James Madison University
Human Research Review Request

FOR IRB USE ONLY:				
Exempt:	☐	**Protocol Number:**	**1st Review:** _____	**Reviewer:** _____
Expedited:	☒	**IRB:** _____	**2nd Review:** _____	**Reviewer:** _____
Full Board:	☐	**Received:** _____	**3rd Review:** _____	

Project Title:	Health Benefits of Group-Based Cooking with Fresh Produce in a Skilled Nursing Facility
Project Dates: (Not to exceed 1 year minus 1 day)	From: 3 /31/15 To: 3/30/16 MM/DD/YY MM/DD/YY
Minimum # of Participants:	20
Maximum # of Participants:	24
External Funding:	**Yes:** ☐ **No:** ☒ **Internal Funding:** **Yes:** ☐ **No:** ☒ **If yes, Sponsor:** _____ **Will monetary incentives be offered with funding? Yes:** ☐ **No:** ☒ **If yes: How much per recipient?** _____ **In what form?** _____
Must follow JMU Financial Policy:	http://www.jmu.edu/financemanual/procedures/4205.shtml#.391Incentives
Responsible Researcher(s):	Dr. Twylla Kirchen, Jenny Nguyen, Kacey Ewing
E-mail Address:	krichentm@jmu.edu; nguye2jk@dukes.jmu.edu; ewingkl@dukes.jmu.edu
Telephone:	(540) 568-7749; (540) 435-9508; (540) 746-8694
Department:	Health Sciences (Occupational Therapy)
Address (MSC):	James Madison University Department of Health Sciences; 801 Carrier Dr., MSC 4301; Harrisonburg, VA 22807
Please Select:	☒ Faculty ☐ Undergraduate Student ☒ Administrator/Staff Member ☒ Graduate Student
(if Applicable):	
Research Advisor:	Twylla M. Kirchen, Ph.D., OTR/L
E-mail Address:	kirtchetm@jmu.edu
Telephone:	540-568-7749
Department:	Health Sciences (Occupational Therapy)
Address (MSC):	HHS 3110

Investigator: Please respond to the questions below. The IRB will utilize your responses to evaluate your protocol submission.

1. ☒ **YES** ☐ **NO** Does the James Madison University Institutional Review Board define the project as ***research?***

   The James Madison University IRB defines "research" as a "*systematic* investigation designed to develop or contribute to *generalizable knowledge*." All research involving human participants conducted by James Madison University faculty and staff and students is subject to IRB review.

2. ☒ **YES** ☐ **NO** Are the human participants in your study ***living*** individuals?

"Individuals whose physiologic or behavioral characteristics and responses are the object of study in a research project. Under the federal regulations, human subjects are defined as: living individual(s) about whom an investigator conducting research obtains:
(1) data through intervention or interaction with the individual; or (2) identifiable private information."

3. ☒ **YES** ☐ **NO** Will you obtain data through ***intervention*** or ***interaction*** with these individuals?

"Intervention" includes both physical procedures by which data are gathered (*e.g.*, measurement of heart rate or venipuncture) and manipulations of the participant or the participant's environment that are performed for research purposes. "Interaction" includes communication or interpersonal contact between the investigator and participant (*e.g.*, surveying or interviewing).

4. ☒ **YES** ☐ **NO** Will you obtain ***identifiable private information*** about these individuals?

"Private information" includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, or information provided for specific purposes which the individual can reasonably expect will not be made public (*e.g.*, a medical record or student record). "Identifiable" means that the identity of the participant may be ascertained by the investigator or associated with the information (*e.g.*, by name, code number, pattern of answers, etc.).

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5. ☐ **YES** ☒ **NO** Does the study present ***more than minimal risk*** to the participants?

"Minimal risk" means that the risks of harm or discomfort anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during performance of routine physical or psychological examinations or tests. Note that the concept of risk goes beyond physical risk and includes psychological, emotional, or behavioral risk as well as risks to employability, economic well being, social standing, and risks of civil and criminal liability.

CERTIFICATIONS:

For James Madison University to obtain a Federal Wide Assurance (FWA) with the Office of Human Research Protection (OHRP), U.S. Department of Health & Human Services, **all** research staff working with human participants must sign this form and receive training in ethical guidelines and regulations. "Research staff" is defined as persons who have direct and substantive involvement in proposing, performing, reviewing, or reporting research and includes students fulfilling these roles as well as their faculty advisors. The Office of Research Integrity maintains a roster of all researchers who have completed training within the past three years.

Test module **at ORI website http://www.jmu.edu/researchintegrity/irb/irbtraining.shtml**

Name of Researcher(s) and Research Advisor	Training Completion Date
Twylla Kirchen	**4/17/2013**
Jenny Nguyen	**3/6/2013**
Kacey Ewing	**02/12/2013**

For additional training interests, or to access a Spanish version, visit the National Institutes of Health Protecting Human Research Participants (PHRP) Course at:
http://phrp.nihtraining.com/users/login.php.

By signing below, the Responsible Researcher(s), and the Faculty Advisor (if applicable), certifies that he/she is familiar with the ethical guidelines and regulations regarding the protection of human research participants from research risks. In addition, he/she agrees to abide by all sponsor and university policies and procedures in conducting the research. He/she further certifies that he/she has completed training regarding human participant research ethics within the last three years.

_____ _____

Principal Investigator Signature Date

_____ _____

Principal Investigator Signature Date

_____ _____

Faculty Advisor Signature Date

Submit an electronic version (in a Word document) of your **ENTIRE** protocol to researchintegrity@jmu.edu.
Provide a **SIGNED** hard copy of the Research Review Request Form to:
Office of Research Integrity, MSC 5738, 601 University Boulevard, Blue Ridge Hall, Third Floor, Room # 342

Purpose and Objectives

Please provide a lay summary of the study. Include the purpose, research questions, and hypotheses to be evaluated. (Limit to one page)

Minimal research has been conducted using a control group to explore the health benefits of a group-based cooking program in skilled nursing facilities.

Purpose: The purpose of this study is to determine whether a therapeutic, 6-week group-based cooking intervention increases health and well-being outcomes among older adults at a skilled nursing facility in Harrisonburg, Virginia.

Research Questions:

1. Does engagement in cooking improve health and well-being outcomes in patients who reside in a skilled-nursing facility?
2. How does engagement in cooking vs. engagement in other activities compare in relation to health and well-being outcomes?
3. What are the lived-experiences of the participants who participated in the cooking group?

Hypothesis: Therapeutic cooking will improve depression indicators in patients who reside in skilled nursing facilities when compared to patients who participate in typical activities.

Procedures/Research Design/Methodology/Timeframe

Describe your participants. From where and how will potential participants be identified (e.g. class list, JMU bulk email request, etc.)?

This study will be conducted at Harrisonburg Health and Rehabilitation Facility in Harrisonburg, VA. Participants will be patients from 60 to 95 years of age who reside in the facility and who have scored at least a 5 out of 10 on the Short Portable Mental Status Questionnaire. If the participants have a power of attorney, approval will be required from them.

How will subjects be recruited once they are identified (e.g., mail, phone, classroom presentation)? Include copies of recruitment letters, flyers, or advertisements.

Participants will be recruited by flyers (attached), which will be viewed on the facilities electronic activity board. Also, researchers will conduct a recruitment presentation the first week of July 2015 in the activities department of the facility to recruit participants. Participants for the control group will be recruited at several activities meetings for typical activities. Participation will be voluntary and will have the right to withdraw from the intervention group at any time with no adverse consequences.

Control Group participants will be recuited at the same time as the intervention participants. The control group participants will consist of patients who prefer to engage in typically scheduled activities rather than cooking, but are willing to complete a cognitive screen (SMPSQ) and pre and post test-Depression Scale.

Describe the design and methodology, including all statistics, IN DETAIL. What exactly will be done to the subjects?

<u>Assessment methodology:</u>

The research design will compare 10 to 12 participants who choose to participate in the cooking group with 10 to 12 participants who choose to participate in typical activities that are offered at the facility, i.e. BINGO, watching a movie, etc. This study will use pre-test, post-test quantitative tools to examine the effectiveness of therapeutic cooking in relation to the health and well-being of older adults in a skilled nursing facility. These pre-test, post-test tools will also be used to examine the control group, who are participating the typical activities to provide a comparison. This study will also use a post

intervention qualitative interview to gain insight to the lived-experiences of participants in the cooking group. Participants in the control group will not receive the qualitative interview.

Due to the age related physiological changes in the participants, researchers have decided to administer all assessment tools verbally. The participants will be read the questions by the researcher, and will answer the questions out loud. Quantitative assessment tool questions and answer options and qualitative questions will be read verbatim to the participants. Participants will be able to hold a copy of the assessment tools to refer to as well.

Quantitative Tools:

Tool	Author(s)	Purpose	Reliability/Validity
Short Portable Mental Status Questionnaire (SPMSQ) * This tool is only used for pre-test. Participants must score at least 5 out of 10 on this assessment to participate in the study.	Pheiffer, 1975	Used to assess cognitive status	The Short Portable Mental Status Questionnaire (SPMSQ), a 10-item examination, has been found reliable and valid in distinguishing demented Ss from cognitively intact Ss when given face to face. Test versions correlated significantly with the Mini-Mental State Examination. In distinguishing demented from non-demented Ss, sensitivity and specificity were 0.91 for the face-to-face test
Geriatric Depression Scale (Short Form) * Pre and Post-test	Yesavage JA, Brink TL, Rose TL, Lum O, Huang V, Adey MB, Leirer VO: Development and validation of a geriatric depression screening scale: A preliminary report. Journal of Psychiatric Research 17: 37-49, 1983. Friedman, B., Heisel, M., & Delavan, R. (2005). Psychometric properties of the 15-item geriatric	Used to assess for depression in the geriatric population.	Consists of 15 questions with yes or no response. A score of > or = 5 indicates depression. Research indicates good reliability scores when compare to the GDS (Long Form).

	depression scale in functionally impaired, cognitively intact, community-dwelling elderly primary care patients. *Journal Of The American Geriatrics Society*, *53*(9), 1570-1576. doi:10.1111/j.1532-5415.2005.53461.x		

Post-Intervention Interview Questions (Intervention Group:

1. Did this cooking experience change how connected you feel to this facility? How?
2. What did you like about this cooking experience?
3. What did you not like about this cooking experience? How would you change this?
4. What do you feel you have taken away from this cooking experience?

Data collection procedures:

Data collection may be conducted over a span of two months, depending on availability of participants. Between twenty and twenty-four participants from a skilled nursing facility in Virginia will participate in pre-tests and post-tests using the tools listed above. One group of 10 to 12 participants will be in the intervention group (cooking) and the other 10 to 12 participants will be in the control group (typical activities, such as Bingo, crafts, etc.).

The intervention will consist of six, one hour to one and a half hour group-sessions, one session per week, for six weeks. The intervention will be held in the activities room and accompanied courtyard at the skilled nursing facility in Harrisonburg, VA. The researchers will use a group protocol-based intervention to ensure consistency of approach. The pre-tests including the Short Portable Mental Status Questionnaire and The Geriatrics Depression Scale will be administered prior to beginning the intervention. A post-test of The Geriatrics Depression Scale will be administered to each participant within one week of the conclusion of the intervention. The post-intervention interview questions will be administered within one week of the conclusion of the intervention only for the treatment group. If any participant was to leave the facility after data collection has begun, that participant's data will not be included for the research. Comparison of pre and post-test data will be conducted within the intervention group and comparing the intervention group to the control group in order to determine whether or not the intervention was effective in improving the participants' health and well-being. The qualitative data will be analyzed to understand the lived-experiences of participants in the intervention group. If the outcome measures indicate that the cooking intervention is statistically significant in promoting health and well-being of participants, the control group will be notified of the findings and given the opportunity to engage in cooking activities as well.

Residents of the facility who do not qualify to be in the study, but are interested in participating in the cooking program will be allowed to participate however, data will not be collected.

Group Protocol:

Dr. Twylla Kirchen, Jenny Nguyen and Kacey Ewing will facilitate the groups.

Session 1: Introduction, Cooking experience discussion

1. Become acquainted with other participants in the group.
2. Discuss the purpose of the group and timeline of the intervention
3. Share cooking recipes and experience with the group
4. Begin discussing what should be cooked
    - Activity: keeping vegetables grown in mind, discuss possible recipes and look through cooking magazines
5. Make plans for the next session

Session 2: Cooking Brainstorming Session

1. Orient the group to the purpose of the project/intervention
2. Discuss the purpose of the group for this session
3. Share cooking experience with the group
4. Brainstorm and create a list of items needed for cooking
5. Make plans for the next session

Session 3: Cooking

1. Become acquainted with other participants in the group.
2. Discuss the purpose of the group and timeline of the intervention
3. Share cooking experience with the group
4. Prep and cook recipes
5. Make plans for the next session

Session 4: Cooking

1. Become acquainted with other participants in the group.
2. Discuss the purpose of the group and timeline of the intervention
3. Share cooking experience with the group
4. Prep and cook recipes
5. Make plans for the next session

Session 5: Cooking

1. Become acquainted with other participants in the group.
2. Discuss the purpose of the group and timeline of the intervention
3. Share cooking experience with the group
4. Prep and cook recipes
5. Make plans for the next session

Session 6: Cooking

1. Become acquainted with other participants in the group.
2. Discuss the purpose of the group and timeline of the intervention
3. Share cooking experience with the group
4. Prep and cook recipes
5. Make plans for completing and distributing cook books to participants

* The participants will not be near heat or sharp objects during the cooking intervention. If heat or cutting with a knife is involved, the researchers will perform this part of the cooking process in a separate room. The participants will be involved in the prep work, such as washing, measuring, stirring, and mixing ingredients.

Retention:

Retention will be addressed through a variety of efforts:

1. Facilitators will make reminder calls or stop by to all participants before each group session stating the day, time, and location of the group session.
2. Facilitators will provide each participant a calendar of group sessions for posting in the participant's room.
3. Facilitators will arrive at the facility one to one and a half hours before each group meeting, if not an employee of the facility, to assist participants in preparation for and in moving to the meeting place.
4. A record of participation will be kept for each session by the facilitator.
5. Facilitators will follow-up with participants who are absent and document reason for absence.
6. If family members or visiting friends request to attend the group with the participant, the group facilitator should confer with the participant and if the participant would like his or her family member to join the session, that should be encouraged.

Emphasize possible risks and protection of subjects.

Risks for the intervention group include:

- Allergic reactions to the food being used
- Fatigue or possible injury due to physical activity involved with the cooking group
- Possible emotional response from the participation in cooking
- Issues with medical management for clients with medical conditions

We will minimize the above-mentioned risks by collaborating with the Activities Director to ensure all participant allergies and/or patient health concerns are noted in the researcher's field notes prior to commencement of the study. In addition, patients will wear latex-free gloves to avoid direct contact with food. Researchers will conduct the group sessions in the Activities Room, with the Activities Director present and will have access to immediate medical care if a participant should require medical attention. If a participant should become fatigued or emotionally distraught, he or she is able and encouraged to withdraw from the session or the study, if he or she so chooses. Participants will be informed of their right via Informed Consent to withdraw from the study at any time, without repercussions, if they so choose.

What are the potential benefits to participation and the research as a whole?

Benefits for Harrisonburg Health & Rehabilitation Center:

Contribution of recipe book for residence and staff member to enjoy left in the activities room and a fully planned and facilitated cooking group to add to their schedule of activities.

Benefits for Participation in the intervention (cooking) group:

The opportunity to engage in cooking groups that allows socialization, learning, and active participation in cooking. There may be possible increase of health and well-being to the participants.

Benefits for the control group:

If the outcome measures indicate that the cooking intervention is statistically significant in promoting health and well-being of participants, the control group will be notified of the findings and given the opportunity to engage in cooking activities as well.

Will data be collected from any of the following populations?

_____ Minors (under 18 years of age); Specify Age: _____
_____ Prisoners
_____ Pregnant Women, fetuses, or neonates
_____ Cognitively impaired persons
__X__ Other protected or potentially vulnerable population
Data will be collected from older adults ages 60-95 that may have physical disabilities.
_____ Not Applicable

Where will research be conducted? (Be specific; if research is being conducted off of JMU's campus a site letter of permission will be needed)
Research will be conducted at the Harrisonburg Health & Rehabilitation Center: 1224 Reservoir St, Harrisonburg VA 22801. The cooking group will be facilitated in the activities room and non-smoking courtyard that is a part of the facility. Data will be collected in the activities room of this facility. A site letter of permission is attached.

Will deception be used? If yes, provide the rationale for the deception:
No, deception will not be used.

What is the time frame of the study? (List the dates you plan on collecting data. This cannot be more than a year, and you cannot start conducting research until you get IRB approval)
3/31/15-3/30/16

- May 2015: IRB Approval
- July 2015-August 2015: Flyer distributions, recruitment, obtain informed consents, administer cognitive screen and pretest
- August 2015-September 2015: conduct study
- October 2015: Conduct post-intervention tests (Intervention and Control Group), administer the survey to the control group
- October 2015-March 2016: Conduct data analysis, complete written interpretation of the data analysis and overall study
- March 30, 2016: concludes study

Data Analysis
For more information on data security, please see:
http://www.jmu.edu/researchintegrity/irb/irbdatasecurity.shtml.

How will data be analyzed?

Statistical analysis of the data will analyze the pre- and post-test scores using an analysis of covariance (ANCOVA). ANCOVA is used in pretest-posttest control group designs to examine within group differences while using the pretest scores as a covariate. Thus, it adjusts the posttest scores for differences in pretest scores between the experimental and control groups, allowing for any change to represent a treatment effect (Newton & Rudestam, 1999).

The post-intervention interview questions will be administered to the intervention group only. It consists of four questions, which will be asked verbally by the researchers to the participant who will be provided with a written copy of the questions to read along with the researcher. The researchers will annotate the participant's responses verbatim in a designated notebook. No identifying information such as participant name, etc. will be annotated.

How will you capture or create data? Physical (ex: paper or tape recording)? Electronic (ex: computer, mobile device, digital recording)?
Participants will be assigned a number to ensure confidentiality within the data. There will be one notebook that will include the participants name and code number. Researchers will use a separate notebook containing only the participant's code number which will be used to take attendance during the group sessions (intervention group) and to document responses of the post intervention survey. The researchers will refer to the notebook with the name and code number at each session in order to record data in the notebook containing only their code number. The cognitive screen and pre and post intervention assessment tools, as well as the notebook containing codes will be kept in a locked file cabinet in the researcher's office with only one key that is kept by the research advisor. The master list with the name and code will be stored in a different locked file cabinet in the researcher's office with the key kept by the research advisor

Do you anticipate transferring your data from a physical/analog format to a digital format? If so, how? (e.g. paper that is scanned, data inputted into the computer from paper, digital photos of physical/analog data, digitizing or video recording?)
The assessment responses will be transferred from paper into Qualtrics to be more easily transferred into SPSS for data analysis.

How and where will data be secured/stored? (e.g. a single computer or laptop; across multiple computers; or computing devices of JMU faculty, staff or students; across multiple computers both at JMU and outside of JMU?)
Data will be stored on Dr. Twylla Kirchen's University Computer only. The data will not be taken outside of JMU on a personal computer. Furthermore, the data on the computers is only accessible by logging in with a confidential username and password. Paper data will be secured in a lockbox prior to leaving HHRC and the primary researchers will have the box and the key with them at all times during the transport of paper data from HHRC to James Madison University Occupational Therapy Department. The lock box will not be opened until it is in Dr. Kirchen's office. It will be secured in a locked file cabinet in Dr. Kirchen's office for six months past the conclusion of the study. At that time it will be shredded.

Who will have access to data? (e.g. just me; me and other JMU researchers (faculty, staff, or students); or me and other non-JMU researchers?)
Responsible researchers listed on the study: Dr. Twylla Kirchen, Jenny Nguyen, and Kacey Ewing

If others will have access to data, how will data be securely shared?
No one else will have access to the data.

Will you keep data after the project ends? (i.e. yes, all data; yes, but only de-identified data; or no)
The data will be kept for six months after the study ends and then will be destroyed. The data will be deleted from SPSS, and any papers will be shredded.

Reporting Procedures

Who is the audience to be reached in the report of the study?
The report of the study will be presented to students and faculty that make up the James Madison University Occupational Therapy Students. If the report of study is published, the audience will include occupational therapy students and practitioners across the country. The results will be submitted for presentation to the American Occupational Therapy Association Conference in April of 2016 and will reach occupational therapists across the United States (pending presentation acceptance).

How will you present the results of the research? (If submitting as exempt, research cannot be published or publicly presented outside of the classroom)

Student researchers will present and defend their completed research in at a formal seminar scheduled by JMU OT faculty during the Spring 2016 semester. Student researchers must demonstrate competence in their knowledge of the topic and research procedures to the satisfaction of the OT faculty. The results will be submitted for presentation to the American Occupational Therapy Association Conference in April of 2016 and will reach occupational therapists across the United States (pending presentation acceptance). A manuscript will be developed and submitted for publications to the American Journal of Occupational Therapy. The research findings will also be shared with the Harrisonburg Health and Rehab and the participants, upon request.

How will feedback be provided to subjects?

Feedback will be verbally provided to subjects in a designated meeting in the activities room of the facility. If the outcome measures indicate that the cooking intervention is statistically significant in promoting health and well-being of participants, the control group will be notified of the findings and given the opportunity to engage in cooking activities.

Experience of the Researcher (and advisor, *if student)*:

What is the prior relevant experience of the researcher, advisor, and/or consultants?

Dr. Twylla Kirchen completed her dissertation entitled Adaption of Veterans to Long-Term Care: The Impact of Military Culture (completed research study involving human subjects). Quantitative portion of the dissertation was published in *Physical and Occupational Therapy in Geriatrics* in June of 2014.
Experience with survey development- Qualtrics training Fall 2014
Certified by the Institutional Review Board 4/24/13
Completed dissertation in December 2013

Jenny Nguyen:
Undergone HIPPA training 2014
Certified by the Institutional Review Board 3/06/13
Completed HTH 408: Research Methods
Enrolled in OT 590: Foundations of Research in Occupational Therapy Practice

Kacey Ewing:
Undergone HIPPA training 2014
Certified by the Institutional Review Board 2/14/13
Completed HTH 408: Research Methods
Enrolled in OT 590: Foundations of Research in Occupational Therapy Practice

Consent to Participate in Research

Identification of Investigators & Purpose of Study

You are being asked to participate in a research study conducted by Jenny Nguyen, OTS, Kacey Ewing, OTS, Twylla Kirchen, Ph.D., OTR/L from James Madison University. The purpose of this study is to determine whether a therapeutic 6-week group-based cooking intervention increases health and well-being outcomes among older adults at a skilled nursing facility in Virginia. This study will contribute to the researcher's completion of their master's thesis as required by the James Madison University Occupational Therapy Program.

Research Procedures

Should you decide to participate in this research study, you will be asked to sign this consent form once all your questions have been answered to your satisfaction. You will be asked to participate in a six week cooking program. You will also be asked to provide answers to a series of questions related to the health and well-being of older adults in a skilled nursing facility.

Time Required

Participation in this study will require a total of 10 hours of your time. Sessions will be held over a consecutive 6-week period, one day per week, with sessions lasting approximately 1.5 hours (90 minutes) each and approximately 1 hour total for the pre and post questionnaires.

Risks

The investigators perceive the following are possible risks arising from your involvement with this study:

1. Using cooking as part of the therapeutic process has the potential to elicit traumatic or distressing memories for some participants.
2. Researchers need to be aware of potential risks to people suffering allergies, phobias, or environmental sensitivities since fresh produce and cooking materials serve as the foundation of this intervention.
    - Following HIPPA protocol, researchers will review participants' medical history/charts before first session to ensure all participants are medically able to participate in activities.
3. Invasion of privacy, inquiring about health habits, family histories, illegal substance use, etc. may cause discomfort to participants.
    - Researchers will not ask about such topics.
4. Some participants will be considered medically fragile.
    - Researchers will take necessary precautions to ensure participants do not physically overexert himself/herself and will be aware of fatigue and other visceral stress signs.

Benefits

- Benefits for participation in the intervention (cooking) group include
    - The opportunity to engage in cooking groups that promote socialization, learning, and active participation in cooking
    - The possibility of increased health and well-being

Confidentiality

The results of this research will be presented to faculty, staff, and students from James Madison University's occupational therapy program *the American Occupational Therapy Association Conference in April of 2016 (upon acceptance).* The results of this project will be coded in such a way that the respondent's identity will not be attached to the final form of this study. The researcher retains the right to use and publish non-identifiable data. While individual responses are confidential, aggregate data will be presented representing averages or generalizations about the responses as a whole. All data will be stored in a secure location accessible only to the researcher. Upon completion of the study, all information that matches up individual respondents with their answers will be destroyed.

Participation & Withdrawal

Your participation is entirely voluntary. You are free to choose not to participate. Should you choose to participate, you can withdraw at any time without consequences of any kind.

Questions about the Study

If you have questions or concerns during the time of your participation in this study, or after its completion or you would like to receive a copy of the final aggregate results of this study, please contact:

Jenny Nguyen, OTS
Occupational Therapy Program
James Madison University
nguye2jk@dukes.jmu.edu

Kacey Ewing, OTS
Occupational Therapy Program
James Madison University
ewingkl@dukes.jmu.edu

Twylla Kirchen, Ph.D., OTR/L
Occupational Therapy Program, Assistant Professor
(540) 568-7749
kirchetm@jmu.edu

Questions about Your Rights as a Research Subject

Dr. David Cockley
Chair, Institutional Review Board
James Madison University
(540) 568-2834
cocklede@jmu.edu

Giving of Consent

I have read this consent form and I understand what is being requested of me as a participant in this study. I freely consent to participate. I have been given satisfactory answers to my questions. The investigator provided me with a copy of this form. I certify that I am at least 18 years of age.

_____

Name of Participant (Printed)

_____ _____

Name of Participant (Signed) Date

_____ _____

Name of Researcher (Signed) Date

Consent to Participate in Research

Identification of Investigators & Purpose of Study

You are being asked to participate in a research study conducted by Jenny Nguyen, OTS, Kacey Ewing, OTS, and Twylla Kirchen, Ph.D., OTR/L from James Madison University. The purpose of this study is to determine whether a therapeutic 6-week group-based cooking intervention increases health and wellbeing outcomes among older adults at a skilled nursing facility in Virginia. This study will contribute to the researcher's completion of their master's thesis as required by the James Madison University Occupational Therapy Program.

Research Procedures

Should you decide to participate in this research study, you will be asked to sign this consent form once all your questions have been answered to your satisfaction. You will be asked to provide answers to a series of questions related to the health and well-being of older adults residing in a skilled nursing facility. You will not be agreeing to participate in the cooking intervention.

Time Required

Participation in this study will require a total of 1 hour of your time. Assessments will be given pre and post intervention during the 1st and 6th session lasting no longer than 30 minutes.

Risks

The investigators do not perceive more than minimal risks from your involvement in this study (that is, no risks beyond the risks associated with everyday life).

Benefits

- Benefits for the control group include
    - Helping to determine if the outcome measures indicate that the cooking intervention is statistically significant in promoting health and well-being of participants
        - The control group will be notified of the findings and given the opportunity to engage in cooking activities as well.

Confidentiality

The results of this research will be presented to faculty, staff, and students from James Madison University's occupational therapy program *the American Occupational Therapy Association Conference in April of 2016 (upon acceptance).* The results of this project will be coded in such a way that the respondent's identity will not be attached to the final form of this study. The researcher retains the right to use and publish non-identifiable data. While individual responses are confidential, aggregate data will be presented representing averages or generalizations about the responses as a whole. All data will be stored in a secure location accessible only to the researcher. Upon completion of the study, all information that matches up individual respondents with their answers will be destroyed.

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Questions about the Study

If you have questions or concerns during the time of your participation in this study, or after its completion or you would like to receive a copy of the final aggregate results of this study, please contact:

Jenny Nguyen, OTS
Occupational Therapy Program
James Madison University
nguye2jk@dukes.jmu.edu

Kacey Ewing, OTS
Occupational Therapy Program
James Madison University
ewingkl@dukes.jmu.edu

Twylla Kirchen, Ph.D., OTR/L
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Questions about Your Rights as a Research Subject
Dr. David Cockley
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Giving of Consent

I have read this consent form and I understand what is being requested of me as a participant in this study. I freely consent to participate. I have been given satisfactory answers to my questions. The investigator provided me with a copy of this form. I certify that I am at least 18 years of age.

_____
Name of Participant (Printed)

_____ _____
Name of Participant (Signed) Date

_____ _____
Name of Researcher (Signed) Date

Date _____

Participant ID _____

Interviewer Initials _____

Question	Response	Score
1. What are the date, month, and year?		
2. What is the day of the week?		
3. What is the name of this place?		
4. What is your phone number?		
5. How old are you?		
6. When were you born?		
7. Who is the current president?		
8. Who was the president before him?		
9. What was your mother's maiden name?		
10. Can you count backward from 20 by 3's?		

Geriatric Depression Scale (short form)

Instructions: Circle the answer that best describes how you 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 things?	yes	no
10.	Do you feel that 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 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

Total Score _____

http://www.qualtrics.com/academic-solutions/james-madison-university/

Site Coordinator Letter of Permission

March 27, 2015

Institutional Review Board
James Madison University
MSC 5738
601 University Boulevard
Harrisonburg, VA 22807

Dear Institutional Review Board,

I hereby agree to allow Dr. Twylla Kirchen, from James Madison University to conduct her research at Harrisonburg Health and Rehabilitation. I understand that the purpose of the study is to improve resident quality of life by creating a cookbook and using resident-grown garden vegetables to prepare a variety of dishes.
By signing this letter of permission, I am agreeing to the following:

☒ JMU researcher(s) have permission to be on Harrisonburg Health and Rehabilitation premise.

☒ JMU researcher(s) have access to the data collected to perform the data analysis both for presentation at James Madison University, National and State Conferences and/or for publication purposes.

Sincerely,

Adam Filbey, Administrator
Harrisonburg Health and Rehabilitation

Flyer for recruitment:

Do you have a love for cooking?
Do you want to experience cooking for the first time?

Please join the COOKING group!

Where: Activities Room

When: Date and time of first meeting

What: Socialize, cook, create recipe book, learn and teach!