

# Salutogenic Intervention for Diabetes Type 2: the SALUD-study

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<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Glucose metabolism disorders (incl diabetes mellitus)
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON52561

### Source

ToetsingOnline

### Brief title

The SALUD-study

### Condition

- Glucose metabolism disorders (incl diabetes mellitus)

### Synonym

Type 2 Diabetes Mellitus; adult-onset diabetes

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Wageningen Universiteit

**Source(s) of monetary or material Support:** Ministerie van OC&W,Edema-Steernberg Stichting

## Intervention

**Keyword:** Healthy eating, Lifestyle intervention, Salutogenesis, Type 2 Diabetes Mellitus

## Outcome measures

### Primary outcome

Primary outcomes are food literacy (indicator of food-related skills and knowledge)

This outcome measures the effect of the intervention on eating behavior in the broadest possible way (nutrition knowledge, skills and behaviour). For a long-term behavioral change it is important that there is an improvement in knowledge, skills and behaviors needed to eat healthy (and not on actual food intake alone). This shows whether people are actually better able to eat healthier after the intervention in the context of their daily life. A higher degree of food literacy has been associated with a healthier food intake in both the general population and group of patients.

### Secondary outcome

Secondary outcomes are BMI (indicator of amount of body fat), waist-hip ratio (indicator of body fat distribution) quality of life (indicator of psycho-social health), self-efficacy (indicator of empowerment), sense of coherence (indicator of coping), and the Dutch healthy eating index-2015 (indicator of the quality of the nutritional intake)

## Study description

## **Background summary**

Type 2 diabetes is one of the most common chronic diseases worldwide with an enormous impact on quality of life, micro and macrovascular complications, life expectancy and economy. Type 2 diabetes is a typical nutritional- and lifestyle-related disease, but it is often approached pharmacologically. There are many glucose-lowering agents on the market. For a long term, it has been thought that type 2 diabetes was not reversible. However, recent intervention studies have shown that type 2 diabetes is preventable in 50% of the cases and that the disease is reversible by a (strict) healthy diet. It appears to be difficult for people to adhere to strict healthy diets as very few lifestyle intervention studies for type 2 diabetes had a lasting beneficial effect on the eating behaviour and health.

An important cause for this may be that the lifestyle interventions so far take had limited attention for the complexity of everyday life in which people with type 2 diabetes have to navigate dietary changes in everyday life. A theoretical framework that pays particular attention to daily life is salutogenesis. Salutogenesis focuses on the factors that create and enhance health. At an individual level this is for example dealing with stress, and at a social level receiving support from friends or family. Previous research shows that people prefer to participate in interventions that make life worth living rather than interventions that are solely focused on dealing with the illness. The evidence base of health effects of salutogenic interventions for various diseases is also growing in the last few years.

Therefore, this study used salutogenesis for the development of the SALUD-intervention program. SALUD stands for 'SALUtogetic intervention for Diabetes type 2'. \*Salud\* is also the Spanish word for \*health\*. The development of the SALUD-program consisted of several (quantitative and qualitative) studies about the opinions and preferences of diabetes patients and caregivers. This resulted in an intervention that aims to support people with type 2 diabetes to eat healthier in the everyday life. The SALUD-intervention consists of multiple components. The core components are the developing of self-identity and social support. Additional components include goal setting, stress management, and nutritional knowledge and skills. The current study is needed to investigate whether the SALUD-intervention has a beneficial effect on healthy eating and health of people with type 2 diabetes.

## **Study objective**

The aim of this study is to determine the effects of the SALUD-intervention on food literacy (a measure of food-related knowledge and skills)

## **Study design**

Randomized, blinded controlled trial (two-armed)

## **Intervention**

The SALUD-intervention differs from the standard diabetes care by its holistic, salutogenic and practical approach to healthy eating in daily life. It is a program consisting of 12 weekly online group sessions. The groups consist of 6-8 diabetes patients and professional lifestyle coach that guides the sessions. A dietician will also be present at some meetings.

The SALUD-program consists of several components. The core components are developing of self-identity and social support. Additional components include goal setting, stress management, and nutritional knowledge and skills. During the online-group sessions, participants are supported in setting and achieving personal health goals. Every session, participants reflect on their goals and share experiences with each other. In addition, every session has its own theme (e.g. building confidence or stress). One session is "open", which means that the participants can choose the theme of this session according to their needs at that time. The last session is a festive celebration in which the participants reflect on their experiences during the intervention. Three months after this session, there is a booster day to meet again and share experiences.

The control group receives the usual care for type 2 diabetes (conform to the Dutch NHG protocols). The researchers will make separate appointments with the participants for the measurements.

Measurements are performed at baseline, 12 and 24 weeks and are conducted at the participant's homes.

After completion of the third measurement (at 24 weeks), the SALUD programme is offered to the participants of the control group without any obligation. Participants who choose to follow the programme still undergo a fourth measurement.

## **Study burden and risks**

Participation in the SALUD-study does not pose major risks to the health or safety of participants since the study does not test a medical product or dictates behavioural rules. Instead, the SALUD-intervention recommends a healthy diet (based on the Dutch nutritional guidelines 2015) and supports people in implementing healthy eating practices in their daily lives.

The burden consists of completing questionnaires and the time investment (the time investment differs between the intervention and control group).

A burden is filling in the questionnaires. It takes about 60-90 minutes at a

time to complete all questionnaires. In addition, the questionnaires regarding psycho-social health (self-efficacy, quality of life and sense of coherence) can possibly cause negative feelings. To reduce the risk of this, participants will be given a clear explanation of the purpose of the questionnaires. In addition, the researchers will monitor the subjects mental well-being during the study and contact a healthcare provider if they have concerns about the subjects' well-being during the study.

The time investment is approximately 30 hours (over 24 weeks) for the participants in the intervention group. The participants will be well informed about this and it will be explained that the participants can stop at any time, without having to give a specific reason. We expect that most participants will experience participating in the SALUD-program as enjoyable, because the SALUD-program will be tailored to individual wishes and needs. It is also possible that the participants will experience health benefits and improved quality of life during the SALUD-program. The SALUD-program was developed on the principle 'learning by doing' and there was also attention during development to make the intervention fun and informal.

The time investment is considerably smaller for the control group (approximately 4-6 hours over 24 weeks). They will follow the standard care for type 2 diabetes. The time investment mainly consists of the measurements. For the participants in the control group, the discomfort will be relieved as much as possible by providing good explanations about the study/the procedures and making the measurements as easy as possible for the participants (e.g. measurements are performed at the participant's home). In addition, the SALUD programme will still be offered to the participants of the control group after the completion of the third measurement moment.

At the end of the study, all participants will be informed about the study insights and results. All participants receive a reward of 150 euro after completion of the study.

## 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**

Official diagnosis (i.e. by a GP) type 2 diabetes mellitus

Adult (>18-75 years of age)

Fluent in Dutch

Competent to make own decisions/declared mentally competent

In possession of laptop/computer with internet connection

### **Exclusion criteria**

No severe other chronic diseases (e.g. kidney disease, cancer, depression or dementia)

Pregnancy (or intend to become pregnant in the upcoming 6 months)

Lactating women

Bariatric surgery in the past

Eating disorders (e.g. anorexia, bulimia)

## **Study design**

## Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)

**Primary purpose:** Treatment

## Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	10-11-2021
Enrollment:	56
Type:	Actual

## Ethics review

Approved WMO	
Date:	18-08-2021
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	
Date:	14-11-2021
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	
Date:	21-07-2022
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

## 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	NL73748.081.20
Other	NL8963