Information about participation in the Microbiome Group research programme

Thank you for your interest in taking part in this research programme to investigate and document how effectively Microbiome Analysis recommendations treat health conditions. Before you decide whether to join the study, please take time to read the following information to understand why the research is being done and what it will involve. If there is anything that is unclear, or if you would like more information, please contact us.

Why is this research happening?

Medical research has shown that the gut microbiome plays an important role in our health, and that microbiome changes are associated with most health conditions, including a wide range of chronic health conditions, such as Long Covid[1] [2]. We now understand that the gut microbiome can play a role in both promoting and regulating systemic inflammation[3] which may underlie many chronic illness symptoms. There is also a growing body of evidence that certain microbiome interventions can improve health outcomes. However, there is almost no robust research documenting how Microbiome Analysis enables treatment recommendations to be individualised to a person's unique gut microbiome and how this can result in positive health changes. Through this study, we will be able to collect vital information about the effects of Microbiome Analysis recommendations on a variety of health conditions.

Why have I been invited to take part?

As a client of The Microbiome Group you will be using microbiome testing to individualise microbiome interventions and track progress. Recording changes in your symptoms alongside changes in the bacterial populations that form your gut microbiome will provide vital information on how effective microbiome interventions can be in treating health conditions.

Do I have to take part?

Taking part in this research programme is entirely voluntary. If you want to take part you will be asked to indicate your consent using an online form. Your consent should be based on the details in this information sheet, and we encourage you to keep a copy for future reference. If you choose to take part in the research but then change your mind, you are free to withdraw at any time without giving a reason. **Your practitioner will not know whether you take part in the research study or not. Participating in the study, or withdrawing from the study, will not affect the standard of care you receive from the Microbiome Group**. A decision not to take part, or to withdraw at any time, will be fully respected, and your data will not be used to form any conclusions from the programme (unless you consent to that when you withdraw). Please convey your decision to withdraw your data in an email to The Microbiome Group.

What will happen if I take part?

You will receive treatment from your Microbiome Group practitioner as usual. The research programme will monitor results over a 12-month period. It's most helpful to have information for the full 12 months, but we will also be grateful for data covering any part of that period.

You will complete online surveys at the start of your treatment, and at 3 months, 6 months, 9 months and 12 months after commencing treatment – you will receive an automated email requesting you repeat those same surveys and consent form each time. **You will not receive reminders**, so please complete the surveys at your earliest convenience. All participants will be requested to complete a consent form and one symptom survey, and some will complete two further surveys – depending on their symptoms at the start of treatment. The surveys are **based on research instruments that have been validated in peer reviewed research** as accurate measures of changes in symptoms. This is important for robust research findings.

What are the costs of taking part?

There are no additional costs to taking part in this research project. All costs will be associated with your standard treatment with the Microbiome Group, and remain the same whether you choose to take part or not.

Will participation affect my conventional medical treatment?

Your treatment with the Microbiome Group is not a substitute to any medical diagnosis, advice or conventional medical treatment you may be receiving. You should continue to follow the medical advice or treatment you are given by your consultant or GP.

Will I be able to seek other complementary medical treatment?

You will be able to seek other treatment during the 12-month period but are advised to discuss this with your practitioner before starting it, as usual. If the treatment directly affects the microbiome (such as medicinal herbs) we request you make a note of it in the consent form.

What are the possible disadvantages of taking part?

The disadvantages and risks of taking part in this research are minimal. You may experience some digestive discomfort with certain supplements, but this should always feel mild and manageable. You will be able to review recommendations if necessary with your practitioner.

What are the possible benefits of taking part?

There are now many peer-reviewed articles published in the medical literature that suggest microbiome interventions can be beneficial in a wide range of health conditions. While we cannot guarantee a beneficial outcome to your treatment, we very much hope you will experience benefit and significant improvement in symptoms. **Taking part will contribute to the wider knowledge base about the efficacy of microbiome interventions in the treatment of health conditions, including Long Covid, which we hope will benefit others.**

What will happen to my personal information and microbiome data?

You will retain access to your microbiome data, as usual, through the testing company Biomesight's online portal. You will also be able to download the raw test data. Alongside your microbiome data, the Biomesight will only have access to your name, any personal details you

choose to give them, and your email address for your account. As with all treatment, the Microbiome Group will keep a copy of the microbiome data, written notes of your case history and subsequent sessions, analysis and written report; all in electronic format on a password-protected computer and secure cloud storage. All clinical information is stored separately from your personal information using anonymised codes. None of your personal data will be passed on to any third party, although processed, anonymised data may be published (as outlined below). **All information collected about you during the study period will be kept confidential in accordance with General Data Protection Regulation (GDPR) legislation, as set out in the Microbiome Group privacy policy.**

How will my results be used?

The findings of this study may be published in a variety of formats, such as online articles, social media posts, and possibly in printed formats such as professional journals. They may also be discussed in professional meetings with other microbiome practitioners, interviews, seminars for healthcare practitioners, group sessions for long-term condition sufferers, and other teaching settings. All information will be anonymised, so none of the microbiome data or case details will be identifiable to anyone taking part in the study. Your microbiome data and case details will only ever be discussed using a pseudonym and other personal details (such as occupation and age) may be altered to further anonymise your results if necessary.

What if there is a problem?

If you have any queries or complaints about any aspects of this research or your treatment, please contact The Microbiome Group, who will do their best to answer any of your questions and address any of your complaints swiftly.

What will happen when the research has finished?

You will not be contacted again after participating in this research unless you choose to sign up to our email lists or arrange for follow-up contact after the end of the programme.

Can I get information about the study's findings?

You can choose to receive information about the study's findings by subscribing the Microbiome Group email list, by reading the Microbiome Group's website or following us on Instagram or Facebook for links to published findings.

Thank you for taking the time to read this information sheet. To take part, please return to www.themicrobiomegroup.com/researchproject and fill out the consent form and relevant surveys before you commence any treatment recommendations. You will next receive an automated email requesting you complete those same surveys around 12 weeks' after your results consultation.

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[1] Gu et al (June 2020) Alterations of the Gut Microbiota in Patients with COVID-19 or H1N1 Influenza, Clinical Infectious Diseases
[2] Zuo et al (May 2020) Alterations in Gut Microbiota of Patients with COVID-19 During Time of Hospitalization, Gastroenterology
[3] *For example;* Jialal and Rajamani (2014) Endotoxemia of metabolic syndrome: a pivotal mediator of meta-inflammation. Metabolic Syndrome Related Disorders 12(9): 454-456 *and* BerniCanani, et al (2012). The epigenetic effects of butyrate: potential therapeutic implications for clinical practice. Clinical Epigenetics, 4(1), 4