

Study protocol to evaluate cardiovascular disease prevention and control programs in an oil company

Protocolo de estudo para avaliar programas de prevenção e controle de doenças cardiovasculares em uma empresa de petróleo

Maria Lúcia Ribeiro Rocha¹ 

Ana Marice Teixeira Ladeia² 

¹Corresponding author. Empresa Brasileira de Serviços Hospitalares/EBSERH (Salvador), Escola Bahiana de Medicina e Saúde Pública (Salvador). Bahia, Brazil. mluciarocha@bahiana.edu.br

²Escola Bahiana de Medicina e Saúde Pública (Salvador). Bahia, Brazil. anamarice@bahiana.edu.br

ABSTRACT | INTRODUCTION: Health professionals in companies have implemented programs for the prevention and control of chronic noncommunicable diseases (CNCDs) in order to reduce illness and deaths of employees. These programs differ in the methodology adopted, with no data in the literature on the strategy that offers the best cost benefit. **OBJECTIVES:** To assess whether the interdisciplinary model of a CNCDs prevention and control program is superior to the multidisciplinary model in cardiovascular risk reduction (CVR) in workers of an oil company and to describe the health profile of workers of the company. **METHODS:** The study will analyze a retrospective cohort of employees of an oil company in Bahia, with data from the period from 01.01.2016 to 12.31.2018. The available sample was divided into two groups, according to the program to which the employee was allocated. Health data were collected from electronic medical records, which will be analyzed using the SPSS version 12.0 statistical package. The impact of the programs will be verified by comparing the frequency of the RCV variable between the years 2016 and 2018, using the McNemar and Chi-square tests, with $P < 5\%$. This study was approved under protocol CAAE 14107619.3.0000.5544. **PREDICTED RESULTS:** Results of this study should allow the redirection of actions by this company, considering technical, scientific and economic issues involved, in order to effectively reach a larger number of people. Other companies may adopt the most appropriate model to reduce CVR among their employees, helping to reduce deaths from this group of diseases in Brazil.

KEYWORDS: Cardiovascular risk. Prevention programs. Cardiovascular diseases.

RESUMO | INTRODUÇÃO: Profissionais de saúde em empresas têm implementado programas de prevenção e controle de doenças crônicas não transmissíveis (DCNT) no intuito de reduzir adoecimento e mortes de empregados. Estes programas diferem na metodologia adotada, não havendo na literatura dados sobre a estratégia que oferece o melhor custo benefício. **OBJETIVOS:** Avaliar se o modelo interdisciplinar de um programa de prevenção e controle de DCNT é superior ao modelo multidisciplinar na redução de risco cardiovascular (RCV) em empregados de uma empresa de petróleo e descrever o perfil de saúde de empregados desta empresa. **MÉTODOS:** Estudo analisará uma coorte retrospectiva de empregados de uma empresa de petróleo da Bahia, com dados do período de 01.01.2016 a 31.12.2018. A amostra disponível foi dividida em dois grupos, de acordo com o programa ao qual o empregado está vinculado. Foram coletados dados de saúde em prontuário eletrônico, os quais serão analisados utilizando o pacote estatístico SPSS versão 12.0. O impacto dos programas será verificado comparando a frequência da variável RCV entre os anos 2016 e 2018, por meio dos testes McNemar e Qui-quadrado, com $P < 5\%$. Estudo aprovado através de CAAE 14107619.3.0000.5544. **RESULTADOS ESTIMADOS:** Resultados deste estudo possibilitarão o direcionamento de ações por parte desta empresa, considerando questões técnicas, científicas e econômicas envolvidas, no intuito de atingir de forma efetiva um maior número de pessoas. Outras empresas poderão vir a adotar o modelo mais adequado para reduzir o RCV entre seus empregados, colaborando com a redução de mortes por este grupo de doenças no Brasil.

PALAVRAS-CHAVE: Risco cardiovascular. Programas de prevenção. Doenças cardiovasculares.

Introduction

The health profile of the global population has changed over time, owing to factors such as technological advances, economic and educational development, and demographic growth. This has led to redirection of social policies and strategies for the promotion, prevention, and control of diseases¹⁻⁴.

According to the Pan American Health Organization (PAHO), in 2016, chronic noncommunicable diseases (CNCDs) were responsible for 71% of all deaths worldwide, with over 85% of premature deaths occurring in low- and middle-income countries being associated with existing socioeconomic inequalities⁵⁻⁷. In Brazil, in 2018, 54% of all deaths were due to CNCDs according to data from the Ministry of Health⁸.

In view of this reality, CNCDs have become a major public health problem, determining the need to develop coping strategies on the part of agencies and institutions working in the health field worldwide⁹⁻¹⁵.

Companies which keep individuals in the productive phase as employees—have an important role in the control of modifiable risk factors, since by legal determination they monitor the health of these people annually¹⁶.

Literature data indicate that companies have adopted actions to reduce the risk of CNCDs, however, information related to the comparison of effectiveness obtained by different strategies is scarce¹⁷⁻²⁰.

This work will offer the results obtained from the implementation of two intervention programmes in an oil company. These programmes, being run by occupational health professionals, aim to

reduce cardiovascular risk (CVR) among employees using different resources and strategies. As a main objective, we hypothesise that the interdisciplinary model of a programme for the prevention and control of CNCDs that will be tested is superior to the multidisciplinary model in reducing cardiovascular risk in employees of an oil company, in addition to describing the health profile of these employees for the period from 2016 to 2018.

With this information, it will be possible to redirect actions—considering technical, scientific, and economic aspects involved—to effectively reach a larger number of people and to contribute to the reduction of medical absenteeism, which will have a positive impact on business results. Other companies may adopt the most appropriate model to reduce CVR among their employees to help reduce deaths from this group of diseases in Brazil.

Methodology

Study Design

A retrospective cohort study of a restricted and fixed population (whose information was included in the electronic medical record from 1 January 2016 to 31 December 2018) was carried out for this study.

Location

An oil company in Bahia, Brazil with Occupational Health Services in Salvador and at the operational base of São Sebastião do Passé, was selected as the study site.

Target population

Employees of the oil company who were active in the period from 2016 to 2018 participated in this study.

Sample Selection

The available sample consisted of employees who fulfilled the inclusion criteria; they were divided into two groups according to the type of programme to which they were linked. Employees accompanied by a team from Salvador will be part of group A (multidisciplinary/control model) and those who participated in the programme on the operational base will form group B (interdisciplinary model/case).

Inclusion criteria

- a) To be linked to the company in the period from 1 January 2016 to 31 December 2018;
- b) Have performed a medical evaluation for each year evaluated;
- c) Have remained in the same position/function, in the same place of work, and in the same regime for the period studied;
- d) Have blood pressure, weight, and height records for each year studied, as well as the result of total cholesterol, high-density lipoprotein cholesterol (HDL-C), low-density lipoprotein (LDL) cholesterol, triglycerides, and fasting blood glucose.

Exclusion criteria

- a) Individual removed from the company for more than four months over the course of one year due to illness, except cardiovascular disease (CVD);
- b) Individual diagnosed with pathology that can distort the calculation of cardiovascular risk, such as neoplasms, psychiatric disorder, thyroid disease, prolonged use of corticosteroids, etc.

Study Protocol

Data already collected from employees who were active in the period from 1 January 2016 to 31 December 2018, obtained from the electronic medical record, will be analysed. The income was obtained from the table of the Positions and Salaries Plan of the company, considering the range attributed to the position, without considering additional factors such as length of service or remuneration for paid function.

Medical record data were extracted from medical evaluations performed annually by employees and include clinical and occupational information, and complementary exams.

Blood pressure was obtained using manual or digital sphygmomanometer devices, calibrated by INMETRO, with the individual sitting in a chair with a back, feet flat on the floor, and left upper limb on the table.

Weight was checked on calibrated digital or analogue scales, with an individual wearing work clothes and without shoes, recorded in kilograms to two decimal places. The height was reported by the individual or obtained with the use of a stadiometer, in centimetres, with the individual standing and barefoot. Body mass index (BMI) was obtained from the weight/height formula².

Laboratory tests were carried out in accredited clinics with the fasting individuals.

Criteria adopted for the diagnosis of obesity, dyslipidemia, hypertension, diabetes were those established in guidelines of the respective scientific societies²¹⁻²⁴ described in Chart 1.

Chart 1. Criteria for the diagnosis of metabolic diseases

INDICATOR	CRITERION
BMI ²¹ Normal Overweight Grade 1 Obesity Grade 2 Obesity Grade 3 Obesity Abdominal Circunference (AC)	18,5 Kg/m ² - 24,9 Kg/m ² 25 Kg/m ² - 29,9 Kg/m ² 30 Kg/m ² - 34,9 Kg/m ² 35 Kg/m ² - 39,9 Kg/m ² 40 Kg/m ² - 94 cm in men; 80 cm in women
Isolated Hypercholesterolemia ²² Isolated Hypertriglyceridemia Mixed Hyperlipidemia Total Cholesterol Low HDL-c	LDL-c = 160 mg/dL TG = 150 mg/dL LDL-c = 160 mg/dL and TG = 150 mg/dL TC = 190 mg/dL HDL-c < 40 mg/dL (men) HDL-c < 50mg/dL(women)
High Blood Pressure ²³ Prehypertensive	HBP 140 x 90 mmHg Systolic HBP
Diabetes ²⁴ Prediabetes	Glycated hemoglobina (HbA1c)=6,5% ou Fasting blood glucose=126mg/dl (7,0mmol/l) Glycated hemoglobina (HbA1c) entre 5,7% e 6,4% ou Fasting blood glucose entre 100 mg/dl e 125mg/dl (7,0mmol/l)

Cardiovascular risk was calculated according to the Framingham score^{25,26}, which indicates the probability of occurrence of cardiovascular events in 10 years, using age, sex, smoking, blood glucose, systolic blood pressure, total cholesterol, and HDL-C as variables. The individuals will be distributed according to the risk classification as low (<10%), moderate (>10% and <20%), and high (>20%).

Behavioural variables will be categorised according to the criteria established in Chart 2.

Chart 2. Categorisation of behavioural variables

VARIABLE	EVALUATION	CLASSIFICATION
Tobacco use	Ex smoker Smoker Non-smoking Passive smoker Experimenter	1. Quit smoking and did not return 2. Smoked >100 cigarettes/life and smoke 3. Never smoked 4. Does not smoke and lives with a smoker 5. Smoked <100 cigarettes/life and smoke
Alcohol use	Every day 1 to 4 times a week 1 to 3 times a month Less than once a month Less than once a year or never drank	1. Frequent heavy 2. Frequent 3. Less frequent 4. Not frequent 5. Abstainer
Diet (consumption of fruits, vegetables, and greens)	Number of meals day with fruits, vegetables, and greens	1. Does not consume 2. Very low – 1 3. Low – 2 to 3 4. Regular – 4 5. Good – 5
Physical activity level	Physical activity level (light, moderate, vigorous) for days of the week; practice time/day	1. Inactive 2. Irregularly active 3. Regularly active 4. Very active

Source: Sistema informatizado corporativo de saúde

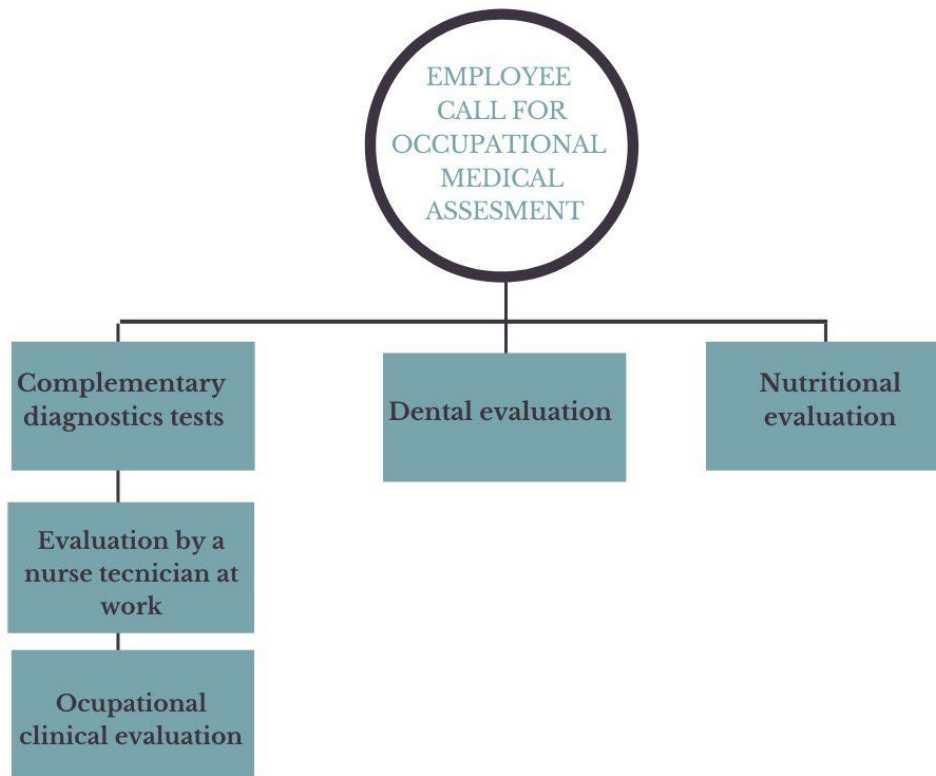
Models of Health Intervention Programmes

Two NCD prevention and control programmes, which differed in methodology, were implemented in the company. The multidisciplinary model (control) was developed by the health team in Salvador, while the interdisciplinary model (case) was implemented at the operational base of São Sebastião do Passé.

A. Multidisciplinary Model (Control)

After taking complementary exams at accredited services, employees scheduled the periodic evaluation, which started with the nursing technician checking anthropometric data, blood pressure, and immunisation status. Subsequently, the employee was evaluated by a doctor, dentist, and nutritionist. Each respective professional guided the employee according to identified problems and encouraged the adoption of healthy habits, such as the practice of physical activity, healthy eating, and reduced use of tobacco, alcohol, or other drugs (Figure 1). There was no discussion of cases among the professionals who make up the health team.

Figure 1. Flowchart of care by multidisciplinary team



The meals of these employees were taken outside the workplace and the company sponsored physical activity in external gyms for those interested, as long as they submitted to semiannual evaluations with the physical educator.

B. Interdisciplinary Model (Case)

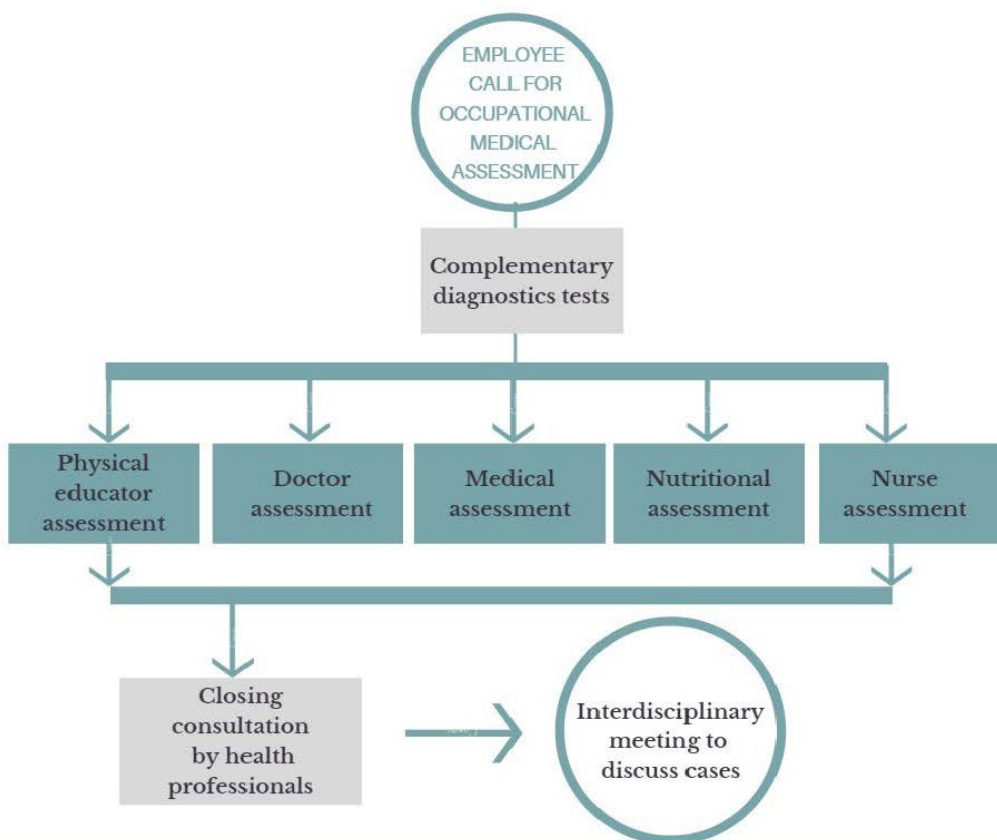
In the operational area, the programme had as its proposal the interdisciplinarity of actions carried out by health professionals. After completing complementary exams in accredited services, the employee attended the Occupational Health Service for the periodic evaluation previously scheduled. This started with the physical educator, continued with the doctor, nutritionist, nurse, dentist, and oral hygiene technician, who provided recommendations, according to identified problems, focusing on self-care. At the end of the process, a health professional, nurse, or psychologist discussed all the problems identified by each professional who had performed the service and reinforced the need for the adoption of healthy lifestyle habits and submission to treatments, when necessary.

After the consultations, each case was discussed by the team and an employee follow-up plan was established according to the degree of risk for CVD, according to the Framingham score^{25,26}. This included scheduling the return and referral to specialists, if necessary. From this stage on, it was defined whether the employee would also be attended by a physiotherapist, social worker, and psychologist, depending on the health need that she or he presented. The actions instituted were aimed at controlling chronic pathologies and reducing risk factors for NCDs, in addition to monitoring people with anxiety disorder, depression, or chronic pain. As a strategy, there was the encouragement of the consumption of fruits and vegetables and the adoption of physical activity (Figure 2).

This programme offered the employee an internal space to practice physical exercise for 30 minutes of his workday, or subsidised the frequency in spaces outside the unit. Participants were evaluated by a physical educator before starting the programme and every six months, regardless of the CVD risk classification they presented.

The employees monitored in the programme were discussed in monthly interdisciplinary meetings when decisions related to the needs of individual intervention were established. The team's goal was to reduce the health risk of each participant, with the programme indicators being presented and discussed in critical management analysis meetings.

Figure 2. Flowchart of care by interdisciplinary team



Employees in operational areas received food from the company, prepared according to a menu supervised by a nutritionist from the health team; this provided a reduction in the supply of simple fats and carbohydrates, as well as an increase in the supply of fibres.

It is worth mentioning that the employee was not obliged to join the programme and that there was no administrative loss foreseen for cases in which the proposed monitoring plan was not complied with. However, when the state of health was incompatible with the requirements of the tasks, temporary or permanent removal of activities occurred.

Statistical Hypotheses

Null Hypothesis (HO): The multidisciplinary and interdisciplinary programmes do not present significant differences in results in reducing cardiovascular risk.

Alternative Hypothesis (HA): The interdisciplinary programme has a superior result in reducing cardiovascular risk than that obtained by the multidisciplinary model.

Variables

Employees will be analysed according to age, sex, education, income, place of work, company time, work regime, type of activity developed (operational, administrative, managerial), weight, height, BMI, waist circumference, blood pressure, fasting blood glucose, total cholesterol, HDL, LDL, cardiovascular risk, level of physical activity, and consumption of fruits and vegetables.

Statistical Analysis Plan

Data analysis will be performed using the statistical package SPSS (Statistical Package for the Social Sciences) version 12.0 to test the hypothesis that the interdisciplinary model (case) of the NCD prevention and control programme obtained a superior result in reducing the cardiovascular risk to that of the multidisciplinary model (control), developed in an oil company.

The sample size calculation obtained an N of 118 individuals for each group, based on the proportions rule, which considered that after the intervention, the interdisciplinary group had 20% of individuals at high cardiovascular risk, while the multidisciplinary group would have 40% at high cardiovascular risk. This was to demonstrate the difference between the groups, with α values of 0.05 and β of 80%. However, it is intended that the sample is composed of all the company's employees—as long as they meet the inclusion criteria. As of 31 December 2018, this group consisted of 880 people, with 646 in operational areas and 234 in Salvador.

The difference in impact between the two programmes will be verified by comparing the frequency of high cardiovascular risk, according to the Framingham score^{25,26}, between the years 2016 and 2018, presented by employees in groups A (multidisciplinary/control) and B (interdisciplinary/case), using the Chi-square test (between groups, categorical variables).

The impact of each programme will be verified by comparing the frequency of cardiovascular risk, according to the Framingham score^{25,26}, presented by the employees of each group in the years 2016 and 2018, using the McNemar test (intra-group, paired) to observe if there was a reduction in the percentage of individuals classified as high risk.

Groups will be compared for the years 2016 and 2018, intra and between groups, for health-related and behavioural variables using the McNemar test (intra-group, paired, categorical variables) and the Chi-square test (between groups, categorical variables), and Student's t test to compare means (numerical variables).

The health profile of employees will be described for the period from 2016 to 2018, according to demographic, behavioural, occupational, and health variables, using the mean and standard deviation for numerical variables and frequency for categorical variables to verify the trend in the period studied.

It will be checked whether there is a difference in the distribution of risk factors and high cardiovascular risk according to the Framingham score^{25,26} by age group, sex, position, work areas, work regime, physical activity, and diet. Logistic regression analysis will be performed to verify the confounding effect of these variables, considering high cardiovascular risk as an outcome.

Statistical analyses will be performed assuming a significance level of 5% ($p < 0.05$) for all tests used.

Feasibility

The study will use electronic medical record data, which one of the researchers (MLR) has access to because she is a company doctor. Consent was granted by the Coordinating Physician of the Occupational Health Medical Control Program (PCMSO) and the company's legal guardian.

The company supports the project and will benefit from the verification of the effectiveness of actions developed in the prevention and control of CVD risk factors, being able to adapt the programme planning to optimise resources, and improving the results achieved.

Risk

This research will be carried out using secondary data, which results in minimal risk to the participants, according to the criteria of Resolution CNS 466/2012.

There will be no disclosure of the identity of the participants, with the names being replaced by a numerical record, making it impossible to associate data with people.

The data will be processed by doctors, who are subject to the professional category code of ethics and are committed to safeguarding the privacy of individuals.

Benefits

Results of this study will be published in the form of an article, contributing to the production of knowledge in the area of public health—more specifically in the area of occupational health—enabling actions to prevent and control risk factors for CVD to be reviewed and/or adopted by companies from various segments, benefiting a large number of workers. This is expected to reduce the number of people who become ill or die from this cause.

In the evaluated company, the study will be used to define unique guidelines for the health area, expanding care for employees and optimising human and financial resources.

Ethical aspects

A study will be carried out using secondary data, without the need for additional interventions to those already carried out to assess the work capacity of employees, according to legal requirements.

Employees who are in the company will be contacted and asked to complete the Free and Informed Consent Form.

Data will be processed by doctors as well as researchers linked to this project with CAAE 14107619.3.0000.5544, who will respect the privacy of the subjects under investigation, taking care that there is no disclosure of individuals' information.

Access to the medical records had the consent of the Coordinating Physician of the company's PCMSO.

Expected results

The analysis of the data resulting from the monitoring of the health of employees monitored in prevention programmes allows evaluation on the effectiveness of the actions developed, identifying points of improvement, which will be considered in the planning for subsequent periods. This is a recommended practice in public health, although it is not common to compare results obtained by different methodologies, notably in the field of occupational health.

There are few publications that evaluate different intervention models, especially with a fixed population. Viterbo²⁷ published a study comparing the results of an interdisciplinary NCD prevention programme with data from employees from different areas of an oil company—without systematic monitoring by the health area and with dynamic cohorts.

This study will provide new knowledge about the impact of health programmes, as it will show results of the comparison of two prevention programmes developed in the same company, with a fixed population for the period studied. This care will reduce biases related to exits and entrances in the cohort, filling existing epidemiological gaps.

Occupational health professionals will be able to compare the methodologies they have adopted, with the proposals discussed in this study, discovering new ways of approach and intervention in health, with a focus on reducing risk factors for CVD.

This study does not propose to evaluate the cost benefit of the programmes, but the data obtained can be used in the development of future interventions to identify which of the strategies offer results that justify the investments made in health.

Author contributions

Rocha MLR developed the protocol. Ladeia AMT carried out the critical review and approved the final text.

Competing interests

There are no conflicts of interest related to project financing or the type of results that could be obtained. The researcher, despite being employed to the company where the study will take place, was not part of the teams related to the evaluated programmes. The company did not influence the study design nor will it influence the data analysis. No other financial, legal or political competing interests with third parties (government, commercial, private foundation, etc.) were disclosed for any aspect of the submitted work (including but not limited to grants, data monitoring board, study design, manuscript preparation, statistical analysis, etc.).

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