



### **Participant Information Sheet**

Nutrition Innovation Centre for Food and Health (NICHE)  
School of Biomedical Sciences  
Ulster University

**Food4PD:  
Validation of a novel functional food designed to  
meet the nutritional needs of People living with Parkinson's Disease**

### **Invitation**

You are being invited to take part in a research study being conducted at Ulster University. Before you decide whether or not to take part, it is important that you understand what the research is for and what you will be asked to do. Please read the following information carefully and do not hesitate to ask any questions about anything that might not be clear to you. Take time to consider whether or not you want to take part in this research.

**Thank you for taking the time to consider this invitation**

**What is the purpose of the study?**

Constipation is a common complication of Parkinson's disease (PD), affecting up to 80% of people living with PD. Research suggests that increasing the amount of fibre in your diet could help to alleviate the symptoms of constipation. Inulin is a type of fibre widely found in a variety of vegetables, and recent studies have shown that inulin can improve constipation in people with PD. With the assistance of a food company (ABC Nutritionals), we have co-developed a fruit flavoured drink product (in the form of a powdered shake) enriched with chicory inulin (a type of dietary fibre) and other key nutrients, including B-vitamins and vitamin D. We plan to conduct a 12-week study to test the effectiveness of this product in improving nutritional status, alleviating constipation and potentially improving quality of life for people living with PD.

**Why have I been chosen?**

You have been chosen because you are living with PD and/or attend a PD community support group, you are aged  $\geq 18$  years, are not currently consuming antibiotics and/or using any supplements containing B-vitamins, inulin or probiotics. Probiotics are live microorganisms that, when administered in adequate amounts, could confer health benefits. They are found in foods including kefir and probiotic yogurts (e.g. Activia, Yakult drinks).

**Do I have to take part?**

It is up to you to decide whether or not you take part. You have the right to withdraw from the study at any time without giving a reason. If you withdraw, all personal information and data collected to that point will be retained unless you request otherwise.

**What will happen to me if I take part?**

If you decide to participate, you will be given this information sheet to keep and you will be asked to sign a consent form. You will be asked to attend either the Human Studies Intervention Unit at Ulster University (Coleraine campus), the Clinical Translational Research and Innovation Centre (CTRIC), or Health Hub Professionals Clinic in Derry/Londonderry on two occasions: at the start of the study and at the end after consuming the drinks for a period of 12 weeks.

On each occasion you will be asked to do the following:

- Have physical measurements recorded, including, height, weight, waist and hip circumference, blood pressure and hand grip strength. Please note that you will be asked to remove any heavy outer clothing and take your shoes off during height and weight measurements.
- Provide answers to some questions about your own general health, PD symptoms, diet, lifestyle, use of vitamin supplements and medications.
- Complete The Parkinson's Disease Questionnaire (PDQ-39) to assess quality of life.

- Record bowel habits using the Gastrointestinal Symptom Rating Scale, a Daily Bowel Habit Diary and the Bristol stool chart which is used to assess the consistency of your stools.
- Provide a stool sample, which you will collect at home. We will provide you with a container and instructions on how to collect your sample. Stool samples are being collected to look at the changes in the microorganisms in your gut during the 12-week study.
- Provide a 38ml non-fasting blood sample to assess blood levels of nutrients, including B-vitamins and vitamin D, and to measure markers of inflammation. Please ensure you wear either a short-sleeved shirt or a top with loose fitting sleeves that can be rolled up for providing your blood sample.
- Record dietary intake for 4 days using a paper-based food diary.
- Complete the MDS-Unified Parkinson's Disease Rating Scale to evaluate various aspects of Parkinson's disease. This includes Part I (non-motor experiences of daily living), Part II (motor experiences of daily living), Part III (motor examination) and Part IV (motor complications). Each part will involve the researcher either observing your behaviour or carrying out manual examinations of your movement/physical ability e.g., rigidity. Please note that every effort will be made to ensure you are comfortable during this assessment.

Your participation in the study will involve two appointments at a clinic of your choice, each of which will take approximately 1 hour 30 minutes in total (excluding travel time).

In the event that any abnormal findings (e.g., abnormal blood results) are identified, we will contact you via letter advising you to contact your GP – a copy of your results will also be included with this letter.

We would ask for your permission to retain your blood samples for use in future Ulster University approved studies.

We will also ask you if you agree to be contacted by researchers from Ulster University at a later date to be invited to take part in similar nutrition-related studies. You will only be agreeing to receive information and will not be under any obligation to take part in any future studies. If you decide not to consent to being contacted in the future, it will have no influence on your involvement in this research study and will not affect your rights in any way.

### **What do I have to do?**

Throughout the 12-week study period, you will go about your daily activities as normal, and we will ask you to consume either an enriched drink or a control drink in the form of a powdered shake up to two times per day for the duration of the study. The drinks will be fruit flavoured and you will make each drink up with 250mls of water. For weeks 1 and 2, you will consume one drink daily and from weeks 3 to 12 consume two drinks per day to allow for a

gradual increase in inulin (fibre) intake. The drinks will be provided to you during your first study appointment in individually packaged portions alongside instructions for consumption, storage and shelf life. A full list of ingredients in the drinks along with allergen and nutritional information will be provided to you. The drinks should be incorporated into your normal diet and are intended to accompany one of your main meals or snacks. You will be provided with a water bottle that can be reused to prepare and consume your drink from.

The enriched drink will contain key nutrients of importance: chicory inulin (a type of dietary fibre), B-vitamins (folic acid, B12, B6, riboflavin) and vitamin D. The control drink will contain a similar energy content but without the additional nutrient provision.

**Are there any alternative interventions?**

Following your normal dietary patterns and ensuring adequate hydration.

**What about side effects?**

There are no known side effects of consuming these drinks. A full list of ingredients will be provided should you have any allergies.

**Risks and/or disadvantages?**

There is a very small risk of bruising when giving a blood sample, but a fully trained and qualified phlebotomist will take your blood sample to ensure that any discomfort or risk of bruising is kept to a minimum.

**Are there any possible benefits in taking part?**

Upon completion of the study, you will be reimbursed for your travel expenses. You will also be kept informed of the study outcomes and your participation may help to develop more effective strategies to help in the management of constipation in people living with PD.

**What if new information becomes available?**

If new information becomes available during the course of the study, you will be kept informed, and any options or requests/requirements of the study will be fully explained to you. New information could result in termination of the study, withdrawal of certain participants or modification/amendment of the study procedures.

**What happens when the study ends?**

Once the study is finalised, you will be sent a copy of the overall study findings via post or email. We will also invite you to attend an information event for study participants (and any interested friends/family) of the Food4PD study. If you require any specific details on the outcomes/findings of the study, please feel free to contact us.

**What if something goes wrong?**

It is very unlikely that something will go wrong during this research. However, you should know that the University take complaints and concerns seriously and has procedures in place for reporting, investigating, recording, and handling adverse events. The University is insured for its staff and students to carry out research involving people; however, this does not extend to non-negligent harm. The University is aware about this research project and has approved it. Any complaint should be made in the first instance to the Chief Investigator identified for this particular study and will be reported to the appropriate authority. Further details on insurance can be found in the University's research indemnity statement. Please ask us if you would like a copy.

**Will my taking part in this study be kept confidential?**

All data collected from you for the study will be held securely and kept strictly confidential. Any information that leaves Ulster University will have your name and address removed so that you cannot be identified as required under Data Protection legislation. All samples collected from you will be coded so that you cannot be identified from them and will be stored in a restricted access freezer until they are analysed. Following the end of the ten-year data retention default period, information will be safely destroyed once it is no longer required. Please note that depending on the type of study, disclosure of personal information may be desirable or required – for example, it may be in your best interests to have certain test results passed, with your consent, to your GP. The University is compliant with the General Data Protection Regulation (GDPR), more information can be found using this web link: <https://www.ulster.ac.uk/about/governance/compliance/gdpr>. Should you require any further assistance, please contact the University's Data Protection Officer at [GDPR@ulster.ac.uk](mailto:GDPR@ulster.ac.uk).

**What will happen to the results of the study?**

It is intended that the findings from this study will be published in scientific or medical journals and presented at relevant conferences. In addition, the findings will be shared with relevant PD advocacy groups. You will not be identified in any report or publication. Once the study is complete, we will send you a summary of the results by post or email. We hope that the results of this study will help inform future research in this area.

**Who is organising and funding the research?**

This study is organised by researchers from NICHE at Ulster University, Coleraine. Funding for this research is provided by the UK Research and Innovation - Biotechnology and Biological Sciences Research Council (UKRI-BBSRC) under its RIPEN Innovation Hub scheme.

**Who has reviewed this study?**

This study has been reviewed by peers knowledgeable in the conduct of scientific research and has been reviewed by Ulster University, School of Biomedical Sciences Ethics Filter

Committee (in accordance with university procedures), and the University Research Ethics Committee. Should you require further details, you can contact the University Research Governance section.

**Contact Details**

If you have any questions or would like more information, please contact our researchers:

Dr Michelle Clements (Researcher): (+44) 028 701 24596 or [m.clements@ulster.ac.uk](mailto:m.clements@ulster.ac.uk)

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**\*Thank you for taking the time to read this information\***