Nutrition Intervention for Cardiovascular Disease: Home-Delivered MNT and DASH Meals

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The IOM (2000) has recommended medical nutrition therapy (MNT) for promoting the health of older individuals with various chronic illnesses, including cardiovascular disease. 

What is Medical Nutrition Therapy? (Gehling, 2001; Michael, 2001; Rezabek, 2001)

- Medical nutrition therapy (MNT) is a set of steps, developed through a consultative process by a Registered Dietitian (RD), which incorporates current professional knowledge and research, and clearly defines the level, content, and frequency of nutrition care that is appropriate for a disease or medical condition. MNT is a multi-session intervention that is generally far more intensive, diagnosis-specific, and behavior-oriented than traditional nutrition counseling.

MNT has been recommended as the initial intervention for many chronic diseases, such as hypertension and hyperlipidemia (ADA, 2003) and the best option of treatment for most individuals with hyperlipidemia (Baron, 2005).
Background

- MNT has been found to lower serum total cholesterol and LDL levels among those with high cholesterol (Delahanty et al., 2001; Delahanty et al., 2002; Lim et al., 2008; Sikand et al., 2000).
- In 2000, Congress made Registered Dietitians eligible providers of MNT under Medicare, but only for patients with renal disease and diabetes, where the evidence of effectiveness was particularly robust (Franz et al., 2008).
- A recent literature review of nutrition services found that MNT was a cost-effective way to reduce serum cholesterol levels but found little support for the cost-effectiveness of MNT for elevated blood pressure levels (Pavlovich et al., 2004). However, the RCTs identified were not restricted to older adults, many studies included only intervention related costs, and outcome measures varied across studies.
Background

- Therapeutically designed meals may be an adjunct to medical nutrition therapy or provide a separate means of managing disease.
- **Therapeutic meals** are meals that are designed in accordance with dietary guidelines in an effort to assist in disease management through dietary modification.
- The *Dietary Approaches to Stop Hypertension* (DASH) diet, in particular, has been found effective for reducing blood pressure through lifestyle and nutrition intake changes (Appel et al., 1997; Blumenthal et al., 2008; Dickinson et al., 2006; Elmer et al., 2006; Lin et al., 2007; Sacks et al. 2001).
Background

• The DASH diet is designed to reduce intake of saturated fat, total fat, sodium, and cholesterol; increase intake of fruits and vegetables; and increase consumption of potassium, calcium, magnesium, fiber, and protein.

• Adherence to DASH diet guidelines is a key component to controlling blood pressure as recommended by the Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure.

• However, population based rates of adherence to DASH guidelines have been declining among individuals with hypertension (Mellen et al., 2008).

• Cost-effectiveness of therapeutic meals is important to the Administration on Aging, which funds meal programs for older adults.
  – <50% of all congregate meal sites and <33% of home-delivered meal programs offer modified or therapeutic meals.
Key Contributions

• As the Aging Network continues to target vulnerable populations, there will be increasing interest in extending services to targeted older populations by seeking alternative funding, such as Medicare for MNT, and providing therapeutic meals to vulnerable elderly individuals with chronic diagnoses.

• In the context of a 52-week clinical trial, we considered the effect of MNT and therapeutic meals provided to community dwelling older adults (aged 60+) diagnosed with hyperlipidemia and/or hypertension on changes in dietary adherence to a DASH diet and changes in dietary knowledge.

• We also considered the cost-effectiveness of both MNT and therapeutic meals using a societal perspective for costs and QALYs as the outcome.

• To our knowledge, there have been no other controlled, randomized clinical trials of MNT and therapeutic meals for seniors who are diagnosed with hyperlipidemia or hypertension, where extensive data has been collected on dietary intake, health outcomes, and costs.
Clinical Trial Design

Participant
Cardiovascular Study

- Literature
  Medical brochures regarding participant’s diagnoses
  12 months

- Meals
  7 frozen therapeutic meals delivered weekly
  12 months

- MNT
  3 personalized MNT sessions
  12 months

- MNT and Meals
  7 frozen meals and 3 MNT visits
  12 Months

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Participants were placed in ONE of four Groups at Random: Reduce Your Risk: The Diet/blood Pressure Connection, Copyright 2000 National Dairy Council and Milk Processor Education Program; DASH to the Diet, adapted with permission from the Idaho Dairy Council and Dairy Council of Arizona, Copyright 2000 National Dairy Council.

High blood pressure, or hypertension, is one of the leading causes of stroke, heart disease, kidney failure and premature death in this country. Yet a third of the 50 million Americans who have it don’t know it. If you have high blood pressure or if you have a family history of cardiovascular disease, here’s some good news on how to help reduce your risk of this “silent killer.”

New research indicates that a simple shift in eating habits can dramatically lower your risk of developing high blood pressure. And if your blood pressure is already high, this eating plan can help bring it down—often as much as drug treatment in some people.

The eating plan is called the Dietary Approaches to Stop Hypertension (DASH) Diet. It’s rich in fruits, vegetables, low-fat dairy, and lean meats and fish. The diet is high in calcium, potassium, magnesium, and fiber, and moderately high in protein. And it is similar to the eating plans outlined in the USDA Food Guide Pyramid and recommended by leading health professional organizations like the American Heart Association and National Cancer Institute.

The best part is, it’s available in your local grocery store. No exotic foods, pills or potions.

But it does mean you need to reach for at least 3 to 5 servings of low-fat milk each day (which is the current recommendation), and boost fruits and vegetables to 1 to 10 daily servings—which is about twice the current recommendation.

The results can be dramatic. In fact, the researchers believe the DASH diet may be as effective as drug therapy for some people with mild hypertension. It may be safer and less expensive than medications. The eating plan has been helpful for men and women of all ages and ethnic backgrounds, and even in helping kids who are overweight. But government guidelines stress the DASH diet in the latest recommendations for preventing and treating high blood pressure. It’s the first time these guidelines have included specific food recommendations.
Inclusion Criteria

• General Inclusion Criteria:
  1. Must be 60 years of age or older
  2. Must live in Mecklenburg County, NC
  3. Must have a diagnosis of high blood pressure (hypertension) or high cholesterol (hyperlipidemia)
  4. Be able to communicate in English
Exclusion Criteria

• **Key Exclusion Criteria:**
  1. Coronary artery bypass, diabetes, myocardial infarction within the 12 months prior to enrollment
  2. Renal insufficiency
  3. Major surgery in the 12 weeks prior to enrollment
  4. Unstable angina, uncompensated congestive heart failure, liver disease, pancreatic disease, current serious gastrointestinal disease (for example, colitis), or current cancer or other life-limiting diagnoses

• **We did NOT exclude:**
  1. Individuals taking medications to manage blood pressure or cholesterol
  2. Individuals with normal cholesterol and/or blood pressure levels
Study Participants

- Data collection at baseline, 6 months, 12 months
- A total of 321 eligible people were enrolled and assigned to one of the four study arms.
  - 23 withdrew and did not permit us to continue all data collection
  - 298 participants in the analysis either
    - completed their term on the trial (267)
    - or ended the intervention but permitted us to continue to collect data (31)
Study Participant Characteristics

- 61% white
- 83% women
- 57% had income > 165% of the poverty level
- 52% had both hypertension and hyperlipidemia
  - 28% had only hypertension
  - 20% had only hyperlipidemia
- 80% were taking medications to manage their hypertension or hyperlipidemia
Question #1: Do home-delivered DASH meals change adherence to a DASH diet?

Motivation: Provision of therapeutically designed meals should affect the overall diets of older adults.

– Change might not occur if consumers feel like there is more room in their diet for unhealthy foods.

– Change might not occur if the individual feels they are managing their disease with medication.

Data Collection

• The DASH diet consists of dietary recommendations for 9 nutrients (protein, total fat, saturated fat, cholesterol, fiber, magnesium, calcium, potassium, and sodium).

• Meeting a nutrition target added 1 point to the overall DASH score with a total possible individual score of 9. DASH accordance was defined as having a DASH score of >4.5.

• Meeting a nutrition target added 1 point to the intermediate DASH score and meeting the intermediate DASH target added 0.5 points to the intermediate DASH score. Intermediate DASH accordance was defined as having an intermediate DASH score of >4.5.

• We limit the sample to those who were NOT Intermediate DASH accordant at baseline to allow us to focus on individuals who are in need of dietary change (n = 210 out of 298 with complete data).
Results

• There was a significant increase in the percentage of participants who were intermediate DASH accordant and DASH accordant from baseline to 6 months among those who received therapeutic meals.

• Participants who received meals had a 20 percentage point higher probability of being intermediate DASH accordant at 6 months ($p = 0.001$) than did those who did not get therapeutic meals.
  – Gains in the probability of being intermediate DASH accordant were marginally higher for whites and higher-income individuals.

• There was less change between baseline and 12 months.

• When looking at the DASH score (continuous measure), non-whites who received meals had significant reductions in cholesterol intake and significant gains in intermediate DASH score and fiber intake when compared with non-whites who did not receive meals.
**Question #2: Does home-delivered MNT affect dietary knowledge and dietary change?**

Motivation: Provision of MNT should affect dietary knowledge. In turn, a higher level of dietary knowledge should affect and dietary behavior.

- Change in knowledge might not occur if MNT is ineffective.
- Change in diet might not occur if the individual feels they are managing their disease with medication or if they are not ready to change.

Data Collection

• Dietary knowledge
  – *Heart Disease and Food Selection Diet/lifestyle Knowledge Questionnaire*
  – 20 questions
  – Excluded those with a score of 18 or above

• Dietary adherence – continuous measures

• We limit the sample to those who were in the literature only or MNT only groups (n = 147 out of 298 with complete data).
Results

• Effect of MNT on Dietary Knowledge
  – No significant effect of MNT from baseline to 6 months.
  – From baseline to 12 months, on average, MNT recipients had a 1.88 point higher increase in the knowledge score (out of 20 points) than the control group.
  – The effects of MNT on knowledge gain are higher for those not living alone, for whites, for those with less than a high school diploma, and for those with incomes below the poverty level.

• Effect of Dietary Knowledge on Dietary Adherence to the DASH Diet
  – Few significant results and no positive change.
**Question #3: Are home-delivered MNT and DASH meals cost-effective?**

Motivation: MNT and Therapeutic meals are expensive to provide. Are the costs worth the gains in quantity and quality of life?

Data Collection

• Costs
  – We assessed the cost of MNT and therapeutic meals from a social perspective by obtaining data on all costs in three broad categories:
    • MNT administration
    • Therapeutic meal production and delivery
    • Participant-level medical costs, pharmaceutical, and personal assistance costs
      – Health care use was measured continuously over one year using a Healthcare Utilization Diary.
      – Average prices applied were used to get health care costs.
      – We considered both costs directly related to cardiovascular disease and costs that are indirectly related.
Data Collection

• Quality Adjusted Life Years (QALYs)
  – The SF-36 is a 36 item instrument that measures physical function, social function, role limitations, pain, vitality, mental health, and perceptions of general health.
  – The SF-6D utility index can be calculated from six of the eight dimensions addressed by the SF-36 (Brazier et al., 2002).
    • The utility index ranges from zero to one.
    • The index reflects how the general public values the health status that each participant reports.
Cost Effectiveness Analysis

- We used two related approaches to consider the cost-effectiveness of MNT and therapeutic meals: the incremental cost-effectiveness ratio (ICER) and the net monetary benefit (NMB) approach.
  - In our study, the ICER measures the added cost associated with each intervention relative to the added QALYs resulting from being in the intervention arm.
  - This tells us how much it costs for the intervention to generate a year of life at full health.

- If one is willing to place a value on a QALY, one can also use the NMB approach to estimate whether the costs for the intervention arm are less than the value of the gain in QALYs for those getting the intervention.
Cost-Effectiveness Results – Therapeutic Meals

Figure 1: Therapeutic Meals Cost Effectiveness Acceptability Curve

Cost-Effectiveness Results – Medical Nutrition Therapy

Figure 2: MNT Cost Effectiveness Acceptability Curve

Results

• Using a willingness to pay for a Quality Adjusted Life Year of $109,000 (Braithwaite et al., 2008) and considering intervention and medical costs directly related to cardiovascular disease, the probability that
  – Therapeutic meals are cost-effective is 95%
  – MNT is cost-effective is 90%
  – TM plus MNT is cost-effective is less than 50%
Recommendations

• Home-delivered DASH meals are likely to change adherence to a DASH diet in older adults with hypertension and/or hyperlipidemia.
  – Future research should consider the extent to which meal customization for those with multiple chronic conditions is viable and cost-effective.
  – Differential effects of meals by income should be explored.

• We find that home-delivered MNT does affect dietary knowledge but does not affect dietary change for older adults with hypertension and/or hyperlipidemia.
  – Future research should consider the dose-response relationship, the role that food insecurity plays in behavior change, and the benefits/costs of home-delivered MNT.
Recommendations

• Our cost-effectiveness findings suggest that Medicare should strongly consider paying for MNT for cardiovascular disease.
  – Our study includes a lot of costs of MNT that would likely be less if MNT were done in a “real world” setting.
  – Over 80% of our sample was taking one or more medications to manage their high blood pressure or high cholesterol.
  – The study uses only three MNT sessions (a small dose).
  – We use an intention-to-treat approach to the analysis.
  – If there are longer term positive effects, we did not capture them in this study.

• While expensive, therapeutic meals are clearly cost-effective.
  – An expansion of therapeutic meals programs may be warranted.
References


References


References


