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Feasibility of intervention in elder self-neglecters: setting the stage for future research

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Abstract

Objectives: Interventions are critical to improving clinical outcomes in elder self-neglecters. This study assessed feasibility of a randomized controlled trial of oral vitamin D in Adult Protective Services-substantiated self-neglect clients 65 years.

Methods: Participants were directly observed to consume ergocalciferol 50,000IU (treatment) or ergocalciferol 400IU (control), once a month, for 10-months. For months 6–10, half the control group randomly crossed into the treatment group (crossover). Intervention feasibility was measured by number of potential participants who agreed to participate and by retention rates during the study.

Results: Ninety-four referrals were received and 59 (63%) agreed to participate. Forty-nine participants were enrolled after pre-screening, and 35 completed the two-phase trial for a 72% retention rate. The participants' average age was 75.2±6.8 years, mainly female (59%), African-American (47%), and living alone (41%).

Discussion: Despite assumptions that self-neglecters are resistant to care, we have successfully conducted the first clinical intervention in this vulnerable population.

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CONFLICTS OF INTEREST

The authors have no financial or personal conflicts.

Keywords

randomized controlled trial; clinical trial; self-neglect; elder mistreatment

INTRODUCTION

Self-neglect is the inability or unwillingness to provide for oneself the goods or services to meet basic needs. Associated effects and disabilities, often coupled with the refusal of intervention, make self-neglect an independent risk factor for hospitalization and death (1–4). Older adults who self-neglect often live alone in destitute living conditions, have severe functional impairments, and multiple chronic diseases; all of which are risk factors for self-neglect (5–7). Other common risk factors and conditions of self-neglect include cognitive or psychiatric issues, such as dementia and depression, and refusal of interventions (8). Possible impairments of specific brain regions such as the mesiofrontal region, could lead to apathy, distractibility, and failure to keep targeted goals, while lesions in the orbitofrontal region may cause irritability, mood lability, and resistance to care, and lesions in the dorsofrontal region could affect planning, judgement, and insight (9). These impairments can lead to self-neglecters having difficulty with medication adherence (10) and performance in other executive tasks. As the number of older adults in the United States rapidly increases, the prevalence of those who self-neglect is also likely to rise, making self-neglect an increasingly important public health issue.

To date, the authors have identified no published intervention studies in self-neglecting older adults, thus the feasibility of systematic interventions in this population is unknown. In fact, much of the literature regarding self-neglecting older adults has been created using secondary data analyses of administrative databases, with the exception of some primary data collection studies using cross-sectional designs which required one-time assessments and minimal participation (11–13). It remains unknown as to whether self-neglecting older adults would be willing to participate in longitudinal studies and more so, interventional studies. The primary purpose of this study was to test the feasibility of enrolling community-dwelling older adults with Adult Protective Services (APS)-substantiated self-neglect to participate in a 10-month randomized controlled trial (RCT).

Vitamin D replacement was selected as the intervention modality because it has been found to be easy to administer, readily available, and had low risk for toxicity. Also, in 2006, a study conducted by the Consortium for Research in Elder Self-neglect of Texas (CREST) reported significantly lower 25-hydroxyvitamin D (25-OHD) levels in self-neglecters compared to a demographically matched control group selected from a community-based geriatric outpatient clinic. More than one-third of the self-neglecters had 25-OHD concentrations less than 25 nmol/L, a level considered vitamin D deficient (11). Moreover, low vitamin D status was associated with decreased physical function and ability to perform basic and Instrumental Activities of Daily Living when compared to self-neglecters who had higher vitamin D levels (14). Therefore, vitamin D was considered a needed, low risk, and objectively measureable intervention modality.

METHODS

A 10-month parallel group, double-blind RCT with a two-phased (i.e., baseline and 5 months) random allocation method and adaptive treatment-switching design, was conducted using vitamin D supplementation in APS clients age 65 and older with self-neglect. Prior to enrollment, the protocol was reviewed and approved by The University of Texas Health Science Center's Institutional Review Board.

Sampling Strategy

This study was conducted in Houston, Texas and participants (N=50) were recruited consecutively from Texas APS region VI. A three-step identification, contact, and consent process, developed previously to study this vulnerable population, was used to ensure confidentiality and protection of the participants (11). Briefly, 1) APS caseworkers received written permission from the self-neglecting client to release their name to the research team, 2) the research team then scheduled a home visit with the participant, and 3) the consent form was read aloud to the participant at which time the participant repeated back the purpose of the study, the risks and benefits of the study, and the option to withdraw from the study at any time with no penalty or disruption in APS services.

Inclusion criteria for the study were 1) 65 years of age or older, 2) community-dwelling resident of Houston, Texas, 3) APS-substantiated self-neglect, and 4) able to provide written and verbal consent directly or through a legal proxy. For this study, self-neglect was defined, by the Texas Legislative Statute 48.002, Human Resources Code, as "the failure to provide for one's self the goods or services, including medical services, which are necessary to avoid physical or emotional harm or pain (15)." After consent, participants were excluded if any of the following conditions were met: 1) pre-diagnosed terminal illness, 2) nursing home resident, 3) moving out of the study area during the proposed follow-up period, 4) taking vitamin D supplements, digoxin, antacids containing magnesium, cholestyramine, or mineral oil, 5) suffering from liver disease, biliary disease, malabsorption syndromes, or kidney disease, or 6) abnormal labs: serum calcium >1.32 nmol/L; blood urea nitrogen (BUN) >24 mg/dL; serum creatinine >1.3 mg/dL for men, >1.2 mg/dL for women; and electrolyte values outside the standard reference range.

Adaptive Treatment-Switching Design

Although assessing changes in serum vitamin D status was a secondary aim, we used an adaptive design or staggered enrollment approach to improve statistical power to detect a clinically meaningful effect of 30 nmol/L change from baseline to 10-month follow-up. Switching from the control to the treatment group occurred at 5 months if the interim analysis demonstrated benefit and safety of the initial treatment (16–18). In Phase 1 (months 1–5), participants were assigned using simple random allocation, 1/3 (intervention group: 50,000 IU vitamin D monthly) or 2/3 (control group: 400 IU vitamin D monthly). Although only minimal risks were expected, these allocation probabilities allowed the minimization of any potential harm. At 5 months, 17 (50%) of the participants receiving the lower dosage of vitamin D (i.e., 400 IU monthly) were randomly selected to cross-over and receive the higher dosage (i.e., 50,000 IU monthly) for the remaining 5 months of the study. Having this

design also enabled us to monitor within-individual changes in serum vitamin D levels across the 5-month intervals in Phase 2.

Intervention

The intervention consisted of home-based, directly observed administration of oral vitamin D2 (ergocalciferol) (Nivagen Pharmaceuticals, Sacramento, CA) to the participants. A registered nurse visited the participant's home to directly administer the study medications. Participants randomized to the treatment group consumed 50,000 IU of ergocalciferol once a month for 10 months while participants in the control group consumed 400 IU of ergocalciferol once a month for 10 months. The pills were identical in color and size and the research nurse remained blinded to the study groups. After an interim analysis indicated no intervention-related adverse events, half of the control group, through random selection, crossed over to the treatment group at month 5 and received 50,000 IU of ergocalciferol monthly for the remainder of the study. The research nurse remained with the participants for at least 30 minutes following vitamin D administration to monitor for potential adverse events. The entire study period for participants, including consent, enrollment, and intervention was approximately 12 months.

Data Collection and Measurement

The research nurse conducted baseline, 5 month, and 10 month assessments in the participants' homes, obtaining a brief social and medical history (including demographics such as age, sex, and ethnicity), and conducting a physical examination and blood assays. Anthropometric assessments included height and weight, which were used to calculate body mass index (BMI). A thorough assessment of medications was conducted to determine whether other sources of vitamin D were being taken. A blood draw was conducted for real-time analysis (i-STAT, Abbott, Princeton, NJ) of ionized calcium, electrolytes, BUN, and creatinine concentrations, to check for abnormalities that would exclude the participant from further participation in the study.

Primary Outcome: Intervention Feasibility

Intervention feasibility was the primary outcome for this study and was measured by evaluating a) how many potential participants agreed to participate once they were approached by the research team, and b) the dropout rate/retention rate during the different intervals of the study. The secondary outcome measured was change in vitamin D status between baseline to 5 and 10 month follow-up. Refusal and dropout rates were compared to those for intervention studies in similar populations, to facilitate interpretation of feasibility.

Secondary Outcome: Change in Vitamin D Concentrations

Serum 25-OHD concentrations were determined at baseline and after 5 (Phase 1) and 10 (Phase 2) months in the control, treatment, and crossover groups. Vitamin D blood samples (8 mL) were collected and centrifuged (<1 hour after the blood draw), with the serum aliquoted and frozen to be delivered weekly to Nutritional Biochemistry Laboratory personnel at the National Aeronautics and Space Administration (NASA) Johnson Space Center for further analysis. All samples were stored according to NASA guidelines, and all

vitamin D assays were performed in the NASA Nutritional Biochemistry Laboratory, which participates in the Vitamin D External Quality Assessment Scheme (DEQAS). Serum 25-OHD was determined by radioimmunoassay (RIA) and the data are in good agreement with other labs around the world using the DiaSorin RIA (19).

Analytic Strategy

Simple descriptive statistics were used to characterize participants and reasons for withdrawal. Characterization variables included gender, age (in years), ethnicity, BMI, living situation, marital status, monthly income level, education level (in years), and Mini-Mental State Examination (MMSE) score.

Standard data screening techniques (20) were used to identify and address violations of normality, presence of outliers, and missingness for variable values. Model assumptions were evaluated using graphical plots and, when possible, formal statistical estimates. Simple descriptive statistics were used to assess dosage group assignment imbalances in the study participant characteristics, using Fisher's and ANOVA tests for dichotomous and continuous data, respectively. Means and standard deviations were computed for continuous variables. Frequencies and proportions were used to describe the noncontinuous data. Beta levels, standardized errors, t-tests, and 95% confidence intervals are reported. The conventional probability value of 0.05 was used to define statistical significance.

The unadjusted comparison of control group and treatment group dosage post-treatment changes was conducted using the two-sample t-test or paired t-test. The design of the study required random allocation of the participants to dosage groups; however, because of the small sample size, some of the risk factors may still have been significantly imbalanced even after randomization. To adjust for group assignment imbalances, we assessed the changes in vitamin D levels using applied multiple-variable regression including age, sex, ethnicity, baseline vitamin D concentration, and BMI as covariates. Because of the two-phase study design, vitamin D concentrations measured at 5 and 10 months were correlated for certain individuals, so we included the two correlated response variables in the adjusted model along with a random effect. Main effects, along with interactions between the dosage and covariates, were analyzed. Missing data were addressed with the multiple imputation method.

RESULTS

Participant Demographics

Each participant was initially assigned at random to either the treatment group taking 50,000 IU of ergocalciferol monthly (n=18) or the control group taking 400 IU of ergocalciferol monthly (n=31). At 5 months, half of the control group was reassigned at random to the 50,000 IU dosage group to become the crossover group. Table 1 characterizes the 3 groups with respect to demographics, BMI, social status, MMSE score, and baseline 25-OHD concentrations. The probability (*P*) values of the homogeneity tests are also listed. The assignment groups were mostly balanced on the baseline characteristics with the exception of ethnicity (*P*= 0.07). This is not uncommon when a large number of

characteristics are compared in a situation of small sample size. Regardless of imbalances, all variables in Table 1 were analyzed as covariates to adjust for possible confounding effects on dosage.

Overall, the participants were obese, with an average age of about 75 years, there were more female than male participants, and they had low baseline 25-OHD concentrations. The majority were African American, lived alone, and were either married or widowed. Income level was mostly below the poverty line, with education level around 10 years, and average MMSE scores of 26.

Feasibility of Interventional Study in Older Adults Who Self-neglect

Ninety-four eligible self-neglect referrals were received by the research team. Of those, 35 (37%) refused to consent for the following reasons: 16 (46%) were not interested, 5 (14%) reported being too ill, 4 (11%) did not want to take pills, 4 (11%) reported being too busy, 3 (9%) had guardians who refused, 2 (6%) reported that their doctors recommended not participating, and 1 (3%) did not want to have their blood drawn. Of the 59 enrolled, 9 (15%) were withdrawn by the investigators because of inability to draw blood or abnormal blood values during pre-screening. One individual was withdrawn from the study due to loss to follow-up before the full baseline assessment could be completed. Thirty-five (72%) of the 49 enrolled completed the two-phase trial (Table 2). 18% dropped out by the end of Phase 1 and 10% dropped out by the end of Phase 2.

On further analysis of the characteristics of the 14 total participants that dropped out, the average age was 73.8 ± 6.0 , average monthly income was $\$916 \pm \138 , average education level was 8.3 ± 3.9 years, and average MMSE score was 26 ± 3 . Those who dropped out were mostly male (57%), African American (43%), lived alone (36%), and were married (50%).

Compliance with Oral Vitamin D Supplementation

Overall, the participants in the treatment group did have larger serum vitamin D increases at the 5- and 10-month follow-ups, than participants in the control or crossover groups. This secondary outcome mainly indicated that compliance to a clinically significant dose of vitamin D can lead to improved vitamin D levels in this population.

DISCUSSION

This study is the first to test the feasibility of a longitudinal clinical intervention in community-dwelling older adults with APS-substantiated self-neglect. Since the link between self-neglect and increased mortality has been established (2), more attention has been focused on self-neglect; however, previous studies have only focused on observational and epidemiologic characterization of this population. Evidence supporting the feasibility and efficacy of experimental intervention studies in this population have been lacking primarily due to access issues and assumptions that self-neglecting older adults characteristically cannot participate or refuse formal participation in research and clinical interventions. Our findings suggest that not all self-neglecting older adults fit these assumptions and that a longitudinal and participant-intensive clinical trial is possible in this

population. This first step is critical for how self-neglecters are viewed and approached by researchers and clinicians.

Our participants were similar to the national characterization of self-neglecting older adults in that they tended to live alone, were female, had less than a high school education, were married or widowed and had an income level that was below the poverty line. However, because most lived alone and consent was required, the MMSE scores were higher than what might be expected for self-neglecters, limiting generalizability. Nevertheless, self-neglecters are a heterogeneous group (21) and this study, by necessity, focused on those who were cognitively capable of understanding the risks and benefits of participating. While this may not cover the full continuum of self-neglect, our interest was to assess the feasibility of enrolling substantiated self-neglecters into a longitudinal study and thus, their ability to consent was important for assessing this aim. Using the previously established three-step process of consent, we were able to attain participation rates at levels similar to those seen in other elder mistreatment intervention studies (22,23). Moreover, we did not use incentives for participation, so we suspect that applying incentives to this population would have increased retention rates and should be a consideration in the future. During the study, the withdrawal rates did not seem to be related to the design or intervention since there were equal dropouts in the control, treatment, and crossover groups. Despite the longevity of the study, overall dropout rates were less than 30%, which is a lower attrition rate when compared with other interventional studies in vulnerable populations such as older adults with psychoses (24) and substance abuse (25). This attrition rate also suggests that oversampling by 30% when conducting similar studies in elder self-neglecters may be needed.

The finding that we were able to recruit and enroll self-neglecters is important for advancing the understanding of elder self-neglect, intervention and prevention. Most of the epidemiologic research in this population, with exception of the CREST trial, has used secondary data analyses to characterize elder self-neglect and associated outcomes. Being able to actively enroll self-neglecters in longitudinal studies allows for more control over study designs which can optimize data collection and provide inferences regarding outcomes and modifiable risk factors. Moreover, our findings refute the assumption that all older adults with substantiated self-neglect are unwilling to engage in interventional trials. Adhering to this assumption would severely limit finding and testing evidence-based interventions for reducing self-neglect and preventing detrimental outcomes.

Our finding that the attrition rate was relatively low is also of considerable importance. A major problem stalling the progress of understanding elder self-neglect and its progression is the lack of longitudinal data. Being able to follow self-neglect participants for extended periods of time provides a critically needed opportunity to establish and test models that may lead us to identifying critical time points or abrupt versus natural changes in the older adult's sociocultural context that leads to worsening behaviors and the need for more aggressive approaches to ensure their safety, protection and survival.

While change in vitamin D status was a secondary outcome for this study, we will briefly comment on its implications for the field. It was not unsuspecting that vitamin D would change based on our approach, but it is encouraging because we now have evidence that we

can intervene and alter a micronutrient that is associated with conditions such as muscle weakness, walking speed, frailty and memory(26–29); commonly seen in elder self-neglecters (5–10). Therefore, this study provides a framework for assessing this link as a possible point of intervention to reduce some of the difficulties that may facilitate self-neglecting behaviors.

It remains unknown as to why our participants agreed to be part of this study. After all, the comprehensive assessments were lengthy and multiple blood assays were performed. One hypothesis is that these individuals received a social benefit from the in-person visits by the research team. Many of our participants lived alone and most were socially isolated as a result. This is consistent with elder self-neglecters research and perhaps participants in this study looked forward to their visits with the research team. Moreover, our participants did not get compensation and yet they were still willing to undergo 3 hours of initial screening, medication administration, monthly visits and blood draws for almost a year. It is not clear if the social contact with the study team enhanced participation and this hypothesis should be tested in future studies. Another hypothesis is that vitamin D is a well-known vitamin with very little negative publicity. Other interventions may be seen as less acceptable and therefore, more feasibility studies are needed regarding other interventions.

LIMITATIONS

Despite its strengths, our findings should be considered within the context of several limitations. This study utilized a small convenience sample from a single APS region. Also, the primary aim of feasibility and the established consent process limited the coverage of the full self-neglect spectrum and subsequently, generalizability. Also, using a directly-observed approach to administration of the vitamin D may not be as feasible due to the intensive participant follow-up and interaction. Nevertheless, this study demonstrated a successful approach that future studies can adopt or adapt to test the efficacy of other interventions or to test generalizability of intervention approaches in similar self-neglect populations.

CONCLUSION

Our evidence suggests that interventions are feasible in this population with reasonably good retention rates despite historical arguments. Older adults are willing to engage in longitudinal intervention-based studies that utilize APS recruitment, participant-intensive designs and have a low risk, but potentially beneficial intervention modality such as vitamin D. This study provides a paradigm for future studies to consider when seeking to intervene in this population. Future studies may seek more generalizable and less participant intensive approaches by offering incentives. Ultimately, more clinical research in this vulnerable, often overlooked population could lead to improved survival and better quality of life for a group that is at high risk for morbidity and death.

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Table 1

Self-neglecting Older Adult Demographics, BMI, and Baseline Vitamin D Concentrations, by Dosage Group.

Characteristic	Total Sample N=49	Dosage Group			P-value ^a
		Control N=16	Treatment N=18	Crossover N=15	
Sex, N (%)					0.63
Male	20 (41%)	8 (50%)	7 (39%)	5 (33%)	
Female	29 (59%)	8 (50%)	11 (61%)	10 (67%)	
Ethnicity, N (%)					0.07
White	18 (37%)	8 (50%)	7 (39%)	3 (20%)	
African American	23 (47%)	6 (38%)	10 (56%)	7 (47%)	
Hispanic	7 (14%)	2 (12%)	0 (0%)	5 (33%)	
Asian ^b	1 (2%)	0 (0%)	1 (5%)	0 (0%)	
Living Situation, N (%)					
Alone	20 (41%)	6 (38%)	9 (50%)	5 (33%)	
With Spouse	11 (22%)	4 (25%)	3 (17%)	4 (27%)	
With Family	15 (31%)	5 (31%)	6 (33%)	4 (27%)	
With Provider	3 (6%)	1 (6%)	0 (0%)	2 (13%)	
Marital Status, N (%)					
Married	18 (37%)	7 (44%)	5 (28%)	6 (40%)	
Divorced	12 (24%)	2 (12%)	7 (39%)	3 (20%)	
Widowed	18 (37%)	7 (44%)	6 (33%)	5 (33%)	
Never Married	1 (2%)	0 (0%)	0 (0%)	1 (7%)	
Age (years) ^c	75.2 ± 6.8	76.9 ± 7.4	74.6 ± 5.9	74.2 ± 6.7	0.65
Body Mass Index (kg/m ²) ^c	30.1 ± 8.8	31.3 ± 11.1	31.3 ± 6.6	27.5 ± 8.2	0.38
Income Level (\$/month) ^{c,d}	972.6 ± 251.6	1100 ± 245.1	775.4 ± 112.5	1054 ± 235.0	
Education Level (years) ^{c,e}	10.2 ± 4.0	9.1 ± 2.8	12.8 ± 3.1	9.2 ± 4.8	
Mini Mental State Exam ^c	26.2 ± 2.9	26.6 ± 2.8	26.7 ± 2.2	25.3 ± 3.2	
25-OH-Vitamin D (nmol/L) ^a	66.8 ± 22.1	63.1 ± 19.1	69.5 ± 23.7	67.1 ± 24.5	0.70

^aThe P-value for ethnicity is derived from Fisher's exact test; others are from either the Chi-square or the ANOVA test, depending on variable type.^bFor the purpose of model stability, the only Asian, who withdrew, was excluded from multivariable analysis.^cData are mean ± SD.^dN=25^eN=44

Table 2

Specific Reasons for Study Withdrawal in Self-neglecting Older Adults.

Withdrawal Reason	Dosage Group			
	Control (N=16)	Treatment (N=18)	Crossover (N=15)	Total (N=49)
<i><u>Phase 1</u></i>				
Refused to continue	3	3	2	8
Ineligible	0	0	1	1
Completed Phase 1	13	15	12	40
<i><u>Phase 2</u></i>				
Refused to continue	2	1	1	4
Lost to follow-up	1	0	0	1
Completed study	10	14	11	35

Table 3

Serum Vitamin D Concentrations by Dosage Group, at Baseline and after 5 and 10 Months of Vitamin D Supplementation.

Dosage Group	Baseline (nmol/L)	5 months (nmol/L)		10 months (nmol/L)	
	Mean $\pm$ SD	Mean $\pm$ SD		Mean $\pm$ SD	
Control	67.1 $\pm$ 24.5	76.9 $\pm$ 17.6	8.8 $\pm$ 36.4	74.7 $\pm$ 17.7	11.5 $\pm$ 35.1
Treatment	69.5 $\pm$ 23.7	85.5 $\pm$ 25.4	19.7 $\pm$ 35.1	81.8 $\pm$ 31.9	16.3 $\pm$ 28.0
Crossover	63.1 $\pm$ 19.1	74.5 $\pm$ 12.0	14.1 $\pm$ 27.5	76.2 $\pm$ 23.0	11.1 $\pm$ 20.3

= Change in vitamin D concentration from baseline.