Reducing the chronic disease burden in China: tailoring a self-management intervention among Chinese people with chronic lung disease

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Chapter 1

General introduction

Introduction

The burden of hypertension and chronic lung disease

In China, chronic diseases such as hypertension and chronic lung disease (CLD) threaten health and well-being, representing a high public health burden. Hypertension affects more than 32.5% of Chinese people and accounts for nearly 2.1 million cardiovascular deaths annually in China [1,2]. Among the patients with hypertension in China, around 67.8% are accompanied by frailty [3]. Frailty is a dynamic state affecting an individual who experiences losses in one or more domains of human functioning (physical, psychological, social), which can be caused by various variables and increases the risk of adverse outcomes [4]. The coexistence of hypertension and frailty leads to a higher risk of disability and mortality and increases healthcare utilization compared to patients with hypertension without frailty [3,5].

Similarly, CLD – with chronic obstructive pulmonary disease (COPD) and asthma being the most prevalent – pose a high disease burden in China [6]. More than 144 million Chinese people have CLD [7,8]. In China, disability-adjusted life years caused by COPD was 1,445.53/100,000 in 2017, higher than those worldwide in the same year, i.e., 1,038.02/100,000 [9]. Notably, COPD ranks as the fourth leading cause of death in Chinese urban areas and third-leading in Chinese rural areas [10,11]. In addition, CLD leads to considerable healthcare costs [12,13]; the annual cost for CLD is more than $156.3 billion in China [12,13]. The exacerbations cause most of the medical expenses [12,13]. Exacerbation is the sustained worsening of a patient's condition beyond normal day-to-day variations that are acute in onset, which may also require a change in medication and/or hospitalization [14]. Identifying cost-effective approaches to help patients manage their disease is essential to reducing the Chinese chronic disease burden [15,16].

Self-management interventions can help to reduce the chronic disease burden

A promising approach to improving health outcomes and reducing healthcare costs associated with chronic conditions is self-management (SM) [17]. There are many definitions of SM [18-20]. Richard et al. have defined SM as "an individual's ability to manage the symptoms, treatment, physical and psychosocial consequences, and lifestyle changes inherent to the life with a chronic condition" [18]. Audulv et al. defined SM as "strategies an individual undertakes to manage an illness and life with that illness." [19]. Furthermore, SM has been described by Miller and his colleagues as an ongoing process of fulfilling the individual's needs to care for a chronic illness [20]. They argued that "SM is a fluid, iterative process during which patients incorporate multidimensional strategies that meet their self-identified needs to cope with chronic illness within the context of their daily living." [20]. In this thesis, the SM definition by Richard et al. is used because it specifies patients' primary tasks, e.g., treatment,

emotion, and role management [18]. SM puts the patient in a central position in the healthcare process. During the SM process, patients are informed and supported by healthcare professionals (HCPs) to increase patients' responsibility in decisions affecting their healthcare [21].

Self-management intervention (SMI) refers to interventions that aim to increase patients' involvement and control in their treatment with or without support from HCPs [22]. Studies have shown that SMI can help to reduce the chronic disease burden [19,23]. To explain, SMI can be delivered face-to-face, digitally (through eHealth), or blended care. eHealth refers to health services and information delivered or enhanced through the internet and related technologies [24]. It can include, for example, video calls, web platforms, and applications [24]. Blended care is a treatment program that uses face-to-face and eHealth intervention elements, including integrating and sequential treatment formats [25].

SMI can help people with chronic diseases improve their SM capacity to tackle chronic disease, consequently contributing to improved healthcare outcomes and reduced disease burden [26,27]. Evidence focusing on people with CLD reported that (blended) SMI could help to prevent patients' adverse outcomes (e.g., mortality), reduce hospital readmission, and improve physical and psychosocial functioning [28-30]. Besides, previous systematic reviews have demonstrated that SMI can help patients with hypertension improve their SM and reduce their blood pressure [31,32].

Collectively, SMIs are beneficial for people with chronic diseases, especially those with poor SM. Chinese people with CLD have shown poor SM [31-33 34,35]. For example, a study showed that this group did not use regular daily controller medications before admission [34,35], which indicates poor SM. The irregular medication use led to an increased exacerbation time that needed treatment and resulted in higher medical costs [34,35]. Effective SMIs are needed to help such patients improve their SM, which can optimize their health outcomes and decrease medical expenditure.

Currently, most research on SMI tackling chronic diseases has been developed and tested in high-income countries, whereas the chronic disease burden is highest in low-and middle-income countries [36,37]. To illustrate, around one-fourth of the global burden of CLD is in China, and in this country, there is inefficient care and poor SM [38-40]. SMIs developed and tested in high-income countries may not be (fully) appropriate for patients in China and may result in decreased effectiveness. The inappropriateness of the intervention is due to the different health, economic, and cultural backgrounds between high-income countries and China [36,37]. Therefore, it is necessary to identify what can be done to align such SMIs with Chinese healthcare settings.

Tailor a SMI tackling CLD in the Chinese context

Evidence has shown that SMI implementation may fail due to a mismatch between the selected SMI and the local context. The implementation – an act of carrying an intervention into effect – is a challenging process [41]. When implementing a SMI from a high-income country, e.g., the Netherlands, to a low-and middle-income country, e.g., China, the implementers should consider the local context. Context is a set of unique characteristics and circumstances surrounding the implementation effort [42]. Local context refers to the set of characteristics and circumstances surrounding the implementation effort, such as the local beliefs, health- and political- infrastructure, socioeconomic aspects, and the network of the relevant stakeholders [42]. It is necessary to identify feasible implementation strategies to improve the alignment between the SMI and the local context. Implementation strategies are any action aimed at integrating innovation into practice [43]. One implementation strategy is tailoring effective interventions to another context [44,45]. Evidence has demonstrated that tailoring a SMI to the local context is vital because the tailored SMI can help improve patient outcomes and optimize local resource use [46-48]. Thus, it is necessary to tailor the proven-effective SMI in a different context [49,50]. However, there is a lack of evidence on tailoring SMI to another context, especially in low-and middle-income countries. To meet this need, this thesis aims to tailor a proven-effective SMI tackling CLD, developed and tested in a high-income country, to the Chinese context. CLD is a focus of this thesis because it is a severe chronic disease, leading to a high disability and mortality rate and economic burden [9,38]. Second, exacerbations cause a significant disease burden [12,13]. Recent studies on the effectiveness of SMIs in people with CLD have reported that SMIs focusing on exacerbation management optimize patients' quality of life and lead to reduced healthcare visits and hospital admission [51-53]. Furthermore, compared with other diseases, such as hypertension, the research to advance the effective treatment of CLD has been woefully inadequate [54].

Aligned with previous research [55,56], tailoring a SMI for Chinese people with CLD will be done in this thesis as follows (**Figure 1**): (a) identify the Chinese context, (b) select SMI and mode of delivery, (c) identify factors that influence the SMI implementation, and (d) integrate SMI into the Chinese context.

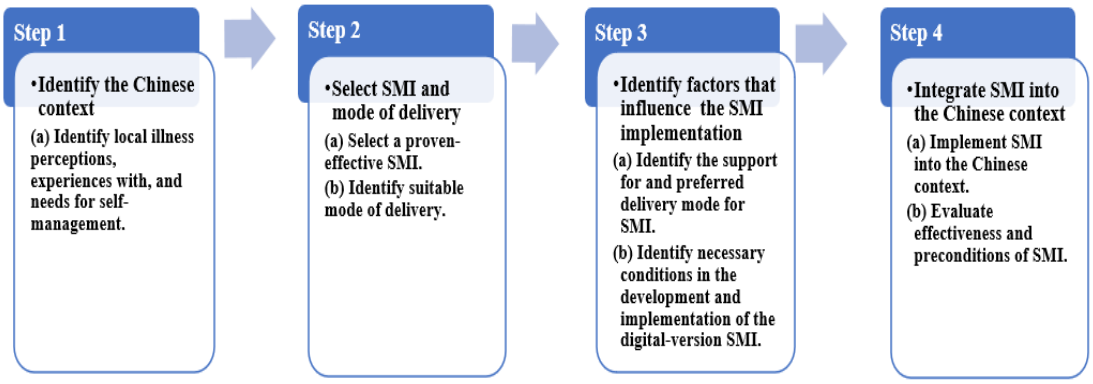

Figure 1. Process of tailoring self-management intervention (SMI) into the local context

In summary, this thesis will tailor a SMI for people with CLD, which has been proven effective in a high-income country, to the Chinese context. Researchers and other professionals who wish to implement a SMI for chronic diseases in a different setting can use the methods and lessons learned from the tailoring process.

Identify the Chinese context

Local context (e.g., illness perceptions, experience with and needs for SM) matters when transferring an intervention from one setting to another and translating the research into everyday practice [57,58]. The contextual information in China can also help tailor SMI to the Chinese context, improving the possibility of implementing SMI successfully and optimizing local resource use [59].

To date, no research has examined the local context of CLD in China. Yet, Kurmi et al. reviewed the patterns of COPD burden and management of COPD in China [60]. The review showed that despite the substantial burden of COPD, research on illness understanding and disease management is limited in China [60]. Thus, this thesis will help to identify the local context to understand (a) how patients and HCPs perceive the disease, (b) how patients self-manage their disease and (c) the unmet needs in the existing SMIs.

Identifying illness perceptions helps to inform SM strategies within a context [61-64]. Over the last two decades, health and illness behaviors have changed significantly after the advocation of Engels [65]. Specifically, a disease-oriented medical model has transitioned to the theoretical conceptualizations emphasizing environmental factors and individual perceptions of health and illness [65]. Leventhal et al. developed a self-regulatory model of illness (SRMI), which integrated the above factors within a patient's common-sense representations of health and illness [61,66]. The SRMI has been used widely to help understand chronic illness and treatment perceptions [62,63,67,68]. Recent illness perception reviews – focusing on COPD patients in high-income countries – have demonstrated that

assessing the illness perceptions about COPD offers opportunities to identify goals for SM [63]. To identify how Chinese people with CLD cope with the disease, SRMI is applied to identify the illness perceptions of Chinese people with CLD and HCPs in this thesis. Next, identifying experiences with and needs for SM from the patients and HCPs will help tailor the SMI to the local context [69-71]. For example, recent reviews have demonstrated that understanding patients' experiences with SM can support HCPs in identifying effective SMIs [69,70]. Besides, there is evidence that identifying the experience with and unmet needs for SMI from the perspective of HCPs can assist in reforming transitional care practices for chronic disease [70,71]. Altogether, identifying the local context through illness perceptions, experiences with, and needs for SM, in patients and HCPs, can help to increase the uptake and implementation success of SMIs.

Select the SMI and mode of the delivery

In the pilot study by Hallensleben et al., they developed and tested a SMI –REducing Delay through edUcation on eXacerbations or REDUX – for patients with COPD in the Netherlands [51]. The REDUX intervention was designed to educate patients on symptom management by helping them recognize their early-onset symptoms and teach them how to react when this happens. The essential part of the program is a personalized paper-based action plan completed by patients and HCPs [51]. The action plan includes four boxes. The first box helps patients determine how they can recognize the worsening of symptoms; patients can fill in their personal, specific early signs of an exacerbation. In the second box, personalized advice is given on medications to use in case of worsening symptoms. The third box details how long patients need to use increased medication dosage when the medication gives relief. The last box provides advice about what the patient should do when the symptoms worsen, explicitly indicating how long the patient should wait until contacting the general practitioner [51]. The pilot study showed that REDUX increased patients' SM; that is, there was a decrease in the number of days between exacerbation recognition and time to seek medical help, and REDUX helped reduce the disease burden [51]. One training session about coaching patients using the action plan is delivered to HCPs, including general practitioners and nurses in primary care settings.

Given the previous positive effect on people with COPD in the Netherlands, REDUX shows the potential to help people with CLD self-manage the disease effectively in China. Notably, the action plan is helpful for patients to engage in their disease management actively in two aspects. First, patients gain disease knowledge and SM skills on self-managing the exacerbations by filling in the action plan together with HCPs. This knowledge and these skills can help patients self-manage their exacerbations at home [49]. Second, the implementation of REDUX matches the local long-term policy priority, which reflects the needs of Chinese people with CLD. It is pointed out in the Action for

Healthy China 2030 that public education will support progress toward improved medication use [72]. Therefore, this thesis selects REDUX as the effective SMI.

SMIs with different delivery modes – face-to-face intervention, digital treatment, and blended care – can help improve patient healthcare outcomes and reduce the disease burden [27-29,73,74]. To illustrate, (fully) online SMI using a health application or web page has helped patients self-manage their disease [27,73]. Blended care, including face-to-face and digital care, is an alternative to fully online treatment. Blended SMI could retain the positive aspects of face-to-face intervention and online treatment by mitigating their negative aspects [28,29]. For example, blended SMI could help patients reduce face-to-face consultation time by offering online support or materials (e.g., psychoeducation). The preferred or suitable delivery mode also depends on the target population and context. For example, patients in remote districts can benefit from online education since it is difficult to assess the healthcare settings physically [27-29,73,74]. Conversely, older patients may prefer face-to-face education because they can gain SM skills during the interaction with HCPs [74]. Not all patients benefit from a 'one size fits all' intervention [49], so it is vital to identify what delivery mode is suitable within the local context.

However, it is unclear which mode of delivery is preferred in China regarding SMI. This thesis will identify the preferred SMI delivery mode in China by assessing the locally preferred mode to deliver a SMI, such as REDUX. Currently, REDUX consists of a paper-based action plan that patients and HCPs complete during a face-to-face consultation [51]. It is possible to transfer such an action plan into a digital one. With this adaption, patients could access the action plan and professional help without time or place restrictions [27,73]. Altogether, the thesis will select REDUX as the proven-effective SMI. The suitable mode of delivery will be determined after identifying the local preferred ones.

Identify factors that influence the SMI implementation

Implementing the REDUX intervention depends on whether it is feasible and compatible within the specific context [16,75]. And thus, it is necessary to identify the factors influencing the REDUX implementation.

Local stakeholders play an essential role in the SMI implementation [75]. Stakeholders are groups or individuals affected by or are in some way accountable for the outcome of a specific undertaking [76]. It has been demonstrated that one fundamental way to improve the implementation success of a SMI in a different context is to engage the local stakeholders [75-80]. To illustrate, local stakeholders such as patients, HCPs, and policymakers can make efforts to promote the adoption and sustainability of SMI within the local context. Yet, frequently, stakeholder analysis studies on

innovations in healthcare only focus on policymakers [81-85]. However, it is also necessary to hear the voices of other stakeholders, such as patients, HCPs, and those involved in developing and implementing healthcare innovations [75-80]. That is because these stakeholders play an essential role in the SMI implementation (**Figure 2**) [75-85]. A comprehensive overview of the factors influencing the SMI implementation from different stakeholders will optimize implementation successes [77].

Accordingly, this thesis will include patients, HCPs, policymakers, app developers, and cyber-security officers to identify the factors influencing the REDUX implementation. Specifically, the support for REDUX from patients, HCPs, and policymakers can help determine whether REDUX will be adopted in China. Furthermore, their preferred mode to deliver REDUX can help shape the feasible method to implement the intervention, which can assist the program implementation successfully [51,86-88].

Given that Chinese stakeholders can prefer the digital version of REDUX, it is crucial to identify the conditions that should be addressed when developing and implementing the digital version of REDUX. To our knowledge, there needs to be more evidence on the conditions to develop and implement a digital version of a SMI in China. Such missing information may result in these interventions failing in a different context [89]. Therefore, this thesis will identify the necessary conditions to develop and implement the digital version of REDUX by collecting data from Chinese app developers and cyber-security officers.

To sum up, the factors that influence SMI implementation will be identified in different stakeholders. Specifically, the support for and preferred version of REDUX will be identified in patients, HCPs, and policymakers. The necessary conditions in the digital-version REDUX development and implementation will be observed in app developers and cyber-security officers.

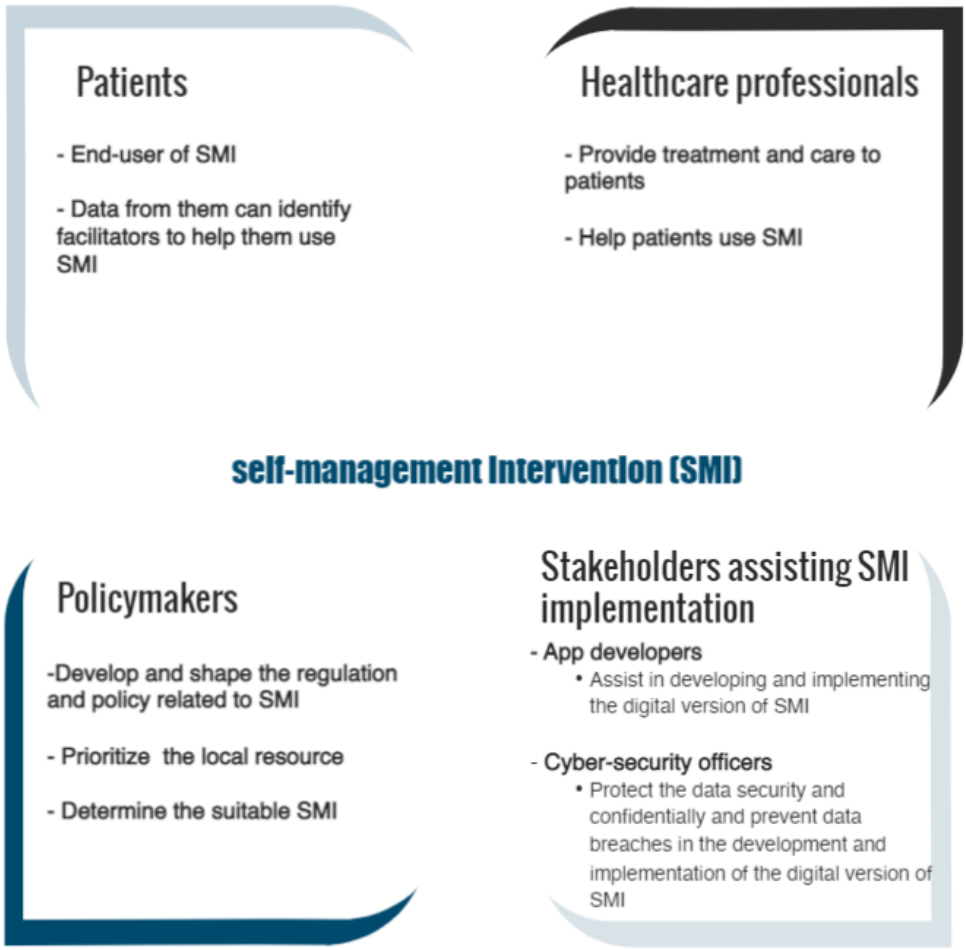

Figure 2. The roles of different stakeholders in the self-management intervention implementation

Integrate SMI into the Chinese context

Lastly, it is necessary to integrate REDUX into the Chinese context and evaluate the effectiveness of REDUX in people with CLD. Identifying such information can help identify the potential of REDUX in exacerbation management. Also, it is recommended that the preconditions, e.g., acceptability, appropriateness, and feasibility, should be measured in the pre-implementation phase to determine the intervention uptake [90]. Most studies targeting SMI implementation have examined the effectiveness of the SMI [91-95], but few address the (partly) preconditional measurement indicators [95,96]. For example, a study protocol focusing on COPD only evaluated the feasibility and acceptability of SMI for patients [96]. Yet, it is still being determined whether the intervention is effective or appropriate for patients. A comprehensive evaluation of the effectiveness and preconditions is essential to determine the desired service delivery and clinical outcomes [90].

This thesis aims to conduct a study to examine these measurements and evaluate their effectiveness and preconditions. Such evaluation can provide preliminary insights into the uptake of such interventions, which will help optimize sustainable use in the future.

The planned study is designed on a small scale, i.e., pilot study design. Pilot studies refer to so-called feasibility studies, which are "small scale version(s), or trial run(s), done in preparation for the major study" [97]. This thesis describes the study with a pilot design that can help optimize resource use and provide insights for a full-scale study [98]. Subsequently, full-scale REDUX implementation in China can inform future research on tailoring SMIs in different contexts.

Therefore, this thesis will set up a study to evaluate the effectiveness and preconditions of REDUX in China with a pilot study design.

Aim and research objective

This thesis aims to (a) provide fundamental insight into the disease burden for Chinese people with chronic diseases and (b) reduce the disease burden with SMI through a tailored, context-sensitive SMI. Specifically, the disease burden in Chinese people with chronic disease is assessed by identifying the prevalence of frailty and risk factors in Chinese people with hypertension (**Chapter 2**). Then, a systematic review and meta-analysis is conducted to get an up-to-date and comprehensive overview of the effect of SMI on people with CLD (**Chapter 3**). A four-step process is employed to tailor SMI addressing CLD, which can help reduce the disease burden in China. First, a mixed-method study identifies the local context in Chinese HCPs and people with CLD in Chinese primary and secondary care (**Chapter 4**). Next, we identify factors influencing the REDUX implementation in China with a stakeholder analysis (**Chapter 5**). This chapter evaluates the level of support for and the preferred version of REDUX with the qualitative approach in patients, HCPs, and policymakers. The factors influencing the digital version of REDUX development are assessed with the quantitative approach of app developers and cyber-security officers. The knowledge gained about tailoring SMI will allow us to tailor REDUX to the Chinese context. The study design on the effectiveness and preconditions of culturally tailored REDUX for people with CLD in China is described in **Chapter 6**.

In the end, in **Chapter 7**, the main findings from other chapters are summarized and discussed. Furthermore, the thesis' limitations and implications are presented.