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Award Number: DAMD17-03-1-0301

TITLE: A Research Program of Weight and Body Composition
Management for Women with Breast Cancer

PRINCIPAL INVESTIGATOR: Carolyn Ingram

CONTRACTING ORGANIZATION: McMaster University
Hamilton, Ontario L8N 3Z5
Canada

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Fort Detrick, Maryland 21702-5012

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13. ABSTRACT (Maximum 200 Words) The objectives of this award are to establish a viable program of research focusing on weight and body composition management in breast cancer, and to lay the groundwork for a feasibility study of a home-based exercise intervention for weight and body composition management. The specific aims of the award are: 1) to develop a systematic literature review of studies on exercise and breast cancer that include the outcomes of weight and/or body composition, 2) to examine the relationships between physical activity and body composition changes during adjuvant chemotherapy, and the changes in proportions of body water and lean tissue underlying changes in body composition that were suggested in the PI's dissertation research, 3) to acquire skills in designing and applying tailored exercise programs, measuring fitness and weight-related outcomes, managing clinical trials research, and designing exercise intervention trials, and 5) to develop multidisciplinary teambuilding and grantsmanship capabilities. All tasks outlined in the Statement of Work have been addressed and all are completed or nearing completion. One manuscript has been accepted for publication thus far, and a systematic literature review has been carried out. The major differences for the original submission are in the timeline first proposed.				
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Introduction

At the one-year point, all tasks outlined in the Statement of Work of the original proposal "A Research Program of Weight and Body Composition Management for Women with Breast Cancer" have been addressed. Most are completed or nearing completion. Some have become part of other work, while others continue to stand alone. The major differences from the original submission are in the timelines (and therefore the timing of the expenditures) first proposed (see revised timeline, Appendix A). These differences have occurred for two main reasons: 1) the timeline in the original submission was based on a start date of January, 2003, but the funding for this award was not received and processed by McMaster University until May, 2003, and 2) a suitable research assistant was not recruited, trained and able to contribute to the ongoing work until October, 2003, more than five months into the first year of the award.

Body

The progress of the project is outlined below in relation to the tasks outlined in the final Statement of Work for the award.

Task 1. Develop a systematic review of the literature on exercise interventions for weight and body composition management in women with breast cancer. The proposed steps of this task were to: conduct a systematic literature search; collect all available published and unpublished articles and reports on exercise in cancer that include weight and/or body composition as outcomes; perform a critical analysis of each, focusing on both the content and scientific rigor; summarize the results in both chart and narrative form; submit the review to Drs. Courneya and Degner for comment and prepare a manuscript of the results suitable for publication. The first three steps (collection, screening, analysis) are completed, and the draft of the manuscript is currently being prepared. Dr. Courneya will be a co-author on the manuscript. Nine electronic databases were searched in consultation with the McMaster University Evidence Based Practice Unit (who assisted with developing the search terms and strategies), and several key researchers have been contacted for sub-analyses and works in progress. Titles and abstracts of 1315 references were screened, 82 references have undergone full text reviews, and 13 primary studies were found which met the eligibility screening criteria for inclusion in the review. Preliminary findings indicate that, while the benefits of exercise on other breast cancer outcomes have been extensively examined, changes in weight and body composition have rarely been examined or have been of secondary interest to exercise researchers. Where these outcomes have been studied there is usually evidence of a beneficial effect on the intervention group. The problem of lymphedema, which can profoundly affect weight and body composition estimates, has been studied as a completely separate entity. Because weight and body composition have not been the primary foci of most breast cancer and exercise studies, there is a clear need to pursue research in which these outcomes are of primary importance. There are also numerous methodological issues relative to measurement of the weight and body composition outcomes in the existing literature that need to be addressed in planning future studies.

Task 2. Extend dissertation data analysis re: relationship of physical activity levels with changes in subjects' LBM and fat mass. The proposed steps of this task were to: to augment the data bases used in the principal investigator's (PI's) dissertation study; enter necessary data from dissertation subjects' files, and transfer other data from existing databases; verify correct data entry; analyze the data;

interpret the findings (in consultation with Dr. Courneya); and prepare a manuscript of the results to be reviewed by Drs. Courneya and Degner. All steps except the interpretation of the findings, review by Drs. Courneya and Degner, and preparation for publication have been completed. There is some evidence of an inverse relationship between activity levels and change in fat mass among the PI's dissertation research participants, with higher activity levels related to less increase in fat mass. Further analysis and interpretation is required. These results alone are not sufficient to warrant a publication. However, a manuscript of the PI's dissertation results concerning predictors of weight and body composition change is being prepared for publication, and these results will be included in that manuscript.

Task 3. Extend dissertation data analysis re: percentages of body water and lean tissue comprising subjects' LBM increases. The proposed steps of this task were to: to augment the data bases used in the PI's dissertation study; enter necessary data from dissertation subjects' files, and transfer other data from existing databases; verify correct data entry; analyze the data; interpret the findings (in consultation with Dr. Courneya); and prepare a manuscript of the results to be reviewed by Drs. Courneya and Degner. All steps except the review by Dr. Degner have been completed. The results indicated that virtually all increases in lean body mass experienced by the participants in the PI's dissertation research were attributable to increased body water. These results alone were not sufficient to warrant a publication. However, a manuscript of the PI's dissertation results concerning the patterns of changes in participants' weight and body composition, which includes this secondary analysis, has been accepted (April, 2004, pending revisions) for publication in the journal *Cancer Nursing*. Because the article focuses primarily on the PI's dissertation results, the article was co-authored with the PI's doctoral dissertation chair, Dr. Jean K. Brown, RN, PhD, FAAN. Results of the secondary analysis were reviewed by Dr Courneya. A third review by Dr. Degner was not deemed necessary in this instance.

Task 4A. Acquire advanced skills in designing and applying tailored exercise regimens and exercise outcome measurement. The proposed steps of this task were to: plan and carry out a two-week site visit to Dr. Kerry Courneya's Behavioral Medicine Research Unit at the University of Alberta in which the PI would work with staff and patients to learn methods of tailoring exercise regimens according to need and risk profiles, work with Fitness Testers to learn advanced methods for measuring fitness and activity outcomes; and carry out intensive consultation with Dr. Courneya and key personnel regarding the development of a tailored, home-based exercise intervention. An initial, written protocol of the exercise intervention, to be used in the PI's feasibility study was to result, and Drs. Courneya and Degner would review this protocol. The PI was also to complete a distance version of Dr. Courneya's "Exercise Oncology" course.

A two-week intensive study visit to Dr. Courneya's research unit took place from June 9-20, 2003. During this time the PI consulted and worked with key faculty and graduate students who work for and/or collaborate with Dr. Courneya in planning and conducting his exercise studies. These included physical education faculty who specialize in exercise testing, body composition measurement, and prescription of resistance exercise. There were opportunities to participate in baseline fitness testing of and exercise intervention with Dr Courneya's research participants. By spending a day with each of Dr. Courneya's graduate students, there was the opportunity learn about their projects and the studies they were working on for Dr. Courneya (See Appendix B for a listing of faculty and graduate students

consulted during the site visit). Numerous issues that have become central to the PI's subsequent research planning were initially raised and examined through these discussions. Furthermore, a daily meeting was held with Dr. Courneya in which issues related to the PI's research planning were discussed. A home-based exercise feasibility study is currently being developed. The exercise intervention (a combination of aerobic and resistance exercise) has been delimited through ongoing consultation with Dr. Courneya and his post-doctoral student, Dr. Lee Jones, but requires further refinement.

The requirements of the "Exercise Oncology" Graduate Course were discussed by Dr. Courneya and the PI during the site visit. Because the PI was living in a geographically distant locale at the time of the course, an alternative plan for meeting the course requirements was developed and implemented. The plan that resulted is outlined in the attached letter from Dr. Courneya (see Appendix C).

Task 4B. Acquire skills in developing, funding, and running randomized controlled trials (RCTs) of exercise interventions for breast cancer patients. The proposed steps of this task were to: plan and carry out a two-week site visit to Dr. Kerry Courneya's Behavioral Medicine Research Unit at the University of Alberta in which the PI would work with the Clinical Trials Coordinator and Dr. Courneya to learn the methods they use for establishing and maintaining data integrity in their multi-site clinical trials, and carry out intensive consultation with Dr. Courneya and his team regarding the design of the PI's proposed feasibility study. The outcome of this task was to be a draft of a feasibility study proposal on which Drs. Courneya and Degner would review and comment.

A two-week intensive study visit to Dr. Courneya's research unit took place from June 9-20, 2003. During this time the PI consulted and worked with key faculty and graduate students who work for and/or collaborate with Dr. Courneya in planning and conducting his exercise studies. Unfortunately the Clinical Trials Co-ordinator position for Dr. Courneya's research unit was vacant at the time of this site visit; however, several individuals were consulted whose expertise amply met the stated objectives. Among the individuals consulted on the management of multi-site RCTs were a researcher in the Physical Education Faculty (Dr. Wendy Rodgers) who was running a large multi-site exercise study and her project manager. The PI also participated in Dr. Courneya's weekly staff meetings at which all studies by or involving the unit were reviewed and discussed. One of Dr. Courneya's graduate students who serves as project co-ordinator for the Unit's "START" trial also provided valuable information. A proposal for a trial of an exercise intervention for weight and body composition management in breast cancer survivors, focusing on the intervention protocol noted in Task 4A, is currently being developed in consultation with Dr. Courneya, and will be submitted to the National Cancer Institute of Canada's (NCIC) Breast Cancer Research Alliance for their annual grants competition in October, 2004.

Task 5. Develop multidisciplinary research teambuilding and grantsmanship capabilities. The proposed steps to this task were to: consult with Drs. Courneya and Degner on each project throughout the award period, solicit comments from Drs. Courneya and Degner on each project and incorporate their comments into all final drafts; and meet with Drs. Courneya and Degner in conjunction with their trips to the Toronto area and our mutual trips to various national and international conferences. A further step was to visit Dr. Degner's Evidence Based Nursing Research Unit at the University of Manitoba, School of Nursing for one week. The goals for this visit were to further crystallize our ideas on team development, grant opportunities and the PI's proposed feasibility study, examine the operations of the

Evidence-Based Cancer Nursing Research Unit, and meet with key members of the University of Manitoba Physical Education faculty and surrounding fitness research facilities to discuss possible research collaborations. The outcome of this task was to further assist in the preparation and submission of the exercise feasibility study for external funding from the grant competitions, and to establish ongoing collaborative relationships with Drs. Courneya and Degner and their research units.

I have had one "outside" meeting with Dr. Degner in conjunction with the 2003 Oncology Nursing Society biennial Cancer Nursing Research Conference in San Diego. The proposed site visit to Dr. Degner's research unit took place from March 21-26, 2004. During this time the PI consulted and worked with key faculty, managers and graduate students who study and/or collaborate with Dr. Degner (see list of individuals consulted, Appendix D). These included: four faculty members in the Evidence Based Cancer Nursing Research Unit who have obtained or have become candidates for new investigator career awards under Dr. Degner's guidance, oncology nursing graduate students, and physical education faculty and managers who offered opportunities for future research collaboration. Visits to a leading edge fitness facility and breast health center in the Winnipeg area were also included. Several issues that have become crucial to the PI's subsequent research program planning were raised and examined through these discussions, and numerous research collaborations were established. Furthermore, a daily meeting was held with Dr. Degner in which issues related to the PI's research program planning were discussed. Dr. Degner also provided initial advice on the development of the PI's proposed feasibility study of exercise for breast cancer weight and body composition management, and the appropriate steps to follow in seeking NCIC funding. It was her recommendation that the study be submitted specifically to the NCIC Feasibility Grants competition. It was also her recommendation that, having submitted a proposal to NCIC in Fall, 2004, the PI should submit an application for an NCIC "New Investigator" Award in the February, 2005 competition.

Dr. Courneya and his research team have been and continue to be consulted regularly on the development of the systematic review, the secondary data analyses and the exercise feasibility study (see above). A further week's intensive site visit is planned with Dr. Courneya at the University of Alberta in September, 2004 in conjunction with the PI's attendance at the annual Canadian Association of Nurses in Oncology conference in Calgary, Alberta. The timing is ideal, as it precedes the NCIC grant deadline by three weeks, and will allow us to discuss and implement very specific final revisions to the feasibility proposal. It will also allow the PI to acquire further hands-on experience in the exercise testing and research facilities, and provide an opportunity to consult with faculty and staff who were unavailable during the first site visit. Although it is viewed as meeting the spirit of Task 5, *the September visit will be financed out-of-pocket as it was not included in the budget for the original DOD award.* Dr Courneya has agreed to be a co-author on the manuscript of the systematic review and co-investigator on the exercise feasibility study grant submission.

Key Research Accomplishments

- Completion of the systematic literature review (being written up)
- Secondary data analyses completed (Task 2 and 3) and incorporated or being incorporated into suitable manuscripts for publication
- Site visits to mentor and consultant as outlined in Statement of Work
- Establishment of relationships with numerous key research collaborators in conjunction with site visits
- Clarification of plans for developing an ongoing program of research
- Preliminary outline of intervention protocol for feasibility study

Reportable Outcomes

- Manuscript accepted April, 2004, for publication (with revisions) in *Cancer Nursing*: **Ingram, C. & Brown, J. K.** "Patterns of weight and body composition change in premenopausal women with early stage breast cancer: Has weight gain been overestimated?"

Conclusions

The first year of the Breast Cancer Research Nurse award has been an unparalleled experience that has provided the PI the opportunity to establish collaborative research relationships with two of Canada's premier cancer researchers and their teams. It has also provided the opportunity to advance the PI's research program on weight and body composition management for breast cancer survivors, and consolidate unfinished or secondary work that was needed to support these ongoing research efforts. All tasks in the Statement of Work are completed or nearing completion and will be concluded by October, 2004.

APPENDIX A

REVISED SCHEDULE FOR BREAST CANCER RESEARCH NURSE
GRANT DAMD17-03-1-0301

Revised Timeline for Research Grant

<i>Task</i>	<i>Month (5/2003-6/2005)</i>																		
	M	J	J	A	S	O	N	D	2004	J	F	M	A	M	J	J	A	S	O
Systematic Review of literature and development of manuscript (12 months)	<----->																		
Extend data analyses and prepare manuscript #1 (5 months)	<----->																		
Extend data analyses and prepare manuscript #2 (3 months)	<-->																<-->		
On-site exercise research site visit (PI to Alberta ~ 14 days)	<->																		
Complete requirements for University of Alberta graduate course in Exercise Oncology (4 months)	<----->																		
On-site visit to research unit (PI to Manitoba ~ 7 days)																<->			
Design exercise intervention (4 months)																<----->			
Design feasibility study (4 months)																<----->			
Prepare funding proposal for feasibility study and submit for external funding																<----->			
Present results at "Era of Hope" conference in Philadelphia																		X	

APPENDIX B

**LIST OF FACULTY AND GRADUATE STUDENTS CONSULTED DURING THE SITE VISIT
TO DR. COURNEYA'S RESEARCH UNIT**

FACULTY AND GRADUATE STUDENTS CONSULTED DURING THE SITE VISIT TO DR. COURNEYA'S RESEARCH UNIT, UNIVERSITY OF ALBERTA

Individual consulted	Role and/or Expertise
<ul style="list-style-type: none"> Kerry Courneya, PhD, Faculty of Physical Education 	Mentor for award, Director of Behavioral Medicine Research Unit and Fitness Center
<ul style="list-style-type: none"> Gordon Bell, PhD, Faculty of Physical Education 	Exercise/fitness testing
<ul style="list-style-type: none"> Dan Syroituik, PhD, Faculty of Physical Education 	Prescription of resistance exercise
<ul style="list-style-type: none"> Vicki Harber, PhD, Faculty of Physical Education 	Body composition measurement
<ul style="list-style-type: none"> Wendy Rodgers, PhD, Faculty of Physical Education 	Director of University of Alberta, Faculty of Physical Education "Couch Potato" Exercise Study (RCT; Kerry Courneya, Co-investigator)
<ul style="list-style-type: none"> Karin Olson, RN, PhD, Faculty of Nursing 	Opportunities for research collaboration with Cross Cancer Institute and School of Nursing
<ul style="list-style-type: none"> Terra Murray, PhD (c), Faculty of Physical Education 	Project manager, "Couch Potato" study re: practicalities of RCT project management
<ul style="list-style-type: none"> Lee Jones, PhD, Post-doctoral Fellow, PhD student, Behavioral Medicine Research Unit 	Post-doctoral research
<ul style="list-style-type: none"> Jeff Vallance, PhD student, Behavioral Medicine Research Unit 	Graduate work; overview and management of START exercise trial for breast cancer patients
<ul style="list-style-type: none"> Kristin Campbell, PhD student, Behavioral Medicine Research Unit 	Graduate work; issues related to measurement of biological markers in exercise studies; fitness testing participant-observation
<ul style="list-style-type: none"> Margie McNeely, PhD student, Behavioral Medicine Research Unit 	Graduate work; lymphedema issues in body composition measurement and exercise; lymphedema measurement participant-observation
<ul style="list-style-type: none"> Aliya Lahda, Masters student, Behavioral Medicine Research Unit 	Graduate work; meta-analysis of cancer and exercise studies
<ul style="list-style-type: none"> Carolyn Peddle, Masters student, Behavioral Medicine Research Unit 	Graduate work; meta-analysis of cancer and exercise studies; survey of oncologists on exercise beliefs
<ul style="list-style-type: none"> Co-op student, Faculty of Physical Education 	Participant-observation of exercise for research participants in Dr. Courneya's fitness center.

APPENDIX C

**LETTER FROM DR. COURNEYA OUTLINING THE COMPLETION OF THE
REQUIREMENTS FOR THE "EXERCISE ONCOLOGY" GRADUATE COURSE**



May 19, 2004

To Whom It May Concern:

This letter is to verify that Dr. Carolyn Ingram has met the requirements of my graduate course in Exercise Oncology, as noted in the statement of work for her Breast Cancer Research Nurse award # DAMD17-03-1-0301.

During her site visit to our research unit in June, 2003, Dr. Ingram and I discussed the course requirements and how she might meet these, given her geographic distance from our locale during the time that the course was to be held (Fall, 2003). The course objectives are as follows: (1) gain a basic knowledge of cancer biology and epidemiology, (2) learn about current cancer treatments, and (3) appreciate the potential contribution of exercise to cancer control.


It was evident to me that, because of her strong background in clinical oncology, Dr. Ingram was already well versed on the introductory material re: cancer biology, epidemiology and treatment. This material is the focus for approximately five of the 13 weeks of this course (weeks 2, 3, 5, 6, and 7). Indeed, while she was visiting our unit she provided me with several suggestions for revision of the required and recommended readings for these units. She and another cancer nurse researcher also provided my research group with a very informative overview of cancer biology, cancer treatment and new treatment developments, which is further testimony to her command of this information.

With regard to the remaining course components, the course evaluation is based on the following: class participation, a class presentation and a major research paper. During her visit to our unit Dr. Ingram gave a very informative presentation to my research group (several of whom also took my course) concerning the background of weight and body composition problems in breast cancer, the results of her own research and how this led to her current and future research directions. I felt this more than met the requirements I have set for our in-class presentations. The systematic review of breast cancer, exercise and body composition outcomes that Dr. Ingram has produced more than meets the requirements I have set for my students' major research paper. I will, in fact, be a co-author on this paper.

Dr. Ingram had or has completed many of the weekly readings that I assign my students either in her previous clinical practice, in the course of her work with my research unit, or in developing her systematic review. With regard to the issue of class participation, Dr. Ingram corresponded with one of my graduate students to gain insight into the issues that were being discussed in class. This graduate student also provided her with all the materials handed out in class, which she was then able to review on her own.

Overall I feel that Dr. Ingram has amply met the requirements of my graduate course. Please feel free to contact me if you require further information or have questions.

Sincerely yours,


Kerry S. Courneya, PhD
Professor and CIHR Investigator

Subject: [Fwd: RE: Letter]

Date: Wed, 26 May 2004 10:25:01 -0400

From: Carolyn Ingram <ingramc@mcmaster.ca>

To: ingram carolyn <ingramc@mcmaster.ca>

----- Original Message -----

Subject: RE: Duh!

Date: Thu, 20 May 2004 11:57:04 -0600

From: "Kerry Courneya" <kerry.courneya@ualberta.ca>

Reply-To: <kerry.courneya@ualberta.ca>

To: "Carolyn Ingram" <ingramc@mcmaster.ca>

Carolyn, here is the letter, please sign on my behalf. It won't be a problem. The basic issue is whether I am endorsing the letter, which I am.

Kerry

Kerry S. Courneya, PhD
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APPENDIX D

FACULTY AND OTHER INDIVIDUALS CONSULTED DURING THE SITE VISIT TO DR.
DEGNER'S RESEARCH UNIT, UNIVERSITY OF MANITOBA

FACULTY AND OTHER INDIVIDUALS CONSULTED DURING THE SITE VISIT TO DR.
DEGNER'S RESEARCH UNIT, UNIVERSITY OF MANITOBA

Individual consulted	Expertise and/or Area of Interest
<ul style="list-style-type: none"> • Dr. Lesley Degner, RN, PhD, Faculty of Nursing 	Consultant for award and Director, Evidence Based Cancer Nursing Research Unit
<ul style="list-style-type: none"> • Dr. Susan McClement, RN, PhD, Faculty of Nursing 	Research Associate with Cancer Care Manitoba. Potential research collaboration related to nutrition and exercise for palliative breast cancer patients
<ul style="list-style-type: none"> • Dr. Michelle Lobchuk, RN, PhD, Faculty of Nursing 	Discussion of research program; application process for career awards; evidence-based practice graduate nursing course - attended course and reviewed web-based course materials
<ul style="list-style-type: none"> • Dr. Thomas Hack, PhD 	Research Associate with St Boniface Cancer Research Center and Career Scientist, CIHR/NCIC. Discussed research program and potential research collaboration related to women's issues with lymphedema
<ul style="list-style-type: none"> • Dr. Roberta Woodgate, RN, PhD, Faculty of Nursing 	Discussion of research program; application process for career awards; and potential research collaboration related to exercise in the pediatric cancer population
<ul style="list-style-type: none"> • Dr. A. Elizabeth Ready, PhD, Director of Graduate Program, Faculty of Physical Education 	Opportunities for research collaboration
<ul style="list-style-type: none"> • Darren Brereton, MS, Director, Health and Fitness Programs, Seven Oaks Hospital Wellness Center 	Unique model of hospital-based wellness and fitness center. New wellness program for cancer survivors. Possibilities for research collaboration with Seven Oaks as a research site.
<ul style="list-style-type: none"> • Wanda Martin* and Megan Doyle, Nursing Graduate Students 	Programs of study in Dr. Degner's cancer nursing graduate program. Tour of St Boniface Breast Health Center. *Ms. Martin is also a recipient of a DOD Breast Cancer Research Nurse award for 2003-2005.