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Towards tailored medication self-management

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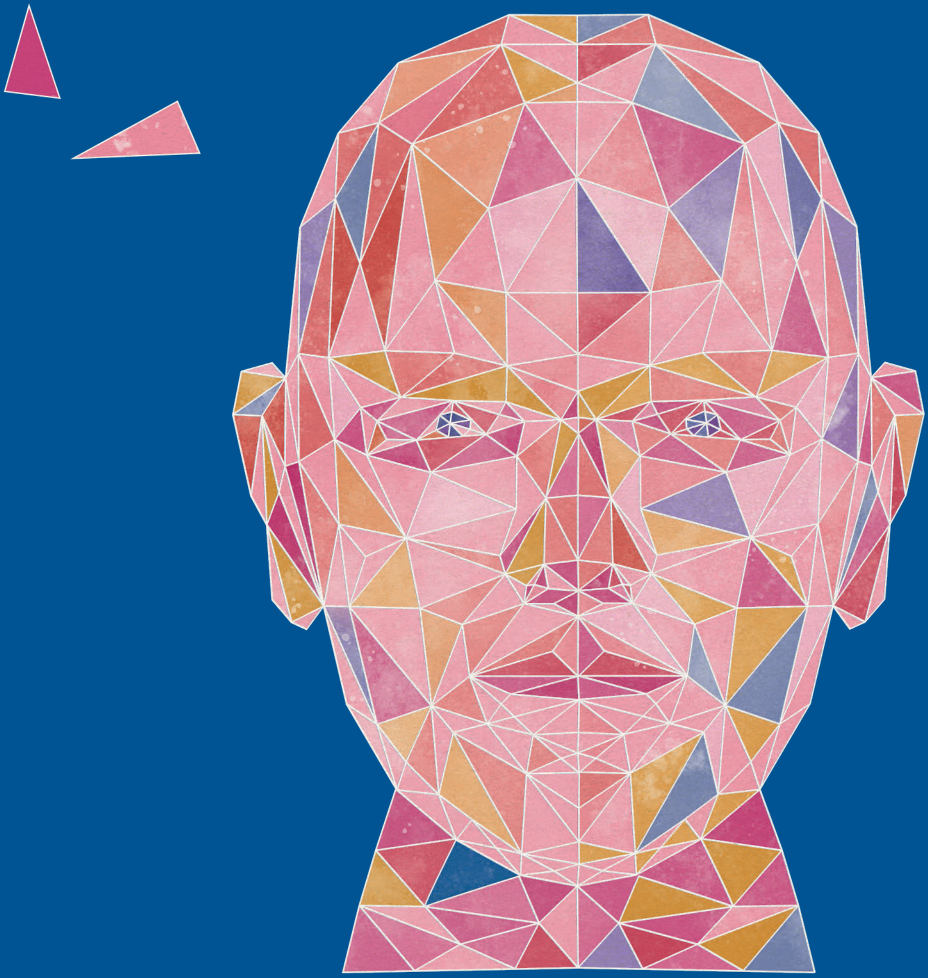
Needs of and support for patients with limited health literacy



Boudewijn Visscher

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DISSERTATION

To obtain the degree of Doctor at the Maastricht University,
on the authority of the Rector Magnificus, Prof. Dr. Pamela Habibović,
in accordance with the decision of the Board of Deans, to be defended in public
on Monday 17 April 2023, at 10.00 hours

By

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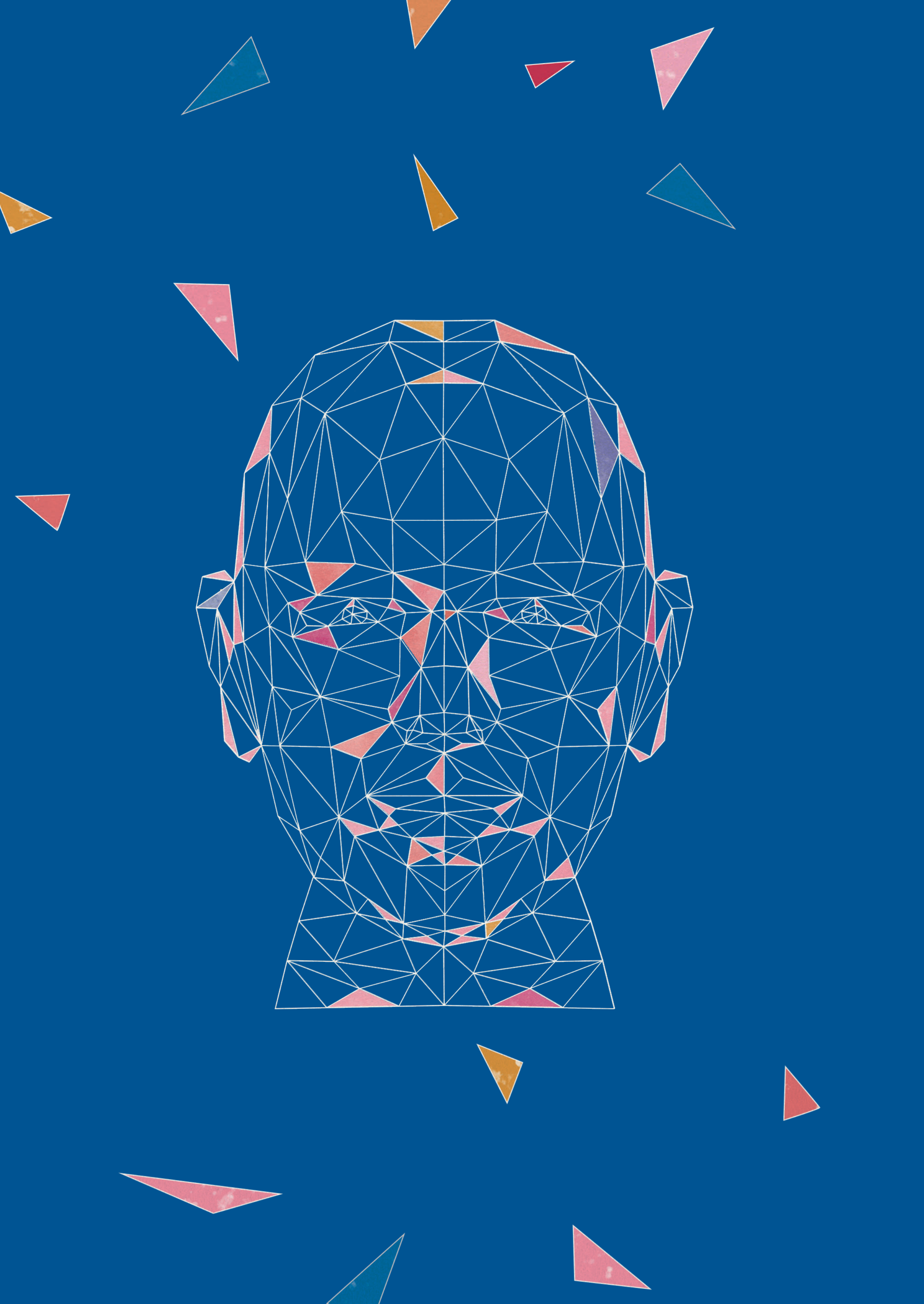


Summary

Summary

In Europe, the population's life expectancy is increasing, which means that people are living longer on average; thus, the proportion of elderly people is increasing. Approximately 80% of people aged over 65 years are affected by one or more chronic diseases. Europe's aging population is leading to a growing number of people affected by chronic disease, which will continue over the coming decades. Healthcare systems are under pressure to deliver appropriate care, partly due to the burden imposed on their limited financial and human resources by the growing number of people with (multiple) chronic diseases. Therefore, there is a strong call for patient self-management to meet these patients' healthcare needs.

Chapter 1 (Introduction) of this thesis describes how a crucial component in the management of chronic conditions is adequate pharmacotherapy. While many patients experience medication self-management as difficult, it poses additional challenges for people with limited health literacy. Health literacy encompasses people's knowledge, motivation, and competencies for accessing, understanding, appraising, and applying health information, which is used to make judgments and decisions in their everyday life concerning healthcare, disease prevention, and health promotion to maintain or improve their quality of life during their life course. To improve patients' medication self-management, it is critical to adequately support and facilitate those with limited health literacy. In general, such patients have a greater need for practical, recognizable, and simpler information as well as step-by-step explanations of how certain actions should be taken. Unfortunately, most medication self-management support interventions do not sufficiently meet these needs of people with limited health literacy. As a result, they make less use of available support programs.

This thesis aims to explore the needs of patients with a chronic disease and limited health literacy regarding medication self-management and how support for medication self-management can be tailored to those needs. Several of the studies presented in this thesis focused on multiple chronic diseases, of which diabetes was of special interest due to the extensive medication self-management behaviors that patients require. The following two research questions were formulated:

1. What are the needs of patients with chronic disease and limited health literacy regarding medication self-management?
2. How can patients with chronic disease and limited health literacy best be supported and facilitated in their medication self-management?

Empirical studies – Main findings

Chapter 2 addresses the needs of patients with limited health literacy and type 2 diabetes mellitus regarding medication self-management and their preferences for medication support. A two-stage qualitative needs assessment study was performed using in-depth individual interviews and focus groups. Patients were found to prefer to be supported in three domains. The first domain was support with information, including the provision of information that is reliable and relevant, easy to understand, and preferably presented with animations or as spoken text. The second domain was support in interactive communication: patients preferred more frequent contact with their healthcare professionals and wanted more contact with their peers to share their experiences of coping with their disease. Lastly, the third domain was stimulation and advice for adequately managing one's pharmacotherapy, which included advice on the dosing of medication in altered circumstances or positive stimuli to improve adherence to medication therapy. Future interventions should be created in co-creation with people with limited health literacy and fulfill their expressed needs regarding information, communication, and tools for improving self-management.

Chapter 3 describes the association between health literacy and beliefs about the overuse and harmful effects of medication. An online survey was sent to the 'Medication panel' of the Dutch Institute for Rational Use of Medicine. A total of 539 (25%) of the 2,157 panel members returned complete questionnaires, which were included in the analysis. The results indicated that patients with a lower level of health literacy had more concerns about the overuse and harmful effects of medication. Moreover, age, gender, and number of medications had no modifying effects on the association between health literacy and beliefs about medication. These results suggest that extra attention should be paid to individuals with a limited health literacy to decrease their concerns about the overuse and harmful effects of medication and to improve their adherence to self-management.

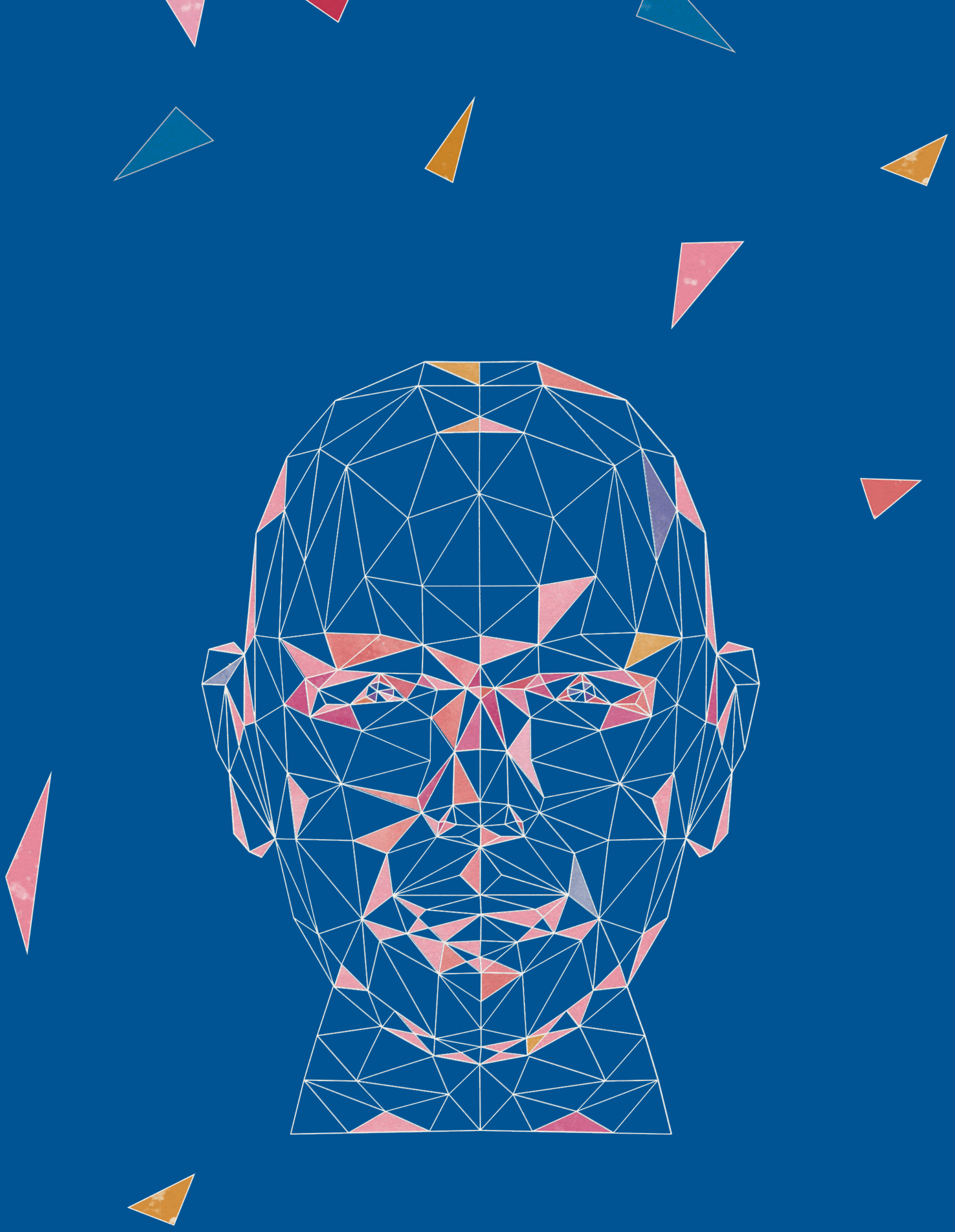
Chapter 4 describes evidence regarding the effectiveness of health literacy interventions in Member States of the European Union (EU). The study presented was the first systematic review on health literacy interventions in the EU. In total, 23 intervention studies published from 1995 until 2018 were identified. The interventions described in these studies either (a) aimed to improve (aspects of) health literacy; (b) were specifically tailored to different health literacy levels; or (c) were general interventions that aimed to improve health outcomes, which referred to the specific effects for patients with different health literacy or numeracy levels. The following three factors were likely to characterize promising interventions: (1) tailoring activities to the needs of participants (with limited health literacy); (2) addressing interactive and/or critical skills (as opposed to only knowledge); and (3) presenting the information in an appropriate manner (e.g., not complicated and with animated spoken text).

Chapter 5 describes the usability of an animated diabetes information tool ('Watch your diabetes') for patients with diabetes with limited and adequate levels of health literacy. The study design was qualitative; 25 semistructured interviews were conducted with patients with diabetes. The tool seemed to meet the needs of patients with limited health literacy as it provides information that is in understandable plain language as well as practical for supporting diabetes self-management. Moreover, most of the information is presented through spoken animations. In addition to animated videos, the tool enables users to contact fellow patients with diabetes through an online platform, where they can share knowledge and experiences. They can also perform a knowledge test to check whether they have understood the information. The videos are personalized by gender, age, and the medication and blood glucose meters used; thus, a patient will only receive information that is relevant to him or her. The tool was perceived as easy to use and usable by many patients with diabetes, both those with limited and adequate health literacy levels. Those with limited health literacy indicated that they had learned from the tool and had the intention to continue using it in the future. These participants also expressed the need for the tool to be more actively offered by healthcare professionals, while participants with adequate health literacy expressed the need for more in-depth information.

Chapter 6 describes the implementation of an animated medication information tool ('Watch your meds') in Dutch community pharmacies, with a special focus on patients with limited health literacy. A cross-sectional survey was conducted among community pharmacies in the Netherlands, which were recruited through email newsletters to pharmacy networks (N = 140). The majority of the pharmacists surveyed offered the tool to all of their patients, including those with limited health literacy. They stated that they offered the tool because the health insurance company offered them financial incentives and the tool complemented other existing medication information. According to the surveyed pharmacists, most patients are interested in using the tool. However, the main reasons why patients refuse to use the tool were reported to be a lack of affinity for or access to the required technology. The tool was mainly passively offered through sending a link to it. A more active method of offering the tool might be warranted to more effectively reach patients with limited health literacy.

Discussion and conclusion

Chapter 7 concludes the thesis by addressing and reflecting upon the main findings. It also describes practical implications and recommendations for future research. The goal of the thesis was to understand the needs of patients with chronic diseases and limited health literacy in regard to medication self-management, as well as how to most effectively tailor support to them. Medication self-management is known to be difficult for many people, especially those with limited health literacy. This thesis demonstrates that patients with limited health literacy can be supported in their medication self-management through tailored health information that is more accessible, understandable, and easier to assess. In addition to providing health information and improving knowledge, medication self-management support should also focus on helping patients to acquire skills and self-confidence. This thesis provides recommendations for the design, content, and strategies of future self-management interventions for this group of patients. It also discusses strategies for reaching patients with limited health literacy and the importance of including them in the design of future interventions. Although healthcare professionals are willing to support medication self-management, a more active delivery approach and training are required to reach patients with limited health literacy.



1

General introduction

General introduction

In Europe, people are living longer, which represents a major success in public health. This has been achieved through a consistent reduction in mortality, particularly in young and middle-aged people, and also better care for the elderly.[1,2] The life expectancy at birth in Europe is expected to increase from an average of 84.0 years for women and 78.5 years for men in 2019 to 92.8 years for women and 90.5 years for men by 2065.[3,4] This greater longevity is resulting in an increased proportion of elderly among the population.[2] Chronic diseases affect over 80% of people aged over 65 years in Europe and account for an estimated 77% of the disease burden, as measured in disability-adjusted life years.[2,5] Over the past decades, a growing number of people in the Netherlands and other European countries have been living with one or more chronic disease(s).

Thus, an aging population leads to a growing number of people affected by chronic diseases, which is expected to rise substantially over the next few decades, as well as to a decreased potential labor force in the healthcare sector.[6,7] Therefore, strong calls for patient self-management have been made to meet the healthcare needs of patients with a chronic condition.[6,7]

Patients with diabetes

Diabetes is an example of a chronic disease that requires constant self-management. It is one of the most prevalent chronic diseases in Europe and in the Netherlands.[8] Approximately 6.2% of the European population and 5.4% of the Dutch population are diagnosed with diabetes, and these figures continue to grow.[9] Based on demographic developments alone, the absolute number of cases of diabetes mellitus in the Netherlands is expected to increase by 29% from 1.14 million to 1.46 million from 2019 to 2040.[8,10] Diabetes is associated with disabling long-term complications due to consistently elevated blood glucose levels, including cardiovascular disease, retinopathy, neuropathy, kidney failure, and lower-limb amputation.[11-13] These complications have a significant impact on patients' disease burden, quality of life, and life expectancy.[11-13] In 2016, the healthcare costs of diabetes and its complications were €2.8 billion, which constituted approximately 3.0% of the total health expenditure in the Netherlands.[11] Approximately 85% of all patients with diabetes in the Netherlands have at least one comorbidity, while 25% have four or more comorbidities.[11,14,15] Such multimorbidity is associated with higher levels of healthcare utilization compared with people with a single chronic disease.[6,16]

Self-management

Appropriate care can contribute to controlling chronic diseases such as diabetes as well as to improving patients' quality of life. Healthcare systems are under pressure to deliver appropriate care, among other things, because of the growing number of people with (multiple) chronic diseases and the resulting burden on financial and human resources.[16] As a result, healthcare policies in many Western countries are aimed at enabling and facilitating independent living among older adults within the community.[17,18] This increasing attention to self-management is also reflected in a new definition of health, where health is defined as "the ability to adapt and self-manage in the face of social, physical, and emotional challenges."[19]

Historically, Western healthcare systems are built around an acute, episodic model of care, in which healthcare professionals are seen as the main actors and patients as passive recipients of care. This approach to care does not match the reality for most patients with chronic diseases. Part of the care for these people is delivered by professional caregivers, but the majority is performed by the patients themselves (or with the help of informal caregivers) through self-management, out of sight of healthcare professionals.[20,21] Therefore, people with a chronic disease play a crucial role in the management of their disease.[22] Over the past decades, the importance of patients' own beliefs and behavior has been recognized, and a shift has occurred in healthcare from traditional professional-driven care toward more patient-centered care; here, patients play a more active role, and healthcare professionals and patients are considered equally important partners in chronic disease management.[23,24]

Self-management is defined as a patient's ability to manage symptoms, treatment, and physical and psychosocial consequences, and also to implement lifestyle changes inherent to living with a chronic disease.[25] Self-management can be categorized into the following four different types of tasks or challenges for patients: (1) performing medical self-management; (2) communicating with healthcare professionals; (3) coping with the consequences of one's illness; and (4) making lifestyle changes.[24,26,27] The self-management of a chronic disease requires many ongoing patient activities to occur in parallel. In diabetes, for example, self-management involves the following activities: taking medications as directed, self-monitoring blood glucose, eating a healthy diet, taking regular physical activity, and performing foot care.[28-30] The sheer number of tasks can be overwhelming for individuals, and the required activities and changes are often viewed by patients as difficult to achieve.[31,32]

Importance of medication self-management

A crucial component of the management of chronic conditions is adequate pharmacotherapy.[33] Pharmacotherapy may improve health-related outcomes by slowing or halting disease progression and easing the symptoms of disease.[33,34] Incorrect use or nonadherence to pharmacotherapy may cause a substantial worsening of the disease, the deterioration of patients' quality of life, and increased morbidity, mortality, hospital admissions, and healthcare use.[34-40] Furthermore, the pharmacotherapy of chronic diseases is often complex, especially when medication is used for multiple diseases.[14,15] This treatment complexity is associated with therapy nonadherence and lays a heavy burden on patients' self-management capacities.[29]

Many patients with a chronic disease experience their medication self-management to be difficult.[41-44] For adequate medication self-management, patients with chronic diseases require information and knowledge about the need to take medication and its appropriate use, motivation to implement medication intake in their daily practice, and the necessary behavioral skills to do so.[45,46] For example, skills such as the comprehension and processing of medication information, the planning and organization of medication use, medication administration, management of beliefs about the medication, shared decision making about appropriate medication, adherence to the medication schedule, and communication with the healthcare provider.[41,43,44] Moreover, factors related to pharmacotherapy and healthcare professionals can contribute to unsafe situations and inadequate medication self-management.[34,47,48] For example, the use of a large number of medicines with multiple dosing schedules each day or information from multiple healthcare professionals about medications, each with their own instructions, would influence the difficulties that a patient experiences in their medication self-management.[34,47,48]

Health literacy and medication self-management

While medication self-management is experienced as difficult by many patients, it poses additional challenges for people with limited health literacy. Health literacy "entails people's knowledge, motivation and competencies to **access, understand, appraise** and **apply** health information to make judgments and take decisions in everyday life concerning healthcare, disease prevention and health promotion to maintain or improve quality of life during the life course."[49] In the United States, the concept of health literacy was introduced to research in the 1990s. Since then, many different conceptualizations of health literacy have been developed.[49]

Originally, studies focused primarily on basic reading, writing, and numeracy skills in the healthcare setting. Subsequent conceptualizations encompassed a range of skills, including social and communication skills that enable people to obtain, understand, and use health information in ways that improve their health, well-being, and involvement in medical decision-making.[50] More recent definitions have also included the ability to apply these skills in different situations and throughout one's lifespan.[49] In a recent model, the cognitive skills related to the ability to access, understand, and appraise information were referred to as the "capacity to think" (Figure 1).[51] However, to be able to take an active role in healthcare, the "capacity to act" is equally as critical in relation to the various aspects of self-management.[52] The capacity to act concerns the ability to apply information to one's own situation; moreover, it is related to self-efficacy and motivation and is therefore seen as a major driver of behavioral change and the extent to which people feel able to self-manage.[52] In addition to the model displayed in Figure 1, Hibbard and Mahoney developed patient activation theory, where patient activation is defined as "the individual's knowledge, skill and confidence in managing his/her own health and care."[53] Increased patient activation is related to positive changes in a variety of self-management behaviors, such as doing physical exercises, managing stress, or informing oneself of the benefits, risks, and use of a medication.[54,55] The concept of patient activation underlines the importance of the capacity to act.

In European countries, an average of 47.6% of all adults have limited health literacy, but huge differences exist among countries.[56] In the Netherlands, 24.5% of the population have limited health literacy.[57] People with limited health literacy are relatively more likely to have a chronic condition than people with adequate health literacy.[58] Moreover, they tend to suffer disproportionately from chronic diseases as they generally have worse health outcomes, including higher mortality, worse general health, more hospitalizations, greater use of emergency care, and higher healthcare costs.[59-61] These negative outcomes are partly due to worse medication adherence and self-management in general.[62,63]

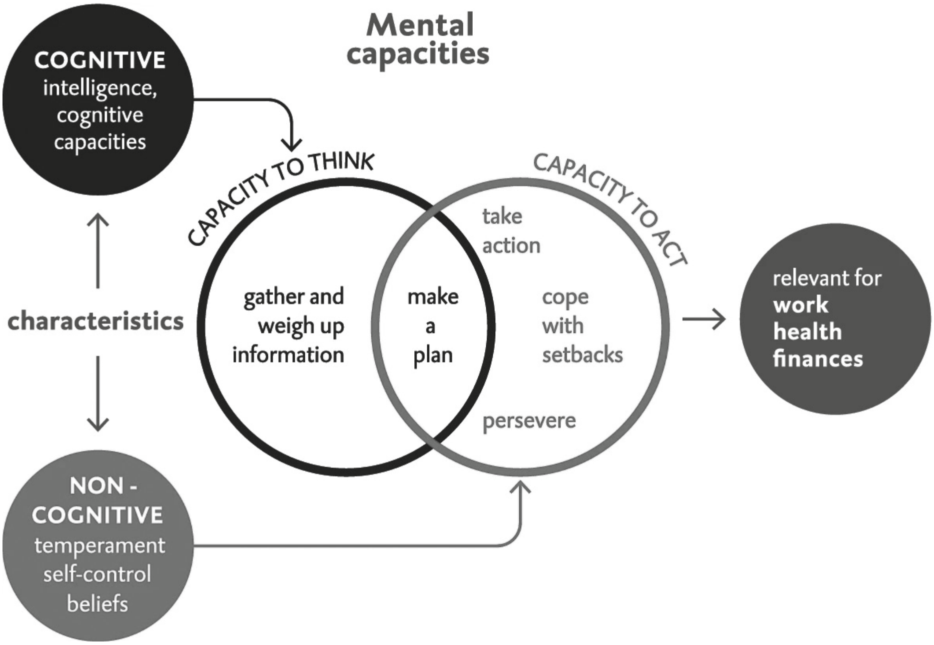


Figure 1: Characteristics, mental capacities, and societal domains[51]

The fact that patients with limited health literacy have more difficulties regarding their medication self-management is associated with several factors. First, people with limited health literacy experience difficulty in seeking, finding, and obtaining health information; therefore, they have limited **access** to it. Moreover, people with limited health literacy sometimes have difficulty with basic reading skills, which are necessary for accessing written information. Regarding medication use, they often experience more difficulties reading information about medication use, such as print prescriptions, instructions on pill bottles, and medication leaflets.[64] Limited access also results from having fewer digital competencies. People with limited health literacy are less able and inclined to search for health information on websites.[65] Second, they have difficulty in **understanding** health information as – due to cognitive limitations – they are less able to comprehend its contents; therefore, people with limited health literacy are also at greater risk of misunderstanding the medical terms and jargon used by healthcare professionals or those found in written instructions concerning the dosage, duration, and frequency of medication use.[59,62,66-68] This misunderstanding contributes to medication nonadherence, which may lead to reduced quality of life and increased drug-related problems.[69,70] Third, people with limited health literacy experience difficulty in **appraising** health information (e.g., for trustfulness) and whether the information is applicable to their situation. For example, they find it difficult to judge what to do when they receive conflicting information from many information sources, such as different healthcare providers, informal caregivers, leaflets, and the media.[71] This often leads them to experience confusion due to the perceived abundance, complexity, and inconsistency of the information received, which prevents them from absorbing and applying it. Fourth, people with limited health literacy experience difficulty in **applying** health information to their own situation. Compared with people with adequate health literacy, people with limited health literacy take less control during conversations with their doctor and experience more difficulty in performing self-management tasks.[52,72]

Medication self-management support

To improve patients' medication self-management, it is vital to adequately support and facilitate them. Over the last decade, several initiatives have been implemented to support people in their self-management tasks.[73,74] Self-management support involves a patient-centered collaborative approach to enhance patients' self-management by promoting patient activation, self-efficacy, education, and empowerment. Self-management support changes and expands the role of healthcare professionals from delivering information and traditional patient education to helping patients build confidence and make choices that lead to improved self-management and better outcomes.[75] A large variety exists in the **form, content,** and **goals** of existing self-management support interventions. For example, support is provided through patient education, reminders, medication adherence counseling, telephone-based counseling providers, decision aids, and individual-tailored prescription labels with instructions for medication.[76-79] With regard to **form**, individual guidance or group interventions are offered face-to-face by telephone or the Internet. In terms of the **content** of existing self-management support interventions, the emphasis is mainly on educating patients about knowledge and to a lesser extent on behavioral change (e.g., problem solving, goal setting, and time management). Lastly, the **goals** of these interventions mainly focus on improved medication intake, specific areas of health, quality of life, use of care, and lifestyle.[80-82]

Despite the fact that people with limited health literacy experience difficulties in adequate self-management, they make less use of current self-management support programs than people with adequate health literacy.[72,83] This could be explained by the fact that people with limited health literacy are less likely to actively seek support, that current support is less effective for them, and that existing self-management support programs do not sufficiently meet their needs.[26,72,83] More promising support tools for people with limited health literacy are distinguished from less promising ones by being specifically tailored to the needs of this patient group as well as addressing skills beside knowledge.[52,84] In general, patients with limited health literacy have a greater need for practical, recognizable, and simpler information as well as step-by-step explanations of how to take certain actions; moreover, they have a greater need for support in making choices.[80,83,85] Unfortunately, most medication self-management support interventions do not sufficiently meet such needs of people with limited health literacy.[80,83,86]

Aim and research questions

This thesis aims to explore the needs of patients with a chronic disease and limited health literacy regarding medication self-management as well as how medication self-management support can be tailored to these needs. Several of the studies presented in this thesis focused on patients with chronic diseases in general. The studies that focused on one chronic disease focused on diabetes because of the extensive medication self-management behaviors required by patients with diabetes. Thus, the following two research questions were formulated:

1. What are the needs of patients with chronic disease and limited health literacy regarding medication self-management?

This first research question was aimed at discovering the current barriers to medication self-management, current attitudes toward medication use, the need for support for medication self-management, and the preferred way to receive such support.

2. How can patients with chronic disease and limited health literacy best be supported and facilitated in their medication self-management?

This second research question was aimed at examining health literacy interventions, exploring the usefulness of tailored medication self-management support, and addressing how such support can be optimally designed and implemented to reach people with chronic disease and limited health literacy.

Outline of the thesis

In line with the two research questions, this thesis is structured in two parts, which are outlined as follows:

Part I: Needs of patients with chronic disease and limited health literacy regarding medication self-management

- **Chapter 2:** Medication self-management support for people with diabetes and low health literacy: A needs assessment.
- **Chapter 3**: The impact of health literacy on beliefs about medication in a Dutch medication-using population.

Part II: Support of patients with chronic disease and limited health literacy in their medication self-management

- **Chapter 4:** Evidence on the effectiveness of health literacy interventions in the EU: A systematic review.
- **Chapter 5:** Usability of an animated diabetes information tool, with a special focus on health literacy: a qualitative study.
- **Chapter 6:** Implementation of an animated medication information tool in community pharmacies, with a special focus on patients with limited health literacy.

Chapter 7: General Discussion

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Medication self-management support for people with diabetes and low health literacy: a needs assessment

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Abstract

Introduction

An adequate level of health literacy is regarded as a prerequisite for adequate medication self-management. Low health literacy skills are relatively more common in people with Diabetes Mellitus type 2. The aim of this study was to explore the needs regarding medication self-management of people with type 2 diabetes and low (functional, communicative and critical) health literacy, and their preferences for medication self-management support.

Materials and methods

A two-stage qualitative needs assessment study was performed using in-depth individual interviews and focus groups.

Results

The participants preferred to be supported with reliable and easily understandable information, adequate interactive communication with health care professionals and fellow people with diabetes and tools for medication self-management support.

Discussion

Future interventions should be created in co-creation with people with low health literacy and fulfill the expressed needs on information, communication and tools to improve self-management.

Introduction

Diabetes Mellitus type 2 (DM2) is a complex and demanding chronic disease that requires extensive self-management.[1] Inadequate self-management can accelerate the onset of complications caused by DM2 and deteriorate the quality of life of people with DM2.[1,2] The self-management activities in DM2 mainly focus on lifestyle and medication treatment.[3] Regarding medication treatment, self-management activities consist of e.g. measuring glucose, adjusting insulin dosage, adherence to oral antidiabetics (OAD) and dealing with side effects. This so-called 'medication self-management' is defined as the range of tasks people have to undertake to successfully manage their therapeutic regimen and sustain safe medication use.[4] Medication self-management requires a high level of control from a person and some autonomy to adjust his or her medication if necessary.[5]

Health literacy is the ability of individuals to gain access to, understand and use information in ways that promote and maintain good health. [6] Health literacy consists of different sets of skills, as is described in the model of health literacy by Nutbeam (Table 1).[7] People with low health literacy more often experience problems with misunderstanding on prescription medication labels and medication nonadherence. [7-9] Moreover, low health literacy skills are relatively more common in people with DM2. [10-12]

Interventions aimed at improving medication self-management are available.[13,14] These interventions have been proven effective, however seem to be too difficult to use and understand for people with low health literacy (e.g. the language in the presented information is too complex).[15,16] A review focusing on multiple illnesses/chronic diseases highlighted the urgency for interventions tailored to the needs of people with low health literacy.[15] That's why Rademakers et al. recommended involving people in all stages of intervention development (co-creation).[17]

Table 1: Three types of health literacy

Functional health literacy	"basic skills in reading and writing that are necessary to function effectively in everyday situations." [7]
Communicative or interactive health literacy	"advanced cognitive and literacy skills which, together with social skills, can be used to actively participate in everyday situations, extracting information and deriving meaning from different forms of communication, and applying this to changing circumstances." [7]
Critical health literacy	"advanced cognitive skills which, together with social skills, can be applied to critically analyze information and use this to exert greater control over life events and situations." [7]

A first step in co-creating an intervention is a needs assessment. [18] Previous studies have focused on the needs of people with DM2, but most do not measure the level of health literacy, except for the study of Fransen et al. that concluded that people preferred personal support rather than written information and there was heterogeneity in attitudes towards self-management. [19] However, that study focused on functional literacy only and indicated that the association between functional health literacy and self-management was not straightforward. The authors suggested assessing interactive and critical health literacy skills as well, since they may be better predictors for self-management. [19] In addition, the study by Fransen focused on self-management in general and gave little specific attention to adequate medication self-management, while medication is an important therapy option in the treatment of DM2 and people with health literacy often experience problems with medication self-management.[7-9,19] Therefore the aim of our study was to explore the needs of people with low (functional, communicative and critical) health literacy and DM2 regarding medication self-management and to explore the preferences for medication self-management support.

Materials and Methods

Design

A two-phase qualitative study was performed involving in-depth individual interviews and focus groups. First, in-depth individual interviews were performed with people with DM2 and a low level of health literacy. Second, results from the interviews were further discussed in focus groups and preferences for diabetes medication self-management support were explored. The Institutional Research Board of the Department of Pharmaceutical Sciences of Utrecht University approved the study protocol. The study conformed to the provisions of the Declaration of Helsinki. [20]

Study setting and participants

Convenience sample

People with DM2 and low health literacy were recruited by means of a convenience sample from two pharmacies in Amersfoort in the Netherlands serving a total population of 28,000 people. There were two inclusion criteria: having DM2 and low health literacy. The first step was screening potentially eligible participants. In the Netherlands, people are registered at the pharmacy. The participating pharmacists extracted a list of people from the pharmacy information system that were dispensed the most common diabetes medication (metformin or insulin) at least once during the past year. The pharmacists selected people with low health literacy on the basis of potential risk groups (e.g. lower education level, higher age), statements known to be used to cover-up the lower level of health literacy (e.g. I have forgotten my glasses so I cannot sign the papers) and behavioral signals of not understanding information (e.g. no response to explanation of medicines). The potentially eligible participants were contacted by telephone by the pharmacists (starting at the top of the list) or contacted when visiting the pharmacy. The pharmacist informed them about the study in suitable, understandable language and asked permission to make an appointment for an intake interview with the researcher.

Health literacy level

In the intake interview the level of health literacy was determined by means of the Functional, Communicative and Critical Health Literacy scale.[21] The Functional, Communicative and Critical Health Literacy scale measures three aspects of health literacy, using 14 questions: functional (5 questions), interactive/communicative (5 questions) and critical (4 questions). All questions were scored on a four point Likert-scale (1-4) with a range from never perceiving difficulties too often perceiving difficulties. Mean total and mean sub-scale scores of the Functional, Communicative and Critical Health Literacy scale were calculated by summing items scores and then dividing the sum score by the total number of items (in total or in sub-scale). Based on previous research, potentially eligible participants with a mean score ≤3 in total or on a sub-scale were defined as having limited health literacy and were included in the study. [21,22]

Informed consent

The informed consent was written in an easy and understandable language, and additional information was given and questions were answered during the intake interview. All included participants signed a written informed consent form. To create a relationship of trust between the researcher and the participants, two meetings were planned before the interview and/or focus groups. The first encounter was the intake interview at the pharmacist and the second one was a phone call a week before the interview and/or focus group, to see if there were any ambiguities about the planned interview and/or focus group and to hear if the participant would like to discuss specific topics. Trust between the researcher and the participants was necessary so that the participants could freely communicate about perceived barriers and needs. [23]

Interviews and focus groups

Individual interviews

The interviews were conducted at the participant's home to develop the relationship of trust in an informal setting. A topic list was developed to explore the perceptions, barriers and needs. The topic list (S1 Table. Topic list interview) was based on a framework used the study of Fransen et al. that measured the needs of people with DM2, which was guided by the results of a literature review. [19,24] To adapt the framework to our study, self-management was changed to medication self-management. The framework included the following categories: perceived impact of diabetes medication self-management, experiences of diabetes medication self-management, attitudes towards diabetes medication self-management and preferences for diabetes medication self-management support (Fig 1). The interview process was iterative and was performed by one of the researchers (BBV). The recruitment of participants by the pharmacists, the intake interviews and the interviews was done simultaneously. The total number of interviews was based on data saturation, meaning that when a new interview did not lead to more information related to the research question, the recruitment of participants for the interviews was stopped. Two researchers independently (BBV and BS) determined whether the data saturation had been reached by discussing if the interview has led to more information related to the research question.

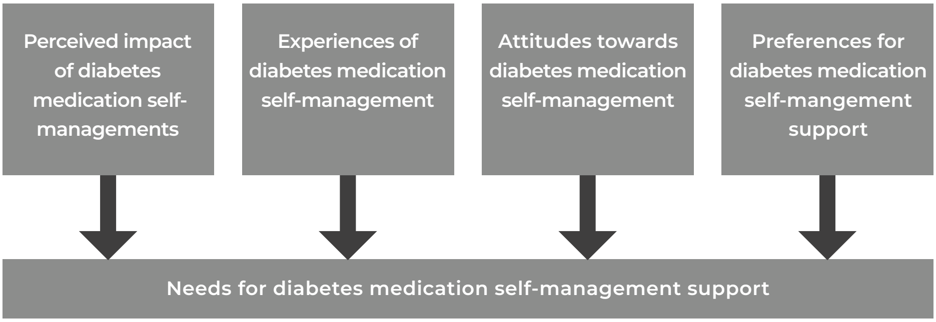

Figure 1. Framework for ordering person' needs for diabetes medication self-management support.

Focus group

The focus groups were used to explore the perceptions, barriers and needs. Two focus group meetings were organized: one focus group with a part of the participants who also did the interview by drawing random numbers that corresponded with participants by an independent researcher (BS) and a second focus group with participants that did not participated in the first phase to gain new insights.

Recruitment of these participants was conducted in the same way as recruitment of the participants that participated in the interview and they were recruited from the same population. The focus groups were conducted in a room at the University of Applied Sciences Utrecht (Amersfoort location). The focus group meetings consisted of three phases. First, the topics of the topic list (Annex A) were discussed. Second, the main outcomes of the interviews were discussed, to gain more insight into the previously given answers. Third, existing interventions to improve medication self-management were shown and discussed. These interventions were not tailored to people with low health literacy. The existing interventions were the book "I have diabetes, what can I do?" [25], MySuggr App [26] and Appsuline [27]. The existing interventions were intended as a starting point to broaden and deepen the conversation and to explore preferences in medication self-management support.

Analysis

Both the interviews and focus groups were audio recorded and transcribed verbatim. The focus groups were also recorded on video. The Atlas.ti 8 software program was used for the management and analysis of the transcripts. The analysis proceeded through three stages, consisting of open, axial, and selective coding with constant comparisons taking place throughout each phase. In the selective coding phase, the codes were placed in the framework based on Fransen (Figure 1). The analysis was done by two researchers independently (BBV and BS), and where differences occurred, consensus was reached through discussion with a third researcher (JR).

Results

Characteristics of participants

For the interviews and focus groups, 21 potentially eligible participants were recruited by the pharmacist and they had an intake interview with the researcher. Three potentially eligible participants with a mean score >3 in total or on a sub-scale on Functional, Communicative and Critical Health Literacy scale did not meet the criteria of low health literacy and were excluded. In total 18 participants participated in the study: 7 participants participated in the interviews, 6 participants participated in the interviews and focus group and 5 participants were recruited for the focus group only.

Table 2 shows the background characteristics of the participants. Most participants were male (11/18) and the age of the participants varied from 40 to 79 years old. Most of the participants had a Dutch ethnic background (15/18) and those with a migration background live for more than 30 years in the Netherlands. On the functional health literacy scale, 14 participants had low health literacy skills and can be considered low literate.

Table 2. Background characteristics of participants with diabetes type 2 and low health literacy (n=18)

					Functional, communicative and critical health literacy scale - mean scores[a]			
Gender	**Age**	**Migrant Background**	**Years since DM2 diagnosis**	**Inject Insulin**	**Functional**	**Communicative**	**Critical**	**Mean**
Male	64		10		2.8	2.8	2.5	2.7
Female	67		8	x	2.4	3.2	4.0	3.2
Female	64		10	x	2.2	2.4	2.0	2.2
Male	73	x	23	x	1.6	2.6	1.0	1.7
Male	67		35	x	1.4	1.6	1.8	1.6
Male	77		20		3.0	2.6	1.5	2.4
Female	79		18	x	2.8	2.8	1.7	2.4
Male	53		17	x	2.2	1.0	1.0	1.4
Female	74	x	26	x	2.8	2.8	3.0	2.9
Female	43		14		3.6	2.4	2.0	2.7
Male	40		2		1.0	1.0	1.0	1.0
Male	68		18	x	1.8	1.8	2.0	1.9
Male	69		9	x	2.0	2.8	1.0	1.9
Male	48	x	12		2.8	2.4	2.0	2.4
Male	66		14		3.2	2.8	2.8	2.9
Male	65		15		1.6	1.4	1.0	1.3
Female	79		16		2.4	2.0	1.8	2.1
Female	60		10	x	4.0	2.6	1.0	2.5

[a] Range score 1-4. Mean score ≤3 in total or on a sub-scale were defined as having limited health literacy and were included in the study

Perceived impact of diabetes medication self-management

The participants described that their lives had barely changed since the diabetes diagnosis. Especially on a day at home following a daily routine, the participants hardly perceived any impact of their illness and their medication intake. The participants experienced difficulties with medication self-management when they changed their daily routine, for example when leaving home for a visit. In such cases they had to think of many things to take with them (medicines, nutrition), which cost them a lot of energy. Participants expressed the need to make it easier to remember all the necessary things when changing their daily routine.

> *''Taking medication is not always easy, especially with that insulin. Especially when we go to someone in the evening, we forget it. In the morning we are always at home, but if we go to dinner with someone at night I forget the insulin.''*
>
> **''***Well when I eat at a table, I have my medication in sight and then I know that I have to take my medication''*

Experiences of diabetes medication self-management

Initially, most participants stated that they strictly adhered to their medication schedule and that they did not need additional support. After additional in-depth questions about the way they adhere to their medication schedule, it became clear that they did experience problems with their adherence. The participants who used insulin explained that the amount of insulin they inject depended on their overall feeling, without measuring the actual blood glucose values. Reasons for injecting insulin without measuring blood glucose values varied: they did not want to measure, it hurt when inserting a needle or it did not make sense because ''the blood glucose values are always the same''. Some expressed the desire for monitoring blood glucose values without having to prick.

All participants linked their medication intake (OAD, short and long acting insulin) to their daily eating and sleeping rhythm (e.g. before breakfast, during dinner and before going to bed). The participants had different ways of ensuring themselves that the medicines were taken. A tool to preserve, distribute and organize the medicines was a frequently expressed method. These systems could be supplied by the pharmacy in the form of prefilled packages, or through use of their own medication boxes. These medication boxes were bought at a pharmacy or created by the participants themselves. Especially the insulin was put in a visible place, so that they did not forget it. Some participants were helped by their partner or informal caregivers to remember the medication intake. Many participants used an alarm clock for taking medication.

> *"I make boxes with pills for the entire week for my husband and also for me"*
>
> *"On the basis of how I feel I can judge whether I am high or low in my sugar and therefore I do not measure glucose"*

> *“I do not measure my blood glucose before injecting insulin, because my blood glucose values are often the same”*

Attitudes towards diabetes medication self-management

In the selective coding phase, there was a wide range of attitudes towards diabetes medication self-management. All codes were printed and two researchers discussed the codes to formulate subgroups from the codes. The discussion resulted in that the codes in this category could be subdivided into three groups of attitudes towards diabetes medication self-management. Every participant fitted into one of these groups.

Adequate self-management

The first group consisted of participants reporting that they had adequate medication self-management and were motivated because they wanted to live as long as possible with as few complications as possible. They have also changed their lifestyle (nutrition and exercise) after the diagnosis.

Unaware

The second group included participants with an unaware attitude to medication self-management who wanted to keep charge of their own life, lifestyle and the amount of taken medication. Most of the participants in this group expressed that they did not understood the relationship between medicines, diabetes and their lifestyle.

Aware but not activated

The third group of participants were aware of the importance of adequate medication self-management but did not know where to start or how they could adequately self-manage their medication.

> *“I am not very good at taking medication on time. I use metformin five hundred milligrams three times a day, but I sometimes forget … and I do not know how I can always take my medication…”*
>
> *“I know it is good to always take my medication, I tried, but I just don’t succeed.”*

Participants’ preferences for diabetes medication self-management support

Participants found it hard to distinguish the medication self-management preferences from other preferences in self-management support. For completeness these preferences are shown, partly because they have a relationship with medication self-management support. All codes were printed and two researchers discussed the codes to formulate subgroups from the codes. The preferences for support can be divided into 3 categories: preferences for information, communication and tools for medication self-management (Table 3).

Table 3. Participants' preferences for diabetes medication self-management support

Information	Communication	Tools for medication self-management

• **Reliable and relevant information**
• **Short and easy information**
• **Spoken information**
• **Multiple languages**
• **Overview on all medication**
	• **Healthcare professionals**
	  • *Extra checks*
	  • *Information about new medication*
	  • *Emoticons to express overall feeling*
	  • *Service desk*
	• **Fellow diabetics**
	  • Exchange experiences
		• **Real time automatic blood glucose measurement**
		• **Advise amount of insulin**
		• **Alarm clock with intake confirm button**
		• **Positive stimuli**

Information

The participants found it difficult to read and understand the information on the labels of the medication package and medication prescription due to the small print and difficult words. A part of the participants were satisfied with the current support of the healthcare professionals. According to the participants, the current support consisted mainly of presenting or giving information. The participants expressed that the medication information was clearly presented by their healthcare professional and that they could easily ask them questions if something was unclear. Besides the information from their healthcare professionals, participants received information about medication self-management from other sources: the internet (mainly through the first hits on google.com), the Dutch diabetes association, or family. They found it difficult to estimate whether the information from other sources than the healthcare professionals are relevant and reliable and therefore they trusted mainly the information of the healthcare professionals and tried to follow those instructions for medication self-management. The participants would like to have more information about medication, side effects and new available medicines. The information should be short and easy to read and some participants preferred spoken information / animations in multiple languages, because they experienced reading difficulties.

In the focus groups, there was a heterogeneity in preferences in presenting information: some participants preferred a booklet with information (e.g. ''I have Diabetes, what can I do?''), and others preferred an application. They preferred a simpler version of an application as was shown with less written information. Most participants had other diseases besides DM2 and they also had medication for those diseases. The participants expressed the feeling that they found it hard to distinguish which medication was used for exactly which disease. The participants preferred to have an overview of all the medication, including an overview of contraindications and side-effects of the medicines on other medicines.

Communication

The participants distinguished between communication with the healthcare professionals and fellow people with diabetes. The participants expressed the feeling that they preferred to be informed by the healthcare professional when new medicines were available and to have extra checks to see if the medication was taken properly. It was suggested in the focus group that including self-report on daily mood to an app. For example adding emoticons to the apps would be of added value, which can be discussed during the check-ups with healthcare professionals. Some participants would like to be advised by a 24-hour general service desk, which addresses all their medication related questions. Others did not want this because they preferred to have one healthcare professional that they trust and who already knows their background and medical history. The participants discovered in the focus group how valuable it is to be in contact with fellow people with diabetes. They would like to meet fellow people with diabetes more often to exchange experiences and tips about how to live with diabetes.

Tools for medication self-management

Some participants found information on a recently developed real time, automatic blood glucose measurement system and would like to have such system as a tool for their medication self-management. The system has recently become available but is often not reimbursed by the health insurer and none of the participants had tried the system. The blood glucose values can be displayed online, whereby they preferred to receive advice about the amount of insulin they need to take. Some participants preferred for the alarm clock to be set remotely by the healthcare professional. An experienced difficulty of the alarm was that users snooze or turned off the alarm, because of being busy with other things (e.g. having a conversation), and then did not remember whether they had the medication. The participants indicated that it could be useful to confirm to the alarm that the medication was taken. This would also create an overview of the taken medication. There was an ambiguous preference for obtaining positive stimuli: some would like it if good glucose values or walking enough steps were rewarded with positive stimuli (e.g. short positive messages), others found it rather irritating.

> *"Look, if they have something new, I would like to know. If they have new medication with fewer side effects or something, then I am interested. Something new can also be good, I am interested in that."*
>
> *"When I get new medicines my daughter says, you really have to take breakfast. She really has to explain it in Arabic. I cannot read and understanding other languages than Arabic is difficult for me."*

Discussion

This study explored the needs and preferences of people with DM2 with low health literacy regarding medication self-management and the preferences for medication self-management support. The participants differed in their needs, attitudes and preferences. With respect to attitudes towards diabetes medication self-management, three groups could be discerned: adequate self-management, unaware and aware but not activated. The preferences for support could be divided into three categories: preferences for information, communication and tools for medication self-management.

This study highlighted additional needs and preferences of people with DM2 and low health literacy, which will be used in the development of an co-created intervention in the next phase of this project. In the development of the intervention, options to personally modify and tailor the intervention may be important to create an optimal fit between the intervention and the needs and preferences of the user of the intervention. [15,17] For example, the three distinguished groups on attitude could function as a persona to tailor the preferences and needs for improving medication self-management. In addition, consideration should be given to mechanisms and factors that influence medication self-management. The self-determination theory emphasizes the importance of the underlying reasons for behavior. The self-determination theory indicates that skills and knowledge are not sufficient to change behavior, but that autonomous motivation is needed.[28] This autonomous motivation can increase in various ways, whereby the preferences differ per person. [29] When developing an intervention, the various routes to increase autonomous motivation must also be studied and taken into account.

The added value of patient engagement in the development of interventions is increasingly recognized and valued, but there is little literature on how to best involve people with low health literacy. [30,31] A strength of our study is the recruitment and involvement of people with low health literacy in this study, and there are a number of possible success factors for involving people with low health literacy.

First, the people with low health literacy and the self-management problems should be noticed by the healthcare provider. At the start of the interviews, most of the participants expressed that they have an adequate level of medication self-management. However, additional questions (on e.g. medication adherence, understanding prescription labels) showed that the level of medication self-management was often insufficient. This discrepancy could contribute to the fact that healthcare professionals not sufficiently notice and recognize problems with self-management and that care users perceive no need to ask for help since they regard their medication self-management as adequate. Health professionals should be better trained in identifying people with DM2 with low health literacy and problems with medication self-management. There are tools available for this, for example the RALPH interview guide (Recognizing and Addressing Limited Pharmaceutical literacy).[32] In this study motivated and experienced pharmacists participated, who were personally involved and selected the respondents. This surely increased the number of included people.

A second possible success factor, was the importance paid to the relationship between the researcher and participants, so the participants feel free and secure to communicate about perceived barriers and needs.[23] The frequent contact prior to the interview (intake interview and telephone conversation a week before the interview / focus group) and the interviews that were conducted at the participant's home, created an informal setting in which participants could communicate their perceived barriers and needs for medication self-management. The researcher was especially trained to communicate in line with the level of this subgroup. This relationship of trust was initiated by their own pharmacist when introducing the researcher to the respondents. In the interviews, the people also indicated that they trusted their pharmacist, which increased the likelihood that they will also trust the introduced researcher. [31]

A third possible success factor for involving people, were the focus group meetings. Initially, the participants found it very difficult to express needs and preferences for support. The focus group meetings were helpful in expressing needs and preferences for improving medication self-management with the suggestions of other participants and the shared interventions. In addition, the participants also preferred to have more contact with fellow people with diabetes in general. In other studies, such contact with fellow people with diabetes empowered people and improved their self-management.[33,34] In Dutch healthcare there are already opportunities to have more contact with fellow people with diabetes. In the focus group setting we did discuss the added value of peer group support, no one expressed that they ever attended structured group education. It could be that the participant does not know that there are peer groups available or that they are not yet found by the target group. Awareness of the existence of such peer groups should be increased and healthcare professionals could better inform persons with low health literacy, or even better introduce them to a peer group.

The pharmacists selected participants on potential risk group, verbal statements and behavioral signals of not understanding. A pre-condition for this kind of selection is that the participants visits the pharmacy and are known to the pharmacist, which can make the results less representative for the target group at a whole of people with low health literacy skills (who might not come to the pharmacy). However, this convenience sampling method was a successful strategy of involving this hard-to-reach target group in research. Another limitation in this study is that the persons with low health literacy find it difficult to think in concepts and express their feelings in concrete themes and needs. To increase the reliability of the results, a relationship of trust between the researcher and participants was created. However, there is still a possible bias in the interviews and focus group meetings that the participants have given socially desired answers about their barriers, needs and preferences. The focus group meetings were helpful in expressing needs and preferences with the suggestions of other participants and the shared interventions. Further research to gain more insight in how to explore the needs of persons with low health literacy and how to search for an adequate way to co-create with persons with low health literacy is needed. Another limitation of this study is that we only included people with DM2. We have deliberately opted for people with DM2 because they generally got DM2 later in life and had to adopt a different lifestyle and learn medication self-management skills. Medication self-management is equally important in people with Diabetes Mellitus type 1, and this study warrants repetition in that population.

The results of this needs assessment will be used to develop a medication self-management intervention that addresses the great heterogeneity in needs and preferences and will be developed in co-creation with people with low health literacy and DM2 using the intervention mapping method.[18]

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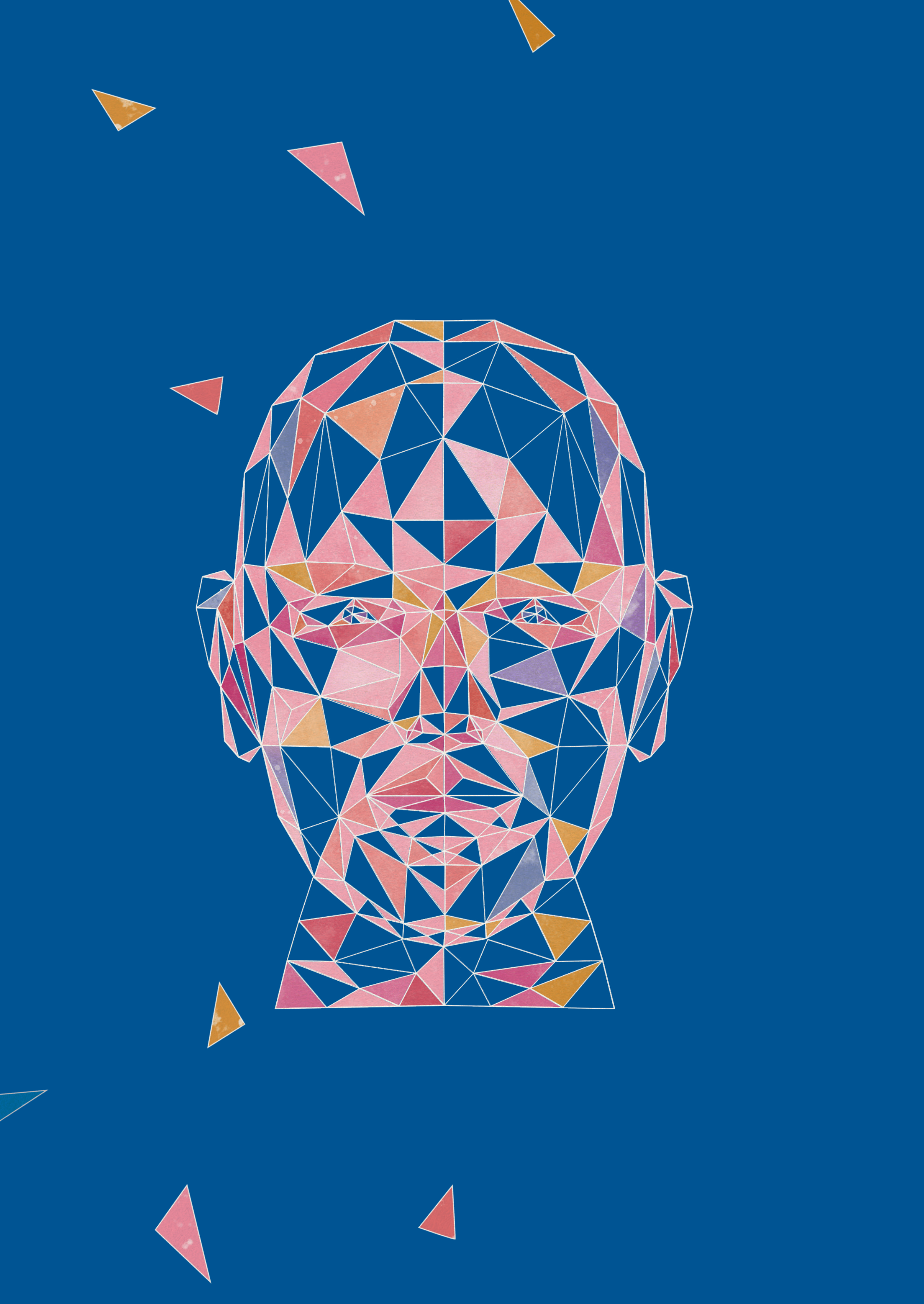
S1 Table. Topic list interview

Perceptions	o Expercienced effect medicine use
	o Frequenty medicine use
	o Type medicine
	o Management of medication
	o Obtained information medicine use
	o Help with medication inake
Barriers	o User-friendly intake of medicines
	o Dosing schedule
	o Forgotten medication intake
	o Understanding usefulness and necessity of medication
	o Fear of side effects
Needs	o Internet /apps
	o Tools
	o User-friendly information
	o Information



3

The impact of health literacy on beliefs about medication in a Dutch medication-using population

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Abstract

Purpose

Medication beliefs are likely contingent on aspects of health literacy: knowledge, motivation and competences to access, understand, appraise, and apply health information. An association between medication beliefs and health literacy is expected as they both influence self-management The aim of this study was to examine the association between health literacy and the beliefs about overuse and harmful effects of medication and to examine modifying effects of age, gender and number of medications on this association.

Methods

The data were collected using the online ‘Medication panel’ of the Dutch Institute for Rational Use of Medicine. A linear regression model was used to examine the association between health literacy and beliefs about medication and the modifying effects of age, gender and number of medications on this association.

Results

Respondents with a lower level of health literacy had more concerns about overuse (β adj.= -.174, $p<.001$) and harmful (β adj.= -.189, $p<.001$) effects of medication. This study found no modifying effects.

Conclusions

A lower health literacy level is associated with more concerns about the overuse and harmful effects of medication. The results of this study suggest that extra attention should be given to persons with low health literacy level by healthcare professionals, to decrease their concerns about overuse and harmful effects and improve adherence to self-management behaviour.

Introduction

Over the last decade, an increased focus has been placed upon patients' ability to self-manage their health and to organize their care. Health literacy plays an important role in this development.[1,2] Low health literacy is associated with poorer health outcomes and poorer use of health care services.[3] Most of the existing research focuses on a functional definition of health literacy (the ability to read and write), but a more comprehensive perspective on health literacy is needed as an important prerequisite in order to take up a pro-active role in one's own health.[1,4-10] Health literacy is 'linked to literacy and encompasses people's knowledge, motivation and competences to access, understand, appraise, and apply health information in order to make judgments and take decisions in everyday life concerning healthcare, disease prevention and health promotion to maintain or improve quality of life during the life course.'.[11] This definition addresses a broader range of competences compared to functional health literacy, including communication and social skills and the ability to apply health information which are essential for an active patient role in shared decision making and self-management.

Medication beliefs are cognitive representations of treatment, for example whether persons believe that taking their medication is necessary or whether they are concerned about side effects of medication. These medication beliefs are likely contingent on aspects of health literacy: knowledge, motivation and competences to access, understand, appraise, and apply health information. Medication beliefs have been shown to be associated with medication adherence which is a crucial component of effective self-management behaviours. An association between medication beliefs and health literacy is therefore to be expected as they both influence self-management.[12-16]

Previous studies have examined the relation between health literacy and beliefs about medication. These studies were focused on the functional health literacy in populations with a specific illness (asthma, COPD, diabetes type 2) or pregnancy.[13,17-19] These studies showed that lower health literacy levels were associated with stronger beliefs in necessity, harm and overuse of medication.[17,18,20,21]

Aim of the study

The primary aim of the current study was to examine the association between health literacy and beliefs about overuse and harmful effects of medication. This study focuses on health literacy that addresses a broad range of competences and includes persons using medication, regardless of type of disease. The secondary aim of the study was to examine the modifying effects of age, gender and number of medications on the association between health literacy and beliefs about overuse and harmful effects of medication.

Methods

Study design and study population

Data were derived from the online 'Medication panel' of the Dutch Institute for Rational Use of Medicine, Utrecht, The Netherlands. This panel was founded in 2016 to map opinions of medication users about different themes concerning pharmaceutical and pharmacotherapeutical care. There was a 2 step self-selection process. First people who visited the website www.meldpuntmedicijnen.nl to share their experiences with medication could register to participate in the panel via a button on the website. Second, all registered members received an invitation for the study by e-mail, with background information about the study and a survey-link. Informed consent was obtained from all individual participants included in the study. The panel members were not incentivized to respond. The mean age of the panel members was 60 years. 69% of the panel members were female and 93% of the panel members were taking medication. The educational level of the panel members can be classified as high (40%), intermediate (53%) and low (7%). For the current study, an online questionnaire was sent to all 2,157 panel members in February of 2018, with the inclusion criterion that they use medication. All members received an invitation for the study by e-mail, with background information about the study and a survey-link.

Measurements

The survey was divided into 3 parts: respondents' characteristics, a health literacy questionnaire (Health literacy survey (16-item)(HLS-EU-Q16)) and a questionnaire to measure beliefs about medication (beliefs about medicines questionnaire (BMQ-general)).[22,23] The questionnaires were in Dutch.

Respondents' characteristics

The respondents' characteristics section consisted of background questions on age, gender, number of medications, education level and illnesses. Education level was classified based on the highest level of education accomplished: low (primary school or preparatory vocational training), intermediate (intermediate or advanced general education or intermediate vocational training) and high (high vocational education or university).

Health literacy

The validated HLS-EU-Q16 in Dutch was used for measuring health literacy[23]. This HLS-EU-Q16 measures health literacy in terms of the three domains (healthcare, disease prevention and health promotion) that concern people's health and are expressed in terms of accessing, understanding, appraising and applying information to manage disease, risks and health. Additional information about the HLS-EU-Q16 is given in Online Resource 1. Respondents with a score <9 were categorized as having "inadequate" health literacy, respondents with a score 9–12 were categorized as having "problematic" health literacy, and respondents with a score >12 were categorized as having "sufficient" health literacy. [22-24]

Beliefs about medication

Medication beliefs were measured with the BMQ. The BMQ consists of two parts, a specific part and a general part. The BMQ-specific assesses whether a person believes that taking their medication is necessary or whether they are concerned about side effects regarding medication they take themselves. The BMQ-general assesses whether a person believes that taking medication in general is harmful and that medication is overused by doctors. In this study, the BMQ-general was used with its 2 subscales of 4 items each. The "overuse" subscale addresses the concept of over-prescription of medication by doctors who place too much trust in them (e.g., "Doctors place too much trust in medication"). The "harm" subscale assesses beliefs about how harmful medications are (e.g., "Medications do more harm than good"). Each item was measured on five-point Likert-type scales with strongly disagree to strongly agree as the response options. The scoring method is the total subscale; scores range from 4 to 20. Higher scores indicate stronger concerns about overuse and harm. The BMQ and its Dutch translation have been validated in studies that involved patients with various chronic diseases.[23,25,26]

Data analysis

Cronbach's Alpha was used to determine the internal consistency of the HLS-EU-Q16, BMQ-overuse and the BMQ-harm scores. Linear regression was used to assess the association between the independent variable HLS-EU-Q16 and the dependent variables BMQ-overuse and BMQ-Harm. To test whether age, gender and number of medications were confounding factors, they were added to the linear regression model with a change of more than 10% in the adjusted **β** indicating confounding. To assess whether age, gender and number of medications were effect modifiers, HLS-EU-Q16, age, gender and number of medications were standardized and interaction terms between HLS-EU-Q16 and the possible effect modifiers age, gender and number medications were calculated and added to the linear regression. The distribution of the data, including skewness and kurtosis, were examined. Statistical significance level was set at 0.05. All data analyses were conducted using IBM SPSS Statistics version 24.

Results

Respondents' characteristics

A total of 777 (36%) of the 2,157 panel members returned the questionnaire, 195 questionnaires were incomplete and these questionnaires were excluded from analysis. After exclusion, 582 completed questionnaires remained. 43 of the panel members who returned a complete questionnaire indicated that they did not use medication and were excluded, so the data of 539 respondents were analyzed.

Table 1 lists the characteristics of the respondents. Most were female (69%) and the mean age was 64 (± 11.4) years old. The youngest participant was 18 years old and the oldest was 92 years old. The mean number of medications used concomitantly was 4.00 (± 2.32), the frequency of medication intake was 2.50 (± 1.43) per day and 29% did not report an illness. Overall, 62% of respondents had a sufficient health literacy level, 25% had a problematic health literacy level and 13% had an inadequate health literacy level (Table 2). Table 2 also shows the mean score of BMQ-overuse and BMQ-harm for the inadequate, problematic and sufficient health literacy levels.

Health literacy and beliefs about medication

The internal consistency of the BMQ and HLS-EU-Q16 was good, .84 and .90 respectively (Cronbach's alpha). For each statement in the BMQ and HLS-EU-Q16, Cronbach's alpha decreased if a statement was removed. The mean score of BMQ-overuse was 11.94 (SD=3.44), which was normally distributed with acceptable skewness (-0.06) and kurtosis (−0.52). The mean score of BMQ-harm was 9.89 (SD=3.12), which was normally distributed with acceptable skewness (0.42) and kurtosis (−0.08). Table 2 shows that people with a lower level of health literacy had a higher score on the BMQ-overuse and BMQ-Harm. This implies that people with a lower level of health literacy had more concerns about overuse and harmful effects of medication compared to people with a higher level of health literacy. To examine this association, a linear regression was performed (Table 3). Linear regression shows that respondents with a lower level of health literacy had more concerns about overuse and harmful effects of medication. Confounder analysis showed that age, gender and number of medications did not change the adjusted **βs** of Health literacy more than 10% for both BMQ-overuse and BMQ-harm, so were not considered confounders.

Table 3 shows that adding the interaction terms health literacy and gender, health literacy and age and health literacy and number of medications were not significantly associated with BMQ-overuse and BMQ-harm, and thus showed no modifying effect.

Table 1. Respondents' characteristics

		n (%) or mean (SD)
		n=539
Gender	Male	168 (31%)
	Female	371 (69%)
Age in years	Average	64 (11.4)
	≤ 60	185 (34%)
	> 60 ≤ 70	199 (37%)
	> 70	155 (29%)
Number of medications	Average	4.00 (2.32)
	< 3	218 (31%)
	≥ 3	321 (69%)
Education	Low	32 (6%)
	Intermediate	264 (49%)
	High	243 (45%)
Self-reported illness*	Cardiovascular	223 (41%)
	Asthma / COPD	97 (18%)
	Mental health	88 (16%)
	Rheumatism	83 (15%)
	Diabetes	77 (14%)
	Stomach / Bowel	71 (13%)
	Parkinson	25 (5%)
	Psoriasis	24 (4%)
	Epilepsy	18 (3%)
	Glaucoma	14 (3%)
	Human immunodeficiency virus	2 (1%)

*More than 1 answer possible per subject

Table 2. BMQ-scores per level of health literacy

	n	**BMQ-overuse**	**BMQ-harm**
Health literacy level		**Mean (SD)**	**Mean (SD)**
Sufficient	336	11,68 (3,33)	9,57 (3,01)
Problematic	133	11,85 (3,55)	10,02 (3,10)
Inadequate	70	13,56 (3,41)	11,27 (3,08)
Overall	539	11,94 (3,44)	9,89 (3,12)

Table 3 Linear regression model of the association between beliefs about medication and health literacy and the modifying effect of age, number of medications on the association.

BMQ-overuse		
	β adj.	***p*-value**
Health literacy	-.174	< .001
Health literacy and gender[a]	.011	.801
Health literacy and age[a]	.068	.110
Health literacy and number of medications[a]	.006	.881
BMQ-harm		
	β adj.	***p*-value**
Health literacy	-.189	< .001
Health literacy and gender[a]	-.020	.644
Health literacy and age[a]	.023	.594
Health literacy and number of medications[a]	.013	.767

*Significant at $p < 0.05$; [a]Interaction term between two variables

Discussion

The results of this study showed that respondents with a lower level of health literacy had more concerns about overuse and harmful effects of medication. This is in line with previous research on the association between functional health literacy and beliefs about medication and health literacy.[12] This study found that age, gender and number of medications had no modifying effect on the association between health literacy and beliefs about medication. This is in line with a previous study in an obstetric population, this study also did not find an effect of the number of medications on the domains BMQ-overuse and BMQ-harm.[17] This study is one of the first studies that examine the association between health literacy and the BMQ-overuse and BMQ-harm in multiple illnesses. Future research should examine the association between health literacy and the BMQ-overuse and BMQ-harm in specific patient populations, to gain more insight into possible differences in associations between those populations.

This study showed that people with difficulties in knowledge, motivation and competences to access, understand, appraise, and apply health information in order to make judgments have more concerns about overuse and harmful effects of medication. These concerns may negatively influence decisions in self-management, disease prevention and health promotion. Therefore, extra attention should be given to persons with a low health literacy level using medication by healthcare professionals. A healthcare professional could help those persons voice their concerns and where possible, resolve concerns. A number of tools have been developed for healthcare professionals to recognize health literacy level, e.g. the RALPH interview guide (Recognizing and Addressing Limited Pharmacetical literacy).[27] Such tools can be helpful in recognizing persons with low health literacy and to anticipate the health literacy level in communication. Moreover, future research is needed to explore how to enhance understanding of the necessity of taking medication and allay concerns to shift form an emphasis on concerns to necessity.

Beside health literacy that influences beliefs about medication, other factors that might influence beliefs about medication are cognitive illness perception and emotional responses to the disease.[14-16] These cognitive illness perceptions consist of five domains according to the self-regulatory model: illness perceptions as identity, timeline, cause, consequences and control.[28] These cognitive illness perceptions activate behavioural actions, for example medication adherence. All these five factors might influence the beliefs about medication and should be investigated in future research.

A limitation of this study was that the study population was drawn from an online panel in a two-step selection process. Respondents must already have a degree of digital skills to register for participating in the panel on the website and be subsequently motivated to share their experiences. The findings of our study might only be representative of relatively motivated, digitally skilled medication users. In the Netherlands, the level of health literacy is inadequate in 9.5% of the overall population, problematic for 26.9% and sufficient for 63.6%.[29] The data of this study showed similar percentages (13% inadequate, 25% problematic and 62% sufficient). We expected that the level of health literacy of the panel members would be better compared to the Dutch population, because the digital panel members were motivated to participate and were required to read and use digital skills. To increase the generalizability of the results, there is a need to repeat this study in a larger group of patients with low levels of health literacy.

In this study we did not measure medication adherence, therefore the results of this study do not show whether low levels of health literacy lead to improved or decreased levels of medication adherence. Measuring adherence, health literacy and beliefs about medication could give more insights in the factors that influence the beliefs about medication. Future research should gain more insights into these associations, so interventions can be developed which decrease patients' concerns about overuse and harmful effects of medication and increase medication adherence.

Conclusion

In conclusion, this study showed that there is an association between health literacy and beliefs about medication. A lower health literacy level is associated with more concerns about the overuse and harmful effects of medication. The results of this study suggest that extra attention should be given to persons with low health literacy level, to decrease their concerns about overuse and harmful effects and improve adherence to self-management behaviour.

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4

Evidence on the effectiveness of health literacy interventions in the EU: systematic review

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Abstract

Background In the last decade, the attention for health literacy has increased in the European Union. This is due to three main reasons. First, reviews have shown that inadequate health literacy is associated with worse health outcomes, higher health care use and expenditure. Second, in all European countries the population is aging and the number of chronically ill people is rising. Improving health literacy in this group can offer greater opportunities to take an active part in society, be independent and improve quality of life. Third, since most research on health literacy has been conducted outside Europe and relatively little is known about the development of health literacy interventions and its effects on outcome measures in European countries. The aim of this systematic review was to assess the evidence on the effectiveness of health literacy interventions in the European Union published between 1995 and 2018.

Methods Searches have been performed in Medline, PubMed, EMBASE, CINAHL, Cochrane library, PsychINFO, ERIC, Web of Science and SCOPUS for publications on health literacy intervention studies in European Union countries. Studies were included if the research was conducted in one or more Member States of the European Union, the publication described an intervention study, the intervention was aimed at health literacy, the publication described an outcome measure related to health literacy and the publication was written in English, French or German.

Results A total of 23 studies were included. Three types of interventions were identified; aimed at improving health literacy, tailored to different health literacy levels and aimed at improving health outcomes in general that differentiated in effects for people with different health literacy levels. Most interventions identified in the review focus on the functional level of health literacy or numeracy. The strength of evidence from the European health literacy intervention studies was low and there was a huge heterogeneity in study design, measurement tools and outcomes measured.

Conclusions Promising interventions were tailored to the needs of patients, addressing functional, interactive and critical skills and use not difficult animated spoken text. Future research should focus on the development and assessment of such interventions and use stronger designs.

Background

Health literacy is a topic of growing importance in European public health research. In general, health literacy is 'linked to literacy and encompasses people's knowledge, motivation and competences to access, understand, appraise, and apply health information in order to make judgments and take decisions in everyday life concerning healthcare, disease prevention and health promotion to maintain or improve quality of life during the life course.' This is the definition of health literacy as it was developed in the European Health Literacy Project (HLS-EU).[1,2] This definition includes the public health perspective on health literacy and can also be specified to an individual approach.

Apart from this one, there are many different definitions and conceptualisations of health literacy.[1] Narrow definitions focus on basic literacy (the ability to read and write), while others also include a wider range of cognitive and psychosocial skills in the definition. Furthermore, definitions differ with respect to the actions, information and resources, objectives, context and time aspects which they do or do not include.[1] Nutbeam et al.[3] distinguishes in the broad definition of health literacy three dimensions of health literacy: functional, interactive and critical literacy. Functional health literacy is the ability to read health information. Sometimes numeracy (the ability to use mathematics in everyday life) is also included in the concept of functional health literacy. Interactive health literacy refers to 'more advanced cognitive and literacy skills which, together with social skills, can be used to actively participate in everyday situations, extract information and derive meaning from different forms of communication, and apply this to changing circumstances.'[3]Critical health literacy refers to 'more advanced cognitive skills which, together with social skills, can be applied to critically analyse information and use this to exert greater control over life events and situations'.[3] Most of existing research on health literacy focusses on functional health literacy.

Especially in the last decade, the attention for health literacy has increased in the European Union (EU). This is due to three main reasons. First, studies mainly from the United States of America (USA) have shown that inadequate health literacy is associated with worse health outcomes, poor preventive care behaviours, higher health care service use and expenditures. In addition these studies showed that health literacy influences the effects social determinants of health have on health status and as such is an important determinant of health inequalities.[4-8] Therefore more attention for health literacy can lead to a substantial return at both the individual and the community level, by improving health and well-being on one hand and reducing unnecessary healthcare visits and costs on the other. Second, in all European countries the population is aging and the number of chronically ill people is rising. Much is expected from this group in terms of self-management. However, adequate health literacy is required to fulfil an active role regarding health and healthcare. Third, most research on health literacy has been conducted outside Europe, in the USA and more recently in Japan, Taiwan and Australia. As a consequence, relatively little is known about the development of health literacy interventions and its effects on outcome measures in European countries. While many of the USA studies on health literacy primarily focus on functional health literacy in the clinical or medical setting, EU studies more often use a broader definition of health literacy, and address issues both inside and outside the clinical setting.[9] Instead of a risk (inadequacy in the context of healthcare), health literacy is also defined as an asset, a means to exert greater control over health and over personal, social and environmental determinants of health.[1,3,9] Furthermore, the health and social welfare systems between USA and Europe differ. The USA health systems have a limited government involvement with an important role for the private sector stakeholders (e.g. health care providers and insurers) and most of the payment is on fee for service basis.[10] In Europe there is a stronger government involvement than in the USA. In some countries (e.g. the Netherlands) there is a gatekeeping role for the primary care and paying on capitation basis, and in other countries (e.g. the UK) there is a system of National Health Service which offers (predominantly) free health care services.[10,11] These fundamental differences between the USA and Europe areas an important reason why the largely USA based body of evidence cannot simply be assumed to also be true in a European setting. In the USA, Sheridan et al.[12] and Berkman et al.[13] found interventions that improved participants´ comprehension of health information. Moreover, interventions aimed at self-management that took the level of health literacy of patients into account reduced emergency department visits and hospitalizations and self- and disease-management interventions reduced disease severity. Effects of health literacy interventions on other outcomes were mixed or limited. Most studies in the field of health literacy are correlational, there is a lack of convincing studies that show that health literacy can change as a result of an intervention.

To determine the efficacy of health literacy interventions in the EU context, a similar systematic review as the review conducted by Berkman et al.[13] and Dennis et al.[14] in the USA was undertaken for EU countries, using similar search strategies for optimal comparability of the results. The aim of this systematic review is to assess the evidence on the effectiveness of health literacy interventions in the EU published from 1995 until 2018. This is the first systematic review on health literacy interventions in the EU context. The results of this review will be compared to the results of the review in the USA context.

Methods

This systematic review was conducted in accordance with the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines.[15] This research is based on and an update of the work done in Work Package 1 of the HEALIT4EU research project, executed under the EU Health Programme (2008–13) in the framework of contract no. 20146201 with the Consumers, Health and Food Executive Agency (Chafea) acting under the mandate of the European Commission. The content of this article represents the views of the contractor (the EPHORT consortium) and is its sole responsibility; it can in no way be taken to reflect the views of the European Commission and/or Chafea or any other body of the European Union. The full HEALIT4EU report is available via
http://ec.europa.eu/health/ health_policies/docs/2015_health_literacy_en.pdf.

Search methods for identification of studies

Studies were identified by searching Medline, PubMed, EMBASE, CINAHL, the Cochrane library, PsychINFO, ERIC, Web of Science and SCOPUS. English, French and German language publications on health literacy intervention studies in EU countries. According to our knowledge, no research on health literacy has been done before 1995, therefore studies from January 1995 to Augusts 2018 were included. Recent reviews on health literacy that developed search strategies based on a list of key words and text words for use in the different databases were used to construct our own search strategy. For the search strategy, the reviews of Berkman et al.[13] and Dennis et al.[14] were combined into a new search strategy (see Annex A). Contrary to most other search strategies, this search strategy for health literacy publications explicitly included 'functional health literacy', 'interactive health literacy' and 'critical health literacy'.[3] As in Berkman et al.[13] we also used the terms 'literacy', 'literate', 'reading skills', 'writing skills' etc.). This led to 2515 publications in PubMed and Embase alone. All these abstracts were screened by two researchers but it turned out that the majority of these publications did not address health literacy (or health related issues) at all. Therefore we limited the search terms for health literacy by leaving out the terms of general literacy, reading and writing skills and dyslexia. The terms used in our search strategies to find 'interventions studies' were the same search terms as used by Dennis et al..[14]

Types of studies

All studies that describe an intervention study with one of the following designs were included: randomized controlled trials, quasi randomized controlled trials, controlled before and after studies or interrupted time series. Studies with no original data, studies with only case report and studies with only ecological data were excluded.

Studies involving people living in one or more member states of the EU were included. The Member States of the EU are Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden and the United Kingdom.

Types of interventions

Studies with an intervention that focused on health literacy were included. Interventions at population level, as well as interventions on specific populations and individual level were searched for and included. Studies on the basic experimental science of reading ability were excluded as were studies examining normal reading development in children and studies about dyslexia. Contrary to the strategy of Berkman et al.[13], the search was not limited to publications mentioning the use of a health literacy measurement tool, because the way health literacy in Europe was measured differed from the way described in reviews with predominantly American studies (where validated health literacy instruments are used more often).

Types of outcome measures

Studies that described an outcome measure related to health literacy were included. These outcome measure included among others: knowledge, skills, attitudes, self-efficacy, stages of change, motivation and patient activation, behaviour change, health care access, service use, health status, costs of care.

Data Collection and analysis

The study selection consisted of two phases: first the selection on title and/or abstract and second the selection of the remaining articles based on full text. The search results were screened by two researchers each in two independent phases (JH, MH (1995-2014); BV, BS (2015-2018)). Consensus meetings were held with the researchers of both phases to resolve disagreements. A 20% sample of the excluded scientific publications was screened by a third researcher (JR 1995-2018). Studies were included if they met the inclusion criteria.

The abstracts were systematically screened on the basis of our in- and exclusion criteria. In case a publication did not meet a criterion, the publication was excluded and the next publication was screened. Of all the studies, fulfilling the inclusion criteria, full texts were read. For the inclusion of full texts the same in- and exclusion criteria were used. To assess the quality of the studies the "Quality Assessment Tool For Quantitative Studies" developed by the Effective Public Health Practice Project (EPHPP)[16] was used. The criteria for quality in this tool include selection bias, study design, confounders, blinding, data collection methods, withdrawals, intervention integrity and data analysis. The global rating is calculated using information across all six domains (selection bias, study design, confounders, blinding, data collection methods & withdrawals and drop-outs): strong (no weak ratings), moderate (one weak rating), or weak (two or more weak ratings).

Results

Our literature search yielded 6,206 publications between 1995 and mid-2018. Of these publications 6,042 (97%) were excluded based on title and abstract because they did not fulfil one or more of the inclusion criteria: 3,950 (65%) were excluded because not describing an intervention, 1,037 (17%) did not meet the first criterion (being conducted in one or more of the European Member States), 1,024 (17%) of the European interventions were excluded because they were not focusing on health literacy and 26 (1%) of the studies were excluded because there was no health literacy outcome measure (see also Figure 1, PRISMA diagram). The remaining 164 publications were retrieved in full text for further assessment, of which 141 failed to meet the inclusion criteria. The main reason for excluding full texts was that they were unrelated to health literacy. Finally, 23 articles were included.

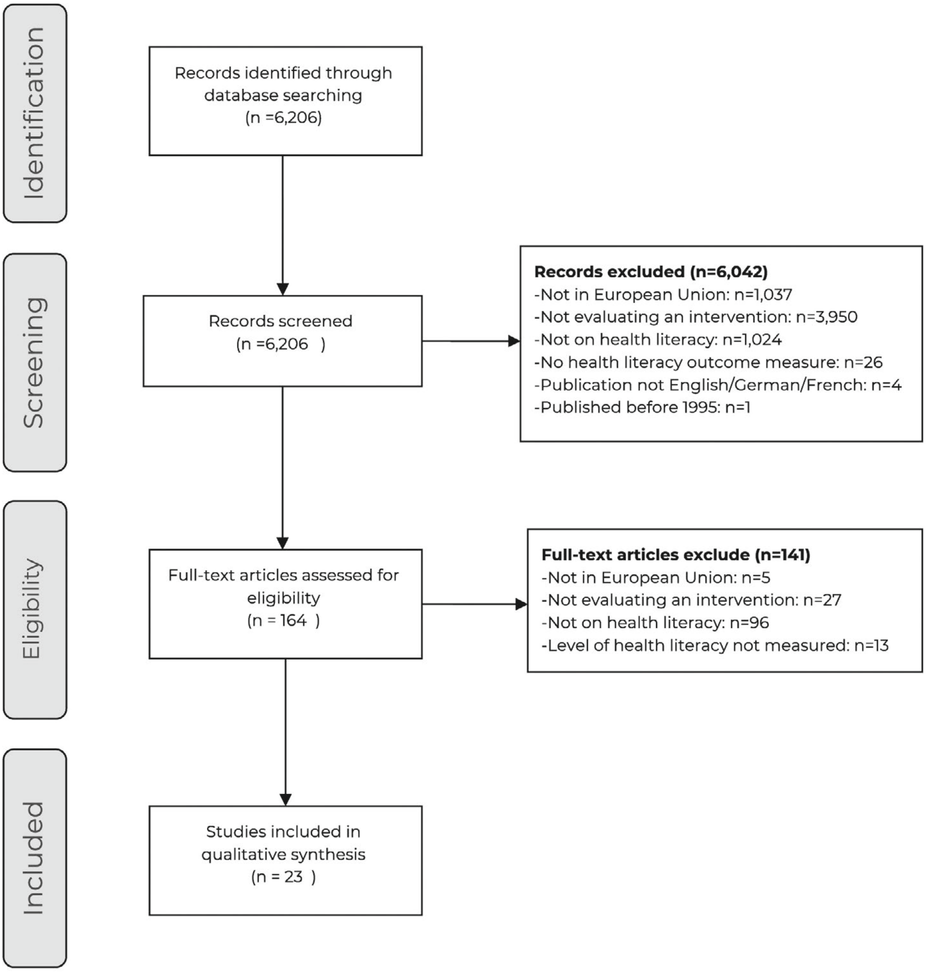

Figure 1. PRISMA diagram

Principal findings

There were not a sufficient number of studies with similar outcome measures or similar interventions to consider quantitative analysis (meta-analysis or statistical pooling) of data; therefore a qualitative analysis was performed. The 23 included intervention studies and their characteristics are summarized in Table 1. The references, the evidence tables, the intervention type and outcome of each of these studies can be found in Table 2. All studies were conducted in North-western Europe, no studies from Eastern and Southern European countries were found. All studies except one[17] were interventions developed for adults.

Table 1. Characteristics of interventions included (n=23)

Characteristics	
Publication year	• 2005 (n=2)
	• 2007 (n=1)
	• 2010 (n=2)
	• 2011 (n=3)
	• 2012 (n=5)
	• 2013 (n=3)
	• 2015 (n=2)
	• 2016 (n=3) • 2017 (n=2)
Country	• Austria (n=3)[1]
	• Denmark (n=3)[1]
	• Germany (n=6)[1]
	• Ireland (n=2)[1]
	• Netherlands (n=4)
	• United Kingdom (n=8)[1] • Taiwan (n=1)[1]
Study design	• Cohort analytic group design (n=2)
	• Cohort (one group pre/post) (n=9)
	• Controlled trial (n=5)
	• Interrupted time series (n=1)
	• Randomized controlled trial (RCT) (n=5)
	• Observational study (n=1)
Study Setting	• Community (n=6)
	• Health Professionals (n=2)
	• Outpatients (n=5)
	• Telephone and/or mail intervention (n=10)
Duration of intervention and follow-up	• No follow-up (n=13)
	• Follow up ≤ 3 months (n=4)
	• Follow-up>3 months (n=4)
	• Unknown (n=2)
Age of participants	• Children (8-12) (n=1)
	• Adults (>16) (n=22)

Table 1. (continued)

Characteristics	
Health Literacy Measure	• Critical Health Competence List (n=1) • Brief questions to identify patient with inadequate health literacy (n=1)
	• Critical HL assessed by interview (n=1)
	• Level of Knowledge (n=3)
	• REALM-R (n=2)
	• Newest Vital Sign Test (n=1)
	• Level of reading ability (n=2)
	• Level of mild intellectual disabilities (n=1)
	• Numeracy competence (n=4)
	• Skills towards decision making in a health context (n=1)
	• Not specified (n=1)
	• Danish version of TOFHLA (n=3)
	• Dutch version of SAHL (n=2)
Focus of included studies	• Disease specific: (n=9) of which Diabetes (n=5), Cancer (n=1), COPD (n=3), Osteoarthritis (n=1), Rheumatoid arthritis (n=1), Multiple Sclerosis (n=1), Renal patients (n=1);
	• People working or using health care (n=2)
	• Hard to reach groups (n=3)
	• Outpatients not specified (n=1)
	• People with mild intellectual disabilities (n=1)
	• Smokers (n=1)
	• General population (n=4)
Health issues	• Diabetes, Cancer, OA, MS, RA, participation in treatment, knowledge, understanding of medication, adherence to medication, interpretation of information about treatment, appraisal skills in judging medical information, self-management, active participation in treatment, empowerment, self-management skills and confidence, motivation to self-manage, risk-communication, decision-making in medical treatment, symptom monitoring and recognition, reaching disadvantaged groups, health promotion, health status, social participation and integration, access to health care, health care use, communication of medical information.

[1] The total number of countries is more than 23, because the study of Muller et al. was performed in the United Kingdom, Austria, Germany, Ireland, and Taiwan.

Health literacy measure

Studies varied considerably in their measurement of health literacy. Commonly used instruments in the USA to assess health literacy such as the Rapid Estimate of Adult Literacy in Medicine (REALM) [18,19], the Newest Vital Sign (NVS)[20], Test Of Functional Health Literacy in Adults (TOFHLA)[21-23], and the Short Assessment of Health Literacy (SAHL)[23,24] were used in eight studies. All these measures focus on functional health literacy. Four other studies also focused on functional health literacy skills by assessing reading ability[25,26] or the level of mild intellectual disability[27]. Three studies measured critical health literacy skills by questionnaire[28] or interview[29] or assessing skills towards decision-making[30]. The study by Webb et al.[31] focussed on functional and interactive health literacy skills by measuring health literacy as the level of verbal and cognitive abilities. Three studies measured health literacy by the level of disease-specific knowledge.[20,3233] One study measured health literacy by the Brief questions to identify inadequate health literacy.[34] In one study the way health literacy was measured was not specified.[31] Numeracy was assessed in four studies.[35- 38]

Type of intervention

There was also a huge variation in the type of interventions given: group interventions, individual interventions, web-based interventions, one component interventions (e.g. an information leaflet) and multi-component interventions including chat-groups, lectures, training sessions, a help-desk, computer programs and leaflets among others. Most interventions were web-based interventions (n=9). The web-based interventions were conducted during the most recent years, most of them (n=7) in 2015, 2016 and 2017. In only one study it was explicitly mentioned that the patients were involved in the development of the intervention on a module designed for the development of a decision aid about MS-immunotherapy.[38]

Study design

Five studies used a Randomised Clinical Trial (RCT) design [19,23,26,27,34] and five studies a Controlled Clinical Trial (CCT) design[18,21,24,25,33]. In two studies two groups were compared pre- and post-test (Cohort analytic design)[17,28], but most studies (n=9) used the same group that was pretested and post-tested immediately after the intervention (Cohort study). The study by White et al.[31] used an interrupted time series design and there was one observational study. The type of design in combination with the frequent missing or nor reported use of covariates makes that for most studies (n=15) the quality was rated as weak (EPHPP[16], Table 2). The quality of seven studies was rated as moderate on the base of the EPHPP[16] assessment tool and one study was judged as strong.

Table 2. Quality assessment (using the EPHPP), intervention type and outcome of reviewed studies N = 23.

Study (primary author)	Selection bias	Study design	Con-founders	Blinding	Data collection methods	Withdrawals and drop-outs	Global rating	intervention type	Dimension of health literacy	Outcome
Meppelink et al., 2015 [24]	S	S	S	M	S	S	Strong	Web-based intervention	Functional	Functional health literacy
									Critical	Critical health literacy
Elbert et al., 2016 [26]	M	S	S	M	S	W	Moderate	Web-based intervention	Functional	Healthy lifestyle
Gilbert et al., 2012 [27]	M	S	S	S	W	M	Moderate	Tailored information leaflet	Functional	Healthy lifestyle
									Critical	
Meppelink et al., 2015 [25]	W	S	S	M	S	M	Moderate	Web-based intervention	Functional	Functional health literacy
									Critical	Critical health literacy
Heasum et al., 2017 [23]	M	S	S	W	S	M	Moderate	Web-based intervention	Functional	Functional health literacy
Sahm et al., 2011 [18]	M	S	S	M	M	W	Moderate	Tailored information leaflet	Functional	Understanding of drug label
Walker et al., 2007 [19]	M	S	S	M	S	W	Moderate	Tailored information leaflet	Functional	Knowledge
Webb et al., 2008 [32]	M	M	W	M	M	M	Moderate	Group-based intervention	Functional	Self-management
									Interactive	Healthy lifestyle
										Health status
										Access to health care
										Ability to make treatment choices
										Symptom recognition and monitoring
Berger et al., 2013 [29]	W	M	W	M	W	M	Weak	Group-based intervention	Critical	Level of critical health literacy
										Self-management

Table 2. (continued)

Study (primary author)	Selection bias	Study design	Con-founders	Blinding	Data collection methods	Withdrawals and drop-outs	Global rating	intervention type	Dimension of health literacy	Outcome
Blanson Henkeman et al., 2013 [17]	W	S	W	W	S	S	Weak	Individual, personal contact	Functional	Knowledge
										Self-management
Boxell et al., 2012 [20]	W	M	W	M	S	S	Weak	Tailored information leaflet	Functional	Symptom recognition and monitoring
Garcia-Retamero et al., 2010 [36]	W	M	S	M	M	W	Weak	Web-based intervention	Functional	Understanding of health risk
Galesic et al., 2011 [37]	W	S	W	M	M	W	Weak	Aids to support numerical concepts	Functional	Understanding of health risk
Galesic et al., 2013 [38]	W	S	M	W	W	W	Weak	Aids to support numerical concepts	Functional	Ability to make treatment choices
Haesum et al., 2016 [21]	W	M	W	M	M	S	Weak	Web-based intervention	Functional	Functional health literacy
										Self-management
										Shared decision making
Kasper et al., 2005 [39]	M	M	M	W	M	W	Weak	Aids to support numerical concepts	Functional	Level of functional health literacy
										Shared decision making
Lilholt et al., 2016 [22]	M	M	W	M	W	M	Weak	Web-based intervention	Functional	Functional health literacy
										Health status
										Self-management
										Shared decision making
Long et al., 2011 [30]	W	M	W	M	W	W	Weak	Self-management support by call-center	Functional	Knowledge
									Critical	Empowerment
										Self-management
										Critical health literacy

Table 2. (continued)

Study (primary author)	Selection bias	Study design	Con-founders	Blinding	Data collection methods	Withdrawals and drop-outs	Global rating	intervention type	Dimension of health literacy	Outcome
Matic-Strametz et al., 2012 [33]	W	S	W	W	M	S	Weak	Group-based intervention	Functional	Knowledge
									Critical	Critical health literacy
Muller et al., 2017 [35]	W	S	S	M	S	W	Weak	Web-based intervention	Functional	Functional health ltieray
										Healthy lifestyle
										Self-management
Neville et al., 2005 [28]	W	M	W	M	W	W	Weak	Web-based intervention	Functional	Understanding of health risk
								Multi-component programme		Self-management
								Individual, personal contact		Understanding of drugs label
Reiter et al., 2012 [34]	W	M	W	W	W	W	Weak	Group-based intervention	Functional	Knowledge
								Multi-component programme		Healthy lifestyle
										Health status
White et al., 2012 [31]	S	S	W	W	S	W	Weak	Individual, personal contact	Functional	Self-management
									Critical	Ability to make treatment choices
										Access to health care
										Empowerment
										Healthy lifestyle

S, strong; M, moderate; W, weak. Global Rating is calculated using information across all six domains: strong (no weak ratings), moderate (one weak rating), or weak (two or more weak ratings).

Types of intervention studies

The types of interventions in the 23 studies could be categorized as follows;

1. Interventions aimed at improving (aspects of) the health literacy level of individuals.
2. Interventions that were specifically tailored to different health literacy levels.
3. General interventions that aimed at improving health outcomes, which described the specific effects for patients with different health literacy or numeracy levels.

1. Interventions aimed at improving (aspects of) health literacy

A group training of 2 x 2,5 days in evidence based-medicine for patients, patient counsellors, consumer representatives and healthcare professionals resulted in a significant increase in health related knowledge and in the level of critical health literacy of the participants.[29] In the evaluation of the training they stated that they had broadened their knowledge, were more critical in handling health information and considered themselves more confident on making the right decisions on the basis of the information they found. The content of the training was tailored to the needs of the participants. A second group intervention[39] specifically focused on so-called 'hard to reach' groups (e.g. unemployed women of minority groups and female migrants from Islamic backgrounds). This intervention combined different elements: computer courses, lectures, and language training. Topics related to health and well-being were being discussed. Also this intervention led to an increase in knowledge and comprehensive health literacy. Another group intervention targeted patients with mild intellectual disabilities and was tailored to their verbal and cognitive abilities. In the training, patients were taught how and when to access healthcare.[22] The evaluation showed that the intervention had a significant positive effect on the participants' ability to recognize disease symptoms, identify illnesses and choose appropriate courses for action.

An intervention that was developed to improve self-care among diabetes patients was evaluated after two years. The patients had received tailored tele-carer education as well as support to change specific lifestyle behaviours.[30] The evaluation showed that these diabetes patients were better able to use knowledge in their day-to-day self-care and expressed a greater control over their self-care decision-making. A UK community study that evaluated the impact of a self-care skills training initially (after 6 months) found a positive effect on decision making skills regarding use of health services (critical health literacy). However, after 12 months the effect was no longer found.[31] In three studies in Denmark, the tele-homecare intervention ´Telekit´ was evaluated. The Telekit focuses on the management of COPD in general, how to manage COPD during exacerbations and collect date on the current state of the patient´s health. Both studies did not found a significant difference on functional health literacy.[21-23] The Telekit increases the feeling of insecurity, greater freedom, more control and greater awareness of symptoms.[22]

Five interventions specifically focused on the improvement of numeracy skills, i.e. the ability to understand numerical risk information.[21,35-37] The evaluations of these interventions had similar conclusions. In general numerical information is presented in ways too difficult for people with low competencies. Another way of presenting (e.g. by using visual aids and/or lowering the level of detail of information) led to improved understanding in participants with low numeracy competencies.

2. Interventions tailored to different health literacy levels

Three studies[17,27,28] performed an evaluation with an intervention and a control group, comparing the outcome variables. In one study among children with diabetes (age 8-12) the impact of a personalized robot on diabetes knowledge and motivation for self-management was compared to a neutral robot. The reactions of the personalized robot were adjusted to the knowledge level of the child. In the evaluation, children in the intervention group (with the personalized robot) scored higher on diabetes knowledge and motivation for self-management. A tailored training programme on peritoneal dialysis for renal patients with low health literacy resulted in lower incidence of peritonitis and stronger feelings of control and ownership over treatment among the participants in the intervention group, as well as less supervision time needed of nurses.[28] The intervention comprised lowering the amount of written information and using more verbal material, and reducing the use of medical jargon. A computer-tailored intervention for smoking-cessation (booklet and web-based programme) was compared to a general self-help booklet. The tailored approach led to more attempts to quit smoking as well as higher abstinence rates, specifically for participants with lower literacy levels.[27] An intervention that was tailored to the verbal and cognitive abilities of patients with mild intellectual disabilities was evaluated in a one group pre/post-test design.[32] The evaluation showed there was an improvement in symptom recognition, better health-related decision making, improved understanding of medical procedures and a better ability in formulating personal health goals.

Three studies focused on the way of presenting information to persons with different health literacy levels.[24,25,34] One study varied in presenting information on spoken versus written text and illustration versus animation. In almost all conditions, the high health literate persons had a better recall on information compared to the low health literate persons, except for the spoken animations. In the spoken animation condition, the low health literate persons recalled the same amount of information as the high literate persons. The other study varied in presenting information on illustrated versus text-only and in not difficult versus difficult texts. Persons with low and high health literacy recalled the not difficult information better than difficult information. Illustrated text improved the recall and attitudes in low health literate persons and had no effect in high health literate persons. Another study stated audio-visual leads to better knowledge. The study also stated that clear, person-based intervention development is more important than interactivity and audio-visual presentation to improve health literacy outcomes.

3. General interventions that aimed at improving health outcomes, which described the specific effects for patients with different health literacy or numeracy levels

In general, patients with low health literacy benefit less from general interventions compared to patients with higher levels of literacy, e.g. with respect to understanding medication labels [18,35] and other health messages.[19,20] In a study on the knowledge level of rheumatoid arthritis patients after being exposed to a pictorial 'mind map' together with a Arthritis Campaign booklet, analysis showed that less literate participants gained fewer knowledge from both the booklet alone and the booklet in combination with the mind map, compared to high literate patients.[19] Similarly, a leaflet was developed to improve gynaecological cancer symptom awareness and to reduce barriers to access medical services.[20] Though in general after reading the leaflet awareness improved and barriers to access medical services were reduced, these effects were less in patients with lower health literacy. In general, patients with low levels of health literacy were found to experience more barriers to access health care services.

Four studies reported on outcomes relevant for the daily management of chronic illness or health in general such as knowledge, empowerment, ability to self-manage, decision-making skills, ability to taken an active role in treatment. Increased levels of health literacy were associated with higher levels of empowerment, better decision-making skills, and a more active role in treatment. [29-32] The evidence were graded as weak due to the fact that results mainly came from uncontrolled studies and results were often based on small groups or a limited number of observations. One study focused on a mobile phone app intervention targeting fruit and vegetable consumption. The information provided via the app where either textual or auditory tailored to the person's characteristics. The app increased the fruit and vegetable intake, but only in persons with high health literacy.[26]

Discussion

In this systematic review the evidence on the effectiveness of health literacy interventions in the EU published from 1995 until mid-2018 was assessed. There were not a sufficient number of studies with similar outcome measures or similar interventions to consider quantitative analysis (meta-analysis or statistical pooling) of data; therefore a qualitative analysis was performed. The evidence collected gives insight into the gaps in research in the context of the European Union, compared to the evidence presented in the already published reviews outside Europe, and provide recommendations for research. To our knowledge, this is the first systematic review on health literacy interventions in the EU context. The results of this review are compared to the results of reviews in the USA context.

In total, 23 intervention studies were identified. The interventions described in these studies either (a) aimed at improving (aspects of) health literacy, (b) were specifically tailored to different health literacy levels or (c) were general interventions that aimed at improving health outcomes, which described the specific effects for patients with different health literacy or numeracy levels. As was found in other review studies [13,14,40] most interventions focus on functional health literacy, fewer (also) target interactive or critical health literacy.

The studies varied with respect to their study design, measurement instruments and outcomes. Health literacy was also operationalized and measured differently, thus impeding comparability of the results. Most studies did not give information whether their study results were stratified across health literacy levels. This was also concluded in the review of D ‘Eath et al..[40] As a result of this, it is not possible to measure the impact of interventions on people with varying levels of health literacy. The quality of most studies was weak (15) or moderate (7). Only one was rated as strong. The number of RCT’s or controlled studies was limited.

Because of the low quality of the studies no firm conclusions can be drawn with respect to the effective components of health literacy interventions. It seems that the type of intervention (e.g. group, individual, community based) is not of major importance. However, three factors are likely to be distinctive of promising interventions: (1) they tailor their activities to the needs of the (low health literate) participants, (2) they also address interactive and/or critical skills (instead of knowledge only) and (3) they present the information in an appropriate way, i.e. not difficult and using animated spoken text. Studies that also focus on interactive and/or critical skills led to improvements in outcomes such as motivation, knowledge, empowerment and self-confidence. These findings are congruent with those from the review by Berkman et al..[13] Interventions that present the information in an appropriate way results in better recall, positive attitudes and more informed decision making. [24,25,34]

Conclusions

Despite the small number of studies, findings from the EU are in line with the results from other international reviews.[5-7,13,14,40] Most interventions in this review focus on functional level of health literacy, these results were also found in the other USA reviews.[5-7,13,14,40] In our review we found that not all studies identified whether the study results were stratified across health literacy levels. These results were also found by the USA review.[40] Similar to the review of Berkman et al. [13] we identified that increased levels of health literacy were associated with higher levels of empowerment, better decision making skills, and a more active role in treatment. In our review, the quality of most of the studies were rated as low. In contrast to our included studies, the quality of most of the included studies of the USA reviews [5-7,13,14,40] were rated as moderate/fair and high/good.

There are definitely considerable gaps in the research evidence concerning which interventions are most effective in improving health literacy or health literacy related outcomes in Europe. In order to be able to draw firm conclusions, there should be more agreement among researchers about the definition of health literacy, and more systematic use of validated measurement tools in interventions as a ‘’golden standard’’. In the past years several studies on the development, translation and validation of (both subjective and objective) health literacy measurement instruments have been done. As a consequence, the assessment of health literacy varies depending on the setting and scope of the health literacy definition. The results of future intervention research then become more comparable and generalizable, leading to a more rapid insight in what constitutes effective health literacy interventions in the EU context.

New developed interventions should be tailored to the needs of the patients; address functional, critical and interactive skills and the way of presenting should be not difficult animated spoken text. Web-based interventions might be suitable for patients that have digital skills, but also blended interventions (combining face-to-face with online activities) and other types of interventions might integrate these three factors in their design. Future research should focus on the assessment of such interventions and use stronger designs e.g. in well-reported, large-sampled randomized controlled trials.

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5

Usability of an animated diabetes information tool for patients with different health literacy levels: a qualitative study

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Abstract

Objective: Most currently available medication self-management support tools do not meet the needs of patients with limited health literacy. Recently, tools that are better tailored to the needs of patients with limited health literacy have been developed. This study aimed to assess the usability of an animated diabetes information tool by patients with diabetes with limited and adequate health literacy levels.

Methods: Participants with limited and adequate health literacy levels were selected based on 3 health literacy questions in a screening interview, and asked to use the tool for three times a week, after which individual semi structured interviews were conducted. The interview topics were based on the technology acceptance model (i.e., perceived ease of use, perceived usefulness, and intention to use). Twenty-five patients with diabetes were included in the study.

Key findings: All participants perceived the tool as easy to use due to a clear overview of topics and only personalized information being provided. Those with limited health literacy indicated that they had learned from the tool and had the intention to continue using it in the future. These participants also expressed the need for the tool to be more actively offered by healthcare professionals, while participants with adequate health literacy expressed the need for more in-depth information.

Conclusion: The tailored self-management support tool was perceived as usable by all participants. To better serve them, the tool could be further improved by addressing the additional needs of people with limited as well as adequate health literacy.

Introduction

Diabetes mellitus is a complex chronic disease that requires extensive self-management.[1] Self-management activities contribute to healthy outcomes and include maintaining a healthy diet and physical activity, monitoring diabetes control indicators, taking medication, and coping with stress and emotions.[1,2] Many patients experience difficulty with self-management tasks involving medication.[1,2] Inadequate medication self-management can accelerate the onset of complications and deteriorate the quality of life of patients with diabetes.[1,3]

Medication self-management poses extra challenges for people with limited health literacy. Health literacy "encompasses people's knowledge, motivation and competences to access, understand, appraise, and apply health information to make judgments and take decisions in everyday life concerning healthcare, disease prevention and health promotion to maintain or improve quality of life during the life course."[4] In the Netherlands, 24.5% of the population has limited health literacy.[5] People with limited health literacy often experience difficulty in reading and writing as well as in communicating with their healthcare provider.[6] Furthermore, medication information is often highly complex due to the use of difficult words, medical terms, abbreviations, and long and compound sentences.[7,8]

Several studies have demonstrated that people with limited health literacy have different needs regarding information provision compared with people with adequate health literacy.[8,9] For example, people with limited health literacy may require more practical, tailored information and step-by-step explanations about performing certain actions, such as using a blood glucose meter.[9] People with limited health literacy may be better able to remember information when it is presented as simple and understandable text and in plain language.[10,11] The use of videos or animations may improve the ability of people with limited health literacy to access, understand, appraise, and apply information, and thus, may lead to improved knowledge.[12] Moreover, this way of presenting information to people with limited health literacy may result in them perceiving the message as more positive and recalling an equal amount of information as individuals with adequate health literacy.[12]

Tools are available that aim to support patient with diabetes' medication self-management.[13,14] However, studies have shown that the tools available often do not meet the information needs of people with limited health literacy, partly because too little attention is paid to people with limited health literacy in the development of self-management support tools, and consequently, these people do not always use them.[15] To reach this group, new tools have recently been developed for self-management that could meet the skills and needs of people with limited health literacy. An example of such a new, tailored tool is a Dutch tool for patients with diabetes called “Watch Your Diabetes” (Dutch = “KIJKopDiabetes”).

Recent research has demonstrated that healthcare professionals positively value the animated medication information included in the tool.[16] However, how people with limited and adequate health literacy levels and diabetes perceive the ease of use and usefulness of such tools is unclear, as is whether they have the intention to use them. Therefore, the aim of this study was to assess the usability of this animated diabetes information tool by patients with diabetes with limited and adequate health literacy levels. Having better insight in the usability of this specific tool will help tool designers and developers to better tailor their products to this group of patients, and will help healthcare professionals to better implement these tools and support patients in using them.

Methods

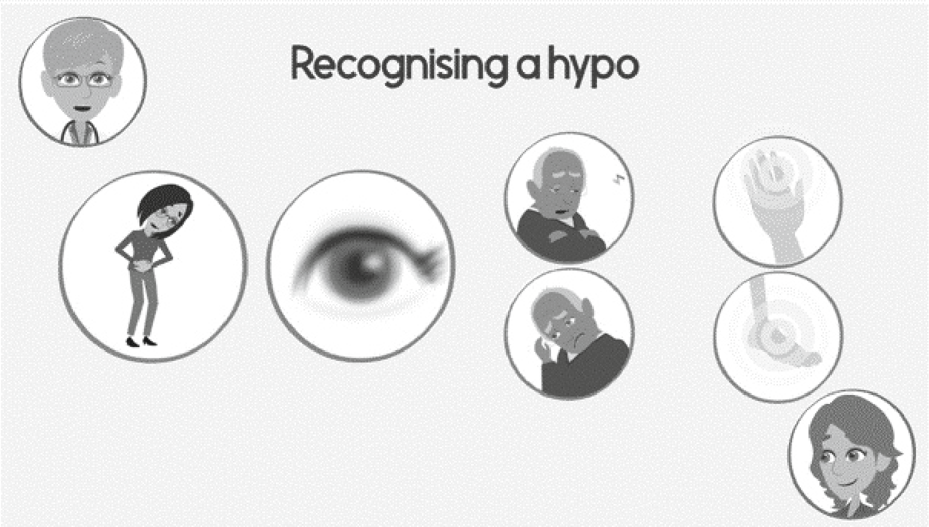
A qualitative study was conducted from September 2021 to April 2022 that involved individual semi-structured interviews with patients with diabetes. The interviews involved an interpretive approach with perspectives that embraced a view of reality as made meaningful by the patients’ understanding of events. Patients with diabetes were recruited with convenience sampling in 3 community pharmacies in the province of Utrecht, the Netherlands, and through networks of students at Utrecht University of Applied Sciences. For patient recruitment, there were 2 inclusion criteria: having Internet access and being treated with insulin or oral antidiabetic drugs (OADs). The participating pharmacists invited patients who were dispensed the most common diabetes medication (metformin or insulin) to participate in the study, either by telephone or when visiting the pharmacy. Furthermore, students of healthcare management at Utrecht University of Applied Sciences were asked by email to ask patients with diabetes in their network to participate in the study.

One of the researchers (BV, male PhD-student) with sufficient experience in conducting qualitative research, conducted an intake interview with potentially eligible participants, where information about the research was provided and background characteristics were collected. Then, the researcher estimated whether a person had limited health literacy based on the following 3 questions: (1) Do you have difficulty reading information about medicines? (2) Do you have difficulty understanding the doctor? (3) Do you find it difficult to follow your doctor's instructions? The first question was based on the validated brief questions of Chew[17], whereas the second and third questions were formulated to estimate broader health literacy skills than only reading and writing. If a patient answered at least 1 of the 3 questions affirmatively, then he or she was considered to have limited health literacy; otherwise, the patient was considered to have adequate health literacy. At the end of the intake interview, the tool was personalized by the researcher on gender, age, and the medication and blood glucose meters used, resulting in participants only receiving information that applied to them. The participants were sent a link to the tool and were instructed how to open the link and were instructed to use the tool three times a week. The informed consent was signed by all participants or verbal consent was given during the intake interview, depending on whether it took place in the pharmacy or by telephone. The informed consent was written in an easy and understandable language, moreover the informed consent was also explained orally.

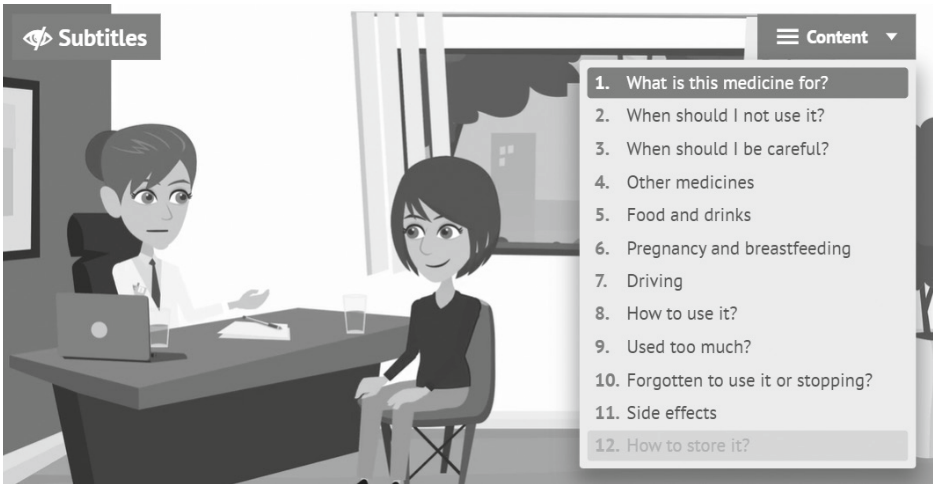
Approximately 7 days after the intake interview, the participants were contacted by telephone for an interview. The technology acceptance model (TAM) was used to develop the interview topics: perceived ease of use, perceived usefulness, and intention to use (Supplementary material).[18] The topics and questions used in this study were checked for comprehensibility and feasibility by a pharmacist and an independent researcher and had already been used in previous studies.[19,20] The participants were also invited to express what they would like to see improved or included in the tool. The interviews were performed by one of the researchers (BV). The total number of interviews was based on data saturation. Specifically, two of the researchers (BV and RH) determined separately for participants with limited and adequate health literacy whether data saturation had been reached, by discussing whether two recent interviews had led to more information related to the aim. The research proposal was submitted to the Medical Research Ethics Committee Utrecht and they confirmed that the study was exempt from further ethical review. Therefore the study needed no further ethical approval. This study also conformed to the provisions of the Declaration of Helsinki.[21]

Content of WatchYourDiabetes

The tool provides information in understandable plain language with practical information to support diabetes self-management. Most of the information is presented through spoken animations; an animated healthcare professional and an animated patient are shown having a conversation about a diabetes-related topic (Figure 1). The WatchYourDiabetes tool provides 400 animations videos with information on diabetes, medication, blood glucose meters, symptoms, complications,



Animation about hypoglycemia



Animation about Dapagliflozin

Figure 1: Examples of spoken animations.

the importance of blood glucose control, and tips for daily living with diabetes (Figure 2). The tool is available in different languages (Dutch, English, Turkish and Arabic). Several animations included in the tool have been tested for comprehensibility by people with limited health literacy. The information of the tool can be categorized into 3 themes:

1. General: What is Diabetes Mellitus?; Why measure Blood Glucose?; Hyperglycemia; Hypoglycemia; Lifestyle, Foot care.
2. My treatment: Animations about my medication; My glucose meter; My insulin pump.
3. Tips for...: Illness; Vacation; To play sports.

In addition to animated videos, the tool includes options for users to get in touch with fellow patients with diabetes through an online platform, where patients can share knowledge and experiences as well as perform a knowledge test to check whether they have understood the information. The videos are personalized by gender, age, and the medication and blood glucose meters used; thus, the patient only receives information that is relevant for him/her.

Data management and analysis

The interviews were audio-recorded and transcribed verbatim. The transcripts were coded and analyzed by one researcher (BV) using Atlas.ti 9 software package. A deductive thematic analysis was performed using the TAM as the theoretical foundation.[22] The thematic analysis was performed in the following 6 steps: becoming familiarized with the data, generating initial codes, searching for themes, reviewing the themes, naming the themes, and categorizing them according to the TAM.[22] To increase reliability of the results, a sample of 20% of the interviews were analyzed by a second researcher (RH). Where differences occurred, a consensus was reached through discussion with a third researcher (JR).

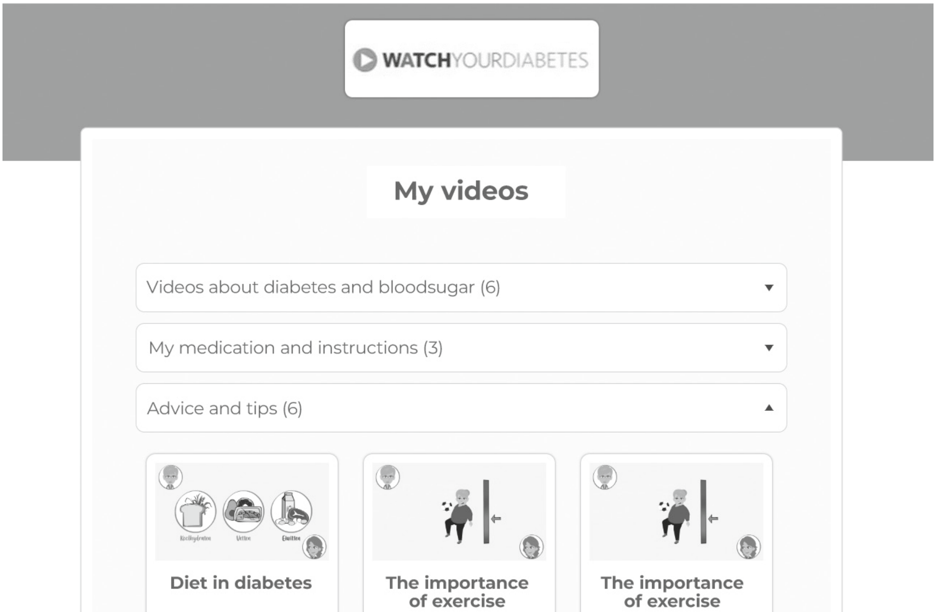


Figure 2: Main menu of the "Watch Your Diabetes" tool.

Results

A total of 25 eligible participants were recruited and had an intake interview with the researcher. Table 1 presents the background characteristics of the participants. For each topic of the TAM, the first part of the subsections that follow presents the general findings, while the second part presents and compares the opinions of participants with limited and adequate health literacy.

Ease of use

In general, most of the participants perceived the tool as easy to use and used the tool multiple times. The main reason that they gave was that they experienced the *navigation* of the tool to be easy. They indicated that this was mainly because the tool was structured in a well-organized manner and the main menu provided a clear overview of the topics that can be found in the tool (Figure 1). The information from the themes ''general'' and ''my treatment'' were mainly viewed by people with limited health literacy and people with adequate health literacy also viewed the tips. The fact that only personalized information was presented further contributed to the perception of most participants that it was easy to use.

Table 1. Background characteristics of the participants (n = 25)

	Participant	Gender	Age	Diabetes Mellitus type	Years since diagnosis	Type of medication	Comorbidities
Limited health literacy	LHL-1	Female	22	1	11	Insulin	
	LHL-2	Female	23	1	2	Insulin	
	LHL-3	Male	68	2	*	Insulin & OADs	Cardiovascular & Epilepsy
	LHL-4	Male	89	2	1	OADs	
	LHL-5	Male	66	2	25	Insulin & OADs	
	LHL-6	Male	42	1	1	Insulin	
	LHL-7	Male	52	2	*	OADs	
	LHL-8	Male	67	2	*	Insulin & OADs	
	LHL-9	Female	69	2	19	Insulin	
	LHL-10	Male	63	2	5	OADs	Cardiovascular
	LHL-11	Male	67	2	25	Insulin & OADs	Cardiovascular
	LHL-12	Male	69	2	8	OADs	Cardiovascular
Adequate health literacy	AHL-1	Female	49	2	11	Insulin	
	AHL-2	Female	32	1	11	Insulin	
	AHL-3	Female	23	1	12	Insulin	
	AHL-4	Female	57	2	*	OADs	Lupus
	AHL-5	Male	50	1	37	Insuline	Osteoarthritis, retinopathy, neuropathy, thyroid problems
	AHL-6	Male	80	2	12	OADs	
	AHL-7	Male	83	2	7	OADs	Cardiovascular &
	AHL-8	Male	31	1	12	Insuline	
	AHL-9	Female	31	1	27	Insuline	Graves
	AHL-10	Female	68	2	2	OADs	
	AHL-11	Female	69	2	15	OADs	Chronic Leukemia
	AHL-12	Female	72	2	27	Insulin & OADs	
	AHL-13	Female	57	2	2	OADs	Cardiovascular, Asthma, Thyroid problems

*Unknown by the participants; LHL-number = Participant with Limited Health literacy – Participant number; AHL-number = Participant with Adequate Health Literacy – Participant number

Some participants with limited health literacy perceived *difficulty in using the tool*. They indicated that they had difficulty opening the link in the email to access the tool, opening the information videos, and using a computer in general. In the end, most of the experienced technical problems were solved through trial and error.

> *"What I noticed is that sometimes I found it complicated to go back to all the videos. It ended up just being on a button. But I missed that button. So I clicked on a video and I didn't know how to get back to all the videos together" – LHL4.*

Second, differences existed in *the device on which the tool was used* – that is, on a computer or smartphone. The participants with adequate health literacy more often opened the tool on a smartphone compared with the participants with limited health literacy, who opened the tool on a computer. Some participants with adequate health literacy tried using both devices, and they perceived the interface of the tool on the phone as more difficult compared with that on the computer because the information was difficult to read due to small font size.

Perceived usefulness
Almost all participants indicated that they perceived the tool as useful in the provision of information about diabetes, for which they provided several reasons. First, it was mentioned that the *tool can be used on demand*, so they can choose the desired time to use the tool and the information can be repeated to enable them to understand it.

> *"I think this is a relief… when I get out of the hospital I always get a lot of information… You forgot that at home, but now you have a video" – LHL8.*

Second, they perceived it useful that the *information is applicable to their situation*. Almost all participants liked that the tool was personalized and that they did not have to search for reliable information that specifically applies to them through an overwhelming amount of information on the Internet.

Furthermore, differences existed in perceived usefulness between participants with limited and adequate health literacy. The first difference was in the extent to which the participants stated that they *learned* from the tool. In particular, participants with limited health literacy indicated that they had learned about diabetes through using the tool. They indicated that the tool was highly valuable to them because, according to them, there are almost no websites with diabetes information that they can understand. The participants with adequate health literacy sometimes indicated that they had learned through using the tool, but they often already knew most of the information and skills. Second, differences existed in the use of the tool's *interactive options* that focused more on skills, these were only mentioned by participants with adequate health literacy, and they perceived them as useful options. They perceived these options to be related to increasing their knowledge and applying it in daily life with diabetes. Third, differences existed in the *way the strategies on presenting information* were perceived. More than half of the participants with adequate health literacy and all of the participants with limited health literacy experienced the spoken animations as a pleasant and useful way to receive information, and as much more pleasant and understandable than, for example, information through a package leaflet. However, a few participants with adequate health literacy indicated that the animations were long-winded and childish and perceived the voices in the animations as unrealistic.

> *"Sometimes I thought, 'Please speak a little faster'"* – *AHL1.*

Intention to use

Most participants would *recommend the tool* to other patients with diabetes. All of the participants would recommend the tool to people who have just been diagnosed with diabetes and to people in the social environment (for example colleagues and family members) of patients with diabetes.

> *"You could also inform that environment, take a look at Watch Your Diabetes. Then it would give insights to others who may not have diabetes. Your parents or something... Then you also have an idea of what it is. Everyone has an idea. I have an idea of what it is. Then you often think about old people with diabetes"* – *LHL6.*

Moreover, the participants indicated that when one is diagnosed with diabetes, too much information is provided. For patients at this stage in particular, the tool contains only the relevant information for learning about diabetes and its treatment and, according to the participants, these patients will benefit most from the tool. In addition, they recommended the tool for use by people in their social environments, because in the participants' opinions there are still many misunderstandings about diabetes. Therefore, it would be helpful for people within their social environment to understand what life with diabetes is like.

A large proportion of the participants with limited health literacy and half of those with adequate health literacy indicated that they had the *intention to continue using* *the tool* in the future. The participants with limited health literacy mainly preferred to continue to use it for reading information again to understand it better or if they have forgotten parts. The participants with adequate health literacy wanted to use the tool to monitor new developments in diabetes. Some of the participants did *not intend to continue using the tool* in the future. The main reason for those participants with limited health literacy was that they prefer to receive verbal information from healthcare professionals because they consider it more reliable than all of the other information that can be found. The main reason for people with adequate health literacy was that they already knew everything they wanted to know about diabetes.

Suggestions for improvement

Most participants indicated that they would like to have *written information presented beside the animated videos*. The participants with limited health literacy wanted to be able to read the information again if the animation was too fast, whereas those with adequate health literacy felt that it would enable them to go through the information faster.

> *“I would like it, if you could read the text again, so that you no longer have to watch the animation completely for certain information” – AHL2.*

Half of the participants with limited health literacy stated that they would like to receive *instruction in healthcare practice on the use of the tool*, such as through using the tool for the first time together with a healthcare professional.

> *“It would be helpful for me if my pharmacist showed me how I could best use the tool” – LHL8.*

Another suggestion for improvement was to *add extra options to the tool*. Some of the participants with limited health literacy skills stated that they would like one portal in which all appointments with healthcare professionals are listed and in which one can directly ask one’s healthcare provider a question. In their opinion, these extensions would be helpful for providing a better overview of their schedule as well as make it easier to contact a healthcare provider. The participants with adequate health literacy stated that they would like an enriched tool with more in-depth information about the topics currently covered in the tool, and also for this information to be extended with possible complications, more attention to lifestyle, and new developments. Moreover, they would prefer to have extra interactive options in the tool, such as the ability to check glucose levels. They expressed a strong preference for learning even more about diabetes and medication self-management.

Discussion

The aim of this study was to assess the usability of an animated diabetes information tool by patients with diabetes with limited and adequate health literacy levels and demonstrated that most participants considered the practical information, reliable and applicable to their situation as useful. In addition, most of the participants perceived the tool as easy to use because the information was offered with simple navigation, presented in understandable plain language, and could be acquired on demand. The participants especially recommended such a tool for people newly diagnosed with diabetes and for people within these patients' social environments.

A strength of this study was that it explored which elements were experienced as usable and which elements require attention for people with limited or adequate health literacy. Until now, little research has been done into the usefulness of self-management tools for people with limited and adequate health literacy. The findings of this study could contribute to the sustainable use of other support tools, which may be beneficial for people with adequate and limited health literacy to understand, remember, and interpret medication information. A limitation of this study was a potential selection bias caused by the convenience sampling method that was chosen. The participants might not have been a representative sample, but that does not detract from the purpose of this qualitative study; exploring experiences and opinions about the use of the tool by different patients. Another limitation is that usability testing was obtained through an interview and self-reported data and not through an observation of using the tool. However, since we were primarily interested in patient's experiences of the usability and perceived barriers, subjective measures were also suitable to provide us with these insights.

Elements that may improve usability for people with limited health literacy

In general, the tool tested in this study was perceived as highly usable by participants with limited health literacy, and therefore, they had the intention to continue using the tool. According to people with limited health literacy, three elements contribute to this: First, the practical and easy to understand information ensures that they perceive to learn more from the information in the tool compared with information from other sources. Second, easy-to-use navigation and in the form of spoken animations is especially valuable for people with limited health literacy. This is in line with the findings of previous studies; the use of animations in the provision of information to people with limited health literacy caused them to be more positive about the message and to be better able to remember and apply the information.[12] Third, information tailored to their own situation with only the main message, thus ensuring that they no longer have to search and then select between large amounts of information (or a large numbers of sources).[10,11]

Difficulties with usability for people with limited health literacy

This study also provides insight into the difficulties experienced by people with limited health literacy when using a self-management support tool, some of them perceived technical difficulties when using the tool. They had problems with opening the link to the tool in the email, opening the information videos, or using a computer in general. People with limited health literacy are more likely to have difficulties using the Internet and websites than people with adequate health literacy.[23-25] For example, they have more difficulties scrolling, accessing links, and searching for and finding information online.[23,24] Moreover, previous research indicated that the use of digital tools by patients with limited health literacy is lower than patients with adequate health literacy.[26] Although patients with limited health literacy use digitals tools less often than patients with adequate health literacy, they can sufficiently use it if they are properly supported.[10,11] To diminish the barrier of difficulty in using the tool, having someone who can provide instructions on how to use it is necessary. Therefore, to reach patients with limited health literacy and stimulate their use of the tool, actively offering the tool with tailored information through demonstrating it to patients and then guiding them in using it may be helpful.[16]

Elements that may improve usability for people with adequate health literacy

The tool tested in this study that is tailored to the needs of people with limited health literacy was experienced as usable by people with adequate health literacy. The participants with adequate health literacy were already well-informed about living with diabetes and hardly learned any new knowledge or skills through using the tool. Participants with adequate health literacy needed more in-depth information as well as information about the latest developments to be presented in a more interactive way to make using such a tool attractive to them. Previous research has found that these patients prefer more in-depth information and more interactive sources of information compared with patients with limited health literacy.[27,28] A layered approach, where additional in-depth information is offered in another layer of the tool, may stimulate optimal usability for people with limited and adequate health literacy. By applying such layering, support tools could be offered to everyone and then tailored even further to the needs of all patients.

In conclusion, the tool assessed in this study was perceived as easy to use and usable by many patients with diabetes, both with limited and adequate health literacy levels; however, some improvements can be made to further optimize it for use in both groups. Future research should investigate whether patients will use the tool. Subsequently, it will have to be investigated whether the use contributes to better medication self-management and whether this contributes to improved outcomes such as delaying complications and improving the quality of life of patients with diabetes.

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Supplementary file

Interview Topics

Ease of use

- How do you experience the use of Watch Your Diabetes?
- What do you perceive as difficult about Watch Your Diabetes?
- How do you perceive the ease of use of Watch Your Diabetes?

Perceived usefulness

- How do you experience the usefulness of Watch Your Diabetes?
- How did Watch Your Diabetes help you?
- To your opinion, is Watch Your Diabetes of added value?
- How do you perceive the quality of Watch Your Diabetes?

Intention to use

- Do you think you would use Watch Your Diabetes in the future if you were offered the opportunity?
- Would you recommend Watch Your Diabetes to others?

Suggestions for improvement

- To your opinion, how can Watch Your Diabetes be improved?

Implementation of an animated medication information tool in community pharmacies, with a special focus on patients with limited health literacy

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Abstract

Objective: The animated medication information tool 'Watchyourmeds' provides information in an accessible manner through animated videos and therefore appears to be especially suitable for people with limited health literacy. This study aimed to assess the implementation of this animated medication information tool in Dutch community pharmacies, with a special focus on patients with limited health literacy.

Methods: A cross-sectional survey based on the Reach, Effectiveness, Adoption, Implementation and Maintenance (RE-AIM) framework was sent to approximately 75% of the ±1900 community pharmacies in the Netherlands through email newsletters of pharmacy networks.

Key findings: 140 pharmacists (~10%) completed the survey and 125 of them (89%) indicated that they offered the animated medication information tool to their patients. 108 pharmacists indicated that the tool was offered to all patients, not only to patients with limited health literacy. The distribution method was primarily passive (patients were given a leaflet and were not explicitly pointed to or informed about the tool). Two frequently cited motivations for offering the tool were that it complemented other sources of information and that the health insurer provided a financial incentive. The main reasons patients refused to use the tool were that they had no access to and/or no affinity for the required technology.

Conclusion: This study demonstrated that the tool is used in community pharmacies and that it is offered to all patients, regardless of their presumed health literacy level. A more active method of offering the tool may be warranted to better reach patients with limited health literacy.

Introduction

To promote appropriate and safe use of medication, patients need to be well informed about their medicines.[1,2] In order to improve patients' understanding of the expected benefits and risks, they should be provided with practical instructions as well as information about possible side effects, expected pharmacological action, and consequences of not taking the medication.[3-6] Patients who are better informed about their treatment risks and benefits, and who understand how to use the medication, are more adherent,[7] which leads to improved quality of life and reductions in drug-related problems, morbidity, mortality, healthcare utilization and healthcare costs.[8,9]

As medication experts, pharmacists have an important role to inform patients to consult the package information leaflet (PIL) when a medicine is collected from the pharmacy or delivered to them.[10] However, for many patients the information in the PIL is difficult to understand or even unreadable.[11] Beside the PIL, pharmacists offer cognitive pharmaceutical services, which include patient education, pharmacist-led clinical medication review, medication adherence counselling and individual-tailored prescription labels with instructions for medication use.[12-15]

People with limited health literacy have difficulty understanding information about medication and medical terms.[16-18] In the Netherlands, 36% of the population have limited health literacy.[19] Health literacy 'encompasses people's knowledge, motivation and competences to access, understand, appraise, and apply health information in order to make judgments and take decisions in everyday life concerning healthcare, disease prevention and health promotion to maintain or improve quality of life during the life course'.[20] These patients are at higher risk of misinterpreting instructions for dosage, duration and frequency provided in the PIL as well as other written information or verbal pharmacist counselling.[3,21-23] The current cognitive pharmaceutical services may not be sufficiently tailored to the needs of people with limited health literacy.[24]

Previous needs assessments regarding medication information for people with limited health literacy indicate that they need understandable, reliable and practical information focused on a single main message, which reduces cognitive load, resulting in better recall of information.[25-29] Presenting information to people with limited health literacy in the form of narrated animations, illustrations or spoken text also helps promote understanding and recall of information.[26,27,30-33]

In the Netherlands, an animated medication information tool called 'Watchyourmeds' is available. This online library contains more than 8,000 animated videos which use lay language to explain the most important information from the PILs for more than 95% of all medicines dispensed in the Netherlands.[34] Due to the method of presentation, this tool appears to be especially suitable for people with limited health literacy. The videos are personalized by gender, age and medication. The tool is available in different languages (Dutch, English, Turkish and Arabic) and can be offered by a pharmacist.

Since January 2019, the largest health insurer in the Netherlands recommends the use of the animated medication information tool as part of their quality improvement policy. Community pharmacies receive a financial incentive to provide this tool to their patients, with the aim of promoting proper use of medicines. Pharmacists were informed by 'Watchyourmeds' about the various ways the tool could be offered to patients. It could be offered with an informational flyer, through a general web link to the tool or a medication-specific web link to the tool sent by email or text message, by allowing patients to view the tool in the pharmacy on a PC or tablet, or the patient can be referred to their pharmacy's patient portal in which the tool can be viewed. Some methods of offering the tool are more passive and provide general written information without explicitly pointing to the tool, while other methods are more active and tailored to the patient with explicit information about and direction to the tool. It is the pharmacists who decide how the tool is offered, to fit in with their own working practices. The aim of this study was to assess the implementation of the animated medication information tool in Dutch community pharmacies, with a special focus on patients with limited health literacy. The following research questions were explored:

1. To what extent and in what way do pharmacists offer the animated medication information tool to their patients and specifically to patients with limited health literacy?
2. Why do pharmacists offer the animated medication information tool to their patients?
3. According to pharmacists, what are the reasons patients accept or refuse to use the animated medication information tool?

Methods

Study design & setting

A cross-sectional study was performed using an online survey of community pharmacists. The survey was conducted from September 2019 to February 2020. Pharmacists were invited to complete the survey through email newsletters from three professional networks: the Utrecht Pharmacy Practice network for Education and Research (UPPER), the network of the foundation 'Watchyourmeds' and the pharmacy network of Groningen University. The invitation to the UPPER network was repeated once in the newsletter. Combined, these networks reach approximately 75% of the ± 1900 pharmacies in the Netherlands. In the Netherlands, completing a survey does not fall under the scope of the Dutch Medical Research Involving Human Subjects Act, therefore, a medical ethics review of the study was not required.[35] All respondents participated on a voluntary basis.

Survey

The survey (Supplementary Appendix S1) was developed by researchers of the Netherlands Institute for Health Services Research (Nivel). The questions were checked for comprehensibility, feasibility and completeness (options that are correct in pharmacy practice and that no answers were missing) by a pharmacist and an independent researcher. Only minor textual changes were made. The survey consisted of five multiple choice questions regarding the characteristics of the pharmacies and 16 multiple choice questions about the implementation of the tool derived from the RE-AIM framework.[36] The RE-AIM framework comprises five dimensions for evaluating the public health impact of interventions (Table 1). Effectiveness was not assessed in this study because the survey was distributed only to pharmacists and focused on the implementation of an intervention, whereas the effectiveness of an intervention must be measured in patients. In the results section, we linked our results to the dimensions of the RE-AIM framework by placing the corresponding dimension in brackets.

Table 1. The five dimensions of the RE-AIM framework [36]

Dimension	
Reach	Number of patients reached, which patients are reached and how many patients are offered the tool when dispensing the medication
Effectiveness	Assessment of the positive and negative consequences of the tool
Adoption	Proportion of pharmacies willing to offer the tool
Implementation	Extent to which pharmacies offer the tool to all patients who could benefit from it
Maintenance	Extent to which the tool becomes part of daily routine in the pharmacy

Analysis

Only completed surveys, without missing variables, were included in the analysis. Data was held in an SPSS database (SPSS Statistics for Windows, version 25.0 (SPSS Inc)).

Results

Participant characteristics

In total, 172 pharmacists started the online survey and 140 (81%) of them completed it. 45% of the pharmacists estimated that their patient population was predominantly older and 31% of the pharmacists estimates that their patient population had a low education level (Table 2). About one third (35%) of the pharmacists estimated that a relatively high number of their patients had a limited health literacy level; 18% reported having a patient population with predominantly adequate health literacy.

Table 2. Pharmacy characteristics and their patient population (n = 140)

Pharmacy characteristics		**N**	**%**
Type of pharmacy	Community	129	92
	Outpatient	3	2
	Dispensing GP	8	6
Employee capacity	1–1.9 fte*	7	5
	2–4.9 fte*	28	20
	5–9.9 fte*	83	59
	≥ 10 fte*	22	16
Distribution of patient population (estimated by the pharmacist)		N	%
Age	Predominantly young (< 40 y)	13	9
	Predominantly middle (40–64 y)	32	23
	Predominantly old (> 64 y)	34	45
	About equally distributed	32	23
Educational level	Predominantly low	44	31
	Predominantly intermediate	33	24
	Predominantly high	22	16
	About equally distributed	40	29
Health literacy	Many patients with limited health literacy level	49	35
	Many patients with adequate health literacy level	25	18
	About equally distributed	66	47

*Fte = Fulltime equivalent

To what extent and in what way do pharmacists offer the animated medication information tool to their patients and specifically to patients with limited health literacy?

Of the 140 pharmacists who completed the survey, 89% indicated that they currently offered the animated medication information tool to their patients (adoption), 7% indicated that they had offered it but stopped, and 4% of the pharmacists never offered it to their patients. 42% of the pharmacists indicated that the tool was included in the usual routines of the pharmacy (maintenance). Of the 125 pharmacists currently offering the tool, 86% of them offered the tool to all patients and 14% offered it to specific groups based on presumed health literacy level, education level, type of medicine or age of the patient (reach/implementation). 61% of the pharmacists indicated that they actively offered the tool to their patients by explicitly recommending it, and 39% of the pharmacists indicated that they passively offered it (reach). Table 3 shows the various ways the responding pharmacists reported offering the medication tool. This was mainly passively using a flyer (65%) or with a general web link to the tool (33%). The other more active methods of distribution were less used, such as the medication-specific web link (26%) or referral to the pharmacy patient portal (21%), and only 2% of the pharmacies offered access to the tool on a PC or tablet in the pharmacy. Table 3 illustrates the distribution of the animated medication information tool by the pharmacists to patient populations with different levels of health literacy. Pharmacists whose patients were predominantly of limited health literacy distributed the tool relatively frequently, using a medication-specific web link, compared to the other two patient populations (Table 3). In the other four distribution methods, there were minor differences between the three patient populations.

Why do pharmacists offer the animated medication information tool to their patients?

Figure 1 provides an overview of motivating factors for pharmacists (n=125) to offer the animated medication information tool (implementation/adoption). Two factors frequently reported were that it complements other sources of information and that the health insurer offers a financial incentive; 73% of all pharmacists gave a score of 6 or higher in the question whether they would recommend using the tool to other pharmacies. The pharmacists generally considered the tool to be of added value (81%) and held the opinion that it should be used by all patients (67%) and that it fitted well in the digitisation of healthcare (93%). However, in most pharmacists' experience, the tool did not save their time for other activities (91%), and it did not reduce the number of questions at the first refill (80%).

Table 3. Distribution of the animated medication information tool in different patient populations*

	Flyer	Medication specific web link	General web link	Referral to patient portal	Viewed in pharmacy
All pharmacies offering the tool (n = 125)	81 (65%)	41 (33%)	32 (26%)	26 (21%)	3 (2%)
Health literacy:					
Many patients with adequate health literacy level (n = 22)	12 (55%)	8 (36%)	8 (36%)	3 (14%)	2 (9%)
Equally distributed (n = 60)	40 (67%)	11 (18%)	14 (23%)	17 (28%)	0 (0%)
Many patients with limited health literacy level (n = 43)	29 (67%)	22 (51%)	10 (23%)	6 (14%)	1 (2%)

* The pharmacists estimated the health literacy level of their patient population. Multiple answers were possible.

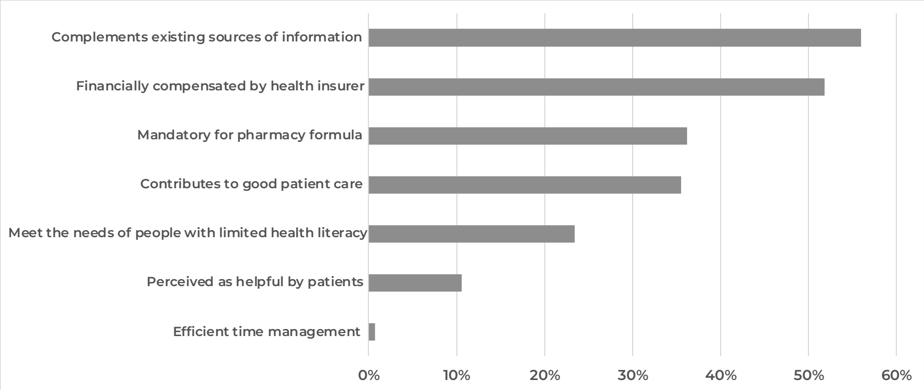

Figure 1. Motivations of pharmacists to offer the animated medication information tool to patients (n = 125)*
*Percentage of the pharmacists surveyed who choose this motivations for offering the animated medication information tool. Multiple answers were possible.

Perceived reasons for patient acceptance or refusal of the tool

More than half of the pharmacists (n=125) reported that patients use it because they find it easy to use (60%) and are interested in the tool (52%). Reasons for accepting or refusing the tool were that patients did not have access to the required technology (58%) or they had no affinity for the required technology (53%). The pharmacists estimated that half of patients refused to use the tool because they did not need any additional information and approximately one third (37%) of patients refused to use the tool because they thought it childish and/or preferred personal interaction with the pharmacist (35%).

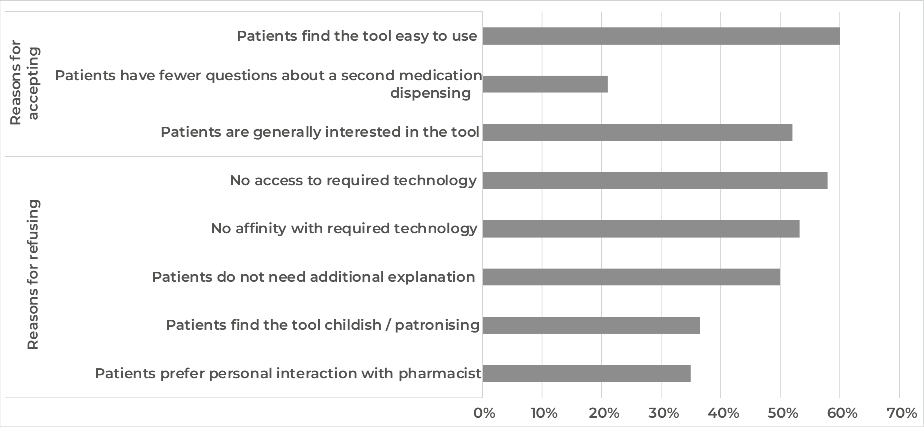

Figure 2. Reasons according to pharmacists why patients accepted or refused to use the animated medication information tool (n = 125)*
*Percentage of the pharmacists who reported each reason why patients accepted or refused to use the animated medication information tool. Multiple answers were possible.

Discussion

Key Findings

The majority of the pharmacists surveyed offered the tool to all of their patients, including patients with limited health literacy. The tool was mainly offered because of the financial incentive provided by the health insurer and because the tool complements other existing medication information. Most patients were interested in using the tool and found it easy to use; according to the pharmacists surveyed, the main reasons patients refused to use the tool were a lack of affinity for or lack of access to the required technology.

Strengths and Limitations

This study has several strengths and limitations. One strength is that the survey was widely distributed among approximately three quarters of all Dutch community pharmacies. Furthermore, this study assessed the implementation of an intervention at the pharmacy level. Although more and more interventions are available for pharmacies, there is still little research assessing the implementation of these interventions.[37,38] The questions used to assess the implementation were based on the RE-AIM framework. However, due to the distribution of the survey to pharmacies and not patients, the effectiveness was not assessed. Future research should also assess the effectiveness of the intervention in patients to complete all the dimensions of the RE-AIM framework. Another limitation of this study is that pharmacists estimated the health literacy level of their patients instead of measuring it with a validated measure, while research has shown that pharmacists find it difficult to estimate the level of health literacy.[39,40] On the other hand, this study showed that pharmacists estimations of the health literacy level of their population did not lead to a selection of the patient population to which the tool was offered, which is in line with the universal precautions approach. Another limitation of this study is that it is unclear to what extent the respondents who volunteered to participate in this study are representative of pharmacists in the Netherlands, limiting the extent to which the results can be generalized to all Dutch pharmacies. Furthermore, the pharmacists reported the reasons they believed patients chose whether or not to use the animated medication information tool. Patient experiences with the tool are currently being investigated, which could be used to improve the fit of the tool and the method used to offer the tool. This could contribute to sustainable use of a tool which is beneficial for understanding, remembering and interpreting medication information for people with adequate and limited health literacy.

Comparison to existing knowledge

Regarding the reach and adoption dimensions of the RE-AIM framework, pharmacists reported offering the tool to all patients, not exclusively to those with limited health literacy. Previous research has indicated that pharmacists find it difficult to estimate the level of health literacy and assessing health literacy levels takes time, partly because patients are not likely to expose their limited health literacy skills because they feel ashamed.[41] The universal precautionary approach advocates structuring the delivery of care as if every patient may have limited health literacy, thus with information that is easy to process and understand.[31,42-44] This is beneficial for understanding, remembering and interpreting medication information for both people with adequate and people with limited health literacy.[44-46]

While the majority of the pharmacists offered the animated medication information tool to all patients, it is possible that patients with limited health literacy more often refused the tool. Previous research showed that patients with limited health literacy have more difficulty using internet and websites and use digital tools less often than patients with adequate health literacy.[22,47-49] Patients with limited health literacy might thus not be reached through the current methods pharmacists use to offer the tool, while they may benefit most of the tool.

In order to reach patients with limited health literacy, an active method of recommending the tool to all patients with tailored information may be more effective. Although patients with limited health literacy use digital tools less than patients with adequate health literacy, they can effectively use digital tools if they are properly guided.[50-52] Pharmacists often play a pivotal role in this active provision of tailored information. For example, a pharmacist can actively offer the tool by showing it to patients or providing a medication specific web link. These types of access were less reported in the pharmacies, possibly because not all pharmacies had all distribution methods available at the time of the study. For example, they may not have had a tablet or PC available yet or the tool may not yet have been integrated into the patient portal. Further research is needed to explore how the intervention can be best offered to patients with limited health literacy.

The motivations pharmacists reported for offering the tool can be divided into two categories. First, the pharmacists considered the animated medication information tool to be of value to their patients because it complements the existing information provided when medication is dispensed. Second, the financial incentive from the health insurer. This finding aligns with the results of previous research which indicates that financial incentives promote more frequent offering of cognitive pharmaceutical services.[53] It is not clear from this study which reason contributed most to implementation of the tool; future research could further investigate the primary motivating factor to maintain sustainable use of the tool.

Conclusion

This study demonstrates that the animated medication information tool is used in pharmacies and that it is offered to all patients, regardless of their presumed health literacy level. The current method of distribution is mainly passive. A more active method of offering the tool may be warranted to better reach patients with limited health literacy.

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Appendix S1 – full survey

Part A – Characteristics of the pharmacy

1. In what type of pharmacy do you work?
   A. Community
   B. Outpatient
   C. Dispensing GP

2. What is the employee capacity at the pharmacy where you work?
   A. 1 – 1,99 FTE
   B. 2-4,99 FTE
   C. 5-9,99 FTE
   D. 10 or more FTE

3. How would you describe the patient population in your pharmacy on age?
   A. Predominantly young (<40 y)
   B. Predominantly middle aged (40-64 y)
   C. Predominantly old (>64 y)
   D. About equally distributed

4. How would you describe the patient population in your pharmacy on education level?
   A. Predominantly low
   B. Predominantly intermediate
   C. Predominantly high
   d. About equally distributed

5. How would you describe the patient population in your pharmacy on health literacy level?
   A. Many patients with limited health literacy level
   B. Many patients with adequate health literacy level
   C. About equally distributed

Part B: Offering Watchyourmeds

6. Does your pharmacy offer Watchyourmeds to patients?
   A. No, and I don't know Watchyourmeds (end of questionnaire)
   B. No, but I do know Watchyourmeds (go to question 7)
   C. Yes, we offered Watchyourmeds, but we have stopped now (go to questions 8)
   D. Yes, we currently offer Watchyourmeds (go to part C)

7. Why was it decided not to offer Watchyourmeds to patients in your pharmacy? (Multiple answers possible) (Hereafter to part F)
   A. Watchyourmeds is not attractive enough
   B. The financial compensation is insufficient for me
   C. Better alternatives are available
   D. Watchyourmeds is too childish for my patients
   E. The information provided by Watchyourmeds is not complete
   F. The videos that Watchyourmeds offers are too long
   G. There is no need for such a tool in my pharmacy
   H. The implementation of Watchyourmeds in my pharmacy was too complex
   I. I have no control over this because of my role within the pharmacy

8. Why has your pharmacy stopped offering Watchyourmeds to patients? (multiple answers possible) (hereafter only part C, to question 11. Then to part F)
   A. Most of the patients were not interested in Watchyourmeds
   B. The financial compensation for offering Watchyourmeds was insufficient
   C. The quality of the Watchyourmeds videos was insufficient
   D. We have opted for an alternative information source
   E. Offering Watchyourmeds appeared to take more time than had been estimated in advance
   F. The implementation of Watchyourmeds in my pharmacy turned out to be too complex

Part C: General Impression Watchyourmeds
In this section we ask about the general impression you have of Watchyourmeds. We ask you to give a specific score of 1 – 10 (1-4 = bad, 5-7 moderate, 8-10 good).

9. Which score between 1 and 10 do you give your opinion about Watchyourmeds in general?

10. What score between 1 and 10 do you give the number of medicines about which Watchyourmeds offers videos?

11. Which score between 1 and 10 do you give the medical explanation of Watchyourmeds?

12. What score between 1 and 10 do you give the way in which Watchyourmeds is used in your pharmacy? (NOTE: only ask this question if the answer to question 6 states that Watchyourmeds was or is being offered)

Part D: The use of Watchyourmeds (Reach/Adoption)
In this section we ask questions about how your pharmacy uses Watchyourmeds, and whether a special target group is being approached.

13. Is Watchyourmeds used actively or passively in your pharmacy?
    A. Active (the patient is referred to the Watchyourmeds) (Go to question 14)
    B. Passive (Watchyourmeds is not explicitly mentioned) (Go to question 15)

14. After actively pointing to Watchyourmeds, patients in my pharmacy receive (multiple answers possible): (hereafter to question 16)
    A. A flyer with information with a general link to Watchyourmeds
    B. A medication specific web link sent by email or text message
    C. A general web link sent by email or text message
    D. Watchyourmeds can be seen on a pc / tablet in the pharmacy
    E. The advice to consult their personal medicine overview on the patient portal where Watchyourmeds is linked

15. Watchyourmeds is offered to patients in my pharmacy via: (multiple answers possible) (hereafter to question 16)
    - A. A flyer with information with a general link to Watchyourmeds
    - B. A medication specific web link sent by email or text message
    - C. A general web link sent by email or text message
    - D. Watchyourmeds can be seen on a pc / tablet in the pharmacy
    - E. The advice to consult their personal medicine overview on the patient portal where Watchyourmeds is linked

16. Are there specific target groups to whom your pharmacy offers Watchyourmeds?
    - A. Yes (go to question 17)
    - B. No, Watchyourmeds is offered to all patients (go to question 18)

17. My pharmacy chooses the target group to which Watchyourmeds is issued on:
    - A. The type of drug being dispensed
    - B. The patient's education level
    - C. The degree of literacy of the patient
    - D. Socioeconomic status of the patient
    - E. The patient's cognitive level
    - F. The age of the patient
    - G. The migration background of the patient
    - H. Possible different language of the patient
    - I. Suspicion of the patient's limited health skills

Part E: Implementation and Barriers of Watchyourmeds

In this section we ask questions about the implementation of Watchyourmeds in your pharmacy, and possible barriers to this.

18. What are the reasons that Watchyourmeds is used in your pharmacy? (multiple answers possible)
    - A. Watchyourmeds is compulsory (in case the pharmacy is part of a chain)
    - B. Watchyourmeds ensures that I can use my time more efficiently
    - C. Watchyourmeds is a good initiative
    - D. Watchyourmeds is a good addition to the information sources that already exist
    - E. Watchyourmeds meets a need for low-literate patients
    - F. Watchyourmeds meets a need for patients with limited health literacy
    - G. Watchyourmeds contributes to good patient care
    - H. Watchyourmeds is financially compensated by the health insurer
    - I. Watchyourmeds is perceived as useful by patients

19. What do you think are reasons for patients to refuse Watchyourmeds? (Multiple answers possible)
    A. The patient does not have access to the required technology
    B. The patient has no affinity with the required technology
    C. The patient prefers to have personal interaction with the pharmacist / assistant
    D. The patient does not need additional explanation on top of existing sources
    E. The patient finds Watchyourmeds patronizing or childish
    F. Other, namely

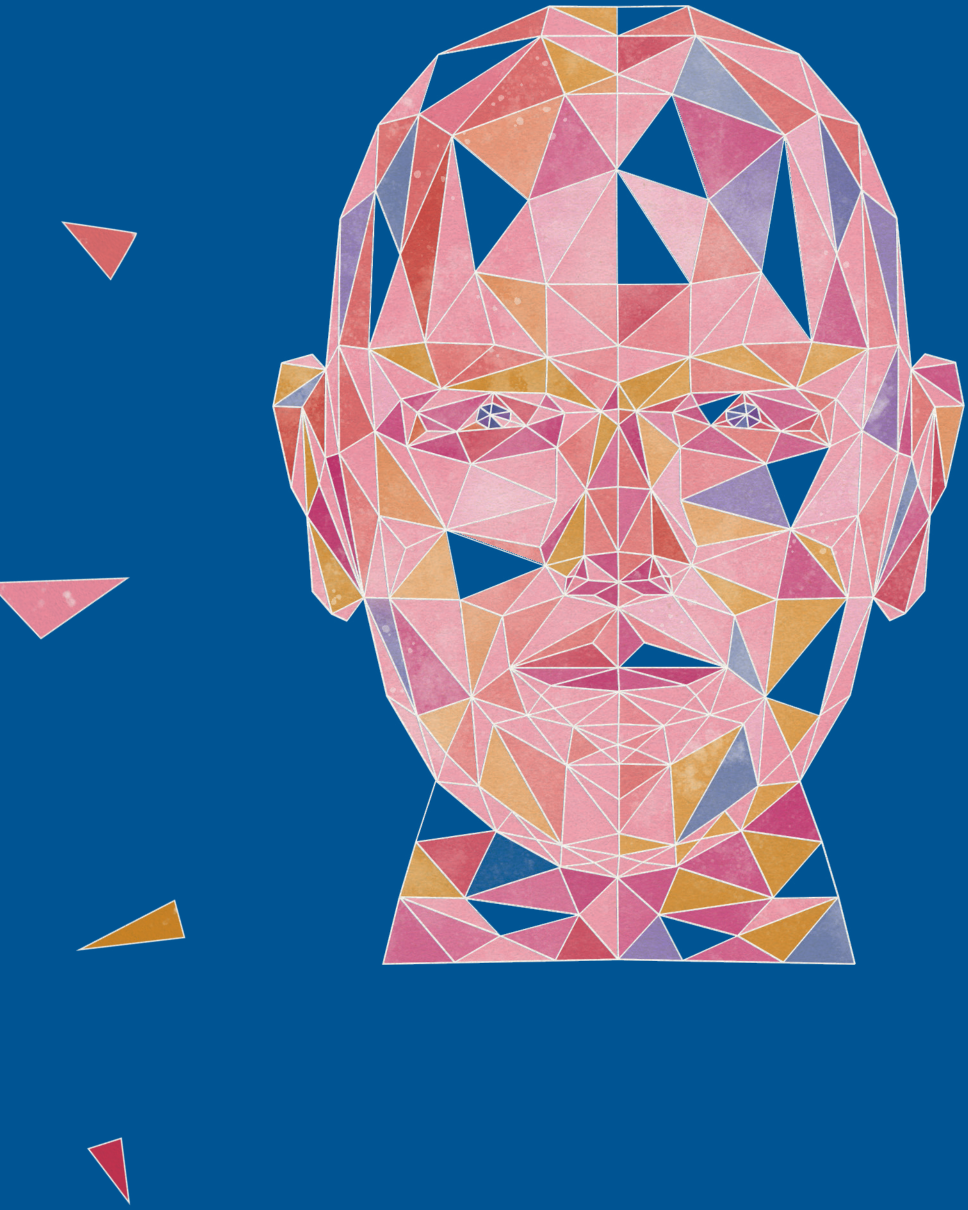
Part F: Your opinion about Watchyourmeds

In this section you will be presented with 11 propositions regarding Watchyourmeds. For each of these statements, please indicate to what extent you agree or disagree with it? (1 = completely disagree, 2 = slightly disagree, 3 = slightly agree, 4 = completely agree).

20. To what extent do you agree with:
    A. Watchyourmeds fits well in the current digitization of healthcare
    B. Watchyourmeds is of added value in my pharmacy
    C. Watchyourmeds should be used in all patients
    D. Patients are generally interested in Watchyourmeds
    E. Patients find Watchyourmeds easy to use
    F. It is common for patients to ask about Watchyourmeds
    G. Watchyourmeds ensures that patients generally have fewer questions on the second issue
    H. Watchyourmeds ensures that there is more time for other things
    I. Offering Watchyourmeds to patients does not take more time than regular information
    J. Offering Watchyourmeds is completely part of our prescription delivery routine
    K. The level of information provision of Watchyourmeds is difficult

Part G: closing

21. To what extent would you recommend the use of Watchyourmeds in the pharmacy to colleagues? (0 = very unlikely - 10 Very likely)



7

General discussion

General discussion

In Europe, the population's life expectancy is increasing, which means that people are living longer on average.[1] This greater longevity results in an absolute and relative increase in the number of elderly people, among whom a significant proportion are affected by one or more chronic diseases.[2-4] Appropriate healthcare can contribute to the adequate control of chronic diseases and the improvement of patients' quality of life. While part of the care for people with chronic diseases is delivered by healthcare professionals, the majority is performed by the patients themselves through self-management.[5,6] A key component in the management of chronic diseases is adequate medication use. Many patients experience their medication self-management to be difficult, especially those with limited health literacy, who are faced with extra challenges, such as a limited understanding of health information and inadequate numeracy skills.[7-9]

To improve patients' medication self-management, adequate support is essential. In the last decade, many initiatives have been implemented to support people with chronic disease in their self-management tasks.[10,11] Despite the fact that people with limited health literacy experience difficulties in achieving adequate self-management, they make less use of current self-management support programs and activities compared with people with adequate health literacy.[12,13] Therefore, offering accessible and understandable support tailored to the needs of this specific patient group seems an appropriate strategy for supporting them.[14,15] Unfortunately, the medication self-management needs of people with limited health literacy have rarely been studied, as has how to adequately support this patient group in terms of medication self-management.[12,16,17] Therefore, this thesis aimed to explore the needs of patients with a chronic disease and limited health literacy regarding medication self-management as well as how medication self-management support can be tailored to those needs. Thus, the following two research questions were formulated:

1. What are the needs of patients with chronic disease and limited health literacy regarding medication self-management?
2. How can patients with chronic disease and limited health literacy best be supported and facilitated in their medication self-management?

The following sections address and reflect upon the main findings of this thesis.

1. Main findings

1.1 What are the needs of patients with a chronic disease and limited health literacy regarding medication self-management?

This thesis has explored the medication self-management needs of patients with a chronic disease and limited health literacy. The needs were summarized according to the four levels of health information management as discerned from the definition of health literacy – namely accessing, understanding, assessing, and applying health information.[18]

Access

The studies presented in this thesis have demonstrated that patients with limited health literacy have difficulty accessing information about medication, for which there are three main reasons. First, in the study described in Chapter 2, patients with limited health literacy explained that they often have difficulty reading. As most information about medication is presented in a written format, patients with insufficient reading skills cannot access it. Second, some people with limited health literacy have difficulties with the language in which the information is presented; for example, it might not be their mother tongue. This leads to insufficient access to spoken or written health information (Chapter 2). Third, a proportion of patients with limited health literacy have difficulty accessing online information (Chapters 5 and 6). Some do not have an Internet connection or they experience difficulty accessing digital information, such as scrolling, accessing links, and searching for and finding information online.

In this thesis, three aspects that contribute to improving access to health information were identified. First, spoken information is valued by patients as useful for having better access to health information (Chapters 2 and 5). For patients who have difficulty reading and writing, accessibility is increased by spoken information. Spoken information about medication can be provided by a healthcare professional or through an audio clip, which can be offered digitally through an app or website. The advantage of spoken information being provided by a healthcare professional is that it involves two-way communication, where the possibility exists of interaction between the patient and healthcare professional. The disadvantage of offering spoken health information through a healthcare professional is that access to the information is limited to the contact time that the patient has with the professional. Furthermore, it is difficult for a patient to remember all of the information they obtain during this contact time to be able to use it another time. The second aspect that contributes to having access to health information is the provision of information in the patient's native language; thus, the language barrier is reduced, and this patient group will have better access to health information (Chapter 2). The third aspect for improving access to health information is to make digital health information accessible to patients with limited health literacy. This requires websites and apps to be designed co-creation with this target group and for adequate instruction and support in using this digital information to be provided (Chapter 5).

Understand

In addition, the studies presented in this thesis have demonstrated that patients with limited health literacy have difficulty understanding information about medication. Difficult words, the use of jargon, and the presence of long, abstract compound sentences in information about medication are the main reasons for this information being too difficult to understand for such patients (Chapters 2 and 4). The inclusion of many long, abstract compound sentences discourages people with limited health literacy from reading all of the information because they quickly find it overwhelming and intimidating (Chapter 2).

This thesis identified two aspects that contribute to understanding health information. The first aspect is the reduction of large amounts of information to single main messages, which contributes to an enhanced understanding of information (Chapter 2). Single main messages reduce people's cognitive load, enabling those with limited health literacy to remember information better compared with messages that contain detailed information. Second, people with limited health literacy prefer information to be presented with images or animations, which facilitate understanding (Chapter 4). The use of images or animations improves the ability of people with limited health literacy to remember the information as well as increases their knowledge in relation to written materials (Chapter 4). If they have difficulty reading, an image or animation will overcome this barrier.

Assess

Moreover, the studies presented in this thesis have demonstrated that patients with limited health literacy have difficulty assessing information about medication, for which there are two main reasons. First, these patients have difficulty estimating the reliability of information. The large amount of information available from various sources (e.g., healthcare professionals, informal caregivers, leaflets, and the Internet) makes assessing its reliability even more difficult (Chapters 2 and 5). When different sources seem to contradict each other, it becomes even more difficult for people with limited health literacy to distinguish reliable from less reliable information. Second, these patients have difficulty estimating the extent to which and what part of the information applies to them, mainly because they find it difficult to distinguish between main and side issues within the abundance of information available (Chapter 2).

This thesis identified two aspects that contribute to a better assessment of health information. First, it is crucial to tailor information to the individual's needs, personal characteristics, and medical situation (Chapters 2, 4, 5, and 6). Then, the patient only receives information that is relevant to him or her. Second, patients with limited health literacy prefer to be informed by their healthcare professional rather than actively searching for information from other sources (Chapter 2). Moreover, such patients often have an intensive relationship with healthcare professionals, such as the diabetes nurse, general practitioner, and pharmacist, whom they trust (Chapters 2 and 5). As a result, they assess the information they receive from healthcare professionals to be reliable. In addition, the healthcare professional has knowledge about the patient's personal needs, personal characteristics, and medical situation, which makes them ideally suited to providing tailored information.

Apply

To be able to apply health information, people with limited health literacy require reliable information that they can understand. Such health information is a condition for further self-management. However, this knowledge does not automatically result in appropriate behavior. An example of this was a finding from Chapter 2, where some patients with limited health literacy repeatedly indicated that they were aware of the importance of adequate medication self-management but did not perform the associated actions. Health information for people with limited health literacy must be practical information that specifies exactly what they have to do and how it works(Chapter 2). More details and background information are considered less relevant. Practical information contributes to an increase in involvement in the patients' medication self-management and increases the chance of them not only understanding the information but also applying it.

Second, to apply health information, people must develop the appropriate skills. Examples include calculating the correct amount of insulin, adhering to one's medication schedule through effective time management, discussing medication-related information with a healthcare professional, and adapting one's medication to changing circumstances. The study described in Chapter 2 revealed that patients with limited health literacy want to be supported in obtaining the skills necessary for adequate medication self-management.

Third, the application of health information requires support from both the healthcare professional and peers (Chapters 2, 5, and 6). The healthcare professional can tailor support to the patient's characteristics, ensuring that only relevant information is provided. Moreover, healthcare professionals can demonstrate or practice actions with patients with limited health literacy, such as the correct use of medicines or the access to and application of a self-management support tool. Finally, the healthcare professional has a critical role in supporting the application of health information through making decisions and setting goals together with the patient. In addition to support from healthcare professionals, a need also exists for support from peers, who are essential for social support in medication self-management. The study described in Chapter 2 highlighted that peer support groups serve as sources of reassurance, which healthcare professionals often do not provide. Contact with peers provides the opportunity to share experiences and tips about living with a chronic disease (Chapter 2). Patients with limited health literacy also like to rely on other patients' experiences. Such contacts assist them in understanding and dealing with their disease as well as learning about the disease and the treatment options.

Overall, the needs of patients with chronic diseases and limited health literacy regarding medication self-management are focused on the improvement of the relevant health knowledge necessary for medication self-management through making health information more accessible, understandable, and easier to assess. On the other hand, a need exists to develop skills for medication self-management and to receive appropriate support from both healthcare professionals and peers.

1.2 How can patients with chronic disease and limited health literacy best be supported and facilitated in their medication self-management?

In addition to studying the needs of patients with limited health literacy regarding medication self-management, we investigated how those needs can be met through the provision of adequate support for medication self-management. As a starting point, a review was performed of general health interventions in Europe that have targeted people with limited health literacy (Chapter 4). These health interventions have not all specifically targeted medication self-management; however, they are relevant because they have demonstrated which factors are important to consider when developing interventions for people with limited health literacy. The results of this review revealed that from 1995 to 2018, only 23 studies were published about interventions that have specifically targeted people with limited health literacy. The results also indicated the following three critical factors in interventions for this target group: First, support should be focused on both knowledge and skills. Most existing interventions for people with limited health literacy have only focused on knowledge, whereas interventions that have also focused on skills in addition to knowledge have led to improvements in patients' motivation, knowledge, empowerment, and self-confidence (Chapter 4). Second, the information and required skills must be tailored to the needs and health literacy level of patients. People with limited health literacy are not a homogeneous group; each individual has their own needs, personal characteristics, and medical situation. Therefore, a person-oriented, individual approach is necessary to optimally support people with limited health literacy. Third, support should preferably be presented as easy-to-understand information, and the use of images is recommended, both of which make it easier for people with limited health literacy to access, understand, and apply health information. The three aforementioned factors partly mirror the needs of people with limited health literacy formulated in research question 1.

As described in the study presented in Chapter 4, few interventions have specifically targeted people with limited health literacy, among which only one has specifically targeted medication self-management. However, a new tool was recently developed that does address medical self-management and is aimed at people with limited health literacy – namely the Dutch tool "Watchyourmeds." In Chapters 5 and 6, this digital tool was evaluated. It provides information in plain, understandable language with the most critical information from the Patients Information Leaflet (PIL) and practical information to support medication self-management. Moreover, most of the information is presented through spoken animations.

To investigate the extent to which this tool is suitable for people with limited health literacy, the usability of the tool for diabetes patients with limited health literacy was assessed (Chapter 5). All of the participants had digital access. Furthermore, most perceived the tool as easy to use because the information is offered with simple navigation, presented in understandable plain language, and can be used on demand. The tool is therefore useful for people with limited health literacy and Internet access. In general, patients with limited health literacy preferred to be supported when using the tool for the first time through, for example, a demonstration of how to use it. Some patients had difficulty using the tool due to a lack of affinity with the required technology (Chapter 5). For them and people without Internet access (who were not included in the study), this tool and other digital tools in general are not appropriate; thus, a different strategy is required to support them.

Notably, a substantial number (89%) of community pharmacies in the Netherlands provide this tool to their patients with the aim of promoting the proper use of medicines. To explore the experiences of community pharmacies related to offering this animated medication information tool, its implementation in Dutch community pharmacies was studied in Chapter 6. Most of the pharmacists offered the tool to all of their patients, regardless of their estimated health literacy level. The main motivation of pharmacists to provide the tool to their patients was the financial incentive provided by the health insurer. Another motivation was that they considered the tool to complement other forms of medication information. The pharmacists believed the tool to fit the needs of patients with limited health literacy and considered it promising for supporting and facilitating their medication self-management. However, they also reported that some patients refused to use the tool because they had no access to and/or no affinity with digital sources.

In summary, patients with chronic disease and limited health literacy can be supported and facilitated in their medication self-management by tailoring the information and required skills to their needs and health literacy level. Furthermore, interventions should focus on both knowledge and skills; information should be presented in an easy-to-understand format; and the use of images is recommended. The tool Watchyourmeds was perceived to be usable for people with limited health literacy who have Internet access. Such a digital medication self-management support tools seems promising for patients with limited health literacy as well as digital access and skills; however, for patients without digital access and skills, another medication self-management support strategy is required.

2. Discussion of main findings

2.1 Aim of medication self-management support for patients with limited health literacy

Medication self-management is defined as the range of tasks that patients must undertake to successfully manage their therapeutic regimen and sustain safe medication use.[19] Medication self-management for a chronic disease is a constantly demanding process that requires an active role from the patient to ensure accurate medication intake, storage, and disposal, as well as the discussion of medication therapy issues with healthcare professionals.[20] Many patients with chronic diseases struggle with medication self-management, and several factors contribute to such difficulty. First, there are factors related to the patient, such as their living circumstances (e.g., living alone or with others) and beliefs about medication (Chapter 3).[21,22] Second, there are factors related to the treatment, such as a complex medication regimen or polypharmacy, which may also increase the risk of insufficient medication self-management.[23] Third, there are factors related to healthcare professionals, such as insufficient communication between patients and healthcare professionals.[24]

Because of the difficulty of medication self-management, patients may not benefit optimally from the pharmacotherapy. To optimally benefit, patients must be supported in their medication self-management. The positive effects of medication self-management interventions have been established across multiple conditions.[25-27] Medication self-management support integrates multiple components aimed at activating patients to take medications effectively and safely, such as health behavior change, patient education, shared decision making, and goal setting.

Patient activation is the most reliable indicator of the willingness and ability to manage health and care autonomously.[28,29] Hibbard and Mahoney developed patient activation theory, where patients' activation is defined as "the individual's knowledge, skill and confidence in managing his/her own health and care."[30] According to this theory, patients go through four stages of patient activation. In stage 1, people tend to be overwhelmed and unprepared to play an active role, and they are predisposed to being passive recipients of care. In the case of medication self-management, for example, the patient may only take medication in the presence of a home care nurse. In stage 2, individuals lack knowledge and confidence for self-management. For example, patients may attempt to adhere to their medication but also believe that the impact on their health is out of their control, thus quickly stopping the medication after experiencing side effects. In stage 3, people begin to play an active role but may still lack confidence and skills to support new behaviors. For example, they may mostly take their medication correctly and on time but have difficulties when their daily routines change. Finally, in stage 4, people have confidence and perform adequate behaviors but may not be able to maintain them in the face of stress. For example, patients generally adhere to their medication schedule, adjust the dosage themselves if necessary, and adapt their lifestyle to the disease and medication, but they may struggle with these tasks in times of stress or change, such as when their health condition deteriorates. Increased patient activation is related to positive changes in a variety of self-management behaviors, such as doing physical exercises, managing stress, or informing oneself of the benefits, risks, and use of medication.[31,32] Furthermore, increased patient activation scores are associated with lower healthcare costs.[33]

Fulfilling an active role in medication self-management is difficult for many people, but especially for people with limited health literacy. They tend to be passive in medical encounters as well as less effective self-managers.[34] According to patient activation theory, patient activation is influenced by the three factors of knowledge, skills, and self-confidence. People with limited health literacy have less knowledge about their needs and medical situation compared with people with adequate health literacy. Health information is often presented in a manner that is too difficult to comprehend, and therefore, these patients have more difficulty accessing and understanding it (Chapters 2, 4, and 5). In addition, they have fewer skills for adequate medication self-management, such as adequate literacy and numeracy, participation in shared decision making, or the measurement of blood glucose levels.[34] The results in Chapter 4 also provided evidence that for interventions to be effective for this target group, they should focus not only on knowledge but also skill acquisition. Finally, people with limited health literacy are generally less confident about managing their medication; for example, they often do not feel confident about asking questions to their healthcare professional, feel ashamed about their limited health literacy, or lack motivation for adequate self-management.[35-38] To more effectively support patients with limited health literacy in their medication self-management, the aim of the support should be to increase patient activation by enabling them to increase their knowledge, improve their skills, and gain self-confidence through positive experiences.[30]

2.2 Content of medication self-management support for patients with limited health literacy

Furthermore, the content of medication self-management support for patients with limited health literacy must focus on both knowledge and skills, or on the concepts of the model presented in the introduction of this thesis – namely the “capacity to think” and the “capacity to act.”[15,30,39] This was confirmed by the study described in Chapter 4, which found that promising interventions should pay attention to communicative and critical health literacy skills, in addition to focusing on functional skills and knowledge. Most existing tools for supporting people with limited health literacy in dealing with their health and illness aim to increase the cognitive aspects of health literacy, such as knowledge (Chapter 4). The cognitive aspects (i.e., the capacity to think) are crucial prerequisites for adequate self-management as they contribute to the feeling of being in control and of confidence in managing one’s health and medication; however, the main challenge lies in translating this knowledge into the desired behavior (i.e., the capacity to act).[15,39-41] The study described in Chapter 2 clearly demonstrated that patients require support regarding both the knowledge and skills for medication self-management. Furthermore, patients emphasized the struggle related to the gap between knowledge and the ability to put this knowledge into practice. In particular, noncognitive aspects like skills and self-confidence are critical for outcomes that require an active role, such as seeking and using health information, choosing a healthcare professional, and performing (medication) self-management.[15] These aspects are major drivers of behavioral change and the extent to which people feel able to self-manage. It is therefore vital to invest in how skills for medication self-management and self-confidence can be supported in people with limited health literacy, thereby improving patient activation.

It is evident from research and the studies presented in this thesis that the current range of self-management supports, with their focus on knowledge, should be supplemented with the learning of skills to be attractive and effective for patients with limited health literacy. Several strategies seem promising for providing the education of skills to this patient group. First, it seems important to actually practice medication self-management skills. Practice contributes to improving not only the skills required for medication self-management but also to the self-confidence to be able to take control.[30] Practical, functional situations can be practiced, such as asking questions to a healthcare professional, clearly formulating one's problems and questions through adequate preparation of the consult, preparing or demonstrating the intake of medication together with a professional, and learning to measure blood glucose levels (Chapter 2). In addition, the study in Chapter 5 revealed that patients with limited health literacy require a demonstration or support for using digital support tools. If people with limited health literacy are given clear instructions and demonstrations the first time, this will help them to use digital tools to deal with their disease and health.[42,43] These instructions and demonstrations are essential to the ability to benefit from the digital possibilities that exist.

Second, in the acquisition of skills as well as knowledge, it is crucial to take small, realistic steps aimed at activating more passive patients.[30] The results described in Chapter 2 indicated that patients with limited health literacy can be overwhelmed by the wide variety of information, making it difficult for them to select which information is appropriate and relevant and to determine which is not. As a result, patients lack the knowledge required to take an active role in their medication self-management. In addition, the study described in Chapter 3 demonstrated that people with limited health literacy are more concerned about the harmful effects of and overuse of medication. While these beliefs cannot be changed immediately, they can be changed over time by reassuring these patients and informing them correctly in small steps.[44] Realizing small successes can initiate an upward cycle toward positive affect and self-perception, just as failure produces the opposite.[30]

In addition to the conclusion that the content for medication self-management support should focus on both knowledge and skills, it is critical for the content to be tailored to the needs, personal characteristics, and medical situation of the patient (Chapters 2 and 4). A growing number of interventions exist for supporting medication self-management, but they often prove not to be effective or to have only modest and short-term effects on outcomes.[45-47] Previous research has indicated that self-management support is more effective when it is tailored to a patient's individual needs, personal characteristics, and medical situation, as a vast variation exists in the extent to which patients are able and motivated to self-manage.[48-50] These findings were also reflected in Chapters 2, 4, and 5 of this thesis. By tailoring support to the patient, the patient will receive unambiguous and applicable information, making it easier for them to apply it and thus increasing the chance of better medication self-management.

2.3 Strategies for offering medication self-management support for patients with limited health literacy

This thesis has explored how medication self-management support can best be provided to patients with limited health literacy, so that they actually can and will use these support tools and activities. Various strategies exist for providing medication self-management support. Two main differences are individual versus group support and the provision of written materials (leaflets and brochures) versus face-to-face support versus online support. First, this section examines the (dis)advantages of individual versus group support. Most medication self-management support is offered individually to patients, as in the studies described in Chapters 2, 5, and 6. The advantage of individual medication self-management support is that it can be tailored to the needs, personal characteristics, and medical situation of the specific patient. The patient will thus only receive support that applies to him or her, which is valued as usable by patients (Chapter 5). The study described in Chapter 6 demonstrated that individually offering medication self-management support is perceived as time-intensive by the support provider, who is usually a healthcare professional. For example, a pharmacy in the Netherlands has, on average, 8000 patients, 25% of whom have limited health literacy and require additional medication self-management support. If that support is for 15 minutes twice a year, this amounts to 1000 hours of support per year that must be offered by the pharmacy. This calculation is oversimplified, but it illustrates the enormous labor intensity of individual face-to-face support.

Another strategy for offering medication self-management support is group-based support, which has the advantages of patient meetings, discussions, and peer motivation.[51] People with limited health literacy often rely on the experiences of other patients; moreover, tips for adequate medication self-management can be exchanged.[45,52] During the focus group meetings, it was noticed that the threshold for indicating barriers or needs was reduced by entering a group discussion (Chapter 2). Furthermore, group-based support contributes to improvements in clinical, lifestyle, and psychosocial outcomes.[46,51] Another advantage of offering medication self-management support in a group setting is that it is less burdensome for the support provider. The disadvantage of offering medication self-management support in a group is that it can be tailored to the needs of the individual patient to a lesser extent. The findings of this thesis indicate the importance of individually tailored medication self-management support as well as the importance of support from peers. Thus, both approaches to offering support can be useful for patients with limited health literacy and can complement each other.

In addition to the choice of whether to offer medication self-management support individually versus in a group, another choice exists of whether to offer support as written materials (leaflets and brochures) versus face-to-face versus online. Written materials, such as PILs, have the advantage that the information is available to the patient anytime and anywhere. Unfortunately, providing written support as the only form of support does not match the needs of people with limited health literacy (Chapter 2). The major drawback is that they often have difficulty reading and writing, which makes the information less accessible to them. Most written documents are currently too complex for many people to understand, especially for those with limited health literacy. Presenting information as simple and understandable text and in plain language reduces people's cognitive load, resulting in improved information recall by people with limited health literacy.[42,43,53] Presenting information to them in the form of narrated animations, illustrations, or spoken text also helps to promote the understanding and recall of information.[43,54,55] These findings were reflected in Chapters 2, 4, 5, and 6. Finally, a disadvantage of written information is that it is not tailored to the needs, personal characteristics, and medical situation of the patient, which makes it more difficult for them to assess and apply it.

In addition, patients with limited health literacy most commonly prefer face-to-face support, as this is spoken information and they do not have to read (Chapter 2). Furthermore, the information is provided in an interactive situation, usually by a healthcare professional whom the patient trusts.[56,57] The study described in Chapter 2 demonstrated that patients with limited health literacy perceived the spoken information provided by healthcare professionals to be comprehensible, and that they preferred the possibility to ask questions for clarification. Most previous studies have indicated that patients with limited health literacy often do not understand their diagnoses and treatment plans and complain about difficult and ineffective communication from their healthcare professional.[58-60] Easy-to-understand information does not seem to be routinely incorporated into clinical practice.[58] Although most healthcare professionals want to provide clear instructions and information to patients with limited health literacy, they often do not know how to communicate with them effectively. They also do not tailor their messages to the needs and skills of these patients, instead tending to use a one-size-fits-all communication style.[61] Appropriate tailored support for patients with limited health literacy is also regarded as time-consuming by providers. In addition to the quality of current communication lacking, another disadvantage of face-to-face support is that it only occurs at that moment of contact. As a result, the patient does not have the opportunity to read or look at the information provided another time (Chapter 2).

Another strategy for offering medication self-management support is through digital health tools and services. These are considered promising as they can provide interactive formats, such as spoken messages, videos, or animations, which are less cognitively demanding than written information.[43,62] In addition, offering support through digital health tools and services increases the chance that information will be remembered and that the recipient will be more positive about the information.[43,54,55] In recent years, an increasing number of digital tools have become available to support self-management in people with a chronic illness, of which a proportion are specifically aimed at medication self-management.[10,63-66] The World Health Organization recognizes that digital health tools and services have the potential to accelerate toward cost-effective care by improving health services.[67] While such tools and services are an essential element for the successful transformation of health and care systems, it is vital to ensure that no-one is left behind, such as those with limited health literacy.

In Europe and the Netherlands, 44% and 21% of the population have insufficient digital skills, respectively.[68] For people with limited health literacy, including elderly people who use a relatively large amount of medication, these figures are likely to be more unfavorable. These people have more difficulty using simple online functions, such as scrolling, accessing links, using search engines, and formulating search terms, making them less likely to use online tools (Chapters 2 and 5).[69] People with limited health literacy are less likely to have access to digital health tools and services, nor do they have the skills required to take advantage of their benefits.[69-71] This leads to unequal opportunities to benefit from available digital health resources. The issue of unequal access, use, and/or skills with respect to digital resources by people with limited health literacy is a recognized public health problem.[72,73] Two strategies exist for dealing with this inequality problem. The first is to more effectively educate and support people with limited health literacy in how to deal with digital health tools and services, so that they can use them to deal with their illness and health. The second is to more effectively incorporate the needs and competences of people with limited health literacy into the design of new digital tools, so that they are easier to use and tailored for this patient group. This would require co-creation with patients with limited health literacy.[15,74,75] For people without Internet access, a different strategy is required to support them in their medication self-management. If this is not provided, people with limited health literacy will be less able to benefit from the digital possibilities that exist, and health disparities will only increase.[73,76]

Overall, all strategies for providing medication self-management support have advantages and disadvantages. The different strategies for providing medication self-management support do not exclude each other but can be combined and complement each other. The strategies for provinding medication self-management support should also depend on the patient's preferences, their reading and communication skills, and their Internet access and digital skills. To increase the effectiveness of self-management support interventions, how they are provided must be tailored to patients' needs, preferences, and skills.[48,49]

2.4 Provider of medication self-management support

Previous studies and the study described in chapter 2 demonstrated that people with limited health literacy prefer to receive support from their own healthcare professional, whom they know and trust.[56,57] People with limited health literacy prefer to receive information from a person who knows them. Healthcare professionals can therefore be an effective provider to support these people. Moreover, people with limited health literacy are more likely to request information from a healthcare professional than to actively seek information themselves. In addition, they indicated that receiving support from their healthcare professional is preferable because they consider this information to be reliable (Chapter 2).

The healthcare professional has three critical tasks and roles in providing medication self-management support to patients with limited health literacy. First, they should create a relationship of trust with the patient. To share barriers or needs, or to ask questions, these patients have to feel comfortable with a healthcare professional.[77] The findings described in Chapter 2 underscore the importance of the relationship of trust, as patients stated that they tried to follow the instructions of their healthcare professional because of the trust they have in them and because the professional already knows their background and medical history.[77] Second, the healthcare professional must be knowledgeable in the field of medication self-management, such as medication effects, side effects, medication schedule, and necessary skills for the use of the medication. In our study, patients with limited health literacy expressed that the medication information was clearly presented by their healthcare professional and that they could easily ask them questions if something was unclear (Chapter 2). Contrary to the findings described in Chapter 2, other studies have indicated that patients with limited health literacy often have difficulty understanding health information provided by a healthcare professional and asking questions.[58-60] Therefore, the professional's communication skills are of the utmost importance, especially in tailoring their communication to people with limited health literacy. Third, the ability of healthcare professionals to motivate patients toward medication self-management is important. Their ability to support the patient's autonomy in self-management predicts the ability of their patients to adopt an active role in healthcare and to adhere to treatment.[29,78] The study described in Chapter 5 demonstrated that patients with limited health literacy like to receive instruction and demonstration in healthcare practice on the use of a digital medication self-management tool. By observing and asking what is going well with the patient's medication self-management and what information and skills are still required, the healthcare professional can stimulate an active patient role.[79]

People with chronic diseases and limited health literacy primarily associate the term "healthcare professional" with general practitioners, pharmacists, and nurse practitioners (Chapter 2). These are also the professionals with whom they have the most contact. In the experience of patients, nurse practitioners invest the most effort into establishing a good relationship with the patient, which is probably partly the result of them having more time for the patient. Patients perceived pharmacy staff to be the least involved in their well-being (Chapter 2).[77] All three types of healthcare professionals were experts in the field of medication self-management; however, it is the core business of pharmacy staff to inform patients about a medication when it is dispensed at the pharmacy or delivered to them.[80] They are easily accessible and can play an important role in improving medication self-management and reducing medication-related problems.[81,82] Several studies have demonstrated that many healthcare professionals still require additional training to adapt to their role of supporting and facilitating adequate medication self-management.[81-83] For example, the teach-back method has barely been used as a routine practice component.[84] With this method, the healthcare professional can check whether information has been received correctly, which they can do by asking the patient to say, in their own words, what has just been discussed. The healthcare professional can then, if necessary, adjust or supplement the information. The teach-back method ensures that healthcare professionals are constantly checking patients' comprehension without blame, which is associated with better health outcomes.[85,86] Healthcare professionals also need to be trained to develop the habit of routinely applying the teach-back method.[85] As another example, support and activation in the use of digital health tools and services require a new role for healthcare professionals, namely to model, support, and promote patients' digital skills.[87] The literature indicates that to fulfill this new role, healthcare professionals must be strengthened in their own digital skills as well.[87-89]

While patients with limited health literacy prefer medication self-management support from a healthcare professional, professionals find this difficult to implement due to their increasing workload, which is caused by a growing number of patients and a decreasing number of healthcare professionals.[90] Healthcare is under pressure in many Western countries, including the Netherlands, where an integral care agreement was recently signed between organizations of hospitals, mental healthcare, and care for the elderly. The aim of this agreement is to keep qualitatively good healthcare accessible and affordable for the future. One of the pillars of this agreement is to work together on appropriate care, whereby there is more cooperation between various healthcare professionals, which is expected to reduce the pressure on them.[91] This intensification of the collaboration between different healthcare professionals could contribute to mapping the problems and needs of people with limited health literacy, such that support can be tailored more adequately. In addition, the intensification of the collaboration can contribute to more uniform support for people with limited health literacy; thus, these patients would perceive the support of different healthcare professionals to be consistent rather than contradictory, as is now sometimes the case.

Another option for face-to-face support would be to offer (part of) the medication self-management support through volunteers or people who have low-threshold contact with people with limited health literacy, such as people from the same social network or community (e.g., church).[92,93] Because these people already have contact with the person with limited health literacy, they would be more likely to reach them. This method was used in the study described in Chapter 5.[74,75] They may not be experts in the field of medication, but they could, for example, educate and support digital skills. Improving digital skills is useful for improving access to health information, and it may also be used for other sectors of society.[94,95] This option seems promising. The difficulty lies in the continuity of support. In the case of collaboration between (different) healthcare professionals and volunteers, an unambiguous plan must exist regarding the division of roles and tasks, such that the deployment of volunteers can be guaranteed for a longer period for a sustainable approach.

All in all, people with limited health literacy prefer to be supported in their medication self-management by people they know, preferably by their healthcare professional. This is because they are experts in medication self-management. However, since this may be too burdensome due to shortages of time or personnel, a division of tasks between healthcare professionals and lay people, such as volunteers, could also have added value.

2.5 Reaching patients with limited health literacy

Although self-management support that fits the needs of people with limited health literacy can be further designed and implemented, another challenge lies in recognizing and reaching this group. This was mentioned as the most critical problem by Dutch healthcare professionals.[61] Studies have demonstrated that people with limited health literacy are less likely to participate in health-promoting programs.[39,73,96] Furthermore, they are less likely to actively seek health information or support and to share the difficulties they experience in their medication self-management with their healthcare professionals.[39,96] They usually do not feel confident about asking their healthcare professional questions, and they feel ashamed of their limited health literacy.[35,36] As a result, they remain under the radar of healthcare professionals and thus do not receive the support they require.

Strategies exist for increasing the likelihood of reaching people with limited health literacy for self-management support. First, to increase accessibility, it is important that the support is offered where people with limited health literacy are located – that is, the support should be brought to the people. This is because they do not actively search for support themselves. In the studies described in this thesis, the community pharmacy was used as a meeting place. Patients can be reached when they collect a medicine or have it delivered to them.[80] Another example is a physical meeting organized close to the patient at a suitable time, which is important as limited health literacy is relatively more common in the elderly, people with a low income or level of education, and people with a migrant background.[97-99] For example, they can be met in community centers in deprived areas or through activities specifically aimed at the elderly, such as those held at a health center or sports club.

Second, in this thesis, people with limited health literacy were reached through acquaintances in their network (Chapter 5). These included not only family members and friends but also members of a social community, such as churchgoers, close neighbors, or sports club members. People with limited health literacy are more likely to trust people they know, which means that acquaintances in their network have a good opportunity to reach them and refer them to a healthcare professional for appropriate medication self-management support.[73,100]

Third, a success factor in continuing to reach these people is the building and maintenance of a relationship of trust. In recruiting patients with limited health literacy for the studies described in this thesis, it was clear that they could be reached mostly through a trusted healthcare professional who knew about their problems with dealing with health information and/or self-management. By trusting the healthcare professional, they also trusted the researcher and were willing to participate in the study (Chapters 2 and 5). In general, it could be helpful to designate a coordinating practitioner or case manager for a patient with limited health literacy in the healthcare system – one who knows their specific barriers and needs. Continuity is crucial to be able to support someone for a longer period, as people with limited health literacy are less likely to use support if it is not offered by someone they know and trust. In other studies, these trusted healthcare professionals have already been proven to contribute to patient involvement and to make patients more motivated to take an active role in their health and healthcare.[101,102]

Finally, a promising strategy is to focus not only on reaching patients with limited health literacy but also on all patients. Previous research indicated that healthcare professionals found it difficult to estimate the level of health literacy, and also that assessing health literacy levels takes time, partly because patients are not likely to expose their limited health literacy.[103] The so-called "universal precautions approach" advocates for structuring the delivery of care as though every patient may have limited health literacy, using information that is easy to process and understand.[13,55,104,105] This would be beneficial for understanding, remembering, and interpreting medication information for both people with adequate and those with limited health literacy.[42,43,105] The universal precautions approach can be used as a starting point in healthcare, but healthcare professionals must pay close attention to which people the approach does not work well enough for and then offer additional tailored support.

2.6 Development of medication self-management support for people with limited health literacy

The findings of this thesis contribute to improving the development of medication self-management support for people with limited health literacy. Only a limited number of interventions have been specifically designed for this target group, and therefore, many self-management support programs do not fit their needs (Chapter 4). The study described in Chapter 4 highlighted the urgent requirement for interventions tailored to the needs of people with limited health literacy, and also the importance of involving patients with limited health literacy in all stages of medication self-management support development (i.e., co-creation).[15] Several models exist for determining the level at which patients want to and can be involved. This can be achieved by using a specially developed “involvement matrix” or Arnstein’s Ladder of Involvement.[106,107] An involvement matrix indicates that patients can be involved in different stages of projects, such as the preparation, execution, or implementation phase, and that they can play different roles such as listener, co-thinker, advisor, partner, or decisionmaker.[106,107] Furthermore, an involvement matrix allows all involved participants to clearly agree on the nature of the involvement. A focus group can be a useful strategy for co-creation. In our study described in Chapter 2, the use of focus groups with people with limited health literacy was successful at articulating needs and barriers. The patients complemented and inspired each other regarding their needs for medication self-management support. Another example of a strategy for co-creating with people with limited health literacy is community engagement, which involves working with a group of people who are connected by, for example, geographical features (e.g., the same residential area), special characteristics, or similar situations that affect their well-being.[108]

In addition, this thesis has revealed two major aspects that seem to be lacking in many current programs for medication self-management: First, medication self-management for people with limited health literacy should not only include information transfer but also skills training. The results of the studies in this thesis demonstrate that most self-management support only focuses on knowledge, whereas for adequate medication self-management, knowledge, skills, and self-confidence are required. Patients stressed the importance of this; for example, they indicated that they preferred being supported in the use of medication when they changed their routine, and also that they would like to be supported in learning to use digital tools (Chapters 2 and 5).

Second, patients with limited health literacy perceived the focus group meetings to be useful for sharing problems they encounter with fellow patients as well as for helping each other. Therefore, it would be desirable to develop medication self-management support for them that includes a peer support component. During the development of the peer-system, who the suitable peers are should be explored, whether they are other patients with limited health literacy, other patients with the same disease, or people without a disease. Peers can motivate each other to use medication adequately as well as offer motivation in other areas, such as lifestyle improvement.[109,110]

3. Methodological reflection

In this section, the strengths and limitations of the various studies presented in this thesis are discussed. The main strength of this thesis is that the researchers were able to include difficult-to-reach, vulnerable patients in the studies. The inclusion of people with limited health literacy in the research was facilitated by the healthcare professionals, who acted as an intermediary between patients and the researcher. Only in Chapter 5's study was the first contact between the researcher and patients facilitated by acquaintances, such as family. The relationship of trust was initiated by the healthcare professional or acquaintances, who introduced the researcher to each patient. The patients trusted their healthcare professionals or acquaintances, which increased the likelihood that they would also trust the introduced researcher (Chapter 2).[57] From the first contact between the researcher and patients, the relationship of trust was further developed in a telephone meeting prior to the interview or focus group. This contributed to open communication about the perceived barriers and needs of the patients.[111] The inclusion of patients with limited health literacy in our research also allowed us to focus on the patient perspective.

A limitation of the studies presented in this thesis was that a selection bias existed. For the studies described in Chapters 2 and 5, most of the patients with limited health literacy were recruited by healthcare professionals, and some of those in the study in Chapter 5 were recruited by acquaintances. The healthcare professionals made a first estimation of the patients' level of health literacy, which has certain limitations. First, the professionals could only estimate the levels of patients they actually saw in their practice, while vulnerable patients who did not enter their practice would have remained under the radar and not been selected. In addition, patients had to be willing to actively participate in the study. Due to this selection method, it is plausible that a subgroup of people with limited health literacy was not included in the studies. This subgroup would likely be even less active in their medication self-management or might have more severe or additional problems with respect to language, literacy, or otherwise. Therefore, our results are not generalizable to all patients with limited health literacy in the Netherlands. Such patients who avoid healthcare use, who did not want to participate in the study, and who did not have access to the Internet (for the study described in Chapters 5 and 6) were not included in the studies described in this thesis. Therefore, it is likely that the included participants were already relatively active in their medication self-management and were therefore a positive sample. In this sense, the barriers and needs discovered are probably an underestimation of the actual problems regarding the medication self-management of all people with limited health literacy. While our findings may contribute to improved access to and understanding, assessment, and application of health information for all people with limited health literacy, another strategy is required to reach and support the unreached group.

Since many conceptualizations of health literacy and various health literacy measurements are available, health literacy scores can be complex to interpret and compare. In this thesis, the following measurement instruments were used to establish patients' health literacy level: the Functional Communicative and Critical Health Literacy scale (FCCHL), part of the Set of Brief Screening Questions (SBSQ), the European Health Literacy Survey Questionnaire (HLS-EU-Q16), and subjective estimations of the healthcare professionals.[112-114] For each individual study, a choice was made for a specific measurement instrument for determining health literacy. A limitation of the research methods was that the different measures of health literacy in our studies made it complex to compare the results. The three instruments that we used in our studies have been validated and can be considered reliable based on their psychometric properties, but they differ in how they measure health literacy and which aspects of literacy they measure; that is, they differed between performance-based and perception-based and between being more focused on measuring the capacity to think versus the capacity to act. Performance-based refers to testing and observing actual performances (e.g., REALM, SAHL, and Newest Vital Sign) with a focus on specific aspects of health literacy, such as reading skills and numeracy (functional health literacy). On the other hand, there are perception-based measures, such as the HLS-EU-Q16 and the FFCHL, which are based on self-report. These measurement instruments have the advantage of including more dimensions of health literacy. The FCCHL measures functional, communicative, and critical health literacy, while the HLS-EU-Q16 focuses on access to and understanding, assessment, and application of information. In this thesis, we sought to focus on both the capacity to think and the capacity to act, since both cognitive and noncognitive aspects of health literacy are crucial for the self-management of medication. Although the concept of health literacy has become broader to include more than just knowledge and information management, this is less true of most measurements. Noncognitive aspects are partly reflected in the FCCHL and HLS-EU-Q16, but they still concern only a small part of the questionnaires. Other measurements that focus more on the ability to act, such as the Patient Activation Measure (PAM), which focuses on knowledge, skills, and self-confidence, could be a suitable addition to the current toolbox of health literacy measurement instruments. An overlap exists among the concepts of patient activation and health literacy, especially in the noncognitive domains, but with the broader conceptualization of health literacy, the elements of the PAM are highly relevant and of added value to include in the measurements.[15,39,115,116]

4. Implications for daily practice and future research

The results of this thesis have implications for daily practice, starting with the role of the healthcare professional. The term health literacy is becoming increasingly familiar to healthcare professionals, but what the concept entails exactly is not always clear to them. During the studies, we noticed that healthcare professionals often associated limited health literacy with limited reading and language skills, while the definition of health literacy used in this thesis included a broader perspective, such as the skills required to apply health information. In addition, healthcare professionals often find it difficult to estimate a person's health literacy, which makes the provision of tailor-made support more difficult. Therefore, our first recommendation is to provide more education for healthcare professionals about what limited health literacy is, how it affects health outcomes, and how to identify and communicate with this patient group. Moreover, the support offered by healthcare professionals is often aimed at transferring knowledge, but knowledge alone is not sufficient for ensuring adequate medication self-management. Healthcare professionals should therefore also be educated in supporting the development of skills and self-confidence in patients. Several trainings and tools exist for better supporting patients with limited health literacy, such as the teach-back method. Many professionals are still unaware of these tools and methods and do not know how to support this group of patients.[61] Instead of having the role of an expert, healthcare professionals in self-management support partly switch to being a coach to the patient.

In addition to the implications for healthcare professionals, the results of this thesis also have implications for the organization of healthcare to better meet the needs of patients with limited health literacy. Here, our first recommendation is to reduce the complexity of healthcare as the patients perceive it. These patients interact with a wide range of healthcare professionals. During the study described in Chapter 2, it emerged that patients with limited health literacy find it complicated to determine which healthcare professional they should contact for which kind of care. One coordinating practitioner/case manager, as a first point of contact, can be helpful for reducing the perceived complexity in healthcare. In addition, making aspects of healthcare simpler and recognizable will increase the trust in health information of people with limited health literacy. They are less likely to use information if they do not recognize the sender or do not recognize themselves in the search information provided.[117] A need exists for consistency in medication provision, such as through not changing the manufacturer for the same type of medicine every year, which would make it unrecognizable to the patient. The same applies to the recognizability of the health insurer and healthcare professionals, among others. This could contribute to motivating these people to process information and actually take action.[101,102]

Lastly, the results of this thesis also have implications for future research. First, future research should focus on the short- and long-term effects of medication self-management support in people with limited health literacy. The studies in this thesis mapped out needs regarding medication self-management and evaluated a tool that seemed to be a good fit in terms of usability. However, the effects of this medication self-management support tool on, for example, medication adherence, health outcomes, and the side effects of using medication have not yet been studied. More randomized controlled trials about the effectiveness of medication self-management support tools specifically designed for people with limited health literacy are recommended. Second, the current range of medication self-management support interventions is predominantly focused on knowledge, but little is known about how the skills required for medication self-management can be learned and practiced most effectively. In co-creation with patients with limited health literacy and various healthcare professionals, the needs of patients in terms of acquiring the skills required for medication self-management must be further explored. Subsequently, how the organization of healthcare can be further tailored to these needs should be investigated, such that patients are facilitated in fulfilling an active patient role within their medication self-management.

5. Conclusion

This thesis aimed to explore the needs of patients with a chronic disease and limited health literacy regarding medication self-management as well as how medication self-management support can best be tailored to these needs. Medication self-management is difficult for many people, especially those with limited health literacy. This thesis demonstrated that patients with limited health literacy can be supported in their medication self-management by tailoring health information to them. In addition to providing health information and improving knowledge, medication self-management support should also be aimed at the acquisition of skills and self-confidence. Finally, the results of this thesis demonstrated that while healthcare professionals are willing to support medication self-management, a more active delivery approach and training are required to reach patients with limited health literacy.

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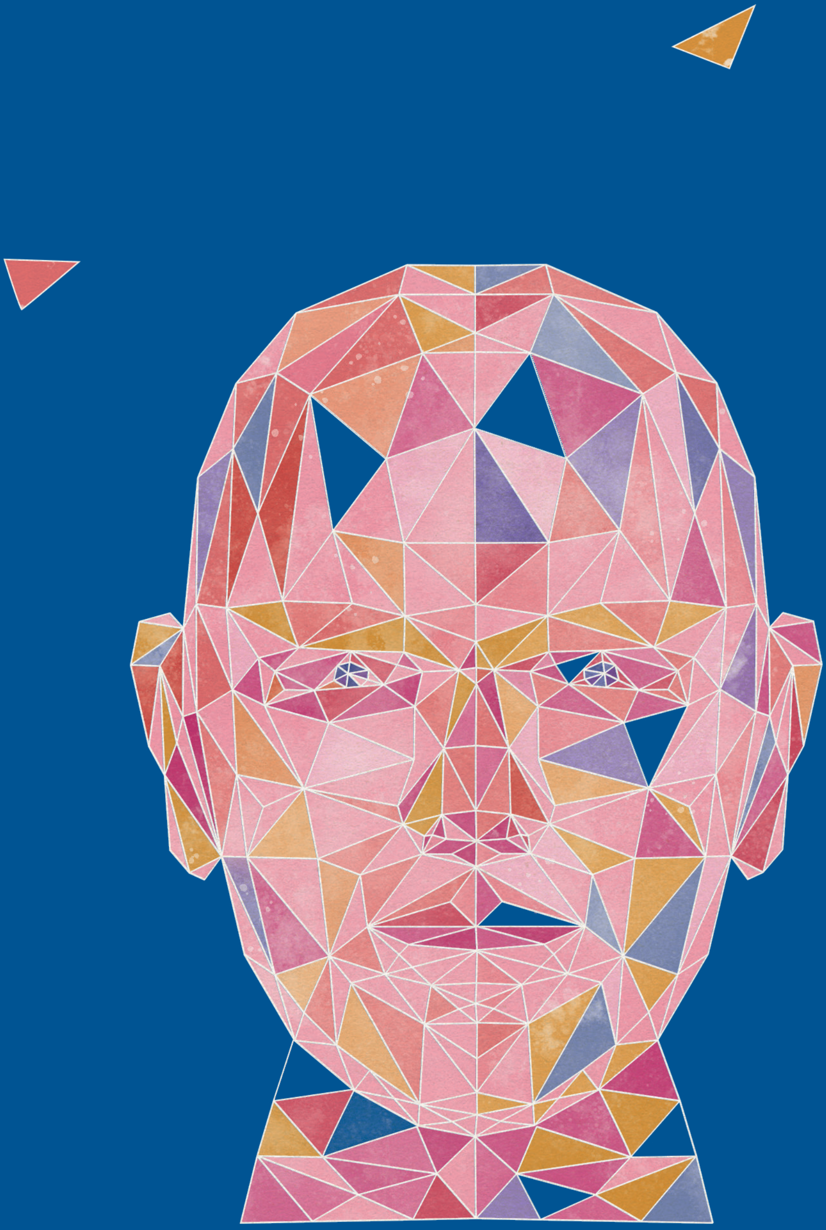

8

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In Europe, people are living longer, which results in an increased number of elderly people. Among them, a significant proportion are affected by one or more chronic diseases. The majority of care is provided through self-management by the people with the chronic disease themselves. A vital component in the management of chronic diseases is adequate medication use. Many patients experience their medication self-management to be difficult, especially those with limited health literacy. To improve patients' medication self-management, support is essential. Therefore, this thesis aims to explore the needs of patients with a chronic disease and limited health literacy regarding medication self-management as well as how medication self-management support can be tailored to those needs.

Scientific impact

This thesis maps the needs for medication self-management of people with limited health literacy. This patient perspective is a valuable contribution to the scientific knowledge on medication self-management support. How health interventions for patients with limited health literacy should be designed and implemented is a critical field that has received increasing attention over the last decade. This thesis adds scientific knowledge and insights to this domain, specifically in the area of medication self-management. First, it clarifies the medication self-management needs of people with limited health literacy and a chronic disease, thus providing scientific evidence upon which to build further research in this area. This will also allow intervention developers to more effectively tailor medication self-management support tools to the needs of this patient group. Second, this thesis provides an overview of current interventions tailored to people with limited health literacy in the Netherlands as well as other European countries. The studies conducted on these interventions provide further insights into the promising elements for interventions for people with limited health literacy. For example, they reveal that the content of medication self-management support for people with limited health literacy should focus on acquiring both knowledge and skills, and that information should be provided in clear and easy-to-understand language, preferably with the aid of images or animations.

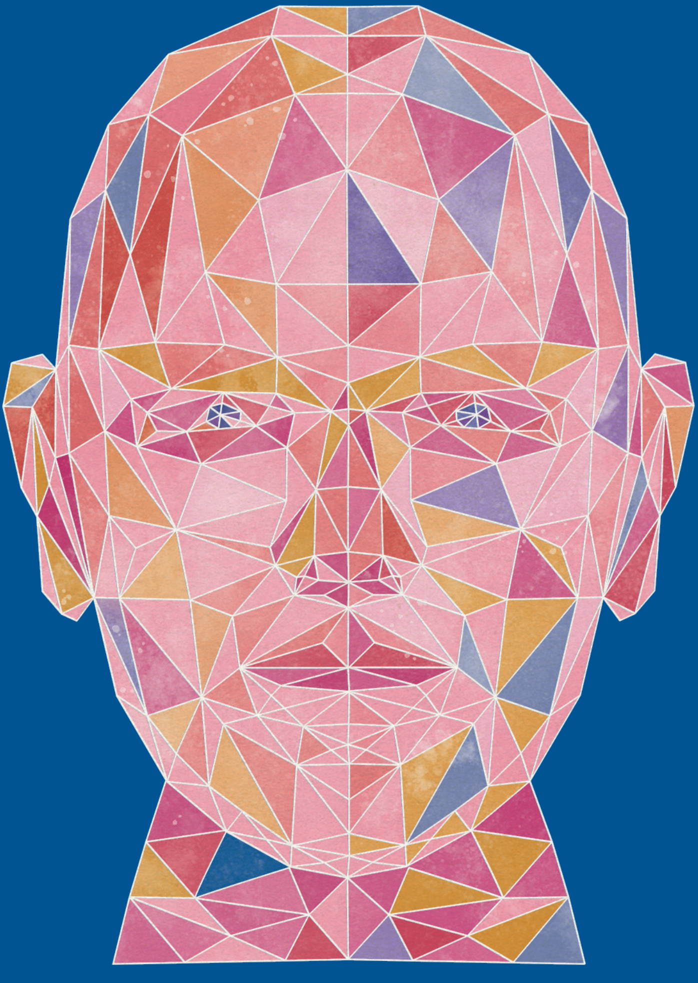
Societal impact

This thesis could lead to improved medication self-management support for patients with limited health literacy and a chronic disease. This would benefit not only this group of patients, who are currently often not actively involved in self-management programs, but also the healthcare system and society as a whole.

When patients are better able to perform self-management activities, their health outcomes are enhanced and they rely less on healthcare professionals, which leads to a lower healthcare demand and reduced healthcare costs. This thesis addresses how to optimally support patients with limited health literacy in their medication self-management. Medication self-management support should not only focus on increasing knowledge but also address learning skills and the acquisition of self-confidence. The content should be tailored to the needs of patients, and furthermore, the support can be provided most effectively by people who the patients with limited health literacy know and trust. The studies presented in this thesis demonstrate that healthcare professionals often have difficulty estimating patients' health literacy level and find it difficult to tailor their communication to this patient group. This thesis reveals that while healthcare professionals are willing to support medication self-management, a more active delivery approach and training for professionals are required to reach patients with limited health literacy.

Dissemination of findings

Various channels have been used to disseminate the findings of this thesis to researchers, healthcare professionals, and other stakeholders. All of the articles in this thesis have been published in international, peer-reviewed journals. Two of the articles are accessible free of charge since they are open access. Moreover, all articles are accessible free of charge through the Nivel.nl website. The findings of this thesis have also been presented at national and international conferences, such as the 4th European Health Literacy Conference and the Spring Congress 2021 of the Royal Dutch Society for the Promotion of Pharmacy. The abovementioned channels reach researchers and other stakeholders, such as pharmacists. In addition, the findings have been shared at courses of the bachelor's program Pharmaceutical Business Administration and Healthcare Management at the University of Applied Sciences Utrecht, with the aim of enabling future healthcare professionals to understand the concept of health literacy as well as how they could more effectively support people with limited health literacy.



Appendices

Samenvatting

In Europa is de levensverwachting van de bevolking toegenomen, wat resulteert in een groter aandeel ouderen. Ongeveer 80% van de 65-plussers heeft één of meer chronische ziekten. Door vergrijzing neemt het aantal mensen met chronische ziekten toe en dit zal de komende jaren blijven stijgen. Zorgsystemen staan hierdoor onder druk om passende zorg te leveren. Daarom is zelfmanagement van patiënten belangrijk om de zorgbehoeften te vervullen.

Hoofdstuk 1 (Inleiding) van dit proefschrift beschrijft dat farmacotherapie cruciaal is bij de behandeling van chronische aandoeningen. Veel patiënten vinden medicatie-zelfmanagement moeilijk, vooral voor mensen met beperkte gezondheidsvaardigheden. Gezondheidsvaardigheden omvat de kennis, motivatie en competenties om toegang te krijgen tot gezondheidsinformatie, deze te begrijpen, te beoordelen en toe te passen. Dit is belangrijk om oordelen te vormen en beslissingen te nemen in het dagelijks leven met betrekking tot zorg, ziektepreventie en gezondheidsbevordering om hun kwaliteit van leven te behouden of te verbeteren. Het verbeteren van medicatie-zelfmanagement vereist het ondersteunen en faciliteren van mensen met beperkte gezondheidsvaardigheden. Zij hebben meer behoefte aan praktische, herkenbare en begrijpelijke informatie en aan een stapsgewijze uitleg. Helaas voorzien de meeste medicatie-zelfmanagement ondersteuningsinterventies onvoldoende in de behoeftes van mensen met beperkte gezondheidsvaardigheden. Hierdoor maken ze minder gebruik van de beschikbare ondersteuningsprogramma's.

Het doel van dit proefschrift is de behoeften van patiënten met chronische ziekten en beperkte gezondheidsvaardigheden met betrekking tot medicatie-zelfmanagement te onderzoeken en na te gaan hoe ondersteuning voor zelfmanagement van medicatie op die behoeften kan worden afgestemd. Een aantal studies richten zich op patiënten met verschillende chronische ziekten, waaronder diabetes. De volgende onderzoeksvragen zijn geformuleerd:

1. Wat zijn de behoeften van patiënten met een chronische ziekte en beperkte gezondheidsvaardigheden ten aanzien van medicatie-zelfmanagement?
2. Hoe kunnen patiënten met een chronische ziekte en beperkte gezondheidsvaardigheden het beste worden ondersteund en gefaciliteerd bij medicatie-zelfmanagement?

Empirische studies - Belangrijkste bevindingen

Hoofdstuk 2 bespreekt de behoeften van patiënten met beperkte gezondheidsvaardigheden en type 2 diabetes met betrekking tot medicatie-zelfmanagement. Er werd een kwalitatief behoeftenonderzoek uitgevoerd met behulp van individuele diepte-interviews en focusgroepen. Patiënten bleken op drie domeinen behoefte te hebben aan ondersteuning. Het eerste domein was ondersteuning met informatie, en dan vooral informatie die betrouwbaar en relevant is, gemakkelijk te begrijpen en bij voorkeur gepresenteerd met animaties of in gesproken tekst. Het tweede domein was ondersteuning bij communicatie: patiënten gaven er de voorkeur aan meer en vaker contact te hebben met hun zorgverleners en wilden ook meer contact met lotgenoten om hun ervaringen met het omgaan met hun ziekte te delen. Het derde domein was stimulatie en advies om adequaat met de medicatie om te gaan, waaronder advies over doseringen bij gewijzigde omstandigheden, of ondersteuning bij het verbeteren van therapietrouw. Toekomstige interventies dienen te worden ontwikkeld in co-creatie met mensen met beperkte gezondheidsvaardigheden en te voldoen aan hun behoeften op het gebied van informatie, communicatie en hulpmiddelen voor het verbeteren van medicatie-zelfmanagement.

Hoofdstuk 3 beschrijft het verband tussen gezondheidsvaardigheden en opvattingen over overmatig gebruik en schadelijke effecten van medicatie. Er is een online enquête gestuurd naar het ‘Medicatiepanel’ van het Nederlands Instituut voor Verantwoord Medicijngebruik. In totaal hebben 539 (25%) van de 2.157 panelleden complete vragenlijsten teruggestuurd. De resultaten laten zien dat patiënten met een lager niveau van gezondheidsvaardigheden zich meer zorgen maakten over overmatig gebruik en schadelijke effecten van medicatie. Leeftijd, geslacht en aantal medicijnen hadden geen effecten op de associatie tussen gezondheidsvaardigheden en overtuigingen over medicatie. Deze resultaten suggereren dat er extra aandacht moet worden besteed aan patiënten met beperkte gezondheidsvaardigheden om hun zorgen over overmatig gebruik en schadelijke effecten van medicatie te verminderen en zo de therapietrouw te verbeteren.

Hoofdstuk 4 beschrijft een studie naar de effectiviteit van interventies op het gebied van gezondheidsvaardigheden in lidstaten van de Europese Unie (EU). Dit was de eerste systematische review over interventies op het gebied van gezondheidsvaardigheden in de EU. In totaal zijn er uit de periode 1995 tot 2018, 23 gepubliceerde interventiestudies geïdentificeerd. De in deze studies beschreven interventies waren ofwel (a) gericht op het verbeteren van (aspecten van) gezondheidsvaardigheden; (b) specifiek toegesneden op verschillende niveaus van gezondheidsvaardigheden; of (c) algemene interventies die tot doel hadden gezondheidsuitkomsten te verbeteren, waarbij werd verwezen naar de specifieke effecten voor patiënten met verschillende niveaus van gezondheidsvaardigheden of rekenvaardigheden. De volgende drie factoren waren kenmerkend voor veelbelovende interventies: (1) activiteiten afstemmen op de behoeften van deelnemers (met beperkte gezondheidsvaardigheden); (2) het aanpakken van interactieve en/of kritische vaardigheden (in tegenstelling tot alleen kennis); en (3) de informatie op een gepaste manier presenteren (bijvoorbeeld niet ingewikkeld en met geanimeerde of gesproken tekst).

Hoofdstuk 5 beschrijft de bruikbaarheid van een diabetesinformatiehulpmiddel dat gebruik maakt van animaties ('KijkopDiabetes') voor zowel patiënten met beperkte als met voldoende gezondheidsvaardigheden. Het was een kwalitatief onderzoek waarin 25 semigestructureerde interviews zijn gehouden met patiënten met diabetes. Het hulpmidel zou tegemoet kunnen komen aan de behoeften van patiënten met beperkte gezondheidsvaardigheden, aangezien het informatie verstrekt die in begrijpelijke taal is en met praktische handvatten om zelfmanagement van diabetes te ondersteunen. Bovendien wordt de meeste informatie gepresenteerd door middel van gesproken animaties. Naast geanimeerde video's stelt de tool gebruikers in staat om via een online platform in contact te komen met medepatiënten met diabetes, waar ze kennis en ervaringen kunnen delen. Ook kunnen ze een kennistoets doen om te controleren of ze de informatie hebben begrepen. De video's zijn gepersonaliseerd op basis van geslacht, leeftijd en de gebruikte medicatie en het type bloedglucosemeter; zo krijgt een patiënt alleen informatie die voor hem of haar relevant is. De tool werd door veel patiënten met diabetes als eenvoudig te gebruiken en bruikbaar ervaren, zowel door degenen met beperkte als degenen met voldoende gezondheidsvaardigheden. Degenen met beperkte gezondheidsvaardigheden gaven aan dat ze van de tool hadden geleerd en dat ze de intentie hadden om deze in de toekomst te blijven gebruiken. Deze deelnemers gaven ook aan dat de tool actiever aangeboden zou moeten worden door zorgprofessionals, terwijl deelnemers met voldoende gezondheidsvaardigheden behoefte hadden aan meer verdiepende informatie.

Hoofdstuk 6 beschrijft de implementatie van een geanimeerde medicatie-informatietool ('Kijksluiter') in Nederlandse openbare apotheken, met speciale aandacht voor patiënten met beperkte gezondheidsvaardigheden. Er is een dwarsdoorsnede onderzoek uitgevoerd bij openbare apotheken in Nederland, die via e-mailnieuwsbrieven zijn geworven in apotheeknetwerken (N = 140). De meerderheid van de ondervraagde apothekers bood de tool aan al hun patiënten aan, ook aan degenen met beperkte gezondheidsvaardigheden. Ze gaven aan de tool aan te bieden omdat de zorgverzekeraar financiële prikkels bood en de tool een aanvulling was op andere bestaande medicatie-informatie. Volgens de ondervraagde apothekers zijn de meeste patiënten geïnteresseerd in het gebruik van de tool. De belangrijkste reden waarom patiënten weigerden de tool te gebruiken, is een gebrek aan affiniteit met of toegang tot de vereiste technologie. De tool werd voornamelijk passief aangeboden door een digitale link naar de patiënt te sturen. Een actievere methode om de tool aan te bieden lijkt nodig te zijn om patiënten met beperkte gezondheidsvaardigheden beter te bereiken.

Discussie en conclusie

Hoofdstuk 7 sluit het proefschrift af door de belangrijkste bevindingen te bespreken en erop te reflecteren. Het beschrijft ook praktische implicaties en aanbevelingen voor toekomstig onderzoek. Het doel van dit proefschrift was om inzicht te krijgen in de behoeften van patiënten met chronische ziekten en beperkte gezondheidsvaardigheden met betrekking tot zelfmanagement van medicatie. Daarnaast is onderzocht hoe de ondersteuning het meest effectief op deze doelgroep kan worden afgestemd. Het is bekend dat medicatie-zelfmanagement voor veel mensen moeilijk is, vooral voor mensen met beperkte gezondheidsvaardigheden. Dit proefschrift laat zien dat patiënten met beperkte gezondheidsvaardigheden beter kunnen worden ondersteund bij hun medicatie-zelfmanagement door middel van op maat gemaakte gezondheidsinformatie die toegankelijker, begrijpelijker en gemakkelijker te beoordelen is. Naast het geven van gezondheidsvoorlichting en het vergroten van kennis, zou de medicatie-zelfmanagementondersteuning zich ook moeten richten op het helpen van patiënten bij het verwerven van vaardigheden en zelfvertrouwen. Dit proefschrift geeft aanbevelingen voor het ontwerp, de inhoud en de strategieën van toekomstige zelfmanagementinterventies voor deze groep patiënten. Het bespreekt ook strategieën om patiënten met beperkte gezondheidsvaardigheden te bereiken en het belang om ze te betrekken bij het ontwerp van toekomstige interventies. Hoewel gezondheidszorg- professionals bereid zijn om zelfmanagement van medicatie te ondersteunen, zijn een actievere aanpak en training van de professionals vereist om patiënten met beperkte gezondheidsvaardigheden te bereiken.

Curriculum Vitae

Boudewijn Visscher was born on the 4th of April 1990 in Hoogeveen, the Netherlands. He completed secondary school at Roelof van Echten College Hoogeveen. In 2011, he obtained a bachelor's degree in Human Movements Sciences at the University of Groningen. After obtaining his bachelor's degree he enrolled in a 2-years research master Human Movements Sciences at the University of Groningen. In the same period of the Master, he studied at the Free University of Amsterdam to become a teacher of higher healthcare education and taught at the Hanze University of Applied Sciences in Groningen. In 2013, he obtained his master's degree in human Movements Sciences and the teacher's degree with honor. From 2013 to 2015, Boudewijn worked as a teacher at the Free University of Amsterdam at the Bachelor Human Movements Sciences and the Master higher healthcare education. In 2014, he started working as a teacher at the Bachelor Healthcare Management of the University of Applied Sciences. Beside his work as a teacher, he started in 2017 as an external PhD candidate to the department of Family Medicine of Maastricht University. Boudewijn is married and has four beautiful children.

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CAPHRI

NIVEL