

# The role of nutritional deficits in depression in patients with coeliac disease

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In the present research we will focus on the role of nutrition in the relationship between depression and coeliac disease.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Autoimmune disorders
<b>Study type</b>	Observational invasive

## Summary

### ID

NL-OMON33110

### Source

ToetsingOnline

### Brief title

coeliac disease and depression

### Condition

- Autoimmune disorders
- Mood disorders and disturbances NEC

### Synonym

coeliac disease, gluten-intolerance

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Universiteit Leiden

**Source(s) of monetary or material Support:** NWO-MaGW, Leids Universiteits Fonds & Gratama stichting

## Intervention

**Keyword:** coeliac disease, depression, nutrition

## Outcome measures

### Primary outcome

Results of psychiatric interview.

Results of blood-tests.

Results of food frequency questionnaire.

### Secondary outcome

Not applicable.

## Study description

### Background summary

Coeliac disease (CD) is a genetically predisposed intolerance for gluten, which affects approximately 0.5 - 1% of the population. There is no cure for CD, however a gluten-free diet improves symptoms. During the past decades it has become clear that CD is associated with an increased prevalence of several neurological and psychiatric disorders, including cerebellar ataxia, peripheral neuropathy, epilepsy, dementia and depression. Some studies find a rapid improvement of depressive symptoms after initiation of gluten-free diet, whereas others find no improvement or even worsening of depression rates. In a survey among Dutch CD patients, we found that 37.7% (N = 715) had a lifetime diagnosis of depression, which is more than twice the lifetime prevalence of 15.4% in the general population (Bijl, Ravelli & van Zessen, 1998). We also identified 163 participants with a probable diagnosis of current depression despite a good to very good adherence to gluten-free diet. Of the people with a lifetime depression, 28.2% had the first onset of probable depression after the start of the gluten-free diet. This is an unexpected finding considering the general assumption in the field that depression in CD is caused by the extended period of illness before diagnosis and treatment. The underlying mechanisms of these associations remain unclear.

### Study objective

In the present research we will focus on the role of nutrition in the

relationship between depression and coeliac disease.

## **Study design**

We will perform a case-control study in a large group of CD patients with and without depression and who adhere strictly to a gluten-free diet, as well as healthy individuals on a normal diet. We will investigate several nutritional factors, and test the hypothesis that in some patients, the depressive symptoms are related to low serotonergic function, caused by prolonged tryptophan depletion induced by the gluten-free diet. Dietary intake will be assessed using a food frequency questionnaire. We will also measure fasting plasma tryptophan concentrations in this population along with a range of other nutritional biomarkers that have previously been related to depression. Participants will also be asked to complete self-report questionnaires related to mood and health status and a structured psychiatric interview will be performed.

## **Study burden and risks**

The risks of participating in this study are limited, test-results can be informative and even beneficial to participants. The burden of the study consists of travelling to the test-location, being present for two hours, being interviewed, filling out questionnaires and undergoing venapuncture.

## **Contacts**

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## **Trial sites**

## Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

- participated in our previous survey and consented with follow-up studies.
- strict adherence to gluten-free diet
- current diagnosis of depression (for cases)
- no diagnosis of depression lifetime (for CD controls and healthy controls)

### Exclusion criteria

- age younger than 18

## Study design

### Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2010

Enrollment:	300
Type:	Actual

## Ethics review

Approved WMO	
Date:	20-01-2010
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

## 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
CCMO	NL28268.058.09