Does Online "Working Out Work" as a Treatment and Prevention for Depression in Older Adults? An Analysis of a Prescribed and Monitored Exercise Program Administered via the Internet for Senior Adults with Depression.

By
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Submitted to
Professor Kathleen Waldron
In partial fulfillment of the requirements for
ALD 593 Applied Project: Aging and Lifespan Development

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Master of Science in Aging and Lifespan Development
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7. Arizona State University
8. The volunteers who participated in the study

SPECIAL ACKNOWLEDGMENT

I would like to give a special acknowledgment to my dear Mother, the late Evelyn June Garcia. As a Senior Adult, my Mother inspired my research and continued studies in Gerontology.

Thank You

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Abstract

RESEARCH QUESTION: Does Online "Working Out Work" as a Treatment and Prevention for Depression in Older Adults? An Analysis of a Prescribed and Monitored Exercise Program Administered via the Internet for Senior Adults with Depression.

OBJECTIVE: The purpose of this study is to investigate and access the effectiveness of an online prescribed and monitored exercise program for the treatment of depression in Older Adults. The Dependent Variable for the study is Depression. The Independent Variable for the study is the Effects of Exercise administered via the Internet and the population is geriatric adults defined as senior adults aged 50 and older. Depression is defined by Princeton University Scholars (Wordnet, 2006) as a mental state characterized by a pessimistic sense of inadequacy and a despondent lack of activity.

METHODS: The presence and severity of depression will be assessed by using The Merck Manual of Geriatrics (GDS-15) Geriatric Depression Scale. Assessments will be performed at baseline, before and after the treatment is concluded. The subjects will complete the Physical Activity Readiness Questionnaire (PAR-Q) prior to participating in an exercise program three times per week.

LIMITATIONS OF RESEARCH: The limitations of this study are: 1) There is a small sample size limited to Senior Adults aged 50 - 80, and 2) there is no control group with structured activity or placebo, therefore researcher is unable to evaluate if the marked improvement was due to a non-specific therapeutic effect associated with taking part in a social activity (group online exercise program). Further research could compare and analyze the positive effects of a muscular strength training exercise program verses a cardiovascular training exercise program.

COOPERATING ORGANIZATION: Senior University, Scottsdale, Arizona.
KEY WORDS: depression, senior adults, aging, gerontology, geriatrics, exercise, online fitness, Internet, telehealth, e-health, bio-gerontology, behavioral health, health

Does Online "Working Out Work" as a Treatment and Prevention for Depression in Older Adults? An Analysis of a Prescribed and Monitored Exercise Program Administered via the Internet for Senior Adults with Depression.

Introduction: Exercise Therapy as a Behavioral Health Treatment Modality

The current research project investigates the effectiveness of a prescribed and monitored online exercise program for the treatment of depression in Older Adults. Many studies have been conducted showing that exercise is an effective treatment for depression in adults, (Livni, 2007; Singh 2001; Johnsgard, 2006; Hays, 2002). However, there is limited research using seniors as the population and the Internet as a modality. This study is devoted to the goal of providing empirical support for the notion that an exercise program administered via the Internet (world wide web) is a feasible and effective treatment for depression in older adults.

According to the Surgeon General, "Lack of exercise is the #1 health concern facing this country" (Walters, 2011; Benjamin, 2011). Exercise has been shown as the most effective treatment for depression in elderly people (Singh, 2001). Health professionals from multiple disciplines concur on the myriad of mental health benefits that a regular exercise program can provide (Dias, 2003).

“With nearly 70 percent of the U.S. population having Internet access, we have the technology to improve the overall fitness and health of the nation” says Paul Williams, a staff scientist in Berkeley Lab’s Life Sciences (Williams, 2006). Berkeley Lab is a U.S. Government National laboratory that conducts scientific research.

Recent research and longevity studies have demonstrated that seniors who are physically active can eliminate or significantly reduce depression and or depression symptoms. Dr. Chhanda Dutta from The National Institute of Aging promotes exercise for seniors and geriatric patients. She tells her patients that exercise is the healthiest thing you can do for your mental health. Dr. Dutta also suggests that not exercising is risky behavior (Dutta, 2004). Gary MacDonald, who is on the National Depression Institute Board, agrees that exercise is the best treatment for depression. Research has shown that exercising three times per week is more effective than medication in relieving the psychological symptoms of depression (Livni, 2007).

Depression is not a normal part of aging. Experiences of sadness, sorrow, grief, response to loss, and temporary “blue” moods are normal. Ongoing depression that interferes significantly with ability to function daily is not. Depression in older adults should be treated when it occurs at the same time as other medical illnesses. Untreated depression can delay recovery or worsen the outcome of many other illnesses (Reynolds, 2006).

The scope of this issue crosses professional disciplines. Using exercise as a treatment for depression in older adults is beneficial for psychiatrists, psychologists, physical therapists, personal trainers, physicians, social workers, and any other health professional that treat the elderly. The findings of this study will increase the viable treatment options available for decreasing depression symptoms in depressed senior adults and comorbid geriatric patients.

Review of Literature

Review of literature reveals that working out relieves the symptoms of major depression in elderly people and may also decrease the chances that depression will return. Kinesiology and psychology research has demonstrated that staying active moderates depression quickly. Dr. Robert Butler (2005), President of International Longevity Center at Mount Sinai Medical School, agrees that exercising is the number one anti-depression treatment. “It’s also cheap, and it avoids problems such as the side-effects of medication” says Dr. Butler (2005).

Researchers at Duke University Medical Center (Blumenthal, 2007) studied chronically depressed patients 50 and older and found that after 16 weeks, those who exercised showed significant improvement compared to those who either took medication alone or those who combined the therapies. In a six-month follow up study, the psychologists found that depression only returned in 8 percent of the patients in the exercise group versus 38 percent in the drug only group. The main conclusion from this study is “that maintaining an exercise program can significantly help in reducing depression” says the study’s lead researcher Dr. Blumenthal. He believes this just confirms what a lot people think exercise can do anyway (Blumenthal, 2007). The results of this research reveal that my independent variable, the effects of exercise, will decrease symptoms of my dependent variable, depression. Depression is widespread and prevalent in the elderly. A report by the National Institute of Mental Health called depression in the elderly “a serious public health concern” (Kelly, 2003).

Surveys suggest from 15 to 50 percent of the aging population has experienced depression, while an additional 25 percent of elderly individuals have long periods of persistent sadness (Steinman, 2007). Another study addressing this issue by Dr. Blumenthal and Duke University Medical Center researchers in 2004 revealed that exercise reduces death rate in half for depressed heart attack patients (Blumenthal, 2004). This was a large-scale study, with 2,078 participants.

Another ground-breaking study that utilized the same Independent and Dependent Variable is one of Dr. Blumenthal’s projects. Dr. Blumenthal’s (1999) study of one hundred fifty-six men and women with Depression, analyzed the effectiveness of an aerobic exercise program compared with standard medication (i.e., antidepressants) for treatment of Depression in older adults. The authors of this study conclude that exercise is comparable to antidepressant agents in the treatment of depression in older adults (Blumenthal, 1999).

Antidepressant drugs are successful in treating depression in older adults, but they can have severe side effects and are usually very expensive. The medical community is increasingly recognizing the important role of exercise as a treatment for depression. We are seeing a heightened awareness in physicians and health care providers in regard to non-pharmaceutical treatments of mental health (Russell, 2011).

Many are agreeing that the prescription of an exercise routine is a good alternative or addition to medication (Steinman, 2007; Hays, 1999; Dubbart, 2006; Moore, 1998). Physical activity is becoming a more recognized form of therapy.

Doug Burke, with the Department of Veteran Affairs, would agree, he has developed a nationwide structured exercise program that is very successful in treating Vietnam Vets suffering from depression (Scott, 2001). For Veterans and other seniors who cannot afford pharmaceutical therapy, exercise therapy is the least expensive antidepressant available. The results of empirical studies reveal that my independent variable, the effects of exercise, will decrease symptoms of my dependent variable, depression, (Johnsgard, 2004; Singh, 2001).

Exercise for the Elderly

Before initiating an exercise program, older adults should complete a medical history and undergo a physical examination. The American College of Sports Medicine suggests exercise stress testing for sedentary adults who plan to begin working out a vigorous level. My participants will fill out a PAR-Q Exercise Readiness Questionnaire, (Canadian Society for Exercise Physiology, 1998). Most elderly patients can begin a moderate exercise routine safely without stress testing, if they begin slow and increase exertion levels moderately. Older Adults and geriatric patients should be advised to discontinue exercise and seek medical help if they experience warning signs of any adverse cardiac events.

Online Fitness Programs

“A study published in the Journal of the American Medical Association shows that Web exercise programs are an effective method for achieving weight loss” (Tate, 2003). More and more people are using the Internet for their health and fitness needs.

Online fitness programs are convenient, they offer anonymity, they are accessible at any time from the comfort of your home or work, and they are very affordable. These programs offer the five A’s of telehealth: accessibility, affordability, anonymity, acceptability, and adaptability (Mahue et al., 2005). “Research shows that most adults would prefer to lose weight without having to participate in a structured face-to-face program” (Adams, 2008). This type of online fitness class gives you the option of exercising in the privacy of your own home, without the intimidation of a public gym. Many online programs also offer 24-hour access to progress tools, which can increase your motivation to stick with the workout. Another advantage is that you can workout on your schedule instead of a scheduled class time and continue workouts even when you are traveling.

More research is needed to determine the long-term health and fitness maintenance among Internet-based programs. My review of literature did not reveal any studies that combined online fitness classes with depressed Senior Adults. However, most of the research suggests that Internet-based health and fitness programs can facilitate weight loss and weight maintenance.

In one study, published in Obesity Research (Puhl, 2009), 255 overweight and obese men partook in a six-month behavioral weight control program conducted on the Internet. After this study, participants were placed into one of three groups (frequent in-person support, minimal in-person support, or internet support) as part of a 12-month weight maintenance phase. The participants in the internet-based weight

maintenance program lost about the same amount of weight over eighteen months as those who met with counselors in person. This study supports the theory that the Internet is a viable method for promoting weight loss and maintenance (Puhl, 2009).

Statement of Research Hypotheses

By the year 2030, an estimated 70 million people will be older than 65 and review of literature reveals that depression is widespread and prevalent among the elderly (Older Americans Update, 2006). In the future, it will be even more imperative that health professionals counsel sedentary seniors to become or stay physically active. Exercise has been shown as the most effective treatment for depression in elderly people. Multiple disciplines concur on the myriad of mental health benefits that a regular exercise program can provide. This study will analyze the effect of a monitored online exercise program on Senior adults to show that exercise is an effective treatment for Depression. Based on the literature review, it is hypothesized that a monitored exercise program, administered via the Internet, will have a beneficial effect on depression among senior adults.

Methodology

Data/Site Plan: The study was conducted, and data was collected at Senior University online website. This organization serves older adults in the Scottsdale, North Phoenix, and Paradise Valley areas. There are many program volunteers and 10 instructional staff members. The number of participants varies throughout the year, depending on programs being offered. Participants will also be recruited from Active Minds Institute, Scottsdale College, The Minderful Center, and DUET Healthy Aging.

Sample: The population is senior adults. The participants are volunteers aged 50-80 years old who met GDS criteria for Depression at study entry (Appendix E).

Data Collection Plan: Volunteer Participants completed THE MERCK MANUAL OF GERIATRICS (GDS) Geriatric Depression Scale Questionnaire. Assessments were performed at baseline, before and after the treatment was concluded. The subjects also sign a Minimal Risk Consent form (Appendix B). In addition, the subjects completed the (PAR-Q) Physical Activity Readiness Questionnaire. This Questionnaire (PAR-Q) was evaluated by the researcher prior to subjects participating in the treatment exercise program three times per week.

Pre-Exercise Assessment: Volunteer Participants completed THE MERCK MANUAL OF GERIATRICS (GDS) Geriatric Depression Scale Questionnaire (Appendix E). Assessments were performed at baseline. The sample will also file out and sign an ASU Minimal Risk Consent form. In addition, the subjects complete the (PAR-Q) Physical Activity Readiness Questionnaire prior to participating in the treatment exercise program three times per week.

Treatment/Exercise Program: On completion of the baseline assessments, participants start an exercise program, three times per week.

Exercise Prescription

The Exercise Program “Working Out” will include the following:

Warm-up: Flexibility Exercises - Stretch every day before exercise (three times per week), (e.g., stretch and hold each flexibility exercise for at least 15 seconds as demonstrated online by instructor). 10 Flexibility Exercises for Warm-up & Cool-down are; 1. Inverted Hurdler 2. Biceps Stretch 3. Butterfly Stretch 4. Triceps Stretch 5. Pretzel Stretch 6. Shoulder Crosses 7. Straddle Stretch 8. Chest Pectorals Door Stretch 9. Quadriceps Stretch and 10. Calf Stretch

Workout: Cardiovascular Endurance Activity - Also known as Aerobic Exercise and or Cardio. Participants complete 30 minutes of Aerobic Exercise (e.g., Brisk Walking, Stationery Bicycle, Elliptical, or Swimming) with a frequency of three times per week for eight weeks for a total of twenty-four workouts.

Cool-down: Flexibility Exercises - Stretch every day after exercise (three times per week), when your muscles are warm and more compliant (same 10 flexibility exercises as warm-up).

Post-Exercise Assessments - Depression evaluations using THE MERCK MANUAL OF GERIATRICS (GDS-15) Geriatric Depression Scale Questionnaire were performed immediately after the treatment was concluded.

Measurement of Variables

1) Dependent Variable – The Dependent Variable for the study is Depression. Dependent Variable of Depression will be measured using THE MERCK MANUAL OF GERIATRICS (GDS-15) Geriatric Depression Scale Questionnaire.

2) Independent Variable - The Independent Variable for the study is the Effects of Exercise. The population is older adults. This is measured by facilitating the GDS before and after the subject’s participation in the actual exercise program.

3) Control Variables - The population is senior adults, aged 50-80 years old.

4) Data Analysis Plan - Descriptive statistics will be utilized to analyze the data which will include frequencies, means and standard deviations when appropriate.

Results of the Analysis

The results of this project benefit the population of the study (older adults) by adding to the available options of depression treatment. The participants showed an

overall improvement on the GDS Post Exercise Assessment after participating in an online fitness class.

Participant Depression Scores on GDS

Pre	Post
Mildly Depressed	Normal
6.06	3.9

This research study provides evidence and considerable support for the importance of exercise in reducing depression symptoms in Senior Adult populations. Therefore, online exercise programs can be recommended as an additional treatment to the more traditional pharmacological therapies. This online exercise class exhibited a decline in depressive symptoms as noted below.

EFFECTS ON DEPRESSION

Pre-Exercise Assessment Scores:

Geriatric Depression Scale Questionnaire Group Mean Score: 6.06 (Depressed)

Geriatric Depression Scale Questionnaire Group Total Score: 182

Post-Exercise Assessment Scores:

Geriatric Depression Scale Questionnaire Group Mean Score: 3.90 (Not Depressed)

Geriatric Depression Scale Questionnaire Group Total Score: 117

Depression is widespread and prevalent in the elderly. A regular exercise program (3 times per week) is a positive aid in the treatment of depression in elderly adults. The two figures below illustrate the positive effects on the depression scores for the exercise treatment group.

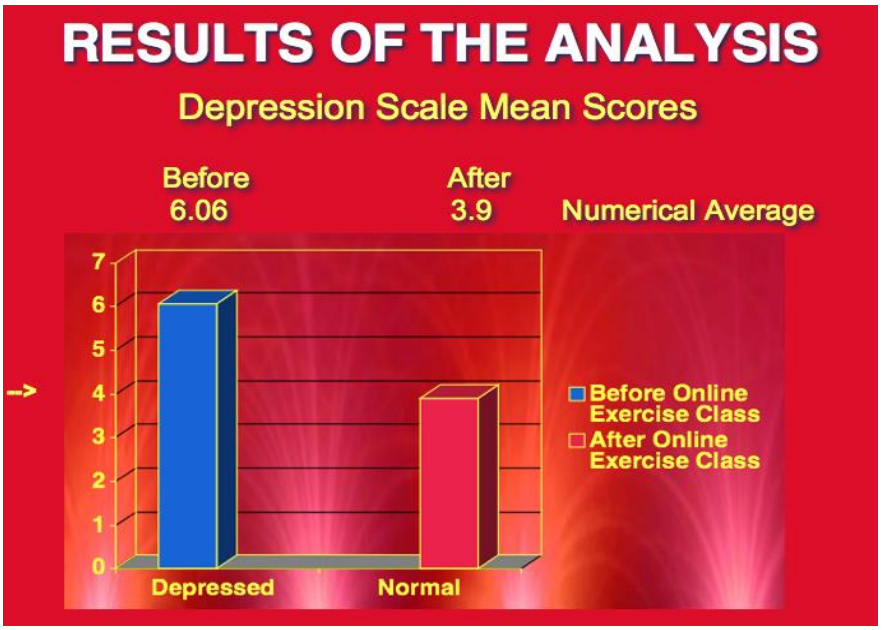
Data Analysis Figures

Depression Scale Post-Test Statistics

Scores: 5,2,3,4,5,4,3,4,4,3,3,4,4,4,3,4,5,3,3,4,3,3,5,5,5,5,4,3,4,5

Total Numbers:	30
Range:	3
Mean (Average):	3.86667
Standard deviation:	0.86037
Variance (Standard deviation):	0.74023
Population Standard deviation:	0.84591
Variance (Population Standard deviation):	0.71556

➢REFLECTS A NORMAL DISTRIBUTION
➢ALL *n* POST-TEST SCORES WERE LOWER THAN PRE-TEST



Sample Data Analysis: The population is older adults (50-80 years). The participants were volunteers aged 50 years and older who met GDS-15 criteria and scored at least 84 on the GDS (Appendix E) at study entry. This would classify all participants to be at least Mildly Depressed. The sample was made up of 19 women and 12 men. In addition, participants also met the following criteria: 1) no medical contraindications to

exercise (eg, significant orthopedic problems or cardiopulmonary disease that would prevent regular aerobic exercise); as shown on the PAR-Q, and 2) have reliable Internet access with a working email address.

ADHERENCE TO TREATMENT. Only one participant dropped out of the study.

Sample Demographics Table: 30 Participants (Started with 31)

Gender	Male 38% 12 Participants	Female 62 % 19 Participants	
Age	50 – 60 years 20 Participants	61 – 69 years 10 Participants	69-80 years 1 Participant
Marital Status	Single 66% 21 Participants	Married 34% 10 Participants	

Implications for Agency and Community

Results of this study support the recommendation of an online fitness class for Senior University and its’ community. Senior Adults aged 50 – 80 will see improvement in depression symptoms from a therapeutic effect associated with taking part in a group online exercise program.

Discussion

In summary, working out utilizing an online fitness class relieves depression in senior adults, geriatric patients and elderly people. Kinesiology and psychology research has demonstrated that staying active diminishes depression symptoms quickly (Butler, 2005). The results of this study reveal that my independent variable,

the effects of exercise, will decrease symptoms of my dependent variable, depression. In conclusion, a monitored online exercise program, as a stand-alone treatment or in conjunction with other medical treatments will have a beneficial effect on depression among senior adults and geriatric patients.

Recommendations for Further Study

Further research could compare and analyze the positive effects of a muscular strength training exercise program verses a cardiovascular training exercise program. Research could also include a larger population size with varied levels of depression. In addition, a control group can be added to future research for more detailed analysis and comparison of data.

Appendices/Collection of Data Tools

Appendix A

Human Subjects Research

Arizona State University
Research Compliance Office
P.O. Box 871103
Tempe, AZ 85287-1103
Phone: 480-965-6788
Fax: (480) 965-7772

For Office Use Only:
Date Received: _____
HS Number: _____

ARIZONA STATE UNIVERSITY
APPLICATION FOR EXEMPT RESEARCH

PROTOCOL TITLE: An Analysis of a Prescribed and Monitored Exercise Program administered via the Internet for Seniors with Depression		DATE OF REQUEST: 8/01/2010
PRINCIPAL INVESTIGATOR: Dr. Robelyn Garcia 4455 E. Paradise Village Pkwy Townhouse 1063 Paradise Valley, AZ 85032	DEPARTMENT/CENTER: Department of Human Services, Aging and Lifespan Development Department of Student Recreation Department of Student Health	UNIVERSITY AFFILIATION: X Post Doc Scholar X Graduate Student X Staff
CAMPUS ADDRESS: Mail Code: 0420	PHONE: 480-221-7773	
	E-MAIL: Dr.RobelynGarcia@asu.edu	
CO-INVESTIGATOR:	DEPARTMENT/CENTER:	UNIVERSITY AFFILIATION: ☐ Professor ☐ Associate Professor ☐ Assistant Professor ☐ Instructor ☐ Other: Please specify.
CAMPUS ADDRESS: (include campus mail code)	PHONE:	
	EMAIL:	

STUDY OVERVIEW

1. Provide a brief description of the background, purpose, and design of your research. Avoid using technical terms and jargon. Be sure to list all of the means you will use to collect data (e.g. tests, surveys, interviews, observations, existing data). Provide a short description of the tests, instruments, or measures and attach copies of all instruments and cover letters for review:

The current research project investigates the effectiveness of a prescribed and monitored exercise program, administered via the Internet, for the treatment of depression in Older Adults. The Dependent Variable for the study is Depression. The Independent Variable for the study is the Effects of Exercise and the population is older adults. This study will analyze the effect of a monitored exercise program on Seniors to show that exercise is an effective treatment for Depression. The design of the research is a systematic review and analysis of controlled trials.

Many studies have been conducted showing that exercise is an effective treatment for depression in adults. However, there is limited research using the internet as the modality. This study is devoted to the goal of providing empirical support for the notion that an exercise program, administered via the Internet, is a feasible and effective treatment for depression in Senior adults.

The following instruments (attached in Appendices) will be used for the study: 1) ASU IRB Consent Form for Minimal Risk, 2) Physical Activity Readiness Questionnaire (PAR Q) which includes Personal Information and Waiver Liability Section, 3) The Merck Manual of Geriatrics Geriatric Depression Scale (GDS), and 4) The Merck Manual Geriatric Depression Scoring Table. Study participants will join a study involving research of the effects of a monitored online exercise program on Seniors to show that exercise is an effective treatment for Depression.

All participants will complete a IRB ASU Consent Form, Physical Activity Readiness Questionnaire and Geriatric Depression Scale Questionnaire. All subjects will then be monitored in a prescribed exercise program to help them decrease and/or eliminate the magnitude of their depression symptoms. At the end of the study, participants will then repeat the Geriatric Depression Scale Questionnaire to determine if they are less depressed.

RECRUITMENT

2. Describe how you will recruit participants (attach a copy of recruitment materials).

Participants will be recruited through Senior University by offering free of charge Geriatric Depression testing, exercise prescription, and exercise monitoring program. Senior participants will also be recruited from local agencies (Minderful Center, DUET) which serve depressed elder patients.

PROJECT FUNDING

3. How is the research project funded? (A copy of the grant application(s) must be provided prior to IRB approval)
X Research is not funded (Go to question
4) Funding decision is pending
__Research is funded

a) What is the source of funding or potential funding? (Check all that apply)

____ Federal	_____ Private Foundation	_____ Department Funds
_____ Subcontract	_____ Fellowship	_____ Other _____

b) Please list the name(s) of the sponsor(s):

c) What is the Project grant number and title (for example NIH grant number)?

d) What is the ASU account number/project number?

e) Identify the institution(s) administering the grant(s):

STUDY POPULATION- If you are doing data analysis only, please write DA.

4.Indicate the total number of participants that		Indicate the age range of the participants that	50 to 80

you plan to include or enroll in your study.	30	you plan to enroll in your study	

SUPPLEMENTAL MATERIALS

5. Attach a copy of the following items as applicable to your study (Please check the ones that are attached):
3406576. __Research Methods (Research design, Data Source, Sampling strategy, etc)
X Any Letters (cover letters or information letters), Recruitment Materials, Questionnaires, etc. which will be distributed to participants
__If the research is conducted off-site, provide a permission letter where applicable
__If the research is part of a proposal submitted for external funding, submit a copy of the FULL proposal
Note: The information should be in sufficient detail so IRB can determine if the study can be classified as EXEMPT under Federal Regulations 45CFR46.101(b).

DATA USE

6. How will the data be used? (Check all that apply)

☐ Dissertation
☐ Thesis
X Results released to participants/parents
☐ Results released to agency or organization
X Publication/journal article
☐ Undergraduate honors project
☐ Results released to employer or school
☐ Conferences/presentations
X Other: Graduate Applied Project, ALD 593 Research

EXEMPT STATUS

7. Identify which of the 6 federal exemption categories below applies to your research proposal and explain why the proposed research meets the category. Federal law 45 CFR 46.101(b) identifies the following EXEMPT categories. Check all that apply to your research and provide comments as to how your research falls into the category.

SPECIAL NOTE: The exemptions at 45 CFR 46.101(b) do not apply to research involving prisoners. The exemption at 45 CFR 46.101(b)(2), for research involving survey or interview procedures or observation of public behavior, does not apply to research with children, except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.

X (7.1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Study will analyze the effectiveness of teaching depressed Hispanic Seniors to use exercise as a tool to help reduce and / or eliminate depression symptoms.

____(7.2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; AND (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

__(7.3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if:
(i) The human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

Please provide an explanation as to how your research falls into this category:

____7.4) Research, involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
Note-Please review the OHRP Guidance on Research Involving Coded Private Information or Biological Specimens: http://www.hhs.gov/ohrp/humansubjects/guidance/cdebiol.pdf

X (7.5) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs. (Generally does not apply to the university setting)
Study will analyze the effectiveness of teaching depressed Seniors to use exercise as a tool to help reduce and / or eliminate depression symptoms. This procedure will be beneficial to all mental health agencies servicing adults with Depression.

____(7.6) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.
Please provide an explanation as to how your research falls into this category:

PRINCIPAL INVESTIGATOR

In making this application, I certify that I have read and understand the ASU Procedures for the Review of Human Subjects Research and that I intend to comply with the letter and spirit of the University Policy. I may begin research when the Institutional Review Board gives notice of its approval. I must inform the IRB of ANY changes in method or procedure that may conceivably alter the exempt status of the project. I also agree and understand that records of the participants will be kept for at least three (3) years after the completion of the research
Name (first, middle initial, last):
Robelyn A. Garcia

Signature: Date:
X

FOR OFFICE USE:	This application has been reviewed by the Arizona State University IRB: ☐ Exempt Category/Categories: _____ ☐ Approved ☐ Deferred to other review ☐ Recommended that investigator submit for expedited or Full Board review.
	Authorizing Signature: Date: X

Appendix B

INFORMED CONSENT FORM MINIMAL RISK

****

Does Online "Working Out Work" as a Treatment and Prevention for Depression in Older Adults? An Analysis of a Prescribed and Monitored Exercise Program Administered via the Internet for Senior Adults with Depression.

INTRODUCTION

The purposes of this form are to provide you (as a prospective research study participant) information that may affect your decision as to whether or not to participate in this research and to record the consent of those who agree to be involved in the study.

RESEARCHERS

Robelyn Garcia, Graduate Student, Arizona State Universiy, and Staff at Senior University, Principal Investigator has invited your participation in a research study.

STUDY PURPOSE

The purpose of this study is to investigate and access the effectiveness of an online prescribed and monitored exercise program for the treatment of depression in Older Adults. The Dependent Variable for the study is Depression. The Independent Variable for the study is the Effects of Exercise administered via the Internet and the population is older adults. Depression is defined by Princeton University Scholars, (Wordnet, 2006) as a mental state characterized by a pessimistic sense of inadequacy and a despondent lack of activity. This study is devoted to the goal of providing empirical support for the notion that an online exercise program is a feasible and effective treatment for depression in older adults.

DESCRIPTION OF RESEARCH STUDY

If you decide to participate, then as a study participant you will join a study involving research of the effects of a monitored online exercise program on Seniors to show that exercise is an effective treatment for Depression. All participants will complete a Consent Form, Physical Activity Readiness Questionnaire and Geriatric Depression Scale Questionnaire. All subjects will then be monitored in a prescribed exercise program to help them decrease and/or eliminate the magnitude of their depression symptoms. At the end of the study, participants will then repeat the Geriatric Depression Scale Questionnaire to determine if they are less depressed.

INFORMED CONSENT FORM MINIMAL RISK

****

RISKS

And as with any research, there is some possibility that you may be subject to risks that have not yet been identified.

BENEFITS

The possible/main benefits of your participation in the research are: Exercise has been shown as the most effective treatment for depression in elderly people. All disciplines concur on the myriad of mental health benefits that a regular exercise program can provide.

NEW INFORMATION

If the researchers find new information during the study that would reasonably change your decision about participating, then they will provide this information to you.

CONFIDENTIALITY

All information obtained in this study is strictly confidential unless disclosure is required by law. The results of this research study may be used in reports, presentations, and publications, but the researchers will not identify you. In order to maintain confidentiality of your records, Dr. Robelyn Garcia will keep the names of the subjects confidential, the use of subject codes will be utilized.

WITHDRAWAL PRIVILEGE

It is ok for you to say no. Even if you say yes now, you are free to say no later, and Withdraw from the study at any time. Your decision will not affect your relationship with
Arizona State University or Senior University.

COSTS AND PAYMENTS

There is no payment for your participation in the study.

COMPENSATION FOR ILLNESS AND INJURY

If you agree to participate in the study, then your consent does not waive any of your legal rights. However, no funds have been set aside to compensate you in the event of injury.

VOLUNTARY CONSENT

Any questions you have concerning the research study or your participation in the study, Before or after your consent, will be answered by Dr. Robelyn Garcia. She can be contacted at Dr.RobelynGarcia@asu.edu or 480-221-7773.

INFORMED CONSENT FORM MINIMAL RISK

****

Your signature below indicates that you consent to participate in the above study.

_____ _____

Subject's Signature Printed Name

Date _____

INVESTIGATOR’S STATEMENT

"I certify that I have explained to the above individual the nature and purpose, the potential benefits and possible risks associated with participation in this research study, have answered any questions that have been raised, and have witnessed the above signature. These elements of Informed Consent conform to the Assurance given by Arizona State University to the Office for Human Research Protections to protect the rights of human subjects. I have provided the subject/participant a copy of this signed consent document.

Signature of Investigator_____

Date_____

“If you have any questions about your rights as a subject/participant in this research, or if you feel you have been placed at risk, you can contact the Chair of the Human Subjects Institutional Review Board, through the ASU Research Compliance Office, at (480) 965-6788.”

This form explains the nature, demands, benefits and any risk of the project. By signing this form you agree knowingly to assume any risks involved. Remember, your participation is voluntary.

You may choose not to participate or to withdraw your consent and discontinue participation at any time without penalty or loss of benefit. In signing this consent form, you are not waiving any legal claims, rights, or remedies. A copy of this consent form will be given (offered) to you.

Appendix C

PAR-Q Physical Activity Readiness Questionnaire

For most people physical activity should not pose any problem or hazard. This questionnaire is suitable for those aged between 15 and 69. If you are over 69 years of age, and you are not used to being very active, check with your doctor. Common sense is your best guide in answering these questions. Read the questions carefully and answer each one honestly.

1. Has your doctor ever said that you have a heart condition and that you should only do physical activity recommended by a doctor?

2. Do you feel pain in your chest when you do physical activity?

3. In the past month, have you had chest pain when you were not doing physical activity?

4. Do you lose your balance because of dizziness or do you ever lose consciousness?

5. Do you have a bone or joint problem (for example, back, knee or hip) that could be made worse by a change in your physical activity?

6. Is your doctor currently prescribing drugs (for example, water pills) for your blood pressure or heart condition?

7. Do you know of any other reason why you should not do physical activity?

If you answered YES: If you answered "yes" to one or more questions, talk with your doctor in person or on the phone before you start a new exercise program or before you have a fitness test. Tell your doctor about the PAR-Q and which questions you answered "yes".

If you answered NO: If you answered "no" honestly to all of the questions, you can be reasonably sure that you can start becoming much more physically active or take part in a physical fitness appraisal – begin slowly and build up gradually. This is the safest and easiest way to go.

Things Change: Even if you answered "no" to all questions, you should delay becoming more active if you are temporarily ill with a cold or a fever. If your health changes so that you then answer "yes" to any of the above questions, tell your fitness or health professional.

Personal Information

Name:

Address:

City, State, Zip:

Phone:
Email:
Birth Date:
Marital Status:
Height:
Weight:

Emergency Contact:
Relationship:
Phone:

Waiver of Liability

I, the undersigned, as additional consideration for the acceptance of my application to participate in one or more fitness activities, hereby certify and agree as follows:

I understand and acknowledge that only a physician is qualified to advise me regarding the specific health risks which I may be exposed to as a result of participation in any exercise program and that I have consulted with my personal physician and I have determined in my own judgment together with my physician’s advice that it is acceptable for me to participate in this program.

I, therefore, hereby agree to release and hold harmless Robelyn Garcia liability, claims, suits or damages whatsoever on account of any injury or other damages suffered or incurred by me as a result of my participation in this program.

Signature_____

Date_____

Appendix D

THE MERCK MANUAL OF GERIATRICS (GDS-15)

Circle the best answer for how you have felt over the past week:

1. Are you basically satisfied with your life? YES / NO

2. Have you dropped many of your activities and interests? YES / NO

3. Do you feel that your life is empty? YES / NO

4. Do you often get bored? YES / NO

5. Are you in good spirits most of the time? YES / NO

6. Are you afraid that something bad is going to happen to you? YES / NO

7. Do you feel happy most of the time? YES / NO

8. Do you often feel helpless? YES / NO

9. Do you prefer to stay at home, rather than going out and doing new things? YES/NO

10. Do you feel you have more problems with memory than most? YES / NO

11. Do you think it is wonderful to be alive now? YES / NO

12. Do you feel pretty worthless the way you are now? YES / NO

13. Do you feel full of energy? YES / NO

14. Do you feel that your situation is hopeless? YES / NO

15. Do you think that most people are better off than you are? YES / NO

Appendix E

SCORING AND CATEGORIES FOR GERIATRIC DEPRESSION SCALE-15

Score: One point for "No" to questions 1, 5, 7, 11, and 13.

One point for "Yes" to other questions.

Scoring: Out of a possible total score of 15:

Normal:	≤ 3
Mildly depressed:	7 - 4
Moderately depressed:	8 - 11
Very depressed:	≥ 12

Adapted from Sheikh JI, Yesavage JA: "Geriatric depression (GDS)." Edited by TL Brink, A Guide to Assessment and Intervention, Clinical Gerontology, pp. 165 -173. Haworth Press Inc., Binghampton, N.Y., 1986.

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