[redacted]

[redacted]
Global Oncology Young Investigator Award (GO YIA)

Applicant Information Form

Completed Sep 21 2020

Applicant Information

The information below is pulled directly from your ASCO profile. If you need to make any changes to your information, visit profile.asco.org. *Changes made to your profile do not save in this form in real-time but will be reflected before submission of your full application.*

Please make sure that your profile has the most up-to-date information before you submit your full application.

Upon completing this form, click **Mark as Complete** at the bottom of the page.

First Name

[redacted]

Middle Name

[redacted]

Last Name

[redacted]

Degree

[redacted]

Primary Organization Name

[redacted]

Address 1

[redacted]

Address 2

[redacted]

City

[redacted]

State/Province

Zip/Postal Code

[redacted]

Country

[redacted]

Primary Email Address

[redacted]

ORCID ID

[redacted]

ASCO Member ID

[redacted]

Do you have a medical degree (MD, DO) or the international equivalent?

[redacted]

If you have a doctorate degree, enter the date you completed or will complete your final doctoral fellowship training.

[redacted]

Do you have a full-time faculty appointment (this includes the Instructor position)?

[redacted]

Enter your initial faculty appointment date (This is your first faculty appointment after completing your training).

[redacted]

Academic Rank

(No response)

Subspecialty Training

(No response)

Field of Clinical Training

Select all that apply.

Responses Selected:

Geriatric Medicine
Hematology and Oncology
Psychosomatic Medicine

Field of Research Training

Select all that apply.

Responses Selected:

Health Behavior
Health Services Research
Psychology

GO YIA Project Information Form

Completed Sep 23 2020

Project Information

Enter general information about the research project being proposed in this section.

At the bottom of the page:

Click **Save and Continue Editing** to save the information you have entered.

Click **Mark as Complete** once you have completed all fields. If you need to edit any information you have previously entered, click (...) at the top right corner of the form and hit **Edit**.

Research Project Title

Enter a short descriptive title of the research project, not to exceed 250 characters.

Assessing Feasibility and Acceptability of a Geriatric Assessment Program for Older Patients Starting New Treatment with Chemotherapy in a [redacted] Telehealth System

Brief Research Project Description/Abstract

Provide a brief abstract of the proposed research project, not to exceed 3000 characters.

Background: Cancer patients living in developing countries face considerable challenges in obtaining access to specialized medical attention due to a lack of human resources and healthcare infrastructure. Geriatric assessments have now been recommended as part of the standard evaluation of an older adult considering cancer therapy. Evidence suggests that incorporating such an evaluation could be useful for potentially determining the patient's chemotherapy tolerability or treatment completion, toxicity, and survival, as age alone has been shown to poorly predict treatment failure, and performance status assessments commonly used in oncology practice may lack predictability. Our hypothesis is that integrating a geriatric assessment through telehealth into the care of older patients receiving chemotherapy will be feasible and may positively impact on physical function detected by the functional assessment.
Methods: This will be a pilot study to establish feasibility of a Brazilian geriatric assessment program for older adults with cancer starting chemotherapy. Patients older than 65 years old, diagnosed with any type of solid cancer, ECOG 0-2 and scheduled to undergo new cytotoxic treatment will be approached and invited to participate. If they agree to participate, a psychologist will conduct the geriatric assessment through telehealth. Results will be discussed with a multidisciplinary team and recommendations will be determined. Feasibility will be defined if 70% of the participants have completed all intended adherence at both time points. As a secondary aim, preliminary efficacy will be evaluated through physical function. We will assess changes from baseline to month 3 of Instrumental Activities of Daily Living - IADLs.
Discussion: Our proposal could potentially improve current methods and transform the way in which cancer care is delivered in developing countries by reaching a particularly vulnerable population with a mobile platform. The present application seeks to shift current clinical and research paradigms by demonstrating that providing older adults with cancer living in low- and middle-income countries (LMIC) with remote geriatric assessment is feasible, and by proving that such monitoring can be useful for measuring performance-based functional status and for early detection of chemotherapy toxicity.

Lay Abstract

Provide a layperson summary of the project, not to exceed 2500 characters. Describe your work in a way that it will be understood by people who do not have scientific or medical backgrounds. Be clear and avoid technical and scientific terms when possible. It should not include confidential information. If selected to receive an award, Conquer Cancer may use the content of this layperson summary on its website and/or other public facing materials.

The aging population is a significant challenge and a great opportunity for developing countries design strategies that can improve the care of older patients with cancer. We are planning to test a Telehealth system intended to provide geriatric care for older patients receiving chemotherapy. Geriatric assessment will help us to prioritize existing problems, detect unrecognized problems, and develop a treatment plan taking into account medical, psychological, functional, social and environmental factors (e.g., activities of daily living, cognition, emotion, mobility). These assessments will be followed by referrals to appropriate intervention to assist those patients in greatest need.

SPECIFIC AIMS

List succinctly the specific objectives of the proposed research project. The aims should state concisely and realistically what the research intends to accomplish and/or what hypothesis is to be tested, and should list measurable objectives for the proposed project. At least one specific aim is required.

How many aims do you have?

2

Specific Aim 1

To evaluate the feasibility and acceptability of a Geriatric Assessment Program among older adults starting new chemotherapy treatment in a [redacted]

Specific Aim 2

To explore preliminary efficacy of this program through physical function assessment as measured by the Instrumental Activities of Daily Living - IADLs three months after initiating treatment.

CLASSIFICATION

Subject Area

Select one Subject Area from the drop-down list that best describes your research grant project. If "Other" is selected, provide information in the text field.

Geriatric Oncology

Focus Area(s)

Scroll through the list to find research areas that may apply to your research project. You may check several research areas, but at least one focus area is required. If "Other" is selected, provide information in the text field.

Responses Selected:

Access to Cancer Care
Delivery of Cancer Care
Diagnostics and Screening
Geriatric Oncology
Global Oncology
Health Outcomes
Quality of Cancer Care
Quality of Life
Supportive Care

Research Classification

Select from the drop down list your research classification.

Cancer Control, Survivorship, and Outcomes Research

Type of Research Study

Select from the drop down list the nature of your research.

Health services research.

ASSURANCES

Animal Use

Indicate whether animals will be used in the research.

No

Human Subjects

Indicate whether human subjects will be involved in the research.

Yes

Assurance Status

Pending

USE OF DRUG(s)

Will your research involve the use of drug(s)?

No

RESUBMISSION

Indicate if this application is a resubmission from a prior cycle. If yes, you will be required to upload a one-page resubmission document addressing the feedback of the reviewers of your prior application.

No

How many mentors do you have?

If you select "2", the task "Mentor Invite 2" will appear once you hit "Mark as Complete" below.

2

Is at least one of your mentors an ASCO member?

[redacted]

GO YIA Upload Research Strategy

Completed Sep 24 2020

Upload your research strategy, limited to four (4) typewritten, single-spaced pages, with one-inch margins and 11 point Arial font type. All pertinent tables, pictures, and graphs MUST be included within the 4-page limit. Please refer to the Request for Proposals for details on what must be included in the Research Strategy.

If the document you uploaded exceeds the page limit, Conquer Cancer will return your application.

Use this file naming convention: [year program abbreviation] Research Strategy [Last name]

For example: 20xxGOYIA Research Strategy Smith

[redacted]

GO YIA Upload Biostatistical Plan

Completed Sep 24 2020

Upload a detailed biostatistical plan limited to one (1) typewritten, single-spaced page with one-inch margins and 11-point Arial font type. Please refer to the Request for Proposals for details on what must be included in the Biostatistical Plan.

If the document you uploaded exceeds the page limit, Conquer Cancer will return your application.

Use this file naming convention: [year program abbreviation] Biostatistical Plan [Last name]

For example: 20xx GOYIA Biostatistical Plan Smith

In addition, upload a letter of support from a biostatistician in the Additional Supporting Documentation section.

[redacted]

GO YIA Upload Cited References

Completed Sep 24 2020

Upload a bibliography of any references cited in the Research Strategy. The Cited References has no page limit, must be typewritten with single-space, one-inch margins and using an 11-point Arial font type.

Use this file naming convention: [year program abbreviation] Cited References [Last name]

For example: 20xxGOYIA Cited References Smith

[redacted]

GO YIA Budget Form

Completed Sep 24 2020

Budget

Enter the amount requested in the appropriate categories in the "Year 1" column. **DO NOT USE A COMMA** when entering budget amounts.

Budget justifications for each category requested must be entered in the "Description of Costs" column. You may upload additional justification in the **Upload Additional Supporting Documentation**, if needed.

*NOTE: Enter **N/A** in the "Description of Costs" for categories not being requested.*

The following budget limitations apply:

- Total Award: Total project cost can range from $25,000 to $50,000 (direct and indirect combined). All funds will be paid directly to the sponsoring institution.
- Research Support: Award funds in this category must include salary, supplies or equipment. Budgeted items must be consistent with available institutional facilities and resources.
- Travel*: Up to $1,500 should be allotted specifically for the applicant's travel to the Conquer Cancer Grants and Awards Ceremony and for any other travel directly related to the conduct of the research project. **allowed starting 2023*
- Indirect Costs: Up to 10% of the total award cost may be applied to overhead or facilities and administrative costs.

Direct Costs

	Year 1	Description of Costs (Required)
Consortium/Contractual Costs	0	N/A
Consultant Costs	0	Statistical analysis will be provided by the [redacted] (see letter of support). The costs for statistical will be waived.
Equipment	0	N/A
Other Expenses	0	N/A
Patient Care Costs (Inpatient)	0	N/A
Patient Care Costs (Out-patient)	0	N/A
		1) 27,000 USD will be allocated for the applicant's salary support. This amount is the equivalent of 13 times the minimum wage in Brazil and is the average salary received by a clinical investigator in the country. [redacted] She will

		independently collect and analyze the data derived from this project. The proposed work will be her primary area of research over the award period, if she is selected for funding. 2) 7,500 USD dollars will be allocated for the co-Investigator's salary. This amount will be allocated for a part-time oncologist, who will serve as the primary source for patient referrals for this study. He will provide general recommendations and offer clinical input for the data obtained. He will also assist in manuscript preparation. 3) 7,500 dollars will be allocated for a part-time research assistant's salary. This amount is the 3 times the minimum wage for Brazil in 2020. The selected research assistant will be a geriatrician who will offer clinical input for the geriatric assessment, and will offer a treatment plan for vulnerable or frail patients, identified in this study.
Personnel Costs	42,000	
Subcontracts	0	N/A
Supplies	1,000.00	700 USD will be allocated to the purchase of office materials, and for printing informed consents and questionnaires.
		Travel funds are requested for international travel to professional conferences to present findings associated with the investigation. Project personnel will attend the ASCO

Travel	5,000.00	Annual Meeting 2022. Funds are budgeted for 1 attendee ($5,000.00), and includes lodging, Per Diem, Transportation and Airfare. Due to the fact that this involves international travel, the entire travel costs will be dedicated to attending this meeting. Additional travel stipends will be acquired from other funding sources if the applicant wishes to attend other meetings.

Indirect Costs

	Totals	Description of Costs (Required)
Indirect/Facilities and Administrative Costs	2,000	$2,000 in facilities and administrative costs will be allocated for the [redacted] conduct and administer research project.

Indirect Total Costs

0

Direct Total Costs Year 1

0.0

Total Costs Year 1

0.0

GO YIA Upload Project Timeline

Completed Sep 23 2020

Use this project timeline template and upload once completed.

Use this file naming convention: [year program abbreviation] Project Timeline [Last name]

For example: 20xxGOYIA Project Timeline Smith

[redacted]

[redacted]

GO YIA Upload Resubmission Documentation

Incomplete Hidden from applicant

Upload a one-page introduction to address the reviewers' feedback and critiques on your previous application. The introduction must be typewritten, single-spaced page with one-inch margins and 11-point Arial font type. Please refer to the Request for Proposals for details on what must be included in the Resubmission Document.

I**f the document you uploaded exceeds the page limit, Conquer Cancer will return your application.**

Use this file naming convention: [year program abbreviation] Resubmission Doc [Last name]

For example: 20xxGOYIA Resubmission Doc Smith

GO YIA Personal Statement Form

Completed Sep 23 2020

Personal Statement

Answer the questions below. Each response must not exceed 2000 characters.

At the bottom of the page:

Click **Save and Continue Editing** to save the information you have entered.

Click **Mark as Complete** once you have completed all fields. If you need to edit any information you have previously entered, click **(...)** at the top right corner of the form and click **Edit**.

Applicant's career plan

Provide a brief description of your career plan.

1. To develop and lead a Geriatric Assessments program at my home institution. My goal is to create a multidisciplinary clinic in which older adults with cancer receive dedicated care by a team composed of oncologists, geriatricians, psychologists, nurses and other healthcare professionals with a geriatric patient-oriented approach. This would represent the [redacted], the [redacted] This will also be a steppingstone for the development of this field nationally.
2. To become a leading clinical researcher in the field of Geriatric Oncology in Brazil. The ASCO GO YIA, along with the support of my mentor and co-mentors, will provide me with adequate funding to start a meaningful research agenda. I plan to apply for ASCO's Career Development Award by the year 2022. My goal is to develop a career as a researcher examining social issues among older adults with cancer in Brazil, particularly regarding family structure and access to healthcare. The knowledge generated by my planned research could be useful not only locally, but also nationally and internationally, since it would potentially allow for a better understanding of the sociocultural aspects of Brazilian older patients, which could in turn lead to a more accessible, appropriate and equitable care for a growing underserved population. I would share this knowledge with leaders in the field in the US through networks I have created with [redacted]
3. To disseminate the principles of Geriatric Assessments in Brazil in order to help prepare the country for the imminent increase in older adults with cancer over the next decade. This research proposal constitutes the first step for this goal.

Impact of award on applicant's career

Provide a brief explanation on how receiving this award would affect your career.

1. Receiving this award would allow me to dedicate time to mentored research. Economic resources for science in Brazil are scarce, there are almost no funding opportunities for young investigators, and most grants are awarded to established researchers. Unlike this award, most grants for young investigators in developed countries are not open to international applicants. This is a critical barrier to research in developing countries; since many creative young physicians with valuable research ideas are unable to dedicate time to research. Receiving ASCO's GOYIA would represent a pivotal event in my career, since the funding and mentorship provided would allow me to allocate time to research that I otherwise would be unable to conduct.
2. Receiving this award would help me become a leader in the field of Geriatric Oncology in Brazil. International notoriety is highly valued in the Brazil scientific community. Receiving this very prestigious award would make me a highly recognized member of the Brazilian oncology community, particularly due to the fact that most past recipients of the YIA have been from institutions within the United States. This recognition, as well as having the support of a mentor [redacted] would give me leverage and support to move the field of Geriatric Oncology forward in my country, thus fulfilling my career goals of developing meaningful knowledge and resources for patients.
3. Receiving this award would provide me with the background to request further support for my career. Receiving this award and completing the proposed research would be a very valuable asset for requesting additional funding from other international and national institutions. Proving that I can successfully carry out an investigator-initiated project in a limited resource setting like Brazil, with the assistance of the GOYIA, would give me a better background to apply for ASCO's Career Development Award and for ASCO's Leadership Development Program.

Percentage time of research activities

Provide the percentage time you will spend on total research activities.

70

Applicant's role

Describe briefly your role versus your mentor's role in the proposed research study.

Applicant’s role

1. Leading the investigation as principal investigator
2. Development of the project with guidance and input from mentoring team
3. Prepare all IRB, regulatory, and funding documents
4. Assume primary responsibility for organizing patient recruitment, data collection and analysis of results
5. Oversee study staff to make sure that procedures are being followed directly
6. Performing the Geriatric Assessments through telehealth and daily monitoring for study patients
7. Conduct weekly meeting with collaborators (mentor, oncologist and international collaborators) to review potential enrollments, active study patients, data collection process and double checking of data
8. Work with the mentor and co-mentors to organize the data management of the study and data analysis of the results once the study is completed
9. Draft all abstracts, presentations, and manuscripts

Mentor’s role

1. Providing research guidance that will allow the applicant to successfully lead and complete the study, and providing the structure of the cancer center in order to deal with issues that would potentially distract the applicant from conducting the proposal
2. Double check all data using patient records and other original information
3. Provide the applicant with protected time for conducting the proposed research
4. Provide access to the facilities of the cancer center and to the patients seen at the Institution
5. Provide her help as the director in order to solve potential study pitfalls regarding barriers to recruitment or follow up
6. Critically reviewing study results, abstracts, presentations, and manuscripts

Sources of salary support

List the sources of your salary support.

Salary support that is not covered by the ASCO GOYIA will be provided through departmental funding, with the understanding that I will have a maximum of 40% of my time devoted to clinical activities. In addition, the clinical activities will encompass a Geriatric Oncology focus and thus provide direct translation of research into patient care.

Collection and analysis of data

Briefly describe who will collect and analyze the data.

The applicant will personally conduct the collection data and the daily monitoring of patients with a research assistant. The following tasks will be performed by the applicant:
1. Reviewing daily clinic visits for potential enrolments and eligibility criteria.
2. Collecting tumor and patient clinical data.
3. Collecting data from Geriatric Assessments, daily monitoring and toxicities.
4. Supervising the transcription of data into the study database.
5. Analyzing and presenting the data in cooperation with the mentor, the international co-mentor and a biostatistician.
The following tasks will be performed by a dedicated research assistant:
1. Obtaining informed consent from the patients.
2. Applying acceptability questionnaires.
3. Transcribing and coding data into the study database

The following tasks will be performed by the mentor:
1. Reviewing, double checking and critically analyzing all obtained data.

Clinical potential of research project

Briefly describe the clinical potential of this research project.

One of the main barriers for delivering high quality cancer care in developing countries is poor access to healthcare. It is usual for patients undergoing chemotherapy to arrive at their end-of-cycle appointment and reveal that they have been suffering from relevant toxicities since the beginning of treatment. This is caused by shortcomings of the healthcare system and by socioeconomic and cultural issues and is particularly pressing for vulnerable populations from remote geographical areas. The main clinical potential of this research project is:

1. If the project is successful, we would demonstrate that it is feasible to remotely perform a Geriatric Assessments of older adults with cancer undergoing chemotherapy in a limited-resource setting. If we identify patients with vulnerabilities, then interventions could be developed to assist older adults with cancer and improve patient outcomes. This is important as patients routinely have no kind of supervision and monitoring during chemotherapy and thus would receive the benefits of the prompt detection of clinically relevant toxicities.
2. Telehealth is particularly relevant in countries with limited human resources and infrastructure. By developing a remote Geriatric Assessments program, like the one we propose, a trained health professional would be able to assess, monitor and intervene among patients remotely and thus result in a better utilization of available resources and improved patient outcomes.
3. Ultimately, increasing the awareness and availability of Geriatric Assessments program throughout the country will increase the quality of care for older adults with cancer. Since there are many similarities between Brazil and other LMIC, our methodology and results could also inform parallel initiatives in comparable settings.

Other funding sources

List other funding agencies/organization where this research proposal was or will be submitted. If none, please indicate N/A.

This research proposal has not been submitted for any alternative sources of funding other than ASCO and the Conquer Cancer Foundation. If the requested funding is obtained, we believe that it will adequately cover all the expenses generated by the study, and additional funding will not be required in order to successfully complete the proposed project.

[ARCHIVED] GO YIA Upload Biosketch

Completed Sep 23 2020 Hidden from applicant

Upload your biosketch using the most recent NIH Biosketch template. Please refer to these **instructions.**

If the document you uploaded exceeds the page limit, Conquer Cancer will return your application.

Use this file naming convention: [year program abbreviation] Biosketch [Last name]

For example: 20xxGOYIA Biosketch Smith

[redacted]

[redacted]

GO YIA Mentor Invite 1

Completed Sep 23 2020

Invite your Mentor to submit a recommendation for your application. If your Mentor has an ASCO user account, use your Mentor's email address associated with his/her ASCO account to ensure access to the recommendation task in the Application Portal. If you used an incorrect email address, you may withdraw your request and create a new request using the correct email address.

To resend or withdraw your request, click the ellipsis **(...)** and select from the options.

Once your Mentor submits the recommendation, you will receive a notification. Click **Mark as Complete**.

Recommenders

[redacted]

Mentor Invite 1

First Name

[redacted]

Middle name

(No response)

Last name

[redacted]

Degree(s)

[redacted]

Institution Name

[redacted]

Email Address

[redacted]

ASCO ID

Enter your ASCO Member ID. If you are not an ASCO Member, enter N/A.

[redacted]

Biosketch (Maximum of 5 pages)

Upload your biosketch using the most recent NIH Biosketch template. Please refer to these **instructions.**

Use this file naming convention: [year program abbreviation] Biosketch [Last name]

For example: 20xxGO YIA Biosketch Smith

[redacted]

[redacted]

Letter of Support (Must be signed and on official institutional letterhead)

Upload your letter of support. For more details on what to include in the letter of support, please refer to the Request for Proposal (RFP) posted on asco.org/global-oncology-YIA.

Use this file naming convention: [year program abbreviation] LOS [Your Last name]

For example: 20xxGO YIA LOS Smith

[redacted]

GO YIA Mentor Invite 2

Completed Sep 24 2020

Invite your Mentor to submit a recommendation for your application. If your Mentor has an ASCO user account, use your Mentor's email address associated with his/her ASCO account to ensure access to the recommendation task in the Application Portal. If you used an incorrect email address, you may withdraw your request and create a new request using the correct email address.

To resend or withdraw your request, click the ellipsis **(...)** and select from the options.

Once your Mentor submits the recommendation, you will receive a notification. Click **Mark as Complete**.

Recommenders

[redacted]

Content:
Form

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

Institution Name

[redacted]

Email Address

[redacted]

[redacted]

ASCO ID

Enter your ASCO Member ID. If you are not an ASCO Member, enter N/A.

[redacted]

Biosketch (Maximum of 5 pages)

Upload your biosketch using the most recent NIH Biosketch template. Please refer to these **instructions.**

Use this file naming convention: [year program abbreviation] Biosketch [Last name]

For example: 20xx GOYIA Biosketch Smith

[redacted]

Filename: [redacted]

Letter of Support (Must be signed and on official institutional letterhead)

Upload your letter of support. For more details on what to include in the letter of support, please refer to the Request for Proposal (RFP) posted on asco.org/global-oncology-yia.

Use this file naming convention: [year program abbreviation] LOS [Your Last name]

For example: 20xx GOYIA LOS Smith

[redacted]

Filename: [redacted]

GO YIA Sponsor Invite

Incomplete Hidden from applicant

Invite your Sponsor to submit a recommendation for your application. Use your Sponsor's email address associated with his/her ASCO account to ensure access to the recommendation task in the Application Portal. If you used an incorrect email address, you may withdraw your request and create a new request using the correct email address.

To resend or withdraw your request, click the ellipsis **(...)** and select from the options.

Once your Sponsor submits the recommendation, you will receive a notification. Click **Mark as**

Complete.

Recommenders

GO YIA Upload Institutional Letter of Support

Completed Sep 24 2020

Upload a signed letter on official institution letterhead written by the Department Chair or Dean at your sponsoring institution that includes a statement confirming institutional support that will enable you to perform the proposed research. If your mentor is the Department Chair, the Institutional Letter of Support must come from the Dean. Please refer to the Request for Proposals for details on what must be included in the Institutional Letter of Support.

I**f the letter is not signed and not printed on official letterhead, Conquer Cancer will return your application.**

Use this file naming convention: [year program abbreviation] Institutional LOS [Last name]

For example: 20xxGOYIA Institutional LOS Smith

[redacted]

Filename: [redacted]

GO YIA Upload Clinical Protocol

Incomplete

If the research project involves a clinical protocol, it is strongly encouraged to upload a copy of the protocol.

Use this file naming convention: [year program abbreviation] Clinical Protocol [Last name]

For example: 20xxGOYIA Clinical Protocol Smith

GO YIA Publication Form

Completed Sep 23 2020

Publication(s)

Up to two prior publications that highlight the applicant's experience and qualifications may be included. The applicant must be at least a co-author on these publications. Please enter the publication information in this section including the title, the year published, the type of publication, publication status, and funding (whether the project was funded by Conquer Cancer or not).

Scroll to the bottom of the page to upload the actual publication.

How many publications are you including in your application?

[redacted]

Publication 1

Publication Title

[redacted]

Publication ID

Enter your PubMed ID number.

[redacted]

Publication Year

If the status of your publication is "In Press" or "In Preparation", please enter "0000" in the Publication Year field.

[redacted]

Publication Type

[redacted]

Publication Name

[redacted]

Publication Status

Select the status of your publication.

[redacted]

URL

Enter the URL in PubMed format: http://www.ncbi.nlm.nih.gov/pubmed/[PMID] where [PMID] is your publication's PubMed ID number.

For example: https://www.ncbi.nlm.nih.gov/pubmed/18276894

[redacted]

Funding Status

Indicate if your publication was a result of Conquer Cancer funding or not.

[redacted]

Upload Publications

File naming convention: [year program abbreviation] Publication 1 [last name]

For example: 20xx GOYIA Publication 1 Smith

[redacted]

Filename: [redacted]

Publication 2

Publication Title

[redacted]

Publication ID

Enter your PubMed ID number.

[redacted]

Publication Year

If the status of your publication is "In Press" or "In Preparation", please enter "0000" in the Publication Year field.

[redacted]

Publication Type

[redacted]

Publication Name

[redacted]

Publication Status

Select the status of your publication.

[redacted]

URL

Enter the URL in PubMed format: http://www.ncbi.nlm.nih.gov/pubmed/[PMID] where [PMID] is your publication's PubMed ID number.

For example: https://www.ncbi.nlm.nih.gov/pubmed/18276894

[redacted]

Funding Status

Indicate if your publication was a result of Conquer Cancer funding or not.

[redacted]

Upload Publications

File naming convention: [year program abbreviation] Publication 2 [last name]

For example: 20xx GOYIA Publication 2 Smith

[redacted]

Filename: [redacted]

GO YIA Upload Additional Supporting Documentation

Completed Sep 24 2020

Upload any additional documents relevant to your application (See Request for Proposals for examples). Letter of support from a biostatistician is required.

Use this file naming convention: [year program abbreviation] Supporting Doc# [Last name]

For example: 20xxGOYIA Supporting Doc1 Smith, 20xxGOYIA Supporting Doc2 Smith

[redacted]

Filename: [redacted]

[redacted]

Filename: [redacted]

[redacted]

[redacted]

Re: [redacted]

ASCO Global Oncology Young Investigator Award

To the members of the Committee

As Director of the *Centro de Câncer de Brasília*, I strongly support [redacted] Global Oncology Young Investigator Award grant proposal entitled "Assessing Feasibility and Acceptability of a Geriatric Assessment Program for Older Patients Starting New Treatment with Chemotherapy in a [redacted] has shown to be an outstanding psychologist with a remarkable aptitude for research. She has dedicated her expertise and efforts to this unique and much needed sector of psychology for well over a decade and most recently served as a postdoctoral fellow under [redacted] direct supervision in the Department of Medical [redacted] She has an extremely prolific publication record and has presented abstracts at both national and international meetings, but it is her dedication to the field and thorough, hard-working, and inquisitive nature that make her most deserving of this award. With the resources provided by this grant, and the full support of our institution outlined below, I have no doubt the project proposed by [redacted] will succeed.

[redacted] has authored or co-authored more than forty highly referenced publications and book chapters. She has been invited to present her work in several national and International symposia and has served as a reviewer for numerous international journals such as the [redacted] and others. She is an enthusiastic and dedicated researcher, with a deep knowledge of her field. [redacted] is remarkably competent and possesses excellent ethic and technical skills. As such she is undoubtedly qualified to conduct the proposed research on the feasibility and acceptability of a Geriatric Assessment Program among older adults in our cancer center. It is likely that the discoveries arising from this project will have relevance to the development of new resources for older patients with cancer and to promote access to effective comprehensive cancer care.

The resources necessary to accomplish this work are in place, and the [redacted] is perfect for this investigation. We are committed to the success of her research.

Organization's legal status

[redacted] is a private cancer center located in the [redacted] Its activities include the provision of tertiary-level medical care with technical, physical facilities, equipment and human resources to provide expert care in the diagnosis and treatment of cancers. This cancer center has recently integrated the group Unity, a holding that includes other cancer care from different states in Brazil. A total of 18 cancer centers, located in 3 states, integrate the group Unity, which means 163 places for chemotherapy infusion, more than 60,000 chemotherapy infusion per year, partnership with 5 large hospitals, 2 radiotherapy center, and 192 physicians

(oncologists, hematologists, surgeons, radiotherapists). In addition, the research department (Instituto Unity) launched its activities that include the development of scientific research, education and training of health care personnel.

Resources and Infrastructure Provided for the Project

As one of the [redacted] we have a profound commitment to fully support our research personnel. Our researchers have protected time, technical support, and a variety of institutional resources. As Director, I can assure that we will provide the infrastructure to facilitate the completion of the proposed research at [redacted]. Specifically, we will guarantee that existing resources such as facilities, meeting rooms, telephone and internet access, and technical staff will support this research program. Additionally, [redacted] will have access to research personnel for this project (research assistants, administrative assistants). All the equipment that is currently assigned to our cancer center may be used to support this research in order to accomplish the objectives of the grant. [redacted] ill also have protected time at our cancer center to ensure the development of the project [redacted] will also have our full support to attend national and international meetings in order to present the results of this project, as well as pursue publication in leading journals.

Prior Experiences Administering Research Grants.

[redacted] has participated in many clinical researches, and has a partnership with the [redacted] which lead us to perform high quality researches. Resources were provided by nonprofit institutions and pharmaceutical companies.

Experience with Conquer Cancer, the ASCO Foundation

Currently, most physicians working at [redacted] e members o[redacted] As such, researchers from our cancer center have submitted abstracts and attend the ASCO Annual Meeting regularly.

Support for Applying the Findings

Upon completion of her proposed research project, [redacted] ill continue to have full support for continuing a research program in geriatric oncology. We will provide her with resources that will enable her to implement her validated program and provide her with networking opportunities to disseminate the new knowledge obtained by the proposed project. We will also fully support her to implement this geriatric assessment program in [redacted] In addition, we will fully support her in obtaining additional funding for any other research projects that may stem from this proposal. As a very relevant and influential cancer center, we are sure that our backing will allow [redacted] o establish future goals and pursue the next steps of her research agenda.

Financial Consideration

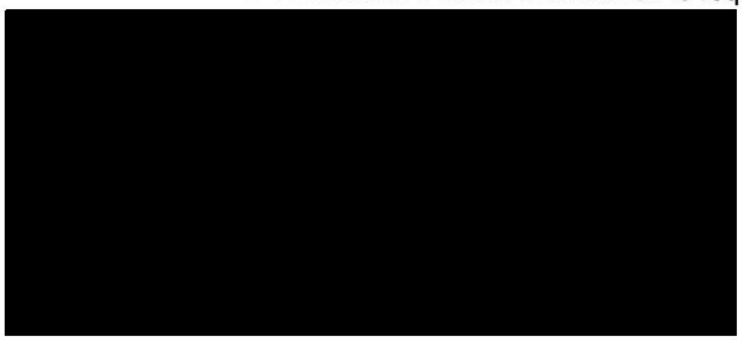
[redacted] ill ensure the appropriate handling and management of the requested funds according to the approved budget. We will put together monthly financial reports for the grant, which can be sent to granting organization as required. We will certainly provide reports for expenses after six months during the research project period and at the conclusion of the grant.

In summary, [redacted] roposal would address a priority for cancer control that needs national attention. We at [redacted] hat the potential of her research is outstanding, and we have committed our support to her. [redacted] and her team have strong research experience, full institutional support, and we are sure that her project

[redacted]

will be successful. I hope that you find her application just as valuable and likewise provide her with support.

Please feel free to contact me if further information is requested.



September 21, 2020

ASCO Conquer Cancer Foundation
2020 Global Oncology Young Investigator Award

RE: [redacted]

To the Members of the Committee:

I am pleased to lend my support to [redacted] for her Conquer Cancer Foundation Global Oncology Young Investigator grant proposal entitled: “Assessing Feasibility and Acceptability of a Geriatric Assessment Program for Older Patients Starting New Treatment with Chemotherapy in a Brazilian Cancer Center”. For her proposed project, I was involved in the design and statistical considerations of the study.

I have been working as a biostatistician for over five years in the medical field. My statistical experience includes analyzing retrospective and prospective observational longitudinal studies as well as large medical databases and data from randomized controlled trials. I am familiar with various advanced statistical methods, including mixed-effects modelling procedures. I joined [redacted] where I regularly attend the supportive care team meetings and enjoy rich collaboration with the geriatric program. I met [redacted] during the time she did her Postdoctoral Fellowship and started to develop and work on collaborative projects.

I am very happy to be one of the co-investigators on her proposed research and will provide any statistical support that she needs. I will work with [redacted] to help analyzed and monitor her data. I am also willing to be a co-author on any abstracts and manuscripts from this project.

I am excited to work with [redacted] and I wish her the best of luck with the grant application.

[redacted]

[redacted]

[redacted]

RE: "Assessing Feasibility and Acceptability of a Geriatric Assessment Program for Older Patients Starting New Treatment with Chemotherapy in a Brazilian Cancer Center"

[redacted]

Conquer Cancer, Global Young Investigator Award Grant Evaluation Panel

Dear Members of the Panel:

It is my pleasure to provide my highest level of support to [redacted] in her application for a Conquer Cancer Global YIA. The aging of the population is a significant challenge, and at the same time an enormous opportunity, for healthcare systems in developing countries, and designing strategies which can improve the care of older adults with cancer in LMIC are essential. [redacted] thoughtful proposal will address one of the critical issues for geriatric oncology in developing countries, which is accessibility to specialized human resources. In this proposal, [redacted] will test a telehealth system intended to provide geriatric care for older adults with cancer in areas of Brazil where geriatricians may not be available. Furthermore, [redacted] and her team will evaluate the efficacy of the intervention utilizing geriatric specific measures, such as the instrumental activities of daily living. I am very enthusiastic about this proposal, and I believe it could change the way geriatric oncology care is delivered in Latin America.

I am a [redacted], and I currently lead the Cancer Care in the [redacted] and [redacted]. My main area of research is focused on improving access to care for vulnerable older patients with cancer living in underserved areas of [redacted] As such, I have previously developed and conducted studies utilizing mobile health and telemedicine for increasing access to cancer care among older adults with cancer.

As a collaborator of this study, I will provide my expertise in the design and implementation of research in geriatric oncology. I have participated in the design of the protocol and I will continue to provide feedback as needed. I will make sure that [redacted] can disseminate her research and network with leaders in the field of geriatric oncology in Latin America. Additionally, I will assist in the interpretation of the obtained data as well as in preparing

the study manuscripts. I have previously worked with the Conquer Cancer Foundation and I will provide that expertise to [redacted] in order to carry the project forward successfully.

This study has the potential to move the field of geriatric oncology forward and lead to an improvement in care of older patients with cancer and their families. Furthermore, I believe that this collaboration represents a great opportunity to generate global solutions to shared problems [redacted].

Sincerely yours,

[redacted]

[redacted]

[redacted]

ASCO Conquer Cancer Foundation
2020 Global Oncology Young Investigator Award

RE: [redacted]

To the Members of the Committee:

It is a great honor to write this letter of recommendation on behalf of [redacted] an applicant for the Global Oncology Young Investigator Award from the American Society of Clinical Oncology and the Conquer Cancer Foundation. [redacted] nothing short of an international star in the field of cancer research, she has excelled throughout her career as a Psychologist and I believe that she is truly an ideal candidate for this Award. I firmly believe that [redacted] has a strong educational background, and a true interest in improving the care of older adults with cancer in [redacted] as is shown by her already completed research and a well-developed, focused and realistic career plan.

[redacted] has trained at [redacted] for the last [redacted] and she currently holds the position of [redacted] During her postdoctoral research fellowship, she has demonstrated a strong interest in the area of Geriatric Oncology, both in clinical and in research activities. She has worked with [redacted] and several other medical oncology clinicians [redacted] Center, showing great dedication to achieve her accomplishments. As a Psychologist, she has successfully contributed to the professional and personal development of her co-fellows. She also possesses great networking skills, as shown by her ability to foster cooperation between [redacted] for the development of the current project (see letters of support). Through these collaborations, I have no doubt that [redacted] will succeed in starting to develop her research career.

[redacted] project represents the first step towards testing the feasibility of a Geriatric Assessment program through telehealth in Brazil. Unfortunately, Geriatric Oncology training and practice in our country is scarce. This proposal is supported by previous pilot data from research done in the [redacted] is appropriately designed and has adequately defined aims and plans to achieve them. I also believe that the project is feasible that it will be approved by our institutional IRB before the grant period starts, and that it can be completed with the funding provided and in the proposed time period. [redacted] has also secured statistical support from biostatisticians at the [redacted] which will help her overcome one of the main issues with studies performed in [redacted] which is a lack of dedicated statistical support.

As indicated in her application, [redacted] has independently developed a comprehensive career plan in the context of this award, which consists of the following:

[redacted]

1. [redacted] and I will have a dedicated time for discussing advances in the project and in [redacted] This time will be scheduled every two weeks on Thursdays from 1 PM to 2:30 PM. We will prepare a bi-weekly agenda and touch on important issues regarding the development of the protocol.
a. Status of IRB approval and necessary administrative issues
b. Review of accrual
c. Review of all obtained data
d. Pitfalls and problems
e [redacted] career progress
2. [redacted] attend the following multidisciplinary sessions, where she will be involved in the discussion and decision making of older adults with cancer being treated at our Institution.
a. Journal Club. Wednesdays 9:30-10:30 AM.
b. Tumor Board. Tuesday, Wednesday and Thursday 7:00-8:00 PM
3. [redacted] will attend the Cancer and Aging Research Group call every other Tuesday at 11:00 AM PST. In this call, attended by the leading experts in the field of Geriatric Oncology in the [redacted] will be able to report the progress achieved in her protocol and discuss potential pitfalls and barriers to the project's success. This call will be highly beneficial to [redacted] since she will be able to receive feedback from international experts.
4. [redacted] will have a dedicated call every week with [redacted] aspects and barriers to the project. Biostatistics support will be provided during this call by Dr. [redacted] om the [redacted] see attached letters of support).
5. [redacted] will attend the [redacted] twice a week (Tuesday and Thursday), and the rest of the week will be dedicated research time. Her clinic time will be limited to 8 hours per week.
6. [redacted] will participate in clinical and research teaching activities at [redacted] I will directly supervise her involvement in teaching activities and encourage and foster the start of a mentoring role for [redacted] within our institution.
7. [redacted] will have dedicated time and support for attending national and international symposiums and meetings in oncology and geriatrics in order to obtain further knowledge and disseminate her results. The following meetings will have the highest priority:
a. American Society of Oncology Annual Meeting 2021 and 2022.
c. International Society of Geriatric Oncology Annual Meeting 2022.

[redacted] verall research topic ---Geriatric Assessment--- is extremely relevant to our aging patient population and is one of the most pressing issues facing the developing world. In Brazil older adults are an underserved population by the healthcare system. As our country is undergoing an epidemiologic transition with aging of the population and a higher incidence of non-communicable diseases such as cancer, it is imperative to adapt the healthcare system for the impending increase of cancer among older adults. At our institution, we anticipate that Dr. [redacted] will become one of the leading experts in Geriatric Oncology in Brazil, with a specific focus in genitourinary tumors. Because of that, we are highly committed to supporting and guiding her career development as an independent clinical researcher. Through our institution, Dr. [redacted] will have access to adequate facilities and contact with cancer healthcare providers. Dr. [redacted] will have 70% of her time at our institution as protected research time. Through my mentoring, the support from her co-mentors, and the institutional resources provided, I have no doubt that [redacted] will be able to successfully complete the proposed work. I truly believe that [redacted] is the right candidate for a Global Oncology Young Investigator Award. She has the knowledge, training and passion [redacted]

develop meani[redacted]as that are relevant both at a national and an international level. I hope th[redacted] her with this invaluable award and provide a foundation for her very promising

[redacted]

[redacted]

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ABSTRACT

Objective: Utilizing the Cancer and Aging Research Group (CARG) chemotherapy toxicity risk score before starting treatment in older adults with cancer is guideline recommended. However, this has not been tested in most developing countries. We investigated the use of a Portuguese version of the CARG score, including the association between this score and physical symptoms, among older Brazilian adults with cancer.
Patients and methods: We enrolled patients aged ≥65 starting chemotherapy at a public Brazilian hospital. A Portuguese version of the CARG tool was created and linguistically validated. Patients were assessed for chemotherapy toxicity risk using the CARG score, and physical symptoms were evaluated using the Functional Assessment of Cancer Treatment General (FACT G) scale. Multivariable logistic regression was used to identify physical symptoms associated with high CARG scores, including pain, nausea, and fatigue.
Results: Older patients (65+) with cancer were enrolled (n = 117). Patients were mostly female (57.3%), white (52.1%), married (52.1%), and had less than high school education (75.2%). Breast, gastrointestinal and lung cancers were the most common diagnosis, and 66.7% had metastatic disease. Elevated pain scores ($P < .01$) were associated with higher chemotherapy toxicity risk scores, even after adjusting for potential confounders.
Conclusion: We created and implemented a Portuguese language version of the CARG tool. We found that, although physical symptoms are not included in the CARG model, elevated pain was strongly associated with having a high CARG score. As a modifiable risk factor, pain should be addressed among older patients with cancer considering chemotherapy, to help mitigate their risks for toxicity.

1. Introduction

Over 400 million people aged 65 years and older live in developing regions of the world, and approximately 50% of cancer cases in older adults occur in low and middle income countries (LMIC) [1,2]. Unfortunately, despite rapid advances in cancer treatment and subsequent improvements in patient outcomes, LMIC do not enjoy the same level of access to these therapeutic agents, often lacking even essential medicines and services [3]. Treatment options available in LMIC are limited, and patients usually receive older therapy options or modified versions of treatment regimens used in high income countries (HIC) [4,5]. In both cases, chemotherapy is a standard component; a treatment that has well recognized toxicity and side effects that can impair patient's quality of life and impact treatment decision making among older patients [6].

Identifying potential areas of vulnerability among older patients prior to the start of treatment is essential to providing effective and comprehensive care [7,8]. The evaluation of an older adult with cancer requires the performance a geriatric assessment, which includes a combination of measures assessing functional status, cognition, physical performance, falls, nutritional status, social activity/support, psychological state, comorbidities, and medication use [9]. Validated geriatric assessment based tools have been developed to assist clinicians in their discussions of risk and benefit with regard to various therapies and to help avoid under or overtreatment, such as the Cancer and Aging Research Group (CARG) toxicity tool [6,10], and the Chemotherapy Risk Assessment Scale for High Age Patients (CRASH) score [11]. Although these tools include various geriatric domains, there is a

[redacted]

paucity of information regarding whether the presence of common patient reported symptoms related to cancer such as pain or fatigue are associated with higher chemotherapy toxicity risk scores among older patients.

Various initiatives have been implemented to provide geriatric assessment based care for older patients living in LMIC [12], including the creation of geriatric oncology programs in Brazil and in other Latin American countries [13,14]. However, in order to successfully implement current recommendations in clinical practice, the translation of validated geriatric assessment based chemotherapy toxicity tools is needed [15]. In an attempt to fill this gap, we translated the CARG chemotherapy tox icity tool into the Portuguese language, and examined the association be tween chemotherapy toxicity risk scores and common physical symptoms in older patients treated at a Brazilian public hospital.

2. Patients and Methods

2.1. Participants and Setting

The current cohort based study was undertaken at a large public hospital in Sao Paulo, Brazil. Patients aged 65 and older diagnosed with cancer and about to initiate chemotherapy treatment were consec utively recruited from August 2016 to January 2017. We excluded those patients that had already started their treatment, as well as those re ceiving other form of therapies, such as targeted therapy or immuno therapy. Eligible patients were contacted prior to receiving their first treatment and the purpose and goals of this study explained. Upon agreement, patients signed the consent form and answered three ques tionnaires outlined below. One patient refused to participate, and no compensation was offered. This study was approved by the ethics com mittee of the *Universidade Federal de Sao Paulo*.

2.2. Measures

Patients completed questionnaires concerning their sociode mographic and clinical data (e.g., age, gender, marital status, education, type of cancer, disease stage) and the Portuguese version of the CARG chemotherapy toxicity tool. This tool, developed by Hurria et al. [6,10] to determine the risk of chemotherapy toxicity among older patients, includes geriatric assessment questions (e.g., prior falls, hearing prob lems, limitation in walking one block), and clinical data (e.g., type of cancer, laboratory values, number of chemotherapy, dosing), taking <5 min to complete. Risk scores divide patients into three categories: low (0 5 points), medium (6 9 points) and high risk (10 19 points). In addition, patients completed the Portuguese version of the Functional Assessment of Cancer Treatment General (FACT G) [16]. The FACT G scale uses a 4 point Likert scale to assess physical, social/family, emo tional, and functional well being. For the purposes of this study, only physical symptoms pain, fatigue and nausea were used for compar ative data analyses.

2.3. Translation of the CARG Chemotherapy Toxicity Tool

After receiving permission to translate and use the CARG chemo therapy toxicity tool, two forward translations into Portuguese were performed by native speakers from Brazil. Reconciliation of the two forward translations was performed by a third native speaker. Then, one back translation of the reconciled version into English was done by a native English speaker, and this version was reviewed by FACITrans staff (the translation and formatting team of the Functional Assessment of Chronic Illness Therapy [FACIT] organization). A review and finaliza tion by a language coordinator was completed in conjunction with the FACITrans team, as well as ensuring consistency of meaning across lan guages. A quality review of the finalized translation was performed by FACITrans staff, and test versions were formatted in Microsoft Word. Proofreading was completed by two translators working independently from one another, and reconciliation performed. Finally, linguistic vali dation was completed with the assistance of five patients.

2.4. Statistical Analyses

Descriptive analyses were performed and the patients' demographic and clinical characteristics were displayed across two groups: patients with low chemotherapy toxicity risk scores (<8) and patients with high chemotherapy toxicity risk scores (≥ 8). The threshold of 8 was se lected based on the median value of the chemotherapy toxicity risk scores (continuous scale).

In order to evaluate the association between the dependent variable, chemotherapy toxicity risk scores (high/low), and the independent var iables: fatigue, nausea, and pain (physical symptoms), unadjusted logis tic regressions were applied. Related odds ratios were computed and 95% confidence intervals were generated. Fatigue and pain were recoded as binary variables: not at all or a little bit (0), versus somewhat to very much (1). Nausea was recoded with the following classification: not at all (0) versus a little to very much (1).

Following the results of the above analysis, the physical symptom which was statistically associated with chemo toxicity scores was fur ther evaluated through a multivariable logistic regression model, adjusting for demographic variables: gender, race, education and mari tal status. Age was excluded from this list of covariates, having been pre viously used as a risk factor for the computation of chemo toxicity score. The analyses were performed using SPSS and SAS. Statistical signifi cance was defined as p value ≤.05.

3. Results

A total of 117 older patients with cancer (prior to initiate chemo therapy treatment) were included in this study. Patients were primarily at high (51.3%) and low chemotherapy toxicity score (48.7%). Most pa tients at low chemotherapy toxicity score were female (70.2%) and not married (50.9%). In contrast, patients at high chemotherapy toxicity score were male (55.0%), and married (55.0%). In general, patients were white (52.1%), less educated (75.2%), and had low monthly in comes (82.9%). The mean age was 72 years (SD 5.5). They were mostly diagnosed with breast (27.3%), gastrointestinal (27.3%) and lung (18.8%) cancers, at advanced disease stage (stage III IV: 87.2%). Patient characteristics are presented in Table 1.

The individually unadjusted logistic regressions demonstrated that pain was significantly associated with a higher chemotherapy toxicity risk score: (OR: 6.47 95% CI: 2.25 18.57) (Table 2). However, the other two physical symptoms were not statistically related to chemo toxicity score: fatigue (OR: 2.17 95% CI: 0.95 4.96), nausea (OR: 1.96 95% CI: 0.87 4.41). Since pain presented a strong and significant associ ation with chemotherapy toxicity score, its effect was further explored within an adjusted model. This additional analysis showed that pain remained positively associated with chemotherapy toxicity, when con trolling for demographic variables: (OR: 6.8; 95% CI: 2.18 21.16) (Table 3). This adjusted model also revealed the confounding effect of gender among demographic variables. Indeed, gender was significantly associated with chemotherapy toxicity risk scores, with male patients being more likely to have higher chemotherapy toxicity risk scores (OR: 3.86 95% CI: 1.43 10.42) (Table 3).

4. Discussion

We translated and implemented the CARG chemotherapy toxicity risk tool among older adults with cancer treated in a public hospital in Brazil, and assessed the association of its results with common physical symptoms. Our results highlight important factors which might modify the CARG chemotherapy toxicity risk scores. Patients with pain were at greater risk of having a high CARG chemotherapy toxicity risk score, suggesting that additional assessments and targeted screening may be

Table 1
Patient characteristics, physical symptoms and CARG chemotherapy risk (N = 117).

Characteristics	Low toxicity risk score (n = 57)	High toxicity risk score (n = 60)	Total (N = 117)
Gender [n (%)]			
Male	17 (29.8)	33 (55.0)	50 (42.7)
Female	40 (70.2)	27 (45.0)	67 (57.3)
Age [M (SD)]	70 (4.8)	73 (5.9)	72 (5.5)
Race [n (%)]			
White	28 (49.1)	33 (55.0)	61 (52.1)
Black	10 (17.6)	10 (17.0)	20 (17.1)
Other	19 (33.3)	17 (28.0)	36 (30.8)
Marital status [n (%)]			
Not married	29 (50.9)	27 (45.0)	56 (47.9)
Married	28 (49.1)	33 (55.0)	61 (52.1)
Education [n (%)]			
<High school	41 (71.9)	47 (78.0)	88 (75.2)
≥High school	16 (28.1)	13 (22.0)	29 (24.8)
Monthly income [n (%)]			
<$2.364 BRL	46 (80.7)	51 (85.0)	97 (82.9)
≥$2.364 BRL	11 (19.3)	9 (15.0)	20 (17.1)
Cancer type [n (%)]			
Breast	21 (36.8)	11 (18.0)	32 (27.3)
Gastrointestinal	12 (21.0)	20 (33.0)	32 (27.3)
Lung	11 (19.3)	11 (18.0)	22 (18.8)
Hematological	6 (10.5)	0 (0.0)	6 (5.2)
Gynecological	3 (5.3)	5 (8.0)	8 (6.8)
Genitourinary	2 (3.5)	9 (15.0)	11 (9.4)
Head and Neck	1 (1.8)	4 (7.0)	5 (4.3)
Others	1 (1.8)	0 (0.0)	1 (0.9)
Disease stage [n (%)]			
I	2 (3.5)	0 (0.0)	2 (1.7)
II	9 (15.8)	4 (7.0)	13 (11.1)
III	6 (10.5)	18 (30.0)	24 (20.5)
IV	40 (70.2)	38 (63.0)	78 (66.7)
Physical symptoms			
Fatigue			
Not at all or little	45 (79.0)	38 (63.0)	83 (70.9)
Somewhat to very much	12 (21.0)	22 (37.0)	34 (29.1)
Nausea			
Not at all	44 (77.2)	38 (63.0)	82 (70.1)
A little to very much	13 (22.8)	22 (37.0)	35 (29.9)
Pain			
Not at all or little	52 (91.2)	37 (62.0)	89 (76.1)
Somewhat to very much	5 (8.8)	23 (38.0)	28 (23.9)

useful in promoting symptom management prior to the start of treatment [7,8].

Recent efforts by the American Society of Clinical Oncology (ASCO) have sought to incorporate the geriatric assessment, as well as geriatric assessment based chemotherapy toxicity calculators, into standard of care practice [8]. The recently published ASCO Geriatric Oncology guideline recommends that all patients over the age of 65

Table 2
Physical symptoms of fatigue, nausea and pain associations with chemotherapy toxicity risk score in individual logistic regression models.

	Unadjusted odds ratios				
	Total	Coefficient	Odds ratio	95% CI	P-value
Pain					
Not at all or little	89		Ref		
Somewhat or very much	28	1.87	6.47	(2.25, 18.57)	<0.01
Fatigue					
Not at all or little	83		Ref		
Somewhat or very much	34	0.78	2.17	(0.95, 4.96)	0.07
Nausea					
Not at all	82		Ref		
A little to very much	35	0.67	1.96	(0.87, 4.41)	0.100

Table 3
Pain associated with chemotherapy toxicity risk score in a multivariable logistic regression.

	Adjusted odds ratio				
	Total	Coefficient	Odds ratio	95% CI	P-value
Pain					
Not at all or little	89		Ref		
Somewhat or very much	28	1.92	6.80	(2.18, 21.16)	<0.01
Gender					
Female	67		Ref		
Male	50	1.35	3.86	(1.43, 10.42)	0.01
Race					
White	61		Ref		
Black	20	0.41	0.67	(0.20, 2.22)	0.51
Other	36	0.17	1.19	(0.46, 3.06)	0.72
Marital status					
Married	61		Ref		
Not married	56	0.64	1.90	(0.72, 5.00)	0.20
Education					
≥High school	29	0.68	Ref		
<High school	88	0.68	1.97	(0.73, 5.27)	0.18

be screened using validated and practical geriatric assessment tools in order to estimate the risk of adverse outcomes and to guide decision making and individualized treatment planning [8]. In general, common barriers to incorporating this into everyday clinical practice include lack of time and clinic space, limited provider reimbursement, lack of clinical support staff and resources, lack of training regarding geriatric assessments, uncertainty about which assessment tools to use, and limited evidence to support their use in practice [8]. This may be an even more pressing issue in LMIC like Brazil, where the needs of an expanding population of older adults are not adequately covered due to a low availability of personnel with geriatric training and expertise. Brazil is experiencing one of the fastest rates of population aging worldwide, and by 2060 approximately a third of all Brazilians will be aged 60 years or older [17]. In contrast, Brazil has few geriatricians, with recent statistics showing that there is one geriatrician for every 15,000 to 22,000 older Brazilians [14,18]. In this context, practical tools such as the CARG chemotherapy toxicity risk calculator (which is also freely accessible online at mycarg.org/tools) may represent valuable assets for clinicians at the point of care, which makes translating and validating them very relevant. The Portuguese language, into which we translated the CARG tool, is currently spoken by 221 million people across fifteen countries, making it the sixth most widely spoken language in the world [19].

In our study, patients classified at high chemotherapy toxicity risk were mostly men and married individuals, when compared with those classified at low risk. A paucity of research exists regarding the role of marital status on symptom burden and risk of chemotherapy toxicity; although this might be related to worse social support (which is one of the variables of the CARG chemotherapy toxicity tool), this relationship is certainly worthy of further investigation. There is suggestive evidence that unmarried patients across all age groups experience worse clinical outcomes, including inferior treatment completion and decreased overall survival [20]. Our results also showed that men were at higher risk of having high CARG chemotherapy toxicity risk scores according to the CARG tool, which may be related to the fact that genitourinary tumors, which are more common in men, increase the CARG score. Despite the fact that, historically, gender has played an important role in adjustment to cancer, past studies mostly highlight the frailty associated with female gender, described by worse physical and emotional well being, and lower global physical functioning [21 26].

Physical symptoms have been associated with worse physical, psy

with high CARG chemotherapy toxicity risk scores tended to report more symptoms of fatigue, nausea, and pain. This emphasizes the relevance of symptom management in promoting functional outcomes and potentially better tolerance of treatment regiments, as well as the relationship between some patient reported outcomes and geriatric syndromes. Nevertheless, pain was the only important risk factor, suggesting the importance of assessing this symptom in routine geriatric assessment in cancer care. Despite the fact that physical symptoms should be screened as part of routine cancer care, studies have shown that health care professionals often fail to assess and treat pain [30,31].

This study has some limitations. First, our small sample size, consisting of older patients from a single institution, which can impact the generalization of these findings. Despite this, South American patients are and underrepresented population in geriatric oncology studies, and thus our data provides important insight from a broader global geriatric oncology perspective. Further, the current study was cross sectional by design and thus does not provide insight as to the causal relationships that may exist between study measures, nor how these patients managed throughout the course of their disease. Finally, our study was not designed to assess whether the CARG chemotherapy toxicity risk calculator was able to predict toxicity among older Brazilian adults with cancer. This, however, might be relevant in light of recent findings suggesting that the predictive value of the CARG score might vary in different geographic settings with differing practice patterns [32].

In summary, we have produced a translated and validated Portuguese version of the CARG chemotherapy toxicity risk calculator. Additionally, we have shown that pain is strongly associated with higher CARG chemotherapy toxicity risk scores. Our findings highlight the need to adequately address patient reported outcomes prior to commencing treatment, in addition to performing of a geriatric assessment as recommended by current guidelines. This study provides a strong foundation towards incorporating the CARG chemotherapy toxicity tool as part of routine care for millions of Portuguese speaking older adults with cancer around the world.

Author Contributions

Declarations of Competing Interest

The authors declare no disclosures.

Funding

None.

Abstract

Objective International guidelines recommend routine screening for distress as part of care practices. Accordingly, a Brazilian cancer center developed and implemented a distress screening program (DS) in 2007, which was enhanced in 2009 through the inclusion of a psychosocial care meeting group (DS + PCM) regarding patients' psychosocial needs. The current paper will provide an overview of the development and pilot implementation of this program and initial analyses to assess patient outcomes and report initial results to extend international research on this key aspect of cancer care.

Method Patients were assessed for distress, anxiety and depression, and in the DS+PCM phase for quality of life at the first day of chemotherapy infusion, at midpoint, and at treatment end. We compared data from program phases (DS vs DS + PCM), with a sequential cohort design and mixed effects modeling.

Results Clinical and demographic characteristics were similar between groups. Patients receiving DS + PCM showed significantly lower distress and depression/anxiety upon chemotherapy initiation (*P*s < .001). While both groups reported significantly lowered distress and total depression/anxiety scores across time (*P*s < .003), patients receiving DS + PCM maintained the lowest distress and total anxiety/depression at all assessments. Patients from DS + PCM group also reported improvements in quality of life over time.

Conclusions The current study provides preliminary evidence that a multidisciplinary structured screening program utilizing validated measures and team meetings is associated with reduced impairment in patients' psychological well being. This program provided more opportunities for collaboration among providers with increased multidisciplinary meetings, enabled patients to more easily report problems, and ensured rapid access to relevant resources.

KEYWORDS

distress, cancer, guidelines, oncology, psychosocial care

1 | INTRODUCTION

Approximately, 35% of cancer patients will experience significant distress during the disease continuum.[1] National agencies, researchers, and clinicians alike have thus proposed that distress be assessed as part of routine cancer care,[2–7] and that supportive care services be available to patients and survivors in a comprehensive and culturally sensitive manner.[7,8] Further, distress has been proposed as the sixth vital sign and greater efforts have been encouraged in recognizing the psychosocial aspects of the cancer experience.[6,9,10]

The guidelines proposed by the National Comprehensive Cancer Network (NCCN) and the Institute of Medicine identify 4 process components constituting best practices—screening, assessment, treatment, and follow-up. The guidelines explain that providers should be engaged in each phase of these processes.[2,11] Follow-up and communication with the members of the oncology treatment team is also an

important component in the overall management of patient distress.[12] In practice, several institutions have implemented distress screening procedures based on these process components.[8,12] Researchers have also endorsed the benefits of these continuum-of-care standards.[13–16]

In Brazil, however, no specific guidelines for distress management in cancer care have previously been formulated, and supportive care has been described by independent clinical effort. Thus, quality and adherence to international recommendations vary. Similar to efforts elsewhere, a lack of formal partnerships between health care teams within and between institutions, limited knowledge and recognition of the importance of psychosocial care among professionals and patients, and a paucity of resources dedicated to supportive care practice and research have hampered the development and implementation of psychosocial care guidelines.[17] In addition, health care in Brazil remains somewhat a paternalistic approach, showing a tendency of patients to prefer that the physician make health care decisions for them, in a more passive decision-making approach.[18]

In 2007, in recognition of the need to provide comprehensive, formalized, and evidence-based psychosocial cancer care, a distress screening program (DS) was developed and implemented in a cancer center in Brazil. The current paper describes of this developmental process, pilot implementation, and initial program results in order to extend research on this key aspect of cancer care. We use mixed-effects modeling to learn whether different phases of the implementation of this program resulted in significant outcome differences across sequential patient cohorts (hypothesizing that implementation of a DS would improve patient outcomes). In addition, we provide an overview of the potential challenges associated with implementing guidelines in non-English speaking cultural settings outside the United States and United Kingdom, where the original guidelines were developed.

2 | METHODS

2.1 | Setting

Centro de Câncer de Brasília (CETTRO) is a private multidisciplinary cancer center, located in Brazil's Federal District, which has been in operation since 1995 and expanded in 2002 to become a day clinic. An average of 15 new patients per month start chemotherapy at this center. As a private center, the majority of patients have health insurance and usually come from high socioeconomic backgrounds and with high literacy levels. CETTRO is a private institution, in which patients pay for all services. However, there is no additional fee for the DS. The institution agreed that this program would be the Psycho-Oncology Service's routine, considering the importance of including all of the patients in the DS. The Psycho-Oncology Service seeks to provide all patients with appropriate supportive care resources across their disease continuum.

The DS was developed from existing international guidelines,[2–5] and adapted to the context and culture of the institution and the country. We reviewed distress screening guidelines published by major agencies over the past decade and delineated general characteristics and recommendations which would be feasible to implement. Consideration was given to implementation issues, screening intervals, suitability of measures, options for intervening with distressed patients, and goals for referral and follow-up.

In a prior study, the distress thermometer (DT) was translated and validated as a clinical screening tool and established a baseline for distress levels among patients at this cancer center.[19] Most patients (62.5%) reported clinically significant distress at some point during their treatment.[20,21] All studies were approved by the ethics committee of the Health Sciences Faculty at Brasília University; a license agreement was obtained for use of the instruments described below.

2.2 | Participant groups

2.2.1 | First phase: distress screening (DS) program group

For phase I (2007-2009), patients were screened on the first day of chemotherapy and completed 2 follow-ups at approximately the midpoint and end of treatment. At initial screening, a 10-minute semistructured interview was conducted during the chemotherapy infusion procedure. Patients subsequently completed a 20-minute assessment packet at initial screening and completed the same packet at both follow-up time points (also during chemotherapy infusion). The screening packet included measures of distress (DT), anxiety and depression (Hospital Anxiety and Depression Scale [HADS]). Demographic and clinical information were already collected, per routine care, and available via medical chart. Patients' feedback regarding the screening procedure was uniformly positive, with many noting it as an important opportunity to raise concerns and receive validation of their cancer experience. In this phase I there is no feedback with the health team. Patients with moderate to severe distress were referred to the mental health services (psychologist or psychiatrist).

2.2.2 | *Second phase: distress screening program plus psychosocial care meeting group (DS+PCM)*

Initial feedback on the DS was received. As documentation of distress in the patient's health record was felt to be insufficient, physicians wished to add routine interdisciplinary meetings to discuss patients' psychosocial needs.[21] Thus, for phase II (2009-2014), this meeting, occurring *in addition to* the DS assessment, was implemented every 2 months to discuss each patient undergoing treatment (data obtained on the first day of chemotherapy and on the follow-ups), with the same screening measures and schedule as described above. A health-related quality of life (HR-QoL) measure was also recommended and added: the Functional Assessment of Chronic Illness Therapy-General (FACT-G). It is important to note that for both phases only new patients starting a new medical treatment regimen (first line of treatment) were included and that the screening routine was maintained at phase II—first day of chemotherapy and 2 follow-ups at midpoint and end of treatment. The first interdisciplinary meeting for each patient occurred prior to the initiation of treatment. For this new patients we also include a prior appointment with the health team (before the chemotherapy infusion) to address concerns related to the treatment (eg, doubts and fears related to side effects, exams, and appointment).

For this meeting a summary of all screening results was prepared. A psychologist leads the psychosocial care meeting (PCM) presenting each patient's results to the physician and nurse responsible for the

case. Patients did not participate. Based on the distress screening results, patients were categorized as high or low risk and the following treatment algorithms used: (1) for those judged to possess moderate to severe distress (DT ≥ 4), the reasons were clarified and an appropriate treatment or referral to specialized care (psychologist, psychiatry, physiotherapist, nurse, or own oncologist) implemented; (2) for those judged to possess no, or mild, distress (DT ≤ 3), educational material, emotional support, and referrals were offered and routine care provided. At the midpoint and conclusion of chemotherapy treatment, screening results were once again presented at the PCM and psychosocial treatment decisions reassessed based on the algorithm noted above; patients were reclassified according to the treatment algorithm at the follow-up time points. These follow-up discussions focused on patients' adjustment to treatment, whether any psychosocial concerns, potential symptoms, or side effects important to consider in ensuring comprehensive care had arisen. All pertinent details of these discussions and referrals made were documented in patients' health records.

2.3 | Outcome measures

For phases I and II data on demographic variables, including patients' age, gender, marital status, education, cancer diagnosis, and disease stage, were collected from patient records. Additional interviews and assessments are described below:

Semistructured interview: A psychologist collected a brief psychosocial history, patient's comprehension of their diagnosis/treatment, and information on potential risk factors (eg, personal or family history of psychiatric disorder, comprehension difficulties related to diagnosis/treatment, family history conflicts or difficult events, and inadequate social support) for psychosocial complications.

Distress thermometer: A self-report Brazilian Portuguese[19] version of the NCCN Distress Guidelines was used. First, patients were asked to rate their distress level during the previous week on an 11-point visual analogue scale—ranging from 0 (no distress) to 10 (extreme distress). Second, patients were asked to endorse problems that they have experienced in the same period across 35 problems, grouped into *practical*, *family*, *emotional*, *spiritual* and *physical problems*. The cutoff score of 4 was used to indicate clinically significant distress, as determined by the developers[2] and an extensive literature review.[22] This cutoff was also suggested by the validation study of the Portuguese version of DT, which was validated against the Portuguese version of the HADS.[23] In this previous study, the receiver operating characteristic (ROC) curve analyses indicated a cutoff score of 4 yielded an area under the ROC curve of 0.82 with a sensitivity of 0.82 and specificity of 0.98.[19]

Hospital Anxiety and Depression Scale: A Brazilian Portuguese version of the HADS was used.[23] This is a 14-item, self-report questionnaire in which patients rated how they felt during the previous week on a 4-point Likert scale. The questionnaire is composed of depression and anxiety subscales (7 items for each). The total score ranges from 0 to 42 for all 14 items, and each subscale is scored from 0 to 21. Subscale scores of 9-21 indicate greater depression and 8-21 greater anxiety[23] on respective subscales.

The Brazilian Portuguese version of the *Functional Assessment of Chronic Illness Therapy-General (FACT-G)*[24] was the only instrument used just in phase II. The FACT-G is composed of 27 items that evaluate quality of life on 4 domains of "well being" (physical, social/family, emotional, and functional) on a 4-point Likert scale. The total FACT-G score is the sum of the scores for the 4 subscales. Scores range from 0 to 28 for the physical, social/family, and functional subscales, 0-24 for the emotional subscale, and 0-108 for the total score.[24]

2.4 | Analytic strategy

Mixed-effects modeling[25,26] compared data from patients who met inclusion criteria described below (n = 548) based on whether they received DS in phase I, or DS + PCM in phase II. Analyses tested group differences at the initial screening, and differential change across the follow-up time points for each outcome. Both fixed (group average effects) and random effects (within-individual variability) were estimated. Fixed effects for group, time, and the group × time interaction were included in all models. In addition, sociodemographic covariates (ie, age and gender) were entered and retained in final models as appropriate. All main effects and 2-way interactions with time were entered into the model. A backward elimination process was employed in which terms ($P > .05$) were eliminated from each model until a final solution was reached.[25] All statistical tests were 2-sided. The Statistical Package for the Social Sciences: release 22.0 was used.

3 | RESULTS

3.1 | Sample

A total of 642 patients participated in the study, including 200 from phase I (DS) and 442 from phase II (DS + PCM). Of the total sample, 94 (14.6%) were excluded in subsequent analyses because of missing data at follow-ups, leaving 548 patients—154 at phase I and 394 at phase II. Primary reasons for missing data included death (76.4%), switching to different hospitals for treatment (11.8%), incompletion of recommended treatment regimen (6.5%), or moving away to different region (5.4%). All patients approached consented to participate in this study.

Clinical and demographic characteristics of the 2 groups were similar, with the majority of the overall sample being female (67.4%), married (61.2%), college educated (60.5%), and with a mean age of 55.4 years. Most frequent cancer diagnoses were breast (26.5%), gastrointestinal (24%), and hematological (22.6%), with 66.1% diagnosed at an advanced disease stage. The only significant statistical differences found between samples were associated with disease diagnosis, with gastrointestinal cancer more prevalent in the DS group ($P = .03$; Table 1).

3.2 | Outcome data

3.2.1 | Psychological distress

Mixed-effects modeling showed that patients receiving DS + PCM reported significantly lower distress (DT) and total depression/anxiety (HADS) upon chemotherapy initiation relative to patients receiving DS ($Ps < .001$). We attribute these significant baseline group differences to the improvements in multidisciplinary collaboration, attention to distress screening, and care made across time—based on what was

TABLE 1 Equivalence of groups at baseline screening on sociodemographic, disease/prognostic, and psychosocial variables

Variable	DS (n = 200) Mean (SD)/%	DS + PCM (n = 442) Mean (SD)/%	Total (N = 642) Mean (SD)/%	Group Comparisons *P*
Sociodemographic				
Age, y	55.45 (15.68)	55.34 (15.51)	55.37 (15.55)	**.05**
Gender (female)	63.0%	69.5%	67.4%	.07
Education (at least college degree)	56.0%	62.7%	60.5%	**.04**
Marital status (married)	62.0%	60.9%	61.2%	.07
Type of cancer/disease stage				
Breast	22.5%	28.3%	26.5%	**.03**
Gastrointestinal	29.5%	21.5%	24.0%	
Hematologic	23.0%	22.4%	22.6%	
Gynecological	9.5%	9.0%	9.2%	
Lung	5.5%	8.1%	7.3%	
Genitourinary	4.5%	4.5%	4.5%	
Others	5.5%	6.1%	5.9%	
I-II	26.0%	32.4%	30.4%	.07
III-IV	63.5%	57.2%	59.2%	
Unknown	10.5%	10.4%	10.4%	
Measures		Possible range		
Distress (DT)	0-10; 5.2 (2.6)	0-8; 3.2 (1.6)	0-10; 3.8 (2.1)	**.01**
HADS anxiety	0-21; 10.1 (5.1)	1-17; 6.5 (3.2)	0-21; 7,6 (4.2)	**.04**
HADS depression	0-21; 7.9 (4.9)	1-17; 5.1 (3.6)	0-21; 5.9 (4.3)	**.04**
FACT-G	-	21-108; 92.4 (11.4)	-	-
Physical well being	-		-	-
Social/Family well being	-	11-28; 24.1 (3.6)	-	-
Emotional well being	-	12-28; 23.9 (2.2)	-	-
Functional well being	-	9-26; 21.8 (2.7) 4-28; 22.8 (4.9)	-	-

DS, distress screening program; FACT-G, Functional Assessment of Chronic Illness Therapy-General; HADS, Hospital Anxiety and Depression Scale; PCM, psychosocial care meeting; SD, standard deviation.

learned from the DS group and prior to caring for the DS + PCM group. While both groups reported significantly lowered distress and total depression/anxiety scores across time (*P*s < .003), patients receiving DS + PCM maintained the lowest distress and total depression/anxiety at all assessments (Table 2).

The prevalence of moderate to severe distress (DT) in the DS group was: T1 = 67%, T2 = 30.8%, and T3 = 16.2%. As above, the incidence of patients with moderate to severe distress was lower in the DS + PCM group: T1 = 40.3%, T2 = 14.4%, and T3 = 5.6%. We also observed changes over time in the frequency of problems reported on the problem list. Emotional and physical problems were the main problem areas reported (Table 3). The prevalence of emotional problems reported by the DS and DS + PCM groups across treatment were T1 = 95% and 85.1%; T2 = 76.9% and 62.4%; T3 = 79.2% and 44.4%, respectively; and for physical problems: T1 = 97% and 92.3%; T2 = 94.1% and 94.6%; T3 = 90.9% and 89.6%, respectively.

3.2.2 | Health-related quality of life

As we only had HR-QoL data from phase II, the comparative mixed-effects modeling analysis was not possible. However, in contrasting these data with the normative data of the general US adult population,[27] we observed that our patients reported an average HR-QoL score the 50th percentile of the US norm at T1 (mean [M] = 86.2; standard deviation [SD] = 13.8) that improved by T2

TABLE 2 Mixed-effects models comparing fixed effects group trajectories

Outcome	Effects	Estimate	Standard Error	*T*
DT	Group	2.001	0.138	14.540***
	Time	−0.335	0.041	−8.120***
	Quadratic term	0.169	0.006	−2.623**
	Group × time	−0.661	0.076	−8.658***
	Group × quadratic	0.072	0.012	5.594***
HADS	Group	6.531	0.496	13.156***
	Time	−1.737	0.151	−11.513***
	Quadratic term	0.140	0.023	6.020***
	Group × time	−1.677	0.273	−6.132***
	Group × quadratic	0.177	0.043	4.109***

DT, distress thermometer; HADS, Hospital Anxiety and Depression Scale.

*$P < .05$;

**$P < .01$;

***$P < .001$.

TABLE 3 Percentages of the distress screening program (DS) and distress screening program plus psychosocial care meeting (DS + PCM) groups endorsing clinically significant distress on the Distress Thermometer (DT) or the presence of distress-related problems over the course of treatment

	T1		T2		T3	
DT Means/Frequency	DS	DS + PCM	DS	DS + PCM	DS	DS + PCM
DT	*67.0*	*40.3*	*30.8*	*14.4*	*16.2*	*5.6*
Practical problems	*61.0*	*36.2*	*46.7*	*22.4*	*43.5*	*17.5*
Child care	1.0	0.5	0.6	0.2	1.3	0.2
Housing	19.0	10.0	14.8	6.3	9.7	5.1
Insurance/Financial	40.0	22.2	32.5	14.1	33.1	8.6
Transportation	14.5	2.7	8.9	2.0	5.8	0.8
Work/School	21.0	15.8	13.6	7.8	12.3	7.6
Family problems	*55.0*	*36.4*	*39.1*	*21.2*	*38.3*	*12.7*
Dealing with children	42.5	27.4	29.0	15.1	29.2	8.9
Dealing with partner	26.0	14.7	16.0	8.8	16.2	5.1
Emotional problems	*95.0*	*85.1*	*76.9*	*62.4*	*79.2*	*44.4*
Depression	56.0	25.3	28.4	14.4	27.9	5.3
Fears	60.5	41.9	24.9	14.4	30.5	11.4
Nervousness	69.5	54.1	47.3	29.8	44.8	17.5
Sadness	74.5	65.6	47.3	41.2	46.1	26.6
Worry	84.0	74.4	60.9	44.1	66.2	34.0
Loss of interest	37.0	25.3	26.6	16.1	26.0	7.4
Spiritual problems	*9.0*	*6.6*	*3.6*	*2.6*	*2.6*	*2.0*
Physical problems	*97.0*	*92.3*	*94.1*	*94.6*	*90.9*	*89.6*
Appearance	48.0	37.3	45.0	52.0	47.4	30.6
Bathing	14.0	0.9	8.9	0.2	3.2	0.1
Breathing	25.0	18.8	10.7	12.0	14.3	8.9
Urination	13.0	9.5	7.7	4.9	3.2	3.5
Constipation	30.0	24.9	21.3	32.0	18.8	17.3
Diarrhea	10.5	8.8	14.8	12.9	11.0	8.9
Eating	39.5	27.4	26.6	26.8	27.3	17.3
Fatigue	44.0	37.3	42.6	48.5	37.0	44.5
Swollen	22.5	17.0	29.0	20.7	29.9	17.0
Fevers	8.5	2.5	4.1	1.2	4.5	0.5
Getting around	31.0	10.9	24.3	8.3	19.5	4.1
Indigestion	9.0	1.4	7.7	1.0	1.3	0.3
Memory/Concentration	41.0	40.3	33.1	34.6	35.1	28.9
Mouth	5.5	3.4	16.0	9.3	9.7	4.1
Nausea	26.0	17.6	32.0	35.4	29.9	15.7
Nose dry/congested	18.0	13.1	21.3	17.1	17.5	9.9
Pain	43.5	37.6	26.0	23.2	21.4	19.3
Sexual	28.5	24.0	23.7	15.4	25.3	13.5
Skin dry/itchy	37.0	29.6	32.5	44.6	29.9	25.8
Sleep	60.5	57.5	49.7	49.0	52.6	38.3
Tingling in hands/feet	15.5	12.9	18.3	23.9	22.1	21.9

(M = 90.3; SD = 11.8) and T3 (M = 92.4; SD = 11.5), being at the 75th percentile of the US norm by T3.

4 | DISCUSSION

A new distress screening and referral routine was implemented institutionally in a Brazilian cancer center in line with international standards, providing preliminary evidence of the feasibility and positive effects of such efforts within a different cultural context. Findings from comparing phase I with phase II may suggest the additional benefit of the DS + PCM. We observed that it was possible to give a voice to the patients' experience, improving the communication between patients/families and the health team, and encouraging the patient to become more active in his or her treatment, although this observation was not measured. Notably, our initial analyses highlighted the potential benefit of interdisciplinary meetings (PCM) in addition to screening,

with less impairment across outcomes for the DS + PCM group. We also made clinical observations that patients began to pay more attention to their physical symptoms, feelings, and thoughts, becoming more engaged in their own care across time. These procedures assured patients' access to psychological assistance and also favored a greater integration of the psychosocial model in our patient care.

At the beginning of the treatment, we noted a high prevalence of moderate to severe distress, particularly during phase I. The prevalence of moderate to severe distress may, of course, relate to the impact of the diagnosis and the patients' anticipation of chemotherapy treatment. It might also relate to cultural differences in adjustment to cancer that are present in Brazil. Finally, we note that many of the patients at CETTRO had been diagnosed with advanced disease, which may have increased the average level of distress in our patient sample. It is also worth mentioning that the DT is known to be more sensitive than specific.[22] We do have the available resources in our setting and the PCM to help us to address or to establish a further assessment, and we feel that it is better to overestimate—rather than potentially underestimate—the number of patients with significant distress. However, this discrepancy may certainly be more unmanageable in many settings. We have thus opted to maintain the screening routine with the DT plus the HADS as well as to conduct further assessments to address specific domains, condition, or problems.[28,29]

In general, the adaptation and implementation of the screening guidelines was achieved with minimal difficulty, served as a first step to destigmatize mental health issues and provided a basis for further intervention. The information available from international guidelines was sufficiently flexible for adaptation to our clinical setting using our available resources. The screening measures, with meaningful clinical cutoffs, helped guide discussions and garner acceptance of screening among multidisciplinary team members. The screening routine helped to identify areas for improvement in patient care, indicated that distress is prevalent among patients (particularly at the start of treatment), reinforced the importance of comprehensive cancer care and the need to translate some of the existing resources to Portuguese (eg, patient education materials), and provided standardized feedback for health professionals involved in this integrated treatment program. Further, the ability of this service to present distress screening data from validated and reliable measures enhanced interest in the Psycho-Oncology Service and provided data that health professionals could monitor among their patients. This study also highlighted the feasibility and benefits of embedding the psychologist in the team in a smaller cancer center, as a strategy to decrease or perhaps even prevent some psychosocial symptoms. Anecdotally, it was observed that professionals from a variety of care teams came to appreciate the importance and relevance of psycho-oncology and expressed an interest in how collaborative psychosocial care can make a valuable contribution to the patient experience.

Nevertheless, certain adjustments were necessary to translate and implement these international guidelines to our clinical and cultural setting. For example, we observed that linking assessment to the treatment phase became a screening routine that was most viable and logical for the health team, ensuring follow-up and integration as part of routine care. Further, the multidomain screen helped to check the efficacy of measures and to give us more information about our patients' experience. Finally, despite cultural difference, the term distress was well accepted by patients and team members. It is important to note that in the first year (2007) of this program, we conducted a qualitative study (n = 100) that included a structured interview, analysis using ALCESTE (*Analyse Lexicale par Contexte d'un Ensemble de Segments de Texte*), and content analysis based on Bardin.[29–31] We examined whether alternative terms for "distress" (eg, "stress") would be more acceptable to patients in this cultural context.[29] As a result of these analyses, it was observed that stress was perceived as a synonym of irritation, anxiety, impatience, worry, nervousness, and nuisance; many patients described their experience as distress, and not as stress.[29] In view of these results, we observed that stigma still remained and that patients preferred to use the term distress, even though it was necessary to explain the meaning of this term to some patients using the NCCN definition.[2,29]

The implementation of this program was conducted gradually, with ongoing discussion with relevant clinical team members. These discussions provided the opportunity to develop strategies to enhance psychosocial care from the beginning and throughout treatment. This included the development of educational materials for specific chemotherapy regimens (information about common side effects and reasons to call the doctor) and the coordination of appointments with nurses to explain and clarify any questions regarding treatment schedule, exams, and procedures.

Importantly, the program also promoted greater communication and integration of care goals between the psychology supportive care service and the physician service. It allowed the health team as a whole to develop a greater understanding and appreciation of the psychosocial issues facing their patients, offered insight into the patients' perspective of dealing with cancer and treatment, and provided them with practical, evidence-based recommendations that could be incorporated into their routine clinical care of cancer patients. It is interesting to observe how the DS customized the treatment, focusing on specific patient needs. Finally, the routine screening implemented enabled patients and providers to more easily recognize and report emergence of problems and ensure rapid access to relevant resources. In response to the work completed in 2011, the DS program was recognized as an important component of our quality practice-accreditation program. The next phase of development will be to expand our screening program to include patients undergoing other treatments (surgery and oral chemotherapy) and to cancer survivors.

Regarding limitations, we acknowledge that the phase-based nature of program implementation may limit the analytical conclusions that can be drawn; however, the flexibility and responsiveness of the program were critical in limiting initial barriers and resistance from health care providers. The iterative implementation of the program, guided by feedback from patients and providers, also enhanced team members' interest and investment in the program's goals. Other limitations should be noted including the limits inherent to self-report data, no control group for comparisons, and little control over confounding variables. Finally, some of our clinical observations (eg, patients drawn by patients) were not measured and reported here as observations only. Future studies should examine patients' perceptions about the program implementation. Moreover, we note that it may be difficult to implement a DS in a similar manner within a larger cancer center,

[redacted]

or across an entire nation. The use of technology will undoubtedly be vital to these endeavors.

In summary, the present study reports the successful development and implementation of a psychosocial screening program in Brazil, showing the viability of incorporating international guidelines in different cultural contents. Initial findings suggest that routine screening and team meetings were associated with improvements in multiple psychosocial domains for patients and thus extended our clinics commitment to comprehensive psychosocial cancer care. Further research, including the implementation of this program in different institutions in Brazil and other South American countries, is required.

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