

The Lincolnshire Poacher study a randomised controlled trial



**A collaborative study involving Lincolnshire Community HealthCare Trust,
Hull Health Trials Unit, United Lincolnshire Hospitals Trust
and the Universities of Lincoln & Nottingham**

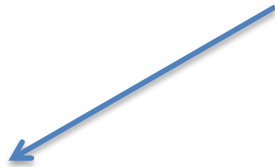
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Study hypothesis

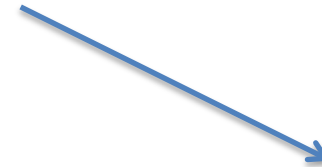
Many patients confidently diagnosed as having IBS with diarrhoea have missed but treatable organic diagnoses due to inadequate investigation of GI symptoms.

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Randomisation



**Standard
care by a GP
following NICE
guidelines**



**A nurse following a predefined
checklist of investigations and
management to rule out organic
disease**

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Primary end point:

Patient symptoms

Secondary end point:

Quality of Life at 1 year

Cost savings at 1 year

Patient recruitment:

n = 134

Study power:

85% to detect a significant improvement in symptoms

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Inclusion criteria,

- Meet Rome IV criteria for IBS/ functional diarrhoea
- Not previously seen for 'IBS' for 5 years
- No investigations for 'IBS' in secondary care
- Taking no prescribed medication for 'IBS'
- No alarm symptoms
- No previous cholecystectomy
- No previous GI surgery except appendicectomy/hernia repair
- No known Inflammatory Bowel Disease, Coeliac, liver or pancreatic disease
- No previous history of cancer (except basal cell carcinoma)

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Patient presents with IBS-like symptoms to primary care

**Clinicians gives patient a trial information sheet
& sends email to the study team**

Research nurse contacts patient, checks eligibility & takes consent

**Research nurse randomises patients to
GP care following NICE Guidance **or** Nurse led care**

**All trial paperwork will be done by the research team
50% of patients will not need to see the GP at all**

GP arm – management as per NICE guidance

Recommended tests

- Full blood count
- Erythrocyte sedimentation rate
- C-reactive protein
- Antibody testing for Coeliac disease.

Not recommended

- Further blood tests
- Any stool tests
- Any breath testing
- Any radiology tests
- Any endoscopy

Lifestyle modification

- Reduce stress
- Fibre intake 30g
- Regular meals
- Fluid
- Less resistant starch
- Limit fresh fruit
- Avoid sorbitol
- Trial wheat / lactose exclusion
- Increase activity
- Use of probiotics

Medication

- Antispasmodic
- Laxative
- Loperamide
- low dose TCA
- SSRI

Nurse led arm

1st consultation

- Assessment of dietary fibre / caffeine / alcohol intake
- FBC, U&Es, LFTs Bone screen, Coeliac screen, CRP, vitamin B12, Red Cell Folate & TFTs
- Stool for Pancreatic Elastase-1; Faecal Calprotectin; FIT
- Glucose hydrogen methane breath test c 50%

2nd line test

- SeHCAT scan c>30%

3rd line tests

- Fructose hydrogen methane breath test c<10%
- Sucrose hydrogen methane breath test

4th line tests

- Flexible sigmoidoscopy c 5%

5th line test

- Trial of low FODMAPs diet c <5%

Both study arms

Symptom and Quality of Life questionnaires – at start & 1 year

Assessment of NHS costs

- From consultations
- From investigations booked
- From medication prescribed

Assessment of patient costs

- From attending appointments eg travel/ time off work
- As a result of their symptoms eg over-the-counter medicines, incontinence pads, deodorants, extra lavatory paper and laundry

Target recruitment across Lincolnshire:

- 20+ participating GP practices**
- 8-10 patients randomised / month**

Trial opening dateMid August 2020