PREVIEW Population studies (PREVention of diabetes through lifestyle Intervention and population studies in Europe and around the World; Population studies)

Submission date 25/09/2017	Recruitment status No longer recruiting	Prospectively registered[X] Protocol
Registration date 28/11/2017	Overall study status Completed	 [] Statistical analysis plan [X] Results
Last Edited 17/05/2019	Condition category Nutritional, Metabolic, Endocrine	Individual participant data

Plain English summary of protocol

Background and study aims

This study is part of a large multi-national diabetes prevention project which aims to identify the best lifestyle for the prevention of type 2 diabetes in a population of pre-diabetic overweight or obese individuals. The focus will be on diet (specifically protein and glycemic index) and physical activity, as well as their interaction with the lifestyle factors, habitual stress and sleeping patterns as well as behavioural, environmental, cultural, and socioeconomic factors.

Who can participate?

People of all age ranges and genders who participated in five studies: Lifelines (the Netherlands), the Nutrition Questionnaires plus (NQplus) study (the Netherlands), the Cardiovascular Risk in Young Finns Study (YFS; Finland), the New Zealand Adult Nutrition Survey 2008/09 (NZANS), and the Quebec Family Study (QFS; Canada).

What does the study involve?

Data is collected from the five studies, including dietary intake, in particular protein intake and glycemic index and load, physical activity and sleep duration, along with the prevalence and incidence of pre-diabetes, diabetes, and fasting blood sugar levels.

What are the possible benefits and risks of participating?

This study will increase knowledge on how specific lifestyle factors can help prevent type 2 diabetes. This study uses existing data from previous studies so there are no additional risks involved.

Where is the study run from? Wageningen University (Netherlands)

When is the study starting and how long is it expected to run for? January 2013 to December 2018 Who is funding the study?

- 1.7th Framework Programme of the European Commission
- 2. Health Research Council of New Zealand
- 3. Ministry of Higher Education, Research and Science and Technology
- 4. Fonds Economische Structuurversterking
- 5. Samenwerkingsverband Noord Nederland
- 6. Ruimtelijk Economisch Programma
- 7. ZonMw
- 8. Academy of Finland
- 9. Social Insurance Institution of Finland
- 10. Turku University Foundation
- 11. Juho Vainion Säätiö
- 12. Research funds from the Turku, Tampere and Kuopio University Hospitals
- 13. Research foundation of Orion Corporation
- 14. Finnish Foundation of Cardiovascular Research
- 15. Suomen Lääketieteen Säätiö
- 16. Suomen Kulttuurirahasto
- 17. Ministry of Health, New Zealand
- 18. University of Otago
- 19. Quebec Department of Education Funds for Research and Training of Scientists
- 20. Quebec Department of Sport and Leisure
- 21. Quebec Health Research Council
- 22. Health and Welfare Canada
- 23. Canadian Diabetes Association
- 24. Natural Sciences and Engineering Research Council of Canada
- 25. Medical Research Council Canada
- 26. Canadian Institutes of Health Research
- 27. Laval University

Who is the main contact? Dr Agnes Berendsen

Study website

http://www.previewstudy.com/

Contact information

Type(s) Scientific

Contact name Dr Agnes Berendsen

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers 312057

Study information

Scientific Title

PREVIEW Population studies (PREVention of diabetes through lifestyle Intervention and population studies in Europe and around the World; Population studies)

Study objectives

The primary goal of PREVIEW is to identify the most efficient lifestyle pattern for the prevention of type-2 diabetes in a population of pre-diabetic overweight or obese individuals. The focus will be on diet (specifically protein and glycemic index) and intensity of physical activity, as well as their interaction with the lifestyle factors, habitual stress and sleeping pattern as well as behavioural, environmental, cultural, and socioeconomic variables.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethical approval was not necessary. The researchers did not have any access to personal information regarding the participants and all data that will be analyzed are based on harmonized variables and are completely anonymized. For the individual observational studies, all participants signed informed consent for the original study.

Study design

Observational cross-sectional and longitudinal/cohort study including 5 cohorts with a follow-up ranging from 2 up to 5 years

Primary study design Observational

Secondary study design Cohort study

Study setting(s) Community

Study type(s)

Prevention

Participant information sheet

Not applicable

Health condition(s) or problem(s) studied

Pre-diabetes (for the prevention of type 2 diabetes)

Interventions

'PREVIEW Population studies' describes cross-sectional and longitudinal analyses from the five population studies included in PREVIEW: Lifelines (the Netherlands), the Nutrition Questionnaires plus (NQplus) study (the Netherlands), the Cardiovascular Risk in Young Finns Study (YFS; Finland), the New Zealand Adult Nutrition Survey 2008/09 (NZANS), and the Quebec Family Study (QFS; Canada). For Lifelines and NQplus baseline data and data from the first follow-up measurement will be used. For YFS, the 27-year follow-up from 2007-2008 was used as baseline and the 30-year follow-up in 2010-2012 as follow-up. NZANS was a cross-sectional survey and thus included in the cross-sectional analyses only. For QFS, phase 2 data acted as baseline and phase 3 data as follow-up, based on the quality of the dietary and physical activity assessment. Additionally, ca. 300 newly recruited participants in Phase 3 were included in the cross-sectional analyses.

Data in the PREVIEW study have been collected within the framework of independent population studies, with different protocols for data collection and distinct original research foci. Therefore, data harmonization was a major task of the study. Harmonized variables were created for all parameters of interest for the PREVIEW data-analysis.

Baseline dietary intake, in particular protein intake and glycemic index and glycemic load, physical activity data, and sleep duration will be related to the prevalence and incidence of prediabetes, diabetes, and levels of fasting plasma glucose or HbA1c.

Intervention Type

Mixed

Primary outcome measure

Prevalence and incidence of prediabetes and diabetes, collected by the five population studies at baseline between 1992 and 2013 and at follow-up between 1997 and 2018

Secondary outcome measures

Glycemic index and food frequency questionnaire data collected by the five population studies between 1992 and 2013

Overall study start date 01/01/2013

Completion date 31/12/2018

Eligibility

Key inclusion criteria

All age ranges and both genders are included

Participant type(s) Healthy volunteer

Age group All

Sex Both

Target number of participants Combining all cohorts a total of 170,000 participants is targetted

Total final enrolment 78851

Key exclusion criteria Participants will be excluded with missing data on baseline dietary intake, physical activity, or sleep and missing data on fasting plasma glucose level or HbA1c

Date of first enrolment 01/01/2013

Date of final enrolment 31/12/2018

Locations

Countries of recruitment Australia

Canada

Finland

Netherlands

New Zealand

Study participating centre Wageningen University Wageningen Netherlands 6700AA

National Institute for Health and Welfare (Terveyden ja hyvinvoinnin laitos) Finland FI-00271

Study participating centre The University of Sydney Sydney Australia NSW 2006

Study participating centre The University of Auckland New Zealand 92019

Study participating centre Universite Laval Canada QC G1V 0A6

Sponsor information

Organisation Wageningen University and Research

Sponsor details Stippeneng 4 PO Box 17 Wageningen Netherlands 6708 WE

Sponsor type University/education

Website www.wur.nl

ROR https://ror.org/04qw24q55

Funder(s)

Funder type Government

Funder Name

Seventh Framework Programme

Alternative Name(s)

EC Seventh Framework Programm, European Commission Seventh Framework Programme, EU Seventh Framework Programme, European Union Seventh Framework Programme, EU 7th Framework Programme, European Union 7th Framework Programme, Siebten Rahmenprogramm, Séptimo Programa Marco, Septième programme-cadre, Settimo programma quadro, 7th Framework Programme, Seventh EU Framework Programme, FP7

Funding Body Type Government organisation

Funding Body Subtype National government

Location

Funder Name Health Research Council of New Zealand

Alternative Name(s) HRCNewZealand, HRC New Zealand, HRC

Funding Body Type Government organisation

Funding Body Subtype National government

Location New Zealand

Funder Name Ministry of Higher Education, Research and Science and Technology (MESRST, PSR-SIIRI-837)

Funder Name Fonds Economische Structuurversterking **Funder Name** Samenwerkingsverband Noord Nederland

Funder Name Ruimtelijk Economisch Programma

Funder Name ZonMw

Alternative Name(s) Netherlands Organisation for Health Research and Development

Funding Body Type Private sector organisation

Funding Body Subtype Other non-profit organizations

Location Netherlands

Funder Name Academy of Finland

Alternative Name(s) Suomen Akatemia, Finlands Akademi, Academy of Finland, AKA

Funding Body Type Government organisation

Funding Body Subtype Universities (academic only)

Location Finland

Funder Name Social Insurance Institution of Finland **Funder Name** Turku University Foundation

Funder Name Juho Vainion Säätiö

Alternative Name(s) Juho Vainio Foundation, Reppy Institute

Funding Body Type Private sector organisation

Funding Body Subtype Trusts, charities, foundations (both public and private)

Location Finland

Funder Name Research funds from the Turku, Tampere and Kuopio University Hospitals

Funder Name Research foundation of Orion Corporation

Funder Name Finnish Foundation of Cardiovascular Research

Funder Name Suomen Lääketieteen Säätiö

Alternative Name(s) Finnish Medical Foundation

Funding Body Type Private sector organisation

Funding Body Subtype Trusts, charities, foundations (both public and private) **Location** Finland

Funder Name Suomen Kulttuurirahasto

Alternative Name(s) Finnish Cultural Foundation, SKR

Funding Body Type Private sector organisation

Funding Body Subtype Trusts, charities, foundations (both public and private)

Location Finland

Funder Name Ministry of Health, New Zealand

Alternative Name(s) Manatu Hauora, Ministry of Health - Manatū Hauora, minhealthnz

Funding Body Type Government organisation

Funding Body Subtype National government

Location New Zealand

Funder Name University of Otago

Alternative Name(s) Te Whare Wānanga o Otāgo, Te Whare Wānanga o Ōtākou

Funding Body Type Government organisation

Funding Body Subtype Universities (academic only) **Location** New Zealand

Funder Name Quebec Department of Education Funds for Research and Training of Scientists

Funder Name Quebec Department of Sport and Leisure

Funder Name Quebec Health Research Council

Funder Name Health and Welfare Canada

Funder Name Canadian Diabetes Association

Alternative Name(s) Association Canadienne du Diabète, The Canadian Diabetes Association, CDA

Funding Body Type Private sector organisation

Funding Body Subtype Associations and societies (private and public)

Location Canada

Funder Name Natural Sciences and Engineering Research Council of Canada

Alternative Name(s) Conseil de Recherches en Sciences Naturelles et en Génie du Canada, NSERC, CRSNG

Funding Body Type Government organisation

Funding Body Subtype

National government

Location Canada

Funder Name Medical Research Council Canada

Alternative Name(s) Medical Research Council, Canada, Medical Research Council, Medical Research Council of Canada, MRC

Funding Body Type Government organisation

Funding Body Subtype National government

Location Canada

Funder Name Canadian Institutes of Health Research

Alternative Name(s)

Instituts de Recherche en Santé du Canada, Canadian Institutes of Health Research (CIHR), CIHR_IRSC, Canadian Institutes of Health Research | Ottawa ON, CIHR, IRSC

Funding Body Type Government organisation

Funding Body Subtype National government

Location Canada

Funder Name Universit&x00E9; Laval

Alternative Name(s) Laval University, ULaval, Universitas Laval, UL **Funding Body Type** Government organisation

Funding Body Subtype

Universities (academic only)

Location

Canada

Results and Publications

Publication and dissemination plan

Main results will be published in peer-reviewed journals and presented at scientific conferences or symposia.

Intention to publish date

30/10/2017

Individual participant data (IPD) sharing plan

As the 'PREVIEW Population studies' makes use of existing data from different cohort studies the participant level data will be the property of and stored at the local study sites. Moreover, recruitment and analyses will continue for some cohort studies outside the scope of the 'PREVIEW Population studies' and so data cannot be made publicly available right now.

IPD sharing plan summary

Not expected to be made available

Study outputs					
Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2019	08/05/2019	Yes	No
Protocol article	protocol and baseline results	20/06/2017	17/05/2019	Yes	No
<u>Protocol article</u>	protocol and baseline results	01/05/2018	17/05/2019	Yes	No