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Daily choices of functional foods supplemented with milled flaxseed by a patient population over one year

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ABSTRACT

Dietary supplementation with milled flaxseed has provided significant health-related benefits to patients with cardiovascular disease (the FlaxPAD Trial). The purpose of this study was to examine which foods that contained flaxseed were best accepted over the one year duration of daily supplementation. Milled flaxseed (30 g) or a placebo (30 g of milled wheat) was incorporated into muffins, bagels, snack bars (all in different flavours), buns, tea biscuits and pasta or distributed in bags to sprinkle into their food of choice. Patients were free to choose each day the type of food product that they would consume. Over the course of one year, bagels were consumed > muffins > bars > sprinkles > biscuits > pasta > buns. The trends and quantities chosen were the same for flax and placebo foods. More flavourful varieties were generally better accepted. In conclusion, functional foods containing milled flaxseed will be ingested by a patient population over extended periods similar to placebo foods.

1. Introduction

Functional foods are defined as "foods with physiological benefits that can reduce the risk of chronic diseases" (Moghadasian & Eskin, 2012). Unlike nutraceuticals that appear as extracts like oils and in pill form, functional foods are presented to the consumer as traditional foods like muffins and snack bars. Functional foods supplemented with milled flaxseed have shown significant health-related benefits in both animal and

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human trials (Ander et al., 2004; Bassett et al., 2011; Bassett, Rodriguez-Leyva, & Pierce, 2009; Caligiuri et al., 2014b; Caligiuri, Aukema, Ravandi, & Pierce, 2014a; Caligiuri, Edel, Aliani, & Pierce, 2014c; Dupasquier et al., 2006, 2007; Edel et al., 2015; Francis et al., 2013; Rodriguez-Leyva, Dupasquier, McCullough, & Pierce, 2010; Rodriguez-Leyva et al., 2013). This includes a recent, year-long FlaxPAD clinical trial (Rodriguez-Leyva et al., 2013) where patients with high blood pressure who ingested foods that contained 30 g of milled flaxseed daily received some of the most significant decreases in blood pressure ever observed with a dietary intervention. This dosage of milled flaxseed was derived from preliminary studies that ascertained this to be an optimal form and dosage of flaxseed to provide healthy bioactives to the body (Austria et al., 2008; Patenaude et al., 2009). Unfortunately, no foods are commercially available today that contain 30 g of milled flaxseed to provide these health-related benefits. Therefore, 12 different functional food choices that contained milled flaxseed were created to test the effects of dietary supplementation with flaxseed in tightly controlled clinical conditions in a patient population with cardiovascular disease.

Several unique data sets were generated through the successful completion of this trial. As identified above, data on the health status of patients ± dietary flaxseed supplementation have been reported from this trial (Caligiuri et al., 2014b; Edel et al., 2015; Rodriguez-Leyva et al., 2013). Data have also been generated on what food choices these patients freely made during the trial. It is important to note that these data are important for several reasons. First, it was carried out over an unusually long period of time: one full year. Second, the data were obtained from a patient population. Both of these aspects are relatively uncommon in conventional food studies. Because a placebo food was also created that did not contain flaxseed but instead contained milled wheat, it was also possible to determine if milled flaxseed itself was well accepted as a dietary supplement in a variety of food products. Thus, the potential value of such data is that it was obtained under "real life conditions" as opposed to that obtained in conventional, tightly controlled sensory trials. The purpose of the present study, therefore, was to tabulate the types of food choices made by the patients over a year of daily supplementation with 12 different food choices during which the patients and researchers were blinded as to whether the foods did or did not contain milled flaxseed.

2. Materials and methods

2.1. *Trial design*

The FlaxPAD clinical trial was registered (NCT00781950) at clinicaltrials.gov. The study design for this double blinded, placebo-controlled, randomised trial has been described in detail previously (Rodriguez-Leyva et al., 2011). Briefly, 110 patients >40 years old who had peripheral arterial disease (PAD) for >6 months with an ankle brachial index <0.9 were recruited. As reported previously (Rodriguez-Leyva et al., 2011), the Flax-PAD patients had an average age of 67 years, 90% were current or ex-smokers, 75% were hypertensive, 32% diabetic, and 79% were hyperlipidaemic at baseline. The majority of these patients were administered one or more medications to lower blood sugar, lipids, blood pressure or thrombotic complications.

2.2. *Trial food*

The patients were fed a variety of foods (bagels, muffins, snack bars, buns, pasta, tea biscuits) that contained 30 g of milled flaxseed or a placebo that resembled in appearance and texture the foods that contained flaxseed. The bagels, muffins and snack bars came in different flavours to provide variety for the consumer. There were three bagel flavours (plain, cinnamon-raisin and sunflower-sesame), three flavours of snack bars (orange cranberry, cappuccino chocolate and gingerbread raisin), and two flavours of muffins (apple spiced and cranberry orange). There was also pasta, a tea biscuit and a sundried tomato bun available to the patients. Brown non-GMO flaxseed was provided by Glanbia Nutritionals Inc. Each individual product contained 30 g of milled flaxseed and one product was ingested per day over one year. Details concerning the ingredients have been described previously (Aliani, Ryland, & Pierce, 2011, 2012; Edel et al., 2015). Milled flaxseed or a milled wheat placebo product (30 g) was also distributed in small bags to allow the patient to sprinkle the product into their food of choice (yoghurt, beverages, cereals, etc). This form of food choice has been identified as "sprinkles" throughout this paper.

For the first month of the trial, each patient was given at least one of each food product to insure they could taste each food choice. Thereafter, from months 2 to 12, each patient could order a one month quantity of the type and number of each individual food product that they would consume over the coming month. The food was delivered by van to their residence. The muffins, bagels, buns and tea biscuits were delivered in a frozen form and the patients stored these in their residence in a freezer until ready to consume. One of the inclusion criteria for this study was that the patient must have a freezer (Rodriguez-Leyva et al., 2011). The snack bars, bags of milled product ("sprinkles") and pasta were stored by the participant at room temperature over the month. The patient was asked to discard any product not consumed over the month. Following the month, another one month supply was then again delivered by study personnel according to the new choices provided by the patient for that month.

Fig. 1 depicts the area of the city that was required for food distribution for this study. The trial was carried out in Winnipeg, Manitoba, Canada, a city with a population of >700,000 people. The majority of the patients recruited were within city limits but about 11% were found outside of the city. Each patient was supplied with a detailed list of the food choices available to them. The specifics of the order were received by our personnel by phone. Orders were taken 5 days in advance. Subjects were then given a 30 day supply based on their products of choice. Instructions to properly store and prepare the food products were provided. Foods were delivered with ice packs in a thermal bag. A company van was used to deliver all the food products to their home. All patients had food driven to their residence on a monthly basis. All food products requested during the study were recorded and tabulated at the end of the study.