How to carry on an effective community program of exercise-oncology. A pilot experience.

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Abstract

Introduction:

Exercise-oncology is an emerging area, but exist a lack of information about an effective methodology to establish counseling programs long-lasting and not based on research objectives. This observational study objective was to evaluate the feasibility and effective exercise-oncology community intervention in a real patients sample.

Material and Methods

inclusion criteria were evaluated firstly in Asociación Española Contra el Cáncer from Madrid by a nurse, to ensure patients safeness. After that, patients in different cancer moments (after treatments, under treatments or metastatic) were evaluated their fitness and functional capacity and organized in 4 different level exercise programs of 12 weeks (wk), 2d/wk, attending not only their physical but also their individual necessities (treatments, limitations...). Physical tests were repeated at the end, 6 months and 12 months after program. Physical changes, adherence to program and post-program exercise were evaluated with STATA 15.0 program.

Results

309 patients with an age of 52,45 ± 11,03 were finally evaluated and followed-up. Patients' adherence to the program were 83% and after 6 months 52% of them maintain exercise levels. Significant improvements in fitness capacity, strength and in lean mass percentage and significant reductions in fat mass percentage were observed in all groups.

Conclusions

Exercise-oncology programs must adapt intervention to patients' necessities depending illness moments and patients' physical outcomes. This strategy proposing fitness level cut offs and objective adaptations has been proved as effective, feasible and safeness in order to be implemented in other community or health programs.

Introduction

The application of exercise-oncology in a real stage is a growing field, having a crucial role throughout the illness. In this sense, exercise has been proved as an effective intervention to prevent reductions in fitness and functional capacity, muscle mass and strength loss; and risings of fat mass, fatigue, anxiety and quality of sleep [1, 2]. Moreover, there has been increasing evidence proving the positive effects of exercise training on some prognostic biomarkers related to cancer such as reductions in sex hormone

levels, [3, 4] insulin levels, [5] inflammation levels [6–9] and rising the immune function [10]. The balance of these biomarkers has been directly linked to an improvement in survival in active patients of breast, colon and prostate cancer.

Despite all these benefits, patients and clinical specialists present a reduced adherence to clinical or community exercise-oncology programs, specially when patients are under oncology treatments. In order to provide support, the multidisciplinary roundtable organised by the American College of Sport Medicine (ACSM) published their professional guidelines in 2010 and reviewed in 2018, describing not only the exercise benefits but also the exercise interventions effectiveness [11, 12]. In addition, other institutions, such as the American Cancer Society (ACSM) or the Canadian Society for Exercise Physiology (CSEP), have highlighted the same idea, publishing general recommendations for cancer patients and cancer survivors to support clinicians and promote exercise adherence [13, 14].

However, in Spain, there is still a tremendous lack of these kind of programs. This is really surprising, even more if one considers the statement of the Sociedad Española de Oncología Médica (SEOM) which enlightened the necessity to develop effective community exercise-oncology interventions to support oncologists and patients by ensuring the performance of exercise in safeness conditions as well as a long-lasting adherence to physical exercise [15].

For this reason, the main objective of this pilot experience was to propose a feasible model for the implementation of an exercise-oncology program into specific community programs, providing specific support to clinicians. An effective exercise dose-response, to reduce side effects, as well as the safeness and exercise adherence after the program in cancer patients in different stages, were also evaluated.

Material And Methods

Experience Model

Design

A prospective clinical analysis about a pre/post exercise-oncology intervention of a real sample of patients was developed in Madrid. A total of 405 Patients participated into the exercise-oncology programas of the Asociación Española Contra el Cáncer (AECC) of Madrid, from September 2018 to December 2019. The intervention was designed following by the Programs Area of AECC, following a multidisciplinary model including different AECC profiles such as a nurse, a psycho-oncologist and exercise-oncology specialists.

This study was performed in line with the principles of the Declaration of Helsinki and an informed consent was obtained from all individual participants included in the study. STROBE Guidelines for Epidemiological Studies were followed to write this paper.

Study Population

Three different type of patients were included: a) patients that recently finished their treatments but still presented secondary effects (patients under hormonotherapy are included here); b) patients under chemotherapy, radiotherapy or target therapy treatments; and c) patients with advanced or metastatic cancer. The patient inclusion criteria consisted of three main requirements: to have an Eastern Cooperative Oncology Group (ECOG)≤1, to be able to walk 500 meters without resting, and to feel or present any physical side effect related to cancer treatments, like weakness, fatigue, change in body composition and/or physical pain, without significant clinical implications. Exclusion criteria were as follows: to present any physical or psychological disability, to have an ejection fraction below 50%, to have any American Thoracic Society recommendations to not develop a Cardio Pulmonary Exercise Test [16], to present joint limitations with need of rehabilitation exercise, grade 1-2 lymphoedema, or to present active bone metastasis.

Patients were informed about this exercise-oncology program by hospital clinicians, hospital volunteers or coordinators from AECC or another AECC workers. A nurse, with an assistant role, helped all patients when they arrived to AECC facilities, providing them detailed information about AECC programs. Regarding exercise, all the participants were evaluated by the assistant nurse before starting the program to check if they fulfilled the participation criteria. Medical informed consent was mandatory to be enrolled in the program and the entire group of participants had to sign an informed consent and a Physical Activity Readiness Questionnaire (PAR-Q). After the first initial contact with the nurse, a one-to-one structured session was programed with the objective to gain information regarding the patients' clinical history, to evaluate the patients' physical necessities and to incorporate them to the most adequate exercise group.

In order to guaranteed patients' safeness and following the ACSM guidelines, four exercise groups with different levels were organized:

Level I: include patients with a VO_{2max} between 18 -26 ml.kg.min and leg strength under normal rates (1,62/1,05), especially for metastatic patients.

Level II: include patients with VO_{2max} between 26-33/39, with normal rates of leg strength, especially for patients under treatment with acute side effects.

Level III: patients with normal VO_{2max} (> 33/39) but low strength level. Patients with acute side effects after treatments of patients under treatments with a history of active lifestyle, usually were included here.

Level IV: patients with normal levels of fitness capacity or strength with a previous sport history were most included here.

In addition, each patient persuaded a personalized objective depending on his or her body composition, such as to achieve a body fat mass reduction or a lean mass improvement.

Exercise-oncology intervention

The exercise program was designed and conducted by two qualified exercise physiologists with oncology training aligned with ACSM guidelines [11].

It consisted on a 12-week supervised and in group intervention, with twice per week sessions of 90 minutes and was developed in a friendly and close environment, which promoted social interaction between participants. Apart from the twice-weekly supervised sessions, as early as the fifth week, one or two individualized home-based sessions were established for each patient in order to achieve his/her specific objectives with the help of any required supporting material such as documents and video references with exercise examples.

All sessions had the same structure: 10 min of warm-up at 60-70% maximal heart rate (MHR), followed by 600-70 minutes of specific training and 10 minutes of stretching exercises. At least, 20% of the total session time was based on cardiovascular work over 70% of the maximum heart rate (MHR) in order to have an impact on the levels of prognostic biomarkers [17-19].

As it can be observed in Figure 1, fitness work in the first eight sessions was planned following 30 minof the time on cardiovascular exercise 55 min on work out in low to moderate intensity In the next eight sessions, the time spent on cardiovascular work was slightly increased to 35 min , with 50 min focused on work out to reach the maximum number of structural and neuronal adjustments, combining moderate to high intensity sessions. Finally, the last eight sessions presented the same structure as the first ones but combining moderate to high intensity.

Initial cardiovascular intensity was set at 65 to 75% of maximum heart rate (HR) and was increasing 5% every 3 weeks until 90% of maximum HR in HIITs interventions. Initial strength intensity was set at 40% of the estimates 1-RM for upper body exercise and 65% of the estimated 1-RM for lower body exercises.

The intensity and exercises of the sessions were fully adapted to each patient’s necessities, monitoring the aerobic intensity with a heart control device (POLAR H10)(Lake Success, NY). The strength intensity was personalized by the 5 Resistance Maximum (5RM) test and, in addition, this test was reviewed at week 6 to fit strength intensity to the patients’ neural adaptations.

Exercise intervention was complemented with three theoretical sessions consisting on: 1) the analysis of exercise intervention benefits, program characteristics and adaptations to the program to each patient goal; 2) the review of the objectives and home-based plan sessions developed until week 12, including general nutrition information; 3) the analysis of the motivation and barriers anticipation in order to achieve better levels of follow-up adherence. This last session was developed at the end of the program with the help of the psycho-oncologist.

Measurements

Demographic data, disease and treatment information, physical activity test and patient reported outcomes (PRO) were collected in the one-to-one baseline session. The physical and PRO measurements were repeated after 12-weeks program and in the follow up 6 and 12 months after the program ending.

The final and the follow-up assessments were developed with the objective to provide personalized exercise counseling which encourage the adherence to leisure time physical activity. To complete this information and follow up the patients exercise adherence and quality of life, the exercise professionals contacted the patients 3 months after the 12-weeks program finished..

To determine the *feasibility of this community exercise intervention,* four different items were taking into account:

1) percentage of every patient assistance to the classes;

2) percentage of patients' drop out during every program;

3) percentage of occupation obtained by the comparison of the number of potential patients' attendance with real ones;

4) and the leisure-time physical activity adherence after 6 months of exercise intervention.

In addition, other factors as distance to the center, previous physical activity level, physical status at baseline and fatigue level were analyzed as well..

The effective dose-response of exercise was evaluated by physical tests and the achievements of expected changes in every patient. These tests were:

a) *Fitness capacity:* It was evaluated by a sub maximum test on a treadmill. Oxygen volume was registered by a gas analyzer (FitMate MED) [20] which estimated the maximal oxygen uptake (VO_{2max}) and measured METS. In addition, 6 minutes walking test (6MWT) was recorded. Normal VO_{2max} level has been established as 33 m ml/kg/min for women and 39 ml/kg/min for men. An expected change of 3.39ml.kg.min in estimated VO_{2max} and a rise in 60 meters in 6MWT was planned as significant change [21, 22].

b) Strength level: was evaluated by two maximum tests of pectoral and leg press. Maximal strength was assessed by 5 Maximal Strength protocol to predict 1RM [11] and Mayhew formulae were used to predict 1RM [23]. Tests were developed in Technogym machines. Strength level (SL) was obtained dividing Weight Pushed/Body Weight, focussed on leg press [24]. SL Low was established in 1,62 for men and 1.05 for women and an expected rise of 15% in upper-limbs RM and 30% in legs press RM was planned to the patients.

c) *Body composition:* it was evaluated by bioimpedance (Inbody 770) recording: weight, fat mass percentage (FM%), lean mass percentage (LM%) and visceral fat. Recommendations about hydration and fasting period before test were followed. Objectives were adapted depending on body composition characteristics: a) patients without treatments and with low LM% goal was to gain 2,2% of LM% or to achieve normal levels [25]; b) Patients under treatments with low LM% goal was to maintain same LM% ratio; c)patients with normal LM% and high levels of FM% goal was to lose 1,5% of FM% [26].

Statistical Analysis

The program was evaluated during 15 months in order to know the patients' adherence after 12 months. Demographic data and patients' characteristics were presented by frequency or mean ± standard deviation (mean±SD) if they are qualitative or quantitative, respectively.

All results are divided between three different patients' profiles: Not-treatment patients (NTP) but with side effects; under-treatments patients (UTP) and patients with metastatic disease (MP).

Program results regarding patients' assistance; dropouts and long-lasting adherence were presented by frequencies. Effectiveness-dose response was presented by differences between means and confidence interval at 95% and were analyzed by related mean t-test comparisons, comparing pre and post test results. Objective achievement per patients was presented by percentage.

Results

A total of 309 patients were included in the exercise-oncology programs of 2019 with an occupation level of 85,68%. Demographic and personal characteristics were showed in table 1, and the consort diagram with the model experience were presented in Fig. 2.

Sample description

Related to sample main characteristics, most of the participants were women with breast cancer (60,8%), followed by ovary cancer ones (9,7%), and patients (both male and female) with lung (7,4%) and colorectal cancer (6,7%). Most of the patients lived in an area close from the AECC facilities (less than 15 km), and 79% of patients reported low fatigue levels. Curiously, around 50% of patients had a low previous physical activity levels and 40% of them reported medium physical activity level.

In terms of baseline status, most of patients included showed levels of fitness capacity under healthy rates and 47% of patients showed low levels of strength. The patients with lower fitness levels included in groups Level I and II were especially metastatic patients (67,86%), followed by patient with no treatments (55,83%); and patients included in Level II and IV were mostly patients under treatments (54,28%) followed by patients with no treatment at the moment of baseline assessments (44,17%). In addition, with regard to patients' objective, more than 50% of them showed high level of fat mass, with special attention in patients after treatments (Fig. 3).

Principle Objective

Regarding the main objective, adherence to the program was above 80% in all types of patients, and the lower dropout were observed in under-treatment patients. Over 50% of patients that were contacted 6 months after the program, maintained adequate physical activity adherence, specially those patients who initiated the program under treatment (67,48%). Curiously, 54,54% of metastatic patients showed physical

activity in healthy rates. By contrast, patients that started the program after treatments showed the lowest levels of exercise adherence (43,74%) (Table 3)

All physical parameters assessed related to program efficacy (fitness capacity, strength level and body composition) showed significant improvements in pre-post comparisons (Table 3). Regarding fitness capacity, metastatic and after treatments groups showed the lowest levels in baseline assessment, showing the greater improvements during the final measurement (over 60% achieved fitness objective). In addition, strength was the parameter with the highest risings, achieving the planed objective over 70% in every group. On the other hand, the objectives planed in body composition were relative low, specially in lean mass improvements (not treatment: 42,86%; under treatment: 41,67%; and metastatic: 22,22%).

Discussion

This pilot experience shows that the exercise-oncology program performed at AECC from September 2018 to December 2019 as a community intervention was a feasible, safe and effective strategy to reduce side effects of oncology treatments, with the innovative concept that cancer patients in different stages were included in the exercise intervention. The multidisciplinary assistance was essential for enabling the exercise dose response to the baseline level of the patients, which encourage patients' adherence. In similar lines, the combination of an exercise intervention with an educative program developed by a psycho-oncologist might increase safeness, attendance and long-lasting adherence.

In terms of the main objective, the proposed methodology not only achieved high rates in assistance and adherence to the program (over 80% patients) but also encouraged maintained healthy levels of physical activity 6 months after the exercise intervention (over 50% patients).

Most long-lasting adherence of exercise were observed in the group of patients who started the exercise intervention during active treatments, which suggests that as the sooner the exercise is introduce, the higher the exercise adherence might be. Furthermore, our results show that this group of patients presented lower fitness and physical impairments than those that have finished the treatments. In this case, exercise might be used to prevent the most disabling side effects such as fitness capacity reduction and changes in body composition, related to metabolic and cardiac disabilities that may appear in a future [27].

However, it has been observed that most vulnerable patients, those with metastatic cancer, present higher ratio of dropouts, specially due to treatment side effects. Related to this situation, a combination of different programs to attend their specific necessities, including home-based or online interventions, might be an alternative way to support all their necessities.

Curiously, patients without treatments at the beginning of the exercise program showed low rates of adherence in the 6 months follow-up contact. This suggests that other complementary strategies such as specific programs close to their area and more motivational interventions are needed to increase their physical activity.

In this pilot experience, it has been observed that, most of the cancer patients presentlow rates of fitness capacity, specially metastatic and after treatment patients' groups. These low rates, are directly linked with the patients' survival and with patients' cancer-related fatigue which might condition their quality of life, their reincorporation to work or the continuity of the cancer treatments[21, 28]. This type of experience suggests that 12 weeks exercise intervention, supervised by a professional, may increase fitness capacity over the level determined as effective (3,39 $ml.kg^{-1}.min^{-1}$), not only improving patients' health at this moment but also preventing future comorbidities.

Other important side effect observed was the high level of fat mass in baseline assessments, which is related to a worse cancer prognosis, especially in colorectal, breast or ovarian cancer [29–31, 28, 32]. This exercise dose-response has been shown as effective tool, reducing significantly the fat mass rate in patients that presented unhealthy levels.

Despite the significant results, the targeted objective of lean percentage gain was not achieved in more than 50% of patients, specially in metastatic ones. Treatment lines accumulation might difficult this challenge and nutrition orientation should be needed to improve muscle mass ratios as other studies have shown [33].

In spite of the interesting remarks highlighted by this intervention, these results should be considering with caution, in first place because patients that come into the AECC are not representative of the total of patients in the hospitals reality; in second place, because the male representation is residual; and finally, because there is a lack of specialists in exercise-oncology in Spain by both, a lack of exercise professional qualifyedand a lack of a recognized professional area in the health care system.

Conclusions

This pilot experience proposes a feasible and effective intervention with a multidisciplinary approach capable to include a high number of potential patients in different stages and ensuring patients safeness. In addition, this experience suggests that exercise intervention should be included as near as possible of the diagnostic moment, with the objective to prevent or minimize the impact of the side effects on the patients' health as well as to increase exercise adherence long-lasting.

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Declarations

Funding

No founds.

Conflicts of interest/Competing interests

Any author present conflict of interest

Availability of data and material

Data are in a Data Base from AECC with only access from AECC site and from researchers' computers.

Authors' contribution

All authors contributed to the study conception and design. Material preparation and data collection were performed by Soraya Casla, Lucia Gil, Monica Castellanos, Enrique Casas, Sonia Vizcaino y Ana González and analysis were performed by Soraya Casla. The first draft of the manuscript was written by Soraya Casla and Lucía Gil and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

Ethics approval

This is an observational study recording data from clinical practice. All patients sign an informed consent where data publication are explained. Ethical Approval is not needed.

Consent to participate

This study was performed in line with the principles of the Declaration of Helsinki. Patients sign an informed consent before going under the exercise intervention, accepting the data collection and publication

Consent for publication

The informed consent includes a specific point about data collection and publication.

Tables

Please see the supplementary files section to view the tables.

Figures

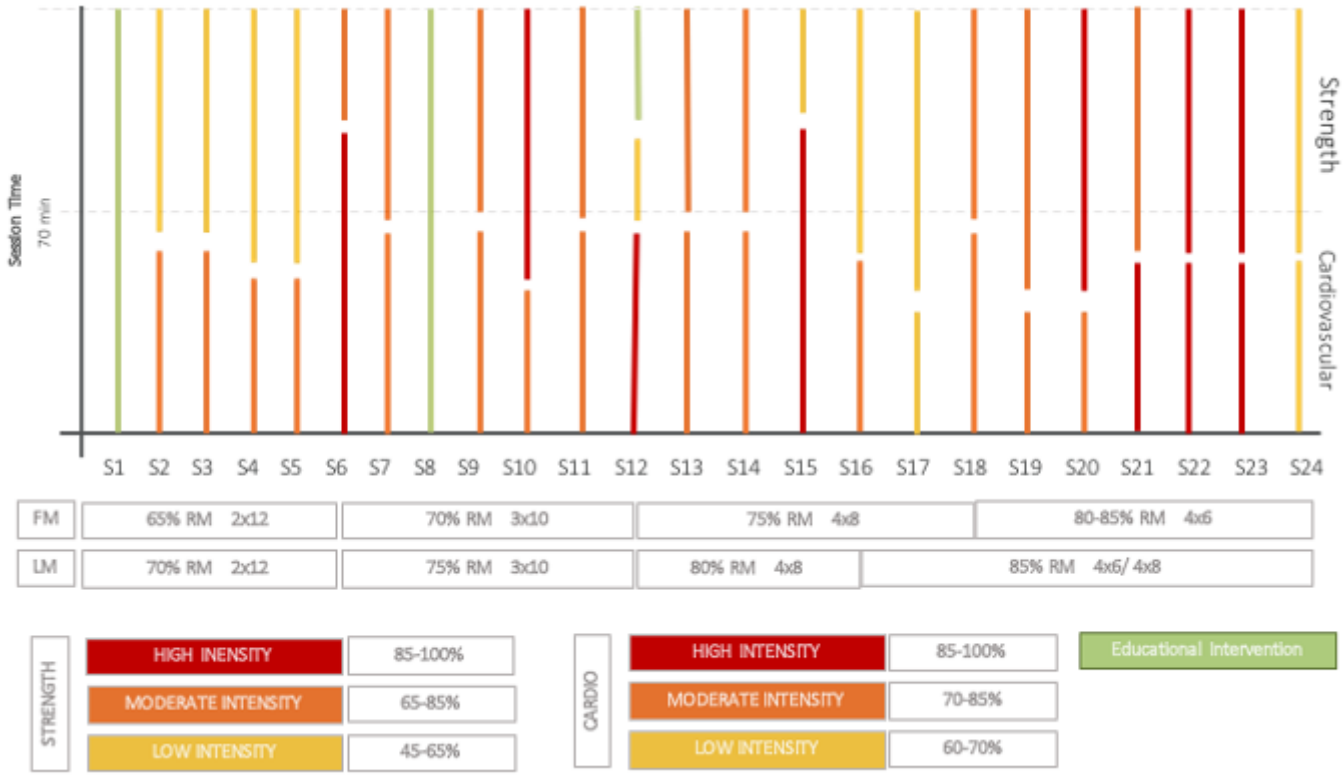

Figure 1

Intensity schedule of the program. Exercise type duration and intensity in each session are represented in figure 1. Upper lines are related to strength training and lower lines are related to cardiovascular training.

Lines' colours are related to intensity trainings and are specified in lower tables. Strength progression of the different body composition goals are shown below the lines' schema.

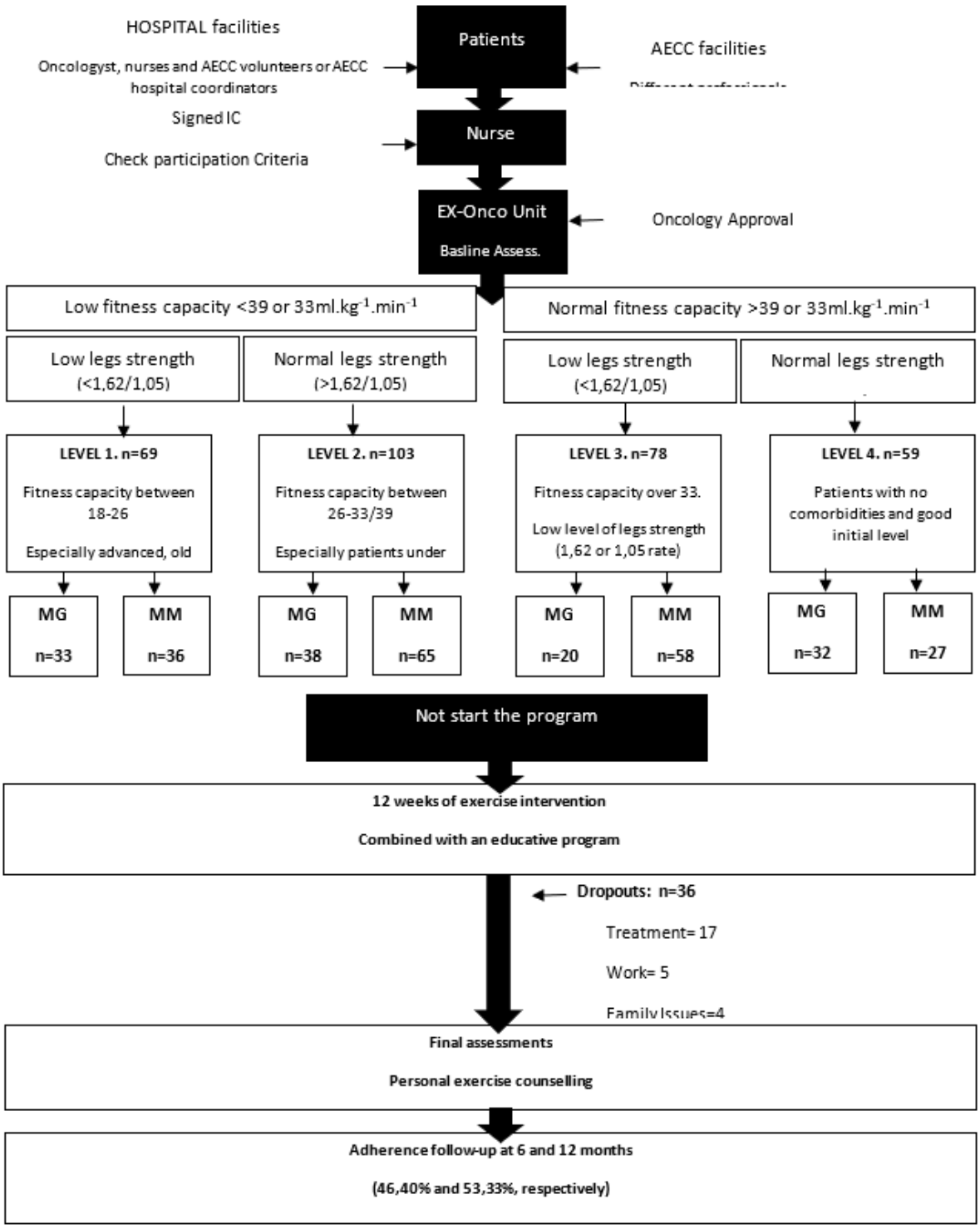

Figure 2

CONSORT diagram. Model experience.

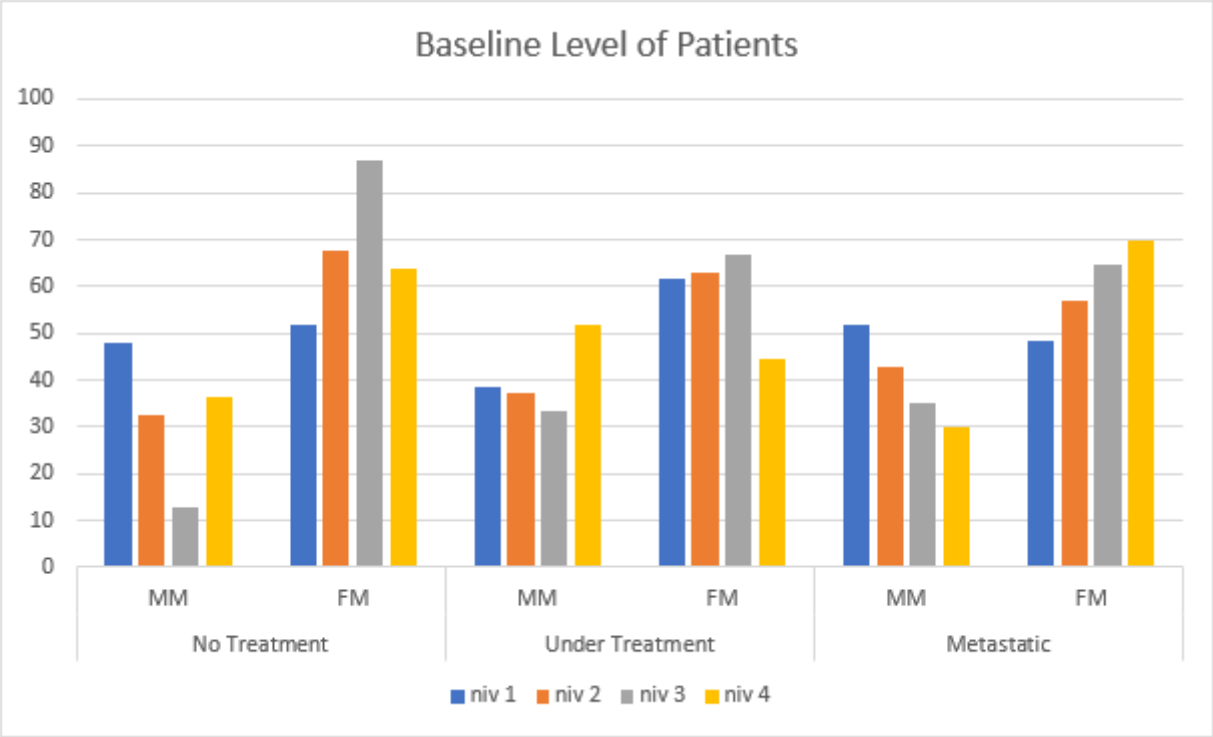

Figure 3

Baseline physical status. Diagram shows distribution by level and body composition objective in the different patients' profiles. Patients overweight and obese are more usual in patients after treatments, while patients with sarcopenia are distributed usually in metastatic and under treatment patients' profiles. Patients with lower fitness levels had present lower muscle mass in survival patients. However, patients under treatment showed lower fitness level with higher fat mass ratios. The most metastatic patients showed fitness level 1 or 2 in both sarcopenic and overweight groups.

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- Tables.pdf