Compliance with physiotherapeutic guidelines : a method applied in a pulmonary rehabilitation protocol

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Abstract

Background: In this study the extent to which physiotherapist comply with prescribed protocols of physiotherapeutic treatment programs was measured, as well as the extent to which they contaminated the control group program with the experimental group program in a randomised controlled study (COPE II).

Methods: Individual interviews were held with patients with chronic obstructive pulmonary disease (COPD), focusing on the extent to which their physiotherapist applied aspects of the prescribed "COPE ACTIVE" protocol in their physiotherapy sessions. By quantifying interview data on a scale from 0 to 10.50 a score per patient was determined. A score of 10.50 means full implementation of the treatment protocol; a score of 0 means not any aspect of the treatment protocol is applied in the patient's treatment. Scores of patients receiving the physiotherapeutic intervention were compared with control group COPD patients receiving usual physiotherapeutic care.

Results: The mean scores of the control group differed significantly from the scores of the intervention group. The mean score of the intervention group was 9.20 (sd 0.78); the mean score of the control group 2.33 (sd 1.25). The ten "COPE ACTIVE" aspects in the intervention group are similarly represented in the total scores, while in the control group there were large differences. Physiotherapists did not seem to have contaminated usual physiotherapeutic care with the "COPE ACTIVE" protocol.

Conclusion: This quantitative study suggests that physiotherapists followed the prescribed protocols correctly for both groups under study.

Introduction

More and more people suffer from Chronic Obstructive Pulmonary Diseases (COPD). Incidence rates are growing, especially in countries with a rapidly ageing population and even in populations with reduced smoking rates (1). Mortality due to COPD is substantial and a considerable rise is expected: According to calculations the disease will be the world's third cause of death in 2020 (2). COPD is a generic term for both chronic bronchitis and lung emphysema (3). It is characterized by an irreversible respiratory impairment that has primary effects on the lungs (4;5). COPD is mainly caused by smoking and up till now only smoking cessation appears to effectively slow down the progression of the disease (6).

Several studies have shown that, next to medication, pulmonary rehabilitation programs can improve the patients' quality of life and their exercise tolerance (7;8). Like pulmonary rehabilitation self-management programs for patients with COPD often include physiotherapy. Physiotherapy can improve the health status of COPD patients (7;9). During physiotherapy sessions, different protocols are used to treat patients and improve their health condition. In the literature there is considerable discussion about what the most effective physiotherapy program is and many studies focus on evaluating this effectiveness (10;11). In some of these cases, both the intervention and control group are treated by the same physiotherapists. Next to practical aspects, an advantage of physiotherapists treating both groups under study is that provider mediated-biases are avoided: the features of both research groups are similar. However, since both the intervention group and the control group in such studies are treated by the same physiotherapist, there is a danger that the control group is (partly) exposed to the intervention. This kind of selection bias is called contamination bias (12). It describes the problem of the physiotherapists "infecting" the control group with the intervention. As a result, there is a chance that the control group is receiving aspects of the physiotherapeutic intervention. Consequently, potential differences between the control and intervention group will be reduced.

Another potential threat to this study design, which concerns all intervention studies, is the performance of the intervention. In this intervention study this concerns compliance of the physiotherapists. Compliance refers to the extent to which a person’s behaviour (in term of taking medications, following diets, or executing lifestyle changes) coincides with medical or health advice

(13). Health care professionals are just as likely to be non-compliant as patients (14). There has been written less about this specific subject compared with patients' compliance, but several studies indicate that physicians do not always adhere to prescribed protocols (15;16;17).

An important determinant of compliance is self-efficacy (18). Within social cognitive theory (19;20), self-efficacy is the belief "in one's capabilities to organize and execute the courses of action required to produce given attainments" (19). Physiotherapists who have little confidence in their ability to use a treatment protocol, who are dissatisfied with their physiotherapeutic skills or who are uncomfortable using the treatment may be said to have weak self-efficacy beliefs. Those with low self-efficacy should be less likely to perform related behaviours (20), in this case, adopt and use the treatment protocol, than those with high degrees of self-efficacy.

In some cases, non compliance occurs because protocols do not reflect the practical needs of the health care workers (21). When the contents of the protocol are formulated well, it is likely that causes of professional non-compliance can be categorised in two different types (22). The first is lack of knowledge of the protocol, forgetting about the agreements on the enforced exercises and a lack of familiarity with the protocol. Another reason for non-compliance may be that physiotherapists have no affinity towards the physiotherapy program and do not believe in its success. Lack of knowledge of protocols and attitudinal factors may therefore be important determinants of professionals' non-compliance. There is some evidence that educational effort, reminders and behavioural strategies can reduce this type of non-compliance (23).

Several factors determine the uptake and continued use of clinical guidelines by professionals (24;25). It is important that the protocol adjusted to the professional background, knowledge, and skills of the health care workers (21). Next, an effective implementation consists of three important aspects: it should be managed like a process and it should concern a systematic approach and evidence-based renewals (25). A comprehensive strategy to disseminate such a program is also important (24). If all of these aspects are taken into account, a good implementation of the treatment protocol may be expected. Compliance then is considered to be an outcome of a successful implementation process.

This study was part of the COPE II project which focuses on the effectiveness of an intensive physiotherapy program (“COPE ACTIVE”) within a self management program. It focuses on the

compliance of physiotherapists and the extent to which their potential non-compliance influenced the results of the COPE II project. Within the COPE II project, patients in the intervention group received COPE-active, while patients in the control group received usual care. The participating physiotherapists were treating patients in both groups under study.

This study can be seen as an extensive manipulation check. The aim was to determine to what extent the intended discrepancy between the control and intervention group is maintained by the physiotherapists. This was done by determining (1) to what extent the protocol of "COPE ACTIVE" was followed by the participating physiotherapists and (2) to what extent aspects of the "COPE ACTIVE" protocol were applied in the treatment of the intervention group only.

Methods

The physiotherapists executing the “COPE ACTIVE” program all had affinity with COPD. The "COPE ACTIVE" program is a high intensity physiotherapy program based on the most recent literature about lung rehabilitation and has been developed for COPD patients. The COPE-active program starts one month after the start of the self-management-program and is supervised by physiotherapists who have received additional training in COPD. Patients assigned to this intervention group are obliged to participate in this program for a period of six months. "COPE ACTIVE" patients attend two one-hour sessions a week with their physiotherapists. Additionally, one hour a week they exercise at home.

The physiotherapists operate in private practices, situated in the adhesion area of the Medisch Spectrum Twente, a large general hospital in Enschede (The Netherlands). They had all taken part in a study with COPD-patients before. Therefore, they had already attended a general COPD course. Additionally, as part of the COPE II-study, a specific course in which the "COPE ACTIVE" program was discussed had to be followed.

In this research project 13 physiotherapy practices were studied. Because the inclusion period of the COPE II study is still ongoing, not all of them had patients assigned in the intervention group yet. The practices were represented by their patients participating in the COPE II study. Because the COPE II study is still including patients, the first included patients were interviewed in this study. Hence, random selection was not possible.

In the COPE II study a total of 200 patients will participate, of which 100 will be assigned at random to the intervention group and 100 will be assigned at random to the control group. For this study, 14 patients in the intervention group (receiving "COPE ACTIVE") were interviewed concerning compliance of their physiotherapists. Additionally, 10 patients assigned in the control group (receiving usual care) were interviewed concerning potential contamination bias. Patients assigned in the intervention group were treated at seven physiotherapy practices. Patients assigned in the control group were treated at nine physiotherapy practices: Six practices treated only patients in the control group and three practices treated patients in the control as well as patients in the intervention group.

At the time of the interviews patients were aged between 40 and 75 and were out-patients of Medisch Spectrum Twente. They had a clinical diagnosis of "moderate to severe COPD" (26) as defined by the GOLD-criteria (27).

Data collection

The interview questions were based on the protocol of CA. Patients were asked questions about the activities they were instructed to perform during their physiotherapy sessions and home exercises. In this way it was examined to what extend the "COPE ACTIVE" protocol was used correctly by the physiotherapists. This indirect measurement of compliance by the physiotherapists was done to avoid social desirability bias (28) by physiotherapists. This bias contains, that when physiotherapists know that they are being watched, they will tend to behave in a way they believe is socially acceptable and desirable. Observational methods were therefore considered inappropriate.

Structured interviews were conducted by an independent researcher (MK), not affiliated to the COPE II project. Because patients were participating in the COPE II study, an informed consent was already acquired. At the beginning of the interview it was explained to the patient that questions would be asked about the patient's exercises at the physiotherapy practice and at home. Permission was asked to record the interview by audio tape and no patient refused this request.

The core of the interview consisted of three parts. In the first part general questions were asked about the location of the physiotherapy, the number of sessions per week and the duration of the

sessions. The second part started with an open question about the exercises the patient had to perform during the physiotherapy sessions. Next, the researcher discussed all "COPE ACTIVE" exercises and other exercises mentioned by the patient concerning physiotherapeutic aspects: questions were asked about the changes in the exercises (increasing resistance, increasing frequencies of the exercise within a certain period of time, increasing the time of exercise, etc.), the use of BORG scores (29) and the performance of duration exercises (interval or duration). The third part of the interview was similar to the second, but was about the home exercises the patient had to perform. Patients were blinded to the purpose of the study and did not know the contents of the “COPE ACTIVE” protocol. All patients (both the “COPE ACTIVE” and the usual care group) were interviewed using similar questionnaires. All interviews took place at the patients' homes.

Pretest

Before the start of the study a pilot of the interview was performed by an independent researcher (MK). Three COPD-patients having regular physiotherapy but not participating in the COPE II study were interviewed to detect flaws in the instruction and questionnaire. The questionnaire appeared to be well structured and the items comprehensive and unambiguous. However, there appeared to be some missing items: questions about possible adjustments in exercises not included in the protocol of “COPE ACTIVE” were added. The pretest also led to some adjustments in the lay-out of the questionnaire to increase its feasibility.

Data analysis

In total, the questionnaire consisted of 78 questions. Only 35 questions were about the performance of the actual physiotherapeutic exercises. The other questions served as introduction to the discussion of the exercises. Every question could receive the scores: 1: execution of physiotherapy according to the “COPE ACTIVE” protocol, or 0: no execution of physiotherapy according to the “COPE ACTIVE” protocol. However, the items could not be questioned in such a dichotome way for two reasons. First, it was important to avoid the possibility that patients would turn to answering automatically: COPE-

active patients would always have to answer "yes", and usual care patients "no". Second, it was important not to give patients of the control group a feeling of being treated inaccurate. Therefore, the questions were open in nature (see Appendix A).

The formulated 35 items were classified in ten different categories (see table 1), which altogether described the "COPE ACTIVE" protocol. Summing the scores on items of one category led to a total score per category. Every category initially was assigned similar importance. The maximum score per category was determined on a value of 1. Because the number of items per category varied, the score per item was standardized by the outcome of: 1 / (the number of items in the category). In order to score optional exercises, there were two aspects with a surplus value of 0.25 (see table 1). Hence, there were 8 categories with a value of 1 and 2 categories with a value of 1.25. Summarizing all categories' scores consequently led to an overall score per patient with the maximum of 10.50.This score implies the “COPE ACTIVE” protocol is fully implemented.

Aspect	Description	Number of items measuring the aspect
1	The frequency of physiotherapy sessions: twice a week.	1
2	The duration of physiotherapy sessions: 60 minutes	1
3	The specific combination of exercises within the physiotherapy sessions (cycling, walking, walking stairs, lifting; push/pull (optional)).	5*
4	Structural change within the exercises within physiotherapy sessions: increasing resistance, increasing frequencies of the exercise within a certain period of time, increasing the time of exercise, etc..	6*
5	The frequency of the home exercises program: once a week.	1
6	The specific combination of exercises within the home exercises program, consisting of: subdivision 1: one exercise of the lower extremities + subdivision 2: one exercise of the higher extremities + subdivision 3: one exercise for endurance training	7
7	Structural change within the exercises within the home-exercises program within each subdivision (increasing resistance, increasing frequencies of the exercise within a certain period of time, increasing the time of exercise, etc.).	7
8	The determination of or duration or interval training (considering the patients' limitations and a sub maximal cycling test) consisting of: subdivision 1: during physiotherapy sessions subdivision 2: during the home exercises program	4
9	The frequency of "COPE ACTIVE" sessions: 3 times a week (two physiotherapy sessions + one time the home exercises program).	2
10	Use of BORG scores	1
	Total	35

Table 1. The ten aspects of the COPE-active program with additionally the number of items measuring the aspect.

* At aspect 3 and 4 a surplus value of 0.25 was determined .

Additionally to the unweighted calculation method mentioned above, a weighted calculation method was used, based on the uniqueness of the ten "COPE ACTIVE"aspects. It was expected that unique aspects would receive a high weighing score. Because of that high weighing score, the share of a unique aspect in the total score would increase. Because it is expected the unique aspects are more applied at patients in the intervention group than in the control group, the absolute increasement of the score is expected to be higher in the intervention group than in the control group. Applying this method could enlarge the discrepancy in scores between the groups under study and make the differences in treatment more clear.

A weight per category was assigned by the researcher of COPE II (TE), who functioned as an expert of COPE-active (table 2). The weights were measured on a visual analogous scale (VAS). In this graphical method the respondent is asked to choose position between the two extremes “not unique at all “ and “very unique” (30). Advantage is that it is a rather easy method and it enables respondents to determine aspects at similar values. The assigned weights in the VAS could vary from 0 to 1 and were measured with two decimals. Table 2 shows the assigned weights were standardized by multiplying the scores with 1.58. This is the ratio of the maximum unweighted score (10.50) and the total of assigned weights (6.66).

Aspect	1	2	3	4	5	6	7	8	9	10	**Tot.**
Assigned weight	0.18	0.23	1.00	0.81	0.33	0.95	0.85	0.97	0.85	0.49	**6.66**
Adapted ass. weight	0.28	0.36	1.58	1.28	0.52	1.50	1.34	1.53	1.34	0.77	**10.50**

Table 2. The ten aspects of the COPE-active program with both their assigned weights and these weights in proportion to the aspects’ values without assigned weights.

In short, aside of determining the total scores per patient, there was assigned a weight per category by an expert of “COPE ACTIVE” (TE). In this manner an overall score was obtained for every patient with and without a weighing factor. Data analyses were executed by SPSS 12.0. Concerning compliance descriptive statistics were used to compare the scores of the groups under study, the scores per physiotherapist practice and the scores per “COPE ACTIVE” aspect. Using a Mann-Whitney U test ($p<0.05$), differences between research groups were tested. Regarding potential contamination bias, within physiotherapists who treated both groups under study, usual care patients were compared to “COPE ACTIVE” patients. Additionally these usual care patients were compared with usual care patients of a physiotherapist who treated only usual care patients. At last, there was looked at the distribution of the ten “COPE ACTIVE” aspects in percentages of both groups under study. The distribution of the aspects in the mean score of the intervention group was compared to the distribution of aspects in the control group.

Results

In the study 24 patients were interviewed. Their mean age at the time of the interviews was 63 with a range from 48 to 76. The weighing factors did not seem to have much effect on the discrepancy of the total scores: the gained difference in the total score was 0.01 in the intervention group and 0.15 in the control group. Since these differences on the results were deemed small, only the crude scores are presented in this article.

Figure 1 depicts the median, the 25th and 75th percentile, and the extreme values (whiskers) of the total scores on the “COPE ACTIVE” protocol of both groups under study. There is a clear discrepancy between the groups under study (Mann-Whitney U test; p=0.00).

The intervention group had a mean score of 9.20 (sd 0.78) on a scale of 10.50. The mean score of the control group was 2.33 (sd 1.25).

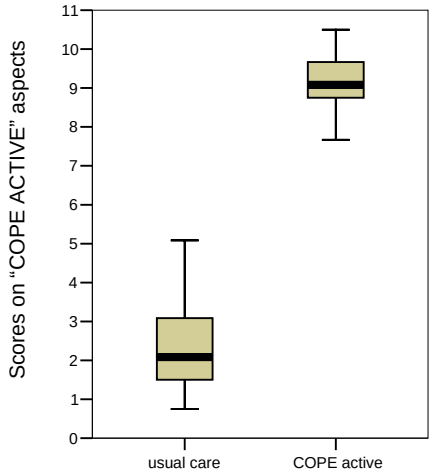

Figure 1. The median, the 25th and 75th percentile and the extreme values of the total scores on the “COPE ACTIVE” protocol of both groups under study.

Figure 2 shows the distribution of the patients' scores on the “COPE ACTIVE” protocol within the physiotherapy practices. Concerning the intervention group, practice 2 and 9 scored highest (both 10.50) and practice 11 scored lowest (7.67). Regarding practices treating patients in the control group, practice 7 scored highest (5.08) and practice 5 scored lowest (0.75). All three practices had significant differences between scores of their patients in the two research groups.

As can be seen the lowest score of the patients receiving “COPE ACTIVE” and the highest score of the patients receiving usual care were not treated by the same practice.

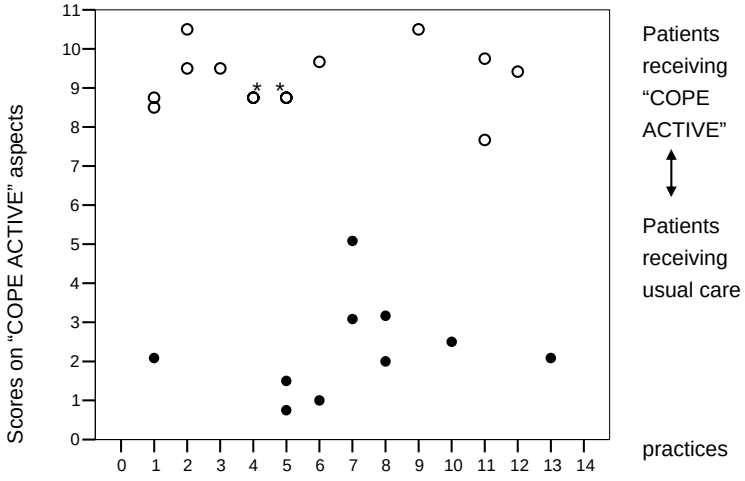

Figure 2. Patients’ scores per physiotherapy practice.

* Practices 4 and 5 both treated two “COPE ACTIVE” patients with exact the same score, so only one circle is visible.

Regarding potential contamination bias, on the one hand the discrepancy in scores of usual care patients between practices treating only usual care patients and practices treating both groups under study was measured. On the other hand the discrepancy in scores between research groups within one practice was measured. There were three practices that treated patients in both research groups. These practices (1, 5 and 6) had a mean discrepancy between the scores of their patient(s) receiving usual care and the scores of their patient(s) receiving “COPE ACTIVE” of 7.61. The difference within practices 1, 5, and 6 was 6.54, 7.62, and 8.67, respectively. The mean of scores of usual care patients treated by practice 1, 5 and 6 was 1.33 and the mean of other usual care patients was 2.99. This difference indicates usual care aspects were less applied at patients receiving usual in practices were both groups under study were treated.

Figure 3 depicts the distribution of the total scores concerning the ten aspects of the protocol in percentages (see table 1). With a range from 7 to 12 percent the share of every aspect in the

intervention group was roughly similar, which indicated all aspects were applied with comparable frequency in these patients. In the intervention group, aspect 8 (the determination of the kind of treatment in endurance exercises) scored lowest (7%). Of all aspects this one contributed least to the total scores. Aspect 4 (structural change within the exercises within physiotherapy sessions) scored highest (12%). This aspect contributed most to the total scores. In the control group, aspect 1, 2 and 3 together represent 64% of the total scores. This indicates that exposure of usual care subjects to COPE-active treatment is in the majority of cases caused by these three aspects of the COPE-active protocol. These aspects contain the frequency of session at the physiotherapist per week, the duration of one session at the physiotherapist and the kind of exercises instructed at the physiotherapy practice. Aspect 5 and 9 contributed least to the scores of the control group (4%). Finally, aspect 6 and 7 are not represented in the total scores of the control group. This indicates these are not applied at the treatment of patients receiving usual care.

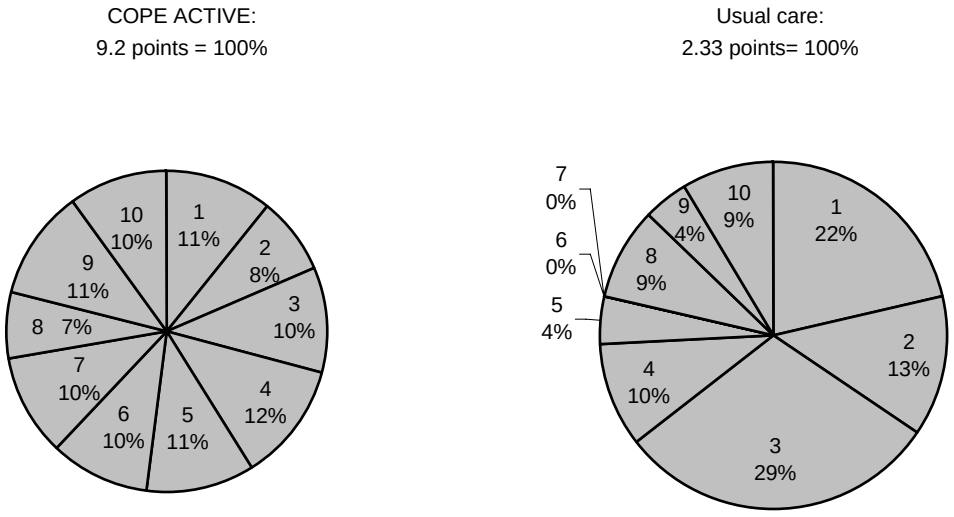

Figure 3. The distribution in percentages of the total score per research group in ten aspects of COPE active.

Discussion

This study suggests that in general the physiotherapists used the “COPE ACTIVE” protocol correctly. The compliance was considered high and there was a major discrepancy between the scores on the aspects of the treatment protocol of both groups under study.

Concerning compliance the mean score in the intervention group of 9.20 on a scale of 10.50 was considered extremely high, when a score of 10.00 means full implementation of the treatment protocol and 10.50 means the optional exercises are performed too. Hence, the observed mean score in the intervention group differed only 0.8 from the score indicating full implementation. The standard deviation in the intervention group differs with 0.47 from the control group. This can be explained by the great variation there is in usual care physiotherapy, while whereas the “COPE ACTIVE” physiotherapy program is defined in detail. Hence, a smaller standard deviation was expected in the “COPE ACTIVE” groups compared to the usual care groups.

The two practices that seemed to be least compliant, 7 and 11, treated a relatively good (practice 7) and bad (practice 11) patient concerning health. The less healthy patient, assigned to the COPE-active treatment, was unable to perform some exercises, while the more healthy patient, assigned to the usual care treatment, was able to perform a lot of exercises and improve fast. This might have caused the remarkable low score of the patients in the intervention group and the remarkable high score of the patient in the control group. There can be noted, that if these practices did not adhere to the treatment protocol, incompliant behaviour was expected at other patients in the practice too. But, because the other patients treated in practices 7 and 11 have much lower respectively higher scores, it is assumed compliance is not an issue here.

The ten aspects of the treatment protocol are almost similarly represented in the intervention group (see figure 3). This indicates physiotherapists seem to be compliant with every aspect of the treatment protocol.

Since there is no objective standard available of the contents of usual care physiotherapy, a clear conclusion about the extent to which the control group was contaminated with the treatment protocol can not be drawn. However, some assumptions can be made. First, there was a clear discrepancy between the scores of both groups under study of 6.87. Second, the mean score of the usual care patients of practices who treated both research groups was lower (1.33) than the mean scores of patients of practices who treated only patients in the control group (2.99). If contamination was involved, a higher mean score was expected of patients within practices treating both groups.

It is considered remarkable that usual care patients from practices that treated both groups

under study scored lower than patients from practices who treated only usual care patients. It is possible these lower scores are found, because patients of practices who treated both groups have received physiotherapy of lower quality than what usual care actually contains. While this leads to a greater discrepancy in observed scores between both groups under study, it is also possible aspects of the protocol of “COPE ACTIVE” are deliberately applied in the treatment of patients from practices who only treated usual care groups. This can be explained because physiotherapists might expect the “COPE ACTIVE” program, however it is not (yet) proved, has more benefits for their patients than regular physiotherapy programs. Another motivation for last described behaviour could be physiotherapists want to make a good impression at the patient’s lung doctor, expecting a good image might lead to more patients refered to them by the lung doctor. Consequently, that would lead to more income. Next to this, social desirability bias might be involved (28). Such behaviour would decrease the ability to demonstrate discrepancy between both research groups. But, since the results show a discrepancy in scores between both groups under study of 6.87, this kind of bias is not deemed to be involved.

Looking at the distribution of the score within the ten aspects of the treatment protocol, it is not likely contamination bias is involved. In the score of the control group, aspect 1, 2, and 3 form the majority of the total score. Hence, the question arises if these aspects of the treatment protocol were contaminated with the usual group. Aspect 1 concerned the frequency of physiotherapy sessions a week, aspect 2 the duration of one session at the physiotherapy practice and aspect 3 the kind of exercises performed in such session. This large share in the mean of the scores was expected concerning aspect 1 and 2, because these are not very unique for “COPE ACTIVE” according to the weights the expert assigned to them. The weight assigned to aspect 1 was 0.18; the weight assigned to aspect two was 0.23. These scores indicate both aspects are commonly used in usual care physiotherapy. Regarding the high weighing scores assigned to aspect 3 the following can be noted. Aspect 3 is about the combination of exercises. The combination itself is unique for the "COPE ACTIVE"protocol, but interview data revealed that some exercises within it are no: walking and cycling are often applied in usual care. These two exercises score partly, as every question in this aspect can provide a score of 0.25 (see table 1). This could explain the relative major share in the total scores.

Due to the used indirect method, data might be inaccurate. There are potential biases regarding the patients. Memory bias could be involved considering patients' rather high ages. Since the "COPE ACTIVE" program is complicated, patients receiving "COPE ACTIVE" groups are more likely to mistake than patients receiving usual care. Additionally, at the time of the interview "COPE ACTIVE" patients received their treatment for a short period of time, while usual care patients have received their physiotherapy for a long time. It is also possible questions were unclear to patients. However, since the interview questions were simple of nature (see Appendix A) and formulations are based on recent literature (31-34), this is not deemed to be a threat. Patients were blinded for the purpose of this study. In this way the influence of social desirability bias (28), meaning that patients tend to answer in a way they believe is socially acceptable and desirable, is minimized.

There was aimed for a high-quality performance of this study. First, before the start of this study the interviews were pre-tested with several individuals fitting the patients' features. Addition of questions about possible adjustments in exercises not included in the treatment protocol, made the questionnaire more feasible. Consequently, failures were tracked down. Therefore it can be assumed interviews were performed well. Second, the classification of aspects in which the items were distributed was done carefully. Third, the calculation methods were considered logical and accurate. Additionally can be noted that, since the treatment protocol the items of the interview were based on was detailed, there was only a small chance flaws occurred by making the questionnaire.

The developed method used in this study is rather simple and easy to adopt. It is suitable in situations where (1) patients with different treatments treated by the same health practitioner, (2) it concerns an intervention and a control group, (3) a treatment protocol is used, which is (4) pretested. However, a detailed treatment protocol is required, because that enables to formulate the items. Additionally, making dichotome answering to the items possible enables to construct an easy calculation method as used in this study.

The major discrepancy within both research groups in the extend of the use of the intervention indicates the execution of this knowledge-based implementation (35) was successful. The implementation is defined as a systemic and strategic introduction of evidence based innovations and/or mutations with the aim to give them a structural place in health care (26). It is one of the

aspects an innovation process exists of (36). There are several reasons for the apparently successful execution of the treatment protocol by physiotherapists. First, the implementation process is operated by the physiotherapists themselves, which makes it feasible and acceptable (23). Second, guidelines of the “COPE ACTIVE” protocol were well-designed (evidence-based), well prepared and pilot tested before use. Third, the program was built into the normal operating procedure and structures of physiotherapeutic programs within the physiotherapy practices (24). Another factor which determines the uptake and continued use of clinical guidelines is that the change in treatment according to the treatment protocol was significant, but rather easy to perform. Additionally, it can be noted that feedback is given on physiotherapists' performances by the researcher, which has been shown to increase implementation rates (23-25). Finally, it was important physiotherapists were willing to participate in the COPE II study. An important reason was that in physiotherapy there is a sense of urgency for scientific proof of physiotherapy treatment having positive effects on patients’ physical performances. Physiotherapists depend on the financial support of health insurance companies. Their participation to the study could contribute to get this required proof and secure the future of their practice. Besides this, participation enabled physiotherapists to upgrade their skills (becoming specialized in treating COPD patients). Since aspects mentioned above are performed well, it can be assumed the observed compliance is a result of that.

For measuring physiotherapists’ compliance an indirect method was used. Direct methods to measure adherence like direct observation are seldom used in studies with patients. Hence, in this study was chosen for an indirect method (37). Individual interviews were held at patients’ homes, because of the feasibility of it concerning their features (elderly lung patients). Interpersonal interaction, the ability to take time for the patients and the possibility to achieve greater dept and meaning of communication experiences enabled the researcher to gain the required information (38;39).

As a result of this study it can be concluded that in general physiotherapists complied with the treatment protocol to a large extent. Besides, there seemed to be no contamination of the treatments of both groups under study. However, in future studies measurement of the score on the protocol in the control group should be performed before the start of such a study. Since that would provide an

objective standard of the contents of usual care, clear conclusions about the extent to which the control group was contaminated with the treatment protocol then can be drawn. In this way, contamination bias can be determined exact in study designs in which this is a threat, like the COPE II study. Another improvement concerning the study design could be repetition of the study after a certain period. This would enable measurement of an important aspect of the innovation process: the maintenance of the implementation (40). When confirmation to the protocol during a period of time is determined, conclusions can be drawn about the success of the implementation over time. It is expected the control group becomes more contaminated with the treatment of the intervention group. In such a future study this expectation could be verified by comparing its results with the results of this study.

Another aspect is that in this study design it was not able to determine causes of problems with the compliance. Hence, qualitative methods like interviews with physiotherapists are considered appropriate to add to the study design. Since information about it enables researchers to improve the innovation process, addition of such interviews are deemed relevant. At last a larger sample is desirable as it would make results more precise.

Finally, a further (extensive) research about professionals' compliance can be of great importance in health-related studies. Understanding physiotherapists' compliance can be of help in successfully accomplishing innovations, of which implementation is an aspect. As professionals' compliance can affect the success of an implementation, knowledge of it is considered valuable. This article attempts to contribute to that.

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References

1. Feensta, T.L., Genugten, M.L. van, Hoogenveen, R.T., Wouters, E.F. and Rutten-van Molken, M.P. (2001). The impact of aging and smoking on the future burden of chronic obstructive pulmonary disease. *American Journal of Respiratory and Critical Care Medicine* 164 (4): 590-596.

2. Godfrey, S. and Barnes, P., J. (1997). *Chronic obstructive pulmonary disease.* London: Martin Dunitz.

3. Dekhuijzen, P. N. R. (2004). *COPD, chronisch obstructief longlijden.* Alphen aan den Rijn: Van Zuiden Communications B.V.

4. Barnes, P. J. (2000). Chronic obstructive pulmonary disease. *The New England Journal of Medicine* 343: 269-80.

5. Pauwels, R. A., Buist, A. S., Calverley, P. M., Jenkins, C. R., Hurd, S. S. (2001). Global strategy for the diagnosis, management and prevention of chronic obstructive pulmonary disease. *American journal of Respiratory Critical Care Medicine* 163: 1256-76.

6. Barnes P. J. (1998). New therapies for chronic obstructive disease. *Thorax* 53: 137-147.

7. Goldstein, R. S., Gort, E. H. and Stubbing, D. (1994). Randomized controlled trial of respiratory rehabilitation. *The Lancet* 93: 237-252.

8. Rooyackers, J.M., Dekhuijzen, P. N. R., Herwaarden., C. L. A. van, Folgering, H. T. M. (1997) in: Pulmonary rehabilitation in patients with severe chronic obstructive pulmonary disease. Van Rooyackers, J. M. Nijmegen: SSN pp. 97–140.

9. Griffiths, T.L., Burr, M. L., Cambell, I. A., Lewis-Jenkins, V., Mullins, J., Shiels, K., Turner-Lawlor, P. J., Payne, N., Newcombe, R. G., Lonescu, A. A., Thomas, J., Tunbridge, J. (2000). Results at one year of outpatients multidisciplinary pulmonary rehabilitation: a randomized controlled trial. *The Lancet* 355: 362-368.

10. Bourbeau, J., Julien, M., Maltais, F., Rouleau, M., Beaupre, A., Begin, R. (2003). Reduction of Hospital Utilization in Patients with Chronic Obstructive Pulmonary Disease: A Disease Specific Selfmanagement Intervention. *Archives of Internal Medicine* 163 (5): 585-591.

11. Monninkhof E, van der Aa M, van der Valk P, van der Palen J, Zielhuis G, Koning K, Pieterse M. (2004). COPE. A qualitative evaluation of a comprehensive self management programme for COPD patients: effectiveness from the patients' perspective. *Patient Education and Counseling* 55(2):177-84.

12. Bouter, L. M., Dongen, M. C. J. M. van. (1991). *Epidemiologisch onderzoek. Opzet en interpretatie* (2nd edition). Houten/Zaventem: Bohn Stafleu Van Loghum.

13. Haynes, R. B. (1997). Introduction. In: R. B. Haynes, D. W. Taylor and D. L. Sackett. *Compliance in health care.* Baltimore: Johns Hopkins University press.

14. Midence, K. and Myers, L. B. (1998) *Adherence to treatment in medical conditions.* Amsterdam: Harwood academic publishers.

15. Solberg, L.I.(2000). Guideline implementation: what the literature doesn't tell us. *The Joint Commission journal on quality improvement* 26 (9): 525-37.

16. Sheckler, W. E. & Bennet, J. V. (1970). Antibiotic usage in seven hospitals. *Journal of the American Medical Association* 213, 264-267.

17. Schleifer, S. J., Bhardwaj, S., Levobits, A., Tanaka, J. S., Messe, M. and Strain, J. J. (1991). Predictors of physician nonadherence to chemotherapy regimes. *Cancer* 67, 945-951.

18. O'Keefe, D. J. (2002), *Persuasion, Theory & Research*, 2nd edition, Thousand Oaks, California: Sage Publications.

19. Bandura, A. (1997). *Self-efficacy: The exercise of control*. New York: W.H. Freeman.

20. Bandura, A. (1982).Self-efficacy mechanisms in human agency. *American Psychologist*, 37, 122-147.

21. Gemert-Pijnen, J. van, Hendrix, M. G. R., Palen, J. van der, and Schellens, P. J. (2005). Performance of methicillin-resestant Staphylococcus aureus protocols in Dutch hospitals. *American journal of Infection Control* 33 (7): 377-384.

22. Ley, P. (1988). *Communicating with patients.* London: Croom Helm.

23. Grol, R. & Jones, R. (2000).Twenty years of implementation research. *Family Practice* 200; 17: S32-S35.

24. Grol, R. (2001). Successes and failures in the implementation of evidence-based guidelines for clinical practice. *Medical Care* 39 (8): II-46-II-54.

25. Hulscher,M., Wensing, M. and Grol, R. (2000). *Effectieve implementatie, theorieën en strategieën.* Den Haag: Zorgonderzoek Nederland.

26. Global Initiative for Chronic Obstructive Lung Disease. Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease. NHLBI/WHO workshop report. Bethesda, National Heart Lung and Blood Institute, April 2001; NIH Publication No 2701: 1-100.

27. Pauwels RA, Buist AS, Calverely PM. (2001). Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease. NHLBI/WHO Global Initiative for Chronic Obstructive Lung Disease (GOLD) Workshop Summary. *American journal of Respiratory and Critical Care Medicine* 163: 1256– 276.

28. Fisher, R. J. (1993). Social desirability bias and the validity of indirect questioning. *Journal of Consumer Research, 20*, 303-315.

29. Borg, GAV Psychophysical basis of perceived exertion. (1982). *Medicine and Science in Sports and Exercise* 14, 377-381.

30. Hart, H., (1997). *Onderzoeksmethoden (2nd edition).* Amsterdam: Boom.

31. Patton, M. Q. (1990). *Qualitative evaluation and research methods (2nd edition).* Newbury Park: Sage

32. Emans, B. (1990). *Interviewen. Theorie, techniek en training.* Groningen: Wolters-Noordhof.

33. Hargie, O & Tourish, D. (2002). *Handbook of communication audits for organisations.* New York: Routledge.

34. Steehouder, M. (1999). *Leren Communiceren. Handboek voor mondelinge en schriftelijke communicatie.* Groningen: Wolters-Noordhoff.

35. Rogers, E. M. (1983). *Diffusion of innovations.* New York: The Free Press.

36. Paulussen, T. G. W. (1994). *Adoption and implementation of AIDS education in Dutch secondary schools.* Utrecht: Landelijk Centrum GVO.

37. Myers, L. B. and Midence, K.(1998). *Adherence to treatment in medical conditions.* Amsterdam: Harwood academic publishers.

38. Hargie, O.and Tourish, D. (1999). The physiology of interpersonal skill. In A. Memon and R. Bull. *Handbook of the Psychology of Interviewing.* Chichester: Wiley.

39. King, N., Bailey, J., and Newton, P. (1994). Analyzing general practitioners' referral decisions. Developing an analytical framework. *Family practice* 11, 3-8.

40. Bartholomew, K., Parcel, G., Kok, G., & Gottlieb, N. (2001*). Intervention Mapping: Developing theory and evidence-based health education programs.* Mountain View, CA: Mayfield.

Appendix A

Part I – general questions

1. Which kind of physiotherapy do you receive?
2. At which physiotherapy practise do you train?
3. How many times a week do you train at your physiotherapist practise?
4. What is the duration of one physiotherapy session?
5. Which exercises are you told to perform at you physiotherapist practise?
6. Are you told to perform home exercises by your physiotherapist?
7. How many times a week do you have to perform home exercises?
8. Which exercises do you have to perform at home?

Part II – Physiotherapy sessions

IIa Not-"COPE ACTIVE" exercises:

1. Have you experienced changes in the exercise?
2. Could you describe the kind of change you experienced?
3. When do these changes take place?

IIb "COPE ACTIVE" exercises:

1. Is it correct you have to perform this exercise at you physiotherapy practice?
2. Do you have to perform the exercise every physiotherapy session?
3. How do you have to perform the exercise? (How many rehearsals, how many minutes, etc.)
4. Do you have to perform the exercise as one duration exercise or in certain intervals?
5. Have you experienced changes in the exercise?
6. Could you describe the kind of change you experienced?
7. When do these changes take place?
8. Does your physiotherapist ask you how you manage performing the exercise?
9. When does he ask you about this?
10. How does he ask this? (using BORG-scores)

Similar questions were asked to discuss other exercises at the physiotherapist practice.

Part III - Home exercises program

IIIa Not-"COPE ACTIVE" exercises:

1. Have you experienced changes in the exercise?
2. Could you describe the kind of change you experienced?
3. When do these changes take place?

IIIb "COPE ACTIVE" exercises:

1. Is it correct you have to perform this exercise at you physiotherapy practice?
2. Do you have to perform the exercise every physiotherapy session?
3. How do you have to perform the exercise? (How many rehearsals, how many minutes, etc.)
4. Do you have to perform the exercise as one duration exercise or in certain intervals?
5. Have you experienced changes in the exercise?
6. Could you describe the kind of change you experienced?
   When do these changes take place?

Similar questions were asked to discuss other exercises of the home exercise program.