Short- and long-term effects of a physical activity counselling programme in COPD: A randomized controlled trial

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KEYWORDS
COPD; Behaviour modification; Exercise capacity; Health related quality of life; Randomized controlled trial

Summary
Background: We were interested in the effects of a physical activity (PA) counselling programme in three groups of COPD patients from general practice (primary care), outpatient clinic (secondary care) and pulmonary rehabilitation (PR).

Methods: In this randomized controlled trial 155 COPD patients, 102 males, median (IQR) age 62 (54–69) y, FEV1 predicted 60 (40–75) % were assigned to a 12-weeks’ physical activity counselling programme or usual care. Physical activity (pedometer (Yamax SW200) and metabolic equivalents), exercise capacity (6-min walking distance) and quality of life (Chronic Respiratory Questionnaire and Clinical COPD Questionnaire) were assessed at baseline, after three and 15 months.

Results: A significant difference between the counselling and usual care group in daily steps (803 steps, \( p = 0.001 \)) and daily physical activity (2214 steps + equivalents, \( p = 0.001 \)) from 0 to 3 months was found in the total group, as well as in the outpatient (1816 steps, 2616 steps + equivalents, both \( p = 0.007 \)) and PR (758 steps, 2151 steps + equivalents, both \( p = 0.03 \)) subgroups. From 0 to 15 months no differences were found in physical activity. However, when patients with baseline physical activity >10,000 steps per day (n = 8), who are
Introduction

Patients with COPD in general show a less active lifestyle than healthy subjects [1-6] which is already present in mild disease [7]. Low physical activity levels are clinically relevant in COPD as they are associated with lower quality of life [3], more frequent hospitalisations and higher mortality [8]. A downward circle of dyspnoea induced physical inactivity and deconditioning is thought to be responsible for developing psychosocial problems such as depression and social isolation [9]. Up to now, several strategies have been proposed to increase physical activity in COPD, such as exercise training alone or in combination with a self management programme [10,11]. An alternative strategy to improve physical activity levels might be to aim at enhancing lifestyle physical activity instead of focussing on exercise training.

The intensity level of lifestyle physical activities, such as walking, gardening and housekeeping in general is moderate, which makes it attractive for patients with COPD with reduced ventilatory capacity, because vigorous intensity often causes feelings of dyspnoea and muscle fatigue. In this respect lifestyle physical activity is well assessed using pedometers or more sophisticated activity monitors, which can even be used as an intervention tool for increasing daily physical activity, showing positive results at least in patients with diabetes type II [12-15]. Inspired by these studies, we developed a pedometer-based physical activity counselling programme using cognitive behavioural strategies [16], aiming at enhancement and incorporation of physical activities of moderate intensity in daily life. The counselling programme has been studied in two pilot studies in two different COPD populations, namely patients from the outpatient clinic [17] and patients following PR [18], and suggested an increase in physical activity after 3 months in the counselling group compared to usual care.

Our hypothesis for the current study is that the counselling programme will result in an increase in physical activity in COPD patients, in the short as well as long term. This hypothesis was tested in three groups of COPD patients: patients from general practices (primary care), outpatient clinics (secondary care), and patients following a PR programme. In the last group, the counselling programme was additional to the conventional pulmonary rehabilitation programme.

Methods

Study design

The study design was randomized and controlled, as patients were assigned to a physical activity counselling programme or usual care. Randomization was computerized and patients were allocated to counselling or usual care group in a 1:1 ratio, with minimization for age (<60/≥60 years), FEV₁ (<50/≥50% predicted) and sex (male/female). Allocation was open to the researcher, counsellor and patient. Patients were recruited from general practices (primary care), outpatient hospital clinics (secondary care) and a pulmonary rehabilitation centre (PR), all in the Netherlands, from 2007 till 2009. The last follow-up measurement was performed in December 2010. The study was approved by the medical ethical committee of the University Medical Center Groningen and all participating patients signed a written informed consent form. The trial was registered with ClinicalTrials.gov: registration number NCT00614796.

Subjects

Inclusion criteria were COPD according to the GOLD Guidelines and age between 40 and 80 years. Excluded were patients with comorbidities which severely limited physical activity, such as severe orthopaedic or neurological disorders or heart failure or having exacerbations or respiratory tract infections within two months prior to the study.

Intervention

Patients in the counselling group participated in a 12-weeks’ customized lifestyle physical activity counselling programme designed to enhance physical activity in COPD patients, which is described in more detail elsewhere [17,18]. Lifestyle physical activity in our study comprised all activities in daily life, including leisure time, occupational and household activity. Patients were free to choose type, time point and location of activity to enhance their physical activity level. Patients received the physical activity counselling programme in addition to usual care. Two trained exercise counsellors performed all counselling. The

Conclusion: Our PA counselling programme effectively enhances PA level in COPD patients after three months. Sedentary patients at baseline still benefit after 15 months.

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individual counselling was predominantly based on principles of goal-setting and implementation of goals [16] and motivational interviewing techniques were used. Patients wore a pedometer all day during the intervention period, which was used for feedback and motivation. A diary was kept with steps taken and activities other than steps (e.g. cycling, swimming etc.) were noted as well. Patients in the counselling group attended 5 individual 30 min counselling sessions spread over 3 months. Counselling took place in the setting where patients were recruited. The usual care group received care appropriate to their health status. For the PR group usual care included a multidisciplinary PR programme, which consisted of 9 weeks of exercise training, 3 sessions a week, with a duration of 1–2 h per session. Training forms used to achieve increased exercise capacity were cycling, walking, swimming and sports. In addition, patients followed educational courses and received psychological and/or nutritional support if necessary.

Measurements

All measurements took place prior to the intervention (baseline), at the end of the intervention (3 months after baseline) and 15 months after baseline. In the PR group baseline meant prior to the intervention and prior to PR, as the physical activity counselling started together with PR. Lung function and bio-impedance were measured at baseline and 15 months after baseline.

Primary outcome measures

Physical activity was assessed in all patients in daily steps using a pedometer (Digiwalker SW-2000, Yamax; Tokyo Japan) and in daily physical activity [19]. The Compendium of physical activities of Ainsworth et al. was used to calculate metabolic equivalents for cycling, (cardio)fitness and swimming [20,21]. A step equivalent is defined as the physical activity with the energy expenditure of one step. At each measurement point patients from the counselling as well as the usual care group wore a pedometer during two weeks, from waking up until going to bed, and recorded number of steps per day and other activities (minutes per day) in a diary. The mean of the last week of steps was used for further analysis. Data were only used when at least 5 days of 7 were filled out.

Secondary outcome measures

Spirometry was performed according to standardized guidelines (Jaeger MS-IOS). Fat free mass was measured with bioelectrical impedance analysis (Bodystat 1500) [22]. Patients performed a 6-min walking distance (6MWD) test to measure submaximal exercise capacity [23]. General health status was assessed by the Short Form 36 (SF-36) and disease specific health status by the Clinical COPD Questionnaire (CCQ) and the Chronic Respiratory Questionnaire (CRQ) [24–26]. Fatigue was assessed by the Dutch Exertion and Fatigue Scale (DEFS) [27]. Anxiety and depression were assessed by the Hospital Anxiety and Depression Scale (HADS) [28]. Self-efficacy was assessed by the Perceived Physical Ability Subscale (PPAS, Dutch version) (10 items) of the physical self-efficacy scale [29]. Intrinsic motivation for physical activity was assessed by the Self Regulation Questionnaire for Exercise (SRQ-E) [30].

Statistical analyses

Characteristics are shown as median (IQR) due to non-normal distribution of outcome variables. Sample size calculations for this two-armed study were based on changes in steps found in one of our pilot studies using an increase of 2000 steps/day (SD 4017 steps/day) [17]. To have a two-sided significance of $p < 0.05$ at a power of $\beta = 0.80$ 130 patients were needed. To compensate for expected dropout 20% extra patients were included. Because of non-normality of data, differences between counselling and usual care group were tested with a Mann–Whitney U test for 0 to 3 months and 0 to 15 months for the total group and subsequently for the three healthcare settings separately.

To assess the associations between the different outcome measures Spearman’s correlations were calculated between change scores of daily steps, daily physical activity, 6MWD, CRQ and CCQ in the counselling group.

All statistical analyses were performed using Scientific Package of Social Sciences (SPSS) version 18.0. $P$-values $<0.05$ were considered to be significant.

Results

In total 173 patients were screened and 155 were randomized. A detailed flow diagram of the study is shown in Figure 1, including information on reasons of dropout. The dropout rate from the counselling group (29.9%) did not differ significantly from that in the usual care group (27.6%). Baseline characteristics of the total group and the three subgroups are shown in Table 1. Patients in the PR group were significantly younger, less physically active, had a higher RV%TLC, and had worse sumscore on the CRQ than patients in the primary care or secondary care group. Additionally, all the groups differed from each other in FEV1% predicted, FEV1% FVC, 6MWD and CCQ sumscore. Table 2 shows the characteristics of the counselling and usual care group at different measurement points.

Effects of physical activity counselling programme

Primary outcomes

The changes in daily steps and daily physical activity, from 0 to 3 months and 0 to 15 months are presented in Table 3 and Figures 2 and 3. Daily steps and daily physical activity significantly increased after 3 months in the counselling group compared to usual care; subgroup analysis showed significant changes in the secondary care and PR groups. After 15 months a trend for increased physical activity level ($p = 0.062$) was found in the total group but not in the subgroups. When we excluded patients with a baseline daily steps level $>10,000$/day, who can be considered to be sufficiently active already, a significant long-term difference in daily physical activity, between counselling and usual care in the total group could indeed be demonstrated ($p = 0.017$) (online Table 1).
Secondary outcomes

Overall, no significant changes in secondary outcome variables were found except for the improvements in 6MWD ($p = 0.049$) and CRQ sumscore ($p = 0.006$) after 3 months in the secondary care group (see online Table 2).

There were no significant correlations between changes in physical activity (daily steps and daily physical activity) and changes in 6MWD, CRQ, CCQ, neither for the total group (see online Table 3), nor for the subgroups.

Discussion

This study demonstrates that the physical activity counselling programme effectively increased daily step count and daily physical activity after 3 months compared to usual care. The median difference between counselling and usual care was 803 steps (13% increase in the counselling group, 4% decrease in usual care), and 2214 step equivalents, (22% increase in the counselling group, 12% decrease
in usual care). A trend for increased daily physical activity after 15 months was found in the total group \( p = 0.062 \); when patients with a baseline daily steps level \( \geq 10,000 \) per day, who can be considered to be sufficiently physically active already, were excluded, the long-term effect of the counselling on daily physical activity was statistically significant. No effect was shown on exercise capacity and quality of life except for the change in 6MWD and CRQ scores after 3 months in the secondary care group. This group benefitted most as it showed the largest improvements (1816 daily steps and 2616 steps + step equivalents). Dropout rates were rather high, but did not differ from those in usual care.

Physical activity counselling studies have demonstrated positive results in other disease populations [31–35]. Content and duration of the interventions differed, which may explain differences in effectiveness. Fibromyalgia patients were stimulated to achieve 30 min of moderate-intensity activity per day and reported a decrease in perceived functional deficits and pain and an increase in physical activity after 12 weeks that could not be maintained after 6 and 12 months [31]. A pedometer-based telephone intervention of 6 weeks in cardiac patients resulted in an increase in physical activity, which was still present after 6 months [35]. It is generally acknowledged that behavioural change programmes are more likely to succeed when the intervention period is longer than 6 months. The Stages of Change model suggests that a person, who tries to change behaviour, should start and stay in the ‘action’ phase for about six months before entering the ‘maintenance’ phase [36]. Two recent studies with longer intervention periods indeed showed sustained effects. A home-based programme of 11 months aimed at integrating physical activity into daily routine supported by telephone calls compared to regular supervised exercise training and a control group of sedentary older subjects [33]. The lifestyle intervention group in this study showed improvements in physical activity, functional performance and cardiorespiratory fitness, directly after the intervention which was maintained after 12 months [33,34]. A 24 weeks’ pedometer-based intervention in diabetes type 2 patients resulted in an increased activity pattern, which was maintained after one year [32]. In COPD a six months period of PR was necessary to increase physical activity, although three months of rehabilitation was sufficient to improve exercise capacity and quality of life [37]. This also suggests that longer intervention periods are needed to improve physical activity in COPD patients.

In our study, significant changes in physical activity level between counselling and usual care group were shown in the secondary care group and the PR group, whereas no significant change was found in the primary care group. We suggest that this difference is caused by differences in severity of disease between these three groups. A number of behavioural change theories, like the Health Belief Model, the Self Determination Theory and the Goal Setting theory, suggest that individuals are only motivated to change behaviour, when they fear health consequences of an unhealthy lifestyle or expect benefits of behavioural change [38–40]. Patients with less severe disease, such as those in the primary care group, suffer less from their disease and it may therefore be less likely that they change...
### Table 2  Characteristics of counselling vs. usual care group on the three measurement points of the study.

<table>
<thead>
<tr>
<th></th>
<th>Total group</th>
<th>Baseline (n = 155)</th>
<th>3 months (n = 120)</th>
<th>15 months (n = 101)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Counselling (n = 78)</td>
<td>Usual care (n = 77)</td>
<td>Counselling (n = 65)</td>
</tr>
<tr>
<td>Daily steps (n)</td>
<td></td>
<td>4292 (2182–6596)</td>
<td>4132 (2979–6030)</td>
<td>5751 (3598–7238)</td>
</tr>
<tr>
<td>Daily physical activity (n)*</td>
<td></td>
<td>6563 (3919–8847)</td>
<td>6238 (4530–8986)</td>
<td>8239 (5453–10,207)</td>
</tr>
<tr>
<td>6MWD (m)</td>
<td></td>
<td>454 (361–509)</td>
<td>450 (351–530)</td>
<td>484 (416–555)</td>
</tr>
<tr>
<td>CRQ</td>
<td></td>
<td>102 (86–118)</td>
<td>109 (87–119)</td>
<td>114 (96–126)</td>
</tr>
<tr>
<td>CCQ</td>
<td></td>
<td>1.40 (0.85–2.20)</td>
<td>1.35 (0.70–2.28)</td>
<td>1.00 (0.50–1.80)</td>
</tr>
<tr>
<td><strong>Primary care</strong></td>
<td></td>
<td>(n = 24)</td>
<td>(n = 24)</td>
<td>(n = 22)</td>
</tr>
<tr>
<td>Daily steps (n)</td>
<td></td>
<td>5961 (3788–8243)</td>
<td>4785 (2850–6757)</td>
<td>6540 (5252–8619)</td>
</tr>
<tr>
<td>Daily physical activity (n)*</td>
<td></td>
<td>8043 (6111–10,567)</td>
<td>6202 (3583–9205)</td>
<td>8857 (7703–10,747)</td>
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<tr>
<td>6MWD (m)</td>
<td></td>
<td>508 (475–600)</td>
<td>519 (443–587)</td>
<td>550 (485–633)</td>
</tr>
<tr>
<td>CRQ</td>
<td></td>
<td>118 (102–134)</td>
<td>116 (103–125)</td>
<td>131 (118–135)</td>
</tr>
<tr>
<td>CCQ</td>
<td></td>
<td>0.80 (0.20–1.30)</td>
<td>0.70 (0.40–1.20)</td>
<td>0.40 (0.20–0.95)</td>
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<tr>
<td><strong>Secondary care</strong></td>
<td></td>
<td>(n = 23)</td>
<td>(n = 23)</td>
<td>(n = 21)</td>
</tr>
<tr>
<td>Daily steps (n)</td>
<td></td>
<td>4820 (2526–6563)</td>
<td>4285 (3609–6292)</td>
<td>5751 (3801–9701)</td>
</tr>
<tr>
<td>Daily physical activity (n)*</td>
<td></td>
<td>5816 (3863–8880)</td>
<td>5536 (4490–9315)</td>
<td>8685 (5453–12,647)</td>
</tr>
<tr>
<td>6MWD (m)</td>
<td></td>
<td>457 (364–506)</td>
<td>444 (418–533)</td>
<td>480 (443–533)</td>
</tr>
<tr>
<td>CRQ</td>
<td></td>
<td>107 (102–122)</td>
<td>114 (88–124)</td>
<td>111 (94–121)</td>
</tr>
<tr>
<td>CCQ</td>
<td></td>
<td>1.40 (0.902.10)</td>
<td>1.20 (0.80–1.70)</td>
<td>1.50 (0.85–1.95)</td>
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<tr>
<td>PR</td>
<td></td>
<td>(n = 31)</td>
<td>(n = 30)</td>
<td>(n = 22)</td>
</tr>
<tr>
<td>Daily steps (n)</td>
<td></td>
<td>2276 (1883–4800)</td>
<td>3668 (2581–5389)</td>
<td>4138 (2599–6413)</td>
</tr>
<tr>
<td>Daily physical activity (n)*</td>
<td></td>
<td>5110 (3291–7579)</td>
<td>7371 (4951–8835)</td>
<td>6423 (4735–8414)</td>
</tr>
<tr>
<td>6MWD (m)</td>
<td></td>
<td>395 (270–451)</td>
<td>351 (270–461)</td>
<td>419 (284–483)</td>
</tr>
<tr>
<td>CRQ</td>
<td></td>
<td>86 (77–98)</td>
<td>90 (77–109)</td>
<td>101 (92–116)</td>
</tr>
<tr>
<td>CCQ</td>
<td></td>
<td>2.15 (1.28–3.23)</td>
<td>2.30 (1.45–2.90)</td>
<td>1.75 (0.98–2.30)</td>
</tr>
</tbody>
</table>

PR: Pulmonary Rehabilitation; 6MWD: 6 min walking distance; CRQ: Chronic Respiratory Questionnaire; CCQ: Clinical COPD Questionnaire.

*Steps + metabolic equivalents.
their activity pattern. In addition these patients generally had already higher baseline physical activity levels, leaving less room for improvement than in patients with more severe disease, indicating that interventions aiming at physical activity are probably more beneficial in patients with more severe disease.

The effects of the physical activity counselling programme on physical activity were not well maintained after 15 months, though a clear trend was shown ($p < 0.062$) towards positive effects. In line with that, when excluding patients with a baseline step level $>10,000$, who can be considered as sufficiently active already, a significant long-term change in the counselling group compared to usual care was found. Our suggestion for the PR group that improvements in exercise capacity and muscle function, induced by PR, could be maintained in presence of a more active lifestyle after PR, was not proven. Our interpretation of these findings is that patients in the PR group had more severe COPD, making them more frail and susceptible to exacerbations greatly influencing their physical activity level. The high number of dropouts (45% from the counselling arm of the study) in the PR group supports this explanation, but also hinders firm conclusions. For the

<table>
<thead>
<tr>
<th>Table 3</th>
<th>Changes in daily physical activity after 3 and after 15 months.</th>
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<tbody>
<tr>
<td></td>
<td>Daily steps</td>
</tr>
<tr>
<td></td>
<td>Counselling</td>
</tr>
<tr>
<td>Total group</td>
<td></td>
</tr>
<tr>
<td>0–3 months</td>
<td>618 (−137–1771)</td>
</tr>
<tr>
<td>0–15 months</td>
<td>218 (−1423–1863)</td>
</tr>
<tr>
<td>Primary care</td>
<td></td>
</tr>
<tr>
<td>0–3 months</td>
<td>537 (−611–1740)</td>
</tr>
<tr>
<td>0–15 months</td>
<td>157 (−1679–994)</td>
</tr>
<tr>
<td>Secondary care</td>
<td></td>
</tr>
<tr>
<td>0–3 months</td>
<td>1002 (−612–3077)</td>
</tr>
<tr>
<td>0–15 months</td>
<td>1128 (−1322–2707)</td>
</tr>
<tr>
<td>PR</td>
<td></td>
</tr>
<tr>
<td>0–3 months</td>
<td>547 (187–1323)</td>
</tr>
<tr>
<td>0–15 months</td>
<td>−569 (−2512–1551)</td>
</tr>
</tbody>
</table>

Values are presented as median (IQR), change expressed as percentage of the initial value, $p$-value $<0.05$ printed bold.

<sup>a</sup> Steps $+$ metabolic equivalents.

Figure 2 | a–d. Change in daily steps throughout the total study period for: a) total group, b) primary care, c) secondary care, d) pulmonary rehabilitation. * indicating a significant difference between counselling and usual care.

Figure 3 | a–d. Change in daily physical activity throughout the total study period for: a) total group, b) primary care, c) secondary care, d) pulmonary rehabilitation. * indicating a significant difference between counselling and usual care.
secondary care group long-term results were somewhat better but not significant. Apparently, maintaining an active lifestyle is much more challenging than starting it.

Our physical activity counselling programme had only limited effect on secondary outcomes, like the improvement of 6MWD and CRQ score in the secondary care group after 3 months. This may off course be due to type 1 errors, as this study was powered to detect relevant change in steps and not in quality of life or exercise capacity. However some other explanations are possible. In the primary care setting this absence of effect may be due to a higher baseline physical activity level, CRQ sumscore and 6MWD (95% of predicted) in these patients, which leaves not much room for improvement. On the other hand, in the PR group, both treatment arms received physical training and psychosocial education, which may have limited the additional benefits of our physical activity counselling programme on exercise capacity and quality of life. In general, an increase in physical activity might not easily be translated into additional improvements in quality of life and exercise capacity, which is supported by the weak and non-significant correlations between both in our study. On the other hand, exercising on moderate intensity, the intensity of most lifestyle physical activity, for 15 min/day or 90 min/week already reduces all cause mortality with 14% and increased life expectancy with 3 years in the general population [41]. Every additional increase of 15 min of physical activity beyond this minimum of 15 min/day further reduced all cause mortality by 4%. Thus, the relationships between PA on the one hand, and quality of life, physical fitness and mortality on the other hand are not fully elucidated and further studies in the general population as well as in COPD are definitely needed.

Our study design has particular strengths and weaknesses. A strong point is that a broad range of COPD patients was included, with three well-defined subgroups, which enables generalization of outcomes. Another strong point is that not only short-term but also long-term effects of a physical activity counselling programme in COPD were studied: the absence of significant long-term effects emphasizes the need for developing interventions for maintenance of beneficial effects of counselling such as in the present study. And finally the tool for intervention and measurement of the primary outcome variable, physical activity, was the same namely the pedometer, which obtains actual values of walking, an important form of physical activity.

Some limitations should be mentioned. Firstly, the pedometer we used does not measure non-ambulatory physical activity like cycling or swimming. We chose to calculate step equivalents from activities that could not be measured by the pedometer and were noted in activity diaries in minutes/day [20,42].

Secondly, usual care was not the same for all subgroups, as patients in the PR group additionally received PR. As the power calculation was based on a pilot study in which counselling was the single treatment, the power for this study would theoretically be lower. Despite this we found a significant short-term effect of the counselling on physical activity.

For clinical practice the results of our study show that pedometer based counselling is a useful tool in the treatment of COPD patients in various settings. It can be used as a single treatment option in less severe COPD patients, but also be part of a regular PR programme, adjunct to exercise training and other psychosocial interventions. We suggest that more feedback moments over a longer period could make the intervention more effective in the long term. It has been demonstrated that adherence counselling after PR leads to maintenance of increases of daily activity, exercise adherence and exercise capacity after 1 year [43]. Furthermore, we suggest that in primary care patients should be selected more specifically for having low baseline physical activity, low exercise capacity and/or high motivation for physical activity.

In developing other physical activity counselling programmes modern tools for real time feedback may be used, such as sound or visual signals from a pedometer, accelerometer or smartphone. The feasibility of using an accelerometer and pedometer integrated into a mobile phone to support exercise training and physical activity has already been investigated in cardiac patients and the effects will be further investigated in a randomized controlled trial [44].

In conclusion, our study shows that a 12 weeks’ physical activity counselling programme enhances physical activity level in COPD patients in the short term, which is maintained at 15 months in patients with baseline daily step count <10,000 steps per day. The effects were most prominent in patients attending the outpatient clinic. Physical activity counselling might be used in various healthcare settings.

Conflicts of interest

All authors declare to have no conflicts of interest.

Acknowledgements and funding

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WA had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis, including and especially any adverse effects. JW, Nth, and MdG participated in the study design. WA and LB collected the data. WA and MdG performed statistical analysis. WA, JW, MdG, Nth and HK interpreted the data. All authors participated in writing the manuscript and approved the final version of the manuscript.

Appendix A. Supplementary data

Supplementary data related to this article can be found at http://dx.doi.org/10.1016/j.rmed.2014.10.020.

References


