

Pre-Screening Questionnaire

Study: The 8x5 Diet for bile acid diarrhoea

- This study is investigating a novel diet trial **for adults living with bile acid diarrhoea (BAD/BAM) who have ongoing diarrhoea**
- The trial is a healthy dietary pattern which aims to meet your nutritional requirements
- We want to know if the trial works under scientific conditions
- The study involves voluntarily taking part for 8 weeks
- **You may be suitable to participate if you answer Yes to:**

1	Is your age between 18 and 80 years?	Yes / No
2	Are you living at a permanent address in the United Kingdom for the next 3 months?	Yes / No
3	Do you have a confirmed diagnosis of BAD? <i>See page 2</i>	Yes / No
4	Do you have ongoing diarrhoea? <i>See page 3</i>	Yes / No
5	To treat your BAD, do you feel that you have fully explored medication? <i>See page 3</i>	Yes / No
6	Do you use digital technology (computer/laptop/smartphone/tablet) more than once every other day?	Yes / No
7	Would you be willing to keep a 7-day food diary twice, at the beginning of the study and again 8 weeks later? <i>See page 4</i>	Yes / No

If your 7 answers are all Yes, please follow the **next steps**:

1. Read the Participant Information Sheet to understand what this study involves.
2. Then, if you are keen to participate, email:
yvonne.mckenzie@postgrad.manchester.ac.uk Subject: *BAD & Diet Study with, "I have answered Yes to all 7 pre-screening questions and read the Participant Information Sheet. Please email me your Eligibility Questionnaire to further check my suitability to take part."*

If you are thinking about taking part in this diet study, please be aware of the following:

A. Do you have a confirmed diagnosis of BAD?

We need to be sure that you have bile acid diarrhoea/malabsorption (BAD).

You may be suitable to participate if:

- The cause or origin of your BAD is unknown
- You were diagnosed after you had your gallbladder removed
- You were informed about your diagnosis of BAD by a gastroenterologist after SeHCAT testing. In this study, BAD is defined as an abnormal 7-day SeHCAT retention result of $\leq 20\%$.

You would be unsuitable to participate if:

- You were not informed by a gastroenterologist that you have a diagnosis of BAD that was confirmed by SeHCAT testing
- The type of BAD you have followed after cancer treatment, or a diagnosis of Crohn's disease or surgery or disease to your ileum (the last section of your small bowel), or a diagnosis of diabetes, coeliac disease, HIV, or microscopic colitis.




B. Do you have ongoing diarrhoea?

For this study, using the Bristol Stool Chart on page 3, ongoing diarrhoea is defined if you have:

- I. at least 1 watery stool (types 6 – 7) per day on average every week, or
- II. 3 or more stools per day

for at least the last four weeks.

If neither I. or II. apply, then your poo consistencies are not suitable for your participation in this study.

Bristol Stool Chart		
Type 1		Separate hard lumps like nuts (hard to pass)
Type 2		Sausage-shaped but lumpy
Type 3		Like a sausage but with cracks on its surface
Type 4		Like a sausage or snake, smooth and soft
Type 5		Soft blobs with clear-cut edges (passed easily)
Type 6		Fluffy pieces with ragged edges, a mushy stool
Type 7		Watery, no solid pieces, entirely liquid

C. Have medicines not worked adequately well to treat BAD?

You may be suitable to participate if:

- You have tried, or could not tolerate, or currently use any of the following medicines to treat your BAD but still have diarrhoea:
 - Colestyramine/Questran/Questran Light, 4g powder in sachet: prescription allowance - up to 4 sachets per day
 - Colesevelam/Colestagel, 625 mg tablet: prescription allowance is up to 6 tablets per day
 - Loperamide/Imodium.

D. Would you be willing to keep a food diary?

You would be suitable for this study if:

- You are willing to keep a diary of everything you eat and drink over 7 days at the very beginning of the study and for a second time at the end of the study. This is an important part of the study because people with BAD want to understand the nutritional adequacy of their diet. Completing a food diary carefully takes some time.

You would be unsuitable for this study if:

- You would not be willing to weigh food items using a household measuring spoon or kitchen weighing scales (e.g. spread on bread)
- You know you would refuse to include any of the following four food groups in your diet:
 - Starchy foods (e.g. rice, potato)
 - Fruits and vegetables
 - Protein-rich foods
 - Dairy or plant-based alternatives

For example, if you insisted on sticking to a ketogenic diet in which you don't eat any starchy foods, then this study would be unsuitable for you.

If you are unsure about your answers to any of the 7 questions, then ask by emailing: yvonne.mckenzie@postgrad.manchester.ac.uk

E. Reliable Internet access is necessary for conducting the video consultations in this study. There will be either two or four sessions with the Specialist Dietitian. This depends on which of the two groups a participant is assigned to.