

# Pilot study on the effect of different dietary fatty acids on impaired glucose tolerance in obese urban Gambian women

<b>Submission date</b> 23/10/2006	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 03/01/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 03/12/2019	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

## Secondary identifying numbers

Medical Research Council Gambia SCC Project # 854

# Study information

## Scientific Title

Pilot study on the effect of different dietary fatty acids on impaired glucose tolerance in obese urban Gambian women

## Study objectives

Whether modifying the ratio n-3:n-6 polyunsaturated fatty acid dietary intake could prevent deterioration of impaired glucose tolerance in obese Gambian women.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

The study was approved by the Gambia Government/MRC Joint Ethics Committee (Project # 816), approved March 2001.

## Study design

Randomised double-blind control longitudinal intervention trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Other

## Study type(s)

Prevention

## Participant information sheet

## Health condition(s) or problem(s) studied

Obesity-related disease, non-insulin dependent diabetes mellitus

## Interventions

Intervention group: High n-3 cooking oil (rapeseed oil) plus fish oil derived EPA/DHA capsules (3 g daily)

Control group: High n-6 cooking oil (sunflower oil) plus placebo corn oil capsules (3 g daily)

## Intervention Type

Drug

## Phase

Not Specified

**Drug/device/biological/vaccine name(s)**

n-3 cooking oil (rapeseed oil), n-6 cooking oil (sunflower oil), fish oil derived EPA/DHA capsules.

**Primary outcome measure**

Outcomes were measured before baseline, at baseline, at three and six months of the intervention:

1. Full plasma and adipose tissue fatty acid analysis
2. Fasting glucose
3. Fasting insulin
4. Oral glucose tolerance test

**Secondary outcome measures**

1. Anthropometric measurements (fat mass and fat free mass, waist-to-hip ratio)
2. Diastolic and systolic blood pressure
3. Full lipid profile
4. Plasma Tumour Necrosis Factor (TNF)alpha and receptors
5. Plasma InterLeukin-6 (IL-6) and receptors
6. Sialic acid

**Overall study start date**

25/10/2001

**Completion date**

08/05/2002

## **Eligibility**

**Key inclusion criteria**

1. Female living in Bakau (urban area in the Gambia)
2. Aged 30 years or older
3. Being obese i.e. having a body mass index more than or equal to  $27 \text{ kg/m}^2$
4. Having an impaired glucose tolerance (oral glucose tolerance test; 120-minute glucose between 6.7 and 10.0 mmol/l)
5. Subjects consent

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Female

**Target number of participants**

A total of 61 participants were recruited for the trial

**Key exclusion criteria**

Subjects diagnosed as diabetic by their doctor or on medication

**Date of first enrolment**

25/10/2001

**Date of final enrolment**

08/05/2002

## **Locations**

**Countries of recruitment**

England

Gambia

United Kingdom

**Study participating centre**

**MRC International Nutrition Group**

London

United Kingdom

WC1E 7HT

## **Sponsor information**

**Organisation**

Medical Research Council (MRC) (UK)

**Sponsor details**

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**Sponsor type**

Research council

**Website**

<http://www.mrc.ac.uk>

**ROR**

<https://ror.org/03x94j517>

# Funder(s)

## Funder type

Research council

## Funder Name

Medical Research Council (UK)

## Alternative Name(s)

Medical Research Council (United Kingdom), UK Medical Research Council, MRC

## Funding Body Type

Government organisation

## Funding Body Subtype

National government

## Location

United Kingdom

## Funder Name

Supplementary project grant to Gambia MRC Nutrition/NCD Programme

# Results and Publications

## Publication and dissemination plan

Not provided at time of registration

## Intention to publish date

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration