ISRCTN10145611 https://doi.org/10.1186/ISRCTN10145611

# Implementation of oral care in primary diabetes care in the Netherlands

**Submission date**
31/01/2017

**Recruitment status**
No longer recruiting

**Registration date**
01/02/2017

**Overall study status**
Completed

**Last Edited**
15/03/2023

**Condition category**
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

## Plain English summary of protocol

Background and study aims
Type 2 diabetes mellitus (T2DM) is a long term condition where sufferers have difficulty controlling their blood sugar (glucose) as they do not produce enough insulin to function properly (insulin deficiency), or that the body's cells don't react to insulin as they should do (insulin resistance). High blood sugar levels can lead to a range of complications, including damage to the eyes, kidneys and nerves. In the Netherlands, diabetic patients are treated in the primary diabetes care system (so-called "ketenzorg", or chain care), in which several medical specialists work together closely. Patients are checked regularly for the traditional complications, and treated if necessary, to improve their health and quality of life. Besides the classic complications, there is evidence that T2DM can lead to oral (mouth) complications, such as gum disease (periodontitis), dry mouth and mouth ulcers. This has led to the formation of guidelines for the medical community on how to deal with oral health in diabetes mellitus patients. These guidelines encourage close collaboration between healthcare professionals and dental specialists. Regardless of the existence of these guidelines, until now, the Dutch GPs pay little to no attention to oral health, simply because they lack the knowledge, resources and time to do so. Furthermore, the collaboration between GPs and dentists is non-existent. The aim of this study is to look at the effectiveness of incorporating oral care into primary care to see if it can improve the oral health and quality of life of T2DM patients.

Who can participate?
Adults who have T2DM

What does the study involve?
Participating GP practices are included and randomly assigned to either the experimental or control group. The general practitioners or nurse practitioners in the experimental group inform their diabetic patients about the relationship between diabetes and oral health. They also encourage their patients to visit a dentist, using a referral form. The patients also receive an introduction kit that contains preventive dental care products and an information brochure. In the control group, the diabetes care professionals do not pay extra attention to oral health, and perform their usual care protocol. At the start of the study and then again after one year, participants in both groups complete a range of questionnaires to measure their quality of life and have their mouths examined by dentists to assess their oral health.

What are the possible benefits and risks of participating?
Participating in this study will make patients aware of the importance of their oral health, which could lead to them visiting the dentist more often. This could help in the prevention and treatment of oral complications, such as periodontitis and dry mouth, improving their quality of life. There are no anticipated risks involved with participating.

Where is the study run from?
24 GP practices located in the area of Amsterdam (Netherlands)

When is study starting and how long is it expected to run for?
January 2015 to December2017

Who is funding the study?
Sunstar Suisse SA (Switzerland)

Who is the main contact?
Mr Martin Verhulst
m.verhulst@acta.nl

# Contact information

### Type(s)
Scientific

### Contact name
Mr Martijn Verhulst

### Contact details
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# Additional identifiers

### Protocol serial number
14/585

# Study information

### Scientific Title
Best practice model for interdisciplinary medicine in treating diabetes patients. The need for implementation of oral care

### Study objectives

Primary research questions:
1. Will incorporation of oral care, using a strict protocol, in primary diabetes care result in improvement of diagnosis of oral complications, like periodontitis and other oral diseases?
2. Will the improvement in diagnosis of oral diseases lead to prevention and/or treatment of oral complications?
3. Will this preventive strategy, including the use of oral care products, lead to improvement of oral health, general health and quality of life in diabetes patients?

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
The Medical Ethics Review Committee VU University Medical Center (registered with the OHRP as IRB00002991) discussed the application. On 29 January 2015, it was confirmed that the Medical Research Involving Human Subjects ACT (WMO) did not apply for this study, and an official approval of this study by the committee was not required.

## Study design
Multi-centre cluster randomized controlled trial

## Primary study design
Interventional

## Study type(s)
Quality of life

## Health condition(s) or problem(s) studied
Diabetes Mellitus Type 2

## Interventions
24 participating GP practices are randomly 24 participating GP practices are randomly allocated to either the control group or the intervention group, using the SNOSE (sequentially numbered, opaque, sealed envelopes) protocol.

Intervention group: Nurse practitioners at participating practices are were instructed to pay extra attention to oral health during their consultation hours, on top of their usual care. This consists of:
1. Informing the diabetes patients about the relationship between oral health and diabetes mellitus, and emphasizing it's important to take care of their oral health.
2. Actively stimulating the patients to visit the dentist at least once/twice a year, using a standard referral letter. This referral letter also contained a return form, meant for the dentist. When the patient actually visited the dental office, the dentist would fill in this form and send it back to the GP practice.
3. Providing the patients with an introduction kit, containing (preventive) oral care products (e.g. oral rinse, tooth paste, interdental brushes etc.)

Control group: Nurse practitioners provide care as usual, without paying extra attention to oral health.

For all participants, the follow-up time is 12 months. Usually, a patient visits the GP/nurse practitioner every three months in the Dutch primary care, and these moments were used to continue motivating the participating patients to visit a dentist during the 12 months follow-up.

### Intervention Type
Behavioural

### Primary outcome(s)
1. Self-reported oral health, using a questionnaire based on large epidemiological studies from the United States, measured at baseline and 12 months
2. Oral health is assessed using an oral examination by a dentist at baseline and 12 months
3. Oral health related quality of life is assessed using the OHIP-14 questionnaire at baseline and 12 months
4. General quality of life is assessed using the SF-36 questionnaire at baseline and 12 months

### Key secondary outcome(s))
Parameters of protocolization and optimalization:
1. Number of patients which are referred to a specialist by the dentist during the 12 months follow up. This is registered by the dentist on the return form that the patient received at baseline.
2. Number of patients which are seen by the dentist is measured by the number of return forms that the GP practices received during the 12 months follow-up
3. Number of patients which are treated by the dentist is registered on the return forms that the they received during the 12 months follow-up
4. Feasibility and effectiveness of our intervention protocol is assessed using a questionnaire related to the opinion of diabetes practitioners, measured as soon as they finished the follow-up period.

Change in general health as recorded by the diabetes practitioner:
1. Number and severity of diabetes-related complications is assessed through medical record review at baseline and 12 months
2. (Bio)markers of metabolic control of diabetes mellitus (Glucose, HbA1c, Lipids, etc..) is assessed through medical record review at baseline and 12 months
3. General characteristics (BMI, smoking habits, diet, etc..) is assessed through medical record review at baseline and 12 months
4. Medication use is assessed through medical record review at baseline and 12 months

### Completion date
31/12/2017

## Eligibility

### Key inclusion criteria
1. Aged 18 years and over
2. Diabetes mellitus Type 2
3. Follows the standardized primary diabetes care protocol
4. Understands spoken and written Dutch

### Participant type(s)
Patient

**Healthy volunteers allowed**
No

**Age group**
Adult

**Lower age limit**
18 years

**Sex**
All

**Total final enrolment**
764

**Key exclusion criteria**
1. Don't understand spoken and written Dutch
2. Attend secondary diabetes care (i.e. internal medicine at the hospital)

**Date of first enrolment**
01/03/2015

**Date of final enrolment**
07/09/2016

# Locations

**Countries of recruitment**
Netherlands

**Study participating centre**
**Huisartsenmaatschap Holtrop & Sieben**
's-Gravesandeplein 19-B
Amsterdam
Netherlands
1091 BB

**Study participating centre**
**Reinds en Hogewind Huisartsen**
Meer en Vaart 58
Amsterdam
Netherlands
1068 ZZ

**Study participating centre**
**Thiel en van Maanen-Thiel, huisartsen**
Ekingenstraat 23
Amsterdam
Netherlands
1069 DA

**Study participating centre**
**Huisartsencentrum pniël**
Bos en lommerweg 189
Amsterdam
Netherlands
1055 DT

**Study participating centre**
**Gezondheidscentrum Vlaanderen**
Laan van Vlaanderen 466
Amsterdam
Netherlands
1066 MT

**Study participating centre**
**Huisartsenpraktijk van Raalte**
Gerard Terborgstraat 46
Amsterdam
Netherlands
1071 TP

**Study participating centre**
**J.G. van der Veen, Huisarts**
Gerard Terborgstraat 46
Amsterdam
Netherlands
1071 TP

**Study participating centre**
**Huisartsenpraktijk Amsteldorp**
Fahrenheitsingel 32
Amsterdam
Netherlands
1097 NS

**Study participating centre**
**Huisartsenpraktijk Dr. J. van Keimpema**
Osdorper Ban 92
Amsterdam
Netherlands
1068 MK

**Study participating centre**
**Huisartsenpraktijk de Lairesse Acherman & Woertman**
De Lairessestraat 42
Amsterdam
Netherlands
1071 PB

**Study participating centre**
**Huisartsenpraktijk Swart**
Pascalstraat 10
Amsterdam
Netherlands
1098 PB

**Study participating centre**
**Huisartsenpraktijk Reguliersgracht**
Reguliersgracht 78C
Amsterdam
Netherlands
1017 LV

**Study participating centre**
**Gezondheidscentrum Helmersstraat**
Anna Spenglerstraat 101
Amsterdam
Netherlands
1054 NJ

**Study participating centre**
**Huisartsenpraktijk Kappeyne**
Nassaukade 116

Amsterdam
Netherlands
1052 EB

**Study participating centre**
**M Staal Huisarts**
Sumatrastraat 84
Amsterdam
Netherlands
1094 NJ

**Study participating centre**
**Praktijk H.L. Kieviet**
Keizer Karelweg 94 C
Amstelveen
Netherlands
1185 HX

**Study participating centre**
**Huisartspraktijk van Wijngaarden**
Lootsstraat 35
Amsterdam
Netherlands
1053 VN

**Study participating centre**
**Gezondheidscentrum Staatsliedenbuurt**
Van Hallstraat 200
Amsterdam
Netherlands
1051 HL

**Study participating centre**
**Huisartsenpraktijk Nijpels & van Drooge**
Meester P.N. Arntzeniusweg 84
Amsterdam
Netherlands
1098 GS

**Study participating centre**
**Huisartsenpraktijk Oud**
Oosterpark 62
Amsterdam
Netherlands
1092 AR

**Study participating centre**
**Huisartsenpraktijk Luykx**
Graaf Aelbrechtlaan 108
Amstelveen
Netherlands
1181 SX

**Study participating centre**
**Huisartsenpraktijk Javaeiland**
Azartplein 45-47
Amsterdam
Netherlands
1019 PA

**Study participating centre**
**Huisartsenpraktijk Verhaar**
C.J. van Houtenlaan 1 C
Weesp
Netherlands
1381 CN

**Study participating centre**
**Huisartsen Diemen Centrum; Praktijk Bruinsel & Praktijk van Griek**
Prinses Beatrixlaan 7
Diemen
Netherlands
1111 EX

# Sponsor information

**Organisation**
Academisch Centrum Tandheelkunde Amsterdam

**ROR**
https://ror.org/04x5wnb75

# Funder(s)

**Funder type**
Industry

**Funder Name**
Sunstar Suisse SA

# Results and Publications

**Individual participant data (IPD) sharing plan**
The datasets generated during and/or analysed during the current study are/will be available upon request from Martijn Verhulst (m.verhulst@acta.nl)

**IPD sharing plan summary**
Available on request

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | | 18/06/2019 | 15/03/2023 | Yes | No |
| Results article | | 10/05/2021 | 15/03/2023 | Yes | No |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |