Published in final edited form as:
J Acad Nutr Diet. 2013 December ; 113(12): . doi:10.1016/j.jand.2013.06.352.

A randomized controlled trial of a theoretically based behavioral nutrition intervention for community elders: Lessons learned from the B-NICE study

Julie L. Locher, **Kristin S. Vickers**, **David R. Buys**, **Amy C. Ellis**, **Jeannine C. Lawrence**, **Laura Newton**, **David L. Roth**, **Christine S. Ritchie**, and **Connie W. Bales**
Division of Gerontology, Geriatrics, and Palliative Care, University of Alabama at Birmingham (UAB), Birmingham, AL (JLL, DRB, CSR); Center for Aging, UAB, Birmingham, AL (JLL, DRB, CSR); Department of Health Care Organization and Policy, UAB, Birmingham, AL (JLL); Lister Hill Center for Health Policy, UAB, Birmingham, AL (JLL); Nutrition Obesity Research Center, UAB, Birmingham, AL (JLL); Department of Psychiatry and Psychology, Mayo Clinic, Rochester MN (KSV); Department of Nutrition Sciences, UAB, Birmingham, AL (ACE, LN); The University of Alabama, Department of Human Nutrition and Hospitality Management, Tuscaloosa, AL (JCL); Center on Aging and Health, Johns Hopkins University, Baltimore, MD (DLR); Department of Medicine, University of California at San Francisco, San Francisco, CA (CSR); Dept. of Medicine, Duke University Medical Center, Durham, NC (CWB); Geriatric Research, Education, and Clinical Center, Durham VA Medical Center, Durham, NC (CWB)

Abstract

Background—Older adults with multiple co-morbidities are often undernourished or at high risk for becoming so, especially following a recent hospitalization. Randomized controlled trials of effective, innovative interventions are needed to support evidence-based approaches for solving nutritional problems in this population. Self-management approaches where participants select their own behavioral goals may enhance success of interventions.

Objective—The purpose of this study was to evaluate the feasibility and efficacy of a multi-level self-management intervention to improve nutritional status in a group of high-risk older adults.

Design—The Behavioral Nutrition Intervention for Community Elders (B-NICE) trial used a prospective randomized controlled design to determine whether the intervention, compared to standard care, maintained or increased caloric intake (depending on baseline body mass index) and, consequently, stabilized or increased body weight.

Participants/Settings—Participants were 34 Medicare-eligible, ≥65 years old, homebound, adults who were consuming insufficient calories *and/or* had a history of weight loss ≥ 2.5% over 6 months. The intervention took place within participants' homes.

Main Outcome Measures—Outcome measures, including energy intake (based upon collection of 3 24-hr dietary recalls) and body weights were assessed at baseline and at 60 days post-randomization.

Statistical Analyses Performed—The primary analyses included analyses of covariance and Pearson's chi square. We hypothesized that the intervention would result in increased caloric

Corresponding author: Julie L. Locher, PhD MSPH; CH19, Room 218F; 1530 3rd Avenue South; Birmingham, Al 35294-2041; Telephone: 205.934.7542; Fax: 205.975.5870; jlocher@uab.edu.

This trial is registered with Clinical Trials.gov as NCT01197768.

There are no disclaimers to report.

intake and weight gain in underweight older adults and increased or stabilized caloric intake and weight for everyone else.

Results—The intervention was feasible; however it did not result in differences between groups for desired outcomes of either caloric intake or body weight.

Conclusions—Future interventions might either deliberately involve caregivers or reduce burden for both patients and caregivers.

INTRODUCTION

While public attention is increasingly focused on escalating rates of obesity, a considerable proportion of the older population continues to experience undernutrition, the hallmarks of which include energy deficits evidenced by unintentional weight loss and/or marginal intakes of vitamins and minerals which may contribute to frailty, infection, and other negative health outcomes. Undernutrition in older adults occurs in 5–12% of those residing in the community, 11% of medical outpatients, and 32–50% of those who are hospitalized.[1] It is well established that older adults who are homebound for medical reasons are at especially high risk for experiencing undernutrition, with prevalence estimates ranging between 70% – 93%.[2, 3, 4, 5]

There are many factors associated with inadequate caloric intake in older adults who are homebound.[2, 6, 7] Just like younger individuals, older adults tend to consume less food when they are sick compared to when they are well. But unlike younger persons, they often do not resume their pre-morbid food intake if and when they become well.[8, 9] This places them at increased risk for undernutrition and related adverse outcomes following an illness. Additionally, while undernutrition is commonly expected in those who are underweight, overweight and obese individuals undergoing a health crisis can also experience acute nutritional deficits that may lead to sarcopenic obesity and its sequelae.[10, 11] Social risk factors include eating alone or with fewer persons, living alone, being single or widowed, having inadequate social or caregiver support, living in a rural area, having low or no religious attendance, and poor access to food and community resources.[12, 13, 14, 15, 16, 17] Psychological risk factors may include depression, grief, poor cognitive status, dementia, and stress.[6, 7] Common symptoms, such as pain, nausea, and fatigue contribute to poor food intakes as do medication side effects, diminished sensory perception, and functional impairment.[18, 19, 20, 21] Poverty is another major contributing factor[17], as are poor oral health and swallowing difficulties.[22]

Longitudinal and epidemiological studies have repeatedly demonstrated that weight loss in older adults, including that following a recent hospitalization[23], is associated with increased risk of mortality.[24, 25, 26, 27, 28] It is associated with functional decline, increased likelihood of infection, higher rates of adverse complications from other health conditions, and decreased quality of life across all settings.[29, 30, 31] Finally, nutritional risk among older adults receiving Medicare home health services has been found to be associated with subsequent health service utilization, including specifically nursing home admission for overweight and obese older adults who are at nutritional risk.[32]

Of the few available interventional studies targeted at undernutrition, most have concerned seriously malnourished older adults and have used invasive and/or costly approaches, such as appetite stimulation agents, or enteral/parental nutrition support. Unfortunately, these interventions have been mostly ineffective in improving health outcomes.[33] Commenting on the disappointing outcomes of their trial of nutritional supplementation, Edington, et al.[34] concluded that for older persons who are already malnourished, it may be too late to expect functional improvements and noted that “prevention is key”. Recognizing this, we examined

the potential feasibility and effectiveness of a self-management nutritional intervention to improve caloric intake in at-risk older adults. We hypothesized that the intervention would result in increased caloric intake and weight gain in underweight older adults and increased/stabilized caloric intake and weight in normal and overweight older adults.

SUBJECTS AND METHODS

The Behavioral Nutrition Intervention for Community Elders (B-NICE) trial used a prospective randomized controlled design to determine whether individually tailored counseling focused on social and behavioral aspects of eating maintained or increased energy intake (depending on baseline body mass index) in older adults who were receiving Medicare home health services. The development and implementation of the B-NICE protocol, including the theoretical framework, the methodology, the specific elements of the behavioral intervention, and assurances of the treatment fidelity, as well as the health policy implications of the trial results have been previously reported.[35] The intervention was guided by the theoretical approaches of the Ecological Model and Social Cognitive Theory. Institutional Review Board approval was obtained.

Participants

We recruited Medicare-eligible recipients of skilled home health care for whom a dietary intervention of the type being proposed might be beneficial and appropriate. To be eligible for the study, potential participants had to be: 1) at least 65 years old, 2) homebound (based upon Medicare's definition of homebound status),[36] 3) able to communicate or have a caregiver who was able to communicate, 4) living in a private residence (either house or apartment), 5) experiencing either an acute illness or chronic condition, and 6) undereating. Undereating was defined as either: A) consuming insufficient calories to maintain current body weight (caloric intake of 5% or more below the Estimated Energy Requirement (EER) (using equations developed by the Institute of Medicine) *and/or* B) having a history of unintentional body weight loss ≥ 2.5% over the past six months (and BMI not greater than 40 without comorbidities or not greater than 35 and less than 40 with diabetes or hypertension).[37] Sufficiency of calorie consumption was determined by subtracting a participant's EER from their mean daily caloric intake. Exclusion criteria included: 1) cognitive impairment (i.e., scoring less than 8 out 10 if living alone or without a caregiver or less than 5 out of 10 if living with someone or having a caregiver present using the Short Portable Mental Status Questionnaire,[38] 2) terminal illness, 3) cancer diagnosis within past 5 years, 4) end-stage renal disease, 5) any tube feedings, or 6) ventilator dependence. Individuals who met eligibility criteria were visited in the home by the research interviewer (DRB) for an Eligibility Screening/Baseline Assessment.

Sample size calculations were based upon the ability to detect a difference of 248 calories on post dietary recalls between the groups (at a type I error rate of alpha = .05).[16] The sample size of 42 per group has the ability to detect an effect size of 0.62 standard deviation units and a power of .80 in an analysis of covariance with the two groups (α =.05).

Design

Participants were randomly assigned to either a Usual Care group or to the B-NICE group. Using stratified blocked randomization, participants were stratified by gender and BMI (with BMIs categorized as either underweight [BMI < 18.5], normal weight [BMI ≥ 18.5 and BMI < 25], or overweight [BMI ≥ 25]). Usual care consisted of whatever care or treatment a patient was currently receiving for any reason, not specific to nutrition.

Because this is a social-behavioral intervention study, it was not possible for participants or intervention study personnel (ACE, JCL, LN) to be blinded to group assignment. However, research interviewers collecting outcomes data were blinded to group assignment.

Participants assigned to the B-NICE arm were initially visited in their homes by a Registered Dietitian (RD) (ACE, JCL, LN), who utilized self-management education approaches to guide the participant/caregiver, providing both verbal and written instructions regarding how to improve caloric intake. The process involved collaborative goal-setting with the participant/caregiver, identifying areas for initial behavior change that matched best with the participant's preferences, motivation, and confidence; and a maximum of three goals were set that were short-term, specific, and measurable. Participants were also asked to consider potential barriers. B-NICE recipients also received a self-management support call from an RD at 1, 2, and 4 weeks following the intervention.

All participants received an in-home follow-up assessment conducted 60 days post-randomization. Caloric intake at each time period was measured using aggregated data from three 24-hr dietary recalls; the first was conducted face-to-face in participants' homes, the second and third by telephone.[39] At each in-home visit, body weights were obtained using a calibrated floor scale on (ThinnerTM digital electronic scale Model 68978 "Soft Step") for all participants who were able to stand. Only one person was not able to stand. In this case, we relied upon participants' self-report of weight based upon the most recent medical encounter for both baseline and follow-up time points to calculate EER only (described below).

Primary Outcome Measures

The primary outcome measures were caloric intake and body weight as continuous variables. We additionally created dummy variables to indicate desired outcomes of "increasing (for underweight participants) or maintaining (for normal, overweight, or obese participants) caloric intake or body weight" versus maintaining (for underweight participants) or decreased (for normal, overweight, or obese participants) caloric intake or body weight.

Analyses

The primary analysis is an analysis of covariance (ANCOVA) on the post-treatment caloric intake values with baseline caloric intake used as a covariate. For the categorical variables, the primary analysis was a cross-tabulation using Pearson's Chi-Square.

RESULTS AND DISCUSSION

The feasibility of the study was confirmed with 207 persons assessed for eligibility between October, 2008 and January, 2011. Forty participants were randomized into the study and 34 participants are included in the analyses—16 assigned to Usual care and 18 assigned to Intervention.

The average age of participants was 81.4 ± 8.2 (SD) and ranged from 65 to 97 years old. There were 6 males and 28 females, of which equal numbers were African and European Americans. Close to two-thirds of participants (64.7%) were not consuming enough calories to maintain their current body weight and 15.2% were underweight (having a BMI < 18.5). There were no differences observed at baseline between the Usual Care and Intervention groups. The randomization schedule was successful in balancing for both gender and BMI.

Table 1 presents the behavioral nutrition goals that were selected by participants in collaboration with the RD. Participants most often selected goals that involved changing the

frequency, amount, and type of foods and beverages consumed with the intent to increase overall caloric intake.

Table 2 presents pre and post data relevant for assessing primary outcome measures. An ANCOVA revealed no main effects of the intervention for either caloric intake, $F(2, 32) = .038$, p=.847 or weight, $F(2. 32) = <.000$, p=.996. The Usual Care group reported higher caloric intake compared with the Intervention group at baseline and post-treatment, and did not increase their caloric intake as much as the intervention group did from baseline to post-treatment. Similarly, chi-square analysis revealed no effects of the intervention for either caloric intake or weight post-treatment. The percentage of participants who were meeting caloric needs to maintain body weight did not differ significantly between groups (43.8% for Usual Care versus 27.8% for the Intervention group) ($\chi^2=.946$, df=1, p=.331); and the percentage of participants who were weight stable did not differ between the groups (60.9% for the Usual Care group versus 55.6% for the Intervention group) ($\chi^2=.066$, df=1, p=.797). Of note, in sensitivity analyses we adjusted for multiple variables (including ethnicity, living arrangement, etc.) and none of these made any difference in the results.

It is unclear if the null findings are a result of reduced study power as a consequence of being unable to achieve our desired sample size or the ineffectiveness of the intervention. Regardless, the findings of our study are important because they reveal that studies such as the one we conducted with the population we targeted are feasible, but not without substantial obstacles and with limited impact on the primary outcomes of caloric intake and/or weight. This discussion focuses on the limitations of the study with insights offered into how future studies might go about things differently.

First, with respect to lower than expected recruitment, we met only approximately 50% of our targeted enrollment over an approximately two-year grant period. Our recruitment estimates were based on previous work conducted by our research team with the same population. The previous study, however, was an observational study that did not involve an intervention. Our experiences here are not unique; Sahyoun and her colleagues reached exactly 50% of their targeted enrollment in the Community Connections Demonstration Project, an intervention study supported by the Administration on Aging that recruited from a similar population and from comparable sources.[40, 41]

There are multiple reasons why recruitment may have been less than anticipated. It is possible that recruitment for intervention studies requires more time than recruitment for observational studies. Because greater involvement may be required of potential participants in intervention studies, older adults may be more reluctant to participate because of the perceived additional effort. Lending support to this speculation, we note that Villareal and his colleagues conducted a randomized controlled intervention of weight loss in older adults and recruited 93 participants over an approximately four- year study period that overlapped with the timeframe of our study.[42] Their rate of accrual was nearly identical to that observed in our study. Had we had similar resources and time, it is likely that we would have met recruitment goals.

Additionally, we earlier reported on the significant difficulty we encountered in receiving referrals from home health nurses, discharge planners, social workers, and case managers for the study.[43] Reasons why and potential solutions are described in our paper, as well as in those by Sahyoun, et al.,[40, 41] We additionally encountered patient resistance to enrollment in the study because of its' ultimate goal of weight gain or maintenance during the recovery period. In previous work with older cancer patients, we found that patients interpreted weight loss as a positive outcome of the cancer and engaged in deliberate efforts to keep the weight off.[44] The same was observed in this study. In future work, we will not market such a

study as one to either increase or maintain caloric intake or weight, but instead one to improve nutritional intake or energy intake.

Nonetheless, we do not believe our inability to detect an effect for the intervention is entirely a consequence of inadequate power. Roughly 60% of persons in both groups either maintained or gained weight, and 44% of the control group and 28% of the intervention group were consuming enough calories post-intervention to maintain their baseline weight. There is considerable variability for all data points and no patterns observed for either group; and, in fact, the Usual Care group demonstrated higher and better caloric intake at pre- and post-treatment compared with the intervention group and lower BMIs at baseline—though, no statistically significant differences were observed. Future work might better target under or overweight participants or those who are undereating at baseline for inclusion in order to demonstrate effectiveness in a more homogenous sample.

What else might additionally account for the null findings? The study was meticulously designed with close attention paid to detail and the intervention was delivered in the home by highly motivated RDs, all with advanced degrees and all trained in behavioral self-management techniques. Furthermore, participants selected their own behavioral goals to target for change (e.g., from a range of options including: eating with family and friends, moderating therapeutic diets, participating in home-delivered meals program, etc.) and were supported in reaching goals in collaboration with the RD interventionist. It may well be that the behavioral goals identified by participants were not ones that either 1) would have the greatest impact on the study objectives or 2) were easy to implement. In fact, as illustrated in Table 1, the goals participants overwhelmingly selected were those associated with increasing the frequency, amount, and type of foods eaten.

Of note is that our previous work revealed that eating with others and having caregiver support were significantly associated with increased caloric intake among a similar group of older adults receiving Medicare home health services.[2, 38] In this study, however, participants did not want to burden family and friends by seeking their involvement in activities surrounding food and meals. In other work with the same population, we also found that food choices were motivated primarily by sensory appeal (i.e., tastes good), convenience (i.e., is easy to prepare, simple to cook, etc.), and price.[45] It may have been the case that implementing dietary changes, even those that were self-chosen, were too taxing for this group who may have been experiencing competing demands of dealing with medical issues associated with their recovery. Future work in which we engage to improve nutritional well-being in this population will focus specifically on either soliciting caregiver support or eliminating all but minimal effort on the part of participants (e.g., through provision of already prepared meals).

It is also the case that our inclusion criteria included history of weight loss or currently not consuming enough calories to maintain current body weight and our sample includes underweight, as well as normal and overweight/obese participants, any of whom may have experienced weight loss. These may have contributed to making differences difficult to detect. Although, our randomization scheme was stratified according to baseline BMI, and our analyses controlled for baseline caloric intake. Additionally, we note that other goals (e.g., increasing dietary protein, improving quality of life, reducing hospital readmissions) might be important endpoints to evaluate, as well.

While our work was undertaken in a Southern US location and our sample size was small, we have no reason to believe that our findings are not generalizable to older adults who are homebound and recovering from an illness in other places. Because of problems with recruitment, though, future work might benefit from multi-site participation.

CONCLUSIONS

In 2012, the Academy of Nutrition and Dietetics issued a position paper stating that "all Americans aged 60 years and older receive appropriate nutrition care; have access to coordinated, comprehensive food and nutrition services; and *receive the benefits of ongoing research* to identify the most effective food and nutrition programs, interventions, and therapies".[46] The paper highlighted the many challenges involved in maintaining and improving nutritional health in the population we studied. Similarly, in 2011 the Institute of Medicine held a workshop entitled "Nutrition and Healthy Aging in the Community." One of the major conclusions was that nutritional interventions that support successful transitions from acute to home settings, enabling independent living in the community, are research priorities.[47]

Because our intervention did not result in statistically significant differences between groups, one should not infer that this population cannot benefit from behavior interventions to improve nutritional intake. Rather, findings from this study and previous research suggest that this population may have unique needs, and these individuals also have unique perceptions about what their preferences are in addressing those needs. While collaborative goal-setting is important, it may be equally important to minimize discussion of "weight and calories," to identify support systems, and to minimize inconvenience of implementation.

Acknowledgments

This work was supported by the National Institutes of Health/National Institute on Aging (K07 AG043588 and R21 AG027560 to JLL).

List of abbreviations

B-NICE	Behavioral Nutrition Intervention for Community Elders
EER	Estimated Energy Requirement
kcal	kilocalorie
y	years
PAC	Physical Activity Coefficient
wt	weight
kg	kilograms
ht	height
m	meters
BMI	body mass index
SPMSQ	Short Portable Mental Status Questionnaire
RD	registered dietitian

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TABLE 1

Behavioral Nutritional Intervention Self-Management Goals

Type of goal	# set	Examples
Increase calories	11	Drink 1 glass of fruit juice daily Add 1 snack per day
Increase protein	10	Add 1 scoop of protein powder to a beverage once daily Add 1 egg white to scrambled eggs with breakfast
Increase calories and protein	20	Replace evening glass of water with milk Make soup with milk instead of water or chicken broth
Medication/supplement	2	Ask son to fill pill box weekly Take multivitamin daily
Social interaction/community assistance	2	Attend church on Sundays Pursue participation in Meals on Wheels or other community resources
Medical nutrition therapy	3	Consume dates or prunes daily (for constipation) Replace water with cranberry juice (for UTI prophylaxis)

J Acad Nutr Diet. Author manuscript; available in PMC 2013 December 01.

TABLE 2

Pre- and Post- Primary Outcome Measures

		Baseline Estimated Energy Requirment	Pre Caloric Intake	Post Caloric Intake	Pre-post Change in Caloric Intake	Post Deficit in Caloric Intake	Meeting Caloric Needs Pre	Meeting Caloric Needs Post	Baseline Body Mass Index	Pre Weight	Post Weight	Weight Stable or Gain Post
Usual Care												
	1	1480	1190.91	1502.36	311.45	22.36	no	yes	17.9	119	122	yes
	2	1523	1438.11	1328.47	−109.64	−194.53	no	no	18.2	127	125	no
	3	1271	1191.26	825.33	−365.93	−445.67	no	no	20	99	110	yes
	4	1747	1237.61	2162.4	924.79	415.4	no	yes	20.1	130.5	125	no
	5	1241	814	1308.67	494.67	67.67	no	yes	20.2	112	111	no
	6	1390	1378.03	1540.98	162.95	150.98	yes	yes	20.7	113	104.5	no
	7	1444	1689.28	1124.82	−564.47	−319.18	yes	no	21.5	112	113	yes
	8	1587	1125.81	1699.55	573.74	112.55	no	yes	21.6	122	124	yes
	9	1992	1842.09	967.46	−874.62	−1024.54	no	no	23.4	128	131.4	yes
	10	1563	1421.48	670.47	−751.01	−892.53	no	no	23.4	154	173	yes
	11	999	1012.39	1173.42	161.02	174.42	yes	yes	25.2	140	148	yes
	12	1492	1774.79	998.96	−775.83	−493.04	yes	no	25.8	123.5	120.5	no
	13	1776	938	877	−61	−899	no	no	26.4	158.5	168.9	yes
	14	1632	1311.96	2415.53	1103.57	783.53	no	yes	28.6	151.2	169	yes
	15	1769	1369.75	1216.02	−153.72	−552.98	no	no	32.2	184.5	172.5	no
	16		762.71	1082.08	319.37							
Group Means		1527.07	1281.14	1305.85	24.71	−206.30	20% Yes	44% Yes	23.01	131.61	134.52	60% Yes
Intervention												
	17	1667	1284.08	822.33	−461.75	−844.67	no	no	17.5	127	125.5	no
	18	1317	1006.79	1880.14	873.35	563.14	no	yes	18	101	101	yes
	19	1412	1336.84	1717.04	380.2	305.04	no	yes	18.4	114	109.5	no
	20	1903	1782.51	1972.16	189.66	69.16	no	yes	19.9	143	161	yes
	21	1582	1105.66	1213.86	108.2	−368.14	no	no	20	129.5	136.5	yes
	22	1955	849.78	947.57	97.79	−1007.43	no	no	20.5	123.5	140	yes
	23	1275	603.33	805	201.67	−470	no	no	22.3	118	110	no

	Baseline Estimated Energy Requirment	Pre Caloric Intake	Post Caloric Intake	Pre-post Change in Caloric Intake	Post Deficit in Caloric Intake	Meeting Caloric Needs Pre	Meeting Caloric Needs Post	Baseline Body Mass Index	Pre Weight	Post Weight	Weight Stable or Gain Post
24	1601	2004.28	1824.08	−180.2	223.08	yes	yes	22.5	135	150	yes
25	1536	289.2	1253.29	964.09	−282.71	no	no	22.8	135	133	no
26	1491	671.67	512.5	−159.17	−978.5	no	no	24	139	133	no
27	1914	1309.35	1052.94	−256.4	−861.06	no	no	25.1	185	189	yes
28	1620	924.63	1236.9	312.27	−383.1	no	no	27.6	151	150.5	no
29	1573	1440.12	1444.04	3.92	−128.96	no	no	28.3	154.5	162.5	yes
30	1704	901.43	1191.08	289.65	−512.92	no	no	28.6	182	191	yes
31	1963	834.05	1230.72	396.67	−732.28	no	no	28.7	170	175	yes
32	1666	661.51	590.56	−70.95	−1075.44	no	no	28.9	163	160.8	no
33	1474	1380.94	1722.82	341.89	248.82	no	yes	31.3	147	153.5	yes
34	1510	617.67	982	364.33	−528	no	no	39.5	199	190	no
Group Means	1620.17	1055.77	1244.39	188.62	−375.78	6% Yes	28% Yes	24.66	145.36	148.43	55.6% Yes