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NHS Foundation Trust

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SPACER Study

Patient Information Sheet

Title of Project: ***S**ymprove, a **P**ilot **A**ssessment of its **C**linical **E**ffect on **R**eflux*

A pilot study exploring the use of Symprove for the management of gastroesophageal reflux symptoms

Name of Researchers:

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Invitation and Brief Summary

We are inviting you to take part in a research project where we will assess the impact of a gut supplement (Symprove™) in people with gastroesophageal reflux disease (GORD) over 6 weeks.

This study is being sponsored by Manchester University NHS Foundation Trust (MFT) and funded by Symprove Ltd.

Please read this information before you decide whether you would like to take part.

What is the purpose of this research?

The gut microbiome is the ecosystem of microbes that live in your intestines and can influence health. More recently, scientists have found that the gut microbiome may play a role in the risk of developing Gastro-Oesophageal Reflux Disease (GORD). Since the gut microbiome is flexible and can be changed, treatments that target it - like probiotics - could offer a new way to manage symptoms and are worth exploring further. This will be the first study collecting data on the impact of a supplement called Symprove in people with GORD.

What is Symprove?

Symprove is a water-based solution that contains billions of live and active bacteria. The water-based formula makes sure that the bacteria are alive, active and ready to help stimulate the good

bacteria already in the gut. Symprove is backed by over 15 years of research and is already available to buy.

It has been tested across many different clinical groups (e.g. Irritable Bowel Syndrome, Inflammatory Bowel Disease, Parkinson's disease, Multiple sclerosis, long COVID) including vulnerable groups (e.g. children with rare dermatology conditions and Down's syndrome) with no adverse events reported.

This study will not generate efficacy data for the Symprove product; its purpose is to collect preliminary data to inform future research instead.

What happens if you agree to take part?

If you decide to take part in this study, the study team at Manchester University NHS Foundation Trust will complete your baseline visit at Wythenshawe Hospital and help you to complete an order request for a free course of Symprove to take 70 ml once a day in the morning for 6 weeks on an empty stomach.

During the next 6 weeks, you will have contact with a member of the research team weekly via telephone to ask you questions about your symptoms.

What to expect during the consent process

After discussing the study with the research team and if happy to take part, you will be asked to sign a consent form. You will be given a copy of the consent form alongside this participant information sheet to take away with you.

What are the possible benefits of taking part?

Although you may not receive any health benefit from taking part, research like this can improve our understanding of GORD and help develop new ways to manage it in the future.

All participants who complete the study will receive a code for an additional free 12-week course of Symprove.

What are the possible disadvantages and risks of taking part?

A small number of people may experience mild gut disturbances (such as bloating or change in bowel habit) when they first start taking Symprove™. As with any nutritional intervention the gut needs a little time to adapt. Disturbances will usually resolve in the first few weeks.

Do I have to take part?

No, you do not have to take part if you do not wish to, and your decision will not affect any standard of care you receive at Manchester University NHS Foundation Trust.

What happens if I change my mind?

Taking part in this study is completely voluntary and it does not affect your standard care within the NHS. If you decide that you no longer want to take part into the study, you can withdraw at any point

and your care will not be affected. Only the study data collected from you up until the withdrawal point will be used.

What happens if something goes wrong?

If you have a concern about any aspect of this study, you should ask to speak with the lead researchers who will do their best to answer your questions (***Sharon Archbold on sharon.archbold@mft.nhs.uk and Sorela MaziluWood on Sorela.maziluwood@mft.nhs.uk)***

If you remain unhappy and wish to complain formally, you can do this by contacting local NHS Patient and Liaison Service (PALS) or equivalent: **email pals@mft.nhs.uk** or call 0161 276 8686.

The hospital is insured to carry out clinical research through the NHS Indemnity scheme, however the normal National Health Service complaints procedures should be available to you. In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against Manchester University NHS Foundation Trust but you may have to pay your legal costs

What will happen with the results of the study?

We will publish the results of the study in an international research journal and will disseminate results at relevant conferences. You will not be identified in any publication.

How will we use information about you?

We will need to use information from you and your medical records for this research project.

This information will include the following:

- Initials
- NHS number
- Name
- Contact details
- Medical History including test results

People will use this information to do the research or to check your medical (hospital and GP) records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure by:

- Using password protected documents and file sharing systems

Symprove company will require your personal details (full name, address and telephone number) for the purpose of delivering the Symprove product. No medical details are required, and your in-

formation will be deleted 12 months after the study completion. Your data will be handled according to GDPR laws and the specific European legislations listed in the Symprove privacy policy; More about it, can be found by accessing Symprove privacy policy. (www.symprove.com/pages/privacy-policy).

How will we use information about you for the duration of the study and after the study ends?

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

Identifiable participant data will be deleted after 12 months of study completion.

Anonymised study data will be archived for 10 years and will be destroyed after that.

Study Results will not be automatically shared with study participants, but they are available on request.

Where can you find out more about how your information is used?

You can find out more about how we use your information:

- at www.hra.nhs.uk/patientdataandresearch
- at https://research.cmft.nhs.uk/getting-involved/gdpr-and-research
- by asking one of the research team You can phone us on 01612914188 during working hours 08:00- 16:00 Monday to Friday

or by sending an email to sharon.archbold@mft.nhs.uk & sorela.maziluwood@mft.nhs.uk

For any Adverse Events:

- you can phone us on 01612914188 during working hours 08:00- 16:00 Monday to Friday

- for urgent queries outside of working hours please contact NHS 111 or seek emergency medical care through the normal channels if appropriate.