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A Culture-Specific Nutrient Intake Assessment Instrument in Patients with Pulmonary Tuberculosis

Jennifer K. Frediani¹, Nestani Tukvadze², Ekaterina Sanikidze², Maia Kipiani², Gautam Hebbar³, Kirk A. Easley⁴, Neeta Shenvi⁴, Usha Ramakrishnan^{1,5}, Vin Tangpricha^{1,3}, Henry M. Blumberg^{5,6,7}, and Thomas R. Ziegler^{1,3}

¹Doctoral Program in Nutrition and Health Sciences, Graduate Division of Biological and Biomedical Sciences, Emory University, Atlanta, GA 30322

²National Center for Tuberculosis and Lung Disease, Tbilisi, Georgia

³Division of Endocrinology, Metabolism and Lipids, Department of Medicine, Emory University School of Medicine, Atlanta, GA 30322

⁴Department of Biostatistics and Bioinformatics, Emory University Rollins School of Public Health

⁵Hubert Department of Global Health, Emory University Rollins School of Public Health, Atlanta, GA 30322

⁶Division of Infectious Diseases, Department of Medicine, Emory University School of Medicine, Atlanta, GA 30303

⁷Department of Epidemiology, Emory University Rollins School of Public Health, Atlanta, GA 30322

Abstract

Background and Aim—To develop and evaluate a culture-specific nutrient intake assessment tool for use in adults with pulmonary tuberculosis (TB) in Tbilisi, Georgia.

Methods—We developed an instrument to measure food intake over 3 consecutive days using a questionnaire format. The tool was then compared to 24 hour food recalls. Food intake data from 31 subjects with TB were analyzed using the Nutrient Database System for Research (NDS-R) dietary analysis program. Paired t-tests, Pearson correlations and intraclass correlation coefficients

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*To whom correspondence should be addressed: Thomas R. Ziegler, Atlanta Clinical and Translational Science Institute, Suite GG-23, Emory University Hospital, 1364 Clifton Rd., Atlanta, GA 30322. Phone: (404) 727-7351 Fax: (404) 727-5563 tzieg01@emory.edu.

Statement of Authorship

JKF carried out study training, participated in development of the tool, conducted nutrient data analyses, and drafted the manuscript. NT participated in development of the tool and contributed to overall study organization in Tbilisi. ES and MK carried out the study in Tbilisi. GH participated in the design of the study, including the case report form, and overall study coordination. KAE and NS performed the statistical analysis. UR helped to conceive the study design. HMB and VT helped to conceive the study design and participated in overall design and coordination. TRZ helped to conceive the study, participated in overall design, coordination and development of the tool, and contributed to drafting the manuscript. All authors read and approved the final manuscript.

Conflict of Interest Statement

Jennifer K. Frediani, Nestani Tukvadze, Ekaterina Sanikidze, Maia Kipiani, Gautam Hebbar, Kirk A. Easley, Neeta Shenvi, Usha Ramakrishnan, Vin Tangpricha, Henry M. Blumberg and Thomas R. Ziegler have no conflicts of interest.

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(ICC) were used to assess the agreement between the two methods of dietary intake for calculated nutrient intakes.

Results—The Pearson correlation coefficient for mean daily caloric intake between the 2 methods was 0.37 ($P = 0.04$) with a mean difference of 171 kcal/day ($p = 0.34$). The ICC was 0.38 (95% CI: 0.03 to 0.64) suggesting the within-patient variability may be larger than between-patient variability. Results for mean daily intake of total fat, total carbohydrate, total protein, retinol, vitamins D and E, thiamine, calcium, sodium, iron, selenium, copper, and zinc between the two assessment methods were also similar.

Conclusions—This novel nutrient intake assessment tool provided quantitative nutrient intake data from TB patients. These pilot data can inform larger studies in similar populations.

Keywords

nutrition; diet; assessment; tuberculosis; micronutrient; macronutrient

Introduction

Tuberculosis (TB) is an enormous global health problem. In 2011, the World Health Organization (WHO) estimated that there were 8.7 million new cases of TB and 1.4 million deaths attributable to TB disease, with the overwhelming majority of cases occurring in low- and middle-income countries¹. The country of Georgia, a former Soviet republic, has been designated by the World Health Organization (WHO) as a one of 27 high-burden countries for multidrug-resistant (MDR)-TB. The annual incidence rate of TB in Georgia exceeds 100 cases per 100,000².

Malnutrition is a risk factor for the development of TB disease. The link between nutritional status and TB has long been appreciated, but remains an emerging area of study that has focused on investigations of related biomarkers and nutrient supplementation trials. A recent Cochrane review on the quality of evidence of trials on nutrient supplementation in TB concluded there is insufficient evidence to determine whether an increase in energy intake improves patient outcomes; further, rigorous research on the clinical impact of various strategies for micronutrient supplementation in patients with TB was found to be limited³. Surprisingly little data are available in the literature on habitual macronutrient and micronutrient intake in patients with TB. One study from Singapore focused on energy intake in TB patients using the 24-hr recall method⁴. In a pilot study in patients with pulmonary TB in Tbilisi, Georgia (using the nutrient intake assessment tool described in detail in this report), we estimated that vitamin D intake from diet was markedly lower than the Recommended Dietary Allowance (RDA) for this micronutrient, concomitant with a high prevalence of vitamin D insufficiency (low plasma 25 hydroxyvitamin D concentrations) in this patient population⁵.

Accurate dietary intake data is historically difficult to obtain and continues to be particularly problematic in subjects studied in the developing world due to lack of training and resources, logistical issues and lack of validated nutrient content of certain food items. Several studies have been conducted involving the validity of self-administered food frequency questionnaires (FFQ) in various populations of patients without TB, but involve the validation of only a few macro- or micronutrients^{6–14}. These studies used a variety of validating instruments, including nutrition-related biomarkers⁷, three day food records⁸, serial 24-hour recalls¹⁰, and use of food journal data in comparison to specific FFQs^{11–14}. The study of Schroder et al, in a Spanish population, was the only investigation that validated both a FFQ and a structured 72-hour recall using three-day food records⁹.

The purpose of this study focused on the development of a novel instrument to serially estimate micronutrient and macronutrient intake data from a generally low income, non-English speaking, Georgian population via a structured interview process administered by trained personnel. We also sought to assess the validity of this structured 72-hour recall tool in a specific population—namely patients with pulmonary TB in Tbilisi, Georgia. The tool was developed as a component of a current double-blind, randomized, controlled study assessing the efficacy of high-dose vitamin D treatment to enhance *Mycobacterium tuberculosis* clearance in patients with pulmonary TB in Tbilisi, Georgia (clinicaltrials.gov identifier NCT00918086)⁵.

METHODS

Study Subjects

Subjects were recruited from the Georgian National Center for Tuberculosis and Lung Diseases (NCTBLD) and the Tbilisi Ftizio-Pulmonologic Center (an outpatient TB clinic) in Tbilisi, Georgia. The inclusion criteria included age ≥ 18 years, documented new case of smear-positive pulmonary TB, ≥ 1 week of anti-TB therapy, agreement to receive anti-TB therapy in Tbilisi, completion of the 72-hour recall instrument at baseline (week 1) and the serial 24-hr recalls during week 2, and a signed informed consent. Exclusion criteria included > 30 days of TB therapy, current pregnancy or lactation status, history of organ transplant, cancer during the previous 5 years, seizure disorder, cirrhosis, hypercalcemia, hyperparathyroidism, sarcoidosis, or nephrolithiasis, use of oral corticosteroids during the past 30 days, current use of cytotoxic or immunosuppressive drugs, current significant renal dysfunction (serum creatinine concentration >250 mmol/L), requirement for dialysis therapy, current incarceration, markedly elevated week 1 mean daily caloric intake (defined *prehoc* as mean daily caloric intake of > 6000 kcal/day) and inability to complete all study visits in Tbilisi. The Institutional Review Boards from Emory University in Atlanta, USA and the NCTBLD Ethics Committee in Tbilisi approved the study protocol. All subjects provided written informed consent in their native language for participation in the study.

Nutritional Assessment

The nutrition assessment instrument was developed to capture the mean daily micronutrient and macronutrient intake over the previous three-day period via face-to-face interviews by trained investigators (ES and MK; please see below). The dietary intake interviews were performed at baseline and again at the eight and sixteen-week time points, respectively, of the randomized clinical trial (RCT). The instrument was designed prior to initiation of the RCT to assess nutrient intake in a low socioeconomic status, non-English speaking adult population. During the instrument developmental phase, we initially explored typical foods and meal patterns of adult Georgians by face-to-face and email discussions between the Georgian- and United States (U.S.)-based investigators involved in the RCT. The instrument was designed to follow principles routinely utilized by nutritionists and dietitians in standardized food record intake forms. In addition, food items (including beverages and snacks) consumed commonly in Georgian culture and typical recipes for these were included in the questionnaire as prompts. For example, Table 1 outlines details of the questions for typically consumed tea and soup, respectively. A free text comment section at the end of the questionnaire was added to allow for additional details regarding recipes.

The Georgian-based physician investigators (ES, MK) were extensively trained prior to the initiation of the RCT by the registered dietitian investigator (JKF) on the interview process via video training uploads (YouTube), demonstrations with mock face-to-face interviews, a comprehensive training DVD, and regular live training sessions via Skype. TRZ also conducted face-to-face training sessions with the Georgian investigators on the specific

methodologies at the NCTBLD in Tbilisi during a study initiation visit prior to beginning the RCT. Standardized food models and common household measurement instruments were provided to the investigators in Tbilisi and used in the patient interviews to help to determine accurate serving sizes.

The Georgian language face-to-face interviews with TB patients were completed within 30–40 minutes at outpatient research visits; food and beverage intake during the previous 3 days was recalled and recorded in the case report form (CRF). The food intake data were then transcribed in English by the multilingual investigators into a web-based case report form (CRF) for review in the Bionutrition Unit of the Atlanta Clinical and Translational Science Institute (ACTSI) by the U.S.-based research dietitian investigator (JKF). Review of intake data for individual subjects took place within 1–3 days after data entry in Tbilisi and since all subjects returned to the two outpatient TB clinics on a daily basis for directly observed anti-tuberculosis drug therapy and vitamin D or placebo administration per standard clinical care guidelines and the RCT protocol. Communications between JKF in Atlanta and the interviewer investigators in Tbilisi to clarify any questions regarding the specific food intake item entries were discussed via email or Skype telephone conferences in real time. As needed, the Tbilisi-based investigators ES and MK then discussed the food items to be clarified with the specific study subjects in person during their daily visits. The clarified information was reported directly to JKF at the ACTSI via email or Skype calls during the Monday-Friday workweek.

Data were analyzed by JKF at the ACTSI using state-of-the-art dietary analysis software [Nutrition Data System for Research (NDSR), University of Minnesota, Minneapolis, MN]. Final calculations were completed using NDSR version 2011. The NDSR time-related database updates analytic data while maintaining nutrient profiles true to the version used for data collection. NDSR analyzes for specific quantities of over 160 different micronutrient and macronutrients and dietary compounds with well-described accuracy and completeness¹⁵. Mean daily intake was determined for each subject from the 3-day food recall questionnaire. Specific methods were used to enter the Georgian food items into the NDSR software program, which was developed for foods commonly consumed in the U.S. First, the format of the structured 3-day food recalls did not distinguish between different versions of the same food type. For example, beef was always entered as a trimmed sirloin if it was eaten on its own and as stew beef if consumed in a soup regardless of the cut of meat that was actually consumed. These assumptions were based on most common food servings given by the Georgian investigators during the development phase of the instrument. Some assumptions were also needed for food items that were specific to Georgian culture in order to find a similar item in the U.S.-based NDSR nutrient database. For example, “matsoni”, a concentrated yogurt food item, was entered as plain whole milk yogurt into the NDSR software. All milk intake was entered as a fresh whole milk to eliminate the extraneous micronutrients supplied by milk fortification in the U.S. captured by the NDSR database, but not present in the unfortified Georgian commercial milk supply.

Validation Methodology

The goal of the current study was to assess the validation of the nutrient intake assessment tool in a subset of the total of 199 subjects entered into the full RCT. During the course of the ongoing RCT and prior to data collection for this report, two U.S.-based investigators (JKF and TRZ) conducted additional face-to-face training sessions with the Georgian interviewer-investigators (ES and MK) in Tbilisi to standardize the conduct of typical 24 hour recalls. Expertise was validated by the registered dietitian investigator (JKF), who also gave guidance as needed throughout the validation data collection process. A convenience sample of 31 enrolled study subjects who completed both the 3-day food recall questionnaire at baseline and were able to also complete three consecutive face-to-face 24-hr recalls

during the following week. This proportion (31/199 or 16% of total study subjects) is in line with previous diet intake tool validation studies in which 10–20% of the total patient population was studied^{8–11}. This study was a pilot study and therefore a *prehoc* sample size calculation was not performed.

A series of three standardized and conventional 24-hour recalls was conducted in the 31 pulmonary TB subjects during the week following their baseline visit, at which the current assessment tool was previously completed. We chose to focus only on subjects following their baseline visit to reduce the potential “learning effect” of serial face-to-face interviews to provide recent food intake data. This format was utilized to capture 3 days of food intake data via both 24-hr recall and by the RCT assessment tool and to evaluate the impact of recalling foods eaten two and three days prior to the interview in the RCT tool.

Statistical Analysis

The differences between the food questionnaire and food record recall of each outcome were summarized by the mean difference (questionnaire – recall), the standard deviation (SD) of the differences, and the 95% agreement limits¹⁶. The differences between the 2 measurements and their mean for each outcome were summarized by use of scatterplots (Bland-Altman plots). A 1-sample paired t-test was used to compare the mean differences between the food questionnaire and food record recall measurements. The concordance correlation coefficient (CCC)¹⁷ was used to evaluate the degree to which pairs of observations fall on the 45° line through the origin. This coefficient ranges from zero (no agreement) to one (perfect agreement). The intra-class correlation coefficient (ICC) was also used as a measure of agreement and was estimated by variance components based on statistical modeling as described by Bartko¹⁸. The ICC is large (i.e., near 1) when there is little within-participant variation. All statistical analyses were carried out using SAS software, Version 9.3. (Cary, NC, USA).

Results

A total of 31 subjects were included in this study; demographic information for these individuals is shown in Table 2. Nineteen subjects (61%) were male and about half were unemployed and/or of low socioeconomic status (income < 3000 Georgian lari/yr, or \$1800 USD/yr). The mean and standard deviation of calculated daily intake of specific macronutrients and micronutrients (vitamins, minerals and trace elements) from both the 72-hr nutrient intake assessment tool and the paired three 24-hour recalls, with mean differences between the methods, the upper and lower 95% agreement limits and p values between the two methods are shown in Table 3. The p-value reflects the 1-sample paired t-test between the means of the intakes for each nutrient estimated by the new nutrient intake instrument and the conventional 24-hr recalls. There were no significant differences between assessment methods for estimated mean daily intakes of total calories, total fat, total carbohydrate, total protein, retinol, vitamins D and E, thiamine, calcium, sodium, iron, selenium, copper, and zinc. In contrast, mean daily intake for vitamin C and potassium were overestimated by the nutrient intake instrument by approximately 43 and 22%, respectively compared to the mean of the three 24-hr recalls (Table 3).

The ICC and Pearson R values for each nutrient contrasting the two intake assessment methods and the 95% confidence limits for these are illustrated in Figure 1. The Pearson correlation coefficient (R value) for mean daily caloric intake between the 2 dietary intake methods was 0.37 (P = 0.04). The mean difference for calories (nutrient intake tool minus 24 hour recall data) was 171 kcal/day and not significantly different from zero (p = 0.34). The ICC value was 0.38 (95% CI: 0.03 to 0.64) suggesting the within-patient variability may be larger than the between-patient variability (Figure 1). The ICC and Pearson R values for all

nutrients ranged from 0.13 to 0.46 and thus showed good agreement between the two nutrient intake assessment methods. The CCC for each nutrient was also calculated and did not differ from the ICC data (data not shown).

Discussion

There are very limited data on evaluation and comparison of multi-day food recalls in resource limited countries, such as Georgia, especially in adult populations with specific disease states. The majority of such studies published to date, including the few from industrialized countries, are related to FFQs and not specifically to multi-day food recalls, as we have done in Tbilisi. Studies validating FFQs, including reports by Ogawa et al¹² from rural Japan and Pandey et al¹³ from northern India, administered the FFQ on two separate occasions along with a three to five day food journal to compare nutrient intake to that calculated from the FFQs. These studies differed in the length of time between administering the validating questionnaires (e.g. from one month to one year later). In addition, there was no determined sample size in these reports which range from 23 participants in the northern Indian study¹³ to 138 participants in the Danish study of Biloft-Jensen et al¹⁴.

To our knowledge, our study provides the first such data from a patient population with TB and is also the first study from a former Soviet republic. Taken together, our data in this study provide confidence that the 3-day food recall questionnaire developed to assess serial macronutrient and micronutrient nutrient intake from adults living in Tbilisi, Georgia has utility and relative accuracy for this purpose. A limitation of our study, despite the comprehensive data obtained from two methods, was the relatively small sample size. Larger studies in this and other Georgian adult populations will be necessary to accurately estimate interrater and intrarater reliability.

Collecting reasonably accurate food intake data from specific populations is a difficult problem due to language, logistical and cultural barriers, including the translation of meaningful information between native investigators working in a low- resource country to investigators in the data coordinating center in a developed country^{6, 13}. In our case, Georgia does not have a professional discipline of dietetics or clinical nutrition in health professions education to help guide development of the tool we incorporated. Accurate food composition tables derived in Georgia are non-existent and compiling accurate tables is expensive, adding to the challenges of nutrient intake analysis. In this Georgia-U.S. collaboration, we utilized bilateral face-to-face instruction of the Georgian team of investigators with experienced U.S.-based clinical nutrition professionals and electronic tools in both the development of the data collection instrument and for methodological training prior to study initiation.

The steps we outline in this report could potentially be used to develop nutrient intake assessment tools in other low- or medium-resource countries without a developed capability for such studies. Low literacy populations may benefit from an interviewer process, as we incorporated here, whereas more educated populations may be able to self-report on a designated form that can be easily translated. A structured multiple-day recall format can be useful in remote populations where no previous method for nutrient intake exists. Utilizing classification techniques and dividing sample data into quartiles is one method to interpret such data. In our study, the interview method was developed to take advantage of the serial availability of subjects to the Georgian physician-investigators (who worked at the NCTBLD and were responsible for the TB care of the subjects) for daily directly observed anti-TB therapy per WHO protocols. We designed the nutrient intake assessment instrument questionnaire and study methods for a low-socioeconomic status and poorly educated patient

population. The method we used took advantage of an extensive, complete and well-established U.S.-based nutrient analysis software resource (NDSR) given the lack of such a database from Georgia.

Our method (a hybrid between a conventional 3-day dietary history and a face-to-face 24-recall method) may be superior to developing a new traditional (FFQ) in countries, such as Georgia, without a nutrient composition database of usual food items. This method allows the investigator to obtain information on several consecutive days of food intake in a concise, structured manner and can be done serially throughout a study. Data can be easily analyzed and interpreted, using a resource such as NDSR for relatively quantitative nutrient intake information. Although developing new FFQs for a particular population may be an important tool, these may be difficult to design and analyze initially due to their complex nature^{11–13}. For example, FFQ development requires previous data collection, often in the form of 24-hour recalls, in addition to cultural insight from in-country partners. FFQs are also considered semi-quantitative and nutrient values may not be directly related to outcomes^{11–13}. The instrument described in this report is analyzed exactly the same as a food record and can be utilized similarly.

A strength of our specific nutrient intake instrument is that it provided a picture of the habitual diet of a patient population within a previously little-studied culture in terms of dietary intake. The major limitation to this study, in addition to our small sample size, is that our method is novel and therefore there is little reference for comparison of accuracy, particularly given the lack of habitual dietary intake data available in healthy adult Georgians. On the other hand, more conventional methods were felt to not be feasible in the population with TB that we studied. In summary, the novel nutrient intake assessment tool described here appeared to provide accurate quantitative nutrient intake data from TB patients in Georgia. These pilot data can be used to inform larger studies of nutrient intake in Georgians and also to further assess agreement between dietary intake assessment methods in this population. Further, the approach we used could potentially be a model for development of other culture-specific nutrient intake assessment tools in other countries.

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Non-Standard Abbreviation

TB	Tuberculosis
NDS-R	Nutrient Database System for Research
ICC	Intraclass Correlation Coefficient
MDR	Multi-drug resistant tuberculosis
FFQ	Food frequency questionnaire
NCTBLD	Georgian National Center for Tuberculosis and Lung Diseases
RCT	Randomized clinical trial
CRF	Case report form

ACTSI Atlanta Clinical and Translational Science Institute
CCC Concordance correlation coefficient

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Figure 1. Intraclass correlation coefficient (ICC) and Pearson R estimate with 95% confidence levels for mean of three 24-hr dietary recalls compared to 72-hr questionnaire method

Table 1

Example questions in Georgian food intake instrument

Q2. How many glasses of tea did you have? ___ ___ ___ number of glasses ___ ___ ___ ml volume of each glass

If 0 glasses, skip to Question 3

Below are questions about what you added to the tea. Each question should be the amount added per glass (one glass)

Did you add sugar? Yes No

If yes, how much?

If the sample spoon is 15 ml, how many spoonfuls did you have? ___ ___ number of spoonfuls ___ converted to ml

Did you add fruit syrup? Yes No

If yes, how much?

If the sample spoonfull is 15 ml, how many spoonfulls did you have? ___ ___ number of spoonfulls ___ converted to ml

Q12. Soup “Borshi”

Did you have this in the last three days? Yes No **If no, Skip to the next dish**

How much did you have at one time ? ___ ___ ___ ml

How many times have you had this recipe for dinner in the last three days? ___ ___ times

Below are typical ingredients in borshi. Please comment if there are any major differences in ingredients from what you eat. Yes No

1 kg Beef, 1 kg cabbage, 100g carrots, 200g red beetroot, 1 kg potatoes, 0.5 kg tomatoes, 300 g onion, 30 g garlic, 100 g of greens, sour cream
50–100 mg per serving black pepper, salt to taste

Table 2

Demographic characteristics

Characteristic	Total Sample (n=31)
Age mean(SD)	33 (11%)
% Male n(%)	19 (61%)
Ethnicity n(%)	
Georgian	29 (94%)
Education n(%)	
Secondary	11 (35%)
Some college or university	20 (65%)
Yearly Income n(%)	
(1000 lari = 478 euro or 604 USD)	
<1000 lari	10 (32%)
1000–3000 lari	9 (29%)
3001–10,000 lari	9 (29%)
10001–20000 lari	3 (10%)
Employment Status n(%)	
Employed	15 (48%)
Unemployed	16 (52%)
Marital Status n(%)	
Single/never married	15 (48%)

Table 3

Nutrient intake and agreement between nutrient intake assessment methods

Nutrients	24 hour recall		Nutrient Intake Instrument		Mean Difference		LL Agreement, UL Agreement		P-value
	Mean (SD)		Mean (SD)		Mean (SD)		LL Agreement, UL Agreement		
Calories (kcal)	2983 (830)		3153 (940)		171 (990)		(-2288, 2489)		.34
Total Fat (g)	124 (51)		127 (57)		3 (56)		(-109, 115)		.77
Total Carbohydrate (g)	386 (93)		417 (102)		31 (115)		(-199, 262)		.14
Total Protein (g)	91 (37)		97 (35)		6(38)		(-71, 83)		.41
Retinol (mcg)	725 (812)		679 (836)		-47 (1086)		(-2220, 2126)		.81
Vitamin C (mg)	96 (63)		137 (76)		41 (92)		(-142, 225)		.02
Vitamin D (mcg)	3.2 (2.4)		5.1 (7.0)		1.9 (6.7)		(-11.5, 15.3)		.12
Vitamin E (mg)	9.8 (3.5)		11.4 (4.9)		1.5 (5.5)		(-9.5, 12.5)		.14
Thiamine (mg)	2.4 (0.7)		2.6 (0.6)		0.2 (0.7)		(-1.2, 1.6)		.23
Calcium (mg)	1221 (410)		1260 (446)		39 (487)		(-935, 1012)		.66
Sodium (mg)	3728 (1141)		4029 (1135)		301 (1246)		(-2192, 2794)		.19
Potassium (mg)	2925 (866)		3566 (1122)		641 (1208)		(-1776, 3057)		<.01
Iron (mg)	19.2 (5.1)		21.3 (5.9)		2.1 (6.7)		(-11.3, 15.5)		.09
Selenium (mcg)	142 (60)		143 (49)		1.3 (65)		(-129, 131)		.92
Copper (mg)	2.2 (1.3)		2.3 (1.2)		0.2 (1.6)		(-3, 3.4)		.54
Zinc (mg)	11.7 (4.1)		12.2 (4.0)		0.5 (4.8)		(-9.1, 10.1)		.57

LL= lower limit; UL= upper limit of 95% confidence intervals