AWARD NUMBER: W81XWH-18-1-0461

TITLE: The Role of Mitochondria in ADT-Induced Sarcopenia in Prostate Cancer Patients

PRINCIPAL INVESTIGATOR: Dr. Jose M Garcia, MD, PhD

CONTRACTING ORGANIZATION: Seattle Institute for Biomedical and Clinical Research

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PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

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6. AUTHOR(S)
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0011152374

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7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
Seattle Institute of Biomedical and Clinical Research
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Approved for Public Release; Distribution Unlimited

13. SUPPLEMENTARY NOTES
None.

14. ABSTRACT

Prostate cancer (PCa) is the most common cancer among men. Androgen deprivation therapy (ADT) is the standard treatment for advanced and metastatic PCa and nearly 400,000 men remain on androgen deprivation therapy (ADT) for advanced PCa in the U.S. Unfortunately, ADT also induces a decrease in muscle mass and function, known as sarcopenia, a condition that leads to decreased endurance, increased fatigue, falls, poor health-related quality of life (HR-QOL) and increased mortality. The mechanisms underlying the development of ADT-induced sarcopenia are incompletely understood and remain a significant barrier to the development of therapies for this condition. Mitochondria play an essential role in generating the adenosine triphosphate (ATP) needed for muscle contraction and abnormalities in mitochondria function have been reported in animal models of sarcopenia. The extent to which mitochondrial dysfunction mediates ADT-induced sarcopenia and muscle dysfunction is not known.

The *overall goal* of this proposal is to establish the role of mitochondrial dysfunction on ADT-induced sarcopenia in patients with PCa. Our *hypothesis* is that ADT in men with PCa will induce mitochondrial dysfunction leading to sarcopenia. To test this hypothesis, we will carry out a pilot study of men with PCa undergoing ADT (n=60).

As of August 26, 2020, we have enrolled seventeen research participants in the study. Research participant recruitment and performance of study visits were impacted beginning in March due to the COVID-19 epidemic. We are following local VA and UW communications closely to ensure we meet their recommended guidelines for resuming human subjects research activities.

15. SUBJECT TERMS					
Mitochondrial dysfunction, prostate cancer, androgen deprivation, sarcopenia					
16. SECURITY CLASSIFICATION OF:			**17. LIMITATION OF ABSTRACT**	**18. NUMBER OF PAGES**	**19a. NAME OF RESPONSIBLE PERSON** USAMRMC
a. REPORT	**b. ABSTRACT**	**c. THIS PAGE**			**19b. TELEPHONE NUMBER** *(include area code)*
Unclassified	Unclassified	Unclassified	Unclassified	19	

Standard Form 298 (Rev. 8-98)
Prescribed by ANSI Std. Z39.18

TABLE OF CONTENTS

1. **INTRODUCTION:** *Narrative that briefly (one paragraph) describes the subject, purpose and scope of the research.*

Prostate cancer (PCa) is the most common cancer among men. Androgen deprivation therapy (ADT) is the standard treatment for advanced and metastatic PCa. Unfortunately, ADT also induces a decrease in muscle mass and function, known as sarcopenia, a condition that leads to decreased endurance, increased fatigue, falls, poor health-related quality of life (HR-QOL) and increased mortality. The mechanisms underlying the development of ADT-induced sarcopenia are incompletely understood and remain a significant barrier to the development of therapies for this condition. Mitochondria play an essential role in generating muscle contraction but the extent to which mitochondrial dysfunction mediates ADT-induced sarcopenia and muscle dysfunction is not known. The overall goal of this proposal is to establish the role of mitochondrial dysfunction on ADT-induced sarcopenia in patients with PCa. Our hypothesis is that ADT in men with PCa will induce mitochondrial dysfunction leading to sarcopenia.

2. **KEYWORDS:** *Provide a brief list of keywords (limit to 20 words).*

Prostate cancer, androgen deprivation, sarcopenia, mitochondria

3. ACCOMPLISHMENTS: *The PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency grants official whenever there are significant changes in the project or its direction.*

What were the major goals of the project?

List the major goals of the project as stated in the approved SOW. If the application listed milestones/target dates for important activities or phases of the project, identify these dates and show actual completion dates or the percentage of completion.

Major Task 1: Obtain regulatory approvals for Study 1 (Months 1-3)

- *Milestone Achieved: Regulatory approvals obtained* (COMPLETED: 4/26/2018)

Major Task 2: Coordinate Study Staff for Clinical Trials (Months 1-3)

- *Milestone Achieved: Research staff trained* (COMPLETED: 12/1/2018)

Major Task 3: Equipment certification/calibration and data transfer plan (Months 1-3)

- *Milestone Achieved: Equipment certification/calibration and data transfer plan established* (COMPLETED: 11/30/2018)

Major Task 4: Participant Recruitment, Participant Evaluation for trial 1 (Months: 4-30)

- *Milestone Achieved: Recruitment and evaluation completed for study 1* (Percentage of completion: 28.3%)

Patients screened	**Patients Eligible**	**Patients Enrolled**
1827	20	17 (one lost to FU)

Major Task 5: Measure LBM and muscle performance (Months: 4-30)

- *Milestone Achieved: Measures of LBM and muscle performance obtained* (Percentage of completion: 18.3%)

Median (STD)	**Baseline (*n* = 13)**	**3moFU (*n* = 11)**	**6moFU (*n* = 9)**
ALM (kg)	27.02 (3.87)	26.57 (3.29)	25.88 (3.28
Mean HGS (kg)	39.50 (10.33)	35.0 (7.60)	35 (7.42)
6MWT (m)	484.00 (134.43)	488.90 (100.14)	478 (95.05)
SCP (W)	420.75 (136.61)	309.8 (79.43)	282.91 (104.46)

Major Task 6: Measure Mitochondrial Function (Months: 4-30)

- *Milestone Achieved: Measures of mitochondrial function obtained* (Percentage of completion: 10%)

Median (STD)	**Baseline (*n* = 7)**	**6moFU (*n* = 5)**
Basal respiration (OCR)	278.8 (190.12)	205.14 (202.33)
ATP-linked respiration (OCR)	215.96 (181.75)	187.26 (161.66)
Maximal respiration (OCR)	208.04 (289.23)	118.24 (392.76)
Non-mitochondrial respiration (OCR)	15.24 (29.35)	9.41 (22.25)

Major Task 7: Measure Fatigue and HR-QOL Scores (Months: 4-30)

- *Milestone Achieved: Measures of Fatigue and HR-QOL scores obtained* (Percentage of completion: 21.1%)

Median (STD)	**Baseline (*n* = 16)**	**3moFU (*n* = 12)**	**6moFU (*n* = 10)**
FACIT-F (QOL)	107.5 (20.69)	96.5 (18.51)	104 (23.27)
QLQ-C30 (%) (fatigue score percentile)	38.83 (30.63)	44.3 (17.86)	33.3 (17.86)

Major Task 8: Explore the predictive value of the baseline measurements (Months: 6-30)

- *Milestone Achieved: Recruitment and evaluation completed for study 2* (Percentage of completion: 0%)

Major Task 9: Data analysis manuscript preparation and dissemination of results (Months: 30-36)

- *Milestone Achieved: Report results from data analyses* (Percentage of completion 0%)

What was accomplished under these goals?

For this reporting period describe: 1) major activities; 2) specific objectives; 3) significant results or key outcomes, including major findings, developments, or conclusions (both positive and negative); and/or 4) other achievements. Include a discussion of stated goals not met. Description shall include pertinent data and graphs in sufficient detail to explain any significant results achieved. A succinct description of the methodology used shall be provided. As the project progresses to completion, the emphasis in reporting in this section should shift from reporting activities to reporting accomplishments.

Research participant recruitment and performance of study visits were impacted beginning in March due to the COVID-19 epidemic. We have taken this time to complete and corroborate the accuracy of data entry on our database. We have also worked with our coinvestigator to perform the analysis of the data obtained so far on magnetic resonance spectroscopy (MRS). These analyses are ongoing. More recently, the Research Coordinator has been actively screening potential participants from the VA Urology clinic in order to be able to recruit patients when feasible again. As of this reporting period, we have enrolled seventeen participants. We are following local VA and UW communications closely to ensure we meet their recommended guidelines for human subjects research activities.

What opportunities for training and professional development has the project provided?

If the project was not intended to provide training and professional development opportunities or there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe opportunities for training and professional development provided to anyone who worked on the project or anyone who was involved in the activities supported by the project. "Training" activities are those in which individuals with advanced professional skills and experience assist others in attaining greater proficiency. Training activities may include, for example, courses or one-on-one work with a mentor. "Professional development" activities result in increased knowledge or skill in one's area of expertise and may include workshops, conferences, seminars, study groups, and individual study. Include participation in conferences, workshops, and seminars not listed under major activities.

Nothing to Report.

How were the results disseminated to communities of interest?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how the results were disseminated to communities of interest. Include any outreach activities that were undertaken to reach members of communities who are not usually aware of these project activities, for the purpose of enhancing public understanding and increasing interest in learning and careers in science, technology, and the humanities.

Nothing to Report.

What do you plan to do during the next reporting period to accomplish the goals?
If this is the final report, state "Nothing to Report."

Describe briefly what you plan to do during the next reporting period to accomplish the goals and objectives.

During the next reporting period, we anticipate to be able to resume recruitment activities. These efforts have been affected by the COVID-19 epidemic beginning in March 2020. As Clinical care is resuming for these subjects, we expect research activities to gradually return over the next recruitment period. We anticipate that having two open recruitment sites will significantly increase our recruitment numbers and thus aid in accomplishing our end goal of enrolling 60 participants in the study.

4. **IMPACT:** D*escribe distinctive contributions, major accomplishments, innovations, successes, or any change in practice or behavior that has come about as a result of the project relative to:*

What was the impact on the development of the principal discipline(s) of the project?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how findings, results, techniques that were developed or extended, or other products from the project made an impact or are likely to make an impact on the base of knowledge, theory, and research in the principal disciplinary field(s) of the project. Summarize using language that an intelligent lay audience can understand (Scientific American style).

Nothing to Report.

If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how the findings, results, or techniques that were developed or improved, or other products from the project made an impact or are likely to make an impact on other disciplines.

Nothing to Report.

What was the impact on technology transfer?

If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe ways in which the project made an impact, or is likely to make an impact, on commercial technology or public use, including:

- *transfer of results to entities in government or industry;*
- *instances where the research has led to the initiation of a start-up company; or*
- *adoption of new practices.*

Nothing to Report.

What was the impact on society beyond science and technology?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how results from the project made an impact, or are likely to make an impact, beyond the bounds of science, engineering, and the academic world on areas such as:

- *improving public knowledge, attitudes, skills, and abilities;*
- *changing behavior, practices, decision making, policies (including regulatory policies), or social actions; or*
- *improving social, economic, civic, or environmental conditions.*

Nothing to Report.

5. CHANGES/PROBLEMS: *The PD/PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency grants official whenever there are significant changes in the project or its direction. If not previously reported in writing, provide the following additional information or state, "Nothing to Report," if applicable:*

Changes in approach and reasons for change

Describe any changes in approach during the reporting period and reasons for these changes. Remember that significant changes in objectives and scope require prior approval of the agency.

Nothing to Report.

Actual or anticipated problems or delays and actions or plans to resolve them
Describe problems or delays encountered during the reporting period and actions or plans to resolve them.

Research activities slowed down significantly in March as the COVID-19 epidemic affected Seattle. This has resulted in recruitment being slower than originally anticipated. We are following local VA and UW communications closely to ensure we meet their recommended guidelines for human subjects research activities. We anticipate clinical research activities gradually resuming in the upcoming reporting period as clinical care activities are currently resuming. We anticipate UWMC, being a major tertiary care center that has Urology clinics open every weekday, will allow for continued recruitment and boost our enrollment numbers.

Future wave pandemic-level of new cases of COVID-19 may affect our ability to recruit patients. We will monitor the situation closely and follow the advice from institutional, local, state and federal regulatory bodies. To mitigate this potential problem, we plan to open the study at other institutions in Seattle when feasible and only after obtaining all necessary approvals.

Changes that had a significant impact on expenditures
Describe changes during the reporting period that may have had a significant impact on expenditures, for example, delays in hiring staff or favorable developments that enable meeting objectives at less cost than anticipated.

The COVID-19 pandemic had an impact on the expenditures, decreasing the amount of expenditures on personnel and subcontract and increasing the expenditure for supplies. As indicated above, research activities slowed down significantly in March as the COVID-19 epidemic affected Seattle. This has resulted in recruitment being slower than originally anticipated. We are following local VA and UW communications closely to ensure we meet their recommended guidelines for human subjects research activities. We have purchased more personal protective equipment (PPE) and anticipate resuming recruiting on this coming month which will increase the expenditures on personnel.

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents
Describe significant deviations, unexpected outcomes, or changes in approved protocols for the use or care of human subjects, vertebrate animals, biohazards, and/or select agents during the reporting period. If required, were these changes approved by the applicable institution committee (or equivalent) and reported to the agency? Also specify the applicable Institutional Review Board/Institutional Animal Care and Use Committee approval dates.

Significant changes in use or care of human subjects

Nothing to Report.

Significant changes in use or care of vertebrate animals

Nothing to Report.

Significant changes in use of biohazards and/or select agents

Nothing to Report.

6. PRODUCTS: *List any products resulting from the project during the reporting period. If there is nothing to report under a particular item, state "Nothing to Report."*

- **Publications, conference papers, and presentations**
  Report only the major publication(s) resulting from the work under this award.

  Journal publications. *List peer-reviewed articles or papers appearing in scientific, technical, or professional journals. Identify for each publication: Author(s); title; journal; volume: year; page numbers; status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

1. Anderson LJ, Chong N, Migula D, Sauer A, Garrison M, Wu PC, Dash A, **Garcia JM**. Muscle mass, not radiodensity, predicts physical function in cancer patients with or without cachexia. Oncotarget. 2020 May 19;11(20):1911-1921. PMID: 32499874 [original work, federal support acknowledged]
2. Anderson LJ, Lee J, Mallen M, Migula D, Liu H, Wu PC, Dash A, **Garcia JM**. Evaluation of physical function and its association with body composition, quality of life and biomarkers in cancer cachexia patients. Clin Nutr. 2020 Jul 15;. doi: 10.1016/j.clnu.2020.07.001. [Epub ahead of print] PubMed PMID: 32713720. [original work, , federal support acknowledged]

Books or other non-periodical, one-time publications. *Report any book, monograph, dissertation, abstract, or the like published as or in a separate publication, rather than a periodical or series. Include any significant publication in the proceedings of a one-time conference or in the report of a one-time study, commission, or the like. Identify for each one-time publication: author(s); title; editor; title of collection, if applicable; bibliographic information; year; type of publication (e.g., book, thesis or dissertation); status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

Nothing to Report.

Other publications, conference papers and presentations. *Identify any other publications, conference papers and/or presentations not reported above. Specify the status of the publication as noted above. List presentations made during the last year (international, national, local societies, military meetings, etc.). Use an asterisk (*) if presentation produced a manuscript.*

1. Anabolic Therapies in Cancer Cachexia. UW Diabetes Medicine Institute Inaugural Meeting. Seattle, WA, September 2019.
2. UW Monthly Uro-Oncology Meeting. The role of mitochondria in ADT-induced sarcopenia in prostate cancer patients. UWMC teleconference. Seattle, WA, September 2019
3. "Clinical trials in cancer cachexia". Development of Small Molecules to Reduce Muscle Atrophy & Weakness in Hospitalized Veteran Patients Conference. University of Iowa. Iowa City, IA, June 2019.
4. The biology of muscle loss in cancer and current therapeutic trials for the treatment of muscle loss. NIH-Sponsored Body Composition and Cancer Webinar Series, January 2020.
5. Sex Differences in Responses to Treatment in Cancer Cachexia. Society for Sarcopenia Cachexia and Wasting Annual Meeting. Berlin, Germany. December 2019.

- **Website(s) or other Internet site(s)**

List the URL for any Internet site(s) that disseminates the results of the research activities. A short description of each site should be provided. It is not necessary to include the publications already specified above in this section.

Nothing to Report.

- **Technologies or techniques**
  Identify technologies or techniques that resulted from the research activities. Describe the technologies or techniques were shared.

Nothing to Report.

- **Inventions, patent applications, and/or licenses**
  Identify inventions, patent applications with date, and/or licenses that have resulted from the research. Submission of this information as part of an interim research performance progress report is not a substitute for any other invention reporting required under the terms and conditions of an award.

Nothing to Report.

- **Other Products**
  Identify any other reportable outcomes that were developed under this project. Reportable outcomes are defined as a research result that is or relates to a product, scientific advance, or research tool that makes a meaningful contribution toward the understanding, prevention, diagnosis, prognosis, treatment and /or rehabilitation of a disease, injury or condition, or to improve the quality of life. Examples include:
  - *data or databases;*
  - *physical collections;*
  - *audio or video products;*
  - *software;*
  - *models;*
  - *educational aids or curricula;*
  - *instruments or equipment;*
  - *research material (e.g., Germplasm; cell lines, DNA probes, animal models);*
  - *clinical interventions;*
  - *new business creation; and*
  - *other*

Nothing to Report.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Provide the following information for: (1) PDs/PIs; and (2) each person who has worked at least one person month per year on the project during the reporting period, regardless of the source of compensation (a person month equals approximately 160 hours of effort). If information is unchanged from a previous submission, provide the name only and indicate "no change".

Name:	Jose M Garcia, MD, PhD
Project Role:	Principal Investigator
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	1 CM
Contribution to Project:	Dr. Garcia was responsible for the overall scientific and administrative aspects of the project, and shared responsibilities regarding data review, scientific publications and presentations as well as maintenance and monitoring of the integrity of the research.
Name:	Atreya Dash, MD
Project Role:	Co-Investigator
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	1 CM
Contribution to Project:	Dr. Dash was responsible for conducting muscle biopsies on patients, as well as assisted in the identification and screening of potential participants from the Urology clinic.
Name:	Jonathan Lee, B.S.
Project Role:	Research Coordinator
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	1 CM
Contribution to Project:	Mr. Lee acted as the primary POC for the study and was responsible for all subject-related procedures, including screening potential subjects for eligibility, obtaining informed consent, and coordinating study visits.
Name:	Gary Miranda, LPN
Project Role:	Research Coordinator
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	6 CM
Contribution to Project:	Mr. Miranda acted as the UW research coordinator for the study and was responsible for assisting in all subject-related procedures, including screening potential subjects for eligibility, obtaining informed consent, and coordinating study visits.

Name:	Haiming Liu, Ph.D.
Project Role:	Research Scientist
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	3 CM
Contribution to Project:	Dr. Liu was in charge of the tissue analysis portion of the study including assessment of skeletal muscle mitochondrial function ex-vivo.

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

If there is nothing significant to report during this reporting period, state "Nothing to Report."

If the active support has changed for the PD/PI(s) or senior/key personnel, then describe what the change has been. Changes may occur, for example, if a previously active grant has closed and/or if a previously pending grant is now active. Annotate this information so it is clear what has changed from the previous submission. Submission of other support information is not necessary for pending changes or for changes in the level of effort for active support reported previously. The awarding agency may require prior written approval if a change in active other support significantly impacts the effort on the project that is the subject of the project report.

Two NIH RO1 grants were awarded to Dr. Garcia during the last year. These clinical trials have no scientific, budgetary effort overlap with this grant. They are:

R01 CA239208 (MPI-Garcia) 05/01/2019-04/30/2024 1.8 cal mo
NIH/NCI $720,928
Improving Patient-Important Outcomes with Testosterone Replacement in Hypogonadal Men with a Prior History of Cancer
This project will study the efficacy of testosterone replacement on cancer-related fatigue in male cancer survivors who report fatigue and have testosterone deficiency.
Role: Principal Investigator

R01 AG061558 (MPI-Garcia) 07/01/2019-06/30/2024 1.8 cal mo
NIH/NIA $723,385
Improving cancer-related fatigue, sexual dysfunction and quality of life in older men with cancer and androgen deficiency
This project will study the effects of testosterone in elderly men with androgen deficiency and cancer.
Role: Principal Investigator

What other organizations were involved as partners?

If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe partner organizations – academic institutions, other nonprofits, industrial or commercial firms, state or local governments, schools or school systems, or other organizations (foreign or domestic) – that were involved with the project. Partner

organizations may have provided financial or in-kind support, supplied facilities or equipment, collaborated in the research, exchanged personnel, or otherwise contributed.

Provide the following information for each partnership:
Organization Name:
Location of Organization: (if foreign location list country)
Partner's contribution to the project (identify one or more)

- *Financial support;*
- *In-kind support (e.g., partner makes software, computers, equipment, etc., available to project staff);*
- *Facilities (e.g., project staff use the partner's facilities for project activities);*
- *Collaboration (e.g., partner's staff work with project staff on the project);*
- *Personnel exchanges (e.g., project staff and/or partner's staff use each other's facilities, work at each other's site); and*
- *Other.*

Organization Name: University of Washington
Location of Organization: (if foreign location list country): Seattle, WA, United States
Partner's contribution to the project: Facilities (recruitment site)

Organization Name: UW (Harborview Medical Center)
Location of Organization: (if foreign location list country): Seattle, WA, United States
Partner's contribution to the project: Facilities (recruitment site)

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS: *For collaborative awards, independent reports are required from BOTH the Initiating Principal Investigator (PI) and the Collaborating/Partnering PI. A duplicative report is acceptable; however, tasks shall be clearly marked with the responsible PI and research site. A report shall be submitted to* ***https://ers.amedd.army.mil*** *for each unique award.*

QUAD CHARTS: *If applicable, the Quad Chart (available on https://www.usamraa.army.mil) should be updated and submitted with attachments.*

9. APPENDICES:

Attach all appendices that contain information that supplements, clarifies or supports the text. Examples include original copies of journal articles, reprints of manuscripts and abstracts, a curriculum vitae, patent applications, study questionnaires, and surveys, etc.

PC170059: The role of mitochondria in ADT-induced sarcopenia in prostate cancer patients

PI: Dr. Jose Garcia, MD, PhD, SIBCR

Budget: $912,113 **Topic Area:** Prostate Cancer **Mechanism:** W81XWH-17-PCRP-IA

Research Area: 0300 **Award Status:** September 1, 2018 – August 31, 2021

Study Goals: To establish the role of mitochondrial dysfunction on ADT-induced sarcopenia in patients with PCa

Specific Aims:

To determine the extent to which ADT induces changes in:

1) Lean body mass (LBM) and muscle performance
2) Mitochondrial function measured both in-vivo and ex-vivo
3) Fatigue and Health-related-quality of life (HR-QOL) scores

Key Accomplishments:

Publications: 1.Anderson LJ, Chong N, Migula D, Sauer A, Garrison M, Wu PC, Dash A, Garcia JM. Muscle mass, not radiodensity, predicts physical function in cancer patients with or without cachexia. Oncotarget. 2020 May 19;11(20):1911-1921. PMID: 32499874 [original work]

2.Anderson LJ, Lee J, Mallen M, Migula D, Liu H, Wu PC, Dash A, Garcia JM. Evaluation of physical function and its association with body composition, quality of life and biomarkers in cancer cachexia patients. Clin Nutr. 2020 Jul 15;. doi: 10.1016/j.clnu.2020.07.001. [Epub ahead of print] PubMed PMID: 32713720. [original work]

Patents: None.

Funding Obtained: None.