Self-management support by primary care nurses

Between promise and practice

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Zelfmanagementondersteuning door praktijkondersteuners
Tussen belofte en praktijk

(met een samenvatting in het Nederlands)

Proefschrift

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CONTENTS

CHAPTER 1

General Introduction

GENERAL INTRODUCTION

Self-management for patients with a chronic condition is widely considered an essential part of chronic disease management to enhance patients' quality of life and care and to reduce healthcare costs.[1-5] Health and governmental policies encourage the adoption of self-management in routine care, in which patients have an active role in managing their condition and actively collaborate with healthcare providers. Interventions to support patients' self-management are increasingly evaluated within research settings. However, despite the large body of evidence, the causal pathway towards health benefits is still not fully understood. In Dutch primary care, comprehensive self-management interventions are normally not applied in a programmatic way but integrated in routine mono-disciplinary consultations. Whether providing self-management support fits within a primary care context and whether primary care nurses are equipped with the competences to support patients' self-management, need to be further clarified.

In this chapter, we describe the concept of self-management, its effectiveness and meaning for patients' daily life and nurses' routine care and how we can contribute to enhancing our understanding of how self-management interventions work and which patients benefit in the context of primary care.

THE CONCEPT OF SELF-MANAGEMENT IN CHRONIC CARE

Worldwide, the number of patients with one or more chronic conditions is expanding. Given demographic trends with an aging society, behavioural patterns and diagnostic improvements, this number is expected to increase over the next decades.[6,7] In the Netherlands, approximately 5.1 million people have one or more chronic conditions, such as cardiovascular diseases, respiratory diseases, and diabetes mellitus. Comparable to other European countries, the vast majority of older people suffer from at least one chronic condition.[8] Chronic conditions are the leading cause of mortality and morbidity in Europe, and projections indicate these will impose an even larger burden in the future.[8,9] To safeguard quality, continuity and affordability of the care for these patients, chronic care has shifted from the traditional professional driven healthcare model towards a more patient-centred driven healthcare model.[10] Instead of being a passive recipient of care, patients are expected to be actively involved in their care.[10] In accordance with this paradigm shift self-management is widely adopted in chronic disease management, in which patients are active and informed partners in taking responsibility in decisions affecting their chronic disease.[11,12] Throughout this thesis the widely applied patient focused definition of Barlow et al is used to define self-management, in which self-management

is regarded as: *'the individual's ability to manage the symptoms, treatment, physical and psychosocial consequences and behaviour changes inherent in living with a chronic condition. Efficacious self-management encompasses ability to monitor one's condition and to effect the cognitive, behavioural and emotional responses necessary to maintain a satisfactory quality of life'*.[10]

This definition highlights that self-management encompasses behaviour change and enhancing skills, such as changing physical inactivity and unhealthy diets, as well as coping with emotional and social impact of the chronic condition in daily life.[10]

Self-management is identified as one of the four major components of the Chronic Care Model in which the patient has a central position in the healthcare process and influences both community and the healthcare system to achieve better chronic disease management.[7] Furthermore, self-management is included in the recently defined concept of health, in which health is regarded as *'the ability to adapt and to self-manage, in the face of social, physical and emotional challenges'*.[13]

Since the introduction of self-management in chronic care, self-management is widely embedded in the governmental and health policies, general nursing competences profile, nurse and patient education.[14-16] For example, self-management is embedded in disease management programmes and healthcare standards for some of the most prevalent chronic conditions, such as diabetes mellitus type 2, cardiovascular diseases, chronic obstructive pulmonary disease (COPD) and asthma. As a result of a shift of chronic disease management from secondary care to primary care and the reallocation of patients from general practitioners to primary care nurses,[17] nurses are designated to adopt self-management into their routine care as they play an eminent role in providing subsequent support of these patients according to healthcare standards of disease management.[18,19] Despite the enthusiasm of policymakers, researchers, healthcare providers and patients, self-management generally remains an umbrella and contested concept. Definitions are used interchangeably and do not specifically describe what the concept entails and its meaning for nurses' daily practice and accompanying competences remains unclear. Consequently, self-management is interpreted and applied in many different ways.[10,20,21]

EFFECTIVENESS OF SELF-MANAGEMENT

Over the last decade, many interventions to enhance patients' self-management are developed and evaluated. Several meta-analyses have evaluated the effectiveness of such interventions and showed improved health-related outcomes, positive effects on quality of life and decreased healthcare costs.[1-5] However, more recently conducted trials have shown no effects[22-25] or even negative effects of self-management interventions.[26,27] The variance in outcomes can be explained by a heterogeneity in patient characteristics, outcome measures, content, intensity, duration, mode of delivery of interventions, and scarcely measured and reported intervention fidelity, which hampers our understanding of the effectiveness of self-management interventions. Recently, within our TASTE (TAilored Self-managemenT & Ehealth) research programme,[28] we performed several individual patient data (IPD) meta-analyses attempting to unravel the heterogeneity in outcomes across trials and by assessing which program-specific characteristics and patient-specific characteristics are associated with improved outcomes.[29-32] These analyses were carried out simultaneously in patients with heart failure and in patients with COPD. From these IPD meta-analyses we can conclude that patients benefit from self-management interventions in terms of an improved health-related quality of life at 12-months and a reduction in disease-specific hospitalisations. Furthermore, patients with COPD showed a reduction in all-cause hospitalisations and patients with heart failure showed a reduction in heart failure-related hospital admissions and death.[29-32] The IPD meta-analyses showed a diffuse pattern of treatment effects, which is caused by limited details on interventions, intervention fidelity, contextual factors and the diversity of the collection of (baseline) variables.[33] These aspects emphasise the complexity of unravelling the heterogeneity of trial outcomes. To enhance our understanding of how such interventions work and which patients benefit, the use of a theoretical framework underlying such interventions is needed to specify and understand the active ingredients of interventions and working mechanisms underlying the effects of self-management interventions.[34,35] A promising theoretical framework to develop behaviour change interventions is the comprehensive Behaviour Change Wheel (BCW).[36,37] This multiple layer framework guides the systematic understanding of the behaviour that needs to change by using the COM-B model (capability, opportunity, motivation generating behaviour). The BCW finally results in the selection of proper behaviour change techniques -as active ingredients- which need to be applied to target the behaviour.[36,37]

Furthermore, a thorough process evaluation, including an evaluation of the intervention fidelity, nurses' and patients' perspectives towards the intervention and contextual factors, enhances further understanding of the effectiveness of self-management interventions.[38,39]

THE MEANING OF SELF-MANAGEMENT FOR PATIENTS

In the daily lives of patients, it is inevitable for patients not to self-manage their chronic condition.[11] Integrating the consequences of the condition in daily life is challenging as this requires certain tasks from patients, such as medication management and emotional management.[11] Furthermore, living with a chronic condition demands adapting healthy behaviours (such as staying physically active and eating healthy) to decrease a further progression of the condition and improve patients' prognosis.[12] Accomplishing these challenging tasks requires skills, such as problem-solving, decision making, resource utilisation, formation of a partnership with healthcare professionals, taking action, and self-tailoring.[11] Moreover, it demands patients to change their behaviour, which is essential to boot up a sequence of effects.[40] Some patients succeed in achieving these tasks themselves.[41] However, the majority of patients need support of healthcare providers in self-managing their condition.[41,42] Patients differ in their capacity in making well-informed decisions, changing their (unhealthy) behaviour and maintaining these changes, and dealing with other priorities in life due to personal circumstances.[43,44] Furthermore, patients' needs and coping behaviour depends on the duration and severity of the condition.[41,42] As such, acquiring and mastering self-management skills is complex and involves an active role of patients' in their healthcare process.[11,45]

THE MEANING OF SELF-MANAGEMENT FOR NURSES

As nurses play a prominent role in providing self-management support, self-management support has gained a central position in the new Dutch general nursing competence profile,[15] in Dutch healthcare standards,[46-48] and is increasingly integrated in the vocational training of primary care nurses.[16] This central position assumes a broad integration of self-management in nurses' role and tasks in their busy daily practice. However, incorporating self-management support into daily practice is complex to achieve. Nurses need to comply with other clinical demands as prescribed in the healthcare standards within a short consultation time and often infrequent follow-up consultations, leaving less time and continuation for adequate self-management support. Adequate self-management support requires from nurses to apply other strategies in their support then providing advice and transferring knowledge about patients' condition, which they are traditionally taught and expected.[14] Nurses are required to adapt their expert-oriented consultation style towards a more a coaching-oriented consultation style to ensure partnership and person-centred care.[7,12,14] This coaching-oriented consultation style asks from nurses to shift between different roles, such as being an expert or a coach in specific situations, dependent on patients' needs.[41,42] Nurses are expected to support patients in all aspects

of self-management, such as decision support, behaviour change support, goal setting, problem-solving, and coordination of care.[11,12,49] Consequently, self-management support requires from nurses to adapt their communication skills and psychological counselling techniques. They need to understand the impact of the chronic disease from the individual patients' perspective, identify patients' strengths and current capacities, improve their knowledge of community support resources, and collaborate with other care providers.[14,50]

Nurses should involve the patient as a partner, who makes his or her own well-informed decisions and tailor their support to the patient's own situation.[11] Remarkably, how nurses could support patients' self-management and their required competences of nurses has not been specifically described.[50,51] The lack of clarity in the meaning of self-management support for nurses, combined with the variety of definitions and interpretations of what self-management entails within the daily context of competing other clinical demands, has led to substantial confusion.[20,52,53] Nurses regard self-management predominantly as a shift in responsibility from the professional to the patient to increase patients' adherence to the prescribed regimen, whereas other nurses consider self-management as a concept to optimise patients' skills and change health behaviour.[21,54] Nurses' views of self-management directly influences how they provide and tailor self-management support; some nurses actively support patients in enhancing their necessary skills, whereas others more cautiously let patients become more active in their disease management.[54]

Adequate self-management support is complex to accomplish and implies behaviour change in nurses for which they often need to be trained. The person-centred approach, including an active involvement of patients, is integrated in the education of nurses and includes motivational interviewing.[16,20,55] However, nurses often refrain from putting these principles and techniques into their routine practice. They tend to focus on traditional tasks such as supporting patients to adhere to the professional advice instead of integrating the chronic condition in their daily life.[16,55,56]

AIMS OF THE THESIS

The general aim of this thesis is to unravel how self-management interventions work and which patients benefit from such interventions within the context of primary care. We aim to examine how and to what extent nurses provide self-management support in their current practice. Furthermore, we aim to comprehensively develop and evaluate a nurse-led behaviour change intervention for primary care (the Activate intervention). In this intervention, we deliberately deduct the complexity of self-management interven-

tions by targeting the intervention at one self-management component, namely physical activity, rather than focusing on the concept of self-management as a whole. By targeting the intervention to a heterogeneous subgroup of primary care patients, namely patients at risk for cardiovascular disease, we aim to identify how the Activate intervention works and which patients benefit. The BCW -as theoretical framework- guided the development of the intervention to increase patients' physical activity and to equip nurses with the required competences to deliver this intervention. A thorough evaluation of the intervention enables our understanding of the effectiveness, the active ingredients, patients' and nurses' perspectives, intervention fidelity and contextual factors of the intervention and which patients benefit from the intervention.

OUTLINE OF THE THESIS

To gain insight in how and to what extent nurses provide self-management support in their current practice, we examine which health and self-management topics nurses addressed, the duration and frequency of these addressed topics and the applied behaviour change techniques as part of their self-management support in routine consultations **(chapter 2)**. To understand the different components of a behaviour change intervention and to allow an in-depth evaluation, a detailed description of the development of the Activate intervention and the training programme for nurses, study design, methods and methodological challenges is provided **(chapter 3)**. Patients' experiences with the Activate intervention in relation to their success in increasing their physical activity are explored using a convergent mixed methods design **(chapter 4)**. Nurses' perceptions towards delivering the Activate intervention and towards the feasibility of this intervention for future practice are qualitatively explored **(chapter 5)**.The effectiveness of the Activate intervention and the identification of pre-specified potential patient-related characteristics that modify behaviour change have been evaluated in a two-armed cluster-randomised controlled trial **(chapter 6)**. The fidelity of the delivery of the Activate intervention is evaluated to explore whether nurses delivered the intervention as intended **(chapter 7)**. Finally, the main findings and methodological aspects of the intervention and studies are reflected on **(chapter 8)**. This reflection includes a specific emphasis on the nurses' role in providing self-management support. Furthermore, this reflection provides recommendations for clinical practice, education, policymakers and future research.

REFERENCES

1. Chodosh J, Morton SC, Mojica W, et al. Meta-analysis: Chronic disease self-management programs for older adults. *Ann Intern Med*. 2005;143(6):427-438.
2. Zwerink M, Brusse Keizer M, van der Valk PDLPM, et al. Self management for patients with chronic obstructive pulmonary disease. *Cochrane Database Syst Rev*. 2014(3):CD002990.
3. Effing T, Kerstjens H, van der Valk P, Zielhuis G, van der Palen J. (Cost)-effectiveness of self-treatment of exacerbations on the severity of exacerbations in patients with COPD: The COPE II study. *Thorax*. 2009;64(11):956-962.
4. Deakin T, McShane CE, Cade JE, Williams RD. Group based training for self-management strategies in people with type 2 diabetes mellitus. *Cochrane Database Syst Rev*. 2005;(2):CD003417.
5. Jovicic A, Holroyd-Leduc JM, Straus SE. Effects of self-management intervention on health outcomes of patients with heart failure: A systematic review of randomized controlled trials. *BMC Cardiovasc Disord*. 2006;6:43.
6. Mathers CD, Loncar D. Projections of global mortality and burden of disease from 2002 to 2030. *PLoS Med*. 2006;3(11):e442.
7. Wagner EH. Chronic disease management: What will it take to improve care for chronic illness? *Eff Clin Pract*. 1998;1(1):2-4.
8. Nationaal zorgkompas. Available from: https://www.volksgezondheidenzorg.info/onderwerp/chronische-ziekten-en-multimorbiditeit/cijfers-context/prevalentie. Assessed 20 February 2018.
9. World Health Organisation (2014). Global status report on noncommunicable diseases. Geneva, Switzerland: World Health Organisation.
10. Barlow J, Wright C, Sheasby J, Turner A, Hainsworth J. Self-management approaches for people with chronic conditions: A review. *Patient Educ Couns*. 2002;48(2):177-187.
11. Lorig K, Holman H. Self-management education: History, definition, outcomes, and mechanisms. *Ann Behav Med*. 2003;26(1):1-7.
12. Bodenheimer T, Lorig K, Holman H, Grumbach K. Patient self-management of chronic disease in primary care. *JAMA*. 2002;288(19):2469-2475.
13. Huber M, Knottnerus JA, Green L, et al. How should we define health? *BMJ*. 2011;343:d4163.
14. Elissen A, Nolte E, Knai C, et al. Is Europe putting theory into practice? A qualitative study of the level of self-management support in chronic care management approaches. *BMC Health Serv Res*. 2013;13:117-6963-13-117.
15. Schuurmans MJ, Lambregts J, Projectgroep V&VN 2020, Grotendorst A (2012). *V&VN 2020. deel 3 beroepsprofiel verpleegkundige. [Part 3. Dutch general nursing competence profile].* Utrecht, the Netherlands: V&VN.
16. Noordman J, van der Weijden T, van Dulmen S. Effects of video-feedback on the communication, clinical competence and motivational interviewing skills of practice nurses: A pre-test posttest control group study. *J Adv Nurs*. 2014;70(10):2272-2283.
17. Tsiachristas A, Hipple Walters B, Lemmens KMM, Nieboer A, Rutten-van Mölken MPMH. Towards integrated care for chronic conditions: Dutch policy developments to overcome the (financial) barriers. *Health Policy*. 2011;101(2):122-132.
18. Baan CA, Hutten JBF, Rijken PM (2003). *Afstemming in de zorg: Een achtergrondstudie naar de zorg voor mensen met een chronische aandoening. [Coordination of care. A study into the care for people with a chronic condition].* Bilthoven, the Netherlands: RIVM.

19. van Houtum L, Heijmans M, Rijken M, Groenewegen P. Perceived quality of chronic illness care is associated with self-management: Results of a nationwide study in the netherlands. *Health Policy*. 2016;120(4):431-439.
20. Jonsdottir H. Self-management programmes for people living with chronic obstructive pulmonary disease: A call for a reconceptualisation. *J Clin Nurs*. 2013;22(5-6):621-637.
21. Sadler E, Wolfe CDA, McKevitt C. Lay and health care professional understandings of self-management: A systematic review and narrative synthesis. *SAGE Open Med*. 2014;2:2050312114544493.
22. Bischoff EW, Akkermans R, Bourbeau J, van Weel C, Vercoulen JH, Schermer TR. Comprehensive self management and routine monitoring in chronic obstructive pulmonary disease patients in general practice: Randomised controlled trial. *BMJ*. 2012;345:e7642.
23. Kennedy A, Bower P, Reeves D, et al. Implementation of self management support for long term conditions in routine primary care settings: Cluster randomised controlled trial. *BMJ*. 2013;346:f2882.
24. Bucknall CE, Miller G, Lloyd SM, et al. Glasgow supported self-management trial (GSuST) for patients with moderate to severe COPD: Randomised controlled trial. *BMJ*. 2012;344:e1060.
25. DeWalt D, Schillinger D, Ruo B, et al. Multisite randomized trial of a single-session versus multisession literacy-sensitive self-care intervention for patients with heart failure. *Circulation*. 2012;125(23):2854-2862.
26. Fan VS, Gaziano JM, Lew R, et al. A comprehensive care management program to prevent chronic obstructive pulmonary disease hospitalizations: A randomized controlled trial. *Ann Intern Med*. 2012;156(10):673-683.
27. Takahashi PY, Pecina JL, Upatising B, et al. A randomized controlled trial of telemonitoring in older adults with multiple health issues to prevent hospitalizations and emergency department visits. *Arch Intern Med*. 2012;172(10):773-779.
28. Trappenburg J, Jonkman N, Jaarsma T, et al. Self-management: One size does not fit all. *Patient Educ Couns*. 2013;92(1):134-137.
29. Jonkman N, Westland H, Groenwold RHH, et al. Do self-management interventions work in patients with heart failure? an individual patient data meta-analysis. *Circulation*. 2016;133(12):1189-1198.
30. Jonkman NH, Westland H, Trappenburg JC, et al. Characteristics of effective self-management interventions in patients with COPD: Individual patient data meta-analysis. *Eur Respir J*. 2016;48(1):55-68.
31. Jonkman N, Westland H, Trappenburg J, et al. Do self-management interventions in COPD patients work and which patients benefit most? an individual patient data meta-analysis. *Int J Chron Obstruct Pulmon Dis*. 2016;11:2063-2074.
32. Jonkman N, Westland H, Groenwold RHH, et al. What are effective program characteristics of self-management interventions in patients with heart failure? an individual patient data meta-analysis. *J Card Fail*. 2016;22(11):861-871.
33. Jonkman N, Groenwold RHH, Trappenburg JCA, Hoes A, Schuurmans M. Complex self-management interventions in chronic disease unravelled: A review of lessons learnt from an individual patient data meta-analysis. *J Clin Epidemiol*. 2017;83:48-56.
34. Michie S, Abraham C. Interventions to change health behaviours: Evidence-based or evidence-inspired? *Psychol Health*. 2004;19(1):29-49.
35. Michie S, Richardson M, Johnston M, et al. The behavior change technique taxonomy (v1) of 93 hierarchically clustered techniques: Building an international consensus for the reporting of behavior change interventions. *Ann Behav Med*. 2013;46(1):81-95.
36. Michie S, Atkins L, West R (2014). *The behaviour change wheel. A guide to designing interventions.* United Kingdom: Silverback Publishing.

37. Michie S, van Stralen MM, West R. The behaviour change wheel: A new method for characterising and designing behaviour change interventions. *Implement Sci*. 2011;6:42-5908-6-42.
38. Moore G, Audrey S, Barker M, et al. Process evaluation of complex interventions: Medical research council guidance. *BMJ*. 2015;350:h1258.
39. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: The new medical research council guidance. *Int J Nurs Stud*. 2013;50(5):587-592.
40. Bourbeau J, Nault D, Dang-Tan T. Self-management and behaviour modification in COPD. *Patient Educ Couns*. 2004;52(3):271-277.
41. van Houtum L, Rijken M, Heijmans M, Groenewegen P. Patient-perceived self-management tasks and support needs of people with chronic illness: Generic or disease specific? *Ann Behav Med*. 2015;49(2):221-229.
42. van Houtum L, Rijken M, Heijmans M, Groenewegen P. Self-management support needs of patients with chronic illness: Do needs for support differ according to the course of illness? *Patient Educ Couns*. 2013;93(3):626-632.
43. Nijman J, Hendriks M, Brabers A, de Jong J, Rademakers J. Patient activation and health literacy as predictors of health information use in a general sample of dutch health care consumers. *J Health Commun*. 2014;19(8):955-969.
44. Wahlich C, Beighton C, Victor C, et al. 'You started something … then I continued by myself': A qualitative study of physical activity maintenance. *Prim Health Care Res Dev*. 2017:1-17.
45. Coventry P, Fisher L, Kenning C, Bee P, Bower P. Capacity, responsibility, and motivation: A critical qualitative evaluation of patient and practitioner views about barriers to self-management in people with multimorbidity. *BMC Health Serv Res*. 2014;14:536-548.
46. Long Alliantie Nederland (LAN) (2012). *Zorgstandaard astma volwassenen. [Healthcare standard for adult patients with asthma].* Amersfoort, the Netherlands: LAN.
47. Long Alliantie Nederland (LAN) (2013). *Zorgstandaard COPD. [Healthcare standard COPD]*. Amersfoort, the Netherlands: LAN.
48. Nederlandse Diabetes Federatie (NDF) (2009). *NDF zorgstandaard. [Dutch diabetes healthcare standard].* Amersfoort, the Netherlands: NDF.
49. Newman S, Steed L, Mulligan K. Self-management interventions for chronic illness. *Lancet*. 2004;364(9444):1523-1537.
50. Lawn S. What skills do primary health care professionals need to provide effective self-management support? seeking consumer perspectives. *Australian journal of primary health*. 2009;15(1):37-44.
51. Pols R, Battersby M, Regan Smith M, et al. Chronic condition self-management support: Proposed competencies for medical students. *Chronic Illn*. 2009;5(1):7-14.
52. Bos Touwen I, Dijkkamp E, Kars M, Trappenburg J, De Wit N, Schuurmans M. Potential for self-management in chronic care: Nurses' assessments of patients. *Nurs Res*. 2015;64(4):282-290.
53. Koch T, Jenkin P, Kralik D. Chronic illness self-management: Locating the 'self'. *J Adv Nurs*. 2004;48(5):484-492.
54. Bos-Touwen I, Dijkkamp E, Kars M, Trappenburg J, De Wit N, Schuurmans M. Potential for self-management in chronic care: Nurses' assessments of patients. *Nurs Res*. 2015;64(4):282-290.
55. Noordman J, Koopmans B, Korevaar JC, van der Weijden T, van Dulmen S. Exploring lifestyle counselling in routine primary care consultations: The professionals' role. *Fam Pract*. 2013;30(3):332-340.
56. Ter Maten-Speksnijder AJ, Dwarswaard J, Meurs P, van Staa A. Rhetoric or reality? what nurse practitioners do to provide self-management support in outpatient clinics: An ethnographic study. *J Clin Nurs*. 2016;25(21-22):3219-3228.

CHAPTER 2

Self-management support in routine primary care by nurses

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ABSTRACT

Objectives: To examine how and to what extent self-management support, including behaviour change support, is provided by primary care nurses in routine consultations with chronically ill patients.

Methods: An observational study design was used. Routine consultations of primary care nurses in the Netherlands with chronically ill patients were audiotaped and analysed. The analysis identified health topics addressed according to healthcare standards, self-management topics addressed using a validated set of topics and behaviour change techniques using the Behaviour Change Techniques Taxonomy v1.

Results: Seventy-eight routine consultations of 17 primary care nurses with chronically ill patients were included in the analysis. Nurses addressed both health topics and self-management topics in brief, fragmented and often inconsistent manners. Dietary intake and physical activity were the most frequently addressed topics. Nurses applied 21 behaviour change techniques to target behaviour change, but the use of these techniques was mainly inconsistent and implicit. The most consistently used behaviour change techniques were review behaviour goal(s) (56.4%) and feedback on behaviour (51.3%).

Conclusion: Nurses addressed both health topics and self-management topics in their routine consultations. The duration, frequency and number of addressed topics differed throughout the consultations. Nurses tended to prioritise the monitoring and optimisation of patients' medical treatment and provided limited self-management support. Nurses seldom deepened their focus on behaviour change and infrequently used effective techniques to support this change. Adoption of self-management in primary care, including behaviour change, might be enhanced if nurses consistently and explicitly use effective behaviour change techniques in their consultations.

BACKGROUND

Over the past decade, in most Western countries, chronic care has been subjected to change. The increasing number of people living with a chronic condition[1,2] has led to the shift from a paternalistic approach to a wide adoption of self-management approaches in chronic care.[3,4] Furthermore, the disease management of complex chronic conditions is largely provided by medical specialists and specialised nurses in hospitals, while the disease management of some of the most prevalent chronic conditions, such as diabetes mellitus type 2 (DM2), Chronic Obstructive Pulmonary Disease (COPD) and asthma, has shifted away from hospitals to primary care. In primary care, tasks have been reallocated from primary care physicians to primary care nurses, in which nurses play a pivotal role in monitoring treatment outcomes, promoting self-management and offering follow-up contacts.[5] Self-management is a widely accepted approach to improve health-related outcomes, address patients' needs, and decrease healthcare costs.[6-8] Self-management refers to 'the individual ability to manage the symptoms, treatment, physical and psychosocial consequences and lifestyle changes inherent in living with a chronic condition'.[3] Self-management support, provided by healthcare professionals, aims to equip patients with the essential skills to manage their disease and to adapt healthy behaviours, such as staying physically active and eating healthy.[9] Adoption of self-management in routine clinical practice is encouraged in Dutch healthcare standards.[10-12] Furthermore, self-management has a central position in the Dutch general nursing competences profile[13] and in the vocational training of primary care nurses.[14]

Adequate self-management support implies that nurses share an understanding of their role and tasks in self-management.[15] However, nurses vary in their understanding of what self-management entails and predominantly perceive self-management as incorporating the traditional biomedical approach, which is premised on compliance with professional advice, the monitoring of symptoms and patients' individual responsibility to self-manage their chronic condition.[16] This is contrary to the view of self-management that underpins the self-efficacy concept.[16] Furthermore, for adequate self-management support, nurses should meet patients' individual needs and support patients' behaviour change. This requires that nurses move away from a traditional consultation style of providing advice, information and education to patients about their condition and adapt their communication skills and psychological counselling techniques.[17] However, traditional nursing training is often insufficient in equipping nurses with communication skills and psychological counselling techniques; therefore, most nurses with a consulting role in chronic care have followed vocational skills training to counsel patients in changing their behaviour, such as in motivational interviewing. Although most primary care nurses are trained in the motivational interviewing approach, they often refrain from putting it into practice.[14,18] The psychological counselling

techniques that primary nurses apply in self-management support during their routine consultations with chronically ill patients are scarcely reported.[19] Such techniques were recently classified and defined in the Behaviour Change Techniques Taxonomy v1 (BCTTv1) by Michie et al.[20] The BCTTv1 contains 93 distinct behaviour change techniques (BCTs), as active components of behaviour change. The BCTTv1 is developed for use in intervention design, in which specifying the BCTs used in behaviour change interventions facilitates replications of research evaluations and faithful implementation of effective interventions, and it enables the reliability of the reporting content of interventions.[20] Furthermore, as they are linked with theories of behaviour change with the aim to directly influence patients, BCTs allow for testing the hypothesised mechanisms of actions.[20] The BCTTv1 is normally applied in designing and reporting behaviour change interventions but could also provide a meaningful way to examine how self-management support, including behaviour change support, is provided by primary care nurses.

Other than insight regarding which BCTs nurses apply when providing self-management support, little is known regarding what extent nurses focus on discussing self-management, including behaviour change, during their routine consultations. Insight regarding how nurses actually support patients and which BCTs they apply is essential to understand and align with nurses' training needs in counselling techniques, which might optimise the adoption of self-management support in primary care. Therefore, this study aims at examining how and to what extent self-management support, including behaviour change support, is provided by primary care nurses in routine consultations with chronically ill patients.

This study had three objectives: (1) to examine which health and self-management topics nurses addressed; (2) to examine the duration and frequency of these addressed topics, and (3) to examine which BCTs primary care nurses applied to address behaviour change as part of their self-management support in routine consultations.

METHODS

Design, participants and procedure

An observational study design was used. Routine consultations performed by primary care nurses in the Netherlands were audiotaped to examine to what extent they provided self-management support, including behaviour change support, in routine care with chronically ill patients. Primary care nurses who were working in general practices located throughout the Netherlands and were involved in the care for patients with prevalent chronic diseases, such as DM2, COPD or asthma, were recruited by an invitational e-mail, by telephone, through personal contacts with primary care nurses from the researchers'

network and through a Dutch nurses' association platform. Nurses were asked to audiotape their scheduled consultations with patients with DM2, COPD, or asthma who were routinely followed by a nurse according to the healthcare standards,[10-12] and to exclude patients who were scheduled for an extra consultation to control on e.g. exacerbations or currently poorly controlled condition. Nurses were familiar with the patients and their past behaviour since patients with DM2 have a consultation once every three months and patients with COPD or asthma have an annual consultation with a nurse. To ensure diversity of self-management support among the participating primary care nurses, nurses were asked to recruit five patients, and each patient could participate once. Prior to the recording of the consultations, all nurses and patients were asked to fill in an informed consent form. Tape recording started at the very beginning of each consultation. The socio-demographic characteristics of both nurses and patients were collected.

Ethical considerations

The Medical Research Ethics Committee of the University Medical Center Utrecht in the Netherlands waived the full ethical review for recording the consultations, according to the Medical Research Involving Human Subjects Act (WMO). All participating nurses and patients gave written informed consent prior to the recording of the consultations. Patients could withdraw their consent at any time.

Analysis

The audiotapes of the consultations were transcribed. To code all topics that were addressed during the consultations, a coding list was developed using two methods. First, health topics, such as general condition or lab results, were derived from healthcare standards for DM2, COPD and asthma.[10-12,21] Second, self-management topics were extracted (stage A) and validated (stage B). In stage A, self-management topics were derived from published effect studies of self-management programs[22,23] and healthcare standards.[10-12,21] This resulted in 49 self-management topics, which were checked for duplicates and coverage of the concept of self-management. Furthermore, the topics were checked for content validity and for relevance in primary care in two focus groups: one focus group with five patients with a clinical diagnosis of DM2, COPD or asthma and one focus group with seven primary care nurses who were routinely involved in the care for these patients. Both focus groups took two hours, followed a specified roadmap, and were videotaped and transcribed verbatim. Field notes were made. This stage was peer reviewed by three experts in self-management research. In stage B, the content validity of the selected self-management topics was assessed. Seven experts in the field of self-management checked the topics for face validity. Patients were recruited from social media and patient organisations. Primary care nurses were recruited by an invitational e-mail, by telephone, through personal contacts with the primary care nurses and through a platform of the

Dutch nurses' association. To increase the likelihood of reflecting different perspectives of patients and nurses and to increase the representativeness of the data, maximum variation sampling was obtained by aspiring diversity in patients' age, level of education, chronic condition, and years since diagnosis and nurses' age and years of working experience with patients with DM2, COPD or asthma in primary care.

As a result of the focus group of patients, one topic was merged with another topic, and three topics were added to the coding list ('understanding the disease', 'understanding emotional and social consequences of the disease' and 'alcohol use'). Nurses jointly confirmed the selected topics, and no further changes were made. To complete the content validity assessment, a panel of ten experts in self-management research indicated on a four-point rating scale (1=not relevant, 2=somewhat relevant, 3=quite relevant, 4=highly relevant) whether each topic was relevant for self-management support and whether the topics were relevant for the scope of the primary care nurses to apply during self-management support in routine consultations with patients with a chronic condition. All experts considered the selected topics to be highly relevant and confirmed the selected topics for the coding list.

After this analysis, the selection of topics for the coding list was finalised. It consisted of two general self-management topics, 'understanding the disease' and 'understanding emotional and social consequences of the disease', and seven self-management behaviours, 'symptom monitoring', 'symptom and exacerbation management', 'physical activity', 'dietary intake', 'medication management', 'smoking cessation', and 'alcohol use'. The development of the coding list and the descriptions of the topics are shown in Appendix 1 and Appendix 2.

The addressed health and self-management topics were coded when present. Duration of the addressed topics included both nurses' and patients' questions and comments and was assessed using NVivo qualitative data analysis Software (QSR International Pty Ltd. Version 11, 2015). Duration was analysed in terms of the median length (minutes:seconds) using SPSS Windows Version 21.[24]

To examine which BCTs nurses applied as part of their self-management support, the BCTTv1 was used. Two psychologists independently coded the applied BCTs using the BCTTv1 for each of the seven self-management behaviours. After coding the first eight consultations, and again after coding the subsequent eight consultations, the findings were compared to ensure consistent application of the taxonomy. Discrepancies were resolved through discussions. The BCTs were coded when present. Furthermore, the variability of BCTs within each individual nurse and between nurses was explored descriptively.

RESULTS

Of the 107 primary care nurses who were invited to participate, 17 agreed to participate (15.9%). Seventy-eight routine consultations with patients with DM2 (n=70), COPD (n=3) and asthma (n=5) were audiotaped. On average, 5 (range 2-9) consultations per primary care nurse (n=17) were audiotaped. The majority of nurses had consultations with patients with DM2, COPD and asthma. The majority of patients were Dutch and were diagnosed at least 6 months prior to data collection. Characteristics of the primary care nurses and patients are shown in Table 1.

Table 1. Characteristics of primary care nurses and patients

Participant characteristics	
Primary care nurses (n)	17
Female, n (%)	16 (94.1)
Age in years, mean ±SD	43.3 ±11.5
Working experience as a primary care nurse in years, mean ±SD	6.7 ±4.4
Area of expertise, n (%)	
DM2	3 (17.6)
COPD, asthma	1 (5.9)
DM2, COPD, asthma	13 (76.5)
Received training in motivational interviewing or self-management, n (%)	
Motivational interviewing only	11 (64.7)
Motivational interviewing and self-management	6 (35.3)
Patients (n)	78
Female, n (%)	31 (39.7)
Age in years, mean ±SD	64.6 ±11.1
Level of education, n (%)	
Primary education or below	37 (47.4)
Secondary education	24 (30.8)
Higher education	17 (21.9)
Ethnicity, n (%)	
Dutch	59 (75.6)
Other	19 (24.4)
Chronic condition, n (%)	
DM2	70 (89.7)
COPD	3 (3.8)
Asthma	5 (6.4)
Years since diagnosis, n (%)	
<6 months	6 (7.7)
>6 months	72 (92.3)

Abbreviations: DM2 diabetes mellitus type 2; COPD Chronic Obstructive Pulmonary Disease

The median duration of all consultations was 20:49 minutes (range 7:25-53:02). Asthma consultations had the highest median consultation time (40:00 minutes; range 29:04-53:02), followed by COPD consultations (25:06 minutes; range 16:24-49:00). DM2 consultations had the lowest median consultation time (19:52 minutes; range 7:25-38:27).

Discussed topics

Nurses addressed all health topics prescribed in the healthcare standards, but there were large differences in the extent to which these topics were addressed; see Table 2. Measurements such as blood pressure, weight, and BMI were assessed in almost all consultations (n=71; 91.0%), as was discussing the general health condition of the patient (n=64; 82.2%). Lab results and the optimisation of medication treatment were addressed in half of all consultations. Perceived stress (n=7; 9%) was barely discussed, and sexuality was only briefly discussed in one consultation (0:13 minutes). The DM2-specific topic glycaemic control was briefly discussed (0:40 minutes; range 0:13-1:19) in a minority of the DM2 consultations (18.6%). Patients' lung function was assessed in a majority of the COPD and asthma consultations (n=5; 62.5%) and comprised a substantial part of these consultations (5:33 minutes; range 1:08-13:10).

Almost all self-management topics are integrated into the healthcare standards, except the general self-management topics 'understanding the disease' and 'understanding emotional and social consequences of the disease'. Self-management was addressed in almost all consultations (n=77; 99%); however, there were large differences in the duration, frequency and number of addressed topics. Overall, nurses addressed the self-management topics briefly and in a fragmented manner throughout the consultations. In none of the consultations did the nurses address all self-management topics. The median duration of self-management support was 7:16 minutes and ranged from 0:02 minutes for 'smoking cessation' and 'physical activity' to 13:08 minutes for 'symptom management'. The self-management topics 'dietary intake' (n=60; 76.9%) and 'physical activity' (n=56; 71.8%) were most frequently addressed, followed by 'understanding the disease' (n=51; 65.4%), 'symptom and exacerbation management' (n=48; 61.5%) and 'medication management' (n=45; 57.7%). 'Understanding emotional and social consequences' was only touched upon in two consultations (2.6%; 0:40 minutes; range 0:06-1:15).

During the consultations, nurses and patients frequently addressed other topics, such as patients' personal life (n=43; 55.1%), nurses' personal life (n=11; 14.1%), and small talk (n=10; 12.8%). Scheduling a follow-up appointment was integrated into almost all consultations (n=76; 85.9%) and accounted for a considerable portion of the consultation time (1:34 minutes; range 0:06-7:44).

Table 2. Discussed topics during routine consultations

Discussed topics	**Number of consultations** *N=78* *n (% total)*	**Duration of addressed topics** *median minutes:seconds (range)*
Health topics		
General health condition	64 (82.2)	1:55 (0:04-9:36)
Lab results	41 (52.6)	0:56 (0:02-3:02)
Measurements (blood pressure, weight, BMI)	71 (91.0)	1:37 (0:08-5:35)
Medication optimisation	41 (52.6)	0:50 (0:10-3:30)
Stress	7 (9.0)	1:18 (0:08-7:47)
Sexuality	1 (1.3)	0:13
DM2 only	*n (% total, N=70)*	
Glycaemic control	13 (18.6)	0:40 (0:13-1:19)
COPD and asthma only	*n (% total, N=8)*	
Lung function	5 (62.5)	5:33 (1:08-13:10)
Self-management topics		
Understanding the disease	51 (65.4)	0:56 (0:12-10:28)
Understanding social and emotional consequences	2 (2.6)	0:40 (0:06-1:15)
Symptom monitoring	32 (41.0)	2:50 (0:05-6:38)
Symptom and exacerbation management	48 (61.5)	1:28 (0:09-13:08)
Physical activity	56 (71.8)	1:00 (0:02-9:35)
Dietary intake	60 (76.9)	1:36 (0:08-8:17)
Medication management	45 (57.7)	1:22 (0:07-7:56)
Smoking cessation	27 (34.6)	0:16 (0:02-4:18)
Alcohol use	29 (37.2)	0:24 (0:03-1:50)
Other topics		
Small talk (weather, environment, etc.)	10 (12.8)	0:53 (0:23-2:15)
Personal life patient	43 (55.1)	1:29 (0:09-8:09)
Personal life nurse	11 (14.1)	0:44 (0:10-5:00)
Scheduling a follow up appointment	67 (85.9)	1:34 (0:06-7:44)

Abbreviations: DM2 diabetes mellitus type 2; COPD Chronic Obstructive Pulmonary Disease; BMI Body Mass Index

Applied behaviour change techniques

Overall, nurses used 21 of the 93 BCTs described in the BCTTv1 to address behaviour change during their consultations; see Table 3. All nurses applied at least one BCT during their consultations. However, the number of BCTs used differed both between and within nurses (median 6; range 1-12 BCTs); see Table 4. Nurses used different BCTs and used them to different extents in consultations.

Table 3. Number of behaviour change techniques applied in routine consultations

Applied BCTs in number (%) of consultations	**Addressed self-management behaviours in consultations**	
	Symptom monitoring (n=32)	**Symptom and exacerbation management** (n=48)
Goal setting (behaviour)	-	-
Problem-solving	-	-
Goal setting (outcome)	-	-
Action planning	-	7 (14.6)
Review behaviour goal(s)	-	1 (2.1)
Discrepancy between current behaviour and goals	-	-
Review outcome goals	-	-
Feedback on behaviour	-	4 (8.3)
Self-monitoring of behaviour	2 (6.2)	-
Self-monitoring of outcomes of behaviour	1 (3.1)	4 (8.3)
Biofeedback	-	2 (4.2)
Feedback on outcomes of behaviour	-	2 (4.2)
Social support (unspecified)	-	-
Instruction on how to perform the behaviour	-	10 (20.8)
Information about health consequences	-	3 (27.1)
Behavioural practice/rehearsal	-	-
Behavioural substitution	-	-
Pros and cons	-	-
Incentive (outcome)	-	-
Pharmacological support	-	-
Adding objects to the environment	-	-
Overall number (%) of 21 applied BCTs	*2 (9.5)*	*8 (38.1)*

Abbreviations: BCTs behaviour change techniques

	Addressed self-management behaviours in consultations				
	Physical activity	**Dietary intake**	**Medication management**	**Smoking cessation**	**Alcohol use**
	(n=56)	(n=60)	(n=45)	(n=27)	(n=29)
	6 (10.7)	4 (6.7)	1 (2.2)	-	2 (6.9)
	2 (3.6)	1 (1.7)	3 (6.7)	-	-
	1 (1.8)	-	-	-	-
	-	2 (3.3)	1 (2.2)	-	-
	16 (28.6)	11 (18.3)	12 (26.7)	2 (4.4)	2 (6.9)
	1 (1.8)	-	-	-	-
	-	9 (15.0)	-	-	-
	17 (30.4)	9 (15.0)	4 (8.9)	5 (11.1)	1 (3.4)
	1 (1.8)	-	1 (2.2)	-	-
	-	-	-	-	-
	-	5 (8.3)	1 (2.2)	-	1 (3.4)
	3 (5.4)	15 (25.0)	-	-	-
	2 (3.6)	3 (5.0)	1 (2.2)	-	-
	2 (3.6)	7 (11.7)	8 (17.8)	-	-
	4 (7.1)	13 (21.7)	1 (2.2)	1 (2.2)	1 (3.4)
	-	-	1 (2.2)	-	-
	-	3 (5.0)	-	-	-
	-	1 (1.7)	-	1 (2.2)	-
	-	1 (1.7)	-	-	-
	-	-	-	1 (2.2)	-
	-	-	1 (2.2)	-	1 (3.4)
	11 (52.4)	*14 (66.7)*	*12 (57.1)*	*5 (23.8)*	*6 (28.6)*

Table 4. Applied behaviour change techniques per primary care nurse in routine consultations

Primary care nurses (n=17)	P1	P2	P3	P4	P5	P6
Number of consultations (n=78)	*n=2*	*n=3*	*n=8*	*n=5*	*n=4*	*n=5*
	Applied BCTs in number of consultations					
Goal setting (behaviour)	-	-	1	-	1	-
Problem solving	-	-	2	-	-	-
Goal setting (outcome)	-	-	-	-	-	-
Action planning	-	1	-	-	2	1
Review behaviour goal(s)	-	1	2	-	2	2
Discrepancy between current behaviour and goals	-	-	-	-	-	-
Review outcome goals	-	-	2	1	-	2
Feedback on behaviour	-	2	1	1	-	-
Self-monitoring of behaviour	1	2	-	-	-	-
Self-monitoring of outcomes of behaviour	1	-	1	-	-	-
Biofeedback	1	-	2	-	1	-
Feedback on outcomes of behaviour	-	1	2	1	-	2
Social support (unspecified)	1	-	-	-	1	-
Instruction on how to perform the behaviour	1	2	4	1	1	2
Information about health consequences	-	-	2	3	1	-
Behavioural practice/rehearsal	-	-	-	-	-	1
Behavioural substitution	-	-	1	-	-	-
Pros and cons	-	-	1	-	-	-
Incentive (outcome)	-	-	-	-	-	-
Pharmacological support	-	-	-	-	-	-
Adding objects to the environment	-	-	-	-	-	-
Overall number (%) of applied BCTs	*5*	*6*	*12*	*5*	*7*	*6*

Abbreviations: BCTs behaviour change techniques; P primary care nurses

P7 *n=6*	P8 *n=4*	P9 *n=3*	P10 n=9	P11 n=5	P12 n=3	P13 n=6	P14 n=4	P15 n=4	P16 n=2	P17 n=5	
Applied BCTs in number of consultations											***Total***
1	-	-	2	-	2	1	2	-	-	1	*8*
2	-	-	1	-	1	-	-	-	-	-	*4*
1	-	-	-	-	-	-	-	-	-	-	*1*
-	-	-	4	-	-	1	1	-	-	-	*6*
3	-	1	8	1	2	-	2	-	-	3	*11*
-	-	-	-	-	1	-	-	-	-	-	*1*
2	-	-	1	-	-	1	-	-	-	-	*6*
5	-	1	6	1	-	2	3	2	1	4	*12*
-	-	-	-	1	-	-	-	-	-	-	*3*
1	1	-	-	-	-	-	-	-	-	-	*4*
-	-	2	1	-	-	-	1	-	-	-	*6*
-	1	-	3	-	1	3	2	1	-	1	*11*
2	-	-	-	-	1	-	1	-	-	1	*6*
-	2	1	5	2	1	-	-	-	-	2	*12*
2	1	1	3	2	1	1	2	1	-	1	*13*
-	-	-	-	-	-	-	-	-	-	-	*1*
-	-	1	-	-	-	-	1	-	-	-	*3*
-	-	-	-	-	-	-	1	-	-	-	*2*
1	-	-	-	-	-	-	-	-	-	-	*1*
-	-	-	-	-	-	1	-	-	-	-	*1*
1	-	-	-	-	-	-	-	-	-	-	*1*
11	*4*	*6*	*10*	*5*	*8*	*7*	*10*	*3*	*1*	*7*	*113*

Table 5. Examples of applied behaviour change techniques in routine consultations

BCTs	Example
Goal setting (behaviour)	"Try to consequently take your pills the upcoming months, so that I can see how this affects your cholesterol level." (P3)
Problem solving	"What is the reason that she succeeds in cycling daily and you do not?"(P7)
Goal setting (outcome)	"The goal is to lose weight."(P7)
Action planning	"Cycling while listening to music and watching television, how often per week are you going to do this?" (P7) "Suppose that you have a low blood glucose level and you are quivering and shivering, then you know that you should eat." (P10)
Review behaviour goal(s)	"Last time you also said: "I have eaten a lot of noodles lately, I will reduce that…" (P6) "You used to walk one and a half hours each day, or you cycled a lot. Did you pick that up again?" (P3)
Discrepancy between current behaviour and goals	"Actually, you say: "I want to weigh less than 90 kg, but you cannot activate yourself." (P12)
Review outcome goals	''You wanted to lose weight. Your BMI is now 23.1, so that is perfect for your health. Where do you draw the line?" (P6)
Feedback on behaviour	"So you are being active, well done." (P7)
Self-monitoring of behaviour	"Do you sometimes use your pedometer?" (P11) "The moment that you experience symptoms, it is wise to write down the date, your symptom and your response to the symptom." (P2)
Self-monitoring of outcome of behaviour	''You could monitor your blood glucose level every 6 weeks. In the meantime, you could monitor your blood glucose level once before a meal and after a meal to see if you serve too much compared to the little amount of insulin." (P8)
Biofeedback	"The lab results show that you are doing the right thing because you have lower blood values now. So you have made a lot of progress by changing your dietary habits." (P14)
Feedback on outcomes of behaviour	"If you succeed in stabilising your weight, which is also fine. Gaining weight is not what we want. But it would be better if you could lose some weight." (P3)
Social support (unspecified)	"Do you have support in your neighbourhood? Then you can take those steps together. That will give you the extra support and courage." (P5) "Shall I contact your wife to explain to her what the situation is now? She understands Dutch better." (P7)
Instruction on how to perform the behaviour	"You can put the pills in a little box; then, you carry it with you all the time." (P17)

Table 5. Continued

BCTs	Example
Information about health consequences	"The moment that you gain weight or decrease your activity level, you will notice that your blood glucose level will increase. So if you could maintain or even improve what you are doing now, I could reduce your pills." (P3)
Behavioural practice/ rehearsal	"You can now open it and slide the lever down. How much force do you use when you do this.[…] Something like this, and then once." (P6)
Behavioural substitution	"You know, you can replace the rice waffle for a biscuit rusk." (P9) "Take something else instead of cheese and cold cuts." (P14)
Pros and cons	"What are the advantages of keeping on smoking, and what are the advantages of quitting smoking?" (P14)
Incentive (outcome)	"But, why can't you reward yourself once a week?" (P7)
Pharmacological support	"Medication that will help you to quit smoking, whereas it's easier to get cigarettes." (P13)
Adding objects to the environment	"You say: "I forget my medication." "Does it help you to set an alarm clock or to put them ready somewhere?" (P7)

Abbreviations: BCTs behaviour change techniques; P primary care nurse

In 15 (19.2%) of the consultations, nurses did not apply any BCT. Nurses applied the BCTs *review behaviour goal(s)* (n=44 consultations; 56.4%) and *feedback on behaviour* (n=40 consultations; 51.3%) to address behaviour change most consistently throughout their consultations; see Table 3. These two BCTs were used by the majority of nurses. The BCT *information about health consequences* was used by most nurses (n=13; 76.5%), but this BCT was applied in only 21 (26.9%) of the consultations; see Table 4.

Nurses applied the largest variety of BCTs when focusing on the behaviour 'dietary intake' (n=14 BCTs). The BCT *feedback on outcomes of behaviour* was applied most consistently in these consultations (n=15; 25%). This was followed by the behaviour 'medication management' (n=12 BCTs), in which nurses applied the BCT *review behaviour goal(s)* most consistently (n=12; 26.7%). When nurses focussed on the behaviour 'physical activity' (n=11 BCTs), the BCT *feedback on behaviour* was used most consistently (n=17; 30.4%). Nurses applied the least variety in BCTs when focusing on the behaviour 'symptom monitoring' (n=2 BCTs), although this topic was addressed in 32 (41.0%) consultations and had the highest median duration of the behaviour topics (2.50 minutes). The BCT r*eview outcome goal(s)* was only applied to address dietary intake (n=9 consultations, n=6 nurses).

Furthermore, the extent to which nurses applied the BCTs according to their definitions described in the BCTTv1 differed between and within nurses. When nurses applied BCTs, they did so mainly implicitly; see Table 5. Nurses reviewed patients' behaviour in more general terms and provided feedback on their behaviour without using self-monitoring tools, such as keeping logs or using pedometers. Nurses often gave advice about patients' behaviour according to the medical norms and put effort into convincing patients to follow their suggestions; they left out an in-depth and clear plan to change patients' behaviour using techniques such as *goal setting (outcome)* (n=1), *goal setting behaviour* (n=11) or *action planning* (n=10). Furthermore, nurses spent time discussing the barriers to behaviour change but often did not discuss how to overcome these barriers.

DISCUSSION

The study results showed that nurses addressed both health topics and self-management topics in their routine consultations. However, there were large differences in the duration, frequency and number of topics that they addressed. Overall, nurses addressed the health and self-management topics briefly and in a fragmented manner throughout the consultations. Nurses seldom focused deeply on behaviour change, and their explicit and consistent use of BCTs was low.

In this study, nurses tended to prioritise the optimisation of patients' medical treatment according to the healthcare standards; they educated patients about monitoring and controlling their condition and gave advice, seeking little input from patients' own perspective. The finding that primary care nurses address health behaviours, such as being physically active, briefly and in a fragmented way has also been found in other studies.[18,25,26] The behaviours 'dietary intake' and 'physical activity' were the most frequently addressed behaviours during the consultations, which is in line with results from another Dutch study among primary care nurses.[18] Nurses seldom discussed psychological topics, such as 'understanding emotional and social consequences of the disease' and 'stress'. This is in contrast with the result of the preceding focus groups, in which both patients and nurses identified these psychological topics as important topics to address during a consultation. This discrepancy between what nurses addressed during their consultations and what they reported to be important might be explained by the fact that during the focus group, nurses accentuated that they perceived difficulties in supporting patients in these matters.

During the consultations, nurses continuously multi-tasked and rapidly shifted between medical examinations and health topics according to the healthcare standards, without leaving room for an in-depth focus on patients' perspectives and self-management topics.

Other studies have found that the decision to address self-management topics and induce behaviour change is influenced by the variety in nurses' perceptions of their roles, tasks and responsibilities of self-management[15,27,28] and a lack of consultation time.[29-31]

Nurses tended to steer patients to follow their suggestions according to medical norms. This tendency is also found in another Dutch study.[32] Nurses mostly queried patients about their behaviour in general terms and provided feedback on their behaviour. Nurses seldom initiated an in-depth discussion of behaviour change during their consultations. Patients barely raised BCTs themselves and mostly responded to the nurse-initiated questions. If patients asked questions or addressed BCTs themselves, nurses frequently did not ask additional questions or deepen their focus on patients' words. When nurses addressed behaviour change, they infrequently applied BCTs, and when they did apply BCTs, it was not in a very explicit and consistent way. Three out of the 5 most frequently applied BCTs were supported by research evidence in promoting behaviour change: *feedback on behaviour,*[33,34] *review behaviour goal(s)*[34,35] and *instruction on how to perform the behaviour.*[34-36] Other BCTs that are likely to be effective were rarely applied, such as *goal setting,*[34,35,37] *action planning,*[36] *problem-solving,*[35,38] *self-monitoring,*[35,39] *social support,*[34,35] *demonstration of behaviour,*[38] *and prompts/cues.*[34] Although some similarities might exist in motivational interviewing techniques and BCTs,[19] the participating nurses were not specifically trained in applying and tailoring BCTs. Therefore, it could not be expected that they would apply these BCTs explicitly and consistently in their consultations. The results of this study underline the need to strengthen the quality of self-management support, including behaviour change, given by nurses and improve evidence-based practice. Providing vocational theoretical and skills training on self-management support, including nurses' understanding of self-management and explicit and consistent use of effective BCTs in routine practice, might boost the efficacy of self-management support in primary care.[14,30,40,41] To further enhance the adoption of self-management in primary care, efforts must be devoted to the sustainability and integration of the gained knowledge and skills into routine practice while maintaining compliance with other clinical demands.[18,40,42,43]

Although self-management interventions have been shown to positively affect health outcomes and cost-effectiveness, current evidence for its effectiveness remains inconclusive due to methodological issues, such as intervention components, follow-up time, outcome measurements, scarcely reported and measured intervention fidelity and the heterogeneity in included subgroups of patients.[44,45] Given nurses' current limited and inconsistent use of (effective) BCTs, questions arise regarding whether nurses' role in providing self-management support might affect the intervention fidelity of self-management interventions.

Strengths and limitations

To appreciate the findings, some aspects of the study must be addressed. To our knowledge, this is the first study to examine the extent of self-management support in routine primary care and to report which BCTs nurses applied using a behaviour change taxonomy. A limited number of studies have solely focussed on behaviour change support provided by primary care nurses.[18,25,46] They have not examined the self-management topics 'symptom monitoring', 'symptom and exacerbation management' or 'medication management' and did not report which BCTs were applied. Taxonomies are usually not applied outside research settings; however, they could enable researchers and trainers to better describe the core components of behaviour change that are integrated into self-management support and to better train nurses in these components. In addition, taxonomies allow the identification of where self-management support could be enhanced to improve the match with evidence-based practice.

It was challenging to validly judge the presence of topics and BCTs in the consultations. To increase the validity of the judgements, the topics were coded by researchers, and the BCTs were coded by trained psychologists. However, due to the fragmented addressed topics and the implicit use of BCTs, the topics and BCTs were identified based on consensus, which might have overestimated the duration of the discussed topics and used BCTs. Nurses were aware that their consultations were audiotaped to examine how they provided self-management support, which might have influenced their consultation style and content. Therefore, several consultations were taped per nurse. Afterwards, all nurses perceived that the presence of the small audio-recorder did not affect their consultation. Nurses selected which consultations to record and this selection might be influenced by the nurses' preference of patients. This might have affected the generalisability of the results. To enhance patients' decision to participate, nurses were instructed to inform patients that they were voluntary to participate in the study and patients' decision about participation did not have any consequences for their treatment.

Furthermore, patients were recruited via social media and patient organisations, which is more likely to attract patients who are more actively involved in managing their condition. To increase the likelihood of reflecting perspectives of different patients and to increase the representativeness of the results, maximum variation sampling was obtained.

This study included nursing consultations with patients with different chronic conditions. DM2 consultations were dominant since these consultations were the most prevalent. Only a limited number of COPD and asthma consultations were included. Although our study found similar results for all consultations across these different conditions, this might limit the generalisability of our findings. Lastly, the response rate was relatively low, but it

was comparable to other studies on self-management among nurses. The invited nurses often did not respond to the invitation and mostly did not provide a reason for declining to participate. Nurses who already had an interest in self-management support might have been more tempted to participate in this study. All participating nurses had received vocational training in motivational interviewing and/or self-management in the past and were convinced that they used these skills in practice. This might have influenced the representativeness of our sample for the Dutch population of primary care nurses and might have resulted in an overestimation of the number of health and self-management topics that were addressed and BCTs that were used.

CONCLUSION

Primary care nurses provided self-management support in a brief and fragmented manner throughout the consultations. Nurses tended to prioritise the optimisation of patients' medical treatment and seldom focussed on behavioural change. When nurses did support patients in changing their behaviour, they infrequently applied BCTs that are likely to be effective, and they applied BCTs in an inconsistent and less explicit way. The adoption of self-management in primary care, including behaviour change, might be enhanced when nurses incorporate the consistent and explicit use of effective BCTs in their consultations.

REFERENCES

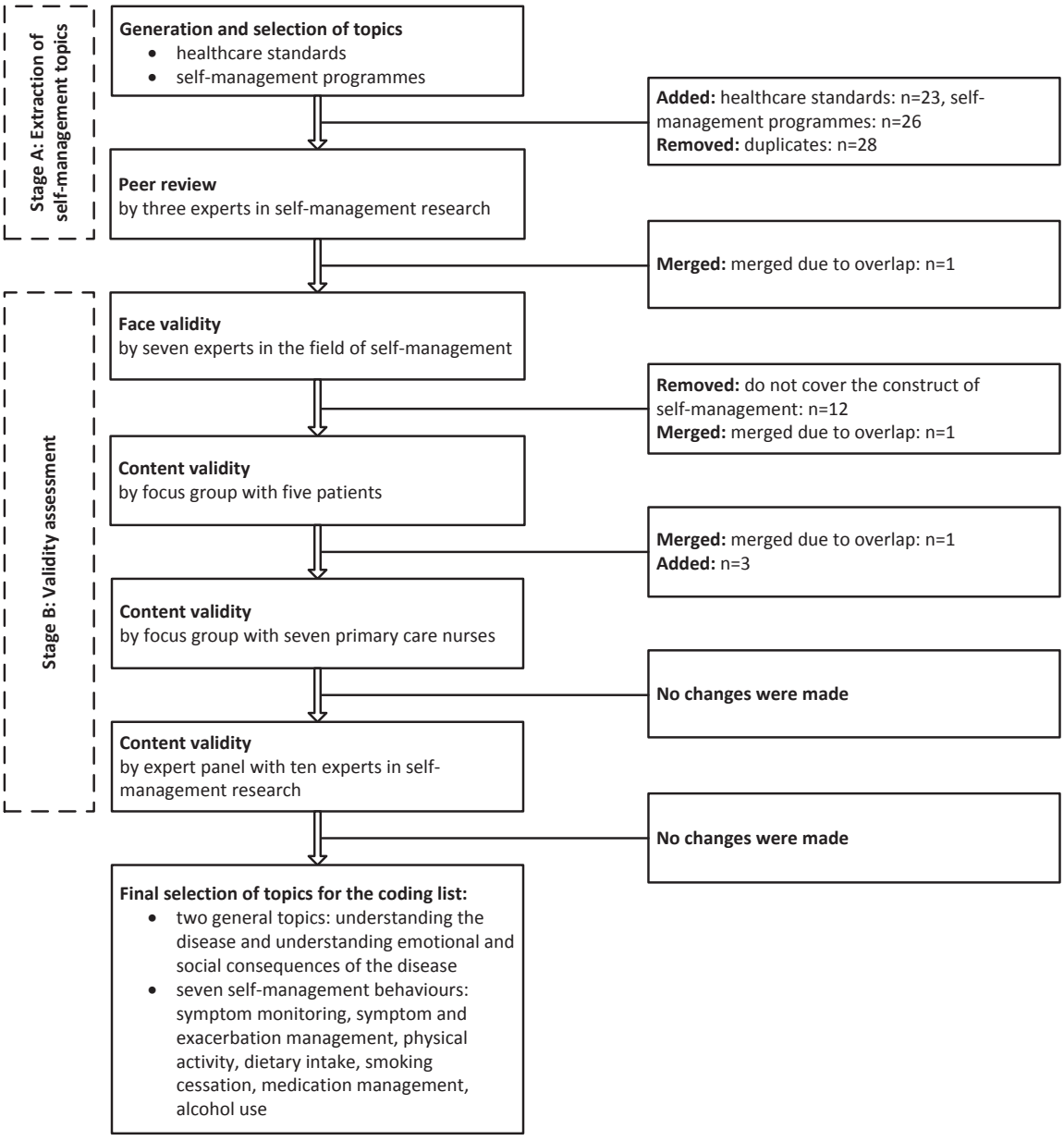
1. Mathers CD, Loncar D. Projections of global mortality and burden of disease from 2002 to 2030. *PLoS Med*. 2006;3(11):e442.
2. Mathers CD, Stevens G, Mascarenhas M (2009). *Global health risks: Mortality and burden of disease attributable to selected major risks.* Geneva, Switzerland: World Health Organisation.
3. Barlow J, Wright C, Sheasby J, Turner A, Hainsworth J. Self-management approaches for people with chronic conditions: A review. *Patient Educ Couns*. 2002;48(2):177-187.
4. Bodenheimer T, Lorig K, Holman H, Grumbach K. Patient self-management of chronic disease in primary care. *JAMA*. 2002;288(19):2469-2475.
5. Baan CA, Hutten JBF, Rijken PM (2003). *Afstemming in de zorg: Een achtergrondstudie naar de zorg voor mensen met een chronische aandoening. [Coordination of care. A study into the care for people with a chronic condition].* Bilthoven, the Netherlands: RIVM.
6. Effing T, Kerstjens H, van der Valk P, Zielhuis G, van der Palen J. (Cost)-effectiveness of self-treatment of exacerbations on the severity of exacerbations in patients with COPD: The COPE II study. *Thorax*. 2009;64(11):956-962.
7. Chodosh J, Morton SC, Mojica W, et al. Meta-analysis: Chronic disease self-management programs for older adults. *Ann Intern Med*. 2005;143(6):427-438.
8. Zwerink M, Brusse Keizer M, van der Valk PDLPM, et al. Self management for patients with chronic obstructive pulmonary disease. *Cochrane Database Syst Rev*. 2014(3):CD002990.
9. Newman S, Steed L, Mulligan K. Self-management interventions for chronic illness. *Lancet*. 2004;364(9444):1523-1537.
10. Nederlandse Diabetes Federatie (NDF) (2009). *NDF zorgstandaard. [Dutch diabetes healthcare standard].* Amersfoort, the Netherlands: NDF.
11. Long Alliantie Nederland (LAN) (2012). *Zorgstandaard astma volwassenen. [Healthcare standard for adult patients with asthma].* Amersfoort, the Netherlands: LAN.
12. Long Alliantie Nederland (LAN) (2013). *Zorgstandaard COPD. [Healthcare standard COPD]*. Amersfoort, the Netherlands: LAN.
13. Schuurmans MJ, Lambregts J, Projectgroep V&VN 2020, Grotendorst A (2012). *V&VN 2020. deel 3 beroepsprofiel verpleegkundige. [Part 3. Dutch general nursing competencies profile].* Utrecht, the Netherlands: V&VN.
14. Noordman J, van der Weijden T, van Dulmen S. Effects of video-feedback on the communication, clinical competence and motivational interviewing skills of practice nurses: A pre-test posttest control group study. *J Adv Nurs*. 2014;70(10):2272-2283.
15. Been-Dahmen JMJ, Dwarswaard J, Hazes JMW, van Staa A, Ista E. Nurses' views on patient self-management: A qualitative study. *J Adv Nurs*. 2015;71(12):2834-2845.
16. Sadler E, Wolfe CDA, McKevitt C. Lay and health care professional understandings of self-management: A systematic review and narrative synthesis. *SAGE Open Med*. 2014;2: 2050312114544493.
17. Elissen A, Nolte E, Knai C, et al. Is Europe putting theory into practice? A qualitative study of the level of self-management support in chronic care management approaches. *BMC Health Serv Res*. 2013;13:117-6963-13-117.
18. Noordman J, Koopmans B, Korevaar JC, van der Weijden T, van Dulmen S. Exploring lifestyle counselling in routine primary care consultations: The professionals' role. *Fam Pract*. 2013;30(3):332-340.
19. Hardcastle S, Fortier M, Blake N, Hagger M. Identifying content-based and relational techniques to change behaviour in motivational interviewing. *Health Psychol Rev*. 2016:1-16.

20. Michie S, Richardson M, Johnston M, et al. The behavior change technique taxonomy (v1) of 93 hierarchically clustered techniques: Building an international consensus for the reporting of behavior change interventions. *Ann Behav Med*. 2013;46(1):81-95.
21. Peeples M, Tomky D, Mulcahy K, Peyrot M, Siminerio L, AADE Outcomes Project and AADE/UMPC Diabetes Education Outcomes Project. Evolution of the american association of diabetes educators' diabetes education outcomes project. *Diabetes Educ*. 2007;33(5):794-817.
22. Bischoff EW, Akkermans R, Bourbeau J, van Weel C, Vercoulen JH, Schermer TR. Comprehensive self management and routine monitoring in chronic obstructive pulmonary disease patients in general practice: Randomised controlled trial. *BMJ*. 2012;345:e7642.
23. Lorig KR, Ritter P, Stewart AL, et al. Chronic disease self-management program: 2-year health status and health care utilization outcomes. *Med Care*. 2001;39(11):1217-1223.
24. IBM Corp. (2012). *IBM SPSS statistics for windows, version 21.0.* Vol version 21.0. Armonk, NY: IBM Corp.
25. van Dillen SM, Noordman J, van Dulmen S, Hiddink GJ. Examining the content of weight, nutrition and physical activity advices provided by dutch practice nurses in primary care: Analysis of videotaped consultations. *Eur J Clin Nutr*. 2014;68(1):50-56.
26. Bardach SH, Schoenberg NE. The content of diet and physical activity consultations with older adults in primary care. *Patient Educ Couns*. 2014;95(3):319-324.
27. Bos Touwen I, Dijkkamp E, Kars M, Trappenburg J, De Wit N, Schuurmans M. Potential for self-management in chronic care: Nurses' assessments of patients. *Nurs Res*. 2015;64(4):282-290.
28. Morgan HM, Entwistle VA, Cribb A, et al. We need to talk about purpose: A critical interpretive synthesis of health and social care professionals' approaches to self-management support for people with long-term conditions. *Health Expect*. 2016;20(2):243-259.
29. Lawn S, Schoo A. Supporting self-management of chronic health conditions: Common approaches. *Patient Educ Couns*. 2010;80(2):205-211.
30. Jansink R, Braspenning J, van der Weijden T, Elwyn G, Grol R. Primary care nurses struggle with lifestyle counseling in diabetes care: A qualitative analysis. *BMC Fam Pract*. 2010;11:41-48.
31. Taylor C, Shaw R, Dale J, French D. Enhancing delivery of health behaviour change interventions in primary care: A meta-synthesis of views and experiences of primary care nurses. *Patient Educ Couns*. 2011;85(2):315-322.
32. Dwarswaard J, van de Bovenkamp H. Self-management support: A qualitative study of ethical dilemmas experienced by nurses. *Patient Educ Couns*. 2015;98(9):1131-1136.
33. Jamtvedt G, Young JM, Kristoffersen DT, O'Brien MA, Oxman AD. Audit and feedback: Effects on professional practice and health care outcomes. *Cochrane Database Syst Rev*. 2006(2):CD000259.
34. Hankonen N, Sutton S, Prevost AT, et al. Which behavior change techniques are associated with changes in physical activity, diet and body mass index in people with recently diagnosed diabetes? *Ann Behav Med*. 2015;49(1):7-17.
35. Greaves C, Sheppard K, Abraham C, et al. Systematic review of reviews of intervention components associated with increased effectiveness in dietary and physical activity interventions. *BMC Public Health*. 2011;11:119-131.
36. Williams SL, French DP. What are the most effective intervention techniques for changing physical activity self-efficacy and physical activity behaviour--and are they the same? *Health Educ Res*. 2011;26(2):308-322.
37. Bravata D, Smith Spangler C, Sundaram V, et al. Using pedometers to increase physical activity and improve health: A systematic review. *JAMA*. 2007;298(19):2296-2304.

38. French D, Olander E, Chisholm A, Mc Sharry J. Which behaviour change techniques are most effective at increasing older adults' self-efficacy and physical activity behaviour? A systematic review. *Ann Behav Med*. 2014;48(2):225-234.
39. Michie S, Abraham C, Whittington C, McAteer J, Gupta S. Effective techniques in healthy eating and physical activity interventions: A meta-regression. *Health Psychol*. 2009;28(6):690-701.
40. van Eijk-Hustings YJ, Daemen L, Schaper NC, Vrijhoef HJ. Implementation of motivational interviewing in a diabetes care management initiative in the netherlands. *Patient Educ Couns*. 2011;84(1):10-15.
41. van Hooft S, Dwarswaard J, Bal R, Strating M, van Staa A. What factors influence nurses' behavior in supporting patient self-management? an explorative questionnaire study. *Int J Nurs Stud*. 2016;63:65-72.
42. Heinrich E, Candel MJ, Schaper NC, de Vries NK. Effect evaluation of a motivational interviewing based counselling strategy in diabetes care. *Diabetes Res Clin Pract*. 2010;90(3):270-278.
43. Jansink R, Braspenning J, Laurant M, et al. Minimal improvement of nurses' motivational interviewing skills in routine diabetes care one year after training: A cluster randomized trial. *BMC Fam Pract*. 2013;14:44-2296-14-44.
44. Jonkman N, Westland H, Trappenburg J, et al. Do self-management interventions in COPD patients work and which patients benefit most? an individual patient data meta-analysis. *Int J Chron Obstruct Pulmon Dis*. 2016;11:2063-2074.
45. Jonkman N, Westland H, Groenwold RHH, et al. Do self-management interventions work in patients with heart failure? an individual patient data meta-analysis. *Circulation*. 2016;133(12):1189-1198.
46. Poskiparta M, Kasila K, Kiuru P. Dietary and physical activity counselling on type 2 diabetes and impaired glucose tolerance by physicians and nurses in primary healthcare in finland. *Scand J Prim Health Care*. 2006;24(4):206-210.

APPENDIX

Appendix 1. Development of the coding list for self-management topics



Appendix 2. Description of self-management topics in the coding list

Self-management topics	Description of the self-management topics
Two general topics	
Understanding the disease	Raising awareness of the chronic condition(s) and transfer of information/education about the disease, knowledge about the consequences, timeline, treatment, prognosis and symptoms.
Understanding emotional and social consequences of the disease	Raising awareness of the emotional and social consequences of living with the chronic condition(s). Includes knowledge about emotional consequences (e.g. stress, anger, grief, fear, sadness, despondency) and social consequences (e.g. consequences for family, relationships, work, leisure time, voluntary work) and finding ways to prevent and manage (e.g. by actively seeking to organise support systems) these consequences.
Seven self-management behaviours	
Symptom monitoring	Monitoring of signs and symptoms, fluctuation in signs and symptoms, the risk for complications, e.g. keeping a diary/log.
Symptom and exacerbation management	(Self-)treatment of signs and symptoms of exacerbations, treatment of fluctuations in signs and symptoms, the risk for complications, e.g. deciding whether to seek medical help if symptoms are flaring up, taking extra medication for symptom worsening, nutritional adaptation in case of hypo- or hyper-glycemic diabetes mellitus.
Physical activity	Maintaining or increasing daily physical activity.
Dietary intake	Maintaining or adopting healthy daily dietary intake, e.g. losing weight, eat less fat or carbohydrates.
Smoking cessation	Quitting or reducing smoking.
Medication management	Taking medication as prescribed (e.g., taking medication on time, ensuring good supply, ensuring correct administration and dose, recognising side effects and seeking advice/help to minimise them). Not included: adjustments of medication for treatment of condition(s).
Alcohol use	Stopping or reducing drinking alcohol.

CHAPTER 3

Unravelling effectiveness of a nurse-led behaviour change intervention to enhance physical activity in patients at risk for cardiovascular disease in primary care: study protocol for a cluster-randomised controlled trial

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Trials. 2017; 18 (1), 79-94

ABSTRACT

Background: Self-management interventions are considered effective in patients with chronic disease, but trials have shown inconsistent results, and it is unknown which patients benefit most. Adequate self-management requires behaviour change in both patients and healthcare providers. Therefore, the Activate intervention was developed with a focus on behaviour change in both patients and nurses. The intervention aims for change in a single self-management behaviour, namely physical activity, in primary care patients at risk for cardiovascular disease. The aim of this study is to evaluate the effectiveness of the Activate intervention.

Methods: A two-armed cluster-randomised controlled trial will be conducted to compare the Activate intervention with care as usual at 31 general practices in the Netherlands. Approximately 279 patients at risk for cardiovascular disease will participate. The Activate intervention is developed using the Behaviour Change Wheel and consists of 4 nurse-led consultations in a 3-month period, integrating 17 behaviour change techniques. The Behaviour Change Wheel was also applied to analyse what behaviour change is needed for nurses to deliver the intervention adequately. This resulted in a one-day training and two coaching sessions (including 21 behaviour change techniques). The primary outcome is physical activity, measured as the number of minutes of moderate to vigorous physical activity using an accelerometer. Potential effect modifiers are age, body mass index, level of education, social support, depression, patient-provider relationship and baseline number of minutes of physical activity. Data will be collected at baseline and at 3 months and 6 months of follow-up. A process evaluation will be conducted to evaluate the training of nurses, intervention fidelity, and to identify barriers to and facilitators of implementation as well as to assess participants' satisfaction.

Discussion: To increase physical activity in patients and to support nurses in delivering the intervention, behaviour change techniques are applied to change behaviours of the patients and nurses. Evaluation of the effectiveness of the intervention, exploration of which patients benefit most, and evaluation of our theory-based training for primary care nurses will enhance understanding of what works and for whom, which is essential for the further implementation of self-management in clinical practice.

BACKGROUND

Considering the rising number of patients with one or more chronic diseases, there is an urgent need for effective interventions to enhance self-management. The aim of self-management interventions is to support patients to actively participate and take responsibility for self-managing their symptoms, treatment, physical and psychosocial consequences, behaviour and lifestyle changes in daily life.[1] Adequate self-management requires behaviour change in both patients and healthcare providers.

Self-management interventions have become an important part of care for patients with chronic diseases because they have been shown to positively affect health outcomes, including disease-specific outcomes, quality of life, self-management behaviour and cost-effectiveness.[2-7] However, a substantial proportion of patients does not comply with or respond to these interventions, raising new questions regarding for whom these interventions work best.[8] Trials have included different groups of patients with varying characteristics, which may also contribute to this heterogeneity in effect size. Self-management interventions might be more or less effective in specific subgroups of patients. Patients characterized as having, for example, low self-efficacy, low health-related quality of life, young age, no depressive symptoms, low education level, low income and low baseline self- management capacity tend to benefit more from self- management interventions.[9-11] However, the current evidence is inconclusive and needs further research.[12]

Furthermore, heterogeneity in trial designs, intervention components, follow-up time, outcome measures, and scarcely measured and reported intervention fidelity may contribute to the heterogeneity in effectiveness of self-management.[2-4,13] Therefore, further research is essential to unravel the effectiveness of self-management interventions and to explore for whom these interventions work best and whether they can be delivered as intended. For this purpose, we designed the Activate intervention, in which we focus on a large heterogeneous subgroup of patients monitored in primary care, namely patients at risk for cardiovascular disease (CVD). Patients who are at risk for CVD have at least one of the following major risk factors: high blood pressure, high cholesterol, diabetes mellitus type 2 (DM2) or a positive family history of CVD.[14] Guidelines on CVD prevention recommend pharmacotherapy and increasing the patient's level of physical activity, healthy diet, reduction of alcohol consumption and cessation of smoking.[15,16] The Activate intervention is targeted at increasing physical activity, which is considered to be one of the most relevant self-management components for patients at risk for CVD. Adequate physical activity is associated with a lower risk of developing diabetes and with decreased mortality, blood pressure, obesity, cholesterol level and CVD-related symptoms.[17-23] Patients are recommended to engage in at least 30 minutes of moderate

activity per day for at least 5 days per week.[24] Yet, patients often fail to achieve this threshold, which emphasizes the need to change their inactive behaviour.[25,26]

Achieving behaviour change is complex and requires skills and competences of both patients and healthcare professionals. In routine consultations, behaviour change support is often brief and fragmented and rarely includes recommendations on how to achieve behaviour change.[27-29] This underlines that healthcare providers also need to change their behaviour in order to adequately support patients in behaviour change. Nurses need to change their consultation style from traditional patient education to teaching patients problem-solving skills and supporting them in changing their behaviour, goal setting and action planning.[30-32] Unfortunately, training of healthcare providers does not always lead to sufficient improvement of their skills and competences or to maintenance of the acquired skills in their daily routines.[28] Insufficient adoption of trained skills and competences might influence the ability to adhere to study protocols and dilute the effect of the intervention.[33-35]

A promising approach for developing interventions to enhance behaviour change in patients and healthcare providers is the comprehensive Behaviour Change Wheel (BCW).[36,37] The BCW incorporates 19 theoretical behaviour change frameworks. The approach begins at the hub of the wheel, where the capacity, opportunity or motivation influencing behaviour (COM-B) model is used to conduct a behavioural analysis to understand the target behaviour. The COM-B model consists of three components, capability, opportunity and motivation, which interact to generate behaviour. Surrounding the COM-B model is a layer of intervention functions to choose from, which can be used to address deficits in one or more of capability, opportunity or motivation. These intervention functions can then be linked to appropriate behaviour change techniques (BCTs).[36,37] BCTs are regarded as active components of behaviour change and were recently defined in the Behaviour Change Technique Taxonomy v1 (BCTTv1) by Michie et al.[38] Finally, the outer layer identifies types of policy that one can use to deliver the intervention functions.[36,37] The Activate intervention is developed using the BCW. Specifying the BCTs is intended to unravel the effectiveness of the intervention and to explore which patients benefit most.

The primary objective of this study is to evaluate the effect of the Activate intervention on increasing physical activity in primary care patients at risk for CVD. Secondary objectives are to

1. Evaluate the effect of the Activate intervention on sedentary behaviour, self-efficacy, level of activation and health status in primary care patients at risk for CVD.
2. Identify which patient-related characteristics modify change in physical activity levels.
3. Evaluate the training of nurses, intervention fidelity, perceived barriers to and facilitators of implementation, and satisfaction with the Activate intervention.

METHODS/DESIGN

Design

We designed a two-armed cluster-randomised controlled trial with the general practice as the unit of randomisation to compare the Activate intervention with care as usual. Figure 1 shows a schematic overview of the trial design.

To optimise reporting of this trial and to enhance validity, this study is reported according to the 2013 Standard Protocol Items: Recommendations for Interventional Trial (SPIRIT). A SPIRIT checklist (Appendix 1) and a SPIRIT figure (Figure 2) are provided. Protocol modifications will be reported to the institutional review board of the University Medical Center Utrecht and will be uploaded to the ClinicalTrials.gov database. The final report will be written according to the Consolidated Standards of Reporting Trials (CONSORT) extension to cluster trials.[39]

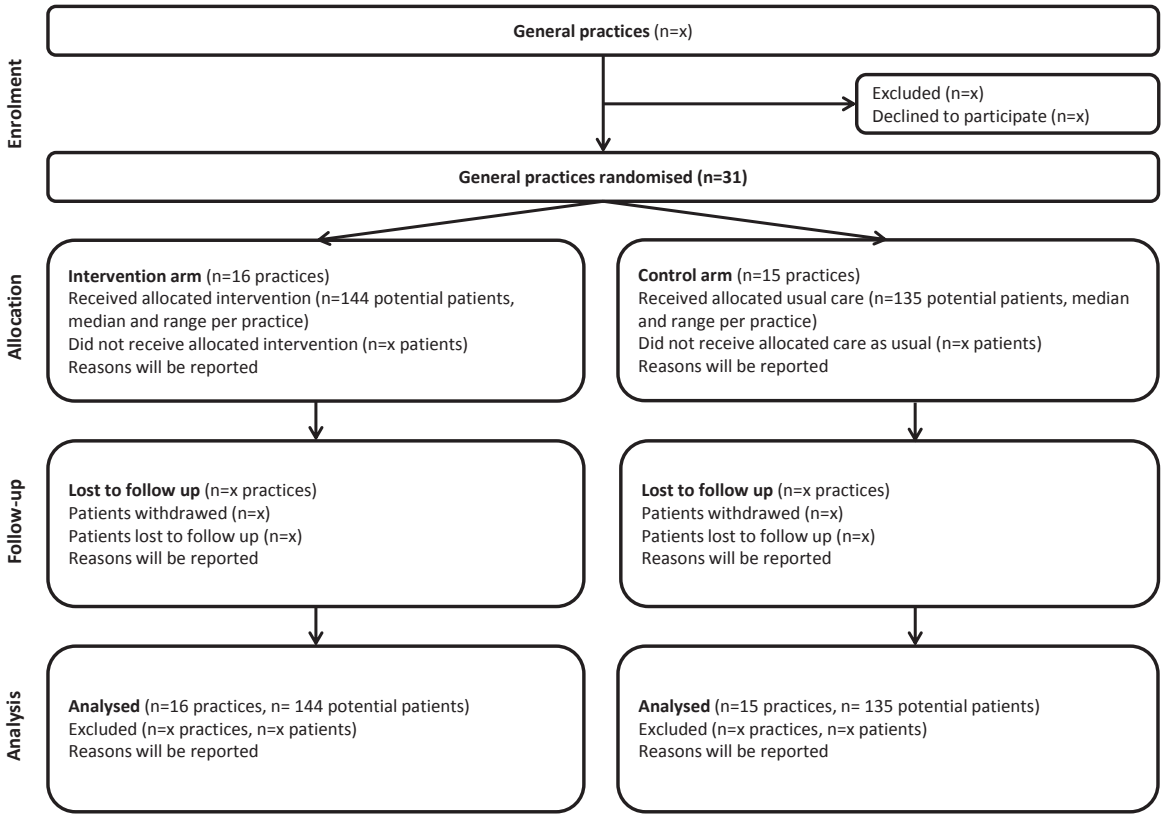

Figure 1. Consolidated Standards of Reporting Trials (CONSORT) diagram[39] for the Activate intervention showing participant flow through each stage of the randomised trial

Figure 2. Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) figure

	Study period			
	Enrolment Allocation	**Post-allocation**		**Close-out**
TIMEPOINT	**0**	**Intervention period**	**T1 3 months**	**T2 6 months**
ENROLMENT				
Eligibility screen	x			
Informed consent	x			
Allocation	x			
INTERVENTIONS				
Activate intervention		⟷		
ASSESSMENTS				
Characteristics of patients				
Age (Q)	x			
Gender (Q)	x			
Employment status (Q)	x			
Living alone/ with others (Q)	x			
Ethnicity (Q)	x			
Years since diagnose (Q)	x			
Level of physical activity (Q: SQUASH)	x			
Smoking status (Q)	x			
Alcohol consumption (Q)	x			
Healthy food intake (Q)	x			
BMI (C)	x			
Blood pressure (C)	x			
Cholesterol levels (C)	x			
HbA1c (DM2 only) (C)	x			
Level of education (Q)	x			
Health literacy (Q: HLS-EU-Q)	x			
Social support (Q: MSPSS)	x			
Depression (Q: HADS)	x			
Patient-provider relationship (Q: CAT)	x		x	x
Diagnosis of DM2, hypertension, hypercholesterolemia (C)	x			
Medication for DM2 (C)	x			
Medication for high blood pressure (C)	x			
Medication for high cholesterol level (C)	x			
Primary outcome				
Level of physical activity (Accelerometer)	x		x	x

Figure 2. Continued

	Study period		
	Enrolment Allocation	**Post-allocation**	**Close-out**
ASSESSMENTS			
Secondary outcomes			
Sedentary behaviour (Accelerometer)	x	x	x
Self-efficacy for physical activity (Q: ESS)	x	x	x
Patient activation (Q: PAM-13)	x	x	x
Health status (Q: EQ-5D)	x		x
Process evaluation			
Questionnaire		x	
Semi-structured interview			x

Abbreviations: BMI Body Mass Index; C Chart review; CAT Communication Assessment Tool; CVRM CardioVascular Risk Management; DM2 diabetes mellitus type 2; ESS Exercise Self-efficacy Scale; HADS Hospital Anxiety and Depression Scale; HbA1c glycated haemoglobin; HLS-EU-Q European Health Literacy Project questionnaire; MSPSS Multidimensional Scale of Perceived Social Support; PAM-13 Patient Activation Measure; Q Questionnaire; SQUASH Short QUestionnaire to Asses Health

Participants

Patients will be recruited from general practices by primary care nurses in agreement with the general practitioner. The study population consists of adult patients at risk for CVD who are supported by a primary care nurse working in a general practice.

Inclusion criteria

Eligible patients will have at least one of the following risk factors as described in the Dutch guideline for cardiovascular risk management (CVRM):[15]

- Aged 40–75 years

AND will have at least one of the following criteria:

- High blood pressure (≥140 mmHg) or already treated for high blood pressure
- High total cholesterol (≥6.5 mmol/L) or already treated for high cholesterol
- DM2
- A positive family history of CVD

AND do not meet the Dutch Norm for Healthy Exercise[24] according to the Short Questionnaire to Assess Health (SQUASH).[40]

Exclusion criteria

Patients are excluded from the trial if they are unable to give informed consent (e.g. owing to cognitive impairment); are unable to speak, write and read Dutch; have contraindications to increasing their physical activity level (e.g. unstable angina pectoris, unstable heart failure, acute illness); or have a terminal illness or have a severe psychiatric illness or chronic disorder(s) that seriously influence their ability to improve their psychical activity level. Moreover, patients should not have participated in a structured programme conducted in a medical setting to increase their level of physical activity in the past two years, because including these patients might bias the effect of the Activate intervention by other prior interventions targeted at enhancing physical activity.

Selection and recruitment

Recruitment will start with primary care nurses working in general practices located in the Netherlands. Nurses will be recruited by an invitational e-mail, by telephone and by personal contact with primary care nurses, general practitioners and practice managers until 31 general practices are enrolled. Each general practitioner identifies as many patients who fulfil the inclusion and exclusion criteria determined in scheduled consultations with the nurse as needed to recruit nine or ten patients. In this way, the general practitioner guarantees a random selection of eligible patients without further selection by the preference of the general practitioner or the nurse. The attending nurse will send eligible patients an envelope by mail containing an invitational letter signed and dated by their attending nurse and general practitioner, along with study information, an informed consent form and a short self-assessment of the patient's physical activity level using the SQUASH.[40] Patients are asked to bring the letter, informed consent form, and completed SQUASH to their next scheduled visit with the nurse. During the consultation, the nurse will check whether patients are eligible according to their level of physical activity and are willing to enrol in the trial. Patients' enrolment in the trial is voluntary, and their decision about enrolment does not have any consequences for their treatment. If patients are eligible and are willing to enrol, their written informed consent will be obtained.

Ethical considerations

The Activate trial is ethically approved by the institutional review board of the University Medical Center Utrecht with protocol ID NL54286.041.15. Personal data will be coded and handled confidentially. All participants gave written informed consent prior to trial participation.

Informed consent

An informed consent to postponed information procedure is being used,[41] keeping patients unaware of the Activate intervention as the major study aim, randomisation

and allocation of their general practice until the end of the follow-up period. With this procedure, a valid assessment of subjective outcomes can be obtained even when patients cannot be blinded to the intervention.[41] Using the modified informed consent procedure in our trial, selection bias by attrition or drop out can be reduced. A patient's preference for allocation to the treatment arm above care as usual might result in increased drop out in the control group owing to dissatisfaction or lack of interest shown by the patient.[42]

Randomisation and blinding

Participating general practices will be randomly allocated to the intervention group or control group after formalisation of participation. Randomisation at the level of the general practice allows evaluation of the intervention without contamination bias arising from diffusion of the intervention towards control patients. For comparability of patients' characteristics such as employment status, literacy level and education, minimisation will be used to balance urbanisation areas of the general practices.

To safeguard allocation concealment, the randomisation procedure is supervised by an independent data manager and performed using web-based randomisation software. Blinding the general practices and their nurses is not possible because nurses will perform the intervention. The investigators will be aware of the allocation as they directly communicate with the general practices and nurses about the trial and are involved with the training of nurses. All patients will be informed about the assessment of their level of physical activity. Patients will be blinded as a result of the postponed information procedure. Patients who are allocated to the intervention group will only be informed about the intervention. Patients allocated to the control group will only be informed about the data collection in the control group.

Intervention development

The Medical Research Council framework was used as a guide for the development and evaluation of the Activate intervention.[43,44] The BCW was used to systematically develop the Activate intervention. We applied the BCW twice. Firstly, we applied the BCW to understand what hinders and facilitates patients in changing their level of physical activity. Secondly, we applied the BCW to analyse what behaviour change is needed for nurses to deliver the Activate intervention adequately. The BCW consists of three layers (see Figure 3). In the first layer, we identified the source of the behaviour that could prove targets for the intervention (what needs to change) by conducting a COM-B analysis. To elaborate the behavioural analysis, we expanded on COM-B using the Theoretical Domains Framework (TDF).[45,46] The TDF is based on a synthesis of numerous overlapping theories of behaviour.[46] The 14 domains of the TDF can be mapped onto the capability, opportunity and motivation components of COM-B (see Figure 3, Appendix 2 and 3). In the second

layer, we used COM-B to generate a list of intervention function options. Intervention functions (e.g. education, persuasion) are broad categories of means by which an intervention can change behaviour. To determine which intervention functions to use, we applied the APEASE criteria (affordability, practicability, effectiveness and cost-effectiveness, acceptability, side effects/safety and equity). The third layer of the BCW identifies seven types of policy (e.g. guidelines, social planning, legislation) that can be used to deliver the intervention functions.[36,37] This layer was not applicable to the present trial, because the intervention is not being implemented on a broad scale, but is being studied in a small number of practices. Finally, the intervention functions were linked to the BCTs described in BCTTv1, and we selected BCTs considering the APEASE criteria and available evidence of their effectiveness in the literature.

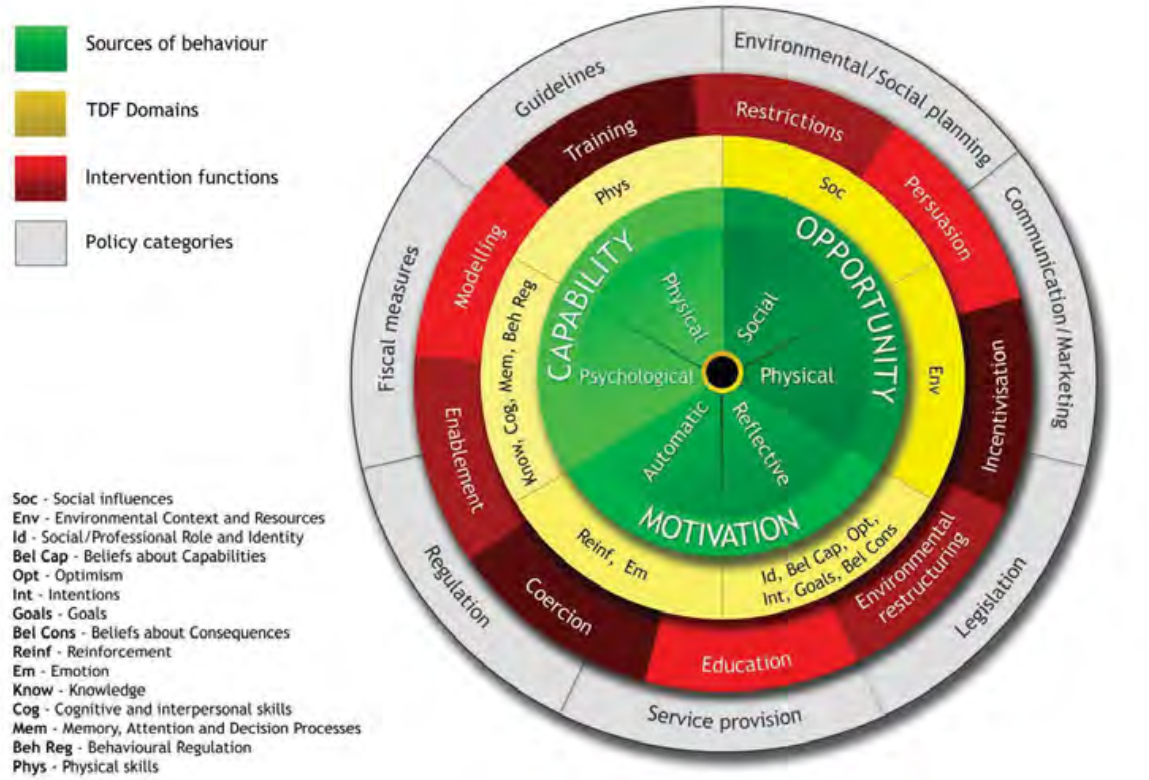

Figure 3. The Behaviour Change Wheel and Theoretical Domains Framework (TDF) domains. Reprinted with permission from Michie et al.[36,37]

Applying the BCW to enhance physical activity in patients

We conducted a pragmatic literature review of qualitative studies to understand the behaviour of patients and to identify the perceived barriers to and facilitators of enhancing patients' physical activity. The electronic databases MEDLINE and Embase were searched to retrieve publications of patients' perceived barriers to and facilitators of increasing their level of physical activity. Also, relevant references in included papers were added. Possible relevant publications were assessed to extract perceived barriers and facilitators until saturation was achieved. Results of the review were mapped onto COM-B and TDF. In the second layer of the BCW, we selected intervention functions likely to be most effective in encouraging the target behaviour to occur (Appendix 2).

Subsequently, the intervention functions were directly linked to a selection of appropriate and effective BCTs, resulting in 17 BCTs (Table 1). This selection of BCTs is guided and peer-reviewed by experts in behaviour change. Each BCT is thoroughly designated for application in the Activate intervention following the definition of each BCT as described in the BCTTv1 taxonomy,[38] resulting in four different consultations to enhance physical activity in the patients' home environment. During this process, two focus groups were held with primary care nurses to apply the APEASE criteria and to validate the intervention for feasibility in practice.

Table 1. Selected BCTs for the Activate intervention and division of BCTs over consultations

Selected BCTs from BCTTv1 *(Examples of application of included BCTs)*		BCTs divided over four consultations			
		1	2	3	4
1.	Goal setting (behaviour) *(e.g. agree on a personal daily activity goal)*	x	x	x	x
2.	Problem-solving (includes barrier identification and relapse prevention) *(e.g. prompt to identify personal advantages and disadvantages of physical activity, focus on advantages and deal with disadvantages. Discuss ways to prevent or deal with relapse)*	x	x	x	x
3.	Goal setting (outcome) *(e.g. agree on a personal health goal (e.g. a decrease in patients' blood pressure)*	x			
4.	Action planning *(e.g. prompt to plan specific activities at particular times during the week using the personal activity log)*	x	x	x	x

Table 1. Continued

Selected BCTs from BCTTv1 *(Examples of application of included BCTs)*		BCTs divided over four consultations			
		1	2	3	4
5.	Review behavioural goal(s) *(e.g. examine how the patient worked on the agreed goal, and consider to re-set, modify or continue the agreed goal)*		x	x	x
6.	Commitment *(e.g. ask to affirm the agreed goal and action plan)*		x	x	x
7.	Feedback on behaviour *(e.g. give feedback using the personal activity log)*	x	x	x	x
8.	Self-monitoring of behaviour *(e.g. ask to wear the accelerometer and to fill in the personal activity log daily)*	x	x	x	x
9.	Social support (unspecified) *(e.g. encourage support from patients' spouse or 'buddy')*	x	x	x	x
10.	Social support (practical) *(e.g. encourage practical help from patients' spouse or 'buddy')*		x	x	x
11.	Information about health consequences *(e.g. inform about health benefits of physical activity)*	x	x		
12.	Prompts/ cues *(e.g. advise to use the post-its and the pen with the Activate logo to remind on physical activity)*		x	x	x
13.	Habit formation *(e.g. prompt to rehearse and repeat the planned daily activities)*			x	x
14.	Graded tasks *(e.g. assist to increase the level of activity step-by-step by agreeing with achievable and challenging goals)*	x	x	x	x
15.	Restructuring the physical environment *(e.g. advice to repair the bike, buy good shoes or rain clothes)*		x	x	x
16.	Restructuring the social environment *(e.g. advise to go walking with a friend instead of drinking coffee)*		x	x	x
17.	Focus on past success *(e.g. encourage to think about occasions on which the patient succeeded in being physically active)*		x	x	x

Abbreviations: BCTs behaviour change techniques; BCTTv1 Behaviour Change Technique Taxonomy v1

Applying the BCW to deliver the Activate intervention by primary care nurses

Subsequent to the development of the Activate intervention, we applied the BCW in nurses. In the first layer of the BCW, we explored qualitative literature by searching the electronic databases MEDLINE and Embase to retrieve publications on nurses' perceived barriers and facilitators in delivering a behaviour change intervention and scrutinised reference lists of identified papers. Publications were assessed to extract perceived barriers and facilitators until saturation was achieved. In addition to the literature review, a focus group with primary care nurses was held to identify what nurses need to change to deliver the intervention. Prior to the focus group, nurses were asked to give their opinion, using a four-point Likert scale (1=totally disagree, 4=totally agree), on the APEASE criteria regarding the 17 BCTs in daily practice and to reflect on their capability, opportunity and motivation to apply these BCTs. Results of the review were mapped onto COM-B and TDF. Results of the literature and focus group showed that all components of COM-B need to be targeted to adequately deliver the BCTs integrated into the Activate intervention (Appendix 3).

In the second layer of the BCW, we selected intervention functions (Appendix 3) and directly linked these to appropriate and effective BCTs (Table 2). This resulted in a selection of 21 BCTs. Each BCT is thoroughly designated for application in standardized training for nurses to equip them to deliver the intervention as intended. This process is peer-reviewed by experts and checked for face validity by four primary care nurses during a second focus group.

Table 2. Division of selected BCTs over the different components of the training of primary care nurses

Selected BCTs from BCTTv1 *(Examples of application of included BCTs)*		**BCTs divided over components training**			
		Preparation	**One-day training**	**Coaching sessions**	**Available resources**
1.	Information about health consequences *(e.g. inform about health benefits of physical activity using the background video, presentation during the one-day training and the workbook)*	x	x		x
2.	Information about social and environmental consequences *(e.g. inform about the social and environmental consequences of increasing physical activity using the background video, a presentation during the one-day training and the workbook)*	x	x		x

Table 2. Continued

Selected BCTs from BCTTv1 *(Examples of application of included BCTs)*		**BCTs divided over components training**			
		Preparation	**One-day training**	**Coaching sessions**	**Available resources**
3.	Prompts/cues *(e.g. advise to use the post-its and the pen with the Activate logo, send a monthly newsletter, have regular contact with nurses)*		x		x
4.	Feedback on behaviour *(e.g. provide feedback on nurses' performance during the role-plays and their audiotapes of the consultations)*		x	x	
5.	Information about others' approval *(e.g. inform nurses about professionals' and patients' approval of their performance of their learned skills)*		x	x	
6.	Credible source *(e.g. all training components are developed and delivered by experts)*	x	x	x	x
7.	Focus on past success *(e.g. focus on what went well while (practising) delivering the consultations)*		x	x	
8.	Verbal persuasion about capability *(e.g. tell that nurses can successfully deliver the consultations, improve their skills by practising and feedback, and coach on self-doubts)*		x	x	
9.	Reward (outcome) *(e.g. nurses improve their coaching skills by participating in the trial and the training is accredited)*		x	x	
10.	Monitoring of behaviour by others without feedback *(e.g. observe role-plays and listen to the audio-tapes without feedback)*		x	x	
11.	Monitoring outcome of behaviour by others without feedback *(e.g. results from questionnaires, interviews with patients)*		x		
12.	Instruction on how to perform the behaviour *(e.g. train how to apply the BCTs using role-plays)*	x	x	x	x

Table 2. Continued

Selected BCTs from BCTTv1 *(Examples of application of included BCTs)*		**BCTs divided over components training**			
		Preparation	**One-day training**	**Coaching sessions**	**Available resources**
13.	Demonstration of the behaviour *(e.g. demonstrate how to apply the BCTs using the instructional videos)*		x	x	x
14.	Behavioural practice/rehearsal *(e.g. prompt practice of applying the BCTs during the role-plays and the actual consultations)*		x	x	x
15.	Habit formation *(e.g. prompt repetition of applying the BCTs by including several eligible patients)*		x	x	x
16.	Adding objects to the environment *(e.g. provide a handbook with example sentences, post-its and a pen with the Activate logo, use patients' daily activity log)*		x	x	x
17.	Restructuring the physical environment *(e.g. facilitate consultations to focus on solely physical activity, encourage use of the handbook with example sentences during the consultations, use patients' daily activity log)*		x	x	x
18.	Social support (unspecified) *(e.g. encourage and coach regularly by e-mail and telephone, provide a monthly newsletter*		x	x	
19.	Social support (practical) *(e.g. provide nurses with all study materials and answer questions and remarks)*		x	x	
20.	Problem-solving (includes barrier identification and relapse prevention) (*e.g. prompt to deal with lack of motivation and adherence to the trial protocol)*		x	x	x
21.	Self-monitoring of behaviour *(e.g. prompt making audio-tapes of consultations)*		x	x	

Abbreviations: BCTs behaviour change techniques; BCTTv1 Behaviour Change Technique Taxonomy v1

The Activate intervention

The Activate intervention is developed for patients at risk for CVD. The intervention is standardised in four nurse-led consultations to enhance physical activity -in the first week and after 2, 6 and 12 weeks- and will take place in the patient's own general practice. Although the BCTs are systematically applied in the intervention, the content of the intervention will be individualised to the patient's unique circumstances, needs and preferences by adapting the BCTs during the consultations (e.g. goal setting, action planning, feedback on behaviour). The duration of the first consultation is 30 minutes, and the subsequent consultations last 20 minutes. During the first consultation, patients will receive a workbook containing information about the study, useful websites and apps, tips and tricks, activity logs and action plans.

In the first consultation, the nurses will discuss the patient's CVD risk profile, the consequences of a sedentary versus an active lifestyle, and self-assessment of their activity level in order to raise awareness to improve the patient's level of physical activity. Together, the patient and nurse formulate an overall outcome goal and an exercise goal, considering physical activity in minutes per day. In order to raise awareness of self-monitoring and how to self-monitor, the patient is asked to self-monitor physical activity during the next 2 weeks by using an accelerometer and a paper activity log, which provide feedback on the patient's level of goal attainment. Additionally, the patient is asked to identify facilitators to goal attainment.

During the second consultation, the nurse rehearses the information about the consequences of an active lifestyle, reviews the goal attainment using the activity log kept by the patient, and discusses the identified facilitators. If applicable, the physical activity goal is reformulated. A specific action plan to attain the level of physical activity formulated as their goal is set up. The patient is supported in finding ways to use facilitators for physical activity, is asked to self-monitor activities during the next weeks in order to attain the set physical activity goal, and is asked to identify possible barriers to goal attainment.

In the third consultation, the nurse will give feedback on the reached level of goal attainment during the past weeks, using the log kept by the patient. If applicable, the activity goal and specific action plan are adjusted. Furthermore, the nurse will discuss how to prevent relapse into an inactive lifestyle (old habits) by discussing the barriers leading to relapse as well as how to build new habits to maintain the active lifestyle. The patient is asked to self-monitor his/her activity level during the next weeks in order to attain the set physical activity goal and to identify possible barriers to and facilitators of goal attainment. In the last consultation, the nurse will give feedback on the reached level of goal attain-

ment during the past 6 weeks, using the results of the patient's self- monitoring and activity log and the identified facilitators. Furthermore, the nurse will rehearse how to prevent relapse into old habits and the formation of new activity habits.

Training of primary care nurses

A comprehensive, standardised training for nurses is developed in collaboration with an educator and a health psychologist, in which the 21 BCTs are integrated (see Table 2). Prior to the inclusion of patients, nurses allocated to the intervention arm will receive a one-day, interactive, educational, face-to-face, accredited training in a small group outside the general practice, led by a health psychologist. To prepare themselves for the training, nurses will be asked to watch an instructional video of the study procedures and to watch a video of background information on the importance of physical activity in patients at risk for CVD provided by a physiotherapist.

At the start of the one-day training, nurses will be asked to fill out a questionnaire and discuss their results in a group discussion. In this questionnaire, nurses will be asked to reflect on their beliefs towards their capability, motivation and confidence regarding delivering the Activate intervention and each of the 17 BCTs integrated into the Activate intervention and the effectiveness of the intervention and BCTs on a seven-point Likert scale (1=completely disagree to 7=completely agree). This questionnaire is specifically developed for the trial. The key focus of the one-day training is learning how to address the BCTs in each consultation. Furthermore, the one-day training entails an explanation of the intervention and its timeline, as well as information about the health consequences of physical activity. The training will contain a combination of didactic presentations, short instructional videos on how to apply the BCTs in each of the consultations, small-group discussions and role-plays. Furthermore, nurses receive two individual coaching sessions by the health psychologist in which the trained skills in applying the BCTs are rehearsed and optimised. Prior to each coaching session, nurses will be asked to audiotape one of their consultations of the Activate trial in their practice, which will be discussed during the coaching session.

The nurses will be provided with several resources, which they can use during their consultations. They will have a workbook for each patient in which checklists (what to do when) and example sentences are given to help them deliver the BCTs effectively. In addition to the individual coaching sessions, nurses will be asked to watch the instructional videos on how to apply the BCTs in the intervention to reinforce their skills and competences in delivering the Activate intervention. The division of selected BCTs between the different components of the training is shown in Table 2.

Feasibility and piloting

The training for nurses was pilot-tested in a small feasibility study. To evaluate whether the consultations were feasible in time and to ensure the intervention matched with the patient's needs and could be incorporated into daily life, two primary care nurses completed the training, and one patient at risk for CVD completed the consultations. Their experiences, barriers, strengths, limitations and time investments were evaluated. The nurses indicated that the training adequately equipped them to deliver the intervention. They suggested minor adaptations, namely inclusion of patients across a broader age range (40–75 years), easier interpretation of the level of adherence to the Dutch Norm for Healthy Exercise according to the SQUASH, and clear instructions on how to recruit and include patients. The time spent on the consultation was acceptable and in accordance with the protocol. The patient was satisfied with the intervention and suggested minor adaptations in the layout of the activity log.

Care as usual

Patients in the control arm will receive care as usual, according to the national healthcare standards for patients at risk for CVD,[15] during regular consultations with their nurse and will not receive additional consultations beyond the standard of care to increase their physical activity level. Patients at risk for CVD have at least one consultation per year with their nurse; however, this frequency can be extended when considered necessary (e.g. in case of medication change). Patients with DM2 have at least four consultations with their nurse annually. In order to keep the nurses in the control arm motivated, the one-day training will be offered to them at the end of the trial.

Data collection

To assess the characteristics of the nurses participating in the trial, a short questionnaire will be sent to nurses. To assess whether patients are eligible for improving their level of physical activity, patients will be asked to fill in a short self-assessment using the SQUASH prior to consenting to participate in the trial. Nurses will interpret the completed SQUASH using clear guidelines to see if a patient fits the inclusion criteria regarding an insufficient level of physical activity. After enrolment, patient data will be collected at baseline (T0), after 3 months (T1) and after 6 months (T2) by use of an accelerometer, questionnaires and chart review (see Figure 2). At time point T0, the nurses will distribute the questionnaires and accelerometer after enrolment during their regular scheduled visit. At time points T1 and T2, the research team will distribute the questionnaires and accelerometers. To maximize retention of general practices, the research team will contact each general practice regularly, and nurses can easily contact the research team for remarks and questions. Nurses will receive a monthly newsletter to keep them updated on the number of recruited patients in the other attending general

practices and to invite them to share their experiences with other nurses. To maximise retention of patients, the research team will contact patients by telephone or e-mail if no questionnaire and accelerometer are received within 3 weeks. If the research team is not able to contact the patients after several attempts, we will ask the attending nurse to contact the patient. Furthermore, patients are encouraged to contact the research team if they have remarks and questions.

Data management

Data collection, as well as handling and storage of data and documents, will be coordinated at the University Medical Center Utrecht. Entering of objective data collected from the accelerometers will automatically be uploaded from the accelerometer by two researchers on the research team. Entering of subjective collected data will be performed electronically by an independent data manager who is not aware of patient allocation.

Outcome measures

Primary outcome

The primary outcome is physical activity objectively measured as the number of minutes of physical activity in the moderate to vigorous category. This will be assessed with a personal activity monitor (Pam AM300; Pam bv, Oosterbeek, The Netherlands).[47] The Pam AM300 is a small, valid, and reliable tri-axial accelerometer which can easily be worn on the hip. Additionally, patients will be asked to write down in a paper log the number of minutes they have swum, cycled or done strength training, because the accelerometer cannot measure these activities accurately.

The number of minutes of physical activity in the moderate (3–6 metabolic equivalents (METs)) and vigorous (≥6 METs) categories at 6 months of follow-up will be considered as the primary outcome measure. Patients will be asked to wear the accelerometer during 7 consecutive days for 12 h daily at baseline (T0), at 3 months of follow-up (T1) and at 6 months of follow-up (T2).

For a valid measurement, the accelerometer has to be worn for at least 4 weekdays and 1 weekend day for 8 h. After each data collection point, patients will be asked to send the accelerometer to the research team to upload the data from the accelerometer to a data file. The outcome is the average number of minutes of moderate to vigorous activity on all the valid days. With the Activate intervention, a mean difference in minutes of 20% of the at least moderate level of physical activity from baseline is considered to be clinically relevant and reasonable to achieve within 3 months of intervention.

Secondary outcomes

The following are secondary outcomes of this trial:

1. Sedentary behaviour using the accelerometer to measure the number of minutes in the sedentary category (<1.8 METs)
2. Self-efficacy for physical activity using the Exercise Self-efficacy Scale[48-50]
3. Patient activation using the PAM-13 short form[51,52]
4. Health status using the EQ-5D-3L questionnaire[53]

Potential effect modifiers to investigate which patient characteristics modify change in physical activity level include age, depression measured using the Hospital Anxiety and Depression Scale,[54,55] body mass index (BMI), level of education, social support using the Multi-dimensional Scale of Perceived Social Support,[56] patient-provider relationship using the Communication Assessment Tool,[57] and baseline number of minutes of moderate to vigorous level of physical activity using the accelerometer.

Process evaluation

A mixed methods process evaluation will be performed at the end of the trial. To evaluate the fidelity of delivery,[34,44,58] nurses allocated to the study arm will randomly audiotape one consultation from among the four consultations. The audiotapes will be coded using a coding list developed specifically for this trial consisting of the content of each of the four consultations and the Behaviour Change Counselling Index.[59] Additionally, nurses will be instructed to self-report the presence of the patient and the discussed content during a consultation, the time needed per consultation, and reasons for the patient's drop out if applicable. To evaluate the nurses' perceptions of their capability, motivation, confidence and effectiveness towards delivering the intervention and applying the BCTs, nurses will be asked to complete the questionnaire at the start of the training, after the training, during the intervention period, and at the end of the trial. At the end of the trial, nurses in the intervention arm will be invited to a semi-structured interview to explore their perceptions towards delivering the intervention and the feasibility of the intervention. Included topics will be perceptions of the study procedures, barriers to and facilitators of implementation of the intervention, applying the BCTs, the training programme, self-efficacy, motivation of nurses and patients, perceived effect of the intervention, and the acceptability of the intervention for implementation in routine primary care. Furthermore, descriptive data will be collected to identify existing socio-demographic variation in who received the intervention and who dropped out of the intervention.

To explore patients' experiences with the intervention, patients in the intervention group will be asked additional questions in the T1 questionnaire. To deepen our understanding of patients' experiences, a sample of patients from the intervention group will be

invited to a semi-structured interview at the end of the trial. Included topics in the T1 questionnaires and interviews will be perceptions of the outcome, capability, self-efficacy, motivation, intentions, opportunity, barriers and facilitators, and satisfaction with the intervention.

Additional parameters

Patients' socio-demographic characteristics, including sex, employment status, living alone/with others, years since diagnosis, smoking status, alcohol consumption and healthy food intake will be collected by using questionnaires at baseline. Blood pressure, cholesterol levels, glycated haemoglobin (DM2 only) and medication use will be extracted from the patients' medical charts at baseline. Characteristics of nurses, including age, level of nursing education, number of years of experience working as a primary care nurse, number of years working in the field of CVRM, achievement of self-management training and geographical area of the general practice will also be collected at baseline.

Statistical analysis

Effectiveness of the Activate intervention

Data will be analysed primarily according to intention-to-treat and secondarily according to per protocol principles. All patients with outcome data will be included in the intention-to-treat analysis, regardless of their adherence to the intervention. Patients in the intervention group will be included in the per protocol analysis if they received a minimum of three consultations (75%), based on the registration forms obtained from the nurses. Patients from both groups will be excluded from this analysis if they do not complete the T1 measurement. To examine the effect of the Activate intervention between the arms, a multilevel analysis will be performed (three levels: time, participant and general practice). Data will be quantified by mean, SD and 95% CI using linear mixed effects models. All mixed effects models include a random intercept for changes over time and between practices. An interaction term will be added for time and study arm. Missing data will be handled according to the rules of the questionnaires of missing data. Missing outcome data will not be imputed because multilevel analysis is a flexible method for dealing with missing outcome data.[60] Sensitivity analyses, such as an analysis of protocol deviations, definitions of outcomes, and outliers, will be performed to assess the robustness of the findings.

Potential effect modifiers

To examine which patient characteristics modify the effectiveness of the intervention as reflected by increased physical activity level, pre-specified patient characteristics are selected, including age, BMI, level of education, social support, depression, patient-provider relationship and baseline number of minutes of physical activity. To

identify potential effect modification, we will use generalised estimating equations (GEEs) for each of these patient characteristics separately. The independent variables in the models will be the patient characteristic, random intercept, interaction term for study arm and patient level. Effect modification will be considered significant if the interaction term shows a level of significance <0.05. All quantitative analyses will be performed using IBM SPSS Statistics for Windows version 21.0 software (IBM, Armonk, NY, USA).

Process evaluation

Quantitative data will be analysed using descriptive statistics. The audio recordings will be transcribed and independently analysed by two researchers using the coding list developed for this trial. The interviews with nurses and patients to explore their experiences with the intervention will be audiotaped and transcribed. These transcriptions will be thematically analysed according to Braun and Clarke.[61]

Sample size calculation

The Activate trial is powered to detect a mean difference between the intervention arm and control arm of 20% in the number of minutes of at least a moderate level of physical activity. Based on the results of the It's LiFe! trial,[62] the mean level of physical activity in participants is 38 minutes (SD 18.1). The It's LiFe! trial is a three-arm trial performed in primary care in the Netherlands with patients with chronic obstructive pulmonary disease and DM2 in which the researchers aimed to increase physical activity with a self-management support programme and the It's LiFe! tool (a monitoring and feedback tool). This study revealed an increase in physical activity of 27%, but only in the counselling and It's LiFe! tool group, objectively measured with the Pam AM300. We consider an increase in physical activity of 20% as reasonable to achieve. Taking a power of 80% and a significance level of 5% into account requires 89 patients per arm. Assuming an intra-cluster correlation of 0.05 and a cluster size of 8 patients per general practice requires 30 or 31 participating practices.[60] Allowing a patient drop out rate of 15%, we aim to recruit 279 patients in total and 9 or 10 patients per general practice.

Stopping rules

There are no formal stopping rules. If a patient decides to withdraw, the nurse will stop the intervention for that patient. Patients can withdraw from the trial at any time.

Participant withdrawal

Patients can withdraw from the trial without giving a reason. Nurses will monitor and report any adverse events to the research team and can advise discontinuation of the

study in case of any adverse events. Patients who withdraw from the trial before they have completed the T0 measurement will be replaced. Patients who withdraw after the T0 measurement will not be replaced.

DISCUSSION

Despite the growing evidence for their effectiveness, so far self-management interventions show small effects on health outcomes. The effectiveness of interventions is ambiguous, and the question who benefits most from these interventions is still unanswered. With the Activate trial, we expect to shed light on the effectiveness of self-management interventions and explore which subgroup of patients benefits most. The effectiveness of this intervention and understanding which patients benefit from the intervention may lead to a broader application of this intervention in supporting patients to enhance behaviour change in other self-management components (e.g. dietary intake, alcohol use, managing medication and smoking cessation).

The Activate intervention was comprehensively developed using the BCW and was applied to the behaviour of both patients and nurses. Because the role of a competent healthcare provider is essential in the delivery and fidelity of self-management interventions,[34,35,63,64] we aimed to equip nurses with training that supports them to increase their skills and competences to adequately deliver the intervention.

Strengths and limitations

This study has several strengths. We performed a detailed analysis of the behaviour of both patients and nurses. Subsequently, BCTs were selected and described, which will enhance reproducibility of the intervention. Furthermore, this cluster-RCT is being conducted across several general practices in different urbanisation areas in the Netherlands with the patient's own primary care nurse, rather than trained researchers, delivering the intervention. This strengthens the generalisability and relevance of the findings from this trial for primary care. Another methodological strength is the use of the informed consent for postponed information procedure, which reduces selection bias by attrition or drop out of patients. In our study, the control group might be dissatisfied with not receiving the intervention, which would increase the risk of biased results. Changes in outcome may be affected only because of a demoralised and perhaps less motivated control group. A methodological challenge is the objective measurement of the primary outcome by accelerometry. Because cycling, strength training and swimming are activities that cannot be measured with the accelerometer, we will ask patients to self-report engaging in these activities. However, these self-reported data will not be considered as primary outcomes.

Furthermore, wearing the accelerometer might stimulate patients to be more active; however, these effects apply to patients in both the intervention and control arm. This might reduce the effect of the intervention. The use of the self-reported SQUASH for the inclusion of patients will possibly lead to over-estimation of their level of physical activity, leading to fewer patients eligible for inclusion.[65] The training and consultations were pilot-tested in only two primary care nurses and one patient, which limits the insight into the barriers to and facilitators of performing the intervention.

REFERENCES

1. Barlow J, Wright C, Sheasby J, Turner A, Hainsworth J. Self-management approaches for people with chronic conditions: A review. *Patient Educ Couns*. 2002;48(2):177-187.
2. Chodosh J, Morton SC, Mojica W, et al. Meta-analysis: Chronic disease self-management programs for older adults. *Ann Intern Med*. 2005;143(6):427-438.
3. Deakin T, McShane CE, Cade JE, Williams RD. Group based training for self-management strategies in people with type 2 diabetes mellitus. *Cochrane Database Syst Rev*. 2005;(2):CD003417.
4. Duke SA, Colagiuri S, Colagiuri R. Individual patient education for people with type 2 diabetes mellitus. *Cochrane Database Syst Rev*. 2009;(1):CD005268.
5. Garcia-Alamino JM, Ward AM, Alonso-Coello P, et al. Self-monitoring and self-management of oral anticoagulation. *Cochrane Database Syst Rev*. 2010;(4):CD003839.
6. Jovicic A, Holroyd-Leduc JM, Straus SE. Effects of self-management intervention on health outcomes of patients with heart failure: A systematic review of randomized controlled trials. *BMC Cardiovasc Disord*. 2006;6:43.
7. Zwerink M, Brusse Keizer M, van der Valk PDLPM, et al. Self management for patients with chronic obstructive pulmonary disease. *Cochrane Database Syst Rev*. 2014(3):CD002990.
8. Trappenburg J, Jonkman N, Jaarsma T, et al. Self-management: One size does not fit all. *Patient Educ Couns*. 2013;92(1):134-137.
9. Bos Touwen I, Schuurmans M, Monninkhof E, et al. Patient and disease characteristics associated with activation for self-management in patients with diabetes, chronic obstructive pulmonary disease, chronic heart failure and chronic renal disease: A cross-sectional survey study. *PLoS ONE*. 2015;10(5).
10. Bos Touwen I, Jonkman N, Westland H, et al. Tailoring of self-management interventions in patients with heart failure. *Curr Heart Fail Rep*. 2015;12(3):223-235.
11. Reeves D, Kennedy A, Fullwood C, et al. Predicting who will benefit from an expert patients programme self-management course. *Br J Gen Pract*. 2008;58(548):198-203.
12. Jonkman N, Westland H, Groenwold RHH, et al. Do self-management interventions work in patients with heart failure? an individual patient data meta-analysis. *Circulation*. 2016;133(12):1189-1198.
13. Malanda UL, Welschen LM, Riphagen II, Dekker JM, Nijpels G, Bot SD. Self-monitoring of blood glucose in patients with type 2 diabetes mellitus who are not using insulin. *Cochrane Database Syst Rev*. 2012;1:CD005060.
14. Mathers CD, Stevens G, Mascarenhas M (2009). *Global health risks: Mortality and burden of disease attributable to selected major risks.* Geneva, Switserland: World Health Organisation.
15. Nederlands Huisartsen Genootschap (2011). Multidisciplinaire richtlijn cardiovasculair risicomanagement. Houten, the Netherlands: Bohn Stafleu van Loghum.
16. World Health Organisation (2009). Global health risks: Mortality and burden of disease attributable to selected major risks. Geneva, Switzerland: World Health Organisation.
17. Cooper AR, Moore LA, McKenna J, Riddoch CJ. What is the magnitude of blood pressure response to a programme of moderate intensity exercise? randomised controlled trial among sedentary adults with unmedicated hypertension. *Br J Gen Pract*. 2000;50(461):958-962.
18. Ebrahim S, Smith GD. Lowering blood pressure: A systematic review of sustained effects of non-pharmacological interventions. *J Public Health Med*. 1998;20(4):441-448.
19. Franco OH, de Laet C, Peeters A, Jonker J, Mackenbach J, Nusselder W. Effects of physical activity on life expectancy with cardiovascular disease. *Arch Intern Med*. 2005;165(20):2355-2360.

20. Halbert JA, Silagy CA, Finucane P, Withers RT, Hamdorf PA, Andrews GR. The effectiveness of exercise training in lowering blood pressure: A meta-analysis of randomised controlled trials of 4 weeks or longer. *J Hum Hypertens*. 1997;11(10):641-649.
21. Hu G, Jousilahti P, Barengo N, Qiao Q, Lakka T, Tuomilehto J. Physical activity, cardiovascular risk factors, and mortality among finnish adults with diabetes. *Diabetes Care*. 2005;28(4):799-805.
22. Pate RR, Pratt M, Blair SN, et al. Physical activity and public health. A recommendation from the centers for disease control and prevention and the american college of sports medicine. *JAMA*. 1995;273(5):402-407.
23. Williams PT. Physical fitness and activity as separate heart disease risk factors: A meta-analysis. *Med Sci Sports Exerc*. 2001;33(5):754-761.
24. Kemper HGC, Ooijendijk WTM, Stiggelbout M. Consensus over de Nederlandse norm voor gezond bewegen. *Tijdschr Soc Gezondheidsz*. 2000;78(78):180-183.
25. Burke LE, Dunbar-Jacob JM, Hill MN. Compliance with cardiovascular disease prevention strategies: A review of the research. *Ann Behav Med*. 1997;19(3):239-63.
26. World Health Organization (2010). Global recommendations on physical activity for health. Geneva, Switzerland: World Health Organisation.
27. Bardach SH, Schoenberg NE. The content of diet and physical activity consultations with older adults in primary care. *Patient Educ Couns*. 2014;95(3):319-324.
28. Noordman J, Koopmans B, Korevaar JC, van der Weijden T, van Dulmen S. Exploring lifestyle counselling in routine primary care consultations: The professionals' role. *Fam Pract*. 2013;30(3):332-340.
29. van Dillen SM, Noordman J, van Dulmen S, Hiddink GJ. Examining the content of weight, nutrition and physical activity advices provided by dutch practice nurses in primary care: Analysis of videotaped consultations. *Eur J Clin Nutr*. 2014;68(1):50-56.
30. Bodenheimer T, Lorig K, Holman H, Grumbach K. Patient self-management of chronic disease in primary care. *JAMA*. 2002;288(19):2469-2475.
31. Lorig K, Holman H. Self-management education: History, definition, outcomes, and mechanisms. *Ann Behav Med*. 2003;26(1):1-7.
32. Wagner EH. Chronic disease management: What will it take to improve care for chronic illness? *Eff Clin Pract*. 1998;1(1):2-4.
33. Beighton C, Victor C, Normansell R, et al. "It's not just about walking.....it's the practice nurse that makes it work": A qualitative exploration of the views of practice nurses delivering complex physical activity interventions in primary care. *BMC Public Health*. 2015;15:1236-1236.
34. Hardeman W, Lamming L, Kellar I, et al. Implementation of a nurse-led behaviour change intervention to support medication taking in type 2 diabetes: Beyond hypothesised active ingredients (SAMS consultation study). *Implement Sci*. 2014;9:70.
35. Presseau J, Hawthorne G, Sniehotta F, et al. Improving diabetes care through examining, advising, and prescribing (IDEA): Protocol for a theory-based cluster randomised controlled trial of a multiple behaviour change intervention aimed at primary healthcare professionals. *Implement Sci*. 2014;9:61.
36. Michie S, van Stralen MM, West R. The behaviour change wheel: A new method for characterising and designing behaviour change interventions. *Implement Sci*. 2011;6:42-5908-6-42.
37. S. Michie, L. Atkins, R. West (2014). *The behaviour change wheel. A guide to designing interventions.* United Kingdom: Silverback Publishing.
38. Michie S, Richardson M, Johnston M, et al. The behavior change technique taxonomy (v1) of 93 hierarchically clustered techniques: Building an international consensus for the reporting of behavior change interventions. *Ann Behav Med*. 2013;46(1):81-95.

39. Campbell MK, Piaggio G, Elbourne DR, Altman DG, CONSORT Group. Consort 2010 statement: Extension to cluster randomised trials. *BMJ*. 2012;345:e5661.
40. Wendel-Vos GCW, Schuit AJ, Saris WHM, Kromhout D. Reproducibility and relative validity of the short questionnaire to assess health-enhancing physical activity. *J Clin Epidemiol*. 2003;56(12):1163-1169.
41. Boter H, van Delden JJ, de Haan RJ, Rinkel GJ. Modified informed consent procedure: Consent to postponed information. *BMJ*. 2003;327(7409):284-285.
42. Millat B, Borie F, Fingerhut A. Patient's preference and randomization: New paradigm of evidence-based clinical research. *World J Surg*. 2005;29(5):596-600.
43. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: The new medical research council guidance. *Int J Nurs Stud*. 2013;50(5):587-592.
44. Moore G, Audrey S, Barker M, et al. Process evaluation of complex interventions: Medical research council guidance. *BMJ*. 2015;350:h1258.
45. Cane J, O'Connor D, Michie S. Validation of the theoretical domains framework for use in behaviour change and implementation research. *Implement Sci*. 2012;7:37.
46. Michie S, Johnston M, Abraham C, et al. Making psychological theory useful for implementing evidence based practice: A consensus approach. *Qual Saf Health Care*. 2005;14(1):26-33.
47. Slootmaker SM, Chin A Paw, M J M, Schuit AJ, van Mechelen W, Koppes LLJ. Concurrent validity of the PAM accelerometer relative to the MTI actigraph using oxygen consumption as a reference. *Scand J Med Sci Sports*. 2009;19(1):36-43.
48. Everett B, Salamonson Y, Davidson PM. Bandura's exercise self-efficacy scale: Validation in an australian cardiac rehabilitation setting. *Int J Nurs Stud*. 2009;46(6):824-9.
49. Shin Y, Jang H, Pender NJ. Psychometric evaluation of the exercise self-efficacy scale among korean adults with chronic diseases. *Res Nurs Health*. 2001;24(1):68-76.
50. van der Heijden, M M P, Pouwer F, Pop VJM. Psychometric properties of the exercise self-efficacy scale in dutch primary care patients with type 2 diabetes mellitus. *Int J Behav Med*. 2014;21(2):394-401.
51. Rademakers J, Nijman J, van der Hoek L, Heijmans M, Rijken M. Measuring patient activation in the netherlands: Translation and validation of the american short form patient activation measure (PAM13). *BMC Public Health*. 2012;12:577-2458-12-577.
52. Hibbard JH, Stockard J, Mahoney ER, Tusler M. Development of the patient activation measure (PAM): Conceptualizing and measuring activation in patients and consumers. *Health Serv Res*. 2004;39(4 Pt 1):1005-1026.
53. Kind P (1996). The EuroQol instrument: An index of health-related quality of life. In: *Quality of life and pharmacoeconomics in clinical trials.* 2nd ed. Lippincott-Raven.
54. Spinhoven P, Ormel J, Sloekers PP, Kempen GI, Speckens AE, Van Hemert AM. A validation study of the hospital anxiety and depression scale (HADS) in different groups of dutch subjects. *Psychol Med*. 1997;27(2):363-370.
55. Zigmond AS, Snaith RP. The hospital anxiety and depression scale. *Acta Psychiatr Scand*. 1983;67(6):361-370.
56. Pedersen SS, Spinder H, Erdman RA, Denollet J. Poor perceived social support in implantable cardioverter defibrillator (ICD) patients and their partners: Cross-validation of the multidimensional scale of perceived social support. *Psychosomatics*. 2009;50(5):461-467.
57. Makoul G, Krupat E, Chang C. Measuring patient views of physician communication skills: Development and testing of the communication assessment tool. *Patient Educ Couns*. 2007;67(3):333-42.

58. Bellg A, Borrelli B, Resnick B, et al. Enhancing treatment fidelity in health behavior change studies: Best practices and recommendations from the NIH behavior change consortium. *Health Psychol*. 2004;23(5):443-51.
59. Lane C, Huws-Thomas M, Hood K, Rollnick S, Edwards K, Robling M. Measuring adaptations of motivational interviewing: The development and validation of the behavior change counseling index (BECCI). *Patient Educ Couns*. 2005;56(2):166-173.
60. Twisk JWR (2006). *Applied multilevel analysis: A practical guide for medical researchers.* Cambridge: Cambridge University Press.
61. Braun V, Clarke V. Using thematic analysis in psychology.*Qualitative research in psychology.* 2006;3(2):77-101.
62. van der Weegen S, Verwey R, Spreeuwenberg M, Tange H, van der Weijden T, de Witte L. It's LiFe! mobile and web-based monitoring and feedback tool embedded in primary care increases physical activity: A cluster randomized controlled trial. *J Med Internet Res*. 2015;17(7).
63. Johnston S, Irving H, Mill K, Rowan M, Liddy C. The patient's voice: An exploratory study of the impact of a group self-management support program. *BMC Fam Pract*. 2012;13:65-65.
64. Stenberg N, Furness P. Living well with a long-term condition: Service users' perspectives of a self-management intervention. *Qual Health Res*. 2017;27(4):547-558.
65. Tudor Locke CE, Myers AM. Challenges and opportunities for measuring physical activity in sedentary adults. *Sports Med*. 2001;31(2):91-100.

APPENDIX

Appendix 1. SPIRIT 2013 Checklist
Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	YES
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	YES
	2b	All items from the World Health Organization Trial Registration Data Set	Not applicable
Protocol version	3	Date and version identifier	YES
Funding	4	Sources and types of financial, material, and other support	YES
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	YES
	5b	Name and contact information for the trial sponsor	YES
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	YES
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	Not applicable
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	YES
	6b	Explanation for choice of comparators	YES
Objectives	7	Specific objectives or hypotheses	YES
Trial design	8	Description of trial design including type of trial (e.g. parallel group, crossover, factorial, single group), allocation ratio, and framework (e.g. superiority, equivalence, noninferiority, exploratory)	YES

Appendix 1. Continued

Section/item	Item No	Description	Addressed
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (e.g. community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	YES
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (e.g. surgeons, psychotherapists)	YES
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	YES
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (e.g. drug dose change in response to harms, participant request, or improving/worsening disease)	YES
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (e.g. drug tablet return, laboratory tests)	YES
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	YES
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (e.g. systolic blood pressure), analysis metric (e.g. change from baseline, final value, time to event), method of aggregation (e.g. median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	YES
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended	YES
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	YES
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	YES

Appendix 1. Continued

Section/item	Item No	Description	Addressed
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (e.g. computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (e.g. blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	YES
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (e.g. central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	YES
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	YES
Blinding (masking)	17a	Who will be blinded after assignment to interventions (e.g. trial participants, care providers, outcome assessors, data analysts), and how	YES
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	YES
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (e.g. duplicate measurements, training of assessors) and a description of study instruments (e.g. questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	YES
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	YES
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (e.g. double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	YES

Appendix 1. Continued

Section/item	Item No	Description	Addressed
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	YES
	20b	Methods for any additional analyses (e.g. subgroup and adjusted analyses)	YES
	20c	Definition of analysis population relating to protocol non-adherence (e.g. as randomised analysis), and any statistical methods to handle missing data (e.g. multiple imputation)	YES
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	YES
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	YES
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	YES
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	YES
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	YES
Protocol amendments	25	Plans for communicating important protocol modifications (e.g. changes to eligibility criteria, outcomes, analyses) to relevant parties (e.g. investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	YES
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	YES
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	Not applicable

Appendix 1. Continued

Section/item	Item No	Description	Addressed
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	YES
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	YES
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	YES
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	Not applicable
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (e.g. via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	Not applicable
	31b	Authorship eligibility guidelines and any intended use of professional writers	YES
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	Not applicable
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	YES
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	Not applicable

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license

Appendix 2. Results of the Behaviour Change Wheel in patients

COM-B	TDF	What needs to happen for patients to increase their level of physical activity
Physical capability	Physical skills	• Have the skills and physical capability to walk[1-13]
Psychological capability	Knowledge	• Have the knowledge and understanding of the influence of physical activity on the condition to reduce misperceptions and increase sense of urgency[8,10,14-20]
	Cognitive and interpersonal skills	• Have the skills to increase their level of physical activity[8,10,14-18] • Have the skills to deal with conflicting or confusing recommendations[7,10,11] • Have the skills to set goals, self-monitoring (e.g. wearing an accelerometer), and action planning[9,19]
	Memory, attention and decision processes	• Notice and remember to be physical active, make everyday decisions to exercise according to an action plan[3,21]
	Behavioural regulation	• Concordance to self-monitoring (e.g. wearing an accelerometer), and action planning[9,19] • Break well-established habits[6,15] • Have triggers to prompt (rewards, supervision, mail)[2,17,18,22]
Physical opportunity	Environmental context and resources	• Have time to exercise[3,6,8,9,12,13,16,18,19] • Have good weather or good shoes and clothes for all weather types[2-4,8,12,18] • Have alternatives to deal with bad weather, neighbour insecurities, transport problems[8,18,23] • Improve easy access to affordable and stimulating facilities (at home or in their neighbourhood) tailored to the patients' needs and preferences[1,2,4,18] • Have a flexible routine allowing for an increase in walking[2,9] • Have the opportunity to be physical active during work[9]
Social opportunity	Social influences	• Have positive support from family, friends, caregivers, fellow patients (e.g. have a buddy to exercise with or a buddy that supports exercise)[4,6,8,9,11,13,16,19-21,23-25] • Have a collaborative relationship/ communication with caregiver[5,8,20,23,24] • Have a competent caregiver (knowledge, clear guidance and stimulation, supervision, tailored advice, addressing importance of physical activity)[1-3,11,12,25] • Overcome culture and language barriers[16,20] • Have role models[25]

	Intervention functions	BCTs
	Training	Feedback on behaviour, graded tasks, self-monitoring of behaviour
	Education	Information about health consequences, feedback on behaviour
	Training	Feedback on behaviour, habit formation, graded tasks, self-monitoring
	Training, environmental restructuring, enablement	Feedback on behaviour, prompt and cues, habit formation
	Education, training, enablement	Self-monitoring of behaviour, habit formation, action planning, prompts and cues
	Training, environmental restructuring, enablement	Problem-solving, feedback on behaviour, restructuring the physical environment, restructuring the social environment, social support (practical), self-monitoring of behaviour
	Environmental restructuring, modelling, enablement	Social support (unspecified), problem-solving, restructuring the social environment

Appendix 2. Continued

COM-B	TDF	What needs to happen for patients to increase their level of physical activity
Reflective motivation	Professional/ social role and identity	Not applicable
	Beliefs about capabilities	• Overcome personal struggles (anxiety in unfamiliar surrounds, negative, or depressive emotions, body images)[5,13,18,19,21] • Have insight in own behaviour[10] • Have appropriate self and external monitoring (e.g. must be challenging, improve self-efficacy, provide feedback)[9]
	Optimism	• Cope with negative attitudes and experiences[10,12,26] • Experience health benefits of increasing their level of physical activity[3,4,9,13,18]
	Beliefs about consequences	• Believe that exercise is good, and has positive influences on their condition[9,13] • Believe that exercising helps to sleep well and lose weight[9] • Experience health benefits of increasing their level of physical activity[3,4,9,13,18]
	Intentions	• Motivated to change their physical activity level[2,4,6,12,15,16,18] • Feel they want to take responsibility to be physically active[26] • Feel the need/urgency to change their physical activity level[18] • Perceive health as priority[1,26]
	Goals	• Set achievable and personal goals[3] • Action planning[9] • Deal with conflicting goals[9]
Automatic motivation	Reinforcement	• Have positive prompts and cues in environment[16] • Have routines and habits for daily exercising[6,15]
	Emotion	• Enjoy being physically active[4,6,9,13,18,25]

Abbreviations: BCTs behaviour change techniques; BCW Behaviour Change Wheel; COM-B Capability, Opportunity, Motivation, Behaviour; TDF Theoretical Domains Framework

	Intervention functions	BCTs
	Not applicable	Not applicable
	Education, persuasion, enablement	Focus on past success, feedback on behaviour, self-monitoring of behaviour, problem-solving, graded tasks, goal setting (behaviour), action planning, review behavioural goal(s)
	Education, persuasion	Focus on past success
	Education, persuasion, modelling	Information about health consequences, feedback on behaviour
	Education, persuasion, incentivisation	Commitment, feedback on behaviour
	Education, persuasion, incentivisation, enablement	Self-monitoring of behaviour, goal setting (behaviour), goal setting (outcome), action planning, review behavioural goal(s), problem-solving, feedback on behaviour
	Training, environmental restructuring	Prompts and cues, habit formation
	Incentivisation	Feedback on behaviour

REFERENCES

1. Bethancourt HJ, Rosenberg DE, Beatty T, Arterburn DE. Barriers to and facilitators of physical activity program use among older adults. *Clin Med Res*. 2014;12(1-2):10-20.
2. Casey D, De Civita M, Dasgupta K. Understanding physical activity facilitators and barriers during and following a supervised exercise programme in type 2 diabetes: A qualitative study. *Diabet Med*. 2010;27(1):79-84.
3. Elley CR, Dean S, Kerse N. Physical activity promotion in general practice-patient attitudes. *Aust Fam Physician*. 2007;36(12):1061-1064.
4. Hartman JE, ten Hacken NH, Boezen HM, de Greef MH. Self-efficacy for physical activity and insight into its benefits are modifiable factors associated with physical activity in people with COPD: A mixed-methods study. *J Physiother*. 2013;59(2):117-124.
5. Bayliss EA, Ellis JL, Steiner JF. Barriers to self-management and quality-of-life outcomes in seniors with multimorbidities. *Ann Fam Med*. 2007;5(5):395-402.
6. Mancuso CA, Sayles W, Robbins L, et al. Barriers and facilitators to healthy physical activity in asthma patients. *J Asthma*. 2006;43(2):137-143.
7. Rockwell JM, Riegel B. Predictors of self-care in persons with heart failure. *Heart Lung*. 2001;30(1):18-25.
8. Albarran NB, Ballesteros MN, Morales GG, Ortega MI. Dietary behavior and type 2 diabetes care. *Patient Educ Couns*. 2006;61(2):191-199.
9. Normansell R, Smith J, Victor C, et al. Numbers are not the whole story: A qualitative exploration of barriers and facilitators to increased physical activity in a primary care based walking intervention. *BMC Public Health*. 2014;14:1272.
10. Jansink R, Braspenning J, van der Weijden T, Elwyn G, Grol R. Primary care nurses struggle with lifestyle counseling in diabetes care: A qualitative analysis. *BMC Fam Pract*. 2010;11:41.
11. Bratzke L, Muehrer R, Kehl K, Lee K, Ward E, Kwekkeboom K. Self-management priority setting and decision-making in adults with multimorbidity: A narrative review of literature. *Int J Nurs Stud*. 2015;52(3):744-755.
12. Booth ML, Bauman A, Owen N, Gore CJ. Physical activity preferences, preferred sources of assistance, and perceived barriers to increased activity among physically inactive australians. *Prev Med*. 1997;26(1):131-137.
13. De Bourdeaudhuij I, Sallis J. Relative contribution of psychosocial variables to the explanation of physical activity in three population-based adult samples. *Prev Med*. 2002;34(2):279-288.
14. Jansink R, Braspenning J, Keizer E, van der Weijden T, Elwyn G, Grol R. Misperception of patients with type 2 diabetes about diet and physical activity, and its effects on readiness to change. *J Diabetes*. 2012;4(4):417-423.
15. Booth AO, Lowis C, Dean M, Hunter SJ, McKinley MC. Diet and physical activity in the self-management of type 2 diabetes: Barriers and facilitators identified by patients and health professionals. *Prim Health Care Res Dev*. 2013;14(3):293-306.
16. Fitzgerald N, Spaccarotella K. Barriers to a healthy lifestyle: From individuals to public Policy—An ecological perspective. *Journal of Extension*. 2009;47(1).
17. Schutzer KA, Graves BS. Barriers and motivations to exercise in older adults. *Prev Med*. 2004;39(5):1056-1061.
18. Lascar N, Kennedy A, Hancock B, et al. Attitudes and barriers to exercise in adults with type 1 diabetes (T1DM) and how best to address them: A qualitative study. *PLoS One*. 2014;9(9).

19. Simmons D, Lillis S, Swan J, Haar J. Discordance in perceptions of barriers to diabetes care between patients and primary care and secondary care. *Diabetes Care*. 2007;30(3):490-495.
20. Nam S, Chesla C, Stotts N, Kroon L, Janson S. Barriers to diabetes management: Patient and provider factors. *Diabetes Res Clin Pract*. 2011;93(1):1-9.
21. Rockwell JM, Riegel B. Predictors of self-care in persons with heart failure. *Heart Lung*. 2001;30(1):18-25.
22. Cable TA, Meland E, Soberg T, Slagsvold S. Lessons from the oslo study diet and anti-smoking trial: A qualitative study of long-term behaviour change. *Scand J Public Health*. 1999;27(3):206-212.
23. Johnston S, Irving H, Mill K, Rowan M, Liddy C. The patient's voice: An exploratory study of the impact of a group self-management support program. *BMC Fam Pract*. 2012;13:65-65.
24. Nagelkerk J, Reick K, Meengs L. Perceived barriers and effective strategies to diabetes self-management. *J Adv Nurs*. 2006;54(2):151-158.
25. Allender S, Cowburn G, Foster C. Understanding participation in sport and physical activity among children and adults: A review of qualitative studies. *Health Educ Res*. 2006;21(6):826-835.
26. Coventry P, Fisher L, Kenning C, Bee P, Bower P. Capacity, responsibility, and motivation: A critical qualitative evaluation of patient and practitioner views about barriers to self-management in people with multimorbidity. *BMC Health Serv Res*. 2014;14:536.

Appendix 3. Results of the Behaviour Change Wheel in primary care nurses

COM-B	TDF	What needs to happen for primary care nurses to adequately deliver the intervention
Physical capability	Physical skills	Not applicable
Psychological capability	Knowledge	• Have the knowledge about physical activity[1] • Have the knowledge to perform the BCTs[#] • Have the knowledge to activate a patient and what to do when patients complain of physical pain[#] • Have the knowledge to educate patients on a didactic way[1,2]
	Cognitive and interpersonal skills	• Have the skills to deliver BCTs[#,1,2] • Have the skills to flexible and sensible tailor interventions and device alternative strategies and encourage patients to overcome barriers[1,3] • Have the skills to change their communication style[3,4] • Have the skills to educate patients on a didactic way[1,2] • Have the skills to flexible and sensible tailor interventions and device alternative strategies and encourage patients to overcome barriers[3] • Have the skills to deal with patients' excuses, lack of motivation or have physical complaints, which makes it difficult for the nurse[# 1] • Need education and exercise to know how to develop a concrete and structured action plan[#] • Let the patient participate; not filling in for the patient[#,2,3] • Develop transferable skills for use with other patients[5]
	Memory, attention and decision processes	Not applicable
	Behavioural regulation	Not applicable
Physical opportunity	Environmental context and resources	• Have time to support patients during consultations[#,1,4,5] • Have the tools to perform the BCTs (to self-monitor, overview of physical activity options in the area, information brochures websites, apps, clear protocol, etc)[#2,3,5]
Social opportunity	Social influences	• Have support to participate from general practice (e.g. time and education opportunities)[#,5] • Self-management is encouraged throughout the entire general practice[#,2] • Have the autonomy in planning their own work[2]

	Intervention functions	BCTs
	Not applicable	Not applicable
	Education	Information about health consequences, information about social and environmental consequences, feedback on behaviour
	Training	Feedback on behaviour, habit formation, demonstration of the behaviour, instruction on how to perform the behaviour, self-monitoring of behaviour, behavioural practice/rehearsal, reward
	Not applicable	Not applicable
	Not applicable	Not applicable
	Training, environmental restructuring, enablement	Restructuring the physical environment, adding objects to the environment, social support (practical), instruction on how to perform the behaviour, prompts and cues, problem-solving
	Environmental restructuring, enablement	Social support (unspecified)

Appendix 3. Results of the Behaviour Change Wheel in primary care nurses

COM-B	TDF	What needs to happen for primary care nurses to adequately deliver the intervention
Reflective motivation	Professional/ social role and identity	• Understand that activating a patient is part of the nurses' role and not necessarily of a physiotherapist or health facilitator[#,1,3] • Belief that patients are suitable candidates for behaviour change[2]
	Beliefs about capabilities	• Have tools to deliver the intervention that are easily and readily fit into daily practice[2,3] • Have comprehensive and effective learning methods (role-plays, follow-up sessions, credible source, clear instructions, role-play scenarios, written and verbal feedback)[3,5] • Feel confident that they can do it even the patient is not motivated[#]
	Optimism	Not applicable
	Beliefs about consequences	• Expect that supporting patients in changing their behaviour is effective[1,5]
	Intentions	• Have a positive attitude towards disease management and seriousness of the disease[4] • Have a positive attitude toward collaborative care[4] • Want to use new tools in practice[2] • Feel that they are making a difference[#] • Motivated to support patients in changing their behaviour[1,5] • Feel the need to change their routine practice[2]
	Goals	Not applicable
Automatic motivation	Reinforcement	Not applicable
	Emotion	Not applicable

[#] Results from a focus group with primary care nurses

Abbreviations: BCTs behaviour change techniques; BCW Behaviour Change Wheel; COM-B Capability, Opportunity, Motivation-Behaviour; TDF Theoretical Domains Framework

	Intervention functions	BCTs
	Modelling, education, persuasion	Information about others' approval, feedback on behaviour
	Education, persuasion, modeling, enablement	Credible source, verbal persuasion about capability, demonstration of the behaviour, focus on past success, feedback on behaviour, self-monitoring of behaviour
	Not applicable	Not applicable
	Education, persuasion, modelling	Information about health consequences, information about social and environmental consequences, feedback on behaviour, focus on past success
	Education, persuasion, incentivisation	Feedback on behaviour, monitoring of behaviour by others without feedback, monitoring outcome of behaviour by others without feedback
	Not applicable	Not applicable
	Not applicable	Not applicable
	Not applicable	Not applicable

REFERENCES

1. Jansink R, Braspenning J, van der Weijden T, Elwyn G, Grol R. Primary care nurses struggle with lifestyle counseling in diabetes care: A qualitative analysis. *BMC Fam Pract*. 2010;11:41.
2. Kennedy A, Rogers A, Bowen R, et al. Implementing, embedding and integrating self-management support tools for people with long-term conditions in primary care nursing: A qualitative study. *Int J Nurs Stud*. 2014;51(8):1103-1113.
3. Beighton C, Victor C, Normansell R, et al. "It's not just about walking.....it's the practice nurse that makes it work": A qualitative exploration of the views of practice nurses delivering complex physical activity interventions in primary care. *BMC Public Health*. 2015;15:1236.
4. Nam S, Chesla C, Stotts N, Kroon L, Janson S. Barriers to diabetes management: Patient and provider factors. *Diabetes Res Clin Pract*. 2011;93(1):1-9.
5. Taylor C, Shaw R, Dale J, French D. Enhancing delivery of health behaviour change interventions in primary care: A meta-synthesis of views and experiences of primary care nurses. *Patient Educ Couns*. 2011;85(2):315-322.

CHAPTER 4

Patients' experiences with a behaviour change intervention to enhance physical activity in primary care: a mixed methods study

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In revision

ABSTRACT

Objective: To explore the experiences of patients at risk for cardiovascular disease in primary care with the Activate intervention in relation to their success in increasing their physical activity.

Methods: A convergent mixed methods study was conducted, parallel to a cluster-randomised controlled trial in primary care, using a questionnaire and semi-structured interviews. Questionnaires from 67 patients were analysed, and semi-structured interviews of 22 patients were thematically analysed. Experiences of patients who had objectively increased their physical activity (responders) were compared to those who had not (non-responders). Objective success was analysed in relation to self-perceived success.

Results: The questionnaire and interview data corresponded, and no substantial differences among responders and non-responders emerged. Participating in the intervention increased patients' awareness of their physical activity and their physical activity level. Key components of the intervention were the subsequent support of nurses with whom patients' have a trustful relationship and the use of self-monitoring tools. Patients highly valued jointly setting goals, planning actions, receiving feedback and review on their goal attainment and jointly solving problems. Nurses' support, using self-monitoring tools, and involving others incentivised patients. Internal circumstances and external circumstances challenged patients' engagement in increasing and maintaining their physical activity.

Conclusion: Patients experienced the Activate intervention as valuable to increase and maintain their physical activity, irrespective of their objective change in physical activity. The findings enable the understanding of the effectiveness of the intervention and implementation in primary care.

BACKGROUND

Cardiovascular disease (CVD) is the leading cause of death worldwide, and the mortality rates are expected to increase in the next few decades.[1] It is well established that healthy behaviours, including physical activity, lower the risk of CVD events, comorbidities, and mortality.[2-8] National guideline for the desirable levels of physical activity recommend at least 30 minutes of moderate to vigorous activity five days per week.[9,10] A majority of patients do not meet this target,[11] underlining the need for effective strategies to promote physical activity. In the Netherlands, patients at risk for CVD are monitored, treated and supported in primary care. In collaboration with the general practitioner, primary care nurses play a pivotal role in monitoring treatment outcomes and promoting healthy behaviour.[12] However, nurses' support to patients in adopting healthy behaviour is often brief and fragmented throughout the consultation.[13-15] Structured behaviour change support using behaviour change techniques (BCTs), such as goal setting, action planning and self-monitoring is lacking in most consultations.[15] To adequately support patients in changing their behaviour, nurses need to change their traditional consultation style towards a coaching-oriented consultation style.[16-18] This implies that in order to improve physical activity in patients, nurses also need to change their own behaviour. To enhance this behaviour change in patients and nurses the Activate intervention was developed using the Behaviour Change Wheel (BCW).[19,20] A behavioural analysis for both the behaviour of patients and the behaviour of nurses was made using the COM-B (capability, opportunity, motivation-behaviour) model.[19,20] The application of the BCW resulted in the development of the Activate intervention for patients and a standardised training programme for nurses, in which nurses were equipped with the required competences to deliver the intervention according to the protocol.[20]

The effectiveness of the Activate intervention is currently being evaluated in a cluster-randomised controlled trial in adult patients at risk for CVD in general practices in the Netherlands. To enhance our understanding of the effectiveness of the intervention and to explore how the intervention works in individual patients, a parallel process evaluation from the perspective of the patient alongside the Activate trial was conducted using both quantitative and qualitative research techniques.[21-24] Furthermore, insight into patients' experiences with the intervention and the extent to which they perceive success in increasing their physical activity might enable our understanding of what might occur when implementing the intervention in routine practice.[21,23,24]

The aim of this study was to explore the experiences of patients at risk for CVD in primary care with the Activate intervention in relation to their success with the intervention regarding increasing their physical activity.

METHODS

Study design

A convergent mixed methods design nested within a cluster-randomised controlled trial was used to enhance the understanding of patients' experiences with the Activate intervention.[25] Quantitative data were collected using a questionnaire and were converged with qualitative data from semi-structured interviews, which contained questions regarding the different components of the Activate trial and patients' achieved results.

The Activate trial

Subsequent to this study, the Activate intervention is being evaluated in a two-armed cluster-randomised controlled trial in primary care in the Netherlands, comparing the Activate intervention with care as usual according to the Dutch guideline of cardiovascular risk management.[10] The Activate trial includes 31 participating general practices, 36 primary care nurses and 195 patients (Activate trial, ClinicalTrials.gov NCT02725203). A detailed description of the development and content of the intervention has been described elsewhere.[20] As a result of the behavioural analysis according to the BCW, the Activate intervention is structured around 17 BCTs, including goal setting, action planning, feedback on behaviour, review behavioural goals, problem-solving and self-monitoring. The intervention consists of four standardised nurse-led consultations to enhance physical activity, spread over a 12-week period: one consultation in the first week and the following consultations after 2, 6 and 12 weeks. Consultations occurred in the patients' own general practice, with a duration of 20-30 minutes. Patients received a workbook, which included tips and tricks, useful websites, activity logs and action plans, and they were equipped with an accelerometer (personal activity monitor; Pam AM300)[26] in order to self-monitor their daily physical activity.

The analysis of what nurses need to change in order to adequately deliver the intervention to patients resulted in a selection of 21 BCTs, which are integrated into a standardised, comprehensive training programme for nurses. This training programme consists of a one-day knowledge and skills training, instructional videos on how to apply the BCTs in the consultations, a scripted handbook, checklists describing what to do when, and two individual coaching sessions. The primary outcome is patients' physical activity, measured with an accelerometer (personal activity monitor; Pam AM300),[26] and operationalised as the number of minutes of moderate (3–6 metabolic equivalents (METs)) to vigorous (≥6 METs) physical activity, with a 6-month follow up period (T2). Patient data are collected at baseline (T0), after completion of the intervention (T1) and three months after completion of the intervention (T2). Data collection comprised filling in a questionnaire and wearing

the accelerometer for seven consecutive days. The activity information of the accelerometer was blinded to patients to ascertain objectivity of the measurements, leaving patients unaware of their objective level of physical activity.

Sampling and recruitment

Questionnaire

The study sample consisted of all patients (n=93) from general practices (n=16) situated throughout the Netherlands who participated in the Activate trial and were allocated to the intervention group. Patients were included in the analysis if they completed all four consultations, completed the T1 questionnaire about their experiences with the Activate intervention and wore the accelerometer at T0 and T1. A total of 67 (72.0%) patients were included in the analysis. Patients who dropped out during the intervention (n=22), omitted to complete the questionnaire (n=3) or had invalid accelerometer data (n=1) were excluded from the analysis.

Semi-structured interviews

From the 67 eligible patients, a sub-sample of 22 patients was purposively selected based on either being successful or not successful in increasing their physical activity. The increase was measured using patients' objective change from baseline to 3 months of follow up (T1) for moderate to vigorous physical activity according to the accelerometer. Patients' success of increasing their physical activity was defined as a mean difference in minutes of moderate and vigorous physical activity by at least 20% at T1 compared to baseline.[20] A total of 11 patients who succeeded in achieving this threshold (responders) and 11 patients who did not achieve this threshold (non-responders) were included in the study. Maximum variation in the sample was obtained by selecting patients with a wide distribution range in regard to age, sex, educational level, and living situation.

Selected patients were invited by an invitational letter to participate in the study. To respond, patients could contact the researchers. Patients who did not respond were contacted by telephone within one week to inquire whether they would like to participate in the study and, if desired, were provided with additional information. When patients were willing to participate in the study, an appointment was scheduled. If patients refused, they were asked whether they would like to give a reason for refusal. If so, patient data and the reason for refusal were reported. New patients were purposively selected from the research database to replace them. Purposive sampling was used until the maximum variation in the sample and data saturation were achieved. In total, 29 patients were invited to participate, and 22 patients (75.9%) distributed over 11 general practices agreed to participate. Patients refused to participate due to time constraints (n=1) or personal circumstances (n=1), or they did not report a reason (n=5).

Data collection

Questionnaire

Patients' experiences were explored by a post-intervention questionnaire, which they received directly after they completed the intervention between June 2016 and April 2017. The questionnaire was developed by three members of the research team, and face validity was assessed by the research team and two additional researchers who are experts in conducting process evaluations of complex interventions. Questions regarding patients' perceptions of the intervention, their success of increasing their physical activity and their motivation and confidence towards maintaining their physical activity levels were measured on a five-point Likert scale, ranging from 1 (strongly disagree) to 5 (strongly agree). Questions regarding helpful components of the intervention to increase their activity levels were measured on a four-point Likert scale, ranging from 1 (strongly disagree) to 4 (strongly agree). Additionally, patients were asked to report the components that were most helpful to them in order to increase their physical activity. Characteristics of patients were collected at the start of the Activate intervention.

Semi-structured interviews

Semi-structured individual telephone interviews were performed to evaluate patients' experiences with their participation in the Activate intervention and perceived success with regards to their physical activity. An interview guide with open questions about patients' experiences, their expectations of the study, perceived success and maintenance of their increased physical activity, their experiences with the different components of the intervention and their satisfaction with the intervention was used (Appendix 1). All interviews started with the same question: "What was the reason you agreed to participate in the Activate study?"

Two researchers conducted the interviews (JS, SD). Patients were unknown to the interviewers, and patients were interviewed once at the patients' preferred time and date. The mean duration of the interviews was 30.30 minutes (range: 22.04–40.31 minutes). All interviews were audio-recorded. During and directly after the interviews, memos were made regarding observations, reflections on methodological issues, initial thoughts related to emerging themes, and refinements of the interview guide. The interviewing techniques of the interviewers were discussed and trained by members of the research team (HW, SV). The interviews were conducted between November 2016 and March 2017.

Ethics

The Activate trial, including this process analysis, was ethically reviewed and approved by the Medical Ethics Research Committee of the University Medical Center Utrecht (NL54286.041.15). All patients gave written informed consent prior to the start of the Activate trial. Prior to the interviews, informed consent was obtained verbally.

Data analysis

Questionnaire

Data were analysed and presented according to the patients' level of success (responder or non-responder), defined as a mean difference in minutes of moderate and vigorous physical activity according to the accelerometer by at least 20% at T1 compared to baseline.[20] Patient characteristics and the most helpful components of the Activate intervention as perceived by the patients were presented as numbers and corresponding percentages. Patients' perceptions towards the intervention, their success of the intervention and their motivation and confidence to maintain of Activate intervention were presented as a median and interquartile range (IQR). Quantitative data were descriptively analysed using the Statistical Package for the Social Sciences (SPSS version 21; Chicago, IL, USA).

Semi-structured interviews

Qualitative data were analysed according to the six phases of thematic analysis of Braun and Clarke.[27] Data analysis started after the first four interviews. In phase 1 (familiarizing with the data), the interviews were transcribed verbatim (JS, SD), and after every four interviews, the transcripts were checked for accuracy, read to get an overall picture and re-read to grasp the details (JS, SD, HW). During this phase, initial ideas for coding were discussed (HW, JS, SD, SV). In phase 2 (generating initial codes), transcripts were systematically and independently coded and discussed in the research team after every four interviews (HW, JS, SD, SV). In phase 3 (searching for themes), the research team collated codes into meaningful themes whose relevance emerged from several interviews. A preliminary description of potential themes and subthemes was made and discussed (HW, JS, SD, SV). In phase 4 (reviewing themes), potential themes were reviewed for consistency with the transcripts to ensure the validity of the themes with the entire data. Potential themes were further refined (HW, JS, SV). In phase 5 (defining and naming themes), the specific content of each theme was further worked out using the transcripts, and themes were named and defined (HW, JS, SV). In phase 6 (producing the report), the report was drafted, and vivid quotes to illustrate the themes were selected (HW, JS, SV) and reviewed (HW, JS, SD, JT, CS, SV, MS). Data saturation was achieved prior to completing the 22 interviews; however, as planned, the interviews were continued to ensure a maximum variation in the sample of responders and non-responders. Data analysis was supported by NVivo 11.0 software (QSR International Pty Ltd, Version 11.0, 2011).

To increase the credibility of the data, the validity of the data was ensured by researcher triangulation and peer review throughout the phases of the study.[28] An expert on qualitative research (SV) was involved in all phases of the data collection and data analysis to further strengthen the accuracy and dependability of the process.[28] The process of data analysis was systematically discussed by the research team (HW, JS, SD, SV). The study's

conformability was ensured by an audit trial.[28] The use of the 15-point checklist of Braun and Clarke[27] confirmed the correct application of the six phases of thematic analysis; see Appendix 2. The 32-point consolidated criteria for reporting qualitative studies (COREQ) was used to facilitate reporting of the results;[29] see Appendix 3. Memo writing and expert opinion were used to support the analysis and to enhance study reliability.[30]

RESULTS

Questionnaire

Patients' characteristics are reported in Table 1. The results of the questionnaires are presented in Table 2 and Table 3. Patients' characteristics and experiences with the effectiveness of the Activate intervention on their physical activity were generally similar across both responders and non-responders (Table 1 and Table 2), except for employment and level of education (Table 1). Generally, patients felt that their physical activity increased during the intervention period (responders median 4, IQR 2; non-responders median 4, IQR 1) and that participating in the Activate intervention helped them to increase their physical activity (responders median 3, IQR 1; non-responders median 3, IQR 0). A majority of patients perceived their level of physical activity as pleasant (both groups median 4, IQR 1), and most patients were satisfied with their achieved results (responders median 4, IQR 1; non-responders median 3.5, IQR 1). Overall, patients were motivated (responders median 4, IQR 1; non-responders median 4, IQR 0), felt confident (both groups median 4, IQR 1) and intended (responders median 4, IQR 1; non-responders median 5, IQR 1) to maintain their achieved results. Generally, patients were pleased with the support they received (both groups median 3, IQR 1) and felt that the nurse-led consultations (responders median 3, IQR 1; non-responders median 3, IQR 0), as well as wearing the accelerometer (responders median 4, IQR 1; non-responders median 3, IQR 1) and keeping the activity log (both groups median 3, IQR 1), helped them increase their physical activity. Differences between responders and non-responders were apparent in the perceived most helpful components of the intervention; see Figure 1. Responders perceived the consultations with the nurse (28.0%), wearing the accelerometer (24.0%) and the use of both self-monitoring tools (20.0%) as the most helpful components for increasing their physical activity. Non-responders perceived the combination of the consultations and wearing the accelerometer (17.1%), keeping the log (17.1%) and other components, such as having a supporting partner and perceiving health benefits due to their participation in the intervention (14.6%), as being most helpful.

Table 1. Characteristics of patients

Characteristics	Questionnaire (n=67)		Interview (n=22)	
	Responder* (n=25)	Non-responder* (n=42)	Responder* (n=11)	Non-responder* (n=11)
Female, n (%)	11 (44.0)	17 (40.5)	7 (63.6)	5 (45.5)
Age in years, mean ± SD	62.6 ± 7.8	61.6 ± 9.5	61.8 ± 7.7	61.7 ± 11.7
Employed n (%)	8 (32.0)	17 (40.5)	4 (36.4)	5 (45.5)
Living with others, n (%)	22 (88.0)	35 (83.3)	9 (81.8)	9 (81.8)
Native Dutch, n (%)	24 (96.0)	41 (97.6)	10 (90.9)	11 (100)
Level of education, n (%)				
Primary education or below	2 (8.0)	NA	2 (18.2)	NA
Secondary education	16 (64.0)	34 (81.0)	7 (63.6)	10 (90.9)
Higher education	6 (24.0)	8 (19.0)	2 (18.2)	1 (9.1)
Unknown	1 (4.0)	NA	NA	NA

*According to the accelerometer data

Abbreviations: NA not applicable

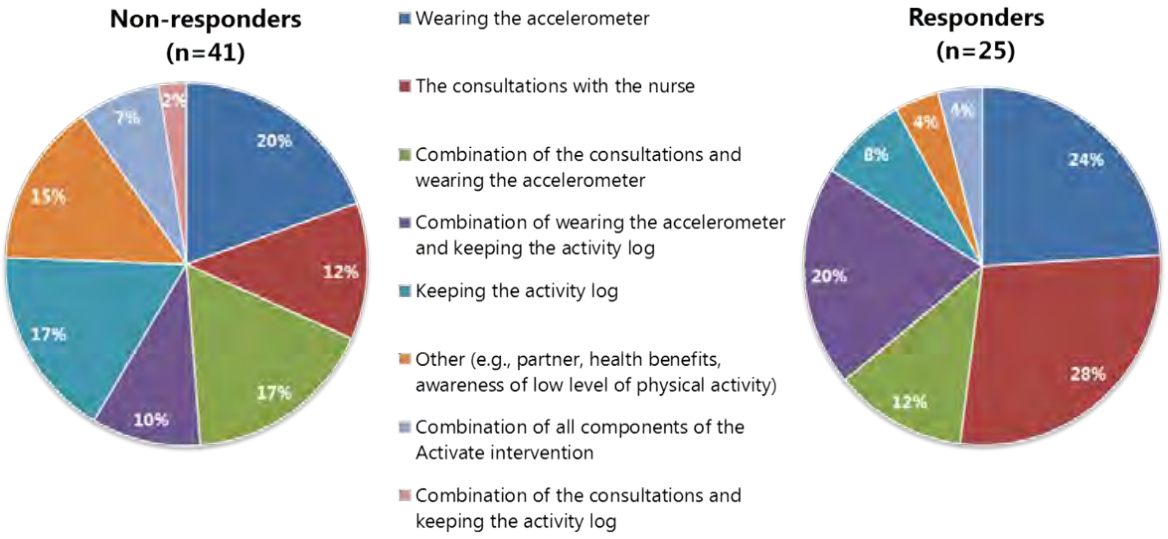

Figure 1. Most helpful components of the Activate intervention on patients' physical activity

Table 2. Patients' experiences with the effectiveness of the Activate intervention on their physical activity

Statements	Total n=67	
	Responder* (n=25) Median [IQR]	Non-responder* (n=42) Median [IQR]
My physical activity increased in the last 3 months[a]	4 [2]	4 [1]
I am satisfied with my level of physical activity[a]	4 [1]	3.5 [1]
I perceive my present level of physical activity as pleasant[a]	4 [1]	4 [1]
I am motivated to maintain my level of physical activity[a]	4 [1]	4 [0]
I feel confident to maintain my level of physical activity[a]	4 [1]	4 [1]
I intend to maintain my level of physical activity[a]	4 [1]	5 [1]
Participating in the Activate intervention helped me to increase my physical activity[b]	3 [1]	3 [0]
Generally, I perceived the support during the Activate intervention as pleasant[b]	3 [1]	3 [1]
The consultations with the nurse helped me to increase my physical activity[b]	3 [1]	3 [0]
Wearing the accelerometer helped me to increase to increase my physical activity[b]	4 [1]	3 [1]
Keeping the activity log helped me to increase my physical activity[b]	3 [1]	3 [1]

*According to the accelerometer data; [a] measured on a five-point Likert scale: 1 (strongly disagree) to 5 (strongly agree); [b] measured on a four-point Likert scale: 1 (strongly disagree) to 4 (strongly agree)
Abbreviations: IQR interquartile range

Semi-structured interviews

A total of 22 patients (11 responders and 11 non-responders) were interviewed. Seven patients in the responder group were female compared to five women in the non-responder group. Overall, maximum variation regarding age, sex, educational level and the living situation was achieved; see Table 1 and Table 3. All patients perceived an increase in their physical activity compared to baseline; however, to different extents. Thirteen patients felt they increased their physical activity (seven responders and six non-responders). Eight patients felt that their physical activity did not increase much, but their participation increased their health or awareness of physical activity on their health (three responders and five non-responders). The perceptions of nine patients (three responders and six non-responders) did not correspond with their objective measured success; see Table 3.

Generally, there was a substantial overlap between the experiences of patients with the intervention in both groups. Therefore, the themes were drawn from patients' experiences as a whole, unless the data showed a substantial distinction between both groups, which is reported accordingly.

Patients' engagement with becoming more active

All patients were aware that being physically active would positively affect their health. Patients often reported their intention to increase their physical activity; however, they could not achieve this increase on their own. Nurses' requests to participate in the intervention aligned with this intention, and the impact of physical activity on their health additionally prompted them to participate. Furthermore, some patients specifically wanted insight into their current amount of physical activity, which prompted them to participate in the intervention. Due to their perceived needs, most patients' felt highly engaged to participate in the intervention and confident in their ability to increase their physical activity. A small difference was seen between responders and non-responders. At the start of the intervention, responders tended to be less motivated opposed to non-responders, and they more often reported physical or emotional constraints of becoming more physically active. Despite these constraints, these patients felt confident to increase their activity because of positive beliefs about the intervention and the support of their nurse. Once patients consented to participate in the intervention, they felt committed to their consent.

"I felt that I should be more active, and this intervention came at the right time. I thought that I had to take advantage of it…I could not succeed in that myself. And then I thought 'Well, this is a nice opportunity to see if I will succeed with this support.'…It is not something I would have picked up myself." (R14, responder)

"I was really ready for it, I just wanted to start it and when I start something…I'm not going to say, 'I don't feel like doing it or something.' Then, I should not participate." (R6, non-responder)

Perceived effects of becoming more active

Most patients felt satisfied with their achieved results. Achieving positive effects resulted in a higher engagement with the intervention and maintenance of increased activity. Patients perceived both physical effects, such as feeling fitter and needing less medication, and emotional effects, such as experiencing better mood and becoming more socially active. Disappointing results negatively affected patients' engagement with the intervention. All patients reported an increase in their physical activity and incorporated this into their daily lives, but to different extents. Patients who reported major improvements were likely to perceive themselves as responders and felt highly engaged in their achieved results. Some patients felt overjoyed by their achieved results, as their results exceeded their prior expectations, which highly motivated them to maintain their increased physical activity. Patients who reported minimal improvement in their physical activity were more likely to perceive themselves as non-responders.

Table 3. Characteristics of interview participants

ID	Male/Female	Age	Living alone	Level of education
R1	Male	74	Alone	Secondary education
R2	Male	73	Not alone	Primary or below
R3	Female	69	Not alone	Secondary education
R4	Male	65	Not alone	Secondary education
R5	Female	68	Alone	Secondary education
R6	Female	57	Not alone	Secondary education
R7	Female	53	Not alone	Higher education
R8	Male	70	Not alone	Primary or below
R9	Female	40	Alone	Higher education
R10	Male	71	Not alone	Secondary education
R11	Male	66	Not alone	Secondary education
R12	Female	68	Not alone	Secondary education
R13	Male	49	Not alone	Secondary education
R14	Female	49	Alone	Secondary education
R15	Female	71	Not alone	Secondary education
R16	Male	63	Not alone	Higher education
R17	Female	48	Not alone	Secondary education
R18	Female	63	Not alone	Primary or below
R19	Female	62	Not alone	Secondary education
R20	Male	50	Not alone	Secondary education
R21	Female	61	Not alone	Secondary education
R22	Male	69	Not alone	Secondary education

+ physical activity increased; +/- physical activity increased a little; o physical activity did not increase much, but participation increased health or awareness of the impact of physical activity on their health

Change in minutes of moderate to vigorous physical activity from baseline		
According to patient	**According to accelerometer**	**Mean diff. minutes (%)**
o	Non-responder	- 15.4 (-44.8%)
+	Non-responder	- 6 (-12.8%)
+	Responder	+ 27.9 (+48.4%)
o	Non-responder	- 3.7 (-10.9%)
+/-	Responder	+10.3 (+21.7%)
+	Non-responder	- 12.1 (-17.6%)
o	Responder	+ 40 (+81.4%)
+	Responder	+ 9.4 (+21.7%)
o	Non-responder	- 16.7 (-21.8%)
+	Non-responder	- 0.4 (-4.2%)
+	Responder	+21.7 (+35.9%)
o	Responder	+10 (+44.6%)
+	Non-responder	- 7.4 (-12.5%)
o	Responder	+ 8.3 (+23.6%)
+	Non-responder	+ 7.4 (+17.3%)
+	Responder	+ 14.0 (+116.7%)
o	Non-responder	+ 1.0 (1.4%)
+	Responder	+ 20.9 (+32.8%)
+	Non-responder	+ 2.3 (+4.8%)
+	Responder	+ 10.6 (+25.0%)
+	Responder	+ 11.0 (+27.5%)
o	Non-responder	- 12.9 (-21.3%)

"At some point, I want to see results. If I don't get a result in spite of all my efforts... then I stop the effort because it is meaningless... Then, the motivation is gone immediately; at least it is immediately affected." (R22, non-responder)

"I also enjoy doing it... I chat with every owner of a dog. It is much more easy-going… Yes, that was very different from when I started. Then, I'd cower and never say anything… Well, I was shy and not feeling so good… Now, I even appeared in the diabetes newspaper...I would never have done that before." (R21, responder)

Increased awareness through participating in the intervention

At the start of the intervention, all patients were aware of the positive effect of physical activity on their health, and patients did not feel the need to read additional information. Despite their prior knowledge, the focus on physical activity in the intervention increased patients' awareness of the importance of being active and its relation to their health. This raised awareness prompted patients to be active daily.

"Of course, I knew that physical activity was important...but I'm much more aware now, certainly. And yes, if I have done nothing at all during a day, eh, I think 'Yes, that's actually not so wise.' Let's walk or do something then. So, it's always on my mind." (R4, non-responder)

Regardless of their perceived extent of increased physical activity, all patients became aware of the amount and intensity of their physical activity, which they highly valued and which positively affected their engagement in the intervention and their ability to maintain activity. Their awareness was particularly raised by wearing the accelerometer and keeping the activity log. Additionally, nurses' feedback on their level of goal attainment, reviewing their set goals and action planning also increased their awareness.

"In the past, I had no idea; I thought, 'I was walking with the dog,' and besides that, I did not know actually…Honestly, I was not aware of it; it was not something that was on my mind... Yes, for me that was important, certainly." (R6, non-responder)

Perceived trustful relationship with the nurses

All patients knew the nurses from their prior routine consultations. Patients highly valued their trustful relationship with the nurse, in which they felt that they could share their honest thoughts without being judged. Their relationship with the nurse prompted patients to participate in the intervention. Patients' perceived their relationship as crucial to increase their physical activity, as nurses' feedback and review of their level of goal attainment offered them an incentive to attain their goals. Some patients reported that

they were highly engaged to attain their goal, since they did not want to disappoint the nurse. Patients often felt rewarded by their nurses' approbation of their attained results. Although some patients felt pressured or controlled by the nurse, they experienced that nurses' support stimulated them to attain their goals.

"During the intervention, she consciously involved me very much... She was very enthusiastic and friendly, and she did not judge... I could be honest... When it did not work out, for example, she did not get angry about that or anything. That was just very pleasant." (R14, responder)

"Just because of our conversations … I had an incentive. Because I want to show that I have done something. And I don't think 'Well, next week then'... so, it worked for me that there is someone who looks at and discusses what I have done. Well, that went all in a pleasant way. Yes, I think that helped me." (R15, non-responder)

Valuing nurses' focus on increasing physical activity

Patients' highly valued the subsequent focus on physical activity during the consultations. Almost all patients reported that, in particular, setting specific and attainable goals, combined with planning their actions, directed them towards increasing their physical activity. The agreed upon goals stimulated their commitment to attain those goals. Patients highly valued nurses' feedback and review of their level of goal attainment, which positively affected their engagement in attaining their goals.

"I liked that...because you know what you have to do and what your goal is. I am someone who likes to work towards a goal, that stimulates me...Somehow, I know, that's what I'm doing it for, that's what I want to accomplish." (R6, non-responder)

"You've set your goal, and between the second or the third or the fourth consultation, you know what gets tough...Well, then, I went to the nurse, and she said, 'Just try again'. I benefitted quite a lot from her support. Yes, because she immediately asked me 'How did it go'? I said 'Well, not exactly the way I wanted it to be.' Then I could talk about it with her, which made me think, 'Well, guys, I'll just continue."(R19, non-responder)

Almost all patients experienced nurses' support in jointly setting specific and attainable goals as very helpful, as without this support they tended to set general, unrealistic or unchallenging goals. A few patients reported that setting goals and planning actions did not match with their unstructured personality or personal circumstances, and therefore, they did not value these elements. These patients perceived this advice as unhelpful and sought their own activities.

"It is difficult for me to see what is realistic and what's not. How do you start with something... I found it difficult to make it more realistic and especially in more bite-sized chunks, in a way that I could oversee it. By clearly indicating, 'Are you not going a bit too fast, you want too much, and is it not more convenient to be active within smaller bouts, which are much more feasible and lead to more results instead of disappointing yourself?' That certainly helped me. She made me realise that I did not have to run a marathon immediately. That was nice." (R14, responder)

"Yes, she provided me with ideas...but that did not really work for me. For example, that I could walk to do the shopping; however, that costs me too much time! Then, I jumped on the bike again." (R7, responder)

Involving others to increase physical activity

Although a few patients preferred solitary activities, most patients experienced that getting support from their family and friends engaged them to improve their physical activity. For some patients, involving others was a prerequisite for improving their physical activity. Family members and friends were seen as common facilitators to be physically active. In particular, spouses who joined the patient in increasing their physical activity often engaged patients to attain their goals.

"And I also do it together with my husband, and yes, I think it's just great that he joined me... We also encourage each other…I like doing that together, and by doing it together, I'm even more motivated...if you're busy doing things at home, one of the two says, 'Hey! Shall we go for a walk now?' Then, we stop our activities and go for a walk." (R3, responder)

Despite the fact that patients enjoyed being active with others, patients felt demotivated when they had to decrease their activity speed to match others. Being active with someone who had an equal or higher walking speed challenged them to increase and maintain their physical activity.

"All those people walk a lot slower than me...Well, I can walk with someone like that, but then I have to adjust my walking speed. I also walk with my wife sometimes...but she doesn't walk as fast as I do. Then, you are busy adjusting your walking speed instead of having a nice walk..." (R22, non-responder)

Physical activity was also seen as an opportunity to meet new people and extend their social contacts, which increased their enjoyment in being physically active and prompted them to maintain being physically active.

"Because I enjoy everything, and I am really eager to go to the gym...I have a lot of confidence in the people who teach there. I really don't want to let it go anymore. It's just those people together, afterwards, we drink coffee with each other... you get new contacts... Well, I think that's great too." (R21, responder)

Furthermore, being active with others often involved making a commitment, which was often regarded as an incentive to being active. The accountability towards others strengthened their engagement.

"It's at a fixed time. So, if I want to go, then I have to be there…and if I walk on my own, then I sometimes think, 'I really don't feel like going or I'll do it later.' That kind of thing. Then, I postpone it, and in this case, I can't." (R18, responder)

Insight into physical activity using self-monitoring tools

Generally, patients regarded the use of the self-monitoring tools such as the accelerometer and activity log as very helpful and stimulating to increase their physical activity because they provide insights into their amount and intensity of physical activity. This insight often challenged patients to extend their activity to attain their goals and to compete with prior results.

"Uh, I will not say it's a game to put a number on the activity log, but it's just that I'm looking somewhere halfway through the day and think, 'Well, it's okay to walk a bit further this evening.'...It's nice to monitor myself and to see where I actually win and where I lose something on my schedule. I can just browse back and review the results of last week. So, yes, I think it's helpful to estimate a little how to pick it up or adjust it again." (R13, non-responder)

Despite being highly valued by most patients, some patients reported that failing to attain their goals or not trusting the accuracy of the accelerometer demotivated them to increase their physical activity.

"Sometimes I thought, 'Well, I just wanted to have done this much'...And, of course, I did not succeed every day, even if I sometimes felt that I had done quite a bit...And then I thought, 'No, I have not done enough'...Then, I felt a bit down...I had the feeling that I did a lot or very much...and then I thought, 'Well it is just disappointing'." (R19, non-responder)

Patients differed in how they perceived the need to use the tools. Some patients reported that once they were aware of the amount and intensity of their physical activity, using the tools was no longer necessary, whereas others continued to use the tools because they felt the need to be stimulated to be physically active, and they perceived the tools as an incentive.

"No, I don't need an activity meter anymore because I know now when I walk that round, it's a one-hour walk." (R11, responder)

The majority of patients said they wore the accelerometer and kept the log daily. Most patients registered their activity at the end of the day, while others registered their activity directly afterwards or when it suited them best. Keeping the log prompted them to reflect on their level of goal attainment, which raised patients' awareness of their physical activity. All patients reported the time spent wearing the accelerometer, and keeping the log was acceptable to them.

"In the evening after dinner, I thought, 'Well, I'll just sit down on the couch. I do not have to walk anymore...so, I can take off the activity meter.' That was the moment to fill in the activity log...I like to do that kind of thing to get insight into what happened, 'What did I do and what conclusions can I draw from that?' Yes, I liked it...sometimes, I felt like 'I had done too little, I have to walk, I have to move'...So, yes that surely helped me...Writing down, monitoring myself, looking back to what I did last week. I thought that was great." (R14, responder)

Most patients found the accelerometer and log easy to use; however, some patients reported technical and practical problems while using the tools. A few patients lost the accelerometer or lost their activity data because the accelerometer automatically resets after midnight. Losing their activity data made them feel disappointed, as they had to estimate their activity levels, which prompted them to find ways to prevent losing the data in the future.

"Well, look, it's not annoying to wear that thing. You put it in your pocket and it measures, so...it does not bother me, or I do not forget about it. The only thing that is awkward is, I think, at midnight, it resets itself. I have had a few times that I lost my measures from that day." (R13, non-responder)

Taking responsibility to increase their physical activity

Despite patients feeling stimulated by both the nurses' support and the self-monitoring tools, patients often reported that in the end, they themselves are responsible for increasing their physical activity and for maintaining their health.

"You start something, and then you keep track of certain goals...You have your own responsibility for something that you promise to do. That you have to be corrected a bit sometimes, well that is logical, and that's what happened...You are actually constantly thrown back onto yourself, 'You have to do it and...there is no one else who is going to do that." (R11, responder)

Patients believed that taking responsibility for their health also included being honest with themselves and the nurses about their level of goal attainment. Not being honest was perceived as useless for themselves and the nurses.

"We are both open to each other...if you keep something back, then it's of no use going there...then, you're fooling yourself...That is a waste of time for both; bothering someone who is serious." (R17, non-responder)

Perceiving the need to use reminders

The majority of patients did not use the reminders they received at the start of the intervention to be active, such as post-it notes and a pen with the study logo. Patients often felt reminded by the self-monitoring tools and by storing the log in a visible place. Other patients did not feel the need to use reminders as they felt self-motivated to be active or were reminded by their spouses.

"I didn't use those post-its and pen, no. That log helped me...and we are each other's support...Yes, we are each other's stimulus." (R3, responder)

Physical capability impacts becoming more active

A majority of patients reported having (chronic) physical constraints, such as asthma, back pain, or joint aches. Some patients had existing physical constraints prior to their participation in the study, while others mentioned a health problem occurring preceding the intervention. Having physical constraints negatively affected patients' self-confidence in achieving their desired results, as they often had to reduce their goals and felt hampered in planning activities and finding tailored activities. This often affected their engagement and made them feel negative about themselves and their participation in the intervention. Patients often perceived difficulties in finding alternatives for being active despite their physical constraints. Patients valued nurses' support in jointly seeking for alternatives, such as finding suitable activities and adapting their activity speed to their circumstances. They often felt strengthened by this support, which helped them persevere to attain their goals.

"I have bursitis in the shoulder, and now I have a tennis elbow, so every time something happens, you know…that makes me think, 'How annoying.' I want to do more but it doesn't work, I just can't…I think that's so unfortunate. Then, I have to boost myself and just try, and if it doesn't work, then it doesn't work…. Still, it is mainly thinking, 'I'm just going to try it, and if I don't succeed, then I have bad luck and I'll only cycle a small lap." (R19, non-responder)

Continually dealing with circumstances affecting being physically active

The majority of patients reported internal and external circumstances that affected their

ability to increase and maintain being active. Perceived internal circumstances included enjoying being active and having physical constraints. Perceived external circumstances included weather and season, patients' working environment, busy family lives, being abroad, cancelation of their activity buddy and taking care of a sick family member. Despite patients' willingness to being physically active, these circumstances challenged patients in prioritising daily physical activity. Furthermore, patients felt challenged in finding ways to address these circumstances themselves. Almost all patients valued nurses' support in jointly finding alternatives and in tailoring activities to patients' preferences and personal circumstances. Finding ways to address their circumstances helped patients to create routines and to persevere in being physically active in daily life. Most patients were able to address their circumstances by adapting their thoughts by focussing on the range of possibilities instead of the limitations, such as incorporating multiple short bouts of physical activity into each day or purchasing home exercise equipment. Patients perceived that being physically active despite their hampering circumstances strengthened their engagement and confidence to maintain their activity after the intervention.
"If the weather was very bad...Then, I did some extra cycling on the home trainer. That is what I discussed with the nurse, that's what we agreed on. When you don't actually go outside, then I'm still moving." (R10, non-responder)

"I have actually noticed that, despite the fact that I want to move more, having dogs, young children, and a busy job, I find it quite difficult to pick a moment to be really active...Well, what I have done more often is bringing my children to school by bike instead of taking the car." (R13, non-responder)

Intending to maintain being physically active after the intervention
After finishing the intervention, all patients intended to maintain being physically active. However, patients felt that, in particular, ceasing their incentives, such as nurses' support, wearing the accelerometer and keeping the log, challenged them in maintaining their achieved level of physical activity. Patients who succeeded in building their activities into their daily lives felt confident in maintaining their achieved level of physical activity.

"When you are doing your usual things again, then yes, you have to think about it carefully, you're less aware, compared to when you're really in that process...Of course, it is now that I know a little bit, if I walk that far or do that much, how much that is. I didn't know that before, so now I know that bit just by heart...But because you do not have to go back to the nurse anymore, then you think, 'Well, no one knows about it...except yourself...Yes, that check, that seems to be necessary." (R6, non-responder)
"It doesn't cost me a lot of extra effort. That's especially after my work, I say 'It's a matter of incorporating it into my routine." (R9, non-responder)

DISCUSSION

Patients who participated in the Activate intervention were satisfied with the intervention. The results from both the questionnaires and the interviews showed that the Activate intervention led to an increased awareness in patients of the importance of physical activity for their health and an increased awareness of the amount and intensity of their current physical activity. Irrespective of their objective changes in activity levels, patients perceived that they became more active and that they benefitted both physically and emotionally from their participation. Getting support from the nurses with whom they have a trustful relationship, including goal setting, action planning, feedback, and reviewing goals, as well as self-monitoring their amount and intensity of activity and involving others, were perceived as highly supportive and incentivised patients to increase and maintain their physical activity. Patients felt responsible for attaining their goals and honestly reflected on their achieved results with themselves and the nurses. Patients perceived that the self-monitoring tools prompted them to be active, and therefore, they did not feel the need to use other reminders. Furthermore, patients' ability to increase and maintain being active was continually challenged by internal circumstances, such as enjoyment and physical constraints, and by external circumstances, such as weather and lack of time.

Patients felt they increased their physical activity due to the intervention. However, patients' perceptions towards their success in many cases did not accurately align with their objective measured success, which is in line with other studies.[31,32] Some patients underestimated their objective success, while some patients overestimated their objective success.

Patients perceived physical and emotional benefits of their increased physical activity, which positively affected their engagement in increasing and maintaining their activity; this has also been found in other studies.[31,33] Patients' increased awareness also engaged them to continue and maintain being physically active.[31-34]

The importance of involving others in initiating and maintaining physical activity has been widely reported.[31,33,35] Our study showed that family members and friends were facilitators, and in particular, spouses who joined the patient, which concurs with other studies.[31,32,36,37] Being active with others also positively affected patients' enjoyment. Enjoying being active strongly engaged the initiation and maintenance of their physical activity, which aligns with other studies.[31,38,39] Additionally, in accordance with other studies, we also found that physical capability is important in initiating and maintaining physical activity.[31,33,35,40,41] Patients reported the need for having an incentive prompting them to be physically active, such as consenting to participate in the intervention, nurses' subsequent support, wearing the accelerometer and keeping the log. Most incentives

ceased after the intervention, and it remains uncertain whether and how the patients maintain being physically active. A study by Wahlich et al.[33] evaluated the maintenance of physical activity in mid-life and older adults after three years of follow up and reported that the facilitators, which helped to maintain regular activity, included maintaining good health, self-motivation, social support and good weather. These facilitators were also reported in our study, in which patients also received nurses' support in finding alternatives to maintaining being physically active despite circumstances such as bad weather. In the study of Wahlich et al.,[33] patients' lack of time was seen as the most important barrier to maintain being physically active. This is in line with our study, implying the importance of focussing on both initiating and maintaining behaviour change, such as finding ways to address circumstances and other conflicting goals or behaviours, which might increase the likelihood of maintaining being physically active.[42,43]
Despite the fact that using prompts and cues has been shown to be effective to change behaviour,[44] the majority of patients did not need additional prompts and cues to use the self-monitoring tools because they felt sufficiently motivated.[33] Consistent with other studies, patients highly valued the use of self-monitoring tools, facilitating them to increase their activity level.[31,32,34] However, patients reported that once they were aware of their amount and intensity or that the novelty of wearing the accelerometer had worn off, they no longer used the accelerometer, which is in line with other studies.[33,45] Furthermore, technical problems affected their engagement, which has also been reported.[31,34] Patients frequently reported the importance of having a trusting relationship with their nurse as being crucial for their participation in the intervention, as well as for their goal attainment, and its being an incentive, which aligns with other studies.[37,46] Despite patients highly valuing the accelerometer and the log, patients found nurses' support invaluable in order to increase their physical activity, which has also been reported.[47-50] The subsequent consultations in which patients' goals were reviewed and (re)set, feedback was received, and actions were planned were highly valued by almost all patients, as these consultations incentivised them to continue.

Furthermore, self-monitoring tools seemed inevitable in an intervention to increase activity, as patients highly valued having insight into the amount and intensity of their activity. This increased their awareness, and patients felt challenged and incentivised by using these tools. Additionally, self-monitoring is a likely effective BCT.[51] Van der Weegen et al.[47] found that the combination of nurse-led consultations with a self-monitoring tool was effective in increasing physical activity in primary care patients, whereas a solely counselling intervention by nurses was not effective when compared to routine care. This implies that interventions focussing on increasing physical activity need to include both the support of a trustful healthcare provider and self-monitoring tools.

Strengths and limitations

The main strength of this study was the use of a convergent mixed methods design, wherein the triangulation of both quantitative and qualitative data was used to gain an in-depth exploration and understanding of patients' experiences with the Activate intervention and their perceived success opposed to their objectively measured success.

Furthermore, this study was conducted alongside a cluster-randomised controlled trial, before the trial results are known, which prevents interpretation bias of the study results and enhances the understanding of the effectiveness once the results of the Activate trial are known.

To enhance dependability of the qualitative data, the interviewers were unknown to the patients prior to the interviews, inviting them to be more candid. During the entire process, data were independently analysed by three researchers and an independent expert in qualitative research. The trustworthiness was enhanced by an audit trail, memo writing, the use of Braun and Clarke's checklist [27] and the COREQ.[29]

Some limitations need to be addressed. After the intervention period, the initial study sample was reduced from 93 to 67 questionnaires and valid accelerometer datasets. Data collection for this study was embedded in the data collection for the Activate trial, and patients who dropped out of the intervention were also excluded from this study. These patients might have expressed different experiences, which could have affected the results. Furthermore, the interviews were conducted by telephone due to logistical reasons. Face-to-face interviews might have invited patients to elaborate on their answers more fully, which might have further enriched the quality of the data.[52]

Implications

Based on the insight gained into patients' experiences with the Activate intervention and their perceived success, we have defined three recommendations that should be addressed in patients' behaviour change support. First, interventions aiming to increase patients' level of physical activity should include both self-monitoring tools and consultations with a healthcare provider who has a trustful relationship with the patient. Second, the effectiveness of such interventions can be enhanced by including the following BCTs: goal setting,[44,53,54] action planning,[55] reviewing behavioural goal(s),[44,54] feedback on behaviour,[44,56] problem-solving,[54,57] self-monitoring of activity,[51,54] and involving others.[44,54] These BCTs were highly valued by patients and are most likely to be effective. Third, support focussing on dealing with both internal and external circumstances to increase patients' physical activity in daily life is needed.

CONCLUSION

Patients who participated in the Activate intervention were satisfied with the intervention. Patients experienced an increase in their awareness of the importance of physical activity for their health and an increase in their level of physical activity. Responders and non-responders did not differ substantially in their experiences with the intervention and their perceived success. Patients' perceptions towards their success did not always align with their objective change in activity. Patients' engagement in the intervention was affected by perceived physical and emotional benefits, level of goal attainment, and perceived incentives. Patients experienced the combination of self-monitoring tools and being supported by the nurses with whom they have a trustful relationship as being invaluable to increasing their physical activity. This mixed methods study has increased our understanding of patients' experiences of their participation in a behaviour change intervention in primary care. The findings contribute to the evaluation of the effectiveness of the Activate trial and might facilitate implementation of such interventions in primary care.

REFERENCES

1. World Health Organisation. Cardiovascular diseases. Fact Sheet (2017). Available from: http://www.who.int/mediacentre/factsheets/fs317/en/ Accessed 12 April 2017.
2. Cooper AR, Moore LA, McKenna J, Riddoch CJ. What is the magnitude of blood pressure response to a programme of moderate intensity exercise? randomised controlled trial among sedentary adults with unmedicated hypertension. *Br J Gen Pract*. 2000;50(461):958-962.
3. Ebrahim S, Smith GD. Lowering blood pressure: A systematic review of sustained effects of non-pharmacological interventions. *J Public Health Med*. 1998;20(4):441-448.
4. Franco OH, de Laet C, Peeters A, Jonker J, Mackenbach J, Nusselder W. Effects of physical activity on life expectancy with cardiovascular disease. *Arch Intern Med*. 2005;165(20):2355-2360.
5. Halbert JA, Silagy CA, Finucane P, Withers RT, Hamdorf PA, Andrews GR. The effectiveness of exercise training in lowering blood pressure: A meta-analysis of randomised controlled trials of 4 weeks or longer. *J Hum Hypertens*. 1997;11(10):641-649.
6. Hu G, Jousilahti P, Barengo N, Qiao Q, Lakka T, Tuomilehto J. Physical activity, cardiovascular risk factors, and mortality among finnish adults with diabetes. *Diabetes Care*. 2005;28(4):799-805.
7. Pate RR, Pratt M, Blair SN, et al. Physical activity and public health. A recommendation from the centers for disease control and prevention and the american college of sports medicine. *JAMA*. 1995;273(5):402-407.
8. Williams PT. Physical fitness and activity as separate heart disease risk factors: A meta-analysis. *Med Sci Sports Exerc*. 2001;33(5):754-761.
9. Kemper HGC, Ooijendijk WTM, Stiggelbout M. Consensus over de Nederlandse norm voor gezond bewegen. *Tijdschr Soc Gezondheidsz*. 2000;78(78):180-183.
10. Nederlands Huisartsen Genootschap (2011). *Multidisciplinaire richtlijn cardiovasculair risicomanagement.* Houten, the Netherlands: Bohn Stafleu van Loghum.
11. Burke LE, Dunbar-Jacob JM, Hill MN. Compliance with cardiovascular disease prevention strategies: A review of the research. *Ann Behav Med*. 1997;19(3):239-263.
12. Baan CA, Hutten JBF & Rijken PM (2003). *Afstemming in de zorg: Een achtergrondstudie naar de zorg voor mensen met een chronische aandoening. [coordination of care. A study into the care for people with a chronic condition].* Bilthoven, the Netherlands: RIVM.
13. van Dillen SM, Noordman J, van Dulmen S, Hiddink GJ. Examining the content of weight, nutrition and physical activity advices provided by dutch practice nurses in primary care: Analysis of videotaped consultations. *Eur J Clin Nutr*. 2014;68(1):50-56.
14. Noordman J, Koopmans B, Korevaar JC, van der Weijden T, van Dulmen S. Exploring lifestyle counselling in routine primary care consultations: The professionals' role. *Fam Pract*. 2013;30(3):332-340.
15. Westland H, Schröder C, de Wit J, Frings J, Trappenburg JCA, Schuurmans M. Self-management support in routine primary care by nurses. *Br J Health Psychol*. 2018;23(1),88-107.
16. Elissen A, Nolte E, Knai C, et al. Is europe putting theory into practice? A qualitative study of the level of self-management support in chronic care management approaches. *BMC Health Serv Res*. 2013;13:117-6963-13-117.
17. Wagner EH. Chronic disease management: What will it take to improve care for chronic illness? *Eff Clin Pract*. 1998;1(1):2-4.
18. Bodenheimer T, Lorig K, Holman H, Grumbach K. Patient self-management of chronic disease in primary care. *JAMA*. 2002;288(19):2469-2475.

19. Michie S, van Stralen MM, West R. The behaviour change wheel: A new method for characterising and designing behaviour change interventions. *Implement Sci*. 2011;6:42-5908-6-42.
20. Westland H, Bos Touwen I, Trappenburg JCA, Schröder C, de Wit N, Schuurmans M. Unravelling effectiveness of a nurse-led behaviour change intervention to enhance physical activity in patients at risk for cardiovascular disease in primary care: Study protocol for a cluster randomised controlled trial. *Trials*. 2017;18(1):79-94.
21. Campbell N, Murray E, Darbyshire J, et al. Designing and evaluating complex interventions to improve health care. *BMJ*. 2007;334(7591):455-459.
22. Michie. Interventions to change health behaviours: Evidence-based or evidence-inspired? *Psychol Health*. 2004;19(1):29-49.
23. Moore G, Audrey S, Barker M, et al. Process evaluation of complex interventions: Medical research council guidance. *BMJ*. 2015;350:h1258.
24. Linnan L, Steckler A. Process evaluation for public health interventions and research. In: Linnan L, Steckler A, eds. *Process evaluation for public health interventions and research.* San Francisco: Jossey-Bass; 2002:1-23.
25. Creswell JW, Plano Clark VL (2017). *Designing and conducting mixed methods research.* Third Edition ed. Sage Publications Inc.
26. Slootmaker SM, Chin A Paw, M J M, Schuit AJ, van Mechelen W, Koppes LLJ. Concurrent validity of the PAM accelerometer relative to the MTI actigraph using oxygen consumption as a reference. *Scand J Med Sci Sports*. 2009;19(1):36-43.
27. Braun V, Clarke V. Using thematic analysis in psychology.*Qualitative research in psychology*. 2006;3(2):77-101.
28. Guba E, Lincoln Y. Competing paradigms in qualitative research. In: Denzin, NK & Lincoln, YS. *Handbook of qualitative research.* London: Sage; 1994:105-117.
29. Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): A 32-item checklist for interviews and focus groups. *Int J Qual Health Care*. 2007;19(6):349-357.
30. Creswell J (2012). *Qualitative inquiry & research design: Choosing among five approaches.* 3rd revised edition ed. Sage Publications Inc.
31. Normansell R, Smith J, Victor C, et al. Numbers are not the whole story: A qualitative exploration of barriers and facilitators to increased physical activity in a primary care based walking intervention. *BMC Public Health*. 2014;14:1272.
32. Victor C, Rogers A, Woodcock A, et al. What factors support older people to increase their physical activity levels? an exploratory analysis of the experiences of PACE-lift trial participants. *Arch Gerontol Geriatr*. 2016;67:1-6.
33. Wahlich C, Beighton C, Victor C, et al. 'You started something … then I continued by myself': A qualitative study of physical activity maintenance. *Prim Health Care Res Dev*. 2017:1-17.
34. Verwey R, van der Weegen S, Spreeuwenberg M, Tange H, van der Weijden T, de Witte L. Process evaluation of physical activity counselling with and without the use of mobile technology: A mixed methods study. *Int J Nurs Stud*. 2016;53:3-16.
35. Gellert P, Witham M, Crombie I, Donnan P, McMurdo MET, Sniehotta F. The role of perceived barriers and objectively measured physical activity in adults aged 65-100. *Age Ageing*. 2015;44(3):384-390.
36. Bratzke L, Muehrer R, Kehl K, Lee K, Ward E, Kwekkeboom K. Self-management priority setting and decision-making in adults with multimorbidity: A narrative review of literature. *Int J Nurs Stud*. 2015;52(3):744-755.
37. Nam S, Chesla C, Stotts N, Kroon L, Janson S. Barriers to diabetes management: Patient and provider factors. *Diabetes Res Clin Pract*. 2011;93(1):1-9.

38. De Bourdeaudhuij I, Sallis J. Relative contribution of psychosocial variables to the explanation of physical activity in three population-based adult samples. *Prev Med*. 2002;34(2):279-288.
39. Allender S, Cowburn G, Foster C. Understanding participation in sport and physical activity among children and adults: A review of qualitative studies. *Health Educ Res*. 2006;21(6):826-835.
40. Bethancourt HJ, Rosenberg DE, Beatty T, Arterburn DE. Barriers to and facilitators of physical activity program use among older adults. *Clin Med Res*. 2014;12(1-2):10-20.
41. Casey D, De Civita M, Dasgupta K. Understanding physical activity facilitators and barriers during and following a supervised exercise programme in type 2 diabetes: A qualitative study. *Diabet Med*. 2010;27(1):79-84.
42. Presseau J, Tait R, Johnston D, Francis J, Sniehotta F. Goal conflict and goal facilitation as predictors of daily accelerometer-assessed physical activity. *Health Psychol*. 2013;32(12):1179-1187.
43. Presseau J, Boyd E, Francis J, Sniehotta F. Goal conflict and goal facilitation in community-based cardiac rehabilitation: A theory-based interview study. *Psychol Health Med*. 2015;20(2):227-238.
44. Hankonen N, Sutton S, Prevost AT, et al. Which behavior change techniques are associated with changes in physical activity, diet and body mass index in people with recently diagnosed diabetes? *Ann Behav Med*. 2015;49(1):7-17.
45. McKay J, Wright A, Lowry R, Steele K, Ryde G, Mutrie N. Walking on prescription: The utility of a pedometer pack for increasing physical activity in primary care. *Patient Educ Couns*. 2009;76(1):71-76.
46. Nagelkerk J, Reick K, Meengs L. Perceived barriers and effective strategies to diabetes self-management. *J Adv Nurs*. 2006;54(2):151-158.
47. van der Weegen S, Verwey R, Spreeuwenberg M, Tange H, van der Weijden T, de Witte L. It's LiFe! mobile and web-based monitoring and feedback tool embedded in primary care increases physical activity: A cluster randomized controlled trial. *J Med Internet Res*. 2015;17(7):e184.
48. Harris T, Kerry S, Victor C, et al. A primary care nurse-delivered walking intervention in older adults: PACE (pedometer accelerometer consultation evaluation)-lift cluster randomised controlled trial. *PLoS Med*. 2015;12(2):e1001783.
49. Harris T, Kerry S, Limb E, et al. Effect of a primary care walking intervention with and without nurse support on physical activity levels in 45- to 75-year-olds: The pedometer and consultation evaluation (PACE-UP) cluster randomised clinical trial. *PLoS Med*. 2017;14(1):e1002210.
50. Mutrie N, Doolin O, Fitzsimons C, et al. Increasing older adults' walking through primary care: Results of a pilot randomized controlled trial. *Fam Pract*. 2012;29(6):633-642.
51. Michie S, Abraham C, Whittington C, McAteer J, Gupta S. Effective techniques in healthy eating and physical activity interventions: A meta-regression. *Health Psychol*. 2009;28(6):690-701.
52. Irvine A. Duration, dominance and depth in telephone and face-to-face interviews: A comparative exploration. *International Journal of Qualitative Methods*. 2011;10(3):202-220.
53. Bravata D, Smith Spangler C, Sundaram V, et al. Using pedometers to increase physical activity and improve health: A systematic review. *JAMA*. 2007;298(19):2296-2304.
54. Greaves C, Sheppard K, Abraham C, et al. Systematic review of reviews of intervention components associated with increased effectiveness in dietary and physical activity interventions. *BMC Public Health*. 2011;11:119.
55. Williams SL, French DP. What are the most effective intervention techniques for changing physical activity self-efficacy and physical activity behaviour--and are they the same? *Health Educ Res*. 2011;26(2):308-322.
56. Ivers N, Jamtvedt G, Flottorp S, et al. Audit and feedback: Effects on professional practice and healthcare outcomes. *Cochrane Database Syst Rev*. 2012(6):CD000259.

57. French D, Olander E, Chisholm A, Mc Sharry J. Which behaviour change techniques are most effective at increasing older adults' self-efficacy and physical activity behaviour? A systematic review. *Ann Behav Med*. 2014;48(2):225-234.

APPENDIX

Appendix 1. Interview guide

Topics	Questions (examples)
General	Standard opening question: What was the reason you agreed to participate in the Activate study?
Expectations prior to the study	What expectations did you have prior to the Activate study? Can you tell me to what extent your expectations were met?
Perceived outcome	Can you tell me whether you think you became more physically active due to your participation in the study?
Perceptions towards maintaining physical activity	Have you made any changes to your routine of life as a result of your participation in the study? To what extend do you think you will maintain being physically active? Now you have finished the intervention, how motivated are you to continue being more physically active? Now you have finished the intervention, how self-confident are you to continue being more physically active? How do you plan to maintain the changes you have made?
Perceived motivation towards increasing physical activity	At the start of the study, how motivated were you to increase your physical activity (grade 1-10)? Did your motivation change during the intervention period?
Perceived self-confidence towards increasing physical activity	At the start of the study, how self-confident were you to increase your physical activity (grade 1-10)? Did your self-confidence change during the intervention period?
Experiences with nurses' support	Can you tell me how you experienced the nurses' support during the consultations? Can you tell me whether you think the consultations helped you increase your physical activity?
Perceptions towards the consultation structure and most prevalent BCTs	How did you experience to set personal goals and action plans? Did the nurses help you to set your own goals and plan your actions? [BCTs: goal setting and action planning] To what extent did this affect your progress? What is your opinion about reviewing the extent to which you attained your goals? [BCT: reviewing behavioural goal(s)] Did this affect your progress?

Appendix 1. Continued

Topics	Questions (examples)
Perceptions towards the consultation structure and most prevalent BCTs (Continued)	Did the nurse discuss how you can get any support from e.g. family or friends? [BCT: social support] To what extent did this affect your progress? Did you discuss strategies to maintain being physically active? Did you bring up the strategies yourself? [BCTs: habit formation, problem-solving and relapse prevention] Can you tell me how the nurse supported you if you were found it difficult to maintain your progress? What did you find helpful and unhelpful? [BCT: problem-solving] Did the nurse prompt you to use any reminders to help you increasing your physical activity (e.g. the Activate study post-its, pen, etc.)? [BCT: prompts and cues] Did you find this helpful? Can you tell me whether you think the study consultations differed compared to the routine consultations? Did the nurse clearly explain to you what you were expected to do at home? (think about your goals, action plan, wearing the accelerometer, keeping the logbook)
Experiences with the study materials and equipment	Can you tell me to what extent wearing the accelerometer and keeping the activity logbook helped you to increase your physical activity? How did this affect your progress? When did you wear the accelerometer and keep the log? Did you perceive any difficulties while wearing the accelerometer or keeping the activity log? How did you handle this? At the start of the study, you received a workbook. Did you use this workbook? What is your opinion about the content of the workbook?
Most and least effective components	Can you tell me what you found most helpful in becoming more physically active? Can you tell me what you found least helpful in becoming more physically active?
Duration of the intervention	What is your opinion about the number and length of the consultations? Generally, how much time did you spend on keeping the activity log? Was this acceptable to you?

Appendix 1. Continued

Topics	Questions (examples)
Satisfaction with the intervention	Can you tell me how satisfied you are with your participation in the Activate study (grade 1-10)? Would you recommend this intervention to other patients?
Additional questions regarding previous or not discussed topics	Do you have anything to add to the questions I have asked?

Abbreviations: BCTs behaviour change techniques

Appendix 2. Checklist of Criteria for Good Thematic Analysis: 15-point checklist*

Process	Criteria		Reported
Transcription	1.	The data have been transcribed to an appropriate level of detail, and the transcripts have been checked against the tapes for 'accuracy'.	YES
Coding	2.	Each data item has been given equal attention in the coding process.	YES
	3.	Themes have not been generated from a few vivid examples (an anecdotal approach), but instead the coding process has been thorough, inclusive and comprehensive.	YES
	4.	All relevant extracts for all each theme have been collated.	YES
	5.	Themes have been checked against each other and back to the original data set.	YES
	6.	Themes are internally coherent, consistent, and distinctive.	YES
Analysis	7.	Data have been analysed - interpreted, made sense of - rather than just paraphrased or described.	YES
	8.	Analysis and data match each other - the extracts illustrate the analytic claims.	YES
	9.	Analysis tells a convincing and well-organised story about the data and topic.	YES
	10.	A good balance between analytic narrative and illustrative extracts is provided.	YES
Overall	11.	Enough time has been allocated to complete all phases of the analysis adequately, without rushing a phase or giving it a once-over-lightly.	YES
Written report	12.	The assumptions about, and specific approach to, thematic analysis are clearly explicated.	YES
	13.	There is a good fit between what you claim you do, and what you show you have done - i.e. described method and reported analysis are consistent.	YES
	14.	The language and concepts used in the report are consistent with the epistemological position of the analysis.	YES
	15.	The researcher is positioned as *active* in the research process; themes do not just 'emerge'.	YES

*Adapted from: Braun V, Clarke V. Using thematic analysis in psychology. *Qualitative research in psychology.*2006;3(2),77-101.

Appendix 3. Consolidated criteria for reporting qualitative studies (COREQ): 32-item checklist*

No.	Item	Guide questions/description	Reported
Domain 1: Research team and reflexivity			
Personal Characteristics			
1.	Interviewer/ facilitator	Which author/s conducted the interview or focus group?	YES
2.	Credentials	What were the researcher's credentials?	YES
3.	Occupation	What was their occupation at the time of the study?	YES
4.	Gender	Was the researcher male or female?	YES
5.	Experience and training	What experience or training did the researcher have?	Completed a course in qualitative research
Relationship with participants			
6.	Relationship established	Was a relationship established prior to study commencement?	YES
7.	Participant knowledge of the interviewer	What did the participants know about the researcher?	YES
8.	Interviewer characteristics	What characteristics were reported about the interviewer/facilitator?	YES
Domain 2: Study design			
Theoretical framework			
9.	Methodological orientation and Theory	What methodological orientation was stated to underpin the study?	YES
Participant selection			
10.	Sampling	How were participants selected?	YES
11.	Method of approach	How were participants approached?	YES
12.	Sample size	How many participants were in the study?	YES
13.	Non-participation No none participants	How many people refused to participate or dropped out? Reasons?	YES
Setting			
14.	Setting of data collection	Where was the data collected?	YES
15.	Presence of non-participants	Was anyone else present besides the participants and researchers?	NO
16.	Description of sample	What are the important characteristics of the sample?	YES

Appendix 3. Continued

No. Item	Guide questions/description	Reported
Data collection		
17. Interview guide	Were questions, prompts, guides provided by the authors? Was it pilot tested?	YES. Not pilot tested
18. Repeat interviews	Were repeated interviews carried out?	YES
19. Audio/visual recording	Did the research use audio or visual recording to collect the data?	YES
20. Field notes	Were field notes made during and/or after the interview or focus group?	YES
21. Duration	What was the duration of the inter views or focus group?	YES
22. Data saturation	Was data saturation discussed?	YES
23. Transcripts returned	Were transcripts returned to participants for comment and/or correction?	NO, because of burden to participants
Domain 3: Analysis and findings		
Data analysis		
24. Number of data coders	How many data coders coded the data?	YES
25. Description of the coding tree	Did authors provide a description of the coding tree?	YES
26. Derivation of themes	Were themes identified in advance or derived from the data?	YES
27. Software What software	What software, if applicable, was used to manage the data?	YES
28. Participant checking	Did participants provide feedback on the findings?	NO, because of burden to participants
Reporting		
29. Quotations presented	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified?	YES
30. Data and findings consistent	Was there consistency between the data presented and the findings?	YES
31. Clarity of major themes	Were major themes clearly presented in the findings?	YES
32. Clarity of minor themes	Is there a description of diverse cases or discussion of minor themes?	YES

* Adapted from: Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care.* 2007;19(6):349-57.

CHAPTER 5

Nurses' perceptions towards the delivery and feasibility of a behaviour change intervention to enhance physical activity in patients at risk for cardiovascular disease in primary care: a qualitative study

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ABSTRACT

Background: Self-management support is widely accepted for the management of chronic conditions. Self-management often requires behaviour change in patients in which primary care nurses play a pivotal role. To support patients in changing their behaviour, the structured behaviour change Activate intervention was developed. This intervention aims to enhance physical activity in patients at risk for cardiovascular disease in primary care as well as to enhance nurses' role in supporting these patients. This study aimed to evaluate nurses' perceptions towards the delivery and feasibility of the Activate intervention.

Methods: A qualitative study nested within a cluster-randomised controlled trial using semi-structured interviews was conducted and thematically analysed. Fourteen nurses who delivered the Activate intervention participated.

Results: Three key themes emerged concerning nurses' perceptions of delivering the intervention: nurses' engagement towards delivering the intervention; acquiring knowledge and skills; and dealing with adherence to the consultation structure. Three key themes were identified concerning the feasibility of the intervention: expectations towards the use of the intervention in routine practice; perceptions towards the feasibility of the training programme; and enabling personal development.

Conclusion: Delivering a behaviour change intervention is challenged by the complexity of changing nurses' consultation style, including acquiring corresponding knowledge and skills. The findings have increased the understanding of the effectiveness of the Activate trial and will guide the development and evaluation of future behaviour change interventions delivered by nurses in primary care.

BACKGROUND

Self-management support is widely accepted as an approach to improve health-related outcomes, enhance patients' involvement and decrease healthcare costs.[1-3] Self-management support by health care providers, such as primary care nurses, aims to equip patients with the essential skills to manage symptoms, treatment, physical and psychosocial consequences of chronic diseases and to change patients' health behaviour.[4,5] Over the past decade, in most Western countries, disease management of some of the most prevalent chronic conditions, including diabetes mellitus type 2 and (risk of) cardiovascular disease (CVD), has shifted away from hospitals and towards primary care. In primary care, chronic care is increasingly reallocated from general practitioners towards primary care nurses.[6] Primary care nurses play a pivotal role in the management of chronic conditions, promoting self-management and offering follow-up consultations and are therefore in a key position to support these patients in changing their health behaviour.[6] Like other behavioural interventions, self-management interventions are considered complex, containing multiple interacting components.[7] Self-management support requires nurses to adapt their traditional consultation style, which is focused on giving advice, informing and educating patients about their condition, towards a more coaching-oriented consultation style aimed at supporting patients in changing their behaviour.[8-10] Adapting their consultation style adequately implies that nurses need to change their behaviour, which is challenging to accomplish.[8,11-14] Furthermore, in order to change and incorporate their adapted consultation style into their routine practice, nurses need to be facilitated and supported by their superiors, for instance through being autonomous, having enough time to integrate self-management into their consultations and to have training opportunities.[11,12]

The effectiveness of self-management interventions is often evaluated in randomised controlled trials that are mainly focused on pre-specified outcomes rather than on in-depth exploration of the delivery and implementation process.[15] Insight into the perceptions of providers towards the delivery and feasibility of such interventions, as part of a process evaluation, might enhance our understanding of the effectiveness of complex interventions and shed some light on how the intervention works.[16-19]

This study evaluated the perceptions of the providers towards the delivery and feasibility of a self-management intervention alongside the cluster-randomised controlled Activate trial. The Activate intervention is a nurse-led behaviour change intervention targeted at increasing physical activity in a large heterogeneous subgroup of patients, namely, those at risk for CVD. The research questions of this study were:

1. What are primary care nurses' perceptions of delivering the Activate intervention to patients at risk for CVD?
2. What are primary care nurses' perceptions of the feasibility of the Activate intervention for routine practice?

METHODS

Study design

A qualitative study of nurses' perceptions of the delivery and feasibility of the Activate intervention, nested within a cluster-randomised trial in primary care, was conducted.

The Activate intervention

To enhance behaviour change in both patients and nurses, the Activate intervention was developed using the Behaviour Change Wheel (BCW).[20] A behavioural analysis was conducted for the behaviour of patients and the behaviour of nurses using the COM-B (capability, opportunity, motivation-behaviour) model.[20] Subsequently, intervention functions were selected, by which patients' level of physical activity and nurses' skills to provide support could be enhanced. The intervention functions were linked to a selection of behaviour change techniques (BCTs) to support behaviour change.[20,21]

Behavioural analysis of the patients resulted in a selection of 17 BCTs, which were integrated into the Activate intervention. The intervention consisted of four standardised nurse-led consultations to enhance physical activity spread over a 12-week period: one consultation in the first week with subsequent consultations after 2, 6 and 12 weeks. Consultations occurred in the patients' own general practice, with a duration of 20-30 minutes.

The intervention structure was described in a handbook for nurses. Nurses were asked to individualise the content of the consultations to the patients' unique circumstances, needs and preferences. Patients received a workbook, which included tips and tricks, useful websites, activity logs and action plans and were equipped with an accelerometer (personal activity monitor; Pam AM300)[22] in order to self-monitor their physical activity daily.

Behavioural analysis of the nurses resulted in a selection of 21 BCTs, which were integrated into a standardised comprehensive training programme to equip nurses with the skills to deliver the Activate consultations to patients. The training consisted of several components: a one-day training, two individual coaching sessions, instructional videos on how to apply the BCTs in the consultations, a handbook with example sentences and checklists

(what to do when). Preparatory to the one-day training, nurses received a workbook, including study procedures and materials and were asked to view two online presentations to reinforce the procedures and the relevance of physical activity for patients at risk for CVD. The one-day training was held in a small group led by a health psychologist, and it focused on learning how to deliver the BCTs in each of the consultations. This training included theoretical background about how to promote behaviour change and included practising skills in delivering the consultation using an outlined structure, which included BCTs, by use of instructional videos and role-playing. To optimise and rehearse the gained skills, nurses received two individual coaching sessions by the health psychologist. For each coaching session, nurses recorded one of their consultations on which they received feedback on their performance during the coaching session. To strengthen their gained skills, nurses were encouraged to use the instructional videos, handbook and checklists. Further details on the development and content of the intervention are described elsewhere.[23]

The Activate intervention is currently being tested for its effectiveness in terms of number of minutes of moderate to vigorous physical activity within a 6-month follow-up period in a two-armed cluster-randomised controlled trial in primary care settings in the Netherlands comparing the Activate intervention with care as usual, according to the Dutch guideline of cardiovascular risk management. The Activate trial entails participation by 31 general practices, 36 primary care nurses and 195 patients (Activate trial, ClinicalTrials.gov NCT02725203). A total of 16 general practices (20 primary care nurses) were randomly allocated to the intervention group and a total of 15 general practices (16 primary care nurses) were randomly allocated to the control group.

Sample and recruitment

The study sample consisted of 20 primary care nurses from 16 general practices situated throughout the Netherlands who participated in the Activate trial and were allocated to the intervention group. Nurses were eligible to participate if they had experience with delivering the intervention, which was operationalised as having completed the training and delivered the intervention to at least two patients. Therefore, two nurses were excluded from this study, as they had delivered the intervention to fewer than two patients due to difficulties recruiting patients. One nurse was excluded because she had changed jobs during the study. After completing the intervention, all eligible nurses (n=17) were invited through e-mail to participate in this qualitative study. In total, 14 nurses (82.4%) agreed to participate, and 3 nurses refused to participate due to busy clinical practice.
To increase the likelihood of reflecting different nurse perspectives and to increase the representativeness of the data, maximum variation sampling was used in the recruitment phase of the Activate trial to obtain diversity with regard to nurses' age and years

of working experience with patients at risk for CVD in primary care. Furthermore, we strived for maximum variation in the sample with regard to nurses' educational background, as some nurses -other than working as a registered nurse- had formerly worked predominantly as receptionists and practitioner assistants in general practices prior to their specialisation in primary care nursing.

Data collection

Face-to-face individual interviews were conducted using a semi-structured interview guide. This consisted of open questions asking about perceptions towards the training, intervention delivery, effect on patients' behaviour, changes in consultation style and feasibility of the intervention in practice (Appendix 1). Based on nurses' narratives, topics that were mentioned were explored in depth. The interview guide was developed by four researchers and peer reviewed by the research team to ensure feasibility and completeness of the topics. All interviews started with the same opening question: "What was the reason you agreed to participate in the Activate study?"

The interviews were conducted by three researchers. An expert on qualitative research was involved in the process to ascertain the methodological quality of the study.

The interviewers were unknown to the nurses, enabling them to express their experiences and opinions without inhibitions. Nurses were interviewed once at the general practice or at the nurses' homes based on nurses' preferences. Interviews ranged in duration from 35 to 62 minutes (mean: 48 minutes). All interviews were audio-recorded.

During and after the interviews, memos were made to describe observations, reflect on methodological issues, capture initial ideas about emerging themes and inform refinements of the interview guide. Furthermore, the interview techniques of the interviewers were discussed and they were trained by the research team to ameliorate the equivocality of the interviews. Nurses' baseline characteristics were collected in the Activate trial.

Ethical approval to conduct the interviews was awarded within the overall approval for the Activate trial, which was approved by the Medical Ethics Research Committee of the University Medical Center Utrecht (NL54286.041.15).

Data analysis

All interviews were transcribed verbatim. Data were thematically analysed.[24] Data analysis started after the first three interviews. The transcripts were read and re-read, initial ideas for coding and refinements of the interview guide were discussed. After every three interviews, the transcripts were double-coded and the codes were assessed for similarities and differences by the research team. Subsequently the initial codes were collated into potential themes, and all relevant data were structured to each potential theme. Potential themes and subthemes were reviewed on consistency with the codes and entire data to ensure they reflect the entire data. Inconsistencies were discussed during joint meetings with the research team and themes were further developed and depicted in a thematic map of the data. Furthermore, the essence of each theme was further considered by the research team, themes were defined and illustrative quotes were selected.

Data saturation was reached after the twelfth interview; however, the data were complemented with two interviews to affirm the potential themes and ensure a maximum variation in the sample.

Data analysis was supported by NVivo 11.0 software (QSR International Pty Ltd, Version 11.0, 2011).

Trustworthiness

Credibility of data collection and analysis was enhanced by researcher triangulation and peer review in all phases of the study.[25] An expert on qualitative research was involved in the process to ensure accuracy and enhance data dependability.[26] Biweekly meetings with four team members to discuss data collection and analysis decisions enhanced methodological quality. In addition, an audit trail ensured the study's confirmability.[25] Memo writing and expert opinion supported the analysis and enhanced study reliability.[26] The use of a 15-point checklist by Braun and Clarke[24] ensured correct application of the phases of thematic analysis; see Appendix 2. The consolidated criteria for reporting qualitative studies (COREQ) were used to facilitate reporting of the results;[27] see Appendix 3.

RESULTS

Between October 2016 and March 2017, 14 nurses were interviewed. All nurses were female. Maximum variation was achieved for age (range 24-63 years; mean 48.9), years of experience working with patients at risk for CVD in primary care (range 2-14 years; mean 7.2) and educational background (n=11; 73.3% registered nurses). Nurses' characteristics are presented in Table 1.

Table 1. Characteristics of participating primary care nurses

ID	Age (years)	Working experience (years)*	Educational background	Additional training	Included patients in the study (n)
R1	55	12	Former practice assistant	None	2
R2	41	14	Former practice assistant	MI, SQ	10
R3	63	2	Former practice assistant	None	3
R4	54	5	Registered nurse	MI	3
R5	52	5	Registered nurse	MI	11
R6	47	9	Registered nurse	None	5
R7	39	9	Registered nurse	None	10
R8	36	2	Registered nurse	MI	2
R9	58	2	Former practice assistant	MI	5
R10	55	11	Registered nurse	MI	7
R11	56	6	Former practice assistant	MI	5
R12	50	13	Registered nurse	MI, SQ	2
R13	24	3	Registered nurse	MI	3
R14	55	8	Registered nurse	MI, SM	5

Abbreviations: CVD cardiovascular diseases; MI motivational interviewing; SM self-management; SQ Socratic Questioning

***** Working experience as a nurse in primary care with patients at risk for CVD

A thematic map was created to depict the emerged themes; see Figure 1. Three themes emerged in order to answer research question 1: to reflect nurses' perceptions towards delivering the Activate intervention:

- Nurses' engagement towards delivering the Activate intervention
- Acquiring knowledge and skills
- Dealing with adherence to the consultation structure

Research question 2: nurses' perceptions towards the feasibility of the Activate intervention for routine practice, was captured in three themes:

- Expectations towards the use of the intervention in routine practice
- Perceptions towards the feasibility of the training programme
- Enabling personal development

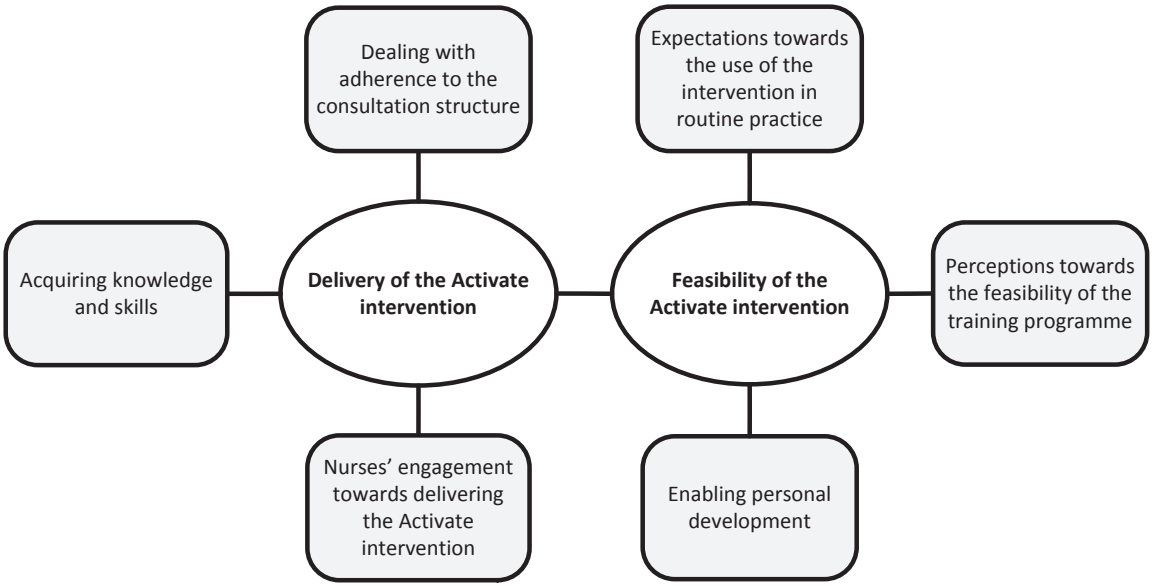

Figure 1. Thematic map of nurses' perceptions of delivering and the feasibility of the Activate intervention

Nurses' engagement towards delivering the Activate intervention

All nurses indicated that contributing to the improvement of patients' health outcomes was the core of their nursing role, which aligned with delivering an intervention to enhance patients' behaviour change. Reasons for participating in the Activate trial corresponded with their beliefs about the advantage of increased physical activity for lowering the risk of CVD and thus improving health outcomes. Based on their experience in supporting patients to change their health behaviour, all nurses expressed a need to increase their skills to enhance their support to patients in order to increase physical activity.

"The main reason was that it's difficult to motivate people to increase their physical activity. I could use some tools for how I could handle this the best way. Very often, questions about patients' motivation remain superficial, and I wanted to know how I am going to ask in-depth questions about their motivation?" (R10)

Directly after the training, all nurses felt engaged to deliver the intervention in their practice. Their engagement was supported by having been convinced that the intervention could be beneficial to patients.

"I felt that I could perform better in my job, that I could make a difference to people and that I have more to offer them." (R6)

Nurses expressed that, during the study period, their engagement towards delivering the intervention strongly depended on their experiences with delivering the intervention.

All nurses valued and felt rewarded by patients' success at increasing their level of physical activity and perceived this as an effect of their intervening activities. Patients' success had a positive impact on the nurses' job satisfaction and their engagement towards delivering the intervention.

"It is very nice to see that it just has an effect on people and that people feel fitter. That makes you excited and willing to continue. Ultimately, it is what you want to do: to help people further." (R13)

However, differences were seen in how nurses dealt with patients' lack of motivation to participate in the intervention or their lack of success at increasing their physical activity, and this negatively affected the engagement of some nurses. Patients' lack of motivation to participate often led to a postponed start for delivering the intervention or fewer practising opportunities. Some nurses felt rewarded by enhancement of their knowledge and skills to support patients, in particular with patients who they perceived as challenging to motivate. They perceived that actual delivery of the intervention increased their confidence and job satisfaction and helped them to positively continue with the study despite perceived difficulties with patient inclusion.

"Otherwise, you have nothing to discuss, right? If someone has 100% perseverance, then you are soon done. You have a lot more to discuss, that's nice. If someone says, 'I have already tried it ten times, but I can't keep it up', well then you have something to look for." (R12)

Despite their high initial engagement, some nurses felt that their engagement towards delivering the intervention strongly depended on patients' motivation. Patients' unwillingness to participate as well as patients' lack of commitment to goal attainment resulted in some nurses questioning their efforts to support them, which affected their engagement negatively.

"For me, it's more fun to support a motivated patient who does his homework perfectly compared to a patient who brings a completely empty diary and says, 'Yes, I did not really keep up.' Then, you think this costs me forty-five minutes, and that patient actually does not do anything. It's a lot more fun when they say, 'I deliberately went cycling to reach my goal.' Yes, then you really feel like that's what I am doing it for." (R2)

While continuing their participation in the study, nurses had to deal with circumstances such as a high work load and absence due to sick leave or holiday, which often negatively influenced their engagement towards delivering the intervention.

Acquiring knowledge and skills

All nurses reported that the training, handbook, checklists, instructional videos and coaching sessions were essential to equip them with the necessary knowledge and skills to establish and deliver the intervention as intended, which strengthened their confidence and engagement in their support.

"After the training, I felt I had a lot of tools I could apply to patients. I was equipped with a lot of techniques for gaining effects in patients, and that feels good. Normally, I asked: 'are you physically active?' Now, I make it more specific and explore with the patient how to continue." (R6)

To strengthen their confidence, nurses reinforced their gained skills and knowledge by rehearsing the consultation structure using the instructional videos and the handbook. Once their initial feelings of uncertainty towards their skills were overcome and their confidence improved, brief repetition of the handbook prior to a consultation was sufficient.

"I really regretted there was a long delay between the training and the first consultation. Then, things dwindled pretty fast since you are not practising it. Only prior to my first and second patient I watched the instructional videos again. Then, I had the idea that I had a better grip on it." (R6)

Most nurses felt that regular practice was the most beneficial factor for developing their skills; however, some nurses felt a need for additional training with the health psychologist to refine their skills.

Furthermore, focusing solely on physical activity without getting in conflict with other clinical demands, enabled them to develop their skills.

"This sure is special, whereas you normally don't do this, since there is a lot more in a consultation. But, yes, you notice that once you have more time, you can practise a lot." (R10)

Nurses' participation in the intervention, in particular the role-playing and coaching, exposed their habits with regard to their own consultation style and skills, such as solving patients' problems by giving advice and filling in for the patient. Once nurses became aware of their habits, they identified that changing their routines by applying the acquired knowledge and skills was challenging, as they easily fell back into their traditional style.

"Sometimes, I noticed I was the one searching for solutions. Of course, that was not how it was meant. That's very typical for nurses' way of doing things. Then I thought, well, I'm sitting here working, while the one in front of me should work." (R14)

"The feedback from the coach was a kind of eye-opener; I do things, but I did not ask in-depth questions…that made me think and I took that with me to the next consultation. I found that to be particularly useful." (R12)

Nurses valued that they could transfer their developed skills to other patients and to other behaviours, such as smoking cessation and dietary intake. This indirect benefit enhanced nurses' engagement to deliver the intervention.

"Now, it is very much focused on physical activity, but I think, in any case, helping people with behavioural change is something that you can see broader applications, like for other lifestyle topics." (R12)

Dealing with adherence to the consultation structure

To ensure fidelity of the intervention, nurses were aware that they had to adhere to the structure of the consultations as described in the handbook, even if they had personal doubts about specific elements. However, some nurses deliberately deviated from the consultation structure when they were not convinced of the effectiveness of a specific element or when they did not feel comfortable with an element. Furthermore, most nurses valued the use of the handbook in their consultations, as this allowed them to follow the structure and use example sentences more easily. Nurses often changed the wording of the sentences to something which they felt more comfortable with.

"There was a question about patients' confidence, which didn't make me very happy. But it is part of the intervention, I know. I have tried to ask it." (R12)

"But you don't talk like these sentences. I make my own sentences. But, yes, of course it helps. You don't literally say it like that though. Because then…the conversation is less fluent. " (R1)

After the training, most nurses reported that adhering to the consultation structure was more difficult than expected, which reduced their confidence in their capabilities. Patients easily initiated other topics, as they were used to doing so in the routine consultations. That distracted the nurses from following the prescribed structure.

"I sometimes found it difficult to follow the script, prompting me to think, well, this is yet more difficult than I thought. So, then, my confidence decreased. I can certainly understand how it works on paper and that it works, but in practice it's different." (R8)

To enhance fidelity of the intervention, nurses were aware that they had to fill in the checklists at the end of each consultation to check if they discussed all of the elements described in the handbook.

Expectations towards the use of the intervention in routine practice

Nurses' beliefs about the use of the intervention in their routine practice strongly depended on their beliefs about the effectiveness of the intervention to increase patients' level of physical activity and health outcomes. Nurses were convinced that the effectiveness of the intervention relied on patients' engagement to set goals and having a reasonable level of health literacy to understand the intervention materials.

"It works in patients who just need a helping hand to perform it. But the truly unmotivated patients who don't want to be active, those patients are not going to be active using this method, no. They still have to do it themselves." (R2)

The nurses were convinced that the combination of the accelerometer, activity log and their subsequent and structural support incentivised patients' goal attainment in changing their physical activity, which strengthened their positive beliefs about the feasibility of the intervention in their routine practice.

"If you would send them home with an activity log but without consultations, then no one would fill it in. But now they have to come back. Then they must do it anyway, because of course they know it will be discussed then…I found the activity log was very good. Patients confirmed that. However, so were the consultations. So, basically, just the combination really made it work." (R2)

Nurses valued the consultation structure, including techniques such as goal setting, action planning, reviewing behavioural goals, feedback on behaviour, self-monitoring and problem-solving, as being feasible to use in their routine practice. Most nurses found that goal setting and action planning enabled them to stimulate patients in formulating their goals and actions, which in turn facilitated patients' goal attainment. The use of the activity log to review patients' level of goal attainment facilitated them in giving feedback on their behaviour.

"You have to make it specific; otherwise, it won't work. If you make it very specific, patients also know: all right, that's my goal and here I go. And then you can say, 'I've done it or not'…I was always aware of the fact that patients specified their planned actions. If patients said, 'I'm going to be active in five days', that's, of course, not very specific, so I tried to make it even more specific." (R13)

The use of self-monitoring tools such as the accelerometer and activity log were seen as additional motivators and incentives for patients, as they provided insight into patients' level of physical activity and challenged patients to goal attainment. The nurses believed that the use of such tools would help them to deliver the intervention in their routine practice.

"The accelerometer just provides insight, which makes your activity very specific. Actually, you normally don't really think about it that much." (R13)

Despite the log and accelerometer being highly valued by nurses, a few nurses questioned the usability of such tools in their routine practice as some patients did not completely understand the user instructions and faced practical and technical problems, such as losing the accelerometer or losing their activity data after the accelerometer automatically reset at midnight.

"I noticed that it was quite complicated for patients…the accelerometer was difficult to operate…And the fact that the accelerometer erased itself after midnight, then they couldn't read it out anymore." (R9)

Although all nurses believed that the intervention was feasible for routine practice, they thought that using the intervention in routine practice might conflict with other clinical demands during routine consultations. Initially, nurses needed more time to deliver the intervention, which may adversely influence the feasibility due to time constraints in their routine practice. However, nurses believed that mastering the necessary skills would enable them to gain more in-depth support, which eventually would save them time. To enhance the fit of the intervention in routine practice, nurses suggested shortening the number of in-depth questions.

"I think it takes too much time to do it in such an extensive way. You also need to check patients and discuss their medications, insulin and whatever." (R14)

"It may seem like it's very time consuming, but once you ask the right questions then I think you can get a lot of information in a short period of time, and it's a bit of an art to let the patients talk themselves."(R10)

Perceptions towards the feasibility of the training programme

All nurses felt appropriately trained and supported by the one-day training in combination with the instructional videos, handbook and checklists to deliver the Activate intervention. The nurses particularly valued the safe learning environment of the small-scale role playing, in which they directly received feedback.

"…first of all, the small-scale, practising with two… At least for me, it's an obstacle to practice a role-play in front of a group… and having someone to observe… who provided feedback. So, it was a very safe setting in which, without being judged or anything, you received objective feedback." (R11)

Although all nurses valued the coaching, some initially felt uncomfortable submitting a recorded consultation and delayed doing so. However, afterwards, the nurses regretted postponing their submissions, because they felt that the feedback would have helped them in delivering other consultations. Some nurses could not overcome their uncomfortable feelings surrounding recording their consultations and did not submit any consultation.

"I just found it difficult to record it, and then it's indelible, and then you will send it, and people will listen to it. That's just a bit of an uncomfortable idea…Therefore, I was a little late with recording a consultation, which was a bit of a pity. So, I could not apply the feedback so much afterwards." (R7)

Enabling personal development

All nurses expressed that participating in the Activate trial enabled their personal development and enhanced their knowledge and skills to support patients in their behaviour change. The nurses tended to incorporate specific skills and elements of the intervention into their routine practice that they were convinced were effective for patients, such as setting specific and attainable goals and planning actions for goal attainment. Nurses became more critical towards patients' answers and used a more positive approach, focusing on solutions instead of traditionally addressing barriers for patients.

"I became more aware of the fact that it's important for someone to come up with their own solution, even though I am staggering with enthusiasm…if I take a step back, more can arise from oneself and that is very powerful in this work." (R8)

"Specifying patients' goal, that's really something I've learned. And giving feedback on that goal once they come again next time. Yes, I have learned that very well." (R6)

DISCUSSION

This qualitative study explored the perceptions of primary care nurses towards delivering the Activate intervention and its feasibility in routine practice. Nurses were dedicated to deliver the intervention in order to improve health outcomes. Nurses felt engaged and rewarded by patients' success in increasing their physical activity. Patients' lack of motivation to participate in the intervention and lack of success negatively affected nurses' engagement. The training, training tools and delivery of the intervention facilitated nurses in acquiring the required knowledge and skills. Acquiring skills was challenging, as the nurses tended to relapse into their traditional habits. The nurses valued and tried to adhere to the intervention structure despite perceived difficulties, such as distraction by patients who initiated discussion of topics other than physical activity.

Nurses were positive towards the feasibility of the intervention in routine practice. Nurses thought that the consultations combined with the self-monitoring tools were effective to increase patients' physical activity and feasible to use in routine practice. However, the use of the intervention in routine practice might be hindered by complying with other clinical demands. Nurses felt appropriately trained and supported to deliver the intervention. Participation in the trial enabled their personal development and changed their routine practice, as they incorporated newly acquired skills, particularly those that they believed were efficacious, in their routine practice with other patients.

The challenges of changing nurses' behaviour in order to enhance the implementation of behaviour change interventions are widely reported.[8,11-14,28] Therefore, a training programme was developed using the BCW, targeting the COM-B components using BCTs. Despite the provided comprehensive training to support their patients in their own context and facilitating them with extra consultation time, changing nurses' behaviour was complex. Delivering the intervention required nurses to shift from their traditional consultation style of being an expert, who gives advice and informs patients to a coaching consultation style that entails being supportive and facilitative to patients' needs and preferences.[8,29] Nurses felt comfortable in their expert role and most nurses had previously received additional training in the motivational interviewing approach; however, they unanimously expressed their need to deepen their support and increase the effectiveness of their support. This suggests that the nurses were willing to acquire the necessary knowledge and skills and to participate in the Activate trial. Participation in the trial raised awareness of their traditional consultation style and facilitated a shift to a more patient-centred approach, allowing patients to take more responsibility rather than advising and telling patients what to do, which is in line with other studies.[11,13,29] Despite increased awareness, it appeared difficult to perpetuate these changes in consultation style, as all nurses

thought they easily relapsed into their traditional consultation style and skills, as also seen in other studies.[11]

The handbook with example sentences guided nurses in structuring their consultations and facilitated their adherence towards the intervention delivery, as also seen in other studies.[13,30] Overall, nurses tended to adjust the content of the intervention if they had personal doubts about specific elements, this finding aligned with other studies.[12,13] This suggests that nurses' beliefs are pivotal with regard to the extent to which they adopt the intervention into their practice. Nurses' tendency to tailor the intervention to their beliefs should be addressed during the training of nurses to maintain sufficient uniform delivery and underlines the need to assess nurses' fidelity of the delivery of the intervention.[13,31]

Nurses' engagement, confidence and job satisfaction were enhanced by patients' success at increasing their physical activity, nurses' personal development and transferability of knowledge and skills to other patients, as has previously been shown.[11,13,32] Nurses' job satisfaction is potentially linked to their intrinsic drive to help and assist patients. Nurses often thought that patients expect and prefer their traditional nursing role in behaviour change support. However, the patient-centred approach of the intervention demands from nurses to reflect on their traditional role and adapt their role towards facilitating and supporting patients in changing their behaviour. Changing nurses' role is challenging as nurses are often wedded to what they do.[11,14] This might complicate nurses' adoption of their gained knowledge and skills in routine practice.[11]

The intervention structure and BCTs were relatively new to the nurses, as they were not specifically trained in applying and tailoring the BCTs prior to their participation in the Activate trial. Another study examining self-management support by primary care nurses in routine care found that nurses seldom focus on behaviour change and infrequently use effective techniques to support this change.[33] This strengthens the need for such training and support, because nurses are in a key position to deliver behaviour change interventions in primary care.[11] Previous studies have also found that appropriate training and support for nurses before and during delivery of the intervention is essential for the implementation of behaviour change interventions.[11,13,32,34] This study showed that nurses particularly valued the small-scale role-playing in the training led by the health psychologist. The role-plays, including the feedback, allowed them to practise and directly reshape their consultation and BCT skills, and different scenarios that they perceived as difficult. This suggests that the training of nurses to deliver a behaviour change intervention should be comprehensive, interactive and delivered by a credible source, such as an expert trainer.

Despite that the nurses became more confident with their skills as they practised more

often and that they were motivated to deliver the intervention as intended, they reported that recording the consultation felt uncomfortable, as they felt judged, which aligns with another study.[35]

The Activate intervention included both self-monitoring tools and nurses' support, similar to other studies.[36-39] The nurses were convinced that combining the self-monitoring tools with offering subsequent consultations was effective in changing patients' physical activity and that the consultations were essential for enhancing patients' engagement to continue and adjust their goals. This is in line with a study by van der Weegen et al.,[36] which found that a combination of a self-monitoring tool and nurse-led consultations was effective to increase physical activity in patients with diabetes mellitus type 2 and chronic obstructive pulmonary disease. That study also found that counselling by the nurses without use of the self-monitoring tool was not effective compared to routine care.

Strengths and limitations

This study was nested within a cluster-randomised controlled trial. Comprehensive process evaluations of complex interventions from the perspective of the providers of such interventions have been largely missing from the literature,[7,17,18] but are increasingly being undertaken.[12,13,34] To prevent interpretation bias, such an evaluation should be conducted before the trial results are known. Furthermore, exploration of the perspectives of nurses may enhance implementation once the effectiveness has been established.

To strengthen the trustworthiness of the study, the data were independently analysed by two researchers and supported by a qualitative research expert during the entire process. Furthermore, an audit trail, memo writing, expert opinion and the use of Braun & Clarke' checklist[24] and the COREQ[27] enhanced trustworthiness.

The interviewers were unknown to the nurses prior to the interviews, which might have positively affected data dependability, as it allowed the nurses to express their experiences and opinions without inhibitions.

Although the results of this study were based on fourteen nurses, maximum variation sampling of nurses' age, years of working experience with primary care patients at risk for CVD and nurses' educational background was used to increase the likelihood of diversity with regard to nurses' perspectives and contribute to the transferability of the results. Data saturation on all themes was achieved within these fourteen interviews, which also strengthened the transferability of the results. A few limitations need to be considered. Despite all efforts to include all seventeen eligible nurses, three nurses refused to participate. Furthermore, three nurses were not eligible, as they had either used the

intervention on fewer than two patients or had changed jobs during the trial. These nurses might have expressed different perspectives, which could have affected the results. The interviews were conducted at a single point in time, namely, after the nurses completed the intervention. The retrospective reflection of the nurses might not have revealed all of the individual processes with regard to delivery of the intervention and behaviour change. Furthermore, despite all efforts, for some interviews, there was a delay between the last trial consultation and the interview, potentially affecting nurses' memory to recall. However, the researchers provided the training tools and study materials and asked further questions during the interviews to help stimulate the nurses' memory.

Implications

This study identified areas of concern regarding the intervention delivery and feasibility of behaviour change interventions in routine practice. First, to improve implementation, nurses need to be convinced that the intervention will be effective and is aligned with their beliefs surrounding good patient care.[12] Second, nurses must be appropriately trained according to a comprehensive training programme. Training should preferably be spread out over time, allowing and facilitating nurses to practice to refine their skills and to discuss how to address perceived difficulties, such as patient engagement and motivation to participate in the intervention. Third, to engage nurses, the developed skills should be transferable for use with other patients and behaviours. Fourth, to enhance success of the intervention, behaviour change interventions should be structured around BCTs that were highly valued by nurses, such as goal setting, action planning, reviewing behavioural goal(s), feedback on behaviour, self-monitoring, and problem-solving. In addition, these BCTs are likely to be successful in changing behaviour.[40-46] Fifth, it is important for researchers and policy makers to acknowledge that adapting complex interventions on the part of providers takes time, as provider and patient behaviour change is a lengthy process.[47]

CONCLUSION

Delivering a behaviour change intervention is challenging as nurses have to change their traditional consultation style towards a more patient-centred consultation style. A process of acquiring and refining knowledge and skills is needed to deliver such interventions without jeopardizing intervention fidelity. Nurses were positive about delivering the intervention using a structured approach with facilitating tools and support. Comprehensive training and practising of their skills requires ongoing support to refrain from traditional habits and optimise their delivery of interventions. The nurses perceived the Activate intervention feasible in routine practice; however, incorporating the intervention into routine consultations is challenged by competing other clinical demands. This qualitative

study contributes to our understanding of the complexity of changing nurses' behaviour towards a more patient-centred consultation style. The findings can be used to enhance our understanding of the effectiveness of the Activate trial and may provide guidance for the development and evaluation of future behaviour change interventions delivered by nurses in primary care.

REFERENCES

1. Effing T, Kerstjens H, van der Valk P, Zielhuis G, van der Palen J. (Cost)-effectiveness of self-treatment of exacerbations on the severity of exacerbations in patients with COPD: The COPE II study. *Thorax*. 2009;64(11):956-962.
2. Chodosh J, Morton SC, Mojica W, et al. Meta-analysis: Chronic disease self-management programs for older adults. *Ann Intern Med*. 2005;143(6):427-438.
3. Zwerink M, Brusse Keizer M, van der Valk PDLPM, et al. Self management for patients with chronic obstructive pulmonary disease. *Cochrane Database Syst Rev*. 2014(3):CD002990.
4. Barlow J, Wright C, Sheasby J, Turner A, Hainsworth J. Self-management approaches for people with chronic conditions: A review. *Patient Educ Couns*. 2002;48(2):177-187.
5. Newman S, Steed L, Mulligan K. Self-management interventions for chronic illness. *Lancet*. 2004;364(9444):1523-1537.
6. Baan CA, Hutten JBF, Rijken PM (2003). *Afstemming in de zorg: Een achtergrondstudie naar de zorg voor mensen met een chronische aandoening. [Coordination of care. A study into the care for people with a chronic condition].* Bilthoven, the Netherlands; RIVM.
7. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: The new medical research council guidance. *BMJ*. 2008;337:a1655-a1655.
8. Elissen A, Nolte E, Knai C, et al. Is europe putting theory into practice? A qualitative study of the level of self-management support in chronic care management approaches. *BMC Health Serv Res*. 2013;13:117-6963-13-117.
9. Wagner EH. Chronic disease management: What will it take to improve care for chronic illness? *Eff Clin Pract*. 1998;1(1):2-4.
10. Bodenheimer T, Lorig K, Holman H, Grumbach K. Patient self-management of chronic disease in primary care. *JAMA*. 2002;288(19):2469-2475.
11. Taylor C, Shaw R, Dale J, French D. Enhancing delivery of health behaviour change interventions in primary care: A meta-synthesis of views and experiences of primary care nurses. *Patient Educ Couns*. 2011;85(2):315-322.
12. Kennedy A, Rogers A, Bowen R, et al. Implementing, embedding and integrating self-management support tools for people with long-term conditions in primary care nursing: A qualitative study. *Int J Nurs Stud*. 2014;51(8):1103-1113.
13. Beighton C, Victor C, Normansell R, et al. "It's not just about walking.....it's the practice nurse that makes it work": A qualitative exploration of the views of practice nurses delivering complex physical activity interventions in primary care. *BMC Public Health*. 2015;15:1236.
14. McDonald R, Rogers A, Macdonald W. Dependence and identity: Nurses and chronic conditions in a primary care setting. *J Health Organ Manag*. 2008;22(3):294-308.
15. Jonkman N, Groenwold RHH, Trappenburg JCA, Hoes A, Schuurmans M. Complex self-management interventions in chronic disease unravelled: A review of lessons learnt from an individual patient data meta-analysis. *J Clin Epidemiol*. 2017;83:48-56.
16. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: The new medical research council guidance. *Int J Nurs Stud*. 2013;50(5):587-592.
17. Moore G, Audrey S, Barker M, et al. Process evaluation of complex interventions: Medical research council guidance. *BMJ*. 2015;350:h1258.
18. Conn V. Unpacking the black box: Countering the problem of inadequate intervention descriptions in research reports. *West J Nurs Res*. 2012;34(4):427-433.

19. Michie S, Abraham C. Interventions to change health behaviours: Evidence-based or evidence-inspired? *Psychol Health*. 2004;19(1):29-49.
20. Michie S, van Stralen MM, West R. The behaviour change wheel: A new method for characterising and designing behaviour change interventions. *Implement Sci*. 2011;6:42-5908-6-42.
21. Michie S, Richardson M, Johnston M, et al. The behavior change technique taxonomy (v1) of 93 hierarchically clustered techniques: Building an international consensus for the reporting of behavior change interventions. *Ann Behav Med*. 2013;46(1):81-95.
22. Slootmaker SM, Chin A Paw, M J M, Schuit AJ, van Mechelen W, Koppes LLJ. Concurrent validity of the PAM accelerometer relative to the MTI actigraph using oxygen consumption as a reference. *Scand J Med Sci Sports*. 2009;19(1):36-43.
23. Westland H, Bos Touwen I, Trappenburg JCA, Schröder C, de Wit N, Schuurmans M. Unravelling effectiveness of a nurse-led behaviour change intervention to enhance physical activity in patients at risk for cardiovascular disease in primary care: Study protocol for a cluster-randomised controlled trial. *Trials*. 2017;18(1):79-94.
24. Braun V, Clarke V. Using thematic analysis in psychology. *Qualitative research in psychology.* 2006;3(2):77-101.
25. Guba E, Lincoln Y. Competing paradigms in qualitative research. In: Denzin, NK & Lincoln, YS, ed. *Handbook of qualitative research.* London: Sage; 1994:105-117.
26. Creswell J (2012). *Qualitative inquiry & research design: Choosing among five approaches.* 3rd revised edition ed.; Sage Publications Inc.
27. Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): A 32-item checklist for interviews and focus groups. *Int J Qual Health Care*. 2007;19(6):349-357.
28. Hardeman W, Michie S, Fanshawe T, Prevost AT, Mcloughlin K, Kinmonth A. Fidelity of delivery of a physical activity intervention: Predictors and consequences. *Psychol Health*. 2008;23(1):11-24.
29. Mead N, Bower P. Patient-centred consultations and outcomes in primary care: A review of the literature. *Patient Educ Couns*. 2002;48(1):51-61.
30. Weldam SWM, Lammers J, Zwakman M, Schuurmans M. Nurses' perspectives of a new individualized nursing care intervention for COPD patients in primary care settings: A mixed method study. *Appl Nurs Res*. 2017;33:85-92.
31. Bellg A, Borrelli B, Resnick B, et al. Enhancing treatment fidelity in health behavior change studies: Best practices and recommendations from the NIH behavior change consortium. *Health Psychol*. 2004;23(5):443-451.
32. Wells M, Williams B, Treweek S, Coyle J, Taylor J. Intervention description is not enough: Evidence from an in-depth multiple case study on the untold role and impact of context in randomised controlled trials of seven complex interventions. *Trials*. 2012;13:95-112.
33. Westland H, Schröder C, de Wit J, Frings J, Trappenburg JCA, Schuurmans M. Self-management support in routine primary care by nurses. *Br J Health Psychol*. 2018;23(1):88-107.
34. Bleijenberg N, Ten Dam V, Steunenberg B, et al. Exploring the expectations, needs and experiences of general practitioners and nurses towards a proactive and structured care programme for frail older patients: A mixed-methods study. *J Adv Nurs*. 2013;69(10):2262-2273.
35. Boase S, Kim Y, Craven A, Cohn S. Involving practice nurses in primary care research: The experience of multiple and competing demands. *J Adv Nurs*. 2012;68(3):590-599.
36. van der Weegen S, Verwey R, Spreeuwenberg M, Tange H, van der Weijden T, de Witte L. It's LiFe! mobile and web-based monitoring and feedback tool embedded in primary care increases physical activity: A cluster randomized controlled trial. *J Med Internet Res*. 2015;17(7):e184.

37. Harris T, Kerry S, Victor C, et al. A primary care nurse-delivered walking intervention in older adults: PACE (pedometer accelerometer consultation evaluation)-lift cluster randomised controlled trial. *PLoS Med*. 2015;12(2):e1001783.
38. Harris T, Kerry S, Limb E, et al. Effect of a primary care walking intervention with and without nurse support on physical activity levels in 45- to 75-year-olds: The pedometer and consultation evaluation (PACE-UP) cluster randomised clinical trial. *PLoS Med*. 2017;14(1):e1002210.
39. Mutrie N, Doolin O, Fitzsimons C, et al. Increasing older adults' walking through primary care: Results of a pilot randomized controlled trial. *Fam Pract*. 2012;29(6):633-642.
40. Bravata D, Smith Spangler C, Sundaram V, et al. Using pedometers to increase physical activity and improve health: A systematic review. *JAMA*. 2007;298(19):2296-2304.
41. Greaves C, Sheppard K, Abraham C, et al. Systematic review of reviews of intervention components associated with increased effectiveness in dietary and physical activity interventions. *BMC Public Health*. 2011;11:119.
42. Hankonen N, Sutton S, Prevost AT, et al. Which behavior change techniques are associated with changes in physical activity, diet and body mass index in people with recently diagnosed diabetes? *Ann Behav Med*. 2015;49(1):7-17.
43. Williams SL, French DP. What are the most effective intervention techniques for changing physical activity self-efficacy and physical activity behaviour--and are they the same? *Health Educ Res*. 2011;26(2):308-322.
44. Ivers N, Jamtvedt G, Flottorp S, et al. Audit and feedback: Effects on professional practice and healthcare outcomes. *Cochrane Database Syst Rev*. 2012(6):CD000259.
45. Michie S, Abraham C, Whittington C, McAteer J, Gupta S. Effective techniques in healthy eating and physical activity interventions: A meta-regression. *Health Psychol*. 2009;28(6):690-701.
46. French D, Olander E, Chisholm A, Mc Sharry J. Which behaviour change techniques are most effective at increasing older adults' self-efficacy and physical activity behaviour? A systematic review. *Ann Behav Med*. 2014;48(2):225-234.
47. Oakley A, Strange V, Bonell C, Allen E, Stephenson J. Process evaluation in randomised controlled trials of complex interventions. *BMJ*. 2006;332(7538):413-416.

APPENDIX

Appendix 1. Interview guide

Topics	Questions (examples)
General	Standard opening question: What was the reason you agreed to participate in the Activate study?
Perceptions towards the training	How did you perceive the one-day training? Which component of the training helped you most/least in delivering the intervention to patients? How did you perceive the instructional videos? How did you perceive the role-plays?
Perceived confidence towards intervention delivery	After the training, how confident were you to deliver the intervention according to the study protocol (grade 1-10)? Did your confidence change during the intervention period?
Perceived motivation towards intervention delivery	After the training, how motivated were you to deliver the intervention according to the study protocol (grade 1-10)? Did your motivation change during the intervention period?
Preparing for delivering the intervention	How did you prepare yourself for delivering the study consultations? Can you tell me your experiences with the handbook? To what extent did you use it? Can you tell me your experiences with the checklists? To what extent did you use them? Can you tell me your experiences with watching the instructional videos? To what extent did you watch them?
Perceived performance of delivery the intervention	How did you perceive the individual coaching sessions by the health psychologist? To what extent did the feedback affect your performance? What do you think of how you performed the intervention? Which of the intervention components suited you well and which components were more difficult to deliver?

Appendix 1. Interview guide

Topics	Questions (examples)
Perceived effect of the intervention on patients' behaviour	Do you think that patients benefit from the intervention? What were characteristics of patients who (not) succeeded? Which components of the study helped the patients most/least in increasing their level of physical activity? Generally, how did you perceive the motivation of participating patients?
Perceived changes of consultation style	To what extent has participation in the Activate study affected your consultation style?
Focus on physical activity during consultations	How did you experience to focus solely on physical activity during the consultations?
Contact with the research team	How did you perceive the contact with the research team
Additional questions regarding previous or not discussed topics	Do you have anything to add to the questions I have asked?

Appendix 2. Checklist of Criteria for Good Thematic Analysis: 15-point checklist*

Process	Criteria		Reported
Transcription	1.	The data have been transcribed to an appropriate level of detail, and the transcripts have been checked against the tapes for 'accuracy'.	YES
Coding	2.	Each data item has been given equal attention in the coding process.	YES
	3.	Themes have not been generated from a few vivid examples (an anecdotal approach), but instead the coding process has been thorough, inclusive and comprehensive.	YES
	4.	All relevant extracts for all each theme have been collated.	YES
	5.	Themes have been checked against each other and back to the original data set.	YES
	6.	Themes are internally coherent, consistent, and distinctive.	YES
Analysis	7.	Data have been analysed - interpreted, made sense of - rather than just paraphrased or described.	YES
	8.	Analysis and data match each other - the extracts illustrate the analytic claims.	YES
	9.	Analysis tells a convincing and well-organised story about the data and topic.	YES
	10.	A good balance between analytic narrative and illustrative extracts is provided.	YES
Overall	11.	Enough time has been allocated to complete all phases of the analysis adequately, without rushing a phase or giving it a once-over-lightly.	YES
Written report	12.	The assumptions about, and specific approach to, thematic analysis are clearly explicated.	YES
	13.	There is a good fit between what you claim you do, and what you show you have done - i.e. described method and reported analysis are consistent.	YES
	14.	The language and concepts used in the report are consistent with the epistemological position of the analysis.	YES
	15.	The researcher is positioned as *active* in the research process; themes do not just 'emerge'.	YES

* Adapted from: Braun V, Clarke V. Using thematic analysis in psychology. *Qualitative research in psychology.*2006*;3(2),*77-101.

Appendix 3. Consolidated criteria for reporting qualitative studies (COREQ): 32-item checklist*

No.	Item	Guide questions/description	Reported
Domain 1: Research team and reflexivity			
Personal Characteristics			
1.	Interviewer/ facilitator	Which author/s conducted the interview or focus group?	YES
2.	Credentials	What were the researcher's credentials?	YES
3.	Occupation	What was their occupation at the time of the study?	YES
4.	Gender	Was the researcher male or female?	YES
5.	Experience and training	What experience or training did the researcher have?	Completed a course in qualitative research
Relationship with participants			
6.	Relationship established	Was a relationship established prior to study commencement?	YES
7.	Participant knowledge of the interviewer	What did the participants know about the researcher?	YES
8.	Interviewer characteristics	What characteristics were reported about the interviewer/facilitator?	YES
Domain 2: Study design			
Theoretical framework			
9.	Methodological orientation and Theory	What methodological orientation was stated to underpin the study?	YES
Participant selection			
10.	Sampling	How were participants selected?	YES
11.	Method of approach	How were participants approached?	YES
12.	Sample size	How many participants were in the study?	YES
13.	Non-participation No none participants	How many people refused to participate or dropped out? Reasons?	YES
Setting			
14.	Setting of data collection	Where was the data collected?	YES
15.	Presence of non-participants	Was anyone else present besides the participants and researchers?	NO
16.	Description of sample	What are the important characteristics of the sample?	YES

Appendix 3. Continued

No. Item	Guide questions/description	Reported
Data collection		
17. Interview guide	Were questions, prompts, guides provided by the authors? Was it pilot tested?	YES. Not pilot tested
18. Repeat interviews	Were repeated interviews carried out?	YES
19. Audio/visual recording	Did the research use audio or visual recording to collect the data?	YES
20. Field notes	Were field notes made during and/or after the interview or focus group?	YES
21. Duration	What was the duration of the inter views or focus group?	YES
22. Data saturation	Was data saturation discussed?	YES
23. Transcripts returned	Were transcripts returned to participants for comment and/or correction?	NO, because of burden to participants
Domain 3: Analysis and findings		
Data analysis		
24. Number of data coders	How many data coders coded the data?	YES
25. Description of the coding tree	Did authors provide a description of the coding tree?	YES
26. Derivation of themes	Were themes identified in advance or derived from the data?	YES
27. Software What software	What software, if applicable, was used to manage the data?	YES
28. Participant checking	Did participants provide feedback on the findings?	NO, because of burden to participants
Reporting		
29. Quotations presented	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified?	YES
30. Data and findings consistent	Was there consistency between the data presented and the findings?	YES
31. Clarity of major themes	Were major themes clearly presented in the findings?	YES
32. Clarity of minor themes	Is there a description of diverse cases or discussion of minor themes?	YES

* Adapted from: Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care.* 2007;19(6):349-57.

CHAPTER 6

Effectiveness of the nurse-led Activate intervention in patients at risk for cardiovascular disease in primary care: a cluster-randomised controlled trial

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Summitted

ABSTRACT

Background: To contribute to a better understanding of the success of self-management interventions and to enable tailoring of such interventions at specific subgroups of patients, the nurse-led Activate intervention is developed targeting one component of self-management (physical activity) in a heterogeneous subgroup (patients at risk for cardiovascular disease) and assessed for effectiveness in primary care.

Methods: A two-armed cluster-randomised controlled trial was conducted in Dutch primary care comparing the Activate intervention with care as usual in patients at risk for cardiovascular disease. Patients in the intervention group received four nurse-led behaviour change consultations within a 3-month period. Data were collected at baseline, 3 months and 6 months. Primary outcome was daily amount of moderate to vigorous physical activity at 6 months. Secondary outcomes included sedentary behaviour, self-efficacy for physical activity, patient activation for self-management and health status. Pre-specified effect modifiers were age, body mass index, level of education, social support, depression, patient provider relationship and baseline physical activity.

Results: 31 general practices (n=195 patients) were included (intervention group: n=93; control group: n=102). No significant between-group difference was found for physical activity (mean difference 2.49 minutes; 95% CI -2.1;7.1; p=0.28) and secondary outcomes. Effect modification analysis showed that patients with a low acuity of perceived social support (p=0.01) and patients with a low baseline activity level (p=0.02) benefitted more from the intervention.

Conclusion: The nurse-led Activate intervention did not improve patients' level of physical activity and other patient-related outcomes in primary care patients at risk for cardiovascular disease. To understand the results, the fidelity of delivery of the intervention and active components for effective self-management requires further investigation.

BACKGROUND

Over the past decades, interventions to support self-management of chronically ill patients are widely accepted given their potential to produce health benefits and reduced healthcare utilisation.[1] Self-management interventions aim to support patients in acquiring skills to actively participate and taking responsibility for self-managing their chronic condition and adopting healthy behaviours.[2] Self-management interventions are considered complex since these interventions contain multiple interacting components[3] and multiple behaviours, such as increasing physical activity, smoking cessation, healthy nutrition and managing symptoms and medication.[2] Individual patient meta-analyses have attempted to unravel the effectiveness of self-management interventions.[4-7] Although these multi-component interventions have shown to be effective, how and which patients benefit is not fully understood due to methodological issues, insufficient details on intervention characteristics, heterogeneity in included behaviours, subgroups of patients and scarcely reported and measured intervention fidelity.[8] To contribute to a better understanding of the success of self-management interventions and to enable tailoring of such interventions to specific subgroups of patients, these complex interventions need to be untangled further.[8,9] Therefore, the design of studies evaluating complex self-management interventions should be guided by understanding active ingredients, underlying mechanisms, intervention fidelity and contextual factors of interventions.[8,10-13] As a result, we developed the nurse-led Activate intervention, in which we deliberately broke down complexity into a single self-management component, namely increasing physical activity, rather than focussing on the multi-behavioural concept of self-management as a whole. As well-established, patients at risk for cardiovascular disease (CVD) benefit from being active for at least 30 minutes of moderate to vigorous activity on at least 5 days weekly[14-18] and patients often need to change their behaviour to reach this threshold.[19] Targeting the intervention to physical activity in a heterogeneous subgroup of primary care patients enables the identification of how and which patients benefit from the intervention.

Furthermore, in order to adequately deliver a complex intervention specific behaviour of healthcare professionals is needed as these healthcare professionals play a vital role in the effectiveness of these interventions. The Activate intervention is designed to be delivered by primary care nurses in the Netherlands as they routinely monitor treatment outcomes, promote self-management and support healthy behaviour in patients at risk for CVD.[20] To adequately provide self-management support, nurses often need to change their consultation style from a traditional style of providing advice, inform and educate patients about their condition to a more coaching style of supporting patients in changing their behaviour including the use of behaviour change

techniques (BCTs).[1,21-23] This implicates that in order to support patients, nurses need to change their behaviour as well. Therefore, the Activate intervention is targeted at both patients' behaviour towards increasing physical activity and at nurses' behaviour towards acquiring the necessary skills to provide structured behaviour change support, including BCTs, to patients in increasing their physical activity level. To enhance replication and our understanding of its effectiveness, the Behaviour Change Wheel as theoretical framework guided the design of the Activate intervention and the design of a thorough process evaluation.[24-26] In this study we specifically focus on patients by evaluating the effectiveness of the intervention and identifying which patient-related characteristics modify the effect.

METHODS

Study design

We designed a two-armed cluster-randomised controlled trial in primary care to compare the nurse-led Activate intervention to care as usual over a 6 months period. Randomisation was performed at the level of the general practice to avoid contamination. A detailed study protocol has been published elsewhere.[24] An informed consent to postponed information procedure was used to reduce selection bias by attrition or drop out.[27] Within this procedure, patients were kept unaware of the major study aim, randomisation, and allocation of their general practice until the end of the follow-up period.[28] Written informed consent was obtained from all participants. The institutional review board of the University Medical Center Utrecht approved the Activate trial (NL54286.041.15).

Setting and participants

General practices throughout the Netherlands were invited when they reallocated the disease management for patients at risk for CVD to a primary care nurse. Patients were recruited from March 2016 to January 2017, follow-up was completed by November 2017. The study population consisted of adult patients supported by a primary care nurse working in a general practice. Patients were eligible when aged 40-75 and had at least one risk factor as described in the Dutch guideline for cardiovascular risk management: high blood pressure (≥140mmHg) or already treated for high blood pressure, high total cholesterol (≥6.5 mmol/l) or already treated for high cholesterol, diabetes mellitus type 2 or a positive family history of CVD.[29] Furthermore, patients were included if they did not meet the Dutch physical activity guideline (≥30 minutes of moderate to vigorous activity on ≥5 days weekly) based on the Short Questionnaire to Assess Health (SQUASH).[30] Patients who were unable to give informed consent, did not master the Dutch language or were mentally or physically unable to participate were excluded. Additionally, patients

were excluded if they participated in a structured programme to enhance physical activity in the past two years. Eligible patients were invited to participate by the primary care nurse in accordance with the general practitioner. Each general practice was instructed to include nine to ten patients.

Randomisation and masking

All participating general practices were randomised using web-based software with a 1:1 ratio. Minimisation was used to balance geography of the general practices to ascertain comparability of patients' characteristics. The randomisation process was supervised by an independent data manager.

Blinding of general practices and/or nurses was not possible since they were part of the intervention and researchers were not blinded for practical reasons. Patients were not blinded to the intervention. However, as a result of the informed consent procedure to postponed information, patients were unaware of the major study aim, randomisation, and allocation of their general practice until the end of the follow-up period.[28] The general practices were instructed not to inform participating patients about the aims of the trial.

Intervention

The Activate intervention was developed using the Behaviour Change Wheel to identify appropriate BCTs to enhance patients' level of physical activity.[26] The Behaviour Change Wheel was subsequently applied to both patients and nurses and consists of three layers. In the first layer, we analysed which components are most important to influence physical activity in patients and to equip nurses with the competences to support patients by using the COM-B (capability, opportunity, motivation-behaviour) model. In the second layer, the results of the COM-B analysis were used to select functions by which the intervention can enhance patient's level of physical activity and nurses' competences to provide patients' support. The third layer, identification of types of policy (e.g. guidelines, social planning, legislation) that can be used to deliver the intervention functions, was not applicable as the intervention was studied in a small number of practices.

Subsequently, the intervention functions were linked to a selection of appropriate BCTs. BCTs are regarded as active components of behaviour change and are subtracted from the BCT Taxonomy v1 (BCTTv1).[23] The application of the Behaviour Change Wheel resulted in a selection of 17 relevant BCTs. We integrated these techniques into the Activate intervention;[24] see Appendix 1. The application of the Behaviour Change Wheel to understand nurses' behaviour in delivering the Activate intervention resulted in a selection of 21 relevant BCTs. These BCTs were integrated into the training programme for nurses;[24] see Appendix 2.

The Activate intervention consisted of four pre-structured, standardised nurse-led consultations to enhance patient' level of physical activity. Consultations were offered at week 1, 3, 7 and 12 in patients' own general practice, with a duration of 20-30 minutes. Nurses were trained to deliver the BCTs while tailoring the consultations to the patients' unique circumstances.

In the first consultation, patients received a workbook about the course of the intervention including activity logs and forms for action planning. Furthermore, information about the study, useful websites and apps, tips and tricks, was provided. During this first consultation, nurses raised awareness about patients' CVD risk profile, their physical activity level and the health consequences. Patients' motivation to increase their physical activity level was discussed and a personal outcome goal and activity goal was set. In the second consultation, nurses repeated the information provided in the first consultation. In the second, third and fourth consultation, nurses reviewed the activity goals and gave feedback on patients' level of goal attainment using the activity logs and adjusted patients' goal and personal physical activity plan. Additionally, in the third and fourth consultation, relapse prevention and the formation of new activity habits were discussed. During the intervention period, patients were asked to self-monitor their physical activity using an accelerometer (personal activity monitor; Pam AM300)[31] and filling out an activity log.
The standardised comprehensive training programme for nurses consisted of a one-day skills training supplemented with two individual coaching sessions from a health psychologist, instructional videos showing how to apply the BCTs in the consultations, a handbook which provided a structure of the consultations and included example sentences and checklists (what to do when).[24]

Care as usual

Patients in the control group received care as usual and nurses were instructed to provide care as usual in accordance with the guideline for cardiovascular risk management.[29] Annually, patients at risk for CVD have at least one nurse-led consultation, and patients with DM2 have at least four nurse-led consultations, which can be extended if necessary.

Data collection

Trial procedures and data-collection are summarised in Figure 1. Patients' characteristics and outcomes were collected at baseline, at 3 and 6 months of follow up using questionnaires and a blinded tri-axial accelerometer (Pam AM300).[31] Additionally, patients were asked to report their amount of minutes of other activities besides walking, such as cycling, swimming and strength training, as the Pam AM300 cannot validly measure these activities. At baseline, patients received the questionnaires and accelerometer from the nurse during their regular scheduled visit. For the other measurements, patients

received the questionnaires and accelerometer by post. Patients were asked to wear the accelerometer for seven consecutive days for 12 h daily. If patients did not respond, the researchers attempted to contact the patients within three weeks. In case a patient could not be reached, a nurse contacted the patient. To retain nurses' attention, nurses received a monthly newsletter and the research team frequently contacted them.

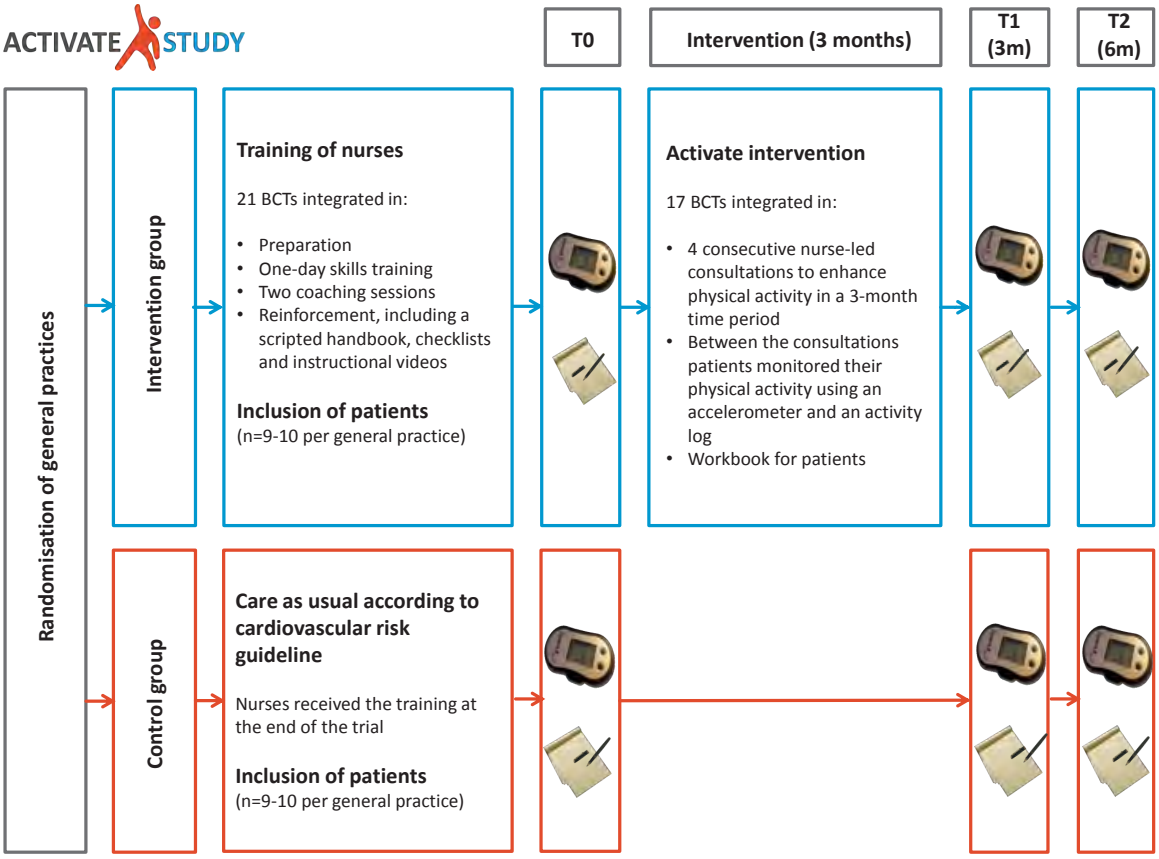


Figure 1. Study design of the Activate cluster-randomised controlled trial

Outcomes

The primary outcome was change (0-6 months) in minutes of moderate to vigorous physical activity (≥3- 6 METabolic equivalent (METS)), assessed by the Pam AM300.[31] For a valid measurement, the Pam AM300 had to be worn for at least 4 weekdays and 1 weekend day for 8 hours.

Secondary outcomes included change (0-6 months) in sedentary behaviour based on Pam AM300 data,[31] as measured as the percentage of the wear time of the Pam AM300 spent in the sedentary category (<1.8 METS). Another secondary outcome was self-efficacy for physical activity, as being an intermediate for changing physical activity levels, measured with the Exercise Self-efficacy Scale.[32-34] In this questionnaire patients' confidence to

adhere to an exercise routine in 18 situations was measured on a 0 ('I cannot do that) - 100 ('I am certain that I can do that') scale, with higher scores reflecting higher levels of exercise self-efficacy.[32-34] As the majority of patients were retired, item 2 ('When I am feeling under pressure from work'*)* was deleted from the analysis. The 13-item Patient Activation Measure (PAM-13) was used to assess patient activation for self-management, including knowledge, skills and confidence in managing their personal health or illness on a 5-point scale.[35,36] Higher scores are positively associated with various self-management behaviours, including preventive care, healthy behaviour, information seeking, healthcare use and medication adherence.[35,36] The EQ-5D-3L was used to measure health status[37] on five dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. The EQ-5D-3L also includes a visual analogue scale (VAS), assessing patients' self-rated health on a vertical scale with end points of 0 ('worst imaginable health state') and 100 ('best imaginable health state').[37]

Both primary and secondary outcome data were collected at baseline (T0), at 3-months of follow-up (T1), and at 6-months of follow-up (T2), except for health status, which was collected at baseline and at 6-months of follow-up.

To identify which patient-related characteristics modify change in physical activity, we assessed the following pre-specified potential effect modifiers: age, body mass index (BMI), level of education, social support using the Multi-dimensional Scale of Perceived Social Support,[38] depression using the Hospital Anxiety and Depression Scale,[39,40] patient-provider relationship using the Communication Assessment Tool,[41] and baseline level of physical activity. These data were collected solely at baseline, except for patient-provider relationship, which was also collected at 3 months and 6 months. Additional outcomes of the process evaluation, as specified in the study protocol,[24] will be published separately.

Statistical analysis

The sample size calculation was based on the detection of a mean difference of 20% moderate to vigorous physical activity (minutes/day) between the intervention and control group at 6-month of follow-up.[24] Therefore, a sample of 279 patients (139-140 patients per group with a cluster size of 9-10 patients per general practice) over 30-31 general practices was required to detect this mean difference between both groups, with 80% power, alpha of 0.05, assuming an intraclass correlation of 0.05 and drop-out rate of 15%.[24]

Patient characteristics, the number of patients who adhered to the Dutch norm of physical activity and (non-) responded to the intervention were descriptively analysed. Primarily an intention-to-treat analysis and secondarily a per protocol analysis was performed. Patients who received at least three consultations (75%) as registered on the nurses'

registration form, were included in the per protocol analysis. Additionally, patients who did not complete the T1 measurement were excluded from this analysis. The primary and secondary outcomes were analysed using multilevel repeated linear mixed models with three levels (time, patients and general practices). Random intercepts for changes over time and general practices were included in all models to account for the cluster randomisation. An interaction term was added for time and study arm. A significant group-by-time interaction (P<0.05) means a significant difference between groups on the outcome over time. All models were adjusted for the baseline value. EQ-5D-3L data were collected at two time points (baseline, T2) and therefore analysed using a one-way between groups analysis of covariance (ANCOVA) to control for the effect of variation that could be explained by clusters. The standardised coefficients and 95% CIs were used to estimate effect sizes.

Missing outcome data was not imputed as linear mixed modelling is a reliable method to handle missing outcome data.[42] We performed sensitivity analyses: 1. by excluding outliers and 2. by adding patients' self-reported additional activities, such as cycling, swimming and strength training as covariate to the Pam AM300.

To examine effect modification by the pre-specified patient characteristics we used generalised estimating equation (GEE). By including random intercepts we accounted for the cluster randomisation. Effect modification is considered significant if the interaction between the outcome and a pre-specified patient characteristic is significant (P<0.05).

Analysis and reporting followed CONSORT guidelines[43] (Appendix 3). The analysis was performed using IBM SPSS Statistics for Windows version 21.0 software (IBM, Armonk, NY, USA).

RESULTS

We invited 478 general practices throughout the Netherlands until 31 agreed to participate (6.5%). Thirty-one participating general practices were randomly allocated to the intervention group (n=16) or the control group (n=15) (Figure 1). A total of 36 nurses participated; 20 nurses in the intervention group and 16 nurses in the control group. General practices included between 0-12 patients (median 7.0; IQR 7.0). Approximately 731 potential eligible patients were invited, 202 patients (27.6%) appeared eligible and gave informed consent and 195 patients (26.7%) completed baseline questionnaires (intervention group n=93; control group n=102). Among patients in the intervention group, 73 patients (78.5%) attended all four consultations. Eighteen patients (19.4%)

in the intervention group discontinued the trial and four patients (3.9%) in the control group. In total, ten patients did not have complete accelerometry data due to technical issues with the accelerometer (n=7) or insufficient wear time (n=3).

At baseline, most patient characteristics were comparable between both groups, except that patients in the intervention group were on average more likely to be female, were more overweight or obese and had a slightly higher metabolic risk profile (Table 1). Overall, patients were on average 62 years old, more likely to be male and overweight or obese. The baseline physical activity measurement showed that, despite the strict inclusion criteria (screened with the SQUASH), the majority of patients met the physical activity guidelines of at least 30 minutes of moderate to vigorous activity on at least five days weekly (measured through accelerometry) (Table 1). Furthermore, patients in the control group were slightly more active (Table 2).

Primary outcome (intention-to-treat)

After 6 months, the level of physical activity did not significantly differ in both groups; see Table 2. However, the level of physical activity in the intervention group was higher (15.3%) after 6 months compared to the control group. Of the patients who returned complete accelerometer data at 6 months, 20 patients (33.3%) in the intervention group gained the clinical relevant 20% increase of their level of physical activity from baseline, compared to 22 patients (23.7%) in the control group. The intraclass correlation coefficient (ICC) for patients in the same general practice was 0.12.

Secondary outcomes (intention-to-treat)

No statistical differences were observed at 6 months between both groups with respect to sedentary behaviour, self-efficacy for physical activity, patient activation for self-management and health status (Table 2). In both groups, patients' self-efficacy increased during the intervention period and stabilised at 6 months. Patients in the intervention group were slightly less activated compared to patients in the control group. Patients graded their health status lower in the intervention group compared to patients in the control group, although patients' VAS score increased in both groups.

Per protocol analyses

Data from 163 patients (Figure 1) were included in the per protocol analyses. The per protocol analyses confirmed the results of the intention-to-treat analyses (Table 3).

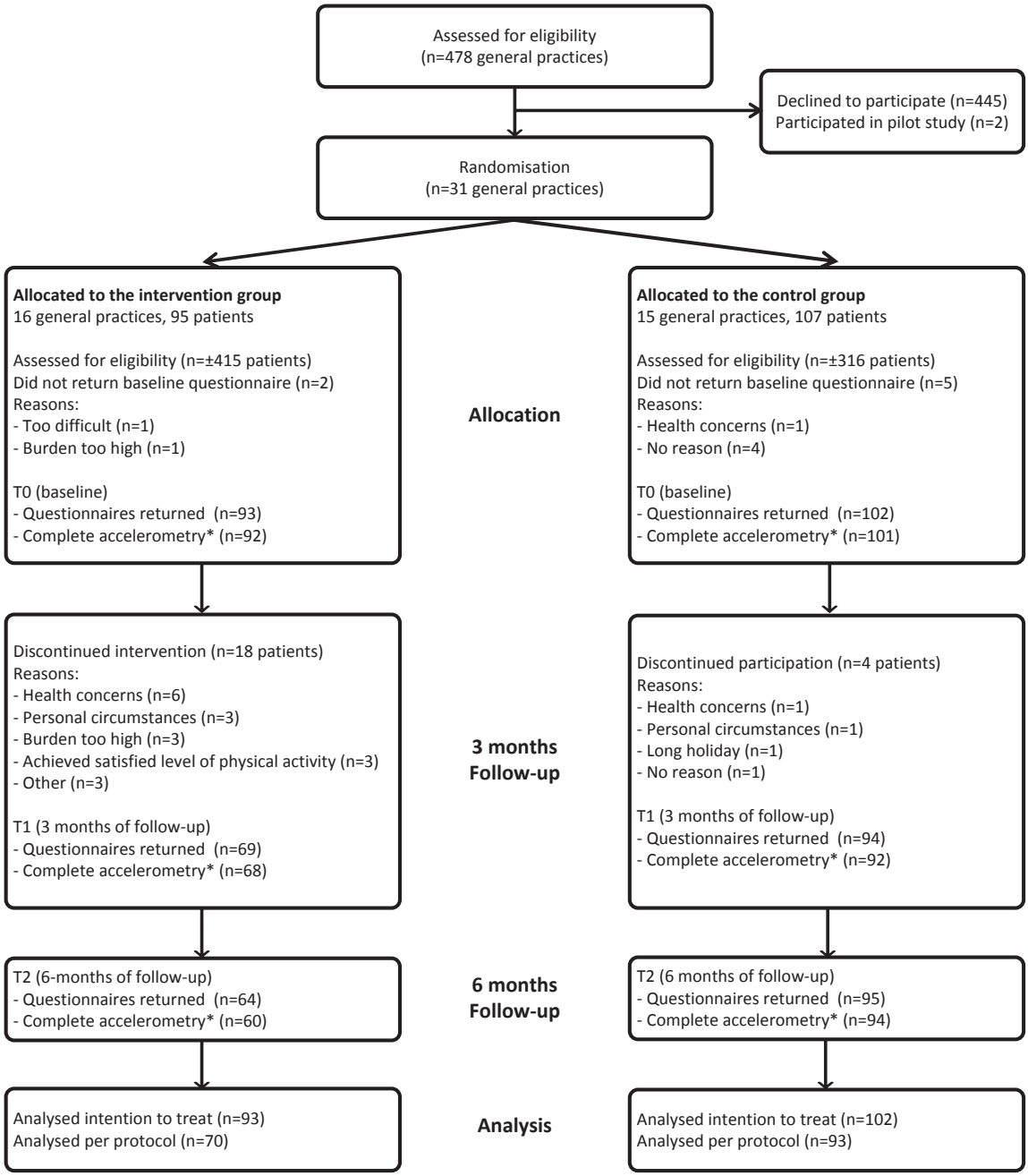


Figure 2. CONSORT-flowchart of general practices and participants assigned to the intervention and control group

* Data available for at least 4 weekdays and 1 weekend day for 8 hours

Table 1. Baseline characteristics of participants of the Activate trial

	Control (n=102)	Intervention (n=93)
Female, n (%)	35 (34.3)	41 (44.1)
Age in years, mean ± SD	63.4 ± 8.3	61.9 ± 9.1
Employed, n (%)	33 (32.4)	34 (36.6)
Living with others, n (%)	87 (85.3)	76 (81.7)
Level of education, n (%)		
Primary education or below	6 (5.9)	3 (3.3)
Secondary education	69 (68.3)	67 (72.8)
Higher education	26 (25.7)	22 (23.9)
Smoking, n (%)	11 (10.8)	14 (15.1)
Body mass index, mean ± SD	29.7 ± 4.8	32.7 ± 5.4
<25, n (%)	15 (14.7)	3 (3.2)
25-29.99, n (%)	47 (46.1)	30 (32.3)
≥30, n (%)	40 (39.2)	60 (64.5)
Cardiovascular risk factors, n (%)		
Hypertension only	23 (22.5)	13 (14.0)
Hypercholesterolemia only	7 (6.9)	5 (5.4)
DM2 only	4 (3.9)	3 (3.2)
Hypertension and hypercholesterolemia	20 (19.6)	25 (26.9)
Hypertension and DM2	9 (8.8)	8 (8.6)
Hypertension, hypercholesterolemia and DM2	25 (24.5)	32 (34.4)
Hypercholesterolemia and DM2	11 (10.8)	4 (4.3)
Risk unknown	3 (2.9)	3 (3.2)
Health literacy (HLS-EU-Q), mean ± SD	35.2 ± 6.9	33.9 ± 7.9
Social support (MSPSS), mean ± SD	65.5 ± 14.8	63.8 ± 13.8
Depression (HADS), mean ± SD	3.9 ± 3.3	5.5 ± 3.6
Patient-provider relationship (CAT)	4.1 ± 0.8	4.1 ± 0.7
Meet Dutch physical activity guideline,[a] n (%)	43 (43.0)	52 (55.9)

[a] Dutch physical activity guideline consist of at least 30 minutes of moderate to vigorous activity on at least five days weekly

Abbreviations: CAT Communication Assessment Tool; DM2 diabetes mellitus type 2; HADS Hospital Anxiety and Depression Scale; HLS-EU-Q European Health Literacy Survey Questionnaire; MSPSS Multidimensional Scale of Perceived Social Support

Sensitivity analyses

Excluding outliers from the analysis did not affect the results presented (data not shown). Adding patients' self-reported additional activities, such as cycling, swimming and strength training to their objectively measured physical activity level did not influence our primary findings (Table 2 and Table 3). Whilst adding these additional activities increased patients' level of physical activity in both groups, no statistical differences were observed between groups.

Effect modification

Social support and baseline level of physical activity showed a significant interaction with patients' activity level between both groups at 6 months. Patients with a low acuity of perceived social support according to the Multi-dimensional Scale of Perceived Social Support, were more likely to benefit more from the intervention than patients with a moderate or a high acuity of perceived social support (P=0.01; Figure 3). Patients with a low baseline physical activity level were more likely to have a larger increase of their activity level at 6 months of follow-up compared to patients who were more active at baseline (P=0.02; Figure 4). Other potential modifiers examined (age, BMI, educational level, depression and patient-provider relationship) did not show an interaction with patients' level of physical activity at 6 months (Appendix 4).

Table 2. Treatment effect for the primary and secondary outcome measures (intention-to-treat)

Outcome measure	Control group (n=102)		
	Mean ± SD (Linear Mixed Models)		
	Baseline	3 months	6 months
Physical activity[a]	38.9±22.6	39.8±25.9	39.9±26.1
Physical activity[b]	50.7±33.4	52.3±35.4	65.4±48.8
Daily sedentary time[c]	82.6±5.7	82.5±5.8	82.9±5.9
Exercise Self-efficacy Scale	51.8±17.7	57.7±16.8	59.0±16.7
PAM-13	59.2±12.2	60.1±14.0	61.6±11.9
	Mean ± SD (ANCOVA)		
EQ-5D-3L	0.8±0.2	NA	0.8±0.2
EQ VAS score	73.6±14.1	NA	75.2±14.6

[a] Daily minutes of moderate to vigorous physical activity; [b] Objective daily minutes of moderate to vigorous physical activity measured with the accelerometer added with self-reported cycling, swimming, strength training; [c] Percentage of the wear time spent in the sedentary category (<1.8 METS); *Adjusted for baseline measurement

Abbreviations: CI confidence intervals; MD mean difference; NA not applicable; PAM-13 Patient Activation Measure short form; VAS Visual Analog Scale

Table 3. Treatment effect for the primary and secondary outcome measures (per protocol)

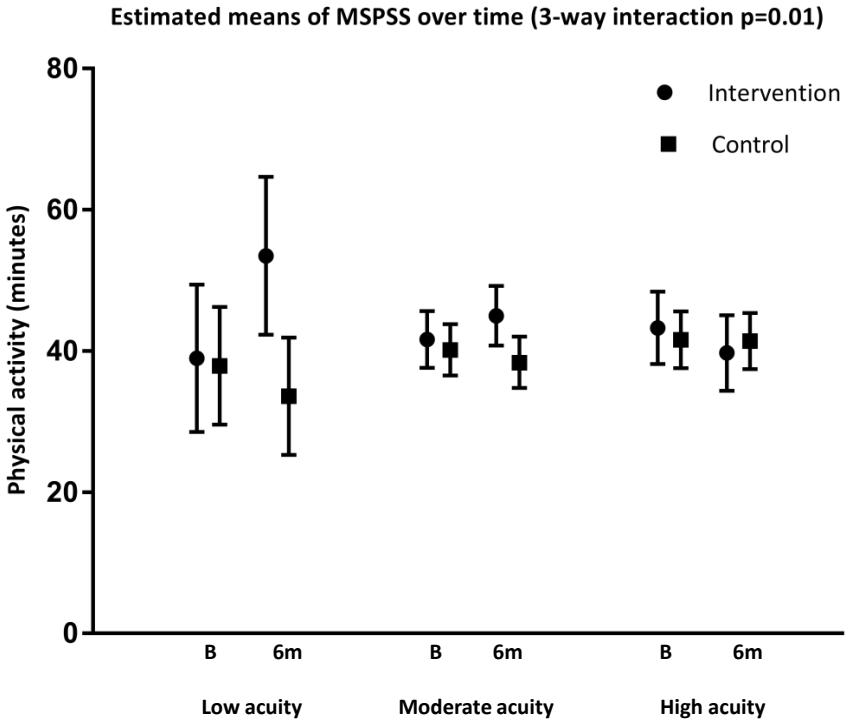
Outcome measure	Control group (n=93)		
	Mean ± SD (Linear Mixed Models)		
	Baseline	3 months	6 months
Physical activity[a]	38.7±22.8	39.8±25.9	39.1±25.4
Physical activity[b]	51.6±33.3	52.3±35.4	65.4±49.2
Daily sedentary time[c]	82.6±5.8	82.5±5.8	82.9±5.9
Exercise Self-efficacy Scale	50.7±17.7	57.7±16.8	58.5±16.5
PAM-13	59.1±11.7	60.6±14.0	61.5±12.0
	Mean ± SD (ANCOVA)		
EQ-5D-3L	0.8±0.2	NA	0.8±0.2
EQ VAS score	73.9±14.5	NA	75.4±14.7

[a] Daily minutes of moderate to vigorous physical activity; [b] Objective daily minutes of moderate to vigorous physical activity measured with the accelerometer added with self-reported cycling, swimming, strength training; [c] Percentage of the wear time spent in the sedentary category (<1.8 METS); *Adjusted for baseline measurement

Abbreviations: CI confidence intervals; MD mean difference; NA not applicable; PAM-13 Patient Activation Measure short form; VAS Visual Analog Scale

Intervention group (n=93)			Treatment effect (6 months)			
Mean ± SD (Linear Mixed Models)			Unadjusted		Adjusted*	
Baseline	3 months	6 months	MD (95% CI)	p-value	MD (95% CI)	p-value
37.5±21.1	43.3±20.7	44.2±24.4	2.92 (-6.2;12.1)	0.52	2.49 (-2.1;7.1)	0.28
49.4±29.6	56.8±29.7	69.4±46.8	3.57 (-8.4;15.5)	0.55	2.41 (-4.3;9.1)	0.48
83.3±5.5	83.0±5.9	83.3±5.3	0.54 (-1.5;2.6)	0.60	0.31(-0.6;1.9)	0.50
49.4±17.1	57.0±17.3	58.8±16.0	-0.82 (-5.8;4.2)	0.75	-0.79 (-4.6;3.0)	0.68
57.2±12.2	59.9±12.7	59.7±14.0	-1.59 (-5.4;2.2)	0.41	0.03 (-2.9;3.0)	0.99
Mean ± SD (ANCOVA)					Standardised coefficients (95% CI)	p-value
0.8±0.2	NA	0.8±0.2			0.02 (0.0;0.05)	0.17
67.3±14.7	NA	70.0±12.4			0.16 (-3.2;3.5)	0.92

Intervention group (n=70)			Treatment effect (6 months)			
Mean ± SD (Linear Mixed Models)			Unadjusted		Adjusted*	
Baseline	3 months	6 months	MD (95% CI)	p-value	MD (95% CI)	p-value
40.8±21.3	43.3±20.7	44.7±24.3	3.98 (-5.0;12.9)	0.52	2.55 (-2.0;7.2)	0.26
54.1±30.1	56.8±29.7	70.1±46.8	4.00 (-8.0;16.0)	0.51	2.43 (-4.3;9.1)	0.48
82.7±5.5	83.0±5.9	83.3±5.3	0.51 (-1.6;2.6)	0.63	0.35 (-0.5;1.2)	0.44
51.5±17.6	57.0±17.3	59.0±16.1	-0.25 (-5.2;4.7)	0.92	-0.71 (-4.6;3.2)	0.72
57.9±12.4	59.9±12.7	60.1±13.9	-1.25 (-5.1;2.6)	0.52	-0.07 (-2.9;3.1)	0.96
Mean ± SD (ANCOVA)					Standardised coefficients (95% CI)	p-value
0.8±0.2	NA	0.8±0.2			0.01 (0.0;0.04)	0.46
67.7±15.3	NA	70.0±12.4			0.24 (-3.2;3.6)	0.89



Abbreviations: B Baseline; 6m 6 months

Figure 3. Estimated means of the Multi-dimensional Scale of Perceived Social Support

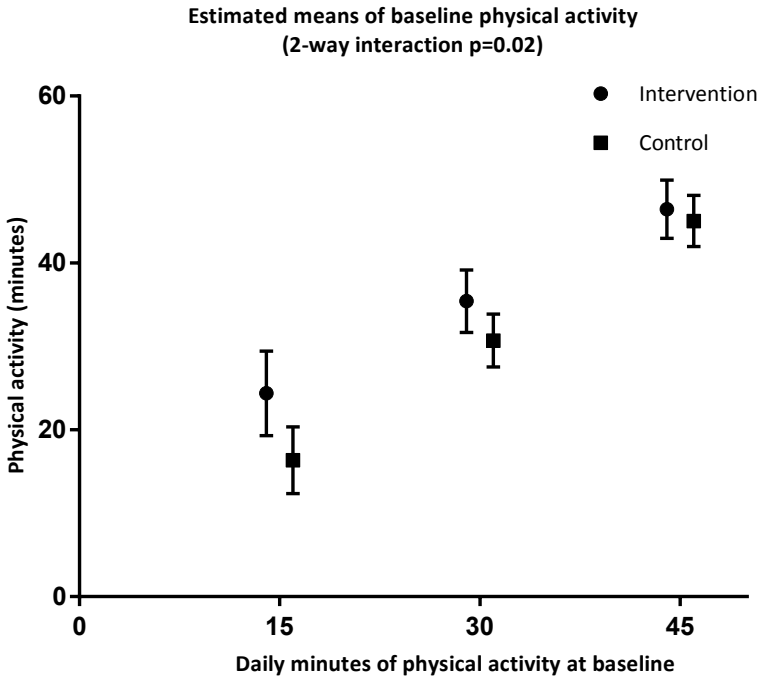


Figure 4. Estimated means of baseline physical activity

DISCUSSION

In a cluster-randomised controlled trial, a nurse-led behaviour change intervention (Activate) in patients at risk for CVD in primary care, did not result in significant improvement in patients' daily amount of physical activity compared to care as usual at 6 months of follow-up. Also, no between-group differences were seen on secondary outcomes, including sedentary behaviour, self-efficacy for physical activity, patient activation for self-management and health status. Pre-defined subgroup analyses showed that patients with a low acuity of perceived social support and patients with a low baseline activity level were more likely to benefit more from the intervention.

The Activate intervention showed an increase in patients' physical activity; however, this increase was not significant. This is in contrast to other recent studies also using BCTs such as goal setting, action planning, self-monitoring, feedback and social support to increase physical activity by nurse-led consultations.[44-46] Our results might be explained by the following reasons. First, patients with a high baseline value of physical activity might easily have reached a ceiling level. Whilst an eligibility criterion of patients was insufficient physical activity according to the self-reported SQUASH, patients' objectively measured mean physical activity level was remarkably high and the majority of patients (in both groups) exceeded the Dutch guideline for physical activity. This was also seen in another Dutch trial.[44] These high baseline levels may indicate invalid physical activity screening or a Hawthorne effect (i.e. patients increase their physical activity level when monitored while participating in a study).[47,48] Patients in the intervention group became used to daily wearing the accelerometer, which could have decreased patients' social desirable behaviour during the follow-up measurements compared to the control group who only wore the accelerometer during the follow-up measurements. Despite the modified informed consent procedure, this undesirable effect of the use of an accelerometer might have diluted the true effect. Second, seasonal changes during the follow-up measurements might have influenced the effect, as the vast majority of baseline measurements occurred during summer in which physical activity levels are higher.[49] Although due to the randomised nature of the trial, this is not different between groups. A longer follow-up might have diminished the influence of seasonal changes. Third, nurses in the control group were not blinded and may have upgraded their usual care, resulting in diminished effectiveness of the intervention. Fourth, participating general practices might have been more prone to behaviour change support and might have incorporated this already into their routine care compared to not participating general practices.

Fifth, treatment effects may have been more pronounced when nurses mastered their skills in providing the intervention.[50] Overall, nurses included few patients, while full

and adequate implementation of the intervention requires time and opportunities to practice their skills with a substantial number of patients as nurses reported a learning curve in delivering the intervention and acknowledged that initially this was difficult.[50] Subsequently, insight into whether nurses delivered the intervention as intended and their quality of delivery is crucial to further understanding of the effects[51,52] and needs to be investigated.

Considering the secondary outcomes, no significant effects of the intervention on sedentary behaviour, self-efficacy for physical activity, patient activation and health status at 6 months were found. Although another physical activity intervention has reported reductions in sedentary time, we were not able to detect such an effect.[53] Patients' self-efficacy of being physically active increased in both groups. A possible explanation for patients' increase in this important intermediate can be sought in the gained insight from the results of the qualitative evaluation among patients, which we conducted parallel to the current study.[54] This qualitative study revealed that patients increasingly felt more confident to goal attainment and highly valued included BCTs targeting self-efficacy. However, we could not explain patients' increase in self-efficacy in the control group, rather than relating this increase to wearing the accelerometer during the follow-up measurements.[54]

Patients' activation for self-management might not have been affected by the intervention as their activation scores indicate that patients in both groups were already taking an active role in building self-management skills and were considered to strive for behaviour change.[55] Patients' health status did not change at 6 months, which is in line with the trial of van der Weegen et al.[44]

A priori, patients' characteristics, such as age, BMI, educational level, social support, depression, patient-provider relationship and baseline physical activity were pre-specified to examine whether treatment effects vary between patients. Patients with a low acuity of perceived social support tend to favour more effect from the intervention. This could be partially explained by patients' inability to elicit social support themselves.[56] Patients with an inactive baseline activity level tend to benefit more from the intervention, which is consistent with other studies.[45,46,57] No interaction effects were shown for age, which might be due to the relatively older population included. BMI also did not modify the effect of the intervention among mostly overweight or obese patients, which is consistent with other studies.[45,46,58] The vast majority of patients received secondary education and perceived a very good relationship with their nurse. These characteristics did not modify patients' physical activity level. Patients' baseline depression scores did not modify patients' level of physical activity, which means that when most patients have a normal

depression level this does not affect their physical activity level, which is in line with other studies.[45,46] However, these results urged caution due to the lack of power of the analysis leaving the complex question unanswered of which patients benefit from self-management interventions. Subsequently, baseline characteristics of patients might shed a light on further hypothesising this question. Relatively active patients with an average age of 60 years, moderate educational level and overweight or obese were well represented, assuming the results are substantial representative to patients having these characteristics. However, patients with low health literacy levels and ethnic minorities were underrepresented as they were more likely to non-participate due to language barriers and difficulties to understand the intervention.

Although we were not able to detect a significant effect on the primary and secondary outcomes, the results of qualitative studies conducted among patients and nurses alongside the Activate trial revealed pivotal insights in the effectiveness.[50,54] The study among patients emphasised that, irrespectively to patients' objective changes in physical activity level, patients' participation led to an increased awareness of the importance of physical activity for their health and the amount and intensity of their activity level.[54] Furthermore, both studies identified the contribution of individual components to nurses' and patients' perceived success of the intervention,[50,54] which often result in tiny changes, each in themselves produce apparently marginal gains accumulating to meaningful successes.[59]

Strengths and limitations

The use of the Behaviour Change Wheel as a theoretical framework to guide behaviour change in both patients and nurses enhances reproducibility and our understanding of the active ingredients of the intervention to further unravel the black box of the effectiveness of self-management interventions. In the design, several methodological challenges were addressed to improve the methodological rigor and generalisability, such as cluster-randomisation at the level of the general practice to prevent contamination; a sample from general practices throughout the Netherlands; the modified informed consent procedure to postponed information to reduce attrition bias and contamination in the control group as patients could not be blinded for the intervention; patients' own nurse rather than researchers or exercise specialists delivered the intervention; objective physical activity measurements using a blank screen accelerometer; self-reported measurements using validated questionnaires; and a thorough conducted process evaluation parallel the trial.

Some limitations should be considered. Despite our expectations and efforts, the number of patients according to the power calculation proved unattainable, which forces a careful interpretation of the results, particularly the effect modification analysis. Despite the commitment of general practices and nurses to recruit sufficient patients, the recruitment

rate of patients was 27.6%. This recruitment rate is lower than another patient-based trial[44] but showed a higher patient recruitment rate than population-based physical activity trials.[45,60] It might be possible that we have missed a real effect of the intervention by including insufficient patients. Furthermore, the low recruitment rate per general practice might have also caused the higher intraclass correlation than anticipated (0.12 instead of 0.05). Non-attending patients frequently reported having a relatively high level of physical activity, being unaware of their inactivity, having other priorities in life, lacking motivation, participating takes too much time, and/or already being involved in research. Furthermore, the recruitment rate of general practices was low and most reported reasons for non-participation were lack of availability of the nurse due to busy daily practices, sick leave, other priorities, and already being involved in other research. The low recruitment rates of both patients and general practices raise issues about generalisability.

To reduce selective inclusion, broad selection criteria were chosen and nurses were instructed to check all scheduled patients for eligibility in agreement with the general practitioner. However, nurses indicated that patients, who they experienced as unmotivated to change their behaviour during prior consultations, were less likely to be included, suggesting that selective inclusion might have occurred. The drop out rate was somewhat higher than anticipated (19.4% instead of 15%). However, it is unlikely that drop outs biased our results as patients' baseline characteristics were comparable and the multilevel analysis flexibly dealt with drop-out.
Finally, the Pam AM300 itself had some limitations, such as the inability to properly measure cycling, swimming and strength training, patients frequently lost the accelerometer and technical issues occurred, which caused loss of data.

CONCLUSION

The nurse-led Activate intervention did not increase the level of physical activity and other patient-related outcomes in patients at risk for CVD in primary care. To better understand the absence of an significant effect, a thorough process evaluation, concerning patients' and nurses' perceptions towards the intervention is performed. The fidelity of delivery of the intervention and active components for effective self-management requires further investigation.

REFERENCES

1. Bodenheimer T, Lorig K, Holman H, Grumbach K. Patient self-management of chronic disease in primary care. *JAMA*. 2002;288(19):2469-2475.
2. Barlow J, Wright C, Sheasby J, Turner A, Hainsworth J. Self-management approaches for people with chronic conditions: A review. *Patient Educ Couns*. 2002;48(2):177-187.
3. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: The new medical research council guidance. *BMJ*. 2008;337:a1655.
4. Jonkman N, Westland H, Trappenburg J, et al. Do self-management interventions in COPD patients work and which patients benefit most? an individual patient data meta-analysis. *Int J Chron Obstruct Pulmon Dis*. 2016;11:2063-2074.
5. Jonkman N, Westland H, Groenwold RHH, et al. Do self-management interventions work in patients with heart failure? an individual patient data meta-analysis. *Circulation*. 2016;133(12):1189-1198.
6. Jonkman NH, Westland H, Trappenburg JC, et al. Characteristics of effective self-management interventions in patients with COPD: Individual patient data meta-analysis. *Eur Respir J*. 2016;48(1):55-68.
7. Jonkman N, Westland H, Groenwold RHH, et al. What are effective program characteristics of self-management interventions in patients with heart failure? an individual patient data meta-analysis. *J Card Fail*. 2016;22(11):861-871.
8. Jonkman N, Groenwold RHH, Trappenburg JCA, Hoes A, Schuurmans M. Complex self-management interventions in chronic disease unravelled: A review of lessons learnt from an individual patient data meta-analysis. *J Clin Epidemiol*. 2017;83:48-56.
9. Trappenburg J, Jonkman N, Jaarsma T, et al. Self-management: One size does not fit all. *Patient Educ Couns*. 2013;92(1):134-137.
10. Conn V. Unpacking the black box: Countering the problem of inadequate intervention descriptions in research reports. *West J Nurs Res*. 2012;34(4):427-433.
11. Moore G, Audrey S, Barker M, et al. Process evaluation of complex interventions: Medical research council guidance. *BMJ*. 2015;350:h1258.
12. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: The new medical research council guidance. *Int J Nurs Stud*. 2013;50(5):587-592.
13. Michie S, Abraham, C. Interventions to change health behaviours: Evidence-based or evidence-inspired? *Psychol Health*. 2004;19(1):29-49.
14. Kemper HGC, Ooijendijk WTM, Stiggelbout M. Consensus over de Nederlandse Norm voor Gezond Bewegen. *Tijdschr Soc Gezondheidsz*. 2000;78(78):180-183.
15. Cooper AR, Moore LA, McKenna J, Riddoch CJ. What is the magnitude of blood pressure response to a programme of moderate intensity exercise? randomised controlled trial among sedentary adults with unmedicated hypertension. *Br J Gen Pract*. 2000;50(461):958-962.
16. Franco OH, de Laet C, Peeters A, Jonker J, Mackenbach J, Nusselder W. Effects of physical activity on life expectancy with cardiovascular disease. *Arch Intern Med*. 2005;165(20):2355-2360.
17. Hu G, Jousilahti P, Barengo N, Qiao Q, Lakka T, Tuomilehto J. Physical activity, cardiovascular risk factors, and mortality among finnish adults with diabetes. *Diabetes Care*. 2005;28(4):799-805.
18. Williams PT. Physical fitness and activity as separate heart disease risk factors: A meta-analysis. *Med Sci Sports Exerc*. 2001;33(5):754-761.
19. Burke LE, Dunbar-Jacob JM, Hill MN. Compliance with cardiovascular disease prevention strategies: A review of the research. *Ann Behav Med*. 1997;19(3):239-263.

20. Baan CA, Hutten JBF, Rijken PM (2003). *Afstemming in de zorg: Een achtergrondstudie naar de zorg voor mensen met een chronische aandoening. [Coordination of care. A study into the care for people with a chronic condition]*. Bilthoven, the Netherlands: RIVM.
21. Elissen A, Nolte E, Knai C, et al. Is Europe putting theory into practice? A qualitative study of the level of self-management support in chronic care management approaches. *BMC Health Serv Res*. 2013;13:117-6963-13-117.
22. Wagner EH. Chronic disease management: What will it take to improve care for chronic illness? *Eff Clin Pract*. 1998;1(1):2-4.
23. Michie S, Richardson M, Johnston M, et al. The behavior change technique taxonomy (v1) of 93 hierarchically clustered techniques: Building an international consensus for the reporting of behavior change interventions. *Ann Behav Med*. 2013;46(1):81-95.
24. Westland H, Bos Touwen I, Trappenburg JCA, Schröder C, de Wit N, Schuurmans M. Unravelling effectiveness of a nurse-led behaviour change intervention to enhance physical activity in patients at risk for cardiovascular disease in primary care: Study protocol for a cluster-randomised controlled trial. *Trials*. 2017;18(1):79-94.
25. Grimshaw J, Eccles M, Steen N, et al. Applying psychological theories to evidence-based clinical practice: Identifying factors predictive of lumbar spine x-ray for low back pain in UK primary care practice. *Implement Sci*. 2011;6:55-68.
26. Michie S, van Stralen MM, West R. The behaviour change wheel: A new method for characterising and designing behaviour change interventions. *Implement Sci*. 2011;6:42-5908-6-42.
27. Millat B, Borie F, Fingerhut A. Patient's preference and randomization: New paradigm of evidence-based clinical research. *World J Surg*. 2005;29(5):596-600.
28. Boter H, van Delden JJ, de Haan RJ, Rinkel GJ. Modified informed consent procedure: Consent to postponed information. *BMJ*. 2003;327(7409):284-285.
29. Nederlands Huisartsen Genootschap (2001). *Multidisciplinaire Richtlijn Cardiovasculair Risicomanagement.* Houten, the Netherlands: Bohn Stafleu van Loghum.
30. Wendel-Vos GCW, Schuit AJ, Saris WHM, Kromhout D. Reproducibility and relative validity of the short questionnaire to assess health-enhancing physical activity. *J Clin Epidemiol*. 2003;56(12):1163-1169.
31. Slootmaker SM, Chin A Paw, M J M, Schuit AJ, van Mechelen W, Koppes LLJ. Concurrent validity of the PAM accelerometer relative to the MTI actigraph using oxygen consumption as a reference. *Scand J Med Sci Sports*. 2009;19(1):36-43.
32. Everett B, Salamonson Y, Davidson PM. Bandura's exercise self-efficacy scale: Validation in an australian cardiac rehabilitation setting. *Int J Nurs Stud*. 2009;46(6):824-829.
33. Shin Y, Jang H, Pender NJ. Psychometric evaluation of the exercise self-efficacy scale among korean adults with chronic diseases. *Res Nurs Health*. 2001;24(1):68-76.
34. van der Heijden, M M P, Pouwer F, Pop VJM. Psychometric properties of the exercise self-efficacy scale in dutch primary care patients with type 2 diabetes mellitus. *Int J Behav Med*. 2014;21(2):394-401.
35. Rademakers J, Nijman J, van der Hoek L, Heijmans M, Rijken M. Measuring patient activation in the netherlands: Translation and validation of the american short form patient activation measure (PAM13). *BMC Public Health*. 2012;12:577-2458-12-577.
36. Hibbard JH, Stockard J, Mahoney ER, Tusler M. Development of the patient activation measure (PAM): Conceptualizing and measuring activation in patients and consumers. *Health Serv Res*. 2004;39:1005-1026.
37. Kind P (1996). *The EuroQol instrument: An index of health-related quality of life. In: Quality of life and pharmacoeconomics in clinical trials.* 2nd ed. Lippincott-Raven.

38. Pedersen SS, Spinder H, Erdman RA, Denollet J. Poor perceived social support in implantable cardioverter defibrillator (ICD) patients and their partners: Cross-validation of the multidimensional scale of perceived social support. *Psychosomatics*. 2009;50(5):461-467.
39. Spinhoven P, Ormel J, Sloekers PP, Kempen GI, Speckens AE, Van Hemert AM. A validation study of the hospital anxiety and depression scale (HADS) in different groups of dutch subjects. *Psychol Med*. 1997;27(2):363-370.
40. Zigmond AS, Snaith RP. The hospital anxiety and depression scale. *Acta Psychiatr Scand*. 1983;67(6):361-370.
41. Makoul G, Krupat E, Chang C. Measuring patient views of physician communication skills: Development and testing of the communication assessment tool. *Patient Educ Couns*. 2007;67(3):333-342.
42. Twisk JWR (2006). *Applied multilevel analysis: A practical guide for medical researchers.* Cambridge: Cambridge University Press.
43. Campbell MK, Piaggio G, Elbourne DR, Altman DG, CONSORT Group. Consort 2010 statement: Extension to cluster randomised trials. *BMJ*. 2012;345:e5661.
44. van der Weegen S, Verwey R, Spreeuwenberg M, Tange H, van der Weijden T, de Witte L. It's LiFe! mobile and web-based monitoring and feedback tool embedded in primary care increases physical activity: A cluster randomized controlled trial. *J Med Internet Res*. 2015;17(7).
45. Harris T, Kerry S, Limb E, et al. Effect of a primary care walking intervention with and without nurse support on physical activity levels in 45- to 75-year-olds: The pedometer and consultation evaluation (PACE-UP) cluster randomised clinical trial. *PLoS Med*. 2017;14(1).
46. Harris T, Kerry S, Victor C, et al. A primary care nurse-delivered walking intervention in older adults: PACE (pedometer accelerometer consultation evaluation)-lift cluster randomised controlled trial. *PLoS Med*. 2015;12(2).
47. Casaburi R. Activity monitoring in assessing activities of daily living. *COPD*. 2007;4(3):251-255.
48. Pedišic Ž, Bauman A. Accelerometer-based measures in physical activity surveillance: Current practices and issues. *Br J Sports Med*. 2015;49(4):219-223.
49. Kimura T, Kobayashi H, Nakayama E, Kakihana W. Seasonality in physical activity and walking of healthy older adults. *J Physiol Anthropol*. 2015;34:33-39.
50. Westland H, Koop Y, Schröder C, et al. Nurses' perceptions towards the delivery and feasibility of a behaviour change intervention to enhance physical activity in patients at risk for cardiovascular disease in primary care: A qualitative study. *Accepted for publication in BMC Family Practice.*
51. Bellg A, Borrelli B, Resnick B, et al. Enhancing treatment fidelity in health behavior change studies: Best practices and recommendations from the NIH behavior change consortium. *Health Psychol*. 2004;23(5):443-451.
52. Borrelli B. The assessment, monitoring, and enhancement of treatment fidelity in public health clinical trials. *J Public Health Dent*. 2011;71 Suppl 1:S52-S63.
53. Mutrie N, Doolin O, Fitzsimons C, et al. Increasing older adults' walking through primary care: Results of a pilot randomized controlled trial. *Fam Pract*. 2012;29(6):633-642.
54. Westland H, Sluiter J, te Dorsthorst S, et al. Patients' experiences with a behaviour change intervention to enhance physical activity in primary care: A mixed methods study. *In revision.*
55. Hibbard J, Mahoney E, Stockard J, Tusler M. Development and testing of a short form of the patient activation measure. *Health Serv Res*. 2005;40(6):1918-1930.
56. French D, Olander E, Chisholm A, Mc Sharry J. Which behaviour change techniques are most effective at increasing older adults' self-efficacy and physical activity behaviour? A systematic review. *Ann Behav Med*. 2014;48(2):225-234.

57. McMurdo MET, Sugden J, Argo I, et al. Do pedometers increase physical activity in sedentary older women? A randomized controlled trial. *J Am Geriatr Soc*. 2010;58(11):2099-2106.
58. Fitzsimons C, Baker G, Gray S, Nimmo M, Mutrie N. Does physical activity counselling enhance the effects of a pedometer-based intervention over the long-term: 12-month findings from the walking for wellbeing in the west study. *BMC Public Health*. 2012;12:206-206.
59. Richards D. Complex interventions and the amalgamation of marginal gains: A way forward for understanding and researching essential nursing care? *Int J Nurs Stud*. 2015;52(7):1143-1145.
60. Tully MA, Cupples ME, Chan WS, McGlade K, Young IS. Brisk walking, fitness, and cardiovascular risk: A randomized controlled trial in primary care. *Prev Med*. 2005;41(2):622-628.

APPENDIX

Appendix 1. Selected behaviour change techniques (BCTs) for the Activate intervention and division of BCTs over the consultations

Selected BCTs from BCTTv1		**BCTs divided over components intervention**					
		Consultations				Between consultations	Workbook
		1	2	3	4		
1.	Goal setting (behaviour)	x	x	x	x		
2.	Problem-solving (includes barrier identification and relapse prevention)	x	x	x	x	x	
3.	Goal setting (outcome)	x				x	
4.	Action planning	x	x	x	x	x	
5.	Review behavioural goals		x	x	x		
6.	Commitment		x	x	x		
7.	Feedback on behaviour	x	x	x	x	x	
8.	Self-monitoring of behaviour	x	x	x	x	x	
9.	Social support (unspecified)	x	x	x	x		
10.	Social support (practical)		x	x	x		
11.	Information about health consequences	x	x				x
12.	Prompt/cues		x	x	x		x
13.	Habit formation			x	x		
14.	Graded tasks	x	x	x	x		
15.	Restructuring the physical environment		x	x	x		
16.	Restructuring the social environment		x	x	x		
17.	Focus on past success		x	x	x		

Abbreviations: BCTs behaviour change techniques, BCTTv1 Behaviour Change Technique Taxonomy v1

Appendix 2. Division of selected BCTs over the different components of the training of primary care nurses

Selected BCTs from BCTTv1	BCTs divided over components training			
	Preparation	Training	Coaching sessions	Available resources
1. Information about health consequences	x	x		x
2. Information about social and environmental consequences	x	x		x
3. Prompts/cues		x		x
4. Feedback on the behaviour		x	x	
5. Information about others approval		x	x	
6. Credible source	x	x	x	x
7. Focus on past success		x	x	
8. Verbal persuasion about capability		x	x	
9. Reward		x	x	
10. Monitoring of behaviour by others without feedback		x	x	
11. Monitoring outcome of behaviour by others without feedback		x		
12. Instruction on how to perform the behaviour	x	x	x	x
13. Demonstration of the behaviour		x	x	x
14. Behavioural practice/rehearsal		x	x	x
15. Habit formation		x	x	x
16. Adding objects to the environment		x	x	x
17. Restructuring the physical environment		x	x	x
18. Social support (unspecified)		x	x	
19. Social support (practical)		x	x	
20. Problem solving		x	x	x
21. Self-monitoring of behaviour		x	x	

Abbreviations: BCTs behaviour change techniques; BCTTv1 Behaviour Change Technique Taxonomy v1

Appendix 3a. CONSORT 2010 checklist of information for the Activate cluster-randomised controlled trial

Section/Topic	Item No	Standard Checklist item	Extension for cluster designs
Title and abstract			
	1a	Identification as a randomised trial in the title: YES	Identification as a cluster randomised trial in the title: YES
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts):[1,2] MOSTLY	See Appendix 3b below
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale: YES	Rationale for using a cluster design: YES
	2b	Specific objectives or hypotheses: YES	Whether objectives pertain to the cluster level, the individual participant level or both: YES
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio: YES	Definition of cluster and description of how the design features apply to the clusters: YES
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons: Not applicable	
Participants	4a	Eligibility criteria for participants: YES	Eligibility criteria for clusters: YES
	4b	Settings and locations where the data were collected: YES	
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered: YES	Whether interventions pertain to the cluster level, the individual participant level or both: YES (also in published protocol)
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed: YES	Whether outcome measures pertain to the cluster level, the individual participant level or both: YES
	6b	Any changes to trial outcomes after the trial commenced, with reasons: not applicable	

Appendix 3a. Continued

Section/Topic	Item No	Standard Checklist item	Extension for cluster designs
Sample size	7a	How sample size was determined: YES	Method of calculation, number of clusters(s) (and whether equal or unequal cluster sizes are assumed), cluster size, a coefficient of intracluster correlation (ICC or *k*), and an indication of its uncertainty: YES
	7b	When applicable, explanation of any interim analyses and stopping guidelines: not applicable	
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence: YES	
	8b	Type of randomisation; details of any restriction (such as blocking and block size): YES	Details of stratification or matching if used: YES
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned: YES	Specification that allocation was based on clusters rather than individuals and whether allocation concealment (if any) was at the cluster level, the individual participant level or both: YES
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	Replace by 10a, 10b and 10c
	10a		Who generated the random allocation sequence, who enrolled clusters, and who assigned clusters to interventions: YES
	10b		Mechanism by which individual participants were included in clusters for the purposes of the trial (such as complete enumeration, random sampling): YES
	10c		From whom consent was sought (representatives of the cluster, or individual cluster members, or both), and whether consent was sought before or after randomisation: YES

Appendix 3a. Continued

Section/Topic	Item No	Standard Checklist item	Extension for cluster designs
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how: YES	
	11b	If relevant, description of the similarity of interventions: not applicable	
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes: YES	How clustering was taken into account: YES
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses: YES	
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome: YES	For each group, the numbers of clusters that were randomly assigned, received intended treatment, and were analysed for the primary outcome: YES (CONSORT diagram)
	13b	For each group, losses and exclusions after randomisation, together with reasons: YES	For each group, losses and exclusions for both clusters and individual cluster members: YES (CONSORT diagram)
Recruitment	14a	Dates defining the periods of recruitment and follow-up: YES	
	14b	Why the trial ended or was stopped: not applicable	
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group: YES	Baseline characteristics for the individual and cluster levels as applicable for each group: YES (for individuals for each group)
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups: YES (CONSORT diagram)	For each group, number of clusters included in each analysis: NO (but not necessary, as individual analyses, taking account of clustering in analyses)

Appendix 3a. Continued

Section/Topic	Item No	Standard Checklist item	Extension for cluster designs
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval): YES	Results at the individual or cluster level as applicable and a coefficient of intracluster correlation (ICC or k) for each primary outcome: YES (results at individual level)
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended: not applicable	
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory: YES	
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms[3]): Not applicable	
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses: YES	
Generalisability	21	Generalisability (external validity, applicability) of the trial findings: YES	Generalisability to clusters and/or individual participants (as relevant): YES (to individual participants)
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence: YES	
Other information			
Registration	23	Registration number and name of trial registry: YES	
Protocol	24	Where the full trial protocol can be accessed, if available: YES	
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders: YES	

Appendix 3b. Extension of CONSORT for abstracts[1,2,3] to reports of cluster-randomised trials

Item	Standard Checklist item	Extension for cluster trials
Title		
Trial design	Identification of study as randomised: YES	Identification of study as cluster randomised: YES
	Description of the trial design (e.g. parallel, cluster, non-inferiority): YES	
Methods		
Participants	Eligibility criteria for participants and the settings where the data were collected: Partly	Eligibility criteria for clusters: NO
Interventions	Interventions intended for each group: YES	
Objective	Specific objective or hypothesis: YES	Whether objective or hypothesis pertains to the cluster level, the individual participant level or both: YES (individual)
Outcome	Clearly defined primary outcome for this report: YES	Whether the primary outcome pertains to the cluster level, the individual participant level or both: YES (individual)
Randomization	How participants were allocated to interventions: YES	How clusters were allocated to interventions: YES
Blinding (masking)	Whether or not participants, care givers, and those assessing the outcomes were blinded to group assignment: NO	
Results		
Numbers randomized	Number of participants randomized to each group: YES	Number of clusters randomized to each group: YES
Recruitment	Trial status	Not applicable
Numbers analysed	Number of participants analysed in each group: YES	Number of clusters analysed in each group: NO, not applicable, as analysis at individual level controlling for clustering.
Outcome	For the primary outcome, a result for each group and the estimated effect size and its precision: Yes	Results at the cluster or individual participant level as applicable for each primary outcome: At individual level
Harms	Important adverse events or side effects: Not applicable	

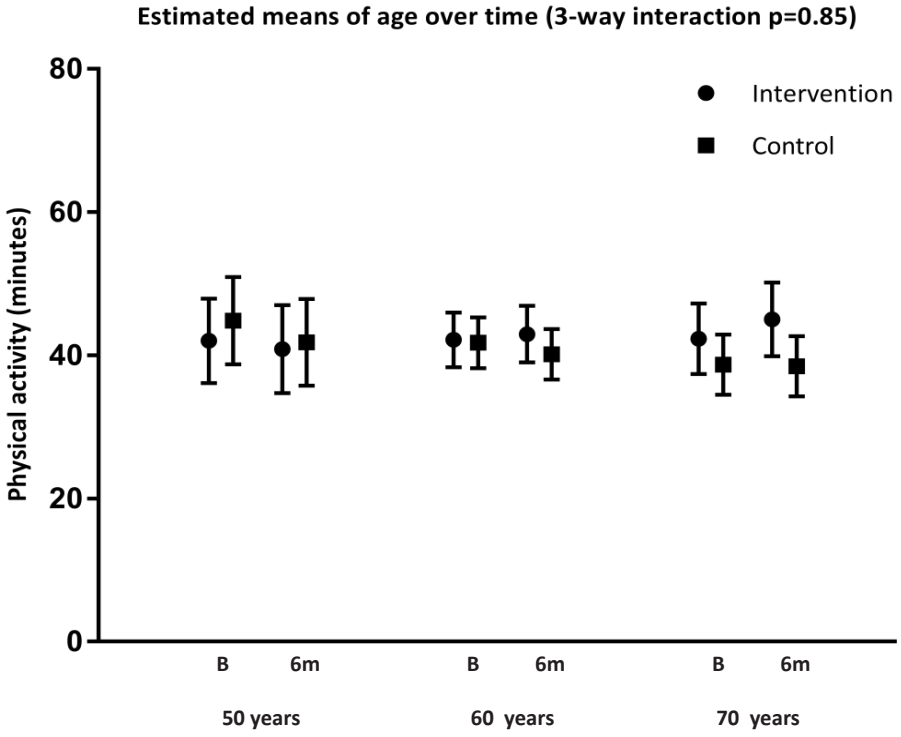
Appendix 3b. Continued

Item Title	Standard Checklist item	Extension for cluster trials
Conclusions		
	General interpretation of the results: YES	
Trial registration	Registration number and name of trial register: YES	
Funding	Source of funding: YES	

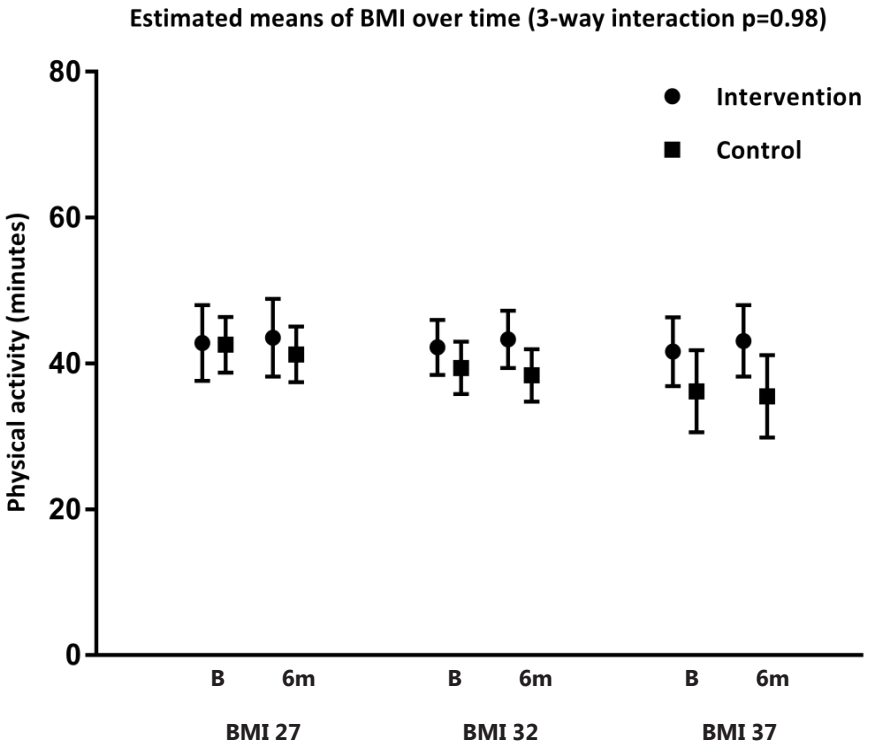
REFERENCES

1. Hopewell S, Clarke M, Moher D, Wager E, Middleton P, Altman DG, et al. CONSORT for reporting randomised trials in journal and conference abstracts. *Lancet* 2008, 371:281-283
2. Hopewell S, Clarke M, Moher D, Wager E, Middleton P, Altman DG at al (2008) CONSORT for reporting randomized controlled trials in journal and conference abstracts: explanation and elaboration. *PLoS Med* 5(1): e20
3. Ioannidis JP, Evans SJ, Gotzsche PC, O'Neill RT, Altman DG, Schulz K, Moher D. Better reporting of harms in randomized trials: an extension of the CONSORT statement. *Ann Intern Med* 2004; 141(10):781-788.

Appendix 4. Estimated means of age, body mass index, educational level, depression, and patient-provider relationship

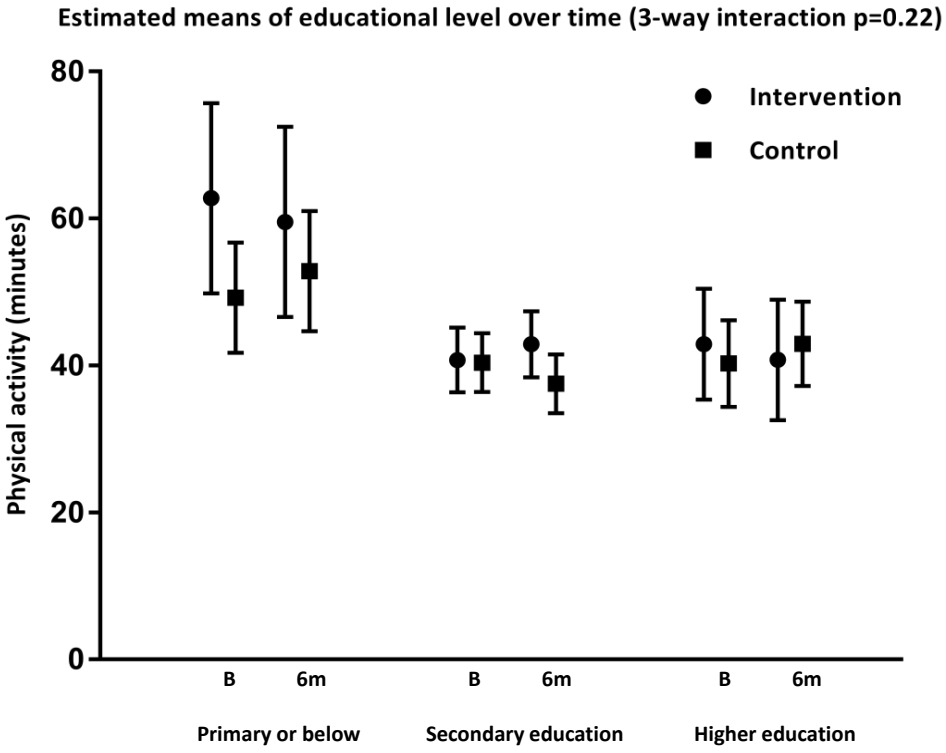


Abbreviations: B Baseline; 6m 6 months

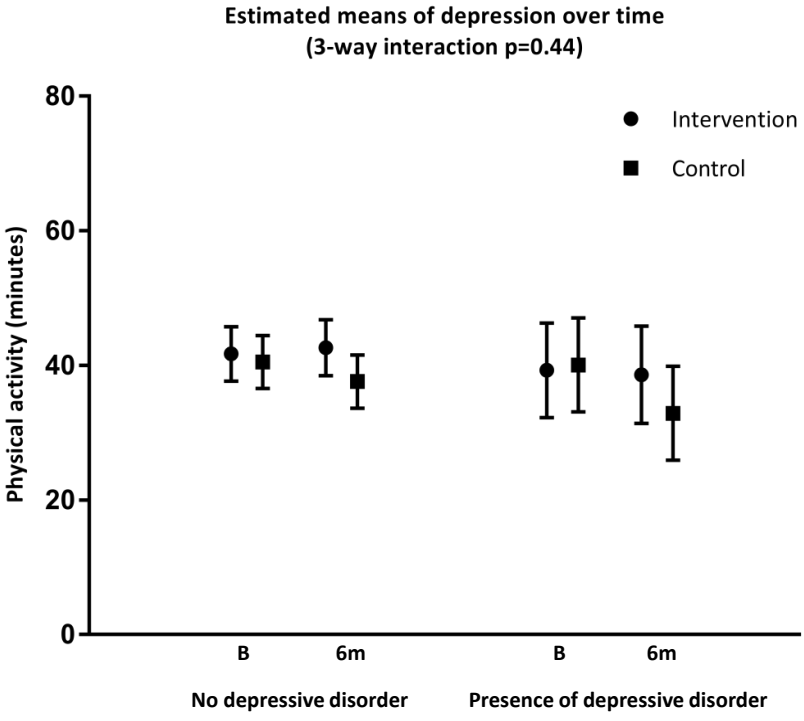


Abbreviations: B Baseline; 6m 6 months; BMI Body Mass Index

Appendix 4. Continued

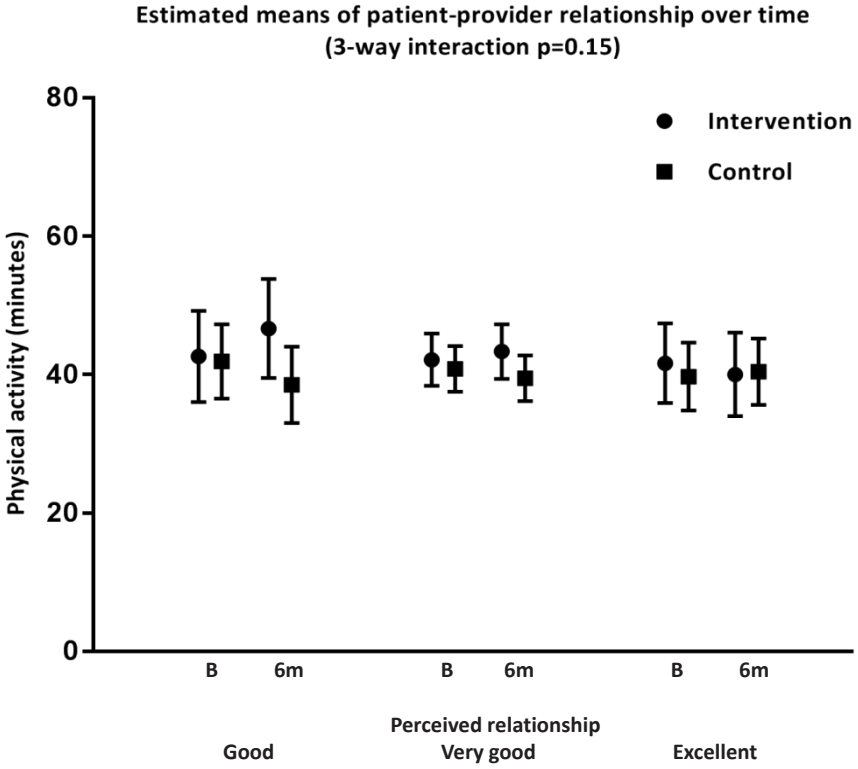


Abbreviations: B Baseline; 6m 6 months



Abbreviations: B Baseline; 6m 6 months

Appendix 4. Continued



Abbreviations: B Baseline; 6m 6 months

CHAPTER 7

Fidelity of delivery of a behaviour change intervention to enhance physical activity in primary care patients

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To be submitted

ABSTRACT

Background: The effectiveness of a nurse-led behaviour change intervention to enhance physical activity, the Activate intervention, was evaluated for effectiveness in primary care patients at risk for cardiovascular diseases in a cluster-randomised controlled trial (n=195 patients, 31 general practices). To enhance our understanding of how the intervention works and to enable reproducibility, this study aimed to evaluate the fidelity of delivery of the Activate intervention by assessing: 1. self-reported fidelity of delivery; 2. observed fidelity of delivery; 3. quality of nurses' delivery of the Activate intervention and 4. nurses' beliefs about their capability, motivation, confidence and effectiveness towards delivering the Activate intervention, including behaviour change techniques (BCTs).

Methods: An observational study was conducted. Nurses' self-reported fidelity was evaluated using checklists (n=279) and the observed fidelity and quality of delivery were examined using audio-recordings of intervention consultations (n=44). Nurses' beliefs towards delivering the intervention were assessed at multiple time points using questionnaires (n=72).

Results: The self-reported fidelity was 87.6% and observed fidelity of the intervention components was 85.6%, representing high fidelity. The observed fidelity of BCTs was moderate (76.8%). The overall mean for quality of delivery was 2.9 (SD 4.4, range 0-4). Nurses stated they were capable, motivated and confident to deliver the intervention and BCTs. They regarded the intervention, including BCTs, to be effective to improve patients' level of physical activity.

Conclusion: Nurses delivered the components of the intervention with high level of fidelity and applied the BCTs with a moderate level of fidelity. Nurses' quality of delivery was sufficient. Nurses felt capable, motivated and confident to deliver the intervention and BCTs and considered the intervention and BCTs to be effective in enhancing patients' level of physical activity.

BACKGROUND

Interventions aiming at behaviour change in patients are considered complex as they contain multiple interacting components.[1,2] Evaluating the effectiveness of such interventions within randomised controlled trials is challenging though increasingly acknowledged.[1,3,4] In addition to evaluating the effectiveness of complex interventions on results of prespecified outcomes,[5] it is necessary to assess the extent to which interventions are delivered as described in the protocol (intervention fidelity).[6,7] Evaluating the intervention fidelity is necessary as complex interventions are susceptible to variations in delivery[2] and delivery with high fidelity is challenging to achieve.[8,9] Conducting an evaluation of intervention fidelity contributes to an accurate interpretation of trial results, enhances understanding of how the intervention works, allows to identify training needs or improvements of the intervention delivery and enables reproducibility.[6,10] Intervention fidelity implies ongoing assessment, monitoring and enhancement of reliability and internal validity of the intervention.[6] Preferably, the evaluation of the intervention fidelity needs to include five dimensions: 1. study and intervention design; 2. provider training; 3. intervention delivery; 4. intervention receipt; and 5. enactment of intervention skills.[6] Accordingly, parallel to the evaluation of the effectiveness of a behaviour change intervention (the Activate intervention) in a cluster-randomised controlled trial comparing the Activate intervention to care as usual, we planned to evaluate the intervention fidelity. The Activate intervention is a nurse-led behaviour change intervention to enhance physical activity in primary care patients at risk for cardiovascular disease (CVD).[11] In the trial, 195 patients of 31 general practices throughout the Netherlands participated. For the primary outcome, the trial findings demonstrated that patients who received the Activate intervention improved their level of physical activity, however not significant, compared to patients who received care as usual after 6 months.[12]

Prior conducted process evaluation covered the fidelity dimensions study and intervention design, provider training, treatment receipt and enactment of treatment skills.[11,13,14] Overall, the assessment of these fidelity dimensions showed that the intervention development using the Behaviour Change Wheel,[15] as theoretical framework, and design of the Activate trial allowed for addressing the research questions (design),[11] the standardised comprehensive training programme for nurses facilitated nurses to acquire essential competences to deliver the intervention, although adopting these competences was challenging (provider training),[11,13] patients understood the intervention and used taught skills well (treatment receipt)[14] and patients performed the intervention and taught skills in their daily lives (enactment).[14] To provide insight into the actual delivered content of the intervention, the fidelity of delivery of the Activate intervention needs to be assessed, which is often considered the core dimension of fidelity.[3,6,16] In addition to the fidelity of delivery, evaluating the quality of delivery is recommended as this has shown to influence

the effectiveness of behaviour change interventions.[17] Furthermore, the extent to which nurses are engaged to deliver the intervention according to the protocol is influenced by their beliefs of their capability, motivation, confidence and effectiveness of the intervention.[18,19] Therefore, the specific objectives of this study were:

1. To assess the fidelity of delivery of the Activate intervention by examining nurses' self-reported fidelity according to the content, consultation duration and dose of the intervention.
2. To assess the observed fidelity of delivery by examining the content and duration of nurses' delivery of the Activate intervention.
3. To evaluate the quality of nurses' delivery of the content of the Activate intervention.
4. To gain insight into nurses' beliefs about their capability, motivation, confidence and effectiveness towards delivering the Activate intervention.

METHODS

Study design

An observational study design was used to assess the fidelity and quality of delivery of the Activate intervention. The self-reported delivery of the content, duration and dose was examined using checklists and the observed fidelity and quality of nurses' delivery was examined using audio-recordings of intervention consultations. Nurses' beliefs towards delivering the intervention were assessed using questionnaires which were filled out during the intervention at multiple time points.

The Activate trial

Details of the Activate trial have been reported in detail previously.[11] In short, the Activate trial is a two-armed cluster-randomised controlled trial aiming at enhancing physical activity in primary care patients at risk for CVD. A total of 195 patients divided over 31 general practices (as clusters) throughout the Netherlands participated in the trial, of which 15 were allocated to the intervention group (n=93 patients; n=20 primary care nurses) and 16 were allocated to the control group (n=102 patients; n=16 primary care nurses). Patients in the intervention group received the Activate intervention and patients in the control group received care as usual according to the healthcare standards. The primary outcome was change from baseline at 6-months of follow-up in the number of minutes of physical activity in the moderate to vigorous category, measured with an accelerometer (personal activity monitor; Pam AM300).[20] Secondary outcomes were sedentary behaviour measured with the accelerometer, self-efficacy for physical activity, patient activation for self-management and health status measured with questionnaires. Outcome data were collected at baseline, at 3-months of follow-up and at 6-months of follow-up.

The intervention was developed using the Behaviour Change Wheel,[15] including a comprehensive behavioural analysis of 1. what hinders and facilitates patients to increase their physical activity and 2. which behaviour is needed from nurses in order to deliver the Activate intervention adequately. The application of the Behaviour Change Wheel for patients' behaviour resulted in a selection of 17 behaviour change techniques (BCTs), described in the BCT Taxonomy V1,[21] which were integrated in four nurse-led consultations during a 3-month period. Consultations were delivered at week 1, 3, 7 and 12 in patients' own general practice. The first consultation aimed to last for 30 minutes, and the following three consultations for 20 minutes.

The first consultation aimed to enhance patients' awareness of their behaviour and health consequences and to discuss patients' motivation towards increasing their physical activity. The second, third and fourth consultation aimed to discuss patients' level of goal attainment and (re)set a personal action plan. The third and fourth consultation also focused on relapse prevention.

The application of the Behaviour Change Wheel for nurses' behaviour resulted in a selection of 21 BCTs. These BCTs were incorporated in a standardised comprehensive training programme for nurses to equip them with the necessary competencies to deliver the intervention. This training programme consisted of a one-day skills training supplemented with two individual coaching sessions held by a health psychologist, instructional videos with examples of how to apply the BCTs in the consultations, a scripted handbook of the content of each of the consultations, and checklists (what to do when).

Participants

The study sample consisted of all primary care nurses (n=20) from 16 general practices situated throughout the Netherlands who participated in the Activate trial and were allocated to the intervention group.[12] In total, these nurses delivered the intervention to 93 patients in 334 consultations.

Data collection

1. Self-reported delivery of the Activate intervention

Self-reported fidelity of delivery of the intervention was assessed by filling out checklists about the discussed content, the consultation duration and dose (n=279 consultations regarding 86 patients). These checklists (what to do when) are developed by the research team. The intervention content was structured in terms of prescribed subsequent intervention components for each of the four consultations separately (Appendix 1). Nurses were asked to rate each prescribed component as

"discussed" or "not discussed" directly after each consultation. Furthermore, nurses were asked to administer the consultation duration in minutes and the number of consultations attended (dose).

2. Observed delivery of the Activate intervention

To observe whether nurses delivered the intervention as intended, nurses were asked to randomly audiotape one of each of the four consultations of the intervention. Prior to each recording of the consultation, patients were asked to verbally consent on the recording. The audio-recordings (n=44 taped by 16 nurses) were used to evaluate whether nurses delivered the prescribed subsequent intervention components and applied corresponding BCTs using a coding list. Specific components and BCTs were rated as "discussed" or "not discussed" (Appendix I). Furthermore, the audio recordings were used to register the duration (in minutes:seconds) of the consultations.

3. Quality of delivery of the Activate intervention

The audio-recordings of the consultations were used to assess the quality of delivery. The quality of nurses' counselling was assessed using the Behavior Change Counseling Index (BECCI)[22] and an additional self-developed scoring list for communication skills. The BECCI is a validated scale to score practitioners' use of behaviour change counselling in consultations. The BECCI consists of 11 items, which are rated on a five-point Likert scale (0=not at all to 4=to a great extent).[22] Two items were excluded ("Practitioner invites the patient to talk about behaviour change" and "Practitioner demonstrates sensitivity to talk about other issues") since these items were not applicable. The mean score per item indicates the extent to which nurses applied behaviour change counselling while delivering the Activate intervention.

To assess the nurses' communication skills that were conditional to deliver the intervention and not covered by the BECCI, a scoring list was developed by members of the research team. The scoring list was checked for face validity by all members of the research team and a health psychologist. The scoring list includes five items such as "Nurse asks open questions" and "Nurse listens actively" that cover communication skills which were integrated in the one-day training. A five-point Likert scale was used to provide an indication of the extent to which the trained communication skills were applied (0=not at all to 4=to a great extent).

4. Beliefs towards delivery of the Activate intervention

To explore the nurses' beliefs towards the delivery of the Activate intervention, their beliefs towards their capability, motivation, confidence to the deliver the Activate intervention and beliefs about the effectiveness of the Activate intervention were assessed using a questionnaire. This questionnaire was developed by members of the research team and checked for

face validity by all members of the research team and a health psychologist. The questionnaire includes four statements about beliefs towards delivering the intervention and the specific BCTs: 1. "I am capable of *[delivering the intervention/BCT]*", 2. "I am motivated to *[deliver the intervention/BCT]*", 3. "I am confident that I can *[deliver the intervention/BCT]*" and 4. "I am convinced *[delivering the intervention/BCT]* is effective to enhance physical activity". Nurses rated each statement using a seven-point Likert scale (1=completely disagree to 7=completely agree). Nurses were asked to fill out this questionnaire at four consecutive time points: at the start of the one-day training, directly after the one-day training, after their first individual coaching session and after they finalised the intervention (n=72).

Data analysis

1. Self-reported delivery of the Activate intervention

The self-reported fidelity of the content of the intervention was analysed by the proportion of delivered prescribed components per consultation and for the intervention as a whole using the checklists. Consensus criteria were used to constitute adherence to the intervention content, in which <50% constitute low fidelity, 51-79% moderate fidelity and 80-100% high fidelity.[7,23] The self-reported duration was analysed by the median duration and range. The dose was analysed by the number and corresponding percentage of patients who attended the consultations.

2. Observed delivery of the Activate intervention

The audio-recordings were transcribed verbatim. Two researchers independently coded the delivered content of the intervention in each of the consultations using the coding list. After coding every four to six audio-recordings, the researchers compared their findings to ensure consistent application of the coding list. Discrepancies were resolved through discussions. The inter-rater reliability was calculated using Cohen's kappa[24] and percentage agreement.[25] The observed fidelity was analysed by the proportion of delivered prescribed subsequent components and corresponding BCTs per consultation and for the intervention as a whole. Consensus criteria were used to constitute fidelity of the intervention content.[7,23] The observed duration of the consultations was analysed by the median duration and range.

3. Quality of delivery of the Activate intervention

Two researchers independently scored the BECCI and the scoring list covering communication skills for each of the audio-recorded consultations. After scoring every four to six audio-recordings, the researchers compared their findings to ensure consistent application of the scoring lists. Discrepancies were resolved through discussions. The inter-rater reliability was calculated using Cohen's kappa[24] and percentage agreement.[25] The BECCI score and observed communication skills were descriptively analysed using the mean score and standard deviation (SD) per item for all consultations and the consultations separately.

4. Beliefs towards delivery of the Activate intervention

To determine whether nurses' beliefs about their capability, motivation, confidence and effectiveness of delivering the Activate intervention and applying the BCTs changed over time, the median score and corresponding interquartile range (IQR) per belief over time were calculated.

All analyses were performed using the Statistical Package for the Social Sciences (SPSS version 21; Chicago, IL, USA).

RESULTS

All participating nurses were female (n=20), had a mean age of 46.9 years (SD 10.7) and had 6.8 years (SD 4.2) of working experience with patients at risk for CVD (Table 1). The majority of nurses received additional training in coaching techniques (n=16; 80%) prior to the Activate intervention.

Table 1. Characteristics of participating primary care nurses

Characteristics (n=20)	
Age in years, mean ± SD	46.9 ± 10.7
Female, n (%)	20 (100)
Working experience in years*, mean ± SD	6.8 ± 4.2
Received additional training in coaching techniques, n (%)	
Motivational interviewing only	11 (55.0)
Motivational interviewing and Socratic questioning	3 (15.0)
Motivational interviewing and self-management	2 (10.0)
None	4 (20.0)

*Working experience as a primary care nurse in patients at risk for cardiovascular disease

1. Self-reported delivery of the Activate intervention

Seventeen nurses (85%) filled out a total of 279 (83.5%) checklists to assess the self-reported fidelity of delivery of the Activate intervention. In consultation 1, the mean proportion of delivered components was 95.8% (89.4%-100%). The mean proportion of delivered components for the second consultation was 85.4% (53.4%-98.6%), for the third consultation 81.6% (48.5%-95.6%) and for the fourth consultation 87.7% (67.2%-98.3%); see Table 2 and Appendix 1. Nurses' overall self-reported fidelity to delivery of the Activate intervention was high: 87.6% (48.5%-100%); see Table 2. Overall, all components were delivered; however, nurses less frequently reported discussing the use of prompts and cues (48.5%-75.9%).

The median self-reported duration of all consultations was 20 minutes (10-50 minutes). The median duration of the consultations was in accordance with the prescribed duration of the consultations in the protocol (consultation 1: 30 minutes; consultation 2, 3 and 4: 20 minutes). However, the duration of all consultations was spread over a wide range; see Table 3.

All participating patients allocated to the intervention group (n=93) attended the first consultation, and 73 (78.5%) patients attended all consultations (Table 3). During the intervention, 18 patients (19.4%) discontinued the intervention due to health concerns (n=6), high burden (n=3), personal circumstances (n=3), achievement of the satisfied level of physical activity (n=3) and other reasons (n=3). In total, 73 (78.5%) patients received at least three (75%) consultations (Table 3).

Table 2. Overall fidelity of delivery of the Activate intervention

Fidelity assessment	**Percentage of delivered subsequent components**				
	Consultations				
	All	**1**	**2**	**3**	**4**
Self-reported fidelity*					
Subsequent components according to the protocol	87.6	95.8	85.4	81.6	87.7
Observed fidelity**					
Subsequent components according to the protocol	85.6	96.0	83.0	81.1	82.2
Applied BCTs according to protocol	76.8	86.0	79.0	71.0	71.3

*Based on self-reported checklists (n=279); **Based on audio-recordings (n=44)

Abbreviations: BCTs behaviour change techniques

2. Observed delivery of the Activate intervention

A total of 44 consultations were audio-recorded (55% of the intended 80 audio-recordings) by 16 (80%) nurses. The inter-rater reliability for coding the intervention components and BCTs was k 0.83; 95% CI (0.81-0.85) and 88.3% agreement; 95% (CI 86.9-89.7), which indicates almost perfect agreement. Mean proportion of delivered intervention components for consultation 1 was 96.0% (60.0%-100%) and for the BCTs was 86.0% (80.0%-100%). The average delivered components for consultation 2 was 83.0% (40.0%-100%) and BCTs was 79.0% (0%-100%). For consultation 3 the mean proportion of delivered components was 81.1% (44.4%-100%) and BCTs was 71.0% (0%-100%) and for the last consultation 82.2% (38.5%-100%) and BCTs 71.3% (7.7%-100%); see Table 2 and Appendix 1.

Table 3. Overview of the duration and dose of the delivered Activate intervention

Duration and dose
Self-reported duration of consultations, median minutes:seconds (range)
Observed duration of consultations, median minutes:seconds (range)
Patients who attended the consultations, n (%)
Patients who continued attending the consultations, n (%)

Table 4. Quality of delivery using the Behavior Change Counseling Index (BECCI)

BECCI items
1. Nurse encourages patient to talk about current behaviour or status quo
2. Nurse encourages patient to talk about change
3. Nurse asks questions to elicit how patient thinks and feels about the topic
4. Nurse uses empathic listening statements when the patient talks about the topic
5. Nurse uses summaries to bring together what the patient says about the topic
6. Nurse acknowledges challenges about behaviour change that the patient faces
7. When nurse provides information, it is sensitive to patient concerns and understanding
8. Nurse actively conveys respect for patient's choice about behaviour change
9. Nurse and patient exchange ideas about how the patient could change current behaviour
Overall BECCI score

*five-point Likert-scale, indicating the extent to which behaviour change counselling was applied (0=not at all to 4=to a great extent)
Abbreviations: BECCI Behavior Change Counseling Index

Table 5. Quality of delivery according to the observed communication skills

Communication skills
1. Nurse asks open questions
2. Nurse listens actively
3. Nurse emphasises successes (learn from success instead of mistakes)
4. Nurse asks questions rather than giving advice or filling in for the patient
5. Nurse focuses on patient's behaviour and patient's efforts to increase physical activity
Overall communication score

*Five-point Likert-scale, indicating the extent to which the communication skill was applied (0=not at all to 4=to a great extent)

	Consultations			
All	**1**	**2**	**3**	**4**
20:00 (10:00-50.00)	30:00 (20:00-30:00)	20:00 (10:00-45:00)	20:00 (15:00-40:00)	20:00 (12:00-50:00)
18:29 (11:11-37:39)	25:13 (11:40-37:04)	20:34 (10:37-23:16)	16:24 (11:11-28:24)	15:58 (11:28-37:39)
73 (78.5)	93 (100)	87 (93.5)	81 (87.1)	73 (78.5)
18 (19.4)	93 (100)	87 (93.5)	81 (87.1)	75 (80.1)

	BECCI score*, mean ± SD			
	Consultations			
All	**1 (n=10)**	**2 (n=10)**	**3 (n=9)**	**4 (n=13)**
3.1 ± 0.4	2.9 ± 0.7	3.3 ± 0.5	3.1 ± 0.3	3.2 ± 0.6
3.1 ± 0.3	2.9 ± 0.7	3.0 ± 0.0	3.2 ± 0.4	3.3 ± 0.6
2.5 ± 0.7	2.3 ± 1.1	2.6 ± 1.0	2.4 ± 0.7	2.7 ± 0.8
2.4 ± 0.8	2.3 ± 1.1	2.3 ± 1.1	2.3 ± 0.7	2.6 ± 0.9
2.1 ± 0.7	1.9 ± 1.1	1.8 ± 1.0	2.2 ± 0.4	2.2 ± 0.8
3.2 ± 0.4	3.0 ± 0.8	3.1 ± 7.4	3.2 ± 0.4	3.2 ± 0.4
3.2 ± 0.6	3.0 ± 0.8	3.3 ± 0.7	3.4 ± 0.5	3.2 ± 0.6
3.4 ± 0.4	3.2 ± 0.6	3.7 ± 4.9	3.2 ± 0.4	3.5 ± 0.5
2.9 ± 0.5	3.1 ± 0.3	2.8 ± 0.9	3.1 ± 0.3	2.8 ± 0.7
2.9 ± 0.4	2.7 ± 0.7	2.9 ± 0.5	2.9 ± 0.3	2.9 ± 0.5

	Communication skills score*, mean ± SD			
	Consultations			
All	**1 (n=10)**	**2 (n=10)**	**3 (n=9)**	**4 (n=13)**
2.4 ± 0.6	2.3 ± 0.9	2.5 ± 0.9	2.4 ± 0.5	2.5 ± 0.5
3.1 ± 0.4	3.1 ± 0.6	3.2 ± 0.4	3.1 ± 0.3	2.9 ± 0.8
3.0 ± 0.4	2.6 ± 0.5	3.2 ± 0.4	3.3 ± 0.5	3.1 ± 0.6
2.5 ± 0.8	2.3 ± 0.7	2.8 ± 1.0	2.4 ± 0.9	2.4 ± 0.9
3.4 ± 0.5	3.0 ± 0.8	3.4 ± 0.5	3.6 ± 0.5	3.6 ± 0.5
2.9 ± 0.4	2.7 ± 0.5	3.0 ± 0.5	3.0 ± 0.4	2.9 ± 0.5

The overall observed fidelity for the intervention components was 85.6% (81.1%-96.0%), which constitutes high fidelity and for the BCTs 76.8% (0%-100%), which constitutes moderate fidelity (Table 2). Although the majority of intervention components and BCTs were delivered, nurses rarely discussed restructuring the physical environment (0%-7.7%), restructuring the social environment (7.7%-20.0%), use of prompts/cues (22.2%-28.5%) and rarely focussed on past success (0%-30.8%); see Appendix 1.

The median observed duration of all consultation was 18:29 minutes (11:11-37:39). Duration decreased over the consultations with a shorter duration than intended, except for the second consultation which aligned to the protocol (Table 3).

3. Quality of delivery of the Activate intervention

The inter-rater reliability for scoring the BECCI was k 0.83; 95% CI (0.81;0.84) and 88.3% agreement; 95% CI (86.9;89.5), which indicates almost perfect agreement. The overall mean BECCI score was 2.9 (SD 4.4, range 0-4) and mean scores were similar among the four consultations (2.7-2.9); see Table 4. Highest scores were seen on the statements 8 ("Nurse actively conveys respect for patient's choice about behaviour change"); mean score 3.4 (3.2-3.7). Nurses scored lowest on statement 5 ("Nurse uses summaries to bring together what the patient says about the topic"); mean score 2.1 (1.8-2.2).

Inter-rater reliability of scoring the communication skills showed substantial agreement according to kappa (k 0.66; 95% CI (0.57;0.73)) and high percentage agreement (80.3%; 95% CI (75.5;84.7)). The overall score for nurses' communication skills was 2.9 (SD 0.4, range 1-4). Mean scores of the items were similar among the four consultations (Table 5). Nurses scored highest on statement 5 ("Nurse focuses on patient's behaviour and patient's efforts to increase physical activity"); mean score 3.4 (3.0-3.6). Nurses scored lowest on statement 1 ("Nurse asks open questions"); mean score 2.4 (2.3-2.5) and statement 4 ("Nurse asks questions rather than giving advice or filling in for the patient"); mean score 2.5 (2.3-2.8).

4. Beliefs towards delivery of the Activate intervention

All nurses filled out the first questionnaire, the second questionnaire was filled out by 15 (75%) nurses and the latter by 17 nurses (85%).

After nurses followed the one-day training, they felt they were capable, motivated and confident to deliver the intervention. The nurses were positive about the effectiveness of the Activate intervention to improve patients' level of physical activity. Nurses' beliefs towards delivering the Activate intervention did not substantially change over time (Table 6).

Generally, nurses' beliefs about their capability (median 4-5) and confidence (median 5-6) to apply the BCTs were moderate at the start of the one-day training and consistently improved afterwards. Nurses' motivation to apply the BCTs and their beliefs about the effectiveness of the BCTs were considerably high and consistent over time (median 5-7); see Appendix 2. Nurses' beliefs about their capability, motivation, confidence of applying the BCTs and its effectiveness tend to slightly fluctuate over time, as scores slightly decreased after their first individual coaching session (measurement 3) and stabilised or increased after finalising the intervention (measurement 4).

Table 6. Beliefs of nurses towards delivering the Activate intervention

Statements about beliefs of delivering the intervention	**Score*, median (IQR)**			
	Measurement**			
	1	**2 (n=20)**	**3 (n=15)**	**4 (n=17)**
I am capable of supporting patients to enhance their physical activity according to the protocol	Not applicable	6 (2)	6 (1)	7 (1)
I am motivated to support patients to enhance their physical activity according to the protocol	Not applicable	7 (0)	6(2)	7 (2)
I am confident in my ability to deliver the consultations according to the protocol	Not applicable	6 (2)	6 (1)	6 (2)
I am convinced the consultations are effective to enhance patients' physical activity	Not applicable	7 (1)	6 (2)	7 (2)

*Score is measured at a seven-point Likert-scale: 1=completely disagree, 7=completely agree
** Measurement: 1=at the start of the one-day training (not applicable as nurses have not yet received training in the intervention, 2=directly after the one-day training, 3=after the first individual coaching session, 4=after finalising the intervention
Abbreviations: IQR interquartile range

DISCUSSION

This study assessed the fidelity of delivery of the Activate intervention by primary care nurses. The self-reported and observed fidelity of delivery of the prescribed subsequent components of the intervention was high. The observed fidelity of the BCTs constituted moderate fidelity. The overall observed quality of delivery was sufficient as nurses frequently applied most communication skills and behaviour change counselling skills. Nurses felt capable, motivated and confident to deliver the intervention. They considered the intervention, including the BCTs, to be effective in improving patients' level of physical activity. Nurses' beliefs regarding their capability and confidence improved consistently

after nurses received the training. Nurses' beliefs about the effectiveness of the BCTs intervention and their motivation to deliver the intervention remained high over time.

The high self-reported and moderate to high observed fidelity of delivery of the Activate intervention was comparable[26] and higher[9,27,28] than observed in other behavioural interventions including BCTs. These differences might illustrate the inconsistency in the way behaviour change interventions are implemented.[27] The high fidelity of the intervention components and moderate fidelity of the BCTs might be explained by numerous reasons. First, the results of our qualitative study about nurses' perceptions towards intervention delivery revealed that the comprehensive training programme, including a one-day training, training tools and individual coaching, equipped nurses in acquiring the competences to deliver the intervention and boosted their delivery.[13] Given the complexity of behaviour change and nurses' tendency to easily relapse into traditional habits, adding training tools and coaching, additionally to a one-day training, are considered to be necessary and recommended to increase the intervention fidelity.[10] Furthermore, the use of training tools that can be easily used in practice is likely to increase fidelity.[19] Second, nurses were instructed to adhere to the protocol to increase the fidelity. Our qualitative study revealed that they tried to adhere to the consultation structure although there were challenges in delivering the intervention according to the protocol, such as distraction by patients who initiated discussion of other topics.[13] Third, the qualitative study showed that nurses were engaged to acquire skills in behaviour change support as they felt a need to improve their support. Patients' success of the intervention strengthened their engagement towards delivering the intervention and aligned with their intrinsic drive of being a nurse.[13] Furthermore, nurses' engagement towards intervention delivery was confirmed by the results of nurses' beliefs towards delivering the intervention. The fidelity of delivery was highest at the first consultation and the subsequent consultations had slightly lower fidelity. This variation of delivery across consultations might be explained by the fact that nurses rarely discussed restructuring the physical or social environment, the use of prompts/cues and past successes, which were included in the second, third and fourth consultation. Despite the fact that they rarely applied these components and corresponding BCTs, our results showed that nurses considered themselves as capable, motivated and confident to deliver these components and BCTs and considered them to be effective. Furthermore, nurses overestimated their delivery of these components and BCTs compared to those observed. Nurses could have reported these components as being discussed while they only discussed a small proportion or only slightly touched upon these components and BCTs. Probably nurses did not recognise the value and content of discussing these components and BCTs as they were not used to discuss these components and apply these BCTs in their routine practice. Moreover, these components and BCTs might not have been relevant to the needs and concerns of all patients. However, nurses strictly adhered

to deliver the core components and BCTs of the intervention, such as goal setting, action planning, review on behavioural goal(s), feedback on behaviour and self-monitoring. Tailoring the intervention to patients' individual circumstances is inherent to behavioural interventions and might result in applying only the prescribed core components and BCTs in one consultation and thus in not achieving 100% fidelity of delivery.[7,29] Therefore, strict adherence to the core components and BCTs of the intervention could be regarded as successful delivery of the intervention.[30]

To optimise nurses' performance and fidelity, nurses received two individual coaching sessions after they started the Activate intervention and delivered several second consultations (coaching session one) and several third consultations (coaching session two). Our qualitative study revealed that nurses highly valued these coaching sessions as these enhanced their perceived quality of delivery.[13] The coaching primarily focused on their delivery of the core components and BCTs of the intervention, which might account for the lack of their delivery of the less essential components and BCTs.

The self-reported fidelity and observed fidelity showed some discrepancies as nurses regularly rated a lower or higher adherence than observed. Such discrepancy is commonly reported in studies as it is difficult to reflect on one's own performance and underpins the importance of observing the fidelity of delivery.[8,9,26]

Interventions with higher levels of fidelity of delivery are associated with the effectiveness of such interventions.[31] Given the high fidelity of the Activate intervention, it is unlikely that the effectiveness of the intervention is underestimated. However, the fidelity of delivery of the BCTs was moderate and therefore showed room for improvement. In routine care, nurses insufficiently focused on behaviour change support and rarely applied BCTs.[32] Therefore, one could argue whether nurses were able to apply the BCTs correctly, despite the comprehensive training. Furthermore, while most nurses highly adhered to the protocol, their quality of delivery showed room for improvement as nurses easily tend to relapse into their own consultation style of closed-questioning, giving advice and filling in for patients, and nurses' tendency to adjust the intervention to their own beliefs and feelings of comfort.[13] Mastering complex interventions, such as the Activate intervention, requires tailored training tools, regular practice opportunities and ongoing coaching.[13,18] The sufficient quality of delivery might have contributed to the lack of significant improvement of patients' level of physical activity. Using a validated comprehensive scoring list might have enhanced the assessment of the quality of delivery. However, to the best of our knowledge, such a scoring list is lacking and therefore a scoring list to measure the quality of delivery was developed.

Furthermore, the fidelity and quality of delivery varied within and across nurses, which is consistent with routine care[32] and might also have influenced the real delivery of the intervention.[33] Moreover, despite our expectations and efforts, nurses submitted only a low number of audio-recordings across the intervention period, which might have over-estimated the fidelity of delivery as these consultations are likely to represent a 'best case' scenario.[27] Given all methodological factors influencing the assessment of the real fidelity of delivery, it is likely to assume that these factors diluted the effectiveness of the Activate intervention.

Strengths and limitations

This study has several strengths. First, the interrater reliability between observers of the intervention content was almost perfect. All audio-recordings were independently coded by two researchers. One of the researchers was independent from the trial, suggesting that coding is likely to reflect actual performance without influences of knowledge related to the nurses. The assessed intervention content was highly specific due to the detailed protocol and the use of the taxonomy to code the applied BCTs,[21] allowing consistent and systematic coding. These aspects suggest that the observed fidelity is reliable. Second, by definition, fidelity of delivery refers to the extent to which the core intervention components are delivered as intended, which is distinguished from how components are delivered, such as quality of delivery.[7] The addition of the quality assessment is recommended[10] as this has been shown to influence the effectiveness of behaviour change interventions.[17] Furthermore, the assessment of nurses' quality of delivery and beliefs of delivery of the intervention and the BCTs deepened our understanding of how and what nurses delivered.

Some limitations need to be addressed. First, nurses reported their discussed components of each of the consultations, but some nurses did not report non-delivery of specific components by leaving these components unfilled. Afterwards, nurses confirmed these components as non-delivered. This inaccuracy is in line with another study.[26] Furthermore, nurses were not required to report the applied individual BCTs. Requiring nurses to self-report their adherence in a detailed level of BCTs might increase the accuracy but decrease adherence to their self-reports.[26] The high probability of inaccuracy and incompleteness of the self-reported data might have resulted in an overestimation of the self-reported fidelity, which we were not able to verify due to the relatively low number of audio-recordings. This suggests that fidelity of delivery should be observed rather than rely on self-reported fidelity of delivery.[9,26,27]

Second, the 44 analysed audio-recordings represent 13.2% of the total n=334 delivered consultations, which is lower than the 20% minimum recommended.[30] The qualitative evaluation among nurses revealed that nurses perceived recording of consultations as

uncomfortable and felt being judged knowing that their performance was being analysed.[13] Despite that nurses were instructed to randomly audio-tape their consultations, the prudency of nurses towards audio-recording their consultations might have introduced selective inclusion of recorded consultations. Recording all delivered consultations might have reduced nurses' reluctance towards recording their consultations; however, this would probably have led to non-participation of nurses and patients in the trial. By using self-reports we strived to gain good insight into the fidelity of delivery. However, the comparison between the self-reported and observed fidelity urged caution due to this low number of audio-recordings. Although the self-reported fidelity was based on 279 of all 334 (83.5%) of intervention consultations and the observed fidelity showed similar high fidelity, the audio-recordings might not reflect all consultations delivered by nurses. Furthermore, we were not able to specifically compare the self-reported versus the audio-recorded consultations as the audio-recordings were depersonalised.

Third, some nurses did not fill out the checklists or audio-record their consultations. These nurses might have shown lower fidelity of delivery.

Fourth, consultation duration varied across consultations. We did not assess whether consultation duration was associated with the degree of fidelity. Therefore, we could not evaluate whether (in)sufficient time to deliver all subsequent components of the intervention and BCTs has contributed to the degree of fidelity of the prescribed intervention content.

CONCLUSION

Nurses delivered the prescribed subsequent components of the Activate intervention with high fidelity. Nurses applied the BCTs with moderate fidelity. The quality of delivery was sufficient. Nurses felt capable, motivated and confident to deliver the intervention and BCTs and considered the intervention, including BCTs, to be effective in enhancing patients' level of physical activity.

REFERENCES

1. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: The new medical research council guidance. *BMJ*. 2008;337:a1655.
2. Oakley A, Strange V, Bonell C, Allen E, Stephenson J. Process evaluation in randomised controlled trials of complex interventions. *BMJ*. 2006;332(7538):413-416.
3. Moore G, Audrey S, Barker M, et al. Process evaluation of complex interventions: Medical research council guidance. *BMJ*. 2015;350:h1258.
4. Boutron I, Moher D, Altman D, Schulz K, Ravaud P. Extending the CONSORT statement to randomized trials of nonpharmacologic treatment: Explanation and elaboration. *Ann Intern Med*. 2008;148(4):295-309.
5. Nelson M, Cordray D, Hulleman C, Darrow C, Sommer E. A procedure for assessing intervention fidelity in experiments testing educational and behavioral interventions. *J Behav Health Serv Res*. 2012;39(4):374-396.
6. Bellg A, Borrelli B, Resnick B, et al. Enhancing treatment fidelity in health behavior change studies: Best practices and recommendations from the NIH behavior change consortium. *Health Psychol*. 2004;23(5):443-451.
7. Borrelli B. The assessment, monitoring, and enhancement of treatment fidelity in public health clinical trials. *J Public Health Dent*. 2011;71 Suppl 1:S52-S63.
8. Lorencatto F, West R, Bruguera C, Michie S. A method for assessing fidelity of delivery of telephone behavioral support for smoking cessation. *J Consult Clin Psychol*. 2014;82(3):482-491.
9. Hardeman W, Michie S, Fanshawe T, Prevost AT, Mcloughlin K, Kinmonth A. Fidelity of delivery of a physical activity intervention: Predictors and consequences. *Psychol Health*. 2008;23(1):11-24.
10. Borrelli B, Sepinwall D, Ernst D, et al. A new tool to assess treatment fidelity and evaluation of treatment fidelity across 10 years of health behavior research. *J Consult Clin Psychol*. 2005;73(5):852-860.
11. Westland H, Bos Touwen I, Trappenburg JCA, Schröder C, de Wit N, Schuurmans M. Unravelling effectiveness of a nurse-led behaviour change intervention to enhance physical activity in patients at risk for cardiovascular disease in primary care: Study protocol for a cluster-randomised controlled trial. *Trials*. 2017;18(1):79-94.
12. Westland H, Schuurmans MJ, Bos-Touwen ID, et al. Effectiveness of the nurse-led activate intervention in patients at risk for cardiovascular disease in primary care: A cluster-randomised controlled trial. *Submitted*.
13. Westland H, Koop Y, Schröder C, et al. Nurses' perceptions towards the delivery and feasibility of a behaviour change intervention to enhance physical activity in patients at risk for cardiovascular disease in primary care: A qualitative study. *Accepted for publication in BMC Family Practice*.
14. Westland H, Sluiter J, te Dorsthorst S, et al. Patients' experiences with a behaviour change intervention to enhance physical activity in primary care: A mixed methods study. *In revision*.
15. Michie S, van Stralen MM, West R. The behaviour change wheel: A new method for characterising and designing behaviour change interventions. *Implement Sci*. 2011;6:42-5908-6-42.
16. Gearing R, El Bassel N, Ghesquiere A, Baldwin S, Gillies J, Ngeow E. Major ingredients of fidelity: A review and scientific guide to improving quality of intervention research implementation. *Clin Psychol Rev*. 2011;31(1):79-88.
17. Donovan H, Kwekkeboom K, Rosenzweig M, Ward S. Nonspecific effects in psychoeducational intervention research. *West J Nurs Res*. 2009;31(8):983-998.

18. Taylor C, Shaw R, Dale J, French D. Enhancing delivery of health behaviour change interventions in primary care: A meta-synthesis of views and experiences of primary care nurses. *Patient Educ Couns*. 2011;85(2):315-322.
19. Kennedy A, Rogers A, Bowen R, et al. Implementing, embedding and integrating self-management support tools for people with long-term conditions in primary care nursing: A qualitative study. *Int J Nurs Stud*. 2014;51(8):1103-1113.
20. Slootmaker SM, Chin A Paw, M J M, Schuit AJ, van Mechelen W, Koppes LLJ. Concurrent validity of the PAM accelerometer relative to the MTI actigraph using oxygen consumption as a reference. *Scand J Med Sci Sports*. 2009;19(1):36-43.
21. Michie S, Richardson M, Johnston M, et al. The behavior change technique taxonomy (v1) of 93 hierarchically clustered techniques: Building an international consensus for the reporting of behavior change interventions. *Ann Behav Med*. 2013;46(1):81-95.
22. Lane C, Huws-Thomas M, Hood K, Rollnick S, Edwards K, Robling M. Measuring adaptations of motivational interviewing: The development and validation of the behavior change counseling index (BECCI). *Patient Educ Couns*. 2005;56(2):166-173.
23. Noell GH, Gresham FM, Gansle KA. Does treatment integrity matter? A preliminary investigation of instructional implementation and mathematics performance. *J Behav Educ*. 2002;11(11):51-67.
24. Landis JR, Koch GG. The measurement of observer agreement for categorical data. *Biometrics*. 1977;33(1):159-174.
25. Steinijans VW, Diletti E, Bömches B, Greis C, Solleder P. Interobserver agreement: Cohen's kappa coefficient does not necessarily reflect the percentage of patients with congruent classifications. *Int J Clin Pharmacol Ther*. 1997;35(3):93-95.
26. French S, Green S, Francis J, et al. Evaluation of the fidelity of an interactive face-to-face educational intervention to improve general practitioner management of back pain. *BMJ Open*. 2015;5(7):e007886.
27. Lorencatto F, West R, Christopherson C, Michie S. Assessing fidelity of delivery of smoking cessation behavioural support in practice. *Implement Sci*. 2013;8:40-50.
28. Sweeney Magee M, Kale D, Galton S, Hamill A, Gilbert H. Assessing the fidelity of delivery of an intervention to increase attendance at the English stop smoking services. *Implement Sci*. 2016;11(1):166-177.
29. Leventhal H, Friedman M. Does establishing fidelity of treatment help in understanding treatment efficacy? Comment on Bellg et al. (2004). *Health Psychol*. 2004;23(5):452-456.
30. Schlosser RW. On the importance of being earnest about treatment integrity. *AAC Augmentative Altern Commun*. 2002;18(1):36-44.
31. Durlak J, DuPre E. Implementation matters: A review of research on the influence of implementation on program outcomes and the factors affecting implementation. *Am J Community Psychol*. 2008;41(3-4):327-350.
32. Westland H, Schröder C, de Wit J, Frings J, Trappenburg JCA, Schuurmans M. Self-management support in routine primary care by nurses. *Br J Health Psychol*. 2018;23(1),88-107.
33. Mc Sharry J, Williams SL, Taylor C, Michie S, Dale J, French D. (2018, August). Intervention fidelity of a provider delivered walking intervention in primary care: A mixed method study. In E. Toomey, *32th Conference Health Psychology Across the Lifespan: Uniting Research, Practice and Policy.* EHPS, Galway, Ireland.

APPENDIX

Appendix 1. Completed subsequent components and BCTs of the Activate intervention

Completed subsequent components and BCTs according to the protocol: consultation 1			
Prescribed components and included BCTs		**Self-reported (n=85)***	**Observed (n=10)****
		n (%) completed according to protocol	
1.	Explain the purpose of the consultation	85 (100.0)	10 (100)
2.	Discuss the results of the SQUASH and provide information on healthy physical activity	84 (98.8)	10 (100)
	BCT: Feedback on behaviour	NA	9 (90.0)
3.	Ask the patient what they think about their physical activity	84 (98.8)	10 (100)
4.	Provide information on the consequences of healthy and unhealthy physical activity	82 (96.5)	9 (90.0)
	BCT: Information on health consequences	NA	8 (80.0)
5.	Discuss the patient's cardiovascular risk profile and risk factors for cardiovascular diseases (use the patient's workbook)	84 (98.8)	9 (90.0)
6.	Discuss the physical and mental advantages of physical activity	84 (98.8)	10 (100)
	BCT: Information on health consequences	NA	10 (100)
7.	Discuss the patient's motivation for increasing his/her physical activity	82 (96.5)	10 (100)
8.	Discuss what the patient wants to achieve and formulate an overall goal	82 (96.5)	10 (100)
	BCT: Goal setting (outcome)	NA	10 (100)
9.	Discuss what the patient wants to achieve with increasing their physical activity (specific, measurable, achievable, realistic, timely)	82 (96.5)	10 (100)
	BCT: Goal setting (behaviour)	NA	10 (100)
	BCT: Problem solving	NA	8 (80.0)
	BCT: Graded tasks	NA	10 (100)
10.	Discuss the importance of self- monitoring the behaviour and stimulate attaining the activity goal	77 (90.6)	10 (100)
	BCT: Self-monitoring of behaviour	NA	10 (100)
11.	Explain the personal activity log and plan activities using the log	81 (95.3)	10 (100)
	Explain the accelerometer	82 (96.5)	10 (100)
	BCT: Action planning	NA	10 (100)

Appendix 1. Continued

Completed subsequent components and BCTs according to the protocol: consultation 1			
Prescribed components and included BCTs		**Self-reported (n=85)***	**Observed (n=10)****
		n (%) completed according to protocol	
12.	Summarise the discussed content of the consultation	76 (89.4)	6 (60.0)
	Discuss the homework for the next consultation	78 (91.8)	10 (100)
	Plan the next consultation	79 (92.9)	10 (100)
	BCT: Social support	NA	1 (10.0)
Total completed components		81.5 (95.8)	9.6 (96.0)
Total completed BCTs		NA	8.6 (86.0)

*According to the self-reported checklists; **According to the audio-recordings of consultations
Abbreviations: BCTs behaviour change techniques; NA Not applicable; SQUASH Short Questionnaire to Assess Health-enhancing physical activity

Completed subsequent components and BCTs according to the protocol: consultation 2			
Prescribed components and included BCTs		**Self-reported (n=71)***	**Observed (n=10)****
		n (%) completed according to protocol	
1.	Briefly repeat the information discussed during the previous consultation concerning the patient's cardiovascular risk profile and the consequences of physical activity on the patient's risk factors	65 (91.5)	9 (90.0)
	BCT: Information about health consequences	NA	8 (80.0)
2. &	Provide feedback on the patient's physical activity since the first consultation (using the activity log)	69 (97.2)	10 (100)
3.	Review on the extent to which the patient has attained the activity goal as set during the first consultation and provide feedback on the level of goal attainment. Reset the goal if needed	70 (98.6)	9 (90.0)
	BCT: Feedback on behaviour	NA	10 (100)
	BCT: Review behavioural goals	NA	10 (100)
	BCT: Self-monitoring of behaviour	NA	10 (100)
4.	Formulate a personal action plan in order to achieve the activity goal	65 (91.5)	10 (100)
	BCT: Goal setting (behaviour)	NA	9 (90.0)
	Fill out the action plan in the patient's workbook	57 (80.3)	9 (90.0)
	BCT: Action planning	NA	9 (90.0)

Appendix 1. Continued

Completed subsequent components and BCTs according to the protocol: consultation 2			
Prescribed components and included BCTs		**Self-reported (n=71)***	**Observed (n=10)****
		n (%) completed according to protocol	
	BCT: Graded tasks	NA	9 (90.0)
	Discuss factors that help the patient to be physically active, stimulate the patient to make use of these factors and include these in the action plan	63 (88.7)	10 (100)
	BCT: Problem solving	NA	9 (90.0)
	BCT: Focus on past success	NA	0
	Discuss whether changes in the physical environment are needed to stimulate being physically active	56 (78.9)	4 (40.0)
	BCT: Restructuring the physical environment	NA	0
	Stimulate the patient to gain support from their partner/ family/friends to be physically active	57 (80.3)	9 (90.0)
	BCT: Social support (unspecified)	NA	9 (90.0)
	BCT: Social support (practical)	NA	8(90.0)
	Discuss time-management and whether this can be improved to increase level of physical activity	49 (69.0)	8 (80.0)
	BCT: Restructuring the social environment	NA	2 (20.0)
	Discuss the use of prompts/cues/reminders	38 (53.4)	3 (30.0)
	BCT: Prompts/cues	NA	3 (30.0)
	Ask the patient to be committed to achieve the set goal	64 (90.1)	10 (100)
	BCT: Commitment	NA	10 (100)
	BCT: Self-monitoring of behaviour	NA	10 (100)
5.	Summarise the discussed content of the consultation	68 (95.8)	7(70.0)
	Discuss the homework for the next consultation	61 (85.9)	9 (90.0)
	Plan the next consultation	66 (93.0)	9 (90.0)
Total completed components		60.6 (85.4)	8.3 (83.0)
Total completed BCTs		NA	7.9 (79.0)

*According to the self-reported checklists; **According to the audio-recordings of consultations
Abbreviations: BCTs behaviour change techniques; NA not applicable

Appendix 1. Continued

Completed subsequent components and BCTs according to the protocol: consultation 3			
Prescribed components and included BCTs		**Self-reported (n=68)***	**Observed (n=9)****
		n (%) completed according to protocol	
1. &	Discuss whether the patient used the action plan and provide feedback on the patient's physical activity since the first consultation (using the activity log)	65 (95.6)	9 (100)
2.	Review on the extent to which the patient has attained the activity goal as set during the second consultation and provide feedback on the level of goal attainment. Reset the goal if needed	65 (95.6)	9 (100)
	BCT: Feedback on behaviour		9 (100)
	BCT: Review behavioural goals		9 (100)
	BCT: Self-monitoring of behaviour		9 (100)
3.	Adjust the personal action plan (if needed)	60 (88.2)	9 (100)
	BCT: Goal setting (behaviour)		9 (100)
	BCT: Action planning		9 (100)
	BCT: Graded tasks		8 (89.9)
	Discuss factors that help the patient to be physically active, stimulate the patient to make use of these factors and include these in the action plan	55 (80.9)	9 (100)
	BCT: Problem solving		9 (100)
	BCT: Focus on past success		0
	Discuss whether changes in the physical environment are needed to stimulate being physically active	43 (63.2)	4 (44.4)
	BCT: Restructuring the physical environment		0
	Stimulate the patient to gain support from their partner/ family/friends to be physically active	51 (75.0)	8 (88.9)
	BCT: Social support (unspecified)		8 (88.9)
	BCT: Social support (practical)		8 (88.9)
	Discuss time-management and whether this can be improved to increase level of physical activity	41 (60.3)	6 (66.7)
	BCT: Restructuring the social environment		1 (11.1)
	Discuss the use of prompts/cues/reminders	33 (48.5)	2 (22.2)
	BCT: Prompts/cues		2 (22.2)
	Ask the patient to be committed to achieve the set goal	58 (85.3)	9 (100)
	BCT: Commitment		9 (100)
	BCT: Self-monitoring of behaviour		9 (100)

Appendix 1. Continued

Completed subsequent components and BCTs according to the protocol: consultation 3			
Prescribed components and included BCTs		**Self-reported (n=68)***	**Observed (n=9)****
		n (%) completed according to protocol	
4.	Discuss how the patient can prevent relapse into old behaviour	58 (85.3)	6 (66.7)
	Help the patient form new habits	57 (83.8)	9 (100)
	Stimulate the patient to reflect on past successes	61 (89.7)	9 (100)
	Identify barriers and discuss how to deal with these barriers	58 (85.3)	9 (100)
	Discuss how the patients can deal with possible set backs	60 (88.2)	7 (77.8)
	BCT: Problem solving		9 (100)
	BCT: Habit formation		7 (77.8)
	BCT: Focus on past success		0
5.	Summarise the discussed content of the consultation	59 (86.8)	4 (44.4)
	Discuss the homework for the next consultation	57 (83.8)	7 (77.8)
	Plan the next consultation	62 (91.2)	8 (88.9)
Total completed components		55.5 (81.6)	7.3 (81.1)
Total completed BCTs		NA	6.4 (71.0)

*According to the self-reported checklists; **According to the audio-recordings of consultations
Abbreviations: BCTs behaviour change techniques; NA not applicable

Completed subsequent components and BCTs according to the protocol: consultation 4			
Prescribed components and included BCTs		**Self-reported (n=58)***	**Observed (n=13)****
		n (%) completed according to protocol	
1. &	Discuss whether the patient used the action plan and provide feedback on the patient's physical activity since the first consultation (using the activity log)	55 (94.8)	13 (100)
2.	Review on the extent to which the patient has attained the activity goal as set during the second consultation and provide feedback on the level of goal attainment. Reset the goal if needed	57 (98.3)	13 (100)
	BCT: Feedback on behaviour		13 (100)
	BCT: Review behavioural goals		13 (100)
	BCT: Self-monitoring of behaviour		13 (100)

Appendix 1. Continued

Completed subsequent components and BCTs according to the protocol: consultation 4			
Prescribed components and included BCTs		**Self-reported (n=58)***	**Observed (n=13)****
		n (%) completed according to protocol	
3.	Adjust the personal action plan (if needed)	50 (86.2)	13 (100)
	BCT: Goal setting (behaviour)		13 (100)
	BCT: Action planning		13 (100)
	BCT: Graded tasks		10 (76.9)
	Discuss factors that help the patient to be physically active, stimulate the patient to make use of these factors and include these in the action plan	51 (87.9)	12 (92.3)
	BCT: Problem solving		12 (92.3)
	BCT: Focus on past success		1 (7.7)
	Discuss whether changes in the physical environment are needed to stimulate being physically active	41 (70.7)	5 (38.5)
	BCT: Restructuring the physical environment		1 (7.7)
	Stimulate the patient to gain support from their partner/ family/friends to be physically active	47 (81.0)	12 (92.3)
	BCT: Social support (unspecified)		12 (92.3)
	BCT: Social support (practical)		11 (84.6)
	Discuss time-management and whether this can be improved to increase level of physical activity	39 (67.2)	10 (76.9)
	BCT: Restructuring the social environment		1 (7.7)
	Discuss the use of prompts/cues/reminders	42 (72.4)	5 (38.5)
	BCT: Prompts/cues		5 (38.5)
	Ask the patient to be committed to achieve the set goal	51 (87.9)	13 (100)
	BCT: Commitment		13 (100)
	BCT: Self-monitoring of behaviour		13 (100)
4.	Discuss how the patient can prevent relapse into old behaviour	57 (98.3)	12 (92.3)
	Help the patient form new habits	54 (93.1)	12 (92.3)
	Stimulate the patient to reflect on past successes	55 (94.8)	12 (92.3)
	Identify barriers and discuss how to deal with these barriers	53 (91.4)	12 (92.3)
	Discuss how the patients can deal with possible set backs	53 (91.4)	12 (92.3)
	BCT: Problem solving		13 (100)
	BCT: Habit formation		10 (76.9)
	BCT: Focus on past success		4 (30.8)

Appendix 1. Continued

Completed subsequent components and BCTs according to the protocol: consultation 4			
Prescribed components and included BCTs		**Self-reported (n=58)***	**Observed (n=13)****
		n (%) completed according to protocol	
5.	Summarise and discuss how the patient will maintain being active	56 (96.6)	8 (61.5)
	Stimulate the use of prompts/cues/reminders	44 (75.9)	5 (38.5)
	BCT: Prompts/cues	NA	5 (38.5)
	Formulate an action plan for the future	55 (94.8)	12 (92.3)
	If applicable, plan to re-discuss physical activity during the next routine consultation	55 (94.8)	11 (84.6)
	Stimulate the patient to keep up with the activity log and advice the patient to use an app or other activity tracker to monitor his/her behaviour	52 (89.7)	11 (84.6)
Total completed components		50.9 (87.7)	10.7 (82.2)
Total completed BCTs		NA	9.3 (71.3)

*According to the self-reported checklists; **According to the audio-recordings of consultations
Abbreviations: BCTs behaviour change techniques; NA not applicable

Appendix 2. Beliefs of nurses towards applying the BCTs

Statements about beliefs per BCT	Score*, median (IQR)			
	Measurement**			
	1 (n=20)	2 (n=20)	3 (n=15)	4 (n=17)
Goal setting (behaviour)				
Beliefs about own capability to apply the BCT	5 (2)	6 (1)	7 (1)	7 (1)
Beliefs about own motivation to apply the BCT	7 (1)	7 (1)	6 (1)	7 (1)
Beliefs about own confidence to apply the BCT	6 (1)	6 (1)	6 (2)	6 (2)
Beliefs about the efficacy of the BCT	6 (1)	7 (1)	7 (1)	7 (1)
Problem-solving (includes barrier identification and relapse prevention)				
Beliefs about own capability to apply the BCT	5 (2)	6 (2)	6 (1)	6 (1)
Beliefs about own motivation to apply the BCT	6 (2)	7 (0)	6 (1)	7 (1)
Beliefs about own confidence to apply the BCT	5.5 (2)	6 (1)	6 (2)	6 (2)
Beliefs about the efficacy of the BCT	6 (1)	7 (1)	7 (1)	7 (1)
Goal setting (outcome)				
Beliefs about own capability to apply the BCT	5 (3)	6 (1)	6 (2)	6 (2)
Beliefs about own motivation to apply the BCT	6.5 (1)	7 (1)	6 (1)	7 (2)
Beliefs about own confidence to apply the BCT	6 (1)	7 (1)	6 (2)	6 (2)
Beliefs about the efficacy of the BCT	6 (2)	7 (1)	7 (2)	7 (2)
Action planning				
Beliefs about own capability to apply the BCT	5 (3)	6 (1)	6 (2)	7 (2)
Beliefs about own motivation to apply the BCT	6 (1)	7 (0)	6 (1)	7 (1)
Beliefs about own confidence to apply the BCT	6 (1)	6 (2)	6 (2)	6 (2)
Beliefs about the efficacy of the BCT	6 (2)	7 (1)	6 (1)	7 (1)
Review behavioural goal(s)				
Beliefs about own capability to apply the BCT	5 (2)	6 (1)	6 (2)	7 (1)
Beliefs about own motivation to apply the BCT	7 (1)	7 (1)	6 (2)	7 (1)
Beliefs about own confidence to apply the BCT	5.5 (1)	6 (1)	6 (2)	6 (1)
Beliefs about the efficacy of the BCT	6 (2)	7 (1)	6 (2)	7 (1)
Commitment				
Beliefs about own capability to apply the BCT	4 (1)	6 (2)	6 (1)	6 (2)
Beliefs about own motivation to apply the BCT	6 (2)	7 (1)	6 (0)	6 (2)
Beliefs about own confidence to apply the BCT	5 (2)	6 (1)	6 (1)	6 (2)
Beliefs about the efficacy of the BCT	6 (3)	6.5 (1)	6 (3)	6 (2)
Feedback on behaviour				
Beliefs about own capability to apply the BCT	5 (3)	6 (2)	6 (2)	7 (1)
Beliefs about own motivation to apply the BCT	6 (1)	7 (0)	6 (1)	7 (2)
Beliefs about own confidence to apply the BCT	5 (1)	6 (1)	6 (1)	6 (2)
Beliefs about the efficacy of the BCT	6 (2)	7 (1)	6 (2)	7 (2)

Appendix 2. Continued

Statements about beliefs per BCT	Score*, median (IQR)			
	Measurement**			
	1 (n=20)	2 (n=20)	3 (n=15)	4 (n=17)
Self-monitoring of behaviour				
Beliefs about own capability to apply the BCT	5 (2)	6 (2)	6 (2)	7 (2)
Beliefs about own motivation to apply the BCT	6 (2)	7 (0)	6 (2)	7 (1)
Beliefs about own confidence to apply the BCT	5 (2)	6 (1)	6 (2)	6 (2)
Beliefs about the efficacy of the BCT	6.5 (2)	7 (1)	6 (2)	7 (1)
Social Support (unspecified)				
Beliefs about own capability to apply the BCT	5 (2)	6 (2)	6 (2)	6 (1)
Beliefs about own motivation to apply the BCT	6 (2)	7 (1)	6 (2)	7 (1)
Beliefs about own confidence to apply the BCT	6 (1)	7 (1)	6 (2)	7 (1)
Beliefs about the efficacy of the BCT	6 (1)	7 (1)	6 (1)	7 (1)
Social support (practical)				
Beliefs about own capability to apply the BCT	5 (2)	6 (2)	6 (1)	6 (1)
Beliefs about own motivation to apply the BCT	6 (2)	7 (1)	6 (2)	7 (1)
Beliefs about own confidence to apply the BCT	5 (1)	6 (1)	6 (1)	6 (2)
Beliefs about the efficacy of the BCT	6 (2)	7 (1)	6 (2)	7 (1)
Information about health consequences				
Beliefs about own capability to apply the BCT	6 (1)	6 (1)	6 (1)	7 (1)
Beliefs about own motivation to apply the BCT	6.5 (1)	7 (0)	6 (1)	7 (1)
Beliefs about own confidence to apply the BCT	6 (1)	7 (1)	7 (1)	7 (1)
Beliefs about the efficacy of the BCT	5.5 (2)	7 (2)	6 (2)	7 (2)
Prompts/cues				
Beliefs about own capability to apply the BCT	4 (2)	6 (1)	6 (2)	6 (2)
Beliefs about own motivation to apply the BCT	6 (3)	7 (1)	6 (2)	6 (2)
Beliefs about own confidence to apply the BCT	5 (2)	6 (2)	6 (2)	6 (2)
Beliefs about the efficacy of the BCT	6 (3)	7 (1)	5 (2)	7 (2)
Habit formation				
Beliefs about own capability to apply the BCT	4 (2)	6 (2)	5 (1)	6 (2)
Beliefs about own motivation to apply the BCT	7 (1)	7 (0)	6 (2)	7 (2)
Beliefs about own confidence to apply the BCT	5.5 (1)	7 (2)	5 (2)	6 (2)
Beliefs about the efficacy of the BCT	5.5 (1)	7 (1)	6 (2)	6 (2)
Graded tasks				
Beliefs about own capability to apply the BCT	5 (1)	6 (2)	6 (2)	7 (1)
Beliefs about own motivation to apply the BCT	7 (2)	7 (0)	6 (2)	7 (2)
Beliefs about own confidence to apply the BCT	5.5 (1)	6.5 (1)	6 (2)	7 (2)
Beliefs about the efficacy of the BCT	7 (1)	7 (1)	6 (2)	7 (1)

Appendix 2. Continued

Statements about beliefs per BCT	Score*, median (IQR)			
	Measurement**			
	1 (n=20)	2 (n=20)	3 (n=15)	4 (n=17)
Restructuring the physical environment				
Beliefs about own capability to apply the BCT	4 (2)	6 (1)	6 (1)	6 (1)
Beliefs about own motivation to apply the BCT	6 (2)	7 (1)	6 (1)	6 (2)
Beliefs about own confidence to apply the BCT	5.5 (1)	6 (2)	6 (2)	6 (1)
Beliefs about the efficacy of the BCT	6 (2)	6.5 (1)	6 (2)	6 (2)
Restructuring the social environment				
Beliefs about own capability to apply the BCT	4 (2)	6 (2)	6 (2)	6 (2)
Beliefs about own motivation to apply the BCT	6 (1)	7 (1)	6 (2)	6 (1)
Beliefs about own confidence to apply the BCT	5 (2)	6 (2)	6 (2)	6 (1)
Beliefs about the efficacy of the BCT	6 (2)	6 (2)	6 (2)	6 (2)
Focus on past success				
Beliefs about own capability to apply the BCT	5 (2)	6 (1)	6 (2)	7 (1)
Beliefs about own motivation to apply the BCT	6.5 (1)	7 (0)	6 (1)	7 (1)
Beliefs about own confidence to apply the BCT	6 (2)	7 (1)	6 (1)	7 (1)
Beliefs about the efficacy of the BCT	6 (2)	7 (1)	6 (1)	7 (1)

*Score is measured at a seven-point Likert-scale: 1=completely disagree to 7=completely agree

** Measurement: 1=at the start of the one-day training, 2=directly after the one-day training, 3=after the first individual coaching session, and 4=after finalising the intervention

Abbreviations: BCTs behaviour change techniques; IQR interquartile range

CHAPTER 8

General Discussion

GENERAL DISCUSSION

Self-management is widely embedded in health and governmental policies. Interventions to support the self-management capacity of patients with a chronic condition are increasingly evaluated. Although self-management interventions have proven their effectiveness, how these interventions work and which patients benefit is still not fully understood. Furthermore, it remains unclear whether self-management support is integrated in the primary care context and whether primary care nurses have the competences to adequately support patients' self-management.

The studies reported in this thesis aimed to unravel how self-management interventions work and which patients benefit from such interventions within the context of primary care. We aimed to examine how and to what extent primary care nurses provided self-management support in their routine consultations. Consequently, nurses' limited and unstructured self-management support emphasised the need to better equip them with the key competences to provide self-management support.

We comprehensively developed and evaluated the nurse-led Activate intervention, in which we deliberately deducted the complexity of self-management interventions by targeting the intervention at one self-management component (physical activity) in a heterogeneous subgroup of primary care patients at risk for cardiovascular diseases. As adequate self-management requires behaviour change in both patients and nurses, the Activate intervention was targeted at changing behaviour of both patients and nurses. The development of the intervention was guided by the Behaviour Change Wheel (BCW), as theoretical framework, using behaviour change techniques (BCTs), as active ingredients.[1,2] The methodological design of the Activate intervention allowed us to comprehensively evaluate the effectiveness of the intervention. This evaluation enabled our understanding of how the intervention worked within the context of primary care and which patients benefitted.

In this chapter we reflect on the main findings and we provide recommendations for clinical practice, education, policymakers and future research.

MAIN FINDINGS

- Self-management support of patients with a chronic condition, provided by nurses in primary care, is addressed briefly and fragmented during routine consultations and lacks focus on behaviour change and explicit and consistent use of BCTs (chapter 2).
- The Activate intervention helped patients to increase their physical activity, but did not significantly increase patients physical activity and other patient-related outcomes (chapter 6).
- Favourable effects were observed in patients with a low acuity of perceived social support and in patients with a low baseline level of physical activity (chapter 6).
- Patients highly appreciated the combination of self-monitoring tools and being supported by their own nurse to increase their physical activity (chapter 4).
- Having a trustful relationship with their nurse was crucial to increase their physical activity as this relationship prompted patients to participate in the intervention and nurses' support incentivised patients' to attain their goals (chapter 4).
- All patients felt they had benefitted from the intervention, irrespectively to their objective change in physical activity (chapter 4).
- Nurses were dedicated to support patients to enhance their physical activity as this aligns with their intrinsic drive of being a nurse (chapter 5).
- Patients' motivation to participate in the intervention, patients' success of the intervention and nurses' personal development enhanced nurses' engagement towards delivering the Activate intervention (chapter 5).
- Nurses ascertained they were facilitated by the training programme to acquire essential competences to deliver the intervention and to change their routine practice towards a more patient-centred consultation style. The training programme included a one-day training, coaching sessions and training tools (chapter 5).
- Implementation in routine care was challenging because of nurses' perceived difficulties in maintaining the acquired skills and time constraints in routine practice (chapter 5).
- The comprehensive evaluation of the fidelity of the Activate intervention showed that nurses delivered most intervention components as intended and that nurses' beliefs about their capability, motivation, confidence and effectiveness towards the delivery of the Activate intervention and BCTs increased during the trial (chapter 7).
- The fidelity assessment of the components of the intervention demonstrated a high fidelity level and the applied BCTs demonstrated a moderate fidelity level. However, several methodological factors and nurses' variation in complex behaviour change delivery might have affected the quality of delivery and therefore might have diluted the effectiveness of the Activate intervention (chapter 7).

REFLECTIONS ON NURSES' CURRENT STATUS OF SELF-MANAGEMENT SUPPORT IN ROUTINE PRIMARY CARE

Reflecting on the current status of self-management support provided by nurses has become a matter of urgency as self-management is widely embedded in the governmental and health policies, general nursing competence profile, and nurse and patient education. In all of these, nurses are designated to adopt self-management. However, a clear and uniform description of what self-management specifically entails, its meaning in nurses' daily practice and accompanying competences is lacking.[3-5] In an attempt to unravel the effectiveness of self-management interventions, we felt the urge to enhance our understanding of the consequences of self-management for nurses' daily practice and their currently provided self-management support. Therefore, prior to the start of the development of the Activate intervention, we operationalised the concept of self-management (chapter 2). We identified two general self-management topics: 'understanding the disease', and 'understanding emotional and social consequences of the disease', and seven self-management behaviours: 'symptom monitoring', 'symptom and exacerbation management', 'physical activity', 'dietary intake', 'medication management', 'smoking cessation', and 'alcohol use'. Subsequently, we examined how and to what extent nurses provided self-management support in primary care, revealing that nurses addressed health and self-management topics briefly and in a fragmented manner throughout their consultations. We found that nurses seldom focused on behaviour change, and their explicit and consistent use of BCTs was low. Nurses continuously multi-tasked and rapidly shifted between medical examinations and health topics according to the healthcare standards, without leaving room for an in-depth focus on patients' perspectives and self-management topics. Nurses tend to prioritise the optimisation of patients' medical treatment in which they generally educated patients about monitoring and controlling their condition and gave advice. This advice was mainly based on healthcare standards, input from patients' own perspective was lacking. This aligns with a traditional expert-oriented consultation style and is also seen in other studies.[6-8]

The lack of self-management support confirms that self-management is not yet well-integrated in the complex healthcare structure of primary care.[9-11] Nurses are not specifically trained in self-management support and focus on healthy behaviour including applying and tailoring BCTs (chapter 2) and therefore lack in the required competences to provide such support. Major prerequisites of proper implementation of self-management by nurses are: 1. having the required competences to provide self-management support tailored to the context of primary care; 2. acknowledging nurses' eminent role and tasks in self-management support in patients; 3. a shared understanding of self-management, nurses' role and specific tasks in self-management by health and governmental policymakers, nurses and other healthcare professionals involved in chronic care;[7] and 4. having the

autonomy to align the content, frequency and dose of their support on patients' context, needs and preferences rather than strictly following clinical routine. Meeting these prerequisites is conditional to enhance the adoption of adequate self-management support by nurses in routine primary care.

REFLECTIONS ON UNRAVELLING A SELF-MANAGEMENT INTERVENTION IN PRIMARY CARE

We conducted a cluster-randomised controlled trial (RCT) to evaluate the effectiveness of the Activate intervention and to identify which patients benefitted from the intervention. The results showed that the Activate intervention increased patients' physical activity over time; however, this increase was not significant. Furthermore, the intervention did not affect patients' sedentary behaviour, self-efficacy for physical activity, activation for self-management and health status. Patients with a low acuity of perceived social support and patients with a low baseline activity level were likely to benefit more from the intervention (chapter 6). However, these results should be interpreted with caution due to power issues, as the number of patients according to the power calculation proved unattainable. Despite our expectations and efforts and commitment of participating general practices, the majority of invited patients were not willing to participate in the trial. Patients reported several reasons for not participating, such as having a relatively high level of physical activity, being unaware of their inactivity, having other priorities in life, lacking motivation, participating takes too much time, and/or already being involved in research (chapter 4).

The effectiveness of the intervention was diluted by several methodological factors, such as 1. the objectively measured high baseline level of physical activity of patients in both the intervention and control group, which easily led to a ceiling level and might indicate a Hawthorne effect, 2. patients in the intervention group got used to daily wearing the accelerometer, which could have decreased patients' social desirable behaviour during the follow-up measurements compared to the control group, 3. nurses in the control group could have upgraded their usual care as they could not be blinded, and 4. participating general practices might have been more prone to behaviour change beforehand compared to non-participating practices (chapter 6). Another methodological issue we faced with was the possible occurrence of selective inclusion. Despite our instructions to check all scheduled patients for eligibility in agreement with the general practitioner, nurses tend to invite patients to participate who they experienced as motivated to change their behaviour during prior consultations. This suggests that patients had unequal changes and opportunities to be exposed to the intervention,[12] and patients who are most in need for the intervention might have missed out the intervention.

Furthermore, although the fidelity assessment of the components of the intervention demonstrated a high fidelity level and the applied BCTs demonstrated a moderate fidelity level, several methodological factors and nurses' variation in complex behaviour change delivery might have affected the quality of delivery and therefore might have diluted the effectiveness of the Activate intervention (chapter 7). Mastering the competences to deliver the intervention within a relatively short trial period and few patients to practice with requires tailored training tools, ongoing training and coaching. In particular, when nurses in their routine insufficiently focused on behaviour change and rarely applied BCTs (chapter 2).

In the appreciation of our findings; however, also several methodological factors can be addressed that strengthen our work. The guidance of the BCW in the development of the intervention and training programme for nurses enhanced the selection and evaluation of BCTs -as active ingredients- to target behaviour change in patients and nurses in the context of primary care and enhanced the reproducibility.[1,2]

We conducted a thorough process evaluation alongside the trial. In this process evaluation we used several methodological designs to assess 1. patients' experiences with their participation in the intervention, 2. nurses' perspectives towards delivering the intervention and towards the feasibility of the intervention and 3. the intervention fidelity (chapter 3, 4,5,7). Such a comprehensive development and process evaluation is highly acknowledged[13-16] and inevitable to deepen our understanding of the non-significant results of the Activate trial.[13,17] The process evaluation revealed on the one hand essential insight into the active and most valued ingredients of the intervention and training programme, and on the other hand contextual factors influencing behaviour and feasibility of the intervention. Furthermore, the conducted process evaluation identified the contribution of individual components to patients' and nurses' perceived success of the intervention. These individual components often result in tiny changes which each in themselves produce apparently marginal gains accumulating to meaningful successes.[18]

Given nurses' insufficient focus on behaviour change and rare application of BCTs in routine care (chapter 2), we focused in the Activate trial on equipping nurses with the key competences to deliver the intervention including the BCTs, and on evaluating how the BCTs were valued by patients and nurses rather than to understand the underlying working mechanism of the BCTs.

Although a RCT is regarded as the gold standard study design to evaluate the effectiveness of interventions,[19] we argue the suitability of this design to evaluate the effectiveness of a complex behavioural intervention in primary care. RCTs usually require large sample sizes

to achieve adequate statistical power. Conducting a cluster-RCT in the context of Dutch primary care seems almost unachievable as enrolling general practices and patients was complex to achieve, and therefore the power calculation proved unattainable, which jeopardised the generalisability of the results. To illustrate this: we invited 478 general practices until 31 agreed to participate (chapter 6). General practices reported several reasons for their non-participation, such as lack of availability of the nurse due to busy daily practices, sick leave, other priorities, and already being involved in other research. However, most general practices did not respond to our invitation. Nurses invited approximately 731 eligible patients to enrol 202 patients.

RCTs are particular considered suitable in drug development. However, unlike drug development, complex behavioural interventions do not follow a linear sequence.[13] RCTs estimate the average effect of an intervention, which often conceals the variance within patients on the primary outcome.[20] This variance in patients facilitates the identification of working mechanisms and within and between patient variability.[13] The use of alternative designs, such as N-of-1 trials, quasi-experimental or observational designs facilitates an evaluation in individual patients and provides data on the variation of the effect. N-of-1 trials offer an alternative design to evaluate the effectiveness of separate ingredients in individual patients and provide data on the variation of the effect. In such trials, individual patients are randomly allocated to conditions and are exposed to both the ingredients and control group in a pre-determined order and time series.[13] Furthermore, observational studies and quasi-experimental studies, if well-designed and adjusted for confounding, can be used to provide insight into the effectiveness of interventions in real-world environment, variability in the delivery of healthcare, and interpretation of heterogeneity among patients.[21,22] The use of such alternative designs might decrease the recruitment issues of general practices and patients, enhances the enrolment of patients who could actually benefit from the intervention, the Hawthorne effect in follow-up measurements and the risk of contamination of the intervention in the control group.

REFLECTIONS ON CHANGING PATIENTS' BEHAVIOUR

To adequately self-manage their chronic condition, patients need to adopt healthy behaviour, which often means that patients need to change their behaviour which is difficult to achieve and support from their nurse is needed (chapter 4). The interviews with patients revealed that having a trustful relationship with their nurse was inevitable to work on behaviour change as patients -beyond their good intentions- struggle with taking action. Irrespective of their objective change in activity levels, patients perceived benefit from their participation. Experiencing success of the intervention enhanced patients' motiva-

tion and confidence to perpetuate in increasing their physical activity. Patients perceived several active ingredients from nurses' support as most important, including the following BCTs: goal setting, action planning, feedback, reviewing goals, self-monitoring and social support. In addition to nurses' support, the use of self-monitoring tools (the accelerometer and activity log) was crucial for raising patients' awareness of the amount and intensity of physical activity and challenged them to compete with themselves. The interviews with nurses (chapter 5) revealed that nurses also highly valued these BCTs and perceived these BCTs as effective to change patients' behaviour. Recently, the effectiveness of BCTs -as active ingredients - is increasingly evaluated and showed that these BCTs are associated with behaviour change.[23-29] Other BCTs included in the Activate intervention were perceived as unnecessary, such as explicit use of prompt and cues and some BCTs were hardly applied by nurses, such as restructuring the social and physical environment (chapter 4, 5, 7).

Furthermore, our findings confirmed that patients' behaviour change and building activities in daily life was challenged by other factors, such as enjoyment, physical constraints, everyday problems, personal circumstances (such as taking care for a family member) and weather conditions.[30-32]

As such, nurses need to focus on integrating the active ingredients which are highly valued by patients and nurses and which are associated with effectiveness into their consultations. Since nurses are not used to apply these BCTs in their current support (chapter 2), comprehensive and ongoing training in how to explicitly integrate these BCTs in their support is required. In addition, interceding in nurses' tendency to give advice, inform and educate patients, ask closed questions and filling in for the patient is needed. Furthermore, nurses need to be aware of the impact of experiencing success on patients' motivation and confidence (e.g. by setting attainable goals) to perpetuate in changing their behaviour. Nurses need to meet patients' preferences and patients' personal circumstances which might jeopardise patients' likelihood of changing their behaviour and maintaining their behaviour.[33-35]

Generally, patients felt increasingly more confident to goal attainment and highly valued included BCTs targeting self-efficacy. Patients also felt that nurses' support incentivised them by taking responsibility for their goal attainment and having a trustful relationship facilitated patients to being honest without being judged. In addition to our gained understanding of the active ingredients of the intervention, such findings enhance our understanding of how the intervention facilitated patients in adopting healthy behaviour.

REFLECTIONS ON EQUIPPING NURSES WITH COMPETENCES TO PROVIDE SELF-MANAGEMENT SUPPORT

The finding that self-management support is not yet integrated in routine care underlines the discrepancy between what is expected from nurses and the reality of routine self-management support (chapter 2). Given this current status of nurses' self-management support and the complex nature of changing nurses' behaviour, it seems unreasonable to assume that trained nurses automatically expose patients to self-management support in a way patients could benefit from such support. Therefore, equipping nurses with the required knowledge and skills to adequately deliver self-management support was regarded as a major component of the Activate intervention (chapter 3), which is rather uncommon in intervention development. We comprehensively developed a training programme for nurses by using the BCW. The conducted behavioural analysis to understand what nurses needed to change in order to deliver the intervention, revealed that we needed to target nurses' capability, opportunity and motivation -as all COM-B components- in the training programme to equip them with the required competences to deliver the intervention. Subsequently, we identified 21 BCTs and structured these BCTs within the training programme, which consisted of a one-day training, two individual coaching sessions, instructional videos showing how to deliver the BCTs of the intervention the individual consultations, a handbook with example sentences and checklists of what to do when (chapter 3). The interviews with nurses (chapter 5) revealed that nurses felt well-equipped with these different training components. Nurses felt engaged to deliver the intervention as they felt equipped by the training, coaching sessions and training tools to increase their coaching skills and experienced that patients benefitted from the intervention. This fulfilled their need to enhance their skills to support patients and aligned with their beliefs about good clinical care by improving patients' health outcomes. Nurses' beliefs about the efficacy and feelings of discomfort regarding specific elements influenced their tendency to adjust the intervention content or the use of training components, such as the coaching sessions. These findings confirm the influence of nurses' beliefs on their openness to change their behaviour.[36-38] Such beliefs are challenging to influence as nurses are often wedded to what they do.[37,38] This also suggests that nurses' beliefs may jeopardise the adoption of principles and delivery of such behavioural interventions. For example, nurses thought that patients expect and prefer their traditional nursing role in behaviour change support and nurses tended to adjust the content of the intervention if they had personal doubts about specific elements (chapter 5).

Moreover, the extent to which patients' were motivated and perceived success of the intervention influenced nurses' engagement towards delivering the intervention. Nurses reported that participation in the trial enabled their personal development and changed their routine practice, as they incorporated newly acquired skills, particularly those they regarded to be efficacious, in their routine practice with other patients. However, our results confirmed that is was difficult to perpetuate in applying the acquired knowledge and skills as nurses tended to easily relapse into their traditional consultation style and skills, which is similar to other studies.[38] Accomplishing and maintaining their acquired skills was also complicated by the fact that the participating nurses were not specifically trained in applying and tailoring BCTs prior to their enrolment in the Activate trial and they were not used to explicitly apply BCTs in a structured way. Additionally, nurses' delivery of the intervention and the quality of delivery varied within and across nurses (chapter 2, 7). This suggests that considering the complexity of behaviour change and nurses' insufficient focus on behaviour change and application of BCTs in their routine care, mastering and delivering the intervention with at least an equal quality level require tailored training tools, regular practice opportunities and ongoing coaching. This underlines the need for comprehensive, tailored and ongoing training of nurses in providing such interventions and enhancing self-management support in routine care.

Furthermore, our findings confirmed that the adoption of such support outside a research context is challenged by contextual factors. For example, nurses are faced with a busy daily practice in which they have to adhere to clinical guidelines rather than having the autonomy to adjust their content, frequency and dose to patients' preferences and needs and provide more patient-centred support.

REFLECTIONS ON THE OPPORTUNITIES OF THE ACTIVATE INTERVENTION

Whilst the Activate intervention was unproven to increase patients' level of physical activity and other patient-related outcomes, most patients and nurses held strong views about the efficacy of the intervention and its feasibility (chapter 4, 5, 6). Understanding the magnitude and sustainability of the trial results in light of the complex nature of changing behaviour in both patients and nurses and the complex context of primary care is challenging.[39] The conducted process evaluation enabled us to understand the value of the intervention for both patients and nurses. This emphasises the relevance to further explore the opportunities of structured nurse-led delivery of behaviour change support in the context of primary care rather than dismiss the intervention prematurely.[40,41] As self-management includes adopting multiple healthy behaviours, such as healthy nutri-

tion, smoking cessation and managing medication, for which patients need support from their nurse, there is a need for further development of generic self-management interventions which focusses on nurses' eminent role in enhancing success of these interventions. Training of nurses and understanding the context in which interventions need to be delivered is crucial to enhance the effectiveness and implementation of these interventions.[38,42-44]

CONCLUSION

To meet the promising expectations of self-management in the context of primary care practice, behaviour change is required in patients, nurses, educators, health and governmental policymakers as well as in researchers, which induces conflicting interests and changes of the healthcare system. To enhance the implementation of self-management in primary care, recommendations are provided for clinical practice, education, policymakers and future research.

CONCLUSION AND RECOMMENDATIONS FOR CLINICAL PRACTICE

Self-management is currently not well integrated in the routine care of primary care nurses. Nurses are faced with the challenge to incorporate self-management support in their already busy clinical practice. Furthermore, the lack of clarity and uniformity in what the concept of self-management entails and insufficient knowledge and skills training to acquire the needed competences to provide adequate self-management support hamper a structural integration of self-management. Our research confirmed that nurses were dedicated to provide support as this aligns with their intrinsic drive of being a nurse. Nurses tend to have strong perceptions of patients' needs and struggle with reflecting on and changing their own consultation style and structured and explicit use of BCTs in their support. To enhance the integration of structured self-management in clinical practice, all primary care nurses should be adequately equipped with competences to provide self-management support including support for behaviour change. As a follow-up to the Activate intervention, we developed and piloted a self-management training programme for nurses for which we received an external grant. In this training we integrated the gained knowledge and insights of the Activate trial, extrapolated and refined the content of Activate intervention to the concept of self-management; see Box 1. We recommend continuing the pilot of the training and optimising the training based on evaluation of the pilot before broadly integrate the training in the vocational training and nursing education.

Furthermore, to properly integrate self-management in primary care adequate reimbursement is required for such a training programme and ongoing support as well as for the autonomy to adjust the content, frequency and dose of consultations. Besides integration in nurses' consultations, self-management also needs to be embedded in the support of other involved healthcare professionals in close collaboration with nurses to ascertain continuity of care and effectiveness of self-management support.

CONCLUSION AND RECOMMENDATIONS FOR EDUCATION

Equipping nurses with the competences for self-management support requires a main role for education. To adequately develop training programmes and train nurses in providing self-management support, all components of the COM-B (capability, opportunity, motivation-behaviour) model are applicable for educators: 1. Motivation. Educators need to be convinced that self-management training is needed and important to enhance nurses' self-management support. Educators need a shared understanding on self-management and its operationalisation into general topics and behavioural topics, resulting in alignment in what is taught about self-management. 2. Capability. Educators need to be well-equipped in teaching self-management support and supervising nurses in providing self-management support. This could be accomplished by the use of the Train the Trainer principle, where educators are trained by experts in self-management support and subsequently the educators train and support other educators. 3. Opportunity. A comprehensive training programme, such as proposed in Box 1, need to be offered as vocational training of primary care nurses. Moreover, self-management should be explicitly embedded in the curriculum of the vocational programme in nursing and the bachelor programme in nursing. This enables nurse students to adopt the principles underlying self-management and accompanying attitude and facilities their reflection on how they provide support. Furthermore, students can learn to act as an innovator and role model towards self-management support, which could enable the implementation of self-management in routine care.

CONCLUSION AND RECOMMENDATIONS FOR POLICYMAKERS

Health and governmental policymakers need to acknowledge that clinical guidelines lack a clear and uniform definition of self-management and that its consequences for clinical practice are not described. Therefore, they need to adopt and integrate a clear and uniform definition of self-management and its explicit operationalisation (e.g. into general and behavioural self-management topics) into their policy and healthcare guide-

lines. Furthermore, policymakers need to acknowledge that adopting self-management skills, including behaviour change is complex to achieve and supporting patients in their self-management requires a systematic approach. Integrating self-management into the clinical guidelines implies interference with other prescribed standardised clinical demands that need to be addressed within the already limited consultation time. If health and governmental policymakers want to successfully integrate self-management in clinical practice, then they should reimburse nurses and other healthcare professionals working in general practices in sufficient consultation time, the autonomy to adjust the content, frequency and dose of consultations as well as in proper training and continuous support. Furthermore, realistic expectations and evaluation of the implementation of self-management in clinical practice are needed.

To enhance further understanding of the effectiveness of self-management in primary care and its working mechanism, governmental policymakers must facilitate researchers in conducting alternative study designs to RCTs, such as N-of-1 trials.

CONCLUSION AND RECOMMENDATIONS FOR FUTURE RESEARCH

The results of our studies confirm the challenging nature of unravelling how self-management interventions work and which patients benefit. To understand how these interventions work, researchers need to target behavioural interventions at both nurses' and patients' behaviour as they both play a pivotal role in this understanding. In the development of self-management interventions, the equipment of nurses with the required competences to provide the support should be a major component of the intervention and should be well and specifically developed and reported. A theoretical framework, such as the BCW, need to guide the development and evaluation of self-management interventions. Researchers need to pre-specify theory-informed hypotheses to allow theory testing and thereby our understanding of the active ingredients and their underlying working mechanisms. The development, active ingredients and proposed working mechanisms should be described in detail to enhance replication and our understanding of how these interventions work. Furthermore, our gained knowledge about the effectiveness of the Activate intervention, methodological, patients, nurses and contextual factors, can guide researchers in future studies in the development of such interventions and selection of variables and relevant outcomes to further unravel the effectiveness of self-management interventions.[1,45] Interventions need to be thoroughly evaluated alongside the study, including patients' and nurses' experiences with their participation in the intervention, the feasibility of the intervention and the intervention fidelity using several study designs, such as mixed methods, qualitative and observational designs. To better understand the

delivery of interventions, the fidelity assessment needs to include both an assessment of the quantity of the delivered content as well as the quality of delivery. A validated and comprehensive scoring list to assess the quality of delivery is needed to enhance the validity of the quality assessment and evaluation of the impact on the real delivery.[46] Furthermore, the variability of delivery within and across nurses needs to be considered in the methodology of the development of behavioural interventions. Researchers should reflect on whether nurses should have a minimum level of required competences to equalise the quality of delivery and dose of the intervention in order validly evaluate and interpret the effectiveness of behavioural interventions.

To enhance our understanding of the effectiveness of self-management interventions in primary care, researchers need to reconsider the use of cluster-RCTs as the recommended design to answer questions of how the intervention work and which patients benefit. Alternative study designs to evaluate behavioural interventions in primary care need to be considered, such as conducting N-of-1 trials to understand and evaluate the working mechanism of the intervention prior to evaluate the effectiveness, quasi-experimental or observational designs. The use of alternative study designs might decrease the recruitment issues of general practices and patients, enhance the enrolment of too active patients who easily reached a ceiling level, the Hawthorne effect in follow-up measurements and the risk of contamination of the intervention in the control group. However, behavioural interventions with the targeted behaviour change as primary outcome are challenging as these interventions almost provoke a Hawthorne effect, which easily result in a ceiling effect and dilution of the true effect of the intervention.

More research is needed on the effectiveness of the intervention using a longer follow-up period to detect whether the perceived active ingredients are effective in sustaining behaviour change and to diminish the potential influence of seasonal changes of patients' level of physical activity. Also, more research is needed on the effectiveness of the other self-management topics and how to equip nurses to flexibly and adequately adjust and tailor their support, including the consistent and explicit use of BCTs, to patients' needs and preferences.

Box 1. The development and pilot of an evidence-based and interactive self-management management training programme for nurses

As a follow-up to the Activate trial, we developed and piloted an interactive accredited evidence-based self-management training programme for nurses to equip them with the required competences to support patients in their self-management. In this external granted project we integrated and build on the gained knowledge and insights of the Activate trial, extrapolated and refined the content of Activate intervention to the concept of self-management and refined the training programme for nurses to equip them with the required competences.

The development of the training programme

Definition and operationalisation of self-management

To define the concept of self-management, we used the definition of Barlow et al.[47] To operationalise self-management we used the identified nine self-management topics (chapter 2), including two general self-management topics ('understanding the disease', and 'understanding emotional and social consequences of the disease'), and seven self-management behaviours ('symptom monitoring', 'symptom and exacerbation management', 'physical activity', 'dietary intake', 'medication management', 'smoking cessation', and 'alcohol use'). For an explicit and practical implication of the two general self-management topics, we used the eight dimensions of the Dutch Brief-Illness Perception Questionnaire (B-IPQ-DLV), which aligns with the content of these two topics, including consequences, timeline, personal control, treatment control identity, concern, emotional response and comprehensibility.[48] As recommended in several studies we added two questions about patients' perceptions towards dealing with conflicting advice and organisation of support.[49-51] To assess whether including the B-IPQ-DLV with two additional questions were relevant to assess the two general self-management topics, we consulted an expert panel. This expert panel consisted of eight experts in self-management research. They were asked to indicate whether these dimensions and questions were relevant to assess the two general self-management topics and whether these were relevant for the scope of nurses to apply during their self-management support on a four-point Likert rating scale (*1=not relevant; 4=highly relevant*). All experts considered the dimensions with two additional questions relevant.

To explicitly and practically implicate the seven behavioural topics we focused on seven BCTs that were highly valued by patients and nurses participating in the Activate intervention and which are associated with behaviour change, namely goal setting, action planning, reviewing behavioural goal(s), feedback on behaviour, problem-solving, self-monitoring of activity, and social support. Additionally, we emphasised on interceding in nurses' tendency to give advice, inform and educate patients, ask closed questions and fill in for the patient. Furthermore, nurses need to learn how to explicitly and subsequently include self-monitoring tools in their support, such as by enhancing the use of activity trackers, logs, etc. Subsequently, the

Box 1. Continued

content of the self-management topics was further developed and described in a handbook for structured self-management support for nurses who support patients with a chronic condition in follow-up consultations. This handbook contains a structured and scripted content for 1. a starting consultation and 2. subsequent consultations. In the starting consultation, nurses discuss patients' illness perceptions, how patients deal with conflicting advice and their need for organisational support. Nurses discuss patients' needs, preference and motivation to change their behaviour and set a personal outcome and behavioural goal and corresponding personal action plan, including the use of self-monitoring tools. In the subsequent consultations, nurses review on patients' level of goal attainment, adjust goals and personal action plan. Each of the consultations follows a strict order for agenda setting, discussing the main content and wrapping up the consultation.

Behaviour Change Wheel

We used the BCW to develop the training programme for nurses. We used COM-B to understand what behaviour change is needed in nurses to enhance nurses' competences in providing self-management support. All COM-B components were relevant: 1. Motivation. Nurses need be aware of their perceptions towards self-management, its effectiveness and explicit consequences for their nursing role and routine care, which influence their motivation to provide self-management support. Furthermore, the programme needs to include self-reflection on their' beliefs and feelings of (dis)comfort and whether this influences their self-management support. 2. Capability. Nurses need knowledge and skills to provide self-management support. 3. Opportunity. Nurses need to arrange support from their colleagues in the general practice and integrated care and discuss their autonomy to adjust the content, frequency and dose of their consultations with their supervisor in the general practice. The application of the BCW resulted in the selection of 16 appropriate BCTs (such as goal setting, action planning, self-monitoring, feedback, problem-solving) in the training programme.

The training programme

The training contains a 3-month programme with innovative, interactive and blended learning methods, including three days of small-group training, two individual coaching sessions, and continuous skills training using instructional videos, online serious gaming with virtual patients and practice in routine consultations using the scripted handbook. The small-group training includes exercises to raise awareness of their attitude, roles and tasks and their working environment i.e. role-play to train nurses in structuring their consultations around effective BCTs. Furthermore, the training included implementation of self-management into routine consultations in nurses' own working environment. During the coaching sessions nurses' themselves and a coach provided feedback on their performance. The online serious gaming with virtual patients also included direct feedback on their performance.

Box 1. Continued

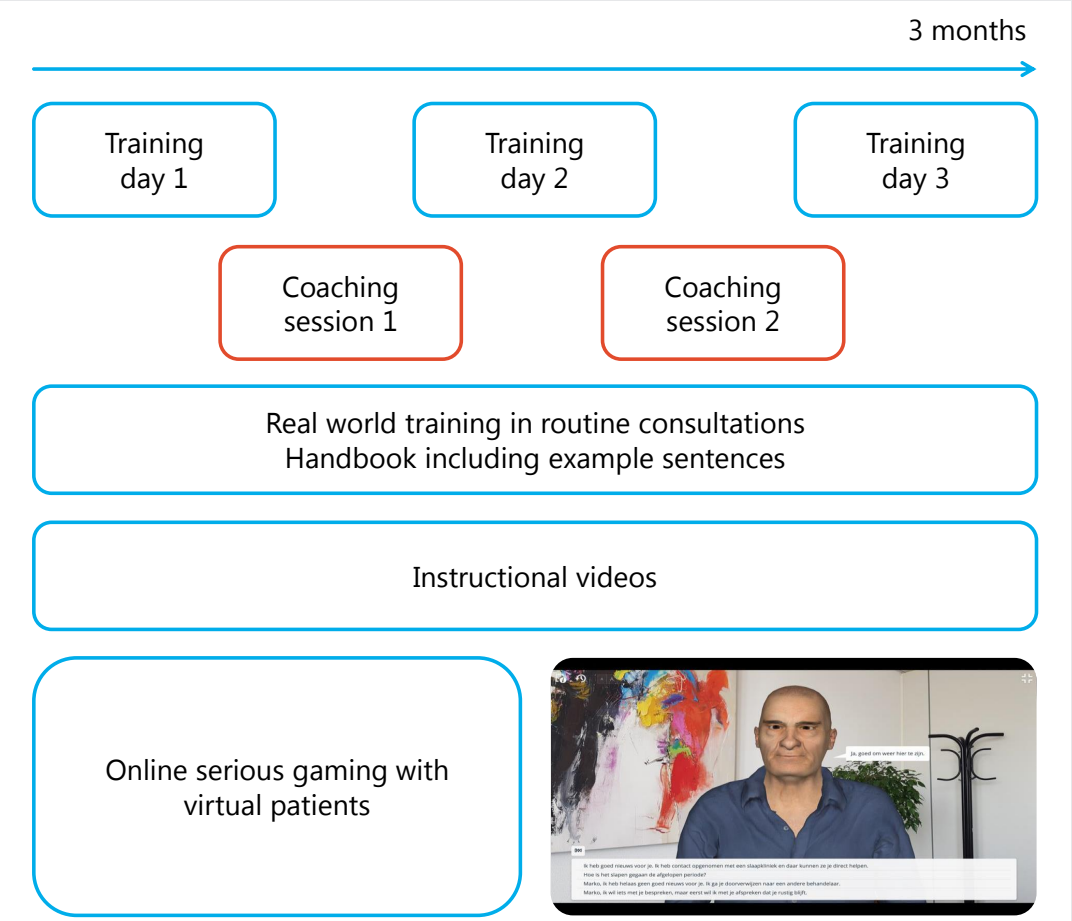


Figure 1. The training programme

Pilot and evaluation

Nurses' experiences and the feasibility of the training were piloted among ten nurses. The pilot was evaluated after each training day using a questionnaire and after finalising the programme using a focus group interview with all participating nurses. The evaluation showed that nurses highly valued the training and reported that the training helped them to develop skills to structure their support and raised their awareness towards self-management, their role and how to implement self-management support in their practice. The role-plays, the handbook, instructional videos and the individual coaching were valued most in order to acquire the competences needed to provide self-management support. The results of the pilot confirmed the results of the process evaluation of the Activate trial, in which nurses found it challenging to change their behaviour but acquiring knowledge and skills led to a changed practice in which they applied BCTs and tried to align their support more to patients' perceived needs and preferences. Moreover, as changing behaviour takes time and practice opportunities, nurses' preferred to spread the training programme over at least six months and to expand the training with an extra moment of training.

REFERENCES

1. Michie S, van Stralen MM, West R. The behaviour change wheel: A new method for characterising and designing behaviour change interventions. *Implement Sci*. 2011;6:42-5908-6-42.
2. Michie S, Richardson M, Johnston M, et al. The behavior change technique taxonomy (v1) of 93 hierarchically clustered techniques: Building an international consensus for the reporting of behavior change interventions. *Ann Behav Med*. 2013;46(1):81-95.
3. Jonsdottir H. Self-management programmes for people living with chronic obstructive pulmonary disease: A call for a reconceptualisation. *J Clin Nurs*. 2013;22(5-6):621-637.
4. Koch T, Jenkin P, Kralik D. Chronic illness self-management: Locating the 'self'. *J Adv Nurs*. 2004;48(5):484-492.
5. Lawn S. What skills do primary health care professionals need to provide effective self-management support? seeking consumer perspectives. *Australian journal of primary health*. 2009;15(1):37-44.
6. Penn M, Kennedy A, Vassilev I, et al. Modelling self-management pathways for people with diabetes in primary care. *BMC Fam Pract*. 2015;16:112.
7. Been-Dahmen JMJ, Dwarswaard J, Hazes JMW, van Staa A, Ista E. Nurses' views on patient self-management: A qualitative study. *J Adv Nurs*. 2015;71(12):2834-2845.
8. er Maten-Speksnijder AJ, Dwarswaard J, Meurs P, van Staa A. Rhetoric or reality? what nurse practitioners do to provide self-management support in outpatient clinics: An ethnographic study. *J Clin Nurs*. 2016;25(21-22):3219-3228.
9. Elissen A, Nolte E, Knai C, et al. Is Europe putting theory into practice? A qualitative study of the level of self-management support in chronic care management approaches. *BMC Health Serv Res*. 2013;13:117-6963-13-117.
10. Hibbard J, Collins P, Mahoney E, Baker L. The development and testing of a measure assessing clinician beliefs about patient self-management. *Health Expect*. 2010;13(1):65-72.
11. Wilson P, Kendall S, Brooks F. Nurses' responses to expert patients: The rhetoric and reality of self-management in long-term conditions: A grounded theory study. *Int J Nurs Stud*. 2006;43(7):803-818.
12. Bos Touwen I, Trappenburg JCA, van der Wulp I, Schuurmans M, de Wit N. Patient factors that influence clinicians' decision making in self-management support: A clinical vignette study. *PLoS ONE*. 2017;12(2):e0171251.
13. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: The new medical research council guidance. *Int J Nurs Stud*. 2013;50(5):587-592.
14. Campbell MK, Piaggio G, Elbourne DR, Altman DG, CONSORT Group. Consort 2010 statement: Extension to cluster randomised trials. *BMJ*. 2012;345:e5661.
15. Hoffmann T, Glasziou P, Boutron I, et al. Better reporting of interventions: Template for intervention description and replication (TIDieR) checklist and guide. *BMJ*. 2014;348:g1687.
16. Möhler R, Bartoszek G, Köpke S, Meyer G. Proposed criteria for reporting the development and evaluation of complex interventions in healthcare (CReDECI): Guideline development. *Int J Nurs Stud*. 2012;49(1):40-46.
17. Moore G, Audrey S, Barker M, et al. Process evaluation of complex interventions: Medical research council guidance. *BMJ*. 2015;350:h1258.
18. Richards D. Complex interventions and the amalgamation of marginal gains: A way forward for understanding and researching essential nursing care? *Int J Nurs Stud*. 2015;52(7):1143-1145.
19. Barton S. Which clinical studies provide the best evidence? the best RCT still trumps the best observational study. *BMJ*. 2000;321(7256):255-256.

20. Johnston D, Johnston M. Useful theories should apply to individuals. *Br J Health Psychol*. 2013;18(3):469-473.
21. Concato J, Shah N, Horwitz RI. Randomized, controlled trials, observational studies, and the hierarchy of research designs. *N Engl J Med*. 2000;342(25):1887-1892.
22. Anderson J, Rhinehart A, Reid T, et al. A practice-based research network focused on comparative effectiveness research in type 2 diabetes management. *Postgrad Med*. 2013;125(3):172-180.
23. Bravata D, Smith Spangler C, Sundaram V, et al. Using pedometers to increase physical activity and improve health: A systematic review. *JAMA*. 2007;298(19):2296-2304.
24. Greaves C, Sheppard K, Abraham C, et al. Systematic review of reviews of intervention components associated with increased effectiveness in dietary and physical activity interventions. *BMC Public Health*. 2011;11:119.
25. Hankonen N, Sutton S, Prevost AT, et al. Which behavior change techniques are associated with changes in physical activity, diet and body mass index in people with recently diagnosed diabetes? *Ann Behav Med*. 2015;49(1):7-17.
26. Williams SL, French DP. What are the most effective intervention techniques for changing physical activity self-efficacy and physical activity behaviour--and are they the same? *Health Educ Res*. 2011;26(2):308-322.
27. Ivers N, Jamtvedt G, Flottorp S, et al. Audit and feedback: Effects on professional practice and healthcare outcomes. *Cochrane Database Syst Rev*. 2012(6):CD000259.
28. Michie S, Abraham C, Whittington C, McAteer J, Gupta S. Effective techniques in healthy eating and physical activity interventions: A meta-regression. *Health Psychol*. 2009;28(6):690-701.
29. French D, Olander E, Chisholm A, Mc Sharry J. Which behaviour change techniques are most effective at increasing older adults' self-efficacy and physical activity behaviour? A systematic review. *Ann Behav Med*. 2014;48(2):225-234.
30. Normansell R, Smith J, Victor C, et al. Numbers are not the whole story: A qualitative exploration of barriers and facilitators to increased physical activity in a primary care based walking intervention. *BMC Public Health*. 2014;14:1272.
31. Wahlich C, Beighton C, Victor C, et al. 'You started something … then I continued by myself': A qualitative study of physical activity maintenance. *Prim Health Care Res Dev*. 2017:1-17.
32. Gellert P, Witham M, Crombie I, Donnan P, McMurdo MET, Sniehotta F. The role of perceived barriers and objectively measured physical activity in adults aged 65-100. *Age Ageing*. 2015;44(3):384-390.
33. Presseau J, Tait R, Johnston D, Francis J, Sniehotta F. Goal conflict and goal facilitation as predictors of daily accelerometer-assessed physical activity. *Health Psychol*. 2013;32(12):1179-1187.
34. Presseau J, Boyd E, Francis J, Sniehotta F. Goal conflict and goal facilitation in community-based cardiac rehabilitation: A theory-based interview study. *Psychol Health Med*. 2015;20(2):227-238.
35. Westland H, Sluiter J, te Dorsthorst S, et al. Patients' experience with abehaviour change intervention to enhance physical activity in primary care: A mixed methods study. *Under review*.
36. Dwarswaard J, van de Bovenkamp H. Self-management support: A qualitative study of ethical dilemmas experienced by nurses. *Patient Educ Couns*. 2015;98(9):1131-1136.
37. McDonald R, Rogers A, Macdonald W. Dependence and identity: Nurses and chronic conditions in a primary care setting. *J Health Organ Manag*. 2008;22(3):294-308.
38. Taylor C, Shaw R, Dale J, French D. Enhancing delivery of health behaviour change interventions in primary care: A meta-synthesis of views and experiences of primary care nurses. *Patient Educ Couns*. 2011;85(2):315-322.

39. Bird L, Arthur A, Cox K. "Did the trial kill the intervention?" experiences from the development, implementation and evaluation of a complex intervention. *BMC Med Res Methodol*. 2011;11:24.
40. Bellg A, Borrelli B, Resnick B, et al. Enhancing treatment fidelity in health behavior change studies: Best practices and recommendations from the NIH behavior change consortium. *Health Psychol*. 2004;23(5):443-451.
41. Borrelli B. The assessment, monitoring, and enhancement of treatment fidelity in public health clinical trials. *J Public Health Dent*. 2011;71 Suppl 1:S52-S63.
42. Wells M, Williams B, Treweek S, Coyle J, Taylor J. Intervention description is not enough: Evidence from an in-depth multiple case study on the untold role and impact of context in randomised controlled trials of seven complex interventions. *Trials*. 2012;13:95.
43. Bleijenberg N, Ten Dam V, Steunenberg B, et al. Exploring the expectations, needs and experiences of general practitioners and nurses towards a proactive and structured care programme for frail older patients: A mixed-methods study. *J Adv Nurs*. 2013;69(10):2262-2273.
44. Campbell N, Murray E, Darbyshire J, et al. Designing and evaluating complex interventions to improve health care. *BMJ*. 2007;334(7591):455-459.
45. Nici L, Bontly T, Zuwallack R, Gross N. Self-management in chronic obstructive pulmonary disease. time for a paradigm shift? *Ann Am Thorac Soc*. 2014;11(1):101-107.
46. Walton H, Tombor I, Spector A, Michie S. (2018, August). Considering the quality of fidelity measures: The promoting independence in dementia intervention. In E. Toomey, *32th Conference Health Psychology Across the Lifespan: Uniting Research, Practice and Policy.* EHPS, Galway, Ireland.
47. Barlow J, Wright C, Sheasby J, Turner A, Hainsworth J. Self-management approaches for people with chronic conditions: A review. *Patient Educ Couns*. 2002;48(2):177-187.
48. de Raaij EJ, Schroder C, Maissan FJ, Pool JJ, Wittink H. Cross-cultural adaptation and measurement properties of the brief illness perception questionnaire-dutch language version. *Man Ther*. 2012;17(4):330-335.
49. Newcomb P, McGrath K, Covington J, Lazarus S, Janson S. Barriers to patient-clinician collaboration in asthma management: The patient experience. *J Asthma*. 2010;47(2):192-197.
50. Lorig K, Holman H. Self-management education: History, definition, outcomes, and mechanisms. *Ann Behav Med*. 2003;26(1):1-7.
51. SchulmanGreen D. A metasynthesis of factors affecting self-management of chronic illness. *J Adv Nurs*. 2016;72(7):1469-1489.

Summary

Self-management is a frequently debated topic in healthcare and widely accepted to improve patients' health outcomes and reduce healthcare costs associated with chronic conditions. Self-management focuses on active participation and taking responsibility in decisions about managing symptoms, treatment, physical and psychosocial consequences of living with a chronic condition. Self-management includes behaviour change, such as increasing physical activity, smoking cessation, healthy nutrition and managing medication. However, patients often struggle with self-managing their condition in daily life. Therefore, in primary care, nurses have a pivotal role in supporting patients in self-managing their condition. Self-management support is widely embedded in health and governmental policies, nurses' competences profile and chronic care guidelines. Despite all this attention, it still remains unclear what self-management specifically entails, how nurses support patients' self-management and which competences of nurses are required. Although self-management interventions have proven their effectiveness, it is still not fully understood how these interventions work and which patients benefit.

The main aim of this thesis is to unravel how self-management interventions work and which patients benefit from these interventions within the context of primary care. We aimed to examine how and to what extent nurses provide self-management support in their current practice. Furthermore, we aimed to comprehensively develop and evaluate a behaviour change intervention for primary care patients (the Activate intervention) delivered by primary care nurses. In this intervention, the complexity of self-management interventions is downsized by focusing on one self-management behaviour, namely increasing physical activity, rather than focusing on the concept of self-management as a whole. The intervention was targeted to patients at risk for cardiovascular disease (CVD). The Behaviour Change Wheel -as a theoretical framework- was used to develop an intervention that increases patients' physical activity and equips nurses with the competences to deliver this intervention. The effectiveness of the intervention was extensively evaluated to understand how the intervention works within the context of primary care and to get insight into which patients benefit.

In **chapter 2** we gained insight into how and to what extent self-management support is addressed by primary care nurses and which behaviour change techniques (BCTs) they apply in their routine consultations for patients with a chronic disease. An observational study was performed in which 78 routine consultations of 17 primary care nurses in patients with a chronic condition were analysed to identify addressed self-management topics and applied BCTs, using the Behaviour Change Techniques Taxonomy v1 (BCTTv1) of Michie et al. This study showed that nurses addressed health topics (such as patients' general health condition, lab results and medication optimisation) and self-management topics (such as physical activity, smoking cessation, healthy nutrition and managing med-

ication) in their routine consultations. However, the amount of topics and the extent to which these topics were addressed differed in the duration and frequency. Nurses addressed these health and self-management topics briefly and fragmented throughout their consultations. Nurses seldom focused on behaviour change and the explicit and consistent use of BCTs was low.

Chapter 3 contains the study protocol of the Activate trial. This protocol describes the development of the Activate intervention and the design of the two-armed cluster-randomised controlled trial in primary care to evaluate the Activate intervention. The Activate intervention consisted of four consecutive consultations over a three-month period, in which patients were supported by their primary care nurse to increase their physical activity. Seventeen BCTs, were integrated in the four consultations, such as goal setting, action planning, feedback on behaviour, review on behavioural goal, self-monitoring, problem-solving and social support. Alongside the consultations patients were instructed to self-monitor their physical activity daily using an accelerometer and an activity log.

Subsequently, a training programme for nurses was developed to equip them with the required competences to deliver the Activate intervention. This training programme was also based on the Behaviour Change Wheel and included twenty-one BCTs, such as feedback on behaviour, instruction on how to perform the behaviour, demonstration of the behaviour and behavioural practice. The training programme consisted of a one-day skills training, two individual coaching sessions, and several training tools.

In **chapter 4** we explored the experiences of patients with the Activate intervention in relation to their success in increasing their physical activity. A convergent mixed methods study parallel to the Activate trial was conducted. Questionnaires of 67 patients who participated in the intervention were analysed. From these patients we interviewed 22 patients, which were thematically analysed. The experiences of patients who had objectively increased their physical activity (responders) were compared to those who had not (non-responders). This study showed that the data of the questionnaires and interviews correspond with no emerging substantial differences among responders and non-responders. Patients highly valued their participation in the Activate intervention and felt they had benefitted, irrespectively of their objective change in activity. Patients experienced the combination of both self-monitoring tools and being supported by the nurses with whom they have a trustful relationship as valuable in order to increase their physical activity. Furthermore, patients' engagement in increasing and maintaining their physical activity was challenged by both internal (e.g. enjoyment, physical constraints) and external (e.g. weather, lack of time) circumstances.

In **chapter 5** we explored the perceptions of nurses towards delivering the Activate intervention and towards the feasibility of this intervention in future practice. Parallel to the trial, a qualitative study with 14 semi-structured interviews was conducted and thematically analysed. This study showed that nurses were dedicated to support patients in enhancing health behaviour. Nurses' engagement towards changing health behaviour and delivering the intervention was influenced by patients' motivation to participate in the intervention, patients' success of the intervention and nurses' personal development. The one-day training, coaching sessions and training tools and practising the intervention structure helped them to deliver the intervention, to develop their skills and to change their routine practice towards a more patient-centred consultation style. Although nurses found it challenging to deliver the intervention, they tried to deliver the intervention according to the protocol.

Nurses thought the intervention was feasible for routine practice. However, implementation in routine practice may be hindered by complying with other clinical demands in their busy practice and maintaining the acquired skills. Nurses felt the training programme equipped them with the necessary competences to deliver the intervention, enabled their personal development and nurses incorporated their newly acquired skills into their daily practice.

In **chapter 6** we reported the results of the Activate trial, in which the effectiveness of the Activate intervention was evaluated among 31 general practices and 195 patients during a follow-up period of 6 months. The intervention led to a small increase in minutes of physical activity in the moderate to vigorous category compared to patients in the control group; however, this increase was not statistically significant. No differences on sedentary behaviour, self-efficacy for physical activity, patient activation for self-management and health status were observed between both groups. Patients with a low acuity of perceived support from others (such as partner, family or friends) and patients with a low level of physical activity at the start of the intervention were likely to benefit more from the intervention.

To enhance our understanding of how the intervention worked and to enable reproducibility, we evaluated in **chapter 7** whether nurses delivered the intervention as intended (fidelity of delivery) using an observational study design. In addition, the quality of nurses' delivery and their beliefs of their capability, motivation, confidence and effectiveness towards delivering the Activate intervention were assessed. Nurses' self-reported fidelity of delivery of the intervention was evaluated using checklists and their observed fidelity and quality of delivery was evaluated using audio-recordings of intervention consultations. Nurses' beliefs were evaluated using questionnaires that were filled out at multiple time points during the intervention. This study showed that nurses delivered most intervention

components according to the protocol and that they moderately applied the BCTs. The quality of nurses' delivery of the intervention was generally sufficient but differed between nurses. Nurses' beliefs about their capability, motivation, confidence and effectiveness towards the delivery of the Activate intervention and BCTs increased during the trial.

Despite these results, several methodological factors and nurses' variation in complex behaviour change delivery might have affected the quality of delivery and therefore might have diluted the effectiveness of the Activate intervention.

Chapter 8 offers a general discussion of the main findings of the studies presented in this thesis, and provides recommendations for clinical practice, education, policymakers and future research.

The conducted studies underline the challenging and complex nature of changing behaviour in both patients and nurses within the context of primary care and their impact on understanding the magnitude and sustainability of the trial results. The results of the process evaluation showed the value of the intervention for both patients and nurses. Several methodological factors and nurses' variation in complex behaviour change delivery might have affected the quality of delivery and intervention fidelity and therefore might have diluted the effectiveness of the Activate intervention. Therefore, the opportunities of structured self-management support, including behaviour change support, need to be further explored within the context of primary care rather than dismiss the intervention prematurely.

To meet the promising expectations of self-management within the context of primary care, behaviour change is required in patients, nurses, educators, health and governmental policymakers as well as in researchers, which induces conflicting interests and change of the healthcare system. Conditional to a proper integration of self-management in routine primary care is the adoption of a clear and uniform definition and operationalisation of self-management by healthcare providers, educators, policymakers and researchers. Another key condition is that nurses need to be adequately equipped with competences needed to provide self-management support using comprehensive training including tailored training tools, regular practice opportunities and ongoing coaching. We proposed an extensive self-management training programme that educators could integrate in future vocational training and nursing education. We further recommend that researchers target behaviour change interventions to both patients' and nurses' behaviour using a theoretical framework and the results of the studies included in this thesis. Such interventions should include an extensive process evaluation alongside the study using alternative and both qualitative and quantitative study designs to better understand methodological, patients, nurses and contextual factors influencing behaviour change.

Samenvatting

Zelfmanagement is een veel besproken onderwerp in de gezondheidszorg en wordt gezien als een essentieel onderdeel om gezondheidsuitkomsten te verbeteren en kosten voor gezondheidszorg te verminderen voor patiënten met een chronische aandoening. Zelfmanagement richt zich op actieve deelname van patiënten en het nemen van verantwoordelijkheid bij beslissingen over het omgaan met symptomen, behandeling, fysieke en psychosociale gevolgen van het leven met een chronische aandoening. Zelfmanagement omvat gedragsverandering. Voorbeelden hiervan zijn meer bewegen, stoppen met roken, gezond eten en omgaan met medicijnen. Patiënten vinden het vaak lastig om in het dagelijks leven met hun aandoening om te gaan. Daarom worden patiënten in de huisartsenpraktijk hierbij ondersteund door praktijkondersteuners (POHs). Zelfmanagementondersteuning is verankerd in het gezondheids- en overheidsbeleid, in het competentieprofiel van POHs en in richtlijnen voor chronische zorg. Ondanks al deze aandacht is het nog steeds onduidelijk wat zelfmanagement precies inhoudt, hoe POHs hun patiënten hierbij ondersteunen en welke competenties POHs nodig hebben. En, hoewel zelfmanagementinterventies bewezen effectief zijn, is het nog steeds niet helemaal duidelijk hoe deze interventies werken en welke patiënten er baat bij hebben.

Het hoofddoel van dit proefschrift is om te ontrafelen hoe zelfmanagementinterventies werken en welke patiënten baat hebben van dergelijke interventies binnen de eerstelijnszorg. Als eerste is gekeken in welke mate POHs in hun dagelijkse praktijk patiënten ondersteunen bij zelfmanagement. Daarnaast is als doel gesteld om een gedragsveranderingsinterventie (In Actie interventie) te ontwikkelen voor patiënten die in de huisartsenpraktijk door een POH worden begeleid en om deze interventie te evalueren. In de In Actie interventie is de complexiteit van zelfmanagementinterventies verkleind door te concentreren op één gedrag, namelijk meer bewegen, in plaats van ons te concentreren op het concept van zelfmanagement als geheel. De interventie is gericht op een heterogene groep patiënten in de eerstelijnszorg, namelijk patiënten met een verhoogd risico op hart- en vaatziekten (HVZ). Het Behaviour Change Wheel is als theoretisch kader gebruikt om de interventie te ontwikkelen. Daarnaast is het Behaviour Change Wheel gebruikt om POHs toe te rusten met competenties om deze interventie uit te voeren. De effectiviteit van de interventie is geëvalueerd. Deze evaluatie hielp om inzicht te krijgen in de werking van de interventie in de context van de eerstelijnszorg en welke patiënten baat hebben bij de interventie.

In **hoofdstuk 2** is onderzocht hoe en in hoeverre zelfmanagementondersteuning wordt besproken door POHs en welke gedragsveranderingstechnieken (behaviour change techniques; BCTs) zij toepassen in hun dagelijkse consulten bij patiënten met een chronische aandoening. In een observationele studie zijn 78 dagelijkse consulten van 17 POHs met patiënten met een chronische aandoening geanalyseerd. Van deze consulten

zijn audio-opnames gemaakt en vervolgens geanalyseerd om te zien welke zelfmanagementonderwerpen POHs bespraken en welke BCTs ze daarbij toepasten, waarbij de BCT taxonomie van Michie en collega's is gebruikt. Deze studie liet zien dat POHs verschillende gezondheidsonderwerpen (zoals de algehele gezondheidstoestand van de patiënt, bloeduitslagen en optimaliseren van de medicijnen) en zelfmanagementonderwerpen (zoals meer bewegen, stoppen met roken, gezond eten en omgaan met medicijnen) bespraken tijdens hun dagelijkse consulten. Het aantal onderwerpen echter dat besproken werd door de POH's verschilde in de duur en frequentie. In het algemeen bespraken de POHs deze gezondheids- en zelfmanagementonderwerpen kort en gefragmenteerd tijdens het consult. Ze gingen zelden dieper in op gedragsverandering en gebruikten nauwelijks BCTs op een expliciete en consistente manier.

Hoofdstuk 3 bevat het onderzoeksprotocol van de In Actie studie. In dit protocol is de ontwikkeling beschreven van de In Actie interventie en de opzet van de tweearmige cluster gerandomiseerde trial in de eerstelijnszorg om de In Actie interventie te evalueren. De In Actie interventie bestaat uit vier opeenvolgende beweegconsulten verdeeld over drie maanden, waarbij patiënten in de eigen huisartsenpraktijk door hun POH worden ondersteund bij het bevorderen van bewegen.

Zeventien BCTs zijn geïntegreerd in de vier beweegconsulten, zoals het stellen van gedragsdoelen, actieplanning, feedback op gedrag, terugkijken op het gedragsdoel, zelfmonitoring, oplossen van problemen en sociale steun. Naast de beweegconsulten kregen patiënten de opdracht om dagelijks zelf hun beweeggedrag bij te houden met behulp van een beweegmeter en een beweegdagboek.

Vervolgens is een trainingsprogramma ontwikkeld voor POHs om hen toe te rusten met competenties om de interventie zo goed mogelijk uit te voeren. Dit trainingsprogramma is eveneens ontwikkeld met behulp van het Behaviour Change Wheel en bevatte 21 BCTs, waaronder feedback op gedrag, instructie over hoe het gedrag uit te voeren, demonstratie van het gedrag en oefenen van het gedrag. Het trainingsprogramma bestond uit een eendaagse vaardigheidstraining, twee individuele coaching sessies en verschillende training tools.

In **hoofdstuk 4** zijn de ervaringen van patiënten met de In Actie interventie onderzocht in relatie tot hun behaalde succes (meer bewegen). Parallel aan de trial is een convergente mixed methods studie uitgevoerd. Vragenlijsten van 67 patiënten die deelnamen aan de interventie zijn geanalyseerd. Van deze patiënten zijn 22 patiënten geïnterviewd en thematisch geanalyseerd. De ervaringen van patiënten over hun succes of uitblijven van succes met betrekking tot de interventie zijn vergeleken met de objectieve gegevens over hun succes. Deze studie liet zien dat de gegevens uit de vragenlijsten en interviews

overeenkwamen. Patiënten waardeerden hun deelname aan de In Actie studie. Patiënten vonden dat ze meer zijn gaan bewegen, ongeacht of ze objectief gezien meer zijn gaan bewegen. Patiënten vonden dat de combinatie van het zelf bijhouden van bewegen met de beweegmeter en het beweegdagboek, en de ondersteunding door de POH met wie zij een vertrouwensrelatie hadden onmisbaar in hun succes. Daarnaast bleek dat patiënten bij het meer gaan en volhouden van bewegen werden uitgedaagd door zowel interne omstandigheden (bijvoorbeeld plezier beleven aan bewegen, fysieke beperkingen) en externe omstandigheden (bijvoorbeeld weersomstandigheden, weinig tijd).

In **hoofdstuk 5** zijn de percepties van POHs onderzocht ten aanzien van het uitvoeren van de In Actie interventie en de haalbaarheid van deze interventie in de praktijk. Parallel aan de trial zijn 14 semigestructureerde interviews afgenomen en vervolgens thematisch geanalyseerd. Deze studie toont aan dat POHs toegewijd waren om patiënten te ondersteunen bij het verbeteren van gezondheidsgedrag. De betrokkenheid van POHs wordt beïnvloed door de motivatie van patiënten om deel te nemen aan de interventie, het ervaren van succes van de interventie door patiënten en de persoonlijke ontwikkeling van POHs. POHS hadden baat bij de eendaagse training, coaching sessies, trainingstools en het oefenen met de gespreksstructuur van de interventie. Het hielp hen om de interventie adequaat uit te voeren, om hun vaardigheden te ontwikkelen en om in hun dagelijkse praktijk een meer patiëntgerichte consultstijl toe te passen. Hoewel POHs het uitdagend vonden om de interventie uit te voeren, probeerden ze hierbij het protocol goed te volgen. POHs vonden de interventie haalbaar om toe te passen in de dagelijkse praktijk. Implementatie in de dagelijkse praktijk kan echter belemmerd worden doordat POHs in hun drukke consult tegelijkertijd ook moeten voldoen aan andere klinische vereisten. Deze combinatie van factoren daagt hen nog meer uit om de verworven vaardigheden te behouden. POHs vonden dat het trainingsprogramma hen toe heeft gerust met de benodigde competenties om de interventie uit te voeren en dat zij deze nieuw verworven vaardigheden in hun dagelijkse praktijk konden integreren.

In **hoofdstuk 6** zijn de resultaten van de In Actie studie beschreven. De effectiviteit van de interventie is geëvalueerd onder 31 huisartspraktijken en 195 patiënten gedurende 6 maanden follow-up. De interventie leidde tot een kleine toename van het aantal beweegminuten in de matige tot intensieve beweegcategorie in vergelijking met patiënten in de controlegroep. Deze toename was niet statistisch significant. Er werden geen verschillen waargenomen in sedentair gedrag, self-efficacy voor fysieke activiteit, patiëntactivatie voor zelfmanagement en gezondheidstoestand tussen beide groepen. Patiënten die weinig steun ervaren van anderen (zoals partner, familie of vrienden) en patiënten met die weinig bewogen aan het begin van de interventie hadden meer kans om meer baat te hebben van de interventie.

Om beter te begrijpen hoe de interventie werkt en om de studie reproduceerbaar te maken, is in **hoofdstuk 7** een observationele studie uitgevoerd om te evalueren of POHs de interventie uitgevoerd hebben zoals bedoeld. Daarnaast is gekeken naar de kwaliteit van de uitgevoerde consulten door POHs en naar de overtuiging van hun eigen bekwaamheid, motivatie, vertrouwen en effectiviteit met betrekking tot het uitvoeren van de In Actie interventie. De POHs hebben op een checklist bijgehouden welke onderdelen van de interventie zij per consult hebben toegepast. Voor een objectieve beoordeling van de toegepaste interventie onderdelen en van de kwaliteit van de consulten zijn audio opnames gemaakt van beweegconsulten. De overtuigingen van POHs zijn geëvalueerd aan de hand van vragenlijsten die POHs tijdens de interventie op meerdere tijdstippen invulden. Uit de studie bleek dat dat POHs de meeste interventiecomponenten uitvoerden volgens protocol en dat zij de BCTs matig toepasten. De kwaliteit van de uitvoering van de interventie was voldoende maar verschilde tussen POHs. De POHS vonden dat hun bekwaamheid, motivatie, vertrouwen en de effectiviteit met betrekking tot het uitvoeren van de interventie toe nam toe gedurende de studie.

In **hoofdstuk 8** zijn de belangrijkste bevindingen samengevat en zijn aanbevelingen gedaan voor de klinische praktijk, het onderwijs, beleidsmakers en toekomstig onderzoek. De uitgevoerde studies benadrukken de uitdagende en complexe aard van gedragsverandering bij zowel patiënten als POHs in de context van de eerstelijnszorg en hun impact op het begrijpen van de omvang en duurzaamheid van de onderzoeksresultaten.

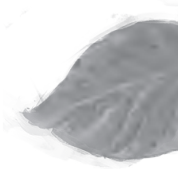
De resultaten van de procesevaluatie lieten de waarde zien van de interventie voor zowel patiënten als POHs. Verschillende methodologische factoren en de variatie waarin POHs patiënten ondersteunen bij gedragsverandering hebben mogelijk de kwaliteit van de uitvoering van de interventie beïnvloed. Dit heeft mogelijk het effect van de interventie verminderd.

Daarom moeten de mogelijkheden van gestructureerde zelfmanagementondersteuning, inclusief ondersteuning van gedragsverandering, door POHs verder verkend worden.

Om de veelbelovende verwachtingen van zelfmanagement in de eerstelijnzorg waar te maken, is gedragsverandering nodig bij patiënten, POHs, opleiders, beleidsmakers en onderzoekers. Dit leidt tot conflicterende belangen en verandering van het gezondheidszorgsysteem.

Een voorwaarde om zelfmanagement goed te integreren in de dagelijkse praktijk van POHs is het aannemen van een duidelijke en uniforme definitie en operationalisering van zelfmanagement door zorgverleners, opleiders, beleidsmakers en onderzoekers.

Een andere belangrijke voorwaarde is dat POHs moeten worden toegerust met competenties om zelfmanagementondersteuning te bieden door middel van een uitgebreid trainingsprogramma met op maat gemaakte trainingtools, mogelijkheden om regelmatig te oefenen en daarnaast doorlopend coaching te krijgen. We hebben een uitgebreid zelfmanagement-trainingsprogramma voorgesteld dat opleiders kunnen integreren in toekomstige verpleegkundige beroepsopleidingen en verpleegkundige vervolgopleidingen. We bevelen verder aan dat onderzoekers zich richten op zowel de patiënt als de POH als het gaat om interventies die gedrag veranderen, waarbij een theoretisch kader en de resultaten van de studies in dit proefschrift gebruikt worden. Het proces van zulke interventies moet uitgebreid geëvalueerd worden, waarbij alternatieve en zowel kwalitatieve als kwantitatieve onderzoeksdesigns worden gebruikt. Hierdoor worden de belangrijkste factoren die gedragsverandering beïnvloeden het beste begrepen: de methodologie, de context, de patiënt en de POH.



List of Publications

Westland H, Schröder C, de Wit J, Frings J, Trappenburg JCA, Schuurmans M. Self-management support in routine primary care by nurses. *Br J Health Psychol.* 2018;23(1):88-107.

Westland H, Bos Touwen I, Trappenburg JCA, Schröder C, de Wit N, Schuurmans M. Unravelling effectiveness of a nurse-led behaviour change intervention to enhance physical activity in patients at risk for cardiovascular disease in primary care: Study protocol for a cluster-randomised controlled trial. *Trials.* 2017;18(1):79-94.

Jonkman N, **Westland H**, Groenwold RHH, et al. Do self-management interventions work in patients with heart failure? an individual patient data meta-analysis. *Circulation. 2*016;133(12):1189-1198.

Jonkman N, **Westland H,** Trappenburg J, et al. Do self-management interventions in COPD patients work and which patients benefit most? an individual patient data meta-analysis. *Int J Chron Obstruct Pulmon Dis.* 2016;11:2063-2074.

Jonkman N, **Westland H**, Groenwold RHH, et al. What are effective program characteristics of self-management interventions in patients with heart failure? an individual patient data meta-analysis. *J Card Fail*. 2016;22(11):861-871.

Jonkman NH, **Westland H,** Trappenburg JC, et al. Characteristics of effective self-management interventions in patients with COPD: Individual patient data meta-analysis. *Eur Respir J.* 2016;48(1):55-68.

Bos Touwen I, Jonkman N, **Westland H**, et al. Tailoring of self-management interventions in patients with heart failure. *Curr Heart Fail Rep.* 2015;12(3):223-235.

Jonkman N, **Westland H,** Trappenburg JCA, et al. Towards tailoring of self-management for patients with chronic heart failure or chronic obstructive pulmonary disease: A protocol for an individual patient data meta-analysis. *BMJ Open.* 2014;4:e005220.

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Curriculum Vitae

Heleen Westland was born on January 20th 1980 in Veenendaal, the Netherlands. After graduating from secondary school at the Ichthus College in Veenendaal, she started to study nursing at the University of Applied Sciences in Ede. After she obtained her bachelor degree in nursing she started working as a registered nurse at the cardiology and cardio-thoracic surgery department of the University Medical Center Utrecht. She worked as a senior medium care nurse at the cardio-thoracic surgery department for five years. In 2006 she started with the master in Nursing Science at the Utrecht University and she obtained her Master of Science degree (cum laude) in 2009. In 2008 she started working as a clinical nurse leader at the cardiology department, in which she focussed at developing and implementing healthcare policy and innovations to improve quality of nursing care. She developed and evaluated a self-management programme for patients with a chronic heart or lung disease. In 2013 she started her PhD project within the Tailored Self-managemenT & E-health (TASTE) research line at the Julius Center for Health Sciences and Primary Care, department of Nursing Science, University Medical Center Utrecht. During her PhD project she obtained her Master of Science degree in Clinical Epidemiology at the Utrecht University.

Heleen intends to continue her research activities at the Julius Center for Health Sciences and Primary Care of the University Medical Center Utrecht.