

# A multicentre randomised controlled trial of nutritional intervention for patients with weight loss who are undergoing chemotherapy for gastrointestinal (GI) Malignancy, Non Small Cell Lung cancer (NSCL) or Mesothelioma

<b>Submission date</b> 12/09/2003	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 12/09/2003	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 12/06/2015	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

<http://cancerhelp.cancerresearchuk.org/trials/a-trial-looking-at-nutrition-supplements-and-dietary-advice-for-people-due-to-have-chemotherapy-for-advanced-cancer>

## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

EudraCT/CTIS number

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

CCR1999

## **Study information**

### **Scientific Title**

A multicentre randomised controlled trial of nutritional intervention for patients with weight loss who are undergoing chemotherapy for gastrointestinal (GI) Malignancy, Non Small Cell Lung cancer (NSCL) or Mesothelioma

### **Acronym**

The NUT Study

### **Study objectives**

Nutritional intervention in people with metastatic gastrointestinal malignancy is associated with survival benefit

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Not provided at time of registration

### **Study design**

Randomised controlled trial

### **Primary study design**

Interventional

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Not specified

### **Study type(s)**

Treatment

### **Participant information sheet**

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

Cancer: Gastrointestinal

### **Interventions**

1. Dietary advice to increase food intake by 600 calories
2. Dietary advice to increase intake by 600 calories plus oral supplement drink providing 588

calories plus mineral and vitamin supplement

3. Supplement drink plus vitamin and mineral supplement but no dietary advice

4. No dietary advice or supplements

### **Intervention Type**

Other

### **Phase**

Not Specified

### **Primary outcome measure**

Survival benefit related to nutritional intervention. Dietary advice to improve nutritional intake results in weight gain.

### **Secondary outcome measures**

Any additional benefits when nutritional supplements are given with dietary advice.

### **Overall study start date**

01/01/2002

### **Completion date**

01/12/2007

## **Eligibility**

### **Key inclusion criteria**

Patients who have agreed to undergo chemotherapy for histologically proven metastatic or locally advanced tumours in the gastrointestinal tract who are fit for chemotherapy and have weight loss defined by at least one of the following criteria: Body Mass Index  $<20 \text{ kg/m}^2$ , weight loss of 55 or more over 3 months or greater, body weight of 5% or more below ideal body weight.

### **Participant type(s)**

Patient

### **Age group**

Adult

### **Sex**

Both

### **Target number of participants**

660

### **Key exclusion criteria**

Clinical condition precluding oral nutrition, unable to tolerate milk, being considered for immediate enteral or parenteral nutrition.

### **Date of first enrolment**

01/11/2002

**Date of final enrolment**

19/10/2006

## Locations

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

Royal Marsden NHS Foundation Trust

London

United Kingdom

SW10 9NH

## Sponsor information

**Organisation**

Royal Marsden NHS Foundation Trust (UK)

**Sponsor details**

Downs Road

Sutton, Surrey

England

United Kingdom

SM2 5PT

+44 (0)20 8661 3882

jane.lawrence@rmh.nhs.uk

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.royalmarsden.nhs.uk/rmh>

**ROR**

<https://ror.org/0008wzh48>

## Funder(s)

**Funder type**

Charity

**Funder Name**

Henry Smith Foundation and Dr J Andreyev's Research Fund (UK)

## 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

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	1. results	01/05/2008		Yes	No
<a href="#">Results article</a>	results	01/10/2011		Yes	No