program (EV2)	p-value
BMI (kg/m ²)	25 (23-28)	25 (23-28)	0.289
Cigarettes/day	20 (15-30)	20 (12-25)	0.003
FEV ₁ /FVC (%)	81±6	80±7	0.501
FEV ₁ (%pred.)	87±13	86±15	0.421

BMI: body mass index; FVC: forced vital capacity; FEV₁: forced expiratory volume in the first second

Table 2. Level of physical activity in daily life and scores of anxiety and depression questionnaires before and after incentive program to increase physical activity in daily life

	Pre-Program (EV1)	Post-Program (EV2)	p-value
PADL (steps/day)	8,323±3,282	10,291±3,420	<0.0001
HADS A	6 (3-11)	5 (2-9)	<0.0001
HADS D	5 (2-8)	3 (0-6)	0.005
STAI	38 (32-48)	35 (25-42)	<0.0001
BDI	9 (5-18)	5 (3-11)	0.0001

PADL: physical activity in daily life; HADS A and D: Hospital Anxiety and Depression Scale; BDI: Beck Depression Inventory; STAI: Spielberger's State-Trait Anxiety Inventory

day after the intervention, while nine (47%) reduced the number of cigarettes smoked per day. Among the 38 individuals who showed no improvement equal to or greater than the MID in at least one of the questionnaires, 28 (74%) increased the number of steps/day, while 14 (37%) decreased the amount of cigarettes smoked per day.

DISCUSSION

This study determined the values of MID for smokers with normal spirometry after a successful intervention, who used pedometers and incentive booklets to increase their level of physical activity in daily life. After the intervention, more than half of participants (53%) increased the number of steps taken per day, enough to be considered physically active, and 40% of smokers decreased the number of cigarettes smoked daily. One possible explanation for these results is that behaviors that are healthy and harmful to health overlap⁹. Smokers are more likely than nonsmokers to have harmful health habits, such as physical inactivity, use of illicit substances, among others. Thus, changing one behavior or habit considered harmful to health can serve as a “gateway” to change other behaviors through motivation and self-confidence⁹.

In a systematic review⁵, which evaluated the association between use of pedometers and physical activity, it was found that their use as a motivational factor significantly increases physical activity (about 2,000 steps/day), especially when a goal is established for participants, for example, walking 10,000 steps/day. This result is similar to the present study, in which most smokers increased their level of physical activity; however, those who failed to reach the goal of 10,000 steps/day may not have been sufficiently motivated to change the habit of being physically inactive.

Another recent study¹⁹ shows that public health guidelines suggest that 30 minutes a day of moderate to vigorous physical activity are needed to decrease the risk of mortality and progression of diseases. The goal of walking 10,000 steps/day is associated with a total 40–47 minutes

per day of moderate to vigorous activity, and it is estimated that 8,000 steps/day are related to 30 minutes of moderate to vigorous activity, which classifies the individual as physically active according to the American College of Sports Medicine. Based on these results, it is observed that a proportion of smokers in this study already walked more than 8,000 steps/day in EV1. Therefore, it is suggested that the impact of these individuals not reaching the goal of 10,000 steps/day after the protocol is small, because, specifically, they could already be considered physically active.

In the present study, the decrease in scores of anxiety and depression questionnaires after the intervention is similar to the results found in the literature²⁰, which suggest that the relationship between depression and the smoking habit is mitigated by the practice of physical activity, as this acts as protection factor against smoking due to its beneficial effects on mood, and is considered a source of reward. Thus, both physical activity and smoking improve the mood and decrease stress, which can make them functionally similar and interchangeable.

After the intervention, about one-third (33%) of smokers decreased the score of at least one anxiety or depression questionnaire for values greater than the MID determined for each instrument. Although it is not considered as disappointing, this number may be regarded by some as relatively low. However, this result may be related to the fact that the smokers had relatively low levels of anxiety and depression in EV1, which could cause them to have a lower benefit from the intervention. Furthermore, the duration (only two months) and type of intervention (which used only pedometers and informative booklets, with no drug treatment) are other aspects that may have interfered with the fact that the decrease in the levels of anxiety and depression was not so high, according to the values of MID. However, this study was able to add to the literature that a simple intervention such as the use of pedometers and brochures only is capable of promoting a major change in anxiety and depression symptoms in a significant number of smokers, and increase levels of PADL in more than half of these individuals. This information is unprecedented in the scientific literature, as they were not found in similar studies determining the MID for anxiety and depression questionnaires in a population of smokers without detectable impairment of lung function.

One limitation of this study was the fact that MID was not calculated by the method based on a reference (anchor-based methods), only by one based on data distribution (distribution-based methods).

Table 3. Responsiveness and minimum important difference

	ES	SRM	SEM	MID
HADS A	-0.4	-0.5	2.6	8
HADS D	-0.4	-0.4	1.8	6
STAI	-0.4	-0.6	3.4	10
BDI	-0.4	-0.5	3.9	11

ES: effect size; SRM: standardized response mean; SEM: standard error of measurement; MID: minimum important difference

The reference-based method uses an instrument that already has its MID established and that is considered a gold standard to estimate the MID of the instrument under study²¹. This method of determining MID is widely used because it enables to interpret if there is any “clinically important” improvement or worsening in individuals. On the other hand, the method based on data distribution operates in the accuracy of the instrument being evaluated by only using statistical criteria, which enables determining MID without the influence of measurement errors that are associated with the instruments²². The combination of the two methods is considered the ideal approach. Therefore, it is suggested that new studies are conducted in the same population with different MDI calculation methods and interventions, so that one can confirm the MID values for anxiety and depression questionnaires in smokers.

CONCLUSION

After an intervention to increase daily physical activity, smokers should present a minimum change of eight points for the HADS-A questionnaire, six for HADS-D, ten for STAI and 11 for BDI, to present an improvement in their anxiety and depression levels that is potentially important and significant, in other words, beyond any measurement error.

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