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INTENSIVE DIETARY INTERVENTION BY A DIETITIAN AS A CASE MANAGER AMONG COMMUNITY DWELLING OLDER ADULTS: THE EDIT* STUDY

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Abstract: *Background:* Clinical trials that have assessed the best approach for treating under-nutrition in old age are scarce. *Objective:* To determine the impact of an intensive nutritional intervention program led by a dietitian on the health and nutritional status of malnourished community dwelling older adults. *Methods:* Sixty-eight eligible participants (age<75) were randomly assigned to a Dietetic Intervention Treatment (DIT), an intensive nutritional intervention led by a dietitian, or a Medical Treatment (MT), a physician-led standard care group, with an educational booklet regarding dietary requirements and recommendations for older adults. An additional 59 eligible participants who were unable to participate in the randomization were included as a non-randomized "untreated nutrition" group (UNG). *Results:* Over the 6-month follow-up, the DIT group showed significant improvement in cognitive function (from 25.8±4.5 to 26.8±4, p=0.04), and depression score (from 7.3±3.9 to 5.4 ±3.9, p=0.04) compared with the change in the other 2 groups. The DIT group showed a significant improvement in intake of carbohydrates (+15% vs. +1% in the MT and +3% in the UNG), protein (+8% vs. +2% in the MT and -3% in the UNG), vitamin B6 (+20% vs. +7% in the MT and +8% in the UNG), and vitamin B1 (+22% vs. +11% in the MT and 0% in the UNG). The DIT group had a significantly lower cost of physician visits than the other 2 groups ($172.1±232.0 vs. $417.2±368.0 in the MT and $428.1±382.3 in the UNG, p=0.005). *Conclusion:* Intensive dietary intervention was moderately effective in lowering cost of services used and improving medical and nutritional status among community dwelling older adults.

Key words: Health care use, undernutrition, malnutrition, older adults, dietary treatment, nutritional treatment, dietitian case manager.

Introduction

Malnutrition among older adults is a continuing source of concern (1, 2) that adversely affects both lifespan and quality of life (3, 4). Undernourished older adults are known to have longer periods of illness, longer hospital stays (3, 4), higher infection rates (5, 6), delayed wound healing, impaired cognitive function (7), reduced appetite (8), and increased mortality rates (9). Under-nutrition is a critical determinant of outcomes of hospitalization (3, 10, 11) and correlates with morbidity and mortality in this population (11–13). A recent survey of nearly 2500 Canadian patients showed that patients admitted to an acute care ward with risk factors for malnutrition had an average length of hospital stay up to twice as long as those without such risk factors. When early nutritional intervention was offered to those at risk, the average length of stay and accompanying health care costs were reduced by 10–30% (14). A Cochrane review of the literature on food supplements has shown that supplementation produces a small but consistent weight gain in older people. Mortality may be reduced in older people who are undernourished and are given food supplements and there may also be a beneficial effect on complications, which needs to be confirmed. However, in this review no evidence was found for an improvement in functional benefit or a reduction in length of hospital stay with supplements (15).

Results of intervention trials in the community indicate that older adults can benefit from nutritional support through the improvement of both nutritional status and biochemical measurements (15–20). While most previous studies have utilized nutritional supplements (as a drink or pudding) as the main intervention strategy (18–20), few have used other approaches. Different strategies include food delivery services, bulk food services, and a home-like dining environment, most of which show positive effects on the older adults' nutritional and health status, particularly among high mal-nutritional risk older adults (18–20). Dietary treatment by a dietitian has been found to be more promising than when delivered by other professionals. A study done in Australia on people receiving treatment for depression and anxiety in general practice settings has shown promising results from diet and exercise assessments and interventions by dietitians and physical activity specialists (21–23). Only a few randomized clinical trials have used comprehensive nutritional intervention approaches, rather than using food supplements as the basis of the intervention (19). Programs such as "meals on wheels", which focus on improving dietary quality and availability, found a positive impact on the dietary intake and health quality of the older adults who took part in the project, compared with those who did not (21). However, despite the positive results of these studies, most were lacking an individualized approach (24–26). Research has shown such an approach to be effective among

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diabetic patients (27) as well as those receiving hemodialysis (28). Given the heterogeneity of the older adult population in terms of health status and food preferences, it was hypothesized that an individualized approach would be particularly effective in this group.

Very few strategies have aimed at improving the quality and the quantity of the food consumed by older adults (29). Our aim was to test a newly developed nutritional intervention led by a clinical dietitian and to compare outcomes with a standard care intervention led by a family physician, as well as a group of untreated participants.

Methods

The study was a partially randomized clinical trial comparing the effectiveness of two modes of nutritional intervention for community dwelling older adults at nutritional risk (older adults patients with a total serum cholesterol of <160 mg/dL, or a serum albumin level of <3.5 mg/dL, or a total lymphocyte count of <1800, as determined by standard testing methods at the Maccabi Central Chemistry Lab.).

The study protocol was approved by the ethics committee of Maccabi Health Services and an informed, signed consent form was obtained from all participants.

Study Participants

Using a computerized database system, 800 community-dwelling patients aged 75 or over at nutritional risk were identified from two districts, the North (Haifa) and Sharon (Petach-Tikva) districts of Maccabi Healthcare Services, the second largest Health care services (HMS) in Israel. Exclusion criteria included a diagnosis of cancer or liver disease, clinical depression, cognitive impairment (MMSE<23), and inability or unwillingness to sign an informed consent.

Screening

The screening process was performed in two stages:

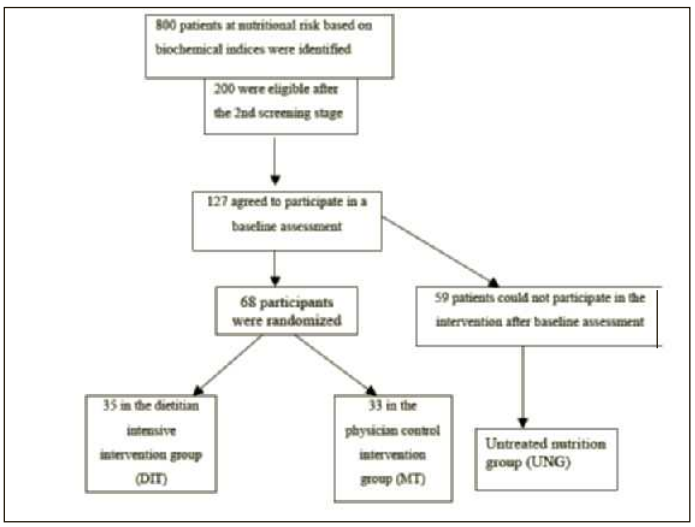
1. Using the criteria developed by Fogt et al. (30), we identified older adult patients with a total serum cholesterol of <160 mg/dL, a serum albumin level of <3.5 mg/dL, or a total lymphocyte count of <1800, as determined by standard testing methods at the Maccabi Central Chemistry Lab.

2. For patients found to be at nutritional risk, the short version of the Mini Nutritional Assessment (MNA-sf) was performed by phone, and data were collected regarding weight loss in the previous six months. The MNA-sf shows prognostic relevance with regard to functionality, morbidity, and mortality of the older adults in different settings (31). Those with an MNA-sf score of <10 (32) or those who had lost more than 10% of their body weight in the last six months were invited to participate in the study. Of the 800 subjects identified in the first stage, 200 were eligible after the second screening stage, and 127 agreed to participate in the study (1).

Allocation to the study groups (Figure 1)

Out of 200 eligible participants, 127 agreed to participate in the study (participation rate of 64%). From the 127 eligible participants, 68 were randomly assigned to either an intensive nutritional intervention led by a dietitian (DIT=Dietetic Intervention Treatment) or a control treatment group (MT=Medical Treatment) led by a physician. The other 59 subjects were not included in the randomization process following baseline assessment, due to communication and language difficulties or unwillingness to have home visits by a dietitian. Since the other 59 eligible participants agreed to be evaluated, they were included as an additional non-randomized "untreated nutrition" group (UNG). At the time of the study, dietary assessment was not performed as part of the geriatric assessment of older patients, thus no routine dietary treatment was offered as standard care.

Figure 1
Study allocation procedure



Study procedure

A letter was sent by the research staff to the primary care physician of each patient, notifying him or her about the patient's nutritional status and inviting him or her to participate in the study. Follow-up assessment was performed at six months for all patients as part of a home medical visit. The patients' biochemical and anthropometric measurements included weight, height, and blood tests (total cholesterol, albumin, total lymphocyte count), which were obtained at baseline and after 6 months.

Outcomes

All outcomes except demographic data were assessed at baseline and after 6 months by trained interviewers and included the following measurements:

Demographic and social characteristics: Data were collected on various demographic characteristics, including sex, age,

place of birth, date of immigration, education, and number of children (in Israel they are most commonly the caregivers). Demographic data were collected at baseline only.

Nutritional assessment: Nutritional status was assessed using three methods:

1. Mini Nutritional Assessment (MNA) (31, 32): The full MNA was completed by the interviewer (a clinical dietitian). The MNA is composed of 18 items, including anthropometrical measurements (weight, height, and weight loss); a global assessment (lifestyle, medication, and mobility); a dietary assessment (number of meals, food and fluid intake); and a subjective assessment (self-perception of health and nutrition). The MNA score was used to classify patients as well-nourished (a score of 24–30) or at risk for malnutrition (a score of <24).

2. Biochemical measurements: included serum albumin, hemoglobin, cholesterol, and total lymphocyte count (TLC).

3. Food Frequency Questionnaire (FFQ): This questionnaire on dietary intake was developed and validated for use in the older adult population in Israel at the S. Daniel Abraham International Center for Health and Nutrition (33). The questionnaire includes 126 items and portion sizes, adapted for older adults. Data were assessed at both baseline and after 6 months (33).

Biochemical measurements: Blood samples were drawn at baseline. The tests included serum albumin, cholesterol, and total lymphocyte count. All analyses were performed at the Maccabi Health Services Central Laboratory.

Cost of services used was measured as the cost of services used by each patient including: 1) number of patient visits to primary care physicians; 2) number of patient visits to medical specialists; 3) number of hospital admissions; and 4) use of medications (quantity and cost of chronic prescribed and purchased medications). Data were obtained from the computerized medical system of Maccabi Healthcare Services for the study period and were calculated using their standard cost for the Maccabi Healthcare Services (HMS) to show the connections between nutritional status and cost for HMS.

Gerontological assessments: Collected at baseline and at 6 months, and included the following measurements:

a. Cognitive status: Using the Folstein Mini Mental State Examination (MMSE) (34) with a score of 0–30, where 30 indicates better cognitive function.

b. Depression score: Using the GDS-sf (Geriatric Depression Screening Scale) (35), which consists of a series of 15 questions in a simple yes/no format. A score greater than 5 indicates depression.

c. Functional status: Using the modified Barthel Index (36), based on basic activities of daily living (ADL). The score ranges from 0 to 100, where 0 represents being totally dependent and 100 being totally independent.

All the questionnaires are validated for use by the Israeli population and have already been used in another study (10).

The intervention protocol: Dietary intensive treatment (DIT)

The nutritional intervention program (DIT) (N=35) was based on the recommendations of the Nutrition Screening Initiative (NSI), a project of the American Academy of Family Physicians, the American Dietetic Association, and the National Council of Aging (37). The dietary intervention protocol is summarized in Table 1. Each case was managed by the study dietitian, who was in charge of the dietary treatment as well as communication with other health care providers. The individualized treatment strategy for each patient was designed by the dietitian, who was the case manager, according to the patient's medical and nutritional characteristics. Thus, the intensity of the intervention varied according to the severity of the under-nutrition, as determined by the assessment of specific nutritional problems (e.g., swallowing). Each patient had five nutritional treatment meetings with the dietitian in the clinic or in their homes, as needed.

Table 1
Dietary intervention protocol for the intensive treatment group*

Visit	Activity
First visit	1. Nutritional assessment 2. Nutritional tailored treatment
Second visit – after two weeks	1. Food supplements, if needed 2. Information regarding centers for subsidized prepared food, if needed
Third and fourth visits – after a month for each	1. Evaluation of dietary intake 2. Recommendation for improving consumption with the goal of increasing quantity and quality of dietary intake
Fifth visit –six months from the initial visit	1. Evaluation of dietary intake 2. Adjust recommendations according to the patient's nutritional status and personal requests

*The nutritional treatment was provided for the patient and if needed, also for an immediate relative or formal caregiver

During the first visit, a thorough nutritional assessment was performed. The assessment included current dietary intake and specific nutritional problems that decreased dietary intake, such as nausea, vomiting, and chewing problems. In addition, food preferences and appetite status were determined. Based on this evaluation, an individualized nutritional treatment was designed for each patient.

During the second visit, the patients received instructions on the availability of food supplements, as well as information regarding centers for subsidized cooked food, if required. Family members or first-contact caregivers were also instructed, as necessary. During the next two visits, the dietitian evaluated the dietary intake of the patients and made changes according to the treatment protocol. During the last visit, patients, as well as their caregivers, received instructions on how to follow the recommended diet (Table 1). The first two visits lasted for 45 minutes and other visits lasted for 30 minutes.

Medical treatment (MT)

The medical treatment was performed by the primary care physician. This group (N=33) received treatment from the primary care physician as well as a booklet on nutrition education for older adults, written in both Hebrew and Russian. The booklet was prepared for the purpose of patient education for this study and included information regarding the nutritional needs of older adults.

Untreated nutrition group (UNG)

The untreated nutrition group (N=59) received the standard care of the HMS. The standard care at the time of the study did not include any routine nutritional assessment or treatment. The group was assessed for changes over time.

Statistical analysis and sample size calculations

Sample size calculation was based on previous studies assessing the effect of supplements on nutritional status. Change in weight (38) was used as key outcome and Kahn's method (39) was used for the calculation. The largest sample size calculation was based on weight change, based on α=.05 (2 sided), β=.20, SD=1.54. The reported minimal differences in weight following an intervention (19) were 0.85 kg, between the intervention and control groups. Therefore, using this extremely conservative estimate, sample size was estimated at 51 patients in each group. According to this calculation, the sample size of the MT group is too small and thus we may not be able to detect a significant difference between the groups. Statistical analysis was performed using SPSS version 14. Continuous variables were examined using ANOVA to compare the differences in outcomes between the groups. The changes over time were determined using repeated measure ANOVA with the appropriate covariates in the models. Dietary data were analyzed at the S. Daniel Abraham International Center for Health and Nutrition at Ben-Gurion University and results were compared to the DRI (Dietary Recommended Indexes) and between the study groups.

Results

At baseline, no differences were found between the three groups in age, number of children, or BMI. However, a trend for higher education emerged in the DIT (11.4 in the DIT, 9.6 in the MT, and 9.2 in the UNG; Table 2). After six months, no difference was shown in the number of diagnoses, number of prescribed medications, or physical functioning. However, there was a significant improvement in the depression scores among the DIT group compared with the other two groups (5.4 vs. more than 6.0, respectively) after six months of intensive intervention and follow-up. The same trend was evident in the cognitive function scores, with comparisons between both the DIT and MT groups and the DIT and UNG groups yielding statistically significant differences (changes in the health status of the patients are shown in Table 3). All the calculated data were assessed at baseline and after 6 months.

Table 2
Characteristics of the study population by treatment group

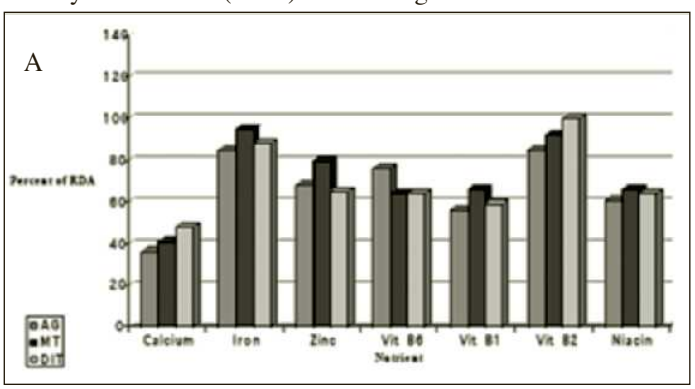
P Value	UNG* N=33	MT* N=35	DIT* N=59	
0.95	37%	36%	40%	Sex, male %
0.80	84.7±4.7	84.2±6.0	84.5±5.6	Age, mean±SD
0.96	27.0±5.2	27.3±5.0	27.4±5.2	BMI, mean±SD
0.33	2.4±1.2	1.9±0.1	2.5±2.6	Number of children, mean±SD
0.20	11.4±4.2	9.6±2.8	9.1±5.3	Years of education, mean±SD
0.35	18%	22%	26%	Albumin <3.5 mg/dL (%)
0.37	58%	64%	63%	Total lymphocyte count <1800 (%)
0.50	56%	40%	42%	Total cholesterol <160 mg/dL (%)

DIT – Dietitian care, MT – Medical care, UNG – Untreated nutrition group

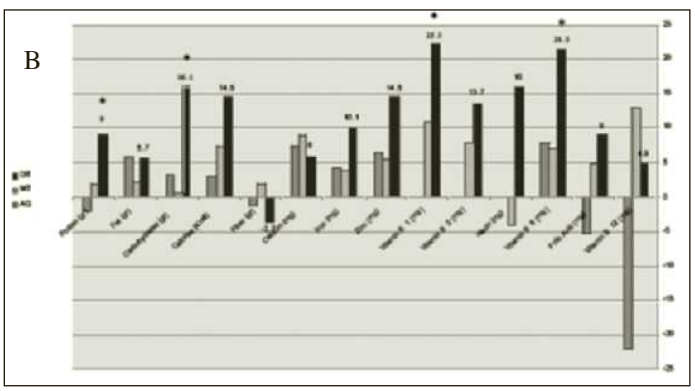
The baseline data of dietary intake as a percent of the Recommended Dietary Allowances (RDA) are presented in Figure 2a. As shown, most of our participants suffered from low dietary intake of several nutrients including calcium, zinc, and B vitamins.

Figure 2
Dietary intake

a) Dietary intake at baseline as percent of the Recommended Dietary Allowances (RDA) for older age



b) Percent change in dietary intake of selected nutrients from baseline and after 6 months by group of intervention



*p<0.05

Table 3
Health status characteristics of the participants at baseline (Time 0) and after 6 months (Time 6) by treatment group

Health status mediator	DIT Time 0	DIT Time 6	MT Time 0	MT Time 6	UNG Time 0	UNG Time 6	P-value #
No. diagnoses	2.4±1.4	2.7±1.4	3.6±2.-5	3.8±2.5	4.2±1.8	4.0±1.8	0.8
No. medications	6.9±2.2	6.3±2.8	6.0±3.2	5.9±3.0	5.2±2.6	5.0±2.3	0.8
Physical functioning score	87.3±12.4	86.9±10.1	95.1±9.5	94.9±9.0	96.1±9.9	95.1±9.2	0.4
Depression score	7.3±3.9	5.4±3.9	6.0±4.0	6.3±4.0	6.8±6.4	6.6±5.9	0.04*
Cognitive function score-MMSE score	25.8±4.5	26.8±4.0	27.0±3.4	27.3±3.8	27.6±3.0	28.0±3.3	0.04*

P-value represents the results of an ANOVA test of the change from baseline in each parameter

After 6 months, a significant improvement in dietary intake was shown in the DIT intervention group compared with the other two groups. The change in dietary intake of protein, carbohydrates, vitamin B1 (thiamine), vitamin B2 (riboflavin), and B6 (pyridoxine) was significantly larger in the DIT group than in the MT and UNG groups after six months of intensive nutritional intervention. A trend of increased intake in other nutrients was also found in other B vitamins, zinc, and iron, reflecting improved diet quality compared with baseline (see Table 2b).

Table 4
Cost of services used (in U.S. dollars during 6 months of follow-up, adjusted for age, functional status and gender)

	DIT Mean±SD	MT Mean±SD	UNG Mean±SD	P-value
Cost of patient visits to primary care physicians	173.2±232.0	420.4±368.0	429.1±382.3	0.005
Cost of patient visits to medical specialists	65.5±155.0	325.5±617.7	324.7±354.9	0.03
Cost of hospital admissions	1112.6±1296.0	1675.6±2203.0	1555.2±2730	0.15
Cost of medications	1660.3±1010.0	2187.4±2809.1	2192.3±1905.2	0.49

Health care use during the six-month study period was compared between the groups. As shown in Table 4, the costs of primary care physician visits ($173.2±232 for the DIT group vs. $420.4±368.0 for the MT group and $429.1±382.3 for the UNG group), and specialist visits ($65.5±155 for the DIT group vs. $325.6±617.7 for the MT group and $324.7±354.9 for the UNG group) were significantly lower in the DIT group compared with the MT and UNG groups. A trend of decreased cost in hospital admissions and prescribed medications can be seen as well, although these differences did not reach statistical significance.

Discussion

This study is the first intervention trial of its kind among community dwelling older adults in Israel in a health provider setting (Maccabi Health Services). The results of the study indicate that intensive dietary intervention led by a registered dietitian yields significant improvement in cognitive function, depressive symptoms, diet quality, and health care outcomes and economy.

While the impact of nutritional intervention as well as the best intervention model for this age group are still debatable, there are some studies showing that nutrition education in the community can help improve food consumption and the quality of food in short and longitudinal studies with health impacts such as blood pressure and pulse, and also in daily food consumption (39–41).

Short-term studies on the use of nutritional supplements have found them to be effective for weight gain and improving functional abilities (42–46). One study conducted in England with malnourished community dwelling older adults showed that eight weeks of nutritional supplementation improved nutritional status from baseline to week 24 in the intervention group, but not in the control group ($p<0.05$). Likewise, in another randomized controlled trial examining the effects of oral nutritional supplementation on the undernourished older adult population, the intervention group showed a greater improvement in muscle strength compared with the control group (13.9% vs. 7.2%, respectively) (17). However, in these studies nutritional supplements were used as the exclusive nutritional treatment, as part of the medical treatment. In our individualized nutritional treatment, nutritional supplements were used to enrich the dietary regimen that was based on foods. In this way the experience of the treatment was more enjoyable and thus we believe will be easier to follow for longer periods. Additionally, individualized treatment will best meet participants' lifestyle and food preferences. Due to the variety of nutritional needs and preferences of elderly patients, it was hypothesized that the individualized approach can be adapted and provide beneficial outcomes for this group.

In the current study, guided dietary treatment based on food was found to be effective in improving health and nutritional status. Over the course of five visits, patients and their families received guidance on how to improve the quality of their diet by getting subsidized prepared meals from the local municipality or voluntary organizations, or by making easy and healthy meals at home. Since the main aim of the study was to try to allow for the continuation of the routine life of the older adults and to keep their appetite for natural foods by building a nutritional protocol based on food and keeping their social

nutritional habits, only in some cases were food supplements such as "Ensure" and "Ensure Plus" added to patients' diets. The study participants enjoyed the dietitian intervention and were anticipating each of her visits. The Israeli health law includes malnutrition treatment and home care treatment by a dietitian, so the cost is covered by the HMS.

Despite differences in intervention strategy, the results of our model of intervention are in accordance with those of previous studies, with improvements found in nutritional status and dietary intake (particularly in the consumption of carbohydrates, protein, vitamin B1, and vitamin B12), as well as in cognitive and functional indicators among the group receiving intensive dietary intervention led by a registered dietitian, compared with the standard care group led by a primary care physician. Intensive dietary intervention was also found to be moderately effective in lowering the length of hospitalization and the quantity of prescribed medications, compared with the other treatment strategies that did not have a significant effect (10). Future studies with larger sample sizes are warranted in order to evaluate the full impact of this model of nutritional intervention.

One of the screening criteria for the current study was recent weight loss of over 10% of body weight. This criterion was used in an English study, which showed that low BMI (<20) was associated with higher rates of both hospital admission and mortality (38). Among older adults, other studies have shown increased mobility limitation and mortality among older adults who lost weight (43–51). Our findings are in accordance with these studies, indicating that patients with a recent weight loss and impaired blood tests have lower cognitive scores and higher depression rates.

The current study merits a discussion of its limitations. First, it was only partially randomized; due to the real life situation of study participants, many who wanted to participate could not actually take part in the intervention process and therefore could not be randomized into the intervention and the control groups. This design flaw may also be viewed as strength, with the current study having used older adult patients and real data. This group of people was used as an untreated nutritional group and the collection of data over time was still successful. The short follow-up period of 6 months can also be seen as a limitation. Theoretically, a longer time period should be used to evaluate the impact of the intervention on aging indicators and health care use. Nonetheless, this study serves as a pilot observation for future, longer term nutritional intervention studies among older adults. Another limitation of our study is the relatively small sample size, which could have limited our ability to reject H0 no differences between the groups. We thus recommend conducting a larger study based on our model of intervention and encouraging preliminary results.

Conclusion

Proper nutrition can promote healthy aging by preventing disease and disability; improving health outcomes, cognitive function and depressive symptoms; and maintaining autonomy, all of which may result in decreased health care service utilization and lowered costs of care for this vulnerable population. The consequences of malnutrition are broad-ranging and increase the length of hospital stays while decreasing the chances of successful treatment outcomes, ultimately affecting quality of life (depression and cognition), as well as morbidity and mortality rates. Failure to acknowledge the risks of malnutrition can seriously impact morbidity, quality of life (depression and cognition), and mortality rates in the older adult population.

The management of malnutrition requires the use of appropriate screening tools to identify older adults at nutritional risk, and initial assessments of the older adults in the community should include information on physical and psychological health, functional ability, socio-environmental factors, and nutrition. Referral to a registered dietitian is recommended to provide personally tailored dietary advice and intensive nutritional treatment for this unique population.

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Author Contributions: R Endevelt and DR Shahar conceptualized the idea, analyzed the data, and wrote the first draft of the manuscript. J Lamberger and Y Bregman contributed to the conceptualization of the idea, interpreted the data, and contributed to drafts of the manuscript. G Kawen, I Berger-Fecht, and H Lander were in charge of the intervention and data collection. T Karpati was in charge of the financial calculations.

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