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Quantifying and modifying ultra-processed food intake in the management of functional dyspepsia

Submission date 15/05/2025	**Recruitment status** Recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 26/05/2025	**Overall study status** Ongoing	
Last Edited 19/12/2025	**Condition category** Digestive System	

Plain English summary of protocol

Background and study aims
Functional dyspepsia (FD) is a common digestive condition that causes discomfort in the upper part of the stomach, such as pain, bloating, and feeling overly full. These symptoms can make it hard for people to go about their normal routines. While medications are the main treatment for FD, they often only provide partial relief and may not work for everyone. Some foods have been linked to FD symptoms, but the idea of using special diets to treat FD hasn't been studied much, and current advice is inconsistent. Recently, there's been growing concern about the effects of ultra-processed foods (UPFs) on health, including digestive issues like FD. UPFs are foods heavily changed through industrial processing and often have added chemicals like preservatives, flavour enhancers, and artificial ingredients. In this study, we want to learn if people with FD tend to eat a lot of UPFs. This could help us understand if high UPF intake is common among people with FD.

Who can participate?
Adults aged between 18 and 65 years with functional dyspepsia

What does the study involve?
For those who eat a lot of UPFs, we'll test if switching to a minimally processed food (MPF) diet can help reduce symptoms. Along with diet changes, we'll support participants in building healthy habits that they can maintain long-term. Over 3 months, we'll track changes in symptoms, quality of life, and other health indicators. Our goal is to see if reducing UPF intake could be a new, effective treatment for people living with FD.

What are the possible benefits and risks of participating?
We do not know whether people will benefit personally from taking part in this study, but the knowledge gained from this study will inform future research and treatments into FD. If patients proceed to phase 2 (the minimally processed food diet intervention), it is likely they will experience a benefit because they will be supported to improve their diet and be more physically active. This may have a benefit on both their digestive symptoms and general health. There are possible disadvantages and risks related to the study assessments, procedures, and

questionnaires that patients will have to undergo when taking part in the study. This can include minor discomfort from blood tests and discussing sensitive or upsetting. Overall, the study is low risk. We do not expect there to be any major risks or adverse events from taking part in the study.

Where is the study run from?
This research study is being organised by the Centre for Obesity Research at University College London (UCL). UCL is the sponsor for this study based in the United Kingdom. The sponsor is the organisation responsible for ensuring that the study is carried out correctly. Participants will be identified from patients be referred to University College London Hospital (UCLH) for the investigation of dyspepsia and subsequently diagnosed with functional dyspepsia based on the findings of 'negative' investigations.

When is the study starting and how long is it expected to run for?
March 2025 to October 2026

Who is funding the study?
This study is being funded as part of a doctoral research project at University College London. Additional funding has been sought but has not yet been confirmed. Any further information about the funding of the study will be provided once additional information has been received from the grant applications.

Who is the main contact?
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Contact information

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
348984

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
176078

Study information

Scientific Title
A prospective, pragmatic, pilot study to quantify the degree of ultra-processed food intake in patients with functional dyspepsia, and assess the impact of a minimally processed food diet as a treatment modality

Acronym
FD-ULTRA

Study objectives
It is hypothesised that adult patients referred to secondary care for investigation of dyspepsia, and subsequently diagnosed with functional dyspepsia based on the presence of negative investigations, will, on average, consume a high proportion of ultra-processed foods (UPFs) in their diet. Furthermore, among those diagnosed with functional dyspepsia who consume the highest proportion of UPF in their diet, as determined by contribution to their daily caloric intake (e.g. ≥50%), a structured dieting programme consisting of behavioural support and an minimally processed food (MPF) diet would be beneficial in terms of improvements to symptoms and quality-of-life.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 18/03/2025, North West - Preston Research Ethics Committee (Barlow House, 4 Minshull Street, Manchester, M1 3DZ, United Kingdom; +44 (0)161 625 7818; nrescommittee.northwest-preston@nhs.net), ref: 25/NW/0055

Study design
Prospective pragmatic pilot study

Primary study design
Interventional

Study type(s)
Efficacy, Quality of life, Treatment

Health condition(s) or problem(s) studied
Functional dyspepsia

Interventions
Current interventions as of 19/12/2025:

The researchers are recruiting 126 patients as part of an observational study to look at the association between functional dyspepsia and ultra-processed food. Among these 126, 24 will be recruited to take part in the interventional proportion, which will be testing a minimally processed food diet and its impact on gastrointestinal symptoms.

Patients initially screened for the observational study (V1) complete a medical assessment and a series of questionnaires, then exit the study. Among those with the highest intake of ultraprocessed food based on the Intake24 dietary recall questionnaire (≥50%), they will be invited to take part in the intervention. This will be a minimally processed food diet, provided by researchers/dietitians/psychologists, which involves education, behavioural changes, recipe advice, leaflets and motivational interviewing at baseline and then 1- and 3-months follow-up. These will be face-to-face. The sessions will be centred around ultra-processed food and will be tailored to the needs of the individual (e.g. work schedule, dietary requirements, cooking skills, finances).

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Previous interventions:

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be tailored to the needs of the individual (e.g. work schedule, dietary requirements, cooking skills, finances).

Intervention Type
Behavioural

Primary outcome(s)
1. The proportion of ultra-processed food intake within the diet of individuals diagnosed with functional dyspepsia measured at screening using the Intake24 dietary recall questionnaire (≥3 24-hour recalls over a 7-day period) that has been modified to account for ultra-processed food intake.
2. Gastrointestinal symptom severity measured using the Patient Assessment of Upper Gastrointestinal Symptom Severity Index (PAGI-SYM) at baseline, and 3-months

Key secondary outcome(s))
Observational cohort:
1. Gastrointestinal symptoms measured using patient assessment of upper gastrointestinal symptoms (PAGI-SYM) and the Visceral Sensitivity Index (VSI) at baseline stratified by groups based on UPF consumption
2. Quality of life measured using the Patient Assessment of Upper Gastrointestinal Disorders–Quality of Life (PAGI-QOL) and EQ-5D-5L at baseline stratified by groups based on UPF consumption
3. Psychological health measured using the Patient Health Questionnaire (PHQ-9) and the Generalised Anxiety Disorder Questionnaire (GAD-7) at baseline stratified by groups based on UPF consumption
4. Eating behaviour and patterns measured using the Food Frequency Questionnaire (FFQ) at baseline stratified by groups based on UPF consumption
5. Biometrics measured using bioelectrical impedance analysis at baseline stratified by groups based on UPF consumption

Interventional cohort:
1. Gastrointestinal symptoms measured using PAGI-SYM, VSI at 1- and 3-months
2. Quality of life measured using PAGI-QOL, EQ-5D-5L at 1- and 3-months
3. Psychological health measured using PHQ-9, GAD-7 at 1- and 3-months
4. Biometrics measured using bioelectrical impedance analysis at 1- and 3-months
5. Eating behaviour and patterns measured using Intake24 at 1- and 3-months

Completion date
01/10/2026

Eligibility

Key inclusion criteria
1. Adults aged ≥18 and <65 years old
2. Diagnosed with functional dyspepsia based on the Rome IV Clinical Diagnostic Criteria; bothersome epigastric pain or burning, early satiation, and/or postprandial fullness of greater than 8 weeks duration, and no evidence of structural disease (including at upper endoscopy) likely to explain the symptoms
3. Able to read and write in English
4. Willing and able to give written informed consent

Additional inclusion (interventional phase):
1. A habitual diet high in UPF, as defined by ≥50% of total energy intake from UPFs
2. Women of childbearing potential (WOCBP) should have a negative urine beta human chorionic gonadotrophin (hCG) pregnancy test within 28 days of diet initiation and agree to use one established method of contraception throughout the study duration
3. Medically safe to participate in a dietary intervention programme
4. Able to comply with the study protocol, including dietary recommendations, attending sessions and confirming adherence throughout dietary recall

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
64 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Confirmed helicobacter pylori infection based on stool antigen test, rapid urease test (CLO), and/or histopathological assessment
2. Coeliac disease or villous atrophy
3. A diagnosed eating disorder
4. Body mass index (BMI) <18.5 or ≥45 kg/m2
5. Use of non-steroidal anti-inflammatory drugs or corticosteroids
6. Inflammatory bowel disease
7. Co-existent diagnosis of irritable bowel syndrome
8. Co-existent diagnosis of gastro-oesophageal reflux disease, functional heartburn or reflux hypersensitivity (bothersome retrosternal symptoms including discomfort, heartburn, regurgitation, and/or chest pain; intermittent symptoms not affecting quality of life are allowed)
9. Known structural disorder of the upper gastrointestinal tract (neoplasia, Barrett's oesophagus, hiatus hernia ≥4 cm, oesophagitis ≥grade B, pharyngeal pouch, oesophago-gastric varices, erosive gastritis, active peptic ulcer disease, previous oesophago-gastric surgery)
10. Severe psychiatric disorder that might interfere with study participation or adherence
11. Women who are pregnant or breastfeeding
12. History of alcohol or substance abuse
13. Use of artificial nutrition
Added 24/10/2025: 14. Any systemic disease or concomitant medication judged by the investigator to be a more likely explanation for the participant's dyspeptic symptoms.

Additional exclusion (interventional phase):
1. Contraindication for dietary intervention
2. Any diagnosed food allergy, or other allergies, which limit the ability to adhere to the intervention diet
3. Any major dietary restrictions which limit the ability to adhere to the dietary intervention
4. A suspected eating disorder based on the EDE-QS questionnaire
5. History of major cardiorespiratory co-morbidities (e.g. myocardial infarction, chronic heart failure exacerbation, stroke, TIA, or major event requiring hospitalisation within the last 6 months)
6. History of new or worsening signs or symptoms of coronary heart disease (CHD) within the last 3 months
7. Known case of symptomatic heart failure with reduced ejection fraction (NYHA Class II-IV) requiring pharmacologic therapy to control symptoms
8. Severe anaemia (≤80 g/L)
9. Known case of severe peripheral vascular disease
10. History of moderate to severe chronic kidney disease (CKD) with an estimated glomerular filtration rate (eGFR) of < 30 mL/min/1.73m2 (estimated by Modification of Diet in Renal Disease (MDRD)), end-stage renal failure, or on dialysis
11. Symptomatic gallstones, symptomatic kidney stones, or acute cholecystitis
12. Clinically active systemic infection
13. Known history of chronic pancreatitis or a recent history of acute pancreatitis within the past year
14. History of active malignancy or partial remission from clinically significant malignancy within the past 5 years (except basal or squamous cell skin cancer, carcinoma in situ, those who received curative treatment and are in complete remission for 5 years, or if the subject is confirmed as cancer free)
15. Participation in another clinical intervention trial
16. Use of a neuromodulating agent (e.g. tricyclic anti-depressants, selective serotonin reuptake inhibitors, anti-psychotics, serotonin norepinephrine reuptake inhibitors, mirtazapine, etc)
17. Use of an anti-acid therapy (e.g. PPI, HR2A), which has been changed within the last four weeks and cannot remain stable for the duration of the trial.
18. Use of a medication that can affect the motility of the stomach (e.g. domperidone, metoclopramide, glucagon-like 1 peptide receptor agonist, prucalopride), which cannot be stopped for the duration of the dietary intervention, including at least 14 days before the baseline visit.
19. Poorly controlled diabetes as evidenced by >2 oral anti-diabetic agents, use of an injectable anti-diabetic medication, diabetes >8 years duration, or a glycated haemoglobin ≥53 mmol/mol.
20. Recovered from severe COVID-19 infection (requiring hospitalization) but with persistent long COVID-19 symptoms (i.e., the individual has not recovered for several weeks or months since
the start of symptoms that were suggestive of COVID-19, irrespective of whether the individual is tested or not)
21. Any other mental or physical condition which, in the opinion of the investigator, makes the subject a poor candidate for clinical-trial participation

Date of first enrolment
01/08/2025

Date of final enrolment
01/07/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University College London Hospitals NHS Foundation Trust
250 Euston Road
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Study participating centre
University College London Centre for Obesity Research
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Sponsor information

Organisation
University College London

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes