UNIVERSIDADE NORTE DO PARANÁ - UNOPAR

SUBSTANTIATED REPORT FROM THE RESEARCH ETHICS COMMITTEE (CEP)

Research Title: Effects of two behavior change programs to increase physical activity and reduce sedentary time in adults with asthma: a randomized clinical trial.

Researcher: KARINA COUTO FURLANETTO

Version: 4

CAAE: 30672220.2.0000.0108

Proposing Institution: EDITORA E DISTRIBUIDORA EDUCACIONAL S/A

Main Sponsor: Own Funding

REPORT DATA

Review Number: 5.005.112

Project presentation:

The information listed in the fields "Project Presentation", "Research Objective" and "Risk and Benefit Assessment" were taken from the Basic Research Information file (PB_INFORMAÇÕES_BÁSICAS_1789621_E1.pdf, of 08/25/2021) and the Detailed Project (Formulario_projeto_UNOPAR_doutorado_ultima_versao_CEP_emenda_PANDEMIA_25/08/2021.docx, of 08/25/2021).

Despite the practice of physical activity (PA) being recommended for people with asthma, few studies have applied intervention strategies to increase PA and reduce sedentary lifestyle in this population. The methods already studied and that proved to be effective were the use of pedometers with targets to increase the number of steps and behavioral change intervention in person. However, it is not yet known whether the application of behavioral change strategies online is effective and whether this population needs the addition of the pedometer with goals as a strategy of extrinsic motivation. Therefore, the aim of this study is to verify whether two online behavior change programs to increase PA and reduce sedentary behavior have positive effects on several clinical aspects in adults with moderate/severe asthma, in the short and medium term. For this, a randomized clinical trial will be carried out with 2 groups: the control group, which will participate in an educational program, and the behavioral change group, which will receive a behavior change intervention through weekly 20-minute online sessions with a pedometer and weekly goals, in addition to the educational program. The duration of

interventions will be 12 weeks. The primary outcomes of this study are asthma control and quality of life.

Hypothesis:

It is hypothesized that the behavior change intervention will be able to increase the level of physical activity and reduce the sedentary lifestyle of people with asthma. In addition, after the intervention, there will be an improvement in quality of life and asthma control, increased functional capacity and reduced symptoms of anxiety and depression.

Proposed Methodology:

After being informed about the study, the Mini Mental State Examination (MMSE) will be applied to verify if the patient has their cognitive function preserved. Once the inclusion and exclusion criteria are verified and the Free and Informed Consent Form is signed, the evaluations will begin at each co-participating research center.

Assessments will be carried out in person at each co-participating center or at the patients' place of residence, depending on patients' availability of displacement. Interventions will be carried out online, by the main researcher, from the study coordinating center (Londrina). All patients will be evaluated before and shortly after the intervention, as well as 6 months after the end of the intervention. They will be evaluated for pulmonary function (spirometry), physical activity level and sedentary lifestyle (Actigraph physical activity monitor), functional capacity (functional tests), asthma control (Asthma Control Questionnaire), quality of life (Asthma Quality of Life Questionnaire), sleep quality (Pittsburgh Sleep Quality Index, Epworth Sleepiness Scale, Actiwatch monitor), anxiety and depression symptoms (Hospital Anxiety and Depression Scale), level of motivation (Behavioural regulation in Exercise Questionnaire) and basic psychological needs in exercise (Basic Psychological Needs in Exercise Scale). After the initial evaluations, patients will be randomized into 2 groups: control group (CG) and intervention group (IG). Both groups will participate in an educational session and people in the intervention group will perform individual weekly online sessions of behavior change intervention and motivation for physical activity, lasting 12 weeks. In addition, the IG will receive a pedometer for objective feedback along with specific strategies related to it.

Randomization and blinding: the randomization sequence will be generated by a computer and implemented by a person who does not know and is not involved in the recruitment, evaluation, or treatment. The randomization sequence will be masked using opaque sealed and sequentially numbered envelopes. Each envelope will correspond to one of the three study groups and the envelope will be opened by the participant himself after the initial assessments. The nature of the interventions will preclude blinding the physical therapist who will provide the behavioral intervention. However, the rater, the patient, and statistician will be blinded to the allocation of patients to groups.

Interventions: the intervention will last for 12 weeks, and all groups will participate in an educational program. Participants in the intervention group will receive weekly online sessions on behavior change and motivation for physical activity, a pedometer, and strategies linked to this specific feedback.

Inclusion Criteria:

Age from 18 to 60 years; diagnosis of moderate to severe asthma according to the Global Initiative for Asthma (GINA); under drug treatment for at least 6 months; clinical stability for at least 1 month; absence of cardiovascular and/or musculoskeletal diseases that may interfere/prevent the testing and physical activity; absence of other lung diseases besides asthma; preserved cognitive function; not being a smoker or having smoked <10 pack-years; reporting not complying with current physical activity guidelines (150 minutes per week of moderate to vigorous physical activity); be able to make video calls through any free platform and/or app available.

Exclusion Criteria:

Presence any new orthopedic limitation that impairs the performance of physical activities; perform 150 minutes per week of moderate to vigorous physical activity during the initial assessment confirmed by objective measurement (Actigraph); desire to drop out of the study.

Research aims:

Primary aim:

To verify if two multicenter online behavior change programs that aim to increase physical activity and reduce sedentary behavior have positive effects on the control of moderate to severe asthma, quality of life, functional capacity, symptoms of anxiety and depression, and sleep quality of adults with asthma in the short and medium term.

Secondary aims:

To observe whether the results found in asthma control, quality of life, level of physical activity and motivation for it, sedentary lifestyle, functional capacity, symptoms of anxiety and depression and sleep quality after the intervention are maintained in the medium term (6 months).

To verify if patients' basic psychological needs are met with interventions and if patients achieve a more self-determined intrinsic motivation for physical activity after each intervention.

To observe whether patients who achieve intrinsic regulation and motivation with the intervention have higher levels of physical activity in the medium term (6 months) compared to those who do not reach this level. To investigate the association of sleep quality with the profile of physical activity and sedentary behavior in adults with moderate-severe asthma.

…

Conclusions or Pending and List of Inadequacies:

All pending issues listed by this committee in a previous opinion (Opinion Number: 4.889.890) were accepted or justified by the researcher. No issues or inadequacies.

Final considerations at the discretion of the CEP:

The research protocol complies with CNS Resolutions No. 466/12 and/or CNS No. 510/2016 and other complementary CNS Resolutions, as well as the provisions of Operational Rules, Manuals and Circular Letters of the National Health Council (CNS) and the Commission National Research Ethics Committee (CONEP). Reports (partial and/or final) must be submitted every 12 months from the date of approval of this protocol. To prepare the report, the researcher must use the specific form available on the CEP UNOPAR website (https://www.pgsskroton.com.br/unopar/comite-humanos.php) and forward it via Plataforma Brasil as NOTIFICATION. The researcher may also present reports at any time, in cases of relevance. Reports of adverse events must be reported to this committee, in accordance with the provisions of Circular Letter CONEP/CNS nº 008/2011.

Any changes in the research protocol during its execution must be informed to CEP UNOPAR as an AMENDMENT, identifying the changes, together with the presentation of the justification. If the relevant reports are not presented, the CEP may temporarily suspend further analysis of other research protocols by the same researcher.

Decision status:

Approved

Joice Sifuentes dos Santos
Unopar Research Ethics Committee Coordinator
e-mail: cep@unopar.br
+55 43 3371-9849
https://www.pgsskroton.com.br/unopar/ce-unopar/cep-pitagoras-unopar/

Comprovante de Assinatura Eletrônica

contraktor

Datas e horários baseados no fuso horário (GMT -3:00) em Brasília, Brasil
Sincronizado com o NTP.br e Observatório Nacional (ON)
Certificado de assinatura gerado em 25/07/2022 às 12:23:16 (GMT -3:00)

parecer CEP ingles 20 07 22 (1)

ID única do documento: #8e72e1f8-67e6-4498-9814-8744858eac1f

Hash do documento original (SHA256): 75eda5350e4ecf68362de0d3057d5a19b25bcac0b81e69bb36cfc33fe124b399

Este Log é exclusivo ao documento número #8e72e1f8-67e6-4498-9814-8744858eac1f e deve ser considerado parte do mesmo, com os efeitos prescritos nos Termos de Uso.

Assinaturas (1)

Joice Sifuentes dos Santos (Participante)
Assinou em 25/07/2022 às 09:23:45 (GMT -3:00)

Histórico completo

Data e hora	Evento
25/07/2022 às 12:23:45 (GMT -3:00)	Joice Sifuentes dos Santos (Autenticação: e-mail joice.sifuentes@kroton.com.br; IP: 177.204.7.156) assinou. Autenticidade deste documento poderá ser verificada em https://verificador.contraktor.com.br. Assinatura com validade jurídica conforme MP 2.200-2/01, Art. 10o, §2.
25/07/2022 às 12:23:16 (GMT -3:00)	Joice Sifuentes dos Santos solicitou as assinaturas.