Trial Review

Trial registered on ANZCTR

Trial ID	ACTRN12616000492459
Ethics application status	Approved
Date submitted	5/04/2016
Date registered	14/04/2016
Date last updated	12/12/2016
Type of registration	Prospectively registered

Titles & IDs

Public title	The prophylactic potential of a Mediterranean dietary pattern enriched with oily fish in improving respiratory function in asthmatic children.
Scientific title	The prophylactic potential of a Mediterranean dietary pattern enriched with oily fish in improving respiratory function in asthmatic children: a randomized control trial.
Secondary ID [1]	NONE
Universal Trial Number (UTN)	U1111-1181-3989
Trial acronym	
Linked study record	

Health condition

Health condition(s) or problem(s) studied:	
CHILDHOOD ASTHMA	
Condition category	**Condition code**
Diet and Nutrition	Other diet and nutrition disorders
Respiratory	Asthma
Respiratory	Normal development and function of the respiratory system

Intervention/exposure

Study type	Interventional
Description of intervention(s) / exposure	The intervention group will be instructed to consume 2 fatty fish meals (150g cooked fish) per week over a period of 6 months. Prior to commencement participants will be provided with an information sheet and consent form. At baseline and at 6 months during usual medical consultations, parents of participants will complete socio-demographics, Asthma Control Questionnaire, Quality of life and food frequency questionnaires (requiring approximately 30 mins). During enrolment, a telephone-interview (lasting approximately 60 minutes) will be conducted by the dietitian to collect medical, dietary and lifestyle information. Dietary advice based on the Greek Mediterranean dietary guidelines (Greek Ministry of Health & Welfare, 1999) including instructions on the dietary intervention will be explained to parents. Participants will be monitored by fortnightly telephone calls and e-mails from the dietitian to address any problems relating to dietary adherence.
Intervention code [1]	Lifestyle
Intervention code [2]	Treatment: Other
Comparator / control treatment	The control group will continue with their usual dietary habits which are in accordance with the Traditional Greek Mediterranean diet. At baseline and at 6 months during usual medical consultations, parents will complete socio-demographic, Asthma Control Questionnaire, Quality of life and food frequency questionnaires. At both time-points, telephone-interviews will be conducted by the dietitian (lasting approximately 60 minutes) to collect medical and dietary information. Patients will be monitored by fortnightly telephone calls and e-mails from the dietitian until the end of the study. At the end of 6 months, the child and their family will have a personalized consultation with the dietitian and will be provided with an information brochure on general healthy eating guidelines (Greek Mediterranean dietary guidelines (Greek Ministry of Health and Welfare, 1999) .
Control group	Active

Outcomes

Primary outcome [1]	Respiratory function as assessed by spirometry (FEV1, FVC, FEV1/FVC, predicted FEV1) and bronchial inflammation by exhaled Nitric Oxide (eNO) analysis.
Timepoint [1]	Measured at baseline and 6 months

Primary outcome [2]	Composite outcome of the number of asthma episodes and severity of asthma as assessed by parent's and doctor's report.
Timepoint [2]	Evaluated at baseline and 6 months
Secondary outcome [1]	Asthma Control assessed by Asthma Control (ACQ) questionnaire
Timepoint [1]	Measured at baseline and 6 months
Secondary outcome [2]	Adherence to dietary intervention evaluated using multiple food recalls (3 recalls) administered via telephone.
Timepoint [2]	Assessed at baseline, 3 months and at 6 months
Secondary outcome [3]	Dietary habits evaluated using a Food Frequency Questionnaire
Timepoint [3]	Assessed at baseline and at 6 months
Secondary outcome [4]	Quality of life using Paediatric Quality of Life questionnaire(PQOL)
Timepoint [4]	Measured at baseline and at 6 months
Secondary outcome [5]	Change in plasma omega 3 fatty acid composition assessed by serum assay
Timepoint [5]	Measured at baseline and at 6 months
Secondary outcome [6]	Change in antioxidant level assessed by serum assay
Timepoint [6]	Measured at baseline and 6 months

Eligibility

Key inclusion criteria	Physician-diagnosed asthma
Minimum age	5 Years
Maximum age	12 Years
Gender	Both males and females
Can healthy volunteers participate?	No
Key exclusion criteria	Children suffering from Cystic Fibrosis, Gerd, food allergies, or chronic illnesses requiring regular treatment with medication which may affect participation, chronic use of anti-inflammatory medications, unable or unwilling to modify diet, including psychiatric or behavioural disorders.

Study design

Purpose of the study	Treatment
Allocation to intervention	Randomised controlled trial
Procedure for enrolling a subject and allocating the treatment (allocation concealment procedures)	Randomization will be carried out by an independent private statistican and the participant's group allocation and number will be provided to the research dietitian on enrolment, who will provided participants with the appropriate dietary instructions.
Methods used to generate the sequence in which subjects will be randomised (sequence generation)	Randomization will be conducted by an independent private statistitian using a computerised random number generator in variable block sizes, stratified by age group.
Masking / blinding	Open (masking not used)
Who is / are masked / blinded?	The people receiving the treatment/s
Intervention assignment	Parallel
Other design features	
Phase	Not Applicable
Type of endpoint(s)	Efficacy
Statistical methods / analysis	G Power Analysis was used to determine sample size. Sample size calculation was undertaken using a medium effect size of 0.40, with 90% power and significance level of 0.05. which produced a sample size of 52 participants. But allowing for a 20% drop out rate gave a final total sample size of 64 participants. Data analysis will be performed using SPSS IBM Inc. Quantitative variables will be analyzed using Anova and qualitative variables by Chi square tests.

Recruitment

Recruitment status	Recruiting

Date of first participant enrolment			
Anticipated	1/10/2016	**Actual**	11/11/2016

Date of last participant enrolment			

Anticipated	30/06/2018	**Actual**	

Date of last data collection			
Anticipated		**Actual**	

Sample size			
Target	64	**Actual**	

Recruitment outside Australia	
Country [1]	Greece
State/province [1]	Attiki

Funding & Sponsors

Funding source category [1]	University
Name [1]	La Trobe University
Address [1]	La Trobe University Department of Rehabilitation, Nutrition and Sport School of Allied Health Bundoora, 3086 Victoria Australia
Country [1]	Australia
Primary sponsor type	University
Name	La Trobe University
Address	La Trobe University Department of Rehabilitation, Nutrition and Sport School of Allied Health Bundoora, 3086 Victoria Australia
Country	Australia
Secondary sponsor category [1]	None
Name [1]	
Address [1]	
Country [1]	
Other collaborator category [1]	Individual
Name [1]	Dr.Charis Katsardis
Address [1]	Private Pediatric Respiratory Allergy Clinic 1 Pafou St Marousi Athens, 15125
Country [1]	Greece
Other collaborator category [2]	Individual
Name [2]	Doctor Dimitris Tsoukalas
Address [2]	Metabolomic Clinic 5 Koumbari Street Kolonaki Square Athens
Country [2]	Greece

Ethics approval

Ethics application status	Approved
Ethics committee name [1]	Latrobe University Ethics Committee
Ethics committee address [1]	Latrobe University Bundoora, 3086 Victoria
Ethics committee country [1]	Australia
Date submitted for ethics approval [1]	30/04/2016
Approval date [1]	08/07/2016
Ethics approval number [1]	HEC 16-035

Summary

Brief summary	Globally, asthma has become one of the most frequent chronic diseases in children during the past two to three decades. Furthermore, it is a debilitating disease and is one of the most common reasons for hospitalization and days absent from school. The change in dietary habits has been implicated in causing childhood asthma. Observational studies revealed that adherence to a Mediterranean type diet by children was inversely associated with asthma symptoms. More specifically, some studies performed to date have reported that fish in the child's diet was associated with reduced risk of wheeze and asthma, whereas others not. However, clinical trials investigating the effect of fish consumption in asthmatic children are limited. Therefore, there is a need for further investigation in order to clarify whether fish is a useful therapy for childhood asthma.
Trial website	
Trial related presentations / publications	
Public notes	

Contacts

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