Effects of a pilot volunteer-based lunch program on feelings of loneliness in elders: a randomized control trial

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Abstract

Background: There is a need for stronger community involvement with the elderly, specifically those with feelings of loneliness. Large proportions of elders in previous studies reported feelings of loneliness, and loneliness at advanced ages is a growing trend seen within the last thirty years despite advances in technology and social media. We propose a randomized control trial to determine the effectiveness of a volunteer-based lunch program on decreasing feelings of loneliness in elderly participants. ***Methods:*** Lonely elders in the community will be identified and matched with a trained medical student. Each student will bring provided lunches once a week to their elder participant's residence, and they will share lunch together for an hour once a week for six weeks. Enrollees are eligible for the study if they are over 60 years of age, speak English, have feelings of loneliness on the three-item scale, and display no cognitive impairment. The participants will be assessed pre and post intervention using the R-UCLA scale for loneliness, PHQ-9 for depressive symptoms, and GAD-7 for feelings of anxiety. Participant satisfaction will be assessed using Likert items as well as open-ended questions. Intervention group responses will be compared to responses of participants that did not receive the lunch meeting intervention. ***Discussion:*** Success of such a companion lunch program would provide an effective route to combat loneliness in the elderly.

Keywords: *Loneliness, elderly, depression, anxiety, RCT.*

1.0 Background

Since the 1960's, the elderly population in the United States has grown steadily. By 2030, one in three people in the U.S. will be over the age of 65 [1]. In addition to being at a greater risk for chronic disease, the elderly are also more vulnerable to being socially isolated and lonely. Simply living alone does not appear to be a significant predictor of loneliness, as the elderly could still have a strong support network while living alone, but prevalence data suggests that one in three adults over the age of 65 are lonely [2]. Furthermore, the oldest of the elderly seem to be the loneliest. Dykstra et al. in a 2009 study estimate 40 to 50 percent of those aged 80 or older to be lonely [3].

Loneliness has been previously defined as the difference between desired and actual relationships, and there is a distinction between loneliness and social isolation [2]. While being considered socially isolated is due to lack of social contact, loneliness is assessed by perceptions of social isolation. Feelings of disconnect, isolation, and not belonging are much more indicative of loneliness than simple aloneness and lack of social contact [4]. Not having a support network or anyone to confide in can lead to feelings of social isolation, and despite advances in technology and the development of social media, feelings of loneliness have increased in the past thirty years [5]. The proportion of Americans who said they had no one to talk to about important matters increased from 10% in 1985 to 25% in 2004 [6]. This is an alarming trend because social support has been consistently shown to increase the likelihood of survival. In a meta-analytic review from 2009, participants with strong social relationships and support were found to have a 50 percent increased likelihood of survival [5]. Additionally, a 2013 study found that mortality rates were significantly higher among socially isolated and lonely elders [7]. Loneliness has a profound effect on our healthcare system and has been linked to a higher degree of healthcare utilization. In a Swedish study from 2014, researchers found that lonely elders use more outpatient services than non-lonely elders [8]. In 2015, Gerst et al. found that the large proportion of elders over 60 years old that reported feelings of loneliness had a significantly higher physician visit rate [9].

There is a demonstrated need for intervention in this lonely, elderly population, with significant public health implications. A randomized control trial from 1999 implementing a visitor volunteer program for the elderly showed that strong community involvement increased

the participants' feelings of worth, social integration, and life satisfaction [10]. More recently, a local food delivery project in Tampa showed that weekly food delivery to an at-risk elderly population decreased participants' feelings of loneliness and increased their measured well-being over the course of two months [11]. While both pilot programs had short evaluation periods, they demonstrated the effectiveness of volunteer-based community involvement. Combining a visitor volunteer program with a food delivery service could serve to effectively combat the elderly community's feelings of loneliness and social isolation.

A local food delivery project in Tampa showed that weekly food delivery to an at-risk elderly population decreased participants' feelings of loneliness and increased their measured well-being over the course of two months [12]. Even though it demonstrated the effectiveness of volunteer-based community involvement, the project was constructed as a pretest-posttest, descriptive study using convenience sampling, and feelings of loneliness were evaluated as a secondary objective using a three-item loneliness screener. In our study, we plan to measure the effects of adding a volunteer visitor to the lunch program; that is, to see if eating meals with a medical student can decrease feelings of loneliness when compared with simply receiving meals through Meals on Wheels. Our study is designed as a randomized control trial in which seniors will be randomly assigned to two groups: paired with a medical student for lunch or not paired with a medical student while still receiving meals.

2.0 Methods

2.1 Aims

We intend to recruit USF medical students as volunteers for the program to allow them the opportunity to improve the well being of the elderly in the community and to participate in service learning. Combining a medical student volunteer program with a food delivery service could serve to effectively address the elderly community's feelings of loneliness and social isolation.

2.1.1 Outcome measures

This RCT will evaluate the effect of a volunteer-based meal program on the feelings of loneliness of elders in the community. We will compare pre- and post-study scores using the R-UCLA scale for loneliness, PHQ-9 for depressive symptoms, and GAD-7 for feelings of anxiety.

2.1.1.1 Primary outcome measure

We will determine the effectiveness of a volunteer-based lunch program on decreasing feelings of loneliness in elderly participants. The full Revised-UCLA (R-UCLA) scale will be administered before and after the six-week trial period electronically using an iPad and Qualtrics software. There are 20 questions on the scale.

2.1.1.2 Secondary outcome measures

We will evaluate whether a volunteer-based lunch program decreases feelings of depression in elderly participants using the patient health questionnaire-9 (PHQ-9). It will be administered before and after the six-week trial period electronically using an iPad and Qualtrics software. There are 9 questions on the questionnaire.

We will also assess whether a volunteer-based lunch program decreases anxiety symptoms in elderly participants using the generalized anxiety disorder 7-item scale (GAD-7). It will be administered before and after the six-week trial period electronically using an iPad and Qualtrics software.

2.2 Design

2.2.1 Identification and enrollment of participants

We plan to administer an initial three-item loneliness scale to all 926 existing Meals on Wheels of Tampa participants. From that population, we aim to enroll 66 participants into the lunch program. 33 will be assigned to the intervention group and 33 to the control group.

- *Inclusion criteria*
    - Enrollees are eligible for the study if they are over 60 years of age, speak English, have feelings of loneliness on the three-item scale, able to give written consent, and answer surveys.
- *Exclusion criteria*
    - Elders who are unable to give informed consent or complete trial documentation.

We are planning a study of a continuous response variable from matched pairs of study subjects. Prior data indicate that the difference in the response of matched pairs is normally distributed with standard deviation 1. If the true difference in the mean response of matched pairs is 0.5, we will need to study 33 pairs of subjects to be able to reject the null hypothesis that this response

difference is zero with probability (power) 0.8. The Type I error probability associated with this test of this null hypothesis is 0.05.

The three-item loneliness scale will consist of the following questions: First, how often do you feel that you lack companionship? How often do you feel left out? How often do you feel isolated from others? Answers to these three questions will be in the following format: Hardly ever (1), some of the time (2), or often (3). Existing Meals on Wheels volunteers will carry envelopes with them on their meal delivery routes and deliver the envelopes to the elders along with their meals. The envelopes will contain this questionnaire, a brief description of the study, and a return envelope. The questionnaire will contain space for each elder to fill out basic identifying information and then the three questions. A score of 5 or higher will prompt the investigators to invite the elder to enroll in the study. A waiver for written consent explaining the project and why the participant has been selected will accompany the pre-screener three-item loneliness scale.

A designated investigator will contact potential participants who qualify via telephone. We will explain our goals and outline the framework of the study using an existing phone call template. Elders will be asked if they are willing to accept lunch company. If the elder is interested, the investigator will meet the elder at their residence with an iPad containing the study information, a written consent form, and pre-study assessment tools.

2.2.2 Recruitment of students

Volunteer medical students will be recruited through the USF Health listserv. After identifying potential volunteers, students will participate in pre-program training modules to ensure both the safety and anonymity of other participants. They will participate in an orientation meeting which will consist of information on filling out an honor code form outlining program expectation, what to do/not to do, and verification that the student is available for the entire six-week period. The Meals on Wheels Director of Programs & Partners will be present at the orientation to assist with presenting program expectations. She will be included in the recruitment and student approval process. Students will stay with the same assigned elder for the entirety of the trial.

2.2.3 Randomization and allocation

Eligible and consenting participants are randomized to one of the two study groups in a 1:1 allocation ratio. A block-stratified method using the computer will be used for generation of randomization sequence. The block size will be random. The randomization sequence will be implemented centrally with one of the co-investigator (Ambuj Kumar) who is off site will retain the list. Once a participant is identified the primary investigator will call the off-site co-investigator for assignment. Given that the co-investigator is not on site will ensure adequate allocation concealment.

2.2.4 Blinding

The following group of people will blinded:

- Study subjects: Study subjects will not be informed of their assignment.
- Outcome assessors and data analysts: Since the outcome data will be collected using a questionnaire, the possibility of interpretation does not exist. Data analysts will not be informed of the subject assignment and the coding for participant will be as group 1 or 2.

2.2.5 Follow-up procedures

After providing written consent to participate in the study, the participants will be assessed further by pre-study assessment using the R-UCLA scale for loneliness, PHQ-9 for depressive symptoms, and GAD-7 for feelings of anxiety.

At six weeks following the start of the trial, participants will complete the R-UCLA scale, PHQ-9, and GAD-7 again. A designated investigator will go to each residence with an iPad containing the post-study assessment tools electronically. He or she will not know the allocation of each elder or what cohort they are in.

Satisfaction will also be assessed on the iPad using Likert items evaluating overall satisfaction (response options: yes, to some extent, no), overall quality (response options for this and subsequent items: very satisfied, satisfied, neither, dissatisfied, very dissatisfied), how medical student treats you, and how you communicate with student. Five open-ended questions will also be used to assess the level of satisfaction: overall impressions, benefits of the program, how we could improve the program, and whether they would recommend the program to others.

3.0 Discussion

This project will work to reduce elder participants' feelings of loneliness and consequently build long-term relationships. Additionally, we hope the project will encourage the elder participants to be more involved and feel more connected to their community. We also want this to be a positive experience for medical students. Overall, we hope that this project is beneficial for both the elderly and medical student participants insofar as providing companionship and novel experiences for all involved. We hope to create a lasting program and relationship with Meals on Wheels, so that students will continue to have an opportunity to befriend and interact with those in the Tampa's senior community.

We hope that the RCT design will provide enough care matching controls to allow us to publish and present our results directly comparing seniors that received the lunch visitor intervention to seniors that did not. We plan to publish our results, as well as present at a future geriatrics conference.

4.0 Trial Status

This the third version of the protocol written on April 25, 2018. Initial recruitment of medical students will begin on June 1, 2018 and continue till August 10, 2018 after which the students will undergo orientation (August 13, 2018). Elders will be given the three-question survey to determine eligibility from July 9th till July 13th. Eligible elders who have provided their written consent will be given a pre-trial survey and randomly assigned into the intervention or the control groups (July 30 – August 3). The trial will last from the 20th of August till the 28th of September, after which post-trial surveys will be administered to both groups starting October 8. Trial structure along with dates are illustrated in Figure 1.

List of abbreviations

"RCT": Randomized Control Trial

"PHQ – 9": Patient Health Questionnaire – 9

"GAD – 7": Generalized Anxiety Disorder – 7

Declarations

Ethics approval and consent to participate

This study was reviewed and approved by the University of South Florida Internal Review Board (IRB) on April 16, 2018. Written consent will be obtained from all participants prior to enrollment in the study as per the USF IRB guidelines.

Consent for publication

As part of the written informed consent, consent for publication without any identifying information will be obtained from all participants.

Competing interests

The authors declare that they have no competing interests.

Funding

Funding was obtained through the Gold Humanism Society grant. Funding will be used to recruit medical students to the project.

Authors' Contributions

BN is the principal investigator who proposed the project idea and had a major role in writing the manuscript. AS was a major contributor to writing the manuscript and will be analyzing data obtained from the study. MC coordinated with Meals on Wheels and will be conducting surveys on the participants. AK played a major role in designing the study and writing the manuscript. LG also assisted in designing the study in addition to helping obtain the proper funding for the project. All authors read and approved the final manuscript. \

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Figure Legends

Figure 1: Study format shown with planned dates. Data will be analyzed after the post-trial surveys are complete.