Study Title:	**Role of AHT#1 (Curcumin/green tea/vitamin D) food supplement on symptom control in diarrhoea predominant irritable bowel syndrome (IBS-D) as assessed by the IBS Severity Scoring System (IBS-SSS)**
Study Code:	
Sponsor:	**University College Hospital NHS Foundation Trust**

Participant Information Sheet

Invitation to take part in the research study

You are being invited to take part in a research study conducted at the University College of London Hospital. Before you decide if you want to take part, it is important for you to understand why the research is being done, how your information will be used and what it would involve for you. Please take time to read the following information and discuss it with your family doctor if you wish. One of our study team will go through the information sheet with you and answer any questions you have. Talk to others about the study and ask us if anything is not clear.

What is the purpose of the study?

Irritable bowel syndrome (IBS) management is often unsuccessful and new treatments are needed. This study will try to establish the impact of a combined mixture of natural ingredients which are normally taken individually, on change in IBS symptom severity.

What is AHT#1?

Taking AHT#1 BOWEL is a combination of natural food supplement including the curcumin, derived from turmeric, green tea extract derived from green tea and vitamin D. The ingredients have been researched for many years and are often taken as part of daily life. They have been shown to be effective in treating gut symptoms such as IBS, inflammation, bloating, wind, abdominal pain and diarrhoea.

Why have I been invited?

You are being asked to take part because you have diarrhoea predominant IBS and meet the study edibility criteria. This study will be conducted at UCL Hospital, and approximately 37 patients like you will be enrolled.

Do I have to take part?

It is entirely up to you to decide if you want to join the study. We will describe the study and go through this information sheet with you. If you agree to take part, we will then ask you to sign a consent form. You are free to withdraw at any time, without giving a reason. This would not affect the standard of care you receive. Whether you agree to participate or withdraw, we will look after you in exactly the same way as normal.

What will happen to me if I take part?

You will receive a 28 days supply of capsules for you to take on a daily basis. On day 1 you would be asked to commence taking 2 capsules of AHT# a day for 28 days without a break. You can take them together or separate.
28 days after starting you will come back to clinic and you will complete the IBS-SSS questionnaire again. You can then choose to stay on the trial for another 2 months or leave the trial if you had no benefit. Should they be having benefit then you will be offered a further 2 months of food supplement for free and return to clinic to complete assessment with a final IBS-SSS.

Patients who wish to continue taking the supplement will have access to 3 months of AHT#1 for free.

If you agree to participate, please read and return this completed form to your Doctor.

Expenses and payments

You will not be paid for participating in this study.

What are the alternatives for treatment?

You can speak to your gastroenterologist or GP about what alternative treatments are available. It may be that you have already tried different medications and exclusion diets without success.

What will I have to do?

By taking part in a research study you are responsible for the following:

- Notifying your study doctor of any changes in your health status
- Notifying your study doctor if you decide to stop taking part in the study
- Following the study procedures and providing information to your study doctor and other members of the study staff, as requested

What are the possible side effects and risks of taking part?

Risks of taking the AHT#1 food supplement are very low and related with the turmeric and caffeine that may stimulate a bowel motion in some individuals and therefore if there is any worsening of IBS symptoms the patient should stop taking the food supplements. Always take advice if you are on or due to be started on other medications by your doctor.

What are the possible benefits of taking part?

We cannot promise the study will help you but it is possible that your IBS severity scoring system score will improve. This means that the number of bowel motions, stool consistency, bloating and associated pain may improve after taking the capsules.

What happens when the research study stops?

You will be notified if for any reason the study is stopped early. The results of the study when published will be made available in the public domain. We will inform you directly of the results if you request us to.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to a member of the study staff who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do this via the NHS Complaints Procedure. Details can be obtained from the study staff or at the end of the document.

Will my taking part in the study be kept confidential?

If you take part in this study, your details would be stored in a protect file with password on the NHS computers your detail will linked with anonymous number, and only the research team would have access no one outside the research team should have access to this after consent.

All individuals who view your data will have a duty of confidentiality to you as a research participant and we will do our best to meet this duty.

By signing the written consent form, you will authorise such access. You may refuse to sign this document and grant this authorisation, but you will not then be able to participate in this study. If you do participate in this study, you may revoke this consent at any time.

What if relevant new information becomes available?

If information becomes available that may be relevant to your safety or willingness to continue participation in the study, you will be informed in a timely manner. Your research doctor will ensure your care continues.

What will happen if I don't want to carry on with the study?

Your decision to take part is voluntary and you may refuse to take part at any time. Refusal to take part initially or at any time during the study will involve no penalty or loss of benefits to which you are otherwise entitled.

If you want to stop taking part in this study, all you need to do is tell your study doctor. You are free to withdraw from the study at any time for any reason with no penalty or loss of medical care or other available treatment for your condition.

It is possible that your participation in the study may be stopped at any time without your consent. For instance, if you do not follow the instructions given to you by the study doctor, they may decide to stop your involvement in the study. The sponsor may also stop the study at any point.

If you withdraw from the study, we intend to use the data collected up to your withdrawal.

Involvement of the General Practitioner/Family doctor (GP)

Letter about your participation in this study will sent to inform your GP. They will also be informed if you need to discontinue the study.

What will happen to the results of the research study?

The results of this study will be published after the study is completed. You will not be identified in any publication. If you are interest, a research doctor will contact you by phone to inform about the result of the study.

Who is organising and funding the research?

The food supplement manufacturer, Profbiotics®, is providing the supplement and the UCL has sponsored the research. There are no conflicts of interest and the Doctors recruiting patients are not specifically being paid for including and looking after the patients in the study.

Who has reviewed the study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given a favourable opinion by *** Research Ethics Committee.

Further information and contact details

If you have any questions or require further information about the study, please contact the study doctor:

Prof Anton Emmanuel	Tel: 020 3447 9311
Dr Valentina Passananti	Tel: 020 3447 9130
For any advice you can contact UCLH PALS office	Tel: 020 3447 3042

Thank you for reading this information sheet – please ask any questions if you need to. Do not sign the consent form unless you have had a chance to ask questions and have received acceptable answers to all of your questions.