

# Fibre supplementation in addition to loperamide for faecal incontinence in adults: a randomised trial

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<b>Registration date</b> 06/11/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 09/06/2008	<b>Condition category</b> Digestive System	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

## Secondary identifying numbers

OEC 01/07/055

# Study information

## Scientific Title

## Study objectives

To evaluate the efficacy of fibre supplementation and loperamide in comparison to a low-residue diet and loperamide in the conservative treatment of faecal incontinence.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Ethics approval received from Otago Ethics Committee on the 30th July 2001.

## Study design

Double-blind randomised cross-over trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

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

Faecal incontinence

## Interventions

All patients received loperamide. Most patients were advised to start by taking one tablet (2 mg) twice a day. Patients with a tendency to constipation were advised to start on one tablet daily. All patients were given both verbal instruction and an advice sheet about using loperamide which advised titrating the loperamide dose to firm stool but to avoid constipation. Glycerine suppositories were supplied for use in the event of troublesome constipation.

Patients were randomised to either combination treatment A or B for six weeks, crossed-over and re-evaluated after a further six weeks. It was assumed that it would take a week or two for the patients to adjust to the new treatment after cross over, and they were advised of this. They

were asked to fill out the outcome questionnaires in relation to previous 4 weeks of the 6 weeks treatment period in each arm of the study. Both participants and clinicians/researchers were blinded.

#### **Treatment A:**

This consisted of:

1. An untitled dietary advice sheet for a balanced low residue diet
2. Placebo supplement (Karicare infant food thickener - light cream colored course powder containing pregelatinised maize starch, maltodextrin, locust bean gum) to be taken as one rounded teaspoon mixed in a glass of water at breakfast and dinner
3. Loperamide (taken as described above)

#### **Treatment B:**

This consisted of:

1. An untitled dietary advice sheet for a balanced diet consisting of both high and low residue items
2. Fibre supplement (psyllium hydrophilic mucilloid) to be taken as one rounded teaspoon with a glass of water at breakfast and dinner
3. Loperamide (taken as described above)

The dietary advice sheets were developed in consultation with the hospital Nutrition department. An important consideration in designing the dietary advice sheets was producing advice that would optimise compliance for a long term change, while encouraging healthy eating.

### **Intervention Type**

Drug

### **Phase**

Not Specified

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

Loperamide, psyllium hydrophilic mucilloid

### **Primary outcome measure**

Faecal Incontinence Severity Index (FISI) patient-weighted score, measured at baseline, 6 weeks at cross over and at 12 weeks at conclusion of the second treatment period.

### **Secondary outcome measures**

1. 36-item Short Form health survey (SF-36)
2. Faecal Incontinence Quality of Life scale (FIQL)

All questionnaires were performed at baseline, 6 weeks at cross over and at 12 weeks at conclusion of the second treatment period.

### **Overall study start date**

01/12/2001

### **Completion date**

01/12/2004

## **Eligibility**

**Key inclusion criteria**

1. Over eighteen years of age
2. Referred to an outpatient colorectal service with the primary presenting problem of chronic incontinence to mucus, liquid and/or solid stool
3. Living independently
4. Able to read and complete the study information and questionnaires

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

60

**Key exclusion criteria**

1. Full thickness rectal prolapse
2. Inflammatory bowel disease
3. Other pathologies requiring surgery
4. Diabetes (chosen supplement contraindicated)
5. Previous treatment for faecal incontinence

**Date of first enrolment**

01/12/2001

**Date of final enrolment**

01/12/2004

**Locations****Countries of recruitment**

New Zealand

**Study participating centre**

Department of Medical and Surgical Sciences

Dunedin

New Zealand

9054

**Sponsor information**

**Organisation**

University of Otago (New Zealand)

**Sponsor details**

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**Sponsor type**

University/education

**Website**

<http://www.otago.ac.nz/>

**ROR**

<https://ror.org/01jmxt844>

**Funder(s)****Funder type**

University/education

**Funder Name**

University of Otago (New Zealand) - Research Grant

**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>	Results	01/07/2008		Yes	No