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**Development and evaluation of a tailored
implementation programme for cardiovascular risk
management in general practice**

For reasons of consistency within this thesis, some terms have been standardised throughout the text. As a consequence the text may differ in this respect from the articles that have been published.

The studies presented in this thesis have been performed at the Scientific Center for Quality of Healthcare (IQ healthcare). This center is part of the Radboud Institute for Health Sciences (RIHS), one of the approved research institutes of the Radboud university medical center.

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Development and evaluation of a tailored implementation programme for cardiovascular risk management in general practice

Proefschrift

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door Elke Margret Huntink

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Promotor: Prof. dr. M.J.P. Wensing

Copromotor: Dr. J. van Lieshout

Manuscriptcommissie: Prof. dr. G.A.P.J.M. Rongen

Prof. dr. A.E.M. Speckens

Prof. dr. J.S. Burgers (Universiteit Maastricht)

Contents

	Title	Page
Chapter 1	Introduction	7
Chapter 2	Perceived determinants of cardiovascular risk management in primary care: disconnections between patient behaviours, practice organisation and healthcare system. <i>Fam Pract 2015; 16: 179.</i>	19
Chapter 3	Identifying determinants of care for tailoring implementation in chronic diseases: an evaluation of different methods. <i>Implement Sci 2014; 9: 102.</i>	43
Chapter 4	Stakeholders' contributions to tailored implementation programmes: an observational study of group interview methods. <i>Implement Sci 2014; 9: 185.</i>	65
Chapter 5	Tailored Implementation of Evidence-Based Practice for Patients with Chronic Diseases. <i>Plos One 2014; 9(7): e101981.</i>	81
Chapter 6	Effectiveness of a tailored intervention to improve cardiovascular risk management in primary care: study protocol for a randomised controlled trial. <i>Trials 2013; 14: 433.</i>	99
Chapter 7	Tailored implementation of cardiovascular risk management in general practice: a cluster randomised trial. <i>Implement Sci 2016; 11: 115.</i>	115
Chapter 8	Practice nurses' counselling skills related to Patient Assessment of Chronic Illness Care score (PACIC) and Patient Activation Measure (PAM). <i>Submitted.</i>	131
Chapter 9	Process evaluation of a tailored intervention programme of cardiovascular risk management in general practices. <i>Implement Sci 2016; 11: 164.</i>	145
Chapter 10	General discussion	165
	Summary	187
	Samenvatting	195
	List of publications	204
	Dankwoord	205
	Curriculum Vitae	208

Chapter **1**

Introduction

Cardiovascular diseases (CVD) are the number one cause of death worldwide [1]. In the Netherlands CVD are the number one cause of death for elderly women and second cause of death for elderly men [2]. The incidence of CVD increases due to ageing populations and lifestyle changes [3]. Patients with established CVD or at high cardiovascular risk are mainly treated in general practice [4]. General practitioners' and practice nurses' tasks are lifestyle counselling, encouraging self-management, and medication treatment [5]. However, they perceive lifestyle counselling as complex, time consuming and difficult to do appropriately [6,7]. In order to optimise the preventive care for patients with established CVD or at high cardiovascular risk in general practices both a clinical guideline and a care standard on cardiovascular risk management (CVRM) were developed [8,9]. Despite these efforts, research suggested room for further improvement [5,10].

Many experts of behavioural and organisational change believe that strategies for the improvement of quality of healthcare need to be tailored to needs and opportunities [11,12]. A tailored implementation strategy is a strategy that is explicitly targeted at prospectively identified determinants of practice (also called barriers and facilitators of change). The international Tailored Implementation for Chronic Diseases (TICD) project was focused on the development and evaluation of tailored programmes for improving primary care for patients with chronic diseases [13]. In the Netherlands, the TICD project aimed at improving preventive care for patients with established CVD or at high cardiovascular risk. To develop a tailored programme we planned to follow consecutive steps starting with identifying determinants of practice. Prioritising mentioned determinants at changeability and importance. Followed by identifying strategies to address these determinants. Next, a tailored implementation programme was developed, implemented and tested in general practices. Simultaneously, the TICD project aimed to contribute knowledge on the usefulness of different methods for tailoring interventions. This thesis describes the consecutive steps we have taken to develop a tailored programme and the subsequent evaluation of effects and processes.

In this introduction chapter, we first describe cardiovascular diseases, the organisation of cardiovascular risk management in general practice in the Netherlands, and perceptions of practice nurses and patients with established cardiovascular diseases or at high cardiovascular risk on changing lifestyle. Current cardiovascular care in the Netherlands will be described as well as strategies which have been used to optimise the care or strategies that are performed so far. Furthermore, the concept of a tailored implementation strategy will be explained and how this strategy was applied in the Netherlands, focussing on the development and evaluation of a tailored implementation programme for improving CVRM. The introduction ends with outlining the main research questions and structure of the chapters of this thesis.

Cardiovascular diseases

This thesis focuses on cardiovascular diseases (CVD), which are caused by atherothrombosis or atherosclerosis. These includes: myocardial infarction, angina pectoris, heart failure, cerebrovascular accident (CVA, stroke), transient ischemic attack (TIA), aortic aneurysm as well as peripheral arterial disease. Globally CVD are an important cause of death [1]. Although mortality rates have declined, they are still the leading cause of death for elderly women and second cause of death for elderly men in the Netherlands. A total of 30% of Dutch women and 29% of Dutch men died due to CVD, which is on average 57 women and 51 men per day [2]. It is estimated that a total number of nearly 1.5 million patients will suffer from CVD in 2025, which is an increase of 40% in comparison with 2005 [14]. CVD causes a high burden of disease, reduces quality of life for patients, and leads to high healthcare costs [2].

Patients at high cardiovascular risk have a risk score of 20% or higher for 10-year morbidity and mortality due to CVD [8]. The risk for CVD is influenced by lifestyle factors [1]. Unfavourable lifestyle factors are unhealthy diet, physical inactivity, harmful use of alcohol and tobacco. These lifestyle factors can lead to obesity, hypertension, hypercholesterolemia and diabetes mellitus [8,15,16]. Gender, age and genetic predisposition all play an important role for having high cardiovascular risk. Also diabetes mellitus and chronic inflammatory rheumatic disease play an important role. Patients with established CVD have a clearly increased risk of progression of their CVD and development of a new event. All these risk factors tend to cluster and reinforce each other, which increases the cardiovascular risk and has a significant negative impact on quality of life [17,18].

An overview of all risk factors is called a cardiovascular risk profile. Data from the risk profile, one or more measurements, can be used to estimate the individual risk of disease or mortality due to CVD in the next ten years and can give a direction to an appropriate treatment to reduce this risk. The currently used risk assessment takes the following items into account: age, gender, smoking status, current systolic blood pressure and total cholesterol/high density lipoprotein ratio. All patients at high cardiovascular risk are offered lifestyle counselling. Patients with an estimated risk < 10% on vascular events in 10 years are offered rarely medication treatment; patients with an estimated risk of 10-20% are offered medication only when additional risk factors are identified; when the estimated risk is $\geq 20\%$ medication for hypertension and/or hypercholesterolemia are indicated if hypertension and/or elevated serum cholesterol are present. The risk of patients with diabetes mellitus or chronic inflammatory rheumatic disease can be estimated by adding 15 years to the current age of the patient [8]. Patients with established CVD or at high cardiovascular risk need appropriate lifestyle counselling and medication to reduce risk factors [1] in order to decrease mortality and increase healthy life expectancy [19,20]. Established CVD and

high cardiovascular risk could be prevented or postponed when these risk factors are addressed [1].

Cardiovascular risk management in the Netherlands

In the Netherlands, patients with established CVD or at high cardiovascular risk are mainly treated in primary care [4,21]. Since about a decade general practitioners have delegated a substantial part of this preventive care to practice nurses [5,22-24]. Practice nurses are specialised in providing chronic care and have been educated in lifestyle counselling [25,26]. General practitioners' and practice nurses' tasks in prevention and treatment of patients with established CVD or at high cardiovascular risk are to influence the risk factors favourably by general health promotion policies and medication treatment [5,27]. Health promotion includes lifestyle counselling, which involves advice about consuming fruit and vegetables, salt reduction, regular physical exercising, avoiding harmful alcohol use and tobacco use [1,28]. Tools providing concrete recommendations are the clinical guideline cardiovascular risk management [8] and the 'care standard' [9]. The guideline on CVRM provides recommendations for diagnosis, treatment and follow-up of risk factors including lifestyle advice and counselling patients with established CVD or at high cardiovascular risk. The 'care standard' is developed for general practice and is focused on how CVRM is best organised in daily practice, based on insights from healthcare professionals and patients. Motivational interviewing is a technique, which is most applied by practice nurses in counselling patients with chronic diseases. Previous research showed room for improvement in terms of this counselling technique by practice nurses [17,29].

Besides the clinical practice guidelines, the Dutch College of General Practitioners (Nederlands Huisartsen Genootschap, NHG) provides materials for continuing education and patient information linked to the guidelines. The Dutch Association for Practice Nurses (Nederlandse Vereniging voor Praktijkondersteuners, NVvPO) and Nurses & Caretakers of the Netherlands (Verpleegkundigen & Verzorgenden Nederland, V&VN) have provided several continuing education trainings on CVRM, and have provided information on their websites and in professional journals about CVRM. In the Netherlands, laws and regulations allow substantial clinical autonomy to licensed nurses, and to a lesser extent to non-licensed practice nurses.

Current cardiovascular care could be improved

Despite all efforts to improve quality of cardiovascular primary care, not all patients with established CVD or at high cardiovascular risk receive optimal cardiovascular care. Patients perceived their 10-year CVD risk different than their actual CVD risk, patients were too optimistic or too pessimistic [30]. Audits in general practices found that only 40-60% of the patients received lifestyle advice [10]. In total 80-90% of the patients

received statin and antiplatelet therapy and 28% of the practice nurse's underestimated patients' risk for CVD [31]. Although the young generations do more physical exercise and smoke less, they have more overweight, obesity and hypertension than predecessors at the same age, so overall the prevalence of these risk factors are increasing [32,33]. This unfavourable trend needs to slow down or even better to stop. CVRM care shows room for improvement [5,10].

In general, patients are satisfied with counselling of practice nurses [34-36], although a few prefer to discuss medical care and treatment, physical problems, emotional issues and medication with the physician rather than the practice nurse [31]. Lifestyle counselling is complex [6,37,38] and difficult to do well [7,17], especially when practice nurses seems to have a lack of knowledge about CVD [39]. More than half of the patients with a chronic condition are not able to take an active role in their own healthcare [40] due to lack of self-management, knowledge, skills and/or confidence [41-43]. Patients find it difficult to change their lifestyle, in particular when they experience other problems such as depressive symptoms. General practitioners and practice nurses insufficiently take into account that CVRM patients are at high risk for depressive symptoms, which has both biological and behavioural determinants [44-46].

Previous programmes to optimise cardiovascular care in the Netherlands

In the Netherlands many strategies have been applied to optimise current care in general practices for patients with established CVD or at high cardiovascular risk. For instance, the General Practice Assistance Prevention Project (Huisarts Assistentie Preventie Project, HAPP), which started in 1988 whereby a nurse conducted outreach visits focusing on implementing guidelines on prevention of CVD. This strategy led to better adherence to the guideline [47]. In 1996 a comprehensive improvement programme in general practices started which provided 15 outreach visits on organisation of preventive care and provided help with clinical decision making (Carpe project) [48]. Results showed that the organisation of preventive care was improved [49]. Effects on clinical decision making were small and the overall costs of this intervention programme were high [50]. Another strategy consisted of training for general practitioners about the risk table, and a decision support tool for patients about lifestyle and 10-year risk of CVD was developed. Performance of general practitioners was not enhanced after application of this strategy. Although the decision support tool was perceived as fair to good, patients' risk perception was not enhanced. A small improvement was measured in patients' physical exercise [51]. The Patients' Adherence to Lifestyle Advices (Impala) intervention started in 2005; it placed practice nurses in a central role in cardiovascular risk management [52]. They received a two-day training which included motivational interviewing, risk assessment, risk

communication, and distribution of a decision support tool. During the first face-to-face consultation patients received information about risk reduction, during the second face-to-face consultation patients' preferences for lifestyle improvement were discussed with the healthcare professional. This strategy increased risk perception, but only small non-relevant effects on lifestyle were found [7,31,53]. Overall, these strategies had some impact on cardiovascular risk management, but nevertheless left room for further improvement.

More recently, other strategies have been applied, with unknown effects so far. The Hoorn study is aimed at patients at high cardiovascular risk or at risk for developing diabetes mellitus type 2. Patients in the intervention group will follow a cognitive behavioural programme aimed at lifestyle changes to a maximum of six individual sessions of 30 minutes given by practice nurses who will receive motivational interviewing and problem solving technique trainings [54]. In 2011 a so called Prevention Consultation was introduced for identification and counselling of patients aged 45 or older at high cardiovascular risk, with diabetes mellitus type 2 or kidney damage, who was not treated yet. The Prevention Consultation comprises online risk estimation; patients at high risk are referred to the general practice where the risk profile will be completed and if necessary treatment will be started [55].

Tailored implementation

The programmes to improve cardiovascular risk management, which were described in the previous section, were not explicitly tailored to local or individual barriers for improvement. An explicitly tailored implementation strategy is a strategy that targets determinants of practice which have been prospectively identified [56-57]. Tailoring means that the implementation strategies are not chosen a priori; the most intensive type of tailoring implies that the intervention programme is not standardised across sites. Instead, the tailored implementation strategies are based on local problems and needs mentioned by healthcare professionals and/or patients, and may thus differ across different healthcare organisations or groups of health professionals. A tailored implementation strategy is based on a process whereby sequential steps are followed; identification of barriers and enablers (the so-called determinants) of healthcare practice, selection of mentioned determinants at changeability and importance, designing implementation strategies aimed at the determinants, and execution and evaluation of implementation strategies that are tailored to the selected determinants. The assumption is that a tailored strategy aimed at specific determinants of practice adds to its impact, a claim that is partly supported by research evidence [11,12,56,57]. Nevertheless, the effectiveness of tailored implementation strategies was found to vary from zero to moderately effective [58]. This variation can be due to the fact that many different tailoring methods were used and some tailoring processes did not seem to target the key barriers for change. Many theories have been developed to support

tailoring of implementation strategies, while research evidence is not clear about whether the use of theory is helpful [59].

Identification of determinants of practice

Important determinants can be defined as factors for which there is a consensus that it would inform the design of an intervention. The tailoring of an improvement programme in chronic illness care is most beneficial if the strategies effectively address the most influential determinants for implementation. Determinants of healthcare can be related to knowledge of healthcare professionals, professional behaviour, organisation of healthcare, and health system arrangements. Also patient behaviours can constrain or enable healthcare improvements. Furthermore, social, political, and legal environment factors might prevent or facilitate change. Different exploratory methods can be used to identify barriers and enablers [60]. The following have been used most frequently: brainstorming, case studies, key informants, interviews, focus groups, direct observations, questionnaires and nominal group technique (a highly structured discussion among a group of people where ideas are pooled and prioritised) [61]. Individual and group interviews with (healthcare) professionals were also used to identify determinants. It is unclear whether a structured procedure for identifying determinants, for example brainstorm sessions and focus groups, indeed results in more valid determinants for eventually tailoring an intervention than a simple procedure, for instance only using a self-made questionnaire.

Designing implementation strategies aimed at the determinants

After the determinants of practice have been identified, the logical next step in tailoring is to gather strategies to overcome these determinants. Matching strategies to determinants can be done at population level, practice level and clinician level. Furthermore, this could be done at the design stage of a tailored strategy or at the delivery stage of a tailored strategy. What is also important is the choice of optimisation of chosen strategies versus an intervention based on global implementation strategies [13]. There is a range of methods available for gathering potential strategies, although not every method may be useful for each type of tailoring; open interview methods (individual or groups); structured interview methods guided by checklists and research evidence; intervention modelling experiments in which a variation of an implementation strategy is applied on individuals and self-reported outcomes are documented; quantitative modelling in which available data are used to identify characteristics of strategies that may be associated with better outcomes; and developmental/action research, an approach where researchers follow the direct needs of knowledge users and research and action are combined. After identifying matching implementation strategies a selection needs to be made which

implementation strategies will be selected for designing the tailored intervention programme [13].

Overall, it can be concluded that tailoring of interventions has not been well conceptualised. A structured process could be used focusing on the suggested implementation strategies to the identified determinants considering the evidence of effectiveness of strategies to change professional behaviour, patient behaviour or healthcare organisation, and available resources [56,57,63]. Research evidence on the usability of various methods for design of implementation strategies is scarce, and comparative studies of tailoring methods seem non-existent in healthcare settings.

Execution and evaluation of implementation strategies

Tailored implementation strategies have a number of challenges in practice. Tailoring methods have been poorly described in published research, and there was a little match between identified determinants of practice and the chosen implementation strategies [60]. The poor documentation of tailoring strategies hinders the opportunity of learning from previous studies. Different methods and models for tailoring implementation strategies reflect opposing approaches. More research using theories for tailored strategy development and evaluation of the effectiveness of these strategies is needed [64]. The TICD project contributes to this research field by performing directly comparing alternative approaches in the tailoring process and by assessing the effectiveness of resulting tailored implementation strategies. These implementation strategies will increase knowledge of implementation processes in chronic illness care.

TICD project

The Tailored Implementation of Chronic Diseases (TICD) project [13] aimed to investigate methods of tailoring implementation strategies to determinants for knowledge implementation in chronic illness care. In the Netherlands the TICD project was aimed at patients with established CVD or at high cardiovascular risk in general practices. At the start of the project key recommendations were selected. In every consecutive step in the tailoring process these key recommendations were to be taken in consideration. Furthermore, a checklist of determinants was developed. For this project three steps were followed to develop a solid tailored intervention. (1) During this first step different methods were used to identify determinants of practice. This was started with brainstorm sessions and focus groups with healthcare professionals followed by interviews with healthcare professionals and interviews with CVRM patients, and then questionnaires based on the checklist of determinants were sent out among healthcare professionals. Each participant completed only one method, except for brainstorm sessions and focus group because these were linked together. Participants were asked to provide insight of current CVRM care by mentioning factors

which could be promoted or improved. The most important and changeable determinants were selected and classified based on the checklist. (2) The following step in tailoring was identification of implementation strategies targeting at the determinants prioritised. Group sessions with a brainstorm and a structured phase were held with a group of implementation researchers (including TICD participants), a group of quality improvement officers, a group of healthcare professionals, a group of authorities, health insurers and/or other purchasers of healthcare, and a group of CVRM patients (optional). All groups were asked to mention solutions/approaches to address the selected determinants of practice. (3) From all suggested strategies a tailored intervention programme was developed and applied in general practices. (4) This tailored implementation programme was evaluated in a cluster randomised trial and a process evaluation.

Research questions and thesis outline

The overall research aim of the TICD project in the Netherlands was to develop valid and effective methods of tailored implementation strategies to improve cardiovascular risk management in general practice. This main research aim led to the following objectives:

- 1: The objective of the first study was to identify determinants of the delivery of CVRM in general practice in the Netherlands based on interviews with health care professionals and patients. (Chapter 2)
- 2: The objectives of the second study were (a) to compare the number and types of strategies generated by different stakeholders in brainstorm sessions; (b) to assess the added value of a structured group interview after brainstorming; and (c) to assess whether stakeholders provided strategies that were actually included in tailored intervention programmes, which were subsequently tested in cluster randomised trials. (Chapter 4 emphasise the methods used + chapter 5 emphasise more the types of strategies)
- 3: The objectives of the third and main study were to examine the outcomes and process of a tailored implementation intervention for improving professional performance of practice nurses for patients with established CVD or at high cardiovascular risk in primary care (Chapter 6, 7, 8 and 9). The primary outcome was the professional performance of practice nurses which was evaluated by the application of recommendations for personalised counselling and education of patients with established CVD or at high cardiovascular risk. Secondary outcomes concerned aspects of cardiovascular outcomes (blood pressure, cholesterol levels, body-mass index, smoking status, diet, and physical exercise) and patient experiences. In the process evaluation, we focused on the fidelity of the intervention programme and the impact on hypothesized determinants of practice.

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Chapter 2

Perceived determinants of cardiovascular risk management in primary care: disconnections between patient behaviours, practice organisation and healthcare system

Elke Huntink
Michel Wensing
Rien Klomp
Jan van Lieshout

Abstract

Background

Although conditions for high quality cardiovascular risk management in primary care in the Netherlands are favourable, there still remains a gap between practice guideline recommendations and practice. The aim of the current study was to identify determinants of cardiovascular primary care in the Netherlands.

Methods

We performed a qualitative study, using semi-structured interviews with healthcare professionals and patients with established cardiovascular diseases or at high cardiovascular risk. A framework analysis was used to cluster the determinants into seven domains: 1) guideline factors, 2) individual healthcare professional factors, 3) patient factors, 4) professional interaction, 5) incentives and recourses, 6) mandate, authority and accountability, and 7) social, political and legal factors.

Results

Twelve healthcare professionals and 16 patients were interviewed. Healthcare professionals and patients mentioned a variety of factors concerning all seven domains. Determinants of practice according to the health care professionals were related to communication between healthcare professionals, patients' lack of knowledge and self-management, time management, market mechanisms in the Dutch healthcare system and motivational interviewing skills of healthcare professionals. Patients mentioned determinants related to their knowledge of risk factors for cardiovascular diseases, medication adherence and self-management as key determinants. A key finding is the mismatch between healthcare professionals' and patients' views on patient's knowledge and self-management.

Conclusions

Perceived determinants of cardiovascular risk management were mainly related to patient behaviours and (but only for health professionals) to the healthcare system. Though healthcare professionals and patients agree upon the importance of patients' knowledge and self-management, their judgement of the current state of knowledge and self-management is entirely different.

Background

In previous decades, mortality due to cardiovascular diseases (CVD) has been substantially reduced, yet CVD remain a major cause of death and suffering in Europe [1]. In the Netherlands, CVD is the leading cause of death for elderly women and second cause of death for elderly men [2]. Multidisciplinary guidelines for cardiovascular risk management (CVRM) provide recommendations for counselling and preventive treatment [3,4]. The European Society of Cardiology issued a practice guideline; a multidisciplinary working group launched an adaptation in the Netherlands [5]. In many industrialised countries a range of educational programmes and financial incentives have been introduced to enhance the implementation of recommended cardiovascular prevention [6]. Even so, not all eligible patients receive optimal cardiovascular care [7]. Audits in general practices found that 40-60% of the patients received lifestyle advice [8], 80-90% received statin and antiplatelet therapy, but 28% of the practice nurses miscategorised patients at risk for CVD [9] and therefore patients could have underused recommended treatment. In addition, patients' health-related lifestyle and 10-year risk of CVD mortality does not seem to be improved [10,11] and treatment targets for blood pressure and cholesterol are not achieved by a great amount of patients [7].

In the Netherlands CVRM is mainly delivered in general practices. In recent years, practice nurses were introduced into almost all general practices in the Netherlands [12,13]. These practice nurses provide a substantial part of CVRM care, which has been delegated by the general practitioner (GP). Increasing numbers of GPs provide CVRM within the organisation of care groups, which arrange the funding of chronic illness care for typically about 100 GPs. Care groups also monitor performance and provide feedback, using quality indicators that are based on data-extraction from computerised patient records. These care groups facilitate the provision of structured chronic care in general practices based on the principles of the chronic care model [14,15]. An important element in the chronic care model is well-organised self-management education and support for patients. There is a range of E-health options available for patient education and health promotion, several of which are provided by the Dutch College of General Practitioners [16].

Thus, many conditions seem favourable for high quality CVRM in Dutch primary care. Yet, audits suggest there is still room for improvement. Several years ago studies identified a range of determinants of CVRM in primary care [17-19], but there have been major organisational changes in the general practice since then. More GPs work together in group practices, the practice nurse with CVRM as one of her tasks was introduced more widely, patient-held electronic patient records were introduced and care groups organise CVRM. Also, there is a broad supply of educational and support programmes for health professionals concerning CVRM. There is no recent comprehensive research focusing on the determinants of CVRM in the Netherlands. The

aim of the current study was to identify determinants of the delivery of CVRM in general practice in the Netherlands based on interviews with health care professionals and patients. We used a previously developed framework with seven domains [20] to categorise the identified factors in a qualitative framework analysis.

Methods

Study design

We performed a qualitative study in the Netherlands, using semi-structured interviews that were held between May 2012 and June 2014. The ethical committee of Arnhem and Nijmegen waved approval (CD/CMO 1351). The Consolidated criteria for reporting qualitative research (COREQ) [21] and RATS [22] were used for the design and description of this study. This study is part of the Tailored Implementation of Chronic Diseases (TICD) project [23]. The overall aim of the TICD project was to provide insight into methods for tailoring implementation of evidence-based chronic illness care.

Study population

Participants in this study were healthcare professionals involved in CVRM care and patients with established CVD or at high cardiovascular risk treated in general practices. We used a purposive sampling to ensure diversity of healthcare professionals regarding their professions and considering patients with respect to age, sex and whether they had established CVD or high cardiovascular risk. Patients with established CVD were also invited, because CVRM relates to both primary prevention and to secondary prevention in patients with established CVD to prevent another event. Patients at high cardiovascular risk have a 10 year risk score of 20% or higher for morbidity and mortality due to CVD based on age, gender, blood pressure level, cholesterol level, smoking status and diabetes mellitus. Healthcare professionals were invited by letter, email or telephone. To recruit patients, four general practitioners and four practice nurses were asked to send written invitations to patients with established CVD or at high cardiovascular risk. Patients who agreed to participate posted their informed consent forms in a postage-paid envelop. The researchers subsequently contacted the participants to make an appointment.

Data collection

The semi-structured interviews of about 30 minute each were divided into three parts (Table 1). The interviews started with a short introduction about the TICD project and information about CVRM. The participants were asked to mention determinants of current practice. During this phase no framework or taxonomy was used and there were no restrictions in number or type of determinants. Next, the interviewer presented the seven domains in the TICD checklist of determinants of practice [20] and then asked the participants if they could think of additional determinants they had not thought of

in the first phase. Finally, the interviewer presented the results of previous research. In a previous phase of the TICD project we held group interviews with general practitioners, practice nurses and practice assistants. The plausibly important and changeable determinants mentioned during the group interviews were presented during the interviews. Participants were asked again if they now had suggestions not mentioned before. Healthcare professionals were interviewed in their working environment and patients were interviewed at their homes. After nine interviews with healthcare professionals and eight interviews with patients we performed an interim analysis. During the subsequent interviews with healthcare professionals and patients we introduced the following topics: training of healthcare professionals, feedback for healthcare professionals, budget, target values, role models, and Dutch healthcare policies. All interviews were conducted by three moderators working on the TICD project (E.H. (junior researcher and nurse, university: health science), M.K. (researcher and GP, university: medicine) and a research assistant, vocational training: analyst). The interviewers were familiar with Dutch healthcare and had experience with interviewing, all three used the same interview format to prevent bias. All interviews were audio taped and described verbatim.

Table 1. Interview schedule

Parts of the semi structured interviews	Presentation for participants	Question for participants
1 st part	<ol style="list-style-type: none"> 1. Introduction of TICD project 2. CVD in the Netherlands 3. CVRM in the general practices 4. Recent research about CVRM in the Netherlands 5. Room for improvement 	<p>What factors plays an important role in CVRM care?</p> <p>Why is the current care sub optimal?</p>
2 nd part	<p>Seven domains of the TICD framework</p> <ol style="list-style-type: none"> 1. Guideline factors 2. Individual healthcare professional factors 3. Patient factors 4. Professional interaction factors 5. Incentives and resources 6. Mandate, authority and accountability 7. Social, political and legal factors 	Do You have additional determinants?
3 rd part	<p>Important and changeable determinants mentioned during the group interviews</p> <ol style="list-style-type: none"> 1. Awareness and motivation of patients 2. Medical files to support patient care 3. Cooperation between GPs and specialists in hospitals 4. Motivation GPs 5. Better implementation of the 'care standard' 6. Financial support 7. Healthy lifestyle supported by the Dutch government 	Do You have additional determinants?

Data analysis

Data-analysis comprised of two phases. In the first phase thematic content analysis was used, which is a qualitative research method focused on describing a phenomenon [24, 25]. The transcribed interviews were analysed using Atlas.ti7 software, started by open coding. All interviews were analysed by one researcher by coding all possible determinants of practice. This researcher also made the codebook. The first three interviews of the healthcare professionals and the first three interviews of the patients were analysed independently by a second researcher to minimise subjectivity and the results were checked for consistency. This second researcher also independently checked the coding of all other interviews. Discrepancies were resolved through discussion. All determinants were described in a clear and concise way so as to be able to compare them, thereby minimising the risk of confusion or misinterpretation.

For the second phase, whereby axial coding was applied, all determinants were transferred into two Excel data files, one for determinants mentioned by healthcare professionals (Fig. 1) and one file for determinants mentioned by patients (Fig. 2). We used the TICD framework [20] for a framework analysis [26] to cluster the determinants. Determinants were divided into one of the following seven domains: 1) guideline factors, 2) individual healthcare professional factors, 3) patient factors, 4) professional interaction, 5) incentives and recourses, 6) mandate, authority and accountability, and 7) social, political and legal factors. Determinants in each domain were clustered on basis of subthemes. Selective coding was applied by summarising the frequent and important subthemes of the determinants. Axial coding and selective coding were performed by one researcher (E.H.) and checked independently by another researcher (J.v.L). Consensus was reached through discussion.

Results

Participants

In total 31 group general practices were approached whereof one practice nurse participated, other healthcare professionals were personally invited and agreed with participation. We have no data on the number of patients approached by the GPs and practice nurses; 16 patients signed the informed consent and were interviewed. The interviews lasted on average 42 min (range 22 to 95 min).

The sample of 12 healthcare professionals consisted of three GPs, an academic GP, a practice nurse and a mental health nurse, a pharmacist, a dietician, a physical therapist, a vascular internist, and an advising GP with a healthcare functionary of a health insurance company (interviewed together). A total of six women and six men participated. Healthcare professionals had a background in 3-6 years of health education from vocational training till university.

Figure 1. Coding tree for determinants mentioned by healthcare professionals

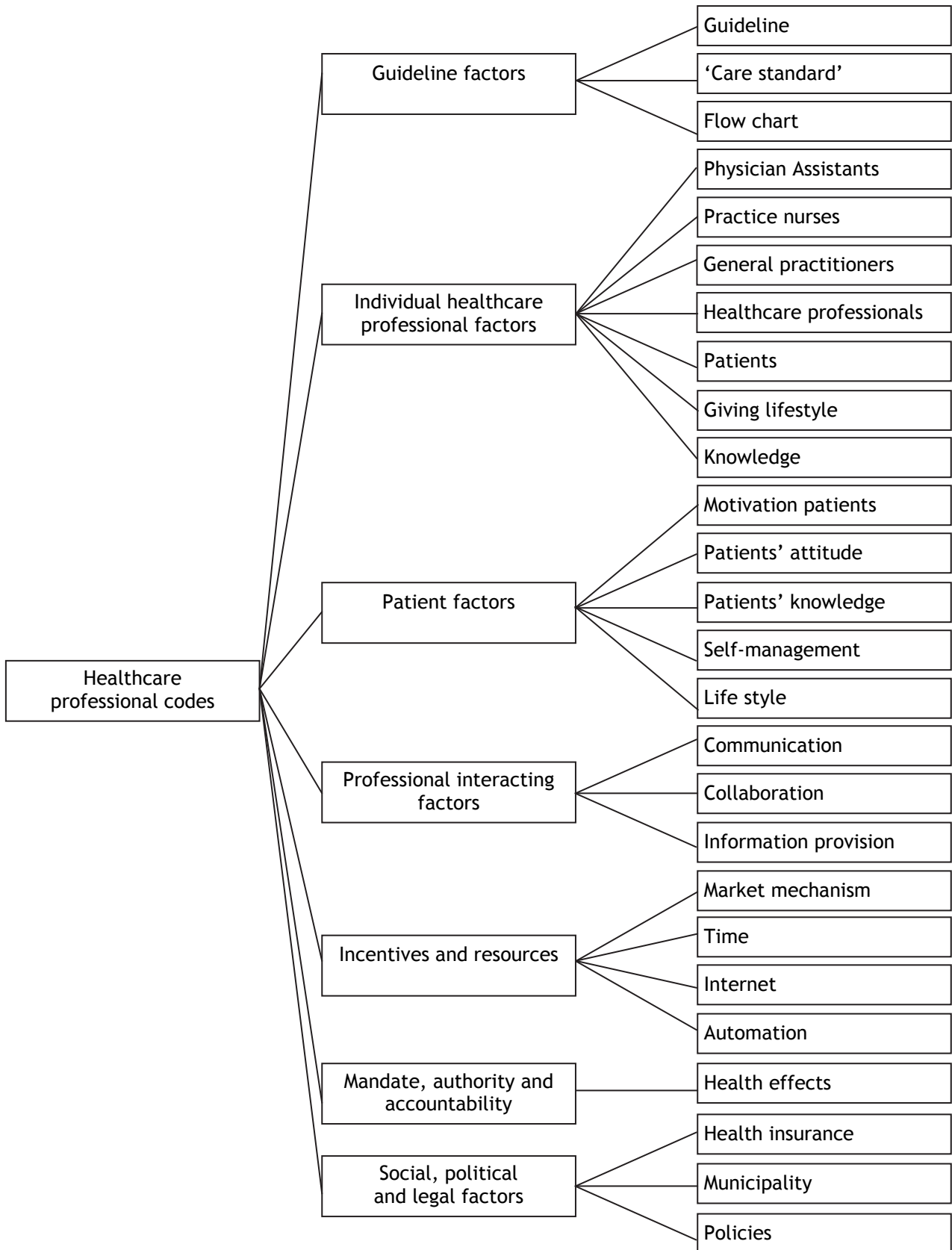
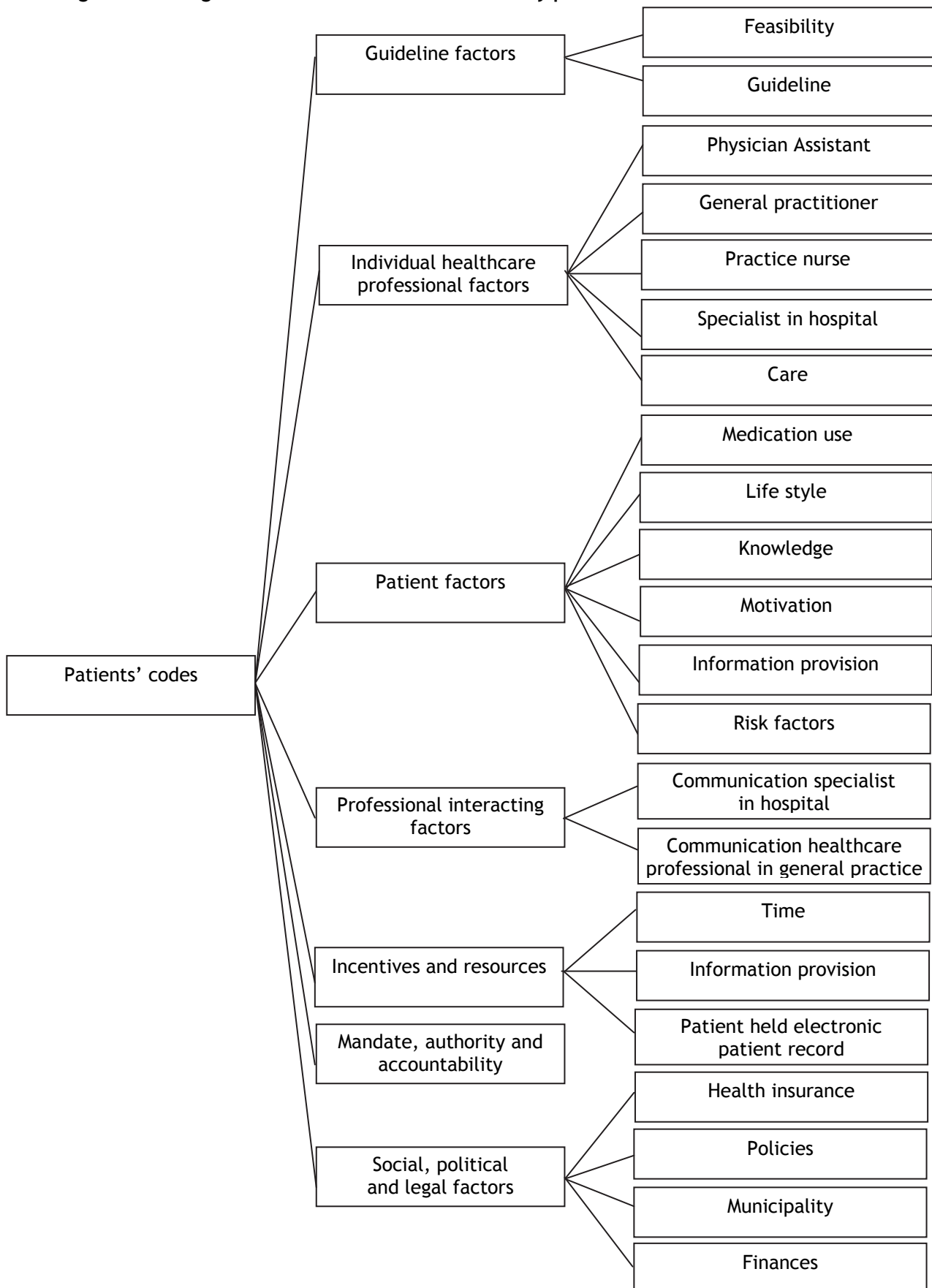


Figure 2. Coding tree for determinants mentioned by patients



The sample of participating patients consisted of six women and 10 men, eight patients with established CVD and eight patients at high cardiovascular risk took part (Table 2), they were aged between 59 and 86 years.

Table 2. Participants characteristics

Participants		Gender
12 Healthcare professionals	General practitioners (n=3) Academic GP (n=1) Practice nurse somatic (n=1) Practice nurse mental health (n=1) Pharmacist (n=1) Dietician (n=1) Physical therapist (n=1) Vascular internist (n=1) Advising GP and Healthcare functionary of a health Insurance company (n=2)	Male Male Female Female Male Female Female Female Male + Female
16 Patients	Patients with established CVD (n=8) Patients at high cardiovascular risk (n=8)	2 Female, 6 men 4 Females, 4 men

We will present the results following the TICD framework. First, we will describe the results of the healthcare professionals followed by the results of the patients. Determinants mentioned by healthcare professionals and patients are summarised in Table 3.

Table 3. Summary of mentioned determinants by healthcare professionals and patients

	Determinants mentioned by healthcare professionals	Determinants mentioned by patients with established CVD or at high cardiovascular risk
1. Guideline factors	<ul style="list-style-type: none"> Practice guideline CVRM 'Care Standard' 	<ul style="list-style-type: none"> Practice guideline CVRM 'Care Standard'
2. Individual healthcare professional factors	<ul style="list-style-type: none"> Positive about practice nurses GPs are role models, too busy and clinical inert Motivational interviewing 	<ul style="list-style-type: none"> Positive about practice nurses GPs listen carefully, motivates patients but not always available Positive about the care and measurements
3. Patient factors	<ul style="list-style-type: none"> Not enough knowledge about CVRM Motivated to improve their health Not positive about patients self-management Money can be an obstacle 	<ul style="list-style-type: none"> Knowledge of a healthy lifestyle Take good care of themselves Medication adherence important but difficult due to side effects
4. Professional interaction	<ul style="list-style-type: none"> Communication can be improved between GPs and specialists Collaboration healthcare professionals in general practice is good Paramedics are important 	<ul style="list-style-type: none"> Communication between GPs and specialists is rather varied Collaboration between healthcare professionals in the general practice is good
5. Incentives and recourses	<ul style="list-style-type: none"> Time as biggest barrier Due to 'open market operation' more critical look is needed Digital patient files are helpful but not always accessible 	<ul style="list-style-type: none"> GP has insufficient time Information provision is satisfactory Internet is consulted by half of the patients Digital patient files are favoured

	Determinants mentioned by healthcare professionals	Determinants mentioned by patients with established CVD or at high cardiovascular risk
6. Mandate, authority and accountability	<ul style="list-style-type: none"> • Cannot make health effects provable 	
7. Social, political and legal factors	<ul style="list-style-type: none"> • Dutch government not rated positive • Health insurers should not determine medical policy • GPs responsible for a lot of patients 	<ul style="list-style-type: none"> • The Ministry of Health is much interested in cash excises • Healthcare too expensive • Reimbursements by health insurers • Reforming healthcare

1. Guideline factors

Professionals considered the practice guideline CVRM to be important and clear, but nevertheless expressed that they experienced difficulties in working accordingly. The practice guideline was not seen as easily accessible, feasible, and covering recent insights. The ‘care standard’ with a focus on the organisation of CVRM was perceived not to match with current practice; it was not sufficiently matched to specific practice characteristics and was perceived to require a lot of training.

- I think that those guidelines are currently quite feasible and clear. (healthcare professional (hp) 18)
- The guidelines now are too big, too blunt and not liberal enough. (hp 23)
- Look, now you have a practice guideline with an endless amount of footnotes. If you want to read it properly then you would need to study all these footnotes, notably because you have to put everything into perspective. I find it a very difficult issue. (hp) 25)
- The care standard is a general guideline and that is fine, but it is by far less differentiated for the general practice, especially for the practice nurse, to effectively work with. (hp26)

Patients mentioned fewer determinants related to the guideline CVRM or the ‘care standard’. Patients considered the guideline not feasible and thought it did not allow room for own interpretation.

- The guideline is clear but might create bureaucracy, a stranglehold. Creativity should play a big role. (patient (p) 9)

2. Individual healthcare professional factors

Healthcare professionals were overwhelmingly positive about practice nurses. Reasons included: practice nurses gave good information and lifestyle advices, formed a role model for patients and created a risk profile for CVRM. Still some critical points were also mentioned; practice nurses did not discuss all CVRM patients with the GP and did

not have enough knowledge about mental health problems, which could have impact on life style changes. GPs were seen as role models with a lot of responsibilities; they might have more impact on patients than practice nurses. Important barriers were that GPs sometimes were too busy and clinically inert. Motivational interviewing was perceived to be a promising way of communication with patients. Nevertheless some healthcare professionals said that results of diagnostic tests were not communicated with patients because GPs had no insight into these results or did not check these results. Due to the fact that many patients have co-morbidities, healthcare professionals expressed they have a lack of time for lifestyle counselling.

- I think that one important thing is, that the professional has no insight into, and does not take the time to check the results of diagnostic tests. (hp 21)
- I think that there should be a protocol for CVRM care and a categorical consultation hour just like for the diabetes care, with a practice nurse to guide the consultation because he/she is much brighter than I am (GP). That really works. (hp 24)
- Part of the patients has a difficult adjustable hypertension. Sometimes they use four to six different drugs and the systolic blood pressure still is not below 140 mmHg. Sometimes you settle for 160 mmHg. (hp 27)
- The practice nurse should pay more attention to the bigger picture; she is now too narrowly focused in her tasks. (hp 28)

Patients mentioned a lot of positive determinants about practice nurses. Some examples: the consultations went well, the practice nurses gave tailored information, motivated patients, and reserved enough time for consultations. Patients said they had a good relationship with their GP. Positive characteristics of the GP were that they made time available when needed, listened carefully and motivated patients. But on the other hand, patients told that the GP was not always available by telephone, had less patience for the patient and some patients had the feeling that the GP wanted to get rid of them. The practice assistant was considered as positive and friendly but a few patients saw the assistant as an obstacle for visiting the GP. In general, patients were positive about the care they received especially about the frequent measurements. On the other hand, patients experienced a sense of frustration when treatment target values were not achieved: this is disappointing for them, which was not acknowledged by healthcare professionals. Patients needed to be complimented by healthcare professionals and did not want to be ignored. Information provision could be improved; assertive patients received more information which was considered unfair.

- I have a very good relationship with my GP. He wants to do everything for me, but I cannot contribute to everything. (p 1)

- I think that at some point they have to admit that something is nicely done. Just once. (p2)
- I had to get used to it, to go to the practice nurse instead of the GP. (p10)

3. Patient factors

Healthcare professionals' impression was that patients did not have enough knowledge about CVRM, especially about healthy food. Patients did not always remember given information correctly or understand given information, and not all of them were aware that vascular conditions are linked with depressive symptoms. Healthcare professionals found it difficult to explain things about CVRM to patients, in particular the concept of 10-years risk score of 20% or higher for morbidity and mortality due to CVD is hard to understand for patients. When patients experience no symptoms they find it more difficult to understand why they should prevent CVD or high risk factors. Healthcare professionals consider patients to be motivated to improve their health, but improvement depends on social influences, whereby language and culture issues underlie their motivation. Healthcare professionals did not assess patient's self-management very positive: patients did not follow lifestyle interventions, forgot appointments, had low therapy compliance, and they stopped prescribed medication. Little interest in CVRM could obstruct changing and managing their lifestyle patterns. Healthcare professionals thought that money could be an obstacle for patients to visit a dietician, purchasing healthcare devices or go to the gym. According to the healthcare professional, only 50% of the patients do exercise, especially patients with overweight do not exercise. Impeding factors for not going to exercise were time and a low economic status.

- Therapy adherence, I mean what we face here are also very often language problems, communication problems. (hp 8)
- I think that especially in highly educated patients, knowledge about food is overrated. (hp 17)
- What we encounter also is that in one way or another, and that continues to be the fact, it is just very difficult to explain something to these people. The conversation with the doctor, well it is still very difficult for some patients to remember things what was said. (hp 18)
- Some are aware of it. Not all. Some say: yes my blood pressure was too high. I did not know how high though. (hp 20)
- What do you want and what do you need to manage your illness? Well, that is actually the thing we try to promote in our general practice. (hp 26)

As opposed to the perceptions of healthcare professionals, a large number of participating patients indicated to have sufficient knowledge of a healthy lifestyle,

healthy food, their own blood pressure, their health condition, and that they were motivated to take good care of themselves. Patients were aware about the consequences of having a high cardiovascular risk. Due to their healthy lifestyle (less fat, sugar and salt) patients felt much better and that improved their state of mind. Contradictory determinants mentioned by a few: patients were unaware of their health, some were not aware of the importance of a low cholesterol level, thought that lifestyle changes were not feasible and difficult to maintain, and some did not visit their GP for CVRM. Some patients were shocked having a high blood pressure because they were not experiencing any symptoms. Therefore, better education is needed to create more awareness for patient's lifestyle and doctors should listen more to patients. Medication adherence was considered to be important, but side effects and changes in medication made therapy adherence difficult. Most patients said to exercise two till seven times a week; especially exercising together was considered as fun and gave them energy. People behaving in a "macho" way at the gym and perceived risk of injuries were some obstacles for exercising.

- I cannot smoke, I should not eat too much fatty foods, I cannot become overweight, what have I got left? (p 2)
- Well yes, what is the difference with other advices, lifestyle advice works differently, and it works on my mind. (p 5)
- The practice nurse learned me a lot, to eat less salt and eat more regularly. I lost some weight, feel much fitter, eat more regularly and healthier. The practice nurse has guided me well. (p 13)
- I exercise a lot and I'm not overweight. (p 15)
- Well I think that patients should talk to the doctor and tell him what is going on. Because that is what is going wrong, patients are not assertive enough. (p 8)
- At the pharmacy, they check what they can give you because I also use other medication, and that is just fine. (p 17)

4. Professional interaction factors

Healthcare professionals stated that communication between GPs and specialists in the hospital could be improved. An example was the difference in which blood pressure or cholesterol levels were accepted. Information subsequently given by the GP or the specialist did not match with each other, resulting in an unclear situation for patients. Some healthcare professionals said that collaboration went well and that GPs got involved in the CVRM care provided by specialists.

Healthcare professionals considered the collaboration between healthcare professionals within general practice as good; they had a clear task differentiation, were aware of each other's tasks and their level of expertise. Mutual consultations took place on a regular basis, although a few healthcare professionals disagreed on this.

Allied health professionals such as physical therapists and dieticians were also important for the CVRM care. Face-to-face meetings between healthcare professionals seemed important for a workable collaboration and mutual feedback.

- A lot of explanation about medication use for patients is lacking from the specialist in the hospital, as well as from the GP. A lot of patients think that the prescribed medication is a treatment for two weeks, they do not realise that they have to use this medication for the rest of their lives. (hp 19)
- So the face-to-face contact with a GP is very important. A telephone meeting is already better than a letter. When a letter is not read, you do not get connected. (hp 20)
- For example, the patient has a broken hip and has been hospitalised. Prior to the operation the cardiologist visits the patient and changes the whole medication schedule without bothering to call the GP. (hp 26)
- I 'am always very clear that I want the systolic blood pressure under the 140, otherwise I 'am not satisfied. And sometimes patients said that the GP is okay with the blood pressure but I find it to high. (hp 28)

Patients' opinions about the communication between GPs and specialists rather varied. An example of good communication was that a specialist sent information such as laboratory results to GPs. Also some patients felt the opposite. Occasionally it happened that a patient wanted to be referred to a hospital-based specialist but the GP did not make the referral. When the patient finally visited the specialist, he/she talked in a negative way about the GP. In a way, the patient then lingers between the GP and the specialist, which was perceived as an uncomfortable position to be in.

Patients indicated that the communication and collaboration between healthcare professionals within the general practice is going well: within the general practice all healthcare professionals gave the same information.

- The practice nurse consults the GP, and then she tells me what the GP has said. There is a very good collaboration between the GP and practice nurse. (p 4)
- There is no collaboration between the specialist and the GP. It could be a lot better. (p 8)
- I have the feeling that my GP really tries to keep me from being referred to a specialist as long as possible. (p 14)

5. Incentives and resources

Healthcare professionals mentioned lack of time as the biggest barrier for the quality of CVRM care. Time prevented them to motivate patients, to give them lifestyle advices or consult other professionals/ colleagues. In particular, GPs suffered from lack

of time; they had to do more work in the same timeframe than some years ago and therefore had less time for treatment.

The leaflets in the general practices were considered a good source of information and helpful, giving patient's confidence. Internet was perceived as not ideal by healthcare professionals because not every patient could find reliable information on the Internet. Due to the introduction of market mechanisms in Dutch healthcare, healthcare professionals felt they were more focused on costs. Nowadays reimbursement is partly based on the volume of consultations and procedures. Some healthcare professionals thought these changes were a waste of resources.

Healthcare professionals' opinion about patient-held electronic patient records was mixed. It was perceived by some as positive because it would enhance patients' autonomy, improved transparency of data and facilitated information transfer to other healthcare professionals. Some negative aspects were about the 'integrated care information system': the system was not easily accessible for GPs, there was no link with hospital systems, and it was perceived as slow, complicated and not stable.

Multidisciplinary care was perceived to be best and most efficiently organised in small organisations, while changes go slow in large organisations.

- Leaflets and information are good for patient's confidence and it should give them the feeling that this is about them, the doctor knows me, and not that I 'am one of those 100,000 patients. That is very important in this district. (hp 19)
- The 'integrated care information system' is a crappy system; other systems are also not great. Our system is too complicated. The system is not stable, very often it fails and it is slow. (hp 20)
- I have been working a long time with cardiovascular risk management. I do not discuss results with patients because it takes ten, fifteen or twenty minutes and then the following patient is waiting for me. I then think I will do it next time and I will then quickly measure the blood pressure and will finished the consultation on time. (hp 24)
- Time is the biggest barrier if you really want to educate patients, ask them what they do for exercise, what they eat on average. And it just takes time to motivate the patient to change his/her lifestyle. (hp 27)

Patients noticed that the GP has insufficient time for CVRM, consultations were going too fast which was perceived as unpleasant. The practice nurse has more time for CVRM patients, which was perceived as positive.

Regarding information provision, the majority of the patients indicated that there were brochures present in the general practice. In one general practice there was a digital screen with information. Half of the patients used Internet to search for information. It was perceived as a reliable source with clear explanations. The other half of the

patients had no Internet access or did not use Internet. According to patients there was enough information on the television and in newspapers about CVRM.

Conditions enabling patients to do physical exercise were: a short distance to the gym, getting a trial lesson, a nice group to exercise with, and personal and sympathetic counselling.

Patient-held electronic patient records were in favour by most patients because all data is available in one file. One patient had concerns about the privacy and the CVRM care in case of a computer crash.

Patients indicated that social contacts have been changed over time. It is different these days; neighbours used to know each other. Also, people in the Netherlands are well-fed and enjoy prosperity.

- One digital file to work in, I have no qualms. (p 8)
- Internet is an easy source to find information. (p 10)
- If I was someone who visits the general practice every week, then I can imagine that the GP thinks “there he is again”. But the GP has not seen me in a year. And when I visit the GP everything goes very fast and that is not nice. (p 12)
- Society has changed quite a bit, as well as social contacts. I greet my neighbours but I do not actually know their names. (p 16)

6. Mandate, authority and accountability

In this domain only one comment was mentioned by a healthcare professional:

- Actually, you cannot make health effects provable. (hp 21)

The patient group did not mention any determinants in this domain.

7. Social, political and legal factors

The healthcare professionals were not positive about general Dutch healthcare policies. A reason for this was the budgetary limitation for healthcare. The market mechanisms in Dutch healthcare were rated positively; changes were imposed by the government with many negative consequences. Government campaigns and television advertisements about healthy lifestyles were not noticed by half of the Dutch people, as perceived by healthcare professionals but the government continues to promote healthy lifestyles. Healthcare professionals perceived that health insurers were also struggling with money, quality of care and the market mechanisms in Dutch healthcare. They felt that health insurers should not be the ones who determine which treatment or medication is going to be prescribed: it should be about the content instead of the money, healthcare professionals declared. The health insurers were not helpful in the development of the integrated CVRM care. The care for CVRM needs finance, but GPs

felt that they get paid less for the care they provide and medical specialists use up a great part of the collective budget. Another negative effect of the budget according to healthcare professionals was that not all patients can be reached and that the drop out of patients in the general practice was due to money. Dutch GPs were responsible for the care of more patients compared to other countries which influenced the CVRM care. There were fewer workplaces for practice nurses and less practice nurses in training will lead to a shortage in the future, thus affecting care also.

- It should be purely about the content and not the bucks. (hp 17)
- I do not think that the government really dares to make any choices. (hp 18)
- Healthcare professionals in health centres are more concerned how to perform check-ups on the population and thinking about improving quality. There, healthcare professionals receive more specific information about indicators, which stimulates them to think about it. (hp 22)
- You cannot rely on health insurances, you will get a contract but you will not know how it goes in the future. Same for the healthcare policies, where do they now take money from? (hp 25)
- I see health insurers struggle with the market mechanisms in Dutch healthcare to recruit as many costumers they can, but on the other side I see them struggling about money and the quality of care. (hp 26)

The national healthcare policies were well known by the participating patients. Although the government cannot demand a healthy lifestyle, they should at least promote it. Not all patients saw commercials about healthy lifestyles on the television. Developing a diagnostic centre and supporting parents and schools in promoting a healthy lifestyle could be a part of the responsibilities of the municipality.

Health insurers have a big say about the money and Dutch healthcare has become far too expensive: still patients generally receive reimbursement for all their treatments and medication. Therefore a collective health insurance was found important. For some patients it has become a problem to pay for their health insurance or their membership fee for the sports centre. Some patients think that the wages of healthcare professionals are too high, in particular the people in higher echelons. The quality of care would be positively influenced when administrative layers will be removed, because it will lead to a reduction in bureaucracy, said some patients.

- One of the problems is that I'm not able to pay the contribution for my medication. (p 1)
- The health insurance has never put anything in the way, about whatsoever. (p 3)

- It is not the lower layer but also the higher echelons, those people want more and more, and they demand more and more. You have to have the money. Salaries are the biggest expense, I think. (p 6)
- When administrative layers are gone it will reduce bureaucracy. (p 9)
- The municipality is trying to tackle obesity, trying to change the way people within families live. It is not easy to change things. (p 15)

Discussion

The determinants of delivering CVRM mentioned by healthcare professionals and patients largely relate to the same domains; there was no systematic difference between the interviews in 2012 and 2014. Both groups mentioned many determinants of CVRM that were related to patient education and patient self-management of health and disease. Furthermore, both felt that the collaboration of healthcare professionals in the general practice was reasonably good, but that the collaboration between healthcare professionals in the general practice and hospital based specialists could be improved. In addition, health care providers had negative feelings about general health policies, the introduction of market mechanisms and a strong role of health insurers in particular, and felt that these posed barriers for improving CVRM. In short, perceived determinants of CVRM were mainly related to patient behaviours and (but only for health professionals) to the healthcare system.

Although there were a lot of similarities, a striking difference was found regarding the perception of patients' self-management between healthcare professionals and patients. Healthcare professionals held the impression that patients did not have enough knowledge about CVRM and self-management and could need more information. In their opinion patients did not sufficiently adhere to recommended lifestyle, were insufficient adherent to drug therapy and forgot appointments with their healthcare professionals. Determinants such as socio-economic status, family-related issues and scientific evidence as mentioned in other research were not indicated by healthcare professionals [27,28]. Healthcare professionals felt that they put a lot of effort in the care for CVRM patients, yet they did not see results in terms of health outcomes. On the other hand, patients perceived that they have sufficient knowledge of CVRM, show sufficient effort to maintain a healthy lifestyle and take medication as prescribed, which are factors that could enhance their quality of life [29]. Other studies suggested, however, that this is not true for all patients [30]. Patients in our study were mostly elderly, so it could be difficult for them to change their lifestyle [31]. Patients mentioned that they were motivated to change their lifestyle, especially by the GP and practice nurse. Patient-centred counselling techniques, such as motivational interviewing, may be applied by healthcare professionals in the general practice [32]. Studies suggest that this is not very effective in patients with diabetes [33] or vascular disease [10] in general practice. A possible explanation is that the counselling

technique was not well used, but it is also possible that it was less effective in these patient populations. When a health care professional applies motivational interviewing, patients have to decide what they want to do and the healthcare professional motivates them. Maybe patients are not used to this approach. Also a gap in given information by healthcare professionals may result in a reduced self-management of patients [34]. The relationship between healthcare professionals and patients plays also an important role. There were positive but also negative aspects mentioned about this relationship. Healthcare professionals found it their task to inform patients and patients found healthcare opinion important.

Organisational changes have been successfully implemented in general practice [35]. Patients with established CVD or at high cardiovascular risk were listed and invited to regularly visit the GP or practice nurse. Compared to a decade ago, a much higher number of patients eligible for CVRM is reached and receives adequate preventive healthcare. Nevertheless, there is still a challenge to motivate patients to enhance their self-management [18,36]. Thus, the changes in practice organisation are to some extent disconnected from the challenges of counselling patients.

In our search for determinants of CVRM care, several determinants at the level of the health system were mentioned, although they did not seem directly related to healthcare for patients with established CVD or at high cardiovascular risk. Many organisational changes that are favourable for CVRM, such as better reimbursement and improved information technology, are in fact supported by changes in the healthcare system. Nevertheless, healthcare professionals mentioned problems related to recent changes in the healthcare system, which were results of policies of the latest decade. Our study reveals the frustration of healthcare professionals about the market mechanisms introduced by Dutch healthcare policies to enhance the efficiency of healthcare. Due to the market mechanisms health insurers have a big say in drug treatment for instance they make contracts with various suppliers of generic drugs. Changes in the packages of the prescribed medication hold the risk of mistakes in drug intake, additional questions of patients and less medication adherence. GPs are expected to prescribe the cheapest drug. If a more expensive drug has been prescribed, it is possible that the patient does not receive (complete) reimbursement of its costs or GPs face extra administrative tasks.

Perceived determinants of the delivery of CVRM in different domains seemed to have little connection with each other. Patients still struggle with self-management and lifestyle. Individualised self-management support is one way to improve its impact. To empower self-management of patients with established CVD or at high cardiovascular risk new information technologies can be used, such as websites, apps for smart phones, twitter or patient web communities. These technologies are used to tailor support to individual patients' needs and capabilities, such as presence of depressive symptoms. Patients with established CVD or at high cardiovascular risk are more prone

in developing depressive symptoms [37,38]. For instance, SeMaS is an online tool to support this approach to self-management support, which is currently tested in a cluster randomised trial [39].

This research was pragmatically aimed at developing a tailored intervention. The results reveal that healthcare performed in general practices for patients with established CVD or at high cardiovascular risk is complex. Performance of healthcare professionals in general practices can be approached from several angles for example quality of care or health outcomes measured by patients in general or disease-specific [40]. Healthcare professionals in the general practice are the first point of contact for a wide variety of signs and symptoms, therefore much general knowledge is required. Another angle is knowledge transfer to patients, whereby healthcare professionals should critically think about how they inform patients [41]. Several determinants of practice are not under the influence of healthcare professionals. How active patients are in following a healthy lifestyle is only partly influenced by healthcare professionals [42].

Strengths and weaknesses

A major strength of the study is that we interviewed both healthcare professionals and patients in our search for determinants of CVRM in primary care. For this study we held 28 interviews in total. Saturation was not planned. The number of interviewed healthcare professionals initially was set at ten; two additional healthcare professionals were interviewed because we were missing two professions that also contribute to CVRM care. On forehand we decided to interview 16 patients based on feasibility within the limits of our research. About the topics ‘individual healthcare professional factors’, ‘patient factors’ and ‘professional interacting factors’ we were close to saturation in the healthcare professional group as well as in the patients group. In particular about the topics ‘incentives and recourses’, and ‘social, political and legal factors’ a wider variety of determinants was mentioned in both groups. Results showed that healthcare professionals mutually have a different view on these last topics, which was also seen in the patient group. It is possible that we missed important items, especially about these topics mentioned last. We selected various disciplines of healthcare professionals who were involved in CVRM in primary care. The patient group existed of both patients with established CVD and patients at high cardiovascular risk, representing the spectrum of primary and secondary cardiovascular prevention. There was a risk of selection bias regarding the sample of patients. Possibly, patients with high health literacy, who are satisfied with their healthcare, take good care of themselves and get enough exercise were most willing to participate in an interview. Another strength of the study was that we analysed the findings according to the previously developed TICD framework, as this contributes to the accumulation of knowledge.

Conclusion

Quality of care in general practices is a complex concept, even so for patients with established CVD or at high cardiovascular risk. The complexity of care is experienced at some points different by healthcare professionals in comparison with patients, also a lot of determinants overlapped each other. An important difference was that healthcare professionals think that patients do not have enough knowledge about risk factors for cardiovascular diseases and self-management, and therefore could need more information. Patients think the opposite: they do have knowledge of risk factors for cardiovascular diseases and try to maintain a healthy lifestyle. Healthcare professionals were negative about the healthcare policies of the Netherlands and health insurers; patients on the other hand, were satisfied because there were no problems with reimbursements. Determinants mentioned regarding healthcare professional and patient, organisation and healthcare system were not in connection with each other. Interviews proved to be a productive method to get insight into the views of both health care professionals and patients. We will use these determinants in further research developing an improvement programme related to cardiovascular care in general practices.

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Chapter 3

Identifying determinants of care for tailoring implementation in chronic diseases: an evaluation of different methods

Jane Krause

Jan van Lieshout

Rien Klomp

Elke Huntink

Eivind Aakhus

Signe Flottorp

Cornelia Jäger

Jost Steinhäuser

Maciek Godycki-Cwirko

Anna Kowalczyk

Shona Agarwal

Michel Wensing

Richard Baker

Abstract

Background

The tailoring of implementation interventions includes the identification of the determinants of, or barriers to, healthcare practice. Different methods for identifying determinants have been used in implementation projects, but which methods are most appropriate to use is unknown.

Methods

The study was undertaken in five European countries, recommendations for a different chronic condition being addressed in each country: Germany (polypharmacy in multimorbid patients); the Netherlands (cardiovascular risk management); Norway (depression in the elderly); Poland (chronic obstructive pulmonary disease—COPD); and the United Kingdom (UK) (obesity). Using samples of professionals and patients in each country, three methods were compared directly: brainstorming amongst health professionals, interviews of health professionals, and interviews of patients. The additional value of discussion structured through reference to a checklist of determinants in addition to brainstorming, and determinants identified by open questions in a questionnaire survey, were investigated separately. The questionnaire, which included closed questions derived from a checklist of determinants, was administered to samples of health professionals in each country. Determinants were classified according to whether it was likely that they would inform the design of an implementation intervention (defined as plausibly important determinants).

Results

A total of 601 determinants judged to be plausibly important were identified. An additional 609 determinants were judged to be unlikely to inform an implementation intervention, and were classified as not plausibly important. Brainstorming identified 194 of the plausibly important determinants, health professional interviews 152, patient interviews 63, and open questions 48. Structured group discussion identified 144 plausibly important determinants in addition to those already identified by brainstorming.

Conclusions

Systematic methods can lead to the identification of large numbers of determinants. Tailoring will usually include a process to decide, from all the determinants that are identified, those to be addressed by implementation interventions. There is no best buy of methods to identify determinants, and a combination should be used, depending on the topic and setting. Brainstorming is a simple, low cost method that could be relevant to many tailored implementation projects.

Background

Tailoring implementation interventions to account for the determinants of practice is a common feature of models or frameworks for getting evidence into practice [1,2]. In this paper, we define tailored implementation as implementation interventions to improve professional practice that are planned taking account of prospectively identified determinants of healthcare practice. Determinants are factors that obstruct or enable changes in targeted professional behaviours or healthcare delivery processes. These factors have been referred to as barriers and enablers [3], barriers and facilitators [4,5], or problems and incentives [6]. For example, in an initiative to implement guidelines for antihypertensive and cholesterol-lowering drugs for primary prevention of cardiovascular disease, structured reflection, a questionnaire for physicians, and pilot testing were used to identify determinants, after which a multifaceted intervention was designed, accounting for the determinants [7]. In a Cochrane systematic review of 26 randomised trials of this approach, we found that interventions tailored to prospectively identified determinants are more likely to improve professional practice than no intervention or dissemination of guidelines. However, the methods used to identify determinants and tailor interventions to address them were judged to be only poorly developed [8].

Chronic conditions are increasingly common amongst the ageing populations of many countries worldwide, such conditions including amongst others diabetes [9], dementia [10], and overweight and obesity [10]. The quality of care of chronic conditions is variable at best, and therefore effective approaches are needed for improving care to minimise the burden of exacerbations and complications that individuals will have to cope with and health systems provide care for [11]. If our understanding of the methods of tailored implementation can be improved, the approach has potential to help health systems manage the growing burden of chronic conditions.

Theories of human behaviour [12] or models of practice change [13] may be used to inform the identification of determinants and provide frameworks for categorizing them. In a review of frameworks for classifying determinants of practice, some of which used behavioural theories in their development [14], we identified the following broad categories: guideline factors, health professional factors, patient factors, professional interactions, incentives and resources, capacity for organisational change, and social, political, and legal factors [15].

However, although a variety of methods has been used to identify determinants of practice, little research has been undertaken on their validity or feasibility for use in routine initiatives to improve the quality of care [3,15,16].

Methods currently used to identify determinants include: brainstorming, focus groups, analysis of performance data, observations, interviews, and simple or complex questionnaires [16,17]. These methods may be used with various groups, including managers, healthcare professionals, patients or combinations of these, and based in

different settings including primary, secondary, and community healthcare. The methods may be used individually or in combinations, and may focus on the subjective perceptions of patients or professionals, or may include more objective methods such as observation [18]. In order to decide on which method, or combination of methods, should be used under different circumstances, evaluation of the methods is required. In particular, it is important to understand how many important determinants are identified by each method.

This study sought to address this lack of evidence by evaluating five different methods for identifying determinants of practice. The aim was to investigate the extent to which the methods identified important determinants and assess their feasibility in use. In particular, we first aimed to compare the extent to which brainstorming, health professional and patient interviews led to the identification of determinants judged to be important, and secondly to determine the additional value of structured group discussions and open questions in surveys of health professionals in identifying further determinants. We also investigated the role of closed questions, derived from the checklist [15] in a questionnaire to samples of health professionals, in identifying the extent to which selected determinants were commonly reported. The study was part of the Tailored Implementation in Chronic Diseases (TICD) programme of research that is seeking to advance the methods used in tailoring [2].

Methods

Study design

The study took place in five countries, each country team addressing a different chronic condition, as follows: UK (obesity), Germany (polypharmacy in multimorbid patients), Norway depression in the elderly), the Netherlands (cardiovascular risk management), and Poland (COPD). The countries were selected because the researchers who developed this EU funded programme of research were based in them; there was no other rationale for the selection of countries. The research team in each country selected the condition to be addressed in their country on the basis of the importance of the condition as they perceived it, and the existence in their country of practice recommendations or guidelines (see Additional file 1 for information on the recommendations targeted in each country). Researchers in each of the five participating countries followed the same protocol.

The study was an evaluation of five methods of identifying determinants (brainstorming, interviews of health professionals, interviews of patients, structured group discussions with health professionals, and questionnaires for health professionals), in which a direct comparison of three methods (brainstorming, health professional interviews, patient interviews) was undertaken, followed by evaluation of the additional value of structured group discussion when undertaken following brainstorming, and the additional value of questionnaires whose design was informed

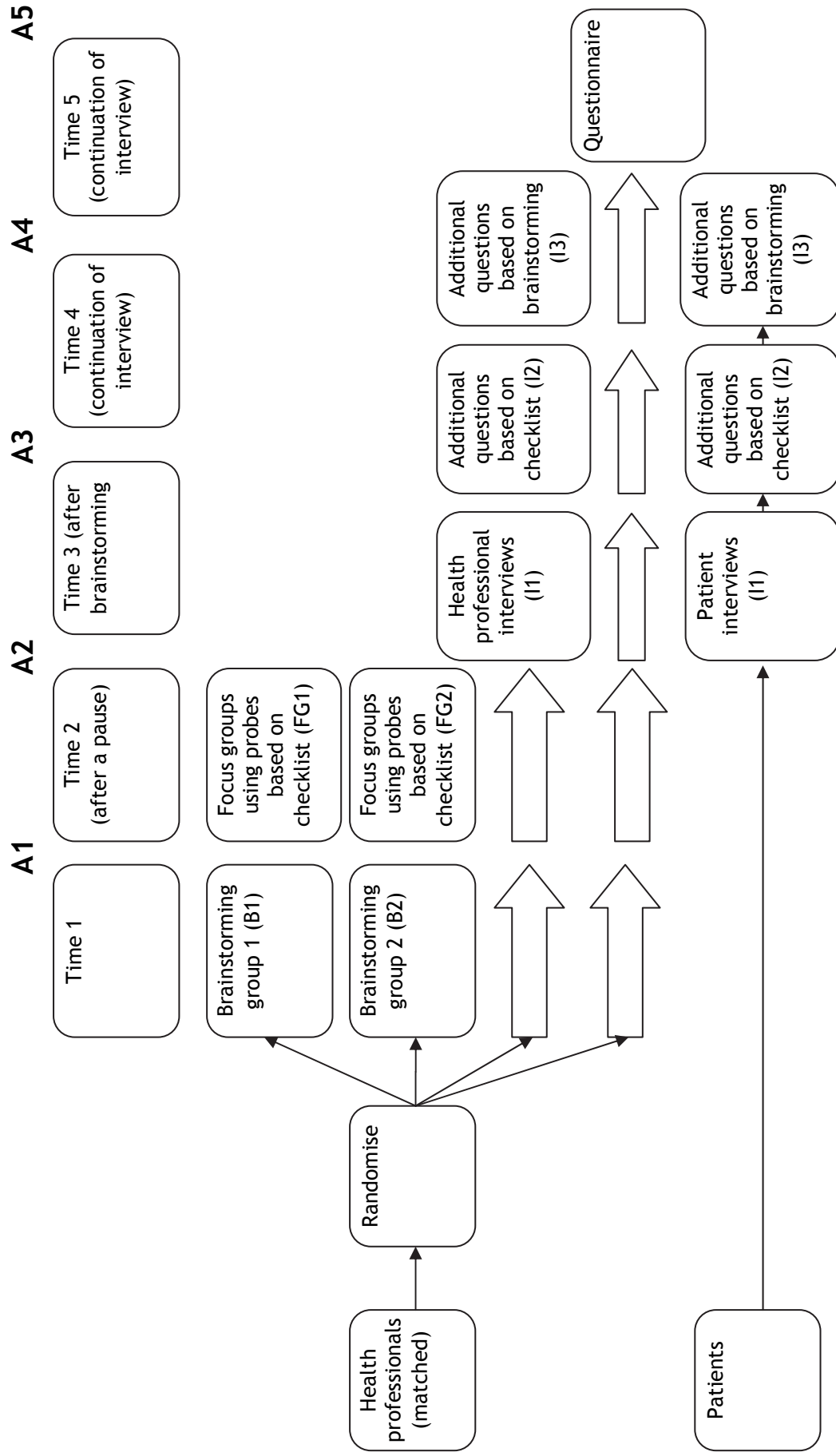
by the brainstorming and health professional and patient interviews, and by reference to the checklist (see Figure 1) [15]. The study received ethics approval from the relevant authority in each country (by the NRES Committee North West - Greater Manchester West for the UK). In order to establish the feasibility of using the various methods, in each country, the research team maintained a diary to record the amount of time spent conducting each of the methods as well as possible difficulties, concerns and benefits that were encountered. In addition, interviews were conducted with a single representative from each of the participating countries. The interview was conducted by one of the researcher team (JK or SA), and sought information on difficulties or challenges in applying the methods, any deviations from the recommended procedures for the methods, and the time taken to conduct and analyse the results of the methods.

Study population

The study was based in a research centre in each participating country, and took place in either primary or secondary care or both, depending on the particular condition and recommendations being addressed in each country. Samples of healthcare and public health professionals and patients were invited to take part. The samples included health professionals targeted by the clinical recommendations (obesity—general practitioners, practice nurses, dieticians; COPD—general practitioners, practice nurses, pulmonologists; depression in the elderly—physicians or nurses from primary care and psychiatrists and specialist nurses from specialist healthcare; polypharmacy in multimorbidity—GPs and healthcare assistants; cardiovascular risk management—GPs and practice staff). Health professionals were defined as professionals involved in patient care in the targeted clinical domain. Some participants may have had other roles, such as team leaders or clinical teachers, and could also be clinicians or managers. We aimed to include healthcare and public health professionals typical of the population that would be targeted by an intervention to improve adherence to guidelines for the selected condition in each country. In order to identify determinants experienced by a wide range of professionals, we sought to ensure that study populations included a mix of male and female participants with a range of work experience, both in duration and with a mix of clinicians and managers. A recently appointed doctor may have different determinants of practice from a doctor who has been in practice for many years, and managers may have a different perspective on the determinants compared to clinicians.

The patients currently had, or previously had, the chronic condition of interest. We aimed to include patients at different stages of the condition, different ages, gender and social status. Both health professional and patient participants were provided with a description of the clinical recommendations to be implemented and data on current performance before participating in one of the study groups.

Figure 1. Schematic protocol, comparative evaluations



Methods for identification of determinants

We identified nine commonly used methods for investigating determinants of practice in a literature review, the methods being: brainstorming by the implementation team, analysis of performance data, focus groups (healthcare professionals), focus groups (patients), observations of practice, interviews with healthcare professionals, interviews with patients, simple questionnaires and more detailed questionnaires [15]. The review was undertaken as part of the TICD programme, in parallel with the review of frameworks and typologies for classifying determinants used in developing the checklist [15]. We searched Medline, CINAHL, and PsychInfo for English language articles reporting investigations of determinants of practice; studies involving all types of health professionals and all types of clinical conditions were included. In the searches, we used terms such as barrier, obstacle, enabler, facilitator, classification, taxonomy, ontology, theory, and framework. The search strategy is reported with the report of the checklist [15].

An online, two round, Delphi procedure was used to reach a consensus amongst the investigators from all five countries on which of these methods should be evaluated in our study. The research team of each country was asked to identify five respondents to complete a questionnaire. The respondents included both researchers interested in methods of implementation and clinical professionals with interest in the chronic conditions addressed in our study. Patients or healthcare managers were not included. Respondents were asked to use a nine-point response format to indicate the extent to which they believed each method for identifying determinants possessed the following six attributes (1 = not at all; 9 = completely); the attributes were feasible, comprehensive, valid, consistent, had reasonable costs, and were relevant. These questions were developed in a face-to-face meeting attended by the research collaborators of all five countries. The responses were entered into a database and the numbers of respondents in each response category tabulated, this information being fed back to participants in the second round. The findings of the second round were presented to a face to face meeting of the research collaborators, at which we reached consensus on including the following four methods: structured group discussions with health professionals, health professional interviews, patient interviews, and health professional questionnaires. These methods were most consistently rated by the respondents as having attributes likely to make them useful and feasible in identifying determinants of practice. In addition, brainstorming was used as a low cost, low intensity method.

Evaluation of methods

Each country used all five methods to identify the determinants of practice for the chronic condition they were addressing.

1. Brainstorming with health professionals (two sessions with between 6 - 10 participants per country),
2. Structured group discussions after brainstorming with health professionals (two sessions with between 6-10 participants per country)
3. Interviews of health professionals (a minimum of 8 participants per country)
4. Interviews with patients (a minimum of 8 patients per country)
5. Questionnaire survey of health professionals based on the checklist derived from previous work within the TICD team (120 participants per country) [15].

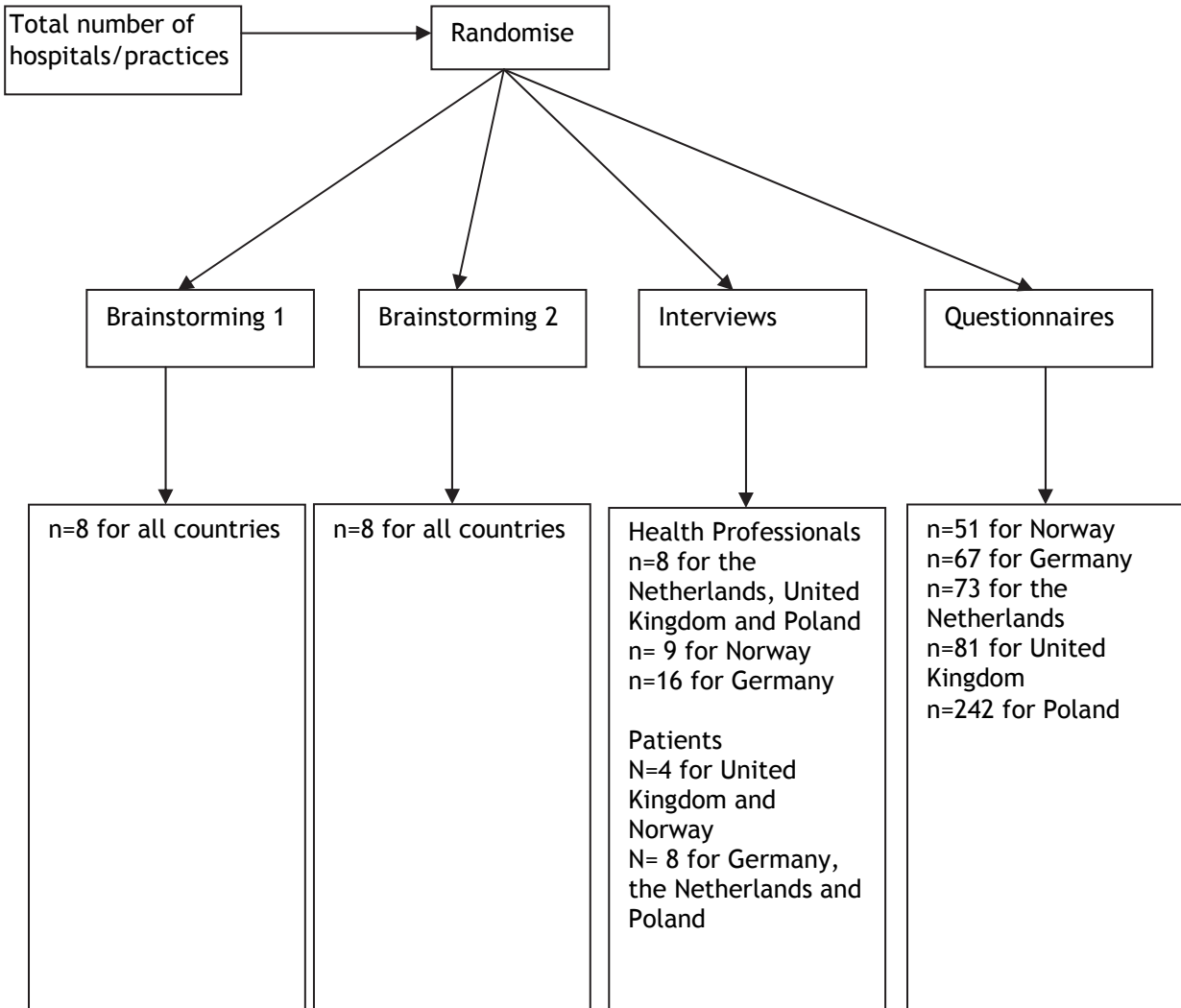
Three methods were compared directly with each other (brainstorming, interviews of health professionals, interviews of patients). We also investigated the additional value if any of undertaking structured group discussions following brainstorming, and the additional value of a questionnaire for health professionals designed following the completion of the other four methods, and devised in the light of the issues raised by these methods and with reference to the checklist previously developed in the TICD programme [15]. This design did not enable us to compare all five methods with each other, although it allowed us to contain the numbers of participants that would be required and mirrored the approach commonly used in studies of determinants in which combinations of methods are employed, for example the use of questionnaires to supplement structured reflection and review of other studies in the study referred to above as an example of investigation of determinants as part of tailoring implementation [7].

Health professionals were matched and randomly allocated into one of three groups (see above for numbers in each group): a group session comprised of an initial brainstorming phase followed by a structured group discussion; interviews with health professionals; questionnaire (Figure 2). If, after the randomisation, health professionals did not wish to participate in the brainstorming session or interviews then they were asked to complete the questionnaire. With the exception of the brainstorming/structured group discussion groups, no participant completed more than one method. Patients who agreed to participate were assigned to a group for interviews of patients. A schematic representation is shown in Figure 1. The sample sizes were chosen on largely pragmatic grounds, to enable both diversity of participants and the numbers that would typically be manageable in an implementation project. Participants were recruited through letters or emails sent to eligible individuals or practices. For example, in the UK, emailed invitations to take part were sent to general practices interested in research in the east midlands region of the country.

Participants randomised to complete the brainstorming then structured group discussion initially completed a brainstorming session, and after a short break the group discussion drew on the checklist as a prompt [15] to structure the discussion. Interviews with health professionals and patients were either conducted face to face or by telephone. The interviews were semi-structured in approach; a single interview guide

was used by each country to produce an interview schedule appropriate for the topic concerned, the checklist being used for additional prompts during the interviews. All interviews were recorded and transcribed.

Figure 2. Randomisation of health professionals. The target numbers of participants are indicated for each method



Interview guide on which condition specific interview schedules were based in each country

1. Please can you tell me about your experience of caring for people with condition X (professionals); please can you tell me a little about your experience of having condition X (patients).
2. Care for patients with condition X does not always reflect up to date research evidence about the best way to help patients. This means that patients do not benefit from the best research evidence. We are trying to understand why this might be. Can

you tell me, from your experience, what you think sometimes explains this (i.e., what the barriers to evidence-based care are)?

3. Are there any other barriers that you think might be relevant?
4. Which do you think are most important?
5. In your experience, what can help ensure that care does reflect current best evidence?
6. Are there any other enablers that you think might be relevant?
7. Which do you think are most important?
8. Thank you very much for your participation in this study.

The questionnaire was based on the checklist, and was developed using the results of the interviews and brainstorming/structured group discussions. The questionnaire included closed questions with Likert format answers to the five same statements used in all countries for each of their recommendations (although translated into the local language, with a back translation procedure being used to check stability of interpretation):

1. I feel that this recommendation is feasible and practical to undertake in my setting.
2. I feel this recommendation fits with my current practice.
3. I have the knowledge required to implement this recommendation.
4. The benefits of implementing this recommendation outweigh the effort of implementing it.
5. I intend to implement this recommendation.

These items were chosen with reference to the checklist, and the literature undertaken in developing the checklist; we selected checklist domains that appeared commonly in the literature as presenting barriers or enablers to implementation [15]. In addition, country teams included additional questions derived from the checklist that were judged to be relevant to the clinical topic and setting. Respondents to the questionnaire were asked to indicate the extent to which they agreed with the determinants above, using the following five-point scale: fully disagree, disagree, neither agree nor disagree, agree, fully agree. We combined the 'agree' and 'strongly agree' responses to enable calculation of the proportion of respondents regarding their ability to implement the recommendation favourably. Open questions were also included inviting respondents to highlight any other determinants not covered by the closed questions.

Measures

The principal measure used to evaluate methods for identifying determinants was the number of plausibly important determinants identified by each method. Plausibly important determinants were defined as 'a factor for which there was a consensus in

the national research teams that it would plausibly inform the design of an intervention'. To inform the design of an intervention, a determinant should firstly have more than a small effect on performance, and secondly, it should be possible to address the determinant in the context of a practical implementation intervention. If a determinant only has a small effect, addressing it in an implementation intervention will not lead to much improvement in care. If addressing a determinant requires an intervention that is not feasible to use, such as the employment of a large number of additional staff or the building of new healthcare facilities, we concluded that we could not plausibly address it. The plausibly important determinants were, therefore, the determinants to concentrate on in tailoring implementation interventions because we expected that it would be possible to deliver interventions to address them and that improved adherence to the recommendations might follow. It should be noted that we did not undertake pilot implementation studies to test our assessments of the importance of individual determinants; furthermore, the research teams in each country may have had different interventions available to them, and an intervention judged not plausible in one country may have been plausible in another. Plausible importance is, therefore, a judgment influenced by context, rather than an absolute property of a determinant. We focus on the plausibly important determinants in this paper (findings on the determinants not judged plausibly important are included in Additional file 2).

To identify the plausibly important determinants from amongst all determinants identified, the following standard procedure was used by the research teams in each country (these teams included a mix of researchers with expertise in health services research and clinical researchers familiar with the clinical field). Each country was asked to rate the determinants using the following criteria, using a five-point scale:

1. How important is the determinant in influencing current practice (as judged by the research team): 1=very low; 5=very high (i.e., important in determining practice)
2. To what extent can the determinant be addressed: 1=very difficult; 5= very easily (i.e., it is likely that interventions could be applied to address the determinant).

A single researcher in each country undertook this, with discussion with other researchers within countries, with discussion across countries being used to promote consistency. In the case of disagreements, final decisions were taken by the study coordinators (JK, SA, RB). Determinants were classified as plausibly important if they scored at least four for both the above categories. In addition, the total numbers of unique determinants as well as the plausibly important determinants for each method were determined. A unique determinant was defined as a determinant identified by only one method, determinants that were not unique being identified by more than one method. If a method identifies a large number of determinants not identified by any other methods, it may be necessary to include this method as one to be used in

investigating determinants. The determinants were also classified by the national research teams according to the checklist developed in earlier work [15].

Data analysis

The analysis was descriptive only; we did not consider statistical tests appropriate in view of the diversity of the topics and countries. The data were loaded into a database, and we first summarised the extent to which the three initial methods (brainstorming, health professional interviews, and patient interviews) identified plausibly important determinants. We simply enumerated the determinants identified by different methods, in the context of different countries and different chronic conditions. In this analysis, the total numbers of plausibly important determinants were calculated, and the numbers identified by each method alone and those identified by any of the other four methods included in the study. We then investigated the number of additional plausibly important determinants identified by either structured focus groups and or open questions on the questionnaire. We recorded whether determinants were identified only by one method (defined as unique determinants), or by more than one method. We also classified the identified determinants by the domains of the checklist [15], and calculated the mean score in response to the closed questions for the guideline recommendations of each country.

Results

Seventy-two health professionals (between 10 and 18 in each country) participated in the brainstorming and structured group discussions, 49 health professionals (between 8 and 16 in each country) took part in health professional interviews, 32 patients (4-8 per country) took part in the patient interviews, and 514 (67-242) health professionals completed questionnaires. The number of plausibly important determinants identified varied according to country (Table 1).

Table 1. Comparison between countries of determinants identified by one method only (unique) and determinants identified by more than one method, in each country

	United Kingdom (obesity)	Norway (depression in the elderly)	The Netherlands (cardiovascular risk management)	Poland (COPD)	Germany (polypharmacy in multimorbid patients)	Total
Unique determinants - Not identified by any other method	43 (39.4)	77 (46.1)	62 (44.6)	9 (29.0)	11 (7.1)	202 (33.6)
Identified by at least one other method	66 (60.6)	90 (53.9)	77 (55.4)	22 (71.0)	144 (92.9)	399 (66.4)
Total	109 (100)	167 (100)	139 (100)	31 (100)	155 (100)	601 (100)
N (%)						

Norway and Germany identified the greatest number of plausibly important determinants (167 and 155 respectively) while Poland identified only 31. Despite Germany identifying a large number of plausibly important determinants, only 11 were classified as unique (i.e., identified by only one method), although in the other countries a third or more determinants were classed as unique. The checklist categories to which the determinants related are shown in Table 2. Incentives and resources, and individual health professional factors, were the most common. Relatively few determinants were classified as guideline factors, capacity for organisational change, or social, political, and legal factors. This pattern was generally repeated for all five countries.

Table 2. Plausibly important determinants identified classified by checklist domain [15]

Domain	United Kingdom	Norway	The Netherlands	Poland	Germany	Total
Guideline Factors	16	24	8	2	3	53
Individual Health Professional Factors	31	51	18	6	36	142
Patient Factors	18	36	18	10	15	97
Professional Interactions	6	14	28	0	33	81
Incentives and Resources	28	30	49	13	41	161
Capacity for Organisational Change	4	12	16	0	2	34
Social, Political and Legal Factors	6	0	2	0	12	20
Miscellaneous	0	0	0	0	13	13

Table 3 shows the numbers of determinants by domain identified in the interviews of health professionals and patients.

Table 3. The numbers of plausibly important determinants identified by interviews of health professionals or patients, by domain

Domain	Health professionals	Patients
Guideline Factors	2	2
Individual Health Professional Factors	34	13
Patient Factors	13	12
Professional Interactions	14	6
Incentives and Resources	30	8
Capacity for Organisational Change	3	0
Social, Political and Legal Factors	4	3
Miscellaneous	4	0

Comparison of brainstorming, health professional interviews and patient interviews

Brainstorming and health professional interviews identified the greatest number of plausibly important determinants, with brainstorming identifying more than three times as many determinants as patient interviews (Table 4). Of the unique determinants, 51.8% were identified by brainstorming, 34.5% by health professional interviews, and

13.7% by patient interviews. In all countries, more than half the determinants were identified by more than one method, although more than one third were classed as unique in Norway, the Netherlands and the UK.

Table 4. A comparison of three methods for identifying plausibly important determinants (brainstorming, health professional interviews and patient interviews)

Method	Number of determinants not identified by any other method (unique determinants)	Number of determinants Identified by at least one other method *	Total
Brain Storming amongst health professionals	72 (37.2)	122 (62.8)	194 (100)
Health Professional Interviews	48 (31.6)	104 (68.4)	152 (100)
Patient Interviews	19 (30.2)	44 (69.8)	63 (100)

*other methods include brainstorming, structured focus groups, open questionnaire, patient interviews, and professionals' interviews.

N (%).

Additional value of the structured focus groups and questionnaire open questions

Both structured group discussions following brainstorming, and, to a lesser extent, open questions in a survey, identified additional plausibly important determinants (Table 5). Both methods contributed unique determinants, although relatively few were identified by the open questions.

Table 5 Additional value of structured focus groups and open questions on questionnaire in identifying plausibly important determinants

Method	Not identified by any other method	Number Identified by at least one other method	Total
Structured Focus Group in addition to Brainstorming	52 (36.1)	92 (63.9)	144 (100)
Open questions in addition to the questionnaire	10 (20.8)	38 (79.2)	48 (100)

N (%)

Closed questions for each recommendation

Five closed questions were used per recommendation in each country. The mean score for all five questions per country are summarised in Table 6. Respondents indicated that most of the recommendations were implementable, with the exception of recommendation one for the UK and recommendations three and six for Norway.

Feasibility

Recruiting participants

Successful recruitment of healthcare professionals and patients for interviews varied between the participating countries, but was assisted by the presence of networks of practices interested in research, as in Germany and the UK.

In some instances, the recruitment of GPs proved difficult due to their busy workloads, and the absence of financial incentives seemed to further contribute to the difficulty in those countries in which reimbursement for professionals' time was not available. Moreover, paper based invitations to participate were less effective than difficulties recruiting patients who were able to discuss their illness and how it related to the recommendation, possibly because of cognitive difficulties or because the recommendations or the task were not presented to the patients in an understandable way.

Interviews of professionals and patients

Generally positive attitudes were expressed by each of the participating teams towards the use of interviews as they appeared to yield more in-depth findings than that of questionnaires. Some felt that those healthcare professionals who agreed to participate were the most enthused and engaged with the topic area and so provided the most significant feedback. There were significant time costs associated with the transcription and analysis of each of the interviews as well as the time implications with the interviews themselves. The diaries showed that interviews required the most time of all the methods.

Brainstorming and structured group discussions

The methods yielded a wide array of issues associated with each of the chronic conditions, and they informed the interview schedule design, which enabled the key topics to be further explored and reinforce the opinions expressed in the group sessions. Some of the participants were familiar with the methodology, and, in the opinion of some research teams, these methods together yielded the most important plausible determinants. However, some felt the initial silent phase in the brainstorming groups was artificial and often informal discussions broke out regardless of protocol. The transcription and analysis of the group sessions took time, but given that each team ran only two group sessions in comparison to several interviews, the time costs were not as large as with the interviews.

Questionnaires

Each of the participating countries experienced significant problems with the questionnaire, and arguably out of each of the methods it was regarded as the most problematic. Firstly, there were problems in achieving adequate response rates, exacerbated by the use of paper based questionnaires when necessary instead of electronic questionnaires. The Norwegian team was unable to obtain email addresses from various healthcare professional organisations due to data protection issues, and so was reliant on paper-based questionnaires. The paper based questionnaires together with follow up reminder letters were costly.

Table 6. Mean percentage of responses either agree or strongly agree (standard deviation) to the five questions of the closed questionnaire

UK	Norway		The Netherlands		Poland		Germany		
	mean (SD)	rec.	mean (SD)	rec.	mean (SD)	rec.	mean (SD)	rec.	
determine degree of overweight	72.4% (10.2)	rec. social contact	80.8% (+15.2)	BP control in raised risk	83.0% (+5.8)	smoking cessation counselling	83.4% (+4.8)	structured medication counselling	66.6% (+19.7)
assess willingness to change	71.1% (+6.8)	collaborative care	59.8% (+17.3)	BP control in cardiovascular disease	87.7% (+3.5)	grade breathless	86.3% (+5.4)	use of medication schedules	92.2% (+6.1)
offer management	78.8% (+4.4)	depression care manager	51.0% (+28.3)	cholesterol control in raised risk	78.9% (+6.1)	information for the patient	87.9% (+5.3)	avoid inadequate medication	59.4% (+15.2)
consider referral	53.1% (+24.9)	counselling	72.2% (+11.5)	cholesterol control in cardiovascular disease	88.2% (+2.1)	inhaler use education	91.8% (+4.2)		
		mild depression	58.4% (+16.4)	lifestyle advice	81.4% (+2.5)				
			47.4% (+21.5)	asses risk in chronic kidney disease	75.1% (+6.4)				

Rec=recommendations.

Discussion

Main findings and interpretation

In this study, we investigated different methods for identifying those determinants of practice that may be addressed in tailored implementation interventions, which we have termed plausibly important determinants. Each of the methods was able to identify such determinants, although brainstorming and interviews with health professionals identified the greatest number of determinants in all countries. The open questions of the questionnaire and interviews with patients identified fewer determinants. Although the number of determinants identified by interviews with patients was relatively low (in comparison to other methods) nearly a third were classified as unique. The findings suggest that there is no single best method for identifying determinants, but that a combination of methods should be considered, chosen depending on the guideline or recommendations being implemented. Thus, although the large number of unique and plausibly important determinants identified by brainstorming suggests that it could be used as a relatively quick and inexpensive method to identify a large number of determinants, if patients or health professionals are particularly affected by the targeted recommendations, interviews of patients and health professionals should be undertaken as well. Therefore, a combination of brainstorming and health professional and patient interviews may be adequate in the case of many chronic conditions. In view of the effectiveness of the structured group discussions in generating additional determinants, the use of the checklist or similar prompting mechanism is likely to be helpful.

It is striking how many determinants were identified in each country. The numbers per country did vary, from 167 in Norway (depression in the elderly) to 31 in Poland (COPD), but it is not clear whether this variation is accounted for by the conditions addressed, or whether the perceptions of professionals and patients and their propensity to report problems in care differ between countries. The finding does suggest, however, that tailored implementation interventions should not be assumed to be transferrable between conditions or countries. We used a systematic approach and several different methods, and identified 601 plausibly important determinants in total (a mean of 120 per country). This finding has implications for implementation strategies; if there are so many determinants of practice that should be accounted for, the process of tailoring will potentially be challenging. For example, it would be difficult, if possible at all, to address 120 determinants in any implementation programme. An alternative might be addressing determinants at the level of the individual, since the number of determinants relating to an individual health professional is likely to be fewer, but the problem of large numbers of determinants will recur if several individuals are involved. In our study, we eliminated determinants that we judged were unlikely to be important, or not amenable to change through an implementation strategy (see Additional file 2). It is possible that our decisions on some

determinants were wrong; the process for selecting the most important determinants to address require developing and testing in future work.

Strengths and limitations

To our knowledge, this is the first study to compare the effectiveness of different methods of identifying determinants of practice to inform tailoring, in different chronic conditions in different countries. A standard protocol was followed in each country, and we believe the procedures followed in each country were broadly consistent. However, there may have been some variation; for example, randomisation of participants to study groups was undertaken separately in each country without central control, and therefore some inconsistency may have crept in. Likewise, the classification of determinants as plausibly important was undertaken within each participating country, leading to opportunities for some inconsistency.

We are unable to judge whether or not all the determinants have been identified, since there is no gold standard method against which to compare the methods used in this study. It is not possible to determine whether the determinants we have identified are genuinely the most important to address in implementing change, and we cannot be certain that our assessments of the importance of the determinants and the extent to which they are amenable to change are valid. We will, however, assess the effectiveness of the tailored interventions by clustered trials in each country, and explore the validity of the determinants addressed through process evaluations of the trials [19-24] of the plausibly important determinants identified, the majority were classified as individual health professional factors and incentives and resources. Relatively few were classified as capacity for organisational change, and social, political, and legal factors, which would be difficult to address in the context of an implementation intervention [14]. The questionnaire was designed in the light of the findings of the interviews since we could not be blinded to the findings of the interviews. We were unable, therefore, to directly compare the ability of questionnaires to elicit determinants with the other methods.

Comparison with literature

Despite a high number of studies on barriers for change, we have identified little other research into different methods of identifying determinants. Bosch et al. [17] investigated the methods used in 20 quality improvement studies, finding that a variety of methods were used. Most were qualitative methods such as interviews of professionals or patients, and it was not possible to recommend which methods should generally be employed.

Practice implications

This study has advanced understanding of determinants of practice by showing that many can be identified by making explicit the process by which identified determinants are assessed and those most important to address selected, and by showing that there is no overall 'best buy' of method for identifying determinants. Different methods tend to lead to the identification of rather different sets of determinants, and consequently use of a combination of methods is more likely to lead to the identification of the key plausibly important determinants than use of any single method alone. The nature of the guideline recommendations being implemented should be taken into account, as patients or health professionals may have particular views in relation to some recommendations. Our findings suggest that brainstorming with a structured group discussion (using a checklist to prompt suggestions) and one additional method (e.g., interviews of health professionals, interviews of patients) should identify a high proportion of determinants in relation to the costs and time involved in conducting each method.

Once the determinants of practice to be targeted have been identified, interventions are required to address them. This step in the process of tailored implementation is not considered in this paper. However, our findings do have implications for the process of tailoring implementation to account for determinants. It is difficult to devise an intervention to address each and every determinant. Tailoring is therefore likely to require a further set of choices to be made about which determinants should be prioritised, or which interventions may be likely to address, at least in part, several determinants. In the TICD research programme, a study is underway to investigate approaches to tailoring [2].

Conclusions

Tailored implementation is a complex approach, a key step of which is the identification of determinants of practice. This step involves selecting which methods to use and deciding which of the determinants are important to address. A selection of methods is available for identifying determinants, and in most implementation initiatives, a mix of methods should be used in order to identify most of the important determinants. Because a large number of determinants are likely to be identified, a process is required to extract from the many those few that can be practically addressed in implementation interventions, with consequent improved adherence to recommendations. In the absence of such a process, implementation risks remaining an often 'hit or miss affair,' with the impact on practice improvement being unpredictable and inadequate. The development and evaluation of systematic approaches to select the most important determinants is now required.

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Chapter 4

Stakeholders' contributions to tailored implementation programmes: an observational study of group interview methods

Elke Huntink
Jan van Lieshout
Eivind Aakhus
Richard Baker
Signe Flottorp
Maciek Godycki-Cwirko
Cornelia Jäger
Anna Kowalczyk
Joachim Szecsenyi
Michel Wensing

Abstract

Background

Tailored strategies to implement evidence-based practice can be generated in several ways. In this study, we explored the usefulness of group interviews for generating these strategies, focused on improving healthcare for patients with chronic diseases.

Methods

Participants included at least four categories of stakeholders (researchers, quality officers, health professionals, and external stakeholders) in five countries. Interviews comprised brainstorming followed by a structured interview and focused on different chronic conditions in each country. We compared the numbers and types of strategies between stakeholder categories and between interview phases. We also determined which strategies were actually used in tailored intervention programmes.

Results

In total, 127 individuals participated in 25 group interviews across five countries. Brainstorming generated 8 to 120 strategies per group; structured interviews added 0 to 55 strategies. Healthcare professionals and researchers provided the largest numbers of strategies. The type of strategies for improving healthcare practice did not differ systematically between stakeholder groups in four of the five countries. In three out of five countries, all components of the chosen intervention programmes were mentioned by the group of researchers.

Conclusions

Group interviews with different stakeholder categories produced many strategies for tailored implementation of evidence-based practice, of which the content was largely similar across stakeholder categories.

Background

Tailored implementation strategies intend to target relevant determinants of practice (also called “barriers and facilitators” for change), which is expected to contribute to their effectiveness [1]. This claim is supported by a systematic review of trials of such strategies, which found an overall positive effect of tailored implementation [2]. However, a qualitative analysis of the methods used for tailoring found substantial heterogeneity and little indication of the usefulness of any method [3]. Comparative studies are needed of different methods for generating strategies for improving healthcare practice. Here, we focus on the potential value of group interviews with different stakeholder groups with this purpose, most particularly on brainstorming followed by structured group interviews [4,5].

A previous study provided a content analysis of the types of strategies for evidence-based practice mentioned by different stakeholders [6], using a previously developed framework [7]. In the present study, we assessed the usefulness of group interviews with stakeholders in terms of numbers and use of suggestions and the added value of different stakeholder groups and interview techniques. Group interviews were chosen because these were perceived by the research team as potentially valid and feasible methods for generating ideas. The main objectives of the study were (a) To compare the number and types of strategies generated by different stakeholders in brainstorm sessions, (b) To assess the added value of a structured group interview after brainstorming, and (c) To assess whether stakeholders provided strategies that were actually included in tailored intervention programmes, which were subsequently tested in cluster randomised trials. Subsequently, we assessed the types of the strategies based on the framework of determinants of practice with seven domains.

Methods

Study design

A prospective observational study was conducted in five countries: Germany, the Netherlands, Norway, Poland, and the United Kingdom (UK). Group interviews with relevant stakeholders were done in the autumn of 2012 based on a written study protocol, which was developed by the group of authors (Additional file 1). Ethical committees in the five countries assessed the study protocol and waived or gave approval (Ethics Committee Heidelberg (Germany), Bioethics Committee of the University of Lodz (Poland), Committee for Research in Humans Radboudumc (Netherlands), Regional Committee for Medical and Health Research (Norway), NRES Committee London - Camden & Islington (UK)).

Setting

This study was part of the Tailored Implementation for Chronic Diseases (TICD) project [8], which aimed to provide insight into the usefulness and effectiveness of methods for tailoring implementation interventions to determinants of practice in chronic illness care. Five different chronic conditions were targeted in five different countries: multi-morbidity (Germany), cardiovascular risk management (CVRM) (the Netherlands), depression in the elderly (Norway), chronic obstructive pulmonary disease (COPD) (Poland), and obesity (UK). In each country, a set of three to six specific evidence-based recommendations were chosen as targets throughout the studies. Subsequently, determinants were identified to enhance those recommendations, using empirical studies guided by a newly developed checklist. In this checklist, 57 potential determinants were defined and grouped in seven domains which are the following: guideline factors, individual health professional factors, patient factors, professional interactions, incentives and recourses, capacity for organisational change, and social, political and legal factors [7]. In this study, we focused on the subsequent phase, which aimed at generating strategies for improving healthcare practice. In the final phase of the TICD project, tailored interventions will be evaluated in cluster randomised trials [9-13].

Study population

In each country, the study involved at least four different categories of stakeholders. Convenience sampling (using a variety of methods) was used to purposefully recruit by mail or email different categories of individuals into groups. Category 1 consisted of healthcare researchers, including members of the TICD project teams and other healthcare researchers. Category 2 comprised quality improvement officers: individuals who develop or coordinate continuing medical education and quality improvement for the targeted patients, professionals or healthcare sector workers. Category 3 comprised healthcare professionals like primary care physicians and primary care nurses. For category 4 authorities, health insurers or other purchasers of healthcare were invited. Additionally, the country research team could decide to include extra group interviews. A fifth category comprised patients and/or relatives. These were only included in the Netherlands and Norway. Each individual joined only one group and most of the participants did not know each other. Patients gave written informed consent for participation; all other participants consented by actual participation.

Group interviews

The group interviews followed a standardised procedure, although the content of the questions and responses differed across countries, depending on the clinical condition and the healthcare system. The interviews consisted of a brainstorming phase followed by a structured interview phase; for each phase, 1 h was indicated. A group moderator

gave an oral presentation at the start of the brainstorming and at the start of the structured interviews. The moderator, who was experienced in leading a group interview, led the interview and took care that the groups did not focus on study designs, research methods, or outcome measures. An observer (present in some countries) recorded all strategies, made field notes, and added question prompts as needed.

The group sessions started by providing a brief general introduction about the TICD project and information about the specific chronic condition followed by the recommendations targeted for implementation (between three and six per country) and the list of prioritized determinants of practice identified in previous research (between 11 and 33 per country) [14]. Using the principles of brainstorming, participants were then invited to suggest interventions and policies to address the determinants and ways to achieve the targets for improvement. The main rules were that criticism had to be avoided, combination and extension of previously suggested strategies was encouraged, and “wild” strategies were welcomed [15]. There was no limit to the number and type of the strategies. No direction or guidance was given except that major omissions regarding goals were signalled by the moderators. After a short break, a short presentation provided information on implementation strategies and research evidence related to their potential impact in the chosen clinical condition in each country to focus on the gaps with recommended practice. This presentation had been prepared before the session and was the same for all group interviews in a country. This was the introduction to the structured interviews, in which additional targets of improvement and domains of determinants of practice were systematically explored, using open questions. Field notes were made by using structured schedules (relating to the targets of improvement and domains of determinants of practice) to fill in. Interviews were not audio taped.

Data analysis

In each country, the national research team listed the strategies in a structured document and translated these into English. These data were sent to the Dutch team which transferred them into a standardised data file for further analysis. The different research teams checked and approved the results of the different phases in this research.

We listed the numbers of strategies of the different categories of stakeholders in the two phases of the group interviews (brainstorming versus structured interview). The numbers of strategies were counted per country, group, and interview phase. Crude figures refer to items regardless of how many similar ones were mentioned.

One researcher determined how many unique strategies were provided in each interview during the brainstorming phase. Next, the same researcher assessed the number of unique strategies added in the structured phase of the interview compared

to the results of the preceding brainstorming phase. This resulted in the numbers of unique strategies per phase, per group, and per country.

One researcher determined how many unique strategies were provided per group, per phase (and how many unique strategies were added in the structured interviews compared to the results of the brainstorming phase), and per country. This was checked independently by a second researcher. Any discrepancies were resolved by consensus. We tended towards listing strategies as unique, unless they were the same or very close to another idea. We also assessed which strategies contributed to the tailored intervention programme (including strategies of the groups of patients and patients' relatives) for each country.

For analysis, we compared the numbers of crude and unique strategies between groups and between interview phases within each country (including strategies of the groups of patients and patients' relatives). A qualitative content analysis of the items has been reported elsewhere [6]. A multiple linear regression analysis was performed to explore the relationship between the number of strategies mentioned and the time spent on the interview (anticipating that longer interviews would provide more strategies). Likewise, we assessed the relationship between the number of strategies and the number of participants in the group interview (anticipating that groups with more individuals would provide more strategies). For this analysis, the stakeholders interviewed in two groups were analysed as separate groups. Norwegian interview time was not available, so Norwegian data were not included in this analysis.

Two researchers categorised the strategies gathered during brainstorming as well as new strategies mentioned in the structured phase in relation to the given set of determinants of practice. We assessed the types of the strategies based on the framework of determinants of practice with seven domains [7]. This analysis was performed post hoc; a significant difference was set at $p < 0.01$. The chi-square test was used to examine whether the distribution of the types of strategies per country differed systematically between stakeholder groups. The statistical analyses were done in SPSS, version 20.

Results

Descriptive data

Overall, 25 group sessions were held in five different countries involving 127 individuals. Groups varied in size from three to nine participants (Table 1), and the group interviews lasted on average 112 min (range 67-135 min). During brainstorming, a total of 881 unique strategies were generated and the structured interviews provided a total of 225 additional unique strategies. Overall, the participants generated a total of 1,106 unique strategies. The differences in the numbers of strategies were larger between countries than between groups within a country (Table 2).

Table 1. Number of participants in the group interviews (n=127 individuals)

	Germany (multimorbidity)	The Netherlands (CVRM)	Norway (depression by elderly)	Poland (COPD)	UK (obesity)	Totals
Implementation researchers	5	7	4	4	6	26
Quality improvement officers	7	3	5	3*	4	22
Healthcare professionals	4	14** (9+5)	11** (5+6)	4	9** (4+5)	42
Authorities, health insurers, other purchasers of healthcare	4	5	6	4	6	25
Patients or their relatives	-	12** (4+8)	3	-	-	15
Totals	20	41	29	15	25	

Legend: *individual interviews, ** two groups interviewed

In Norway and the UK, interviews with primary care physicians and primary care nurses were held separately. In the Netherlands, a mixed group of primary care physicians and primary care nurses and a group of hospital-based vascular nurses were interviewed. The data of stakeholders interviewed in two groups were merged as one group. The Norwegian team did not include the structured interviews as these were not feasible in their setting. The Polish team held three individual interviews with quality improvement officers for feasibility reasons; these data were merged as one and used when appropriate. Data of patients or their relatives were not used in comparative analyses because only two countries performed these interviews. The number of strategies generated during brainstorming was related to interview time and group size, but only a very low proportion of the variation was explained by these two factors (R-square 0.014 for the brainstorm phase and 0.037 for the structured interview). As their impact was low, all further analyses are uncorrected for interview time and number of participants.

Comparison of number of strategies between stakeholders

Table 2 facilitates a comparison of the number of strategies between stakeholder groups. Focusing on the crude number of strategies generated during brainstorming, healthcare professionals provided the most strategies in three countries: the Netherlands (n = 36, 36% of all strategies in this country), Norway (n = 120, 34%), and the UK (n = 81, 45%). Healthcare researchers provided the most strategies in Germany (n = 38, 31%) and in Poland (n = 18, 46%).

Table 2. Numbers of strategies provided in brainstorm phases and structured phase

	Brainstorm phases		Structured phase		Additional unique strategies suggested in structured phase compared to brainstorm phase per group (structured phase)	Total of unique strategies per group per country
	Number of crude and unique strategies ^c	Crude number of strategies	Unique strategies within this group and phase			
Healthcare researchers	Germany	38	8	8	7 (88%)	45
	Netherlands	20	28	14	12 (86%)	32
	Norway	35	-	-	-	35
	Poland	18	17	17	0 (0%)	18
	UK	49	16	16	8 (50%)	57
Quality improvement officers	Germany	33	5	5	4 (80%)	37
	Netherlands	19	27	27	27(100%)	46
	Norway	99	-	-	-	99
	Poland ^a	21	21	21	0 (0%)	21
	UK	22	7	7	7 (100%)	29
Healthcare professionals	Germany	21	12	12	12 (100%)	33
	Netherlands ^b	36	76	55	55 (100%)	91
	Norway ^b	120	-	-	-	120
	Poland	8	8	8	0 (0%)	8
	UK ^b	81	23	23	23 (100%)	104
Authorities, health insurers, other purchasers of healthcare	Germany	32	9	9	9 (100%)	41
	Netherlands	24	35	22	22 (100%)	46
	Norway	93	-	-	-	93
	Poland	13	14	13	1 (7%)	14
	UK	28	13	13	3 (23%)	31
Patients and relatives of patients	Netherlands ^b	36	42	37	35 (95%)	71
	Norway	35	-	-	-	35
Total		881	361	307	225	1106

Totals in brainstorm per country: Germany n = 124, Netherlands n = 135, Norway n = 382, Poland n = 60, UK n = 180.

^a Individual interviews; ^b two groups interviewed; ^c crude items equaled unique items in the phase.

Comparison of types of strategies between stakeholders

The types of strategies from brainstorming did not systematically differ between stakeholder groups within each of the countries, except for the Netherlands ($X^2(15, n = 99) = 35.693$ $p = 0.002$). In this country, quality improvement officers mentioned more strategies aimed at the individual professional, while the healthcare professionals mentioned more strategies aiming at patient factors. There were no significant differences regarding types of strategies from the structured phase in any of the participating countries. This analysis was performed post hoc, and for each country, the results of brainstorming and structured interviews (except Norway) were analysed separately (a total of nine statistical tests).

Number of strategies added in structured interviews

For this analysis, we focused on the unique strategies that were identified during brainstorming and the structured interviews (Table 2). Brainstorming generated 8 to 120 unique strategies per group; the structured interviews added 0 to 55 unique strategies. The highest numbers of additional strategies in the structured interviews of all groups together were found in the Netherlands ($n = 116$, 54% of all unique strategies in this country) and the UK ($n = 41$, 19%). In Germany, 32 (21%) unique strategies were added to the unique strategies of the brainstorming. In Poland, only one (2%) additional item was made during the structured interviews.

Use of strategies in intervention programmes

Table 3 describes the tailored intervention programmes which were developed based on the results of this research and will be evaluated in cluster randomised trials.

Table 3. The tailored intervention programme for each European Country

Germany	<ol style="list-style-type: none"> 1. Training on polypharmacy of primary care clinicians 2. Development and sharing of practice concepts (local protocols) 3. Provision of checklist for medication counselling and medication review 4. Provision of template for medication list 5. Provision of tablet PC with self-learning programme 6. Campaign with posters and leaflets
The Netherlands	<ol style="list-style-type: none"> 1. Refresher motivational interviewing training for primary care nurses 2. E-learning module on cardiovascular risk management for primary care nurses 3. Local treatment protocol for cardiovascular patients. 4. Card with treatment values 5. Support and encouragement of primary care nurses to use e-health applications for patients without symptoms of depression 6. Support and encouragement of primary care nurses to refer patients with mild symptoms of depression to physical activity groups 7. Support and encouragement of primary care nurses to refer patients with severe symptoms of depression to depression treatment
Norway	<ol style="list-style-type: none"> 1. Tools and checklist for developing collaborative care plans for municipalities 2. Information resources for healthcare professionals on treatment options 3. Information resources for patients and relatives

	<ol style="list-style-type: none"> 4. Educational outreach visits to primary care practices. 5. E-learning resources, including CME courses 6. Comprehensive website with information and educational resources.
Poland	<ol style="list-style-type: none"> 1. Training on stop-smoking counselling in primary care physicians. 2. Dyspnoe scale attached to patient records 3. Checklist for managing COPD patients 4. Provision of training inhaler devices to practices.
United Kingdom	<ol style="list-style-type: none"> 1. Training and scripts for counselling patients for primary care clinicians 2. Training in waist measurement for primary care clinicians 3. Educational booklets for patients 4. Discussion on revision of roles regarding obese patients in practices 5. Provision of information on local pathways

This analysis also included strategies identified by the individual interviews in Poland and the group interviews with patients in the Netherlands and relatives of patients in Norway (Table 4). In each country, all groups mentioned strategies which contributed to the tailored intervention programmes. Strategies which were incorporated in the intervention programmes were mostly mentioned during brainstorming, except in the Netherlands.

Table 4. Number of strategies used for the intervention programmes

	Countries (number of parts in the intervention programme)				
	Germany (6)	The Netherlands (7)	Norway (6)	Poland (4)	UK (5)
Healthcare researchers	6	5	6	4	4
Quality improvement officers	6	4	6	3	3
Healthcare professionals	5	5	6	4	4
Authorities, health insurers, other purchasers of healthcare	6	4	6	4	2
Patients/relatives of patients	-	4	4	-	-

Legend: This number presents the contribution all stakeholder groups made (of all mentioned strategies) to the elements of the intervention programme.

All components of the tailored intervention programme were derived from the many mentioned strategies during the group interviews. Researchers were the first group who took part at the group interviews, and they mentioned all the components that were incorporated into the intervention programmes in three countries: Germany (6 out of 6), Norway (6 out of 6), and Poland (4 out of 4). The other stakeholders mentioned also some of the components in those countries. Not all the components of the intervention programme were mentioned by the researchers in the Netherlands and the UK. In the Netherlands, the researchers mentioned strategies contributing to five out of the seven elements in the intervention programme. The contribution of the other stakeholders resulted in one additional element in the programme. The researchers of the UK team mentioned four of the five elements of the intervention programme. The other stakeholders did not mention additional elements for the intervention programme.

Additionally, we assessed the contribution of the patient groups. In the Netherlands, patients provided suggestions contributing to four of the seven elements of the intervention programme. The relatives of patients in Norway mentioned suggestions contributing to four of the six intervention elements.

Discussion

Main findings

Group interviews with stakeholders provided many strategies for implementing evidence-based chronic illness care. The number of strategies varied more between countries than between groups within each of the countries. The highly productive groups seemed to be those of healthcare professionals and healthcare researchers, but this finding has to be interpreted carefully because the group of healthcare professionals consisted of two merged groups in three countries. The added value of structured interviews after brainstorming was highly variable, but in three countries, it led to substantially more strategies. All interviewed stakeholders mentioned strategies that were incorporated in the tailored intervention programmes, which are subsequently tested. The type of strategies generated and their actual use in intervention programmes generally did not differ systematically between stakeholder groups.

Interpretation

Our study used brainstorming, which is based on the assumption that with increasing volume of strategies the number of “good strategies” will also increase [4]. The ultimate proof for this will be provided by the five trials [9-13], which examine the processes and outcomes of implementation programmes that were based on the suggestions made in the group sessions. We felt that it is difficult to assess the “validity” of the strategies generated in the group interviews as we could not think of a meaningful reference for such assessment. Nevertheless, we believe that this exploratory study provides valuable insights that help to interpret results of group sessions to generate ideas, also because comparative research on group interview methods is limited.

Group interviews with healthcare professionals and patients have been successfully used in previous studies to help develop strategies to facilitate the implementation for mentioned barriers and enablers [16,17]. It was striking that the types of strategies of different stakeholders were overall similar if mapped out onto a predefined framework [6]. Other researchers found that stakeholder groups who were individually interviewed [18] or filled out a survey [19] did not differ in their perceptions, a finding that partly corresponds with this study. However, these studies were not using healthcare professionals. The number of strategies seemed to vary more between countries than between groups. These differences in the results can be due to country-specific reasons

(“cultural”) or different healthcare systems [20] or due to the different chronic conditions (multi-morbidity, cardiovascular disease, depression in the elderly, COPD, and obesity) in each country.

Strengths and weaknesses

This study gives extensive information about 25 group interviews in five countries, which is substantially more than in many other group interview studies [21]. The heterogeneity of chronic conditions and healthcare settings adds to the robustness of our findings, but it might also have biased the analyses in unpredictable ways. We did not check whether the study had identified all possible strategies (e.g., by doing more group interviews in each of the stakeholder groups in each of the countries), because this was not feasible. The written international study protocol contributed to the coherence of the study, but nevertheless, the procedures were executed in slightly different ways. In particular, the Norwegian team did not manage to perform a structured phase, and in Poland, one group session could not be arranged and was replaced by three individual interviews. The small effect of group size and interview time on the number of strategies mentioned during brainstorming and structured interview needs to be examined in future studies. Interview group size did not have substantial effect in our study, while other research showed mixed effects [22,23]. Use of suggested strategies in the implementation programmes was intended to be a proxy of usefulness, but use may in fact reflect various criteria: perceived effectiveness, feasibility, preference, or acceptability among the intervention design team.

Recommendations for practice and research

Further studies of methods for tailoring interventions to determinants in healthcare are recommended to provide more insight, because this is to our knowledge the first comparative study on the topic. On the basis of the results, and of a qualitative content analysis [6], we suggest carefully considering which stakeholder groups to involve as we found few differences in the types of suggestions for improving healthcare practice. The groups of researchers provided nearly all components of the implementation programmes, which could illustrate both their broad knowledge of how to improve healthcare practice, the setting, and their task and their rejection of specific suggestions made by other stakeholders. Involving stakeholders expected to contribute to the trustworthiness and impact of implementation programmes and should be included in future studies. Future studies might consider a broader range of methods of involving stakeholders, such as electronic brainstorming sessions, e.g., interactive computer systems or using a phone-based application that supports ad hoc brainstorming sessions [24], conference meetings, or telephone meetings, because bringing groups together is time-consuming and is not always possible [25], and because these alternative methods could reduce the costs.

As this study is one of the first on the topic, we are careful with providing strong recommendations for practice. Our study suggests that an efficient approach to develop a tailored implementation programme may be to start with a group interview with a productive group (clinicians or researchers), subsequently followed by interviews in other stakeholder groups until no new information is received. Involving various stakeholders in group interviews may have the (primary or additional) purpose to enhance the credibility of an implementation programme. If this is the case, procedures and results may be less relevant in later interviews given the focus on buy-in of stakeholders.

Conclusion

The five types of stakeholders mentioned many strategies for improving healthcare for patients with chronic diseases. Group size and interview time had no relevant effect on the number of strategies generated. Our study shows that the type of strategies did not vary between the stakeholders within the participating countries. With structured interviews involving a systematic assessment and presentation of given determinants of practice and results of research on interventions, discussion between the group participants are recommended if feasible, because these interviews provided a substantial number of additional strategies compared to the brainstorming phases. This implies that group interviews need to be carefully prepared in order to optimise their added value.

The strategies gathered from brainstorming and structured interviews were used as starting points for the tailored intervention programmes which will be implemented and tested in the next phase of the TICD project.

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Chapter 5

Tailored Implementation of Evidence-Based Practice for Patients with Chronic Diseases

Michel Wensing
Elke Huntink
Jan van Lieshout
Maciek Godycki-Cwirko
Anna Kowalczyk
Cornelia Jäger
Jost Steinhäuser
Eivind Aakhus
Signe Flottorp
Martin Eccles
Richard Baker

Abstract

Background

When designing interventions and policies to implement evidence based healthcare, tailoring strategies to the targeted individuals and organisations has been recommended. We aimed to gather insights into the ideas of a variety of people for implementing evidence-based practice for patients with chronic diseases, which were generated in five European countries.

Methods

A qualitative study in five countries (Germany, the Netherlands, Norway, Poland, the United Kingdom) was done, involving overall 115 individuals. A purposeful sample of four categories of stakeholders (healthcare professionals, quality improvement officers, healthcare purchasers and authorities, and health researchers) was involved in group interviews in each of the countries to generate items for improving healthcare in different chronic conditions per country: chronic obstructive pulmonary disease, cardiovascular disease, depression in elderly people, multi-morbidity, obesity. A disease-specific standardised list of determinants of practice in these conditions provided the starting point for these groups. The content of the suggested items was categorised in a pre-defined framework of seven domains and specific themes in the items were identified within each domain.

Results

The 115 individuals involved in the study generated 812 items, of which 586 addressed determinants of practice. These largely mapped onto three domains: individual health professional factors, patient factors, and professional interactions. Few items addressed guideline factors, incentives and resources, capacity of organisational change, or social, political and legal factors. The relative numbers of items in the different domains were largely similar across stakeholder categories within each of the countries. The analysis identified 29 specific themes in the suggested items across countries.

Conclusion

The type of suggestions for improving healthcare practice was largely similar across different stakeholder groups, mainly addressing healthcare professionals, patient factors and professional interactions. As this study is one of the first of its kind, it is important that more research is done on tailored implementation strategies.

Introduction

The prevalence of chronic diseases is high and rising worldwide [1]. Although evidence-based recommendations for the diagnosis and treatment are available, many patients with these conditions do not receive evidence-based healthcare [2-4]. A range of interventions and policies for implementing evidence-based practice have been developed and tested, showing mixed, unpredictable, and overall moderate impacts [5]. Experts have emphasised that strategies for implementing recommended practices need to be tailored to the determinants of practice faced by the targeted individuals and organisations [6]. For instance, a lack of knowledge (a determinant of practice) may be addressed by providing education and lack of priority for a recommended practice (also determinant of practice) by organising support from organisational or opinion leaders. Tailoring can be done in different ways, varying from a simple group interview with directly involved clinicians to a systematic stepwise approach, which involves a series of studies involving relevant populations. Generating suggestions for strategies that address barriers to change is an important step in tailoring methods, but research evidence on the validity and efficiency of different approaches to tailoring strategies for improving healthcare is scarce [6].

A systematic review of studies evaluating the effectiveness of tailored strategies suggested that these overall had positive, albeit moderate, effects [7]. This review also reported considerable heterogeneity of tailoring methods, which suggested that the validity of different approaches to tailoring is not well established. It is particularly unclear how strategies for improving practice are best generated. A qualitative analysis of evaluations of tailored improvement programmes found that the reported determinants of practice and the chosen interventions to address those did not necessarily match up well with each other [8]. For instance, organisational factors requiring change frequently remained unaddressed by the chosen interventions. Some authors have argued for a more systematic approach for planning and managing tailoring strategies, using either a behaviour change theory [9] or a pragmatic framework [10]. These authors believe that a systematic and planned approach helps to consider aspects that may otherwise be ignored.

Other authors argued that processes of change in healthcare delivery are complex and socially constructed, so that strategies need to build on the interactions of relevant stakeholders in order to make sense to them [11]. Some have conceptualised implementation of recommended practices as a social process of 'normalisation', which can be influenced by strategies such as regulations and sanctions [12]. This perspective suggests that generating tailored strategies for improving healthcare should engage relevant stakeholders in the design and delivery of strategies.

The 'Tailored Implementation for Chronic Diseases' project aimed to assess methods for constructing tailored strategies to implement evidence-based practice in healthcare for patients with chronic diseases [13]. For generating strategies to improve practice, it

engaged stakeholders in group interviews and, simultaneously, used a pre-defined framework of determinants of practice to guide the group interviews, their analysis and the subsequent choice of interventions for further evaluation [14]. In this paper we report on a thematic content analysis of the items generated by the interviewed stakeholders in five countries. Our primary objective was to explore how the items mapped onto the pre-defined framework of determinants of practice, which guided the group interviews to generate these. In addition, we were interested to compare the items of different stakeholder groups regarding the domains they addressed.

Methods

Study design

A pragmatic interview study using brainstorming in groups to generate items was conducted in five countries: Germany, the Netherlands, Norway, Poland, and the United Kingdom. The study (including participant consent procedure) was assessed and approved by ethical committees in each of the five participating countries: Ethics Committee Heidelberg (Germany), Bioethics Committee of the University of Lodz (Poland), Committee for Research in Humans Radboudumc (Netherlands), Regional Committee for Medical and Health Research (Norway), NRES Committee London - Camden & Islington (UK). Participants were invited several days before the meeting (by letter or telephone). Showing up and giving verbal agreement (after full disclosure on the study) at the location and date of the planned interview was taken as informed consent, with some exceptions. In Germany and the UK, participants also gave written informed consent. In the Netherlands, patients gave written informed consent (these data are not used in this manuscript). Data collection took place between September and December 2012. The research was planned in a written protocol, which is available on request from the authors. We followed COREQ criteria as much as possible in reporting on the study [15].

Setting and research team

The study was part of the international research project, “Tailored Implementation for Chronic Diseases” [13]. The international team of researchers had a background in academic primary care, clinical epidemiology and health services research. Researchers in each country focus on a different clinical condition, but all are linked by being chronic, long term conditions. The clinical foci included chronic obstructive pulmonary disease (Poland), cardiovascular disease (the Netherlands), depression in the elderly (Norway), multi-morbidity (Germany), and obesity (the United Kingdom). In these countries, healthcare for these conditions is mostly provided in primary care settings. In each country, the same series of studies was performed, focusing on a chosen set of recommendations for high-quality healthcare in the targeted condition. In the first study, determinants of practice in the care of the targeted condition were identified

using a mix of methods to interview stakeholders. In the second study, which provided the data for this paper, stakeholders were invited to provide items for improving these previously identified determinants. The third study comprised five distinct cluster randomised trials of tailored implementation programmes, which were designed to address the key determinants of practice that were identified.

Study population

In each country, a convenience sample of participants was used, which was purposeful with respect to the inclusion of different stakeholder groups. Four groups of four to eight individuals each were convened (any individual was in one group only), using mix of methods to approach potential participants. These methods included random sampling in a defined geographic area, an existing professional network, and targeted invitations to specific individuals. The first contact with a potential participant was often in written format, but occasionally by telephone or face-to-face.

Group 1 comprised health researchers, including members of the project teams and other academics with relevant expertise. Group 2 comprised quality improvement officers, not involved in the project teams, who develop or coordinate continuing education and quality improvement for the targeted patients, professionals or healthcare sector. Group 3 comprised healthcare professionals relevant for the implementation, mainly primary care physicians and nurses. Group 4 comprised representatives from external stakeholder organisations, such as authorities, health insurers, and patient organisations. The targeted individuals were unrelated to the researchers, except for group 1. Groups were planned to be homogenous. In some countries, given their differing roles in caring for patients with chronic diseases, physicians and nurses were interviewed in separate groups. In two countries, patients and relatives were also interviewed, but these data have not been included in this paper. The number of sessions was planned to reach data saturation across stakeholder groups, although not necessarily within each of these groups.

Group interviews

Whilst the clinical focus of the group interviews differed across the countries, all interviews followed the same procedure. Detailed instruction was provided in the international study protocol. The purpose of the interviews was presented as scientific and relevant for improvement of healthcare. Interviews were organised in a variety of locations, including multipurpose meeting rooms, healthcare centres and universities. The interviews were led by group moderators, who had an (mostly clinical) academic background, were experienced in leading group interviews, and (if necessary) familiarised with the TICD project. They invited participants to contribute their ideas to the design of an intervention to improve healthcare. Each interview started with a general introduction that presented the chosen targets for improvement (three to eight

specific goals), which had been chosen by the national teams on the basis of analysis of prevailing guidelines and evidence for performance gaps. Data on current performance were presented in the groups to indicate gaps with recommended practice. This was followed by a presentation of a consolidated list of determinants of practice (the same list in each group in a specific country), which was based on a range of empirical studies in earlier phases of the TICD study [14]. Table 1 gives an overview of the determinants of practice, as mapped out onto the pre-defined TICD framework of determinants of practice [14].

Table 1. Determinants given to groups mapped out onto the TICD framework domains

	Multimorbidity (Germany)	Cardiovascular (the Netherlands)	Depression (Norway)	COPD (Poland)	Obesity (United Kingdom)
Guideline factors	2	-	2	4	3
Individual health professional factors	13	7	10	9	6
Patient factors	6	2	4	1	3
Professional interactions	1	1	1	2	-
Incentives and resources	10	1	3	8	2
Capacity for organisational change	-	-	3	-	-
Social, political and legal factors	1	-	-	-	-
Total number of determinants of practice	33	11	23	24	14

Figures indicate number of determinants in each domain, which were given at the start of the group interviews in a country.

Using the method of brainstorming, the participants were then invited to provide items for addressing the given determinants to meet the given targets for improvement. The group moderators were instructed to avoid discussions of study designs, research methods or outcome measures. There was no limit to the number of items for improving healthcare, but the discussions were time limited. Spontaneous categorisation or prioritisation by participants was accepted, but was not actively encouraged by the moderator. The moderator was instructed to check and ask about major omissions regarding goals/determinants and, when present, prompted participants to consider these. The brainstorms were part of a larger group interview, which lasted 105 to 130 minutes in total (median figures per country), except in Poland where they were substantially shorter (median of 67 minutes). A researcher was present to make field notes and provide practical support. The items provided in the brainstorm sessions provided the starting point for a structured interview, which followed directly after the brainstorm (except in Norway, where only brainstorm sessions were done). In this way, the participants had the opportunity to review the items that are used for analysis in this study within the group sessions.

Data- analysis

The interviews were audio-taped and transcribed by the national study teams (except in Norway, where notes were made during the sessions). Each of the five national study teams prepared transcripts in English for analysis, focused on listing the suggested items. These were transferred into pre-formatted data-files, which listed the items by group. These data-files were prepared by one research team (MW, EH) and validated by the national research teams (Data S1). For each item, we coded independently which of the TICD framework domains [14] was addressed. Items which did not seem to address a particular determinant of practice were excluded from other analysis. Then we categorised the items by domains in the framework and grouped items into themes within each domain. Both the coding and the thematic analysis were done by two researchers (MW, EH), who discussed discrepancies of interpretations and reached agreement on codes and themes. We used Excel to organise the codings and SPSS to provide descriptive figures.

Results

A total of 115 individuals participated in 22 group interviews and three individual interviews (Table 2). There were no explicit refusals to participate, but response rates in samples were low and some individuals could not participate in the planned meetings for practical reasons. In three countries (the Netherlands, Norway, and United Kingdom) two groups of health professionals were formed. In Poland it was not possible to arrange a group meeting with quality improvement officers, so this was replaced by individual interviews with three people.

Table 2. Number of participants in the group interviews (n=115 individuals)

	Health researchers	Quality improvement officers	Healthcare professionals	Purchasers, authorities, patient organisations	Totals
Multimorbidity in Germany	5	7	4	4	20
Cardiovascular risk management in the Netherlands	7	3	14 **	5	29
Depression in the elderly in Norway	4	5	11 **	6	26
Chronic obstructive pulmonary disease in Poland	4	3 *	4	4	15
Obesity care in the United Kingdom	6	4	9 **	6	25

*individual interviews, ** more than one group interview

These data were merged as one group. The participants provided a total of 812 items of which 586 addressed particular determinants of practice (Table 3). The absolute numbers of items differed across stakeholder groups; health professionals provided the

highest numbers. The items that did not address a particular determinant (28% of all) were often expressions of high-quality healthcare rather than interventions or policies to implement this. For instance, it was suggested that ‘healthcare providers should counsel patients’ and that ‘they should follow guidelines’.

The largest number of items addressed individual health professional factors: 52% of all items (Table 3). A high number of items addressed patient factors (29%). Professional interactions were targeted by 12% of the items. Other domains in the TICD framework were addressed by much lower numbers of items for interventions or policies to improve healthcare for patients with chronic diseases. Little variation in the relative proportion of items in specific domains was seen across stakeholder groups, except that quality improvement officers seemed to provide fewer items regarding patient factors.

Table 3. Domains in the TICD framework addressed by items (n=811 items)

Groups → Domain addressed:	Health researchers	Quality improvement officers	Healthcare professionals	Purchasers, authorities, patient organisations	Total
Guideline factors	8 (6 %)	2 (1%)	6 (3%)	3 (2%)	19 (3%)
Individual professional factors	64 (52 %)	74 (54%)	97 (50%)	67 (51%)	302 (52%)
Patient factors	37 (30%)	29 (21%)	64 (33%)	37 (28%)	167 (29%)
Professional interactions	10 (8%)	25 (18 %)	19 (10%)	19 (15%)	73 (12%)
Incentives and resources	5 (4%)	6 (4 %)	7 (4%)	2 (1%)	20 (3%)
Capacity for organisational change	0 (0%)	1 (<1%)	0 (0%)	3 (2%)	4 (<1%)
Social, political, and legal factors	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Subtotal of items that target a domain	124	137	193	131	585
Items that did not target a domain targeted (excluded from thematic analysis)	36	57	73	60	226
Total number of items	160	194	266	191	811

Legend. Figures refer to number of items by stakeholder group across countries (column percentages between brackets). Percentages refer to subtotal of items that targeted a domain,

Table 4 lists the themes, which we identified in the qualitative analysis of the items for improving chronic illness care. The countries from which citations were derived have been coded as follows: GE=Germany; NL = the Netherlands; NO= Norway, PL = Poland; UK= United Kingdom. The themes are elaborated in the remaining of this results section.

Table 4. Themes in the items for improving healthcare, mapped onto TICD framework domains

	Themes
Guideline factors	<ul style="list-style-type: none"> -summary version of guidelines -protocols tailored to local conditions -more specific clinical recommendations -cost analysis included in guidelines
Individual health professional factors	<ul style="list-style-type: none"> -content of education -delivery format of education -interventions to enhance the impact of education -enhanced use of information technology -free up time for healthcare professionals -revision of professional roles -making organisational changes -enhanced collaboration with other care providers
Patient factors	<ul style="list-style-type: none"> -delivery formats of patient education -use of counselling techniques -more active patient involvement -involvement of relatives and organisations -improved accessibility of services
Professional interactions	<ul style="list-style-type: none"> -local availability of care providers -enhanced communication and teamwork -involving others in detection of disease -use coordination mechanisms -change role perceptions regarding collaboration
Incentives and resources	<ul style="list-style-type: none"> -overall increase of reimbursement for care providers -supply of specific staff or devices -reimburse specific items -financial incentives for patients
Capacity of organisational change	<ul style="list-style-type: none"> -anchoring in administrative organisation -more resources
Social, political, and legal factors	<ul style="list-style-type: none"> -publicity for healthcare providers

Guideline factors

Examples of determinants of practice in this domain, which were presented in the group interviews, were the availability of clear guidance (UK) and the access to recommendations (PO). Several themes could be identified in the tailored items relating to guidelines for healthcare delivery. A first theme was that guidelines should be made available in a summarised format, for instance ‘leaflets aimed at clinicians providing clear guidance’ (UK). It was also suggested to make summary versions for patients and their relatives. A second theme was that guidelines needed to be translated into tailored protocols, involving local stakeholders. ‘When a protocol is not available, the practice nurse should be involved in developing a protocol’ (NL). A third theme was that guidelines need to be more specific regarding clinical procedures in patients, including referral to other care providers. ‘Specific guidelines e.g. if BMI>X do Y’ (UK). A final theme in this category was that cost analysis needs to be included in the guidelines.

Individual health professional factors

Presented determinants in this domain included, for instance, awareness of specific services (NO), clinical inertia (NL), lack of routine (GE), trained staff (PO). Tailored items regarding knowledge and skills concerned the (continued) education of physicians and nurses. A first theme concerned the proposed content, which covered communication skills (e.g. motivational interviewing, cognitive behaviour therapy), clinical skills (e.g. measuring blood pressure), pharmacological knowledge, use of computerised patient records, and information on options for referring patients (e.g. to a vascular outpatient clinic). A second theme was the format of the education. Items included quality circles, online education, audit and feedback, training with peers, brochures, and role play. A third theme concerned activities or policies to strengthen the impact of the education of healthcare providers. These included financial incentives to take education, a mandate by the chief medical officer, provision of necessary medical devices (e.g. inhalers, PL), coordination with training of other care providers, and organising the education strategically ('one knowledgeable person per cluster who can advise on guidelines and local services', UK).

A wide range of tailored items were directly targeted at changing professional behaviours. Many of these related to making organisational changes, which we have conceptualised as strategies that target individual health professional factors. A first theme was enhancing the use of information technology for a range of purposes, including patient records, individual healthcare plans ('electronic accessibility of a care plan for patient and healthcare professionals', NL), prompts for specific actions, and databases ('list of volunteers who are interested and have knowledge about depression', NO). A second theme comprised making organisational changes to improve time available for health professionals, including lower number of patients listed in a practice (NO), separate or longer consultations for the targeted condition (UK, NO), and evening interviews (UK, NL). A third theme comprised revision of professionals roles, such as the proposal that only primary care physicians prescribe long-term medication (GE), several proposals to involve pharmacists in drug treatment (GE), enhancing the role of nurses (e.g. 'inserting MRC dyspnoea scale to the cards patient's labelled with COPD. To give the scale while waiting for the doctor or check-in on computers,' PL). A fourth theme comprised a range of organisational changes, including the standardisation of clinical instruments (e.g. MRC dyspnoea scale in PL, weight procedures in UK), joint patient record systems (NL), broaden range of services in general practice (NO), organise a separate room for specific clinical procedures (e.g. weighing, UK), and improved continuity of care ('Consistency with the person you are seeing so they can get to know you and your circumstances', UK). A fifth theme comprised proposals regarding improving collaboration with other care providers and volunteers (NO), including guarantee that a service is available (UK), that sufficient numbers of specialist care providers are present (NO), a lowered threshold for referral

(NO, NL), and ideas for coordination of care ('A coordinator in the community who can connect, one office - one website', NO), 'system of pathways for patients', NO). A final theme, mentioned once, was that healthcare professionals should be role models as individuals (e.g. 'lose weight', UK).

Patient factors

Determinants of practice, which were presented in the groups, included patients' adoption of life style advice (NL), handling of patient records (GE), and cognitive problems (GE). Items for improving chronic illness care, which were targeted at patients, addressed the following themes. A first theme comprised a wide range of ideas on how to provide information to patients, including the use of pictures, repetition, information campaigns, helpdesk, leaflets, different language versions, taped spoken information, group interviews, local television station, text messages, map of local life style programmes, and courses. A second theme comprised items for the use of specific counselling techniques, such as goal setting, choosing realistic goals, make a verbal contract with the patient, focus on behavioural consequences (e.g. feeling healthier) rather than health consequences, transparency on 'entitled care' (NL), make an individual care plan, and use serious gaming (computer games with educational purposes). A third theme concerned ideas to involve patients more actively: set goals with patients, allow patients to view their own records (e.g. online), encourage patient self-monitoring of risk factors. Specific examples included the items 'to give choice who weighs the patient' (UK) and 'allowing patients to decide how often they will revisit the clinic will improve attendance rates', (NL). A fourth theme concerned items for involving others, including patients' relatives, peers as buddies, community organisations, work places, and 'commercial slimming clubs', (UK). Other items targeting patient's concerned reminders and rewards for patients, e.g. financial incentive for using only one pharmacy (GE), active follow-up of non-attenders, or checklists for structuring the counselling. A final theme was accessibility of services for patients. Examples were the item: 'Evening consultation for all patients from vulnerable groups like elderly people, psychiatric patients, people that work long hours, people with low education and single men' (NL) and 'walking groups leaving from the general practice', (UK).

Professional interactions

Presented determinants of practice regarding professional interactions included, for instance, the presence of referral pathways (UK), quality of communication between health professionals (NL), and availability of medical records at interfaces between healthcare providers (GE). Tailored items targeted at professional interactions covered the following themes. A first theme concerned the presence and availability of specific providers in the local setting, such as a fitness trainer (UK) and patient educator (PL). A

second theme comprised items to improve communication and teamwork among healthcare providers generally. For instance, specific ideas were ‘to create meeting points where professionals get to know each other where the services are presented’, (NO), ‘using the network in a national programme for improving depression care’, (NO), and ‘enable low threshold for contacts between primary and secondary care’, (NO). Connections with municipalities and community organisations, e.g. ‘weight watchers’ (UK; a self-help organisations for people who want to lose weight), were also mentioned in this context. A third theme was that a wide range of health professionals could be involved in detection of the targeted chronic condition: ‘Utilize other caregivers who are involved in care for specific groups as (possibly signaling) entry. Consider homecare, psychiatrist, doctor of nursing home’, (NL). A fourth theme concerned coordination mechanisms, involving individuals or information technology. For instance, items included ‘Practice nurse as central caregiver, using a concrete protocol’ (NL), ‘Use scannable medication record of the German medical doctors association’ (GE). A fifth and final theme was that collaboration had to be included in the role perceptions of healthcare professionals: ‘Some of GP’s tasks are collaboration - but a motivation for collaboration is needed, GPs may use up to 7.5 h per week for this’, (NO).

Incentives and resources

Examples of presented determinants included the availability of devices and staff (PO), financial reimbursement for specific activities (GE), and access to available services (NO). A small number of items were included in this category. A first theme was the item that overall reimbursement of the healthcare provider had to be increased, either as lump sum or as a bonus for good performance. A second theme comprised items to supply specific resources, including staff in the practice, information technology tools, and medical devices. A third theme was that tailored items were proposed for reimbursement (as currently none existed), including telephone consultations (GE), group consultations (NL), longer consultations (NO). A final theme concerned incentives for patients, e.g. for showing up at planned consultations (NL) or vouchers for attending the Weight Watchers (UK).

Capacity for organisational change

Lack of coordination between municipalities (NO) is an example of a determinant of practice, which was presented to the groups. A few items related specifically to the capacity of organisational change. Most referred to making resources (personal, facilities) available to enable implementation. In addition, there was one item to anchor a new practice in the relevant administrative organisation.

Social, political and legal factors

Only one tailored item was categorised in this domain: publicity for healthcare providers to increase awareness of their existence among potential users (UK).

Discussion

In the brainstorm interviews, the stakeholders provided many items for interventions and policies to implement evidence-based healthcare for patients with chronic diseases. The items largely mapped onto three domains: individual health professional factors (knowledge, skills, behaviours), patient factors, and professional interactions. Items relating to the knowledge, skills, or behaviours of health professionals comprised by far the largest category, covering both educational strategies and organisational changes. Few items specifically addressed guideline factors, incentives and resources, capacity for organisational change; or wider social, political and legal factors. The relative distribution of items across TICD framework domains was largely similar across different stakeholder groups.

Before elaborating on the findings in several domains of practice, we mention a number of limitations of the study. This international study followed a written study protocol and the fidelity of procedures was monitored during data-collection by the study coordinators. Nevertheless, we could not avoid some differences in the application of the methods, such as different numbers of determinants provided as input for the group interviews or the use of individual interviews in one case. Although we included a range of stakeholders, for practical reasons we did not include patients. This might have reduced the range of items, although the group interviews with patients or their relatives in two countries (NL, NO) did not provide different items than the other groups in those countries. The group interviews were focused on identifying tailored items that could be put into practice, so we might have missed theory-based mechanisms of change. The items are likely to be influenced by the professional disciplines of the participants. For instance, we noticed that no items directly related to healthcare professionals' cognitions, although these are seen as crucial in behaviour change psychology. The qualitative analysis required subjective judgments, which we reduced by using a previously developed framework and two independently working researchers. Nevertheless, there is potential bias in the input given at the start of the interviews, the summary of suggestions given by participants and their translation into English. The chosen framework can also be critiqued. For instance, the category 'individual professional factors' may be perceived as broad as it covers both educational and organisational interventions. Finally, the relevance of items may be limited to high income countries with a relatively strong primary care system.

The relatively low number of items regarding the clinical guidelines reflects the low number of determinants related to guidelines, which were derived from the previous phase in the TICD project. This may suggest that these were perceived as a given set of

valid recommendations. The items regarding the clinical guidelines for chronic conditions called both for clarity and specificity of the guidance (consistent with the view that change requires top-down steering) as well as for the possibility of adaptation to local settings (consistent with the view that change is socially constructed). 'Guideline implementability' (the probability that a guideline can be implemented) has received increased attention in recent years [16]. Some aspects of implementability are under the control of guideline developers (e.g. considering comorbidities, definition of performance indicators), but other aspects have to be largely managed by other decision makers (e.g. local adaptation of national guidelines, organising resources).

Consistent with frameworks for learning in the work place from the educational sciences [17], the stakeholders had many items to strengthen social interaction during the learning process of healthcare professionals as well as for support and incentives to translate the knowledge learned into practice. This is consistent with current developments in medical education, which emphasize that teaching healthcare providers requires a broad set of competencies [18]. It may be noted that few items of the stakeholders concerned individual cognitions of health professionals, although a large body of research has emphasised the importance of cognitions for behaviour change [19]. This may be due to the professional disciplines of the group participants (who were not experts on behaviour change), the types of factors we asked them to focus on (not individual cognitions), or such factors being considered but not mentioned as they were considered less relevant for improving chronic illness care.

The large number of items targeted at health professionals' behaviours mainly comprised educational interventions and organisational changes in healthcare, which we interpreted as directly targeted at individual health professionals. Many of the suggested organisational changes directly addressing individual health professionals need to be applied by themselves. Examples include the use of information technology and revision of professional roles. The available evidence supports the idea that such organisational changes can improve quality, efficiency and outcomes of healthcare delivery [20]. It may be noted that we used the domain 'organisational capacity for change' for upstream factors only, such as 'organisational readiness of change' [21], which can influence individual health professionals indirectly. The low number of such upstream organisational items may reflect the background of the participants. For instance, the inclusion of more senior managers in the groups might have led to more organisational ideas.

A wide range of items focused on involving patients more actively in the healthcare for their chronic condition. Healthcare providers tended to provide the highest numbers of items in this category, which may suggest that they have high expectations of involving patients more actively in chronic illness care. While involving patients actively in their care can serve different purposes, the stakeholders were instructed to focus on items to address a given set of determinants related to a given set of evidence-based

recommendations. There is a large literature on patient empowerment, patients' self-management, shared decision making, and related concepts. However, the research evidence that active involvement contributes to better healthcare delivery is limited [22], particularly regarding the use in routine care settings.

While many items were very specific, this was less clear for items regarding professional interactions. While these expressed the idea that teamwork and collaboration of healthcare providers is important for high-quality chronic illness care, the number of tailored items was low. This is consistent with scientific knowledge on the topic. A systematic review found that strengthening of patient care teams can improve quality and outcomes of healthcare, but it was less obvious which factors contributed to team effectiveness [23]. A promising new perspective is offered by social networks analysis, which suggests that the presence of 'collaboration behaviour' may be related to the structure of healthcare providers' networks [24].

The number of items for financial incentives and resources was relatively low. This was remarkable, because in recent years many programmes for improving healthcare have focused on changes in reimbursement of healthcare providers (e.g. pay for performance schemes). In some participating countries (e.g. the Netherlands, the United Kingdom), reimbursement of healthcare for the targeted chronic conditions is relatively good, so that reimbursement may be no longer the primary concern of stakeholders. It may be noted that the stakeholders had few items regarding incentives or structures in the healthcare system, which may reflect the input that we provided to the group and the position of the individuals involved in the group interviews.

Our study is one of the first comparative studies of methods for tailoring strategies to determinants of practice. Brainstorming in groups of stakeholders proved to be a feasible method to identify many ideas on improving healthcare. It is useful to know that different stakeholders provided similar types of items (in terms of TICD framework domains addressed). If resources are limited, it may be advisable to include at least health professionals, because they appeared to be highly productive in the interviews. Another implication of this study is that prioritisation of items is required, given the high number of items, when designing an implementation programme.

As our study is one of the first of its kind, it is important that more comparative studies are done to develop and test methods for tailoring strategies to determinants for improving healthcare. We used group interviews to match strategies to determinants of practice, but a range of other methods is available that can potentially be used for this purpose. These include pragmatic survey and interview methods as well as methods that are more strongly guided by theories on change, such as intervention modeling [25]. The effectiveness of a tailored implementation strategy resulting from a tailoring method is the ultimate outcome of interest, but future evaluations are likely to rely on intermediate outcomes like we did. The validity of such intermediate outcomes needs attention, because it is difficult to assess the plausibility of items in tailoring exercises.

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Chapter 6

Effectiveness of a tailored intervention to improve cardiovascular risk management in primary care: study protocol for a randomised controlled trial

Elke Huntink
Naomi Heijmans
Michel Wensing
Jan van Lieshout

Abstract

Background

Cardiovascular disease (CVD) is an important worldwide cause of mortality. In the Netherlands, CVD is the leading cause of death for women and the second cause of death for men. Recommendations for diagnosis and treatment of CVD are not well implemented in primary care. In this study, we aim to examine the effectiveness of a tailored implementation programme targeted at practice nurses to improve healthcare for patients with (high risk for) CVD.

Methods/design

A two-arm cluster randomised trial is planned. We offer practice nurses a tailored programme to improve adherence to six specific recommendations related to blood pressure and cholesterol target values, risk profiling and lifestyle advice. Practice nurses are offered training and feedback on their motivational interviewing technique and an e-learning programme on cardiovascular risk management (CVRM). They are also advised to screen for the presence and severity of depressive symptoms in patients. We also advise practice nurses to use selected E-health options (selected websites and Twitter-consult) in patients without symptoms of depression. Patients with mild depressive symptoms are referred to a physical exercise group. We recommend referring patients with major depressive symptoms for assessment and treatment of depressive symptoms if appropriate before starting CVRM.

Data from 900 patients at high risk of CVD or with established CVD will be collected in 30 general practices in several geographical areas in the Netherlands. The primary outcome measure is performance of practice nurses in CVRM and reflects application of recommendations for personalised counselling and education of CVRM patients.

Patients' health-related lifestyles (physical exercise, diet and smoking status) will be measured with validated questionnaires and medical record audit will be performed to document estimated CVD risk. Additionally, we will survey and interview participating healthcare professionals for exploration of processes of change. The control practices will provide usual care.

Discussion

Tailored interventions can improve healthcare. An understanding of the methods to reach the improved healthcare can be improved. This research contributes a share of it. Identification of the determinants of practice and developing implementation interventions were two steps which were completed. The subsequent step was implementation of the tailored intervention programme.

Background

Cardiovascular disease (CVD) is an important cause of mortality and reduced quality of life worldwide [1]. In the Netherlands, CVD is the leading cause of death for women and the second cause of death for men [2] and imposes a heavy burden on both patients and healthcare, resulting in high expenditures [3]. Studies have found that primary care for cardiovascular risk management (CVRM) is suboptimal for substantial numbers of patients [4,5]. This is partly related to unfavourable lifestyles of many patients, which are difficult for patients to change and difficult for healthcare professionals to manage [6,7]. Patient education and counselling in primary healthcare can moderately improve patients' lifestyle and self-management [7] but it remains a challenge to implement effective methods of patient education and counselling widely and sustainably in primary care.

The recommendations for diagnosis and treatment of CVD have been summarised in multidisciplinary clinical practice guidelines, including in the Netherlands, which will be the setting of our study [8]. While it includes general recommendations on items of patient education, prevailing clinical guidelines pay little attention to how this is best organised in busy daily practice. In the Netherlands, the latter is provided in related guidelines, called 'care standard', which focuses on organisation of cardiovascular risk management [9]. However, both the clinical guidelines and the 'care standard' do not provide detailed guidance for how to implement this in daily practice [6]. A challenge therefore remains in encouraging patient self-management, informing patients, guiding patients towards a healthy lifestyle and cooperation between healthcare professionals. Firstly, to enhance the current care, six key recommendations were selected from the Dutch multidisciplinary guideline for CVRM (Table 1).

Table 1. Recommendations for cardiovascular risk management (CVRM)

Recommendations	
1	Systolic blood pressure (SBP) < 140 mmHg in patients at high risk for CVD
2	Systolic blood pressure < 140 mmHg in patients with established CVD
3	Low density lipoprotein (LDL) cholesterol < 2.5 mmol/l in patients at high risk for CVD
4	Low density lipoprotein (LDL) cholesterol < 2.5 mmol/l in patients with established CVD
5	Promote lifestyle changes in patients with (high risk for) CVD
6	Create a risk profile for patients with chronic kidney disease

Subsequently, 11 determinants of practice were selected. The identified determinants were categorised under four headings; (1) healthcare professional related factors, (2) patient related factors, (3) professional interaction and (4) incentives and recourses. The first heading 'health professional-related factors' included four determinants: (1) clinical inertia, (2) encouragement of general practitioners and practice nurses to apply motivational interviewing more often, (3) provision of patients with good advice and explanations, and (4) more attention is needed for patient motivation. The second

heading 'patient related factors' also included four determinants: (1) patients should be encouraged to adopt and implement lifestyle advice provided by general practitioners and practice nurses, (2) patients should be able to ask for more information, (3) feasible targets for the patient should be drafted, and (4) more attention for patient compliance is needed. Under the third heading 'professional interaction', the single identified determinant here stated that communication should be improved between healthcare professionals in primary and secondary care. The last heading consists of 'incentives and resources' for which two determinants were found: (1) self-management should be promoted by using E-health, and (2) practice nurses and protocols should be available in general practice. These determinants were the basis for the implementation programme.

This study is part of the Tailored Implementation for Chronic Diseases (TICD) project, which has the overall aim to develop and test methods of tailoring implementation interventions to determinants of practice for knowledge in chronic illness care [10].

Aims and research questions

The primary aim of the study is to examine the effectiveness of a tailored implementation intervention for improving the professional performance of practice nurses for patients at high risk for CVD or established CVD in primary care. The secondary aim is to examine the validity of the process of tailoring implementation interventions to determinants of practice.

Research questions

1. What is the effectiveness of a tailored implementation programme compared to usual care on the professional performance of practice nurses and patient related outcomes?
2. What is the validity of the methods used to tailor the implementation programme to determinants of practice?

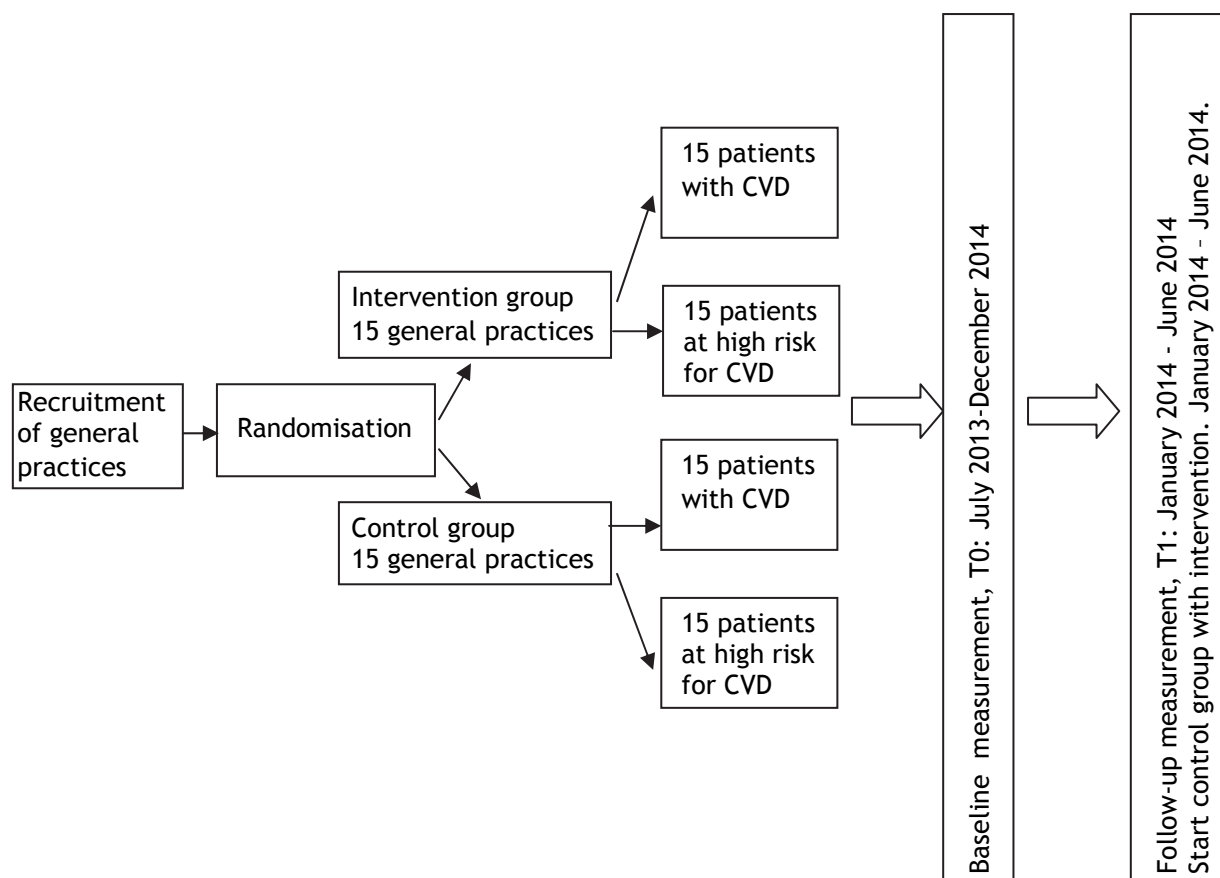
Methods/design

Trial design

This study is a two-arm cluster randomised trial to determine the effectiveness of a tailored intervention programme targeted at practice nurses in primary care and patients at risk for CVD or with established CVD. We will include practice nurses and patients from primary care practices in the Netherlands. The general practices are randomised into two study arms; (1) the intervention group, in which practice nurses and patients are offered a tailored intervention programme, and (2) the control group in which practice nurses provide usual care and patients are not offered any interventions while the intervention programme is implemented. Usual care consists of consults in which practice nurses provide lifestyle advices on diet, exercise, smoking,

and alcohol use. General practitioners are responsible for medication prescriptions. Rates of consults vary from various contacts within weeks during medication dose adjustments to once a year, depending on actual values of treatment parameters and patients' preferences. After the project period in the intervention group, the intervention programme is offered to the control group (see Figure 1).

Figure 1. Study flow chart. This table provides a time schedule in which timeframe the intervention is conducted



Ethical approval

This study was approved by the Medical Ethics Committee of CMO region Arnhem - Nijmegen; the study is registered as 2013/229.

Setting

General practices

A random sample of general practices in several geographical areas in the Netherlands will be invited to participate in the study. After being given approval (by the general practitioner or the practice nurse), general practices will be randomly allocated to the intervention programme or control group. All interventions and data collection procedures are planned for between July 2013 and June 2014.

Participants

Practice nurses

The implementation programme is primarily targeted at practice nurses. Practice nurses eligible for inclusion in the study have CVRM as their task and have been trained for motivational interviewing during their education or as an additional training. Practice nurses will perform measurements of patients' biomedical parameters and provide them with lifestyle advice and also consult the general practitioners about medication policy.

Patients

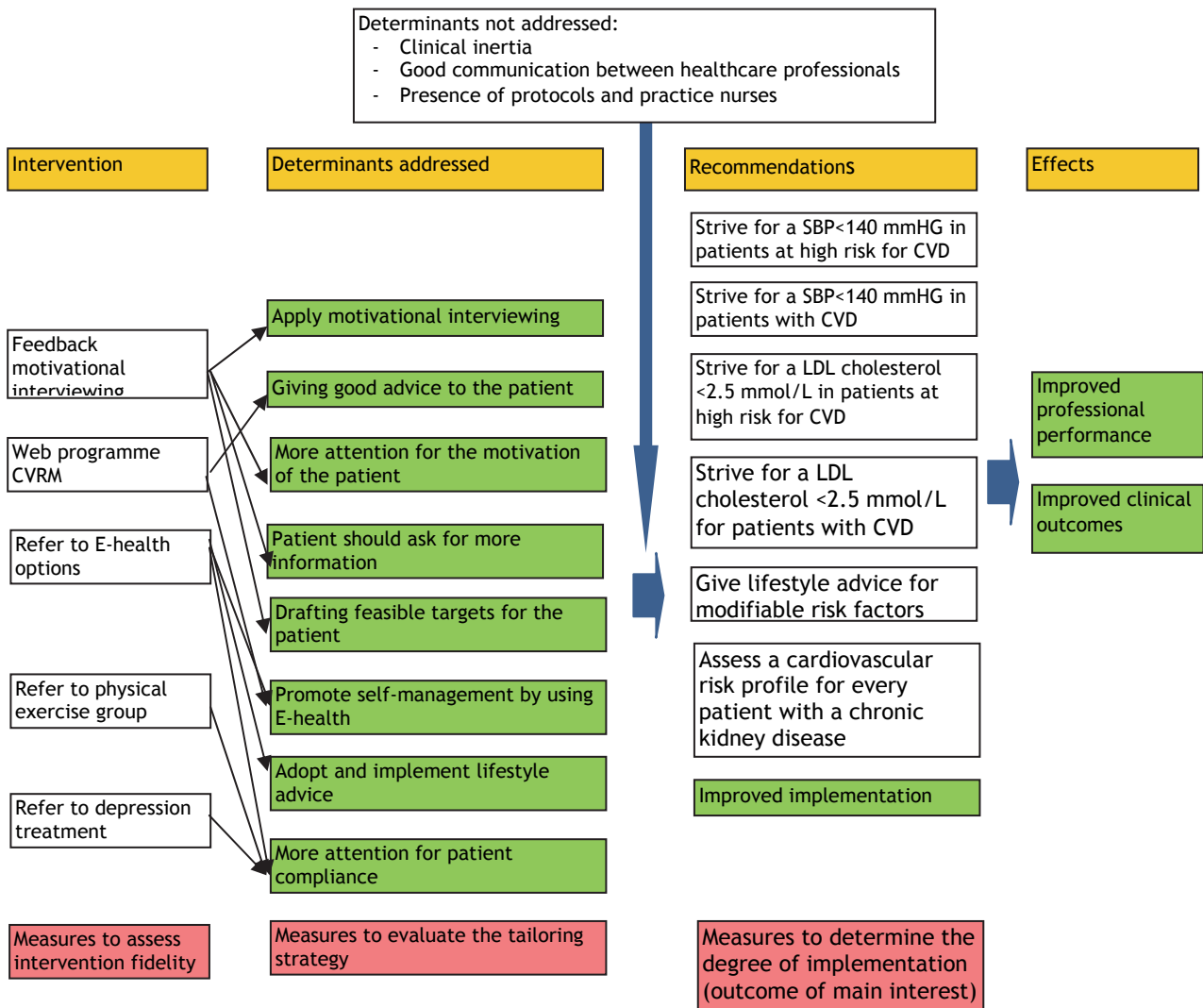
Eligible patients' will be extracted from the medical records by using International Classification of Primary Care (ICPC) codes, K74-K76, K85-K92, K99.1 and T93. Eligible patients are adults aged 18 or older, have a high risk of CVD (but no known CVD) or established CVD and are capable of providing informed consent. These high risk patients have a risk score of 20% or higher for morbidity and mortality due to CVD based on age, gender, smoking status, systolic blood pressure and total cholesterol/high density lipoprotein (HDL) cholesterol ratio [8]. Exclusion criteria are: (1) diabetes mellitus, (2) pregnancy and lactation, (3) terminal illness, (4) cognitive impairment, and (5) poor language skills. Patients with diabetes mellitus will be excluded because this illness has its own guidelines/standard of care. Diabetes care is well developed and monitoring CVD patients with diabetes as co-morbidity would mainly evaluate diabetes care.

A random sample of patients who meet the criteria will be invited by a letter, which provides comprehensive information about the intervention programme. Contact details of TICD researchers are provided so that patients can ask for additional information if desired. Patients will return their informed consent with permission for audit of their medical records during the trial, to Radboud University Nijmegen Medical Center in a postage-paid envelope.

Development of the implementation programme

In previous phases of the TICD project, determinants for the implementation of the aforementioned six recommendations have been identified as well as strategies for addressing those determinants. This process is reported in detail elsewhere [10]. On the basis of this prior work, a tailored implementation intervention has been developed, in which each strategy addresses one or more specific determinants, see the logic model, Figure 2.

Figure 2. Logic model. This table provides information regarding which determinants and recommendations are addressed to the intervention programme and which are not addressed, as well as showing the intended effect



Implementation programme

The implementation programme is based on extensive research on determinants of practices and potential implementation interventions, which can address relevant determinants. Some adaptation (further tailoring) at the level of practice nurses and patients is planned by a structured procedure for translating the treatment protocol for enhanced counselling for local use. In particular, concrete options for E-health and physical exercise in a local community will be specified by the practice nurse on a written treatment protocol. The following implementation interventions are offered:

Refresher training on motivational interviewing and CVRM-knowledge

Practice nurses are closely involved in patient care and capable of performing substantial parts of the standard of care CVRM [8]. To further enhance their knowledge

and skills, two refresher trainings will be offered; one on motivational interviewing and one on knowledge of CVRM.

Motivational interviewing

Practice nurses will be guided by a professional trainer who is affiliated with MINTned (Dutch Association of Trainers in Motivational Interviewing). The trainer will provide feedback directly after two consecutive consultations by using the Behaviour Change Counselling Index (BECCI) code [11]. During this procedure, the practice nurse can directly apply feedback and feel confident that they have applied it appropriately. Previous research has shown that providing feedback is effective for improving motivational interviewing techniques among nurses and that there is room for improvement [12-15].

CVRM-knowledge

For enhancing knowledge of CVRM, we recommend a recently launched e-learning programme. This programme is specifically designed for practice nurses by the Dutch College of General Practitioners and consists of several modules with information about tasks areas of practice nurses involved in CVRM. At the end of every module, the practice nurse is required to answer several questions.

Instruction in E-health and application of Twitterconsult

A short instruction will be offered which emphasizes advantages of using E-health in primary care and describes how this medium can be used effectively by patients. During this instruction, we will recommend the following websites which are selected after careful exploration of available options: 'thuisarts.nl' ('general practitioner at home', developed by the Dutch College of General Practitioners), and 'hartenvaatgroep.nl' ('heart and vessel group') which contains carefully selected and reliable information on health and disease for both patients and the general public. These websites are easy to use by patients and searches can be completed by using search terms or by clicking organs on a picture of a human body. Practice nurses will discuss with the patients the opportunities to access the Internet.

In addition to using informative websites, practice nurses are asked to notify patients on a Twitter-consult. In this Twitter-consult, a general practitioner will answer questions about CVRM.

Clinical interventions in the implementation programme

We aim to target the six chosen treatment recommendations by enhancing the tailored implementation programme of improved counselling by practice nurses which will improve patient self-management. These are provided in prevailing clinical guidelines for CVRM [8], on which we elaborated a few additional procedures. As patients with

CVD have a higher risk for experiencing depressive symptoms [16-19] which can seriously impair the ability of patients to change their lifestyle habits [20], we will suggest that practice nurses pay particular attention, and plan action, according to the presence of depressive symptoms. When the practice nurse has doubts about the presence of depressive symptoms in the patient, the Patients Health Questionnaire (PHQ-9) can be used as supportive material.

This is consistent with guideline recommendations, which state that counselling needs to be tailored to individual patients' capabilities. The following approach will be recommended:

- No depressive symptoms

Patients without symptoms of depression are considered to be eligible for a more independent approach in changing and managing their health behaviours. Therefore, they will be referred to several E-health options. These will consist of educational websites, as mentioned in the E-health training for practice nurses, on which patients can search for information suited for individual goals in CVRM and the Twitter-consult. Although the latter is not particularly emphasised in prevailing guidelines, research found that Internet interventions can reduce cardiovascular risk [21-23] and reduce the number of visits to healthcare providers [24].

Furthermore, and for providing additional support, patients will be given a card on which websites, dates of the Twitter-consult, and target values for blood pressure and cholesterol are stated. This card will be the size of a credit card so that it is easy for patients to keep it with them and use it as a reminder for treatment targets and sources of information to reach their treatment goals.

- Mild depressive symptoms

Practice nurses are recommended to refer patients with mild symptoms of depression to a physical exercise group. A physical exercise group can be particularly suited for these patients as it combines social support and physical exercise, both of which have a beneficial effect on cardiovascular health and on depressive symptoms [25-27]. The specific form of this exercise group will depend on what is available in the local community in which the practice is situated. Examples are exercise groups led by physical therapists or exercise groups at the local gym.

- Major depressive symptoms

In patients with major depressive symptoms, practice nurses are recommended to refer these patients as appropriate within their practice and not to start CVRM until relief of depressive symptoms has been achieved.

Control group

In the control group, no intervention is provided to practice nurses. Patients will receive usual care.

After the project period in the intervention group, the intervention programme is offered to the control group.

After analysing all data, results will be provided to all the general practices in the intervention and control groups.

Outcomes and measurements

Outcomes

Primary outcome

The primary outcome refers to the professional performance of practice nurses and reflects application of recommendations for personalised counselling and education of CVRM patients. As a primary outcome, a dichotomous score is created for measurement in each patient, reflecting adequate or inadequate performance. We considered practice nurses' professional performance to be adequate when at least one of the following conditions is met:

- 1) There is a record in the patient's medical file, or other healthcare provider-based records, that the patient has received advice on at least one lifestyle item as specified in prevailing guidelines of CVRM; diet, smoking or physical exercise, and which are relevant for the individual patient in the previous six months. Also, at least one target for improving an aspect of lifestyle is recorded. This target is maximised 15 months previously. When a patient has a perfect lifestyle then that will be recorded.
- 2) There is a notation in the patient's medical file that the patient has none, mild or major depressive symptoms and that the patient has been referred to E-health, a physical exercise group, or depression treatment respectively.

Secondary outcomes

The secondary outcomes consist of the following:

- Practice nurses

- Quality of effective referral

- Using data from patients' medical files and the patient questionnaires, we will assess whether practice nurses referred patients to treatment options (E-health, a physical exercise group, or depression treatment) in accordance with our recommendations on depressive symptoms. This measurement of quality represents correct referral and is thus an extension of measurement of referral as defined in the primary outcome.

Quality of motivational interviewing

For assessment of quality of motivational interviewing skills, audio-taped interviews of practice nurses in the intervention group and control group will be transcribed verbatim and will be coded by trainers using the Motivational Interviewing Treatment Integrity (MITI) code. Results of these codings will be compared with baseline after six months.

- Patients

Cardiovascular risk predictors

Using prevailing risk estimation tables (based on the Euro score data), the following parameters are used for calculation of the risk score for patients at high risk for CVD; age, gender, smoking status, systolic blood pressure and total cholesterol/HDLcholesterol ratio). For patients with established CVD smoking status, systolic blood pressure and total cholesterol/HDL-cholesterol ratio will be used. Change of the parameters will be measured before and after implementation of the tailored intervention.

Self-management

Using a composite questionnaire, we will assess whether patients applied lifestyle advice for improving their self-management. This questionnaire will be sent at the start of the implementation programme and after six months. The questionnaire will be sent to the patient's home address.

Measurement procedures

In each general practice, measurements on practice nurses and patients are performed at baseline and at follow-up after six months.

The following measurement methods will be used: medical record audit, patient questionnaires, questionnaires for practice nurses and the MITI code for assessing motivational interviewing skills. Specific measures will include:

1. Indicators for clinical performance, using a modified version of a validated abstraction tool for a medical audit in patients at moderate-high risk for, and with, established CVD from the EPA Cardio instrument. Additional information about medication and other chronic diseases will be measured as well. These data will be collected from medical records [3].
2. Health related lifestyles. Questionnaires for specific aspects of lifestyle of patients will be used, including physical exercise (Rapid Assessment of Physical Activity (RAPA), 9 items) [28], diet (reduced Rapid Eating and Activity Assessment (REAP-S), 12 items) [29] and smoking behaviour [30].
3. Other measures on patients, include items on demographic characteristics, healthcare use, changes in patient activation (Patient Activation Measure (PAM), 13

items) [31], Report on adherence to medication (Medication Adherence Measure, 4 items) [32], the Patient Assessment of Chronic Illness Care (PACIC, 26 items) [33]. The depression related items in the Patient Health Questionnaire list will be used for measurement of depressive symptoms (PHQ-9, 9 items) [34]. Data of quality of life will be collected using the EQ-5D (6-items plus Visual Analogue Scale (VAS) [35].

4. A questionnaire for practice nurses will be provided, containing items on demographic characteristics, general practice characteristics, education, familiarity with motivational interviewing and years of employment as practice nurse. The questionnaire will also include questions about participation in the offered e-learning programme.
5. For assessment of motivational interviewing skills, we will use the Motivational Interviewing Treatment Integrity code [36] for the transcribed interviews. The assessor will be blinded for intervention or control group and for the first or second consult.

All the completed questionnaires will be sent to Radboud University Nijmegen Medical Center in a postage-paid envelope. The questionnaires are marked with a unique number, and will be stored in a locked closet.

Process evaluation

Following the international study protocol for the TICD project [37], the aim of the process evaluation is twofold: to examine the fidelity of the planned intervention strategy and how this relates to the effectiveness of the implementation programme, and to identify possible mechanisms underlying effectiveness (or lack of it) on primary and secondary outcomes.

As a complement to the international protocol, interviews will be held with randomly selected patients who participated in this research. Data about the professional performance of the practice nurse, social support and using offered E-health options will be collected. During this interview, the following determinants as perceived by the patients will be evaluated: provision of good explanation for patients; patients' need for knowledge; whether enough attention is paid to patient motivation and using E-health options for promoting self-management.

The MITI code measures the extent to which the practice nurse uses empathic statements. The use of empathic statements will be investigated more extensively using the Empathy Quotient questionnaire [38].

Sample size

The study is powered to detect a 15% difference (17 to 32%) in provided lifestyle advice on all lifestyle variables included in the risk score and as recorded in patients' medical files [30]. The sample size calculation assumed an intra-cluster correlation coefficient (ICC) of 0.05, alpha of 0.05, and a power of 0.80 and indicated that 450 patients per

group will be needed (15 patients at high risk for CVD and 15 patients with established CVD per cluster, sampled in 30 practices).

Recruitment

The aim is to include 30 general practices. Addresses of 1,600 general practices will be obtained from a national database. We will start by sending 800 invitations. Postal reminders will be sent to non responders after two weeks. When insufficient general practices are recruited, another 800 invitations will be sent, together with a reminder to non responders after two weeks.

Per general practice, 15 patients with established CVD and 15 patients at high risk for CVD will be included. Assuming a response rate of 33% of the patients at high risk for CVD and a dropout rate of 35%, we will invite 69 patients at risk for CVD per practice. Similarly, taking into account a response rate of 50% for patients with established CVD and a dropout rate of 35%, 46 patients with established CVD will be invited per general practice.

Randomisation

Randomisation of general practices will be done by an independent research assistant through a computer. The general practices will be allocated randomly to two equal sized groups for the intervention programme and a control group. Block randomisation for practice size and rural/urban area will be performed to control for differences in work processes within small and large general practices.

Blinding

Due to the nature of the intervention programme, blinding of the patients and practice nurses will not be possible for this intervention programme.

Data collection methods

Data collection methods are described in the section of outcomes.

Statistical methods

Data will be analysed using SPSS (version 20, IBM Corp.) and SAS (version 9.2, SAS Institute Inc.) For all statistical testing, two-sided hypothesis testing with an alpha level of 0.05 will be applied. Baseline descriptions and comparisons of practices, practice nurses, and patients will be provided (percentages or means and standard deviations where appropriate) using χ^2 tests for categorical data and t-tests for continuous data. All data analyses will be based on 'intention to treat'.

For assessing differences in the primary outcome (professional performance of practice nurses), the intervention and control group will be compared in terms of provision of

advice on all lifestyle variables and determination of at least one lifestyle target for improvement using a X^2 test.

An additional analysis of the primary outcome will be performed by applying a logistic regression analysis which uses professional performance as dependent variable and group allocation, practice nurse characteristics, refresher training (on motivational interviewing and CVRM), and referring patients to the different options as independent variables.

For the secondary outcomes, 'quality of effective allocation' and 'quality of motivational interviewing', a X^2 test and t-test will be performed respectively.

For assessment of the secondary outcomes reduction in risk score and enhancement of self-management in the two groups, we plan to perform multilevel regression analyses which use the risk score and a composite score for self-management at six months as dependent variables. Independent variables will include, diverse patient characteristics (age, sex, social economic status (SES), co-morbidity), depressive symptoms (none, mild, or major), group allocation (E-health, physical exercise group, depression treatment), quality of effective referring patients, lifestyle advice on treatment parameters and lifestyle targets.

Discussion

This implementation programme has been developed with the aid of the strategy tailored implementation interventions. This strategy exists of three key steps: identification of the determinants of healthcare practice, designing implementation interventions appropriate to the determinants, and application and assessment of implementation interventions that are tailored to the identified determinants. In order to achieve desired changes in healthcare practice in particular the healthcare for patients with established CVD or at high risk in the Netherlands [10,39]. This research focuses on the implementation of the intervention programme and the final evaluation. The results of this trial will be directly applicable to primary care settings. Should the interventions delivered at the level of the practice nurses found to be effective in improving patients' quality of life and lifestyle, then the findings would be accessible for wider application.

Trial status

Invitations are sent to the general practitioners. The first general practices are visited. The practice nurses in the intervention group and control group did received explanation about this research and what is expected from them.

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Chapter 7

Tailored implementation of cardiovascular risk management in general practice: a cluster randomised trial

Jan van Lieshout
Elke Huntink
Jan Koetsenruijter
Michel Wensing

Abstract

Background

Counselling on health-related lifestyles is key to the prevention and management of chronic diseases. After comprehensive study of determinants of its delivery in general practice and strategies to improve, we composed a tailored improvement programme, which included communication skills training, online patient information, and a clinical protocol for managing depressive symptoms. Our aim was to assess the effectiveness of this programme on professional performance and outcomes in cardiovascular patients.

Methods

A two-arm cluster randomised trial in 34 general practices involving 34 nurses was conducted. The primary outcome was an aggregated score of a positive score on lifestyle counselling delivered and an appropriate action on depressive symptoms. Secondary outcomes included the various elements of the primary outcome, vascular risk factors (extracted from patient records), and patient-reported lifestyle behaviours. Data were collected from medical records and a written survey among included patients.

Results

A sample of 1782 patients with recorded cardiovascular disease or high cardiovascular risk was available at follow-up at 6 months. No impact on the primary outcome was found; lifestyle counselling was recorded in a minority of patients (11.4 % in the intervention group and 10.3 % in the control group). An effect was found on a secondary outcome: patients' physical activity level increased (B 0.18; 95 % CI 0.02-0.35) on a seven-point scale.

Conclusions

The tailored improvement programme showed no effect on the primary outcome. This challenges the methodology of tailoring. More involvement of the targeted health care professionals might offer ways to develop more effective implementation programmes. Physical activity might be the lifestyle issue that can be more easily changed than smoking or dietary habits.

Background

Atherosclerosis-related disease is increasingly prevalent as a result of aging populations, unhealthy lifestyles, and survival of patients with potentially lethal cardiovascular diseases (CVD) after effective treatment. Clinical guidelines on cardiovascular risk management (CVRM) provide clear recommendations on risk assessment and monitoring, health-related lifestyles, and preventive medication [1]. Nevertheless, an international study in general practice, which is the setting where many of these recommendations have to be implemented, showed room for improvement of current practice [2,3].

Tailored implementation seems a promising way to improve CVRM. It is an approach in which determinants of practice are prospectively identified, followed by systematic matching of strategies to the identified factors [4]. A systematic review of 32 trials confirmed the positive impact of tailored implementation interventions, but also highlighted the uncertainty on the usefulness of different methods for tailoring [5]. As part of a large, international study of tailored implementation, the Tailored Implementation for Chronic Diseases (TICD) project, we adopted these strategies to CVRM in the Netherlands. In an interview study, primary care professionals, patients, and other stakeholders emphasized the challenges of counselling patients on health-related lifestyles, medication adherence, and self-management [6-8]. We developed and evaluated a tailored implementation programme to address these challenges, based on a comprehensive empirical analysis of determinants of delivering recommended CVRM and suggestions for interventions. The aim of the present study was to determine the effectiveness of the tailored implementation programme on professional performance and outcomes in cardiovascular prevention compared to usual care in general practice. In the Netherlands, patient education and counselling of cardiovascular patients is mainly provided by practice nurses [9], so they were the primary target of the improvement programme.

Methods

Study design

An open-label, two-arm, cluster randomised trial was conducted in the years 2013 and 2014 in the Netherlands [10]. The study was part of the international TICD project [11]. We performed block randomisation of the participating general practices, stratifying for practice size (one general practitioner versus two general practitioners or a group practice) and practice location (rural versus urban), using a computer programme that was handled by an independent researcher. The Medical Ethics Committee of Arnhem-Nijmegen waved approval for the study (file 2013/229).

Samples

A random sample of general practices in seven geographical areas in the Netherlands was invited to participate in the study, resulting in a sample of 34 practices at baseline. Figure 1 presents the flow of participants through the study. In the participating practices, two samples of patients were approached for participation in the study: patients at high cardiovascular risk and patients with established CVD. These high risk patients have an estimated 10-year risk score of 20% or higher for morbidity and mortality due to CVD. Patient selection was based on the following International Classification of Primary Care (ICPC) codes: K74-K76, K85-K92, K99.1, and T93. Patients had to be adults aged 18 or older, have a high risk of CVD (but no known CVD) or established CVD, and capable of providing informed consent. Exclusion criteria were diabetes mellitus, pregnancy and lactation, terminal illness, cognitive impairment, and poor language skills.

Implementation programme

A tailored implementation programme was developed in a systematic, stepwise process. We have reported on the various steps in this developmental process before [6-8,12]. First, prevailing clinical guidelines [13,14] and clinical audit data were analysed to define the following interrelated targets for improvement: systolic blood pressure (SBP) <140 mmHg in patients with established CVD or in patients at high risk for CVD; low-density lipoprotein (LDL) cholesterol <2.5 mmol/l in patients with established CVD or in patients at high risk for CVD; promote lifestyle changes in patients with (high risk for) CVD; create a risk profile for patients with chronic kidney disease.

Then, an interview study was done, involving physicians, nurses, and patients, which identified 139 plausibly important determinants of practice ('barriers or enablers of implementation'). Of this list, a set of 11 determinants was selected based on importance and changeability as judged by the research team and used for subsequent steps [8,12]. Subsequently, group interviews with different stakeholders and patients generated 181 suggested strategies for implementation, which were perceived to address the selected set of 11 most relevant determinants [6].

The research team discussed the large number of strategies suggested. Physicians and nurses in Dutch general practices expressed an interest in continued training of their motivational counselling skills, although research seemed to suggest little impact [15, 16]. They also expressed an interest in using online information tools for patients more actively in their patient counselling. As depressive symptoms are an important moderator of patient counselling, the recommendations suggested addressing depressive symptoms first, before focusing on health-related lifestyles or adherence to preventive drug therapy. Considering feasibility and potential impact, the research team selected the following implementation strategies for this trial: structured

feedback by professional trainers to practice nurses on their motivational interviewing skills in practice ('refresher training'); access to an online educational programme on CVRM, which was developed by the Dutch College of General Practitioners; written guidance on relevant E-health options for patients, emphasizing www.thuisarts.nl and hartenvaatgroep.nl, and a planned Twitter consultation hour for patients; and a flow chart for dealing with depressive symptoms in cardiovascular patients. The last item was an elaboration of the recommendation in the guideline on cardiovascular risk management 'to consider relevant co-morbidities'. It suggested to treat major depression before giving any lifestyle advice and to promote physical exercise rather than any other lifestyle in patients with mild depressive symptoms. A detailed description of the implementation programme has been published in the study protocol [10]. General practices in the control arm of the study provided usual care and were offered a delayed intervention after the follow-up measurements had been completed.

Measures

Two waves of measurements were done in each practice: at baseline and at follow-up six months later. Data for this paper were collected from computerised patient records in the general practices and from a written survey in a cohort of patients. Descriptive characteristics of participating practices and practice nurses were recorded with a structured questionnaire, which was completed by practice nurses.

A modified version of the validated EPA Cardio abstraction tool was applied to collect data from patient records in participating general practices [17]. We collected data on recorded patient counselling on CVD-related lifestyle and on the presence of a record of depressive symptoms in the intervention period and actions related to that record. We recorded the latest value if any of the SBP, the LDL cholesterol level, the BMI and the smoking status in the intervention period, and the latest value before the intervention period started with a retrospective time window of 1 year. Furthermore, we collected data on the presence of the following co-morbidities: asthma, COPD, and rheumatoid arthritis.

Patients received a paper-based questionnaire at inclusion and at the end of the intervention period of six months. We asked for their highest level of education as a proxy for social economic status. Furthermore, we assessed the presence of depressive symptoms using the Patient Health Questionnaire-9 (PHQ-9) [18]. Scores of 5, 10, 15, and 20 represent cut points for mild, moderate, moderately severe, and severe depression, respectively. Based on these cut points, we considered a score up to 5 as no depressive symptoms, 6 to 15 as mild depressive symptoms, and a score above 15 as severe depressive symptoms in our description of the patient sample.

Finally, we used the Rapid Assessment of Physical Activity (RAPA; 9 items) [19] to assess patient's physical activity level and the shortened Rapid Eating and Activity Assessment (REAP-S; 12 items) [20] to assess dietary habits.

Primary and secondary outcomes

In our international working group, coordinating the trials in the countries collaborating, we decided to provide a common primary outcome measure across all trials based on the performance of the health care professional targeted by the interventions. The pre-defined primary outcome referred to the professional performance of practice nurses and reflected adoption of recommendations for personalised counselling and education of CVRM patients. We created a dichotomous score for measurement in each patient, reflecting adequate or inadequate performance. We considered practice nurses' professional performance to be adequate when at least one of the following two conditions was met: (1) there is a record in the patient's record that the patient has received advice on at least one lifestyle item as specified in the prevailing guidelines of CVRM: diet, smoking, or physical exercise. Also, at least one target for improving an aspect of lifestyle is recorded. When a patient has a perfect lifestyle, then that will be recorded. (2) There is a notation in the patient's record that the patient has none, mild, or severe depressive symptoms and that the patient has been referred to E-health, a physical exercise group or depression treatment, respectively. If there was no record, we considered that there was no personalised counselling or education to the patient.

As secondary outcomes, we recorded the various elements contributing to the composite primary outcome: the health care received by each patient (counselling on lifestyle with personal goal setting, referral to a physical exercise group, referral for depression treatment). Furthermore, as secondary outcomes, we documented blood pressure (SBD <140), cholesterol levels (LDL <2, 5), body mass index (BMI <25), smoking status (yes/no), food intake (REAPS, range 1-3), and physical exercise (RAPA, range 1-7).

Statistical power

The study was powered to detect a 15% difference on the primary outcome. For sample size calculation, we used a web-based programme [21], and based on previous research, we assumed an intra-cluster correlation coefficient (ICC) of 0.05 [22,23], alpha of 0.05, and a power of 0.80. The calculation indicated that 450 patients per group (high risk or established CVD) would be needed (15 patients at high risk for CVD and 15 patients with established CVD per cluster, sampled in 30 practices). Assuming high risk patients often only visit the practice once a year and that half of the CVD patients receive specialist care, we doubled the numbers of patients for inclusion. Furthermore, to allow for loss to follow-up, we enlarged the inclusion with another 30%.

Data analysis

Data were analysed using SPSS (version 20, IBM Corp.) and MLWIN (version 2.28). For all primary statistical tests, two-sided hypothesis testing with an alpha level of 0.05 was applied. All data analyses were based on “intention to treat”. For assessing effects on the outcomes, the intervention and control group were compared regarding each of the primary and secondary outcomes. In the study protocol, we planned to perform a chi-square test to assess the primary outcome. However, we reconsidered this in favour of a multilevel regression analysis to meet the highest analytical standards. The primary outcome was based on measurements at follow-up only and therefore a two-level model was used (patients nested in practices). We entered group allocation (intervention/control) at practice level and controlled for the following patient characteristics: age, sex, education (low, medium, high), depressive symptoms (none, mild, severe), and co-morbidities (presence of asthma, COPD, and/or rheumatoid arthritis). To test for differences between the high risk and CVD patients, we entered an interaction term with group allocation (control/intervention) and patient group (high risk/CVD). For the secondary outcomes with baseline and follow-up measures, we used a three-level multilevel regression model with measurements nested in patients, and patients were nested in practices. Therefore, we constructed the data in a long format and by including an extra level, we controlled for differences in individual patients at baseline. We had planned to assess the cardiovascular risk score in the high-risk patient group and changes in these scores, but we had to refrain from these analyses as not feasible.

Results

We invited 1600 practices to participate in our programme; initially, 48 responded that they wanted to participate. Before group allocation and an introductory practice visit, 4 practices withdrew, and after the initial practice visit, another 10 practices withdrew, 5 from both the intervention and the control group. So, 34 practices entered the study and included patients (Figure 1). Two practices in the intervention arm had two practice nurses, all participating and being instructed; in both the intervention arm and the control arm, one practice nurse worked in two practices. No practices were lost to follow-up. One practice nurse dropped out at the end of the intervention period due to the fact that she started to work in another practice but even from that practice, we were able to retrieve data at the end of the intervention period.

In total 2229 patients (41.8% of those invited) gave informed consent for the study in the baseline patient questionnaire. In all groups (intervention and control, high risk, and established CVD), men were about twice as numerous as women. The high risk group patients were about 75 years old, and the CVD patients just under 70. In total, 75% of the patients had no depression, about 23% had mild depressive symptoms and 2% had a severe depression, based on the PHQ-9 questionnaire at baseline. Tables 1 and 2,

respectively, display some practice characteristics and patient characteristics at baseline.

Figure 1. Flow chart of the study

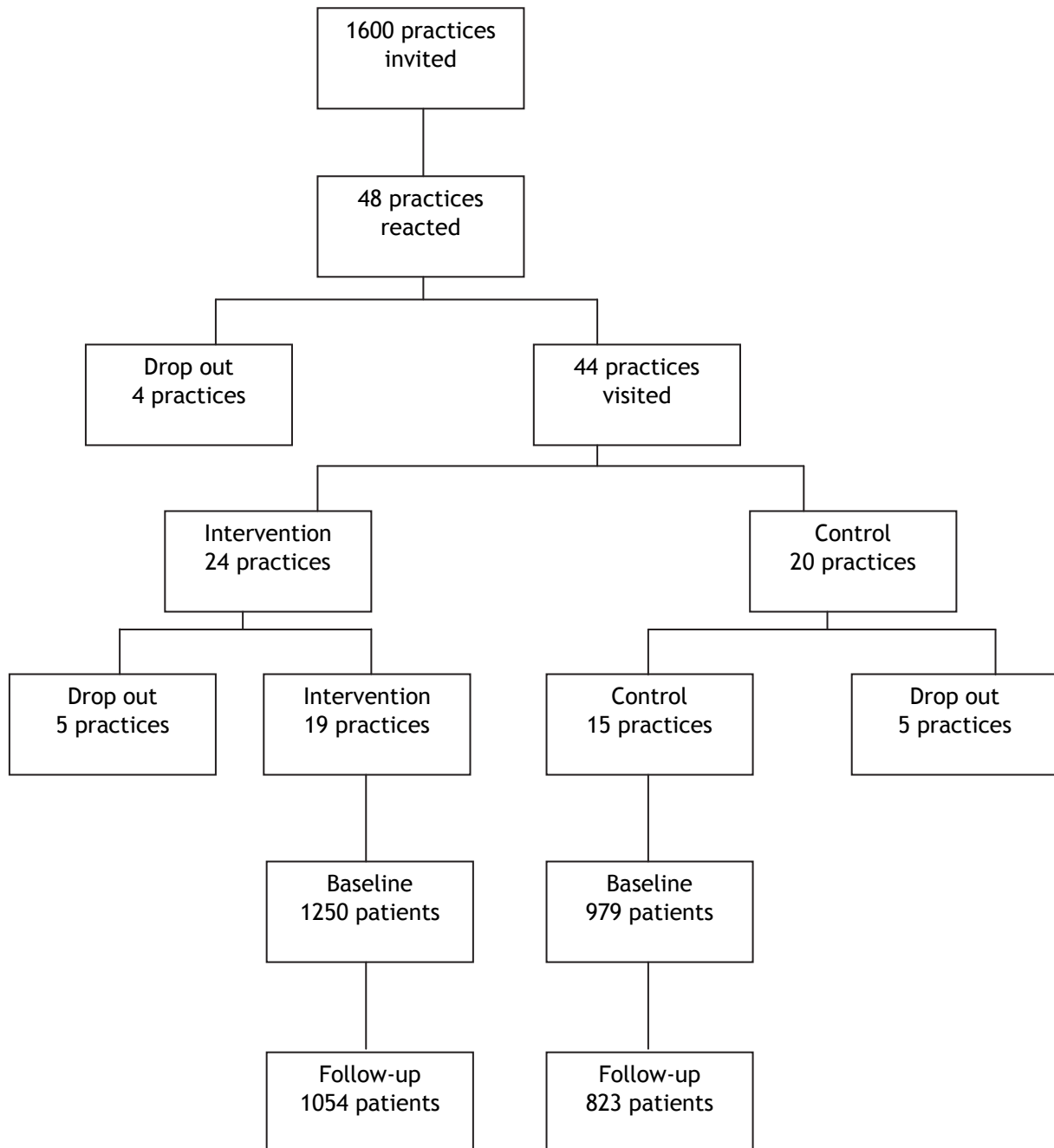


Table 1. Practice and practice nurse characteristics

	Intervention group (n=19)	Control group (n=15)
	19 practices with 20 practice nurses	15 practices with 14 practice nurses
Practice characteristics		
Single-handed practice	10	9
Duo/ Group practice	9	6
Rural area	10	6
Urban area	9	9
Practice nurse characteristics		
Mean age in years	42	43
Mean number of years experience as practice nurse	12	11
Mean number of hours previous training of motivational interviewing skills	14.7	14.8

Table 2. Description of patient sample at baseline

	Intervention group (n=1250)			Control group (n=979)		
	Total	Patients with high cardio-vascular risk	Patients with cardio-vascular disease	Total	Patients with high cardio-vascular risk	Patients with cardio-vascular disease
Women (%)	35.1	32.1	38.4	34.9	31.7	38.5
Mean age (SD)	72.6 (9.7)	75.1 (6.4)	69.6 (11.8)	71.6 (9.7)	74.0 (6.5)	68.9 (11.7)
Education low (%)	39.8	38.3	41.6	43.0	42.0	44.0
Education medium (%)	31.7	30.7	32.8	32.1	30.0	34.5
Education high (%)	28.5	31.0	25.6	24.9	28.0	21.5
Hypertension (%)	59.9	67.7	51.1	59.2	65.6	52.0
Hypercholesterolemia (%)	18.4	16.6	20.4	20.2	16.1	24.8
BMI>25 (%)	30.2	29.4	31.3	30.6	29.3	32.4
Recorded smokers (%)	10.4	7.2	13.8	10.5	8.9	12.2
Other chronic disease (%)	14.8	12.9	16.9	14.5	13.0	16.0
No depression (%)	74.4	79.2	68.8	75.6	85.4	64.9
Mild depression (%)	23.6	19.1	28.7	22.7	13.6	32.7
Severe depression (%)	2.0	1.7	2.5	1.7	1.0	2.4

Primary outcome

We found no effect of our intervention on the primary outcome of this study (see Table 3). A record proving adequate practice nurse performance was present in 11.4% of the patients in the intervention practices and in 10.3% of the patients in the control group. There was in only six patients a record of depressive symptoms. The element of this composed primary outcome measure related to physical exercise advice was more often recorded in the intervention group (6.8 versus 3.7%), though in multilevel regression analysis, this proved to be non-significant. The other components, too, showed no differences.

Table 3. Primary outcomes: medical audit data on patient counselling

	Intervention arm (n=995 patients) % (n)	Control arm (n=787 patients) % (n)	OR (95% CI)
Number of patients who received recommended counselling (=primary outcome measure)	12.1 (120)	10.9 (86)	1.11 (0.57 - 2.16)
-In subgroup of patients with high cardiovascular risk	12.5 (66)	12.2 (48)	1.04 (0.45 - 2.40)
-In subgroup of patients with cardiovascular disease	11.6 (54)	9.6 (38)	1.23 (0.66 - 2.29)
Recorded physical exercise advice/goal	6.8 (68)	3.7 (29)	1.85 (0.68 - 5.04)
Recorded stop-smoking advice	1.4 (14)	1.5 (12)	1.07 (0.43 - 2.64)
Recorded diet advice	7.9 (78)	7.8 (61)	0.95 (0.39 - 2.31)
Recorded weight loss advice	1.5 (15)	1.7 (13)	0.91 (0.35 - 2.34)
Recorded goal for lifestyle change in patients with no record of depressive (99.6%)	12.0 (119)	10.8 (85)	1.10 (0.56 - 2.15)
Recorded physical exercise advice or referral in mild depressed patients (relates to 6 patients)	0.1 (1)	0.0 (0)	NA
Recorded depression treatment or referral in severe depressed patients (relates to 1 patient)	-	0.1 (1)	NA

Secondary outcomes

Regarding secondary outcomes, we found that physical exercise showed a significant improvement in the intervention group compared to the control group (see Table 4). The RAPA score improved on a scale from 1 to 7 from 4.8 to 4.9; in the control group, the activity diminished reflected in a score diminishing from 4.9 to 4.8 (effect size $B = 0.18$ (0.02-0.35), $p < 0.05$). On the other cardiovascular risk factors assessed (SBP, LDL cholesterol, smoking status, BMI, and diet), the improvement programme had no significant effect. We found no difference in the effect of the intervention between the high cardiovascular risk group and the group with established CVD. However, CVD patients had their LDL cholesterol and SBP level more often on target (OR 3.8, 95% CI 2.9-5.1 and OR 1.5, 95% CI 1.2-1.8, respectively).

Table 4. Secondary outcomes: risk factors (medical audit data & patient questionnaires)

	Intervention arm		Control arm		B/OR (95% CI)
	Baseline	Follow-up	Baseline	Follow-up	
Physical exercise (RAPA, 1-7)	4.8 (1.60)	4.9 (1.52)	4.9 (1.59)	4.8 (1.53)	B: 0.18* (0.02 - 0.35)
Diet (REAP-S, 1-3)	2.2 (0.38)	2.3 (0.37)	2.2 (0.38)	2.2 (0.37)	B: 0.03 (0.00 - 0.07)
Smoking (%)	10.3	10.4	12.5	10.5	OR: 1.11 (0.68 - 1.82)
BMI <25 (%)	29.5	30.2	26.3	30.6	OR: 0.84 (0.48 - 1.46)
LDL <2.5 (%)	30.5	32.3	26.6	31.2	OR: 0.85 (0.53 - 1.38)
SBP <140 (%)	57.6	56.9	57.9	57.1	OR: 1.03 (0.72 - 1.48)

* $p < 0.05$

B=regression coefficient, OR=odds ratio

Discussion

The tailored implementation programme had no overall effect on counselling of cardiovascular patients (the primary outcome of the trial). However, we found an effect on one secondary outcome: patients' physical activity level increased. The latter finding may suggest that the messages on physical exercise, as recommended for patients with mild depressive symptoms, were picked up by practice nurses and applied in daily practice. Nevertheless, overall, we conclude that the tailored implementation programme was not effective.

There are several alternative explanations for the lack of effects. In process evaluations, we will report on the outcomes of interviews and questionnaires with practice nurses and a sample of patients, and on scoring of knowledge and motivational interviewing skills [10,24]. In general, we can hypothesize that failure of effectiveness might be due to lack of relevance of determinants or strategies, wrong prioritizing, or inadequate intervention delivery. First, identified determinants of practice may be less relevant than perceived by stakeholders or proposed interventions may be less helpful than expected. For instance, studies in general practice seemed to suggest little effect of motivational interviewing (MI) skills training [15,16]. In the developmental phase of our study, we held focus group discussions with various stakeholders [7,8] and interviewed them about suggestions for interventions to address previous identified determinants of practice. All stakeholder groups suggested motivational interviewing training and participating primary care providers appreciated such training. Koelewijn et al. in the IMPALA study offered an improvement programme providing MI training to practice nurses [15]. Patients included were at high cardiovascular risk without established CVD. They could not prove the programme to be effective. Jansink developed and tested a programme including MI courses for diabetic nurses [16]. This programme, too, showed no improvement in their main outcomes. These findings challenge the use of interviews and surveys with stakeholders in tailored implementation as well as the usefulness of motivational interviewing in the targeted patient populations.

Second, numbers of both determinants of practice and suggestions for improvement were high, so it is possible that in our tailoring procedures, we did not prioritise the right determinants in terms of importance and changeability or the right interventions considering feasibility and impact. For instance, we might have better focused on practice nurses' views on effective interventions, as they were the primary receivers of the tailored implementation programme. Involvement of practice nurses in selecting strategies in the development of the multifaceted programme might have been another method to assure adequate choices in this phase.

Third, we may have chosen interventions adequately, but not delivered them in the required intensity. For instance, a short training session with feedback on two patient contacts may have been insufficient to effectively improve counselling skills. Some of

the information technology tools were innovative, so it may be too early to implement these effectively or more time might be needed. Finally, the presence of a practice nurse with some education in counselling techniques was an inclusion criterion for practices as we intended to provide a refresher course instead of a complete course. So, the practice nurses in the control group were somehow skilled thus reducing the potential for improvement by the tailored programme.

Another explanation of the poor results may relate to the level of tailoring. In our international project, we had clearly defined and separate steps in the developmental phase of the intervention programme. For that reason, we collected information on determinants of practice and suggestions in groups of stakeholders. These groups comprised health care professionals finally targeted but not those from the practices that participated in our trial. In another setting, the tailoring could be on a higher level, i.e., on the level of the practices or health care professionals participating with adjustments. Then, we would have researched the determinants within the practices participating and searched for strategies specifically suitable and tailored per practice. In the process evaluation, we will report on the practice nurses' opinion on the determinants addressed and the interventions offered [21].

We found an overall low score on practice nurse performance in our primary outcome as measured by the results of the chart audit. The maximum feasible score for this outcome is unknown but definitely not 100%. In general, the high risk patients pay a CVRM-related visit to the practice only once a year and a proportion of the patients with established CVD is treated in secondary care. Nevertheless, considering the fact that a large group of about half of the patients did not visit the practice for CVRM in the intervention period and was not exposed to the intervention, the low scores still suggest room for improvement. Poor documentation may add to the low score on the primary outcome. In the introduction and instruction of the project, we emphasised the importance of good registration. The relevance of making record notes in the explanation of the trial results will be part of the process evaluation.

The positive effect on one of our secondary outcome measures relates to physical activity. We advised to refer patients with mild depressive symptoms to physical activities as these are beneficial for both the cardiovascular risk profile and depressive symptoms. As such, in our programme delivery, we had extra attention for physical exercise, more than for other lifestyle issues. Without a record of depressive symptoms, more patients had a record of advice on physical activity with a personal goal. Apparently, this lifestyle issue gained more attention in the intervention group. Recording advice, a process indicator, improved non-significant. The related patient outcome "physical activity" improved significantly which makes it more plausible that this effect is not related to chance.

The study was designed to enhance internal validity as well as reflect routine clinical practice, but it also had a number of limitations. Interviews with stakeholders were

used to identify determinants of practice and suggestions for interventions, but it is difficult to assess the validity of this method. Stakeholder involvement in the design of interventions may in fact have served a different purpose, which is enhanced acceptability of the programme for the targeted health care providers.

The generalisability of findings may be limited by the low recruitment rate, although it seems unlikely that more effects would have been achieved in nonparticipants.

Surveys were planned at baseline and six months later, but this was only partly achieved. Due to practical constraints, patients' questionnaires were sent out up to two months later. Note however that most outcomes, including the primary outcome, were based on chart audits taking into account the start date of the intervention period. As the study was a pragmatic trial, we cannot rule out the possibility that external influences have had impact on the outcomes. In the field of cardiovascular primary care, changes in the reimbursement and quality management may have impacted on practices in both intervention and control arms of the study diluting possible effects of our programme.

Conclusions

For tailoring an intervention, we recommend including a systematic method for assessment and prioritisation of determinants of practice and suggested implementation interventions. The programme may benefit from more attention for the targeted group, the practice nurses in our programme. On the basis of the findings of this trial, we cannot recommend broad implementation of the tested improvement programme. In a process evaluation of the trial, we will explore the impact of interventions on the addressed determinants of practice [10]. This will provide further insight into the validity of the interview methods, which were used in the development of the implementation programme. Our process evaluation and future research may elucidate whether attention on physical activity could be a key target for future programmes to improve cardiovascular prevention. Future studies should explore alternative methods for tailored implementation, such as theory-orientated approaches or different stakeholder involvement methods.

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Chapter 8

Practice nurses' counselling skills related to Patient Assessment of Chronic Illness Care score (PACIC) and Patient Activation Measure (PAM)

Elke Huntink
Jan Koetsenruijter
Michel Wensing
Jan van Lieshout

Submitted.

Abstract

Background

To enhance cardiovascular risk management (CVRM) and patients' self-management, a tailored programme to improve practice nurses' counselling skills was tested in a randomised trial. The study aims were: (1) To examine the effect of the tailored intervention programme on the Patient Assessment of Chronic Illness Care (PACIC) and Patient Activation Measure (PAM), and (2) To explore the impact of practice nurses' counselling skills at baseline on patient assessment of chronic illness care and patient activation at follow-up.

Methods

A two-arm cluster randomised trial was conducted in 34 general practices in the Netherlands. Data of 2184 patients with established CVD or at high cardiovascular risk were gathered at inclusion and at six months follow-up by a composite questionnaire, which included PACIC and PAM. Counselling skills of practice nurses were abstracted from audio taped consultations, which were coded according to the Motivational Interviewing Treatment Integrity (MITI). Multilevel regression analysis was applied, controlling for patient characteristics.

Results

Patient experiences of chronic illness care were increased, while their active disease management deteriorated over time. At follow-up, patients in the intervention group experienced less chronic illness care and were less activated in disease management than patients in the control group. The most important predictors were patient age, gender and education level. The PACIC and PAM scores deteriorated for patients with advancing age, female patients, and patients with lower education, except that patients with lower education had a higher PACIC score. Counselling skills of practice nurses at baseline were not associated with PACIC or PAM scores at follow-up, also after controlling for baseline scores.

Conclusions

The tailored intervention programme did not have an effect on patient experiences with chronic illness care and disease management. Patients' experiences of chronic illness care and their activation in disease management were not associated with motivational counselling skills of practice nurses.

Introduction

Prevention of cardiovascular diseases (CVD) remains high on the agenda in healthcare systems. For over a decade, general practitioners in the Netherlands have delegated preventive activities for patients with established CVD or at high cardiovascular risk to practice nurses [1,2]. These activities include monitoring of cardiovascular risk factors and counselling on lifestyle and medication adherence [3]. The clinical practice guideline cardiovascular risk management (CVRM) [4], and the 'care standard', which describes the organisation of cardiovascular risk management, provide support in performing these tasks [5]. 'Lifestyle counselling and encouraging patients' self-management constitute important elements in prevention [6], yet these are difficult for practice nurses to perform well [7]. More than half of the patients with a chronic condition are not able to take an active role in their own healthcare [8]. Also, care delivered by practice nurses is suboptimal; their counselling skills, for instance, could certainly be enhanced [9]. To enhance CVRM care a tailored intervention programme was developed, aimed at practice nurses' counselling skills [10]. Practice nurses received feedback training on motivational interviewing skills; motivational interviewing is considered a promising counselling technique to enhance patients' self-management of health and disease [11]. However, evaluation of this programme in a randomised trial [12] and a process evaluation [13] showed hardly any improvement in patient cardiovascular risk factors and practice nurses' counselling skills.

In this study we explored whether the intervention programme had any impact on patients' perception of the quality of healthcare counselling by practice nurses and subsequently their self-management. The assumption is that patient perceptions of care influence CVRM outcomes, so it is possible that the tailored intervention programme had an impact on these patient perceptions, but not (yet) on CRVM outcomes. Furthermore, we wondered whether there was any relationship between practice nurses' counselling skills and patient perceptions of care at all. Although counselling skills had been identified as key determinants in achieving optimal outcomes in CVRM [14], it may be possible that the impact was less obvious than was assumed. This would imply that other determinants of CVRM outcomes need to be prioritised. Alternatively, intensified or a different type of training of practice nurses' counselling is required, if the link between practice nurses' counselling skills and patient perceptions of care is to be confirmed. The central aims of this study were: (1) To examine the effect of the tailored intervention programme on the Patient Assessment of Chronic Illness Care (PACIC) and Patient Activation Measure (PAM), and (2) To explore the impact of practice nurses' counselling skills at baseline on patient assessment of chronic illness care and patient activation at follow-up.

Materials and Methods

Study design

This study was based on data from the European Tailored Implementation for Chronic Diseases (TICD) project [15]. In the Netherlands the focus of the TICD project was on patients with established CVD or at high cardiovascular risk. A cluster randomised trial was performed in 2013-2014, whereby a tailored intervention programme was introduced to practice nurses in general practices. Data were collected between April and September 2014. A detailed description of the design and methods has been reported elsewhere [10]. The ethical committee of Arnhem and Nijmegen has granted ethical approval (2013/229).

Participants

Eligibility criteria for practice nurses were: treating CVRM patients and has had motivational interviewing training during their vocational training or as part of their continued education. A total of 44 practice nurses filled out the informed consent form. Per practice up to 75 patients with established CVD and up to 100 patients at high cardiovascular risk were invited to participate. Patients were selected by using International Classification of Primary Care (ICPC) codes K74-76, K85-K92, K99.1 and T93; sometimes two codes or more were needed in order to determine high cardiovascular risk, depending on age, gender and smoking status. Patients at high cardiovascular risk have an estimated 10-year risk score of 20% or higher for morbidity and mortality due to CVD [5]. Eligible patients were aged 18 or older and were able to fill out an informed consent form. Patients were excluded if they had a terminal illness, pregnancy or lactation, cognitive impairment and/or poor language skills. In order to measure CVRM only, healthcare patients with diabetes mellitus were excluded, because otherwise the quality of diabetes care would be measured instead. Here, we will focus on CVRM care.

Data collection

Data were collected at baseline and at follow-up, which was planned for six months but due to practical constraints became four up to nine months. Participating patients completed a composite mailed questionnaire at baseline and at follow-up. This questionnaire included the Patient Assessment of Chronic Illness Care (PACIC) questionnaire to assess patients' experiences of chronic healthcare [16-18], the Patient Activation Measure (PAM) questionnaire which measures patients' self-management [19,20], and patient characteristics questions. We asked patients to only fill out the second PACIC questionnaire at follow up if they had visited the general practice during the intervention period. Counselling skills of practice nurses were documented by a verbatim transcribed audio tape of a conversation between practice nurses and patients at baseline. One of the two professional trainers who were connected to

MINTned (Dutch association of trainers in motivational interviewing) scored the transcriptions using the Motivational Interviewing Treatment Integrity (MITI) [21]. The MITI is a behavioural coding system which assesses motivational interviewing skills.

Data measures

The PACIC contains 20 items and each item could be scored on a 5-point-Likert scale, which ranges from 1 = 'almost never' up to 5 = 'almost always'. Higher scores indicated that patients perceived more quality of chronic healthcare. The PAM questionnaire consists of 13 items. Four answer categories per item, ranging from 'strongly disagree' to 'strongly agree', while a fifth response option 'non applicable' was also given. The items were focused on confidence, beliefs, knowledge and skills. Higher scores indicated better self-management skills of patients. The following descriptive characteristics were also used from the composite questionnaire: gender, age, having established CVD or high cardiovascular risk, and education level.

The MITI score consists of a global score, which comprises five categories: elicit, collaboration, autonomy, direction given, and empathy. Each item could be scored between one and five (low to high).

Data-analysis

Data were analysed using SPSS (version 20, IBM Corp.). The patients' responses to PACIC items were aggregated and divided by the total of the questions answered. Patients with missing scores on one third or more in total were not included for analysis. Any missing values were filled up with the overall mean score of the total answered questions for patients who filled out two thirds or more of the questionnaire. For the PAM questionnaire the raw scores ranged from 13-52, which were converted to 'activation scores' ranging from 1-100. Patients had to answer at least up to nine questions, whereby the missing values were filled up with the overall mean score of the total answered questions. Participants with more than 30% missing values in the PAM were excluded from further analyses.

First, differences between the mean PACIC and PAM scores for baseline and follow-up were documented as descriptive frequencies. To compare the intervention group with the control group and patients with established CVD or at high cardiovascular risk on the difference of the PACIC and PAM scores, a multilevel regression analysis was performed with measurements (pre-post) nested in patients, to test the effect of the intervention programme. An interaction term was added on group allocation (intervention vs. control) and time of measurement (pre-post), controlling for patients' characteristics: age, education level, gender and established CVD vs. at high cardiovascular risk. An additional analysis was done to test whether the effect of the intervention programme was different between patients with established CVD and

patients at high cardiovascular risk; controlling for age, education level and gender. A significant difference was set at $p < 0.05$ and all p -values were 2-sided.

The MITI global score is the sum of the five categories and divided by five; following the MITI it is considered desirable that the global score is above 3.5 [21]. The MITI scores were used as a predictor in the regression analysis with PAM as outcome. A multilevel regression analysis was performed with measurements nested in patients and patients nested in general practices. The association of patient experiences with chronic illness care and disease management with the independent variable, the MITI score, was tested by adding the following variables: age, gender, established CVD or high cardiovascular risk, with either the dependent variables PACIC and PAM scores at follow-up correcting for the PACIC and PAM scores at baseline. We reported estimates by means of Restricted Maximum Likelihood, as well as the standard deviation and if there was a significant difference.

Results

A total of 44 general practices applied for the tailored intervention programme, of which 34 actually started with it, see Figure 1. Of these general practices 19 had been randomly allocated to the intervention group (20 practice nurses; two general practices with two practice nurses each and one practice nurse who worked in two general practices), while 15 general practices had been allocated to the control group (14 practice nurses; one practice nurse who worked in two general practices), see Table 1. All practice nurses handed in the requested audio tape.

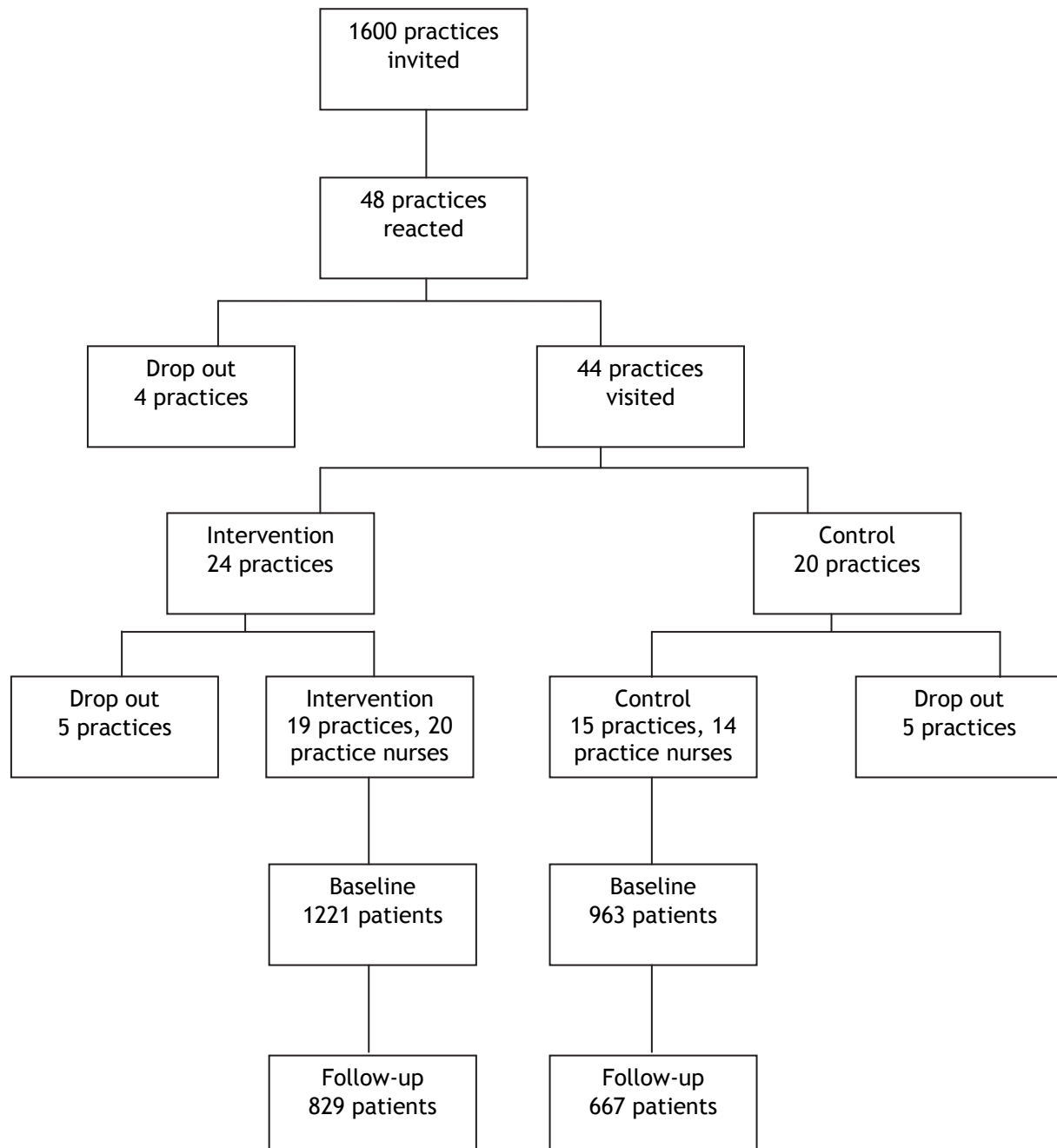
Table 1. General practice, practice nurse and patient characteristics at baseline

	Intervention group	Control group
Practice characteristics	N=19	N=15
Single Solo practice	N=10 (52.6%)	N=9 (60%)
Duo/ Group practice	N=9 (47.3%)	N=6 (40%)
Rural area	N=10(52.6%)	N=6 (40%)
Urban area	N=9 (47.3%)	N=9 (60%)
Mean number of patients visiting the general practice per week (SD)	185.31 (91.56)	141.00 (48.34)
Mean FTE practice nurses (SD)	0.71 (0.35)	0.65 (0.32)
Practice nurse characteristics	N= 20	N= 14
Sex % female	90	100
Mean age in years	42	43
Mean number of years' experience as a practice nurse	12	11
Mean number of hours previous training of motivational interviewing skills	14.7	14.8
Patient characteristics	N=1221	N=963
Sex % female	35.1	34.6
Mean age in years (SD)	72.6 (9.2)	71.6 (9.7)
Patient with established CVD	N=519	N=413
Patients at high risk	N=702	N=550

FTE = full timer equivalent; CVD= cardiovascular disease

We gathered the results of a total of 2184 patients, of whom 1221 patients in the intervention group and 963 patients in the control group at baseline. Two-thirds of these two groups consisted of men. The mean age of patients in the intervention group was 72.7 years and for patients in the control group 71.5 years.

Figure 1. Flowchart of the study



Effect of the intervention programme on PACIC and PAM scores

Patients in the intervention group had a mean PACIC score of 1.86 at baseline and 1.94 at follow-up compared with a mean score of 2.07 for patients in the control group at baseline and 2.09 at follow up, whereby the patients in the intervention group did not show more improvement compared to patients in the control group. Patients in the intervention group had a significant lower score at follow-up than patients in the control group ($p=0.02$) controlled for age, gender, education level, and having established CVD or high cardiovascular risk and baseline scores, see Table 2. There was a non-significant deterioration over time of the PACIC score for patients with established CVD, while no difference was found for patients at high risk at follow-up.

Patients in the intervention group had a mean PAM score of 69.02 at baseline and 67.88 at follow-up compared with a mean score of 70.51 for patients in the control group at baseline and 70.29 at follow up. Patients in the intervention group also had a significant lower PAM score at follow-up than patients in the control group ($p=0.03$), controlled for age, gender, education level, having established CVD or high cardiovascular risk and baseline scores, see Table 2. The PAM scores did not differ between patient groups (established CVD or at high cardiovascular risk).

The most important predictors for the PACIC and PAM scores were age, gender and education level. These were also the variables we controlled for, see Table 2. Both PACIC and PAM scores decreased with the advancing age of patients. For both PACIC and PAM, female patients had lower scores. Patients with low education had a higher PACIC score and a lower PAM score compared to patients with a higher education level.

Table 2. Results of the PACIC and PAM scores at follow-up

	PACIC			PAM		
	intervention + control (SD)	patients with CVD (SD)	patients at high risk (SD)	intervention + control (SD)	patients with CVD (SD)	patients at high risk (SD)
Intercept	2.74 (0.2)**	2.55 (0.2)**	3.29 (0.3)**	81.69 (2.8)**	80.40 (3.17)**	84.76 (4.8)**
Intervention*Time measurement	- 0.01 (0.1)	-0.03 (0.1)	0.00 (0.1)	- 0.24 (0.9)	1.08 (1.3)	-1.32 (1.3)
Established CVD (High cardiovascular risk ref)	0.04 (0.0)			-0.06 (0.7)		
Intervention group (control group ref)	-0.11 (0.0)*	-0.08 (0.1)	-0.11 (0.1)	-1.59 (0.7)*	-1.97 (1.1)	-1.24 (1.0)
Time measurement	-0.01 (0.0)	-0.07 (0.1)	0.03 (0.1)	0.14 (0.7)	-0.46 (1.0)	-0.1 (1.0)
Mean age in years	-0.01 (0.0)**	-0.01 (0.0)	-0.02 (0.0)**	-0.10 (0.0)**	-2.67 (1.0)	-0.15 (0.1) *
Gender (Male ref)	- 0.03 (0.0)	-0.12 (0.1)**	0.07 (0.1)	-2.38 (0.7)**	-0.8 (0.0)	-2.06 (1.0)*
Education level (high level ref)	Education low	0.17 (0.1)**	0.24 (0.1)**	-5.14 (0.8)**	-6.02 (1.3)**	-4.56 (1.1)**
	Education medium	0.10 (0.1)	0.16 (0.1)	-2.80 (0.9)**	-2.87 (1.3)*	-2.98 (1.2)*

* $p<0.05$; ** $p<0.01$; Ref = reference

Practice nurses' counselling skills related to PACIC and PAM scores

The mean global score of the MITI (counselling skills) for practice nurses in the intervention group was 2.1 and for the control group 2.3. MITI scores did not predict for PACIC and PAM, see Table 3. Even after controlling for PACIC and PAM scores at baseline, the MITI was not associated with the PAM score.

Table 3. Prediction of MITI scores for PACIC and PAM scores

	PACIC results at follow-up (n=634) (SD)	PAM results at follow-up (n=1339) (SD)	PAM results at follow-up (n=600) (SD)
Intercept	0.86 (0.3) *	46.55 (5.1)**	44.89 (7.7)**
MITI at baseline	-0.04 (0.1)	-0.02 (0.7)	0.30 (0.9)
Established CVD (High cardiovascular risk ref)	-0.11 (0.1)	1.33 (1.0)	1.64 (1.4)
Intervention group (control group ref)	-0.08 (0.1)	-1.55 (1.0)	-1.49 (1.3)
Mean age in years	0.0 (0.0)	-0.11 (0.1)*	-0.15 (0.1)
Gender (Male ref)	-0.10 (0.1)	-1.14 (1.0)	-0.14 (1.4)
Education level (high education ref)			
Education low	0.18 (0.1)*	-3.77 (1.2)**	-0.81 (1.7)
Education medium	0.23 (0.1)**	-2.71 (1.2)*	-0.70 (1.8)
PACIC baseline	0.65 (0.0)**		1.07 (0.8)
PAM baseline		0.48 (0.0)**	0.48 (0.0)**

*p<0.05; **p<0.01; Ref = reference

Discussion

Patient experiences of chronic illness care were increased, while their active disease management deteriorated over time. Patients in the control group experienced both their chronic illness care and their disease management as better compared to patients in the intervention group at follow-up. The global score of the MITI at baseline was not associated with the PACIC or the PAM score at follow-up, also after controlling for the PACIC and PAM score at baseline. This implies that patient experiences in chronic illness care and active disease management were not influenced by practice nurses' counselling skills.

Patients' experiences in chronic care at baseline and follow-up were lower than those found in previous studies among patients with established CVD or at high cardiovascular risk [22,23] and patients with other chronic conditions [24]. It is possible that the patient perception measures PACIC and PAM lack responsiveness to variation in counselling skills in this suboptimal domain. Overall, patients experienced chronic healthcare as insufficient; in previous research, patients also assessed chronic healthcare as poor [25]. Lower educated patients were more positive about chronic healthcare according to their higher PACIC scores, compared to the lower PACIC scores of higher educated patients. Previous studies showed that female patients experienced chronic care as insufficient compared to male patients [25,26], which was also seen in

our study, while another study showed that female patients scored better on chronic care [26]. Patients' experiences of chronic care deteriorated along with their advancing age [26,27], which corresponds with our study. Patients did not only receive care from practice nurses, but also from general practitioners, physical therapists, or specialised nurses [28]; for that reason it is not clear which healthcare professional patients had in mind when they filled out the composite questionnaire. Moreover, the questionnaire itself is not clear on that either. The number of patients who filled out the PACIC questionnaire was less compared to the PAM questionnaire. This could be due to the fact that some patients did not visit the general practice during the intervention period.

In the past few years Dutch healthcare policies and healthcare professionals emphasised the importance of patients' self-management towards their health and lifestyle [29]. A previous study reported that healthcare professionals who were more in favour of supporting patient's self-management were more likely to achieve a cooperative bond with the patient than less supportive healthcare professionals [30]. Patients were approached in several ways, for instance through websites and public media campaigns, and this approach seemed to be paying off. Patients with better active disease management visit the general practitioner less often and are less often hospitalised. This could be a good means to keep healthcare affordable in the future [1]. Healthcare professionals consider patients' self-management as an important issue and self-management support is therefore more integrated in the care they provide. More attention is needed for patients who have to integrate their disease into their daily life physically, emotionally and socially, and who have to learn to deal with their healthcare professionals [31].

The counselling scores of the practice nurses were lower than 3.5 (one practice nurse in the control group had a score of 4.0 at the start, another practice nurse in the intervention group achieved a global score of 3.6 at follow-up), showing an overall suboptimal counselling performance. However, practice nurses did show better counselling skills when treatment was initiated by patients themselves [32], while self-management of patients increased when practice nurses applied recommended counselling approaches [33]. Previous research showed that an increase of patients' perceptions of their self-management led to a more positive experience of chronic healthcare [34], which could ultimately lead to enhancing cardiovascular risk factors [35]. Our study did not confirm this hypothesised causal chain, though.

A productive relationship between patients with a chronic condition and their healthcare professionals is related to high quality of care, as measured by patient experiences in chronic illness care [30]. Also, better performance of healthcare

professionals in supporting primary care patients' behaviour change could influence the latter's active disease management in a positive way [36,37], whereby healthcare professionals would have to assess their own performance [37]. A good relationship of patients with healthcare professionals seems to pay off regarding patients' experienced healthcare, especially when healthcare professionals support patients in lifestyle advice. The performance of healthcare professionals, such as the use of motivational interviewing, was not measured in this case.

For the research for this article we focused on the patients; practice nurses' perception of their own counselling skills and their opinion of patients' self-management skills have been measured in previous research. Furthermore, it is not clear which healthcare professional exactly was assessed when patients filled out the PACIC questionnaire; it is also not clear what exactly patients were dissatisfied about. This is partly due to the fact that we only used total PACIC scores. More research is therefore needed on what exactly could be enhanced in the future and by which healthcare professional. Although self-management skills of patients were indeed enhanced during the years, a new instrument was recently developed (Self-Management Screening (SeMaS)), which assists healthcare professionals in general practices to personalise their self-management support [34]. In general, more research is needed; qualitative research targeted at both practice nurses and patients could determine how healthcare counselling and self-management are related with each other and how this could influence cardiovascular risk factors.

Strengths and limitations

The PACIC and PAM questionnaires are both validated questionnaires. With both questionnaires we did not use the subscales: as a consequence, we did not check for specific themes in chronic healthcare perception and patients' self-management. Due to the total length of our composite questionnaire for patients, we did not use the PACIC-5A questionnaire (the original questionnaire with 20 items and 6 additional items reflecting on behavioural counselling recommended by the U.S. Preventative Services Taskforce). These additional questions are a means to measure more precisely the experiences of patients, especially about practice nurses' counselling skills. This would have provided additional information from the patients' perspective. However, our research was focused on patients at high cardiovascular risk, meaning that our findings cannot be generalised to patients at moderate or low cardiovascular risk.

Conclusion

This study showed that experiences of chronic illness care enhanced over time for patients in the intervention group and in the control group, while their experiences of self-management deteriorated over time, although there were no significant

differences. After controlling for patients' characteristics, patients in the control group scored their experiences of chronic illness care and active disease management as higher compared to patients in the intervention group. The tailored intervention programme did not have an effect on patient experiences with chronic illness care and disease management. This study showed that practice nurses' counselling skills were not associated with patient experiences of chronic illness care and active disease management. Due to the low scores of practice nurses' counselling skills, it should be seriously considered whether motivational interviewing is suitable for patients with established CVD or at high cardiovascular risk. Practice nurses should continue to educate patients, while focusing less on the guidance of patients.

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Chapter 9

Process evaluation of a Tailored Intervention programme of Cardiovascular Risk Management in General Practices

Elke Huntink
Michel Wensing
Ilse Timmers
Jan van Lieshout

Abstract

Background

A tailored implementation programme to improve cardiovascular risk management (CVRM) in general practice had little impact on outcomes. The questions in this process evaluation concerned: (1) Impact on counselling skills and CVRM knowledge of practice nurses, (2) Their use of the various components of the intervention programme and adoption of recommended practices, (3) Patients' perceptions of counselling for CVRM.

Methods

A mixed-methods process evaluation was conducted. We assessed practice nurses' motivational interviewing skills on audio-taped consultations using Motivational Interviewing Treatment Integrity (MITI). They also completed a clinical knowledge test. Both practice nurses and patients reported on their experiences in a written questionnaire and interviews. A multilevel regression analysis and an independent sample t-test were used to examine motivational interviewing skills and CVRM knowledge. Framework analysis was applied to analyse qualitative data.

Results

Data from 34 general practices were available, 19 intervention practices and 14 control practices. No improvements were measured on motivational interviewing skills in both groups. There appeared to be better knowledge of CVRM in the control group. On average half of the practice nurses indicated that they adopted the recommended interventions, but stated that they did not necessarily record this in patients' medical files. The tailored programme was perceived as too large. Time, follow-up support and reminders were felt to be lacking. About 20% of patients in the intervention group visited the general practice during the intervention period, yet only a small number of these patients were referred to recommended options.

Conclusions

The tailored programme was only partly used by practice nurses and had little impact on both their clinical knowledge and communication skills, or on patient reported healthcare. If the assumed logical model of change is valid, a more intensive programme is needed to have an impact on CVRM in general practice at all.

Background

In the Netherlands, patients with established cardiovascular disease (CVD) or at high cardiovascular risk are mainly treated in general practice [1]. Although many efforts have been made to implement the multidisciplinary practice guideline Cardiovascular Risk Management (CVRM) [2] and the 'Care Standard' [3], which provides clinical and organisational recommendations, not all patients receive recommended preventive interventions [4,5]. Self-management is a crucial component of CVRM; yet about half of the patients are insufficiently active in self-management due to lack of motivation, knowledge and skills [6].

A programme of tailored interventions, focused on improving and facilitating prospectively identified determinants of current practice, may contribute to the improvement of quality of care [7]. The international project Tailored Implementation for Chronic Diseases (TICD) focused on the development and evaluation of a tailored implementation programme [8]. We followed subsequent steps starting with identifying barriers and enablers (so-called determinants) of current practice of CVRM care in general practice in the Netherlands, and strategies to address these [9-11]. Next, we developed a tailored intervention programme, comprising of the prioritised strategies. This intervention programme was largely targeted at improving counselling skills of practice nurses treating patients with established CVD or at high cardiovascular risk and their knowledge of CVRM. Patients at high cardiovascular risk have a 10-year risk score of 20% or higher for morbidity and mortality due to CVD [2]. To evaluate the intervention programme, we performed a two arm, cluster randomised trial in seven provinces in the Netherlands in 2013 and 2014. The outcome evaluation showed hardly any improvements in the delivery of CVRM [12]. Parallel to the outcome evaluation, we conducted a process evaluation to explore explanations for the study outcomes. The questions of this process evaluation concerned: (1) Impact on counselling skills and CVRM knowledge of practice nurses, (2) Their use of the various components of the intervention programme and adoption of recommended practices, (3) Patients' perceptions of counselling for CVRM.

Materials and methods

Details of the study design and methods have been reported elsewhere [13]. In this article we will focus on the methods relevant for this process evaluation.

Study design

In 2013-2014 we conducted a cluster randomised trial in the Netherlands to evaluate a tailored implementation programme that formed part of the TICD project. The primary outcome was: a record in the patient's medical file about lifestyle counselling or an

appropriate referral for patients with depressive symptoms. The secondary outcomes comprised of cardiovascular risk factors and patient reported lifestyle behaviours. Data were collected from patients' medical files and questionnaires aimed at patients [12]. The same group of practice nurses and patients provided us with data for the process evaluation. For this process evaluation we used a mixed methods design. Qualitative components involved interviews with practice nurses in the intervention group and a sample of twelve patients with established CVD or at high cardiovascular risk. Quantitative components were questionnaires for all participating practice nurses and patients, and scores of audio-taped interviews of practice nurses before and after the intervention period. In the context of the TICD project, a framework including seven domains was developed to identify determinants of practice [14], which was used to organise our data. Data for this process evaluation were collected between April and September 2014. The ethical committee of Arnhem and Nijmegen waved approval for the study (2013/229).

Participants

In total 44 practice nurses expressed an interest in participating and gave their written informed consent. Eligible practice nurses treated patients with established CVD or at high cardiovascular risk and had already been trained for motivational interviewing during their vocational training or as part of their continued education. Practice nurses provide patients with lifestyle advice, perform biomedical measurements, and consult general practitioners (GPs) about drug treatment. Patients with established CVD or at high cardiovascular risk were selected in cooperation with their practice nurse. Eligible patients met the International Classification of Primary Care (ICPC) codes K74-76, K85-K92, K99.1 and T93; sometimes two codes or more needed to be present in order to determine high cardiovascular risk, depending on age, gender and smoking status. Patients were 18 years of age or older and had to be able to fill out an informed consent form. Patients were excluded if they had diabetes mellitus, pregnancy or lactation, terminal illness, cognitive impairment and/or poor language skills. We excluded CVRM patients with diabetes mellitus because the results then would have been influenced by the quality of diabetes care with a longer history of programmed care. In this article we will exclusively focus on CVRM care.

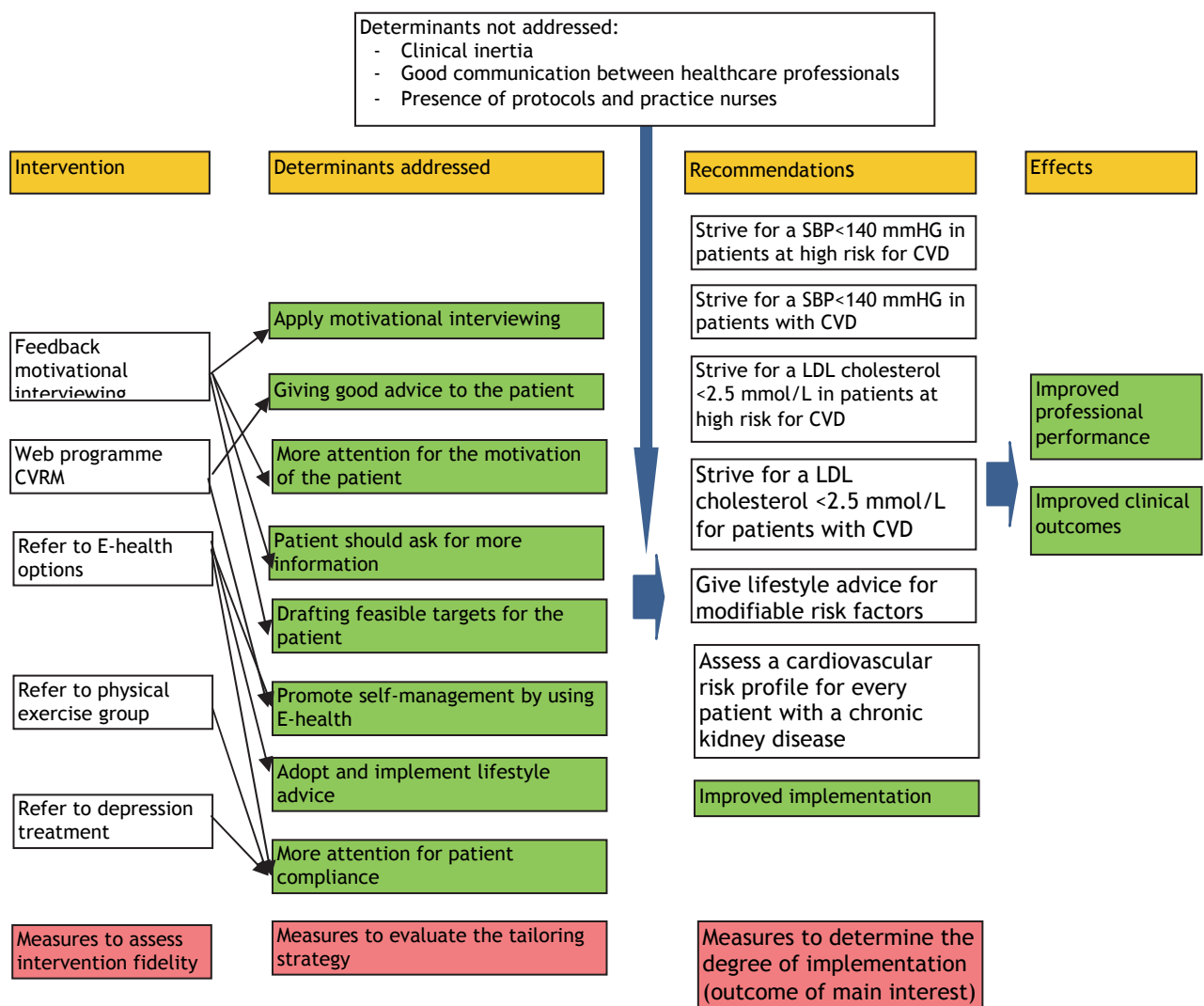
Tailored implementation programme

During the TICD project we developed a tailored intervention programme by following sequential steps, in order to enhance the quality of CVRM care. First, targets for improvement were determined by analysing clinical guidelines [2,3] and clinical audit data. Selected targets were: systolic blood pressure (SBP) < 140 mmHg in patients with established CVD or at high cardiovascular risk; low density lipoprotein (LDL) cholesterol < 2.5 mmol/l in patients with established CVD or at high cardiovascular risk; promote

lifestyle changes for patients with established CVD or at high cardiovascular risk; create a risk profile for patients with chronic kidney disease. Subsequently, interviews were held with healthcare professionals and patients whereby 139 plausibly important determinants of practice were identified. We selected 11 determinants based on importance and changeability. During group interviews, stakeholders and patients suggested 181 strategies for implementation to influence the selected determinants; these strategies were used for developing the tailored intervention programme considering feasibility and potential impact, see Figure 1. The intervention programme consisted of the following components: (1) A mandatory feedback training on motivational interviewing for practice nurses to enhance their motivational interviewing skills, and to address the determinants of: drafting feasible targets for the patients, giving patients good advice and thereby to improve patients' motivation for a better lifestyle. (2) A new educational web programme (CVRM) was offered to enhance practice nurses' knowledge about CVRM, and subsequently the determinants of giving patients good advice and improve their self-management. (3) We formulated the recommendation to categorise the patients in three groups based on the presence of depressive symptoms and tailor care accordingly, because patients without, with mild or with severe depressive symptoms benefit from a different approach [15]. The Patients' Health Questionnaire (PHQ-9) is an instrument for screening, diagnosing, monitoring and measuring the severity of depression, which we offered as supportive material [16]. (4) Patients without depressive symptoms were provided with an information card containing an option to write down personal target values for blood pressure and LDL cholesterol. E-health options were also written down on this information card, namely 'thuisarts.nl' and 'hartenvaatgroep.nl', as well as Twitter consultation options. Practice nurses were asked to explain the information on the card. The E-health options offered addressed the following determinants: to enhance patients' self-management by using E-health, to improve patients' adoption and implementation of lifestyle advice, and to enhance patients' compliance. (5) The recommendation was to refer patients with mild depressive symptoms to a physical exercise group. This could be an exercise group led by a physical therapist or 'Nederland in beweging' ('the Netherlands on the move'), a Dutch television programme. Physical exercise has a beneficial effect on CVD and on depressive symptoms, but we also intended to influence the determinant 'more attention for patients' compliance'. For patients with severe depressive symptoms we advised the practice nurse to refer these patients to their GP, practice nurse mental health or psychologist, as appropriate within the general practice. Severe depressive symptoms negatively influence patients' compliance [2]; for that reason we recommended reducing depressive symptoms before starting with lifestyle advice. Practice nurses in the control group were asked to provide their usual care.

Following a published framework [17] we introduced the intervention programme as follows: three members of the TICD project individually visited each participating general practice, which lasted in general one hour, to instruct practice nurses. They used a standardised script in order to ensure that the intervention programme was clear and that the practice nurses were motivated. Further contacts were related to practical aspects of the feedback training motivational interviewing, the web programme and the handing in of audio taped patient consultations.

Figure 1. Logic model. This table provides information regarding which determinants and recommendations are addressed to the intervention programme and which are not addressed, as well as showing the intended effect



Data collection

Data was collected at the start and at follow up, which was planned six months after the start, but due to practical constraints it was actually seven up to eleven months after delivery of the intervention programme.

Quantitative measures

To assess how practice nurses applied their motivational interviewing skills, we asked them to hand in two audio tapes of their consultations with patients, one at baseline before the feedback training, and an audio tape at follow-up. The audio tapes were transcribed verbatim. Transcriptions were scored by professional trainers, who were affiliated with MINTned (Association of Dutch trainers in motivational interviewing), using the validated Motivational Interviewing Treatment Integrity (MITI) [18]. The MITI is a behavioural coding system assessing motivational interviewing skills. The MITI exists of two components: the global score and behaviour coding. The global score exists of five categories which are scored between one and five. Behaviour coding consists of a percentage of open and closed questions, a percentage of reflection (simple or complex), and a number of given information (motivational interviewing adherent or motivational interviewing non adherent). CVRM knowledge was assessed in a questionnaire with six questions covering knowledge of lifestyle advice, CVRM treatment and risk factors. For practice nurses in the intervention group the questionnaire was expanded, covering all components of the intervention programme. These included: motivational interviewing, web programme CVRM, information cards, E-health, Twitter consultations, physical exercise group and referral to the GP, practice nurse mental health or psychologist. Practice nurses were asked which components they had used, whereby three answer categories (yes/ partly/ no) were provided. All patients received a composite questionnaire after the intervention period with questions on referral as part of the intervention programme and whether they used this advice. Answer categories were: yes/no/once/several times, as applicable to the question concerned. The PHQ9 questionnaire was also included, which comprised of a 0-3 Likert-type scale (not at all/ several days/ more than half of the days/ almost every day) [16], to check whether patients without/ with mild/ with severe depressive symptoms were referred to the suited recommendations as we suggested.

Qualitative measures

All practice nurses in the intervention group were invited to participate in a face-to-face semi- structured interview at follow-up, to answer the question why practice nurses used or did not use our intervention programme. Questions covered all components of the intervention programme. After four and 12 interviews with practice nurses interim analyses were performed wherein the interview script was modified and questions were added about how practice nurses coped with possible depressive symptoms, high blood pressure or high cholesterol levels. During the semi-structured interviews practice nurses were asked whether they felt that their skills to guide and motivate patients had improved after having attended the suggested trainings. Telephone interviews were held with patients to examine how they perceived the various components of the intervention programme. We asked patients whether they

received a referral, whether they acted upon that advice, and what their experiences were about the advice. Of four general practices, 29 patients who visited their general practice during the intervention period were invited by using convenience sampling. We invited only patients who visited the general practice; in doing so we were able to generate more specific information about our intervention programme. Four research assistants working on the TICD project conducted the interviews with both practice nurses and patients. All interviews were audio taped and transcribed verbatim.

Data-analysis

For quantitative analysis we used SPSS (version 20, IBM Corp.) and for qualitative analysis we used Atlas.ti7.

Quantitative analysis

In a multi-level regression model, the MITI scores were compared between baseline and follow-up, and between intervention group and control group. A two level model was used: measurements nested within practice nurses and practice nurses nested in general practices. Furthermore, we added time of measurement (baseline and follow up), allocation to research group (intervention group and control group) and the interaction term between time of measurement and allocated research group to the model. Other independent variables included were the global score and behaviour coding. Following the MITI code, the global score should be above 3.5; it is deemed desirable that the percentage of open questions is above 35%, and complex reflection above 40%; and only two times non adherent information should be given such as advising without permission, making suggestions, or using words such as: should, consider, try etcetera. A significant difference was set at $p < 0.05$. To assess knowledge about CVRM, questions were formulated on a basis of casuistry. All answers were checked using the answer key, whereby missing values were scored as wrong answers providing a conservative picture about the knowledge of practice nurses. Descriptive statistics were used to measure both the correct and wrong answers for the intervention group as well as the control group. An independent sample t-test was used to measure the difference in correct answers between the intervention group and the control group. Results of the practice nurses' questionnaires were used to measure which components of the intervention programme were used. Descriptive frequencies were calculated for each intervention element. Results of patients' questionnaires were analysed by using descriptive crosstabs. First we measured whether patients were referred by practice nurses to some components of the intervention programme, and second we measured whether patients acted upon this advice. The answer categories whether patients acted upon this advice once or several times were merged for better data processing. We checked whether patients visited the general practice during the intervention period, whether they had been exposed to the intervention programme,

whether they perceived no, mild, or severe depressive symptoms, and lastly whether patients were referred to the suited option regarding depressive symptoms. Results of the PHQ9 questionnaires are normally divided into scores of 5, 10, 15 and 20, and represent cut points for mild, moderate, moderately severe and severe depression, respectively [16]. For this study we considered a score up to 5 as no depressive symptoms, 6 to 15 as mild depressive symptoms and a score above 15 as severe depressive symptoms.

Qualitative analysis

The transcribed interviews were analysed using a two-stage content analysis [19]. The first three interviews of practice nurses and of patients were coded independently by two researchers. These results were discussed and agreements were made for further coding. The remainder of the interviews were coded by one researcher and checked by a second researcher. Discrepancies were resolved through discussion. First, open coding was applied by coding all quotes relating to the tailored intervention programme. All quotes were transferred into an Excel data file. Then axial coding was applied, whereby quotes were clustered per element of the intervention programme. The following coding scheme was used: motivational interviewing, web programme CVRM, information cards, E-health, Twitter consultations, physical exercise group and referral of patients with severe depressive symptoms. Furthermore, selective coding was applied by summarising important subthemes of the quotes mentioned. Axial and selective coding were performed by two researchers and checked independently by two other researchers. Consensus was reached through discussion. After this initial stage of content analysis, we categorised determinants of practice into domains of the TICD framework [14] in a second stage. We will present the results following the TICD framework which consists of the following domains: guideline factors, individual health professional factors, patient factors, professional interactions, incentives and resources, capacity for organisational change, and social, political and legal factors. We classified all determinants mentioned by practice nurses and patients during the process evaluation about the intervention programme where possible according to the seven domains, including the results of the feedback training motivational interviewing and the web programme CVRM. Some mentioned quotes associated with the intervention programme could not be classified by the framework. The second stage of content analysis was performed by one researcher and checked by two other researchers.

Results

A total of 34 practice nurses started with the intervention programme. General practices were randomly allocated to the intervention group (19 practices, 20 practice nurses; two general practices with two practice nurses each and one practice nurse

who worked in two participating general practices) and the control group (15 practices, 14 practice nurses; one practice nurse who worked in two participating general practices), see Table 1. One practice nurse in the intervention group dropped out just before the end of the intervention period due to a change of job and was therefore not available for this evaluation. Two audio tapes for the MITI were handed in by each of the 30 practice nurses, while four nurses handed in one recorded consultation at the start of the programme; all recorded consultations were used for analysis.

Table 1. General practice, practice nurse and patient characteristics

	Intervention group	Control group
Practice characteristics	N=19	N=15
Single-handed practice	N=10 (52.6%)	N=9 (60%)
Duo/Group practice	N=9 (47.3%)	N=6 (40%)
Rural area	N=10(52.6%)	N=6 (40%)
Urban area	N=9 (47.3%)	N=9 (60%)
Mean number of patients visiting the general practice per week (SD)	185.31 (91.56)	141.00 (48.34)
Mean FTE practice nurses (SD)	0.71 (0.35)	0.65 (0.32)
Practice nurse characteristics	N= 20	N= 14
Sex % female	90	100
Mean age in years	42	43
Mean number of years experience as practice nurse	12	11
Mean number of hours previous training of motivational interviewing skills	15	15
Patients characteristics	N=1250	N=979
Sex % female	35.1	34.9
Mean age in years (SD)	72.6 (9.2)	71.6 (9.7)
Number of patients that had a contact with the practice during the intervention period	N=303	N=161
Patient with established CVD	N=130	N=66
Patients at high risk	N=173	N=95
No symptoms of depression (%)	74.4	75.6
Mild symptoms of depression (%)	23.6	22.7
Severe symptoms of depression (%)	2.0	1.7

FTE = fulltime equivalent

All 19 practice nurses in the intervention group were interviewed, two men and 17 women; all interviews were held face-to-face except for one interview, which was conducted by telephone. The interviews lasted on average 36 minutes (range 12 to 67 minutes).

In total 1496 patients filled out the questionnaire, whereof 465 patients contacted the general practice during the intervention period, 303 patients in the intervention group and 161 patients in the control group. For the analysis we only used information of patients in the intervention group who contacted the general practice, as only these patients could inform us on how our intervention programme was perceived. Twelve patients were interviewed, six women and six men; the telephone interviews lasted on average 23 minutes (range 12 to 29 minutes).

Results are presented in relation to the research questions. Results corresponding to research question 2 were classified to the TICD framework.

Impact on counselling skills and CVRM knowledge (Research question 1)

All practice nurses except one attended the feedback training motivational interviewing, which consisted of feedback directly after two patient contacts (one practice nurse only had one feedback moment due to lack of time). The MITI results showed small improvements, see Table 2. Not all parts of the behaviour coding of the MITI could be scored for all practice nurses because the audio taped consults were too short, which explains the inequality of the number of practice nurses. The mean global scores for the intervention group were enhanced from 2.1 to 2.4 (scale of 1-5), the global scores in the control group decreased from 2.3 to 2.2. No significant difference ($p=0.169$) was found between groups, after controlling for baseline scores. According to the MITI, the global score, which should be above 3.5, was only achieved by one practice nurse in the control group at the start (4.0), while another practice nurse in the intervention group achieved a global score of 3.6 at follow-up. The percentage of asking more open questions showed a significant difference between the intervention and the control group at follow-up ($p=0.009$), although the overall score was below 35%.

Table 2. Motivational interviewing skills (assessed with the MITI) comparing the intervention group and control group

		Intervention Group at baseline	Intervention Group at follow up	Control Group at baseline	Control Group at follow up	P- value
Global scores (Scale 1-5) (Should be above 3.5)		2.1 (n=17)	2.4 (n=17)	2.3 (n=14)	2.2 (n=13)	0.169
Behavioural coding (percentage open questions) (Should be above 35%)		17.3 (n=17)	20.5 (n=17)	25.0 (n=14)	13.4 (n=13)	0.009*
Reflection (percentage complex reflections) (Should be above 40%)		60.5 (n=14)	27.1 (n=17)	56.9 (n=11)	9.1 (n=12)	0.374
Information given	MI-Adherent (number of scored comments)	6.5 (n=16)	5.7 (n=15)	5.8 (n=14)	7.9 (n=13)	0.467
	MI Non- adherent (number of scored comments) (Should be twice maximum)	6.3 (n=16)	7.7 (n=17)	5.6 (n=14)	9.4 (n=13)	0.474

* $p<0.05$ = Difference between intervention group and control group, controlled for baseline scores.

MITI = Motivational Interviewing Treatment Integrity

Numbers between brackets = Number of records which were scored by the trainers

Furthermore, the score for complex reflections was not above 40% after the training; and the score for non-adherent information giving was far above the advised maximum of two times per consultation. Eleven practice nurses completed the web programme CVRM (including the practice nurse who dropped out later), four practice nurses started the web programme but did not complete it, while five practice nurses never started at all. On a scale from 0 to 6 correct answers on the knowledge questionnaire, the mean score of the intervention group was 3.4 correct answers in comparison with the control group who scored 4.5, a significant difference between groups ($p=0.048$).

Use of interventions by practice nurses (Research question 2)

Table 3 provides figures on the use of interventions resulting from the practice nurses' questionnaire and Table 4 provides figures on how many patients were referred to the components of the intervention programme. The questionnaire was filled out by 29 practice nurses, 16 practice nurses in the intervention group and 13 practice nurses in the control group. The uptake of the different components of the intervention programme ranging from 6.25% to 75.00% (Did you use the PHQ-9 questionnaire?).

Table 3. Use of interventions by practice nurses (n=16)

	Yes	Sometimes	No	Missings
Did you pay attention to possible depressive symptoms in patients with established CVD or at high risk?	8 (50.00%)	5 (31.25%)	3 (18.75%)	0 (0%)
Did you use the PHQ-9 questionnaire?	3 (18.75%)	1 (6.25%)	12 (75.00%)	0 (0%)
Did you refer patients without depressive symptoms to the two websites?	2 (12.50%)	6 (37.50%)	7 (43.75%)	1 (6.25%)
Did you adopt the recommendation to refer patients without depressive symptoms to the two websites?	4 (25.00%)	4 (25.00%)	5 (31.25%)	3 (18.75%)
Did the recommendation to refer patients to the two websites enhance patients' self-management?	1 (6.25%)	7 (43.75%)	5 (31.25%)	3 (18.75%)
Did you give patients the information card?	1 (6.25%)	10 (62.50%)	4 (25.00%)	1 (6.25%)
Did you adopt the recommendation to give patients the information card?	4 (25.00%)	4 (25.00%)	5 (31.25%)	3 (18.75%)
Did you refer patients to the Twitter consultations?	1 (6.25%)	7 (43.75%)	6 (37.50%)	2 (12.50%)
Did you adopt the recommendation to refer patients to the Twitter consultations?	1 (6.25%)	2 (12.50%)	7 (43.75%)	6 (37.50%)
Did you refer patients with mild depressive symptoms to an exercise group?	3 (18.75%)	7 (43.75%)	5 (31.25%)	1 (6.25%)
Did you adopt the recommendation to refer patients to an exercise group?	2 (12.50%)	2 (12.50%)	8 (50.00%)	4 (25.00%)
Did you refer patients with severe depressive symptoms to the GP, practice nurse mental health or psychologist?	8 (50.00%)	0 (0%)	4 (25.00%)	4 (25.00%)
Did you adopt the recommendation to refer patients to the GP, practice nurse mental health or psychologist?	1 (6.25%)	1 (6.25%)	8 (50.00%)	6 (37.50%)

These figures will be clarified with reasons mentioned by practice nurses during the interviews, categorised by TICD domains. Most determinants mentioned by practice nurses and patients belong to two domains: individual health professional factors, and capacity for organisational change. Practice nurses mentioned no determinants in two domains: guideline factors and social, political and legal factors.

Table 4. Patients' reports on exposure to components of the intervention (n=303)

	Yes	No	Missing	Total
Did you receive an information card?	69 (22.8%)	212 (69.9%)	22 (7.3%)	303 (100%)
Did you preserve the information card? *	51 (73.9%)	17 (24.6%)	1 (1.5%)	69 (100%)
Did the practice nurse refer you to the two websites?	28 (9.2%)	239 (78.9%)	36 (11.9%)	303 (100%)
Did you view the websites?*	15 (53.6%)	10 (35.7%)	3 (10.7%)	28 (100%)
Did you found the websites useful? *	14 (93.3%)	1 (6.7%)	0 (0%)	15 (100%)
Did the practice nurse refer you to the twitter consults?	3 (1%)	228 (75.2%)	72 (23.8%)	303 (100%)
Did the practice nurse refer you to an exercise group?	17 (5.6%)	233 (76.9%)	53 (17.5%)	303 (100%)
Did you visit the exercise group?*	11 (64.7%)	2 (11.8%)	4 (23.5%)	17 (100%)
Did the practice nurse refer you to the GP, practice nurse mental health or psychologist due to possible depressive symptoms?	12 (4.0%)	233 (76.9%)	58 (19.1%)	303 (100%)

Data on follow-up questions relate to patients who responded affirmative on the main question.

Domain individual health professional factors

Practice nurses in the intervention group who paid attention to the recommendation to consider depressive symptoms and refer patients to the suited recommendations did this because they found it relevant. Reasons for not paying attention to these recommendations were: lack of knowledge of the linkage between depression and cardiovascular diseases, and practice nurses felt that they were not the right person to diagnose and register this. Most practice nurses forgot to document these data in patients' medical files. One practice nurse decided to place the supportive PHQ9 questionnaire in the waiting room so that patients could fill it out, although she did not use the results of the questionnaire. The information card was perceived as being of little value. Practice nurses had written down the target values elsewhere instead of on the information card or given it verbally. Practice nurses referred patients in particular to the website thuisarts.nl, which was known by most practice nurses and perceived as reliable. Some practice nurses did not consider these websites as helpful for CVMR patients. Reasons for not referring patients to Twitter consultations were: this recommendation was perceived as not useful and practice nurses were not familiar with Twitter themselves. Patients were referred to an exercise group regardless whether they experienced mild depressive symptoms, simply because practice nurses found it difficult to recognize mild depressive symptoms in patients. Practice nurses who referred patients to an exercise group did this already before the intervention period; they already knew physical exercise groups in the area and were also familiar with the television programme 'Nederland in beweging'. Practice nurses who did not

refer patients mentioned that they did not have any patients with mild depressive symptoms. Most patients with severe depressive symptoms were already receiving treatment, so a few patients were eligible for this recommendation. As a result of this implementation programme, some practice nurses worked more consciously with patients with established CVD or at high cardiovascular risk: they recognised depressive symptoms more often. Practice nurses mentioned that their guiding and motivating skills had improved due to the feedback training and the web programme CVRM.

Domain patient factors

Patients were deemed to be too aged for Twitter consultations and for that reason were not referred to this type of consultation.

Domain professional interactions

Our recommendation for patients with severe depressive symptoms was not to give them lifestyle advice but to start with reducing depressive symptoms. Even so, practice nurses gave lifestyle advice anyway because this was agreed upon within their general practice.

Domain incentives and recourses

Reasons for not paying attention to the recommendation to consider depressive symptoms and refer patients to the suited recommendations were: lack of time, and changes in the electronic medical record systems.

Domain capacity for organisational change

Not all practice nurses saw CVRM patients during the intervention period, and CVRM was not very well organised in some general practices. Moreover, changes in personnel and other projects within the general practice led to the fact that our intervention programme was not as well used as intended.

Experiences with the implementation programme

In general most practice nurses mentioned that they successfully adopted components of the implementation programme and would continue to do so. Nevertheless, the intervention programme was perceived as too much. There were too many items to think about. Another bottleneck was the lack of follow-up support and reminders from the research team. For some practice nurses it was not clear how their activities regarding the intervention programme could have been noted. Finally, the intervention programme became blurred and forgotten about, due to part-time jobs.

Referral of patients and patient reported healthcare (Research question 3)

Table 4 provides figures of patients' reports on exposure to components of the intervention programme, ranging from 1% (Did the practice nurse refer you to the Twitter consultations?) to 93.3% (Did you find the websites useful?). Figures of patients who mentioned that they had been exposed to components of the intervention programme were restricted to those who contacted the general practice during the intervention period. Not all patients had been referred to the recommended treatment or support options considering their level of depressive symptoms.

Reasons for not visiting the recommended websites by patients were that some patients had no access to the Internet, while some patients never used the Internet when searching for health related information. Most patients mentioned that they did not know what Twitter was. Half of the patients mentioned that they did not receive lifestyle advice about food, exercise or smoking cessation. None of the patients interviewed visited an exercise group, while none were referred to the GP, practice nurse mental health or physiologist related to depressive symptoms.

Discussion

Although the intervention programme was tailored to predefined key determinants of practice and introduced to practice nurses according to a standardised script, on average half of the practice nurses used and adopted components of the intervention programme. The information card and the recommendation to refer patients to the website 'thuisarts.nl' were the elements in our programme mostly used by the practice nurses. Practice nurses did not distinguish between patients with and without depressive symptoms, although this was an important aspect of the intervention programme. Important reasons for the lack of adherence to the programme were that for some practice nurses it was not clear how to note their activities in patients' medical records regarding the intervention programme and therefore only a few practice nurses made records, lack of time and follow-up support. Some patients mentioned that they had been referred to some components of the intervention programme, while a small group of these patients actually used the interventions offered. These findings provide potential explanations for the absence of impact on evaluation outcomes of the cluster randomised trial.

In a previous stage of our research, targets for improvement were determined, determinants of practice were selected and suggestions for interventions were collected for our tailored intervention programme to address several determinants [10], see Figure 1. The evaluation of the tailored programme was the last phase of this project [8], which showed that there was no improvement on the targets for improvement. Determinants of practice were still perceived to be relevant, what

indicates that these determinants were well selected. Although the intervention programme addressed some of the determinants, healthcare professionals' behaviour did not change. The selected elements of the tailored intervention programme did not meet all the expectations of the practice nurses, which may explain that not all elements were used as recommended. Also the lack of reminders and follow-up support of the research team plays an important role in the failure of the use and implementation of the intervention programme.

This process evaluation showed that the determinant 'motivational interviewing' was influenced by the feedback training with exposure to all practice nurses. The motivational interviewing skills are relatively poor, despite interest of nurses and training received. Determinants such as 'giving good advice to patients' and 'more attention to patients' motivation' were influenced by the feedback training motivational interviewing and the educational web programme CVRM. Practice nurses mentioned they were better able to guide and motivate patients after both training sessions. Although practice nurses are positive about their functioning, knowledge about CVRM remains suboptimal, including knowledge about the relation between depressive symptoms and CVRM. Practice nurses were positive about referring patients to the E-health option thuisarts.nl. These findings imply that the assumed logical model of change may be valid, but the intensity of the intervention programme should have been higher to have any impact.

Despite the fact that we have identified determinants of practice before developing an intervention programme to change healthcare professionals' behaviour, this process evaluation revealed hardly any change in healthcare professionals' behaviour [12]. Several process evaluations of randomised trials in which behaviour change was accomplished or wherein determinants were identified have been published. One study confirmed that it is difficult to change healthcare professional behaviours [20], despite the fact that the participants expressed initial enthusiasm for the intervention programme. It may be possible that our intervention programme needed more instruction tools, such as booklets or online tools. That way practice nurses in the intervention group could constitute a network to inform and motivate each other. Practice nurses in the intervention group felt that they were better able to motivate and guide patients after the intervention programme, which incidentally was also seen in another study of TICD series. In that particular study practice nurses also felt more confident in treating patients after participating in a tailored intervention programme, although no improvements in guideline adherence were found [21]. In our study the implementation of the programme by practice nurses was disappointing: only half of them used and adopted only parts of the programme. Other research showed a considerable variation of adoption of interventions by practice nurses whereof one study showed better adoption of interventions than our study [22-24]. These intervention programmes were deemed important by practice nurses and they expected

better patient results afterwards, yet time was found to be a restriction. Moreover, digital interventions were difficult, a fact that corresponds with our outcomes.

Knowledge and awareness of practice nurses about the correlation of CVD and depressive symptoms might be enhanced in initial training and continuing education of nurses. But what is also needed is more recognition among practice nurses of the role of mental health problems among practice nurses, even if they primarily care for patients with somatic chronic conditions. The practice nurse mental health can provide added value to healthcare professionals, such as treating CVRM patients experiencing depressive symptoms or providing the staff with general information and tools for recognition to provide these patients with adequate care [25]. Training on practice nurses' motivational interviewing skills is also needed to enhance these skills or at least to prevent deterioration. Although healthcare professionals expressed a strong preference for more training on motivational interviewing skills, it seems unlikely that this can enhance motivational skills in preventive care for vascular conditions and diabetes [26-28]. This process evaluation revealed that determinants targeted by the intervention programme did not lead to improvement: motivational interviewing skills and knowledge of CVRM were not positively influenced and with that the basis for behavioural change seems to be lost. Questions hereby are: were the selected determinants indeed important and changeable in current healthcare? And were the chosen strategies feasible and could they have an important impact? Although the use and adoption of recommended practices by practice nurses were limited in this study, a systematic review found that on average tailored interventions improved professional practice [7]. Nevertheless, more in-depth research is needed on how a tailored intervention programme works. What is the best way to obtain and select determinants and strategies so that the best strategies can be used for a tailored intervention programme?

Strengths and limitations

We used multiple angles to illuminate all components of the tailored intervention programme and in doing so achieved a broader view of all aspects, which is a strength of this process evaluation. Although almost all practice nurses handed in the questionnaires and the requested audio tapes, and participated in the interviews, the evaluation was based on a small number of practice nurses, so quantitative results should be interpreted carefully. All practice nurses handed in the first audio tape and we had three missings at follow-up, although some audio tapes were handed in too late, which could fade the effect. We recruited patients by convenience sampling in only four general practices. For that reason it is possible that we have missed information about patients' perceptions of our intervention programme. Some patients indicated that they had not been referred to the websites, yet they did have an opinion about it. It could be that patients had already checked these websites, which provide

health information. Therefore the results of patients' questionnaires need to be interpreted carefully.

Conclusion

Half of the practice nurses only partly applied and adopted the interventions from the tailored implementation programme, because the intervention programme was perceived as too much, practice nurses perceived a lack of reminders and follow-up support from the research team, and practice nurses recorded only a few referrals. The programme aimed at pre-defined determinants such as motivational interviewing skills, CVRM knowledge and self-management promotion using E-health, but scores on these determinants did not change. These findings probably explain the absence of outcomes found in the trial. The assumed logical model of change could still be valid, but apparently practice nurses missed support from the project team for a better adoption.

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Chapter 10

General discussion

Introduction

The aim of the present thesis was to examine tailored implementation strategies to enhance evidence-based chronic illness care, focusing on cardiovascular risk management (CVRM). The presented research was part of the Tailored Implementation of Chronic Diseases (TICD) project [1]. Research teams from five countries participated in this TICD project, focusing on: multi-morbidity (Germany), CVRM (the Netherlands), depression in the elderly (Norway), chronic obstructive pulmonary disease (COPD) (Poland), and obesity (United Kingdom). Tailoring implementation strategies was planned according to three main steps: identification of determinants of current practice, design of implementation interventions appropriate to the determinants, and application and assessment of implementation interventions that target the identified determinants.

In this chapter, the main findings of the studies are summarised and discussed. Then the main methodological issues are reviewed, the methods for tailoring implementation strategies are assessed, and recommendations for future research are given.

In *Chapter 1*, a general introduction of this thesis was presented wherein cardiovascular diseases (CVD), cardiovascular disease management in the Netherlands, current cardiovascular care, and previous programmes to optimise cardiovascular care is described. Furthermore, the TICD project is explained in more detail. Finally, the main objectives of this thesis were presented.

Identifying determinants of current practice

In *Chapter 2*, a three phase semi-structured interview study is described whereby determinants of current practice in Dutch general practice were identified. The TICD framework was used to classify and cluster the determinants of high-quality CVRM [2]. Healthcare professionals and patients generally mentioned similar determinants which affected patient related items (education and self-management) and collaboration of healthcare professionals. Patients were closely involved in their own CVRM healthcare and were satisfied about the care provided by practice nurses. Determinants which could be improved were: making agreements about patients' treatment, and collaboration and communication between general practitioners and specialists. Remarkable differences were mentioned regarding the perception of patients' self-management. Healthcare professionals believed that patients do not have enough knowledge about CVRM and lack self-management skills. Patients felt that they have sufficient knowledge of CVD risk factors and try to maintain a healthy lifestyle. Another difference was also mentioned. Healthcare policies, the introduction of the market mechanism, and the strong role of health insurers retain healthcare professionals from improving CVRM, which frustrated them. Patients were satisfied about health insurers due to the received reimbursements.

Self-management is essential for patients for managing their chronic disease [3]. CVD are complex which makes it difficult to enhance patients' lifestyle or maintain a healthy lifestyle. Previous Dutch studies showed that patients perceived a lack of knowledge about CVRM and self-management skills [4-6]. Healthcare professionals may be focused on what patients do or do not know rather than emphasise the positive. Healthcare professionals did not mention determinants such as socio-economic status, family-related issues and scientific evidence which were reported in other studies [7,8]. This could mean that these determinants are no longer topical. Determinants were mainly related to healthcare professionals, patients, healthcare organisation, and healthcare policies, which described a wide range of CVRM care [9,10]. The identification of determinants of healthcare practice provided a good starting point for the next step in tailoring: designing implementation strategies [1,11].

Group interviews with stakeholders for matching implementation strategies to identified determinants of practice

After identification of the determinants, the logical next step in tailoring is generating strategies that can be matching to the relevant determinants of current practice. *Chapter 4* describes a study in which data was collected through group interviews with different types of stakeholders. In this study we analysed data from five countries participating in the TICD project. The group interviews were divided in two parts: first a brainstorm session, followed by a structured phase. Suggested strategies were assessed with respect to unique numbers per group, per phase, and per country using the TICD framework [2]. The number of strategies varied more between countries than between groups within each of the countries, which was also reported in similar studies [12,13]. These differences may be due to country-specific reasons [14] or due to the various chronic conditions in each of the countries. In three of five countries the structured phase after the brainstorm session provided substantially more strategies. Most strategies were aimed at individual health professional factors (knowledge, skills, and behaviours), patient factors, and professional interactions as mentioned in *Chapter 5* [15], which are all part of patient care delivery. The aims of these strategies were also mentioned in previous studies [16]. After identifying these implementation strategies, a selection was made for designing a tailored intervention programme considering feasibility and potential impact. Types of tailored intervention programmes chosen were targeted at healthcare professionals and patients, and mainly comprised of educational programmes, checklists, and e-learning resources which are common targets [17,18].

Tailored intervention programme

The study protocol of the tailored intervention programme in the Netherlands is described in *Chapter 6*. The tailored intervention programme was evaluated in a two-

arm cluster randomised trial targeted at practice nurses in general practice and patients with established CVD or at high cardiovascular risk. The pre-defined primary outcome referred to the professional performance of practice nurses and reflected adoption of recommendations for personalised counselling and education of patients with established CVD or at high cardiovascular risk. Practice nurses' professional performance was considered to be adequate if one of the following conditions was met: (1) There was a record in patients' medical record that the patient received lifestyle advice on diet, smoking or physical exercise. At least one target for improving an aspect of lifestyle is recorded. When a patient has a perfect lifestyle, then that will be recorded. (2) There is a record in patient's medical record that the patient has none, mild or major depressive symptoms and that the patient has been referred to E-health, a physical exercise group, or depression treatment respectively. As secondary outcomes, we recorded various elements contributing to the primary outcome: healthcare received by each patient (lifestyle counselling and referral to E-health, referral to a physical exercise group, and referral to a general practitioner, practice nurse mental health or psychologist for severe depression treatment). Furthermore, as secondary outcomes we documented blood pressure, cholesterol levels, body-mass index, smoking status, diet, and physical exercise to measure patients' lifestyle. Patients with established CVD or at high cardiovascular risk received a composite questionnaire which also included the Patient Assessment of Chronic Illness Care (PACIC) [19] which assesses patients' experience about chronic healthcare, and the Patient Activation Measure (PAM) questionnaire [20] which measures patients' self-management. Data was also collected by questionnaires for practice nurses, interviews with practice nurses and patients, the Motivational Interviewing Treatment Integrity (MITI), and medical record systems [21].

Evaluation of the tailored intervention programme

In the Netherlands a total 1600 general practice in seven geographical areas were invited to participate, resulting in a sample of 34 practices at baseline. General practices were randomly allocated to the intervention group (19 practices, 20 practice nurses; two general practices with two practice nurses each and one practice nurse who worked in two participating general practices) and the control group (15 practices, 14 practice nurses; one practice nurse who worked in two participating general practices). In total 2229 patients (41.8% of those invited) gave informed consent for the study in the baseline patient questionnaire. The programme had no effect on the primary outcome, see *Chapter 7*. A record of adequate performance of practice nurses' was only present in a minority of patients' records. Practice nurses documented depressive symptoms only six times in patients' medical records. Although our intervention programme consisted of parts which could have improved cardiovascular risk factors [22-24], our results showed only an improvement for physical exercise

according to the Rapid Assessment of Physical Activity (RAPA) [25]. Furthermore, no significant effect was found on the other cardiovascular risk factors.

With respect to secondary outcomes, *Chapter 8*, patients in the intervention group had a significant lower PACIC score at follow-up compared with patients in the control group. For patients with established CVD the PACIC score deteriorated over time. As regards the PAM score, patients in the intervention group had a significant lower score than patients in the control group at follow-up; the PAM scores did not differ between patient groups (established CVD or at high cardiovascular risk). The overall PACIC score found in our study was lower than in previous studies [26], which implies that patients with established CVD or at high cardiovascular risk assessed CVRM healthcare less comprehensively than in other samples of practices in previous years [27]. The MITI showed no association with the PAM score, even after controlling for the PACIC score and PAM score at baseline. This implies that patient experiences' in chronic illness care and active disease management were not influenced by practice nurses' counselling.

Chapter 9 describes the impact of the feedback training motivational interviewing and web programme CVRM on motivational interviewing skills and CVRM knowledge of practice nurses, and if they used and adopted components of the tailored intervention programme. Also, patients' perception of the recommendations of the intervention programme was described. According to the MITI results, no improvements were achieved by practice nurses. The recommended scores of the MITI were not accomplished [21]; the recommended global score of 3.5 (scale 0-5) was only reached by two practice nurses, one practice nurse at baseline and one practice nurse at follow-up. The score of open questions was far below the 35%, which is considered to indicate minimally required quality. It was deemed desirable that only two times non-adherent information was given but this was also not achieved by practice nurses. The web programme did not contribute to CVRM knowledge; practice nurses in the intervention group scored 3.4 (scale of 0-6) while practice nurses in the control group scored 4.5, which was significantly better. We asked practice nurses to refer patients to E-health, a physical exercise group, or depression treatment respectively. Only a small group of patients was alerted by practice nurses at E-health, a physical exercise group, or depression treatment. Most patients received an information card or were referred to E-health. Only half of the patients who were referred to the websites visited them, some patients had no access to the Internet, and some did not use the Internet to search for health related information. Patients were considerably less frequently referred to Twitter consultations or an exercise group. Most patients did not even know what Twitter is.

Although practice nurses believed that they applied motivational interviewing good, our results do not support this. Some possible explanations why practice nurses applied motivational interviewing insufficiently were: practice nurses were possibly more focussed in following CVRM guidelines which distracts them from applying motivational

interviewing in a correct way [28]. Another explanation could be that motivational interviewing is not an appropriate technique for counselling patients with established CVD or at high cardiovascular risk. The concept of this method is that patients become motivated to decide how they want to change their lifestyle instead of counselling by practice nurses which tells them what to do [29]. It may be possible that patients were not used to this approach or that motivational interviewing did not match with their expectation [30]. Perhaps motivational interviewing skills deteriorate over time, and it is possible that our feedback training prevented this deterioration. Previous research showed that most patients were positive about the care provided by the practice nurse [31]. It is possible that patients were not interested in how the information was given, as long as the patients received the information they needed. Although practice nurses are very enthusiastic about motivational interviewing, it is a complex technique which requires a lot of different skills which complicates the application. Previous Dutch studies already showed that motivational interviewing techniques were incorrectly applied by practice nurses [32,33]. Anyway, this is a disappointing result because motivational interviewing proved to be effective at patients' health outcome measures such as blood pressure, body mass index, alcohol use and total blood cholesterol [34,35]. On the other hand, previous research revealed also regrettable results; motivational interviewing did not enhance lifestyle factors of chronically ill patients in the Netherlands [36,37].

Practice nurses were offered a CVRM web programme to enhance or refresh their knowledge about CVRM. Only half of the practice nurses in the intervention group completed the web programme which may partly explain the low score of CVRM knowledge of practice nurses in the intervention group. Suboptimal CVRM knowledge was also found in previous research [38,39], which could be a problem in passing on knowledge to patients. This could subsequently lead to incorrect knowledge or a lack of knowledge by patients. Accurate knowledge is crucial for counselling patients [40,41]. CVRM is still changing and perhaps practice nurses find it difficult to keep up their knowledge.

Half of the practice nurses indicated that they adopted the recommended practices and referred patients to suited interventions as proposed, but did not necessarily record this in patients' medical records. Patients with established CVD have a higher risk for experiencing depressive symptoms [42,43], which can seriously impair the ability of patients to change their lifestyle [44]. Unfortunately, practice nurses did not made a clear distinction between patients without depressive symptoms and patients with depressive symptoms, although this was an important aspect of our recommendations. Not all practice nurses were aware of the relation between CVD and depressive symptoms, and therefore could have missed patients [45]. Supportive material for recognising patients with mild or severe depressive symptoms we recommended the Patients Health Questionnaire (PHQ-9) [46], this questionnaire was only used by three

practice nurses. Practice nurses mentioned that they did not pay attention to possible depressive symptoms due to lack of time. Also the intervention programme was perceived as too much and the lack of knowledge of the linkage between depression and cardiovascular diseases was a bottleneck. Another bottleneck was the lack of follow-up support and reminders from the research team.

Absence of effects may be due to inadequate intervention delivery from the research team to the practice nurse, or from the practice nurse to the patient. Due to ageing population more patients are in need to see practice nurses, which could cause that practice nurses are overloaded. Therefore practice nurses cannot devote enough time to a patient, which suggests that the practice nurse may not have paid enough attention to our tailored intervention programme. Many practice nurses worked alone in a general practice and were not provided with feedback or someone who motivates them; this could make it difficult for them to enhance their skills or to try a new approach by patients. The absence of effect at patient level can be explained by the fact that not all patients experienced the consequences of CVD or being at high cardiovascular risk. This may result in that patients are less willing to change their lifestyle. Practice nurses can only partly influence patients' lifestyle; patients will make their own decisions how active they follow recommendations or advice for a healthy lifestyle [47]. Furthermore, patients do have problems with medication adherence [48]. Patients may experience problems with medication adherence because of changes in medication due to changes in reimbursements by health insurance. The colour of the medication box or the shape of the pills could have been changed which confuses them. Therefore it could be that patients do not take adequately antihypertensive or cholesterol lowering medication which subsequently maintains high blood pressure or high cholesterol levels. Changing lifestyle is complex for patients with established CVD or at high cardiovascular risk, especially when patients also experience depressive symptoms. They find it difficult to maintain a healthy lifestyle and thereby positively influence cardiovascular risk factors. Therefore, it is unfortunate that practice nurses devoted little attention to possibly depressive symptoms. On the other hand, patients may find it difficult to speak up when they experience depressive symptoms. Patients could possibly not identify their symptoms or are ashamed for having depressive symptoms.

CVRM is of high quality in the Netherlands; patients may have set high standards for this care and are more critical. Although the mean PAM score was not enhanced by our intervention programme, it was high (indicating patient activation) and healthcare professionals emphasised the importance of patients' self-management [49]. Patients were approached through several canals such as websites and public media campaigns. *Chapter 2* showed that patients and healthcare professionals did not completely agree about patients' self-management skills. In the perspective of healthcare professionals, patients with a chronic disease often lack motivation, do not show up during follow-up

visits [50], and had a lack of knowledge and organisation skills [51]. Also patients misperceived their lifestyle behaviours and therefore experience problems with lifestyle changes [52]. Enhancing patients' lifestyle is still a challenge.

Methodological reflections

A variety of research methods were used to answer the main objectives of this thesis. To identify determinants of practice semi-structured interviews were held with healthcare professionals involved in CVRM care and patients with established CVD or at high cardiovascular risk treated in general practices (*Chapter 2*). Then strategies were identified to influence the most important and changeable determinants; therefore, group interviews were held with stakeholders and patients (optional) which is described in *Chapter 4*. The implementation of the tailored intervention programme was evaluated by a cluster randomised controlled trial on practice nurses counselling skills and clinical parameters for patients. Various methods were used: MITI instrument, interviews with practice nurses and cardiovascular patients, questionnaires for practice nurses and cardiovascular patients and data extraction of patients' medical records.

Semi- structured interviews

Semi-structured interviews are a frequently used method for identifying determinants [53-55]. Some determinants perceived by healthcare professionals and patients in previous research were not mentioned during our study [7,8]. No saturation was reached and therefore we could have missed topics. Another limitation was the possible selection bias regarding the sample of patients. Patients who are satisfied with their health and with high literacy might be more willing to participate. Despite these limitations semi-structured interviews yielded valuable data and therefore it seems to be a reliable method that could be used for identifying determinants in healthcare practice [56,57].

Group interviews

This method was proven to be effective in providing in-depth information [55,58,59]. The group interviews with different stakeholders were successfully conducted and resulted in gathering many strategies to influence determinants of practice, which correlates with other studies [62]. These mentioned strategies were used by developing the tailored intervention programmes, an approach that has been used more often [16,62,63]. Other methods such as individual interviews [64] or questionnaires [65] did also not differ in stakeholders perceptions, although these studies did not include healthcare professionals.

Randomised controlled trial

A RCT has the lowest risk of bias for the analysis of a potentially causal link between the intervention and an outcome. In a cluster RCT the level of intervention (trainings and recommendations aimed at practice nurses) is different than the level of analysis (patient outcomes). A strength for our study was that four extra general practices were involved than the actual thirty practices we needed, which enhanced the statistical power [66,67]. Besides the advantages of a cluster RCT, this design has some disadvantages too. A limitation was that practice nurses were not blinded for intervention group or control group which could have affected the outcomes. Our trial was part of the international TICD project conducting parallel five trials in five countries. Looking for common grounds in five different trials we concluded that a compound outcome measure of health professional's performance could be constructed for all trials and should be the primary outcome measure in all five trials. So our primary outcome referred to the professional performance of practice nurses measured by documentation which is a poor outcome, instead of CVRM which was our primary focus.

Audio-tapes and MITI instrument

Practice nurses handed in two audio-tapes of consultations with patients. Previous studies used questionnaires [68], which could have resulted in socially desirable answers whereby no actual counselling techniques of practice nurses were measured. Limitation were that audio-tapes were mostly not returned on time and the possible introduction of selection bias, because practice nurses were allowed to decide which consultation they recorded and sent for evaluation.

We used the MITI code [27] for analysis. Other instruments; the Motivational Interviewing Skills Code (MISC) [69], the Behaviour Change Counselling Index (BECCI) [70] or the Motivational Interviewing Supervision and Training Scale (MISTS) [71]. These instruments were not appropriate for our research. The MITI is an acceptable, economical, and most widely used instrument [72,73], whereby the global scores and behaviour of healthcare professionals was rated. The MITI is not a complicated instrument; the interaction between healthcare professional and patient will be assessed, and is appropriate for coaching and feedback and was therefore suitable in our study. However, the MITI is still in development and therefore not complete.

Other measures used

To evaluate the effect and process outcomes, various measures were used. Questionnaires for patients consisted of validated questionnaires, which were experienced by some patients as too long and complex. Although questionnaires yielded useful data, it was filled out by practice nurses and patients themselves which could lead to socially desirable answers. Medical records contain valuable data about

patients' health. Limitation of this resource was that general practices used different medical record systems; for each new system we had to search where cardiovascular risk factors were listed which makes it time consuming, and due to poor documentation we missed some valuable data which could explain the low score on the primary outcome.

Tailoring implementation strategies

Identification of determinants of practice

The research presented in this thesis was aimed at developing and testing methods for tailored implementation. Research evidence is limited about which method or model could be used best for identifying determinants of current practice, and how to select the most influential determinants [2,54]. For the TICD project five different methods were selected: brainstorming, interviews with healthcare professionals, and interviews with patients, structured group discussions with healthcare professionals, and questionnaires for healthcare professionals. The analyses focused on comparing methods in terms of process (time, recourses and expertise required) and outcomes (consistency of factors, and whether the method highlighted the most important determinants) (*Chapter 3*). Most determinants were identified by brainstorming and interviews with healthcare professionals. Structured group discussions with healthcare professionals and open questions in the questionnaire identified unique additional determinants. Interviews with patients yielded fewer determinants and also required the most time. Results of this study suggested that brainstorming and one additional method should be considered to identify most important determinants in relation to time and costs [74]. Other studies gain successfully determinants whereby individual interviews with healthcare professionals and patients were held or questionnaires were handed out [59,75,76]. To authors' best knowledge, this was the first study that compared methods for identifying determinants head-to-head [74]. Furthermore, Dutch healthcare professionals and patients mentioned 139 plausibly important determinants of practice. Most determinants were mentioned at the level of the health system and not specific to healthcare for patients with established CVD or at high cardiovascular risk.

Identification of strategies to overcome determinants of practice

To learn what method is best used to identify strategies, group interviews were held with various groups: healthcare researchers (including TICD members), quality improvement officers, healthcare professionals, stakeholders (authorities, health insurers or other purchasers of healthcare), and patients (only in the Netherlands) or relatives (only in Norway). Structured group interviews actively contributed to the identification of strategies mentioned during the brainstorm sessions. Individual interviews, group interviews and questionnaires were used in previous studies. Although

these methods yielded many suggestions for strategies, the focus was less broad and methods were not compared [12,13]. In our study, all participants mentioned many strategies whereof only a small part could be incorporated in the tailored intervention programmes, which means that a lot of potentially valuable strategies were not used. The study protocol about gathering strategies for implementation was in some countries applied somewhat differently, and we focused on strategies for practice and therefore missed theory based strategies [15].

Implementation of the tailored intervention programme in the Netherlands

The intervention programme was tailored on a general level, meaning that we collected determinants of current practice and implementation strategies for the targeted patients and health professionals combined. Tailoring at the level of the practices participating would require a resource-intensive approach, which was not feasible in the TICD project. In the Netherlands most stakeholders expressed an interest in continued training of healthcare professionals in motivational interviewing. We have chosen for a new approach of motivational interviewing training because practice nurses' motivational interviewing skills were not enhanced in the past [32,36]. In previous research no feedback or only written feedback was given to practice nurses after motivational interviewing training [32,33]. The feedback training was followed by all practice nurses in the intervention group and was perceived as good and useful. For most practice nurses the feedback training was the primary reason for participation, which could explain that other elements of the intervention programme were less to their interest, and therefore not executed well. Expanding the feedback training could potentially lead to better adherence of motivational interviewing skills.

A new web programme CVRM, made by the Dutch College of General Practitioners, was offered which fits well with the preference of health professionals for online training [77]. Online web programmes for practice nurses are increasingly offered. Most web programmes provide accreditation points which practice nurses must achieve to remain registered. Better registration how many practice nurses made use of these web programmes is needed and whether these web programmes lead to enhanced knowledge.

Stakeholders expressed an interest in using online information tools for patients more actively when counselling patients; in addition to that, internet intervention proved to be effective in reducing cardiovascular risk factors [23,78-80]. Practice nurses mostly referred patients with no depressive symptoms to thuisarts.nl, a well known website by practice nurses [22]. Internet use among elderly could increase significantly [81,82], which makes this a missed opportunity because only a small group of patients mentioned to have been exposed to E-health. Patients with established CVD or at high cardiovascular risk were less into E-health because of the little impact CVD has on their lives [83]. And when patients with established CVD or at high cardiovascular risk use

the Internet it is more for email and not searching for information. It is important that these patients will be notified by healthcare professionals, especially practice nurses, what Internet has to offer and how they can search for information about CVRM. Potentially, practice nurses can familiarise small groups of patients on the Internet, how they can search for information about CVRM and lifestyle interventions. Another form of E-health could be used; to send emails to patients including information on lifestyle advice and personal goals which were agreed during a face-to-face consult. Patients and practice nurses did not use the Twitter consultations which may be because both were not familiar with Twitter. To our knowledge, this was the first intervention programme in the Netherlands, which included Twitter consultations. It appears that this may have been too early for practice nurses and patients. Perhaps in a couple of years, when it is time for the next generation, this way of information transfer may be introduced again.

We have chosen for the recommendation to refer patients with mild depressive symptoms to an exercise group, because physical exercise has a positive effect on cardiovascular risk factors and on depressive symptoms [21], combining this with a group includes also social support. Practice nurses were enthusiastic about this recommendation and referred occasionally patients to an exercise group; this attitude could have enthusiasm patients to go exercising. Previous research showed also an increase in patients exercise pattern [84], especially when patients were involved in decision making [36,68,85]. Dutch healthcare policies and healthcare professionals emphasised the importance of exercise to reduce cardiovascular risk factors, therefore it is advisable that practice nurses continue to refer patients to an exercise group and that this recommendation would be broader implemented in general practice. It would be helpful to identify exercise groups in the local setting, so that practice nurses can easily refer patients.

Just a small group of patients with severe depressive symptoms were referred to the general practitioner, practice nurse mental health or psychologist because most patients were already known in the general practice. Some practice nurses found it not their job to assess depressive symptoms, although we think that it is important that practice nurses signal depressive symptoms and suggest an appropriate treatment for the patient [86,87]. What also needed is a clearer role for the profession of mental health nurses, who have been employed in many general practices in recent years [88]. Furthermore, practice nurses need more information about the relation of CVD and depressive symptoms, which can be provided by practice nurses mental health or during the annual conference. Also a better cooperation between practice nurses and practice nurses mental health is needed. For example, that they discuss patients with possible depressive symptoms for one hour a week.

Current cardiovascular care

Before our intervention programme started, many intervention programmes aimed at patients with established CVD or at high cardiovascular risk have been conducted in the Netherlands. For example, the General Practice Assistance Prevention Project (Huisarts Assistentie Preventie Project, HAPP), in which outreach visits were conducted by practice nurses focusing on implementing guidelines of CVD [89]. The Carpe project provided general practices with outreach visits to help with preventive care and clinical decision making [90-92], which was followed by the project Tailored Prevention (Preventie Maatwerk) [93]. The Patients' Adherence to Lifestyle Advices (Impala) intervention promoted practice nurses to involve patients in decision making [36,68,85,94]. Results of these projects and another observational study [95] showed room for improvement in current cardiovascular care. Results from the European Practice Assessment (EPA) Cardio project revealed that patients at high cardiovascular risk were more in need for preventive care [96] and recording of risk factors in patients medical file could be improved [97]. This was the starting point of our research. During our research, there were other studies conducted to improve CVRM care in the Netherlands. In the Hoorn study, patients in the intervention group with high cardiovascular risk received a cognitive behavioural programme aimed at lifestyle changes given by practice nurses who received motivational interviewing and problem solving technique trainings. Results (published after the start of the TICD project) showed no effect on lifestyle behavioural change [98,99]. For the Self-monitoring and Prevention of Risk factors by Nurse practitioners in the region of Groningen (SPRING) study, practice nurses in the intervention group followed a training programme existing of: cardiovascular risk calculation, treatment guidelines, and motivational interviewing. Patients in the intervention group received treatment for all cardiovascular risk factors and counselling regarding self-monitoring. This intervention revealed no significant effects, however, in both groups the cardiovascular risk assessment score was decreased [100]. The Prevention Consultation (PreventieConsult) project invites patients to fill out a questionnaire which measures the CVD risk estimation. Patients at high cardiovascular risk will be advised to consult the general practice [101]. By one out of five patients an increased cardiovascular risk was found. There is no wide support from policies and the population for the Prevention Consultation, and it remains unclear who should pay for the prevention of CVD [102]. These studies showed, like our study, that there is still room to improve CVRM care. Since several years practice nurses are part of the practice team [28]. They are specialised in providing chronic care and have been educated in lifestyle counselling [103,104]. The clinical guideline cardiovascular risk management and the 'care standard' are tools which could be used in treating patients with established CVD or at high cardiovascular risk [105,106]. Lifestyle counselling is difficult to do well [36,51], where the focus should be on long-term effect [107,108]. Counselling skills of practice

nurses were sub optimal [109], although practice nurses were offered multiple interventions to enhance their counselling skills, the results were disappointing [32,51,110,111]. Also multiple interventions were offered to help practice nurses counselling patients [112], practice nurses used only a few interventions offered due to the lack of motivation by patients, insufficient reimbursement, a lack of proven effectiveness or a lack of overview of interventions [113]. Furthermore, to enhance the professionalization of practice nurses, the Dutch College of General Practitioners provides them with education by courses and e-learning [114]. Also other resources were used to enhance the professionalization such as: a professional magazine, annual conference, developing a topical professional competency, organising expert meetings, websites and Twitter [115]. Many interventions and resources were used to enhance practice nurses' skills, despite practice nurses' motivation, effects were moderate.

Implications for further research

A systematic review of studies evaluating the effectiveness of tailored implementation strategies revealed an overall small to moderate positive effect [116]. With this TICD project we provided knowledge on tailoring implementation strategies. Structured group interviews and individual interviews with healthcare professionals and stakeholders have proven to be effective. Other methods such as case studies, key informants, and direct observations could also be valuable, but were not tested in the TICD project. Nevertheless, how best to select mentioned determinants and strategies for further tailoring largely remains unclear. Therefore, we recommend more research on tailored implementation strategies. In particular on how best to recruit and select determinants and strategies to overcome these determinants. Also the effectiveness and cost-effectiveness of tailoring needs to be evaluated.

To get and keep participants motivated [117], another level of tailoring could be applied. Determinants of current practice and strategies to overcome these determinants could be identified per participating practice. A tailored intervention programme would be developed per practice, so that strategies points where it is needed. In previous research such a tailored intervention programme aimed at general practitioners treating patients with minor anxiety and depressive symptoms showed minor improvements [118]. Future tailored interventions need to be better implemented in general practices, providing more support and feedback from the research team. The cost of more intensive tailoring needs to be balanced against the potentially added value.

Absence of effects of the tailored implementation strategy may be due to inadequate intervention delivery: not all interventions were taken up by all practice nurses. The intervention lasted only seven till ten months. It is possible that practice nurses needed more time to use and implement our intervention programme. But also the lack of reminders by the research team plays an important role for lacking implementation of

the intervention programme. In future research we recommend to guide the practice nurses more intensely during the intervention period and also to extend the intervention period if possible.

Our intervention programme was targeted at practice nurses, therefore we may have better involved them in the development of our programme, because our intervention programme was assessed as 'too much'. The selected determinants could be less relevant to them, even so the selected strategies may be less helpful than we expected. With feedback of the practice nurses on beforehand we could have focussed more on the applicability of the intervention programme in daily practice. In future research a pilot study is recommended to refine an intervention programme more on the targeted group.

Motivational interviewing was perceived as an important determinant and additional training for motivational interviewing was mentioned as strategy by almost all participating groups. For that reason this part was included in our intervention programme. Results revealed no improvements and the recommended MITI scores were not reached. We advise policy officers to collect relevant data whether it makes sense to train motivational interviewing skills of practice nurses who take care of patients with established CVD or at high cardiovascular risk.

Discrepancies in the perception of patient's self-management skills between healthcare professionals and patients need to be sorted out. Current healthcare is more focused on patient's self-management but patients need to be able to apply these skills and healthcare professionals should be able to supervise and motivate patients in this process, whereby the SemaS instrument can be used [119]. Policy officers could develop an improvement proposal and implement this in current care.

Conclusion

The TICD project made a contribution to increased knowledge about tailored implementation methods in chronic illness care generally, and in the Netherlands to knowledge about improving primary care for patients with established CVD or at high cardiovascular risk. For identification of determinants of practice brainstorming and individual interviews with healthcare professionals has proven to be useful methods. Group interviews, such as brainstorming and focus groups, with healthcare professionals, stakeholders and patients, turned out to be very productive for generating strategies to overcome determinants of practice; although, patients were not involved in each country. Following the TICD framework, different stakeholders provided similar types of strategies. The tailored intervention programme was evaluated in a two-arm cluster randomised trial. No effect was measured on the primary outcome. Regarding secondary outcomes, a significant improvement for physical exercise was measured comparing the intervention group with the control group. Results showed no improvements on motivational interviewing skills and the

global scores were mostly below the advised level. The process evaluation showed that half of the practice nurses mentioned that they used and implemented parts of the tailored intervention programme, but did not necessarily record this in patients' medical records. This may have led to underestimation of the results of our intervention programme. Practice nurses assessed the intervention programme as too much. Another bottleneck was the lack of follow-up support and reminders from the research team, lack of time and lack of knowledge of the linkage between depression and cardiovascular diseases. Because this study is one of the first of its kind, and how best to select mentioned determinants and strategies for further tailoring is unclear, more comparative research is needed to develop and test methods for tailoring strategies to determinants for improving healthcare for chronic illness care.

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Summary

Introduction

This thesis was aimed at examining tailored implementation strategies to enhance evidence-based chronic illness care, focusing on cardiovascular risk management (CVRM). This thesis was part of the Tailored Implementation for Chronic Diseases (TICD) project; five different chronic conditions were targeted in five different countries: multi-morbidity (Germany), cardiovascular risk management (CVRM) (the Netherlands), depression in the elderly (Norway), chronic obstructive pulmonary disease (COPD) (Poland), and obesity (UK). Collective goals were composited although each country performed their own research. Tailoring implementation strategies include three main steps. First, identification of determinants of current practice. Then, designing implementation interventions appropriate to the selected determinants; strategies to overcome the selected determinants were identified which were used in developing the tailored implementation programme. Finally, application and assessment of implementation interventions that were reflected to the identified determinants. The tailored intervention programmes were evaluated in a cluster randomised trial on outcome measures. Parallel to the effect evaluation, a process evaluation was conducted.

In *Chapter 1*, we present a general introduction of this thesis wherein cardiovascular diseases (CVD), cardiovascular disease management in the Netherlands, current cardiovascular care, and previous programmes to optimise cardiovascular care is described. Furthermore, we explain the TICD project in more detail and presented the main objectives of this thesis.

Determinants of current CVRM practice perceived by healthcare professionals and patients

In *Chapter 2* determinants of current practice perceived by healthcare professionals involved in CVRM care and patients with established CVD or at high cardiovascular risk treated in general practices, were identified. We used semi-structured interviews which consisted of three parts. The interviews started with an open phase whereby no framework or taxonomy was used. Next, the TICD framework with seven domains ((1) guideline factors, (2) individual healthcare professional factors, (3) patient factors, (4) professional interaction factors, (5) incentives and resources, (6) mandate, authority and accountability, and (7) social, political and legal factors) were introduced. Finally results of previous research in the Netherlands were presented. Participants were asked if they could think of additional determinants they had not thought of in the previous phase. We analysed the mentioned determinants by using the TICD framework. Overall healthcare professionals and patients mentioned determinants that largely related to the same domains. Most determinants were related to patients' education, patients' self-management skills and collaboration of healthcare professionals.

Furthermore, we found also some differences. Healthcare professionals felt that patients do not have enough knowledge about CVRM and self-management, while patients perceived that they do have sufficient knowledge about CVRM and do maintain a healthy lifestyle. Healthcare professionals were negative about the healthcare policies and health insurers. Health insurers retain healthcare professionals from improving CVRM. On the other hand patients were content about their health insurers because there were no problems with their reimbursements. Finally, these semi-structured interviews yielded many determinants of current CVRM practice. These determinants were used in further research in a search for strategies for a tailored implementation programme.

Identifying determinants of care for tailoring implementation in chronic diseases: an evaluation of different methods

Chapter 3 describes a study which evaluates five different methods for identifying determinants of practice. Methods used were: brainstorming, structured group discussions, individual interviews with healthcare professionals and patients, questionnaires with open and closed questions for healthcare professionals. Each country used all five methods to identify determinants of practice for the chronic condition they were addressing. The methods brainstorming, interviews with healthcare professionals and interviews with patients were compared directly with each other. The additional value of structured group discussion after brainstorming, and the additional value of questionnaire following the completion of the other four methods were analysed with reference to the TICD framework. Each method identified plausibly important determinants, although brainstorming and interviews with healthcare professionals identified the greatest number of determinants in all countries. The open questions of the questionnaire and interviews with patients identified fewer determinants. These findings suggest that there is no single best method for identifying determinants, but that a combination of methods should be considered.

Stakeholders' contribution to a tailored implementation programme

Determinants of current CVRM practice were identified and selected. The following step in our project was to identify tailored implementation strategies to influence the selected determinants. In each participating country group interviews were held with the following stakeholders: (1) implementation researchers including TICD members, (2) quality improvement officers, (3) healthcare professionals, (4) authorities, health insurers or other purchasers of healthcare, (5) patients (only in the Netherlands) or relatives (only in Norway). The group interviews were divided in a brainstorm phase followed by a structured interview phase. *Chapter 4* describes the usefulness of group interviews with stakeholders in terms of numbers and use of implementation strategies, and the added value of different stakeholder groups and the structured interview

phase. The brainstorm phase yielded 8-120 unique strategies per group; during the structured interview phase 0-55 unique strategies were added. The group of healthcare professionals provided the most strategies in three countries and healthcare researchers in the other two countries. Overall the types of strategies mentioned during the brainstorm phase and the structured interview phase did not systematically differ between stakeholder groups within each of the countries. In each country, all groups listed strategies which contributed to the tailored implementation programmes, mostly mentioned during brainstorming by healthcare researchers.

Tailored implementation of evidence-based practice for patients with chronic diseases

In *Chapter 5* a range of methods for constructing tailored strategies to implement evidence-based practice in healthcare for patients with chronic diseases was assessed. Data of group interviews, which were divided in a brainstorm phase followed by a structured interview phase as described in *Chapter 4*, were used. We used the TICD framework for analysis. Stakeholders provided many items for interventions and policies to implement evidence-based healthcare for patients with chronic diseases during the brainstorm phase. Most strategies were aimed at individual health professional factors (knowledge, skills, and behaviours), patient factors, and professional interactions. Few strategies were mentioned for the domains guideline factors, incentives and resources, capacity for organisational change, and social, political and legal factors. Mentioned strategies addressed knowledge, skills and behaviours of healthcare professionals consisted of educational strategies and organisational changes. Our study is one of the first comparative studies of methods for tailoring strategies to determinants of practice. Brainstorming in groups of stakeholders proved to be a feasible method to identify many items for improving healthcare.

A tailored implementation programme

We developed a tailored implementation programme based on the mentioned determinants and strategies considering feasibility and potential impact. We described this tailored implementation programme in a study protocol, *Chapter 6*. The tailored implementation programme consisted of three main components: (1) a mandatory feedback training motivational interviewing for practice nurses to enhance their motivational interviewing skills. (2) A new educational web programme CVRM was offered to enhance practice nurses' knowledge about CVRM. (3) The recommendation was given to categorise patients with established CVD or at high cardiovascular risk in three groups, thereby taking into account the presence of depressive symptoms. (4) We recommended practice nurses to handed out patients without depressive symptoms an information card with an option to write down target values of the blood pressure and LDL cholesterol. Keywords were provided on the information card to search information

on the recommended websites 'thuisarts.nl' and 'hartenvaatgroep.nl', and data for Twitter consultation options were given. We asked practice nurses to explain both websites and Twitter consultations verbally. (5) The recommendation for patients with mild depressive symptoms was to refer them to a physical exercise group. This could be an exercise group led by a physical therapist or to 'Nederland in beweging' ('the Netherlands on the move'), a Dutch television programme. (6) Finally, the advice was to refer patients with severe depressive symptoms to their general practitioner, practice nurse mental health or psychologist, as appropriate within the general practice. We asked practice nurses to report in patients' medical records that patients received lifestyle advice or have a perfect lifestyle. Furthermore, we asked them to make a notation if patients have none, mild or severe depressive symptoms and that the patient was referred to a suited recommendation option.

Outcome evaluation

A cluster randomised trial was conducted in the years 2013 and 2014 in the Netherlands. We described the outcome results of this cluster randomised trial in *Chapter 7*. In total 34 general practices participated. General practices were randomly allocated to the intervention group (19 practices, 20 practice nurses; two general practices with two practice nurses each and one practice nurse who worked in two participating general practices) and the control group (15 practices, 14 practice nurses; one practice nurse who worked in two participating general practices). A total of 2229 patients filled out the first questionnaire and provided written informed consent for collecting data of their medical record which consisted of: counselling on CVD related lifestyle, a record of depressive symptoms (none, mild or severe) and a record if patients were referred to E-health, a physical exercise group, or depression treatment respectively. Also the latest values before the intervention period with a retrospective time window of one year and values during the intervention period of systolic blood pressure, LDL cholesterol, body mass index, smoking behaviour were collected. No effect was found on adequate practice nurse performance, a few notations were made by practice nurses that patients were informed about the appropriate recommendations, and only six times practice nurses recorded depressive symptoms. An outcome measure related to the recommendation of physical exercise was more often recorded in the intervention group. At patients' level we found a significant improvement of physical exercise for patients in the intervention group compared to the control group. On the other cardiovascular risk factors which were measured: systolic blood pressure, LDL cholesterol, body mass index, smoking behaviour and diet, the intervention programme had no significant effect. There was no difference found in the effect of the intervention programme between patients with established CVD or at high cardiovascular risk. In general, we can hypothesise that failure of effectiveness might be due to the fact that stakeholders perceived the selected determinants as less

relevant. Other explanations might be that the strategies were less helpful than expected, or that prioritising of determinants or intervention delivery was inadequate.

The PACIC and PAM scores generated from completed questionnaires by patients

In *Chapter 8* we explored whether the Patient Assessment of Chronic Illness Care (PACIC) and Patient Activation Measure (PAM) scores at follow-up, which were generated from completed questionnaires by patients, were related to healthcare counselling by practice nurses. Patients filled out a composite questionnaire, at baseline and at follow-up. This questionnaire included besides patients' characteristics, the PACIC questionnaire and the PAM questionnaire. The PACIC questionnaire assesses patients experience about chronic healthcare, and the PAM questionnaire measures patients' confidence in managing health-related tasks. We measured practice nurses counselling skills at baseline by analysing an audio tape of a consult with a patient by using the MITI (Motivational Interviewing Treatment Integrity). Patients in the intervention group had a lower PACIC and PAM score at baseline and had a significant lower PACIC and PAM score at follow-up. The PACIC score deteriorated over time for patients with established CVD and the PAM score was higher in comparison with patients at high cardiovascular risk. The most important predictors for the PACIC and PAM scores were age, gender and education level. With increasing age, the PACIC and PAM scores both decrease. For both PACIC and PAM, female patients had lower scores. Patients with low education had a higher PACIC score and a lower PAM score than patients with a higher education level. Overall, the mean PACIC score was poor and the mean PAM score was fair to good. Practice nurses counselling skills were not a predictor for the PACIC and PAM scores, even after controlling for the PACIC and PAM score at baseline.

Process evaluation

Parallel to the outcome evaluation we conducted a process evaluation (*Chapter 9*). Hereby we examined if the tailored intervention programme was conducted by practice nurses as proposed and if patients were referred to the suited options of the tailored intervention programme. Practice nurses handed in audio-tapes, semi-structured interviews were held with practice nurses in the intervention group and all practice nurses received a questionnaire. Patients were also interviewed (only patients of practices in the intervention group) and received a questionnaire. The audio tapes were transcribed verbatim and we analysed them by using the MITI. In total 30 practice nurses handed in the requested two audio- tapes (one at the beginning of the intervention period and one after six till nine months), while 4 nurses handed in one recorded consultation only at the start of the programme. All 19 practice nurses in the intervention group were interviewed (one practice nurse dropped out) and 29 practice nurses filled out the questionnaire. For the process evaluation 1496 patients filled out

the questionnaire and twelve were interviewed. All practice nurses in the intervention group received the feedback training motivational interviewing. No improvements were measured, the global score of 3.5 following the MITI was not achieved, even so the percentage of asking more open questions, the score for complex reflections, and the score for non adherent information given did not reach the advised levels. Eleven practice nurses finished the web programme CVRM. Results of the knowledge test revealed a mean score of 3.4 (scale 0-6) for practice nurses in the intervention group and a 4.5 for practice nurses in the control group. This proved to be a significant difference. Half of the practice nurses in the intervention group mentioned that they did pay attention to the recommendation to consider depressive symptoms by patients with established CVD or at high cardiovascular risk and refer patients to the suited recommendations. Only a few practice nurses made records of their activities. Practice nurses did not make a clear distinction between patients without depressive symptoms and patients with depressive symptoms, although this was an important aspect of the intervention programme. The recommendations to give patients an information card, to attend patients at the website 'thuisarts.nl' or the physical exercise group was mostly applied by practice nurses. Practice nurses perceived the tailored intervention programme as too much and there was a lack of follow-up support and reminders from the research team. Only a small group of patients mentioned to have been referred to some recommendations. The information card was most received by patients, patients were considerably less referred to an exercise group or Twitter consults.

In the last chapter of this thesis, *Chapter 10*, the main findings were summarised and discussed in the context of previous research. In addition, a methodological reflection and recommendations for future research were given. This thesis contributed to the body of scientific knowledge on developing tailored implementation interventions and also on improving healthcare for patients with established CVD or at high cardiovascular risk. This study showed that brainstorming and individual interviews with healthcare professionals yielded the most important determinants. By conducting group interviews such as a brainstorm phase followed by a structured phase with scientific researchers and healthcare professionals generated many strategies to influence the selected determinants. These mentioned strategies helped to develop a tailored intervention programme. Evaluation of this programme showed that only a few practice nurses made records in patients' medical records about given lifestyle advice and depressive symptoms by patients. Half of the practice nurses indicated that they occasionally had referred patients but did not record this. Motivational interviewing skills of practice nurses showed no improvements, the scores following the MITI were not reached. However, patients in the intervention group did exercise significantly more than patients in the control group. This TICD project has contributed to the knowledge of methods for tailoring implementation interventions to determinants of practice in

chronic illness care. Further research is needed to compare methods which could be used best in generating determinants and strategies to influence these determinants. Also, for future research we recommended to better involve people on whom the intervention programme is aimed at in the development of the programme.

Samenvatting

Introductie

Dit proefschrift was erop gericht om implementatiestrategieën van interventies op maat te onderzoeken die erop gericht waren om de evidence- based zorg voor chronisch zieken te verbeteren. Dit proefschrift was onderdeel van het project ‘Tailored Implementation for Chronic Diseases (TICD)’. Vijf landen namen hieraan deel, ieder land had zijn onderzoek gericht op een chronische aandoening: multi morbiditeit (Duitsland), overgewicht (Engeland), depressie bij ouderen (Noorwegen), cardiovasculair risicomanagement (CVRM) (Nederland) en chronic obstructive pulmonary disease (COPD) (Polen). Hoewel ieder land afzonderlijk zijn eigen onderzoek heeft uitgevoerd werden er ook gezamenlijke doelen opgesteld. Het ontwikkelen van een interventie op maat bestaat uit drie belangrijke stappen. Als eerst identificeren van determinanten van de huidige gezondheidszorg. Daarna, het ontwikkelen van een interventie programma op maat afgestemd op de geselecteerde determinanten; ideeën om de geselecteerde determinanten te beïnvloeden werden verzameld en op basis van deze ideeën is er een interventie programma op maat ontwikkeld. Tenslotte, evaluatie van het interventie programma. Ons interventie programma ‘CVRM op maat’ is geëvalueerd door middel van een geclusterde gerandomiseerde trial op uitkomstmaten. Parallel hebben wij ook een proces evaluatie uitgevoerd.

Dit onderzoek was gericht op patiënten met hart- en vaatziekten (HVZ) of een hoog risico hierop.

In Hoofdstuk 1 beschrijven wij een algemene introductie van het proefschrift waarin het ziektebeeld hart- en vaatziekten wordt uitgelegd, wat cardiovasculair risicomanagement (CVRM) in Nederland inhoud, hoe de huidige CVRM zorg geregeld is en welke interventie programma’s er zijn onderzocht. Verder leggen wij het TICD project in meer detail uit en presenteren de belangrijkste doelen van dit proefschrift.

Determinanten ervaren door gezondheidszorg professionals en patiënten

In Hoofdstuk 2 werden determinanten (bevorderende en belemmerende factoren) geïdentificeerd die ervaren werden door gezondheidszorg professionals betrokken bij CVRM zorg en door patiënten met HVZ of een hoog risico daarop behandeld in de huisartsenpraktijk. We hebben gebruik gemaakt van semigestructureerde interviews die uit drie onderdelen bestonden. De interviews begonnen met een zogenoemde open fase waarin alles mocht worden opgenoemd. Daarna hebben wij de TICD checklist bestaande uit zeven domeinen ((1) richtlijn factoren, (2) individuele gezondheidszorg professional factoren, (3) patiënten factoren, (4) samenwerkingsfactoren van gezondheidszorg professionals, (5) stimulansen en middelen, (6) mandaat, gezag en verantwoordelijkheid, en (7) sociale, politieke en juridische factoren) gepresenteerd aan de deelnemers en gevraagd of zij aanvullende determinanten konden benoemen. Als laatst presenteerden wij resultaten van vorige onderzoeken en vroegen wij de

deelnemers of ze nu nog meer determinanten konden opnoemen waaraan ze in eerste instantie niet hadden gedacht. De genoemde determinanten hebben wij op basis van de zeven domeinen van de TICD checklist geanalyseerd. Over het algemeen noemden de gezondheidszorg professionals en patiënten determinanten die grotendeels gericht waren op dezelfde domeinen. De meeste determinanten gingen over kennis van patiënten, zelfmanagement van patiënten, samenwerking van gezondheidszorg medewerkers en het Nederlandse gezondheidszorg systeem. Ook werden er verschillen genoemd. Gezondheidszorg professionals waren van mening dat patiënten niet genoeg kennis hebben van CVRM en hun zelfmanagement, terwijl patiënten juist vinden dat ze genoeg kennis hebben van CVRM en dat ze een gezonde leefstijl hebben. Gezondheidszorg professionals waren negatief over het beleid in de gezondheidszorg en over zorgverzekeraars. Ze zijn van mening dat zorgverzekeraars hen beletten in het verbeteren van de CVRM zorg. Patiënten echter waren tevreden over de zorgverzekeraars omdat ze geen problemen ervaren met hun vergoedingen. Ten slotte, deze semigestructureerde interviews leverden vele determinanten op over de huidige CVRM praktijk. Deze determinanten werden gebruikt in verder onderzoek waarbij ideeën werden verzameld om deze determinanten te beïnvloeden en een interventie op maat te ontwikkelen.

Identificeren van determinanten van de chronische zorg voor: evaluatie van verschillende methoden

Hoofdstuk 3 beschrijft een studie waarin vijf verschillende methoden voor het identificeren van determinanten van de huidige chronische zorg werden vergeleken met elkaar. De volgende methoden zijn gebruikt: brainstorm fase, gestructureerde groepsdiscussie, interviews met gezondheidszorg professionals en patiënten, en een vragenlijst met open en gesloten vragen. Ieder deelnemend land gebruikten alle vijf methoden om de determinanten te identificeren. De methoden brainstorm fase, interviews met gezondheidszorg professionals en patiënten werden direct met elkaar vergeleken. De aanvullende waarde van gestructureerde groepsdiscussie na de brainstorm fase, en de aanvullende vragenlijst na het voltooien van de vier voorgaande methoden werden geanalyseerd aan de hand van de TICD checklist. Iedere methode leverde belangrijke determinanten op, maar de brainstorm fase en de interviews met gezondheidszorg professionals leverden de meeste determinanten op in alle vijf de landen. De open vragen in de vragenlijst en de interviews met patiënten leverden minder determinanten op. Deze bevindingen suggereren dat er niet één beste methode is voor het identificeren van determinanten, maar dat een combinatie van methoden overwogen zou moeten worden.

Verzamelen van ideeën om een interventie programma op maat te ontwikkelen door middel van groepsinterviews met belanghebbenden

Determinanten van de huidige CVRM praktijk zijn geïdentificeerd. De volgende stap in het TICD project was om ideeën te verzamelen om de geselecteerde determinanten te kunnen beïnvloeden, dus verbeteren of versterken. Om deze ideeën te genereren heeft ieder deelnemend land groepsinterviews gehouden met de volgende belanghebbenden: (1) implementatie onderzoekers inclusief het TICD team, (2) kwaliteit verbeterende ambtenaren, (3) gezondheidszorg professionals, 4) medewerkers bij de overheid op het gebied van gezondheidszorg, medewerkers bij zorgverzekeringen of gezondheidszorg stichtingen, (5) patiënten (alleen in Nederland) of familieleden (alleen in Noorwegen). De groep interviews waren verdeeld in een brainstorm fase, waarin alle ideeën konden worden genoemd. Gevolgd door een gestructureerde fase, waarin alle ideeën werden gerangschikt op basis van de genoemde determinanten maar ook nieuwe ideeën konden worden genoemd. *Hoofdstuk 4* beschrijft de bruikbaarheid van deze groepsinterviews met belanghebbenden in termen van: aantal ideeën die zijn genoemd per fase, welke belanghebbenden opperden de meeste ideeën, verschillen deze ideeën van elkaar en zijn er bruikbare ideeën genoemd om een interventie programma op maat te ontwikkelen. De brainstorm fase leverde in totaal 8-120 unieke ideeën per groep op, tijdens de gestructureerde fase werden 0-55 unieke ideeën per groep toegevoegd. De groep van gezondheidszorg professionals noemden de meeste ideeën in drie landen terwijl in de overige twee landen de implementatie onderzoekers de meeste ideeën noemden. Over het algemeen verschilden de soorten ideeën die zijn genoemd tijdens de brainstorm fase en de gestructureerde fase niet tussen de verschillende belanghebbenden in de verschillende landen. Uiteindelijk heeft ieder land een implementatie programma op maat ontwikkeld op basis van de genoemde ideeën, in veel gevallen zijn deze ideeën genoemd tijdens de brainstorm fase door implementatie onderzoekers.

Welke ideeën zijn genoemd door belanghebbenden om een interventie op maat te ontwikkelen

In *Hoofdstuk 5* werden een aantal methoden onderzocht voor het genereren van ideeën om een interventie op maat te ontwikkelen voor patiënten met een chronische aandoening. Voor dit onderzoek werd data van de groepsinterviews, die bestonden uit een brainstorm fase gevolgd door een gestructureerde fase, gebruikt. Voor de analyse gebruikten wij de TICD checklist. De belanghebbenden opperden veel ideeën tijdens de brainstorm fase. De meeste ideeën waren gericht op individuele gezondheidszorg professionals (kennis, vaardigheden en gedrag), patiënten factoren en op de samenwerking tussen gezondheidszorg professionals. Minder ideeën werden genoemd die gericht waren op bestaande richtlijnen, stimulansen en middelen, de capaciteit voor organisatorische veranderingen en sociale, politieke en juridische factoren. Ideeën

ter verbetering die waren genoemd met betrekking tot kennis, vaardigheden en gedrag van gezondheidszorg professionals bestonden uit educatie en organisatorische veranderingen. Onze studie is één van de eerste die verschillende methodes vergeleek in het genereren van ideeën om een interventie op maat te ontwikkelen. De brainstorm fase met de belanghebbenden bleek een haalbare methode te zijn om ideeën te genereren om de gezondheidszorg te verbeteren.

Interventie programma ‘CVRM op maat’ (studie protocol)

Wij hebben een interventie programma ‘CVRM op maat’ ontwikkeld op basis van de genoemde determinanten en ideeën, waarbij we rekening hebben gehouden met haalbaarheid en impact. Wij hebben een studie protocol van dit interventie programma geschreven, *Hoofdstuk 6*. Het interventie programma bestond uit drie hoofd componenten: (1) een verplichte feedback training voor praktijkondersteuners op hun motiverende gespreksvoering om deze vaardigheden te verbeteren. (2) Een nieuw web programma CVRM werd aangeboden aan de praktijkondersteuners om hun kennis over CVRM op te frissen of te verbeteren. (3) Dit onderdeel betrof de aanbeveling om patiënten in te delen in drie groepen met respectievelijk geen, milde, en ernstige symptomen van depressie. (4) Voor patiënten zonder depressieve symptomen hadden wij informatiekaartjes ontworpen waarop streefwaarden voor de bloeddruk en LDL cholesterol konden worden ingevuld, evenals zoektermen stonden erop voor de aanbevolen websites ‘thuisarts.nl’ en ‘hartenvaatgroep.nl’, en als laatste data voor Twitter consulten. Aan de praktijkondersteuners werd gevraagd om de websites en Twitter consulten mondeling toe te lichten. (5) De aanbeveling voor patiënten met milde symptomen van depressie was om deze groep door te sturen naar een beweeggroep in de buurt. Dit kon zijn een beweeggroep begeleid door een fysiotherapeut of een verwijzing naar het televisie programma ‘Nederland in beweging’. (6) Bij patiënten met ernstige depressieve symptomen gaven wij de aanbeveling hen door te sturen naar de huisarts, praktijkondersteuner GGZ of een psycholoog. Praktijkondersteuners werden gevraagd om in het medisch dossier van de patiënt te noteren of patiënten leefstijladviezen hadden gekregen of dat de patiënt al een perfecte leefstijl had. En verder hebben we de praktijkondersteuner gevraagd om in het medisch dossier te vermelden of de patiënt geen, milde of ernstige symptomen van depressie had en welke geschikte aanbeveling de patiënt had ontvangen.

Uitkomsten evaluatie van het interventie programma ‘CVRM op maat’ door middel van een gerandomiseerde trial

In Nederland is een gerandomiseerde trial uitgevoerd in 2013 en 2014. We hebben de uitkomsten evaluatie van deze gerandomiseerde trial beschreven in *Hoofdstuk 7*. In totaal hebben 34 praktijken deelgenomen. Huisartsenpraktijken zijn willekeurig toegewezen naar 19 interventie praktijken (20 praktijkondersteuners; twee

huisartsenpraktijken met twee praktijkondersteuners per praktijk, en één praktijkondersteuner was werkzaam in twee praktijken) en 15 controle praktijken (14 praktijkondersteuners; één praktijkondersteuner was werkzaam in twee praktijken). In totaal hebben 2229 patiënten de eerste vragenlijst ingevuld en hebben ze schriftelijk toestemming gegeven zodat wij gegevens mochten genereren vanuit hun medisch dossier. De volgende gegevens hebben wij verzameld uit het medisch dossier: was er een aantekening gemaakt door de praktijkondersteuner dat de patiënt leefstijl adviezen heeft ontvangen conform CVRM. Was er een aantekening gemaakt dat de patiënt geen, milde of ernstige depressieve symptomen had gedurende de interventie periode en was er vervolgens een notitie gemaakt dat de patiënt is geïnformeerd over de door ons opgestelde passende aanbevelingen. Ook zijn er uit het medisch dossier patiënten gegevens verzameld met betrekking tot het hebben van HVZ of een hoog risico voor HVZ zoals systolische bloeddruk, LDL cholesterol, rookgedrag, en body mass index. Deze laatste gegevens zijn met terugwerkende kracht verzameld tot maximaal een jaar geleden vanaf de start van de interventie periode en de laatste gegevens gedurende de interventie periode. Geen effect was er gevonden op adequate uitvoering van het interventie programma door praktijkondersteuners, enkele praktijkondersteuners hadden bij enkele patiënten aantekening gemaakt in het medisch dossier dat ze waren geïnformeerd over een geschikte aanbeveling. Praktijkondersteuners hebben alleen in zes gevallen een aantekening gemaakt over depressieve symptomen. De praktijkondersteuner in de interventie groep heeft vaker een aantekening gemaakt dat de patiënt was geïnformeerd over een beweeggroep dan praktijkondersteuners in de controle groep. Op patiënten niveau was een significante verbetering gevonden dat patiënten in de interventie groep meer zijn gaan bewegen dan patiënten in de controle groep. Voor de overige HVZ risico factoren die zijn gemeten: systolische bloeddruk, LDL cholesterol, body mass index, rookgedrag en dieet, waren geen significante verschillen gemeten tussen de interventie groep en de controle groep. Er was ook geen verschil in effect gevonden van het interventie programma tussen patiënten met hart- en vaatziekten en patiënten met een verhoogd risico op HVZ. In het algemeen kunnen we veronderstellen dat het falen van de effectiviteit van het interventie programma kan zijn doordat de determinanten die geselecteerd waren minder relevant waren dan in eerste instantie gedacht. Het zou kunnen dat de geselecteerde strategieën minder behulpzaam waren dan van tevoren gedacht. Maar ook dat verkeerde determinanten en strategieën zijn geselecteerd of dat ons interventie programma niet goed is overgedragen op de praktijkondersteuners.

Is motiverende gespreksvoering van praktijkondersteuners een voospeller hoe de patiënt de gezondheidszorg en zijn/haar zelfmanagement vaardigheden ervaart?

In *Hoofdstuk 8* hebben wij gekeken of de Patient Assessment of Chronic Illness Care (PACIC) score en de Patient Activation Measure (PAM) score waren gerelateerd aan de motiverende gespreksvoering van de praktijkondersteuners. Patiënten hebben een samengestelde vragenlijst ingevuld aan het begin van het onderzoek en op het eind. Deze vragenlijst bevatte naast patiënten kenmerken de PACIC en de PAM vragenlijsten. De PACIC vragenlijst meet hoe patiënten de chronische gezondheidszorg ervaren en de PAM vragenlijst meet het vertrouwen die patiënten hebben in hun zelfmanagement vaardigheden. We hebben de motiverende gespreksvoering van praktijkondersteuners gemeten aan het begin van de interventie periode door middel van een audio opname van een gesprek met een patiënt. De motiverende gespreksvoering werd geanalyseerd met behulp van de MITI (Motivational Interviewing Treatment Integrity). Patiënten in de interventie groep hadden een lagere PACIC en PAM score aan het begin van het onderzoek en een significant lagere PACIC en PAM score aan het eind van de interventie periode in vergelijking met de controle groep. Patiënten met HVZ ervaren de chronische zorg in de loop van de tijd slechter, maar hun zelfmanagement was verbeterd in vergelijking met de ervaring van patiënten met een hoog risico op HVZ. De belangrijkste voorspellers voor de PACIC en de PAM scores waren leeftijd, geslacht en opleidingsniveau. De PACIC en PAM scores werden lager naarmate de leeftijd steeg. Vrouwelijke patiënten scoorden voor beide vragenlijsten lager. Patiënten met een lagere opleiding hadden een hogere PACIC score en een lagere PAM score in vergelijking met patiënten met een hogere opleiding. Over het algemeen was de gemiddelde PACIC score matig en de gemiddelde PAM score redelijk tot goed. Motiverende gespreksvoering van praktijkondersteuners bleek uiteindelijk geen voorspeller voor de PACIC en PAM score, ook niet na het corrigeren voor de PACIC en PAM score aan het begin van het onderzoek.

Proces evaluatie van het interventie programma ‘CVRM op maat’

Parallel aan de uitkomst evaluatie hebben wij ook een proces evaluatie uitgevoerd, *hoofdstuk 9*. We hebben onderzocht of het interventie programma ‘CVRM op maat’ werd uitgevoerd door de praktijkondersteuners zoals wij hebben bedoeld en of patiënten zijn doorverwezen naar de door ons voorgestelde aanbevelingen. Gegevens zijn verzameld bij praktijkondersteuners en patiënten. Aan praktijkondersteuners is gevraagd om audio opnames op te sturen van twee consulten met een patiënt, deel te nemen aan een semigestructureerd interview (alleen praktijkondersteuners in de interventie groep) en een vragenlijst in te vullen. Alle patiënten ontvingen een vragenlijst en enkele patiënten van deelnemende huisartsenpraktijken in de interventie groep werden geïnterviewd. De audio opnames hebben wij geanalyseerd met behulp van de MITI. In totaal hebben 30 praktijkondersteuners twee audio opnames ingeleverd (één in

aan het begin en één na de interventie periode), vier praktijkondersteuners hebben alleen aan het begin een audio opname ingestuurd. Alle 19 praktijkondersteuners zijn geïnterviewd (één praktijkondersteuner was voortijdig gestopt) en 29 van hen hebben de vragenlijst ingevuld en geretourneerd. Voor de proces evaluatie hebben 1496 patiënten de vragenlijst ingevuld en 12 patiënten zijn geïnterviewd. Alle praktijkondersteuners hebben de feedback training motiverende gespreksvoering (MI) ontvangen. Er zijn geen verbeteringen gemeten, de geadviseerde globale score van 3,5 is nagenoeg niet behaald. Evenals het percentage om meer vragen te stellen, complexe reflecties te maken en de score van MI ontrouw informatie verstrekken zijn niet bereikt. Elf praktijkondersteuners hebben het web programma CVRM afgerond. Praktijkondersteuners in de interventie groep scoorden een 3,5 (schaal 0-6) op de kennis test over CVRM, terwijl de praktijkondersteuners in de controle groep een 4,5 scoorden, dit bleek een significant verschil. De helft van de praktijkondersteuners in de interventie groep gaven aan dat ze aandacht hadden besteed aan de aanbeveling om patiënten in te delen in drie groepen aan de hand van depressieve symptomen en ze door te sturen naar de door ons geselecteerde aanbevelingen. Alleen een klein aantal van de praktijkondersteuners hebben aantekeningen hierover gemaakt in het medisch dossier. Tevens hadden praktijkondersteuners geen duidelijk onderscheid gemaakt of patiënten nu geen, matige of ernstige depressieve symptomen hadden, hoewel dit een belangrijk aspect was van het interventie programma 'CVRM op maat'. De aanbevelingen om patiënten een informatiekaartje te geven, ze te attenderen op de website 'thuisarts.nl' of om ze te informeren over een beweeggroep zijn het meeste toegepast door de praktijkondersteuners. De aanbeveling over Twitter consulten was het minst toegepast. Praktijkondersteuners hebben het interventie programma als te veel ervaren en ook het gebrek aan follow-up en ondersteuning van het onderzoeksteam werd als gebrek aangemerkt. Slechts een kleine groep patiënten gaf aan dat ze waren doorwezen naar enkele interventie opties. Het informatiekaartje was het meest ontvangen door patiënten, patiënten zijn aanzienlijk minder doorwezen naar een beweeggroep of Twitter consulten.

Discussie

In het laatste hoofdstuk van dit proefschrift, *Hoofdstuk 10*, werden de belangrijkste bevindingen samengevat en bediscussieerd in het kader van recente literatuur. Daarnaast werd een methodologische reflectie gegeven en werden er aanbevelingen gedaan voor toekomstig onderzoek. Dit proefschrift draagt bij aan de wetenschappelijke kennis op het gebied van de aanpak voor het ontwikkelen van interventies op maat, maar ook op het gebied van de gezondheidszorg voor patiënten met hart- en vaatziekten of een hoog risico daarop. Dit onderzoek leert ons dat brainstorm sessies en interviews met gezondheidszorg professionals de meest belangrijke determinanten opleverden. Het houden van groepsinterviews zoals een

brainstorm gevolgd door een gestructureerde fase met onderzoekers en gezondheidszorg professionals genereerde vele ideeën om de geselecteerde determinanten te beïnvloeden. Vanuit deze ideeën is het interventie programma 'Maatwerk bij CVRM' ontwikkeld. Evaluatie van dit interventie programma: alleen enkele praktijkondersteuners hadden in het medisch dossier van de patiënt gerapporteerd of de patiënt depressieve symptomen had. De helft van de praktijkondersteuners gaven aan dat ze patiënten af en toe hadden geattendeerd op de aanbevelingen maar dit vaak niet hadden genoteerd. Motiverende gespreksvoering was niet verbeterd en de richtlijnen volgens de MITI werd niet behaald. Wel zijn patiënten in de interventie groep significant meer gaan bewegen dan patiënten in de controle groep. Het TICD project heeft een bijdrage geleverd aan de kennis over de methode hoe een interventie op maat ontwikkeld kan worden voor de chronische gezondheidszorg. Verder onderzoek is nodig om methoden te vergelijken welke het beste kunnen worden ingezet voor het genereren van determinanten en ideeën om deze determinanten te beïnvloeden. Ook is het aan te bevelen dat in toekomstig onderzoek de mensen waarop het interventie programma gericht is meer te betrekken bij de ontwikkeling van een programma.

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11. Huntink E, Wensing M, van Lieshout J. Maatwerk bij CVRM: Een op maat ontwikkelde interventieprogramma voor praktijkondersteuners in huisartsenpraktijken gericht op patiënten met (een hoog risico op) hart- en vaatziekten. Ingediend.

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Curriculum Vitae

Elke Huntink werd geboren op 24 februari 1980 in Braamt, gemeente Montferland. In 1996 behaalde zij haar MAVO diploma aan het Ludgercollege in Doetinchem. Vervolgens volgde zij de opleidingen MBO-verzorging bij het Graafschap college in Doetinchem, en HBO-verpleegkunde bij de Hogeschool Arnhem en Nijmegen. Na enkele jaren te hebben gewerkt als verpleegkundige in het Radboudumc en het Rijnstate ziekenhuis ging zij in 2007 Gezondheidswetenschappen studeren aan de Vrije Universiteit te Amsterdam. Na haar wetenschappelijke stage bij de GGD Gelre-IJssel studeerde zij af in 2009 in de richting 'Prevention and Public Health'. Na afronding van haar studie heeft zij gewerkt op de afdeling Oogheelkunde in het Radboudumc als studietoelichting. Op 1 juli 2012 zette ze haar carrière voort op de afdeling IQ healthcare van het Radboudumc als promovenda op het project 'Tailored Implementation for Chronic Diseases'. Elke bleef naast haar studie en promotietraject werken als verpleegkundige op oproepbasis in het Rijnstate ziekenhuis. Momenteel is zij werkzaam als research coördinator bij het Rijnstate ziekenhuis. Zij woont samen met haar man Rob Loskamp, dochter Maud en haar 2 konijnen Elvis en Kees in 's-Heerenberg.