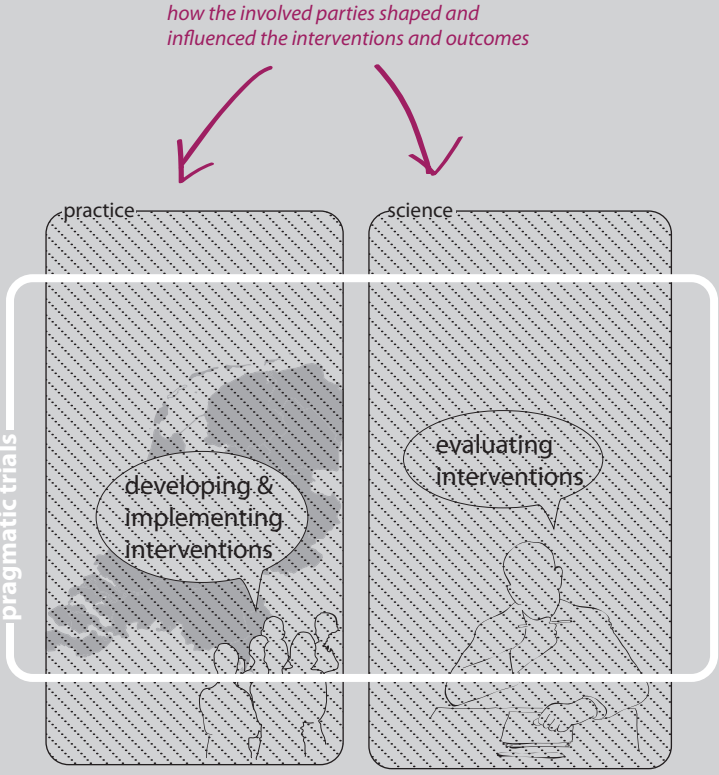
This doctoral thesis allows for a fundamental rethinking of the pragmatic trial methodology as an infrastructure for pragmatically embedding innovation(s) in primary health care

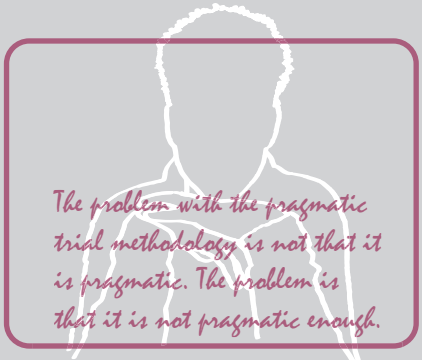
ethnographic study



doctoral thesis

Pragmatic Trials; The Mutual Shaping of Research and Primary Health Care Practice

*An **ethnographic analysis** of the role the **pragmatic trial methodology** fulfils in bridging the **science-practice** gap*



Yvonne J.F.M. Jansen

Pragmatic Trials; The Mutual Shaping of Research and Primary Health Care Practice

An ethnographic analysis of the role the pragmatic trial methodology fulfils in bridging the science-practice gap

Yvonne J.F.M. Jansen

This publication was made possible by the financial support of the Institute of Healthcare Policy and Management (iBMG) of the Erasmus University Rotterdam and The Netherlands Graduate School of Science, Technology and Modern Culture (WTMC).

The Netherlands Organisation for Applied Scientific Research (TNO) is gratefully acknowledged for its support when finishing this thesis.

Jansen, Y.J.F.M.
Pragmatic Trials; The Mutual Shaping of Research and Primary Health Care Practice. *An ethnographic analysis of the role the pragmatic trial methodology fulfils in bridging the science-practice gap.* Dissertation Erasmus University Rotterdam, the Netherlands

Design & layout: Ontwerpstudio Schot, Delft
Printed by: Optima Grafische Communicatie, Rotterdam
ISBN: 978-94-6169-184-2

Pragmatic Trials; The Mutual Shaping of Research and Primary Health Care Practice

An ethnographic analysis of the role the pragmatic trial methodology fulfils in bridging the science-practice gap

Pragmatische trials; de wederzijdse vorming van onderzoek en eerstelijnsgezondheidszorg

Een etnografische analyse van de rol die de pragmatische trial methodologie vervult in het overbruggen van de kloof tussen wetenschap en praktijk

Proefschrift

ter verkrijging van de graad van doctor aan de Erasmus Universiteit Rotterdam
op gezag van de Rector Magnificus Prof.dr. H.G. Schmidt en volgens
het besluit van het College voor Promoties.

De openbare verdediging zal plaatsvinden op
vrijdag 2 maart 2012 om 13.30 uur

door

Yvonne Johanna Francisca Maria Jansen

geboren te Breda

Promotiecommissie

Promotor:
Prof.dr. R.A. Bal

Overige leden:
Prof.dr.ir. A. Burdorf
Prof.dr. K. Horstman
Prof.dr. G.P. Westert

Copromotoren:
Dr. A.A. de Bont
Dr. M.M.E. Foets

Table of Content

Publications		7
General Introduction		9
Chapter 1	Coping with methodological dilemmas; about establishing the effectiveness of interventions in routine medical practice	27
Chapter 2	Tailoring intervention procedures to routine primary health care practice; an ethnographic process evaluation	37
Chapter 3	The contribution of qualitative research to the development of tailor-made community-based interventions in primary care; a review	49
Chapter 4	The role of screening methods and risk profile assessments in prevention and health promotion programmes: an ethnographic analysis	65
Chapter 5	The taming of chance and the actual practice of prevention; rationalised prevention and 'the social'	77
General Conclusion		91
Summary		111
Samenvatting		119
Dankwoord		127
About the author		131

Publications

This thesis is based on articles.

Chapter 1
This chapter is published as:
Jansen, Y.J.F.M., Bal, R., Bruijnzeels, M., Foets, M., Frenken, H., de Bont, A. (2006). Coping with methodological dilemmas; about establishing the effectiveness of interventions in routine medical practice. BioMed Central Health Services Research **6**:160. doi:10.1186/1472-6963-6-160.

Chapter 2
This chapter is published as:
Jansen, Y.J.F.M., de Bont, A., Foets, M., Bruijnzeels, M. and Bal, R. (2007). Tailoring intervention procedures to routine primary care practice; an ethnographic process evaluation. BioMed Central Health Services Research **7**:125. doi:10.1186/1472-6963-7-125.

Chapter 3
This chapter is published as:
Jansen, Y.J.F.M., Foets, M. de Bont, A. (2010). The contribution of qualitative research to the development of tailor-made community-based interventions in primary care; a review. European Journal of Public Health **20**(2):220-226. doi:10.1093/eurpub/ckp085.

Chapter 4
This chapter is published as:
Jansen, Y.J.F.M. and de Bont, A.A. (2010). The role of screening methods and risk profile assessments in prevention and health promotion programmes; an ethnographic analysis. Health Care Analysis **18**(4):389-401. doi:10.1007/s10728-009-0141-0.

Chapter 5
This chapter is published as:
Jansen, Y.J.F.M. (2010). The taming of chance and the actual practice of prevention; rationalised prevention and "the Social". In: Health Promotion and Prevention Programmes in Practice; How Patients' Health Practices are Rationalised, Reconceptualised and Reorganised. VerKörperungen/MatteRealities - Perspektiven empirischer Wissenschaftsforschung. Mathar, Th. and Jansen, Y.J.F.M. (Eds.). Bielefeld: Transcript Verlag. pp. 147-169.

General Introduction

This thesis is situated against the background of two dilemmas that exist within the medical field as a whole and the field of public health in particular, which had its influence on studying and evaluating health care. The first dilemma is how to integrate and sustain prevention and health promotion interventions that are becoming more and more complex, within the organisation of routine primary health care practice. The second dilemma concerns how to evaluate the effectiveness of such interventions in such a way it matches the criteria of evidence-based medicine and at the same time increases the dissemination of knowledge gained by these evaluations. In the remainder of this chapter, I will describe these dilemmas and indicate how I have conducted this doctoral study.

The growing complexity of public health

In the last decades, prevention and health promotion have gained more and more attention in the health policy domain. In Western countries the pressure on health care systems has increased, due to demographic changes and technological development. This also applies to the Netherlands. Due to an increasing population size and changes in population composition, health care expenditures have risen and are expected to rise even further. As a consequence of an increase of elderly and ethnic minorities, as well as an increasing amount of people with chronic illnesses, health care systems are faced with a growing and changing demand on health care (de Hollander, Hoeymans et al. 2006; Helderman 2007). The growing attention for public health policy and suitable prevention and health promotion interventions, aiming to collectively assure the conditions under which entire populations can be healthy, can be seen as an attempt to keep Western health care systems affordable (Hunter 2003; Mathar and Jansen 2010a).

Whereas earlier types of prevention activities, like overall sanitation and basic hygienic improvements, did improve the overall health status of Western populations, current prevention activities do not have the same level of impact. In fact, the impact and effect of public health policy initiatives by means of contemporary prevention and health promotion interventions, is often questioned (cf. (Hunter 2003)). The effect they have on the improvement of population health is in any case more difficult to assess. Despite an overall improvement in the population's health, health inequalities in society remain and have even become larger, creating a prevention paradox (see e.g. (Rose 1985; Hunt and Emslie 2001; Allebeck 2008)). Due to findings that inequalities in health could be linked to specific subpopulations, interventions have become targeted at such populations and aim at eliminating health inequalities of the so-called hard-to-reach groups in society, like elderly, youth, people with

low socioeconomic status, ethnic minorities and marginalised groups (e.g. (Barnett, van Beurden et al. 2004; Mukoma and Flisher 2004; Benoit, Jansson et al. 2005; King and Nazareth 2006; Wallerstein and Duran 2006)). With this diversity in subpopulations to be targeted, a growing combination of strategies for improving the health of these subpopulations became in use. Where the earlier types of interventions used a single strategy (i.e. providing general health information by means of national health campaigns, health information leaflets, or behavioural interventions etc.), current prevention activities use multiple strategies in which educational interventions are combined with behavioural interventions. Current prevention activities are focused on improving the knowledge of individuals about the interrelatedness of (chronic) diseases with lifestyles, and on changing the individuals' attitudes, self-efficacy expectations, and awareness of one's behaviour (Edwards, Mill et al. 2004).

In the field of public health, as a consequence of developments in medicine in general, the realisation grew that initiatives to improve population health could only be achieved in combination with better health service delivery and organisational restructuring of primary health care (cf.(Hunter 2003)). With the publication of the two well-known reports of the leading US Institute of Medicine (IOM) "To err is human" and "Crossing the quality chasm" (IOM 2000; 2001), the field of medicine came to realise that the improvement of quality in health care was not only achieved with medical interventions that proved effective, but also with the organisational restructuring of health care. In the IOM reports, quality problems in health care are depicted as problems of performance, i.e. as a chasm between what the quality of health care should and could be and what it actually was. According to the IOM the health care delivery system is not sufficiently able to translate knowledge into practice. Human errors in care occur due to unstandardised medical decision-making and variation in medical practice. Even quality management and ICT supported decision-support systems, believed to reduce human error in health care, are lacking (de Mul 2009). In 2000 and 2004 the Dutch Health Council of the Netherlands, like the IOM, reported 'a gap between knowledge and practice' in Dutch health care (Gezondheidsraad 2000; 2004). The reports state that the evidence-base of health care was poor. Although much medical evidence about the effectiveness and efficacy of medical treatments and interventions are already known and widely accessible, in primary health care practice – as in the whole of medicine – the delivery of care is not guided by this evidence but mainly by the tacit and experiential knowledge of its professionals. In fact, patient care is not delivered based upon the latest evidence, nor is it delivered in a uniform and standardised manner leading to a variety in primary health care practices that is assumed to endanger patient care and safety. Therefore, the quality of primary care is better served with organisational restructuring: an extensive focus on prevention and health promotion activities, multidisciplinary approaches and the provision of services aligned with the growing ethnic and cultural diversity in society (cf. (Richards, Carley et al. 2000; Fulop, Allen et al. 2003; Gezondheidsraad 2004; Brotons, Bjorkelind et al. 2005)).

In order to improve the quality of public health, it is believed that not only should the organisation of primary health care delivery be restructured, the scientific practice of public health would have to be restructured as well (cf.(Sen 2003)). With Evidence-Based Medicine (EBM) permeating all fields of medicine, including the field of public health, the belief grew that rigorously collected scientific evidence would result in high quality medical practice as well as public health practice (cf.(Sackett and Rosenberg 1995; Sackett, Rosenberg et al. 1996a; Sackett, Rosenberg et al. 1996b)). EBM is heavily reliant on the randomised controlled trial (RCT) methodology as being the 'gold standard' of evidence (Hunter 2003; Timmermans and Berg 2003a). In fact, the focus in medical scientific research on the RCT methodology

indicates the wide consensus that RCTs and meta-reviews of RCTs provide the best method of filtering out beneficial interventions from those that have no important effects or are positively harmful, and identifying those treatments that are likely to be most cost-effective (Blakemore and Davidson 2006). However, the evidence produced by means of this methodology does not translate and disseminate easily into routine medical practice. It is often reported that new medical interventions or treatments when applied in routine medical practice do not achieve the same level of benefit, are not effective at all and/or do not disseminate into other medical settings than the ones in which they were tested (Glasgow, Lichtenstein et al. 2003; Blakemore and Davidson 2006). This proves the use of evidence and knowledge in routine medical practice to be a very complex process that does not correspond with the evidence and knowledge produced with the RCT methodology. Therefore, as organisational restructuring of primary care is considered to foster the improvement of population health, it is believed this can only be achieved with evidence and knowledge that is of more practical use in routine medical practice. The quality of the evidence needs to improve too.

The growing complexity within the field of public health, as described above, is not only found in the growing diversity of interventions using multiple strategies, or in the growing difficulties of fitting these interventions in routine medical practice. It is also found in the changing social and political relations in society. These changing social and political relations resulted in a paradigmatic shift in societal thinking about solidarity and individual responsibility which also permeated the field of public health. As many sociologists studying prevention and health promotion have indicated, the most distinctive feature of today's prevention and health promotion interventions is their emphasis on the facilitation of healthy lives (Bunton, Nettleton et al. 1995; Burrows, Nettleton et al. 1995). In order to have individuals change their lifestyles to healthier ones, prevention and health promotion not only address individuals directly via interventions, they also encourage the creation and implementation of public health policies that actually direct individuals to live healthier lives (Bunton, Nettleton et al. 1995). As a result, these sociologists have argued that current prevention and health promotion interventions reflect as well as foster changes in the patterning of solidarity and the distribution of responsibility. Thus, they implicitly carry a strong moral programme towards an individualisation of health care responsibility. In other words, health is not only seen a responsibility of the State or as the responsibility of health care deliverers, it is foremost a responsibility of individuals themselves.[1] This shift can be interpreted as a change in the State-Subject relationship, or better the emergence of a new moral regime in society, that places the responsibility for health and illness as a dual responsibility of the State, the actual health care deliverers and of citizens (cf.(Mathar and Jansen 2010b; 2010a)).

The diversity of interventions and strategies used, the extensive focus on organisational restructuring of primary health care delivery and the changing views on collective and individual responsibility to health, make public health inherently complex which makes the implementation of public health policy and interventions increasingly difficult (cf. (Hunter 2003)). Together these aspects of prevention and health promotion are considered to have a high potential benefit for population health. The complexity however also provides a dilemma for evaluating the effectiveness and impact of public health initiatives to which I now turn.

1 This last paragraph has been published earlier, and has been reprinted with approval of the publisher. See for a more elaborate description (Mathar and Jansen 2010b; Mathar and Jansen 2010a).

Changing modes of evaluation

Because of the inherent complexity of public health programmes, the effectiveness and impact of prevention and health promotion interventions is difficult to establish. Over the years numerous scholars have argued that, in order to improve the translation and dissemination of scientific research findings into routine medical practice, additional modes of evaluating effectiveness need to be developed as the conventional RCT methodology has proven not to be suitable for evaluating effects of complex prevention and health promotion interventions (see e.g. (Susser 1995; Nutbeam 1996; Macdonald 2000; Black 2001; Twinn 2001; Macdonald 2002; Glasgow, Lichtenstein et al. 2003; Hunter 2003; Blackwood 2006)). Therefore, pragmatic modes of evaluation, like the pragmatic trial methodology, came up as an alternative to the conventional RCT methodology. Where conventional RCTs focus on establishing the effectiveness of new medical interventions and treatments under laboratory-like conditions – through the use of randomisation procedures, blinding, homogenous patient populations, standardisation of intervention procedures and statistical analysis – the pragmatic trial methodology is more practice based in nature. The pragmatic trial methodology focuses on establishing the effectiveness of new medical interventions and treatments in routine medical practice (Schwartz and Lellouch 1967; Armitage 1998; Hotopf, Churchill et al. 1999; Helms 2002; Hotopf 2002; Knatterud 2002; MacPherson 2004), in which it is allowed for interventions to incorporate variations in practice at different sites and for targeting a heterogeneous patient population. In other words, the pragmatic trial methodology allows for taking the complexity of routine medical practice and decision-making into its design. The notion behind this is that if evidence is produced under conditions similar to 'real medical practice', this evidence disseminates much easier from the test settings into routine medical care (Visser 2000; Wolff 2001; Stange, Goodwin et al. 2003).

Moreover, besides pragmatic modes of evaluation, the notion grew that evaluating the process of implementation of prevention and health promotion interventions in routine medical practice when establishing its effect and impact was important (Burton, Goodlad et al. 2006). The contextual information of the conditions under which interventions were implemented and carried out in routine care is believed to provide in depth information relevant for the translation and dissemination of evidence and knowledge into routine practice. This development started a trend towards the application of mixed methods research designs for evaluation purposes, in which qualitative research methods were used alongside RCT/ pragmatic trials or large scale quality improvement programmes (Grol 2001; Øvretveit and Gustafson 2002). In the Netherlands, these developments gave rise to a quality improvement movement that experimented with these new modes of evaluation. Programmes like 'Working Differently' (Anders Werken), 'Better Faster' (Sneller Beter), and 'Care for Better' (Zorg voor Beter)[2] were developed to introduce quality improvement processes throughout the whole medical sector. In public health settings, similar programmes were established, such as the 'Better Prevention' ('Beter voorkomen') programme. With these programmes attempts were made to overcome the gap between scientific practice that produces knowledge on effectiveness and health care practice where this knowledge is not applicable. Although these programmes do have a slightly different focus, they were all based upon the same principles.

2 See for more elaborate descriptions of these programmes (Berg and Bergen 2003; Zuiderent, Bal et al. 2004; Bal and de Bont 2005; Dückers, de Bruijn et al. 2006; Dückers and Wagner 2007; van den Berg, Frenken et al. 2009; Zuiderent-Jerak, Strating et al. 2009; Broer, Nieboer et al. 2010)

On the one hand, they focused on improving health care delivery and quality through the standardisation and reorganisation of health care practices. On the other hand, they tried to improve health care delivery and quality through reorganising scientific practices to ensure the use and translation of scientific medical evidence in routine medical practice by using pragmatic modes of evaluation.

A unique project: the Quattro Study[3]

The developments described in the sections above formed the background of the Quattro Study, which was the study object of my thesis research. Quattro was a unique project. It incorporated the aforementioned developments and was based upon three assumptions on the improvement of health care delivery and quality. Firstly, the Quattro Study focused on a combination of prevention and health promotion activities in deprived neighbourhoods, in order to improve delivery and quality of care in these neighbourhoods and improve the health outcomes of its inhabitants. The study focused on reducing the risk to cardiovascular diseases in low SES and ethnic minority inhabitants of deprived neighbourhoods. Secondly, in order for the reorganisation of primary health practice to take place, the Quattro Study applied an approach for tailoring the intervention to practice needs. It was assumed that if primary health care professionals were closely involved in the development and implementation of new organisational structures, work practices and supportive protocols, organisational changes would become sustainable. And lastly, the project applied the pragmatic trial methodology, as it was assumed that the use of new modes of evaluation corresponded best with the complexity of the intervention and would lead to a better dissemination of knowledge and the uptake of such interventions into routine primary care.

Even though much of the complexity of the setting had been taken aboard in designing both the intervention and its evaluation, the Quattro Study proved to be far more difficult to embed into routine primary care practice and to evaluate its outcomes in health and effectiveness than planned (El Fakiri 2008). The research described in this thesis arose in April 2003 from the pressing dilemma the Quattro Study project found itself confronted with. At that time, the Quattro Study was already running for over a year and the implementation of the new organisational structure in the participating primary health care centres remained difficult and a reoccurring issue. As part of the Quattro Study project, I – as an anthropologist - was asked to study the implementation of the Quattro Study intervention in the participating primary health care centres. The information and insights I would gather were to be used as feedback on the preconditions important to the implementation and execution of complex interventions in primary care, in order to refine the mode of evaluation and the intervention studied. I saw this as an opportunity to ethnographically study what the pragmatic trial methodology as a new mode of evaluation of complex prevention and health promotion interventions comprised, and how the project's researchers, primary health care professionals, and participating patients mutually shaped the intervention and influenced the intervention's delivery and its outcomes.

Aim and research questions

The aim of this thesis is to understand the pragmatic trial methodology – a new mode of

3 See for a full description of the Quattro Study project, the methodology it applied and the outcomes of the study (El Fakiri and Foets 2005; El Fakiri, Hoes et al. 2008).

evaluating complex interventions in prevention and health promotion – as an infrastructure for organisational change in primary health care.

The research questions this thesis addresses are:

1. How are methodological dilemmas stemming from standardisation and localisation dealt with in pragmatic trial research?
2. How does the pragmatic trial methodology allow for tailoring complex interventions to primary health care organisations?
3. What is the role of scientific instruments, such as screenings instruments and risk profile assessments, used within the pragmatic trial methodology for routine medical practice?
4. What is the role of mixed methods research in the development of complex interventions in prevention and health promotion and how does qualitative research contribute to evaluation in pragmatic trial methodology?

Theoretical perspective

In order to understand the pragmatic trial methodology as an infrastructure for organisational change, and to answer the above research questions, I make use of theoretical perspectives developed in the field of Science and Technology Studies (STS), which focus on the nature and organisation of scientific practice, the production of scientific facts and the relation of science and society. In particular the work of different STS scholars that have studied the randomised controlled trial (RCT) methodology in medicine has inspired this thesis.

Based upon the work of scholars from the sociology of science who have studied the nature and organisation of scientific work in different settings, the role of social conventions in establishing consensus on scientific facts (e.g. (Latour and Woolgar 1986; Latour 1987; Knorr Cetina 1995; 2003)), Marks describes the methodological developments in medical research that has led the RCT methodology to become the ideal design for the assessment of medical treatments. In his publications "Notes from the Underground; the Social Organization of Therapeutic Research" (Marks 1988) and "The Progress of Experiment" (Marks 1997), he shows how the organisation and conduct of clinical experiments have been radically transformed by medicine's encounter with the discipline of statistics. He argues that the trend of increasing standardisation and regulation in medical research and therapeutic practice was induced by a growing distrust in personal judgement in medical professional practice combined with an increasing emphasis on efficiency in contemporary society. The logic of randomisation and significance-testing apparent in the disciplines of statistics and clinical decision-making has been embraced to reform and regulate therapeutic practice and establish uniformity and neutrality in clinical research by undoing it from its subjective interpretation.

In concordance to the work of Porter and Hacking, Marks shows – specifically for the field of medicine – the interrelatedness of societal thinking and scientific practice. Both Porter (Porter 1995) and Hacking (Hacking 1990), have argued that scientific reasoning reliant on standardised procedures and statistics became of importance in democratic societies as it was believed to provide objective knowledge that is reduced from subjective interpretation. Porter argued that the growing reliance of a democratic society on bureaucratic authority and objectivity has developed in tandem with the pursuit of objectivity and rationalisation in science. In fact, due to democratic societies dealing with growing complexity in society – in order to inform public policies for dealing with this complexity – they made an increasing

appeal to science for its complex systems of standardised procedures for the production of scientific knowledge that is objective and carefully filtered from subjective interpretation. Through the use of mathematical and logical reasoning, statistical instruments and explicit methodological rules of practice, science has come to function as a 'technology of trust', in which "scientific objectivity […] provides an answer to a moral demand for impartiality and fairness" (Porter 1995). In addition to Porter, Hacking has shown that this shift in scientific reasoning based upon statistics and standardised procedures, is part of the modern project of the 'taming of chance' (Hacking 1990). Aided by statistics and the explanatory power of statistical patterns, nature became perceived as predictable and controllable by science. This has led, as Hacking argues, to a growing dependability of democratic societies on probabilistic reasoning and enumeration. In other words, public policy became more and more reliant on the scientific production of numerical and probabilistic evidence to counter nature's hazards and provided democratic societies the authority and the legitimisation to tackle societal problems with adequate policies and to care for the public's well-being in the modern welfare state.

With the work of the aforementioned scholars pointing to the interrelatedness of societal reasoning and scientific practice in relation to the production of evidence and knowledge, the work of Dehue points to the performativity of the RCT methodology in the production of evidence and knowledge. In her work, she shows the historical context of randomisation procedures and grouping in social experimentation. She argues that the strive for objectivity throughout the twentieth century – as also Porter and Hacking argued – resulted in the hegemony of randomisation procedures as the 'gold standard' for the efficient production of credible evidence. She shows this by presenting a historiography of randomisation in psychophysical research (Dehue 1997). Whereas in earlier psychophysical studies randomisation procedures were used to determine the order in which subjects were exposed to experimental and control situations, in contemporary experiments randomisation procedures are used to construct experimental and control groups of subjects. The technique of constructing groups at random became the ideal for the 'true experiment': the randomised controlled experiment or RCT became the ideal for ensuring the comparability of experimental and control groups and the proper way of evaluating effectiveness of interventions (Dehue 1997). She further argues that the application of the RCT methodology is not a matter of applying a transcendental "logic of science" by neutral scientific researchers. Her historical analysis shows that the contemporary definition of the randomised controlled experiment did not originate in a natural science lab, but in the closely intertwined realms of social administration and social research (Dehue 2001).

In arguing so, Dehue challenges the neutrality of the RCT methodology. She argues that the RCT methodology and the objectivity it depicts never fully discards expert discretion as standardised research involves much deliberations, interpretation and consensus formation (Dehue 2004). She argues that the RCT design used in social sciences and in medicine in particular, embodies three interrelated principles. Firstly, the principle that 'objectivity' should be defined in terms of standardised impersonal procedures; secondly, that instantaneous effectiveness of ameliorative interventions should be demonstrated unambiguously; and finally, that such interventions should be directed at individuals in need of integration into the given social order. These principles provide the RCT methodology its image of neutrality. However, an RCT as a technical procedure does not depict reality as it is, but reshapes reality according to its image and procedures and therefore is in itself not neutral; instead it 'performs'

reality (Dehue 2001; 2002). In order to conduct experiments, researchers need procedures, definitions and classifications for diagnosing physical conditions and the behaviour of subjects, which are based on conventions and extensive deliberations among scientific peers. Therefore, the RCT methodology and the outcomes they produce are formed and shaped by the practice of researchers and their scientific conventions.

The same argumentation can also be found in the work of Bartholomée. Besides that her work also shows that experiments remake reality and create phenomena through the procedures that are established to discover them, she furthers the argumentation by showing how the measurements used in experiments and numerical evidence they produces also create new realities (Bartholomée 2004). Whereas Dehue argued that the RCT methodology and its outcomes are shaped by the practice of researchers and their scientific conventions, Bartholomée argues that the RCT methodology also shapes and formalises scientific practice. In fact, she argues that experiments and measurements used to evaluate the experiments shape their own reality by carefully fitting researchers as well as their subjects to an experimental mould. Both researchers and subjects become disciplined to act according to the experiment. Researchers are disciplined to follow the required strict procedures to retain control over what happens and participants or subjects are disciplined to realign their identity with the behavioural conduct prescribed in the experiment. The measurements and the numerical data they produce provide the proof of how well both researchers and subjects are disciplined or not. Therewith, she argues, social experimentation – of which the RCT methodology is an example – is normative in its essence.

The point of normativity is also found in the work of Horstman and Houtepen. In their book "Wrestling with a healthy life" ("Worstelen met gezond leven") (Horstman and Houtepen 2005), the authors have analysed a community-based prevention and health promotion intervention in the Netherlands that was evaluated for its effectiveness by means of the RCT methodology. They argue that the RCT methodology prevents real effects of prevention and health promotion interventions from happening, as it is not neutral but intrinsically normative. The use of the RCT methodology to capture effects of experiments or interventions underscores a rationalistic manner of reasoning. In fact, this rationalistic perspective that is embedded in the RCT methodology presumes that the value of evidence and knowledge can be proven through the standardisation of and control over the operational conditions of health care practices. However, as prevention work has its own dynamics and thus is hard to standardise and hard to control, the rationalistic character of the RCT methodology depicts the practice of prevention work from a narrow perspective. What is depicted is the extent of standardisation of and control over the practice of prevention work that could be achieved. In other words, the RCT methodology shows to what extent intended effects are achieved in interventions, therewith making unintended effects (or side-effects) invisible. Moreover, the emphasis in the RCT methodology on establishing effect and effectiveness prohibits health care professionals and patients participating in the interventions studied to act; this methodology reduces them to instruments necessary for conducting research. Their opinions, their experience(s) and the adjustments that are made to the interventions during research are therewith made invisible. In other words, the RCT methodology shows to what extent the practice of prevention work and the health care professionals and patients are moulded to the RCT methodology. Therefore, Horstman and Houtepen argue that the RCT design denies individuals the autonomy and self-responsibility to health that prevention ascribes them.

The work of Timmermans and Berg also is important to mention here. Whereas

Marks, Dehue and Bartholomée show in their work how the RCT methodology shapes and forms the scientific practice of medical research, the work of Timmermans and Berg shows the performativity of the RCT methodology and other formalising and standardising instruments in routine medical practice. In their work, they show how guidelines, protocols, classification schemes and other medical technologies are shaped by the routine medical practices they are implemented and used in (cf. (Berg 1995; 1996; Bowker, Timmermans et al. 1996; Berg 1997; Berg and Lyke 1997; Berg 1998; Berg and Timmermans 2000; Timmermans and Berg 2003a; 2003b; Timmermans and Mauck 2005)). In their work they argue that de strive for standardisation and formalisation in health care will always work out differently than expected. They argue that despite the strive to transform work practices in routine medical practice, medical technologies, guidelines, protocols and other standardising instruments become localised and contextualised, changed and reappropriated. In other words, they become 'local universalities'.

The aforementioned scholars have shown that the RCT methodology became the ideal type of experimental design due to changes in societal reasoning, and have shown the RCT as a method for evaluating experiments to be the resultant of the scientific practice of researchers and their conventions and consensus. They have also shown that the RCT methodology shapes and is shaped by scientific practice, the participants and the phenomena that are studied. The RCT methodology is the resultant of changes in societal reasoning and changes in scientific practice. The fact that the RCT methodology shapes practices as well is shaped by them, could not have been shown without the use of ethnographic methods. Both Dehue and Horstman & Houtepen have applied ethnographic methods to inform their arguments. Ethnographic research, in contrast to the experimentation paradigm, allowed them the opportunity to be more informative about the cultural and historical context of the experiments they studied, about the way definitions and classifications constructed outcomes in the experiments, and about the interpretations and experiences of participants (Dehue 2002; 2004; Horstman and Houtepen 2005). It provided them a reflexive stance towards the RCT methodology. Although Dehue acknowledges that ethnographic research is not airtight and free of the researchers' views and interpretations, she argues ethnographic research to be a more adequate method than experiments to offer well-informed interpretations (Dehue 2002). Whereas in experiments the definitions and classifications used by researchers remain inherent and hidden, these are brought to the fore in ethnographic research making them explicit and part of the argument (Dehue 2004). She goes on to argue that, if embraced in the experimentation paradigm, with ethnographic research providing more well-informed contextual information, the combination of experimentation and ethnographic research would provide the possibility to adapt the criteria of effect to this information (Dehue 2002; 2004).

Taking these aforementioned arguments into account, the RCT methodology can be defined an infrastructure that connects the realms of science and routine medical practice. In concordance with the argument of Bowker and Star, in their book 'Sorting things out; Classification and its consequences' (Bowker and Star 2000), the RCT methodology is a infrastructure that binds scientific researchers and health care professionals, with their scientific instruments, medical technology, work practices and classification schemes. In fact, the RCT methodology is an infrastructure for connecting the realms of science and routine medical practice and 'communities of practice' (cf. (Bowker and Star 2000)). In other words, the RCT methodology brings the results of scientific practice, the scientific and methodological

instruments for screening patient populations and performing prevention and health promotion according to theory-based and evidence-based methods and strategies into routine medical practice. And it presents science with patient-level data on health outcomes and workable interventions as the personnel and work processes for monitoring patients' health is already in place in routine medical practice (cf. (O'Sullivan, Thompson et al. 2005)).

Thusfar, the aforementioned paragraphs can be read as a critique towards the RCT methodology and not so much to the pragmatic trial methodology per se. However, pragmatic trial researchers do also – though partly – underscore this critique. According to them, the RCT methodology and the instruments it uses function as an experimental mould that standardises reality too much and does not produce evidence that is usable in real health care practice. The pragmatic trial methodology tries to incorporate the critique as formulated by the aforementioned scholars into its design. As a derivate of the RCT methodology, the pragmatic trial methodology is in that sense 'the best of both worlds': it provides the freedom to health care professionals to organise the intervention format and its core elements to fit their local context, organisational circumstances and work processes, and it corresponds to the societal emphasis on rationalisation to establish the effectiveness according to the criteria of sound scientific evaluation research and a validated trial methodology (see e.g. (Schwartz and Lellouch 1967; Haynes 1999)). In other words, the pragmatic trial methodology is a infrastructure – different from the RCT methodology – for organisational change as the pragmatic trial methodology underscores the importance of health care professionals and participants as co-constructors and co-producers of interventions and their outcomes. The pragmatic trial methodology is therefore focused on the evaluation of interventions as they are shaped and formed in routine medical practice.

The scholarly work described above provides the framework for this thesis research. In fact, it also determines the research methods employed in this research. Three basic principles for STS research guided the choice to apply an ethnographic case study design (cf.(Hackett, Amsterdamska et al. 2008)).

1. A thorough research of formalised work practices (e.g.(Bowker and Star 2000; Timmermans and Berg 2003a)). In this respect, this research is about describing and analysing what happens in the practices of pragmatic trial research and primary health care when performing and evaluating the effectiveness of a complex prevention and health promotion intervention. Thus it is about how the pragmatic trial methodology, its measurements and the numerical evidence that is produced structure, standardise and formalise both scientific practice and the practice of primary health care. An in-depth analysis of work practices is only possible with ethnographic methods.
2. View researchers and participants as co-constructors and co-producers of the pragmatic trial methodology and its measurements and outcomes (e.g.(Latour and Woolgar 1986; Latour 1987; Knorr Cetina 1995; 2003)). In other words, this research studies what the pragmatic trial researchers, primary health care professionals and participating patients actually do in the Quattro Study; how the pragmatic trial researchers conduct the evaluation procedures and how primary health care professionals and patients perform and participate in the intervention in routine medical practice. Through showing this, it is possible to show how the human actors shaped the intervention, the pragmatic trial design and its outcomes.

3. The use of scientific concepts to understand the functioning of the pragmatic trial methodology and its instruments in relation to the routine medical practices the complex prevention and health promotion interventions are implemented and used in (e.g.(Jasanoff 2005)). In other words, this research is about coming to understand scientific practice of generating scientific evidence to inform public health policy and routine medical practice mutually shaping the pragmatic trial methodology. Through the use of scientific and theoretical concepts the ethnographic findings provide insight into how pragmatic trial researchers, health care professionals and patients use and define concepts. Through showing this it contributes to the further understanding of the methodology used.

Methods

An ethnographic case study research was considered suitable as it enables to explore a phenomenon in depth in its natural setting (Segers and Hutjes 1999), using a variety of data collection methods over a sustained period of time (Creswell 2003). Case studies are particularly suitable for the analysis of relations, actions and interactions of various actors involved and to identify the differences in perceptions (Segers and Hutjes 1999). For these reasons, an ethnographic case study design was considered an appropriate research strategy to further the understanding of the pragmatic trial methodology as a new mode of evaluation and as an infrastructure for organisational change in primary health care. It provided the opportunity to explore and explain what the Quattro Study project comprised, how the project's researchers, primary health care professionals, evaluation techniques and participating patients mutually shaped the intervention, and influenced the intervention's delivery and its outcomes. In other words, an ethnographic case study design enabled to study how the project's researchers developed and evaluated the intervention, how the screening instruments and risk profile assessments used functioned in relation to the intervention and its evaluation, how the intervention was delivered in primary health care practices, how both health care professionals and patients actually participated in the intervention. As ten Have illuminated (ten Have 1999), ethnographic research is used to thoroughly describe the daily routines of participants from an insider's perspective. In other words, an ethnographic design was chosen because it was considered a suitable way to see the 'real' actions of all the actors – both human and non-human – in this study, without any a priori implicit or explicit interpretations of those actions of the people observed (cf. (Garfinkel 2003)).

In concordance with an ethnographic case study design, a variety of data collection methods were applied. Participant observations were conducted of the actions of the project's researchers, primary health care professionals and participating patients. Semi-structured face-to-face interviews were held with practice nurses, researchers of the Quattro Study project and patients. And documents about the project were collected: minutes of meetings, the project's questionnaires, health information leaflets, the project's newsletters, etc. Each of the chapters outlines the specific methodology used.

Outline of the thesis

Chapter 1 provides a detailed description and analysis of the difficulties that arise in conducting research by means of the pragmatic trial methodology. The chapter shows that the pragmatic trial design used for evaluating the effectiveness of interventions, in fact provides methodological problems when evaluating effect of interventions performed in routine primary health care practice. Pragmatic trial researchers find themselves confronted with dilemmas of balancing scientific rigour and pragmatism, standardisation and localisation. The chapter argues that, as the pragmatic trial methodology holds the premise of being both 'pragmatic' (enabling the uptake of intervention in routine primary health care) as well as 'systematic' (establishing the effectiveness of interventions by means of experimental design), ethnographic research is imperative to pragmatic trial research as its provides the methodological and practical reflection needed to understand the dynamic process of continuous interactions between scientific practice and primary health care practice.

Whereas in chapter 1 the focus is on the difficulties that arise in the scientific practice of pragmatic trial research, in **chapter 2** the difficulties that arise when performing an intervention evaluated by means of the pragmatic trial methodology in the practice of primary health care are foregrounded. This chapter shows that in order to embed the intervention and its evaluation in routine primary health care practice the application of a tailor-made approach is not enough. Additional instruments, like guidelines, are needed to change and adapt existing interprofessional relations between primary health care professionals. The chapter argues that in order to fully incorporate a tailor-made approach into the pragmatic trial methodology and/or routine primary care practice, a different kind of evaluation of effectiveness is needed that combines both quantitative and qualitative forms of evaluations.

The need to combine quantitative and qualitative modes of evaluation – pragmatic trials combined with qualitative and/or ethnographic research – for the evaluation of complex prevention and health promotion interventions has been acknowledged for better understanding and evaluating the growing complexity of both health care and health care interventions and for making appropriate adjustments to interventions and evaluative designs. **Chapter 3** provides a review of literature to show how qualitative research within the context of pragmatic trials actually contributes to the development of complex interventions to be performed in primary health care. The chapter shows that the contribution of qualitative research insights is limited as of yet. In fact, the chapter argues that qualitative research insights, as found in the literature, may not contribute to adjust interventions during development, nor during evaluation. Qualitative research insights may only contribute to the interpretation of effectiveness after the evaluation period by means of process evaluations. Herewith it is argued that despite the contribution qualitative research insights can have, the pragmatic trial methodology standardises both the content and delivery of interventions. The interventions evaluated by means of the pragmatic trial methodology are still considered to resemble the original intervention as much as possible.

In **Chapter 4** the argument that ethnographic research is imperative to pragmatic trial research is taken up again. In this chapter the role of screening methods and risk profile assessments, used to monitor the progress in behavioural and or lifestyle change in individual patients participating in prevention and health promotion interventions, is examined. The chapter

argues that ethnographic research is indeed imperative, as pragmatic trial methodology needs to redefine the problems of effectiveness and performance. In fact, it is argued that if one takes into account the internal dynamics and logics of medicine in practice and the functioning of screening methods and risk profile assessments when evaluating effectiveness of interventions seriously, a different definition of effectiveness is needed. In this chapter it is shown that such instruments do have effects themselves that are not considered as such in the 'original' pragmatic trial methodology. Herewith the chapter argues that qualitative research should be part of the definition of effectiveness from the development of interventions onwards.

Chapter 5 furthers this argument. In this chapter, through following all the actors – both human and non-human – in the intervention, it is argued that ethnographic research should also be part of the definition of the 'problem of performance'. It is argued that ethnographic research and the reflexive stance it can provide should become an integral part of prevention and health promotion interventions. Only then ethnographic research can take up the intermediary role and provide insights and formative feedback on what is being evaluated and how effectiveness is and should be defined. In other words, it is argued that besides being part of the 'problem of effectiveness' ethnographic research should also be part of the 'problem of performance'. Only than can good quality prevention and health promotion delivered in primary health care be provided that is tailored to the specific health problems and needs of populations resulting in an improvement of the overall public's health.

In the **general conclusion** the questions raised in the general introduction are addressed. The focus in this thesis on the pragmatic trial methodology as a new mode of evaluation of complex prevention and health promotion interventions in primary health care enables to provide a fundamental rethinking of the pragmatic trial methodology. As this thesis showed, the pragmatic trial methodology can be redefined as an infrastructure as it provided an intervention that proved to be the vehicle to bring in guidelines for the change in interprofessional relations and altering work practices. Moreover, the screening methods and risk assessments the pragmatic trial brought to the primary health care practices, proved to be vehicles for primary health care professionals to tackle patients' social problems first that prohibit achieving lifestyle change before targeting health risk behaviours. In fact, the pragmatic trial and the intervention it developed proved to be an infrastructure for changing work practices in primary care. Therefore, it is argued that the scope of evaluating the impact of interventions in medical care by means of the pragmatic trial methodology should be broadened, as the emphasis on establishing the success or failure – inherent to the methodology used – refuses to acknowledge non-anticipated effects as genuine effects of interventions.

References

Allebeck, P. (2008). The prevention paradox or the inequality paradox? European Journal of Public Health **18**(3): 215.

Armitage, P. (1998). Attitudes in clinical trials. Statistics in Medicine **17**: 2675-2683.

Bal, R. and de Bont, A.A. (2005). Taakherschikking en ICT in de zorg In: Kennis in Netwerken: Jaarboek ICT en Samenleving 2005. de Haan, J. and van der Laan, L. (eds.). Amsterdam: Boom. pp. 113-126.

Barnett, L.M., van Beurden, E., Eakin, E.G., Beard, J., Dietrich, U. and Newman, B. (2004). Program sustainability of a community-based intervention to prevent falls among older Australians. Health Promotion International **19**(3): 281-288.

Bartholomée, Y. (2004). Society as a Laboratory; Donald T. Campbell and the history of social experimentation. Psychologische, Pedagogische en Sociologische Wetenschappen. Groningen: Rijksuniversiteit Groningen. [Doctoral thesis].

Benoit, C., Jansson, M., Millar, A. and Phillips, R. (2005). Community-Academic Research and Hard-to-Reach Populations: Benefits and Challenges. Qualitative Health Research **15**(2): 263-282.

Berg, M. (1995). Rationalizing Medical Work; Decision Support techniques and Medical Practice. Dept. Health Ethics and Philosophy. Maastricht: Rijksuniversiteit Limburg. [doctoral thesis].

Berg, M. (1996). Working with protocols: a sociological view. The Netherlands Journal of Medicine **49**: 119-125.

Berg, M. (1997). Problems and Promises of the Protocol. Social Science & Medicine **44**(8): 1081-1088.

Berg, M. (1998). Order(s) and Disorder(s): Of Protocol and Medical Practices. In: Differences in Medicine; Unraveling Practices, Techniques, and Bodies. Mol, A.B., M. (ed.). Durham / London: Duke University Press. pp. 226-246.

Berg, M. and Bergen, C. (2003). Meeting the challenge: Integrating quality improvement and patient care information systems. In: Handbook of health information management. Berg, M.e.a. (ed.). London: Routledge.

Berg, M. and Lyke, S.v.d. (1997). De normativiteit van een infuuspomp. Over zorgpraktijken en technologie. In: Denken over zorg. Concepten en praktijken. Verkerk, M. (ed.). Utrecht: Elsevier. pp. 173-188.

Berg, M. and Timmermans, S. (2000). On the Constitution of Universalities in Medical Work. Configurations **8**: 31-61.

Black, N. (2001). Evidence based policy: proceed with care. British Medical Journal **323**: 275-278.

Blackwood, B. (2006). Methodological issues in evaluating complex healthcare interventions. Journal of Advanced Nursing **54**(5): 612-622.

Blakemore, C. and Davidson, J. (2006). Putting a value on medical research. The Lancet **367**(9519): 1293-1295.

Bowker, G., Timmermans, S. and Star, S.L. (1996). INfrastructure and Oragnizational Transformations: Classifying Nurses' Work. In: Information Technology and Changes in Organizational Work. Orlikowski, W.J., Walsham, G., Jones, M.R. and DeGross, J.L. (eds.). London: Chapman & Hall.

Bowker, G.C. and Star, S.L. (2000). Sorting things out; Classification and its consequences. Cambridge MA/London: The MIT Press.

Broer, T., Nieboer, A. and Bal, R. (2010). Opening the black box of quality improvement collaboratives: an Actor-Network theory approach. BioMed Central Health Services Research **10**:265. doi:10.1186/1472-6963-10-265.

Brotons, C., Bjorkelind, C., Bulc, M., Ciurana, R., Goducki-Cwirko, M., Jurgova, E., Kloppe, P., Lionis, C., Mierzecki, A., Pineiro, R., Pullerits, L., Sammut, S.R., Sheehan, M., Tataradze, R., Thireos, E.A. and Vuchak, J. (2005). Prevention and health promotion in clinical practice: the views of general practitioners in Europe. Preventive Medicine **40**: 595-601.

Bunton, R., Nettleton, S. and Burrows, R. (eds.). (1995). The sociology of health promotion; Critical analysis of consumption, lifestyle and risk. London/New York: Routledge.

Burrows, R., Nettleton, S. and Bunton, R. (1995). Sociology and health promotion: health, risk, and consumption under late modernism. In: The sociology of health promotion; Critical analyses of consumption, lifestyle and risk. Bunton, R., Nettleton, S. and Burrows, R. (eds.). London/New York: Routledge. pp. 1-9.

Burton, P., Goodlad, R. and Croft, J. (2006). How Would We Know What Works? Context and Complexity in the Evaluation of Community Involvement Evaluation **12**(3): 297-312.

Creswell, J.W. (2003). Research Design; Qualitative, Quantitative, and Mixed Methods Approaches. Thousand Oaks/London/New Delhi: SAGE Publications, Inc.

de Hollander, A.E.M., Hoeymans, N., Melse, J.S., van Oers, J.A.M. and Polder, J.J. (2006). Zorg voor gezondheid; Volksgezondheid Toekomst Verkenning 2006. Bilthoven: Rijksinstituut voor Volksgezondheid en Milieu (RIVM). ISBN-10: 90-90-6960-148-6.

de Mul, M. (2009). Managing Quality in Health Care; Involving Patient Care Information Systems and Healthcare Professionals in Quality Monitoring and Improvement Institute of Health Policy and Management. Rotterdam: Erasmus University Rotterdam. [doctoral thesis].

Dehue, T. (1997). Deception, efficiency, and random groups: Psychology and the gradual origination of the random group design. Isis **88**: 653-673.

Dehue, T. (2001). Establishing the experimenting society. The historical origination of social experimentation according to the randomized controlled design. American Journal of Psychology **114**(2): 283-302.

Dehue, T. (2002). A Dutch treat: randomized controlled experimentation and the case of heroin-maintenance in the Netherlands. History of the Human Sciences **15**(2): 75-98.

Dehue, T. (2004). Historiography taking issues: analyzing an experiment with heroin abusers*. Journal of the History of the Behavioral Sciences **40**(3): 247-264.

Dückers, M., de Bruijn, M. and Wagner, C. (2006). Evaluatie Sneller Beter pijler 3. De implementatie van verbeterprojecten in de eerste acht ziekenhuizen Utrecht: NIVEL.

Dückers, M. and Wagner, C. (2007). Evaluatie Sneller Beter pijler 3: het interne vliegwiel. De stand van zaken in de eerste acht ziekenhuizen na twee jaar deelname. Utrecht: NIVEL.

Edwards, N., Mill, J. and Kothari, A.R. (2004). Multiple intervention research programs in community health. Canadian Journal of Nursing Research **36**(1): 40-54.

El Fakiri, F. (2008). Prevention of cardiovascular Diseases in Deprived Neighbourhoods. Institute Health Policy and Management. Rotterdam: Erasmus MC Rotterdam. [doctoral thesis].

El Fakiri, F. and Foets, M. (2005). Effectiveness and efficiency of preventive Quattro-care for cardiovascular diseases in general practice located in deprived neighbourhoods.

Rotterdam: Institute Health Policy and Management, Erasmus MC Rotterdam.
El Fakiri, F., Hoes, A.W., Uiterwaal, P.J.M., Frenken, H.A.A. and Bruijnzeels, M.A. (2008). Process evaluation of an intensified preventive intervention to reduce cardiovascular risk in a multiethnic patient population. European Journal of Cardiovascular Nursing **7**(4): 296-302.
Fulop, N., Allen, P., Clarke, A. and Black, N. (2003). From health technology assessment to research on the organisation and delivery of health services: addressing the balance. Health Policy **63**: 155-165.
Garfinkel, H. (2003 [first published in America, 1967 by Prentice Hall Inc.]). Studies in Ethnomethodology. Cambridge: Polity Press in association with Blackwell Publishing Ltd.
Gezondheidsraad (2000). From Implementing to learning; The importance of a dialogue between practice and science in health care. The Hague: Health Council of The Netherlands**:** pp. 1-56.
Gezondheidsraad (2004). European primary care. The Hague: Health Council of the Netherlands.
Glasgow, R.E., Lichtenstein, E. and Marcus, A.C. (2003). Why Don't We See More Translation of Health Promotion Research to Practice? Rethinking the Efficacy-to-Effectiveness Transition. American Journal of Public Health **93**(8): 1261-1267.
Grol, R. (2001). Improving the Quality of Medical Care; Building Bridges Among Professional Pride, Payer Profit, and Patient Satisfaction. Journal of American Medical Association **286**(20): 2578-2585.
Hackett, E.J., Amsterdamska, O., Lynch, M. and Wajcman, J. (2008). The Handbook of Science and Technology Studies. Cambridge, MA: The MIT Press.
Hacking, I. (1990). The Taming of Chance. Cambridge: Cambridge University Press.
Haynes, B. (1999). Can it work? Does it work? Is it worth it? British Medical Journal **319**(7211): 652.
Helderman, J.-K. (2007). Bringing the Market Back In? Institutional complementarity and hierarchy in Dutch housing and health care. Institute Health Policy and Management. Rotterdam: Erasmus Medical Center Rotterdam. [doctoral thesis].
Helms, P.J. (2002). 'Real World' pragmatic clinical trials: What are they and what do they tell us? . Pediatric Allergy and Immunology **13**(1): 4-9.
Horstman, K. and Houtepen, R. (2005). Worstelen met gezond leven: ethiek in de preventie van hart-en vaatziekten. Amsterdam: Het Spinhuis.
Hotopf, M. (2002). The pragmatic randomised controlled trial. Advances in Psychiatric Treatment **8**: 326-333.
Hotopf, M., Churchill, R. and Lewis, G. (1999). Pragmatic randomised controlled trials in psychiatry. The British Journal of Psychiatry **175**(3): 217-223.
Hunt, K. and Emslie, C. (2001). Commentary: The prevention paradox in lay epidemiology - Rose revisited. International Journal of Epidemiology **30**(3): 442-446.
Hunter, D.J. (2003). Public Health Policy. Cambridge: Polity Press.
IOM (2000). To err is Human; Building a Safer Health System. Kohn, L., Corrigan, J. and Donaldson, M. (eds.). Washington, D.C.
IOM (2001). Crossing the Quality Chasm. A new health system for the 21st century. Committee_ on_quality_health_care_in_America (ed.). Washington, D.C.
Jasanoff, S. (2005). Designs of Nature: Science and Democracy in Europe and the United States. Princeton/Woodstock UK: Princeton University Press.

King, M. and Nazareth, I. (2006). The health of people classified as lesbian, gay and bisexual attending family practitioners in London: a controlled study. BioMed Central Public Health **6**. doi:10.1186/1471-2458-6-127.

Knatterud, G.L. (2002). Management and conduct of randomised controlled trials. Epidemiological Reviews **24**(1): 12-25.

Knorr Cetina, K. (1995). Laboratory Studies; The cultural Approach to the Study of Science. In: Handbook of Science and Technology Studies. Jasanoff, S., Markle, G.E., Petersen, J.C. and Pinch, T. (eds.). Thousand Oaks/London/New Delhi: Sage Publications, published in cooperation with the Society for Social Studies of Science (4S). pp. 140-166.

Knorr Cetina, K. (2003 [1999]). Epistemic Cultures; How the sciences make knowledge. Cambridge/London: Harvard University Press.

Latour, B. (1987). Science in Action; How to follow scientists and engineers through society. Cambridge, MA: Harvard University Press.

Latour, B. and Woolgar, S. (1986 [1979]). Laboratory Life; The construction of scientific facts. Princeton NY/Chichester UK: Princeton University Press.

Macdonald, G. (2000). A new evidence framework for health promotion practice. Health Education Journal **59**(1): 3-11.

Macdonald, G. (2002). Evidence-based Health Promotion; Perkins, E.,Simnett, I. and Wright, L. (eds.) John Wiley & Sons, Chichester, 1999 448 pp. ISBN 0 4719 7851 5 Health Education Research **17**(1): 133-134.

MacPherson, H. (2004). Pragmatic clinical trials. Complementary Therapies in Medicine **12**: 136-140.

Marks, H.M. (1988). Notes from the Underground: The Social Organization of Therapeutic Research. In: Grand Rounds; One Hundred Years of Internal Medicine. Maulitz, R.C. and Long, D.E. (eds.). Philadelphia: University of Pennsylvania Press. pp. 297-336.

Marks, H.M. (1997). The Progress of Experiment; Science and Therapeutic reform in the United States, 1900-1990. Cambridge, UK: Cambridge University Press.

Mathar, T. and Jansen, Y.J.F.M. (2010a). Health Promotion and Prevention Programmes in Practice. In: Health Promotion and Prevention Programmes is Practice; How Patients' Health Practices are Rationalised, Reconceptualised and Reorganised. Mathar, T. and Jansen, Y.J.F.M. (eds.). Bielefeld: Transcript Verlag. pp. 9-27.

Mathar, T. and Jansen, Y.J.F.M. (eds.). (2010b). Health Promotion and Prevention Programmes is Practice; How Patients' Health Practices are Rationalised, Reconceptualised and Reorganised. VerKörperungen/MatteRealities - Perspektiven empirischer Wissenschaftsforschung. Bielefeld: Transcript Verlag.

Mukoma, W. and Flisher, A.J. (2004). Evaluations of health promoting schools: a review of nine studies. Health Promotion International **19**(3): 357-368.

Nutbeam, D. (1996). Achieving 'best practice' in health pormotion: improving the fit between research and practice. Health Education Research **11**(3): 317-326.

O'Sullivan, A.K., Thompson, D. and Drummond, M.F. (2005). Collection of Health-Economic Data Alongside Clinical Trials: Is There a Future for Piggyback Evaluations? Value in Health **8**(1): 67-79.

Øvretveit, J. and Gustafson, D. (2002). Evaluation of quality improvement programmes. Quality and Safety in Health Care **11**(3): 270-275.

Porter, T.M. (1995). Trust in Numbers; The Pursuit of Objectivity in Science and Public Life. Princeton, New Jersey: Princeton University Press.

Richards, A., Carley, J., Jenkins-Clarke, S. and Richards, D.A. (2000). Skill mix between nurses and doctors working in primary care - delegation or allocation: a review of the

literature. International Journal of Nursing Studies **37**: 185-197.
Rose, G. (1985). Sick Individuals and Sick Populations. International Journal of Epidemiology **14**(1): 32-38.
Sackett, D.L. and Rosenberg, W.M.C. (1995). The Need for Evidence-Based Medicine. Journal of the Royal Society of Medicine **88**: 620-624.
Sackett, D.L., Rosenberg, W.M.C., Muir Gray, J.A., Brian Haynes, R. and Scott Richardson , W. (1996a). Evidence based medicine: What it is and what it isn't. British Medical Journal **312**: 71-72.
Sackett, D.L., Rosenberg, W.M.C., Muir Gray, J.A., Haynes, R.B. and Richardson, W.S. (1996b). Evidence based medicine. British Medical Journal **313**(7050): 170-171.
Schwartz, D. and Lellouch, J. (1967). Explanatory and pragmatic attitudes in therapeutical trials. Journal of Chronic Diseases / Journal of Clinical Epidemiology **20**: 637-648.
Segers, J. and Hutjes, J. (1999). De gevalstudie. In: Methoden voor de Maatschappijwetenschappen. Segers, J. (ed.). Asses: van Gorcum. pp. 339-366.
Sen, K. (ed.). (2003). Restructuring Health Services; Changing Contexts & Comparative Perspectives. London/New York: Zed Books Ltd.
Stange, K.C., Goodwin, M.A., Zyzanski, S.J. and Dietrich, A.J. (2003). Sustainability of a practice-individualized preventive service delivery intervention. . American Journal of Preventive Medicine **25**(4): 296-300.
Susser, M. (1995). Editorial: The tribulations of trials - intervention in communities. American Journal of Public Health **85**(2): 156-158.
ten Have, P. (1999). Etnografie. Retrieved from: http://www2.fmg.uva.nl/emca/EGF.htm.
Timmermans, S. and Berg, M. (2003a). The Gold Standard; The Challenge of Evidence-Based Medicine and Standardization in Health Care. Philadelphia: Temple University Press.
Timmermans, S. and Berg, M. (2003b). The practice of medical technology. Sociology of Health and Illness **25**(3): 97-114.
Timmermans, S. and Mauck, A. (2005). The promises and pitfalls of evidence-based medicine. Health Affairs **24**(1): 18-29.
Twinn, S. (2001). The evaluation of the effectiveness of health education interventions in clinical practice: a continuing methodological challenge. Journal of Advanced Nursing **34**(2): 230-237.
van den Berg, M., Frenken, R. and Bal, R. (2009). Data management in quality improvement collaboratives. BioMed Central Health Services Research **9**:175. doi:10.1186/1472-6963-9-175.
Visser, A. (2000). Research methods, interventions and evaluation in patient education: a kaleidoscope. Patient Education and Counseling **39**(2-3): 147-148.
Wallerstein, N.B. and Duran, B. (2006). Using Community-Based Participatory Research to Address Health Disparities. Health Promotion Practice **7**(3): 312-323.
Wolff, N. (2001). Randomised trials of socially complex interventions: promise or peril? Journal of Health Services Research & Policy **6**(2): 123-126.
Zuiderent-Jerak, T., Strating, M., Nieboer, A. and Bal, R. (2009). Sociological refigurations of patient safety; ontologies of improvement and 'acting with' quality collaboratives in healthcare. Social Science & Medicine **69**(12): 1713-1721.
Zuiderent, T., Bal, R. and Berg, M. (2004). Working differently: regorganizing intramural oncology. Daniel den Hoed Cancer News(April 2004): 11-12.

1

Coping with methodological dilemmas; about establishing the effectiveness of interventions in routine medical practice

Abstract

Background
The aim of this paper is to show how researchers balance between scientific rigour and localisation in conducting pragmatic trial research. Our case is the Quattro Study, a pragmatic trial on the effectiveness of multidisciplinary patient care teams used in primary health care centres in deprived neighbourhoods of two major cities in the Netherlands for intensified secondary prevention of cardiovascular diseases.

Methods
For this study an ethnographic design was used. We observed and interviewed the researchers and the practice nurses. All gathered research documents, transcribed observations and interviews were analysed thematically.

Results
Conducting a pragmatic trial is a continuous balancing act between meeting methodological demands and implementing a complex intervention in routine primary health care. As an effect, the research design had to be adjusted pragmatically several times and the intervention that was meant to be tailor-made became a rather stringent procedure.

Conclusions
A pragmatic trial research is a dynamic process that, in order to be able to assess the validity and reliability of any effects of interventions must also have a continuous process of methodological and practical reflection. Ethnographic analysis, as we show, is therefore of complementary value.

Background

The question has been raised to what extent evidence from controlled clinical trials on prevention interventions is of value in the routine clinical practice of primary care (Barnes, Stein et al. 1999; Nutbeam 1999; McQueen 2000; Leys 2003; Anderson, Brownson et al. 2005; Druss 2005). Explanatory trials, the randomised controlled trials (RCTs) measuring the treatments' efficacy, meet the criteria for valid evaluation through randomisation, recruiting a sufficiently large number of subjects and using control situations (Roland and Torgerson 1998; Blair 2004; MacPherson 2004) plus reliable measurements. Pragmatic trials, as opposed to explanatory RCTs, measure the effectiveness of treatments in routine clinical practice (Schwartz and Lellouch 1967; Armitage 1998; Roland and Torgerson 1998). In pragmatic trials, the definition of the treatments is more or less standardised to correspond with daily clinical decision-making. Additionally, the heterogeneity of patients is reflected, fewer exclusion criteria are used, and blinding, randomisation and control situations may not always be used. As Hotopf argues, pragmatic trials are preferable when health care provision and services are to be evaluated, because their external validity to the extent of their usefulness in routine clinical practice is not compromised (Hotopf 2002). In the literature, pragmatic trials are considered to provide a realistic alternative to conventional RCTs (Schwartz and Lellouch 1967; Black 1996; Armitage 1998; Padkin, Rowan et al. 2001).

The way that researchers actually deal with conducting pragmatic trials remains largely unexplored. In fact, there have been few publications examining the work that goes into producing evaluative outcomes and managing pragmatic trials or, for that matter, on RCTs (e.g.(Oakley, Strange et al. 2006)). In this paper we show how researchers balance between scientific rigour and localisation in pragmatic trial research. Our case is the Quattro Study, a pragmatic trial on the effectiveness of multidisciplinary patient care teams used in primary health care centres in deprived neighbourhoods of two major cities in the Netherlands for intensified secondary prevention of cardiovascular diseases (CVD). To increase the chance of implementation of this project, a major condition was that the research interference with daily care routines was kept to a minimum. As the project adopted a 'tailor made approach', the GPs and the supportive staff were asked to develop their own procedures for the program, albeit within preset conditions, as only they could develop guidelines that would fit into their specific local situation. Our main question was: How do researchers cope with the methodological dilemmas of localising the execution of the trial in the participating primary health care centres?

Methods

We used an ethnographic design. By means of participant observations (Spratley 1980; Creswell 2003; Garfinkel 2003), the first author observed the work of two researchers, a data manager, and four research assistants from April 2003 till December 2004. In this period, we also observed 20 research progress meetings. All meetings, observations and conversations were transcribed. Minutes of the meetings, research protocols, documents and questionnaires used for the Quattro Study were collected. From April 2003 until December 2004, the first author observed four out of seven practice nurses in their daily work, each for five workdays. Throughout each observation, it was possible to ask questions or to request clarification. Transcripts were made immediately after leaving the health care centres. Audiotaped semi-

structured interviews were held with the researchers, project leader, data manager and three practice nurses up to January 2006. All interviews were transcribed immediately after the interviews and were sent back to the interviewees for member check.

After the observation period, all transcripts, minutes, and research documents were analysed more in-depth. We analysed all information manually and thematically, establishing overarching categories.

Study setting

Aim of the Quattro-study was to examine the effectiveness and cost-effectiveness of a multidisciplinary collaboration between a practice nurse, a peer health educator, the GP, and assistant in providing intensified preventive care in general practices located in deprived neighbourhoods. The Quattro Study was a randomised controlled trial (RCT) carried out in three primary health care centres located in the deprived neighbourhoods of Rotterdam and The Hague. Patients in the intervention group obtained Quattro-care and three-monthly assessments of the risk profile. Patients from control group A received usual GP care and three-monthly risk assessments and the GP as well as the patient were informed about the results of these measurements. It was thought to be ethically and practically unacceptable to assess a risk profile and not to inform the patient and GP about the results. However, this approach of assessing risk and informing patients and GP interferes with daily practice and may bias the results. Therefore, a blinded control group B was needed to quantify the effect of the risk assessments. This group received usual GP care and was measured once at the end of the study.

The follow-up period for the intervention and control group A was 12 months and the intervention programme lasted 9 months. Participants in the study were patients at high risk of developing CVD; i.e. patients with a modifiable part of the absolute 10-year risk equal or greater than 5% contributed by smoking, hypertension or hypercholesterolemia.

The intervention consisted of the formation of a primary care team in the general practice composed of the GP, assistant, practice nurse and peer health educator (Quattro-care). The intervention protocol was based on GP guidelines for hypertension, hypercholesterolemia, diabetes mellitus, smoking and obesity, and described the procedures for the intervention team (GP (treatment task), practice nurse (risk assessment, coordination and informative task), assistant (logistic task) and peer health educator (ethnic specific health education)). Although the main lines of the protocol were fixed for participating general practices (e.g. 4 structured team meetings of the Quattro-care team and 4 individual education sessions), the protocol allowed adapting to tailor the intervention to the individual practice needs and organisation.

The effectiveness of the multidisciplinary collaboration was assessed by comparing patients from the intervention group with those from control group A after one year follow-up with regards to the reduction achieved in the absolute 10-year risk of developing CVD. Control group B, aimed to quantify the effect of structured risk assessments performed in control group A, was compared with control group A.

The study ran from August 2000 until December 2005. Complementary qualitative research was considered necessary during the execution of the trial to evaluate feasibility, implementation and experiences with Quattro-care of health care professionals, patients and researchers. Ethical approval for the Quattro Study, which also incorporated the

complementary qualitative research, was obtained from the Health Ethics Board of Erasmus University Medical Center in Rotterdam.

Results

Pragmatic decisions

Patient recruitment was a major concern in the Quattro Study. The researchers had to adapt the inclusion procedure to overcome a too homogeneous composition in, and a shortage of, eligible patients. The research team decided to change the age parameters from 18-70 years of age to 30-70 years of age in order to ensure a more representable proportion of the target population (document selection criteria addendum 2). Changing the age parameters in a study performed in deprived neighbourhoods would prevent a possible over-representation of indigenous male patients with a high absolute risk of CVD, with little or no elevated cardiovascular risk factors (document selection criteria addendum 2). Focusing on the absolute 10-year risk alone for both male and female patients would result in excluding a large number of eligible, relatively young, predominantly female patients (El Fakiri, Bruijnzeels et al. 2005). The inclusion of sufficient numbers of women, ethnic groups and the prevention of a possible over-representation of white males became important issues next to the risk of CVD. The adjustment of inclusion criteria enabled a more accurate representation of the patient population of the participating health care centres in the intervention.

The participating GPs were able to decide whether patients had to be protected from the stress of participation because of a too complex medical history (severe co-morbidity). The GPs vetoed 641 patients (document final report). The reasons for rejection were 'the patient being under care of a specialist', 'the patient being correctly monitored' or 'other reason:…' (document patient risk profile form). This elimination of patients proved to be a disproportionate part of the eligible group of patients and adopting the GP vetoes would result in a too small target population needed for the study. Besides, the amount of vetoed patients was unevenly distributed among the participating GPs, making future comparison and extrapolation of found effects difficult. To enable the intervention to represent routine medical decision-making the research team chose to review the vetoed patients and readmitted 43 patients. Eventually, from the selected 2,263 eligible patients between 30-70 years old and with at least one CVD risk factor, the researchers were able to include 1,665 eligible patients into the study (document final report).

Pragmatic approach and systematic design

For the researchers, blinding patients and preventing contamination between intervention and control group A patients were major concerns for establishing the effectiveness of the study. Blinding patients for the health care professional, however, proved to be problematic. The problems started to develop as soon as the patients arrived at the centres for their appointments. For the assistants at the reception desks it was unclear to which group a particular patient belonged and 'mistakes' in the allocation of patients were made. Control group A patients were either seen as intervention group patients when they were not, or were referred back to the researchers without receiving Quattro care (field notes research progress meeting 10-09-2003 and 23-03-2004).

The research team decided to provide the health care centres with a list of names of the patients included in intervention and control group A. This point received an additional remark in the minutes: "Methodologically not really correct, but a concession" (minutes research progress meeting 10-09-2003). As the researchers provided name lists to the health care centres, the researchers endangered the internal validity of the project as they informed the health care centres about which patients belonged to which research group. In the study design the possibility of contamination was already incorporated, as the centres were responsible for the internal organisation of the intervention and adjusting the intervention to the local circumstances (document research proposal). The trial was, therefore, not badly designed; the research team was merely forced to make it workable for the centres.

From a pragmatic to a systematic intervention

For the researchers the assessment of the effectiveness of the multidisciplinary care teams was the core of the whole project. They planned the individual patient education sessions given by the practice nurse and/or migrant health educator. Multidisciplinary team meetings attended by all four professionals were to follow each other continuously within the centres (document manual for intervention 2000). This part of the project differed between the care practices, as multidisciplinary team meetings were either organised (but irregular and without all health care professionals attending), limited to only practice nurses and GPs, or informal deliberations. Because all health centres appropriated the intervention towards their own local circumstances, the set-up of the intervention differed for each centre.

The adjustments in the centres endangered the establishment of the ultimate effect of the project and were seen as "seriously inconvenient for the study. This way, the trial becomes impure." (field note research progress meeting 11-05-2004). As a result, the research team increased its interference in the intervention by having the multidisciplinary team meetings stringently implemented for establishing the effect of the structural collaborative care opposed to regular care on the reduction of CVD risk less ambiguously. "[…] if we make *too many* concessions the results will drift away from the original idea, meaning we cannot say anything about the whole project at the end" (conversation researcher 01-06-2004). The team eventually developed a Quattro guideline for the health care centres to work with and organised regular supportive intervention progress meetings for the practice nurses and peer health educators.

The project leader, however, constantly tried to prevent research interference within the health care centres from happening because, for him, these differences in practice were not a problem but important for gaining insight into what kind of organisational preconditions primary health care must meet if the implementation of prevention projects is to be successful (conversation project leader 10-09-2003). "To be able to say anything about the effects of such a prevention project in real life practice, the trial has to have as little contact with the actual intervention as possible" (conversation project leader 10-09-2003).

From a pragmatic to a systematic follow-up

For establishing the effectiveness of the project, the researchers needed to be informed by the professionals about the data from the follow-up. The needed data were the physical measurements of patients, like BMI, blood pressure, total cholesterol, and fasting capillary glucose levels (or HbA1c). Moreover, they also needed data to measure the (costs of the) intervention, such as time spent by all professionals on the specific parts of this project, i.e.

intake, patient consultations, and multidisciplinary meetings (document research proposal).

Getting the professionals to register and deliver the data, however, proved to be problematic (minutes research progress meeting 20-01-2004). As a result the researchers took measures concerning the data collection. First, the research team decided that the forms used by the health care professionals should contain fixed data, so that the researchers could use these forms too (minutes research progress meeting 20-01-2004). They also decided "[…] the research assistants would have to resolve the lacunas in the research data" (field note research progress meeting 03-02-2004). However, some lacunas in data could not be resolved. Data was either not recorded, and thus the research assistants had to retrieve these missing data from the health care centres, or patients had not gone for their lab measurements, resulting in data not being retrievable at all.

The follow-up of patients in this way increasingly became important as measuring point to establish the effectiveness of the trial, underscoring the systematic nature of the data collection. As the promise of tailoring the intervention resulted in the professionals appropriating the follow-up procedures, informing the researchers about the meantime follow-up results was seen to be an interference with the daily routines. The researchers, however, had to increase their efforts to collect the meantime follow-up results in order to be able to establish the effectiveness of the intervention systematically, as missing data in trials entails a validity problem for analysing the ultimate estimate of effect. The question to what extent the opportunity of tailoring the intervention and its execution to the local circumstances of the health care centres would result in appropriations in data collection was, however, not addressed.

Discussion

Executing a pragmatic trial is a continuous balancing act for the researchers. Researchers constantly balance between meeting methodological demands to produce a scientifically rigorous effectiveness study and applying a pragmatic approach to making feasible and implementing a preventive intervention in primary health care. Both systematic and pragmatic approaches proved to be difficult to retain. By means of ethnographic analysis, we showed that the researchers conducting the Quattro Study had to adjust the research to enable the intervention's uptake in routine primary care. The researchers adapted the inclusion procedure to overcome the homogeneous composition of, and a shortage in, eligible patients and provided the health care professionals the name lists of included patients in order to restrict the provision of care to research groups. Moreover, the researchers had to increase their interference in the pragmatic execution of the intervention to have the trial performed more systematically. The researchers increased their interference in the organisation of the intervention by having the multidisciplinary team meetings implemented stringently and by having the data collected as systematically as possible. Our contention is that this balancing act is not a feature of this specific trial, nor that it points at methodological weaknesses, but a structural dilemma for pragmatic trials.

Pragmatic trials, we showed in this paper, pose substantial challenges to investigators. Such trials hold the premise of being both 'pragmatic' (enabling the uptake of treatments in daily care by limning to routine clinical decision-making and incorporating the heterogeneity of patients and health care professionals) and 'systematic' (establishing the effectiveness of treatments by means of a scientific method of experimental design and predefined outcome

measures). The constant interaction between research and primary care leads to continuous adjustments in research and intervention. Reconciling the tensions between the two different intellectual traditions, as indicated by Campbell et al (Campbell, Fitzpatrick et al. 2000) and illuminated by Marks (Marks 1997) make the pragmatic and the systematic parts of pragmatic trials influence each other in opposite directions.

As pragmatic trial research is a dynamic process in which the parts of research and (health care) practice will be redefined repeatedly, a continuous process of methodological and practical reflection is imperative. Otherwise, pragmatic trials may end up in being just a contradiction in terms. So, we do not suggest to solely focus on practical research strategies for improving study design, trial execution and generalisability of results as advocated by Campbell et al. (Campbell, Fitzpatrick et al. 2000) and Ward (Ward, King et al. 1999). Neither do we suggest to focus the research efforts solely on the development of meaningful evidence about routine care, as is suggested by MacPherson (MacPherson 2004). Stead, we suggest using qualitative (ethnographic) analyses to evaluate the continuous interference of research and care in pragmatic trials, especially to be able to assess the validity and reliability of any effects of interventions (see e.g. (Tones 2000; Visser 2000)). Such analyses, as we experienced with the Quattro case, help the researchers in both finding and accommodating diversions between the pragmatic and systematic aspects of pragmatic trial research.

We therefore consider the information acquired by qualitative research important in both formative (Tones 2000) and process evaluations (Tones 2000) of pragmatic trial projects. As we were able to provide the researchers with ethnographic information concerning, for example, the differences in organising the multidisciplinary team meetings and the follow-up procedures among and within the health care centres, we provided an additional reflexive dimension for making adjustments in both research and practice. In addition, ethnographic process evaluations explicate the sequence of actions (Callon 2002) performed in pragmatic trial projects. Qualitative research not only provides reflection on the inevitability of adjustments in pragmatic trials, it also provides reflection on the consequences of these adjustments.

Our ethnographic analysis itself of course also does have certain limitations. One is that our process evaluation on conducting a pragmatic trial may be biased due to the fact we only observed one pragmatic trial case. Because we did not observe other researchers conducting other pragmatic trials, we are aware that our accounts may not be generalisable in all respects. However, we do argue that balancing pragmatism and systematisation are structural to all pragmatic trials, although this may take different forms in other pragmatic trials. Secondly, our accounts may also be biased due to the fact that systematic ethnographic observations in the Quattro Study only started when the implementation was already taking place. All information about the project prior to those observations came out of the project's archive and on the basis of interviews and may thus be subjected to out-of-context interpretations. However, we have tried to triangulate all data as much as possible to overcome these biases.

Conclusions

Pragmatic trials on complex interventions in primary health care pose substantial challenges to investigators. As we have shown, pragmatic trial research consists of constant interaction between research and health care practices; this leads to adjustments in research with respect to what part of the study should be systematically performed and executed to answer to scientific demands and what part of the project could have a pragmatic set-up in the health care centres. In the practice of pragmatic trial research, parts of research and health care practice will be redefined over and over again. Because pragmatic trial research is a dynamic process, in order to be able to assess the validity and reliability of any effects of interventions, it must also have a continuous process of methodological and practical reflection. Ethnographic analysis, as we showed, is therefore of complementary value.

References

Anderson, L.M., Brownson, R.C., Fullilove, M.T., Teutsch, S.M., Novick, L.F., Fielding, J. and Land, G.H. (2005). Evidence-based public health policy and practice: promises and limits. American Journal of Preventive Medicine **28**(5S): 226-230.

Armitage, P. (1998). Attitudes in clinical trials. Statistics in Medicine **17**: 2675-2683.

Barnes, J., Stein, A. and Rosenberg, W.M.C. (1999). Evidence based medicine and evaluation of mental health services: methodological issues and future directions. Archives of Disease in Childhood **80**(3): 280-285.

Black, N. (1996). Why we need observational studies to evaluate the effectiveness of health care. British Medical Journal **312**: 1215-1218.

Blair, E. (2004). Gold is not always good enough: the shortcomings of randomization when evaluating interventions in small heterogeneous samples. Journal of Clinical Epidemiology **57**: 1219-1222.

Callon, M. (2002). Writing and (re)writing devices as tools for managing complexities. In: Complexities; Social Studies of Knowledge Practices. Law, J. and Mol, A. (eds.). Durham/London: Duke University Press. pp. 191-217.

Campbell, M., Fitzpatrick, R., Haines, A., Kinmonth, A.N., Sandercock, P., Spiegelhalter, D. and Tyrer, P. (2000). Framework for design and evaluation of complex interventions to improve health. British Medical Journal **321**: 694-696.

Creswell, J.W. (2003). Research Design; Qualitative, Quantitative, and Mixed Methods Approaches. Thousand Oaks/London/New Delhi: SAGE Publications, Inc.

Druss, B. (2005). Evidence based medicine: does it make a difference? Use wisely. British Medical Journal **330**: 92.

El Fakiri, F., Bruijnzeels, M.A. and Hoes, A.W. (2005). Prevention of cardiovascular diseases: focus on modifiable cardiovascular risk. Heart **92**(6): 741-745.

Garfinkel, H. (2003 [first published in America, 1967 by Prentice Hall Inc.]). Studies in Ethnomethodology. Cambridge: Polity Press in association with Blackwell Publishing Ltd.

Hotopf, M. (2002). The pragmatic randomised controlled trial. Advances in Psychiatric Treatment **8**: 326-333.

Leys, M. (2003). Health care policy; qualitative evidence and health technology assessment. Health Policy **65**: 217-226.

MacPherson, H. (2004). Pragmatic clinical trials. Complementary Therapies in Medicine **12**: 136-140.

Marks, H.M. (1997). The Progress of Experiment; Science and Therapeutic reform in the United States, 1900-1990. Cambridge, UK: Cambridge University Press.

McQueen, D. (2000). Perspectives on health promotion: theory, evidence, practice and the emergence of complexity. Health Promotion International **15**(2): 95-97.

Nutbeam, D. (1999). The challenge to provide 'evidence' in health promotion. Health Promotion International **14**(2): 99-101.

Oakley, A., Strange, V., Bonell, C., Allen, E., Stephenson, J. and RIPPLE_Study_Team (2006). Process evaluation in randomised controlled trials of complex interventions. British Medical Journal **332**(7538): 413-416

Padkin, A., Rowan, K. and Black, N. (2001). Using high quality clinical databases to complement the results of randomised controlled trials: the case of recombinant human activated protein C. British Medical Journal **323**: 923-926.

Roland, M. and Torgerson, D.J. (1998). Understanding controlled trials: What are pragmatic trials? British Medical Journal **316**: 285.

Schwartz, D. and Lellouch, J. (1967). Explanatory and pragmatic attitudes in therapeutical trials. Journal of Chronic Diseases / Journal of Clinical Epidemiology **20**: 637-648.

Spratley, J.P. (1980). Participant Observation. Fort Worth/Philadelphia/San Diego/New York/ Orlando/Austin/San Antonio/Toronto/Montreal/London/Sydney/Tokyo: Harcourt Brace College Publishers.

Tones, K. (2000). Evaluating health promotion: a tale of three errors. Patient Education and Counseling **39** (2-3): 227-236.

Visser, A. (2000). Research methods, interventions and evaluation in patient education: a kaleidoscope. Patient Education and Counseling **39**(2-3): 147-148.

Ward, E., King, M., Lloyd, M., Bower, P. and Friedl, K. (1999). Conducting randomized trials in general practice: methodological and practical issues. British Journal of General Practice **49**: 919-922.

2

Tailoring intervention procedures to routine primary health care practice; an ethnographic process evaluation

Abstract

Background
Tailor-made approaches enable the uptake of interventions as they are seen as a way to overcome the incompatibility of general interventions with local knowledge about the organisation of routine medical practice and the relationship between the patients and the professionals in practice. Our case is the Quattro project which is a prevention programme for cardiovascular diseases in high-risk patients in primary health care centres in deprived neighbourhoods. This programme was implemented as a pragmatic trial and foresaw the importance of local knowledge in primary health care and internal, or locally made, guidelines. The aim of this paper is to show how this prevention programme, which could be tailored to routine care, was implemented in primary care.

Methods
An ethnographic design was used for this study. We observed and interviewed the researchers and the practice nurses. All the research documents, observations and transcribed interviews were analysed thematically.

Results
Our ethnographic process evaluation showed that the opportunity of tailoring intervention procedures to routine care in a pragmatic trial setting did not result in a well-organised and well-implemented prevention programme. In fact, the lack of standard protocols hindered the implementation of the intervention. Although it was not the purpose of this trial, a guideline was developed. Despite the fact that the developed guideline functioned as a tool, it did not result in the intervention being organised accordingly. However, the guideline did make tailoring the intervention possible. It provided the professionals with the key or the instructions needed to achieve organisational change and transform the existing interprofessional relations.

Conclusions
As tailor-made approaches are developed to enable the uptake of interventions in routine practice, they are facilitated by the brokering of tools such as guidelines. In our study, guidelines facilitated organisational change and enabled the transformation of existing interprofessional relations, and thus made tailoring possible. The attractive flexibility of pragmatic trial design in taking account of local practice variations may often be overestimated.

Background

The appropriateness of the randomised controlled trial (RCT) for evaluating complex interventions is heavily debated (Hawe, Shiell et al. 2004; Audrey, Holliday et al. 2006; Corrrigan, Cupples et al. 2006). The Quattro project was such a complex intervention. It was a prevention programme for cardiovascular diseases (CVD) in high-risk patients in primary health care centres in deprived neighbourhoods. Multidisciplinary care teams (Quattro care-team) were to support high-risk patients on medicine use, smoking, diet and lifestyle changes. An RCT requires that a standardised intervention, with statistical measurable outcomes, be implemented uniformly within a homogenous target audience (Audrey, Holliday et al. 2006). The notion of standardisation seems, however, to be at odds with more complex interventions that have to be implemented in complex health care settings (Hawe, Shiell et al. 2004). While the outcomes of activities in real life practice may be highly dependent on the characteristics of the health care providers, the setting and the patients (Black 1996; Hotopf 2002; Audrey, Holliday et al. 2006; Corrrigan, Cupples et al. 2006), trials of complex interventions are still considered to resemble the original intervention as much as possible, standardising both the content and delivery of the intervention (Hawe, Shiell et al. 2004).

In fact, the limited effectiveness of complex interventions is often attributed to the failure to tailor the design of interventions to local care practices (Corrrigan, Cupples et al. 2006). The uptake of interventions is to be done by tailoring the intervention procedures to routine clinical decision-making and incorporating the heterogeneity of patients and health care professionals. It is argued that as an intervention is tailored to the unique characteristics of each practice, they may be more likely to become incorporated into the structure and function of daily operations resulting in sustainable effects (Stange, Goodwin et al. 2003). This is confirmed by findings from studies on the diffusion and adoption of innovations in clinical practice. The adoption of innovations is often considered to take place according to linear models, but in practice innovations often have a dynamic and fluid nature resulting in their adoption - or parts thereof - over time (Dopson, FitzGerald et al. 2002).

To enable the uptake of Quattro care in routine practice, a tailor-made approach was used. Although the process for the intervention was fixed for participating general practices (i.e. four structured team meetings of the Quattro-care team and four individual patient education sessions per patient), local adaptations to the components and form were allowed to tailor the intervention to individual practice needs and organisation. This tailor-made approach - with the underlying intention to minimise intrusion into normal daily care - was meant as an opportunity for the participating health care centres to frame their preferred procedures for the intervention, instead of following external guidelines that might not be perfectly applicable to the specific context of these centres and which were seen as externally generated research interference. In this, the Quattro project followed the procedures of a pragmatic trial, which aims to measure the effectiveness of interventions under natural - non-experimental - conditions.

In this paper we are concerned with how the professionals tailored the Quattro intervention to their practice needs and organisation. So, as in the Quattro project multidisciplinary care teams had to provide the prevention of CVD by means of a stipulated process, the participating primary health care centres could tailor their components and form.

Therefore our main questions for this ethnographic process evaluation of the Quattro project were: How did the health care professionals tailor the intervention in the participating health care centres? What role did the provided guideline have in tailoring the implementation of the intervention? Did the tailor-made approach have advantages for the implementation of the intervention?

Quattro Care intervention

The Quattro project introduced and evaluated the effectiveness of multidisciplinary patient care teams for the prevention of cardiovascular diseases (CVD) in three primary health care centres located in deprived neighbourhoods of Rotterdam and The Hague. The core of the Quattro project was the collaboration between a practice nurse, a peer health educator, the GP, and assistant (hence Quattro care) in providing intensified preventive care. Multidisciplinary patient care teams are thought to improve the quality of care in general practice, as they are seen as a means of relieving the workload of GPs and to assist them in providing preventive activities (Steptoe, Doherty et al. 1999; Richards, Carley et al. 2000; Brotons, Bjorkelind et al. 2005; VWS 2005). GPs in deprived neighbourhoods have a great deal of information about patients, but - due to their high workload - do not use this information for case-finding and secondary prevention. They lack the time and the organisation to actively invite people for check-ups (Richards, Carley et al. 2000; Campbell, Hann et al. 2001; Lobo, Frijling et al. 2003; VWS 2005). They do not actively assess risk-profiles either. According to the national recommendations, they should (Walma, Grundmeijer et al. 1997; Rutten, Verhoeven et al. 1999; Thomas, Van der Weijden et al. 1999; CBO 2000a; 2000b).

The intervention described the main tasks for the intervention team: GP (treatment task, overall medical responsibility), practice nurse (risk assessment, coordination and prevention tasks), assistant (logistic task) and peer health educator (ethnic specific health education)). Each intervention patient was to receive at least four individual patient education sessions provided by the practice nurse and/or peer health educator. At least four multidisciplinary team meetings were to be organised by the intervention team professionals to jointly establish treatment plans for intervention patients and monitor the patients' risk profiles based on the particular knowledge and abilities of each professional. Although the process for the intervention was fixed for participating general practices, adaptations to the components and form were allowed to tailor the intervention to the individual practice needs and organisation. The practice nurses were meant to be the coordinating axis of the rollout and implementation of the intervention in the practices. No additional guidelines were provided to support this organisation of activities. For the programme the health care professionals had to use the GP guidelines of the Dutch College of General Practitioners (NHG), for hypertension, hypercholesterolemia, diabetes mellitus, smoking and obesity.

For this programme patients were selected with a modifiable part of the absolute 10-year risk on cardiovascular diseases (CVD) of at least 20%, and were randomly assigned to three groups. Patients in the intervention group were to obtain Quattro-care and three-monthly assessments of their risk profile from the practice nurses. Patients from control group A were to receive usual GP care. The assistants were to perform the three-monthly risk assessments of this group, in order to prohibit contamination of the results of the aforementioned groups. Both the GPs and the patients were informed about the results of these assessments. It was thought to be ethically and practically unacceptable to assess a risk-profile and not to inform the patient and GP about the results. However, this approach of assessing risk and informing

patients and GP would interfere with daily practice and could bias the results. Therefore, a blind control group B was needed to quantify the effect of the risk assessments. This group was to receive usual GP care and was measured once at the end of the study. The effectiveness of the multidisciplinary collaboration was assessed by comparing patients from the intervention group with those from control group A after one year follow-up with the outcome measure defined as the reduction achieved in the absolute 10-year risk of developing CVD. Control group B, aimed to quantify the effect of structured risk assessments performed in control group A, was compared with control group A. The follow-up period for the intervention and control group A was 12 months and the intervention programme lasted 9 months.

The pragmatic trial research team supported the participating primary health care centres in several ways. They assisted in finding compensation for this programme and the employment of the practice nurses. They organised an accredited course on organising effective multidisciplinary team meetings for the health care professionals before the start of the trial. Moreover, the research team assisted in case finding: they selected the high-risk patients from the centres´ electronic patient records and were to receive patient monitoring data to calculate the effectiveness of this prevention project in routine medical practice. The study ran from August 2000 until December 2005.

Methods

To evaluate feasibility, implementation and experiences with Quattro-care of health care professionals, patients and researchers, complementary qualitative research was considered necessary during the execution of the trial. Ethical approval for the Quattro Study, which also incorporated this complementary qualitative research, was obtained from the Health Ethics Board of Erasmus University Medical Center in Rotterdam. For our study we used an ethnographic design (Spratley 1980; Creswell 2003; Garfinkel 2003), as ethnographic process evaluations of the implementation of interventions and its adaptations in practice are necessary to be able to assess the validity and reliability of any effects of the interventions (Tones 2000; Visser 2000; Jansen, Bal et al. 2006).

The first author observed four out of seven practice nurses in their daily work, each for five workdays each, and the multidisciplinary team meetings they attended from April 2003 till December 2004. Observing and interviewing the practice nurses was chosen as they had a coordinating key function in the intervention. During the observations no notes were made, because note taking was felt to intrude on the interactions between the practice nurses and their patients and colleagues. Written records were made immediately after leaving the health care centres.

From April 2003 till December 2004, the first author also observed the two researchers, the data manager, and an average of four research assistants in their work in the Quattro trial for two work days a week. The research progress meetings that were organised by the researchers, data manager, and the project leader were also observed. With the project leader, one of the researchers and the data manager audio taped semi-structured interviews were held, which were transcribed afterwards. Written records were made of all meetings, observations and conversations. Minutes of the meetings, research protocols and questionnaires used for the Quattro Study were also collected. Throughout each observation it was possible to ask questions or to request clarification.

In addition, semi-structured interviews were held. With three practice nurses audio

taped semi-structured interviews were held, and with two practice nurses non-audio taped semi-structured interviews were held due to objections to audio taping. In all interviews the practice nurses were asked about their experiences with the Quattro Study, their dealings with patients and their current activities in the primary health care centres. The interviews were transcribed immediately after the interviews. After the observation period, all transcripts, personal jot notes, minutes, and research documents were analysed more in-depth. We analysed all the information thematically through establishing overarching categories by manually identifying and coding all pieces of information without any predefined categories. By means of developing overarching categories (taxonomy) of emerging themes overall descriptions of our findings could be made in more general terms.

Results

Difficulties introducing Quattro care

As the management of participating primary health care centres volunteered to take part in the Quattro trial, they committed themselves to employing practice nurses for the implementation of the intervention in the practices (document practice invitation letter). The practice nurses had to negotiate with their colleagues to plan the implementation and to fine-tune the exact rollout of the Quattro project in practice.

The practice nurses experienced difficulties introducing Quattro care in their health care centres. As one of the formally interviewed practice nurses stated about this initial organisation of the Quattro programme: "It is assumed that practice nurses can apply the knowledge they learned during their education in an instant, organisational skills that is. This is not exactly the case. Before such a project is even organised it takes a lot of time deliberating and coming to agreements with your colleagues assigned to participate in this project on how the project should and could be organised internally" (interview practice nurse 07-06-2004).

First, it proved to be difficult for the peer health educators to gain the trust and confidence of the GPs. In one of the primary health care centres the practice nurse and peer health educator both agreed that the peer health educator would perform the same activities as the practice nurse, but only for the immigrant patients. But this was hard to bring about as the field note shows: "[…] *the practice nurse* writes a short version of the patient files on paper so the peer health educator can do her work. As *the first author asks* her why she does this she answers: "The peer health educators are not allowed to see the electronic patient records. Don't ask me the logic behind it, but the GPs decided the peer health educator will not have access to the system. […] even though she has already worked here for five years" (field note 24-05-2004). So, although the peer health educators were to be seen as full members of the intervention team(s), the lack of status to negotiate their role in the intervention team disabled the peer health educators from becoming full members despite the enabling efforts of the practice nurses.

Second, the GPs were reluctant to take part: "The GPs consented to the project not really knowing what was being asked of them […] that they too had to be involved in the treatment of patients and not just we as practice nurses, but when they finally realised this the multidisciplinary meetings were very hard to organise" (conversation practice nurse 12-05-2004). The GPs were not willing to alter their work schedules and activities to a great extent.

"The practice nurses all were 'new' in the practices, but fairly soon it became obvious that the centres had not anticipated their practices would change" (conversation practice nurse 04-11-2004). Although the practice nurses were to be the coordinating axis of the implementation of the intervention, they were not able to discard the existing hierarchical positions of the GPs, peer health educators and assistants. In fact, it complicated the implementation of the intervention. As the project leader explained: "Quattro Care was set up to evaluate possible effects after its implementation in the health care centres. [...] It was the intention to provide the idea of Quattro Care to the health care centres and that they would take care of the organisational part themselves" (conversation project leader 10-09-2003). The practice nurses, however, were not able to implement and rollout the intervention in practice. "[…] It soon became clear to us that for the health care centres this was a problem" (conversation project leader 10-09-2003).

Thirdly, the decline in manpower and increasing workloads prevented the assistants of being part of the intervention team. As a result the practice nurses ended up seeing both intervention and control group patients. In two health care centres, the practice nurses were former assistants in these centres. When they became practice nurses, the number of assistants declined thus increasing their workload. To resolve this, the GPs used their hierarchical position to decide upon the issue at hand. "In the beginning the GPs thought of Quattro as a good idea. But when they saw it took more time doing intakes and counselling patients than they thought it would, they decided that the practice nurse would have to see both the intervention group and control group patients; the assistants already had too much work" (observation practice nurse 07-06-2004).

Thus, the existing interprofessional relations and local circumstances prohibited the intervention from being implemented as planned. A lot of effort had to be put into harmonising different insights and conflicting values. As all the centres employed multiple GPs and assistants - with their specialist medical interests - alongside only a minimal number of practice nurses and peer health educators, first basic organisational agreements had to be made about the formation of the intervention team and their deployment.

Tailoring and standardisation: the Quattro Guideline

Confronted with these problems the researchers questioned whether they had to develop a guideline for the intervention to increase the fidelity to the intervention's key component: the multidisciplinary meetings. However, within the research team two different opinions prevailed about the researchers' role as interveners in the organisation of the centres. On the one hand, developing a guideline did not correspond with the tailor-made approach, as it meant externally generated research interference with the normal way of working. As the project leader explained: "In order to provide a 'good' implementation, *one of the researchers* developed a protocol based on the existing standards on hypertension, cholesterol, diabetes, etcetera. I opposed this at first […] there must be as little as possible contact between the trial and the actual intervention" (conversation project leader 10-09-2003). Although research interference in daily care should be avoided for objectivity reasons, for the project leader this was not the main argument. For him, minimising research interference was about not forcing the health care professionals to use imposed (externally made) guidelines that do not fit the local organisational circumstances of these centres and about assessing "what trial based effects can be detected after such an implementation process in these practices" (conversation project leader 10-09-2003). So, according to the project leader, minimising

research interference could give insight into what kind of organisational preconditions primary health care has to meet in order for the implementation of prevention projects to be successful in primary care.

On the other hand, for the researchers the development of a guideline implied a means of standardising the fidelity to the programme among the centres and a possibility of ensuring the protection of the outcome validity of their study. As one of the researchers indicated, she had the impression that the primary health care centres made a mess of things; they didn't register the rudimentary data, important for research (field note 03-02-2004). As it turned out, the different practice nurses had different ways of collecting the required data. For example, while attending one of the practice nurses' patient consultation, she told the first author that hip measuring was not done in the same manner among all practice nurses: "I noticed a few times that *my colleague* holds the measuring-tape more downwards instead of horizontally. The outcomes then will not be the same as in reality […] the measurements then will differ a lot" (field note practice nurse 19-01-2004). So, as the patient monitoring data should be uniformly collected in order to be comparable, for the researchers the exactitude of the practice nurses' performance of medical-technical activities was considered a barrier for an uniform execution of the intervention among the participating health care centres. This is a problem that could, in theory, be resolved by providing them with a guideline. The tailoring we have described was, however, from the perspective of the pragmatic trial design not an intended process because it made establishing the effectiveness of the intervention by means of pre-established outcome measures difficult. (see (Jansen, Bal et al. 2006) for more detail on the methodological dilemmas the researchers had to deal with when performing this pragmatic trial).

Role of the guideline

After a long discussion about the different viewpoints the research team decided to develop a guideline. The Quattro guideline was foremost a medical-technical guideline developed by the research team members through combining the most recent separately existing GP-protocols for hypertension, hypercholesterolemia and diabetes mellitus type II, based on the national recommendation of the Dutch College of General Practitioners (NHG), with extra criteria for obesity and smoking.

The guideline described the procedural steps of the intervention's performance. It was written as a sequential procedure, that stated how and which medical-technical actions should be performed, what physical tests and measurements should be done and when, and which pharmaceutical treatments should be started depending on different measurement outcomes, but also how the physical examinations should be done and in what order. It also stated which patients had to be selected and on which grounds, who should perform the prevention, especially to whom, and what length the follow-up period should be in order to have sufficient data. But it also stated which data were necessary for calculating effectiveness outcomes and how and when this data should be returned to the trial researchers.

Furthermore, the guideline stated the elements of the prevention programme that had to be organised; at least four individual patient education sessions with intervention group patients and four multidisciplinary meetings with all intervention team members per patient. Moreover, it was indicated which topics should be discussed during these meetings and in which order, which professionals should attend these meetings, and what tasks the

intervention team members were to have (document manual for the intervention). The guideline thus contained 'research' or 'evidence' elements as well as 'intervention' elements.

As the guideline provided contained instructions for the organisation of the multidisciplinary collaboration - though on a more general level, opposed to the more specified description of the medical-technical performance of the intervention - the instructions still remained open for the practice nurses' interpretation and adaptation to the local organisational circumstances and needs. Moreover, the guideline did not correspond with difficulties the practice nurses were presented with when organising the multidisciplinary collaborations among the different disciplines in the health care centres. Ergo, as the practice nurses were confronted with difficulties concerning the organisation of interprofessional cooperation and in that way achieve implementation of the new organisational structure of multidisciplinary patient care, they were provided with a guideline aimed at performing the medical-technical actions for the prevention of CVD, in which the implication of standardisation kept lingering in the background. The guideline did not enable the practice nurses to disregard all the existing hierarchical professional relations and/or local circumstances within the healthcare centres; i.e. the peer health educators and assistants were still not able to take part as members of the intervention teams. The practice nurses were for example still not able to arrange the multidisciplinary team meetings. And so these meetings were organised irregularly, often limited to only practice nurses and GPs, or were informal deliberations.

The guideline, however, did give the practice nurses the position they needed to negotiate the appropriateness of treatments with the GPs. Especially since within the centres different medical guidelines co-existed for dealing with cardiovascular diseases. In the health care centres the Quattro guideline came into use next to the (most) recent NHG recommendations focussing on hypertension, diabetes mellitus, and hypercholesterolemia separately. Although this mixed use in real life practice caused tensions between professionals, it did provide the practice nurses with the opportunity to negotiate the appropriateness of treatments. "[…] the *(Quattro)* guideline does have strict norm levels you have to adhere to. However, the GP doesn't use the same guideline. So, when a patient has a cholesterol level of 6 or 6.4; 6.5 *mmol/l*……ideally it has to be below 6 *mmol/l,* the GP will say that these levels are alright. […] According to the Quattro high-risk guideline, however, these levels are too high; […] So, the GPs also learned from this new guideline, as we *(the practice nurses)* used the guideline saying these levels are too high; we have to do something. The GPs also have learned that a cholesterol level of 6.4 *mmol/l* can be seen as a risk for patients with cardiovascular diseases" (interview practice nurse 27-01-2006). So, as the Quattro guideline was an integration of separately existing guidelines and focussed on the interdependency of risk factors, the physical outcome measures in the separately existing guidelines were altered, making a cholesterol level of 6 mmol/l too high. As the guideline provided gave the practice nurses the position to negotiate appropriate treatments with the GPs, it provided them with a more crucial role in organising this prevention programme as they all remained in the health care centres as practice nurses even after the Quattro study had ended.

Discussion

Pragmatic trials, which have been developed since the 1980's to evaluate the effectiveness of treatments and/or complex interventions as they are used in routine practice (Roland and Torgerson 1998; MacPherson 2004), are seen as a way to overcome the incompatibility of

general guidelines and recommendations with local knowledge about the organisation of routine medical practice and the relationship between the professionals and the patients. However, as we have shown the liberty provided by a tailor-made approach for health care professionals to develop their preferred procedures for the intervention, did not result in the organisation of multidisciplinary patient care, which was the core of the intervention. In fact, the lack of adequate guidelines hindered the implementation of the intervention.

It is often argued that guidelines coordinate medical practices (Berg 1996; 1997; Timmermans and Berg 1997; 2003), as they guide medical professionals through a sequence of steps in the management of care. As guidelines articulate and delegate tasks to professionals over different sites and time - and thus can be seen as a coordinating tool (Timmermans and Berg 1997) - they structure an approach to diagnosis and/or treatment as a logical process ("when situation X presents itself, than Y should be done") (Berg 1996; Timmermans and Berg 1997). So, as a guideline regulates the content and the sequence of medical work, it also regulates – to a certain extent – its organisation in practice. Guidelines in medical practice, thus, are not purely 'medical' they also involve organisational aspects. Besides having relevant clinical components, care programmes should therefore be seen as multidisciplinary protocols that encompass tasks, decision criteria and work procedures for the care professionals involved in the care trajectory of a specific patient category (Berg, Schellekens et al. 2005). When every health care professional knows his/her tasks, then collaborative meetings could have relevance as formative evaluations of patients' treatment plans.

For evaluating complex interventions conventional RCTs are considered not to be appropriate, because of the rigidness of their designs, the perceived preoccupation with measuring outcomes rather than the process and the implications for health promotion practice (Nutbeam 1998; Judd, Frankish et al. 2001; McQueen 2001; Wolff 2001; Glasgow, Lichtenstein et al. 2003; Hawe, Shiell et al. 2004; Mukoma and Flisher 2004; Audrey, Holliday et al. 2006; Corrrigan, Cupples et al. 2006). As pragmatic trials, on the other hand, measure the effectiveness of intervention under routine conditions (Schwartz and Lellouch 1967; Armitage 1998; Roland and Torgerson 1998; Hotopf 2002; MacPherson 2004), they allow for the incorporation of variations among sites, professional and patient heterogeneity, and less standardised treatments to correspond with daily clinical decision-making. In order to enable permanent uptakes of interventions numerous initiatives are deployed to incorporate these pragmatic adjustments either into the design of pragmatic trials, like phased implementation designs, formative loops, process evaluations (Rowlands, Sims et al. 2005; Byrne, Cupples et al. 2006; Corrrigan, Cupples et al. 2006; Oakley, Strange et al. 2006) or within routine care, like community capacity building, supportive training and involving change moderators (Nazareth, Freemantle et al. 2002; Hawe, Shiell et al. 2004; Flocke, Gordon et al. 2006). Because of this persistent emphasis on flexibility, however, we believe the pragmatic trial discourse to reflect a great fear of standardising trial designs and interventions too much. Indeed as Judd et al. (Judd, Frankish et al. 2001) have argued, standardisation does have a supportive and empowering function for health care professionals in health promotion.

In other words, a tailor-made approach in pragmatic trial research should not rule out the use of guidelines or protocols. Guidelines do not standardise care practices; in practice they will always be localised and contextualised (Timmermans and Berg 2003). So, pragmatic trial researchers should not fear standardising care practices when applying tailor-made approaches (Berg 1996; 1997).

Conclusions

As tailor-made approaches are developed to enable the uptake of interventions in routine practice, they are facilitated by the brokering of tools such as guidelines. In our study, guidelines facilitated organisational change and enabled the transformation of existing interprofessional relations, and thus made tailoring possible. The attractive flexibility of pragmatic trial design in taking account of local practice variations may often be overestimated.

References

Armitage, P. (1998). Attitudes in clinical trials. Statistics in Medicine **17**: 2675-2683.

Audrey, S., Holliday, J., Parry-Langdon, N. and Campbell, R. (2006). Meeting the challenges of implementing process evaluation within randomized controlled trials: the example of ASSIST (A Stop Smoking in Schools Trial) Health Education Research **21**(3): 366-377.

Berg, M. (1996). Working with protocols: a sociological view. The Netherlands Journal of Medicine **49**: 119-125.

Berg, M. (1997). Problems and Promises of the Protocol. Social Science & Medicine **44**(8): 1081-1088.

Berg, M., Schellekens, W. and Bergen, C. (2005). Perspectives on Quality: Bridging the Quality Chasm; Integrating Professional and Organizational Quality. International Journal for Quality in Health Care **17**(1): 75-82.

Black, N. (1996). Why we need observational studies to evaluate the effectiveness of health care. British Medical Journal **312**: 1215-1218.

Brotons, C., Bjorkelind, C., Bulc, M., Ciurana, R., Goducki-Cwirko, M., Jurgova, E., Kloppe, P., Lionis, C., Mierzecki, A., Pineiro, R., Pullerits, L., Sammut, S.R., Sheehan, M., Tataradze, R., Thireos, E.A. and Vuchak, J. (2005). Prevention and health promotion in clinical practice: the views of general practitioners in Europe. Preventive Medicine **40**: 595-601.

Byrne, M., Cupples, M.E., Smith, S.M., Leathem, C., Corrigan, M., Byrne, M.C. and Murphy, A.W. (2006). Development of a Complex Intervention for Secondary Prevention of Coronary Heart Disease in Primary Care Using the UK Medical Research Council Framework. American Journal of Managed Care **12**(5): 261-266.

Campbell, S.M., Hann, M., Hacker, J., Burns, C., Oliver, D., Thapar, A., Mead, N., Gelb Safran, D. and Roland, M.O. (2001). Identifying predictors of high quality care in English general practice: observational study. British Medical Journal **323**(7316): 784-790.

CBO (2000a). CBO Richtlijn Beroerte Utrecht: Kwaliteitsinstituut voor de Gezondheidszorg CBO in samenwerking met de Nederlandse Hartstichting. 90-75141-92-0.

CBO (2000b). Herziening Richtlijn Hoge Bloeddruk. Utrecht: Kwaliteitsinstituut voor de Gezondheidszorg CBO in samenwerking met Nederlandse Hartstichting. 90-75141-92-0.

Corrrigan, M., Cupples, M.E., Smith, S.M., Byrne, M., Leathem, C.S., Clerkin, P. and Murphy, A.W. (2006). The contribution of qualitative research in designing a complex intervention for secondary prevention of coronary heart disease in two different healthcare systems. BioMed Central Health Services Research **6**. doi:10.1186/1472-6963-6-90.

Creswell, J.W. (2003). Research Design; Qualitative, Quantitative, and Mixed Methods Approaches. Thousand Oaks/London/New Delhi: SAGE Publications, Inc.

Dopson, S., FitzGerald, L., Ferlie, E., Gabbay, J. and Locock, L. (2002). No Magic Targets! Changing Clinical Practice To Become More Evidence Based. Health Care Management Review **27**(3): 35-47.

Flocke, S.A., Gordon, L.E. and Pomiecko, G.L. (2006). Evaluation of a Community Health Promotion Resource for Primary Care Practices. American Journal of Preventive Medicine **30**(3): 243-251.

Garfinkel, H. (2003 [first published in America, 1967 by Prentice Hall Inc.]). Studies in Ethnomethodology. Cambridge: Polity Press in association with Blackwell Publishing Ltd.

Glasgow, R.E., Lichtenstein, E. and Marcus, A.C. (2003). Why Don't We See More Translation of Health Promotion Research to Practice? Rethinking the Efficacy-to-Effectiveness Transition. American Journal of Public Health **93**(8): 1261-1267.

Hawe, P., Shiell, A. and Riley, T. (2004). Complex interventions: how "out of control" can a randomised controlled trial be? British Medical Journal **328**(7455): 1561-1563.

Hotopf, M. (2002). The pragmatic randomised controlled trial. Advances in Psychiatric Treatment **8**: 326-333.

Jansen, Y.J.F.M., Bal, R., Bruijnzeels, M., Foets, M., Frenken, H. and de Bont, A. (2006). Coping with methodological dilemmas; about establishing the effectiveness of interventions in routine medical practice. BioMed Central Health Services Research **6**:160. doi:10.1186/1472-6963-6-160.

Judd, J., Frankish, C.J. and Moulton, G. (2001). Setting standards in the evaluation of community-based health promotion programmes— a unifying approach. Health Promotion International **16**(4): 367-380.

Lobo, C.M., Frijling, B.D., Hulscher, M.E.J.L., Bernsen, R.M.D., Braspenning, J.C., Grol, R.P.T.M., Prins, A. and van der Wouden, J.C. (2003). Organisational determinants of cardiovascular prevention in general practice. Scandinavian Journal of Primary Health Care Analysis **21**(2): 99-105.

MacPherson, H. (2004). Pragmatic clinical trials. Complementary Therapies in Medicine **12**: 136-140.

McQueen, D.V. (2001). Strengthening the evidence base for health promotion. Health Promotion International **16**(3): 261-628.

Mukoma, W. and Flisher, A.J. (2004). Evaluations of health promoting schools: a review of nine studies. Health Promotion International **19**(3): 357-368.

Nazareth, I., Freemantle, N., Duggan, C., Mason, J. and Haines, A. (2002). Evaluation of a complex intervention for changing professional behaviour: the Evidence Based Out Reach (EBOR) Trial. Journal of Health Services Research and Policy **7**(4): 230-239.

Nutbeam, D. (1998). Evaluating health promotion - progress, problems and solutions. Health Promotion International **13**(1): 27-44.

Oakley, A., Strange, V., Bonell, C., Allen, E., Stephenson, J. and RIPPLE_Study_Team (2006). Process evaluation in randomised controlled trials of complex interventions. British Medical Journal **332**(7538): 413-416

Richards, A., Carley, J., Jenkins-Clarke, S. and Richards, D.A. (2000). Skill mix between nurses and doctors working in primary care - delegation or allocation: a review of the literature. International Journal of Nursing Studies **37**: 185-197.

Roland, M. and Torgerson, D.J. (1998). Understanding controlled trials: What are pragmatic trials? British Medical Journal **316**: 285.

Rowlands, G., Sims, J. and Kerry, S. (2005). A lesson learnt: the importance of modelling in randomized controlled trials for complex interventions in primary care. Family Practice **22**(1): 132-139.

Rutten, G.E.H.M., Verhoeven, S., Heine, R.J., De Grauw, W.J.C., Cromme, P.V.M., Reenders, K., Van Ballegooie, E. and Wiersma, T.J. (1999). NHG-Standaard Diabetes Mellitus Type II (eerste herziening). Huisarts & Wetenschap **42**(2): 67-84.

Schwartz, D. and Lellouch, J. (1967). Explanatory and pragmatic attitudes in therapeutical trials. Journal of Chronic Diseases / Journal of Clinical Epidemiology **20**: 637-648.

Spratley, J.P. (1980). Participant Observation. Fort Worth/Philadelphia/San Diego/New York/ Orlando/Austin/San Antonio/Toronto/Montreal/London/Sydney/Tokyo: Harcourt Brace College Publishers.

Stange, K.C., Goodwin, M.A., Zyzanski, S.J. and Dietrich, A.J. (2003). Sustainability of a practice-individualized preventive service delivery intervention. . American Journal of Preventive Medicine **25**(4): 296-300.

Steptoe, A., Doherty, S., Kendricka, T., Rinka, E. and Hilton, S. (1999). Attitudes to cardiovascular health promotion among GPs and practice nurses. Family Practice **16**(2): 158-163.

Thomas, S., Van der Weijden, T., Van Drenth, B.B., Haverkort, A.F.M., Hooi, J.D. and Van der Laan, J.D. (1999). NHG-Standaard Cholesterol (eerste herziening). Huisarts & Wetenschap **42**(9): 406-417.

Timmermans, S. and Berg, M. (1997). Standardization in Action: Achieving Local Universality through Medical Protocols. Social Studies of Science **27**(2): 273-305.

Timmermans, S. and Berg, M. (2003). The Gold Standard; The Challenge of Evidence-Based Medicine and Standardization in Health Care. Philadelphia: Temple University Press.

Tones, K. (2000). Evaluating health promotion: a tale of three errors. Patient Education and Counseling **39** (2-3): 227-236.

Visser, A. (2000). Research methods, interventions and evaluation in patient education: a kaleidoscope. Patient Education and Counseling **39**(2-3): 147-148.

VWS (2005). Primary Health Care in the Netherlands; The nature, structure, financing, regulation, supply of, and training and demand for primary health care in the Netherlands. Poorter, J. The Hague: Ministry of Health, Welfare and Sport, The Netherlands.

Walma, E.P., Grundmeijer, H.G.L.M., Thomas, S., Prins, A., Van den hoogen, J.P.H. and Van der Laan, J.R. (1997). NHG-Standaard Hypertensie (eerste herziening). Huisarts & Wetenschap **40**(12): 598-617.

Wolff, N. (2001). Randomised trials of socially complex interventions: promise or peril? Journal of Health Services Research & Policy **6**(2): 123-126.

3

The contribution of qualitative research to the development of tailor-made community-based interventions in primary care; a review

Abstract

Background
In recent years, a trend in the use of tailor-made approaches and pragmatic trial methodology for evaluating effectiveness has been visible in programs ranging from large-scale national health prevention campaigns to community-based initiatives. Qualitative research is used more often for tailoring interventions towards communities and/or local care practices. This paper systematically reviews the contribution of qualitative research in developing tailor-made community-based interventions in primary care evaluated by means of the pragmatic trial methodology.

Methods
A systematic search of Pubmed/Medline and Embase revealed 33 articles. Using a literature mapping process, the articles were arranged according to the development phases identified in the MRC framework for the development of complex interventions to improve health.

Results
The review showed qualitative research is mainly used to provide insight into the contextual circumstances of the interventions' implementation, delivery and evaluation. To a lesser extent, qualitative research findings are used for tailoring and improving the design of the interventions for a better fit with daily primary care practice. Moreover, most qualitative findings are used for tailoring the interventions' contextual circumstances so that the interventions are performed in practice as planned, rather than adjusted to local circumstances.

Conclusions
Pragmatic trials seem to be oxymoronic. Although the pragmatic trial methodology establishes the effectiveness of interventions under natural, non-experimental conditions, no pragmatic fit is allowed. Qualitative research's contribution to the development of tailor-made community-based interventions lies in providing ongoing evaluations of the dilemmas faced in pragmatic trials and allowing for the development of true tailor-made interventions.

Introduction

In recent years a trend is visible in programs ranging from large-scale national health prevention campaigns to community-based initiatives. There is a growing notion that interventions need to be directed at specific communities in society and should to be tailored to the specific health problems and needs of these communities (Saan and de Haes 2005). In fact, it is believed that uniform and standard interventions – which are applicable to the whole population – will not diminish inequalities in health.

These tailor-made approaches demand a different manner for establishing the effectiveness of interventions. Conventional RCTs are not considered appropriate for evaluating complex community-based interventions because of the rigidness of their designs and their perceived preoccupation with measuring outcomes, rather than the process in care practices (Hawe, Shiell et al. 2004). Pragmatic randomised controlled trials that establish the effectiveness of interventions under routine conditions – also known as pragmatic RCTs or pragmatic trials – are presented as an alternative (Hotopf 2002). In order to evaluate the effectiveness of interventions, conventional RCTs require that interventions are standardised, implemented uniformly among sites and target a homogenous patient population. These requirements, however, do not always match the complex character of routine care. In contrast, pragmatic trials allow interventions to incorporate variations in practice at the different sites and for targeting a heterogeneous patient population.

A recent trend is the use of qualitative research in conjunction with pragmatic trials. Various authors have argued that qualitative research can have a valuable contribution to quantitatively oriented research designs like pragmatic trial research, as it enables making appropriate adjustments during intervention development, for making interventions more sustainable, with a better fit to the communities and/or local care practices (Stange, Goodwin et al. 2003). The combination of methods is perceived to be the best strategy for developing and evaluating interventions that fit and reflect primary care practice. For example, medical interventions and/or technologies can be tailored and improved through the understanding of the dynamics and complexity of care practices qualitative research leads to (Zuiderent 2002). However, how qualitative research actually contributes to the development of community-based interventions remains largely unexplored. Therefore, this paper aims to review the contribution of qualitative research to developing community-based interventions in primary care evaluated by means of the pragmatic trial methodology.

Methods

For this review, we searched the Pubmed/Medline database and the Embase database for editorials, reviews, meta-analyses, RCTs, case reports, controlled clinical trials, evaluation studies written in English. We searched these databases for articles published until June, 2007, without establishing a starting point. We did restrict our search to pragmatic trials performed within primary care, which is a good example of a health care setting in which tailor-made, community-based interventions are conducted. Primary health care provides *heterogeneous medical services*, by means of *different (para)medical disciplines* coordinated for a *heterogeneous patient population* (Brotons, Bjorkelind et al. 2005). For the search we used various combinations of the keywords: pragmatic trial, pragmatic randomised controlled trial, pragmatic RCT, clinical trials, qualitative research, ethnography, evaluation studies, program evaluation, primary care, general care,

primary health care, primary nursing care, family practice, routine care, community care, general practice, family physicians, GP care, health promotion, health education, preventive health services, both MeSH and free text. Based upon title and abstract, 239 articles returned in the search were considered relevant. However, because of a large heterogeneity in articles, it was necessary to narrow the inclusion criteria. We excluded articles that did not refer to how qualitative research was used in the development of the interventions. We critically assessed articles on the presence or absence of empirical data hereon. At this point, viewpoint papers, theoretical and methodological discussions or description papers were excluded unless they were considered to make a special contribution to the review. Articles were excluded from this review if the articles:

- reported on pragmatic trials or RCTs performed in routine primary care without the explicit indication of having also used qualitative research or when they did report on the use of qualitative research but did not present evidence on its contribution to the trials and/or the development of interventions;
- reported on evaluation studies other than RCTs or pragmatic trials performed in routine primary care, e.g. evaluations of general organisational and/or care reform initiatives in primary care induced by national policy recommendations;
- reported on community interventions that were evaluated by means of RCT or pragmatic trial designs combined with qualitative research, but not conducted in primary care or in particular GP care, e.g. articles that reported on trials performed in hospital emergency departments, maternity clinics, physiotherapy clinics, mental health services, community care services, psychiatry, geriatrics and rehabilitation departments;
- reported on qualitative studies performed in primary care without the explicit indication that these were performed within the context of a pragmatic trial or an RCT in routine primary care;
- published the research protocols of RCTs or pragmatic trials to be performed in routine primary care, in which qualitative research is intended to be used, but which do not yet provide empirical evidence on the contribution of qualitative research;
- did not report on empirical evidence but had general methodological content, e.g. articles that described the general characteristics of mixed methods research such as the order, the quality of the different data sets, and the methodological strengths and weaknesses of mixed methods research projects;
- reviewed literature on the effectiveness of treatments and/or health services in primary care, in which RCTs, pragmatic trials and qualitative studies were included, but did not report on the contribution of qualitative research to RCTs or pragmatic trials in primary care;
- reported on drug treatments being evaluated by means of RCT or pragmatic trial design in combination with qualitative research, but which were not performed in primary care.

As a result of this exclusion process, 33 articles were included in this review. We applied a literature mapping process (Creswell 2003) based upon the MRC framework for the development of complex interventions to improve health (MRC 2000). According to the MRC Framework, the development cycle of new interventions consists of six sequential phases: the exploration of relevant theory, modelling the preliminary interventions, pilot-testing the preliminary interventions, evaluating the definite interventions, and evaluating the long-term

implementation of interventions. We used these development phases to arrange the literature and analyse the contribution of qualitative research in developing interventions tested in pragmatic trials. Because only a small number of articles (n=3) report on the contribution of qualitative research to the selection and modelling of interventions, we combined the theory and modelling phases in our analysis.

Results

Table 1
Features of studies reviewed

Authors	Applied in intervention development phase	Qualitative research methods used	Information generated	Contribution to development of interventions
Sturt et al. (2006)	Modelling	Semi-structured interviews, questionnaires, and panel interviews with diabetic patients and health care professionals	Information on current self-management activities among patient, their preferred content and needs for additional support, and information of primary care professionals on perceived suitability of the set-up of the programme	Tailoring intervention towards target population
Flottorp et al. (2002)	Modelling	Focus group and semi-structured interviews with health care professionals	Information about barriers or facilitators to guideline implementation and changing professional practice	Tailoring intervention towards obstacles
	Pilot	Semi-structured interviews with health care professionals	Information on the administration of the preliminary intervention, experiences with delivery and participation in project and perceived effects	Alteration of professional behaviour Tailoring practice towards intervention modelled
Corrrigan et al. (2006)	Modeling	Semi-structured individual and focus groups interviews with patients and staff	Information on barriers identified by patients and staff, and practice conditions that may impede upon intervention being carried out as planned	Tailoring intervention towards practice conditions identified
	Pilot	Semi-structured individual and focus group interviews	Information on experiences with delivering, receiving and participation in project and perceived effects	Tailoring intervention procedures to practice

Authors	Applied in intervention development phase	Qualitative research methods used	Information generated	Contribution to development of interventions
Clavarino et al. (2004)	Pilot	Focus group interviews with consumers and health care professionals	Information on perspectives on process of colorectal cancer screening, experiences with methods of service delivery, kit characteristics and perceived impact	Alteration of professional behaviour Tailoring practice to new method of screening
Moffatt, Mackintosh et al. (2006)	Pilot	Semi-structured interviews with participants	Information on participants' views on intervention, outcomes, acceptability and research process	Adjustment of surrounding evaluation / pragmatic trial
Moffatt, White et al. (2006)	Pilot	Semi-structured interviews with participants	Information on participants' views on intervention, outcomes, acceptability and research process	Adjustment of surrounding evaluation / pragmatic trial
Rousseau et al. (2003)	Definite	Qualitative interview study with primary care professionals	Insights into attitudinal and contextual influences on the use of computerised decision support	Assessment of implementation and delivery of intervention to explain effects
Getrich et al. (2007)	Definite	Ongoing ethnographic research with participant observations and semi-structured interviews with intervention participants	Information on impact of practice characteristics on the fidelity of participants to the intervention	Assessment of implementation and delivery of intervention to explain effects
Harrison et al. (2003)	Definite	Qualitative interviews with GPs	Information on attitudes to guidelines, practice information, processes and aspects of practice "culture" and experiences with delivering the intervention	Assessment of implementation, delivery and perceived effects of intervention to explain effects
Smith et al. (2003)	Definite	Focus group discussions with diabetic patients	Information on patients' views and experiences with diabetic service change	Assessment of delivery and perceived usefulness of intervention to explain effects
Rogers et al. (2004)	Definite	Semi-structured interviews with patients	Information on patients' experiences with a self-help clinic and the processes underlying referral and utilisation	Assessment of implementation, delivery and perceived usefulness to explain effects

Authors	Applied in intervention development phase	Qualitative research methods used	Information generated	Contribution to development of interventions
Backer et al. (2005)	Definite	Ongoing ethnographic research with participant observations and semi-structured interviews with primary care staff	Information on interactional patterns among staff, procedures of screening activities and attitudes on and experiences of staff with improvement of service delivery	Assessment of implementation, delivery and perceived usefulness of intervention to explain effects
Bosworth et al (2005)	Definite	Interviews with patients	Information on patients' experiences with receiving the intervention	Assessment of perceived usefulness of intervention to explain effects
Heisey et al. (2006)	Definite	Semi-structured interviews with female potential participants	Information on knowledge and attitudes toward chemoprevention of breast cancer	Assessment of perceived usefulness of intervention to explain effects
Légaré et al. (2006)	Definite	Non-participant observations of workshops directed at primary care staff	Information on the staff's views and perceptions of the intervention	Assessment of perceived usefulness of intervention to explain effects
Rowan et al. (2006)	Definite	Semi-structured interviews with primary care staff	Information on attitudes of staff on performance assessments of preventive services	Assessment of perceived usefulness of intervention to explain effects
Walsh et al. (2007)	Definite	Semi-structured focus group interviews with patients and staff	Information on experiences with administering and receiving the intervention	Assessment of implementation, delivery and perceived usefulness of intervention to explain effects
Sennun et al. (2006)	Definite	Ongoing ethnographic research with observations and semi-structured interviews with community and health officers	Information on experiences with administering and receiving the intervention and attitudes towards improvement of service delivery	Assessment of impact of intervention and change in existing service provision

Authors	Applied in intervention development phase	Qualitative research methods used	Information generated	Contribution to development of interventions
Shuval et al. (2007)	Definite	Focus group and individual semi-structures interviews with staff	Information on experiences with and attitudes towards EBM and intervention	Assessment of impact of intervention and change in existing service provision Overview of strength and weaknesses of intervention
Burroughs et al. (2006)	Definite	Semi-structured interviews with patients and primary care staff	Information on existing care strategies and experiences with and attitudes towards change in service provision	Overview of barriers to change existing in daily care as explanation of intervention's effects
McCormick et al. (2006)	Definite	Audiotaped patient-provider communications on alcohol related discussions	Information on alcohol use and nature of advice offered	Identified patient-provider interactions as barrier to change as explanation of intervention's effects
Weiss et al. (2004)	Definite	Follow-up interviews with patients	Information on patients' attitudes, use of decision aid and the influence of decision aid on decision making	Identified the ability of patients to incorporate behavioural changes into their lives as barrier to change as an explanation of intervention's effects
Bach-Nielsen et al. (2005)	Definite	Qualitative interview study with patients	Information on patients' knowledge of health risks and their perceptions on beneficial risk-lowering behavioural change	Identified the ability of patients to incorporate behavioural changes into their lives as barrier to change as an explanation of intervention's effects

Authors	Applied in intervention development phase	Qualitative research methods used	Information generated	Contribution to development of interventions
Stewart et al. (2005)	Definite	Semi-structured focus group interviews with patients	Information on patients' knowledge and beliefs on importance of blood pressure in diabetes	Identified the ability of patients to incorporate behavioural changes into their lives as barrier to change as an explanation of intervention's effects
Heaven et al. (2006)	Definite	Semi-structured interviews with GPs, patients and non-participant observations of GP-patient consultations	Information on patients' experiences participation in intervention and research project	Identified the understanding of patients of trial and/or prevention research as an explanation of intervention's effects
Rogers et al. (2005)	Definite	Observations of the operation of outpatient clinics, qualitative interviews with patients and specialist consultants	Information on the uptake of the self-management system as planned, experiences of professionals, participants and information of the organisational arrangements	Assessment of implementation, delivery and perceived usefulness of intervention to explain effects
Barton et al. (2005)	Definite	Single semi-structured in-depth interviews with primary caregivers	Information on caregivers' experiences with, attitudes toward and use of written asthma actions plans	Assessment of implementation, delivery and perceived usefulness of intervention to explain effects
Rowlands et al. (2001)	Definite	Preliminary interviews with doctors and manager and non-participant observations of secondary care referral meetings	Information on the functioning of the practice, organisational context, attitudes and group dynamics	Identified the practice as a complex organisation with established group dynamics as barrier to change as explanation of intervention's effects

Authors	Applied in intervention development phase	Qualitative research methods used	Information generated	Contribution to development of interventions
Rowlands et al. (2005)	Definite	Personal reflections of researchers conducting evaluation / pragmatic trial	Information on researchers' rationale for dealing with methodological dilemmas during design, implementation and evaluation / pragmatic trial	Description of methodological dilemmas and contextual circumstances of evaluation of intervention / pragmatic trial
Godwin et al. (2003)	Definite	Personal reflections of researchers conducting evaluation / pragmatic trial	Information on researchers' rationales for choosing intervention, recruitment of participants, randomisation procedures and blinding treatment allocation	Description of methodological dilemmas and contextual circumstances of evaluation of intervention / pragmatic trial
Fransen et al. (2007)	Definite	Personal reflections of researchers conducting evaluation / pragmatic trial	Information on researchers' rationales for choosing intervention, blinding treatment allocation, choosing appropriate study population and choosing essential outcome measures	Description of methodological dilemmas and contextual circumstances of evaluation of intervention / pragmatic trial
Jansen et al. (2006)	Definite	Ongoing ethnographic research with semi-structured interviews and participant-observations of trial researchers and staff-patient consultations	Information on researchers' rationales for dealing with methodological dilemmas during design, implementation and evaluation / pragmatic trial	Description of methodological dilemmas and contextual circumstances of evaluation of intervention / pragmatic trial
Blasinsky et al. (2006)	Long-term	Site visits and semi-structured telephone interviews with primary care staff key informants	Information on implementation experiences, perceived and observed changes in professional/ organisational culture and information on extent of continuation of intervention as originally modelled	Assessment of sustainability of intervention in daily practice

Cupples et al. 2006; Sturt, Taylor et al. 2006). Qualitative research findings can be used either to refine the components of the interventions or to tailor intervention procedures toward the local circumstances of primary care practices. In one article, information from semi-structured interviews, questionnaires, and panel interviews with diabetic patients and health care professionals was used to refine the components of a self-management programme and tailor it to the wishes and perceived needs of the target population people with type 2 diabetes (Sturt, Taylor et al. 2006). Yet, qualitative research on the circumstances of practice seems to provide more possibilities for adjustment. In two studies, individual and focus group interviews generated information on practice conditions (Corrrigan, Cupples et al. 2006), as well as on the barriers or facilitators to guideline implementation and changing professional practice that might impede the intervention being carried out as planned (Flottorp and Oxman 2003). Both Corrrigan et al. and Flottorp et al. indicated that their findings provided an analysis of the possible obstacles to implementation of the guidelines under study; the articles failed to provide information on how the intervention was modelled towards these obstacles.

In summary, qualitative research in the modelling phase is used foremost to tailor interventions to the specific primary care settings in which they will be applied. It offers suggestions for tailoring interventions to anticipated new conditions and routines of the primary care centres by providing an inventory of the possible barriers that may impede interventions in primary care from being carried out as planned.

Pilot-testing preliminary interventions

Qualitative research in a pilot study provides information on whether or not the preliminary interventions correspond with the anticipated practice conditions and routines that have been previously identified. It also evaluates whether or not the anticipated effects are generated when performed under routine conditions. Based upon this information, any subsequent adjustments to the interventions can be made before the definite interventions are evaluated for effectiveness.

In one study, qualitative findings were used to tailor the design of a preliminary intervention to improve its workability for the primary care professionals. For example, through reducing the administrative load and increasing the flexibility in patient follow-up, the intervention's procedures were appropriated to existing practice conditions and routines (Corrrigan, Cupples et al. 2006). In five studies, qualitative research was used in this phase to evaluate the actual administration of the preliminary interventions and their fit with anticipated practice conditions and routines. In these studies, both staff and patients were interviewed about their experiences with delivering and receiving the pilot-tested interventions, about taking part in a research project, and asked about the perceived effects of the interventions (Flottorp and Oxman 2003; Clavarino, Janda et al. 2004; Corrrigan, Cupples et al. 2006; Moffatt, Mackintosh et al. 2006; Moffatt, White et al. 2006). The qualitative findings are mainly used to alter the context surrounding the interventions. They are minimally used for improving the design of the interventions.

In the remaining four studies, the qualitative findings were used to alter the contextual circumstances of the interventions. In two studies, attempts were made to alter professional behaviour and to tailor primary care practice towards the modelled interventions, e.g. additional interactive courses and training sessions attempted to change professional practice and increase adherence to the interventions (Flottorp and Oxman 2003; Clavarino,

Janda et al. 2004). In the other two studies, the use of qualitative findings led to adjustments of the design of the pragmatic trials that surrounded the interventions and were set up to evaluate their effectiveness. The qualitative interviews used in both studies by Moffat et al. generated information to refine the outcome measures for evaluating the definite intervention (Moffatt, Mackintosh et al. 2006; Moffatt, White et al. 2006). In conclusion, qualitative research is mainly used in the pilot-testing phase to adjust the preliminary interventions' contextual circumstances.

Evaluating definite interventions

In 24 of the included articles, qualitative research was used in the definite intervention phase. In this phase, the interventions are considered to be definite and are evaluated for their effectiveness under routine conditions. In this phase, qualitative research is mostly conducted parallel to the pragmatic trials and generates information on the actual performance and the perceived usefulness and impact of the interventions. No adjustments to the interventions are made based upon the information that qualitative research generates, because adjustments are considered to cause difficulties in establishing the effectiveness of the interventions.

Qualitative research is used to assess more thoroughly the contextual circumstances of the interventions' implementation and delivery, and subsequently to explain the effects via process evaluations. Qualitative research exploring the context of interventions' implementation and delivery provides an overview of the barriers to change that exist within the practices (e.g. (Backer, Geske et al. 2005; Burroughs, Lovell et al. 2006; Shuval, Shachak et al. 2007)). For example, the provider-patient interactions during the intervention (McCormick, Cochran et al. 2006), the ability of included patients to incorporate behavioural changes into their lives (Weiss, Montgomery et al. 2004; Bach-Nielsen, Dyhr et al. 2005; Stewart, Brown et al. 2005), or the understanding patients had of trial or prevention research (Heaven, Murtagh et al. 2006; Heisey, Pimlott et al. 2006). Four major focal points can be distinguished. First, information about the implementation process is generated, such as how the implementation was affected by the attitudes of participants and the organisational structure of primary care practices (Rowlands, Willis et al. 2001; Rousseau, McColl et al. 2003; Rogers, Kennedy et al. 2005; Getrich, Heying et al. 2007). Second, information about the participants' experiences in administering and receiving the interventions in daily practice, as was the case in ten studies (Harrison, Dowsell et al. 2003; Smith, O'Leary et al. 2003; Rogers, Oliver et al. 2004; Backer, Geske et al. 2005; Barton, Sulaiman et al. 2005; Bosworth, Olsen et al. 2005; Heisey, Pimlott et al. 2006; Légaré, O'Connor et al. 2006; Rowan, Hogg et al. 2006; Walsh, Yardley et al. 2007). Third, the impact of the intervention is explored, such as the extent the interventions had changed the existing provision of services (Backer, Geske et al. 2005; Sennun, Suwannapong et al. 2006; Shuval, Shachak et al. 2007). Or finally, qualitative research focuses on the contextual circumstances of the interventions' evaluation of effectiveness.

Four studies presented the methodological issues that trial researchers have dealt with, e.g. choosing the right intervention, the recruitment of participants, randomisation procedures and blinding treatment allocation, the contamination of study findings, fidelity of the participants to the intervention, and the researchers' rationale for their methodological choices. This information is presented either in the form of personal reflections of trial researchers (Godwin, Ruhland et al. 2003; Rowlands, Sims et al. 2005; Fransen, van Marrewijk et al. 2007), or as the findings of external ethnographic observations (Jansen, Bal et al. 2006). In conclusion, qualitative research conducted parallel to the interventions' pragmatic trials

provides additional information for interpreting and explaining the actual cause of the interventions' effects via process evaluations. Consequently, qualitative research then only generates information relevant for the development and evaluation of future interventions. It builds a growing overview of facilitators and obstructions related to the interventions being performed in primary care practice as planned. Qualitative research, then, only is able to act as a post-hoc allocation of success or failure to the interventions in this phase, in the hope of starting a learning cycle for the development of future interventions.

Evaluating long-term implementation

Qualitative research in the last phase of evaluating long-term implementation shows the actual fit of the implemented interventions with daily care conditions and routines. It underscores that the sustainability of interventions is dependent upon the extent to which the uniqueness of these daily primary care conditions and routines is taken into account during the interventions' development process. A continuous cycle of adjustment and evaluating interventions such that they have a better fit with primary care practices would result in a higher sustainability. Yet, only one study focused on the long term implementation of an intervention. In fact, it showed the sustainability of the intervention in practice was different than anticipated (Blasinsky, Goldman et al. 2006).

Discussion

The aim of this article was to review the contribution of qualitative research to developing tailor-made community-based prevention interventions in primary care evaluated by means of the pragmatic trial methodology. This proved to be a very recent development. All articles included in this review were published between 2001 and 2007. Qualitative research, this review showed, is mainly used to provide insight into the contextual circumstances of the implementation, delivery and evaluation of interventions. To a lesser extent, qualitative research findings are used for tailoring and improving the design of the interventions to better fit daily primary care conditions and routines. When qualitative findings are used for adjustments, though, they are mainly used to adjust or intervene upon the interventions' contextual circumstances such that the interventions are performed in practice as planned. The qualitative findings are not used to improve intervention design. In 26 articles, qualitative research was used in hindsight to evaluate the interventions via process evaluations. Use of qualitative research for contributing to intervention selection and modelling was discussed in only seven articles. Since the use of qualitative methods is a very recent development – reflected in the short length of the publication period – our conclusions may need to be reconsidered in a few years time in order to include the advancements made in this field of research. It is our contention that the conclusions we draw, reflect the current status of qualitative research's contribution to the development of interventions in primary care.

Although qualitative research is said to be important to the development of interventions, it actually makes a minimal contribution. Much like in RCTs, the interventions in pragmatic trials are still expected to resemble the original intervention as much as possible. Because adjustments are considered to obscure the actual cause of the interventions' effects (Hawe, Shiell et al. 2004), the pragmatic trial methodology thus standardises the design, content and delivery of the interventions. However, whereas the use of qualitative research for developing tailor-made interventions is considered to strengthen and improve the

impact, effectiveness, and sustainability of interventions (Stange, Goodwin et al. 2003), the surrounding pragmatic trial methodology, in fact, prohibits the interventions from being tailored to fit the dynamics and complexity of care practices. Pragmatic trials therefore seem to be a contradiction in terms. Though the pragmatic trial methodology is seen as allowing for interventions to fit the complexity and variability of care practices, this is at odds with establishing the effectiveness of these interventions under natural, non-experimental conditions, in which no pragmatic fit is allowed.

The findings of this review suggest that the development of interventions has become a goal in and of itself and is not seen as a means or infrastructure for making primary care practice more evidence-based. First, the intervention in itself is most important, and adjustments to its design are considered to be of minor detail and less relevant. Second, the shape of the preliminary interventions is portrayed as definite and independent from these conditions and routines in care practices. Once interventions are modeled, they are not to be improved and tailored any further such that they better fit and reflect practice. Any adjustments to the interventions are considered to obscure the actual cause of the interventions' effects; qualitative research is not to be used to refine the interventions any further. Thirdly, hardly any evaluations of interventions' long-term implementation are done, which might suggest that the majority of interventions are terminated after the trial phase, and resulting in a low sustainability rate.

This leads to the question of what contribution qualitative research then might have. Qualitative research in general provides insight into the variety of medical work practices and their organisational contexts (Zuiderent 2002). As the included articles of this review exemplify, qualitative research shows the dynamics of the organisational characteristics of the primary care practices, the work processes and routines of the health care professionals, and the interprofessional relations among the different disciplines within (primary) care that are relevant for intervention development in general. However, for specific pragmatic trials evaluating specific interventions, this will not suffice, because local dynamics shape the content and form of local interventions. We argue, therefore, that the contribution of qualitative research lies in providing ongoing evaluations of the methodological and practical dilemmas that pragmatic trials face locally in order to accommodate solutions. We believe that pragmatic trial research avails with local solutions to its local dilemmas. Only then can one speak of true tailor-made interventions.

Keypoints

- The use of qualitative research in the development of tailor-made community-based interventions in primary care is a recent development. Yet, qualitative research findings are scarcely used for tailoring and improving the design of the interventions
- The emphasis that is placed upon establishing the effectiveness of interventions via (pragmatic) trial methodology hinders tailoring interventions to fit the dynamics and complexity of care practices, resulting in a low sustainable rate of interventions
- In order to develop high sustainable interventions, the view on effectiveness imbued in current health policy decision-making processes should accommodate for the durable use of qualitative research findings in all phases of the intervention development cycle of tailor-made community-based interventions in primary care.

References

Bach-Nielsen, K.-D., Dyhr, L., Lauritzen, T. and Malterud, K. (2005). Long-term impact of elevated cardiovascukar risk detected by screening; a qualitative interview study. Scandinavian Journal of Primary Health Care **23**(4): 233-238.

Backer, E.L., Geske, J.A., McIlvain, H.E., Dodendorf, D.M. and Minier, W.C. (2005). Improving Female Preventive Health Care Delivery Through Practice Change: An Every Woman Matters Study. Journal of the American Board of Family Practice **18**(5): 401-408.

Barton, C.A., Sulaiman, N.D., Clarke, D.M. and Abramson, M.J. (2005). Caregivers' use of, and attitudes towards, written asthma action plans in North-West Melbourne Primary Care Respiratory Journal **14**(3): 143-146

Blasinsky, M., Goldman, H.H. and Unutzer, J. (2006). Project IMPACT: A Report on Barriers and Facilitators to Sustainability. Administration and Policy in Mental Health and Mental Health Services Research **33**(6): 718-729.

Bosworth, H.B., Olsen, M.K., Gentry, P., Orr, M., Dudley, T., McCant, F. and Oddone, E.Z. (2005). Nurse administered telephone intervention for blood pressure control: a patient-tailored multifactorial intervention. Patient Education and Counseling **57**(1): 5-14.

Brotons, C., Bjorkelind, C., Bulc, M., Ciurana, R., Goducki-Cwirko, M., Jurgova, E., Kloppe, P., Lionis, C., Mierzecki, A., Pineiro, R., Pullerits, L., Sammut, S.R., Sheehan, M., Tataradze, R., Thireos, E.A. and Vuchak, J. (2005). Prevention and health promotion in clinical practice: the views of general practitioners in Europe. Preventive Medicine **40**: 595-601.

Burroughs, H., Lovell, K., Morley, M., Baldwin, R., Burns, A. and Chew-Graham, C. (2006). 'Justifiable depression': how primary care professionals and patients view late-life depression? A qualitative study. Family Practice **23**: 369-377.

Clavarino, A.M., Janda, M., Hughes, K.L., Del Mar, C., Tong, S., Stanton, W.R., Aitken, J.F., Leggett, B.A. and Newman, B. (2004). The view from two sides: a qualitative study of community and medical perspectives on screening for colorectal cancer using FOBT. Preventive Medicine **39**(3): 435-641.

Corrrigan, M., Cupples, M.E., Smith, S.M., Byrne, M., Leathem, C.S., Clerkin, P. and Murphy, A.W. (2006). The contribution of qualitative research in designing a complex intervention for secondary prevention of coronary heart disease in two different healthcare systems. BioMed Central Health Services Research **6**. doi:10.1186/1472-6963-6-90.

Creswell, J.W. (2003). Research Design; Qualitative, Quantitative, and Mixed Methods Approaches. Thousand Oaks/London/New Delhi: SAGE Publications, Inc.

Flottorp, S. and Oxman, A.D. (2003). Identifying barriers and tailoring interventions to improve the management of urinary tract infections and sore throat: a pragmatic study using qualitative methods. BioMed Central Health Services Research **3**. doi:10.1186/1472-6963-3-3.

Fransen, G.A.J., van Marrewijk, C.J., Mujakovic, S., Muris, J.W.M., Laheij, R.J.F., Numans, M.E., de Wit, N.J., Samsom, M., Jansen, J.B.M.J. and Knottnerus, J.A. (2007). Pragmatic trials in primary care; Methodological challenges and solutions demonstrated by the DIAMOND-study. BioMed Central Medical Research Methodology **7**. doi:10.1186/1471-2288-7-16.

Getrich, C., Heying, S., Willging, C. and Waitzkin, H. (2007). An ethnography of clinic "noise" in a community-based, promotora-centered mental health intervention. Social Science

& Medicine **65**(2): 319-330.

Godwin, M., Ruhland, L., Casson, I., MacDonald, S., Delva, D., Birtwhistle, R., Lam, M. and Seguin, R. (2003). Pragmatic controlled clinical trials in primary care: the struggle between external and internal validity. BioMed Central Medical Research Methodology **3**:28. doi:10.1186/1471-2288-3-28.

Harrison, S., Dowsell, G., Wright, J. and Russell, I. (2003). General practitioners' uptake of clinical practice guidelines: a qualitative study. Journal of Health Services Research & Policy **8**(3): 149-153.

Hawe, P., Shiell, A. and Riley, T. (2004). Complex interventions: how "out of control" can a randomised controlled trial be? British Medical Journal **328**(7455): 1561-1563.

Heaven, B., Murtagh, M., Rapley, T., May, C., Graham, R., Kaner, E. and Thomson, R. (2006). Patients or research subjects? A qualitative study of participation in a randomised controlled trial of a complex intervention. Patient Education and Counseling **62**(2): 260-270.

Heisey, R., Pimlott, N., Clemons, M., Cummins, S. and Drummond, S. (2006). Women's views on chemoprevention of breast cancer. Canadien Family Physician **52**: 624-625.

Hotopf, M. (2002). The pragmatic randomised controlled trial. Advances in Psychiatric Treatment **8**: 326-333.

Jansen, Y.J.F.M., Bal, R., Bruijnzeels, M., Foets, M., Frenken, H. and de Bont, A. (2006). Coping with methodological dilemmas; about establishing the effectiveness of interventions in routine medical practice. BioMed Central Health Services Research **6**:160. doi:10.1186/1472-6963-6-160.

Légaré, F., O'Connor, A.C., Graham, I., Saucier, D., Côté, L., Cauchon, M. and Paré, L. (2006). Supporting patients facing difficult health care decisions; use of the Ottowa Decision Support Framework. Canadien Family Physician **52**: 476-477.

McCormick, K.A., Cochran, N.E., Back, A.L., Merrill, J.O., Williams, E.C. and Bradley, K.A. (2006). How Primary Care Providers Talk to Patients About Alcohol; A Qualitative Study. Journal of General Internal Medicine **21**: 966-972.

Moffatt, S., Mackintosh, J., White, M., Howel, D. and Sandell, A. (2006). The acceptability and impact of a randomised controlled trial of welfare rights advice accessed via primary health care: qualitative study. BioMed Central Public Health **6**. doi: 10.1186/1471-2458-6-163.

Moffatt, S., White, M., Mackintosh, J. and Howe, D. (2006). Using quantitative and qualitative data in health services research – what happens when mixed method findings conflict? [ISRCTN61522618]. BioMed Central Health Services Research **6**. doi:10.1186/1472-6963-6-28.

MRC (2000). A framework for the development and evaluation of RCTs for complex interventions to improve health. London: Medical Research Council. 2000:18.

Rogers, A., Kennedy, A., Nelson, E. and Robinson, A. (2005). Uncovering the Limits of Patient-Centeredness: Implementing a Self-Management Trial for Chronic Illness. Qualitative Health Research **15**(2): 224-239.

Rogers, A., Oliver, D., Bower, P., Lovell, K. and Richards, D. (2004). Peoples' understanding of primary care-based mental health self-help clinic. Patient Education and Counseling **53**: 41-46.

Rousseau, N., McColl, E., Newton, J., Grimshaw, J. and Eccles, M. (2003). Practice based, logitudinal, qualitative interview study of computerised evidence based guidelines in primary care. British Medical Journal **326**(7384): 314.

Rowan, M.S., Hogg, W., Martin, C. and Vilis, E. (2006). Family physicians' reaction to performance assessment feedback. Canadien Family Physician **52**: 1570-1571.

Rowlands, G., Sims, J. and Kerry, S. (2005). A lesson learnt: the importance of modelling in randomized controlled trials for complex interventions in primary care. Family Practice **22**(1): 132-139.

Rowlands, G., Willis, S. and Singleton, A. (2001). Referrals and relationships: In-practice referrals meetings in a general practice Family Practice **18**(4): 399-406.

Saan, H. and de Haes, W. (2005). Gezond effect bevorderen. Het organiseren van effectieve gezondheidsbevordering. Woerden: NIGZ.

Sennun, P., Suwannapong, N., Howteerakul, N. and Pacheun, O. (2006). Participatory supervision model: building health promotion capacity among health officers and the community. Rural and Remote Health **6**.

Shuval, K., Shachak, A., Linn, S., Brezis, M., Feder-Bubis, P. and Reis, S. (2007). The Impact of an Evidence-Based Medicine Educational Intervention on Primary Care Physicians: A Qualitative Study. Journal of General Internal Medicine **22**: 327-331.

Smith, S.M., O'Leary, M., Bury, G., Shannon, W., Tynan, A., Staines, A. and Thompson, C. (2003). A qualitative investigation of the views and health beliefs of patients with Type 2 diabetes following the introduction of a diabetes shared care service. Diabetic Medicine **20**: 853-857.

Stange, K.C., Goodwin, M.A., Zyzanski, S.J. and Dietrich, A.J. (2003). Sustainability of a practice-individualized preventive service delivery intervention. . American Journal of Preventive Medicine **25**(4): 296-300.

Stewart, J., Brown, K., Kendrick, D. and Dyas, J.o.b.o.t.N.D.a.B.P.S.G. (2005). Understanding of blood pressure by people with type 2 diabetes: a primary care focus group study. British Journal of General Practice **55**: 298-304.

Sturt, J., Taylor, H., Docherty, A., Dale, J. and Louise, T. (2006). A psychological approach to providing self-management education for people with type 2 diabetes: the Diabetes Manual. BioMed Central Family Practice **7**. doi:10.1186/1471-2296-7-70.

Walsh, B., Yardley, L., Donovan-Hall, M. and Smith, H. (2007). Implementation of nurse-delivered vestibular rehabilitation in primary care: a qualitative study of nurses' views on involvement in a innovative service. Journal of Clinical Nursing **16**: 1072-1081.

Weiss, M.C., Montgomery, A.A., Fahey, T. and Peters, T.J. (2004). Decision analysis for newly diagnosed hypertensive patients: a qualitative investigation. Patient Education and Counseling **53**: 197-203.

Zuiderent, T. (2002). Blurring the Center; On the Politics of Ethnography. Scandinavian Journal of Information Systems **14**(2): 59-78.

4

The Role of Screenings Methods and Risk Profile Assessments in Prevention and Health Promotion Programmes: An Ethnographic Analysis

Abstract

In prevention and health promotion interventions, screening methods and risk profile assessments are often used as tools for establishing the interventions' effectiveness, for the selection and determination of the health status of participants. The role these instruments fulfil in the creation of effectiveness and the effects these instruments have themselves remain unexplored. In this paper, we have analysed the role screening methods and risk profile assessments fulfil as part of prevention and health promotion programmes in the selection, enrolment and participation of participants. Our analysis showed, that screening methods and health risk assessments create effects as they objectify health risks and/or the health status of individuals, i.e., they select the individuals 'at risk' and indicate the lifestyle modifications these people are required to make in order to improve their health. Yet, these instruments also reduce the group of participants thereby decreasing the possible effect of interventions, as they provide the legitimisation for people to make choices to whether they enrol or not and what lifestyle changes they incorporate into their lives. In other words, they present a space of interaction, in which agency is distributed across the practice nurses, the participants and the instruments. Decisions were not just made upon the projection of the outcomes of these instruments; decisions that were made by both the patients and practice nurses were the resultant of their opinions on these outcomes that were formed in interaction with the instruments.

Introduction

Scientific knowledge has increasingly become important in the development of prevention and health promotion interventions and legitimising the decisions on which interventions are considered relevant for public health policy (Porter 1995; Hunter 2003). And in the last decades, the scientific knowledge used has also become more and more sophisticated (cf. (May 2009)). With the growing knowledge about diseases and chronic illnesses, more became known about health determinants, health behaviours, risk factors and their distribution among populations. As the public health field uses and produces this kind of knowledge, it has contributed to this increasing sophistication. With its features being among others the collection and use of epidemiological data, population surveillance and other forms of empirical quantitative assessment (Childress, Faden et al. 2002), there is an increasing understanding of complex health determinants and emphasis on establishing the effectiveness of a broad range of interventions (see e.g. (Childress, Faden et al. 2002; Edwards, Mill et al. 2004; Shim 2005; Coughlin 2006)).

Tools that are often used for these purposes are screening methods and risk profile assessments. The screening methods and risk profile assessments function as 'technologies of trust' (cf. (Porter 1995)), as the numerical outcomes they produce have become associated with objectivity and legitimisation (Porter 1995; Bartholomée 2004). However, these tools or instruments are more than just measuring tools; they are components in the interventions like behavioural counselling or health education. In other words, screening methods and risk profile assessment are not neutral. Whereas these instruments create effects, they also reduce the target population and thereby decrease the effects. As they are used to screen and select risk groups for prevention and health promotion programmes, they legitimise medical intervention or treatment to be undertaken (cf. (Jansen 2010)) as they objectify the health status of individuals and remove it from all subjective interpretation and personal discretion. But at the same time, these same instruments decrease the effects. As these instruments are being used to screen and select individuals, eligible for intervention, they exclude individuals that do not match the criteria and reduce the target population thereby decreasing possible effects.

Sociologists have critiqued the emphasis on objectivity in medicine in general and in public health in particular. According to their arguments, the use of epidemiological knowledge and tools such as screening methods and risk profile assessments in medicine and public health define 'health' a matter of individual responsibility and control and therefore stigmatises and victimises selected individuals for having a disadvantaged or 'deviant' health status (Lupton 1993b; 1993a; 1997; Howson 1998; Bodenheimer, Lorig et al. 2002). In other words, with health to be considered a matter of one's self-control, individuals are summoned to live healthy lives, as it is the morally right thing to do. In fact, it is implied that one is to blame for one's future illnesses provided that one uses the epidemiological knowledge that is provided and one alters one's lifestyles accordingly. As Lupton has argued, such an approach to health assumes that people are 'passive patients' that need to be made aware - or better educated - of the prospective threats that are associated with their lifestyle choices and need to be assisted in altering their lifestyles (Lupton 1993b; 1993a; 1997). In addition, Horstman and Houtepen (Horstman and Houtepen 2005) have argued that this view, which has been dominant in critiques about public health, is itself criticised as it does not do justice to individual preferences and choice. In fact, it suggests that people do not have agency and

are victimised and stigmatised by prevention and health promotion programmes and their instruments, whereas health care professionals and participants in fact do have agency and voice.

In this paper, in addition to Lupton and others we focus on the functioning of screenings instruments and risk profile assessments and the role they fulfil in prevention and health promotion programmes, with that difference that we focus on the active role patients fulfil in the interpretation of such instruments and the outcomes and labels they produce. Questions we explore in this paper are: How do these instruments construct a target population for prevention and health promotion programmes as well as construct the health risks that should be targeted? How is the actual intervention shaped by the individuals that are detected by means of these instruments? How do these individuals interpret such instruments, their outcomes and labels? Answers to these questions might relativise Lupton's argument, that patients are victimised by the instruments used in prevention and health promotion interventions. The meaning and definitions patients give to instruments and the outcomes and labels they produce, have to be taken into account in order to come to understand the concept of effectiveness of prevention and health promotion interventions.

The emphasis on establishing effectiveness in prevention and health promotion is the result of its rationalised character (cf. (Jansen 2010; Mathar and Jansen 2010)), which underscores a univocal significance of 'effectiveness' of interventions. In a rationalistic approach, the effectiveness - or better the success of interventions - is reflected by the impact these interventions have on improving the health status of their participants. In successful interventions the well-aimed stimuli of health educational advice, are considered to result in behavioural change in participants in a linear way leading to the improvement of their health status. Alternative interpretations of what 'good health' or 'wellbeing' is according to participants are considered less or not important and subsequently become invisible, as these do not fit the parameters of the screening methods and risk profile assessments used in establishing the effectiveness of interventions. However, numerous interventions have shown no or minimal effects (Mackenbach and Stronks 2002; Uitewaal 2003; Mackenbach and Stronks 2004; Kooiker and van der Velden 2007). And often this lack of effectiveness is classified as a problem of performance (see e.g. (Rousseau, McColl et al. 2003; Blasinsky, Goldman et al. 2006; Getrich, Heying et al. 2007) in (Jansen, Foets et al. 2009)).

Whereas Lupton and others have placed themselves in opposition to medicine in general and public health in particular, in this paper we do not look at prevention and health promotion from a normative point of view nor do we look at it as a 'problem of performance'. We try to overcome these aforementioned approaches and engage with prevention and health promotion by taking the internal dynamics and logics of medicine in practice seriously (cf. (Timmermans and Haas 2008)). In order to take both the 'problems' of effectiveness and performance seriously the screening methods and risk profile assessments need to be followed.

Research Methods

The Quattro Study[4]

The data presented here comes from an ethnographic study that paralleled the Quattro Study, which was a pragmatic randomised controlled trial on the effectiveness of multidisciplinary patient care teams in primary care for the secondary prevention of cardiovascular diseases (CVD) administered in primary health care centres in deprived neighbourhoods or Rotterdam and The Hague, the Netherlands. The intervention consisted of the formation of a Quattro-care team in general practice composed of a general practitioner (GP), a GP assistant, a practice nurse and a peer health educator for the provision of intensified preventive care to high-risk patients. This intensified preventive care consisted of patient-tailored health education about the risk factors associated with CVD, such as hypertension, diabetes mellitus, hypercholesterolemia, smoking and obesity provided by the practice nurse and/or peer health educator. Structural CVD risk profile assessments, containing physical examinations of weight, height and blood pressure and blood tests on cholesterol and glucose levels, were used to assess the intervention participants' risk profiles. And multidisciplinary team meetings, to be organised by the Quattro-care team professionals, functioned as a manner for jointly establishing treatment plans for intervention participants and monitor the reduction in their risk profiles based on the particular knowledge and abilities of each professional.

In order to evaluate the effectiveness of multidisciplinary patient care teams in primary care, the intervention followed the procedures of a pragmatic randomised controlled trial (RCT), which aimed to measure the effectiveness of the intervention under natural - non-experimental - conditions. For this programme, the trial researchers selected patients from the centres' electronic patient records with a modifiable part of the absolute 10-year risk on cardiovascular diseases (CVD) of at least 20%. People eligible for the Quattro Study [1] had to live in deprived neighbourhoods, as defined by the Dutch National Association of General Practitioners (LHV); [2] were to be aged between 18 and 70 years of age; [3] have a medical history of one or more risk factors for cardiovascular diseases (CVD) (e.g. smoking; obesity); [4] a first degree relative with a history of CVD before his/her 60th birthday; hypertension; hypercholesterolemia; Diabetes Mellitus type II; myocardial infarction; angina pectoris; peripheral arterial disease, heart failure, CVA or TIA.; and [5] having an absolute 10-year risk for CVD, higher than 20% after blood tests and physical examinations at baseline (document selection criteria addendum 2).

Eligible patients were randomly assigned to three groups. Patients in the intervention group obtained Quattro-care and three monthly assessments of their risk profile for CVD. Patients from the first control group (A) received usual GP care and three monthly risk assessments and the GP as well as the patient were informed about the results of these measurements. It was thought to be ethically and practically unacceptable to assess a risk profile and not to inform the patient and GP about the results. However, this approach of assessing risk and informing patients and GP was thought to interfere with daily practice and bias the results. Therefore, a second blinded control group (B) was needed to quantify the effect of the risk assessments. This group received usual GP care and was measured once at

4 For a more elaborate description of the intervention, study methods including its methodological justification and overviews of its results see: El Fakiri (El Fakiri 2008).

the end of the study. The research team assessed the effectiveness of the multidisciplinary collaboration with the returned patient monitoring data by comparing patients from the intervention group with those from the first control group after 1-year follow-up with regard to the reduction achieved in the 10-year absolute risk of developing CVD. The second control group, aimed to quantify the effect of structured risk profile assessments performed in the first control group, was compared with the first control group.

The Ethnographic Study

In order to analyse how this prevention programme was shaped in practice, we observed how the practice nurses provided the patient-tailored health education and performed the structural CVD risk profile assessments and how these facilitated the patients in achieving lifestyle modifications. By means of participant observations (Spratley 1980; Creswell 2003), we observed four out of seven practice nurses assigned to the project in their daily work, each for five workdays each, from April 2003 till December 2004. One practice nurse refused cooperation; one practice nurse was on maternity leave and one was not yet in function. During the observations no notes were made, because note taking was felt to intrude on the interactions between the practice nurses and their patients and colleagues. During these observations a total of 63 patient consultations were attended. Because of the recurrent nature of the programme's follow-up, the observations also contain succeeding follow-up consultations of patients. Fieldnotes were made immediately after leaving the health care centres. Throughout each observation it was possible to ask questions or to request clarification. In addition, a total of five interviews were held with the practice nurses: two non-audio-taped semi-structured face-to-face interviews due to objections to audio-taping and three audio-taped semi-structured face-to-face interviews. The interviews were held at the health care centres and lasted approximately one and a halve hour. In all interviews, the practice nurses were asked about their experiences with the Quattro programme, their dealings with patients in the programme and their activities in the primary health care centres. All interviews were transcribed immediately after the interviews.

The patients in the observed consultations were invited to take part in the Quattro programme, as they were all at high risk for developing CVD and not yet properly managed for hypertension, hypercholesterolemia and/or diabetes mellitus type II. All patients were registered at the health care centres and were living in the deprived neighbourhoods the health care centres provided their services to. During the patients consultations observations were made about how both the practice nurses and patients participated in this health promotion programme. Whenever possible, informal conversations with the patients took place about the possibility and difficulties incorporating the recommended lifestyle adjustments into their lives. With three patients audio-taped semi-structured face-to-face interviews were held to go more in-depth into their motives for participating in prevention programmes and the difficulties participation may portray. The interviews lasted approximately one hour and were held at the patients' homes. The interviews were transcribed immediately after the interviews.

In this study the process of analysis took place in a cyclic manner. Emerging insights and themes were jotted down, and were taken into account during succeeding observations, interviews and final analysis. During the final analysis, all transcripts, written records, and personal jot notes were analysed more in-depth. We analysed all information thematically, establishing overarching categories through identifying and coding all pieces of information. By means of developing overarching categories (taxonomy) overall descriptions of the information could be made in more general terms.

Results

The Role of Inclusion Criteria in the Selection and Enrolment of Eligible Individuals

We start our analysis of the role of screening methods and risk profile assessments by looking at the selection of people eligible for prevention interventions. Screening methods and risk profile assessments are not neutral. What we saw in our ethnographic study was interaction between the inclusion criteria as example of such instruments and selected individuals. The inclusion criteria did not determine which individuals participated and which did not. The selected individuals were seen to have an active role in the selection and enrolment of the intervention and therewith they related to the inclusion criteria. The inclusion criteria were part of the individuals' legitimisation to enrol or to reject their participation. Enrolment or rejection of participation thus was more than just the projection of the individuals' opinion on the outcomes of the inclusion criteria; enrolment or rejection of participation was the resultant of the individuals' opinion that was formed in interaction with the inclusion criteria.

For the selection of people eligible for the Quattro intervention, the inclusion criteria were important as they explicated the risk to CVD people had and indicated the danger of having a CVD event in future. The inclusion criteria enrolled only those individuals who were identified with the risk to CVD. What we saw was that people actively negotiated the identity of patienthood the inclusion criteria ascribed them.

> 'what does a 15% risk for CVD matter when I am feeling well'. […] the patients with diabetes […] they clearly have diabetes; a high sugar level, that is more concrete to deal with (interview practice nurse 27-01-2006)

In fact, the inclusion criteria legitimatised the decision to enrol into the prevention programmes or not. The inclusion criteria thus created effects, as people enrolled into the intervention, and at the same time they reduced the group of eligible people thereby decreasing the ultimate effect. In the Quattro programme people enrolled as "they thought that their GP had registered them for the study; that they were screened by their GP. They found it was important to take part, as they thought they had a high risk" (interview practice nurse 27-01-2006). The fact that these people had become selected for the Quattro programme suggested that their enrolment was important as they were 'at risk'. The individuals who enrolled, identified themselves with the danger to their health these inclusion criteria portrayed, as well as identified themselves with the classification of patienthood the inclusion criteria ascribed them.

On the other hand, the inclusion criteria also obstructed individuals to take part in the intervention. In fact, the individuals who felt they were defined as people they felt they were not declined their enrolment. For example, one of the people selected to take part in the trial refused to participate in the trial, because he refused being defined as ill. The man, in his mid-thirties and hardly home from work at four o'clock p.m., explained, while sitting on his couch smoking his hand-rolled tobacco, he had taken blood pressure lowering medication in a very stressful period of his life in which he had to deal with losing his job that caused the rise of his blood pressure levels. "But now I don't take these pills anymore, because that stressful period is over. So, I don't think it is necessary for me to take part" (observation patient selection fase May 2003). Others refused to participate in the programme, as a nurse

explained, "because they fiercely objected to the fact they were assumed to live in deprived neighbourhoods. They felt they were defined as people they felt they were not" (observation data manager 28-02-2006).

> The south of Rotterdam indeed has some bad neighbourhoods, but would you define this neighbourhood in which the houses sell for up to 400.000 euros a deprived neighbourhood? That's why I don't agree seeing the south of Rotterdam as a deprived neighbourhood (interview patient 14-03-2006)

The enrolment of eligible individuals into interventions can thus be understood as the result of individuals actively accepting or rejecting the definition of patienthood and/or as living in deprived neighbourhoods that these inclusion criteria ascribe to them. The use of inclusion criteria as a method for selecting and enrolling individuals in prevention programmes legitimises the decision to enrol into prevention programmes. On the one hand, the inclusion criteria create effects, as they objectify the individual risk to health individuals have by explicating the conditions that make up that risk, like their genetic make-up and/or physical condition and the neighbourhoods with its related lifestyles people live in. Yet, the inclusion criteria reduce the group of eligible people and thus decrease the possible effect of the intervention. The inclusion criteria do not select and enrol all individual who are considered eligible based upon the health risks they have, they only select those individuals 'at risk' that identify with the construction made and are open to adapting their lifestyles to the requirements of the prevention programmes. People thus demonstrate their agency and voice, as they actively decide whether to enrol into prevention programmes or not. And the inclusion criteria provide them the legitimisation for their decision.

The Role of Structural Risk Profile Assessments in the Course of Prevention Programmes

In the course of prevention programmes, the same movement of creating effects and at the same time decreasing possible effects can be seen for structural risk profile assessments. The structural risk profile assessment did not determine how the patients participated and adapted their lifestyle behaviours or not. Also during the course of the prevention intervention patients were seen to have an active role and therewith they related to the structural risk profile assessments. In fact, the structural risk profile assessments were part of the legitimisation to adapt treatment to the personal circumstances of patients or for patients to adopt the recommended lifestyle behaviours or not. Actual treatment and behavioural change was the resultant of the opinion that were formed in interaction with the inclusion criteria.

In the Quattro Study, the three-monthly structural CVD risk profile assessments (re) established the anticipated chance of having a CVD event in future. Through measuring a patient's weight, length and blood pressure and issuing blood tests on cholesterol and glucose levels, the risk for CVD is defined as the conglomerate of various characteristics of the individual's biology and lifestyle that are to be considered traits or advantages to health. As a practice nursed explained:

> Risk factors become more and more important. […] When a patient has a blood pressure over 160 mmHg, you not only look at the height of his blood pressure, you also have to look at other risk factors, like e.g. age, weight, length, smoking and cholesterol. […] Registering is here of utmost importance. First you have to

> gather all the data before you can calculate the absolute risk profile of patients (observation researcher 09-03-2004)

The CVD risk profile also defines which parts of the risk for CVD are changeable through lifestyle modifications and which are not. For example: "a patient's age and gender […] are not modifiable; they are fixed variables in the risk for CVD" (interview researcher 26-01-2006). Whereas the individual's biology is genetically determined, the other variables in the risk for CVD - a person's weight, blood pressure, cholesterol and glucose levels - are modifiable through diet, physical exercise and smoking cessation. Lifestyle, however, does not let itself modify that easy as it involves the continuous abandonment of habits and lifestyle patterns that have been there for long. In other words, with the structural risk profile assessments explicating the unique constellation of a patient's risk for CVD, these assessments drive an individualised management of risk. The personal problems participants have to deal with on a daily basis determine the extent of the improvements in their health. As a practice nurse illuminated:

> The practice nurse is the person for that inventory. […] A GP doesn't see the real problems patients deal with; he only sees e.g. a high blood pressure and not the patients' daily personal problems. To be able to supervise these patients, a practice nurse needs to understand these problems patients deal with (observation intervention progress meeting 20-04-2004)

The structural assessment of participants' risk profiles created effects as they visualised the risk behaviours that made up participants' risk profiles. And at the same time, as the structural risk profile assessments measured the effect of the individualised management of risk on the reduction of the CVD risk in participants, they reduced the possible impact of the intervention as they allowed for the adaptation of the treatment plans depending upon the outcomes of the measurements. Although this was not intended in the original design of the intervention, the risk profile assessments allowed the practice nurses to create a hierarchy in risk factors in individual participants, as they believed not all risk factors could be tackled all at once. In fact, the risk profile assessments made it possible to change those risk behaviours that made up participants' risk profile in which reductions in CVD risk could be achieved with minimal efforts. In other words, the practice nurses negotiated the original purpose of the risk profile assessments as this was not workable in daily practice.

What we saw in participants was that, as these assessments visualised the progress participants were able to make in reducing their CVD risk and improving their health status, they functioned as a motivator for achieving the recommended lifestyle changes. In other words, these assessments created effects as they monitored the effects of the patients' lifestyle choices. For example:

> *The practice nurse* puts on the cuff and starts taking the patient's blood pressure. Both the patient and the practice nurse look at the sphygmomanometer. When she is finished, she takes off the cuff and writes the results on a piece of paper. 'Is it alright now?' the man asks. The practice nurse nods her head and says it looks fine (observation patient consultation 04-11-2004)

And as a patient tells one of the practice nurses about losing weight:

> 'Indeed, you have lost almost three kilos in two weeks' time. How do you keep up?' The female patient tells she does follow a diet since two weeks now […] 'Good, and your kids?' 'They get their own food'. The female patient twinkles when she is telling the practice nurse. 'It feels good. My clothes do fit much better already.' And she lifts up her dress by the shoulder seams […] (observation patient consultation 14-07-2004)

Yet, we also saw that these structural risk profile assessments reduced the groups of patients adopting new lifestyle behaviours and thereby decreasing the ultimate effect of the intervention. In fact, the patients negotiated the lifestyle modifications that the structural risk profile assessments envisaged in order to reduce the risk of cardiovascular diseases. As the structural risk profile assessments visualised their CVD risk profile as a conglomerate of risk factors, these assessments enabled them to make choices in the behavioural changes they were recommended to make and in what order. For example as illustrated in a fragment: "I regularly walk the dog now and take my medication when I'm supposed to, but I still eat my usual mash. I don't like the extra fuss. I told the practice nurse from the beginning I'm not changing that!" (conversation patient 14-07-2004). So, the risk profile assessments as they objectify the risk to CVD have effects and construct the behaviour of patients. These assessments thus prove to be a constructive force. On the one hand, they motivate patients to continuously achieve improvements in their health. On the other hand, they decrease the ultimate effect of prevention interventions as these assessments give patients agency and voice, as they are facilitated to actively decide upon the lifestyle changes they want to incorporate into their lives.

Discussion

In this paper, we analysed the role screening methods and risk profile assessments fulfil as part of a prevention and health promotion programme in the selection, enrolment and participation of participants. Our analysis showed, that screening methods and risk profile assessments create effects as they objectify health risks and/or the health status of individuals, i.e. they select the individuals 'at risk' and indicate the lifestyle modifications these people are required to make in order to improve their health. Yet, these instruments also reduce the group of participants thereby decreasing the possible effect of interventions, as they provide the legitimisation for people to make choices to whether they enrol or not and what lifestyle changes they incorporate into their lives. The outcomes of the risk profile assessments function as a tool for participants for making these choices. The assessment of participants' risk profiles present the risk to health as a collection of smaller parts, from which participants are enabled to choose the changes to their lifestyles. In other words, these instruments present a space of interaction, in which agency is distributed across the practice nurses, the participants and the risk profile assessments. Decisions were not just made upon the projection of the outcomes of these instruments; decisions that were made by both the patients and practice nurses were the resultant of their opinions on these outcomes that were formed in interaction with the instruments.

Our results have two important implications. Firstly, prevention and health promotion programmes have a more limited outreach than is assumed when interventions are developed. Such programmes only exhort a selective group of their target populations to participate. In addition to Howson (Howson 1998), who argued that screening methods and risk profile assessment are instruments of inclusion and exclusion, screening methods and risk profile assessments only include those people that identify with the construction of patienthood that is made. Those people who do not identify with the construction are excluded but may very well benefit from health promotional activities too.

Secondly, the effects of screening methods and risk profile assessments generated in prevention and health promotion programmes should be considered as effects of such interventions. The use of scientific knowledge and method feeds the notion that improvement in health can be rationalised and numerically established and is the only objective proof of the interventions' effectiveness, as the effectiveness is evaluated through comparing the new interventions and/or treatments versus regular care. Subsequently, this leaves no room for other effects - i.e., the positive effects of risk profile assessments on health improvement in prevention interventions [8, 9] - that are found in interventions, as they simply do not count as genuine effects. These effects are considered merely part of regular care of which the effectiveness is not evaluated. Result of such a narrow focus on effectiveness is that the aforementioned effects thus remain invisible, as they are considered outside of the scope of the evaluations.

We therefore argue, in concordance with Horstman and Houtepen (Horstman and Houtepen 2005), that in order to establish the effectiveness of interventions pragmatic forms of evaluation should be applied. Pragmatic evaluations provide the opportunity to broaden up the scope of effectiveness in evaluations in which all effects of interventions can be incorporated and can be classified as effects of the interventions. Pragmatic evaluations allow for the incorporating of multiple evaluation methods (Nutbeam 1998; Tones 2000) that allow for the incorporation of the ongoing dynamics in interventions when performed in practice, as interventions will always be localised and contextualised in practice (Tones 2000; Jansen, Foets et al. 2009). The way in which screening methods and risk profile assessments construct behaviour thus can than also be evaluated as genuine effects of prevention and health promotion interventions.

In conclusion, it is our contention that there should be more attention and appreciation for the role screening methods and risk profile assessments fulfil in generating health effects. Therefore, a broader notion of effectiveness should be obtained in prevention and health promotion. Moreover, screening methods and risk profile assessments fulfil an important role in the empowerment of patients, as these instruments legitimise decisions on enrolment, participation and behavioural change and facilitate them to make autonomous decisions about their care.

References

Bartholomée, Y. (2004). Society as a Laboratory; Donald T. Campbell and the history of social experimentation. Psychologische, Pedagogische en Sociologische Wetenschappen. Groningen: Rijksuniversiteit Groningen. [doctoral thesis].

Blasinsky, M., Goldman, H.H. and Unutzer, J. (2006). Project IMPACT: A Report on Barriers and Facilitators to Sustainability. Administration and Policy in Mental Health and Mental Health Services Research **33**(6): 718-729.

Bodenheimer, T., Lorig, K., Holman, H. and Grumbach, K. (2002). Patient Self-management of Chronic Disease in Primary Care. Journal of American Medical Association **288**(19): 2469-2475.

Childress, J.E., Faden, R.R., Gaare, R.D., Gostin, L.O., Kahn, J., Bonnie, R.J., Kass, N.E., Mastroianni, A.C., Moreno, J.D. and Nieburg, P. (2002). Public Health Ethics: Mapping the Terrain. Joumal of Law, Medicine & Ethics **30** 170-178.

Coughlin, S.S. (2006). Ethical issues in epidemiologic research and public health practice. Emerging Themes in Epidemiology **3**:16. doi:10.1186/1742-7622-3-16.

Creswell, J.W. (2003). Research Design; Qualitative, Quantitative, and Mixed Methods Approaches. Thousand Oaks/London/New Delhi: SAGE Publications, Inc.

Edwards, N., Mill, J. and Kothari, A.R. (2004). Multiple intervention research programs in community health. Canadian Journal of Nursing Research **36**(1): 40-54.

El Fakiri, F. (2008). Prevention of cardiovascular Diseases in Deprived Neighbourhoods. Institute Health Policy and Management. Rotterdam: Erasmus MC Rotterdam. [doctoral thesis].

Getrich, C., Heying, S., Willging, C. and Waitzkin, H. (2007). An ethnography of clinic "noise" in a community-based, promotora-centered mental health intervention. Social Science & Medicine **65**(2): 319-330.

Horstman, K. and Houtepen, R. (2005). Worstelen met gezond leven: ethiek in de preventie van hart-en vaatziekten. Amsterdam: Het Spinhuis.

Howson, A. (1998). Surveillance, knowledge and risk: the embodied experience of cervical screening Health **2**(2): 195-215.

Hunter, D.J. (2003). Public Health Policy. Cambridge: Polity Press.

Jansen, Y.J.F.M. (2010). The taming of chance and the actual practice of prevention; rationalised prevention and 'the social'. In: Health Promotion and Prevention Programmes is Practice; How Patients' Health Practices are Rationalised, Reconceptualised and Reorganised. Mathar, T. and Jansen, Y.J.F.M. (eds.). Bielefeld: Transcript Verlag. pp. 147-169.

Jansen, Y.J.F.M., Foets, M.M.E. and de Bont, A.A. (2009). The contribution of qualitative research to the development of tailor-made community-based interventions in primary care: a review. European Journal of Public Health.

Kooiker, S. and van der Velden, K. (2007). Een nuchtere kijk op gezond gedrag; Vier thema's voor gezondheidsbevordering. Den Haag: Sociaal en Cultureel Planbureau. ISBN: 978-90-377-0280-4.

Lupton, D. (1993a). The Construction of Patienthood in Medical Advertising. International Journal of Health Services **23**(4).

Lupton, D. (1993b). Risk as Moral Danger: the Social and Political Functions of Risk Discourse in Public Health. International Journal of Health Services **23**(3): 425-435.

Lupton, D. (1997). Consumerism, reflexivity and the medical encounter. Social Science &

Medicine **45**(3): 373-381.
Mackenbach, J.P. and Stronks, K. (2002). A strategy for tackling health inequalities in the Netherlands. Britisch Medical Journal **325**(7371): 1029–1032.
Mackenbach, J.P. and Stronks, K. (2004). The development of a strategy for tackling health inequalities in the Netherlands. International Journal for Equity in Health **3**. doi:10.1186/1475-9276-3-11.
Mathar, T. and Jansen, Y.J.F.M. (eds.). (2010). Health Promotion and Prevention Programmes is Practice; How Patients' Health Practices are Rationalised, Reconceptualised and Reorganised. VerKörperungen/MatteRealities - Perspektiven empirischer Wissenschaftsforschung. Bielefeld: Transcript Verlag.
May, C. (2009). Mundane Medicine, Therapeutic Relationships, and the Clinical Encounter: Current and Future Agendas for Sociology. In: Handbook of the Sociologcy of Health, Illness, & Healing: A Blueprint for the 21st Century. Pescosolido, B., Martin, J.K., McLeod, J.D. and Roggers, A. (eds.). New York: Springer.
Nutbeam, D. (1998). Evaluating health promotion - progress, problems and solutions. Health Promotion International **13**(1): 27-44.
Porter, T.M. (1995). Trust in Numbers; The Pursuit of Objectivity in Science and Public Life. Princeton, New Jersey: Princeton University Press.
Rousseau, N., McColl, E., Newton, J., Grimshaw, J. and Eccles, M. (2003). Practice based, logitudinal, qualitative interview study of computerised evidence based guidelines in primary care. British Medical Journal **326**(7384): 314.
Shim, J.K. (2005). Constructing 'Race' Across the Science–Lay Divide: Racial Formation in the Epidemiology and Experience of Cardiovascular Disease Social Studies of Science **35**(3): 405-436.
Spratley, J.P. (1980). Participant Observation. Fort Worth/Philadelphia/San Diego/New York/ Orlando/Austin/San Antonio/Toronto/Montreal/London/Sydney/Tokyo: Harcourt Brace College Publishers.
Timmermans, S. and Haas, S. (2008). Towards a sociology of disease. Sociology of Health & Illness **30**(5): 659-676.
Tones, K. (2000). Evaluating health promotion: a tale of three errors. Patient Education and Counseling **39** (2-3): 227-236.
Uitewaal, P.J.M. (2003). Type 2 Diabetes Mellitus and Turkish Immigrants: an educational experiment in general practice. Institute Health Policy and Management. Rotterdam: Erasmus MC Rotterdam. [doctoral thesis].

5

The taming of chance and the actual practice of prevention; rationalised prevention and 'the Social'

Introduction

The practice of prevention has increasingly become rationalised over the years (Porter 1995; Hunter 2003). As in prevention programmes in general, science and statistics have become part and parcel of the prevention of cardiovascular diseases (CVD). The prevention of cardiovascular diseases is becoming rationalised. And for some time now, the notion of health risk has been a central concept. One reasons for this is, firstly, a changing perception of nature, body and disease from the nineteenth century onwards. As Hacking (1990) has shown, since a new manner of scientific reasoning based upon statistics came into being in the nineteenth century, prevention and health promotion programmes have become about the 'taming of chance'. Aided by statistics and the explanatory power of statistical patterns, the idea grew that nature could be mastered and controlled by science (Porter 1995). With this shift in scientific reasoning, nature was no longer perceived to be deterministic in character, but became perceived as predictable and controllable. In other words, scientific and statistical information about diseases and conditions was - and still is - perceived to generate the possibility to control diseases and even eradicate them (Armstrong 1995).

A second reason for the rationalisation of the prevention of cardiovascular diseases is the rise of 'risk factor epidemiology'. Aronowitz (1998) showed, that with the Framingham Heart Study in the 1950's 'health risk' emerged as a concept, that quickly invaded mainstream medical thinking of and practice on cardiovascular diseases. The notion of health risk has become important, as it provides the information about the chance of hazard – or risk – to health caused by cardiovascular diseases in individuals in terms of probabilities (Carter 1995). In fact, the notion of health risk renders cardiovascular diseases to be known or knowable and thus preventable (cf. (Bunton, Nettleton et al. 1995), as it portrays the probability of cardiovascular events in people in future. Whereas in the pre-risk factor era cardiovascular diseases were considered "not preventable at the present time", contemporary approaches stress that cardiovascular diseases are preventable by identifying and intervening in the modifiable risk factors such as smoking, high blood pressure and high cholesterol (Aronowitz 1998).

The rationalisation and enumeration of prevention allow for the grasping of people's health and their risk for CVD in quantifiable terms (Carter 1995; Gabe 1995b; 1995a). Risk profile assessments produce numerical outcomes of an individual's health status that are considered

objective, neutral, and removed from all subjective interpretation. Because of a growing 'trust in numbers' (Porter 1995) in prevention, scientifically gathered numerical outcomes have become associated with objectivity, neutrality and legitimisation of treatment. In other words, as risk profile assessments measure and objectify the health status of individuals, they enable the classification of individuals as 'deviant' in respect to their health status and legitimise medical intervention or treatment to be undertaken (Howson 1998). For example, individuals with a blood pressure above the norm tension of 140/90 mmHg measured over a longer period of time are considered 'hypertensive' and at risk for cardiovascular diseases. These numbers indicate hypertension and legitimise treatment with blood pressure-lowering medication. The rationalisation and enumeration of prevention thus allow to diagnose the health of individuals, that are 'at risk' for CVD and perceived to be 'deviant' in respect to their health status compared to other individuals (Hacking 1990).

With the best of intentions, a rationalistic approach does hold a deterministic notion towards health. The rationalistic approach in prevention is based upon the idea that nature can be mastered and controlled by science (Porter 1995). It is based upon the idea that nature's hazards can be countered rationally (Carter 1995; Gabe 1995b; 1995a) and diseases can be fought with technoscience. It assumes that once the scientific and numerical information on health risks is known, diseases can be intervened upon scientifically and restored by medicine (Scott and Freeman 1995). Such a view underscores a belief in a kind of medicine that is scientific and determines peoples' behaviours, health, and the outcome of diseases. Moreover, it suggests a deficit in knowledge in relation to health in ordinary people. It assumes that ordinary people have to be assisted and educated about health and health risks (cf. (Lupton 1993)), as medicine is believed to know best. This belief in the deficit model of the public understanding of scientific medical knowledge is embedded in contemporary approaches in health promotion. It is based upon the modern idea of the economical and rational individual that acts upon the information it gathers. It assumes that as once individuals are provided with the necessary scientific and numerical information on health risks; the risks of different choices in life can be compared and decided upon rationally. And when rationally weighting the costs and benefits of these choices in life, those lifestyles are chosen that result in 'good' health. According to Hacking (1990), this is a salient side-effect of the rationalisation and enumeration of prevention and health promotion. Individuals are submitted to an increasing control and intervention upon their health and have less freedom in determining their lifestyles.

Prevention and health promotion programmes reflect such a rationalistic and deterministic approach to health. In fact, they are set up to exhort people to make the necessary lifestyle changes in their lives. For example, the prevention of cardiovascular disease is set up not only to just provide the scientific and numerical health risk information. These programmes are also set up to improve the knowledge of individuals about the interrelatedness of cardiovascular disease and lifestyles, and to change the individuals' attitudes, self-efficacy expectations and awareness of one's behaviour. In other words, a rationalistic approach to health suggests that providing individuals 'at risk' for CVD with sufficient scientific, numerical information and teaching them the skills to interpret and manage this information, individuals will act rationally and start living healthy lifestyles. As is the case in prevention and health promotion programmes in general, the prevention of cardiovascular diseases can thus be characterised as providing individuals with the necessary information on health and health risks and making it easier for them to take responsibility

and control over their own condition and solve their health problems (Bodenheimer, Lorig et al. 2002).

The Dutch Quattro Study project is an example of a prevention programme that employed a rationalistic approach to cardiovascular health. The project was set up to evaluate the effectiveness of multidisciplinary prevention of cardiovascular diseases in primary health care for patients 'at risk' for cardiovascular diseases (CVD) in deprived neighbourhoods. In order to establish sustainable lifestyle modifications in ›at risk‹ patients, the project had taken up an individual-oriented approach. Treatments and health advice were tailored to individuals and their unique risk profiles. However, despite the efforts, the researchers concluded that the Quattro Study project had a limited effect (El Fakiri 2008; El Fakiri, Hoes et al. 2008). After one year follow-up reductions in the risk for CVD were observed but these were not considered significant. In fact, it was concluded that the health education activities provided within the programme did not result in significant reduction in cardiovascular risk (El Fakiri 2008). In a process evaluation, the Quattro Study researchers suggested that the lack of effectiveness was the result of the low commitment to the programme of both health care professionals and participants (El Fakiri, Hoes et al. 2008). The health care professionals and the participants in these interventions had not been participating as expected; health care professionals had not delivered the interventions as planned, and participants were not compliant with the interventions as expected.

The limited results of the Quattro Study, however, are not unique in this respect. Also other prevention programmes targeting cardiovascular diseases in the Netherlands report such disappointing results (see e.g. (Ronda 2003; Ronda, van Assema et al. 2004; Harting 2005; Harting, van Assema et al. 2006; Kloek, van Lenthe et al. 2006)). In the literature, though, numerous authors have argued that a solution to this lack of effectiveness of such prevention and health promotion programmes can be overcome by forcing health care professionals to better perform the interventions in daily care as planned and better urge participants to better comply with the requirements of these programmes (see e.g. the process evaluations in (Jansen, Foets et al. 2009)).

This current state of affairs points to an interesting conflict that exists within prevention and health promotion in general and in the prevention of cardiovascular diseases in particular: Although prevention and health promotion programmes exhort individuals to make the necessary lifestyle changes in their lives, they do not have that effect. When performed in practice prevention and health promotion programmes often work out differently than expected. Moreover, the "messiness" of daily practice is considered to cause these programmes to fail. Considering this "messiness" an epiphenomenon or confounder of the programme rather than an integral part of it, is the result of the deterministic perspective that is embedded in the rationalistic approach to health in prevention and health promotion. This perspective portrays *ideal types* of prevention and does not do justice to the actual character of prevention and health promotion practice. In order to try and understand what happens in the practice of prevention and health promotion programmes, in this chapter I use concepts from Science and Technology Studies (STS) to analyse how the Quattro Study programme was actively shaped in practice by the health care professionals and participants.

STS have formulated a critique to the technological determinism that exists in modern, rationalised societies. Rather than arguing that 'technology' determines its use and purpose it is used for and that its development follows a preset path, STS acknowledge that 'society' plays an important role in the construction of technology and the subsequent form

it takes. 'Technology' and 'the social' are not seen to be separate entities, but are considered to be in constant interaction and therefore they mutually shape each other. STS have argued that technological determinism is wrong and is empirically incorrect as it denies the role 'the social' has in influencing the development and construction of technology (van der Ploeg 2007). In fact, it is said not to provide a sufficient explanation for the ever-present variability in medical practice after implementation of technologies, like programmes for the prevention of cardiovascular risk. If preventive interventions did determine the effects or impact they have in medical practice, than their implementation would result in the desired effects irrespective of the medical settings within which these interventions are implemented. In other words, if this manner of reasoning was correct, implementing prevention and health promotion programmes would be successful in reducing the cardiovascular risk in individuals in society. Moreover, STS have argued that – in order to show how 'technology' and 'the social' mutually shape each other – one should study the informal processes underlying the actual use of these technologies in medical practice (Berg 1995). Therefore, I have conducted an ethnographic case study of the aforementioned Quattro Study, in which I studied what the project comprised, and how the project's researchers, primary health care professionals and participating patients mutually shaped the intervention, and influenced the intervention's delivery and its outcomes. The ethnographic case study design enabled to study how the project's researchers developed and evaluated the intervention, how the intervention was delivered in primary health care practices and how both health care professionals and patients actually participated in the intervention.

The Quattro Study

The Quattro Study was a multi-centred pragmatic randomised controlled trial on the effectiveness of multidisciplinary care teams in primary care for the secondary prevention of cardiovascular diseases (CVD) administered in primary health care centres in deprived neighbourhoods or Rotterdam and The Hague, the Netherlands. In contrast to conventional randomised controlled trials (RCT), like Jonvallen discusses (Jonvallen 2010), pragmatic randomised controlled trials establish the effectiveness of interventions under routine conditions (Armitage 1998; Hotopf 2002), in which they allow for interventions to incorporate variations in practice at the different sites and allow for targeting a heterogeneous patient population. Conventional RCTs, on the other hand, require interventions to be standardised, to be implemented uniformly among sites and to target a homogenous patient population in order to evaluate the effectiveness of interventions. The Quattro Study specifically targeted people living in deprived neighbourhoods, as the prevalence of cardiovascular risk factors is higher among individuals with a low socio-economic status and ethnic minorities than among the indigenous Dutch population (Kloek, van Lenthe et al. 2006; El Fakiri 2008). Moreover, as the cardiovascular risk consists of the non-modifiable risk factors age and sex, and modifiable risk factors, such as cholesterol, systolic blood pressure, obesity and smoking (El Fakiri 2008), the intervention aimed to achieve risk reduction in modifiable risk factors.

Primary health care was considered the best setting for providing the intervention. In the Netherlands, almost all patients are registered within a general practice and the general practitioners (GPs) act as a gatekeeper in the Dutch health care system (El Fakiri 2008). The core of the Quattro Study was the structural collaboration between a practice nurse, a peer health educator, the GP, and an assistant (hence Quattro care) in providing intensified preventive

care[5]. Multidisciplinary patient care teams were thought to improve the quality of care in general practice, as they are seen as a means of relieving the workload of GPs and to assist them in providing preventive activities (Steptoe, Doherty et al. 1999; Cullum, Spilsbury et al. 2005; Raftery, Yao et al. 2005; Callahan, Boustani et al. 2006; Rosemann, Joest et al. 2006). GPs in deprived neighbourhoods have a great deal of information about patients, but – due to their high workload – do not use this information for case-finding and secondary prevention. They lack the time and the organisation to actively invite people for regular follow-up and risk profile assessments (Lobo, Frijling et al. 2003; VWS 2005).

Before participants were enrolled in the intervention, individuals aged between 30–70 years with one or more registered risk factors for CVD (hypertension, hypercholesterolemia, diabetes mellitus, family history of CVD or personal history with CVD, and smoking) were selected from the five centres' electronic GP medical records. Hereafter their risk profile for CVD was established by means of physical examination of blood pressure, weight and height and biochemical measurements of fasting glucose, HbA1c and lipid profile. Using the Framingham Heart Study risk equation their absolute risk for developing a cardiovascular event in the next 10 years was computed. Eligible participants enrolled in the intervention had a modifiable part of the absolute 10–year risk of cardiovascular disease (CVD) of at least 5%[6].

Eligible participants were randomly assigned to three groups. Participants in the intervention group obtained Quattro care and three-monthly assessments of their risk profile from the practice nurses. Participants from control group A received the three-monthly risk assessments performed by the assistants on top of usual GP care. A blind control group B was needed to quantify the effect of the risk assessments. This group was to receive usual GP care and was measured once at the end of the study. The effectiveness of the multidisciplinary collaboration was assessed by comparing the reduction in CVD risk achieved in participants from the intervention group with those from control group A after one year follow-up. Control group B, which aimed to quantify the effect of structured risk profile assessments performed in control group A, was compared with control group A. The follow-up period for the intervention and control group A was 12 months and the intervention programme lasted 9 months.

As multidisciplinary patient care was considered a potential improvement in the provision and organisation of care services in primary care, a Dutch insurance company facilitated the employment of practice nurses in the practices by providing financial compensation. By providing this financial compensation, they offered GPs a financial incentive to participate in the Quattro Study. In the Dutch healthcare system, insurance companies operate as a 'third actor' and are occupied with the organisation of care and improvements thereof by order of the Dutch government. For that reason, Dutch insurance companies often support such improvement project financially.

5 The intervention described the main tasks for the intervention team: GP (treatment task, overall medical responsibility), practice nurse (risk assessment, coordination and prevention tasks), assistant (logistic task) and peer health educator (ethnic specific health education).

6 See for a more elaborate description on how the Framingham Heart Study risk equation was used and how the modifiable part of the absolute risk was determined (El Fakiri, Bruijnzeels et al. 2005).

The set-up of a rationalistic prevention regime

The programme was developed by researchers, but was to be conducted by practice nurses in primary health care centres located in those deprived neighbourhoods where the project aimed to improve people's cardiovascular health. Each patient enrolled in the intervention was invited to visit the primary health care centres for three-monthly individual education sessions with a practice nurse. In these sessions their risk profile was re-assessed every three months through the physical
measurements of height, weight, and blood pressure levels and blood tests on glucose and cholesterol levels. Thereafter, the patients were given health educational advice on what to do to improve their cardiovascular health. According to one of the researchers of the project, these risk profile assessments were more important than the provision of just health advice, as these provided insights into the severity of the cardiovascular health status of individuals. The information from the risk profile assessments determined the necessary treatment and relevant health education, as the researcher explained:

> Risk factors become more and more important. […] When a patient has a blood pressure over 160 mmHg, you not only look at the height of his blood pressure, you also have to look at other risk factors, like e.g. age, weight, length, smoking and cholesterol. […] Registering is here of utmost importance. First you have to gather all data before you can calculate the absolute risk profile of patients. Secondly, you have to motivate patients to change their risk behaviour. The practice nurse and/or peer health educator do have an important task in this. (observation researcher)

Based upon this information the patients' risk profiles for CVD could be established by adding and subtracting the negative and positive aspects of an individual's biology and lifestyle. In line with current epidemiological evidence on cardiovascular diseases and risk factors, the researchers acknowledged that a person's biology provided a non-modifiable part of CVD risk and a part that was modifiable and was lifestyle-related. For example:

> […] a patient's age and gender define the risk on cardiovascular diseases (CVD) that is not modifiable. Age and gender are fixed variables in the absolute risk on CVD; e.g. men are at higher risk than women in getting CVD even when age increases. (interview researcher)

> The researcher indicates this patient has to become more physically active […] 'his weight is the most important factor; as the weight decreases, the glucose levels will decrease too'. (observation conversation researcher with practice nurse)

The risk profile assessment projects the anticipated chance of having a CVD event in future (Carter 1995) into the present in the form of a percentage. The height of the percentage determines the probability of such an event happening in future. In fact, the various characteristics of the individual's biology and lifestyle are considered traits or advantages to health (Carter 1995). Whereas the individual's age and gender, as non-modifiable factors, indicate a person's genetic risk for CVD, the actual change of a CVD event in future is determined by the modifiable variables in the risk for CVD – a person's weight, blood pressure, cholesterol

and glucose levels. The researchers acknowledged that as the influence of a person's biology on the risk for CVD could not be erased; the risk for CVD could only be reduced through identifying the modifiable risk factors and intervening upon lifestyles. But as they reckoned changes to health behaviours and lifestyles difficult to be achieved for patients in deprived neighbourhoods through only the provision of health risk information, an additional support system with practice nurses and/or peer health educators was considered essential. In other words, lifestyle, in relation to biology, was thought of as easily modifiable via additional support of practice nurses, peer health educators, advice and counselling.

In order to diminish the onset of CVD in future and regulate participants towards the risk factors' norm levels stipulated in GP guidelines[7], every three months participants were also given individualised advice and counselling on the importance of regular physical exercise, adherence to regulative medication, their food intake to reduce obesity, and stopping with smoking in order for them to make the changes in their lifestyles. The risk factors norm levels were considered "the (*treatment)* goals *patients* have to meet" (conversation researcher). The health education was tailored to the specific modifiable risk factors with which a patient's risk profile was made up and was provided verbally and through information leaflets by the practice nurses and/or peer health educators.

In the Quattro Study a rationalistic prevention regime for the prevention of cardiovascular diseases was set-up in which the patients were enrolled. In fact, this prevention regime was built upon the attribution of cardiovascular risk to patients and instructed them how to engage in reducing this risk. In common with other prevention programmes, in the Quattro Study patients were encouraged to behave in a sensible and responsible way and to take appropriate actions to protect their future health (Armstrong 2007). In the prevention regime not only the patients' current health status at the time of the three-monthly individual patient education sessions was monitored, also the progress that patients made in achieving lifestyle modifications was monitored through the recurrent use of the physical measurements and blood tests. In other words, this CVD prevention intervention facilitated the living of healthy lives (Bunton, Nettleton et al. 1995). From a scientific medical perspective as elaborated upon in the introduction, the programme facilitated patients in taking responsibility and control over their own condition and solve their health problems (Bodenheimer, Lorig et al. 2002). A structure of additional support by practice nurses and/or peer health educators was organised and considered essential for patients to do so.

This prevention programme, characteristic for prevention programmes in general, provided patients 'at high risk for CVD' with the opportunity to care for themselves and their selves (Vaz and Bruno 2003) and underscored patients' individual responsibility and agency therein (Lupton 1993; Hallowell and Lawton 2002). This was evidenced by, for example, two practice nurses in conversations I had with them about the essence of prevention:

> When you inform patients thoroughly the more risk factors they have, the higher the chance they could develop cardiovascular diseases, you also have to indicate patients have a responsibility in this […] You can give patients leaflets on what patients can do themselves to reduce risks, like smoking cessation, losing weight by means of dietary advice, exercise more and such, but they have to do it. (interview practice nurse)

7 In the Quattro Study, hypertensive patients had to be regulated to a norm tension of 140/90 mmHg or less. The norm value for hypercholesterolemia was an average total cholesterol (tChol) less than 5 mmol/l. And the BMI score had to be reduced to less than 27 (document manual for intervention 2000).

> Patients have to '[…] realise that lifestyle change has more effects than pills and powders'. (fieldnote practice nurse)

Despite these efforts to provide multidisciplinary patient care for the prevention of CVD to assist and support patients in actively managing their health within a rationalistic prevention programme, the researchers concluded that the Quattro Study project had a limited effect (El Fakiri 2008). Although after one year follow-up reductions in the risk of CVD were observed in the participants of the intervention groups and in the participants in control group A who had received regular care, these were not considered significant. The researchers concluded that although the addition of practice nurses and peer health educators in primary care for additional support of patients was assumed to improve the prevention of cardiovascular diseases, the risk for CVD was not sufficiently diminished in programme participants.

The actual practice of prevention and the agency of patients

The ethnographic study, of which the findings are used in this chapter, was nested in the project. The ethnographic findings help to explain these disappointing results of the Quattro Study. Not astonishingly, in the Quattro Study programme the health care professionals and the patients participated differently to the trial researchers' expectations. In fact, the Quattro Study in practice was shaped by the way patients participated in the intervention and the way health care professionals related the rationalistic prevention regime to them.

With the prevention regime of the Quattro Study in place as the basis for the facilitation of patients changing their health behaviours in order to prevent the onset of cardiovascular diseases in future, the practice nurses individualised the management of risk for each patient. In other words, the practice nurses, in order to facilitate patients in changing their lifestyles, translated this individual risk for CVD to patients into something that makes sense to them (Callon 1986). As one of the researchers indicated during an intervention progress meeting that was organised by the researchers to assist the practice nurses in conducting the programme, that in the actual practice of prevention a development is taking place towards a partnership model in which medical professionals have to cooperate with patients, which was also visible in the Quattro project:

> […] a shift is taking place from an authoritarian model – in which patients are told what they have to do – towards a partnership model in which you cooperate with the patient. (observation intervention progress meeting)

In practice, this meant that the rationalistic prevention regime, which was developed by the researchers, had to be related to the patients by the practice nurses and had to be adjusted to the patient's daily circumstances. When patients visited the primary care practices every three months, the practice nurses informed on the patients' knowledge and perceptions of CVD, and informed on their daily circumstances. This information the practice nurses used for determining a hierarchy in risk factors in individual patients to be tackled. One of the practice nurses explained why she related the prevention programme to individual patients. She explained that as the daily circumstances of patients are that directive in patients' lives,

she needed to know these circumstances in order to adjust her supervision and support to.

> The practice nurse is the person for that inventory. […] A GP doesn't see the real problems patients deal with; he only sees e.g. a high blood pressure and not the patients' daily personal problems. To be able to supervise these patients, a practice nurse needs to understand these problems patients deal with. (observation intervention progress meeting)

It was considered that as the risk for CVD comprised a conglomerate of different risk factors, not all risk factors could be tackled at once. Moreover, although prevention and health promotion in general is aimed at achieving reduction in health risks and aimed at health status improvements, the practice nurses acknowledged that the personal problems patients had to deal with on a daily basis would determine the extent of the improvements in health that could be achieved (Rapley 2008).

In fact, these daily circumstances could make it difficult or impossible for patients to modify their lifestyles, even though the practice nurses supported patients in doing so. As a result those risk factors in patients were tackled first in which with minimal efforts the largest gains in risk reduction could be expected. So, for the practice nurses the daily problems and circumstances respectively determined pragmatically the order in which risk factors were treated – not primarily a formal rationalistic risk assessment model. In Jonvallen's words, one could say that the programme's participants are being enacted not as merely biological bodies but as individuals with personal and social problems. In fact, taking into account these daily problems and circumstances that could prohibit patients to alter their behaviours was crucial for the practice nurses, as the cooperation of patients was needed to be able to regulate their health as one 'at high risk' towards 'good health'. As one of the practice nurses explained during an intervention progress meeting: "The patients' motivation is crucial…sometimes when patients don't want to lose weight, they never will" (observation intervention progress meeting).

The practice of the Quattro programme was not only shaped by how the practice nurses related the programme to patients and translated it to their daily circumstances. The Quattro programme was also shaped by how the patients participated in the intervention. The extent to which patients did participate varied throughout the project. In fact, the three-monthly risk profile assessments influenced the way patients participated as well as to what degree they changed their lifestyles, as the outcomes of these assessments enabled them to make choices to what extent they conformed to the prevention regime that was set up. According to the argument of Howson (1998), risk profile assessments, the diagnostic techniques used and their capacity to objectify risks, discipline patients in making appropriate lifestyle changes. This presumes that patients are submitted to prevention regimes and assumes lifestyles and health behaviours to be easily modifiable for patients. What we saw in the Quattro programme, however, was that the level of participation in patients varied along the continuum of 'no participation' to 'full participation' and that aiming to modify lifestyle is not a unilateral process. In fact, the outcomes of the risk profile assessments helped and supported patients to variously conform to the programme.

The structural risk profile assessments helped to support and motivate only those patients who aligned to the goals of the programme and translated these goals into personal goals. The outcomes of the risk profile assessments portrayed a linear and dichotomous image of the future and projected patients' current health status as the result of the lifestyle choices

that were made in the past and one's future health as the consequence of the lifestyle choices individuals make at present. As exemplified in the next fragment of a patient consultation a practice nurse had with a patient:

> 'But if you eat and take your tablets regularly now, we do not have to raise your medication dose.' 'What do you mean?' 'I mean that if you eat healthier, exercise more and take your medication, you do not have to change to insulin later.' (observation practice nurse)

As one of the practice nurses, for example, explained during a recurrent consult why it was important for high-risk patients to take their medication: "It is important to have a patient started on the right dose of medication in an as early as possible stage. The consequences in the long run will than be much less severe" (observation practice nurse). Although one could say that the risk profile assessments created an image of one's future as one of ill health if one does not take control now, they did not submit all patients to this image. It persuaded only those patients to take responsibility and control over their own condition to try to solve their health problems (cf. (Bodenheimer, Lorig et al. 2002)), for whom this image worked appalling. In other words, only those patients participated fully according to regime of the programme, who found conformation to the programme and lifestyle change important: "as they believed they had a high risk" (interview practice nurse). As the practice nurse elaborated further, in the same interview:

> They did come […] they thought it was important. I kept seeing them every three months during the consultations. But this was mainly because of the blood tests….the frequency remained high because they were sent a blood test form every three months by the researchers. That's why they kept coming. (interview practice nurse)

Moreover, as these risk profile assessments objectified their risk for CVD as the conglomerate of different risk factors that could or could not be modified through lifestyle changes, these assessments also enabled patients to make choices in which behavioural changes they made. For example as illustrated in a fragment from a conversation I had with a patient:

> I do take my medication more regularly now, but I still eat my usual mash. I don't like the extra fuss of eating differently. I told *the practice nurse* from the beginning I'm not changing that! (conversation patient)

Like Vaz and Bruno (Vaz and Bruno 2003) have argued: as the Quattro project advocated numerous possible lifestyle changes deemed to prevent the onset of CVD events in future, it enabled patients to make choices. Though prevention and health promotion activities convey the promise of a longer and healthier life provided the individual's self-control over pleasures, patients are seen to bargain between the habits they do not want to abandon and other behaviours that are thought to prevent a disease. So, although prevention and health promotion programmes convey a message of responsibility and self-control, they are not simply rationalistic regimes that submit all participants to a set of rules. In fact, the risk profile assessments did provide patients with agency. They provide the patients with the opportunity to actively shape the practice of prevention and health promotion through the extent of their participation.

Conclusion

In this paper I have shown how primary care professionals and participating patients mutually shape prevention interventions. In the Quattro Study project, a rationalistic prevention regime was set up, that was built upon the attribution of cardiovascular risk to patients and instructed them how to engage in reducing the risk for CVD and the chance of having CVD events in future. In common with other prevention programmes, the Quattro Study encouraged patients to behave in a sensible and responsible way and to take appropriate actions to protect their future health. However, health care professionals and patients participated differently than the trial researchers expected. In fact, this paper showed that although a rationalistic prevention regime was set up, both health care professionals and patients actively shaped the practice of prevention. The practice of the Quattro Study was shaped by the way patients participated in the intervention and the way the health care professionals related the prevention regime to them.

In the context of prevention programmes that are often rationalistic in nature, that are based upon the 'taming of chance' and in which risk profile assessments are used to systematically and objectively monitor the health status of individuals (Moreira 2007), the health of individuals is presumed to be mastered and controllable. The increasing control and intervention upon individuals' health, as Hacking (1990) has argued, is a salient side-effect of the rationalisation and enumeration of prevention and health promotion, in which a direct relation between scientific, medical information and 'good health' in individuals is presumed. However, as the ethnographic analysis shows, there is no such direct relation between health risk information and 'good health'. As in many social science studies, the ethnographic analysis shows that individuals live relatively stable lives rather than changing their habits due to scientific, medical information and intervention. Firstly, the researchers of the Quattro programme defined the programme as ineffective in achieving reductions in cardiovascular health risk in patients. And secondly, patients were not submitted to the rules of the prevention regime that was set up; within the context of this particular preventive intervention patients were seen to have agency. In fact, patients made choices to what extent they conformed to the programme and to what lifestyle and behavioural changes they incorporate into their lives. The programme persuaded only those patients to participate fully who aligned themselves to the rules of the prevention regime and personalised its goals.

Although prevention and health promotion programmes ultimate aim is the mastery and control over the health of individuals, the ethnographic analysis problematises this ultimate aim. In fact, with the biological and physiological make up of individuals considered as non-modifiable risks to cardiovascular health, lifestyles and health behaviours – or better 'the social' – have become the target of medical intervention and restoration in contemporary prevention and health promotion (Scott and Freeman 1995). In relation to biology, lifestyles and health behaviours are considered easily modifiable. The provision of health risk information and systematic monitoring that make up contemporary prevention regimes, are considered the panacea for achieving the wished-for changes in lifestyles and health behaviours in patients for preventing diseases in general and for preventing cardiovascular diseases in particular (Aronowitz 1998). However, ethnographic analysis shows that lifestyle and health behaviours are not easily modifiable. Although they are the target in contemporary preventive interventions, the lives of patients in their respective social contexts (Beck 2010) and their daily circumstances are not taken into account when developing these programmes;

in the practice of prevention and health promotion programmes health care professionals have to relate and translate these programmes to patients to possibly achieve changes in lifestyles and health behaviours. Thus, prevention and health promotion programmes have a double obligation (Mckie 1995). On the one hand, prevention programmes aim at the improvement of the health status of 'at risk' patients, and on the other hand, in these programmes rationalistic prevention regimes have to be tailored, related and translated to individual patients as their cooperation is needed. Taking this double obligation into account prevention and health promotion than is no longer solely about transferring the responsibility for good health to patients, it is about accepting the 'the social' as integral part of prevention and health promotion practices.

References

Armitage, P. (1998). Attitudes in clinical trials. Statistics in Medicine **17**: 2675-2683.

Armstrong, D. (1995). The rise of surveillance medicine. Sociology of Health & Illness **17**(3): 393-404.

Armstrong, N. (2007). Discourse and the individual in cervical cancer screening Health **11**(1): 69-85

Aronowitz, R.A. (1998). Making Sense of Illness; Science, Society and Disease. Cambridge: Cambridge University Press.

Beck, S. (2010). Epilogue: Translating Experience into Biomedical Assemblages. Observations on European Forms of (Imagined) Participatory Agency in Healthcare. In: Health Promotion and Prevention Programmes is Practice; How Patients' Health Practices are Rationalised, Reconceptualised and Reorganised. Mathar, T. and Jansen, Y.J.F.M. (eds.). Bielefeld: Transcript Verlag. pp. 195-222.

Berg, M. (1995). Rationalizing Medical Work; Decision Support techniques and Medical Practice. Dept. Health Ethics and Philosophy. Maastricht: Rijksuniversiteit Limburg. [doctoral thesis].

Bodenheimer, T., Lorig, K., Holman, H. and Grumbach, K. (2002). Patient Self-management of Chronic Disease in Primary Care. Journal of American Medical Association **288**(19): 2469-2475.

Bunton, R., Nettleton, S. and Burrows, R. (eds.). (1995). The sociology of health promotion; Critical analysis of consumption, lifestyle and risk. London/New York: Routledge.

Callahan, C.M., Boustani, M.A., Unverzagt, F.W., Austrom, M.G., Damush, T.M., Perkins, A.J., Fultz, B.A., Hui, S.L., Counsell, S.R. and Hendrie, H.C. (2006). Effectiveness of Collaborative Care for Older Adults With Alzheimer Disease in Primary Care; A Randomized Controlled Trial. Journal of American Medical Association **295**(18): 2148-2157.

Callon, M. (1986). Some elements of a sociology of translation: domestication of the scallops and the fishermen of St Brieuc Bay. In: Power, action and belief: a new sociology of knowledge? Law, J. (ed.). London: Routledge. pp. 196-223.

Carter, S. (1995). Boundaries of danger and uncertainty: an analysis of the technological culture of risk assessment. In: Medicine, Health and Risk; Sociological Approaches. Gabe, J. (ed.). Oxford/Cambridge, MA: Blackwell Publishers Ltd. pp. 133-150.

Cullum, N., Spilsbury, K. and Richardson, G. (2005). Nurse led care; Determining long term effects is harder than measuring short term costs. British Medical Journal **330**(7493): 682-683.

El Fakiri, F. (2008). Prevention of cardiovascular Diseases in Deprived Neighbourhoods.

Institute Health Policy and Management. Rotterdam: Erasmus MC Rotterdam. [doctoral thesis].

El Fakiri, F., Bruijnzeels, M.A. and Hoes, A.W. (2005). Prevention of cardiovascular diseases: focus on modifiable cardiovascular risk. Heart **92**(6): 741-745.

El Fakiri, F., Hoes, A.W., Uiterwaal, P.J.M., Frenken, H.A.A. and Bruijnzeels, M.A. (2008). Process evaluation of an intensified preventive intervention to reduce cardiovascular risk in a multiethnic patient population. European Journal of Cardiovascular Nursing **7**(4): 296-302.

Gabe, J. (1995a). Health, medicine and risk: the need for a sociological approach. In: Medicine, Health and Risk: Sociological Approaches. Gabe, J. (ed.). Oxford/Cambridge MA: Blackwell Publishers Ltd/Editorial Board. pp. 1-17.

Gabe, J. (ed.). (1995b). Medicine, Health and Risk; Sociological Approaches. Sociology of Health and Illness Monograph Series. Oxford/Cambridge MA: Blackwell Publishers Ltd/Editorial Board.

Hacking, I. (1990). The Taming of Chance. Cambridge: Cambridge University Press.

Hallowell, N. and Lawton, J. (2002). Negotiating Present and Future Selves: Managing the Risk of Hereditary Ovarian Cancer by Prophylactic Surgery Health **6**(4): 423-443.

Harting, J. (2005). Individual lifestyle advice: development, implementation and evaluation within the Hartslag Limburg cardiovasculair project. Care and Public Health Research Institute (CAPHRI), Facullty of Health Sciences Maastricht: University of Maastricht. [doctoral thesis].

Harting, J., van Assema, P. and de Vries, N.K. (2006). Patients' opinions on health counseling in the Hartslag Limburg cardiovascular prevention project: Perceived quality, satisfaction, and normative concerns. Patient Education and Counseling **61**(1): 142-151.

Hotopf, M. (2002). The pragmatic randomised controlled trial. Advances in Psychiatric Treatment **8**: 326-333.

Howson, A. (1998). Surveillance, knowledge and risk: the embodied experience of cervical screening Health **2**(2): 195-215.

Hunter, D.J. (2003). Public Health Policy. Cambridge: Polity Press.

Jansen, Y.J.F.M., Foets, M.M.E. and de Bont, A.A. (2009). The contribution of qualitative research to the development of tailor-made community-based interventions in primary care: a review. European Journal of Public Health.

Jonvallen, P. (2010). Prevention as a side effect? Distributing trial participants in a pharmaceutical drug trial. In: Health Promotion and Prevention Programmes in Practice; How Patients' Health Practices are Rationalised, Reconceptualised and Reorganised. Mathar, T. and Jansen, Y.J.F.M. (eds.). Bielefeld: Transcript Verlag. pp. 83-104.

Kloek, G.C., van Lenthe, F.J., van Nierop, P.W.M., Koelen, M.A. and Mackenbach, J.P. (2006). Impact evaluation of a Dutch community intervention to improve health-related behaviour in deprived neighbourhoods. Health and Place **12**(4): 665-667.

Lobo, C.M., Frijling, B.D., Hulscher, M.E.J.L., Bernsen, R.M.D., Braspenning, J.C., Grol, R.P.T.M., Prins, A. and van der Wouden, J.C. (2003). Organisational determinants of cardiovascular prevention in general practice. Scandinavian Journal of Primary Health Care Analysis **21**(2): 99-105.

Lupton, D. (1993). Risk as Moral Danger: the Social and Political Functions of Risk Discourse in

Public Health. International Journal of Health Services **23**(3): 425-435.
Mckie, L. (1995). The art of surveillance or reasonable prevention? The case of cervical screening. Sociology of Health & Illness **17**(4): 441-457.
Moreira, T. (2007). How to Investigate the Temporalities of Health. Forum: Qualitative Sozialforschung / Forum: Qualitative Social Research **8**:13.
Porter, T.M. (1995). Trust in Numbers; The Pursuit of Objectivity in Science and Public Life. Princeton, New Jersey: Princeton University Press.
Raftery, J.P., Yao, G.L., Murchie, P., Campbell, N.C. and Ritchie, L.D. (2005). Cost effectiveness of nurse led secondary prevention clinics for coronary heart disease in primary care: follow up of a randomised controlled trial. British Medical Journal **330**(7493): 707-711.
Rapley, T. (2008). Distributed decision making: the anatomy of decisions-in-action. Sociology of Health & Illness **30**(3): 429-444.
Ronda, G. (2003). The Dutch heart health community intervention "Hartslag Limburg", an evaluation. The Maastricht Research Institute for Prevention and Care (HEALTH). Maastricht: University of Maastricht. [doctoral thesis].
Ronda, G., van Assema, P., Ruland, E., Steenbakkers, M. and Brug, J. (2004). The Dutch Heart Health Community Intervention 'Hartslag Limburg': design and results of a process study. Health Education Research **19**(5): 596 - 607.
Rosemann, T.R., Joest, K.J., Koerner, T.K., Heiderhoff, M.H., Schaefert, R.S. and Szecsenyi, J.S. (2006). How can the practice nurse be more involved in the care of the chronically ill? The perspectives of GPs, patients and practice nurses. BioMed Central Family Practice **7**:14. doi:10.1186/1471-2296-7-14.
Scott, S. and Freeman, R. (1995). Prevention as a problem of modernity: the example of HIV and AIDS. In: Medicine, Health and Risk; Sociological Appraoches. Gabe, J. (ed.). Oxford/Cambridge, MA: Blackwell Publishers Ltd. pp. 151-170.
Steptoe, A., Doherty, S., Kendricka, T., Rinka, E. and Hilton, S. (1999). Attitudes to cardiovascular health promotion among GPs and practice nurses. Family Practice **16**(2): 158-163.
van der Ploeg, I. (2007). Infonomie en nieuwe media: Vragen bij een digitaliserende samenleving. dept. Infonomie en Nieuwe Media. Heerlen: Hogeschool Zuyd. [inaugeral speech].
Vaz, P. and Bruno, F. (2003). Types of Self-Surveillance: from abnormality to individuals 'at risk'. Surveillance & Society **1**:3.
VWS (2005). Primary Health Care in the Netherlands; The nature, structure, financing, regulation, supply of, and training and demand for primary health care in the Netherlands. Poorter, J. (ed.). The Hague: Ministry of Health, Welfare and Sport, The Netherlands. International Publication Series Health Welfare and Sports, no.20.

General conclusion

> The problem with prevention work is always that you have to legitimise what you do, why you do it this way, and can you show results? How many people turn up? Is it useful then? And what are their experiences? Yes, you know yourself, but you have to legitimise your choices towards the subsidisers and that is always a certain tension. (prevention professional cp2 in Horstman & Houtepen 2005:85, translation from Dutch YJ)

The pragmatic trial methodology: an attempt to combine pragmatism and systematic evaluation

This thesis evolved around the issue of how to evaluate the effectiveness of health promotion and prevention such that it matches the criteria for sound scientific research and at the same time produces knowledge that can more easily be embedded in routine medical practice. In other words, this thesis concerned the issue of how to bridge the science-practice gap in complex public health settings. More specifically, I analysed one example of an evaluation methodology that tried to accomplish this: the pragmatic trial methodology.

Despite the enormous sums of funding that are spent to develop prevention and health promotion interventions that are effective for improving the health of populations, and specifically heard-to-reach populations, the 'return on investment' of these interventions proves to be small. The effectiveness and impact of prevention and health promotion interventions has been difficult to establish. The interventions of which the effectiveness and impact were shown in test situations, were single interventions and focussed on the prevention of single conditions (cf. (Glasgow, Lichtenstein et al. 2003; Blakemore and Davidson 2006)). Evaluations of complex interventions targeting multiple conditions have shown time and again no or minimal effects (e.g. (Mackenbach and Stronks 2002; de Vries 2004; Kloek 2004; Kloek, van Lenthe et al. 2006; Schuit, Wendel-Vos et al. 2006)). Also, interventions did not disperse out of test settings into routine medical practice. Some might say because these interventions were not proven (cost-)effective, others suggested the conventional randomised controlled trial (RCT) methodology to be presumed too rigid for evaluating the effectiveness of complex prevention and health promotion interventions. The problems RCTs are confronted with are, firstly, the translation of evidence-based medicine into routine medical practice. Secondly, setting up good RCTs that correspond with the research questions to be answered or the health problems in communities to be tackled has proven to be extremely hard (cf.(Horstman and Houtepen 2010)). For this reason, many

scholars have argued that additional and/or pragmatic modes of evaluation are needed to develop evidence on effectiveness that corresponds with and 'fits' routine medical practice (cf. (Susser 1995; Nutbeam 1996; Macdonald 2000; Black 2001; Twinn 2001; Macdonald 2002; Glasgow, Lichtenstein et al. 2003; Hunter 2003; Blackwood 2006)).

In the search for new modes of evaluation, the pragmatic trial methodology gained much attention as an alternative methodology with the potential to produce evidence that corresponds with routine medical practice and matches the criteria for sound scientific research. The pragmatic trial methodology allows for the interventions tested to 'fit' the dynamics of routine medical practice, and at the same time be evaluated using a trial setup for comparing the intervention with regular care. In the pragmatic trial methodology the approach towards the development and implementation of interventions in routine medical practice is different from conventional RCT designs. In recent years, the notion that for complex interventions to become embedded they have to match the dynamics of routine medical practice has gained ground. In contrast to the conventional RCT methodology in which interventions are considered the standard for practice, it is believed that interventions cannot be fully standardised but have to be embedded in the routines, culture and organisation of specific practices and therefore have to be flexible. The interventions have to – among other things – correspond with the problems in care provision experienced by health care professionals in routine medical practice, and have to be adjustable to existing work processes. Through this tailor-made approach health care professionals are provided the core elements of the intervention that have to be performed, and are given the opportunity to pragmatically develop, organise and adjust the intervention. Such a tailor-made approach provides (primary) health care professionals the opportunity to shape an intervention and its implementation in practice such that the procedures of the intervention can be embedded in and be dynamically adjusted to the organisational circumstances, interprofessional relations and work processes. The pragmatic trial methodology thus allows for complex interventions to be pragmatically developed and implemented within medical practices.

The research reported here focussed on one example of such a dynamically embedded intervention, Quattro Care, and the pragmatic trial set up to evaluate this intervention. The pragmatic approach allowed the Quattro Study intervention to correspond with the (tacit) knowledge of primary health care professionals concerning the functioning of the primary health care centres the intervention was tested in. It emphasised the importance to involve primary health care professionals in the development of interventions and the production of evidence as a form of co-production. It should be noted that I, in relation to health care professionals co-producing interventions, I believe both 'development' and 'implementation' to be non-static phenomena. In concordance to the arguments several scholars of science and technology studies (see e.g. (Bowker and Star 2000; Dehue 2002; Timmermans and Berg 2003)), I believe 'development' and 'implementation' to be intertwined. With this in mind, I argue them to be dynamic processes in which interventions once they are developed and implemented in routine medical practice to become evaluated for the effectiveness by means of the pragmatic trial methodology, they will evolve and become reappropriated (and thus developed further) by the health care professionals who use them. The development of interventions as well as the implementation is never over. Although one could distinguish 'development' from 'implementation' as the formation of the intervention formats before they are tested versus the interventions being introduced into medical practice, in the remainder of this chapter with 'development' and 'implementation' I mean the whole life

cycle of interventions and its dynamic process by which interventions are reappropriated and embedded in medical practice.

In theory the pragmatic trial methodology is 'the best of both worlds'. It provides health care practices with the freedom to organise the intervention format and its core elements to fit local context, organisational circumstances and work processes, and it corresponds to the societal emphasis on rationalisation to establish effectiveness according to the criteria of sound scientific evaluative research and a validated trial methodology. As such the pragmatic trial methodology is suggested to produce evidence on effectiveness that embeds more easily in routine medical practice, as the evidence it produces corresponds with and 'fits' the dynamics of that same practice. This places the pragmatic trial methodology on the crossroads of routine medical practice and evaluation through scientific research. This thesis shows how the pragmatic trial methodology works out in practice.

Pragmatic trial: an oxymoron?

As the pragmatic trial is a methodology allowing for new complex interventions to be developed and implemented pragmatically, this affects the mode of evaluation. In order to establish the effectiveness of complex interventions, the mode of evaluation might consider the causalities between intervention components, the relations between multiple health and non-health outcomes, as well as the processes by which these components bring about change in routine medical practice and in patient groups (cf. (Petticrew 2011)). The evaluation has to deal with the process of intervention further development and enactment in routine medical practice. In other words, it has anticipate the development and implementation cycle and the adjustments made during the intervention process. Therefore, often qualitative methods are conducted alongside or nested within the pragmatic trial methodology. Qualitative methods are used because they are able to provide insights into the intervention process, that are different from for example quantitative process evaluations. As qualitative methods provide insights that are more in-depth, enriched with anecdotal information and more elaborate context descriptions, they are able to provide insights into how routine medical practice is able to make the intervention fit the local context and adjusts the intervention to changes in that local context during its course. And as such qualitative methods may enable to reflect on the consequences of the intervention-in-action for the evaluation of effectiveness. In this way, qualitative methods facilitate an iterative cyclic process of feedback and adjustments. This was also the starting intention of issuing an ethnographic case study parallel to the Quattro Study. The ethnographic case study design enabled to study how the project's researchers developed, implemented and evaluated the intervention, how the intervention was enacted and developed further in primary health care practices and how both primary health care professionals and patients participated in the intervention. Through this, it would be able to help describe the intervention-in-action and allow for adjustments to the evaluation design.

Pragmatic trials, however, are particularly difficult to perform. Because of the dynamics in routine medical practice, the interventions change over time and are different in various settings. Health care professionals make various adjustments to the interventions to adapt to the specific or changing conditions of routine medical practice. In other words, as Timmermans and Berg have argued, interventions always become localised and contextualised (cf. (Timmermans and Berg 2003)) and therefore they start to differ. As a result, the evaluation – using any form of trial design -- is for scientific researchers a continuous and pragmatic process of solving methodological dilemmas ad hoc. In pragmatic trials in

particular, scientific researchers are constantly balancing the internal and external validity of the evaluation designs the interventions are tested with (cf. (Godwin, Ruhland et al. 2003)) due to the inherent combination of pragmatism with systematic evaluation. The pragmatic trial methodology places scientists and health care professionals for numerous dilemmas in which they are confronted constantly with the question what to weight more: the scientific criteria for sound evaluation and research or fitting the interventions to the ever changing circumstances of routine medical practice? Often interventions are seen to have unanticipated effects, which are not the primary outcome but are considered part of the preconditions the interventions have to meet in order to be potentially effective. Also in the Quattro Study more effects than those on health outcomes were visible. To name a few, firstly, practice nurses became embedded in the primary health care centres as primary health care professionals with a function in its own right. And secondly, because of the Quattro Study additional consults, intensified care and support – which was not regularly part of the participating primary health care practices -- could be provided to patients that could use this intensified care.

In concordance with the argument of Petticrew (2011), who states that depending upon the perspective researchers adopt either 'simplicity' or 'complexity' is seen as the inherent characteristic of interventions (cf. (Petticrew 2011)), one could be critical of the pragmatic trial methodology or not. From a 'simplicity' perspective, one could argue that the intervention was not developed correctly or the implementation of the intervention in practices was not guided properly by the scientific researchers. From a 'complexity' perspective these 'other' effects would not remain unanticipated effects of the intervention. But by merely being critical of the pragmatic trial methodology, it's intention of bridging the science-practice gap would not have been taken seriously (cf. (Timmermans and Haas 2008)). It would in fact underscore – instead of overcome – the dichotomy between pragmatism and systematic evaluation and respectively the dichotomy between routine medical practice and scientific research. In this concluding chapter I argue that the pragmatic trial methodology not only is a new mode of evaluation, but has to be considered as an infrastructure for bridging the science-practice gap and for facilitating change and innovation to take place in routine medical practice. Moreover, I argue that in order for the pragmatic trial methodology to be really pragmatic, it needs to employ a complexity perspective incorporating a broader perspective on effectiveness, and needs to fully accept health care professionals, participants as well as instruments co-constructors and co-producers of interventions and their outcomes. The pragmatic trial methodology should focus on the evaluation of complex interventions as they are shaped and formed in routine medical practice, in order not to become an oxymoron.

In order to build the argument, the findings in this thesis will be discussed according to three main themes.

1) the role and value of complexity in the pragmatic trial methodology;
2) the role and value of scientific instruments used within the pragmatic trial methodology for routine medical practice;
3) the role of qualitative methods/mixed methods approaches in the pragmatic trial methodology

The role and value of complexity in pragmatic trial methodology

According to the way of thinking about ideal evidence and evaluation underlying the use

of the conventional RCT methodology, complexity is simplified for the purpose of assessing outcomes. Moreover, the development of prevention and health promotion interventions is considered to be based upon theory and established evidence. Furthermore, to determine the interventions' effectiveness, they should be systematically evaluated under preferably experimental conditions. An important requirement for this is that all the intervention elements, application methods and strategies should be applied in a consistent manner, preferably in different but similar primary health care settings and should deliver the same kind of evidence. Interim adjustments to or deviations from the intervention format during the evaluation of the intervention are to be avoided as much as possible, as they make it (more) difficult to establish the effectiveness through comparing the situation before the start of the intervention with the situation after the intervention in both the experimental and control groups. Alternatively, deviations from the intervention format during the study period are controlled for by scientific researchers using process evaluation as an input. Through these methods the local context and the complexity of routine medical practice are simplified and reduced as much as possible to elements non-important to the actual success or effectiveness of interventions. But as the pragmatic trial methodology combines pragmatism with systematic evaluation, and incorporates the local context and the complexity of routine medical practice as crucial to the development of effective interventions that fit routine medical practice, this gives rise to the question how the pragmatic trial methodology deals with complexity. In this section this question will be explored on the basis of the findings of the research into the Quattro Study.

As shown in chapter 1, initially the researchers in the Quattro Study at least to a certain extend led the primary health care practices themselves implement the intervention. In time, however, the researchers increasingly performed additional activities or interventions in order to have the intervention executed according to its original format and for gathering the information needed to correct any flaws or missing data, which would enable made them to establish the effectiveness of the intervention unambiguously. When performing these additional activities, the researchers influenced the course of the intervention being appropriated and developed further by the health care professionals. Therewith, in a sense they depragmatised the intervention forming a fit with medical practice. Herewith, the emphasis within the pragmatic trial methodology shifted from the intention of pragmatically developing effective interventions that fit the local context of primary health care practice towards evaluation through scientific research in more or less standardised practices. In contrast to its intention, the rationalistic and systematic character of prevention and health promotion gained emphasis over pragmatism within the Quattro Study. Additionally, a process evaluation was performed to account for the remaining differences between the intervention as planned and the intervention as performed using quantifiable process indicators such as e.g. the attendance of health care professionals in multidisciplinary meetings, the attendance of participating patients and the amount of consults delivered according to plan (El Fakiri, Hoes et al. 2008). This points towards a change of the 'logic' of the Quattro Study, showing that this complex intervention evaluated via a pragmatic trial, just like in the conventional RCTs, is undone from its complexity (cf. (Dehue 2002; Bartholomée 2004; Dehue 2004)).

Despite its intentions, and although quantitative process evaluations are undertaken to unravel the intervention process, in the practice of conducting a pragmatic trial methodology the complexity of routine medical practice and intervention enactment is reduced to a black box. The process of intervention enactment is reduced to the process

indicators used in the quantitative process evaluations, leaving other contextual information out of scope. In a sense, black boxing the full process of intervention enactment. Despite its attention for pragmatism and for the local context, within the pragmatic trial methodology process indicators are not primarily incorporated in the evaluation and used to indicate the level of the intervention's adaptation or adjustment to this local context. In fact, the focus of the evaluation within the pragmatic trial methodology is foremost on the effectiveness of prevention and health promotion interventions, which is defined as a specific outcome measure: the health outcomes on an patient group level. The evaluation of complex interventions combining educational activities, health promotion and new organisational approaches is reduced to the results in patient' health outcomes and not to the level of change and innovation the intervention has brought into the health care practices. Process indicators are only used to control for the *deviation* of the intervention and used to assess outcomes in relation to those deviations. As a consequence, the scope of the evaluation remains limited to the evaluation of health outcomes therewith prohibiting a full insight into the intervention's complexity and the dynamics of intervention enactment.

In concordance with the argument of Petticrew (2011), if complexity is seen to be the key feature of interventions, then other types of research may be necessary for illuminating those complex processes (cf. (Petticrew 2011)). A more intensive cooperation between the quantitative and qualitative methods might accommodate for this lack of attention for the process of intervention enactment in relation to the complexity of local routine medical practice. In the Quattro Study, this was also intended by issuing an ethnographic study parallel to the intervention's evaluation. It was intended that an iterative cycle of feedback and adjustment between the realms of science and practice would come into existence that would transform the intervention as well as its evaluation to accommodate for complexity (cf. (Bate and Robert 2002; Zuiderent-Jerak, Strating et al. 2009)). As this thesis has shown by studying the Quattro Study, an iterative cycle of feedback and adjustment between the realms of science and practice did come into existence, but differently than was expected. As the findings of chapter 1 show, that what should have been systematic in the pragmatic trial methodology (the inclusion of patients and maintaining randomisation for evaluation purposes) became more pragmatic, and what should have been pragmatic (the intervention enactment in the primary health care centres; the delivery of Quattro Care and data collection) became more systematic. The iterative cycle of feedback and adjustment did not transform the evaluation parameters or the evaluation design, it did transformed the intervention. The ethnographic findings indicating the variety in intervention enactment among the participating primary health care centres (e.g. the findings that practice nurses, or peer health educators or both delivered the intervention to ethnic minority patients) formed the basis for extra standardisation efforts by the Quattro Study researchers. The developed guideline and the intervision meetings for practice nurses are examples. Instead of the pragmatic trial methodology intertwining the realms of practice and science, the contradictions between those realms became more imperative on the basis of findings from the ethnographic study, emphasising the rationalistic and systematic character of the pragmatic trial methodology. The realms of evaluation and practice remained separated. Although process evaluations could to some degree accommodate for the influence of local context and local intervention enactment on the outcomes, as has been shown in chapter 3, these were only conducted *after the event*. Moreover, they were not focused so much on bridging the science-practice gap, but rather on measuring deviations from the interventions under study. As a result, they are

unable to accommodate for the complexity of routine medical practice and lift the lit of the local intervention enactment processes.

What happens during the intervention process is considered to result in the effectiveness of interventions: the improvement in health or the decrease in health risks in individual patients. This is a narrow definition of effectiveness. It also implies the application of a specific target patient policy as effectiveness can only be shown in a specifically defined patient population. As this thesis has shown by studying the Quattro Study, the intervention is organised among the primary health care centres in a variety of ways, it is not performed as planned by the scientific researchers and care and treatment are not provided to a specific patient population, but are provided to all patients on an ad hoc basis. The use of such a narrow definition of effectiveness makes it difficult to evaluate the intervention as it is shaped, formed and further developed in routine medical practice. For the Quattro Study researchers this induced a continuous balancing act between letting the primary health care centres make adjustments to embed the intervention in local contexts, and establishing the effectiveness of the intervention using a outcome measure that is limited in scope (cf. (Godwin, Ruhland et al. 2003; Jansen, Bal et al. 2006). In other words, when using such a narrow definition of effectiveness in the pragmatic trial methodology scientific researchers are confronted with methodological dilemmas, as they have to balance between establishing effectiveness according to conventional methods and studying the effects of the intervention in relation to their local context(s) pragmatically.

With the outcomes of the interventions being limited to only one very specific outcome measure, other (unanticipated) effects of the intervention as a result of local intervention enactment remain invisible (cf. (Mol 2006)). These other effects are suggested to be merely the conditions under which interventions ought to be considered effective. The narrow definition of effectiveness thus adds to the reduction of the intervention as a black box, in which the complexity of routine medical practice and the dynamic process of intervention enactment are at least partly obscured. But if the effectiveness or success of an intervention was more broadly defined and in accordance with aspects relevant to the local context of primary health care practice, such as tacit knowledge of health care professionals, work processes and organisational circumstances, other results might have emerged. For example, the workability of the intervention for primary health care professionals would have been a more pragmatic definition as it would correspond more with criteria that are of more relevance and importance to routine primary health care. The success of the intervention is not only determined by its format or the particular composition of ameliorative compiled core elements, it is also determined by how well primary health care professionals are able to adapt and provide health educational activities, advice and support to patients that correspond with the personal circumstances these patients are in. As is shown in chapter 4, the results of the intervention are determined on the one hand by the level of participation achieved in patients and on the other hand by the workability of the intervention for primary health care professionals. Moreover, the level of participation is determined by patients deciding upon the need and urgency that is presented to them, their openness to adapting their lifestyles to the requirements of the prevention and health promotion intervention, and the actual decision they make therein.

Through a specific focus on effectiveness as outcomes in health and related to that a specific target patient policy, the pragmatic trial reduces the complexity of routine medical

practice in order to make evaluation possible and less difficult. However, despite its original intentions, this results in an emphasis shift within the pragmatic trial methodology; a shift from pragmatism embedding interventions in the local context of routine medical practice and allowing adaptations to systematic evaluation of improvements in health. Therewith, the pragmatic trial methodology and the instruments it uses provide the image that they are a method for neutrally gathering evaluative data for establishing effectiveness. Just like conventional randomised controlled trials (RCTs), interventions in the pragmatic trial methodology are still considered to resemble the original intervention as much as possible. In other words, just like Dehue and Barthelomée have argued concerning RCTs (Dehue 2002; Bartholomée 2004; Dehue 2004), also the pragmatic trial methodology forms an experimental mould to which routine primary health care practice, primary health care professionals as well as participating and selected patients are formed. Despite its intentions of establishing the effectiveness of complex intervention under routine, non-experimental conditions to allow for the incorporation of the complexity and variability of care processes in interventions, the pragmatic trial methodology standardises the design, the content and the delivery of the interventions (cf. (Hawe, Shiell et al. 2004; Riley, Hawe et al. 2005)). Even in the pragmatic trial methodology, any deviation from the norm this experimental mould forms is for evaluation purposes not wished for.

It is my contention that the dilemmas I indicated and presented in the previous paragraphs are inherent in the pragmatic trial methodology in general. With the pragmatic trial being a derivate of the RCT methodology, though a new mode of evaluation, there are not yet sufficient answers to these dilemmas. And as a result, pragmatic trial researchers deal with local variations and adaptations of interventions according to the existing manners of thinking. Moreover, these manners of thinking are induced by established infrastructures within science. The RCT methodology is since long acknowledged as the 'gold standard' methodology for establishing the effectiveness of interventions. It is an infrastructure that binds "an academic, industrial and regulatory complex" (Wahlberg and McGoey 2007), and its criteria for quality of evidence, for the interpretation of trial results, disclosure and publication bias (cf. (Latour and Woolgar 1986; Latour 1987; Wahlberg and McGoey 2007)). Public health researchers are bound to conform to the criteria the scientific community has laid down with the RCT methodology. In order for researchers to receive external funding, generating research findings and publish, one has to abide to those criteria. Any difficulties in getting evidence into practice are treated as a 'problem of performance' in which routine medical practice and participating patients are at flaw, instead of the evaluation (Fletcher 2002; Catford 2009; Horstman and Houtepen 2010). Furthermore, although numerous scholars have argued in favour of more observational studies both quantitative and qualitative in nature (e.g. (Black 1996; McKee, Britton et al. 1999; Silverman 2009)), the existing scientific infrastructure hinders researchers in the medical field to fully go for full observational studies. In observational studies the pragmatist's strategy 'whatever works, works' is not considered scientific enough.

The role and value of scientific instruments for routine medical practice

As the chapters of this thesis have shown, in order to evaluate the effectiveness of a complex intervention, the complexity of routine medical practice is reduced; with the Quattro Study researchers performing additional activities to have the intervention performed according to its original format, attempts were made to standardise the dynamics of the process of

intervention enactment. In order to assist the primary health care professionals organising the intervention, the preferred intervention's execution, the data gathering procedures and the medical-technical actions to be performed were formalised by means of an additionally developed guideline. In other words, with scientific instruments, such as guidelines, protocols, screening instruments, risk profile assessments and the trial methodology, formalisation and standardisation are brought into routine medical practice for the purpose of minimising the possibility of variations in practices and increasing the possibility of a systematic scientific evaluation.

However, this suggests that with introducing scientific instruments medical practice are provided a blueprint to what practice should formed itself. This analysis does not do justice to the role and value of scientific instruments for routine medical practice. Although for evaluation purposes scientific instruments are used to more or less standardise the execution of interventions and their evaluation, in medical practice these same scientific instruments provide the handles to organise new manners of providing care. For example, as chapter 2 has shown, although a guideline was developed to have the Quattro Study intervention performed as planned by the researchers, the developed guideline also proved to be a means to have the intervention organised and embedded within medical practice and to discard existing hierarchical interprofessional relations. The guideline acted as a reference point for the participating primary health care centres, which does however not mean that it was actually implemented, as the primary health care centres still had leeway to localise it.

This process is also shown in chapters 4 and 5. Here scientific instruments such as screening methods and risk profile assessments not only function as an selection mechanism via inclusion-exclusion (cf. (Howson 1998)) for patients that considered eligible for preventive activities. These same instruments are a means to provide preventive care that is targeted at eligible patients as well as is adjusted to the social and personal circumstances of these patients. In the Quattro Study, screening methods and risk profile assessments were used to select and include the 'right' patients necessary for establishing the effectiveness of the intervention. Based upon physical parameters these instruments created and defined eligible patients, rationalised and objectified the health risks and/or health status and as such they identified preventive regimes of behavioural and lifestyle changes necessary to reduce any health risks. With this one would expect that all eligible patients that were selected, also participated and conformed to the preventive regimes the practice nurses presented them. But this was not the case. Although the outcomes of these instruments persuaded patients to participate, they also convinced patients not to. The outcomes of these instruments enacted a constructive force as the outcomes were given meaning to by patients as well as primary health care professionals. In concordance with the argument of Epstein (cf. (Epstein 2007)), based upon that signification process, that same specific target population policy not only stimulated patients to participate but also exhorted potential patients and decreased the potential effectiveness of the intervention. In fact, the outcomes of these instruments provided the legitimisation for people to make choices to whether they enrolled or not and what lifestyle changes they incorporated into their lives. In other words, whereas the purpose of selecting and including the 'right' patients is important for the purpose of evaluation and establishing the effectiveness of interventions, in primary health care practice these instruments provide patients 'voice' as these instruments provide legitimation to enrol in interventions or not (cf. (Horstman and Houtepen 2005)).

Moreover, whereas these instruments on the one hand exclude patients that do

not match the inclusion criteria for preventive activities, on the other hand these same instruments provide the primary health care professionals the handles to identify patients that are in need of prevention and support. In the Quattro Study these instruments not only brought in a scientifically based selection mechanism for delivering preventive care, these same instruments provided them also the means to provide preventive care that was also adjusted to the social and personal circumstances of patients. Instead of subduing patients to the full prevention regime, the instruments allowed the practice nurses to provide preventive activities to tackle those health risk behaviours in which positive outcomes could be achieved. So, scientific instruments of value to scientific research also are of great value for routine medical practice as these instruments are means to have new manners of providing care organised in correspondence with scientific standards, but also in correspondence with the social circumstances of patients. Put differently, the scientific instruments have a performative nature as they form medical practice to a certain extent, on the other hand these instruments provide health care professionals leeway as to how to adapt preventive activities to individual patients.

This way, the pragmatic trial methodology can be seen as an infrastructure for embedding innovation(s) in primary health care. The pragmatic trial methodology brings scientific instruments into routine medical practice. And there, the scientific instruments fulfil a performative role in having new scientifically based manners of care provision become part of routine medical practice. As these instruments provide a description of interventions, they also provide legitimation of what prevention and health promotion activities and what medical-technical actions need to be performed. Moreover, these instruments also structure the order and/or elements of these activities in time, in importance and among health care professionals (cf. (Timmermans and Berg 2003)). And therewith, they change existing interprofessional relations and embed new health care professionals and new prevention and health promotion processes into routine medical practice. This underscores the performativity of such scientific instruments. To a certain extent, scientific instruments used for evaluation purposes form and shape routine medical practice in concordance to scientific standards. These are interventions in their own right just like health educational activities, lifestyle advice and medical treatments; these instruments are not neutral, they are part of the process of intervention enactment and co-produce the effectiveness of prevention and health promotion interventions.

The role and value of qualitative methods for the pragmatic trial methodology

As the review in chapter 3 has shown, qualitative methods proved to have a minimal contribution to the development and evaluation of complex prevention and health promotion interventions. Although it is a recent trend to use qualitative methods alongside or nested within the pragmatic trial methodology, the data generated by means of qualitative methods have as of yet a minimal contribution to pragmatically adjusting and adapting the interventions to the local context of primary health care. In fact, as chapter 3 has shown, the qualitative methods used generate information on the organisational circumstances, interprofessional relations and work processes in medical practice that may impede the interventions from being executed as planned. Furthermore, qualitative methods generate information about the experiences of primary health care professionals and participating patients and their attitudes towards change. As a consequence, qualitative methods are used to generate information on the barriers and facilitators to the implementation of the

interventions under study, which are mostly used to explain and interpret the outcomes on intervention's effectiveness afterwards (cf. (Tones 2000; O'Cathain, Murphy et al. 2007; O'Cathain, Murphy et al. 2008; Jansen, Foets et al. 2010)). Herewith, I am not claiming that generating evidence on the barriers and facilitators to the implementation is not important, on the contrary. But as interventions always become localised and contextualised, the barriers, facilitators and other lessons learned during evaluation are unique to test settings studied and therefore not transportable to other test settings per se. In fact, it is my contention that generating evidence on the barriers and facilitators to implementation induces a vast growing list of criteria complex interventions are required to meet in order to increase their chance of becoming embedded in routine medical practice, making these complex interventions more complex and therefore difficult to maintain.

Despite the current trend to apply mixed methods for the development and evaluation of complex prevention and health promotion interventions (cf. (Rich and Ginsburg 1999; Sinuff, Cook et al. 2007; de Salis, Tomlin et al. 2008; Britten 2011)), the qualitative and quantitative paradigms are asymmetrically positioned within the pragmatic trial methodology. In line with Roth and Breuer (2003), who have argued that in order for any sort of multidisciplinary or mixed methods research to work, the different research paradigms need to become one activity system in order to create possibilities for innovations in science (cf. (Roth and Breuer 2003)). In other words, interventions should be rethought over and over again – despite their optimal, suboptimal or even staggering effectiveness. Otherwise one could speak of one-sided developments of research paradigms and of practice and science, which inevitably will harm patients, society and the imago of professionals, be it doctors or researchers. The asymmetrical positioning of qualitative and quantitative paradigms in the pragmatic trial methodology, in that way, creates a deprivation of evaluation research. In addition Fulop et al. (2003) and Lomas et al. (2003) have argued that it is vital for the further development of prevention and health promotion research and research on the improvement of health care, that "researchers who have traditionally taken a 'black box' approach focusing on inputs and outputs need to work with researchers who study context and processes" (cf. (Fulop, Allen et al. 2003; Lomas, Fulop et al. 2003)). In other words, to evolve evaluation research researchers from both quantitative and qualitative paradigms need to combine the focus on effectiveness with the process of intervention enactment broadening the definition of effectiveness. Trends towards the acknowledgement of complexity and process of intervention enactment in evaluation research are becoming visible and gain ground as a counterweight to the contemporary emphasis on systematic scientific evaluation and rationalisation in policy and public health research (see e.g.: (Avison, Lau et al. 1999; Reason and Bradbury 2001; Bal and Mastboom 2007; Zuiderent-Jerak 2007; Whitehead 2009)). This is among others also visible in the call texts of recent research funding programmes in the Netherlands such as the proposed Dutch National Programme on the Quality of Care, the Dutch National Programme Elderly 2008-2012, and the Dutch National Programme Prevention 2010-2015 on applied research and implementation studies of prevention programmes (see the website of ZonMw, www.zonmw.nl). However, despite a growing acknowledgement of complexity and process of intervention enactment, the demarcation as described above is still present in much evaluation research, including the pragmatic trial methodology. Some might say that the growing acknowledgement of complexity favours evaluation studies of interventions that are not substantiated with scientific evidence of their effectiveness. Others might argue that in order to have interventions that are already proven effective embedded in medical practice,

the acknowledgement of complexity and process of intervention enactment might facilitate this to happen. I believe, this demarcation hinders actual possibilities for synergy between quantitative and qualitative paradigms to take shape in evaluation research projects in the form of constructive discussions, methodological innovations and new evaluative designs.

Herewith the pressing problem in contemporary prevention and health promotion is likely to remain: despite all research funds and efforts that are put into developing effective prevention and health promotion interventions, the 'return on investment' is likely to remain small. And the dilemma will remain that complex interventions are developed, implemented and evaluated that will not disperse into routine medical practice. This underscores the need for more pragmatic forms of evaluation alternative to the pragmatic trial methodology (cf. (Horstman and Houtepen 2005)). The question than is what pragmatic evaluation should be and what role and value qualitative methods should have vis-à-vis quantitative methods. Egginton and Sandbothe (2004), and also Bernstein (2010), have argued that the development and evaluation of prevention and health promotion interventions should follow what has been called a "pragmatic turn" (cf. (Egginton and Sandbothe 2004; Bernstein 2010)). Pragmatists believe whatever works is what can be empirically observed in practice, which may differ among health care practices (cf. (James 2008)). In other words, pragmatists believe that a focus on change and innovation may often lead to more fruitful results than deductively creating theory on for example effective interventions and hypothesis testing through predefined outcome measures (ibid. 2008). Following this pragmatic turn, pragmatic evaluation should value local context and experiential knowledge as an integral part of intervention development and implementation and should facilitate change and innovation in medical practice locally (cf. (Timmermans and Berg 1997)), before striving for standardisation and formalisation and establishing outcomes on effectiveness. Pragmatic evaluation holds the premise of localisation and accepting that change and innovation in different practices have different trajectories and pace, and that the strategies applied to facilitate change and innovation may differ among different routine medical practices. The question then is how to actually do pragmatic evaluation.

In order to formulate an answer, I will take up the definition of a pragmatic trial from chapter 1, which states that pragmatic (in pragmatic trials respectively) means enabling the uptake of interventions in daily care by tailoring them to clinical decision-making procedures and incorporating the heterogeneity of patients and health care professionals, and establishing the effectiveness of interventions using experimental designs or validated trial methodologies. With this I am not claiming that establishing whether an interventions really works or that establishing effectiveness is not relevant or not important, as this is crucial to know whether changes in medical practice are also improvements and worthwhile investing time and efforts in. I am arguing for establishing the effectiveness of interventions at another moment in time.

Conventionally, interventions are developed outside of medical practice, based upon compiled elements that are individually proven effective and evaluated for their effectiveness, and that are considered ameliorative when combined. This ameliorativeness of compiled interventions is suggested to exist based upon correlations between compiled core elements, but often not on causality. Often it is concluded that complex interventions are not effective, or do not lead to the wished uptake of evidence-based medicine (see e.g. (Susser 1995; Nutbeam 1996; Macdonald 2000; Black 2001; Twinn 2001; Macdonald 2002; Glasgow, Lichtenstein et al. 2003; Hunter 2003; Blackwood 2006)). The process of

intervention enactment and interventions forming a fit with local context is confounding the establishment of the effectiveness. In other words, the 'noise' of change and innovation the interventions bring in influences or 'contaminates' the effect of the interventions (cf. (Groot and Dewez 2009; Straathof 2009; Oeij, Dorenbosch et al. 2010)). Thusfar, the evaluation of complex interventions with the pragmatic trial methodology has not solved this dilemma either. And the issue important to prevention and health promotion is how to embed effective interventions in routine medical practice and maintaining them. With this in mind, it is my contention that usually-used experimental designs are less appropriate for establishing the effectiveness of complex interventions. In complex interventions, the different elements that make up such interventions, have multiple influences on the organisational circumstances, interprofessional relations, work processes and culture of medical practices (cf. (Hawe, Shiell et al. 2004; Petticrew 2011)), which cannot be captured fully neither in the evaluations nor in quantitative process evaluations. Therefore I argue for a different outlook on evaluating complex interventions. Pragmatic evaluation should also be about establishing and assessing the fit of these compiled interventions with medical practice. This has several implications. The first and most important implication is that in the evaluation the perspective should lie on embedding the results of interventions in medical practice and maintaining them as part of daily care, even when the evaluation has stopped. And secondly, in relation to this, the effectiveness of interventions should be broadened focussing not only on health outcomes as primary outcomes but also on the process of intervention enactment. Thirdly, effectiveness should not be established in pre-post intervention situations, but should be assessed using at least a two-point measurement once the noise of change and innovation has disappeared and the intervention has become stable. In other words, the moment of the first measurement is to be moved further ahead in future than is conventionally the case. And finally, this might also have implications for the duration of evaluation periods, which may have to have a longer time span.

Pragmatic evaluation than is about establishing evidence on effectiveness that is appropriate for either the goal this evidence is gathered for and appropriate for the medical settings it is gathered in (cf. (RVZ 2007)). In concordance with the argument of the Health Council of the Netherlands on 'Appropriate Evidence' (Passend Bewijs); scientifically 'hard' evidence is not the only way of proving the effectiveness of health care research. Scientifically 'hard' evidence, generated with experimental designs such as the RCT, should not discount other forms of valuable care and/or medical practices, which cannot be perfectly fitted with experimental and scientific evidence. Evidence on the effectiveness of interventions "should be 'hard' and scientific where it can be, and 'soft' and practical where it should be" (RVZ 2007). This underscores a valuable role and vital contribution of qualitative methods within pragmatic evaluation. In order for an evaluation to be pragmatic, I believe its primary focus should lie on facilitating change and innovation and should remain flexible as to the establishment of effectiveness. With this, I mean that pragmatic evaluation should start with the issues important to health care professionals and their patients, and how they could be facilitated in addressing these issues, finding solutions to them and improving their work processes and organisational circumstances. In other words, it should start with the 'problem of performance' routine medical practice feels itself confronted with. Although not an easy job to do – as this thesis shows --, a qualitative researcher could offer these insights. With his/her ability to provide insight and reflection on the micro politics of (non) human interactions in routine medical practice as well as by being a scientist himself/

herself understanding the realm of science, a qualitative researcher is able to bring in the participatory perspective needed for the 'pragmatic turn' in pragmatic evaluation (cf.(Lloyd 2000; Reason and Bradbury 2001; Zuiderent 2002; Petticrew 2011)). (S)He is able to show and to describe what changes and innovations have been achieved by means of what strategies, to what extent these changes have been achieved and to what effect. A qualitative researchers is able to indicate where possibilities arise for standardisation efforts and how measurement devices could be designed to facilitate processes of change and innovation to take place (as scientific instruments are performative, the performativity of measurement devices can actually be used to help routine medical practices to change). In other words, a qualitative research should be part of the development process of interventions. Moreover, a qualitative researcher then should also be part of determining effectiveness. Qualitative researchers provide practical, methodological as well as conceptual reflection. Through acting as a mirror to routine medical practice as well as to the scientific realm, qualitative researchers are able to provide insights on the difficulties that arise in evaluation, measuring and consequences as adjustments to interventions are made. This means by being part of determining 'effectiveness' the perspective of effectiveness is broadened incorporating the influence of complexity, local context and the consequences hereof in evaluation (e.g. for social relations between professionals and clients). As such qualitative methods are able to contribute to debate and theory on how scientific knowledge and scientific instruments contribute to change and innovation within routine medical practice and provide input for setting future research agendas on the development of pragmatic forms of evaluation. In pragmatic evaluation then, I argue, a qualitative researcher should be an integral part of interventions, their development *and* their evaluation.

Reconceptualising the pragmatic trial methodology

The pragmatic trial methodology is a new mode for evaluating complex prevention and health promotion interventions trying to bridge the science-practice gap. In this thesis I have analysed how the pragmatic trial methodology works out in practice by giving a detailed account of the Quattro Study. This thesis does not provide the panacea for the development, implementation and evaluation of complex prevention and health promotion interventions, nor does it provide a concrete plan of action how to actually perform pragmatic evaluations. But it has provided insights on what the pragmatic trial methodology comprises and what the limitations of this methodology are. It has shown the methodology's inherent dilemma between pragmatically developing and implementing complex interventions that fit the local context of routine medical practice and scientifically evaluating the interventions' effectiveness or success. Despite its intention of pragmatically developing and evaluating prevention and health promotion interventions that fit the complexity and variability of routine medical practice, the emphasis in the pragmatic trial methodology in the end is on systematic evaluation through scientific research and on establishing effectiveness. Moreover, the realms of science and practice seem not bridged but demarcated. However, the conclusions drawn in this thesis underscore that the pragmatic trial methodology can be reconceptualised.

As the pragmatic trial methodology and the instruments it uses formalise and standardise routine medical practice, they are instruments for changing health care, towards a health care system that provides care with standard indications, standard treatments and disease programmes. But as health care become standardised and formalised, these

instruments are also means to organise new manners of care provision and to make these workable in routine medical practice. They induce change and discard existing work processes, organisational structures and interprofessional relations and make new manners of care provision part of routine medical practice. Therewith, the pragmatic trial methodology and its instruments help to overcome the dichotomy between routine medical practice and evaluation; they are the link between the realms of practice and science. Herewith the pragmatic trial methodology can be seen as an infrastructure for the *implementation* as well as the evaluation of complex interventions in routine medical practice and effectiveness. Therefore, the findings of this thesis allow for a fundamental rethinking of the pragmatic trial methodology not as a new mode of evaluating complex interventions in prevention and health promotion, but as an infrastructure for pragmatically embedding innovation(s) in primary health care. Building on the performativity of the infrastructure that is the pragmatic trial, such embedding of innovations can be more fruitfully explored and tested. The problem with the pragmatic trial methodology is not that it is pragmatic. The problem is that it is not pragmatic enough.

References

Avison, D., Lau, F., Myers, M. and Nielsen, P.A. (1999). Action Research; To make academic research relevant, researchers should try out their theories with practitioners in real situations and real organizations. Communications of the ACM **42**(1): 94-97.

Bal, R. and Mastboom, F. (2007). Engaging with technologies in practice: travelling the North-west passage. Science as Culture **16**(3): 253-266.

Bartholomée, Y. (2004). Society as a Laboratory; Donald T. Campbell and the history of social experimentation. Psychology, Pedagogy and Social Sciences. Groningen: Rijksuniversiteit Groningen. [Doctoral thesis].

Bate, P. and Robert, G. (2002). Studying Health Care "Quality" Qualitatively: The Dilemmas and Tensions between Different Forms of Evaluation Research within the U.K. National Health Service. Qualitative Health Research **12**(7): 966-981.

Bernstein, R.J. (2010). The pragmatic turn. Cambridge UK/Malden MA USA: Polity Press.

Black, N. (1996). Why we need observational studies to evaluate the effectiveness of health care. British Medical Journal **312**: 1215-1218.

Black, N. (2001). Evidence based policy: proceed with care. British Medical Journal **323**: 275-278.

Blackwood, B. (2006). Methodological issues in evaluating complex healthcare interventions. Journal of Advanced Nursing **54**(5): 612-622.

Blakemore, C. and Davidson, J. (2006). Putting a value on medical research. The Lancet **367**(9519): 1293-1295.

Bowker, G.C. and Star, S.L. (2000). Sorting things out; Classification and its consequences. Cambridge MA/London: The MIT Press.

Britten, N. (2011). Qualitative research on health communication: What can it contribute? Patient Education and Counseling **82**: 384-388.

Catford, J. (2009). Advancing the 'science of delivery' of health promotion: not just the 'science of discovery'. Health Promotion International **24**(1): 1-5.

de Salis, I., Tomlin, Z., Toerien, M. and Donovan, J. (2008). Qualitative research to improve RCT recruitment: Issues arising in establishing research collaborations. Contamporary Clinical Trials **29**: 663-670.

de Vries, M. (2004). Evaluatie Zuidoost-Drenthe HARTstikke goed! : mogelijkheden van community-based preventie van hart- en vaatziekten in Nederland. dept. Medische Wetenschappen. Groningen: Rijksuniversiteit Groningen.

Dehue, T. (2002). A Dutch treat: randomized controlled experimentation and the case of heroin-maintenance in the Netherlands. History of the Human Sciences **15**(2): 75-98.

Dehue, T. (2004). Historiography taking issues: analyzing an experiment with heroin abusers. Journal of the histroy of the Behavioral Sciences **40**(3): 247-264.

Egginton, W. and Sandbothe, M. (eds.). (2004). The pragmatic turn in philosophy: contamporary engagements between analytic and contentional thought. Albany: State University of New York Press.

El Fakiri, F., Hoes, A.W., Uiterwaal, P.J.M., Frenken, H.A.A. and Bruijnzeels, M.A. (2008). Process evaluation of an intensified preventive intervention to reduce cardiovascular risk in a multiethnic patient population. European Journal of Cardiovascular Nursing **7**(4): 296-302.

Epstein, S. (2007). Inclusion; the politics of difference in medical research. Chicago/London:

The University of Chicago Press, Ltd.
Fletcher, R.H. (2002). Evaluation of interventions Journal of Clinical Epidemiology **55**(12): 1183-1190
Fulop, N., Allen, P., Clarke, A. and Black, N. (2003). From health technology assessment to research on the organisation and delivery of health services: addressing the balance. Health Policy **63**: 155-165.
Glasgow, R.E., Lichtenstein, E. and Marcus, A.C. (2003). Why Don't We See More Translation of Health Promotion Research to Practice? Rethinking the Efficacy-to-Effectiveness Transition. American Journal of Public Health **93**(8): 1261-1267.
Godwin, M., Ruhland, L., Casson, I., MacDonald, S., Delva, D., Birtwhistle, R., Lam, M. and Seguin, R. (2003). Pragmatic controlled clinical trials in primary care: the struggle between external and internal validity. BioMed Central Medical Research Methodology **3**:28. doi:10.1186/1471-2288-3-28.
Groot, G. and Dewez, B. (2009). Waarom steeds weer een cultuurprogramma? Drie perspectieven tegelijkertijd hanteren. In: Cultuurverandering: mythe en realiteit. Praktijken, verhalen en reflecties. van Es, R., Boonstra, J. and Tours, H. (eds.). Deventer: Kluwer. pp. 311-324.
Hawe, P., Shiell, A. and Riley, T. (2004). Complex interventions: how "out of control" can a randomised controlled trial be? British Medical Journal **328**(7455): 1561-1563.
Horstman, K. and Houtepen, R. (2005). Worstelen met gezond leven: ethiek in de preventie van hart-en vaatziekten. Amsterdam: Het Spinhuis.
Horstman, K. and Houtepen, R. (2010). Wat is die onderklasse dom! Slanke hoogopgeleiden weten het zo goed. NRC Handelsblad.
Howson, A. (1998). Surveillance, knowledge and risk: the embodied experience of cervical screening Health **2**(2): 195-215.
Hunter, D.J. (2003). Public Health Policy. Cambridge: Polity Press.
James, W. (2008 [1907]). Pragmatism; A new name for some old ways of thinking. A series of lectures by William James. Rockville, Maryland: Arc Manor.
Jansen, Y.J.F.M., Bal, R., Bruijnzeels, M., Foets, M., Frenken, H. and de Bont, A. (2006). Coping with methodological dilemmas; about establishing the effectiveness of interventions in routine medical practice. BioMed Central Health Services Research **6**:160. doi:10.1186/1472-6963-6-160.
Jansen, Y.J.F.M., Foets, M.M.E. and de Bont, A.A. (2010). The contribution of qualitative research to the development of tailor-made community-based interventions in primary care: a review. European Journal of Public Health **20**(2): 220-226.
Kloek, G.C. (2004). Improving health related behaviour in deprived neighbourhoods. dept. Maatschappelijke Gezondheidszorg. Rotterdam: Erasmus MC rotterdam. [doctoral thesis].
Kloek, G.C., van Lenthe, F.J., van Nierop, P.W.M., Koelen, M.A. and Mackenbach, J.P. (2006). Impact evaluation of a Dutch community intervention to improve health-related behaviour in deprived neighbourhoods. Health and Place **12**(4): 665-667.
Latour, B. (1987). Science in Action; How to follow scientists and engineers through society. Cambridge, MA: Harvard University Press.
Latour, B. and Woolgar, S. (1986 [1979]). Laboratory Life; The construction of scientific facts. Princeton NY/Chichester UK: Princeton University Press.
Lloyd, P. (2000). Storytelling and the development of discourse in the engineering design

process. Design Studies **21**(4): 357-373.
Lomas, J., Fulop, N., Gagnon, D. and Allen, P. (2003). On being a good listener: setting priorities for applied health services research. The Milbank Quaterly **81**(3): 363-388.
Macdonald, G. (2000). A new evidence framework for health promotion practice. Health Education Journal **59**(1): 3-11.
Macdonald, G. (2002). Evidence-based Health Promotion; Perkins, E.,Simnett, I. and Wright, L. (eds.) John Wiley & Sons, Chichester, 1999 448 pp. ISBN 0 4719 7851 5 Health Education Research **17**(1): 133-134.
Mackenbach, J.P. and Stronks, K. (2002). A strategy for tackling health inequalities in the Netherlands. Britisch Medical Journal **325**(7371): 1029–1032.
McKee, M., Britton, A., Black, N., McPherson, K., Sanderson, C. and Bain, C. (1999). Methods in health services research: Interpreting the evidence: choosing between randomised and non-randomised studies. British Medical Journal **319**(7205): 312-315.
Mol, A. (2006). Proving or Improving: On Health Care Research as a Form of Self-Reflection. Qualitative Health Research **16**: 405-414.
Nutbeam, D. (1996). Achieving 'best practice' in health promotion: improving the fit between research and practice. Health Education Research **11**(3): 317-326.
O'Cathain, A., Murphy, E. and Nicholl, J. (2007). Why, and how, mixed methods research is undertaken in health services research in England: a mixed methods study. BioMed Central Health Services Research **7**:85. doi:10.1186/1472-6963-7-85.
O'Cathain, A., Murphy, E. and Nicholl, J. (2008). The quality of mixed methods studies in health services research. Journal of Health Service Research & Policy **13**(2): 92-98.
Oeij, P., Dorenbosch, L., Klein Hesslink, J. and Vaas, F. (2010). Slimmer werken en sociale innovatie: integrale organisatieverandering. Den Haag: Boom | Lemma.
Petticrew, M. (2011). When are complex interventions 'complex'? When are simple interventions 'simple'? European Jouranl of Public Health **21**(4): 397-399.
Reason, P. and Bradbury, H. (eds.). (2001). Handbook of Action Research: Participatory INquiry and practice. London/Thousand Oaks/New Delhi: Sage Publications Inc.
Rich, M. and Ginsburg, K.R. (1999). The Reason and Rhyme of Qualitative Research: Why, When, and How to Use Qualitative Methods in the Study of Adolescent Health. Journal of Adolescent Health **25**: 371-378.
Riley, T., Hawe, P. and Shiell, A. (2005). Contested ground: how should qualitative evidence inform the conduct of a community intervention trial? Journal of Health Services Research & Policy **10**(2): 103-110.
Roth, W.-M. and Breuer, F. (2003). Reflexivity and Subjectivity: A Possible Road Map for Reading the Special Issues. Forum: Qualitative Sozialforschung / Forum: Qualitative Social Research **4**:2.
RVZ (2007). Passend bewijs. Ethische vragen bij het gebruik van evidence in het zorgbeleid. Willems, D.W., Vos, R., Palmboom, G. and Lips, P. (eds.). Den Haag: Centrum voor ethiek en gezondheid. ISBN 978-90-78823-05-6.
Schuit, A.J., Wendel-Vos, G.C.W., Verschuren, W.M.M., Ronckers, E.T., Ament, A., van Assema, P., van Ree, J. and Ruland, E.C. (2006). Effect of 5-Year Community Intervention Hartslag Limburg on Cardiovascular Risk Factors. American Journal of Preventive Medicine **30**(3): 237-242.
Silverman, S.L. (2009). From Randomized Controlled Trials to Observational Studies The American Journal of Medicine **122**(2): 114-120.

Sinuff, T., Cook, D.J. and Giacomini, M. (2007). How qualitative research can contribute to research in the intensive care unit. Journal of Critical Care **22**: 104-111.

Straathof, A. (2009). Zoeken naar de kern van cultuurverandering. Inzicht, meten, sturen. Delft: Uitgeverij Eburon.

Susser, M. (1995). Editorial: The tribulations of trials - intervention in communities. American Journal of Public Health **85**(2): 156-158.

Timmermans, S. and Berg, M. (1997). Standardization in Action: Achieving Local Universality through Medical Protocols. Social Studies of Science **27**(2): 273-305.

Timmermans, S. and Berg, M. (2003). The Gold Standard; The Challenge of Evidence-Based Medicine and Standardization in Health Care. Philadelphia: Temple University Press.

Timmermans, S. and Haas, S. (2008). Towards a sociology of disease. Sociology of Health & Illness **30**(5): 659-676.

Tones, K. (2000). Evaluating health promotion: a tale of three errors. Patient Education and Counseling **39** (2-3): 227-236.

Twinn, S. (2001). The evaluation of the effectiveness of health education interventions in clinical practice: a continuing methodological challenge. Journal of Advanced Nursing **34**(2): 230-237.

Wahlberg, A. and McGoey, L. (2007). An Elusive Evidence Base: The Construction and Governance of Randomized Controlled Trials. BioSocieties **2**(1): 1-10.

Whitehead, J. (2009). Generating living theory and understanding in action research studies. Action Research **7**:85. doi: 10.1177/147650308099599.

Zuiderent-Jerak, T. (2007). Preventing implementation: exploring interventions with standardization in healthcare. Science as Culture **16**(3): 311-329.

Zuiderent-Jerak, T., Strating, M., Nieboer, A. and Bal, R. (2009). Sociological refigurations of patient safety; ontologies of improvement and 'acting with' quality collaboratives in healthcare. Social Science & Medicine **69**(12): 1713-1721.

Zuiderent, T. (2002). Blurring the Center; On the Politics of Ethnography. Scandinavian Journal of Information Systems **14**(2): 59-78.

Summary

General introduction

This thesis is situated against the background of two dilemmas that exist within the field of public health. The first dilemma is how to integrate prevention and health promotion interventions within the organisation of routine primary health care practice as they are becoming more and more complex. The second dilemma is how to evaluate the effectiveness of such interventions in such a way it matches the criteria of evidence-based medicine, and produces knowledge that can be more easily embedded in routine primary health care practice for making it more evidence-based.

Over the years the field of prevention and health promotion has found itself confronted with a growing complexity: prevention and health promotion interventions have become focussed on improving the health of subpopulations in society, consisting of multiple strategies. Moreover, the realisation grew that initiatives to improve population health could only be achieved in combination with better health service delivery and organisational restructuring of primary health care. This induced a growing complexity for the organisation of primary health care; with prevention and health promotion introducing a wider provision of services of care, cure added with educational activities and support and the introduction of new health care professionals. The impact and effect of prevention and health promotion programmes subsequently became more difficult to establish. In order to improve the quality of public health, it was believed that not only should the organisation of primary health care delivery be restructured, the scientific practice of public health would have to be restructured as well. The evidence produced by means of the randomized controlled trial methodology (RCT) did not translate and disseminate easily into routine medical practice. The quality of the evidence needed to improve too. New medical interventions or treatments when applied in routine medical practice did not achieve the same level of benefit, were not effective at all and/or did not disseminate into other medical settings than the ones in which they were tested. The use of evidence in routine medical practice proved to be a very complex process that does not correspond with the evidence produced with the RCT methodology. Therefore, as organisational restructuring of primary care is considered to foster the improvement of population health, it is believed this can only be achieved with evidence that is of more practical use in routine medical practice. In order to improve the translation and dissemination of scientific research findings into routine medical practice, additional

modes of evaluating effectiveness have been developed for complex prevention and health promotion interventions. Therefore, pragmatic modes of evaluation, like the pragmatic trial methodology, came up as an alternative to the conventional RCT methodology.

As a derivate of the RCT methodology, the pragmatic trial methodology is in a sense 'the best of both worlds': it provides the freedom to health care professionals to organise the intervention format and its core elements to fit their local context, organisational circumstances and work processes, and it corresponds to the societal emphasis on rationalisation to establish the effectiveness according to the criteria of sound scientific evaluation and a validated experimental methodology. Therewith the pragmatic trial methodology finds itself at the crossroad of routine medical practice and evaluation through scientific research. The pragmatic trial is an infrastructure for connecting the realms of science and routine medical practice.

In order to understand the pragmatic trial methodology as a new infrastructure for organisational change an ethnographic case study has been conducted of the Quattro Study, a pragmatic trial for evaluating the effectiveness of multidisciplinary patient care teams for the prevention of cardiovascular risk in primary health care practice in deprived neighbourhoods in Rotterdam and The Hague, the Netherlands. The ethnographic case study design, using a theoretical perspective stemming from science and technology studies, enabled to study what the pragmatic trial methodology as a new mode of evaluation of complex prevention and health promotion interventions comprised, and how the project's researchers, primary health care professionals, and participating patients mutually shaped the intervention and influenced the intervention's delivery and its outcomes.

Chapter 1 Coping with methodological dilemmas; about establishing the effectiveness of interventions in routine medical practice

This chapter examines the way researchers actually deal with conducting pragmatic trials. In this chapter it is shown how scientific researchers deal with methodological dilemmas when balancing between systematic scientific evaluation and embedding evidence-based intervention in routine medical practice in pragmatic trial research. The researchers of the Quattro Study adopted – in order to increase the chance of implementation of the intervention – a 'tailor-made approach'. The GPs and the supportive staff were asked to develop their own procedures for the program, albeit within preset conditions, as only they could develop guidelines that would fit into their specific local situation. By means of ethnographic analysis, this chapter showed that both the aspects of systematic scientific evaluation and pragmatism in localisation of the Quattro intervention in the pragmatic trial methodology proved difficult to retain. Instead, the researchers conducting the Quattro Study had to adjust the study design to enable the intervention's uptake in routine primary care. What could have been considered aspects of systematic scientific evaluation, became more pragmatic. The researchers adapted the inclusion procedure to overcome the homogeneous composition of, and a shortage in, eligible patients. In addition they provided the health care professionals the name lists of included patients in order to restrict the provision of care to research groups. This made it possible for the primary health care professionals to organise the intervention – a new manner of providing care and support – next to the existing daily routines. Moreover, the researchers increased their interference in the pragmatic execution of the intervention to make the trial

more systematic, and more uniform and in concordance with the original format. Thus what could have been considered pragmatic, through the increased interference of the researchers became more systematic. The researchers increased their interference in the organisation of the intervention by having the multidisciplinary team meetings implemented stringently and by having the data collected as systematically as possible. The emphasis on a more systematic execution of the Quattro Study intervention enabled the researchers to evaluate the effectiveness of the intervention more unambiguously but increasingly went against its 'pragmatic' character.

The chapter concludes with arguing that because of its inherent dynamics, a continuous process of methodological and practical reflection within pragmatic trials is imperative. Furthermore, it is argued that through using additional qualitative (ethnographic) analyses to evaluate the continuous interference of research and care in pragmatic trials, researchers are able to assess the validity and reliability of any effects of interventions. Additional qualitative methods help pragmatic trial researchers in both finding and accommodating diversions between the pragmatic and systematic aspects of pragmatic trial research, as these aspects influence each other in opposite directions.

Chapter 2 Tailoring intervention procedures to routine primary health care practice; an ethnographic process evaluation

This chapter examines how primary health care professionals deal with a 'tailor-made approach', and how they actually tailored the Quattro Study intervention to their practice needs and organisational circumstances. Since the limited effectiveness of complex interventions is often attributed to the failure to tailor the design of interventions to local care practices, it is argued that the uptake of interventions is to be done by tailoring the intervention procedures to routine clinical decision-making and incorporating the heterogeneity of patients and health care professionals. In other words, as an intervention is tailored to the unique characteristics of each practice, it may be more likely to become incorporated into the structure and function of daily operations resulting in sustainable effects. The adoption of a ' tailor-made approach' in the Quattro Study - with the underlying intention to minimise intrusion into normal daily care - was meant as an opportunity for the participating health care centres to frame their preferred procedures for the intervention, instead of following external guidelines that might not be perfectly applicable to the specific context of these centres and which were seen as externally generated research interference.

The ethnographic findings showed that the practice nurses, which were the coordinating axes of the Quattro Study intervention in the primary health care centres, experienced difficulties when implementing the multidisciplinary patient care teams. With the multidisciplinary meetings and the collection of data being crucial elements for the evaluation of effectiveness of the Quattro Study, the researchers developed an additional guideline to assist the practice nurses implementing the intervention as planned. The guideline described the medical-technical activities to be performed, the elements of the intervention that had to be organised and provided the instructions for organising the multidisciplinary collaborations of primary health care professionals.

In this chapter it is argued that as tailor-made approaches are developed to enable the uptake of interventions in routine practice, they are facilitated by the brokering of tools

such as guidelines. In fact, it is argued that guidelines facilitate organisational change and enables the transformation of existing interprofessional relations. And thus a 'tailor-made approach' in pragmatic trial research should not rule out the use of guidelines or protocols, as it makes tailoring possible. Standardisation and flexibility are not each others' opposites. Rather, they presuppose each other.

Chapter 3 The contribution of qualitative research to the development of tailor-made community-based interventions in primary care; a review

With tailor-made approaches being used increasingly to tailor intervention to specific health problems and/or communities, and with the pragmatic trial methodology being used increasingly to establish the effectiveness of such community-based interventions, qualitative research is used more frequently in conjunction with pragmatic trials for tailoring purposes. In this chapter it is examined how qualitative research actually contributes to the development of community-based interventions, as this remains largely unexplored. By means of a literature review using a literature mapping process, 33 articles were included and categorised according to the six sequential phases of the MRC Framework for the development of complex interventions to improve health. All articles included in this review were published between 2001 and 2007.

Qualitative research, the review showed, is mainly used to provide insight into the contextual circumstances of the implementation, delivery and evaluation of interventions. To a lesser extent, qualitative research findings are used for tailoring and improving the design of the interventions to better fit daily primary care conditions and routines. When qualitative findings are used for adjustments, though, they are mainly used to adjust or intervene upon the interventions' contextual circumstances such that the interventions are performed as planned rather than adjusting the intervention or the trial design to practice. In 26 articles, qualitative research was used in hindsight to evaluate the interventions via process evaluations. Use of qualitative research for contributing to intervention selection and modelling was discussed in only seven articles.

This chapter argues that the use of qualitative research in conjunction with the pragmatic trial methodology currently has a minimal contribution. Whereas the use of qualitative research for developing tailor-made interventions is considered to strengthen and improve the impact, effectiveness, and sustainability of interventions, the surrounding pragmatic trial methodology, in fact, prohibits the interventions from being tailored to fit the dynamics and complexity of care practices. Pragmatic trials therefore seem to be a contradiction in terms. The findings of this review suggest that the development of interventions has become a goal in and of itself and is not seen as a means or infrastructure for making primary care practice more evidence-based. This leads to the question of what contribution qualitative research then might have. It is argue that the contribution of qualitative research lies in providing ongoing evaluations of the methodological and practical dilemmas that pragmatic trials face locally in order to accommodate solutions. Pragmatic trial research, so it is argued, avails with local solutions to its local dilemmas. Only then can one speak of true tailor-made interventions.

Chapter 4 The role of screening methods and risk profile assessments in prevention and health promotion programmes; an ethnographic analysis

In prevention and health promotion interventions, screening methods and risk profile assessments are often used as tools for establishing the interventions' effectiveness, for the selection and determination of the health status of participants. The role these instruments fulfil in the creation of effectiveness – that is, the effects of the use of these instruments themselves – have remain unexplored. In this chapter, the role screening methods and risk profile assessments fulfil as part of prevention and health promotion programmes in the selection, enrolment and participation of participants is explored by means of a ethnographic analysis of the Quattro Study. The chapter shows that screening methods and health risk assessments create effects as they objectify health risks and/or the health status of individuals. They select the individuals 'at risk' and indicate the lifestyle modifications these people are required to make in order to improve their health. Yet, these instruments also reduce the group of participants, thereby decreasing the possible effect of interventions, as they provide the legitimisation for people to make choices to enrol or not and what lifestyle changes they incorporate into their lives. In other words, the instruments create a space of interaction, in which agency is distributed across the practice nurses, the participants and the instruments. Decisions in the Quattro study were not just made upon the projection of the outcomes of these instruments; decisions made by both the patients and practice nurses were the resultant of their opinions on these outcomes that were formed in interaction with the instruments.

In this chapter it is argued that via screening methods and risk profile assessments, prevention and health promotion interventions exhort a selective group of their target population to participate in interventions. They only include those people that identify with the construction of patienthood these instruments make. Moreover, it is argued that the effects such instruments generate in prevention and health promotion interventions should be considered genuine effects of such interventions. Result of the narrow definition of effectiveness that is used for evaluation purposes, is that the effects of screening methods and risk profile assessments remain invisible and outside of the scope of evaluations. They are thought to be neutral, which in practice however they are not. Therefore, it is argued that there should be more attention and appreciation for the role screening methods and risk profile assessments fulfil in generating health effects. In order to enable this, a broader notion of effectiveness should be obtained in prevention and health promotion. Moreover, screening methods and risk profile assessments fulfil an important role in the empowerment of patients, as these instruments legitimise decisions on enrolment, participation and behavioural change and facilitate them to make autonomous decisions about their care.

Chapter 5 The taming of chance and the actual practice of prevention; rationalised prevention and 'the Social'

The practice of prevention has increasingly become rationalised over the years. The notion of health risk therein has been a central concept. Since a new manner of scientific reasoning based upon statistics came into being in the nineteenth century, prevention and health promotion programmes have become about the 'taming of chance', a concept introduced by the Canadian philosopher of science Ian Hacking. Aided by statistics and the explanatory power of statistical patterns, the idea grew that nature could be mastered and controlled by science. With this shift in scientific reasoning, nature was no longer perceived to be deterministic in character, but became perceived as predictable and controllable. In other words, scientific and statistical information about diseases and conditions was - and still is - perceived to generate the possibility to control diseases and even eradicate them. With the best of intentions, a rationalistic approach holds a deterministic notion towards health. It assumes that once the scientific and numerical information on health risks is known, diseases can be intervened upon scientifically and restored by medicine.

Prevention and health promotion programmes reflect such a rationalistic and deterministic approach to health. In fact, they are set up to stimulate people to make the necessary lifestyle changes in their lives and to take responsibility and control over their own condition and solve their health problems. The Dutch Quattro Study project is an example of a prevention programme that employed a rationalistic approach to cardiovascular health. However, the current state of affairs points to an interesting conflict that exists within prevention and health promotion in general and in the prevention of cardiovascular diseases in particular. Although prevention and health promotion programmes exhort individuals to make the necessary lifestyle changes in their lives, they do not have that effect. When performed in practice, prevention and health promotion programmes often work out differently than expected. The "messiness" of daily practice is considered to cause these programmes to fail; it is considered an epiphenomenon or confounder of such programmes. This perspective portrays *ideal types* of prevention and does not do justice to the actual character of prevention and health promotion practice. In order to try and understand what happens in the practice of prevention and health promotion programmes, this chapter examines how the Quattro Study programme was actively shaped in practice by the health care professionals and participants.

In the Quattro Study project, a rationalistic prevention regime was set up, that was built upon the attribution of cardiovascular risk to patients and instructed them how to engage in reducing the risk for cardiovascular incidents (CVD) and the chance of having CVD events in future. In common with other prevention programmes, the Quattro Study encouraged patients to behave in a sensible and responsible way and to take appropriate actions to protect their future health. However, health care professionals and patients participated differently than the trial researchers expected. In fact, this chapter shows that although a rationalistic prevention regime was set up, both health care professionals and patients actively shaped the practice of prevention. The practice of the Quattro Study was shaped by the way patients participated in the intervention and the way the health care professionals related the prevention regime to them.

In the context of rationalised and enumerated prevention programmes in which risk profile assessments are used to systematically and objectively monitor the health status of

individuals, the ultimate aim is the mastery and control over the health of individuals. But with the biological and physiological make up of individuals considered as non-modifiable risks to cardiovascular health, lifestyles and health behaviours have become the target of medical intervention and restoration in contemporary prevention and health promotion. However, although they are the target in contemporary preventive interventions, the lives of patients in their respective social contexts and their daily circumstances are not taken into account when developing these programmes. And therefore, it is argued in this chapter, prevention and health promotion programmes have a double obligation. On the one hand, prevention programmes aim at the improvement of the health status of patients 'at risk', and on the other hand, in these programmes rationalistic prevention regimes have to be tailored, related and translated to individual patients as their cooperation is needed. Taking this double obligation into account prevention and health promotion is no longer solely about transferring the responsibility for good health to patients, it is about accepting the 'the social' as an integral part of prevention and health promotion practices.

General conclusion

This thesis evolved around the issue of how to evaluate the effectiveness of health promotion and prevention such that it matches the criteria for sound scientific research and at the same time produces knowledge that can more easily be embedded in routine medical practice. That is, this thesis concerned the issue of how to bridge the science-practice gap in complex public health settings. More specifically, it analysed one example of an evaluation methodology that tried to accomplish this: the pragmatic trial methodology. In theory the pragmatic trial methodology is 'the best of both worlds'. It provides health care practices with the freedom to organise the intervention format and its core elements to fit local contexts, organisational circumstances and work processes, and it corresponds to the societal emphasis on rationalisation to establish effectiveness according to the criteria of sound scientific evaluation and a validated experimental methodology. As such the pragmatic trial methodology is suggested to produce evidence on effectiveness that embeds more easily in routine medical practice, as the evidence it produces corresponds with and 'fits' the dynamics of that same practice. This places the pragmatic trial methodology at the crossroads of routine medical practice and evaluation through scientific research.

This thesis shows how the pragmatic trial methodology works out in practice. An ethnographic case study design enabled to study how the project's researchers developed, implemented and evaluated the intervention, how the intervention was enacted and developed further in primary health care practices and how both primary health care professionals and patients participated in the intervention. Pragmatic trails are particularly difficult to perform. This thesis does not provide the panacea for the development, implementation and evaluation of complex prevention and health promotion interventions, nor does it provide a concrete plan of action how to actually perform pragmatic evaluations. But it has provided insights on what the pragmatic trial methodology comprises and what the limitations of this methodology are. It has shown the methodology's inherent dilemma between pragmatically developing and implementing complex interventions that fit the local context of routine medical practice and scientifically evaluating the interventions' effectiveness or success. Despite its intention of pragmatically developing and evaluating prevention and health promotion interventions that fit the complexity and variability of

routine medical practice, the emphasis in the pragmatic trial methodology in the end is on systematic evaluation through scientific research and on establishing effectiveness. Moreover, the realms of science and practice seem not to be bridged but rather demarcated.

This being said, the conclusions drawn in this thesis underscore that the pragmatic trial methodology can be reconceptualised. Depending upon the perspective researchers adopt, either 'simplicity' or 'complexity' is seen as the inherent characteristic of interventions, one could be critical of the pragmatic trial methodology or not. From a 'simplicity' perspective, one could argue that the intervention was not developed correctly or the implementation of the intervention in practices was not guided properly by the scientific researchers. From a 'complexity' perspective these 'other' effects would not remain unanticipated effects of the intervention. Being critical of the pragmatic trial methodology, does injustice to it's intention of bridging the science-practice gap. Such critique would in fact underscore – instead of overcome – the dichotomy between pragmatism and systematic evaluation and respectively the dichotomy between routine medical practice and scientific research. In the concluding chapter it is therefore argued that the pragmatic trial methodology not only is a new mode of evaluation, but has to be considered as an infrastructure for bridging the science-practice gap and for facilitating change and innovation to take place in routine medical practice. Moreover, it is argue that in order for the pragmatic trial methodology to be really pragmatic, it needs to employ a complexity perspective incorporating a broader perspective on effectiveness, and needs to fully accept health care professionals, participants as well as instruments as co-constructors and co-producers of interventions and their outcomes. The pragmatic trial methodology should focus on the evaluation of complex interventions as they are shaped and formed in routine medical practice, in order not to become an oxymoron.

Samenvatting

Dit proefschrift is ontstaan tegen de achtergrond van twee dilemma's in het veld van de publieke gezondheidszorg. Het eerste dilemma heeft betrekking op de vraag hoe preventie en gezondheidsbevorderende interventies, die steeds complexer worden, te integreren en in te bedden in de organisatie van reguliere eerstelijnszorgpraktijken. Het tweede dilemma heeft betrekking op de vraag hoe de effectiviteit van dergelijke complexe interventies zo te evalueren, dat ze tegemoet komen aan de criteria van Evidence-Based Medicine en tegelijkertijd wetenschappelijke kennis produceren welke gemakkelijk in reguliere eerstelijnszorgpraktijken ingebed kan worden.

In de loop van de tijd is het terrein van preventie en gezondheidsbevordering complexer geworden: de focus van preventie en gezondheidsbevorderende interventies is meer gericht op het verbeteren van de gezondheidssituatie van subpopulaties in de Nederlandse samenleving en ze zijn daarbij komen te bestaan uit meerdere strategieën. Binnen de publieke gezondheidszorg realiseerde men zich dat initiatieven ter verbetering van de gezondheidssituatie van populaties, alleen kon worden bereikt in combinatie met een betere kwaliteit van zorg verlenen en organisationele veranderingen van de eerstelijnsgezondheidszorg. Dit maakte ook de eerstelijnsgezondheidszorg complexer; met preventie en gezondheidsbevorderings-programma's werden een breder palet van zorgdiensten geïntroduceerd, waarbij zorg en het genezen van aandoeningen gecombineerd werden met preventie, gezondheidseducatie en ondersteuning door nieuwe eerstelijnszorgprofessionals. De impact en het effect van preventie en gezondheidsbevorderende interventies werd hierdoor moeilijk(er) vast te stellen. Om de kwaliteit van de publieke gezondheidszorg te kunnen verbeteren, dienden niet alleen organisationele veranderingen in de eerstelijnsgezondheidszorg plaats te vinden, maar diende ook de wetenschappelijke praktijk verbonden aan de publieke gezondheidszorg geherstructureerd te worden.

De translatie en disseminatie van wetenschappelijk bewijs verkregen door middel van de methodologie van het gerandomiseerd experiment (RCT) in reguliere zorgpraktijken blijft achter. De kwaliteit van de wetenschappelijke bewijslast diende eveneens te verbeteren. Nieuwe medische interventies of behandelingen, wanneer zij uitgevoerd werden in reguliere zorgpraktijken bleken niet dezelfde mate van effect op te leveren, waren niet effectief of vonden geen toepassing in andere medische settings dan waar zij geëvalueerd werden. De toepassing van wetenschappelijk bewijs en kennis in reguliere zorgpraktijken is een complex

proces, dat niet correspondeerde met de wetenschappelijke bewijslast verkregen met de RCT. Dus om beter toegerust te zijn voor het verbeteren van de gezondheid van populaties, was het niet alleen noodzakelijk organisationele veranderingen in de eerstelijnsgezondheidszorg door te voeren maar ook wetenschappelijke bewijslast te verkrijgen die beter toepasbaar is in reguliere zorgpraktijken. Om de translatie en disseminatie van wetenschappelijk bewijs te bevorderen, kwamen alternatieve vormen voor het evalueren van effectiviteit in zwang. De conventionele methodologie van het gerandomiseerd experiment (RCT) wordt minder passend geacht voor het evalueren van de effectiviteit van complexe preventie en gezondheidsbevorderende interventies. Pragmatische evaluatievormen, zoals de pragmatische trial, deden hun intreden, als een alternatief voor de conventionele methodologie van de RCT.

Als een afgeleide van de RCT, bevat de pragmatische trial methodologie het beste van twee werelden: het geeft zorgprofessionals de vrijheid om interventies of de basiselementen ervan zodanig te organiseren dat ze passend zijn aan de lokale context, organisationele omstandigheden en werkprocessen, en het correspondeert met de maatschappelijke nadruk op rationalisatie en het vaststellen van effectiviteit volgens wetenschappelijke criteria en middels een gevalideerde trial methodologie. Daarmee bevindt de pragmatische trial methodologie zich op het snijvlak van reguliere zorgpraktijken en evaluatie door wetenschappelijk onderzoek. Het kan beschouwd worden als een infrastructuur die de werelden 'zorgpraktijk' en 'wetenschap' met elkaar verbindt. Om inzicht te krijgen in de pragmatische trial methodologie – een nieuwe evaluatievorm voor het vaststellen van effectiviteit -- als een nieuwe infrastructuur voor organisatieverandering in de eerstelijnsgezondheidszorg, is een etnografische case study uitgevoerd van de Quattro Study: een pragmatische trial opgezet voor het bepalen van de effectiviteit van multidisciplinaire zorgteams voor de preventie van hart- en vaatziekten in huisartsenpraktijken in achterstandswijken in Rotterdam en Den Haag. Een etnografische case study, met een theoretisch perspectief uit het wetenschap- en techniek onderzoek, maakte het mogelijk te bestuderen wat de pragmatische trial methodologie als een nieuwe vorm voor het evalueren van dergelijke complexe interventies inhield, en hoe de Quattro Study-onderzoekers, de eerstelijnszorgprofessionals en de deelnemende patiënten gezamenlijk de interventie gevormd hebben en de uitvoering en de uitkomsten hebben beïnvloed.

Hoofdstuk één onderzoekt de manier waarop wetenschappelijke onderzoekers pragmatische trials uitvoeren. In dit hoofdstuk wordt zichtbaar gemaakt hoe wetenschappelijke onderzoekers omgaan met methodologische dilemma's die verbonden zijn aan het balanceren tussen systematische wetenschappelijke evaluatie en het inbedden van evidence-based interventies in pragmatische trial onderzoek. De Quattro Study-onderzoekers hanteerden – om de kans op blijvende inbedding van de interventie te vergroten – een 'tailor-made approach'. De huisartsen en het ondersteunend personeel kregen hiermee de mogelijkheid om, binnen het format van de interventie, het interventieprogramma op eigen wijze te organiseren en er eigen procedures voor te ontwikkelen. Op deze manier waren zij in de gelegenheid om het interventieprogramma in te bedden in en eigen richtlijnen te ontwikkelen die passend zouden zijn binnen de specifieke eigen gezondheidscentra. Door middel van etnografische analyse, laat dit hoofdstuk zien hoe zowel systematische wetenschappelijke evaluatie als pragmatisme in lokalisatie van de Quattro interventie zich tot elkaar verhielden. Dit hoofdstuk laat zien hoe de Quattro Study-onderzoekers het design van het onderzoek aanpasten om de interventie

onderdeel te laten worden van de dagelijkse eerstelijnszorgpraktijk. Wat men zou verwachten als aspecten relevant voor het systematisch kunnen evalueren van de interventie, werden deze aspecten meer pragmatisch. De onderzoekers pasten de inclusie procedure aan om een homogene compositie en een tekort aan geschikte patiënten te voorkomen en voorzagen de eerstelijnszorgprofessionals met de overzichtslijsten van in de studie geïncludeerde patiënten. Deze aanpassingen in het study design maakten het voor zorgprofessionals mogelijk om de interventie – een nieuwe manier voor het verlenen van zorg en ondersteuning – te organiseren in bestaande dagelijkse zorgpraktijken. Tevens interfereerden de Quattro Study-onderzoekers in de pragmatische uitvoering van de interventie in de deelnemende centra om de evaluatie systematischer, meer uniform en meer volgens het orginele format, te kunnen uitvoeren. Met andere woorden, wat men zou verwachten als pragmatische aspecten van de pragmatische trial, de uitvoering van de interventie, werd hierdoor systematischer. De onderzoekers verhoogden de bemoeienissen in de pragmatische uitvoering van de interventie door het organiseren van intervisiebijeenkomsten voor praktijkondersteuners om de multidisciplinaire zorgteams op een meer gestandaardiseerde wijze onderdeel te laten worden van de bestaande zorgpraktijken en zij ontwikkelden aanvullende procedures om de benodigde data voor de evaluatie op een zo systematische manier te verzamelen. De nadruk op een systematischere uitvoering van de Quattro Study-interventie maakte het de onderzoekers mogelijk de effectiviteit van de interventie eenduidiger vast te stellen, maar tegelijkertijd ging dit in tegen het pragmatische karakter van de interventie.

De pragmatische trial voorzag de Quattro-onderzoekers van diverse substantiële uitdagingen, waarbij zij voortdurend dienden te balanceren tussen systematische wetenschappelijke evaluatie en pragmatische lokalisering. In dit hoofdstuk wordt betoogd dat vanwege deze inherente dynamiek van de pragmatische trial en continue proces van methodologische en praktische reflectie noodzakelijk is. Tevens wordt betoogd dat wetenschappelijke onderzoekers, door het additioneel gebruik van kwalitatieve (etnografische) onderzoeksmethoden voor de evaluatie van de continue interferentie van wetenschap en reguliere zorgpraktijk in pragmatische trials, de mogelijkheid hebben om de validiteit en betrouwbaarheid van de effecten van complexe interventies vast te stellen. Het additioneel gebruik van kwalitatieve onderzoeksmethoden stelt pragmatische trial onderzoekers in staat oplossingen en aanpassingsmogelijkheden te vinden in zowel de pragmatische als de systematische aspecten van pragmatische trial onderzoek, omdat deze aspecten elkaar in tegengestelde richting beinvloeden.

Hoofdstuk twee bestudeert hoe eerstelijnszorgprofessionals omgaan met een 'tailor-made approach', en hoe zij de Quattro Study-interventie aanpasten aan de behoeften en organisationele omstandigheden van de eigen gezondheidscentra. De beperkte effectiviteit van complexe preventie en gezondheidsbevorderende interventies wordt vaak toegeschreven aan het feit dat bij de ontwikkeling, interventies onvoldoende toegespitst worden op lokale zorgpraktijken. Om interventies in reguliere zorgpraktijken ingebed te krijgen, dienen interventie procedures aangepast te worden aan de in de zorgpraktijken bestaande klinische besluitvormingsprocessen en dient de heterogeniteit van patiënten en zorgprofessionals weerspiegeld te worden in de interventies. Met andere woorden, als interventies worden toegespitst op de unieke karakteristieken van individuele zorgpraktijken, dan is de kans groot dat interventies blijvend ingebed raken in de dagelijkse routines en werkprocessen waardoor er sprake is van duurzame effecten. Met het toepassen van een

'tailor-made approach' in de Quattro Study – met de onderliggende intentie zo min mogelijk te interfereren in dagelijkse eerstelijnszorg – kregen de participerende gezondheidscentra de mogelijkheid om voor de interventie eigen procedures te ontwikkelen, passend in de eigen lokale context. Het gebruik van extern ontwikkelde richtlijnen, welke mogelijk niet geheel pasten in de specifieke, lokale context van de gezondheidscentra, werd gezien als invloed van onderzoek dat buiten de zorgpraktijken stond. De etnografische onderzoeksgegevens laten zien dat de praktijkondersteuners, die de centrale spil vormden van de Quattro interventie in de deelnemende gezondheidscentra, moeilijkheden ondervonden bij het implementeren van multidisciplinaire zorgteams. Met de multidisciplinaire zorgteams, de multidisciplinaire overleggen, en de dataverzameling als cruciale onderdelen voor het evalueren van de effectiviteit van de Quattro Study, ontwikkelden de onderzoekers een additionele richtlijn voor de praktijkondersteuners voor de implementatie van de interventie zoals bedacht. De richtlijn beschreef de uit te voeren medisch-technische handelingen, de te organiseren onderdelen van de interventie, en instructies voor het organiseren van multidisciplinaire samenwerking tussen eerstelijnszorgprofessionals.

In dit hoofdstuk wordt betoogd dat 'tailor-made approaches' van nut zijn voor het inbedden van interventies in dagelijkse zorgpraktijken, omdat instrumenten – zoals richtlijnen – dit faciliteren. Betoogd wordt dat organisatieverandering en de transformatie van bestaande interprofessionele relaties gefaciliteerd worden door het gebruik van richtlijnen. Om deze reden kan een 'tailor-made approach' in pragmatische trial onderzoek niet zonder de toepassing van richtlijnen en protocollen, omdat deze juist aanpassing ('tailoring') van interventies aan dagelijkse zorgpraktijken mogelijk maken.

In hoofdstuk drie wordt ingegaan op de bijdrage van kwalitatieve onderzoeksmethoden aan de ontwikkeling van complexe preventie en gezondheidsbevorderende interventies gericht op populaties in de samenleving ('community-based interventies'). 'Tailor-made approaches' worden steeds vaker toegepast om interventies aan te passen aan specifieke gezondheidsproblemen en/of populaties in de samenleving. De pragmatische trial methodologie wordt steeds vaker gebruikt om de effectiviteit van dergelijke 'tailor-made', populatiegerichte interventies vast te stellen. Vaak worden kwalitatieve onderzoeksmethoden – als onderdeel van de pragmatische trial – toegepast voor het aanpassen van interventies. In dit hoofdstuk wordt onderzocht hoe kwalitatieve onderzoeksmethoden daadwerkelijk bijdragen aan de ontwikkeling van populatiegerichte interventies, omdat dit nog onvoldoende bekend is. Door middel van een literatuurreview, waarbij gebruikt is gemaakt van 'literature mapping', werden 33 artikelen geïncludeerd en gecategoriseerd volgens de zes fases van het MRC Framework voor de ontwikkeling van complexe interventies ter bevordering van gezondheid. Alle geïncludeerde artikelen werden gepubliceerd tussen 2001 en 2007. Kwalitatieve onderzoeksmethoden, zoals deze literatuurreview laat zien, werden voornamelijk gebruikt voor het verkrijgen van inzicht in de contextuele omstandigheden van de implementatie, uitvoering en evaluatie van de interventies. In mindere mate werden kwalitatieve onderzoeksgegevens gebruikt voor het beter later aansluiten van interventies bij dagelijkse zorgpraktijken door het aanpassen en verbeteren van de interventies. In geval kwalitatieve onderzoeksgegevens wel werden gebruikt, werden deze hoofdzakelijk ingezet voor het aanpassen van of interveniëren op de contextuele omstandigheden van de interventies, zodat de interventies uitgevoerd werden zoals bedacht. De kwalitatieve onderzoeksgegevens werden niet gebruikt voor het verbeteren van het evaluatiedesign

van de interventies. In 26 artikelen, werden kwalitatieve onderzoeksmethoden na afloop van de testperiode gebruikt om de interventies middels procesevaluaties te evalueren. In slechts zeven artikelen werd gemeld dat voor de selectie en ontwikkeling van interventies kwalitatieve onderzoeksgegevens waren gebruikt.

In dit hoofdstuk wordt betoogd dat het gebruik van kwalitatieve onderzoeksmethoden als onderdeel van pragmatische trials een minimale bijdrage heeft. Ondanks dat het gebruik van kwalitatieve onderzoeksmethoden voor de ontwikkeling van 'tailor-made', populatiegerichte interventies geacht wordt de impact, effectiviteit en duurzaamheid van interventies te versterken en te verbeteren, voorkomt de pragmatische trial methodologie juist dat interventies worden aangepast aan de dynamiek en complexiteit van zorgpraktijken. Pragmatische trials lijken hierdoor een tegenstrijdigheid te bevatten; een contradictio in terminis. De resultaten van deze literatuurreview suggereren dat het ontwikkelen van interventies een doel op zich zelf geworden is, in plaats van een middel of een infrastructuur om dagelijkse zorgpraktijken meer evidence-based te maken. Dit leidt tot de vraag welke bijdrage kwalitatieve onderzoeksmethoden dan zou kunnen hebben. In dit hoofdstuk wordt betoogd, dat de bijdrage van kwalitatieve onderzoekmethoden juist gelegen is in het feit dat het pragmatische trials voorziet van voortdurende evaluatie van de methodologische en praktische dilemma's zowel in wetenschap als in lokale zorgpraktijken voor het vinden van lokale oplossingen. Pragmatische trial onderzoek, zo wordt betoogd, heeft juist baat bij lokale oplossingen voor lokale dilemma's. Alleen dan kan gesproken worden van échte 'tailor-made' interventies.

In preventie en gezondheidsbevorderende interventies, worden screeningsmethoden en risicoprofiel analyses gebruikt - instrumenten voor het vaststellen van de effectiviteit van dergelijke interventies - voor de selectie en het bepalen van de gezondheidsstatus van deelnemers. De rol van dergelijke instrumenten in het vaststellen van effectiviteit, dan wel het effect dat deze instrumenten zelf hebben is niet eerder onderzocht. In hoofdstuk vier, wordt onderzocht welke rol screeningsmethoden en risicoprofiel analyses - als onderdeel van preventie en gezondheidsbevorderende interventies - hebben in de selectie, deelname en participatie van deelnemers, middels etnografische onderzoeksgegevens van de Quattro Study. Dit hoofdstuk laat zien, dat screeningsmethoden en risicoprofielanalyses zelf ook effect sorteren, omdat deze instrumenten gezondheidsrisico's en/of de gezondheidsstatus van individuen objectiveren. Met andere woorden, deze instrumenten selecteren individuen met 'risico' en identificeren welke leefstijl aanpassingen deze individuen dienen te maken om hun gezondheidssituatie te verbeteren. Echter tegelijkertijd reduceren deze instrumenten ook het aantal deelnemers en het uiteindelijke effect van de interventie, omdat zij individuen voorzien van legitimering van hun keuze wel of niet deel te nemen aan de interventies en welke leefstijl aanpassingen al dan niet te doen. Anders gezegd, geven deze instrumenten individuen handelingsruimte, waarbinnen handelingsmogelijkheden (agency) worden gedistribueerd tussen de praktijkondersteuners, de deelnemers en de instrumenten. Beslissingen worden niet alleen genomen op basis van de uitkomsten van de metingen die deze instrumenten projecteren; beslissingen worden genomen door patiënten en praktijkondersteuners op basis van hun meningen over de uitkomsten, welke in interactie met de instrumenten worden gevormd.

In dit hoofdstuk wordt betoogd dat door het gebruik van screeningsmethoden en risicoprofiel analyses in preventie en gezondheidsbevorderende interventies, een selectieve

groep van de doelpopulatie wordt overgehaald om in de interventies deel te nemen. Deze instrumenten includeren alleen die individuen, die zich identificeren met het feit dat zij door deze instrumenten worden geconstrueerd als patiënten. Tevens wordt betoogd dat de effecten die deze instrumenten zelf sorteren in preventie en gezondheidsbevorderende interventies gezien moeten worden als daadwerkelijke effecten van dergelijke interventies. Het resultaat van een nauwe definitie van effectiviteit dat voor evaluatiedoeleinden normaliter wordt gebruikt, is dat effecten van screeningsmethoden en risicoprofiel analyses onzichtbaar blijven en buiten het zicht van evaluaties vallen. Daarom wordt geargumenteerd dat meer pragmatische evaluatievormen noodzakelijk zijn, omdat pragmatische evaluatievormen de mogelijkheid bieden het zichtveld van evaluaties en de definitie van effectiviteit te verbreden. Tevens dient meer aandacht en waardering te komen voor de rol die screeningsmethoden en risicoprofiel analyses vervullen in het realiseren van gezondheidseffecten. Preventie en gezondheidsbevordering dient een bredere definitie van effectiviteit te hanteren, om deze effecten zichtbaar te maken. En daarbij vervullen screeningsmethoden en risicoprofiel analyses een belangrijke rol in de 'empowerment' van patiënten, omdat juist deze instrumenten beslissingen omtrent deelname, participatie en gedragsverandering legitimeren en hen faciliteren in het nemen van autonome beslissingen met betrekking tot zorg.

De praktijk van preventie en gezondheidsbevordering is door de jaren heen gerationaliseerd. Het begrip 'gezondheidsrisico' vormt hierin een centraal concept. Sinds een nieuwe manier van wetenschappelijke redeneren, gebaseerd op statistiek, zijn intrede deed in de negentiende eeuw, draait het in preventie en gezondheidsbevorderende programma's om het controleren van risico's ('taming of chance'). Met behulp van statistiek(en) en de verklarende kracht van statistische patronen, groeide de notie dat de natuurlijke omgeving kon worden gedomineerd en gecontroleerd door de wetenschap. Met deze verschuiving in wetenschappelijke denken, werd de natuurlijke omgeving niet meer beschouwd als deterministisch, maar bezien als voorspelbaar en beheersbaar. Met andere woorden, door wetenschappelijke en statistische informatie werden – en worden nog immer - ziekten en aandoeningen beschouwd als controleerbaar en elimineerbaar. Met de beste bedoelingen, een dergelijke rationalistische denkwijze heeft een deterministische opvatting met betrekking tot gezondheid in zich. Het gaat er van uit dat wanneer er wetenschappelijke en cijfermatige informatie over gezondheidsrisico's bekend is, ziekten en aandoeningen wetenschappelijk kunnen worden benaderd en door de geneeskunde kunnen worden verholpen. Preventie en gezondheidsbevorderende programma's reflecteren eveneens een dergelijke rationalistische en deterministische opvatting met betrekking tot gezondheid. Zij worden op een dusdanige manier opgezet dat zij individuen overhalen noodzakelijke leefstijlaanpassingen te maken en de verantwoordelijkheid en controle te nemen over hun gezondheid en gezondheidsproblemen op te lossen. De Quattro Study is een voorbeeld van een preventieprogramma met een rationalistische denkwijze met betrekking tot cardiovasculaire gezondheid. Echter de huidige stand van zaken maakt in het veld van de publieke gezondheidszorg een interessant conflict zichtbaar. Ondanks dat preventie en gezondheidsbevorderende interventies opgezet zijn individuen over te halen te zorgen voor hun gezondheid, hebben ze niet dit effect. Uitgevoerd in dagelijkse zorgpraktijken worden dergelijke interventies anders uitgevoerd dan bedacht. De weerbarstigheid van reguliere zorgpraktijken wordt gezien als de oorzaak van het falen van dergelijke programma's. Een rationalistische denkwijze met betrekking tot gezondheid geeft een ideaal beeld van preventie

weer en doet onvoldoende recht aan de praktijk van preventie en gezondheidsbevordering. Om inzicht te krijgen in de daadwerkelijke praktijk van preventie en gezondheidsbevordering, wordt in dit hoofdstuk onderzocht hoe de Quattro Study door de eerstelijnszorgprofessionals en de deelnemers is gevormd.

In de Quattro Study, een rationalistisch preventie regime was opgezet, gebaseerd op het toekennen van cardiovasculair risico aan patiënten en instructie hoe cardiovasculaire risico's te verlagen en cardiovasculaire events in de toekomst te voorkomen. Zoals ook in andere preventie programma's, stimuleerde de Quattro Study patiënten zich bewust en verantwoordelijk te gedragen en afdoende acties te ondernemen ter bescherming van hun gezondheid. Echter, de zorgprofessionals en deelnemende patiënten participeerden anders dan verwacht. Dit hoofdstuk laat zien dat, ondanks dat een rationalistisch preventie regime was opgezet, de zorgprofessionals en patiënten actief de preventiepraktijk hebben gevormd. In dit hoofdstuk wordt betoogd dat in het kader van gerationaliseerde en cijfermatige preventie programma's, waarin risicoprofiel analyses worden ingezet om de gezondheidsstatus van individuen systematisch en objectief te monitoren, het ultieme doel is het beheersen en controleren van de gezondheid van individuen. Echter doordat de biologische en fysieke factoren van individuen worden gezien als niet-veranderbare risicofactoren voor cardiovasculaire gezondheid, zijn leefstijl, gezond gedrag - of beter 'de sociale omstandigheden' - de focus geworden van medische interventie en de hedendaagse publieke gezondheidszorg. De levens van patiënten in hun sociale context en hun dagelijkse omstandigheden worden onvoldoende meegenomen bij de ontwikkeling van dergelijke preventie programma's. Er wordt in dit hoofdstuk dan ook betoogd, dat preventie en gezondheidsbevorderende programma's een dubbele verantwoordelijkheid hebben. Aan de ene kant, richten dergelijke programma's zich op de verbetering van de gezondheidssituatie van 'risico patiënten', en aan de andere kant moeten dergelijke programma's aangepast en vertaald worden naar individuele patiënten omwille van hun medewerking. Rekening houdend met deze dubbele verantwoordelijkheid, dan dienen preventie en gezondheidsbevordering zich niet alleen te richten op het overdragen van verantwoordelijk voor gezondheid naar individuele burgers, maar dienen ze daarbij ook te accepteren dat de sociale en persoonlijke omstandigheden van burgers een integraal onderdeel zijn van preventiepraktijken.

Dit proefschrift is ontstaan tegen de achtergrond van het dilemma hoe de effectiviteit van preventie en gezondheidsbevordering vast te stellen, opdat het tegemoet komt aan de criteria van wetenschappelijk onderzoek en tegelijkertijd kennis produceert dat makkelijker inbedding vindt in reguliere zorgpraktijken. Met andere woorden, dit proefschrift richt zich op hoe in het complexe veld van de publieke gezondheid de kloof tussen wetenschap en praktijk te overbruggen. In dit proefschrift is een voorbeeld van een dergelijke methodologie bestudeerd; de pragmatische trial methodologie. In theorie omvat de pragmatische trial methodologie het beste uit beide werelden. Het geeft zorgpraktijken de mogelijkheden om interventies en de essentiële onderdelen ervan zodanig te organiseren dat ze ingebed kunnen worden in de lokale contexten, organisationele omstandigheden en bestaande werkprocessen. Tevens komt het tegemoet aan de maatschappelijke nadruk op rationalisatie en het vaststellen van effectiviteit volgens wetenschappelijke criteria en een gevalideerde trial methodologie. Op deze wijze wordt de pragmatische trial methodologie geacht bewijs van effectiviteit te produceren, welke makkelijker inbedding vindt in reguliere zorgpraktijken omdat het bewijs dat geproduceerd wordt past bij de dynamiek in deze zorgpraktijken. Dit

plaatst de pragmatische trial methodologie op het kruispunt van dagelijkse zorgpraktijken en wetenschappelijke evaluatie. Dit proefschrift laat zien hoe deze methodologie werkt. Een etnografische case study maakte het mogelijk te onderzoeken hoe de interventie werd ontwikkeld, geïmplementeerd en geëvalueerd door de wetenschappelijke onderzoekers, hoe de interventie werd uitgevoerd een verder gevormd in de deelnemende gezondheidscentra en hoe zowel eerstelijnszorgprofessionals als patiënten participeerden in de interventie.

Pragmatische trials zijn moeilijk uit te voeren. Dit proefschrift laat zien hoe de pragmatische trial methodologie werkt middels gedetailleerde beschrijvingen van de Quattro Study. Dit proefschrift geeft noch een panacee voor de ontwikkeling, implementatie en evaluatie van complexe preventie en gezondheidsbevorderende interventies, noch geeft het een concreet plan van aanpak voor de daadwerkelijke uitvoering van pragmatische evaluaties. Het heeft inzicht gegeven in wat de pragmatische trial methodologie inhoudt en wat de beperkingen ervan zijn. Dit proefschrift heeft de inherente spanning tussen het pragmatisch ontwikkelen en implementeren van complexe interventies die passen zijn in lokale contexten en het wetenschappelijk evalueren van de effectiviteit of succes van dergelijke interventies. Ondanks de intentie preventie en gezondheidsbevorderende interventies passend in de complexiteit en variabiliteit van dagelijkse zorgpraktijken pragmatisch te ontwikkelen en te evalueren, ligt de nadruk in de pragmatische trial methodologie op systematische evaluatie door wetenschappelijk onderzoek en op het vaststellen van effectiviteit. De werelden 'wetenschap' en 'zorgpraktijk' lijken niet overbrugd, maar juist gedemarqueerd te worden.

Echter de conclusies van dit proefschrift benadrukken dat de pragmatische trial methodologie herdefinieerd dient te worden. Betoogd wordt dat afhankelijk van het perspectief onderzoekers hanteren, 'simpliciteit' of 'complexiteit', interventies op dergelijke wijze worden gekarakteriseerd en men kritisch is op de pragmatische trial methodologie. Vanuit het perspectief van 'simpliciteit', kan men betogen dat de interventies niet juist waren ontwikkeld of de implementatie niet afdoende door de onderzoekers waren begeleid. Vanuit een 'complexiteit' perspectief, worden 'andere' effecten niet gezien als onverwachte effecten. Echter door kritisch te zijn op de pragmatische trial methodologie, wordt de intentie van het overbruggen van de kloof tussen wetenschap en zorgpraktijken niet serieus genomen. Het benadrukt, in plaats van overwint, de dichotomie tussen pragmatisme en systematische evaluatie en de dichotomie tussen dagelijkse zorgpraktijken en wetenschappelijk onderzoek. In het concluderende hoofdstuk wordt juist betoogd dat de pragmatische trial methodologie niet alleen een nieuwe evaluatievorm is, maar een infrastructuur voor het overbruggen van de kloof tussen wetenschap en zorgpraktijk omdat het verandering en innovatie in dagelijkse zorgpraktijken faciliteert. Tevens wordt betoogd dat om de pragmatische trial methodologie daadwerkelijk pragmatisch te maken, een 'complexiteit' perspectief gehanteerd dient te worden omwille van een bredere definitie van effectiviteit. Daarnaast dient het zowel zorgprofessionals, deelnemers als instrumenten te accepteren en incorporeren als co-constructeurs en co-producenten van interventies en uitkomsten. Om geen contraditio in terminis te worden, dient de focus van de pragmatische trial methodologie te liggen op de evaluatie van interventies zoals deze door dagelijkse zorgpraktijken worden gevormd.

Dankwoord

De laatste woorden van dit proefschrift. Maar zeker niet het minst belangrijke onderdeel; het bedanken van alle mensen die bijgedragen hebben tot het afronden van dit proefschrift. Over de jaren heen zijn dat toch een hoop mensen...

Marc Bruijnzeels, ik wil je graag bedanken voor de potentie die jij zag in het summiere, nog ondoordachte voorstel dat ik voor mijn sollicitatiegesprek had voorbereid en de mogelijkheid die je bood om als AIO bij het iBMG te beginnen. Roland Bal, jouw rol veranderde in al die jaren van mijn dagelijks begeleider naar die van promotor. Hoewel je het nooit ronduit hebt uitgesproken, heb je ongetwijfeld vaak je twijfels gehad of dit promotieonderzoek ooit zou worden afgerond. Ik wil je graag bedanken voor het gestelde vertrouwen in een goede afloop. Ook Marleen Foets ben ik veel dank verschuldigd. Marleen, jij nam de begeleidingsrol van Marc over na diens vertrek bij het iBMG. Dank voor al je steun.

Zeer grote dank gaat uit naar Antoinette de Bont. Zonder haar had ik dit proefschrift nooit afgerond! Antoinette, je hebt veel met me te stellen gehad in de afgelopen jaren. Je werd mijn dagelijks begeleider in een periode van hoge pieken en diepe dalen, waarin ik meer dan eens twijfelde aan mijn eigen kunnen en meer dan eens mijn proefschrift figuurlijk aan de wilgen wilde hangen. Je hebt altijd gezegd: 'doorgaan duurt net zo lang als stoppen'. Ik moet je bekennen dat ik die zin de laatste jaren vaak als mantra heb gebruikt. Echt mijn promotie aan de wilgen hangen, dat kon ik niet. Ik was te koppig en te vastberaden om me aan mezelf te bewijzen en van tijd tot tijd ook veel te perfectionistisch, wat een snelle afronding in de weg stond. Altijd was jij daar met praktische adviezen, omgegooide stukken tekst en bemoedigende woorden als ik lang niets van me had laten horen. Vaak maande je me om door te zetten, ik was tenslotte toch bijna klaar; een kwestie van afmaken. Antoinette, dit proefschrift is hierbij ook een beetje van jou. Dank je wel!

Ook wil ik graag alle andere leden van de commissie bedanken voor de beoordeling van mijn manuscript en de discussie bij de verdediging ervan. Marise Schot wil ik graag bedanken voor het ontwerp van dit boek: omdat je uit veel tekst iets moois hebt gemaakt.

Het object van dit promotieonderzoek was het Quattro-project. Fatima en Paul, Quattro hoort bij jullie. Ik wil jullie beide hartelijk danken voor het feit dat jullie mij als antropoloog in jullie project toelieten. Ik wil jullie ook gelijk mijn verontschuldigingen aanbieden: ik heb me tijdens de onderzoeksfase van mijn promotietraject onvoldoende gerealiseerd wat mijn bevindingen voor jullie zouden kunnen betekenen of wat het met jullie deed dat er een onderzoeker over jullie schouders meekeek en zo nu en dan kritische vragen stelde. Ik heb nooit de intentie gehad om Quattro of jullie onderzoekswaardigheid in een verkeerd daglicht te plaatsen. Ik hoop dat mijn proefschrift en haar conclusie dat ook laten zien: Quattro was een onderzoeksproject, maar zeker ook een infrastructuur voor veranderingen in huisartsenzorg, door jullie mogelijk gemaakt. Het Quattro-project kon ook niet bestaan zonder deelnemende huisartsenpraktijken. Ik wil in het bijzonder de praktijkondersteuners – Yvonne Kramer (GZC Randweg), Amrita Sardjoe (GZC Zorg-op-Zuid Afrikaanderwijk), Yvonne Lodder (GZC Zorg-op-Zuid Lange Hille), Ans van Kekum (GZC Zorg-op-Zuid Katendrecht) en Anne Mieke Wierda (GZC De Rubenshoek) hartelijk danken voor de mogelijkheid die ze me boden om hen in hun dagelijks werk te mogen volgen.

Met een promotieonderzoek op het snijvlak van epidemiologie/ gezondheidswetenschappen en wetenschap- en techniek onderzoek, participeerde ik

in zowel de onderzoeksgroep Reach als de sectie Healthcare Governance. Ik wil dan ook graag de collega's van het iBMG, waar ik in al die jaren mee heb samengewerkt, hartelijk danken voor de interessante discussies, de leuke lunch- en koffie uurtjes en memorabele congresbezoeken: Rianne Frenken, Hans Harmsen, Liselotte Visser, Radjesh Manna, Semiha Denktas, Lilian Hoonhout, Charles Agyemang. Jos Aarts, Teun Zuiderent-Jerak, Sonja Jerak-Zuiderent, Maartje Niezen-van der Zwet, Hester van de Bovenkamp, Jolanda Dwarswaard, Habib Pirnhadad, Zhara Niazkhani, Wilma van der Scheer, Sarah-Sue Slaghuis, Rik Wehrens, Anneloes van Staa, Iris Wallenbrug, Marleen Bekker, Kim Putters, Pauline Meurs, Femke Mastboom, Kor Grit, Annemiek Stoopendaal, Bert Huisman, Stef Groenewoud, en Lieke Boonen.

Een paar van mijn collega's bij het iBMG wil ik in het bijzonder bedanken. Samantha Adams, omdat spuien en afreageren tijdens een kopje koffie soms ook goed is. Dank voor je nuchterheid, relativeringsvermogen en je humor! Mijn oud-kamergenootjes Marleen de Mul, Stans van Egmond en Dung Ngo, dank voor alle emotionele steun! En ja, doorzetten ís belangrijk. Wim Labree, Anushka Choté, Birgitha van der Meij en Anita Donkers, dank voor de gezellige afleiding, de etentjes geweest en in de toekomst.

Een promotietraject volgen betekent ook deel uitmaken van een AIO-gemeenschap. Ik wil graag de coördinatoren van WTMC bedanken voor de leuke en inspirerende bijeenkomsten. En natuurlijk iedereen die daar als AIO aanwezig was voor de leuke discussies over STS en andere zaken tijdens de winter- en summerschools.

Een nieuwe werkomgeving geeft nieuwe impulsen en inspiratie. Na mijn vertrek bij het iBMG vond ik bij TNO – eerst bij de afdeling ZorgInnovatie en later bij de expertisegroep Duurzame Arbeidsproductiviteit -- een werkomgeving, waar ik de gelegenheid kreeg om mijn kennis om te zetten in praktijk. Hiervoor wil ik graag al mijn directe (oud-)collega's bij TNO bedanken. In het bijzonder Ronald Mooij, Marian Schoone, Hanneke Molema, Meike Smit, Annelies Broerse, Titia Bouten, Joyce Aerts, Wilma Otten, Olivier Blanson Henkemans, Laurence Alpay, Roel Barelds, Yvonne Pijnacker-Hordijk, Rom Perenboom, Carool Teirlink, Robert Bezemer, Eric Franck, Erna de Kleijn, Denise van der Klauw, Evelien Rijken, Wieke Bockstael en Klaas ten Have voor alle interessante gesprekken. Bij TNO ontdekte ik dat het onderwerp van dit proefschrift; het spanningsveld tussen wetenschappelijke evaluatie en dagelijkse zorgpraktijken – nog altijd aan de orde van de dag is. De maatschappelijke ontwikkelingen maken dat steeds meer gezocht wordt naar manieren om de zorg nog slimmer te organiseren. In plaats van een nadruk op uitkomsten van interventies alleen komt meer aandacht voor het proces van verandering. Het zoeken naar nieuwe manieren van evalueren wordt dan ook steeds belangrijker. Aan deze uitdaging draag ik graag bij!

Lieve familie en vrienden, ook jullie ben ik veel dank verschuldigd. Harry, Monique, Annette, Debby, André, Lars en Tanja, jullie wil ik hartelijk danken voor jullie steun en relativering. En omdat tijdens de Qi gong-lessen ontspanning vaak hand-in-hand gaat met veel gelach en gegeeuw. Lieve Jan. Hoewel ik je vaak gekscherend aangaf dat ik je aan het einde zou noemen, is de laatste alinea de belangrijkste plek in het dankwoord. Jan, een groot deel van ons leven hebben we samen doorgebracht. Ik heb veel aan je te danken: toen ik het aanbod kreeg om als AIO te beginnen was jij de eerste die tegen me zei 'moet je doen, want zo'n kans krijg je nooit meer en je kan het'. Ook als ik het proefschrift niet meer zag zitten, was jij diegene die zei dat ik vooral door moest zetten en me voorhield dat ik het mezelf nooit zou vergeven als ik het onafgemaakt zou laten. Maar het was ook zwaar voor jou. Als ik vooraf had geweten hoeveel invloed mijn promoveren op ons beide zou hebben, was ik

er waarschijnlijk nooit aan begonnen. Hoewel ik het niet vaak heb gezegd, en misschien ook wel te veel voor lief genomen, was je heel belangrijk in mijn leven. Aan onze tijd samen heb ik veel mooie en bijzondere herinneringen. Ik prijs ik me zeer gelukkig dat jij er altijd was, en me ondanks alles toch bent blijven steunen bij het afronden van dit proefschrift. Lieve Adri, Leonie en Rachèl, ook jullie wil ik heel hartelijk danken voor de tijd dat ik deel uit mocht maken van jullie gezin. Ook jullie houden een speciaal plekje in mijn hart. Wilhelmien, Henny, Rein, Irmgard, Charlotte, William, Marit, Sabina, Chantal, Suzanne en Annemiek: dank voor jullie liefhebbende steun en gezonde (des)interesse in mijn proefschrift. Jullie waren en zijn altijd daar: bij alle succesjes en ook in moeilijke tijden. Ik kan altijd op jullie rekenen. Het heeft mij meer dan eens bevestigd wat voor bijzondere mensen jullie eigenlijk zijn! Charlotte en Sabina, omdat jullie ook tijdens de promotie naast me staan! Mam en pap, ik weet dat jullie trots op mij zijn. Jullie hebben me geleerd nooit op te geven. Ik hou van jullie!

Het proefschrift is nu af…..een nieuw begin.

About the author

Yvonne Jansen was born in Breda in 1974, where she graduated from Athenaeum at the Markenhage College in 1994. That year she started as a student of Cultural Anthropology of non-Western Cultures at the St. Radboud University in Nijmegen of which she received her master degree in 2001. From 2003 to 2008 she worked as PhD student at the Institute of Health Policy and Management (iBMG) of the Erasmus University of Rotterdam, where she conducted her PhD research this thesis reports on. During her PhD research, she participated in the graduate school for Science, Technology and Modern Culture (WTMC). In addition, she has taught numerous courses: among others qualitative research methods, social-medical sciences, change and innovation, and general scientific skills on both bachelor and master level. She was the coordinator of the bachelor thesis course in 2006-2007, and throughout her employment she also supervised numerous bachelor and master thesis students. Her academic work she presented at several (inter)national scientific conferences in oral as well as in poster presentations. Together with colleague Thomas Mathar of the Humboldt University of Berlin, she co-edited the book "Health Promotion and Prevention Programmes in Practice; How Patients' Health Practices are Rationalised, Reconceptualised and Reorganised", which was published in 2010. In 2009 she started working at the Netherlands Organisation for Applied Scientific Research (TNO), where she continued her focus on health care and its organisation. At TNO she conducts process analyses and studies on the needs and wishes of different patient groups. She is involved in the development, implementation and evaluation of new care concepts to increase sustainable productivity, such as technological innovations, integrated chronic care, new community and regional configurations of care organisations, self-management and patient empowerment. Moreover, she is involved in the development of pragmatic modes of evaluation and instruments for the evaluation of such innovations in care. Yvonne lives in Wilnis.

bridging the science-practice gap

Issue

This doctoral thesis evolved around the issue of how to evaluate the effectiveness of health promotion and prevention such that it matches the criteria for sound scientific research and at the same time produces knowledge that can more easily be embedded in routine medical practice. In other words, this thesis concerned the issue of how to bridge the science-practice gap in complex public health settings.

Approach

In this doctoral thesis one example of an evaluation methodology has been analysed that tried to accomplish this. An ethnographic case study has been performed of the Quattro Study: a pragmatic trial for evaluating the effectiveness of multidisciplinary patient care teams for the prevention of cardiovascular risk in primary health care practice in deprived neighbourhoods in Rotterdam and The Hague in the Netherlands. The ethnographic findings show how the pragmatic trial methodology and its instruments help to overcome the dichotomy between routine medical practice and scientific evaluation.

analysis of an evaluation methodology

the methodology's inherent dilemma is shown

Findings

This doctoral thesis allows for a fundamental rethinking of the pragmatic trial methodology not as a new mode of evaluating complex interventions in prevention and health promotion, but as an infrastructure for pragmatically embedding innovation(s) in primary health care. Building on the performativity of the infrastructure that is the pragmatic trial, such embedding of innovations can be more fruitfully explored and tested. The problem with the pragmatic trial methodology is not that it is pragmatic. The problem is that it is not pragmatic enough!