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PROTOCOL

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REducing delay through edUcation on eXacerbations for people with chronic lung disease: Study protocol of a single-arm pre-post study

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Abstract

Aim: This study protocol aims to examine the effectiveness and preconditions of a self-management program—named REducing Delay through edUcation on eXacerbations (REDUX)—in China.

Background: The high disease burden in people with chronic lung disease is mainly due to exacerbations. There is a need for effective exacerbation-management interventions. A nurse-led program, REDUX, helped patients self-manage exacerbations.

Design: A single-arm pre-post study.

Methods: Fifty-four patients and 24 healthcare professionals (HCPs) in Chinese primary care will be included. The core element of the program is a personalized action plan. HCPs will receive training in using the action plan to help patients manage exacerbations. The intervention will start when a patient is referred to the nurse for a post-exacerbation consultation and ends when the patient presents for the second post-exacerbation consultation. During the first post-exacerbation consultation, the patient and nurse will create the action plan. The primary outcomes in patients will include the delays between the onset of exacerbation and recognition, between exacerbation recognition and action, between exacerbation recognition and consultation with a doctor, and when the patients feel better after receiving medical help from HCPs. The secondary outcomes will include preconditions of the program. The ethics approval was obtained in September 2021.

Discussion: This study will discuss a culturally adapted nurse-led self-management intervention for people with chronic lung disease in China. The intervention could help Chinese HCPs provide efficient care and reduce their workload. Furthermore, it will inform future research on tailoring nurse-led self-management interventions in different contexts.

Impact: The study will contribute to the evidence on the effectiveness and preconditions of REDUX in China. If effective, the result will assist the nursing of people with chronic lung disease.

Trial registration: Registered in the Chinese clinical trial registry (ID: 2100051782).

KEYWORDS

action plan, asthma, chronic lung disease, chronic obstructive pulmonary disease, education, exacerbation, nursing, primary care, self-management, single-arm pre-post study

1 | INTRODUCTION

Chronic lung diseases (CLDs) are diseases of the airways and structures of the lungs, such as chronic obstructive pulmonary disease (COPD) and asthma (Soriano et al., 2020). In China, the prevalence of CLD patients is high (Huang et al., 2019; Wang et al., 2018). In 2018, 8.6% of the Chinese population suffered from COPD (Wang et al., 2018), and 4.2% were affected by asthma in 2019 (Huang et al., 2019). CLDs result in high healthcare costs (Fang et al., 2018; Zhu et al., 2019); the annual cost was recently measured at over $151.6 billion for COPD and $4.7 billion for asthma in China (Fang et al., 2018; Zhu et al., 2019).

A considerable part of the economic burden of CLDs is attributable to exacerbations (Soriano et al., 2020). Exacerbations are sustained deteriorations of a patient's condition beyond normal day-to-day variations. They are acute in onset and may also require changes in medication and hospitalization (Hallensleben et al., 2020). When exacerbations occur, some patients respond to them quickly (early presenters), whilst other patients wait longer to take action (late presenters) (Seemungal et al., 1998). There is evidence that early recognition and prompt exacerbation treatment could reduce recovery times and the risks of hospitalization (Hallensleben et al., 2020). Studies have shown that people with CLD in China frequently recognize the symptoms late and delay action (Bao et al., 2021; Lin et al., 2020). In a study of people with asthma in China, many did not use regular daily controller medications before requiring hospitalization, leading to a high prevalence of exacerbations needing treatment through high-cost medical care (Lin et al., 2020). Therefore, it is necessary to identify effective interventions that include early recognition and prompt action in China.

Typically, people with CLD receive a medication intervention for exacerbation management. These interventions have been shown to reduce exacerbation frequency and decrease recovery times (Yang et al., 2019; Zhang et al., 2020). However, patients take only a passive role in managing their exacerbations with medication intervention. Specifically, passive patients wait longer to take action and delay seeking medical help from healthcare professionals (HCPs), leading to longer recovery times (Yang et al., 2019; Zhang et al., 2020). This finding is not surprising, given that patients typically do not actively seek information on how to self-manage exacerbations (Yang et al., 2019; Zhang et al., 2020). Combining medical intervention with self-management could help patients treat and recuperate from exacerbation at home (Hallensleben et al., 2020; Yang et al., 2019; Zhang et al., 2020). Self-management refers to an individual's ability to manage their symptoms, treatment, physical and psychosocial consequences, and lifestyle changes accompanying a chronic condition (Lorig & Holman, 2003). Self-management interventions, which often consist of education and an individualized action plan (Yang et al., 2019), could help to reduce the burdens of CLD and expedite recovery times by informing patients about how to take an active role in their disease management, including prompt exacerbation recognition and action (Wilkinson et al., 2004). Nurses play an essential role in self-management intervention by coordinating multidisciplinary teamwork and providing education in such interventions (Helvaci & Metin, 2020). One meta-analysis that identified the effect of nurse-led self-management interventions in people with COPD has shown that these interventions can significantly improve patients' quality of life (Helvaci & Metin, 2020). A nurse-led self-management intervention may thus be helpful for people with CLD to manage their diseases.

However, research on CLD self-management interventions has mostly focused on high-income countries, whereas the CLD burden is highest in low- and middle-income countries (LMICs) (Li et al., 2020). Amongst the LMICs, the burden of CLD is particularly high in China, where there are 144 million people with CLDs (Huang et al., 2019; Wang et al., 2018). Around one-fourth of the global burden of CLDs is in China (Soriano et al., 2020). Patients face a heavy disease burden in China due to the lack of efficient care and poor self-management (Bao et al., 2021; Lin et al., 2020). One possible solution to decrease the burden on people with CLD in China is translating CLD self-management interventions proven effective in high-resource settings to China. An example of a potentially effective nurse-led CLD self-management intervention—from the Netherlands—is called REducing Delay through edUcation on eXacerbations (REDUX).

2 | BACKGROUND

A previous intervention study in the Netherlands—led by the nurse in PC settings—examined the effects of REDUX in COPD patients in primary care (PC) settings, focusing on time spent between exacerbation recognition and seeking medical help (Hallensleben et al., 2020). REDUX helped COPD patients decrease the time between exacerbation onset and recognition and between the onset of an exacerbation and the point at which a patient sought medical help (Hallensleben et al., 2020).

REducing Delay through edUcation on eXacerbations includes education and an action plan using a fourfold approach: (a) determining how patients can recognize early exacerbation signs, (b) recommending specific and tailored medication advice when early symptoms emerge, (c) determining an adjusted duration and dosage levels for medication usage when symptoms decrease and (d) laying out a time frame during which patients need to seek medical help when increasing medication dosage is not working. This action plan aims to assist patients in managing their exacerbation by themselves (Hallensleben et al., 2020). Before implementing the action plan in practice, general practitioners (GPs) and PC nurses received training to recognize and treat exacerbations and guide patients to use the action plan (Hallensleben et al., 2020).

There will be some adjustments in patient inclusion criteria to make REDUX more applicable to specific circumstances in China. First, the target population will be CLD patients and not just COPD patients (as was the case in the original Dutch pilot study). That will be done because there is often a misdiagnosis of COPD as asthma in China (Ruparel et al., 2020). Furthermore, COPD and asthma patients have similar exacerbations that can benefit from REDUX. In line with this adjustment for the target population, we will also add inclusion criteria about age. There is a high prevalence in China of COPD in people aged 40 years or older and asthma in people of age 20 years or older (Wang et al., 2018). We aim to include people with CLD of 20 years and older in China (Huang et al., 2019; Wang et al., 2018). Yet another criterion will be added for patients who received treatment in PC settings in the past year. This criterion will be added because patients in China who experience exacerbation can go to different PC settings or different HCPs in the same PC setting. This criterion will help ensure that patients see the same HCP for exacerbation management during the study duration, as patients who went to the same HCPs in the last year tended to go to the same HCPs for subsequent exacerbation consultations (Wan et al., 2021). This additional inclusion criterion could help avoid the risks of missing important study data. Finally, HCPs will be trained online instead of face-to-face to reach more HCPs without undue delays created by distance and the time it takes to deliver the training. It also complies in line with social distancing regulations due to COVID-19.

Applying REDUX in a different context—from a high-income country, i.e. the Netherlands, to an LMIC, i.e. China—can help identify its effectiveness in reducing the disease burden and potential for exacerbation management outside of the Netherlands. Furthermore, it may provide insights on tailoring the international self-management intervention into other contexts.

3 | THE STUDY

3.1 | Aims

In summary, this paper describes a study that aims to examine the effectiveness of REDUX—one nurse-led self-management intervention—in people with CLD in China. In addition, its preconditions (i.e. feasibility, appropriateness and acceptability) will be evaluated in CLD patients and HCPs to assess whether REDUX will be successful in China.

3.2 | Design

The design of the study will be a single-arm pre-post study, and the study will start in October 2022. For a patient, the intervention will start when they see the nurse for the first post-exacerbation consultation and end when they present in PC for their second post-exacerbation consultation with the nurse. The reporting in this study protocol will follow the SPIRIT checklist and TIDier framework (Chan et al., 2013; Hoffmann et al., 2016) (Appendix S1). The study was registered in the Chinese clinical trial registry (ID: 2100051782).

3.3 | Participants

REducing Delay through edUcation on eXacerbations will be conducted in Chinese PCs. Patients will be invited to participate in the study by their HCPs if they: (a) are diagnosed with CLDs (COPD or asthma, or COPD overlapping with asthma), (b) are aged 20 years old or older (Huang et al., 2019; Wang et al., 2018), (c) have received treatment by the HCP in a PC setting in the past year and (d) have had a minimum of two exacerbations in the past year. People with mental disabilities, as diagnosed by the physician, or patients who cannot read will be excluded.

The sample size estimation of patients is based on one of the primary outcomes (i.e. the time between the onset of the exacerbation and action). The effect size used to calculate the sample size is from a study that discussed the relationship between different treatment times and health outcomes amongst 128 people with COPD (Wilkinson et al., 2004). The study showed that there was a significant difference in the effect of different treatment delays, i.e. the time from the onset of the exacerbation to the initiation of treatment, on the recovery time (0.57 days/day delay, 0.34 to 0.79, $p < .001$) (Wilkinson et al., 2004). With the formula calculation, $\sigma = 1.30$ (i.e. $\sigma = \sqrt{n} \times (\text{upper limit} - \text{lower limit})/3.92 = 128 \times (0.79 - 0.34)/3.92 = 1.30$). An effect size of 0.43 was calculated from this ($E = \Delta/\sigma = 0.57/1.30 = 0.43$). When performing a within-group comparison, a sample size of at least 43 participants is needed to detect an effect of 0.43 with a power of 80% and a 0.05 level of statistical significance (Louangrath, 2019). Assuming a 20% dropout rate (In et al., 2020), the required sample size of patients is 54.

The sample size estimation for HCPs is based on one of the primary outcomes (i.e. the proportion of HCPs who complete the training). The proportion is from a study that identified the adoption and implementation of one intervention in PCs (Wilcox et al., 2010). The study showed that the proportion of providers and nurses who complete the training was 57%. To achieve the same proportion of training completion, the required sample size of HCPs is 24 with a 95% confidence level and 15% of the desired margin of error (Louangrath, 2019).

3.4 | Intervention

The REDUX intervention is designed to educate patients on exacerbation management by helping them to recognize their early-onset symptoms and teaching them how to react in that case. The essential part of the intervention is a personalized action plan. 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 what 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 fourth box provides advice about what the patient should do when the symptoms worsen, specifically indicating how long the patient should wait until contacting the GP. The action plan could be accessed via the previous pilot study (Hallensleben et al., 2020). The training about how to coach patients using the action plan will be delivered to HCPs. HCPs, including doctors and nurses who work with CLD patients in Chinese PC, will be invited to participate in the training. Considering that the entirety of the REDUX training lasts for around 3 h, we will divide the training into three consecutive sessions, with 1 h per session. Every training session will be delivered to a group of three to five HCPs per week. The training will be scheduled at a convenient time for the HCPs.

After the training, the HCPs will be asked to include CLD patients when they present with an exacerbation. Their doctors will firstly treat their first exacerbation. After recovery from this exacerbation (which takes a maximum of 6 weeks after onset), the doctor will refer the patient to the nurse for a post-exacerbation consultation. During this consultation, the patient will receive the intervention (i.e. education and action plan). After the patient experiences another exacerbation, the nurse will—during the second post-exacerbation consultation—discuss the action plan with the patient (i.e. how they use the action plan, whether they have reacted to the exacerbation more promptly or not, whether the action plan works or not, and why the action plan may be useful or not, and whether their recovery time is shorter than the previous occurrence).

During the first and second post-exacerbation consultations, the nurse will use a daily registration form to register the time in days between the exacerbation onset and exacerbation recognition, the time between the exacerbation recognition and action taken on the exacerbation, the time between the exacerbation recognition and point at which medical help is sought, and the time between action and improvement and recovery after each consultation. The difference in times between both exacerbation registrations will be part of the outcomes as described below. The two post-exacerbation consultations will be delivered via individual face-to-face intervention in Chinese PC. The duration of the intervention sessions will be decided by the agreement between patients and the HCPs.

3.5 | Study procedures

The Chinese researcher will contact the person responsible for the original REDUX research—one nurse specialist—to ask permission to use the REDUX training and the personal action plan (Hallensleben et al., 2020). The content of REDUX and the personal action plan will be translated from English into Chinese. The first step will be to recruit 24 HCPs by publishing a recruitment advertisement online and sending invitation emails or messages to HCPs. The second step will be delivering the training to the participating HCPs. Considering that the entirety of the REDUX training lasts for around 3 h, we will divide the training into three consecutive sessions, with 1 h per session. Every training session will be delivered to a group of three to five HCPs per week. The training will be scheduled at a convenient time for the HCPs.

After the training, HCPs will be asked to include CLD patients when they present with an exacerbation. After recovery from this exacerbation (which takes a maximum of 6 weeks after onset) (Hallensleben et al., 2020), the HCP should invite the patient for a post-exacerbation consultation. During this consultation, the patient will receive the intervention (i.e. education and action plan) and usual care. After the patient experiences another exacerbation, the nurse will—during the second post-exacerbation consultation—discuss the action plan with the patient (i.e. how they use the action plan, whether they have reacted to the exacerbation more promptly or not, whether the action plan works or not, and why the action plan may be useful or not, and whether their recovery time is shorter than the previous occurrence).

3.6 | Data collection

3.6.1 | Primary outcomes

Healthcare professionals will collect the following outcomes at the first and second post-exacerbation consultation: (a) the delay between exacerbation onset and recognition, (b) the delay between recognition and action, and (c) the delay between recognition and consultation of a doctor and (d) the moment when the patient felt better after the action or medical help from HCPs (Hallensleben et al., 2020).

3.6.2 | Secondary outcomes

The secondary outcomes will be evaluations of the feasibility, appropriateness and acceptability of REDUX. These outcomes will be assessed for both patients and HCPs. In patients, feasibility will be measured with (a) the response rate, that is, the proportion of invited patients who were willing to participate (i.e. data which HCPs will provide), (b) the four-item Feasibility of Intervention Measure (FIM) (i.e. whether the intervention seems implementable,

possible, doable, and easy to use) (Weiner et al., 2018) and (c) an item identifying whether patients find the action plan useful. Appropriateness will be measured with the four-item Intervention Appropriateness Measure (IAM) (i.e. whether the intervention seems fitting, suitable, applicable and matches circumstances well) (Weiner et al., 2018). Acceptability will be measured with a four-item Acceptability Intervention Measure (AIM) (i.e. which will assess whether the intervention meets the participant's approval, is appealing to the participant, whether the participant likes the intervention, and whether the participant welcomes the intervention) (Weiner et al., 2018). The items on the three questionnaires will be answered using a five-point rating scale ranging from 'completely disagree' to 'completely agree'. HCPs will collect the response rate of patients before the first post-exacerbation consultation, and the patients will complete other outcomes at the second post-exacerbation consultation. For HCPs, feasibility will be measured by (a) the proportion of invited HCPs who are willing to participate, (b) the proportion of HCPs who complete the training and (c) FIM. The appropriateness and acceptability of REDUX will be examined with IAM and AIM. The researcher will collect the data before- and after- the training to determine the proportion of HCPs willing to participate and complete the training. HCPs will complete the three questionnaires after finishing the second post-exacerbation consultation with the last patient. All the above outcome measurements will be included in Appendix S2.

3.6.3 | Demographic and clinical characteristics

The following demographic and clinical characteristics in patients will be collected by HCPs at the first post-exacerbation consultation: age, gender, years with the disease, and disease severity based on the global initiatives for COPD (Mirza et al., 2018). The demographic characteristics of gender and years of working experience of the HCPs will be collected by the researcher before HCPs provide the first post-exacerbation consultation.

3.7 | Ethical considerations

Ethics committee approval was obtained from local ethics committees in September 2021 (ZZUIRB-2021-87). Eligible participants will be introduced to the study, including its aim and objectives, their rights of participation and withdrawal and the assurance of confidentiality. Their written consent will be obtained.

3.8 | Data analysis

Frequencies and percentages will be used to (a) describe the categorical variables, e.g. gender and the proportion of participation rate and (b) calculate the proportion of different responses to the feasibility, appropriateness and acceptability assessment. Mean and standard deviation will describe the continuous variables, e.g. age, years with disease and years of working experience. Wilcoxon signed-rank tests will be performed for the outcomes on delay in days between before and after the intervention. All analyses will be performed using SPSS version 23 (IBM).

3.9 | Validity and reliability

All data will be carefully checked immediately after collection, and the researcher will correct any problems which may arise. The data entered into SPSS will be cross-checked for verification. Descriptive statistics will be used for data cleaning. The researchers will also be responsible for the safekeeping of the raw data to ensure confirmability.

4 | DISCUSSION

A previous pilot study provided preliminary evidence that REDUX was an effective self-management intervention for COPD patients for managing their exacerbations with education and creating an individualized action plan (Hallensleben et al., 2020). In the study being proposed here, we aim to examine the effectiveness of REDUX for people with CLD in Chinese PC with a single-arm pre-post study design. Furthermore, the preconditions (i.e. feasibility, appropriateness and acceptability) of REDUX will be assessed in CLD patients and HCPs in China.

REducing Delay through edUcation on eXacerbations is the first nurse-led self-management intervention designed for CLD patients in Chinese PC to the best of our knowledge. Necessary changes will be made in the inclusion criteria to ensure an accurate assessment of the applicability and feasibility of the intervention. The online training for HCPs will be delivered following COVID-19 distance protocols to reach more HCPs and make the self-management intervention widely available. All these changes will help adjust REDUX intervention to the Chinese context appropriately. Considering that REDUX is a tool to support and engage patients in self-managing their exacerbations, the effectiveness of REDUX will be evaluated to assess whether the intervention is effective for people with CLD in China. In addition, the feasibility, appropriateness, and acceptability of REDUX will be measured in patients and HCPs. These aspects are not always assessed (Ali et al., 2020). It is, therefore, necessary to assess these measurements because they are preconditions for attaining the desired service delivery and clinical outcomes (Jones et al., 2021). A reliable and valid assessment of these measurements is essential for monitoring and evaluating the success of the REDUX intervention in China.

4.1 | Limitations

Nevertheless, this study has several potential limitations. One possible limitation is that we only aim to examine the REDUX intervention

in PC. REDUX was initiated by the COPD & Asthma PC respiratory group in the Netherlands (Hallensleben et al., 2020). The REDUX intervention in this study protocol will be conducted in Chinese PCs based on the previous pilot study design (Hallensleben et al., 2020). Therefore, the results may not be generalizable to patients treated in secondary care because REDUX has not been tested there. Future studies are needed to assess the potential of REDUX in secondary care. Furthermore, some factors may negatively influence the implementation of REDUX in China. In PC, HCPs are known to have heavy workloads, which could lead to limited time explaining REDUX to patients or helping patients self-manage their exacerbations. These factors could result in insufficient intervention. However, using REDUX in practice does not require a large time investment and—in the end—can save time for HCPs.

CONCLUSION

This study will contribute evidence on the potential effectiveness of the REDUX intervention in people with CLD in China. If this intervention is found effective, the Chinese HCPs working with CLDs could be trained to help their patients effectively self-manage their exacerbations with REDUX. Furthermore, data on the feasibility, appropriateness and acceptability of the intervention in China will provide insight into whether such personalized, nurse-led self-management intervention is appropriate for people with CLD in China. The study will help determine the feasibility of a large-scale pre-post study to evaluate the impact of the REDUX intervention in China. The experience from this study can also be used to develop other culturally-tailored self-management interventions worldwide.

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CONFLICT OF INTEREST

No conflict of interest has been declared by the authors.

PEER REVIEW

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DATA AVAILABILITY STATEMENT

Data sharing is not applicable to this article as no new data were created or analyzed in this study.

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SUPPORTING INFORMATION

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