Development of a self-treatment approach for patients with COPD and comorbidities: an ongoing learning process

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**Background:** Patient-initiated action plans are an important component of COPD self-management (SM) interventions. When integrated into SM interventions, these action plans have proven to be effective in reducing exacerbation severity, hospitalisations, and costs and in improving health status in patients with COPD without severe comorbidities. Because of overlap in symptoms, a self-treatment (ST) approach that focuses solely on traditional symptoms of COPD is inadequate for patients with COPD and comorbidities. The COPE-III SM intervention combines (I) patient-initiated action plans that are tailored to the individual’s co-morbid disease(s), and (II) ongoing nurse support. In this paper we provide information regarding the integration of information from two previous COPD SM studies (COPE I and II) in the development of the current COPE-III ST approach.

**Materials and methods:** COPE-III ST materials include daily symptom diaries and action plans that take patient’s common comorbidities [chronic heart failure (CHF), anxiety, depression, ischaemic heart disease (IHD), and diabetes] into account. The comorbid diary and action plans components were developed in collaboration with multiple disease-experts.

**Results:** Previous SM studies have highlighted some essential topics that need to be considered when developing a SM or ST approach: ‘when to initiate ST’, ‘how to optimize materials and safety’, and ‘how to achieve behavioural change’. In the COPE-III study, ST is initiated after a significant change in symptoms. This is consistent with the COPE-II approach and was implemented because disease symptoms are often present even when patients are stable. We have tried to ensure patient safety by providing an easily accessible case-manager to patients throughout their involvement in the study. Furthermore, a psychologist has ensured the use of behavioural change techniques throughout the intervention.

**Conclusions:** We should continue to learn from our experiences with SM interventions to further optimize future SM and ST interventions. The use of materials that are suitable for different levels of patient literacy and the training of health care providers are other points of improvement.

**Keywords:** Pulmonary disease; chronic obstructive; self-care; comorbidity

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Introduction

COPD is a leading cause of death and disability internationally (1) that affects approximately 1:10 adults in the developed world and is increasing in prevalence globally (2). High financial and social burdens have been associated with COPD in general (3,4) and COPD exacerbations in particular (5,6). COPD exacerbations, defined by episodes of acute deterioration in respiratory health (7), are also a major contributor to a step-wise worsening of quality of life in patients (7).

The latest Cochrane systematic review of COPD self-management (SM) has documented that COPD-specific SM interventions are associated with a reduction in hospital admissions (8). Patient-initiated action plans are an important component of SM interventions (8,9). When used appropriately, they can lead to accelerated initiation of appropriate treatment (10) and therefore reduce the exacerbation severity (11). When integrated into SM interventions, these action plans have proven to effectively reduce exacerbation severity, hospitalisations, and costs and improve health status (11-13).

Comorbidities are the rule rather than the exception in COPD (14,15). Over two-thirds of COPD patients (68.4%) suffer from at least one comorbidity, about 16% have at least two comorbid conditions (15), and one third of the COPD patients admitted to hospital have at least four coded comorbidities (16-18).

Because the symptoms of COPD and common co-occurring diseases overlap, a “one size fits all” approach that focuses solely on traditional symptoms of COPD is inadequate. For example, increased dyspnoea could relate to either a COPD exacerbation or a sudden deterioration of cardiovascular disease (e.g., heart failure) (19,20). Reliance on specifically designed for COPD symptoms and actions/treatments could therefore lead to the initiation of incorrect or delayed treatment.

The latter is highlighted by a recent study evaluating COPD-specific action plans in a COPD population with comorbidities (21). The study was terminated because of significantly higher mortality rates in the intervention group. No definite reason for this has emerged and the findings contrast positive outcomes of a comparable SM study (22). Nevertheless, the study (21) has resulted in controversy regarding the effectiveness of SM interventions, especially in patients with high burden of disease and co-morbidities (23). In these patients, SM interventions may be more challenging and not without risk of serious adverse events (23). It underlines the need for further evaluation of action plans in COPD patients with comorbidities.

In this paper we provide an insight into how we have used our experiences with our previous SM studies to develop a novel COPD self-treatment (ST) approach for patients with COPD and co-morbidities.

The COPE studies

During the last 15 years we have performed three large randomized controlled trials to explore effects of SM: the COPE-I (24), COPE-II (11,25), and COPE-III study (26). COPE stands for ‘COPD study at Department of Pulmonology Enschede’. Whereas the COPE-I and COPE-II study were performed in the Netherlands, COPE-III is a joint Dutch - Australian research project. Experiences from COPE-I and COPE-II have been used to develop the design for the COPE-III study. Details of all three COPE studies have been summarized in Table 1.

COPE-I

In the COPE-I study the effects of a comprehensive SM intervention were evaluated in 248 patients with moderate to severe COPD and no severe comorbidities (24). The intervention involved an individualized treatment plan that incorporated smoking cessation, optimisation of pulmonary status by pharmacotherapy, a standardised low-intensity exercise program, and a written ST action plan for COPD exacerbations that was based on symptom perception. If patients experienced an increase of respiratory symptoms and normally would have called their physician, they could start with a short course of oral prednisolone, and with onset of purulent sputum a course of antibiotics for which prescriptions were supplied (24).

Effing et al. Self-treatment in COPD: an ongoing learning process

The study results showed no effects on quality of life and exercise capacity, and an increased number of exacerbations, defined as an increase of respiratory symptoms treated with prednisolone and/or antibiotics in the intervention group. However, because daily symptoms were not recorded in either study groups, it could not be clarified whether this meant that there was an over-treatment in the intervention group or an under-treatment in the control group (24).

COPE-II

In the COPE-II study (11), the extra value of a COPD SM component was evaluated. A group of patients who received
### Table 1: Characteristics of the COPE-I, COPE-II, and COPE-III study

<table>
<thead>
<tr>
<th>COPE study</th>
<th>Methods</th>
<th>Participants</th>
<th>SM intervention group</th>
<th>Primary outcome</th>
<th>Secondary outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>I</strong> RCT</td>
<td>SM, ST and non-standardized low-intensity exercise</td>
<td>Usual care</td>
<td>127 intervention; 121 control</td>
<td>COPD diagnosis; (ex) smoker; age: 40-75</td>
<td>HRQoL (SGRQ)</td>
</tr>
<tr>
<td></td>
<td><strong>Design</strong></td>
<td><strong>Intervention</strong></td>
<td><strong>Control</strong></td>
<td><strong>Follow-up (months)</strong></td>
<td><strong>Numbers</strong></td>
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<tr>
<td><strong>II</strong> RCT (2-by-2 factorial design)</td>
<td>SM, ST and standardized exercise</td>
<td>SM intervention and standardized exercise</td>
<td>70 intervention; 72 control</td>
<td>COPD diagnosis; ≥3 exacerbations, and/or 1 respiratory hospitalization in previous 2 years; (ex) smoker; age 40-75</td>
<td>HRQoL (SGRQ)</td>
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<tr>
<td></td>
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<td>Medical condition with low survival or serious psychiatric morbidity; other serious lung or cardiac disease</td>
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<tr>
<td><strong>III</strong> RCT (international-multisite)</td>
<td>SM and ST</td>
<td>Usual care</td>
<td>Recruitment in progress</td>
<td>COPD diagnosis; ≥1 comorbidity: IHD, CHF, AD, DM; ≥3 exacerbations, and/or 1 respiratory hospitalization in previous 2 years; age ≥40</td>
<td>HRQoL (SGRQ)</td>
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<tr>
<td></td>
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<td></td>
<td></td>
<td>Medical condition with low survival or serious psychiatric morbidity; other serious lung disease; low cognitive functions</td>
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6MWT, 6-minute walking test; AD, anxiety and/or depression; ATS, American Thoracic Society; CCQ, clinical COPD questionnaire; CHF, chronic heart failure; CRQ, chronic respiratory questionnaire; CSES, COPD self-efficacy scale; DM, diabetes mellitus; ER, emergency room; FEV1, forced expiratory volume in one second; FVC, forced (expiratory) vital capacity; GOLD, global initiative for chronic obstructive lung disease; GP, general practitioner; HADS, hospital anxiety and depression scale; HR-QoL, health related quality of life; ICFS, identity-consequence fatigue score; IHD, ischaemic heart disease; RCT, randomised controlled trial; SGRQ, St George’s respiratory questionnaire; SM, self-management; ST, self-treatment.
COPE-II study demonstrated that specific COPD ST training within a more general COPD SM training intervention leads to less exacerbation days and lower costs (11). However, these study results cannot be generalized to the large population of COPD patients with comorbidities.

**COPE-III**

The COPE-III SM intervention incorporates (I) patient-initiated action plans that are tailored to the individual’s co-morbid disease(s) as well as their COPD, and (II) phone support from case-managers. The design of the COPE-III study, an international randomised controlled multi-centre trial, has previously been published and the intervention is currently under evaluation in both the Netherlands and Australia (26). Patient recruitment takes place in five hospitals [Netherlands: Enschede (Medisch Spectrum Twente) and Nijmegen (Canisius-Wilhelmina Ziekenhuis); Australia (Adelaide: Repatriation General Hospital, Flinders Medical Centre, Royal Adelaide Hospital)]. We expect that data collection will be completed by the end of 2015.

In the COPE-III study, we have incorporated at similar COPD ST component to that evaluated in the COPE-II study and combined this with action plans for common comorbidities [chronic heart failure (CHF), anxiety, depression, ischemic heart disease (IHD), and diabetes]. The comorbid action plan components have been developed in collaboration with multiple disease-experts (Cardiologist, Cardiac Nurse Practitioner, Endocrinologist, Psychiatrist, and Psychologist). In COPE-III, extensive patient training directed towards individualized materials is provided.

**COPE-III ST approach**

The COPE-III intervention involves a total of 8-9 hours of SM session time and several additional follow-up phone calls. A more specific description of the intervention has been provided in a previous paper (26). Because of the adjustment of intervention materials for comorbidities, materials are more complex than the ones used in previous two studies. It has therefore become necessary to deliver half the COPE-III training sessions individually instead of in a group and to allocate relatively more session time towards specific ST training compared to previous interventions. ST materials include a ‘what are my usual symptoms’ card, a daily symptom diary, and an action plan. During training in the use of these materials, hypothetical scenarios were incorporated to engage the patient in practicing the completion of the diaries and understanding appropriate use of the action plans.

As in previous studies, SM training is provided by case-managers (respiratory nurses). Patients are provided with information on how to contact the case-manager if they have any doubts or questions. Access to case-managers is available during office hours and patients are advised to contact their GP or Emergency Department during out of office hours. The case-manager also acts as a triage nurse when the cause of the change in symptoms is unclear and additional advice is necessary (26).

**COPE-III ST materials**

Even when stable, many patients with COPD experience symptoms of their respiratory disease and comorbidities, especially patients with moderate to severe disease (19). In the COPE-III intervention, the nurse and patient define together the patient’s symptoms during a stable health state and summarize these findings in the patients’ ‘what are my usual symptoms’ card. The patient is advised to use this card while completing the daily symptom diary and to
indicate whether symptoms have changed compared with their stable health state. So as in COPE-II (11), ST actions are linked to changes in symptoms rather than to existing symptoms. This approach requires that patients have skills and knowledge to recognize deterioration in their symptoms (28).

Patients are asked to complete the symptom diary that includes respiratory symptoms and relevant comorbid symptoms, every day. When patients do not experience deterioration in any of the predetermined symptoms listed in the diary during the last 24 hours, they are instructed to tick the box ‘no change in symptoms’ (indicating no further actions are required). Whenever they experience deterioration in any symptom listed in the diary, they are asked to report the level of change for each of the listed symptoms and if this change is of sufficient magnitude, consult their tailored action plan (26).

Besides the COPD component, all daily symptom diaries and action plans include one or more comorbid components in a pre-defined order: (I) CHF; (II) anxiety and/or depression (AD); (III) IHD; and (IV) diabetes. Diabetes action plans differ for patients with type 1, type 2 and prednisolone-induced diabetes. As such, there are 21 possible action plans that can be instigated.

**Cardiac component**

Similar action plans are provided for two cardiac comorbidities, IHD and CHF, in both Australia and the Netherlands.

For CHF three questions are included in the daily symptom diary regarding fluid retention (weight, swelling of ankles and abdomen, and waking up at night short of breath). According to the action plan, patients should increase/start their diuretic medication when they record ‘a significant change’ for two consecutive days for at least one of these questions. The expert team agreed that a change in weight of at least one kilogram in 24 hours should be considered a significant change. Patients are asked to contact the case-manager if symptoms do not decrease with diuretic therapy, or if they think they need more than the 3-day diuretic course as directed in the action plan. In the Netherlands patients are asked to contact their cardiac nurse directly.

A second CHF action plan component is included for safety reasons. Patients are asked to contact the case-manager (or cardiac nurse for Dutch patients) if they become more light-headed and/or dizzy. Consequently, the case-manager contacts the cardiac nurse to see if further actions are required (possible causes for these symptoms include rhythm disorder, over diuresis or a side effect of medication).

The existing action plan for IHD, developed by the ‘National Heart Foundation of Australia’, is being used with minor adjustments in lay-out (29).

**Anxiety and depression**

The action plan for anxiety and depression advises patients to commence relaxation exercises (which are practiced during the SM courses) if they experience increased AD. If symptoms do not improve after 5 days patients are asked to contact the case-manager (Dutch patients could directly contact the mental health worker). When necessary, their predefined ‘plan’ (e.g., seeing their GP to discuss their symptoms and management) is activated and/or a consult with a psychologist arranged.

Prior to inclusion patients are screened with the Hospital Anxiety and Depression Scale (HADS) (30). Patients with scores meeting recognized clinical cut-off points (exceeding 10 per subscale) of the HADS (30) are offered psychological counseling prior to the baseline measurement.

Although experiencing suicidal ideation is an exclusion criterion for the COPE-III study, standardised action plans are used if patients develop suicidal ideation during the study. For example, patients may contact nurses who conduct a risk assessment and patients are also provided with an emergency 24-hour phone number for specialised counselling for suicidal ideation.

**Diabetes**

Prednisolone treatment of COPD exacerbations increases blood glucose levels (BGLs), especially in patients with pre-existing diabetes. Hyperglycaemia in patients treated with prednisolone predominantly occurs between midday and midnight (31). Higher glucose concentrations are associated with increased mortality, morbidity and length of hospital stay during a COPD exacerbation (32,33).

Separate diabetes action plan components were developed for type 1, type 2 and prednisolone-induced diabetes. In contrast with the other comorbidities, the diabetes action plans are not linked to a change in ‘diabetes’ symptoms, but to the start of a COPD exacerbation. When taking prednisolone, patients are advised to check their BGL four times per day (before breakfast, lunch, dinner, and bed time). Extra training on blood glucose monitoring and insulin injections is then arranged with a diabetes nurse if required.

There are differences in the action plans for diabetes used in Australia and the Netherlands, in order to mimic as
much as possible usual care in both countries and simplify possible future implementation.

In Australia, patient management plans have been developed for two main groups of patients: (I) patients with diet-controlled diabetes or taking oral hypoglycaemic agents; and (II) patients already taking insulin. If patients record one BGL above 15 mmol/liter or two measurements above 10 mmol/liter, the action plan directs them to contact the case-manager who then contacts an endocrinologist. Patients who are not already taking insulin are taught to administer insulin isophane during COPD exacerbations, with dosing adjustments by an endocrinologist based on ongoing BGL recordings. Patients who are already taking insulin have their current insulin regimen doses adjusted by the endocrinologist.

In the Netherlands, patients with diet-controlled diabetes or taking oral hypoglycaemic agents are instructed to use insulin injections temporarily if they experience a high BGL (one BGL measurement above 15 mmol/liter or three measurements above 10 mmol/liter during a 24-hour period). Insulin dosing schedules are patient-fitted by the diabetes nurse and discussed during SM training. Patients have a tailored insulin dosing schedule (as advised by the diabetes nurse) or they are instructed to administer short-acting subcutaneous insulin using a sliding scale regimen.

### Optimising of the COPE-III ST intervention

Prior to the start of the randomized controlled trial, the COPE-III ST intervention was tested in six patients with severe COPD to further optimize the intervention. Recruited patients were already included in an intensive nurse-led case-management program to which the COPE-III ST intervention was added. During the pilot, study nurses and patients were asked to provide frank feedback on the materials. During and after the pilot, significant adjustments were made to the ST materials. We have summarized an overview of these adjustments in Table 2. The intervention materials were adjusted to ensure that the intervention could be easily implemented in different health care systems.

### Training of the health care providers

Both the COPE-I and COPE-II studies were extensively piloted (by groups of health care providers and patients). Besides optimising the intervention, the goal of these pilots was to train all health care providers in ‘SM’. In addition, all involved health care providers in the COPE-III study attended a half day course regarding the guidance of group sessions. The content of this course included discussion of behavioural change techniques that were embedded in the SM sessions: components of education, training, modelling, and enablement, which target desirable and specific behaviours including individualised diary use, patient recognition of deterioration in symptoms, and the correct and timely use of an action plan (26). Ongoing, regular follow-up meetings (approximately once a month) were planned with the health care providers involved.

The COPE-III study was also extensively piloted by patients and health care providers. The education in comorbidities was provided by disease experts in both countries (approximately 2-3 hours per comorbidity) and predominantly directed towards triaging of problems that could occur in these complicated COPD patients. Overlap in disease symptoms was discussed intensively. The training in SM and behaviour change principles was provided by an Australian psychologist during a 2-hour group meeting. This meeting was recorded, so it could also be viewed by the study nurse in the Netherlands.

Separate training in the diaries and action plans was provided by the study investigators in both countries (approximately 4 hours), with frequent follow-up meetings, that were especially important during the first year of the study.

### Discussion

The COPE-III study is focused on treatment of COPD and common comorbid diseases. The intervention was developed and adjusted by using experiences and knowledge learnt from two previous COPE studies and by a pilot study. Although the action plans used in COPE-III are established and cannot be changed during evaluation, we are aware that we can continue learning from our experiences with COPD ST.

In the COPE-III study, we are attempting to deal with two of the most important lingering issues within ST, namely dealing with comorbidities and ensuring patient safety. We believe that a ‘one size fits all’ approach that focuses solely on traditional symptoms of COPD is inadequate and in fact, potentially dangerous in patients with (numerous and severe) comorbidities. This was the rationale underpinning the COPE-III approach. We have tried to optimize patient safety by ensuring a case-manager who is accessible to patients throughout the study. This is emphasized during patient training and highlighted on all ST materials. We also incorporated fallback procedures into the action plans, such as contacting usual health care
Table 2 Summary of adjustments of self-treatment materials (usual symptom cards, symptom diary, action plan, course material) as a result of the pilot study

<table>
<thead>
<tr>
<th>Aims</th>
<th>Documents</th>
<th>Adjustments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Simplification of education material</td>
<td>All materials</td>
<td>Comorbidity components are colour coded and numbered</td>
</tr>
<tr>
<td></td>
<td>Symptom diary</td>
<td>Reduction of numbers of items by combining the ‘minor respiratory symptoms’ in one question</td>
</tr>
<tr>
<td></td>
<td>All materials</td>
<td>Remove medical jargon and simplify text</td>
</tr>
<tr>
<td></td>
<td>Symptom diary</td>
<td>Make more clear that the action plan needs to be consulted by using red ‘marked’ boxes for a change that is ‘significantly more than usual’</td>
</tr>
<tr>
<td></td>
<td>All materials</td>
<td>Consistency in wording</td>
</tr>
<tr>
<td></td>
<td>All materials</td>
<td>Consistency in the order in which comorbidities are addressed</td>
</tr>
<tr>
<td>Better discrimination between breathlessness due to COPD or due to IHD and CHF</td>
<td>Usual symptom cards</td>
<td>IHD item: record what patients normally use as IHD medication (e.g., a spray or a tablet)</td>
</tr>
<tr>
<td></td>
<td>Symptom diary</td>
<td>IHD item: use of ‘sudden change in your breathing’ instead of just ‘short of breath’</td>
</tr>
<tr>
<td></td>
<td>Action plan</td>
<td>Inclusion of a final box with the comment: ‘If you have been significantly more breathless than usual (marked red boxes) for at least 2 days in a row but you did not tick any red boxes for other symptoms: please contact the study office’</td>
</tr>
<tr>
<td></td>
<td>Course material</td>
<td>Extensively discussion of breathlessness by working through scenarios</td>
</tr>
<tr>
<td>Stimulating patients to go through the complete action plan</td>
<td>Action plan</td>
<td>Insert a clear message after every box in the action plan to go to the next part of the action plan</td>
</tr>
<tr>
<td></td>
<td>Course material</td>
<td>Practising with the action plan and underlining to read through the complete action plan</td>
</tr>
<tr>
<td>Increasing of safety of the ST approach</td>
<td>Symptom diary, action plan, course material</td>
<td>Making clear that patients can always contact the study nurse if uncertain or having questions</td>
</tr>
<tr>
<td></td>
<td>Action plan</td>
<td>Adding a final box to the action plan with the following messages:</td>
</tr>
<tr>
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<td></td>
<td>- Contact the study office if you have been significantly more breathless than usual (ticked red boxes) for at least two days in a row but you did not tick any red boxes for other symptoms</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Contact your GP if you have a fever (more than 38.5 °C) for at least 2 days in a row but you did not tick any red boxes for other symptoms</td>
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<tr>
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<td></td>
<td>- Please check the action plan tomorrow again and remember: you can always contact the study office during office hours if you have any doubts or questions ‘phone number’ (Monday-Friday: 8.00 am-4.30 pm; excluding Public Holidays)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- If you require assistance during out of office hours: please contact your GP or Emergency Department</td>
</tr>
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</table>

IHD, ischemic heart disease; CHF, chronic heart failure; ST, self-treatment; GP, general practitioner.

provides for unresolved or worsening breathlessness or fever (see Table 2). The safety of the study is monitored by a Data and Safety Monitoring Board.

Another recommendation is that ST approaches have to be included in a formal SM training intervention (10) that includes behavioural change techniques (9) and is tailored to the patient’s individual needs (9). The COPE-III intervention meets all of these criteria. Behavioural change techniques are included in an extensive patient training intervention (e.g., education, training, modeling, individualised action plans, behavioural enablement, individualised goal setting, and feedback on behaviour). Although ST of co-morbidities is patient-tailored, the content of the SM training is part of an intervention with set components (e.g., disease education, relaxation, and breathing techniques). In COPE-III we have utilised a ST approach that provides appropriate tools, training in necessary skills, and the possibility to incorporate the approach in existing health care support systems (9).

Additionally, health literacy of patients should also be taken into account. Literature suggests that only a third of patients with low literacy are able to comply with simple written instruction such as ‘Take two tablets by mouth twice daily’ (34). We are acutely aware that our ST materials are much more complicated than this instruction, and we concede that SM is not an approach that would be suitable...
for all patients with chronic diseases like COPD. However, lessons were learnt during the pilot study and the patient materials were simplified. Although we exclude patients who are non-literate and those assessed as having an impaired cognitive function (26), we have not excluded people with low health literacy in any of the COPE studies.

For ST of COPD exacerbations it is also important to keep in mind that patients should be able to use their action plans regularly. If their symptoms are not varying with some frequency, amounting to repeated exacerbations, there are no opportunities for them to refer to their action plan and therefore learn from or receive feedback on their actions. In COPE-II and COPE-III it was therefore decided to include only frequently exacerbating COPD patients (patients who had at least three exacerbations or one respiratory related hospitalization in 2-year previous to inclusion).

At present there is no general agreement on the specifics of training health care providers to deliver optimal SM interventions, although experts agree that training of health care providers is crucial. In preparation for COPE-III, a psychologist was asked to provide a discussion session regarding behavioural change techniques that could be included in the COPE-III intervention. As this is an important aspect of SM, additional follow-up meetings were organized to discuss behavioural change techniques.

Finally, little is known about the factors influencing the success and failure of SM interventions, although understanding is growing as we acknowledge the intricacies of human behaviour and what drives behaviour change. Perhaps even less is known of the factors influencing the success and failure of ST interventions, and further studies will hopefully shed more light on this in the near future.

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