STUDY PROTOCOL. Elkar laguntza

AIMS

The general aim of the present research will be to evaluate the effectiveness of a peer social support intervention in cancer patients at the Onkologikoa Foundation of Guipuzcoa. Specifically, the immediate and long-term effect that such intervention will have on symptoms of psychological distress, quality of life, coping strategy, perception of social support, perception of the disease and emotional regulation will be evaluated. As a secondary aim of this study, we intend to evaluate the immediate and long-term effect of the peer social support intervention on the immune system (through the determination of the levels of cytokines IL-1β, IL-2, IL-6, IL-8, IL-10, IFN-γ and TNF-α), on the monoaminergic system (through the determination of plasma levels of serotonin, tyrosine, phenylalanine, tryptophan, quinurenine, quinurenic acid and 3-HK), on the HPA axis (through the measurement of the diurnal cycle of cortisol), and on sex hormones (through the measurement of estradiol and testosterone levels), systems that have been related both to the development of anxious-depressive symptoms and to the development, progression and recurrence of cancer.

In addition, it will be studied at what time the application of the program is most effective, being applied in newly diagnosed patients (experimental group 1) and in patients who have just finished medical treatment (experimental group 2).

METHODS

The present project will consist of a longitudinal clinical trial to evaluate the effectiveness of a peer social support intervention in cancer patients at the Onkologikoa Foundation of Guipuzcoa.

The intervention will consist of 8 face-to-face peer social support sessions conducted by volunteers diagnosed with various types of cancer who have finished their medical treatment (chemotherapy, radiotherapy, surgery) or who have been in a stable phase for at least two years and who are motivated to participate in this type of intervention. These people will initially be informed through informative meetings or through letters sent by e-mail by professionals from the Onkologikoa Foundation and the Osakidetza Active Patient program and, afterwards, they will be referred to the program coordinator Joana Pérez Tejada for a series of evaluations with the aim of checking whether these people have an adequate physical and mental recovery and that participation in the program will have the minimum psychological impact on them. Thus, the medical history will be checked and the following psychological variables will be evaluated: personality (through the Big-5 Inventory Short Version questionnaire), coping style (through the COPE-28 questionnaire), presence of anxious-depressive symptoms (through the Hospitalary Anxiety and Depression Scale questionnaire), resilience (through the resilience questionnaire) and emotional regulation (through the Emotion Regulation Questionnaire).

The selected individuals will participate in a training program conducted by experts in the field, including psychologists, physicians and oncologists, in which lectures, group work and role playing will be conducted under the supervision of the researchers. The main topics covered

during the program will include: cancer diagnosis and treatment, management and prevention of side effects, healthy habits, emotional intelligence, empathy and communication skills, among others. All volunteers will be informed of the importance of confidentiality of patient information.

Each of the volunteers will have to be with 2 or 3 patients at the same time since some authors state that performing support to more than one patient can compensate for a poor relationship with another patient, as well as serve as support in the event of a patient's death (Moulton et al., 2013). The volunteer-patient sessions will be conducted in rooms set up for this purpose in the Carlos Santamaría building of the UPV/EHU. After each session with the patients, each volunteer will have to attend an individual session with the program coordinator Joana Pérez Tejada to discuss their emotions and reactions after performing the intervention. Psychological supervision of the volunteers is a fundamental part of avoiding retraumatization and the possible appearance of anxious-depressive symptoms (Giese-Davis et al., 2006). Likewise, volunteers will have to participate in group sessions every two months with the rest of the volunteers and the program coordinator Joana Pérez Tejada in order to strengthen group cohesion, resolve doubts, detect needs and carry out the necessary training.

The patients in this study will be 120 patients with various types of cancer from the Onkologikoa Foundation. Each patient will be matched with a volunteer depending on the type of tumor and medical treatment, since some authors state that for the support program to be effective, the volunteers must have had the same type of tumor and medical treatment as the patients (Pistrang et al., 2012). This is why it will be necessary to homogenize the group of volunteers as much as possible so that the sample of patients has as little variability as possible. The inclusion criteria are: having received the diagnosis of cancer in the last month; not having started medical treatment; the tumor type and medical treatment coinciding with any of the volunteers. The exclusion criteria are: relapse; suffering or having suffered from a serious mental disorder (according to DSM-V criteria). The recruitment of these patients will take place just after the diagnosis, and the professionals of the Onkologikoa Foundation will be in charge of offering this type of intervention to the patients who meet the inclusion criteria of the study.

Those patients who are interested in participating will be informed about the present research project by the coordinator of the program and by the members of the research team of the Onkologikoa Foundation and it will be these same people who will be in charge of giving the information sheet and the informed consent, and of summoning each participant for the collection of data for the first evaluation. Each participant will be given an evaluation questionnaire of sociodemographic, clinical and psychological variables that he/she will have to bring completed for the day of the appointment. Also, each participant will be given four saliva collection bottles, which they will have to collect four times the day before their appointment. The times of collection of these saliva samples will be upon waking up, 30 minutes later, before lunch (between 13:00 and 13:30) and before dinner (between 20:00 and 20:30). The saliva samples will be collected by the program coordinator at the Onkologikoa Foundation and will be coded and managed by the Biobanko. Subsequently, they will be taken to the Psychobiology laboratory of the UPV/EHU for the determination of different biological variables. In addition,

participants will have to undergo a blood draw on the day of the appointment. The blood collection will be performed by a nurse member of the research team of the Onkologikoa Foundation. The blood samples will be coded and managed by the Biobanko. Subsequently, they will be transferred to the Psychobiology laboratory of the UPV/EHU for the determination of different biological variables.

After this first collection of clinical, psychological and biological data, patients will be randomly selected, through a balanced block randomization method, to be part of the experimental group 1 (EG1) or the experimental group (EG2). As this is a crossover design clinical trial, patients in GE1 will start the peer social support program before the start of medical treatment, while patients in GE2 will start the peer social support program after the end of medical treatment.

For each GE1 patient, a specific volunteer will be selected based on the patient's tumor type and medical treatment, although depending on the availability of volunteers, other variables will also be taken into account: age, preferred language, time availability, partner, children and socioeconomic level. Once selected, each patient and volunteer will be given a letter of introduction to the other, in order to learn basic information about the patient before the first session. The social peer support program will begin the week prior to the start of medical treatment. There will be a total of eight sessions, one every fifteen days approximately, for a total duration of four months. The duration of each session will be as follows: the first and second sessions will last approximately one hour, the following sessions will last an average of 30 minutes. Patients and volunteers will be given the possibility to request a change of person in case they feel that the bond between them is not adequate.

Once the support program has been completed in EG1, a second evaluation of clinical, psychological and biological variables will be carried out, and, in addition, satisfaction with the intervention program will be evaluated, thanks to the Treatment Satisfaction Questionnaire. In GE2, the evaluation of clinical, psychological and biological variables will be carried out four months after the first evaluation. A third evaluation of all participants will be carried out 15 days after receiving the news of the end of the medical treatment (chemotherapy or radiotherapy). At four months and eight months after the end of medical treatment (chemotherapy or radiotherapy), the fourth and fifth evaluations will be carried out. In each of these evaluations the procedure will be as follows: each participant will be given a questionnaire of psychological measures to fill in before their appointment and four saliva collection tubes, which they will have to collect the day before their appointment. In addition, they will be scheduled for a blood draw and for the collection of the questionnaires and saliva samples.

GE2 patients will participate in the peer support program, but the application of this intervention will take place 15 days after receiving the news of the end of medical treatment. The intervention in this group will have the same characteristics and the same evaluations as those of GE1.

VARIABLES

The sociodemographic and clinical variables to be collected are: age, marital status, employment status, language, family situation, clinical history of interest, personal and family history of psychopathology, pharmacological, psychological and substance use treatment, tumor type, stage and medical treatment.

The psychological variables will be assessed by means of the following questionnaires: Big-5 brief personality questionnaire, HADS anxiety and depression questionnaire, COPE-28 coping questionnaire, brief illness perception questionnaire, MOS-SSS social support questionnaire, SF-12 quality of life questionnaire, resilience scale, ERQ emotional regulation scale and the program satisfaction questionnaire.

The biological variables to be determined are:

- In blood: levels of cytokines related to tumor development and inflammation (IL1β, IL-2, IL-6, IL-8, IL-10, IFN-γ and TNF-α); monoaminergic activity (tyrosine, phenylalanine, tryptophan, quinurenine, serotonin, quinurenic acid and 3HK) and IDO activity (through the tyrosine-kinurenine ratio).

- In saliva: the diurnal cortisol cycle and estrogen and testosterone levels.

DATA ANALYSIS

The relationships between the variables collected will be analyzed with the SPSS version 22.0 statistical package and with the JMP 10 statistical package. In all the analyses performed, the following variables will be controlled: type and duration of medical treatment and pharmacological treatment. Repeated measures analyses will be performed to study the effect of the intrasubject support program. Also, in order to study the possible physiological and psychological differences between experimental groups 1 and 2, analysis of variance (ANOVA) will be carried out. Pearson's correlation coefficient will be used to analyze the relationships between the different physiological and psychological variables considered in this study. Several General Linear Models (GLM) analyses will be performed to determine the predictive value of each of the variables in the possible benefit obtained after the application of the program. To study the interactions in each of the GLM analyses performed, a simple regression analysis will be carried out.