

**The PREVIEW Project****Current status****Short Facts: Implementation research and cohort studies****Characteristics of the PREVIEW research approaches**

## Implementation research

### “From bed to community”

What is the best prevention strategy to help a pre-diabetic person avoid developing type-2 diabetes mellitus (T2DM)? This is a typical question in implementation or translational research. Finding an answer requires an evaluation of intervention methods, which should be safe, effective, efficient and ethical. The intervention should ideally work in a clinical setting (step 1: *from bench to bed*) as well as in the natural environment (step 2: *from bed to the community*).

To determine the best intervention, there are a variety of research options. A randomized multicentre intervention study has been chosen for PREVIEW.

A randomized intervention study is valued because of its high methodological standard, which enables researchers to extract strong *evidence from the data obtained*. Compared to the data obtained from other methods, a controlled experimental design stands out due to its high internal validity. It is also called the ‘gold standard’. It uses for instance randomization and a control group or “blinding” to prevent methodological confounders such as bias

Before enrolment, participants are asked for their willingness to be randomized to a pre-determined treatment condition (arms). In PREVIEW participants are randomized to four

## Editorial

The PREVIEW project is now in its 3<sup>rd</sup> year and we are in ‘full swing’. Most importantly, the large randomized controlled trial (RCT) enrolled the last study subject after more than 18 months of recruitment. Furthermore, the first data analysis investigating protein intake and pre-diabetes/diabetes has been produced from the population studies.

To achieve the recruitment numbers in the RCT, 1 year was added to the project period. The project will therefore now last 6 years in total and end in December 2018.

In this issue of the newsletter the pros and cons of using these two kinds of studies – RCT and cohort studies - to investigate the role of different lifestyle factors for health are discussed.

Anne Raben, Copenhagen, Denmark

## Current status in PREVIEW

It has been a huge challenge for the 8 intervention centres to reach the numbers needed for the RCT. However, thanks to very dedicated teams this has now been achieved. A total of 15,611 adults and about 185 children have been pre-screened and 5,474 adults and 86 children were screened at the 8 intervention centres. A total number of 2,348 adults and 76 children was found eligible to participate.

While the last PREVIEW participants have been signed-up for the study now, the first enrolled participants have already made it more than half-way through the study. They are now approaching the 6<sup>th</sup> clinical investigation day after almost 2 years of participation.



different arms (see Newsletter no 1, 2013, for more details).

PREVIEW participants are instructed as to what they should eat and how intensely they should be physically active. Further, the PREVIEW staff must also be aware of the behaviour changes they must teach the participants. So, in PREVIEW, only the researchers running the statistical analysis are blind to the interventions. They will not know who is in a particular intervention group until the breaking of the code prior to data analysis.

In implementation research, evidence is only one objective of a study. Effectiveness, also called *practical usefulness* of the results, is another important aim. Realistically useful interventions should work best in the 2<sup>nd</sup> step: the community. PREVIEW is therefore conducted in the naturalistic setting of its pre-diabetic participants, who should otherwise follow their daily routines and lifestyle.

This also means that the PREVIEW participants are likely to follow different traditions, norms, lifestyle habits, and of course differences in their preferred nutrition and/or the way to be active during leisure time.

### **Standardization is inevitable**

Participants in the PREVIEW trial are not hospitalized. They follow their daily routines, except for the prescribed behavioural pattern of the PREVIEW intervention study (i.e. see newsletter No. 2, 2014 and No. 3, 2014). In order to make results comparable across the eight study

centres, the search is for an intervention that is effective and efficient independent of the centre-location or treating staff. To achieve this, a set of approximately 50 SOPs and several workshops for the PREVIEW-staff have been developed. Topics are, for instance: the physical activity and diet prescription, a guide for the counsellors to support participants' behaviour change, the collection of data and the storage of the bio-material across the centres. Questionnaires are delivered on a special online platform and a central data hub, located at the University of Copenhagen, where all data is transferred in a shared format.

## **Cohort studies in PREVIEW**

What are environmental and/or behavioural risks and what could help to prevent the transition from pre-diabetes to T2DM? The science of epidemiology answers questions like that and delivers insight into the association between risk factors and health outcomes.

PREVIEW is not only a multi-centre intervention study. It is an epidemiological study as well. PREVIEW uses five population data sets to take a closer look at factors that potentially determine T2DM development. These five cohort sets stem from Canada (The Quebec Family Study), from Finland (Young Finns study), from the Netherlands (LifeLines and Nutrition questionnaire plus), as well as

from New Zealand (New Zealand Adult Nutrition Survey).

The data from these population-based studies cover the entire lifespan and mirror the results of the intervention study. The focus of the analysis will be on the impact of participant's dietary intake, type of physical activity, sleep and stress as well as social-cognitive determinants on the incidence of T2DM. All together, the cohorts amount to a sample of about 170,000 people.

### **Next topics**

In the next newsletter, we will provide an update on the status of PREVIEW. We will also provide insight into the behaviour modification programme in PREVIEW.

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