The effects of the different bread types of fully known composition on gastrointestinal symptoms in individuals with non-coeliac wheat sensitivity.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal disorders
Study type	Interventional

Summary

ID

NL-OMON52898

Source
ToetsingOnline

Brief title
Different bread types in NCWS.

Condition

- Gastrointestinal disorders

Synonym
Non-coeliac wheat sensitivity, wheat sensitivity

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht

Source(s) of monetary or material Support: Companies contributing with an unconditional grant to the TKI subsidy (e.g. Nutrition Science Corner, Borgesius, AB Mauri, CSM innovation bakery center, Puratos bv, CYMMIT-BIMBO, Int. Wheat Gluten Association, Lantmännen EK, Fazer bakeries oy, Baking industry research trust, DSM Food specialties, Health grain forum, Nutrition et sante, Rademaker BV-bakery equipments, Sonneveld group BV, Zeelandia, Agrasys R&D, VAMIX NV) zie ook http://www.um-eatwell.nl/wow/finance-flows-audits.htm,TKI subsidie Well on Wheat? is financed by a grant of the Dutch Government TKI- Top Knowledge Institute - Sector AgriFood and a wide range of funding partners from the Agro-Food chain based on donations made to ICC (International association for Cereal Science and Technology Vienna).

Intervention

Keyword: - Bread, - GI symptoms, - Non-coeliac wheat sensitivity (NCWS), - Wheat

Outcome measures

Primary outcome

The main study parameter is the change in overall intestinal symptom score,

measured by a 100mm visual analogue scale (VAS), induced by the bread type

consumed.

Secondary outcome

- Individual gastro-intestinal and extra-intestinal symptoms

- Average stool frequency and consistency

- Gut microbiota composition and activity

Study description

Background summary

Although wheat and gluten containing food products are generally considered to be healthy, a large number of individuals in the general population reduce or limit their intake because of possible symptoms and/or replace wheat by other grain, such as spelt. This non-coeliac gluten or wheat sensitivity (NCGS/NCWS) which is accompanied by a range of (extra-)intestinal complaints soon after consuming wheat or gluten, which improve after gluten/wheat withdrawal. Evidence for a biological rationale is however limited, nor for the exact

contributing compound. The term NCGS implies that gluten is the trigger for the reported symptoms. However, besides gluten, wheat, spelt, barley, rye and their derivatives contain other components which may contribute to symptoms, including fermentable carbohydrates and amylase trypsin inhibitors (ATIs). Therefore, the term NCWS is preferred. The biochemical composition differs between grains and specific processing methods in bread, and may impact gastrointestinal tolerability in NCWS.

In this respect, it is unclear what the impact of grain type, bread processing and the resulting compositional changes in the bread to be consumed is. Thus far studies did neither directly compare the effects of different wheat types, nor the effects of their specific processing in bread making on GI symptoms in individuals with NCWS. Ancient wheat species (e.g. Emmer) have been suggested to have health benefits when compared with modern cultivars of bread (e.g. bread wheat and spelt). Moreover, it appears that processing methods in bread making can also influence the biochemical composition of bread, resulting in decreased amounts of (bioactive) proteins and amounts of FODMAPs in bread (28-31) which could theoretically result in improved gastrointestinal (GI) tolerability of wheat products in NCWS. Previous studies suggest the intestinal microbiota may be a relevant factor in symptom generation.

We feel that studies addressing the effects of wheat-based foods, *as consumed part of a typical daily human diet*, are needed to obtain reliable data that are useful for optimizing appropriate food processing and product development as well as for dietary recommendations to consumers. Therefore, we aim to perform a three-arm randomized (cross-over) study to assess the effects of consuming bread made from hexaploid Bread Wheat and Spelt wheat, and/or tetraploid Emmer wheat each prepared as yeast-fermented and sourdough fermented on symptoms in individuals with NCWS. Additionally, we aim to explore the potential role of the microbiome in symptom generation in an in vitro fermentation study.

Study objective

The primary objective of this study is to investigate the effects of breads made from well-characterised Bread wheat, Emmer wheat, or Spelt wheat of fully known composition each yeast (study A) or sourdough (study B) fermented on intestinal symptoms in individuals with NCWS. Further, this study has secondary objectives: first to investigate te effects of the different breads on individual GI and extra-intestinal symptoms in individuals with NCWS. Further to compare the effects yeast or sourdough-fermented within each type of bread (Bread wheat, Spelt wheat, Emmer wheat) on (extra)intestinal symptoms in individuals with NCWS. Additionally, we want to investigate the effects of these breads on the composition and activity of the gut microbiota in vitro.

Study design

The two studies comprise a randomized (cross-over) design.

Intervention

Participants will be recruited into one of two studies. As part of each study, participants will undergo three intervention days (separated by a wash-out period) in a cross-over design, according to the randomisation scheme:
* Study A: randomised order of yeast-fermented bread made of Bread Wheat, Emmer or Spelt.
* Study B: randomised order of sourdough fermented bread made of Bread Wheat, Emmer or Spelt.
Study A will be completed first, thereafter Study B will be completed.

Study burden and risks

Participants may experience some small burden during this study. After the initial screening visit, required to determine eligibility of participants to the study, participants will have to visit the Maastricht University Medical Center + (MUMC+)/Wageningen University (WUR) two times. In total, a participant will to spend approximately 1,5 hours at MUMC+/WUR facility. They will have to consume in total 5 slices of study bread for breakfast and lunch during three separate test days. The study breads are considered to be a harmless food product, consumed on a daily basis by the general population worldwide. The participants may or may not experience (mild) gastrointestinal symptoms after the consumption of the study bread, since the included participants suffer from self-reported wheat sensitivity. Such symptoms typically improve or disappear shortly (mostly within hours) after gluten is withdrawn from the diet. In a subgroup of participants (i.e. those who have not previously been tested for coeliac disease, and who still consume a low level of gluten in their diet) a blood sample will be taken (by venepuncture) during an additional visit of +/- 20 min prior to the screening visit to exclude coeliac disease by means of serological tests on anti-tTG IgA. Faecal sample collection is without any risks. Moreover, questionnaires will have to be filled out at several occasions during this study.

The study results will bring insights about the effects of the different types of bread (grain type and processing type yeast fermented vs. sourdough fermented). This information may help the participants to make well-informed bread choices, with the goals to help minimise consumption related discomfort.

Contacts

Public
Universiteit Maastricht

Universiteitssingel 50
Maastricht 6229ER
NL
Scientific
Universiteit Maastricht

Universiteitssingel 50
Maastricht 6229ER
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Study A and B
- Develops self-reported GI symptoms within 12 hours after a single intake of bread;
- Aged between 18-70 years;
- Asymptomatic or mildly symptomatic (overall symptoms score with VAS below or equal to 30 mm) while on their symptom-free diet;
- Must have a freezer (-18ºC) to store the study breads during the study.

Follow-up measurement
- (1) NCWS subject: develops GI symptoms within 12 hours after consumption of at least one of the study breads of study A or B (+15 mm on VAS); OR (2) Healthy control (sex matched to NCWS subjects): eats bread regularly (min. 5 days per week)
- Age between 18-70 years;
- Must have a fridge (4-7ºC) to shortly store the collected faecal sample.

Exclusion criteria

Study A and B
- Medical history of coeliac disease, wheat allergy, presence of an organic gastrointestinal (GI) disease (such as inflammatory bowel disease) or other disease which may interfere with NCWS symptoms (upon judgment of the physician-clinical investigator (prof. Keszthelyi, Gastroenterologist MUMC+/ prof. Witteman, PI and consulting gastroenterologist WUR));
- Previous major abdominal surgery or radiotherapy interfering with gastrointestinal function;
- Use of medication potentially influencing gastrointestinal function and/or NCWS symptoms is allowed, provided that dosing has been stable for * 1 month before enrolment;
- Administration of probiotic, prebiotic supplements, investigational drugs or participation in any scientific intervention study, which may interfere with this study (to be decided by the principle investigator), in the 14 days prior to the study.

Follow-up measurement - in addition to the criteria listed above:
- Use of antibiotics during the 6 past months prior to faecal sampling;
- Healthy controls: developing GI symptoms after consumption of bread, or following a gluten-free or wheat-free diet.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-09-2019
Enrollment:	44

Type:	Actual

Ethics review

Approved WMO Date:	10-04-2019
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	04-12-2019
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	10-06-2020
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	05-11-2021
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	28-09-2022
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT04084470
CCMO	NL67466.068.18