

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

How do we enlarge the research potential?

Monday 21 March 2016, Amsterdam

Executive Summary

Why do we need to move Beyond RCT's?

The 'golden standard' in biomedical research are the 'Randomized Controlled Trials' (RCT's). They have generated a lot of very valuable insights, but have severe limitations as well. One of those limitations is that patient inclusion criteria are often very strict, thereby excluding the complexity of multiple chronic conditions that people suffer from, and the diversity of lifestyles that people lead. Furthermore, the research setting is highly controlled, severely limiting the ability to translate the results to the environment of daily life. Citizens, and especially patients, increasingly question the usefulness of proposed health approaches to their specific conditions. They demand more inclusive research strategies, in which their highly contextualized experiences tangibly impact the generation of knowledge.

This symposium, organized by patient organisations Platform patients and Food Netherlands and InspireLive, and the research institute TNO, brought together over 90 people representing biomedical researchers, clinicians, health care policymakers, entrepreneurs, patients and citizens and out-of-the-box thinkers. It was born out of the believe that our research potential can and should be greatly enhanced. Patient and citizen centered research strategies are needed to gain knowledge on how health emerges and can be maintained in a daily life context. The morning sessions included 4 keynote presentations to contextualize the debate, and 8 pitches highlighting promising new research approaches with citizens and patients in the lead. Summaries and pdf's can be found at www.BeyondRCT.net The working sessions in the afternoon had two goals. A first round investigated citizen-driven research methods including the role of different stakeholders in the research process. A second and concluding round generated an overview of obstacles to citizen-driven research, ideas as to how these can be overcome and yielded an action-agenda listing the top-three things to do right away. These three things are:

- 1. Invest heavily in awareness building, networking, education and knowledge exchange, regarding the potential and possibilities of Citizen-Driven Research (CDR), for all stakeholders involved**
- 2. Speed up CDR learning and practice by developing inspiring, tangible and collaborative cases and projects around citizens / patient initiatives**
- 3. Establish a safe and fair tool / interface / platform where citizens can drop their insights and data**

This summary documents the highlights of the workings sessions. The detailed brainstorm results are catalogued in the appendix to this executive summary. More background information as to the why of this symposium can be found at the symposium website www.BeyondRCT.net, and at the websites of the organisers.



Dr. Henk Smid (middle), Director of ZonMw (the Dutch Funding Agency for Health Research), emphasizes the need to go beyond RCT's by symbolically cutting a ribbon. Dr Gaston Remmers (left; Platform Patients and Food / Inspire2Live) and Dr. Herman van Wietmarschen (right; TNO) hold both sides of the ribbon to manifest the fact that citizens / patients and biomedical researchers need each other to achieve results.

Obstacles to moving Beyond RCT and suggestions how to do it anyway

In general, the symposium felt that the paradigm that currently rules health and food research obstructs other avenues than RCT's, due to funding structure and wrong career and publication incentives for researchers. There is fear among researchers and clinicians to experiment with other methods. There is considerable mistrust and lack of knowledge among funders, scientists, clinicians, editorial boards of important journals and decision makers of research designs that are not RCT, leading amongst others to a lack of funding for non-RCT based research designs. Both publication pressure and sectoralization and specialization in the biomedical field favours the choice for RCT's – where in fact the research question should be leading for the choice of research design, and not vice versa. The scientific precision that is usually requested sometimes contradicts heavily with the relevance of this precision, and with the type of risks that citizens and patients are used to take in ordinary life. This situation, together with the power inequality between clinicians / researchers on the hand, and patients on the other, enforces a lack of sense of the ultimate purpose of the work: well-being of the patient. Finally, citizen-driven research is hampered by the absence of a platform available for patients /citizens to store their insights.

To overcome these obstacles, the before mentioned top-three action points should pave the way. In order to progress, it was stressed that researchers and clinicians need to develop the desire and guts to do things differently. On the other hand, citizens and patients should organize themselves better

as a countervailing and self-conscious power. And third: all stakeholders win most when engaging in a learning-driven, collaborative action.

The symposium yielded several examples of cases that could be good starting points, like: chronic and complex diseases, immunologic diseases, probiotics, renal diseases, diabetes, endometriosis, Lyme in relation to Wim Hof method, different cancers, CAA, Cystic Fibrosis, etcetera.

In fact, many cases and conditions are suitable for citizen-driven research. Hence, probably more important are the criteria that these cases ideally should meet: an existing strong patient / citizen urge, a good patient / citizen organization that supports it, open minded biomedical researchers and clinicians eager to expand the scope of knowledge and interventions, a disease where a food intervention can make a significant difference (positive effect is either well known or expected), with easily measurable parameters, or contrarily, a disease where a lot of unknowns exist, and that needs a lot of sorting out.

Characteristics of citizen-driven research methodologies

Conventional biomedical research disposes of a large set of research approaches that are alternatives to RCT's, and that could support citizen-driven research. Earlier surveys on alternatives to RCT's have underlined the fact that these approaches are poorly known in the research community, and have a low status. This of course underpins action point 1 on awareness raising and knowledge exchange. Yet, the symposium highlighted the fact that there is also ample scope to expand the repertoire. This is especially so regarding methods that deal with complexity and are capable of appreciating the evolving, real-life embeddedness of interventions. These are typically oriented towards learning-over-time for all stakeholders, instead of towards evaluating a discrete intervention in a static laboratory-like setting. Hence, these research designs are flexible and agile to incorporate new insights and are organized around citizens / patients (their 'ecology') instead of around researchers. Other important characteristics include that quality of data collection and analysis is guaranteed, and ownership of the data is sorted out satisfactorily (e.g. privacy and distribution of revenues following the research). The symposium concluded that Citizen-Driven Research Methods can be employed in virtually all stages of the research process and knowledge development. Patients and citizens can have a valuable role in virtually all of these stages; of particular interest might the use of citizen-driven research to open the scope of relevant hypothesis for further examination, possibly leading to a more integral understanding of the human condition.

- The symposium website www.BeyondRCT.net will remain active for a while to communicate follow-up and further developments.
- Organisations and individuals interested in developing further the action agenda are kindly invited to contact the organisers:
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