Published in final edited form as:

J Assoc Nurses AIDS Care. 2013 ; 24(3): 276–282. doi:10.1016/j.jana.2012.06.006.

Exploratory Study: Evaluating the Effects of Fish Oil and Controlled Diet to Reduce Triglyceride Levels in HIV

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Keywords

controlled diet; elevated triglycerides; fish oil; HIV; lipids

Increased triglyceride levels are commonly seen among individuals with HIV who receive antiretroviral therapy (ART) containing a protease inhibitor (PI; Calza, Manfredi, & Chiodo, 2003). Elevated triglyceride levels can be seen within a few weeks after initiation of a PI-based ART (PI-ART; Chang et al., 2009). In HIV, it is well recognized that the etiology of increased triglyceride levels are multifactorial. These include HIV itself, ART, lipodystrophy, increased visceral adipose tissue, and factors that affect other populations such as obesity, reduced physical activity, increased alcohol intake, fructose in diet, diabetes, and genetics (Grunfeld, 2005).

Treatment recommendations to manage elevated triglyceride levels are similar to those for uninfected people (Grinspoon et al., 2008; Hsue et al., 2008). Dietary guidelines by the National Cholesterol Education Program -Therapeutic Lifestyle Changes (NCEP-TLC) have been recommended as the first-line approach to manage this condition (National Cholesterol Education Program [NCEP], 2002), but well-controlled studies have not been conducted to test the effectiveness of the NCEP-TLC diet on individuals with HIV (Capili & Anastasi, 2006). A supplement available both over the counter and by prescription, fish oil (2 to 4 grams daily) is recommended by the American Heart Association (AHA, 2002) to manage triglyceride levels. Wohl and colleagues (2005) have successfully demonstrated reductions in triglyceride levels using fish oil supplements in HIV-infected individuals taking ART. Therefore, this study builds upon current recommendations and reports the results of an exploratory study that examined the effects of a controlled dietary study supplemented with 4 grams of fish oil daily to reduce triglyceride levels in HIV.

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Methods

Design and Sample

Eighteen men and women living with HIV, between the ages of 18 and 60 years, taking PI-ART regimens with elevated levels of fasting serum triglyceride were randomized to one of two groups in a placebo-controlled, parallel group, feasibility clinical trial: Group 1 subjects received prepared meals for 8 weeks using usual foods based on the NCEP-TLC dietary guidelines supplemented with 4 grams of fish oil per day (Pure encapsulations® EPA/DHA as 2,400mg/1,600mg per day); Group 2 (control group) subjects received prepared meals for 8 weeks using usual foods based on the NCEP-TLC dietary guidelines with placebo. All subjects attended one intake/screening, one baseline, and 16 study sessions conducted twice weekly for 8 weeks for total study duration of 10 weeks. All subjects were administered the same instruments and underwent the same evaluations and laboratory testing for the duration of the study. Subjects were encouraged to maintain usual level of physical activity for the duration of the study. Subjects received \$5 for each completed study visit. This study received institutional review board approval prior to the start of the study and was conducted in an academic medical center in New York City (NYC).

The inclusion criteria were adults between ages 18 and 60, diagnosed with HIV, fasting serum triglyceride level 150–500 mg/dl, serum low density lipoprotein (LDL) level < 130 mg/dl, CD4+ T cell count ≥ 300 cells/mm³, stable PI-ART regimen (drug, dose, combination) for a minimum of 6 months or longer, body mass index (BMI) between 20 to 29 kg/m², treatment naïve to fish oil supplementation, access to refrigerator/freezer and microwave, agreed to attend all study sessions and comply with study protocol, achieved a score of 24 or better on the *Mini Mental State* (MMS) questionnaire, received documentation from primary care provider (PCP) of HIV status, PI-ART regimen (drug, dose, start date of medications), and medical history consistent with the inclusion criteria. Women of childbearing age agreed to use a barrier-method of protection against pregnancy for the duration of the study. Individuals were excluded if they had a diagnosis of diabetes mellitus and/or were being treated with a glucose lowering agent or diet; and/or had liver disease, renal disease, coagulopathies, coronary artery disease, familial hyperlipidemia, peptic ulcer disease, malignancy, Cushing's syndrome, malabsorption syndromes, active opportunistic infections, wasting syndrome, food allergies/reactions, dietary restrictions, allergy, or sensitivity to study drug or formulations; and/or were pregnant or breast feeding. Individuals who used the following medications/supplements were also excluded: amprenavir/vitamin E, antihyperlipidemic agents, beta-blockers, anticoagulants, corticosteroids, laxatives, thiazide diuretics, thyroid hormone, androgens and estrogens, ginkgo biloba, vitamins/minerals that affect lipids, and/or investigational study drugs.

Procedures

Subjects were recruited by informing colleagues (physicians, nurse practitioners, physician assistants) working in the field of HIV in the NYC area who then referred their patients. Advertisements were published in lay magazines that were specific for people living with HIV. Recruitment flyers were also mailed to HIV community-based agencies located in NYC. Potential subjects responding to advertisements, flyers, or PCP referral were telephone screened to assess for study eligibility. PCPs were required to complete a *Medical Clearance Form* that reflected inclusion and exclusion criteria for the study prior to study enrollment.

At the first (face-to-face) session, subjects completed the informed consent process and scheduled questionnaires, and received an appointment to complete a fasting lipid profile (total cholesterol, triglyceride, LDL, high density lipoprotein [HDL]) evaluation. Women

were also given a urine human chorionic gonadotropin (HCG) test to rule out pregnancy. The HCG test was repeated on a monthly basis.

At the baseline session (second study visit), subjects meeting the inclusion criteria were randomized to either the fish oil with NCEP-TLC controlled diet group or the placebo with NCEP-TLC controlled diet group and completed a nutritional assessment to determine appropriate caloric intake to maintain weight. The nutritional assessment focused on anthropometric measures, vital signs, and caloric needs to maintain body weight. Estimated required caloric levels were determined using the Harris-Benedict formula (Frankenfield, Muth, & Rowe, 1998) multiplied by activity factor (Shetty, Henry, Black, & Prentice, 1996) to maintain body weight. Baseline serum phospholipids fatty acid (EPA/DHA – fish oil) level was also evaluated. At each study session, subjects completed a symptom checklist to monitor for study associated complications or worsening of HIV condition.

For study sessions 1 to 16, subjects received prepared meals for breakfast, lunch, dinner, and snacks. The total caloric contents of daily meals were according to caloric need for subjects and were prepared to have 1500 calories, 2000 calories, or 2500 calories/day. Each meal was identified by subject number, study session number, and date of preparation. The Principal Investigator received the nutritional composition for each meal, in terms of total calories, cholesterol, fiber, and dietary fats. Subjects picked up meals twice a week and medications once a week from the research center. Subjects received a printed menu of the meals received for each study session and were asked to check which food items were eaten and the percentage consumed, which was guided by pictorial and verbal descriptors. Subjects took their meals home, packed in freezer tote bags with wheels for easy travel. All subjects received instruction and reinforcement throughout the study on consuming only the meals/snacks provided and the importance of adhering to the study medication. If determined that a subject lost weight, a review of caloric intake was reassessed and adjusted to maintain body weight. Subjects were allowed to drink water or non-caloric beverages and an instructional handout of permitted beverages was provided.

Study meals for groups 1 and 2—Study meals provided for both groups were identical in terms of average dietary composition (6% saturated fat, 9% polyunsaturated fat, 10% monounsaturated fat, 30% of total calories from fat, 55% carbohydrate using whole grains, fruits and vegetables, 30 grams/day of fiber, 15% protein, and 75 mg per 1,000 kcal of cholesterol per day) and actual meals served (National Heart, Lung, and Blood Institute, 2001). A 7-day menu cycle was used during the study. No fish or marine items were served.

Randomization/blinding—Subjects were assigned to one of two study groups by the method of randomly permuted block schema. This method ensures equal allocation of subjects between conditions at the end of a block assignment. Block assignments of 4 were used. The allocation of subjects was concealed by placing each treatment code in an opaque, sealed envelope. The research pharmacy created double-blind kits, consisting of identical medication bottles, dispensed with either fish oil or placebo. Each medication bottle contained a 1-week supply of study medications for weekly distribution to subjects. Our research team remained blinded to treatment assignment until the final statistical analysis.

Measures

Outcome Variables

Fasting lipid profile consisting of serum triglyceride, total cholesterol, LDL, and HDL levels were collected during screening, and study sessions 8 and 16. Serum phospholipid fatty acids were collected at baseline, and study sessions 8 and 16. Nutritional biomarkers, such as serum phospholipid fatty acids have been used to validate self-report of food diaries, food

frequency questionnaires, and 24-hour dietary recall (McKeown et al., 2001; Parra, Schnaas, Meydani, Perroni, Martinez, & Romieu, 2002). Biomarkers for fish oil are recognized as important components to validate dietary intake (Gerber et al., 2000). Serum phospholipids were used to evaluate fish oil consumption based on the average level of EPA/DHA provided by the study. Correlation coefficients between intake and serum levels have been reported to be 0.53 and 0.58 for EPA and DHA respectively (Hjartaker, Lund, & Bjerve, 1997). These levels provided surrogate markers for fish oil adherence. Samples were analyzed by the medical center labs using established procedures.

Descriptive Measures

The demographic questionnaire, medical history form, and mini mental state (MMS) instruments were administered during the screening session. The demographic questionnaire assessed social factors suggested by the public health epidemiology literature as influencing health promotion behaviors. This questionnaire collected personal data such as age, gender, occupation, income, and education level. The medical history form asked about general and HIV medical history, medications, over-the-counter medications, smoking status, and family history of cardiovascular disease (CVD). The MMS (Folstein, Folstein, & McHugh, 1975) is a short measure used to assess the mental state of an individual. Because this proposal required frequent sessions, instruction, instrument completion, and the subject's full attention and memory recall, a short mental status assessment was essential. The MMS addressed six categories: orientation, registration, attention, recall, language, and level of consciousness. Average meal consumption was assessed at every session to provide an additional avenue to evaluate study meal compliance (contained in the symptom checklist).

Safety Assessment

At each session, subjects completed a symptom checklist, which contained a comprehensive list of symptoms associated with HIV and the experimental treatment; recognized side effects of fish oil include belching, nausea, and diarrhea. The symptom checklist was used to monitor for study associated complications or worsening of HIV, which would initiate a referral to the subject's PCP.

Debriefing

The debriefing was administered at the last study session. At the debriefing, subjects provided feedback/comments on the following areas: length of study, number of study sessions, study session scheduling, instrument burden, level of confidence on whether subject received fish oil or placebo, meal distribution, and suggestions/comments. Subjects also commented on the quality of study meals in terms of appeal, smell, taste, aftertaste and palatability.

Data Analysis

All subjects had age, sex, ethnicity, BMI, smoking status, family history CVD, and PI-ART regimen recorded to allow for descriptive statistical comparison between treatment and control groups. The Intent-to-Treat (ITT) Principle, in which randomized subjects completing one or more study sessions were included in the analysis, was used for this study. The last available values were carried forward to replace missing data. Analysis was conducted by repeated measures analysis of variance, implemented as a MANOVA, with repeat factor consisting of baseline session and study sessions 8 and 16 and a fixed factor of group (A or B). Repeated contrasts were used to assess differences between the measures for paired time points. Bonferroni adjustments for multiple testing were also employed. Statistical significance was assessed at the 0.05 level. To evaluate adherence to fish oil

intake, paired-samples T-tests were conducted to compare the mean levels of serum EPA/DHA from baseline and study sessions 8 and 16.

Results

A total of 240 telephone inquiries were received from prospective subjects. From these inquiries, 192 were deemed ineligible and 18 were enrolled into the study. Fourteen subjects completed all sessions of the study, 2 completed up to study session 8, and 2 completed up to study session 2. Table 1 presents the baseline characteristics of the study participants. Group difference was found for the diagnosis of hypertension. The fish oil group had a larger proportion of subjects with hypertension. The primary outcome for baseline lipid levels was not different between groups.

Table 2 shows the triglyceride means and standard deviations by treatment group (fish oil vs. placebo) for each planned-comparison time point. The ITT within-subjects results indicated a significant time effect in changing the triglyceride level for the fish oil group ($F(2, 6)=8.3, p=.019$), but not for the placebo group ($F(2, 8)=3.4, p=.104$). Pair-wise comparisons were conducted for the fish oil group: (baseline vs. session 8) and (session 8 vs. session 16). A mean reduction of 102 mg/dl in triglyceride level was noted from baseline to session 8 ($t(6)=3.5, p=.013$) and an additional reduction of 10mg/dl from session 8 to session 16, but this comparison did not achieve statistical significance ($t(6)=.56, p=.592$). For the placebo group, in analyzing only subjects who completed all sessions, 4 subjects were removed from the analysis. The efficacy analysis did not show a significant time effect in changing the triglyceride level for the placebo group ($F(2, 4)=8.3, p=.071$). Serum EPA/DHA levels for the fish oil group increased from baseline levels but was not statistically significant for any of the pair-wise comparisons.

Debriefing Session Summary

To understand the subjects' perspective of the study, we asked a series of questions about the study schedule, the procedures, the meals, and their levels of confidence in whether they received true fish oil or placebo. Overall, subjects stated that the twice-weekly schedule was appropriate and that the meals were satisfying and tasty. All subjects rated their response as *confident* that they received fish oil. A common statement made by the subjects was that prior to the study, they did not know what an appropriate portion size was for meals. In addition, many felt surprised that vegetables were satisfying in terms of feeling full.

Safety Outcome

Three subjects reported increased gas and belching (2 from fish oil group and 1 from placebo group) post initiation of study medications. The reported symptoms resolved spontaneously without intervention.

Discussion

The subjects in this study began with baseline levels of triglyceride categorized as high (200 mg/dl –499 mg/dl) by the Adult Treatment Panel III (Grundyet al., 2004). After consuming 8 weeks of a controlled diet supplemented with fish oil, triglyceride levels were reduced by 112mg/dl points from baseline, equivalent to borderline high levels (Grundy et al., 2004). Although the dietary composition provided by the study meals mirrored the recommended intake by NCEP-TLC guidelines, subjects randomized to the diet with placebo did not achieve triglyceride level reduction. After consuming 8 weeks of the same diet as the fish oil group, the triglyceride level in the placebo group remained in the high category. For both groups, the mean BMI was considered overweight. Throughout the study, body weight for

both groups remained stable from baseline level with the controlled diet. Therefore, a controlled diet alone, based on NCEP-TLC guidelines without additional weight loss management, was not sufficient to reduce triglyceride levels in this study.

Limitations

Our study was an exploratory study designed to understand the logistics and feasibility of conducting a controlled dietary study in free-living individuals with HIV. Hence, the sample size of this study was small. Other studies that provide prepared study meals generally have subjects eat two to three meals a day at respective research sites. For this study, we opted to have subjects pick up meals from our research center and eat all meals at home. We developed the study schedule based on our experience in conducting multisession studies and a pre-study needs assessment with this population. Input received from the needs assessment assisted us in developing the study design and procedures. Additionally, the subjects' responses from the debriefing supported our decision for the study schema. We used self-report to assess meal compliance and provided continued reinforcement throughout the study that subjects must only consume meals and snacks provided. Despite intensive and repeated instructions, total adherence cannot be assumed in the context of a study design that used free-living individuals.

Strengths

This study used a randomized, placebo-controlled design in which subjects, investigators, and laboratory personnel were blinded to study assignment until final data analysis. Meal compliance based on self-report was greater than 75% for the duration of the study. Studies that have compared adherence to dietary change using prepared meals versus self-selected meal choices have shown that adherence was greater in subjects who consumed prepared meals.

Conclusion

NCEP-TLC diet with fish oil shows promise as an intervention to manage triglyceride levels in patients with HIV. NCEP-TLC diet and fish oil should be considered in managing triglyceride levels in HIV. Fish oil is a supplement available over the counter, adding to the feasibility of this intervention. However, despite the availability of fish oil without a medical prescription, clinicians should monitor the use of this supplement with their patients to ensure safety and to avoid interactions with other medications used to manage HIV or other concomitant conditions.

Acknowledgments

This study was sponsored by the National Institutes of Health, National Institute for Nursing Research. Grant Number: R03 NR009476 and UL1 RR024156-01.

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Table 1

Demographic Baseline Characteristics

	Randomized	Group A Diet & Fish Oil	Group B Diet & Placebo	Between-group difference, <i>p</i> -value
Sample Size	18	8	10	
Gender <i>N</i> (% female)	6 (33.0%)	2 (25.0%)	4 (40.0%)	$\chi^2 = .450, p = .638$
Age Mean $\pm$ SD	46.2 $\pm$ 8.8	46.9 $\pm$ 11.5	45.6 $\pm$ 6.5	$F = .075, p = .788$
Years Living with HIV	11.2 $\pm$ 5.5	9.5 $\pm$ 6.1	12.6 $\pm$ 4.9	$F = 1.42, p = .250$
CD4+	546 $\pm$ 227	573 $\pm$ 284	525 $\pm$ 182	$F = .193, p = .667$
Diagnosis of HTN	3 (16.7%)	3 (37.5%)	0 (00.0%)	$\chi^2 = 4.50, p = .034$
Systolic Blood Pressure	119.9 $\pm$ 14.9	119.6 $\pm$ 15.2	119.8 $\pm$ 15.6	$F = .001, p = .250$
Diastolic Blood Pressure	76.8 $\pm$ 9.3	80.5 $\pm$ 8.1	74.0 $\pm$ 9.6	$F = .932, p = .349$
BMI	25.2 $\pm$ 3.2	25.1 $\pm$ 2.6	25.3 $\pm$ 3.8	$F = .029, p = .867$
Waist circumference	37.1 $\pm$ 3.3	37.5 $\pm$ 2.3	36.9 $\pm$ 4.0	$F = .062, p = .807$
Current Smoker	5 (27.8%)	2 (25.0%)	3 (30.0%)	$\chi^2 = .055, p = .814$
Number Cigarettes Smoked/Day	2.8 (5.7)	1.4 $\pm$ 3.5	4.0 $\pm$ 6.9	$F = .932, p = .349$
Family History HTN	7 (38.9%)	4 (50.0%)	3 (30.0%)	$\chi^2 = .748, p = .387$
Family History of Diabetes	11 (61.1%)	5 (62.5%)	6 (60%)	$\chi^2 = .012, p = .914$
Family History of MI	4 (22.2%)	2 (25.0%)	2 (20.0%)	$\chi^2 = .064, p = .800$
Triglyceride (mg/dl)	266.4 $\pm$ 69.9	281 $\pm$ 69	256 $\pm$ 75	$F = .450, p = .512$
Cholesterol (mg/dl)	201.5 $\pm$ 35.0	186.3 $\pm$ 32.5	213.7 $\pm$ 33.4	$F = 3.04, p = .100$
LDL (mg/dl)	110.3 $\pm$ 36.0	95.2 $\pm$ 36.9	122.3 $\pm$ 31.7	$F = 2.79, p = .114$
HDL (mg/dl)	39.2 $\pm$ 8.1	80.5 $\pm$ 8.1	74.0 $\pm$ 9.6	$F = .354, p = .560$
Race	Black or African American	7 (38.9%)	5 (50.0%)	$\chi^2 = 1.22, p = .543$
	Hispanic	7 (38.9%)	3 (30.0%)	
	White	4 (22.2%)	2 (20.0%)	
Marital status	Never Married/Single	11 (61.1%)	6 (60.0%)	$\chi^2 = .070, p = .966$
	Currently Married	2 (11.1%)	1 (10.0%)	
	Widowed/Divorced	5 (27.8%)	2 (20.0%)	
Education	Less than High School	5 (27.8%)	3 (30.0%)	$\chi^2 = 4.99, p = .172$

	Randomized	Group A Diet & Fish Oil	Group B Diet & Placebo	Between-group difference, <i>p</i> -value
Sample Size	18	8	10	
	2 (11.1%)	2 (25.0%)	0 (00.0%)	
	5 (27.8%)	4 (50.0%)	7 (70.0%)	

Note. HTN = hypertension; BMI = body mass index; MI = myocardial infarction; LDL = low density lipoprotein; HDL = high density lipoprotein

Table 2

Triglyceride Level

Analysis	<i>n</i>	Baseline	Session 8	Session 16
Group A - Diet & Fish Oil				
Intent to Treat ^a Triglyceride	8	281 mg/dl ± 69	179 mg/dl ± 132	169 mg/dl ± 133
Group B - Diet & Placebo				
Intent to Treat ^a Triglyceride	10	256 mg/dl ± 75	232 mg/dl ± 113	289 mg/dl ± 129
Efficacy ^b Triglyceride	6	236.6 mg/dl ± 44.9	196 mg/dl ± 63.5	292 mg/dl ± 124.4

^a All participants included in the analysis. Last available value carried forward for missing values.

^b Only participants completing baseline and all sessions included in the analysis.