

Beyond RCT's: Towards citizen-driven research strategies in food and health

How do we enlarge the research potential?

**Date: Monday 21 March
Amsterdam**

Summary

The dominant way by which 'Evidence Based Knowledge' is generated in biomedical research, mainly by randomized, placebo controlled trials, does not serve all needs. Very often the causal relations are multifold and more difficult to determine in these type of trials. Furthermore, it is difficult to transfer results from studies with very homogeneous study populations and standardized interventions into usual care and prevention. Other study methodologies are available and in development, which are only slowly adopted in research on complex domains such as food, stress, the immune system etcetera. Hence, the potential of research for innovation and product development lags behind. Currently, patients increasingly want to play an active role in biomedical research, grounded in their own experience based and highly contextualized expertise. They demand new and more inclusive research strategies, in which their experiences will tangibly impact the generation of knowledge.

The core question of this symposium is:

How do we foster new research strategies that include the interest of patients, serve the standards of science and help to strengthen business?

The output of the symposium is a **clear action agenda for new research strategies**

The symposium has an **action driven set-up**: we kick off with a few selected presentations of global top researchers and patients, followed by a number of interactive sessions to answer the core question.

The limits of the "Golden Standard"

The 'golden standard' in biomedical research are the 'Randomized Controlled Trials' (RCT's). They have generated a lot of very valuable insights, and yield so-called '*high level evidence based knowledge*'. Yet, there is a knowledge potential that is not being unlocked by this methodological approach. It refers to mostly highly contextualized knowledge, involving multiple complex and dynamic relations. RCT's also suffer from practical drawbacks: they are time-consuming, costly, ethically complicated and often necessarily very specific and one-dimensional, and hence apparently less appropriate for complex domains such as food, lifestyle, stress, the immune system etcetera. It is therefore important to search for new methodological approaches capable of extracting wisdom from so-called unstructured data'.

Patients demand knowledge-in-context

Why is this important? In the first place because patients ask for it. They are the ones who need to integrate the biomedical knowledge in their own biological, psychic, cultural, economic and ecological context. If this context has been insufficiently taken on board, by too narrow inclusion criteria for studies, then chances are

high that the intervention cannot be properly translated into practice and causes unwanted side-effects, that sometimes only become visible after time. The context is furthermore dynamic, while RCT's, bound as they are by strict protocols, lack the agility to sync with it. New forms of research are hence important to generate better, more integral knowledge on how health emerges and can be maintained. From this perspective it seems that at present RCT's are being conducted in too early stages of investigation, leading to apparently 'hard' knowledge, but of little relevance.

Patients as researchers

A second reason why new research strategies are needed is because patients are also bearers of important contextualized knowledge. They are highly accurate observers of the dynamism in their bodies and environment, often look at the world through totally different paradigms and can hence point at relations that may not be observable from a conventional or institutionalized knowledge base. Furthermore, they regularly undertake experiments themselves; research shows e.g. that between 50-75% of Dutch cancer patients experiment with food as a complement to their regular treatments. In fact, patients form an undervalued and underutilized group of researchers, that excel in '*Experience Based Knowledge*'.

Better care, more prevention

If it is true that a better methodological approach leads to better and more relevant insights for patients and citizens, then it is obvious that the health care system will improve too and becomes less expensive. It is well known that more intensive support e.g. through lifestyle programs results in positive health effects; when on top of that patients also have a clear role and possibility for self-management and control in the research process, these effects are likely to further increase.

Furthermore, new research approaches are relevant from the point of view of prevention. Usually interventions take place when the body is clearly out of balance, making the intervention relatively straightforward. However, patients don't want to get to that point at all. The better complex relations are understood, the more likely it is to install targeted interventions to enhance the resilience of the system (including body and environment).

All-in all, new research approaches promise biomedical research to become much richer, more interesting, more relevant and hence more rewarding.

New research approaches

New research approaches don't need to be invented from scratch. Between the n=1 studies and the RCT's there is a whole gamut of quantitative and qualitative methods. Think of different types of observational studies, think of DIY research, think of participatory narrative techniques, think of methods that take Patient Reported Outcome Measures serious. Think about the possibility of building databases through Quantified Self devices, allowing for analyses previously unheard of. The problem is that these methods, especially those based on self-reported data, have a low status in biomedical research. The key reason is that those data run a higher risk of being biased, conferring a lower level of evidence to findings based on that data, and hence are less favorable for publication in renowned scientific journals. Another reason for low-status is that they might stir up vested power relations: it is less the researcher who determines what is being researched, and more the patient and citizen.

In 2015, the Netherlands Organisation for Health Research and Development (ZonMw) commissioned a project on 'Alternatives for RCT's' (in Dutch). This symposium builds on the outcomes of this project, and will focus specifically on research strategies that are more fit to the complex domains, and that are citizen-driven.

The core question of the symposium is:

How do we foster new research strategies that include the interest of patients, serve the standards of science and help to strengthen business?

The **output** of the symposium is:

- *A clear action agenda on these new research strategies*
- *A concrete prospect on research documenting patient experiments with food and health*

The **set-up** of the symposium is:

Based on a few selected presentations of global top researchers and patients, a number of interactive working sessions follow to answer the core question.

Organisation

Inviting parties:

Platform Patients and Food Netherlands www.patientENvoeding.nl (patient organization)

Inspire2Live <http://www.inspire2live.org/> (patient organization)

TNO Innovation for life www.tno.nl (research institution)

Programme Board

Prof. Dr. Claudia Witt - Chair Complementary and Integrative Medicine, University of Zurich

Prof. Dr. Anske van der Bom, Professor of Clinical Epidemiology Univ Leiden

Dr. Roy Montein, Research Manager Microbiology & Systems Biology, TNO

Dr. Ben van Ommen, Head Research TNO, director of TNO systems biology program, director of NuGO - the Nutrigenomics Organisation.

Dr. ir. Gaston Remmers (Patient Advocate Inspire2Live / co-founder Platform Patient and Food Netherlands / Director Habitus)

Committee of Recommendation

Dr. Machteld Huber - senior scientist Louis Bolk Instituut, Institute of Positive Health, physician, member of Dutch Health Council

Prof. Dr. Jaap Seidell – Professor Food and Health (VU), KNAW member

Prof. Dr. Marten Scheffer – Professor of ecology and water quality (WUR), complexity specialist, KNAW member

Prof. Dr. Jelle Barentz – Professor of Radiology, Radboud MC, Nijmegen

Drs. EMIA Tjitske Bezema - Founder Immunowell (www.immunowell.nl)

Drs. Coleta Platenkamp – CCC Foundation, patient experience stories (www.patientvaringsverhalen.nl)

Operational Committee

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Dr. Gaston Remmers – Platform Patient and Nutrition / Inspire2Live / Habitus g.remmers@habitus.nu

Nicole van Leeuwen - Inspire2Live

Program

8:30 Welcome and registration

9:00 Opening

9:10 Opening by Conference chairs

9:20 Introduction: URGENCY

Title: The societal challenge: from virtual and dependent to real and co-creative patients

Dr. Gaston Remmers (Patient Advocate Inspire2Live / Platform Patient and Food Netherlands)

9:40 Keynote lecture: WHY

Title: Alternatives to RCT's: results of a recent research project commissioned by ZonMw

Dr. J. Mathijssen, TRANZO - scientific center for care and welfare, Tilburg University

10:00 Keynote lecture: WHY

Title: Going beyond RCT's: Going Beyond RCT's: why they don't yield useful results in complex dynamic domains, and why we need alternatives

Prof. Dr. Jan van der Greef, Principal Scientist TNO, Professor of Analytical Biosciences at Leiden University, director of the Sino-Dutch Center for preventive and personalized Medicine (SD-PPM)

10:20 Break

10:40 Keynote lecture: HOW

Title: Comparative Effectiveness Research - Methods and Patient Engagement

Prof. Dr. Claudia Witt, Chair Complementary and Integrative Medicine, University of Zurich

11:10 Pitches: HOW

New research approaches on highly contextualized data yielding valid knowledge: 5 examples of novel research approaches.

12:30 Lunch

13:30 MAKING IT HAPPEN: Working sessions

I. *Methodologies: new qualitative and quantitative methodologies that build on citizen based knowledge*

II. *Making it possible: what is the roadmap to develop new, citizen centered research approaches?*

15:30 Break

16:00 Wrap up

16:45 Closing remarks by Henk Smid, Director of ZonMw, Dutch Funding Agency for Health and Healthcare

17:00 closure and drinks

**MORE INFORMATION, REGULAR UPDATES AND
REGISTRATION: www.BeyondRCT.net**