

# PROPER: Quality-of-life feedback using patient-reported outcomes after treatment of parastomal hernia

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<b>Registration date</b> 17/08/2023	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 06/08/2025	<b>Condition category</b> Digestive System	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

PROPER stands for Patient Reported Outcomes after Parastomal Hernia Treatment. The overall aim of the PROPER study is to see what the impact on the patient's quality of life is from having treatment for a parastomal hernia. The study will also look at how parastomal hernias are treated, for example having an operation and any complications that happen in the first 30 days, or deciding to "watch and wait". It will also look at whether there are any links between the way that a surgeon repairs a parastomal hernia and the outcomes.

What is a parastomal hernia? Stoma formation is often necessary after bowel surgery. A common complication of a stoma is a parastomal hernia (PSH), caused by a weakness in the abdominal muscle which results in a local bulge next to or behind the stoma. A PSH can cause skin irritation, problems with getting a stoma bag to stick, as well as pain and other more serious complications such as bowel obstruction. These issues often have a negative impact on a patient's quality of life.

What are patient-reported outcomes? Patient-reported outcome measures (PROMs) are questionnaires that measure the patient's view of their own health. Questionnaires are completed before and after treatment so that healthcare professionals and researchers can see how the treatment has impacted the patient.

### Who can participate?

Patients aged 18 years or above with a symptomatic parastomal hernia. This includes those referred to a colorectal surgeon for consideration of surgical treatment or seen by a clinical nurse specialist. Patients undergoing surgical treatment or conservative/watchful waiting are eligible for entry.

### What does the study involve?

Participants will be asked to complete questionnaires about their parastomal hernia as well as information about how they feel at various stages throughout their treatment. These details will be collected at the start (baseline), at 3 months, 6 months and at 12 months. The hospital team

will also record some additional information about the participant's medical history, and if patients have an operation as part of their treatment, they will record details about the surgery.

What are the possible benefits and risks of participating?

We do not expect any risk to study participants. Joining the study will not have any impact on patient care as participants will be receiving the same treatment they would if they did not join the study. Participants might find messages reminding them to complete the questionnaires a minor inconvenience, given that the study follow-up period continues up to 12 months after joining the study.

There will not be any direct personal benefit to joining the study. However, the data collected from the study will translate into direct benefits for patients in the future. It is possible that a patient participating in PROPER will not achieve successful PSH treatment during the lifetime of the study, or they will develop a new or recurrent PSH in the future. As such, an individual may also be able to personally benefit from their involvement in the study.

Where is the study run from?

University of Birmingham (UK)

When is the study starting and how long is it expected to run for?

March 2021 to August 2030

Who is funding the study?

Bowel Research UK and the European Society of Coloproctology (ESCP)

Who is the main contact?

Miss Nyeshya Henry, n.henry.1@bham.ac.uk

## Contact information

**Type(s)**

Scientific

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**Additional identifiers****Clinical Trials Information System (CTIS)**

Nil known

**Integrated Research Application System (IRAS)**

298207

**Protocol serial number**

CPMS 52007, BRUK334, IRAS 298207

**Study information****Scientific Title**

Patient Reported Outcomes after parastomal hernia treatment - a prospective international cohort study

**Acronym**

PROPHER

**Study objectives**

A prospective international cohort study of parastomal hernia (PSH) treatment, including both operative and non-operative interventions. A global network of clinicians and specialist nurses will collate detailed information on individual interventions used and short-term outcomes, then patients will provide their own medium and longer-term outcomes data including whether their treatment was successful, via a secure online/mobile phone-based system. The study will provide a wealth of contemporaneous information which will improve our ability to counsel patients and facilitate improved selection of appropriate and personalised interventions for those with a PSH.

**Ethics approval required**

Ethics approval required

**Ethics approval(s)**

approved 04/04/2022, South Central - Hampshire B Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)20 7104 8064; hampshireb.rec@hra.nhs.uk), ref: 22/SC/0060

**Study design**

Observational cohort study

**Primary study design**

Observational

**Study type(s)**

Quality of life

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

Parastomal hernia (PSH)

**Interventions**

PROPER is an international multi-centre prospective cohort study. A global network of clinicians and specialist nurses will enrol adults over the age of 18 years with a symptomatic parastomal hernia (PSH) for which treatment or intervention is being sought. The study is observational only - no intervention will be decided by the study protocol and is instead as per treating clinician's decision.

Patients undergoing both operative and non-operative interventions will be included, and identical outcome measures obtained for both populations. These outcome measures of treatment success will be almost exclusively patient-reported up to one year after study and include quality of life, stoma-specific symptom scores and additional treatments including hospital admission. In addition, a modified MYMOP (Measure Yourself Medical Outcomes Profile) will be obtained at study entry and this entirely personalised outcome measure assessed individually at study exit (12 months). A decisional regret analysis will also be obtained at study exit.

Patients undergoing surgical intervention during the study period will have additional detailed information recorded about the operative techniques employed so we can assess any impacts, beneficial or otherwise, on patient-reported outcomes. If a patient in the conservative management arm undergoes surgical repair of their parastomal hernia during the 12-month follow-up period, they will automatically cross over into the surgical group.

**Intervention Type**

Other

**Phase**

Not Specified

**Primary outcome(s)**

This study will collect a range of clinical and patient-reported outcome measures. There is no explicit primary outcome measure.

Patient-reported outcomes:

1. Health-related quality of life reported by the participant using the SF-12 score at baseline and 3, 6 and 12 months post-enrolment
2. Stoma impact reported by the participant using the Stoma Impact Score at baseline and 3, 6 and 12 months post-enrolment
3. Impact of the key symptom or issue the patient is hoping will be improved by their PSH

treatment assessed using the modified Measure Yourself Medical Outcomes Profile (MYMOP) at baseline and 12 months post-enrolment

4. Decisional regret assessed using the Decision Regret Scale at 12 months post-enrolment

Clinician-reported outcomes based on routinely collected data held in patient notes transcribed into electronic case report forms (eCRFs):

1. Patient demographics – including BMI, smoking status and comorbidities assessed using the online case report form (CRF) for the study at baseline

2. PSH details - including index operation, PSH characteristics and symptoms, previous treatments for this PSH - assessed using the online CRF at baseline

3. In those undergoing surgical repair:

3.1. Operation details – including technique employed, type and location of mesh placement (if appropriate) assessed using the online CRF at time of surgery

3.2. Short-term post-operation details assessed using the online CRF up to 30 days post-surgery, including:

3.2.1. Postoperative complications assessed using the Clavien-Dindo Scale

3.2.2. Postoperative complications assessed using the comprehensive complication index (CCI)

3.2.3. Length of stay

3.2.4. Unplanned re-operation

4. In those undergoing non-operative management:

4.1. Details of conservative treatment instigated, including support wear, physiotherapy, other advice given assessed using the online CRF at baseline

### **Key secondary outcome(s)**

There are no additional outcome measures

### **Completion date**

15/08/2030

## **Eligibility**

### **Key inclusion criteria**

1. Adult, aged 18 years and above.

2. A stoma formed from any part of the bowel – whole small bowel and colon, and of any format – including loop, end, double barreled, Abcarian, other

3. All treatments for PSH, including conservative (non-operative) treatment and surgical intervention. All types of surgical approach are included.

4. Elective presentations to outpatient services, including surgical, colorectal, stoma care team are included. Patients presenting primarily as an emergency with a symptomatic PSH requiring urgent intervention are also eligible for inclusion, providing informed consent can be obtained.

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

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

1. Patients with an isolated urostomy
2. Life expectancy less than 12 months
3. Proposed treatment plan for dealing with PSH involves restoration of gut continuity meaning that patient will have no stoma after treatment.
4. Anyone who does not have an email address or does not have access to the internet or a smart device

**Date of first enrolment**

21/08/2023

**Date of final enrolment**

09/08/2027

**Locations**

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

**Queen Elizabeth Hospital Birmingham**

Mindelsohn Way

Edgbaston

Birmingham

United Kingdom

B15 2WB

**Study participating centre**

**Royal Devon and Exeter Hospital**

Royal Devon & Exeter Hospital

Barrack Road

Exeter

United Kingdom

EX2 5DW

**Study participating centre**

**Leicester Royal Infirmary**

Infirmary Square

Leicester  
United Kingdom  
LE1 5WW

**Study participating centre**  
**Royal Lancaster Infirmary**  
Medical Wards  
Ashton Road  
Lancaster  
United Kingdom  
LA1 4RP

**Study participating centre**  
**Royal Victoria Infirmary**  
Queen Victoria Road  
Newcastle upon Tyne  
United Kingdom  
NE1 4LP

**Study participating centre**  
**Salisbury District Hospital**  
Salisbury District Hospital  
Odstock Road  
Salisbury  
United Kingdom  
SP2 8BJ

**Study participating centre**  
**Stoke Mandeville Hospital**  
Mandeville Road  
Aylesbury  
United Kingdom  
HP21 8AL

**Study participating centre**  
**York Hospital**  
Wigginton Road  
York  
United Kingdom  
YO31 8HE

**Study participating centre**

**Bedford Hospital South**

Kempston Road  
Bedford  
United Kingdom  
MK42 9DJ

**Study participating centre**

**Broomfield Hospital**

Court Road  
Broomfield  
Chelmsford  
United Kingdom  
CM1 7ET

**Study participating centre**

**Northern General Hospital**

Northern General Hospital NHS Trust  
C Floor, Huntsman Building  
Herries Road  
Sheffield  
United Kingdom  
S5 7AU

**Study participating centre**

**University Hospital Coventry & Warwickshire**

Clifford Bridge Road  
Walsgrave  
Coventry  
United Kingdom  
CV2 2DX

**Study participating centre**

**Warwick Hospital**

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Warwick  
United Kingdom  
CV34 5BW

**Study participating centre**  
**Royal Cornwall Hospital (treliske)**  
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Truro  
United Kingdom  
TR1 3LJ

**Study participating centre**  
**Blackpool Victoria Hospital**  
Whinney Heys Road  
Blackpool  
United Kingdom  
FY3 8NR

**Study participating centre**  
**Russells Hall Hospital**  
Pensnett Road  
Dudley  
United Kingdom  
DY1 2HQ

**Study participating centre**  
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United Kingdom  
DA2 8AA

**Study participating centre**  
**Milton Keynes University Hospital**  
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**Study participating centre**  
**Scarborough General Hospital**  
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United Kingdom  
YO12 6QL

**Study participating centre**  
**Tunbridge Wells Hospital**  
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Tunbridge Wells  
United Kingdom  
TN2 4QJ

**Study participating centre**  
**Salford Royal Hospital**  
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Eccles  
Salford  
United Kingdom  
M6 8HD

**Study participating centre**  
**Royal Blackburn Hospital**  
Haslingden Road  
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BB2 3HH

**Study participating centre**  
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Poole  
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BH15 2JB

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**Sunderland Royal Hospital**  
Kayll Road  
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United Kingdom  
SR4 7TP

**Study participating centre**  
**Luton and Dunstable University Hospital**  
Lewsey Road  
Luton  
United Kingdom  
LU4 0DZ

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**Aintree University Hospital**  
Fazakerley Hospital  
Lower Lane  
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L9 7AL

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Marlborough Street  
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## **Sponsor information**

**Organisation**  
University of Birmingham

**ROR**  
<https://ror.org/03angcq70>

## **Funder(s)**

**Funder type**  
Charity

**Funder Name**  
Bowel Research UK

**Alternative Name(s)**

Bowel Research United Kingdom, BRUK

**Funding Body Type**

Government organisation

**Funding Body Subtype**

Trusts, charities, foundations (both public and private)

**Location**

United Kingdom

**Funder Name**

European Society of Coloproctology

**Alternative Name(s)**

The European Society of COLOPROCTOLOGY, European Society of Coloproctology, ESCP

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Associations and societies (private and public)

**Location**

United Kingdom

## Results and Publications

**Individual participant data (IPD) sharing plan**

The data-sharing plans for the current study are unknown and will be made available at a later date

**IPD sharing plan summary**

Data sharing statement to be made available at a later date

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>	version 5.0	21/06/2023	03/08/2023	No	Yes
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes