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Summary

The number of individuals with chronic illness and multi-morbidity is growing due to the rapid ageing of the population and a longer individual lifespan. This ageing will bring about an increase in the rate of chronic illnesses with a rapidly growing workload in care. Therefore, structural changes of the healthcare system, with an important role for self-management for patients (including electronic health; eHealth), are necessary (Chapter 1). Currently, the management of most chronic illnesses is characterised by the responsibility that individual patients need to take, and by empowering patients to ‘take charge’ regarding the measures required to improve their own health.

Nowadays, patients that follow self-management programs are usually supported by tailored eHealth platforms. Generally, eHealth interventions are effective in stimulating self-management because they allow patients to cope better with their illness at the time and place of their choosing, enabling them to adapt their lifestyle to their individual condition.

Despite promising pilots with eHealth and the positive experience of patients regarding eHealth, large-scale adoption of self-management and eHealth still lags behind in daily practice. An important reason for this backlog is the difficulty of organising ‘blended care’, in which eHealth is integrated into regular care. Several pre-conditions should be considered before starting the implementation of eHealth. In the studies described in this thesis we thoroughly considered, implemented and analysed these pre-conditions.

The objective of the implementation studies described in this thesis was to investigate the effect of the application of eHealth-supported programs for chronic obstructive pulmonary disease (COPD) and oral anticoagulation therapy (OAT) in primary care.

The aims of this thesis were:

- to examine whether the effects found depend on: 1) subjectively experienced practical added value for patients, thereby making their everyday lives easier; and 2) the level of organisation as an integral part of existing care.

- to evaluate the effect of different approaches of eHealth implementation on the use of eHealth platforms and patient outcomes, focusing on health status in particular.
To achieve these research aims, we designed two studies on the implementation of self-management programs with eHealth called i) e-Vita COPD and ii) PORTALS (PORTal implementation within anticoagulation care; Amplification of self-management).

Chapter 2 describes our viewpoint regarding the expected added value of eHealth-supported self-management for chronically ill patients. There has been an increasing focus on self-management in the aim to handle the growing need for appropriate care for this large group of patients. Research has shown that patients who understand more about their disease, health and lifestyle have better experiences and health outcomes, and often use less healthcare resources; this effect is even greater when these patients are empowered to be/are responsible for managing their own health and disease. In addition to the importance of patient skills, healthcare professionals need to shift to a role of teacher, partner, and professional supervisor of their patients. One way of supervising and coaching patients is to use eHealth, which helps patients manage and control their disease. The application of eHealth solutions can provide chronically ill patients with high-quality care, to the satisfaction of both patients and healthcare professionals, together with a reduction in healthcare consumption and related costs.

For this purpose, we designed two implementation studies on eHealth-supported self-management programs: one focusing on patients with COPD (Chapters 3, 4 and 5) and one for patients that use OAT for atrial fibrillation (AF) or for venous thromboembolism (VTE) (Chapters 6 and 7). The rationale for choosing these two diseases is twofold: the economic and disease burden of both these chronic diseases is considerable, and self-management has been introduced as an effective method to improve the quality of care for both conditions.

For patients using the self-management platform on a regular basis, we expected to see a positive effect on quality of life and complications in both groups. For patients with COPD, we expected to see a relatively small improvement in their everyday lives using the digital platform. Resulting from this, we assumed that the use of the platform would grow less rapidly and take root less rapidly. For OAT patients, a comprehensive self-management program supported by a digital platform will tend to lessen their dependence on the anticoagulation clinic and enhance their sense of self-reliance. Therefore, we expected these OAT patients to use the digital platform more frequently leading to an enhanced improvement in clinical outcomes.
Chapter 3 presents the design and methodology of the e-Vita COPD study. The management of COPD is highly complex, since patients show considerable variation in their symptoms and limitations in daily life. In the last decade, self-management support of COPD was introduced as an effective method to improve the quality and efficacy of care, and to reduce healthcare costs. Despite the urge to change the organisation of health care and the potential of eHealth to support this, large-scale implementation in daily practice still lags behind, especially in the Netherlands.

The e-Vita COPD study compared three different approaches to incorporating eHealth via web-based self-management platforms into integrated disease management (IDM) of COPD in primary care using a parallel cohort design. Three different groups integrated the platforms to different levels. In group 1, the online platform was offered as a highly integrated part of the COPD IDM with a tailored intensive course program on COPD for healthcare professionals that covered i) education on COPD, ii) training related to the possibilities of eHealth, and iii) conversational techniques to approach patients in a way that is equal and also supports coaching. All patients in group 1 started with a personal consultation with the primary care nurse, followed by coaching on the necessity of self-management and an explanation about the burden of their disease and the eHealth program. Group 2 had a medium level of integration with a basic course program for healthcare professionals on COPD that covered education on COPD, and training about the possibilities of eHealth. All patients in group 2 started with a personal consultation with the primary care nurse, followed by coaching and an explanation of the self-management program. With the platform, the patients could work with a coaching program on their personal goals, actions and health-related quality of life. In group 3, the online platform was offered without integration in COPD IDM; healthcare providers and patients received basic instructions about the platform. In the blended care groups (group 1 and 2), randomisation was performed to two different levels of personal assistance for the patients (i.e. high and low level assistance). All programs were offered for a period of 15 months.

Every visit to the web platforms was tracked by collecting log data (number of sessions, and use of the different services). At the first log-in, patients completed a baseline questionnaire including age, gender, education level, scores on the Clinical COPD Questionnaire (CCQ), the dyspnoea scale (MRC), and the quality-of-life questionnaire (EQ-5D). To compare the use of the platforms in the three different groups, multiple linear regression analyses were performed. The association between educational level and
usage, and between the General Self-Efficacy Scale (GSES) and usage, was analysed. An interrupted time series (ITS) design was used to collect CCQ data at multiple time points before and after intervention. Multilevel linear regression modelling was used to analyze the CCQ data emerging from the three groups over time.

This study combined different designs that enabled simultaneous investigation of the clinical effects, as well as the effects of different organizational implementation methods, whilst controlling for the confounding effects of the organisational characteristics. It was expected that when the eHealth program was integrated in existing care and patients received a high level of personal assistance, the use of the platform would be higher, thereby increasing the health status.

Although self-management of COPD through eHealth interventions has shown to be beneficial in several settings, it remains unknown which factors influence the usage of eHealth and, thereby, a change in patients’ behaviour. In Chapter 4 we analysed the factors that successfully promote the use of a self-management platform among COPD patients in the e-Vita study. The COPD patients were recruited from three groups in primary care: of the 702 COPD patients that were invited, 215 (30.6%) registered to a platform. Of the 82 patients in group 1 (high integration IDM), 36 were in group 1A (personal assistance) and 46 in group 1B (low assistance). Of the 96 patients in group 2 (medium integration IDM), 44 were in group 2A (telephone assistance) and 52 in group 2B (low assistance). A total of 37 patients participated in group 3 (non-integration IDM). In total, 107 users (49.8%) visited the platform at least once during the 15-month period. The mean number of sessions differed between the three groups (group 1: mean 10.5, SD 1.3; group 2: mean 8.8, SD 1.4; group 3: mean 3.7, SD 1.8; p=0.01). The mean number of sessions differed between the high-assistance and low-assistance groups in groups 1 and 2 (high: mean 11.8, SD 1.3; low: mean 6.7, SD 1.4; F1,80=6.55, p=0.01). High-assistance participants used more services (mean 45.4, SD 6.2) than low-assistance participants (mean 21.2, SD 6.8; F1,80=6.82, p=0.01).

No association was found between educational level and usage, or between General Self-Efficacy Scale and usage. Our findings highlight the importance of integrating an eHealth platform into IDM; usage of the self-management eHealth platform is higher and more varied when the platform is an integrated part of the care program with personal coaching for patients. Patients in care groups with a high level of integration of the platform in
IDM showed a higher number of sessions and a larger amount of visited digital services with more variation. Patients that received assistance also showed higher usage of the platform. We implemented extensive professional training of healthcare professionals on the COPD care program and self-management supported by eHealth platforms; we also offered personal assistance for the users to guide them through the platform, as well as specific push factors (automated reminders, or messages made by healthcare professionals). Both strategies are essential elements to stimulate the use of platforms.

Chapter 5 describes the effect of the integration of self-management web platforms on health status as measured with the CCQ among COPD patients in the e-Vita study. Patients’ health status was examined using the CCQ in three primary care groups, i.e. with a highly, a medium, and a non-integrated eHealth platform. During the 15-month intervention period, there were four measurement periods with three CCQ questionnaires at each period (3 data points before intervention, and 9 data points after intervention). Higher CCQ values indicate a lower health status. The decrease of CCQ scores in the total group of patients before the intervention was 0.5% per month and after the intervention was 0.08% per month; this difference was not statistically significant. Furthermore, no significant difference was found in CCQ changes when going from pre-intervention to post-intervention between the groups with a high level of personal assistance for COPD and a low level of assistance. The changes in health status CCQ were not within the range of a minimal clinically important difference, meaning that no changes in health status were found before and after introduction of the eHealth-supported COPD programs, and no differences were found between the care groups with a high versus a low level of personal assistance. Despite these results of the e-Vita study, we expect that eHealth interventions will be effective in stimulating self-management and stabilising the health status of COPD patients when these patients use the platforms for a longer period. It is likely that the intervention period in our e-Vita study was too short to give patients sufficient time to change their lifestyle and behaviour in order to show an improved health status. Furthermore, in Dutch primary care the standards of regular COPD disease management are relatively high; this might explain the absence of an improvement of health status after the introduction and integration of eHealth within IDM. It appears that there was too little room for improvement, especially for these particular COPD patients in primary care with a ever-relatively low burden
of disease.

Chapters 6 and 7 of the thesis present the PORTALS study. Both VTE and AF are common causes of mortality and morbidity, with continually rising prevalence and medical costs.

OAT reduces thromboembolic events in AF and other conditions, and is an effective treatment for VTE. There is a narrow therapeutic range for OAT through vitamin K antagonists, with a high need for strict therapeutic adherence. This adherence and consequently the complications due to a deviant therapeutic range, are reduced when OAT patients are supported by self-management programs.

Chapter 6 describes the design and the intervention of the PORTALS study; this is an implementation study with a quality improvement intervention for OAT patients who receive regular thrombosis care. It is a parallel cohort design with two randomised self-management groups, and a group receiving regular care. Two methods to train long-term OAT patients in self-management were developed to improve the quality of care and introduce the use of an eHealth portal. After inclusion, patients interested in participating in a self-management program were randomly divided into a group with education and training by e-Learning, and another group that received face-to-face group training. Both the e-Learning group and the group training consisted of at least three components: i) disease-specific knowledge of VTE and AF; ii) self-testing skills; iii) use of an eHealth portal; and iv) self-adjustment of medication. Patients who did not wish to start with self-management were invited to participate in the non-self-management group, a parallel cohort that received usual care. Health status was the primary outcome, expressed by therapeutic control through International Normalized Ratio (INR) values over time; INR values were registered continuously and converted into the percentage of time within the therapeutic range (TTR) over three time periods (0-6 months, 6-12 months, and 12-18 months) during the intervention that lasted 18 months. Severe complications (bleedings and thromboembolic events) and the usage of the eHealth portal were monitored and registered continuously. Analysis of the usage of the portal (linear regression analysis) allowed us to indirectly estimate the self-management skills of the participants. TTR was analyzed with multilevel linear regression modelling. In this study, we aimed to empower patients with OAT by providing self-management, including an eHealth portal and education. We expected to learn what type of education could be a significant factor in the adoption of self-management. It was expected
that this self-management program would help patients to better manage their own INR values and medication use, thereby increasing their health status and diminishing severe complications.

Chapter 7 describes the effect of the combined education and eHealth programs on the therapeutic control of OAT patients in the PORTALS study. A total of 1,632 vitamin K antagonist patients of the Saltro Thrombosis Service were invited to participate, of which 56% (n=915) declined. Of the 717 patients that were interested to participate in the study, 247 provided informed consent. Of these, 110 patients continued to receive regular care (group 3) and 137 were randomly divided into the self-management groups 1 (e-Learning, n=63) and 2 (group training, n=74). Analyses showed no significant differences in TTR between the three time periods (p=0.520), the three groups (p=0.460), or the groups over time (p=0.263). Comparison of e-Learning and group training showed no significant differences in TTR between the time periods (p=0.614), the groups (p=0.460), or the groups over time (p=0.263). No significant difference was found between the self-management groups in usage of the platform (0-6 months p=0.571; 6-12 months p=0.866; 12-18 months p=0.260). The percentage of complications was low in all groups (3.2%; 1.4%; 0%). No overall significant differences in therapeutic control were found between the three groups. Furthermore, no differences were found between OAT patients trained by e-Learning or by a group course regarding TTR and usage of a supporting eHealth platform. The absence of improvement of the therapeutic control after the intervention seems to be (partly) caused by the fact that further improvement through a self-management program (including education) was difficult to achieve for this group of patients that already received high quality care; in comparison to literature, the baseline quality of OAT management in the present study could be considered high in all groups. Both of the training methods had a similar effect on anticoagulation control; for patients and healthcare professionals this implies that a good e-Learning program is a good alternative for labour-intensive group training. Therefore, we recommend to consider self-management programs supported by e-Learning as the preferred plan of action for the self-management for anticoagulation patients. Furthermore, self-management with an e-Learning component is suitable for motivated patients with sufficient digital skills; in our opinion, regular anticoagulation care needs to remain available for the remainder of the population. In this study, the practical value of the eHealth portal was very high for
patients because of the functionalities of self-monitoring, self-dosage, and digital advice from professional healthcare providers. Patients could manage their anticoagulation in their own time in their own chosen place. Using this self-management program gave them freedom, which might have been a strong motivating factor to use the program during the entire intervention period.

We concluded that with appropriate and sound training through e-Learning or group training, self-management seems safe and reliable for a selected proportion of motivated patients receiving oral anticoagulation treatment.

In Chapter 8 we discuss the implications of our findings regarding the e-Vita and the PORTALS study. We conclude that eHealth-supported self-management integrated into usual care can help patients with COPD and OAT to manage their disease. We assumed that blended care with total integration of eHealth and usual care will provide better quality of care in the long term. Even though eHealth-supported self-management was not superior to usual care regarding health status, the studies produced no negative effects, suggesting that eHealth is a safe option for delivery of self-management support and high-quality disease management.

The usage of eHealth platforms is better under conditions of perfect integration into usual care and with personal assistance and the coaching of patients. The usage is highest for patients with platforms that add high practical value in daily life.

Based on our findings, some recommendations can be made for additional research. Future eHealth applications should be tailored for individuals with varying health literacy, different chronic illnesses, and should focus on empowering them to obtain a healthier lifestyle. The need to educate and coach patients in the use of web-based platforms, and to educate healthcare professionals to take a facilitating role in an equivalent position, is of great importance. Furthermore, eHealth-supported self-management programs need to be offered for a sufficiently long period of time to give patients the chance to gradually change their behaviour and finally achieve a better health status. Therefore, more studies are needed, preferably with larger sample groups, and also including non-users. This will provide more insight into i) the optimal combination of usual care and eHealth-based self-management, ii) the preferences and needs of various types of patients, iii) the necessary education for healthcare professionals and patients, iv) the best platform
for patients that is easy to use, and v) the related costs.

The substantial workload generated by integrating a web-based platform in a self-management program emphasises the importance of piloting and assessing workforce implications for care centres.