Universidade de Aveiro Departamento de Ciências Médicas
2016

JOANA PATRÍCIA DOS SANTOS CRUZ

AUTOGESTÃO NA REABILITAÇÃO DE PACIENTES COM DOENÇA PULMONAR OBSTRUTIVA CRÓNICA: O PAPEL DA TELEMONITORIZAÇÃO E ATIVIDADE FÍSICA

SELF-MANAGEMENT IN THE REHABILITATION OF PATIENTS WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE: THE ROLE OF TELEMONITORING AND PHYSICAL ACTIVITY

Universidade de Aveiro Departamento de Ciências Médicas
2016

JOANA PATRÍCIA DOS SANTOS CRUZ

AUTOGESTÃO NA REABILITAÇÃO DE PACIENTES COM DOENÇA PULMONAR OBSTRUTIVA CRÓNICA: O PAPEL DA TELEMONITORIZAÇÃO E ATIVIDADE FÍSICA

SELF-MANAGEMENT IN THE REHABILITATION OF PATIENTS WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE: THE ROLE OF TELEMONITORING AND PHYSICAL ACTIVITY

Tese apresentada à Universidade de Aveiro para cumprimento dos requisitos necessários à obtenção do grau de Doutor em Ciências e Tecnologias da Saúde, realizada sob a orientação científica da Doutora Alda Sofia Pires de Dias Marques, Professora Adjunta na Escola Superior de Saúde da Universidade de Aveiro, e coorientação da Doutora Dina Brooks, Professora Catedrática no Departamento de Fisioterapia da Universidade de Toronto.

Apoio financeiro da Fundação para a Ciência e Tecnologia do Ministério da Ciência, Tecnologia e Ensino Superior, e do Fundo Social Europeu, no âmbito do POPH-QREN – Formação Avançada – Tipologia 4.1. (Referência SFRH/BD/81328/2011).

Dedico este trabalho ao meu pai

o júri

presidente

Prof. Doutor Joaquim Manuel Vieira
Professor Catedrático do Departamento de Engenharia Cerâmica e do Vidro da Universidade de Aveiro

Prof. Doutora Maria Cristina de Brito Eusébio Bárbara Prista Caetano
Professora Associada com Agregação Convidada da Faculdade de Medicina da Universidade de Lisboa

Prof. Doutor Paulo Alexandre Silva Armada da Silva
Professor Auxiliar da Faculdade de Motricidade Humana da Universidade de Lisboa

Prof. Doutor Rui Alberto Fernandes Antunes Viana
Professor Auxiliar da Faculdade de Ciências da Saúde da Universidade Fernando Pessoa

Prof. Doutora Alda Sofia Pires de Dias Marques
Professora Adjunta da Escola Superior de Saúde da Universidade de Aveiro

Prof. Doutora Paula Maria Gonçalves Pinto
Professora Auxiliar Convidada da Faculdade de Medicina da Universidade de Lisboa

agradecimentos

A realização deste trabalho não teria sido possível sem o apoio, incentivo e colaboração de várias pessoas, às quais expresso aqui o meu sincero agradecimento.

Agradeço aos participantes e instituições envolvidas nesta investigação o tempo e disponibilidade dispensados. Sem eles, este trabalho não teria sido possível.

Agradeço à minha orientadora, Professora Doutora Alda Marques, por me ter acompanhado nesta difícil jornada (mesmo antes de ela começar). Admiro-lhe a competência, a perseverança e a resiliência, pois ajudaram-me a chegar até aqui. Obrigada pela sua disponibilidade e paciência, pelas interessantes discussões que tivemos, pelos momentos de descontração e, sobretudo, pela amizade que construímos. Foi um privilégio poder trabalhar consigo.

Agradeço à minha coorientadora, Professora Doutora Dina Brooks, pelos conselhos e ideias partilhadas ao longo deste percurso. Foi importante para mim ter o reconhecimento de alguém com tão extensa contribuição nesta área.

Agradeço à Dr.ª Lurdes a paciência, carinho e disponibilidade que demonstrou desde o início. O seu apoio foi (e continua a ser) fundamental para a equipa de investigação da qual faço parte.

Agradeço às colegas (mas sobretudo, amigas) Anita, Cristina, Aninha, Giovana Tânia e Marlene, que estiveram comigo em vários momentos e que partilharam os meus anseios, dificuldades, expectativas e alegrias que fui vivenciando ao longo destes quatro anos. Sem vocês esta jornada não teria sido tão agradável! Um especial agradecimento à Cristina por termos trabalhado juntas neste desafio, pelas discussões maioritariamente saudáveis que tivemos e pela sua enorme energia que me foi contagiando durante este processo.

Agradeço ao Nuno, o meu grande companheiro nesta e em outras jornadas. Obrigado por acreditares em mim, por enriqueceres o meu trabalho com os teus comentários, pelas discussões científicas que tivemos e, acima de tudo, por estares ao meu lado neste percurso por vezes sinuoso. O teu incentivo, apoio e encorajamento foram fundamentais para a realização deste trabalho.

Agradeço à minha filha Carolina por me ajudar a 'colocar o trabalho no seu lugar' e por me dar ânimo e energia para concluir esta etapa. A defesa da tese não teria um gosto tão especial se ela não existisse.

Agradeço à restante família, em especial aos meus pais, porque não teria conseguido chegar até aqui se não tivesse tido tão bons exemplos de vida. Obrigado por me ajudarem a ser quem sou hoje.

Por fim, agradeço a todos os meus amigos em geral pelo apoio que me proporcionaram e por compreenderem as minhas ausências ocasionais para trabalhar no doutoramento.

Life gives us the opportunities,
we make them happen...

palavras-chave

Doença Pulmonar Obstrutiva Crónica, gestão da doença, atividade física, rehabilitação, auto-monitorização, tele-saúde, marcha.

resumo

A autogestão tem sido reconhecida como parte fundamental da gestão da Doença Pulmonar Obstrutiva Crónica (DPOC). No entanto, a evidência deste tipo de intervenções é ainda limitada. Esta Tese tem como objetivo compreender se as intervenções de autogestão podem ajudar os pacientes com DPOC a gerir melhor a sua doença e se têm um impacto significativo na sua saúde. Especificamente, esta Tese pretendeu: (i) aprofundar o papel da telemonitorização no domicílio para reduzir a frequência de exacerbações e a utilização de cuidados de saúde por parte dos pacientes com DPOC, bem como melhorar os resultados relacionados com a saúde; e (ii) investigar o impacto de uma intervenção comportamental para a promoção da atividade física (AF) em pacientes com DPOC (Walk2Bactive) durante e após um programa de reabilitação respiratória (RR). Foram realizados cinco estudos. Duas revisões sistemáticas (Capítulo 3) responderam ao primeiro objetivo desta Tese, sistematizando o conhecimento acerca da telemonitorização no domicílio no que diz respeito à sua eficácia, metodologias, adesão e satisfação de pacientes com DPOC. Os resultados revelaram que ainda não existe uma indicação clara de que a telemonitorização no domicílio produz melhorias nos resultados de saúde e na redução da utilização de cuidados de saúde em pacientes com DPOC. O número reduzido de participantes e a tecnologia utilizada em alguns estudos pode ter influenciado estes resultados. Assim, existe a necessidade de mais investigação nesta área antes de a telemonitorização poder ser incorporada na prática clínica. O segundo objetivo desta Tese foi alcançado através de três estudos originais. O primeiro estudo (Capítulo 4) avaliou a precisão dos monitores de AF (pedómetro Yamax PW/EX-510, acelerómetro GT3X+) utilizados no estudo piloto (Capítulo 5) e estudo principal (Capítulo 6). Os resultados principais sugerem que a intervenção comportamental para a promoção da AF pode ajudar os pacientes com DPOC a alcançar um estilo de vida mais ativo. No entanto, não produz melhorias nos resultados relacionados com a saúde. É necessário realizar investigação mais robusta nesta área para corroborar estes resultados e avaliar os efeitos da intervenção a curto e longo prazo. Em suma, o papel da autogestão na DPOC através da telemonitorização no domicílio e de uma intervenção comportamental para a promoção da AF ainda não é totalmente compreendido. Esta Tese contribuiu para avançar o conhecimento nesta área e apresenta recomendações importantes para pesquisas futuras.

keywords

Chronic Obstructive Pulmonary Disease, disease management, physical activity, rehabilitation, self-monitoring, telehealth, walking.

abstract

Self-management has been acknowledged as a critical part of Chronic Obstructive Pulmonary Disease (COPD) management. However, evidence to support this type of intervention is still limited. This Thesis focuses on understanding whether self-management interventions can support patients with COPD to manage their disease and impact significantly on their health. Specifically, it aimed to: (i) gain more insight on the role of home telemonitoring to reduce the frequency of COPD exacerbations and healthcare utilisation and improve health-related outcomes; and (ii) investigate the impact of a physical activity (PA)-focused behaviour intervention combined with pulmonary rehabilitation (PR) on patients with COPD. Five studies were conducted. Two systematic reviews (Chapter 3) addressed the first aim of this Thesis by updating the body of evidence on home telemonitoring in COPD regarding its effectiveness, methodologies, patients' adherence and satisfaction. Findings showed that there is still no clear indication that home telemonitoring improves health-related outcomes and reduces healthcare utilisation in COPD. A number of limitations, such as the small sample sizes and the telemonitoring technology, may have accounted for these results. Therefore, further work needs to be conducted before home telemonitoring can be incorporated into clinical practice. The second aim of this Thesis was addressed with three original studies. One study (Chapter 4) assessed the step-count accuracy of activity monitors (Yamax PW/EX-510 pedometer, GT3X+ accelerometer) which supported the feasibility study (Chapter 5) and the main study (Chapter 6). The main findings suggest that a PA-focused behavioural intervention combined with PR can be used to support patients with COPD in achieving a more active lifestyle. Nevertheless, it did not produce further improvements in health-related outcomes. More robust research is warranted to support these findings and assess the short- and long-term impact of this intervention in COPD. In conclusion, the role of patient self-management through home telemonitoring and a PA-focused behavioural intervention is not fully understood. This Thesis contributes for advancing the knowledge in this area and provides important recommendations for future research.

Table of Contents

List of Figures

List of Tables

List of Abbreviations

6MWD	Six-minute walking distance
$6MWD\%_{pred}$	Percentage predicted of the six-minute walking distance
6MWT	Six-minute walk test
APE	Absolute percent error
BA	Bland and Altman
BMI	Body mass index
CG	Control group
COPD	Chronic Obstructive Pulmonary Disease
EG	Experimental group
FEV1	Forced expiratory volume in one second
GOLD	Global Strategy for the Diagnosis Management and Prevention of COPD
HRQOL	Health-related quality of life
HTMG	Home telemonitoring group
IG	Intervention group
LoA	Limits of agreement
MCID	Minimum clinically important difference
mMRC	Modified Medical Research Council Dyspnea Scale
MVPA	Moderate-to-vigorous physical activity
NA	No available information
NRCT	Non-randomised controlled trial
PA	Physical activity
PR	Pulmonary rehabilitation
RCT	Randomised controlled trial
RR	Risk ratio

SA	Sedentary activities
SD	Standard deviation
SGRQ	St. George’s Respiratory Questionnaire
SMD	Standardised mean difference
WHO	World Health Organization

Chapter 1 – Introduction

Introduction

Chronic Obstructive Pulmonary Disease (COPD) is a chronic respiratory disease that affects 210 million people worldwide (World Health Organization [WHO], 2008). According to the WHO estimates, 3 million people died of COPD in 2012 (WHO, 2015) and it is projected to be the third leading cause of death in 2030 (WHO, 2008). Due to its high morbidity, mortality and associated costs, COPD is a major public health problem and a current societal challenge.

The disease is characterised by "*persistent airflow limitation that is usually progressive and associated with an enhanced chronic inflammatory response in the airways and the lung to noxious particles or gases*" (Global Strategy for the Diagnosis Management and Prevention of COPD [GOLD], 2016). The disease seems initially confined to the lungs, however, patients with COPD become progressively physically limited mainly due to an increase in symptoms (e.g., dyspnoea, fatigue) (Lahaije et al., 2010), leading to functional impairment and long-term disability, seriously affecting patients' quality of life (Reardon et al., 2006). Exacerbations and comorbidities further contribute to the individual progression of the disease and functional performance decline (GOLD, 2016).

A recent guideline has emphasised the role of patient self-management as a critical part of COPD management (Spruit et al., 2013). Self-management interventions consist of patient training and support to help them acquire and practice the skills necessary to improve day-to-day control of their disease, carry out disease-specific therapeutic regimens and guide behaviour change (Effing et al., 2012). There is large variability in the nature of self-management interventions depending on its purposes and outcomes (Harrison et al., 2015, Zwerink et al., 2014). Typically, these interventions aim to reduce the frequency of exacerbations and/or their severity through early recognition and appropriate treatment (Nici and ZuWallack, 2015). One promising intervention is the use of information and communication technologies to monitor patients' clinical status while they are at home, also referred to as home monitoring via telemedicine or home telemonitoring (Bolton et al., 2010, Kaptein et al., 2014). Home telemonitoring aims to empower patients to self-manage their disease by asking them to record symptoms and/or physiological signs on a regular basis and transmit them to a healthcare service, so that early signs of health deterioration can be detected and treatment can be delivered in a timely manner (Bolton et al., 2010, McKinstry, 2013). As a result, home telemonitoring may lead to improved clinical outcomes, reduced face-to-face contact with healthcare

services and thus less costly interventions. However, evidence supporting this type of intervention is still limited.

Another critical component of self-management is the increase of patients' physical activity (PA) levels (Effing et al., 2012). Patients with COPD are markedly inactive in daily life when compared to healthy subjects (Vorrink et al., 2011) and these low levels of PA have been associated with adverse outcomes, including increased risk of exacerbations (Moy et al., 2013), hospital admissions and mortality (Garcia-Aymerich et al., 2006, Waschki et al., 2011). Thus, improving PA levels has become a major topic of COPD research (Spruit et al., 2013). Pulmonary rehabilitation (PR) is the cornerstone of COPD management with well-documented effects on exercise capacity (McCarthy et al., 2015). As a self-management approach, PR would seem the ideal intervention to promote PA behaviours in patients with COPD (Spruit et al., 2013). However, previous studies assessing the impact of PR on PA levels have shown that an increase in exercise capacity does not necessarily translate into significant improvements in patients' PA (Egan et al., 2012, Mador et al., 2011, Pitta et al., 2008). Therefore, interventions coupling PR with other self-management approaches that empower lifestyle modification are needed to increase patients' PA levels.

This Thesis focuses on understanding whether self-management interventions can support patients with COPD in their disease management and impact significantly on their health. Specifically, it aimed to: i) gain more insight on the role of home telemonitoring as a self-management intervention to reduce the frequency of COPD exacerbations and healthcare utilisation and improve health-related outcomes; and ii) investigate the impact of a PA-focused behaviour intervention combined with PR on PA levels and health status of patients with COPD.

The work developed to accomplish these aims is presented in eight chapters. Chapter 1 (Introduction) briefly outlines the impact of COPD at a global level and identifies the research problems addressed in this Thesis. In Chapter 2 (Background), an overview of the main challenges in COPD management is presented along with a description of the research problems. Chapter 3 includes two systematic reviews which provide an update of knowledge regarding home telemonitoring in COPD. The first systematic review (Study 1) assesses the effectiveness of home telemonitoring in reducing healthcare utilisation and improving health-related outcomes of patients with COPD. The second systematic review (Study 2) provides a comprehensive description of the methodologies of home telemonitoring interventions in COPD and summarises the findings related to patients'

adherence and satisfaction with the use of telemonitoring systems. Chapters 4, 5 and 6 compile the original studies developed within the scope of this Thesis. Chapter 4 includes the validation of the technological devices that supported the studies presented in Chapters 5 and 6 regarding step-count accuracy. The study presented in Chapter 5 explores the feasibility of providing feedback on PA levels to patients with COPD during PR. Chapter 6 builds further on the observations of Chapter 5 and assesses the impact of a PA-focused behavioural intervention combined with PR in COPD. The main findings of the studies presented in Chapters 3-6 are integrated and discussed in Chapter 7. Finally, Chapter 8 presents the main conclusions and recommendations for future research and clinical practice. Figure 1 provides a schematic diagram of the rationale for the structure of this Thesis.

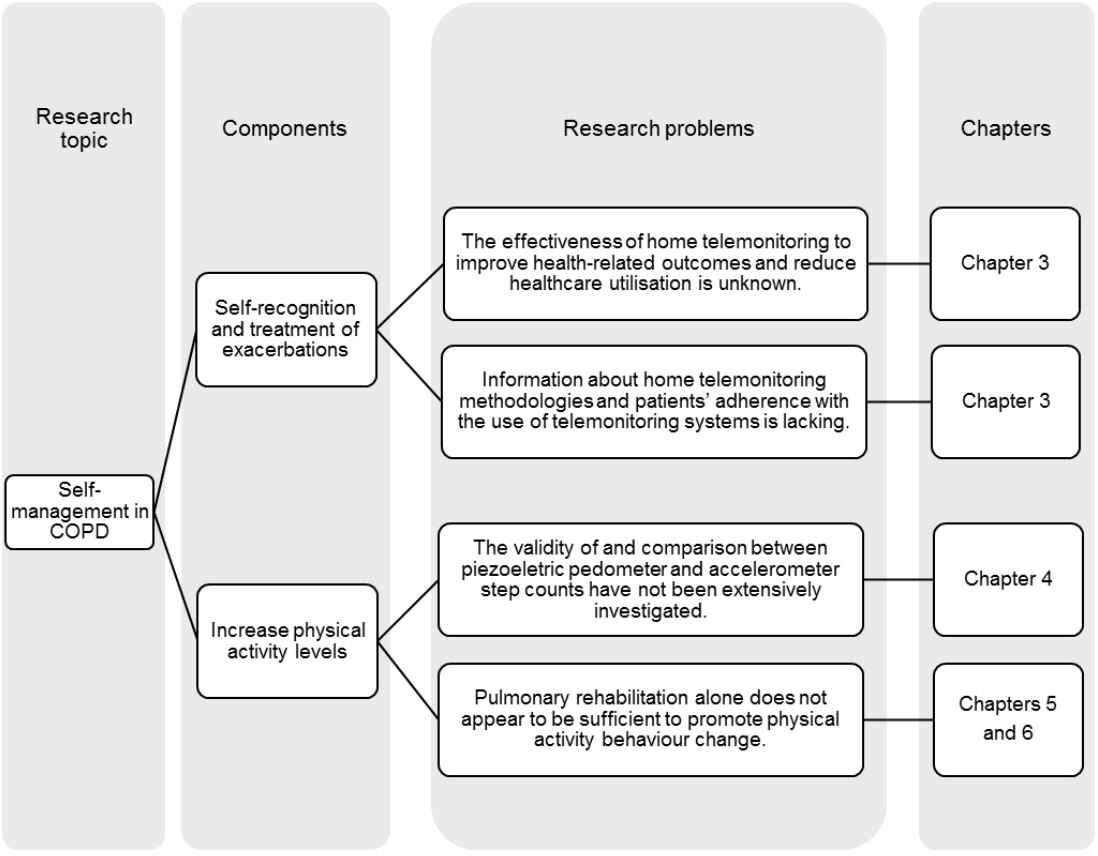

Figure 1. Schematic diagram of the rationale for the structure of the Thesis.

References

Bolton, C. E., Waters, C. S., Peirce, S. & Elwyn, G. 2010. Insufficient evidence of benefit: a systematic review of home telemonitoring for COPD. *J Eval Clin Pract,* 17**,** 1216-22.

Effing, T. W., Bourbeau, J., Vercoulen, J., Apter, A. J., Coultas, D., Meek, P., et al. 2012. Self-management programmes for COPD: Moving forward. *Chron Respir Dis,* 9**,** 27-35.

Egan, C., Deering, B. M., Blake, C., Fullen, B. M., McCormack, N. M., Spruit, M. A., et al. 2012. Short term and long term effects of pulmonary rehabilitation on physical activity in COPD. *Respir Med,* 106**,** 1671-79.

Garcia-Aymerich, J., Lange, P., Benet, M., Schnohr, P. & Anto, J. M. 2006. Regular physical activity reduces hospital admission and mortality in chronic obstructive pulmonary disease: a population based cohort study. *Thorax,* 61**,** 772-8.

Global Strategy for the Diagnosis Management and Prevention of COPD 2016. Global Initiative for Chronic Obstructive Lung Disease (GOLD). Available from: http://www.goldcopd.org/. [Accessed on February, 2015].

Harrison, S. L., Janaudis-Ferreira, T., Brooks, D., Desveaux, L. & Goldstein, R. S. 2015. Self-Management Following an Acute Exacerbation of COPD: A Systematic Review. *Chest,* 147**,** 646-61.

Kaptein, A. A., Fischer, M. J. & Scharloo, M. 2014. Self-management in patients with COPD: theoretical context, content, outcomes, and integration into clinical care. *Int J Chron Obstruct Pulmon Dis,* 9**,** 907-17.

Lahaije, A., van Helvoort, H. A. C., Dekhuijzen, P. N. R. & Heijdra, Y. F. 2010. Physiologic limitations during daily life activities in COPD patients. *Respir Med,* 104**,** 1152-59.

Mador, M. J., Patel, A. N. & Nadler, J. 2011. Effects of Pulmonary Rehabilitation on Activity Levels in Patients With Chronic Obstructive Pulmonary Disease. *J Cardiopulm Rehabil Prev,* 31**,** 52-59.

McCarthy, B., Casey, D., Devane, D., Murphy, K., Murphy, E. & Lacasse, Y. 2015. Pulmonary rehabilitation for chronic obstructive pulmonary disease. *Cochrane Database Syst Rev,* 2**,** Cd003793.

McKinstry, B. 2013. The use of remote monitoring technologies in managing chronic obstructive pulmonary disease. *QJM,* 106**,** 883-5.

Moy, M. L., Teylan, M., Weston, N. A., Gagnon, D. R. & Garshick, E. 2013. Daily Step Count Predicts Acute Exacerbations in a US Cohort with COPD. *PLoS One,* 8**,** e60400.

Nici, L. & ZuWallack, R. 2015. Pulmonary Rehabilitation for Patients with Chronic Airways Obstruction. *J Allergy Clin Immunol Pract,* 3**,** 512-8.

Pitta, F., Troosters, T., Probst, V. S., Langer, D., Decramer, M. & Gosselink, R. 2008. Are patients with COPD more active after pulmonary rehabilitation? *Chest,* 134**,** 273-280.

Reardon, J. Z., Lareau, S. C. & ZuWallack, R. 2006. Functional status and quality of life in chronic obstructive pulmonary disease. *Am J Med,* 119**,** S32-S37.

Spruit, M. A., Singh, S. J., Garvey, C., Zuwallack, R., Nici, L., Rochester, C., et al. 2013. An official American Thoracic Society/European Respiratory Society statement: key concepts and advances in pulmonary rehabilitation. *Am J Respir Crit Care Med,* 188**,** e13-64.

Vorrink, S. N. W., Kort, H. S. M., Troosters, T. & Lammers, J. W. J. 2011. Level of daily physical activity in individuals with COPD compared with healthy controls. *Respir Res,* 12, 1-8.

Waschki, B., Kirsten, A., Holz, O., Muller, K. C., Meyer, T., Watz, H., et al. 2011. Physical activity is the strongest predictor of all-cause mortality in patients with COPD: a prospective cohort study. *Chest,* 140**,** 331-342.

World Health Organization (WHO) 2008. *Action plan of the Global Alliance against Chronic Respiratory diseases, 2008-2013,* Geneva, WHO Library Cataloguing-in-Publication Data.

World Health Organization (WHO) 2015. *Chronic obstructive pulmonary disease (COPD). Fact sheet No. 315 (Updated January 2015)* [Online]. Available: http://www.who.int/mediacentre/factsheets/fs315/en/ [Accessed May, 2015.

Zwerink, M., Brusse-Keizer, M., van der Valk, P. D., Zielhuis, G. A., Monninkhof, E. M., van der Palen, J., et al. 2014. Self management for patients with chronic obstructive pulmonary disease. *Cochrane Database Syst Rev,* 3**,** Cd002990.

Chapter 2 – Background

Background

This chapter provides a definition of Chronic Obstructive Pulmonary Disease (COPD) and its global burden, describes the impact of exacerbations on disease progression and outcomes, and highlights the importance of promoting an active lifestyle in patients with COPD. Then, an overview of the literature regarding self-management interventions in COPD is presented along with a description of the research problems.

COPD definition and global burden

COPD represents an important public health challenge that is both preventable and treatable (Global Strategy for the Diagnosis Management and Prevention of COPD [GOLD], 2016). This chronic respiratory disease affects 210 million people worldwide (World Health Organization [WHO], 2008) and results in a social and economic burden that is both substantial and increasing due to continued exposure to COPD risk factors and the aging of population (Buist et al., 2007). In Portugal, it is estimated that nearly 800.000 people aged 40 years or older suffer from COPD (de Araújo, 2015). The latest WHO estimates (2015) refer that more than 3 million people died of COPD in 2012, which is equal to 6% of all deaths in that year. In 2030, COPD is projected to be the third leading cause of death following ischaemic heart disease and stroke (WHO, 2008) and the seventh leading cause of disability-adjusted life years (DALYs) lost (Mathers and Loncar, 2006).

The disease is characterised by *"persistent airflow limitation that is usually progressive and associated with an enhanced chronic inflammatory response in the airways and the lung to noxious particles or gases*" (GOLD, 2016). Its clinical presentation is very heterogeneous, although the most common symptoms of COPD are dyspnoea, cough and sputum production that can be variable from day-to-day and often throughout the day (Kessler et al., 2011). Additionally, the natural course of COPD includes frequent and recurrent exacerbations and the presence of comorbidities that further contribute to the individual progression of the disease and deterioration of patients' health status. Many people suffer from COPD for years and die prematurely from it or its complications (GOLD, 2016).

Impact of exacerbations on disease progression and outcomes

An exacerbation of COPD is defined as an acute episode characterised by a worsening of the patient's respiratory symptoms that is beyond normal day-to-day variations and leads to a change in medication (GOLD, 2016). The frequency of exacerbations varies greatly between patients (Aaron et al., 2012) and contributes to a faster rate of decline in lung function (Donaldson et al., 2002). These acute episodes have important functional consequences, such as a global impairment of the function of respiratory and peripheral skeletal muscles (Martinez-Llorens et al., 2004), and a reduction in physical activity (PA) levels (Pitta et al., 2006) and health-related quality of life (HRQOL) (Bourbeau et al., 2007). Furthermore, previous studies have found that exacerbations have a negative impact on patient prognosis (Soler-Cataluña et al., 2005) and are responsible for unscheduled healthcare utilisation and increased direct costs (O'Reilly et al., 2007). It has been found that patients with frequent exacerbations requiring hospitalisation had the highest mortality rate with a risk of death 4.3 times higher (95%CI 2.62–7.02) than those requiring no hospital management (Soler-Cataluña et al., 2005). Furthermore, patients who tended not to seek treatment at exacerbation had poorer HRQOL and were more likely to be hospitalised than those who routinely reported their exacerbations for treatment (Wilkinson et al., 2004). These findings emphasise the need for interventions that enable early detection and prompt treatment of exacerbations to reduce the burden of COPD.

Physical (in)activity in COPD: impact and recommendations

Although COPD is primarily a disease of the respiratory system, it also has significant extrapulmonary (systemic) manifestations, including skeletal muscle wasting and dysfunction (Decramer et al., 2005). The pulmonary and peripheral abnormalities lead to an increase in the ventilatory requirements during exercise, resulting in exercise-induced symptoms such as dyspnoea and fatigue (Panagiotou et al., 2013, Stendardi et al., 2005). These symptoms make exercise an unpleasant experience which many patients try to avoid, leading to an inactive lifestyle (Lahaije et al., 2010). Muscle deconditioning and reduced PA further contribute to a worsening of the patients' physical condition and to increased symptoms, yielding a downward spiral of symptom-induced inactivity (Reardon et al., 2006). In the long-term, this spiral may contribute to a decline in patients' functional status and impaired HRQOL (Reardon et al., 2006). Thus, improving PA levels has become a major topic of COPD research (Watz et al., 2014).

Physical activity is defined as any bodily movement produced by skeletal muscles that substantially increases energy expenditure (Caspersen et al., 1985). Physical activity and exercise are often used interchangeably, however, these terms are not synonymous. Exercise is a subcategory of PA which is planned, structured and repetitive and aims to improve and/or maintain physical fitness. Physical activity also includes domestic and occupational tasks, as well as basic everyday tasks required for independent living (Caspersen et al., 1985). The intensity of PA is commonly classified as light, moderate or vigorous, depending on the energy expenditure associated with it. Other parameters, such as the number of daily steps, may also be considered when assessing PA (Garber et al., 2011). A previous systematic review concluded that patients with COPD have a significantly reduced duration and intensity of daily PA when compared to healthy subjects (Vorrink et al., 2011). Furthermore, a large number of patients with COPD do not reach the international recommendations (Troosters et al., 2010, Watz et al., 2009), i.e., a minimum of 30 min/day of moderate intensity activities, 20 min/day of vigorous intensity activities or a combination of both; 7000-10,000 steps/day (Garber et al., 2011). Low levels of PA have been associated with adverse outcomes, including increased risk of exacerbations (Moy et al., 2013), hospital admissions and mortality (Garcia-Aymerich et al., 2006, Waschki et al., 2011). Other studies have shown that PA is correlated with lung function, exercise capacity and HRQOL (Watz et al., 2014). These findings suggest that regular PA may have important health-related benefits in patients with COPD.

Since PA is a modifiable factor with potential to improve COPD prognosis, the latest GOLD guidelines (2016) have underlined the importance of promoting regular PA in COPD management. However, there is still little COPD-specific evidence to support this recommendation (GOLD, 2016). The American Thoracic Society and the European Respiratory Society defined PR as a comprehensive self-management intervention which includes (but is not limited to) exercise training, education and behaviour change, with the purpose of improving patients' physical and psychological condition and promoting long-term adherence to health-enhancing behaviours (Spruit et al., 2013). Hence, it would seem the ideal intervention to promote PA behaviours in patients with COPD. However, previous studies have shown that an increase in exercise capacity after PR does not necessarily translate into significant improvements in patients' PA levels (Egan et al., 2012, Mador et al., 2011, Pitta et al., 2008). One possible explanation for these findings is that PR programmes lack an effective behavioural component that targets changes in PA beyond those related to the structured exercise component of PR (Hill et al., 2015). Therefore, interventions coupling PR with PA-focused approaches may have the potential

to promote behaviour change and empower lifestyle modification in patients with COPD. This is a promising area for future research.

Self-management in COPD

Patient self-management has been proposed as a critical part of COPD management (Effing et al., 2012, Spruit et al., 2013). Although there is still no 'gold standard' definition of self-management, it refers to the patients' ability to manage and cope with their symptoms, treatment, physical and psychosocial consequences and lifestyle changes inherent in living with a chronic disease (Barlow et al., 2002). A WHO policy brief (Coulter et al., 2008) has emphasised the role of patients' self-management in promoting the long-term sustainability of many health systems. The overall goal of self-management is to develop in patients an improved sense of self-efficacy, i.e. the patients' belief regarding whether or not they feel they can successfully implement particular behaviours in order to produce certain outcomes (Bandura, 1977).

In COPD, self-management interventions involve helping patients to acquire and practice the skills necessary to improve day-to-day control of their disease, carry out disease-specific therapeutic regimens and guide behaviour change (Effing et al., 2012). Evidence regarding its effectiveness is still unclear. A recent systematic review found that self-management interventions resulted in a lower probability of hospitalisations and significant effects on dyspnoea and HRQOL of patients with stable COPD (Zwerink et al., 2014). Though, these findings were not observed in self-management interventions delivered to patients following an acute exacerbation (Harrison et al., 2015). The large variability in the nature and outcomes of self-management interventions may explain this lack of evidence (Harrison et al., 2015, Zwerink et al., 2014). Typically, these interventions aim to reduce the frequency of exacerbations and/or their severity through early recognition and appropriate treatment (Nici and ZuWallack, 2015). In recent years, there has also been a growing interest in developing self-management interventions aimed to promote behaviour change with regard to patients' PA (Effing et al., 2012).

Self-management for early recognition and treatment of exacerbations

Researchers and policy makers have been seeking cost-effective strategies to support patients in the early recognition and treatment of exacerbations. One promising

intervention is the use of information and communication technologies to monitor patients' clinical status while they are at home, also referred to as home monitoring via telemedicine or home telemonitoring (Bolton et al., 2010, Kaptein et al., 2014). Home telemonitoring is one of the components of telehealth, which has been acknowledged as a key intervention in future integrated care (WHO, 2010). It is defined as the provision of care at a distance and may also include the use of telephonic/mobile services and tele-consultations.

Home telemonitoring aims to empower patients to self-manage their disease while they are at home by asking them to record daily symptoms and/or physiological signs on a regular basis and transmit them to a healthcare service, so that early signs of health deterioration can be detected and treatment can be delivered in a timely manner (Bolton et al., 2010, McKinstry, 2013). Therefore, this type of intervention has the potential to support patient self-management by increasing day-to-day care responsibilities of patients (and families) and minimising unnecessary face-to-face contact with the healthcare services. This may lead to improved clinical outcomes and less costly interventions (McKinstry, 2013). Nevertheless, evidence to support this type of intervention in COPD is limited. Previous systematic reviews on the topic have included other telehealth approaches (e.g., telephone support, teleconsultations) (Bolton et al., 2010, Kamei et al., 2013, McLean et al., 2011, Polisena et al., 2010), rendering the interpretation of the impact of home telemonitoring alone. Therefore, **Study 1 of Chapter 3** contributed for the development of knowledge in this area by systematically reviewing the effectiveness of home telemonitoring to reduce healthcare utilisation and improve health-related outcomes in patients with COPD.

Making the case for investment in home telemonitoring interventions requires not only knowledge of the existing evidence, but also of how the interventions are delivered. Different forms of implementing telemonitoring applications have emerged over the years as a result of the continuous technological advances and efforts to improve COPD self-management. However, previous reviews (Bartoli et al., 2009, Bolton et al., 2010, Kamei et al., 2013, McLean et al., 2011, Polisena et al., 2010) have provided little or no attention to home telemonitoring methodologies or to the technology employed. Moreover, optimal interventions require patients' adherence (WHO, 2003), but there is still limited information about adherence to and satisfaction with home telemonitoring in COPD. Therefore, **Study 2 of Chapter 3** addresses these issues by presenting a systematic review of the methodologies used in home telemonitoring in COPD and patients' adherence and satisfaction with the use of telemonitoring systems. This review may be a useful resource

for researchers, clinicians and policy makers as it points out important aspects regarding the integration of technology in COPD management and provides recommendations for future interventions.

Self-management to increase physical activity

In the last decade, several PA-focused interventions complementary to PR have been developed hoping to increase the PA levels of patients with COPD (Wilson et al., 2014). Those including self-monitoring using activity monitors and behavioural counselling provided promising results (Altenburg et al., 2015, de Blok et al., 2006) and, thus, may have the potential to produce significant changes in patients' PA levels (Watz et al., 2014).

A small randomised controlled trial conducted by de Block et al. (2006) compared a combined intervention of PR and a lifestyle PA counselling with feedback from a pedometer (experimental group) with PR alone (control group). The pedometer served as a reminder for patients to be physically active by providing them feedback on daily steps taken. Each intervention lasted 9 weeks. No significant differences were found between the experimental and control groups in pre- and post-test steps (de Blok et al., 2006). However, when the same intervention was implemented in a 3-month period, the experimental group presented significant improvements in the number of daily steps when compared to the control group, albeit the improvement was small (547 steps/day in the experimental group and -211 steps/day in the control group) (Altenburg et al., 2015). Furthermore, no significant between-group differences were found in exercise capacity and HRQOL, which questions the hypothesis that a more active lifestyle could translate into improved health-related measures.

Methodological weaknesses, such as the type of pedometer used and patients' experiences with the equipment, may explain in part these results. In both studies, a pedometer with a spring-suspended horizontal lever arm mechanism (Yamax Digi-Walker SW-200) was used to provide patients with feedback and assess the impact of the intervention. Previous research on the accuracy of spring lever arm pedometers (Crouter et al., 2005, Crouter et al., 2003, Le Masurier et al., 2004, Melanson et al., 2004) and, specifically, of the Yamax Digi-Walker SW-200 (Crouter et al., 2005, Le Masurier et al., 2004, Melanson et al., 2004), has found that this type of pedometers significantly underestimates the number of steps at slow walking speeds (i.e., 3.24–5.64 Km/h). Therefore, they may not be appropriate to assess PA levels in slow walking populations,

such as in patients with COPD (Ilgin et al., 2011). Pedometers with a piezoelectric technology have been developed to overcome this problem; however, its accuracy has been scarcely investigated when worn at different walking speeds and body parts, and users' preferences regarding wearing location have been poorly explored despite its importance to improve user's acceptance.

In addition to pedometers, the use of triaxial accelerometers (e.g., GT3X+) to objectively monitor and assess PA has increased in recent years. Accelerometers are often preferred in research and clinical settings because, in addition to step counts, they provide information on the frequency, duration and intensity of PA (Garber et al., 2011, Strath et al., 2013). Accelerometers have shown good validity results regarding activity counts and energy expenditure (Santos-Lozano et al., 2013, Van Remoortel et al., 2012); however, their step-count accuracy has not been extensively investigated. Assessment of accelerometer step-count accuracy along with pedometer accuracy is fundamental to enable comparisons among studies using different activity monitors. **Chapter 4** provides a contribution to this field by: (1) assessing step-count accuracy of a piezoeletric pedometer (Yamax Power-Walker EX-510), when worn at different body parts, and a triaxial accelerometer (GT3X+); (2) comparing device accuracy; and (3) identifying user's preferred location(s) to wear the pedometer. The activity monitors evaluated in this Chapter were further used in the studies presented in Chapters 5 and 6.

Patients' compliance with PA monitoring and their experience with the activity monitors may also have accounted for the results found by de Block et al. (2006) and Altenburg et al. (2015). Although de Block et al. (2006) have assessed patients' compliance of recording daily step counts in the dairies, they did not explore patients' experience of using the activity monitors to self-manage their PA levels. This aspect is a key element to ensure the feasibility of interventions involving activity monitoring and feedback. Nevertheless, it has received little attention in the literature (Troosters, 2009). In order to improve the knowledge in this important field of research, **Chapter 5** explored the feasibility of providing feedback on PA levels of patients with COPD during PR. **Chapter 6** builds further on the observations of Chapter 5 and assessed the impact of a PA-focused behavioural intervention combined with PR in COPD, using a randomised controlled design.

References

Aaron, S. D., Donaldson, G. C., Whitmore, G. A., Hurst, J. R., Ramsay, T. & Wedzicha, J. A. 2012. Time course and pattern of COPD exacerbation onset. *Thorax,* 67**,** 238-43.

Altenburg, W. A., ten Hacken, N. H. T., Bossenbroek, L., Kerstjens, H. A. M., de Greef, M. H. G. & Wempe, J. B. 2015. Short- and long-term effects of a physical activity counselling programme in COPD: A randomized controlled trial. *Respir Med,* 109**,** 112-21.

Bandura, A. 1977. *Social learning theory,* Englewood Cliffs (NJ), Prentice Hall.

Barlow, J., Wright, C., Sheasby, J., Turner, A. & Hainsworth, J. 2002. Self-management approaches for people with chronic conditions: a review. *Patient Educ Couns,* 48**,** 177-87.

Bartoli, L., Zanaboni, P., Masella, C. & Ursini, N. 2009. Systematic Review of Telemedicine Services for Patients Affected by Chronic Obstructive Pulmonary Disease (COPD). *Telemed J E Health,* 15**,** 877-83.

Bolton, C. E., Waters, C. S., Peirce, S. & Elwyn, G. 2010. Insufficient evidence of benefit: a systematic review of home telemonitoring for COPD. *J Eval Clin Pract,* 17**,** 1216-22.

Bourbeau, J., Ford, G., Zackon, H., Pinsky, N., Lee, J. & Ruberto, G. 2007. Impact on patients' health status following early identification of a COPD exacerbation. *Eur Respir J,* 30**,** 907-13.

Buist, A. S., McBurnie, M. A., Vollmer, W. M., Gillespie, S., Burney, P., Mannino, D. M., et al. 2007. International variation in the prevalence of COPD (the BOLD Study): a population-based prevalence study. *Lancet,* 370**,** 741-50.

Caspersen, C. J., Powell, K. E. & Christenson, G. M. 1985. Physical activity, exercise, and physical fitness: definitions and distinctions for health-related research. *Public Health Rep,* 100**,** 126-31.

Coulter, A., Parsons, S. & Askham, J. 2008. *Policy brief: Where are the patients in decision-making about their own care?,* Geneva, World Health Organization, on behalf of the European Observatory on Health Systems and Policies.

Crouter, S. E., Schneider, P. L. & Bassett, D. R., Jr. 2005. Spring-levered versus piezo-electric pedometer accuracy in overweight and obese adults. *Med Sci Sports Exerc,* 37**,** 1673-9.

Crouter, S. E., Schneider, P. L., Karabulut, M. & Bassett, D. R., Jr. 2003. Validity of 10 electronic pedometers for measuring steps, distance, and energy cost. *Med Sci Sports Exerc,* 35**,** 1455-60.

de Araújo, A. T. 2015. *10º Relatório do Observatório Nacional das Doenças Respiratórias 2014/2015 - Panorama das doenças respiratórias em Portugal: Caminhos para o Futuro*. Observatório Nacional das Doenças Respiratórias.

de Blok, B. M., de Greef, M. H., ten Hacken, N. H., Sprenger, S. R., Postema, K. & Wempe, J. B. 2006. The effects of a lifestyle physical activity counseling program with feedback of a pedometer during pulmonary rehabilitation in patients with COPD: a pilot study. *Patient Educ Couns,* 61**,** 48-55.

Decramer, M., De Benedetto, F., Del Ponte, A. & Marinari, S. 2005. Systemic effects of COPD. *Respir Med,* 99, Suppl2**,** S3-S10.

Donaldson, G. C., Seemungal, T. A. R., Bhowmik, A. & Wedzicha, J. A. 2002. Relationship between exacerbation frequency and lung function decline in chronic obstructive pulmonary disease. *Thorax,* 57**,** 847-52.

Effing, T. W., Bourbeau, J., Vercoulen, J., Apter, A. J., Coultas, D., Meek, P., et al. 2012. Self-management programmes for COPD: Moving forward. *Chron Respir Dis,* 9**,** 27-35.

Egan, C., Deering, B. M., Blake, C., Fullen, B. M., McCormack, N. M., Spruit, M. A., et al. 2012. Short term and long term effects of pulmonary rehabilitation on physical activity in COPD. *Respir Med,* 106**,** 1671-9.

Garber, C. E., Blissmer, B., Deschenes, M. R., Franklin, B. A., Lamonte, M. J., Lee, I. M., et al. 2011. American College of Sports Medicine position stand. Quantity and quality of exercise for developing and maintaining cardiorespiratory, musculoskeletal, and neuromotor fitness in apparently healthy adults: guidance for prescribing exercise. *Med Sci Sports Exerc,* 43**,** 1334-59.

Garcia-Aymerich, J., Lange, P., Benet, M., Schnohr, P. & Anto, J. M. 2006. Regular physical activity reduces hospital admission and mortality in chronic obstructive pulmonary disease: a population based cohort study. *Thorax,* 61**,** 772-8.

Global Strategy for the Diagnosis Management and Prevention of COPD 2016. Global Initiative for Chronic Obstructive Lung Disease (GOLD). Available from: http://www.goldcopd.org/. [Accessed on February, 2015].

Harrison, S. L., Janaudis-Ferreira, T., Brooks, D., Desveaux, L. & Goldstein, R. S. 2015. Self-Management Following an Acute Exacerbation of COPD: A Systematic Review. *Chest,* 147**,** 646-61.

Hill, K., Gardiner, P. A., Cavalheri, V., Jenkins, S. C. & Healy, G. N. 2015. Physical activity and sedentary behaviour: applying lessons to chronic obstructive pulmonary disease. *Intern Med J,* 45**,** 474-82.

Ilgin, D., Ozalevli, S., Kilinc, O., Sevinc, C., Cimrin, A. H. & Ucan, E. S. 2011. Gait speed as a functional capacity indicator in patients with chronic obstructive pulmonary disease. *Ann Thorac Med,* 6**,** 141-6.

Kamei, T., Yamamoto, Y., Kajii, F., Nakayama, Y. & Kawakami, C. 2013. Systematic review and meta-analysis of studies involving telehome monitoring-based telenursing for patients with chronic obstructive pulmonary disease. *JJNS***,** 10, 180-92.

Kaptein, A. A., Fischer, M. J. & Scharloo, M. 2014. Self-management in patients with COPD: theoretical context, content, outcomes, and integration into clinical care. *Int J Chron Obstruct Pulmon Dis,* 9**,** 907-17.

Kessler, R., Partridge, M. R., Miravitlles, M., Cazzola, M., Vogelmeier, C., Leynaud, D., et al. 2011. Symptom variability in patients with severe COPD: a pan-European cross-sectional study. *Eur Respir J,* 37**,** 264-72.

Lahaije, A., van Helvoort, H. A. C., Dekhuijzen, P. N. R. & Heijdra, Y. F. 2010. Physiologic limitations during daily life activities in COPD patients. *Respir Med,* 104**,** 1152-9.

Le Masurier, G. C., Lee, S. M. & Tudor-Locke, C. 2004. Motion sensor accuracy under controlled and free-living conditions. *Med Sci Sports Exerc,* 36**,** 905-10.

Mador, M. J., Patel, A. N. & Nadler, J. 2011. Effects of Pulmonary Rehabilitation on Activity Levels in Patients With Chronic Obstructive Pulmonary Disease. *J Cardiopulm Rehabil Prev,* 31**,** 52-9.

Martinez-Llorens, J. M., Orozco-Levi, M., Masdeu, M. J., Coronell, C., Ramirez-Sarmiento, A., Sanjuas, C., et al. 2004. [Global muscle dysfunction and exacerbation of COPD: a cohort study]. *Med Clin (Barc),* 122**,** 521-7.

Mathers, C. D. & Loncar, D. 2006. Projections of Global Mortality and Burden of Disease from 2002 to 2030. *PLoS Med,* 3**,** e442.

McKinstry, B. 2013. The use of remote monitoring technologies in managing chronic obstructive pulmonary disease. *QJM,* 106**,** 883-5.

McLean, S., Nurmatov, U., Liu, J. L., Pagliari, C., Car, J. & Sheikh, A. 2011. Telehealthcare for chronic obstructive pulmonary disease. *Cochrane Database Syst Rev***,** CD007718.

Melanson, E. L., Knoll, J. R., Bell, M. L., Donahoo, W. T., Hill, J. O., Nysse, L. J., et al. 2004. Commercially available pedometers: considerations for accurate step counting. *Prev Med,* 39**,** 361-8.

Moy, M. L., Teylan, M., Weston, N. A., Gagnon, D. R. & Garshick, E. 2013. Daily Step Count Predicts Acute Exacerbations in a US Cohort with COPD. *PLoS One,* 8**,** e60400.

Nici, L. & ZuWallack, R. 2015. Pulmonary Rehabilitation for Patients with Chronic Airways Obstruction. *J Allergy Clin Immunol Pract In practice,* 3**,** 512-8.

O'Reilly, J. F., Williams, A. E. & Rice, L. 2007. Health status impairment and costs associated with COPD exacerbation managed in hospital. *Int J Clin Pract,* 61**,** 1112-20.

Panagiotou, M., Kastanakis, E. & Vogiatzis, I. 2013. Exercise Limitation in COPD. *Pneumon,* 26, 245-56.

Pitta, F., Troosters, T., Probst, V. S., Langer, D., Decramer, M. & Gosselink, R. 2008. Are patients with COPD more active after pulmonary rehabilitation? *Chest,* 134**,** 273-80.

Pitta, F., Troosters, T., Probst, V. S., Spruit, M. A., Decramer, M. & Gosselink, R. 2006. Physical activity and hospitalization for exacerbation of COPD. *Chest,* 129**,** 536-44.

Polisena, J., Tran, K., Cimon, K., Hutton, B., McGill, S., Palmer, K., et al. 2010. Home telehealth for chronic obstructive pulmonary disease: a systematic review and meta-analysis. *J Telemed Telecare,* 16**,** 120-7.

Reardon, J. Z., Lareau, S. C. & ZuWallack, R. 2006. Functional status and quality of life in chronic obstructive pulmonary disease. *Am J Med,* 119**,** S32-S37.

Santos-Lozano, A., Santin-Medeiros, F., Cardon, G., Torres-Luque, G., Bailon, R., Bergmeir, C., et al. 2013. Actigraph GT3X: validation and determination of physical activity intensity cut points. *Int J Sports Med,* 34**,** 975-82.

Soler-Cataluña, J. J., Martínez-García, M. Á., Román Sánchez, P., Salcedo, E., Navarro, M. & Ochando, R. 2005. Severe acute exacerbations and mortality in patients with chronic obstructive pulmonary disease. *Thorax,* 60**,** 925-31.

Spruit, M. A., Singh, S. J., Garvey, C., Zuwallack, R., Nici, L., Rochester, C., et al. 2013. An official American Thoracic Society/European Respiratory Society statement: key concepts and advances in pulmonary rehabilitation. *Am J Respir Crit Care Med,* 188**,** e13-64.

Stendardi, L., Grazzini, M., Gigliotti, F., Lotti, P. & Scano, G. 2005. Dyspnea and leg effort during exercise. *Respir Med,* 99**,** 933-42.

Strath, S. J., Kaminsky, L. A., Ainsworth, B. E., Ekelund, U., Freedson, P. S., Gary, R. A., et al. 2013. Guide to the Assessment of Physical Activity: Clinical and Research Applications: A Scientific Statement From the American Heart Association. *Circulation,* 128**,** 2259-79.

Troosters, T. 2009. Physical activity monitoring: a new outcome facing many challenges, but yielding promising results. *COPD,* 6**,** 82-3.

Troosters, T., Sciurba, F., Battaglia, S., Langer, D., Valluri, S. R., Martino, L., et al. 2010. Physical inactivity in patients with COPD, a controlled multi-center pilot-study. *Respir Med,* 104**,** 1005-11.

Van Remoortel, H., Giavedoni, S., Raste, Y., Burtin, C., Louvaris, Z., Gimeno-Santos, E., et al. 2012. Validity of activity monitors in health and chronic disease: a systematic review. *Int J Behav Nutr Phys Act,* 9**,** 84.

Vorrink, S. N. W., Kort, H. S. M., Troosters, T. & Lammers, J. W. J. 2011. Level of daily physical activity in individuals with COPD compared with healthy controls. *Respir Res,* 12, 33.

Waschki, B., Kirsten, A., Holz, O., Muller, K. C., Meyer, T., Watz, H., et al. 2011. Physical activity is the strongest predictor of all-cause mortality in patients with COPD: a prospective cohort study. *Chest,* 140**,** 331-42.

Watz, H., Pitta, F., Rochester, C. L., Garcia-Aymerich, J., ZuWallack, R., Troosters, T., et al. 2014. An official European Respiratory Society statement on physical activity in COPD. *Eur Respir J,* 44**,** 1521-37.

Watz, H., Waschki, B., Meyer, T. & Magnussen, H. 2009. Physical activity in patients with COPD. *Eur Respir J,* 33**,** 262-72.

Wilkinson, T. M. A., Donaldson, G. C., Hurst, J. R., Seemungal, T. A. R. & Wedzicha, J. A. 2004. Early Therapy Improves Outcomes of Exacerbations of Chronic Obstructive Pulmonary Disease. *Am J Respir Crit Care Med,* 169**,** 1298-303.

Wilson, J. J., O'Neill, B., Collins, E. G. & Bradley, J. 2014. Interventions to Increase Physical Activity in Patients with COPD: A Comprehensive Review. *COPD,* 12**,** 332-43.

World Health Organization (WHO) 2003. Adherence to long-term therapies - Evidence for action. Geneva, WHO Library Cataloguing-in-Publication Data.

World Health Organization (WHO) 2008. *Action plan of the Global Alliance against Chronic Respiratory diseases 2008-2013,* Geneva, WHO Library Cataloguing-in-Publication Data.

World Health Organization (WHO) 2010. *How Can Telehealth Help in the Provision of Integrated Care?*, Geneva, WHO Library Cataloguing-in-Publication Data.

World Health Organization (WHO) 2015. *Chronic obstructive pulmonary disease (COPD). Fact sheet No. 315 (Updated January 2015)* [Online]. Available: http://www.who.int/mediacentre/factsheets/fs315/en/ [Accessed on May, 2015].

Zwerink, M., Brusse-Keizer, M., van der Valk, P. D., Zielhuis, G. A., Monninkhof, E. M., van der Palen, J., et al. 2014. Self management for patients with chronic obstructive pulmonary disease. *Cochrane Database Syst Rev,* 3**,** Cd002990.

Chapter 3 – Home telemonitoring in COPD

Study 1 – Home telemonitoring effectiveness in COPD: a systematic review

Joana Cruz
Dina Brooks
Alda Marques

The International Journal of Clinical Practice, 68(3):369-78 (2014)

Abstract

Objectives: To provide a systematic review of the effectiveness of home telemonitoring to reduce healthcare utilisation and improve health-related outcomes of patients with COPD.

Methods: An electronic literature search in Medline, Embase, B-on and Web of Science was conducted from June to August 2012 and updated until July 2013, using the following keywords: [tele(-)monitoring or tele(-)health or tele(-)homecare or tele(-)care or tele-home health or home monitoring] and [Chronic Obstructive Pulmonary Disease or COPD]. Randomised and non-randomised controlled trials evaluating home telemonitoring interventions in COPD were included. A meta-analysis using risk ratio (RR) and standardised mean difference (SMD) was conducted for healthcare utilisation (hospitalisations, length of stay, emergency department visits) and associated costs, and health-related outcomes (mortality, exacerbations and health-related quality of life (HRQOL)).

Results: Nine articles were included. Significant differences were found for hospitalisation rates (RR=0.72; 95%CI=0.53–0.98; p=0.034); however, no differences in the other healthcare utilisation outcomes were observed. There was a trend to reduced healthcare costs in the telemonitoring group. In two studies, this intervention was associated with a reduced number of exacerbations ($p<0.05$) and a significant increase in HRQOL (SMD=-0.53; 95%CI=-0.97– -0.09; p=0.019).

Discussion and Conclusions: Home telemonitoring appears to have a positive effect in reducing respiratory exacerbations and hospitalisations and improving quality of life. However, the evidence of its benefits is still limited and further research is needed to assess the effectiveness of home telemonitoring in COPD management, as there are still few studies in this area.

Keywords: COPD; healthcare utilisation; quality of life; telemedicine; telemonitoring.

Review Criteria

Medline, Embase, B-on and Web of Science databases were searched (from June to August 2012, updated until July 2013) for randomised and non-randomised controlled trials evaluating the impact of home telemonitoring interventions on healthcare utilisation and health-related outcomes of patients with COPD. Meta-analyses were performed, when appropriate.

Message for the Clinic

Home telemonitoring is an innovative approach which enables the management of patients' health condition at home, by exchanging health-related information with healthcare professionals. Studies included in this review provided limited evidence for the effectiveness of home telemonitoring in COPD on healthcare utilisation and health-related outcomes. To advocate the use of home telemonitoring as a patient management approach and to incorporate it into practice, further work needs to be conducted.

Introduction

Chronic obstructive pulmonary disease (COPD) is a progressive disease which accounts for a great economic and social burden (World Health Organization [WHO], 2008). In the United States, COPD was considered the 2nd cause of disability-adjusted life-years (DALYs) and the 5th cause of mortality in 2010 (Murray and Lopez, 2013). The disease trajectory is characterised by increasing symptoms (e.g., dyspnoea, fatigue) and a progressive decline in health status, punctuated by acute respiratory exacerbations (Global Strategy for the Diagnosis Management and Prevention of COPD [GOLD], 2013). Previous studies have shown that COPD exacerbations have a negative impact on patient prognosis (Soler-Cataluña et al., 2005) and are responsible for the greatest proportion of the total direct costs attributable to COPD (O'Reilly et al., 2007). Therefore, interventions to manage exacerbations at an early stage are urgently needed to reduce morbidity and mortality of COPD population, thereby reducing healthcare utilisation and associated costs.

In recent years, researchers and policy makers have been seeking cost-effective strategies for delivering sustainable care in COPD. One promising approach is the use of information and communication technologies to monitor patients' health status while they are at home, also referred to as home telemonitoring (Bolton et al., 2010). Home telemonitoring allows healthcare providers to review patients' clinical data (e.g., oxygen saturation, heart rate) more regularly and, thus, health deterioration can be quickly detected and addressed. This may lead to improved clinical outcomes, greater patient self-management and less costly interventions (McKinstry, 2013).

While the interest in telemonitoring interventions to manage patients at home is increasing, the evidence to support its effectiveness is still limited (McKinstry, 2013). Previous systematic reviews failed to demonstrate the benefit of home telemonitoring in COPD (Bolton et al., 2010, Kamei et al., 2013, McLean et al., 2011, Polisena et al., 2010). However, these reviews evaluated studies using home telemonitoring and a different telehealth approach, such as telephone support (McLean et al., 2011, Polisena et al., 2010) or teleconsultations with occasional monitoring of patients' clinical data (Bolton et al., 2010, Kamei et al., 2013, Polisena et al., 2010), rendering the interpretation of the impact of telemonitoring alone. Therefore, the question of whether home telemonitoring achieves its purpose, i.e., if it reduces healthcare utilisation and costs by effectively detecting and responding to COPD exacerbations in a timely manner, remains unanswered. This systematic review aimed to assess the effectiveness of home

telemonitoring to reduce healthcare utilisation and improve health-related outcomes of patients with COPD.

Methods

Information sources and search strategy

An electronic literature search was performed from June to August of 2012 in Medline, Embase, B-on Online Knowledge Library and Web of Science databases. Search terms were based on a combination of the following keywords: [tele(-)monitoring or tele(-)health or tele(-)homecare or tele(-)care or tele-home health or home monitoring] and [Chronic Obstructive Pulmonary Disease or COPD]. Additional studies were searched within the reference list of the included articles, review articles on the topic (Bolton et al., 2010, Jaana et al., 2009, Kamei et al., 2013, McLean et al., 2011, Paré et al., 2007, Polisena et al., 2010) and weekly automatic updates retrieved from the databases until July 2013.

Eligibility criteria and study selection

This systematic review was reported according to preferred reporting items for systematic reviews and meta-analyses (PRISMA) guidelines (Moher et al., 2009). Eligible studies were randomised (RCT) and non-randomised controlled trials (NRCT) involving patients with COPD and comparing a home telemonitoring intervention (experimental group – HTMG) to usual care (control group – CG). Patients in the HTMG had to periodically record clinical data (e.g., oxygen saturation, heart rate, symptoms) in their homes and transmit the data on a regular basis (i.e., ≥5days/week) using information and communication technologies, for further assessment by a healthcare team. The outcomes of interest were healthcare utilisation (i.e., hospitalisations, length of hospital stay, emergency department visits) and associated costs, mortality rates, respiratory exacerbations and health-related quality of life (HRQOL), collected during or immediately after the intervention.

Studies were excluded if they: i) included patients with diseases other than COPD; ii) included only regular telephone calls, video-consultation or teleconference interventions with infrequent transmission of clinical data; iii) involved downloading the data during healthcare visits or just at the end of the study; iv) provided telemonitoring in other places than patients' home; v) did not include a group without home telemonitoring (i.e., a CG); vi) did not collect the outcomes of interest during or immediately after the intervention.

Studies with a different design (e.g., one group pretest-posttest, observational or case studies), review papers, abstracts, papers on conference proceedings, editorials, commentaries to articles and study protocols were excluded. Papers without abstracts or written in languages other than English, Portuguese and Spanish were also excluded.

Initial screening of articles was based on type of publication and relevance for the scope of the review, according to their title and abstract. Then, the full-text of potentially relevant articles was screened for content to decide its inclusion. Studies with multiple publications were identified to avoid duplicate reports.

Data collection

One reviewer (JC) extracted the data from the included studies and a second reviewer (AM) checked the extracted data. Disagreements were resolved by consensus. If consensus could not be reached, a third reviewer (DB) was consulted. A structured data extraction was performed, focusing on: study design, country where the study was conducted, sample size, type of intervention (HTMG) and comparator (CG), telemonitoring duration, outcome measures and results.

Quality assessment

The quality of the studies was independently assessed by two raters (JC and AM) using a modified version of the scoring system developed to evaluate telemedicine research by Hailey and co-workers (2011), summarised in Polisena et al. (2010). It consists of 5 levels, from A (high quality) to E (poor quality), based on study design and performance. Inter-rater agreement was assessed using Cohen's kappa coefficient, considering the cut-off points (Landis and Koch, 1977): slight agreement (≤0.20), fair agreement (0.21–0.40), moderate agreement (0.41–0.60), substantial agreement (0.61–0.80) and almost perfect agreement (≥0.81). Disagreements between raters were resolved by consensus.

Synthesis of results

Meta-analyses were conducted to evaluate the effects of home telemonitoring in healthcare utilisation and associated costs, mortality rates, respiratory exacerbations and HRQOL. In case of missing data, the corresponding authors were contacted via e-mail to provide more information. Five authors (De San Miguel et al., 2013, Koff et al., 2009,

Lewis et al., 2010b, Paré et al., 2006, Pedone et al., 2013) were contacted; however, only one replied. Effect sizes were calculated with the risk ratio (RR) for dichotomous variables and the standardised mean difference (SMD) for continuous variables. The 95% confidence intervals (95%CI) and significance tests were also computed (statistical significance: $p<0.05$). Effect size data were synthesised into forest plots and a fixed-models effect was used in the absence of substantial heterogeneity across studies. Heterogeneity was measured using the I^2 test, which represents the percentage of the variation in effect sizes that is due to heterogeneity rather than sampling error (Higgins et al., 2003). When substantial heterogeneity was found ($I^2 \geq 50\%$) (Deeks et al., 2008), a random-effects model was applied. If appropriate, subgroup analyses for study design, COPD severity and telemonitoring duration were also conducted to explore reasons for heterogeneity. Publication bias was assessed by visual inspection of funnel plots and Egger's regression intercept test if more than 5 studies were included in the meta-analysis (Sterne et al., 2005). Quantitative analyses were performed using Comprehensive Meta-Analysis software v2.0 (Biostat, Englewood, New Jersey).

Results

Study selection

The literature search identified 455 records. After duplicates removed, 130 records were screened for content through title and abstract. From these, 114 were excluded. The full-text of 16 articles was then assessed for eligibility and 11 articles were excluded (Figure 1). Five articles were identified as relevant from the automatic updates of the databases and the reference lists and were included in the review. One study had 2 publications reporting healthcare utilisation (Lewis et al., 2010b) and health-related outcomes (Lewis et al., 2010a), thus both articles were considered. In total, 10 articles on 9 studies were included, all published in English: 7 RCTs (Antoniades et al., 2012, Chau et al., 2012, De San Miguel et al., 2013, Jódar-Sánchez et al., 2013, Koff et al., 2009, Lewis et al., 2010a, Lewis et al., 2010b, Pedone et al., 2013) and 2 NRCTs (Paré et al., 2006, Trappenburg et al., 2008).

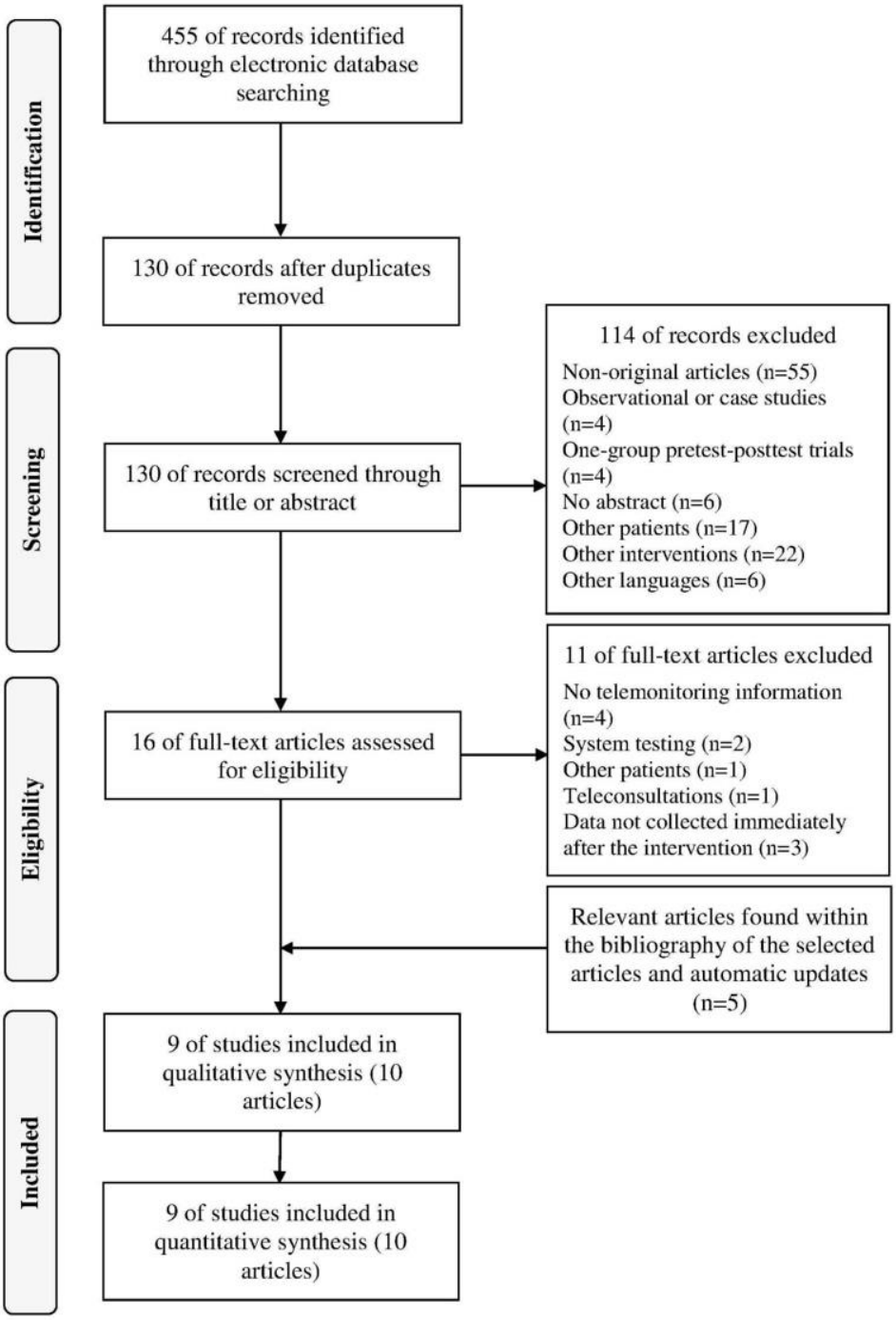

Figure 1. Flow diagram for study selection.

Quality assessment

Two articles were rated as A (high quality) (Chau et al., 2012, Lewis et al., 2010b), 7 as B (good quality) (Antoniades et al., 2012, Koff et al., 2009, Lewis et al., 2010a, Paré et al., 2006, Trappenburg et al., 2008, Jódar-Sánchez et al., 2013, Pedone et al., 2013) and 1 as C (fair to good quality) (De San Miguel et al., 2013). Two articles rated as good quality

were in the borderline to be considered as high quality (Antoniades et al., 2012, Lewis et al., 2010a). Cohen's kappa coefficient revealed substantial agreement between raters (κ=0.63; p=0.036).

Study characteristics

Five studies were published from 2011 to the present (Antoniades et al., 2012, Chau et al., 2012, De San Miguel et al., 2013, Jódar-Sánchez et al., 2013, Pedone et al., 2013). Table 1 provides an overview of the characteristics of each study.

COPD severity was an inclusion criterion in all studies. Patients had to present moderate to severe COPD (n=4) (Antoniades et al., 2012, Chau et al., 2012, Lewis et al., 2010a, Lewis et al., 2010b, Pedone et al., 2013), severe COPD (n=2) (Paré et al., 2006), severe to very severe COPD (n=5) (Jódar-Sánchez et al., 2013, Koff et al., 2009, Trappenburg et al., 2008) and/or receive oxygen therapy (n=1) (De San Miguel et al., 2013, Jódar-Sánchez et al., 2013). Samples included varied from 30 (Paré et al., 2006) to 165 (Trappenburg et al., 2008), mostly older people (mean age ≥65 years old).

Telemonitoring data were generally transmitted to a monitoring centre on a daily basis, during 2 (Chau et al., 2012) to 12 (Antoniades et al., 2012) months. Patients' compliance with data transmission was assessed in 5 studies (Antoniades et al., 2012, Chau et al., 2012, Jódar-Sánchez et al., 2013, Lewis et al., 2010b, Pedone et al., 2013) and ranged from 40% (Antoniades et al., 2012) to 98% (Chau et al., 2012), depending on the clinical measurement. In all studies, patient's readings outside pre-determined values triggered an immediate action from the healthcare team monitoring the data. Usual care included the same healthcare component provided to the HTMG, but without telemonitoring (Table 1).

Synthesis of results

An overview of the outcomes assessed in each study is provided in Table 2.

Table 1. Main characteristics of the studies.

First author (year)	Study design	Country	Participants	Telemonitoring duration	Home telemonitoring (experimental group)	Usual care (experimental and control groups)
Antoniades (2012)	RCT	Australia	44 patients with moderate to severe COPD and with ≥1 hospitalisations/year: HTMG (n=22) and CG (n=22).	12 months	Transmission of data about spirometry parameters, weight, temperature, blood pressure, oxygen saturation, electrocardiogram, sputum colour and volume, symptoms and medication usage, on a daily basis (on weekdays).	Clinical management according to Australian and New Zealand guidelines with provision of outreach nursing, a written action plan and availability of pulmonary rehabilitation (chronic disease management programme).
Chau (2012)	RCT	Hong Kong	53 older people with moderate to severe COPD and with ≥1 hospitalisations/year: HTMG (n=30) and CG (n=23).	2 months (mean duration 54.36 days)	Measurements of oxygen saturation, heart rate and respiration rate 3 times a day (on weekdays). The technology provided patients with a medication and pursed-lips breathing reminder with a feedback function.	In-home nurse visits to offer education on self-care and symptom management techniques.
De San Miguel (2013)	RCT	Australia	71 patients with COPD treated with long-term oxygen therapy: HTMG (n=36) and CG (n=35).	6 months	Daily transmission of blood pressure, heart rate, oxygen saturation, weight, temperature and of data related to patients' general state of health. Patients also received an educational book about COPD.	Educational book about COPD.

(table 1 – continued)

First author (year)	Study design	Country	Participants	Telemonitoring duration	Home telemonitoring (experimental group)	Usual care (experimental and control groups)
Jódar-Sánchez, (2013)	RCT	Spain	45 patients with clinically stable COPD and chronic respiratory failure, receiving long-term oxygen therapy and with ≥1 hospitalisations/year: HTMG (n=24) and CG (n=21).	4 months	Daily measurement (on weekdays) of blood pressure, heart rate and oxygen saturation and spirometry 2 days per week, 20 minutes after taking prescribed inhaled therapy, seated and rested, and while on oxygen therapy.	Conventional medical care.
Koff (2009)	RCT	United States of America	40 patients with severe to very severe COPD (GOLD 3 and GOLD 4): HTMG (n=20) and CG (n=20).	3 months	Transmission of data about symptoms, oxygen saturation, spirometry parameters and steps in six-minute walking distance, on a daily basis (on weekdays), plus disease-specific and self-management education and interaction with study coordinators through the telemonitoring system (proactive integrated care programme).	Usual access to healthcare providers.
Lewis (2010a, 2010b)	RCT	United Kingdom	40 patients with moderate to severe COPD after undertaken pulmonary rehabilitation: HTMG (n=20) and CG (n=20).	6 months	Data transmission twice a day regarding the condition of patients' chest over the preceding day/night, oral temperature, heart rate and oxygen saturation.	Standard care.
Paré (2006)	NRCT	Canada	30 patients with severe COPD that required frequent home visits: HTMG (n=20) and CG (n=10).	6 months	Daily transmission of peak flow rate, symptoms and medication taken.	Traditional system of in-home visits (CG only).

(table 1 – continued)

First author (year)	Study design	Country	Participants	Telemonitoring duration	Home telemonitoring (experimental group)	Usual care (experimental and control groups)
Pedone (2013)	RCT	Italy	99 older people with moderate to severe COPD (GOLD 2 and GOLD 3): HTMG (n=50) and CG (n=49).	9 months	Data transmission 5 times a day, every 3 hours, of oxygen saturation, heart rate, respiratory rate, physical activity and body temperature.	Standard care.
Trappenburg (2008)	NRCT	Netherlands	165 patients with severe to very severe COPD (GOLD 3 and GOLD 4) with ≥1 hospitalisations/6 months: HTMG (n=101) and CG (n=64).	6 months	Daily transmission of data about symptoms, medication compliance and knowledge, with immediate feedback from the system.	Usual access to healthcare providers.

COPD – chronic obstructive pulmonary disease; CG – control group; HTMG – home telemonitoring group; GOLD - Global Initiative for Chronic Obstructive Lung Disease; NRCT - non-randomised controlled trial; RCT – randomised controlled trial.

Table 2. Types of outcomes measured in the home telemonitoring and control groups.

	Hospitalisations		**Length of hospital stay**	**Emergency department visits**		**Healthcare costs**	**Mortality**	**Quality of life**	**Respiratory exacerbations**		**Other outcomes***
First author (year)	Rate	Mean	Mean	Rate	Mean	Mean	Rate	Mean	Rate	Mean	
Antoniades (2012)		●	●				●	●			
Chau (2012)	●		●	●				●			●
De San Miguel (2013)	●	●	●	●	●	●		●			●
Jódar-Sánchez, (2013)	●	●	●	●	●		●	●			●
Koff (2009)	●			●		●		●			
Lewis (2010a, 2010b)	●	●	●		●		●	●			●
Paré (2006)	●	●	●			●					●
Pedone (2013)	●		●						●		
Trappenburg (2008)	●	●	●		●		●	●		●	●

*Other outcomes: forced expiratory volume in 1 second (FEV_1), forced vital capacity (FVC) and FEV_1/FVC ratio (Chau et al., 2012), type and quantity of prescribed medication (Trappenburg et al., 2008), six-minute walking distance (Antoniades et al., 2012), anxiety and depression symptoms (Lewis et al., 2010a), primary care contacts (chest and non-chest) (Lewis et al., 2010b), specialised consultations (Jódar-Sánchez et al., 2013), healthcare team phone calls and home visits (De San Miguel et al., 2013, Jódar-Sánchez et al., 2013, Koff et al., 2009, Lewis et al., 2010b, Paré et al., 2006), mortality (Jódar-Sánchez et al., 2013, Lewis et al., 2010b) and costs related to telemonitoring equipment and healthcare resources (Paré et al., 2006).

Hospitalisation rates

Six RCTs (Chau et al., 2012, De San Miguel et al., 2013, Jódar-Sánchez et al., 2013, Koff et al., 2009, Lewis et al., 2010a, Pedone et al., 2013) and 2 NRCTs (Paré et al., 2006, Trappenburg et al., 2008) including 486 patients reported hospitalisation rates in both groups. Patients receiving home telemonitoring had a significantly lower risk of hospitalisation than those receiving usual care (RR=0.72; 95%CI=0.53–0.98; Z=-2.12; p=0.034; Figure 2; I^2=4.73%). Publication bias was not evident either from visual inspection of the funnel plot (data not shown) and the Egger's regression intercept test (intercept=-0.21; 95%CI=-2.46–2.03; p=0.824).

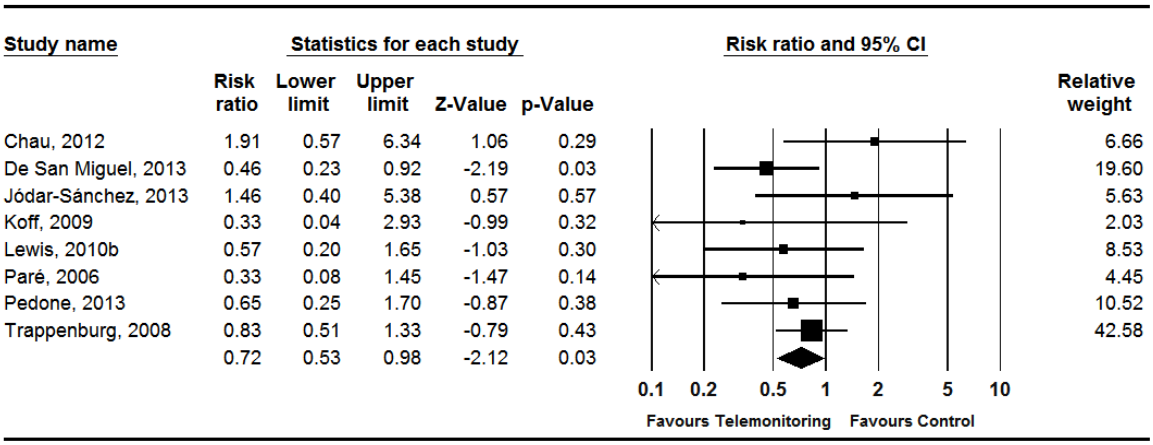

Figure 2. Risk ratio of hospitalisation in the home telemonitoring and control groups (fixed-effects model).

Mean number of hospitalisations

Seven studies reported the mean number of hospitalisations per patient (Antoniades et al., 2012, De San Miguel et al., 2013, Jódar-Sánchez et al., 2013, Koff et al., 2009, Lewis et al., 2010a, Paré et al., 2006, Trappenburg et al., 2008). Three studies were excluded from quantitative analysis due to missing data (De San Miguel et al., 2013, Koff et al., 2009, Paré et al., 2006). Therefore, 4 studies including 244 patients with COPD were included (Antoniades et al., 2012, Jódar-Sánchez et al., 2013, Lewis et al., 2010a, Trappenburg et al., 2008). There were no significant differences between groups (SMD=-0.06; 95%CI=-0.32–0.19; Z=-0.50; p=0.617; I^2=16.42%).

Length of hospital stay

Eight studies providing information about hospitalisations also reported the mean length of hospital stay (in days) (Antoniades et al., 2012, Chau et al., 2012, De San Miguel et al.,

2013, Jódar-Sánchez et al., 2013, Lewis et al., 2010b, Paré et al., 2006, Pedone et al., 2013, Trappenburg et al., 2008). Four studies were excluded from the quantitative analysis due to missing or non-comparable data (De San Miguel et al., 2013, Lewis et al., 2010b, Paré et al., 2006, Pedone et al., 2013). Four studies with 244 patients with COPD were included (Antoniades et al., 2012, Chau et al., 2012, Jódar-Sánchez et al., 2013, Trappenburg et al., 2008). The length of hospital stay was not different between groups (SMD=0.06; 95%CI=-0.19–0.31; Z=0.48; p=0.635; I^2=0%).

Emergency department visit rates

Only 4 studies with 194 patients, all RCTs, reported emergency department visit rates (Chau et al., 2012, De San Miguel et al., 2013, Jódar-Sánchez et al., 2013, Koff et al., 2009). There was no evidence of a significant effect of home telemonitoring on emergency department visit rates (RR=0.68; 95%CI=0.38–1.18; Z=-1.34; p=0.179; I^2=22.53%).

Mean number of emergency department visits

Five studies reported the mean number of emergency department visits (De San Miguel et al., 2013, Jódar-Sánchez et al., 2013, Koff et al., 2009, Lewis et al., 2010b, Trappenburg et al., 2008). Three studies were excluded from the quantitative analysis due to non-comparable data (De San Miguel et al., 2013, Lewis et al., 2010b, Koff et al., 2009). Two studies, 1 RCT (Jódar-Sánchez et al., 2013) and 1 NRCT (Trappenburg et al., 2008), comparing home telemonitoring to usual care for 4-6 months in 160 patients with severe to very severe COPD were included. The number of emergency department visits was not significantly different between groups (SMD=0.20; 95%CI=-0.49–0.88; Z=0.56; p=0.576). There was substantial heterogeneity across studies (I^2=74.81%) (Deeks et al., 2008), therefore, a random-effects model was applied and a subgroup analysis of study designs was conducted.

The NRCT (Trappenburg et al., 2008) reported a significantly lower mean number of emergency department visits in the HTMG (SMD=0.51; 95%CI=0.14–0.88; Z=2.70; p=0.007). This positive trend was not observed in the RCT (Jódar-Sánchez et al., 2013) (SMD=-0.19; 95%CI=-0.78–0.39; Z=-0.65; p=0.515).

Healthcare-related costs

Three studies assessed the costs related to healthcare services (De San Miguel et al., 2013, Koff et al., 2009, Paré et al., 2006). De San Miguel et al. (2013) reported total cost savings of 112,439US dollars (USD) in the HTMG. Koff et al. (2009) suggested that home telemonitoring reduced healthcare-related costs (mean change=-1,401USD; 95%CI=-6,566–3,764USD) when compared to usual care (mean change=1,709USD; 95%CI=-4,349–7,768USD); however, the difference was not significant (p=0.21). Paré et al. (2006) found that telemonitoring yielded a reduction in hospitalisation costs (29,686USD) and a total cost reduction of 6,750USD when compared to usual care, including the costs associated with the implementation of each intervention (e.g., home visits or technology).

Mortality rates

Four studies with 294 patients presented mortality rates (Antoniades et al., 2012, Jódar-Sánchez et al., 2013, Lewis et al., 2010b, Trappenburg et al., 2008). Two of them reported non-COPD related reasons for death (Antoniades et al., 2012, Lewis et al., 2010b). Mortality rates were not different between groups (RR=1.43; 95%CI=0.40–5.03; Z=0.55; p=0.582; I^2=0%).

Respiratory exacerbations

One RCT (Pedone et al., 2013) and 1 NRCT (Trappenburg et al., 2008) including 214 patients assessed the number of respiratory exacerbations during the intervention in both groups. These studies found that the CG had a higher incidence of respiratory events (HTMG:9/50; CG:15/49; p=0.152) (Pedone et al., 2013) and mean number of exacerbations (HTMG=0.65±1.4; CG=1.01±1.4; p=0.004) (Trappenburg et al., 2008).

Two studies reported the number of exacerbations detected by the telemonitoring system in the HTMG (Jódar-Sánchez et al., 2013, Koff et al., 2009). In Jódar-Sánchez et al. (2013) the device provided 40 alerts and in Koff et al. (2009) it detected 9 exacerbations. A worsening of peripheral oxygen saturation was the most frequent altered clinical finding in the detection of a respiratory exacerbation (Koff et al., 2009, Pedone et al., 2013).

Health-related quality of life

Seven studies evaluated patients' HRQOL before/after the intervention, using either disease-specific (Chronic Respiratory Disease Questionnaire (Antoniades et al., 2012), Chronic Respiratory Questionnaire (Chau et al., 2012, De San Miguel et al., 2013), St. George's Respiratory Questionnaire (SGRQ) (Jódar-Sánchez et al., 2013, Koff et al., 2009, Lewis et al., 2010a), Clinical COPD Questionnaire (Trappenburg et al., 2008)) or general (EURO-QOL-5D Questionnaire (Jódar-Sánchez et al., 2013, Lewis et al., 2010a), Medical Outcome Study Short-Form 36 Questionnaire (Antoniades et al., 2012)) quality of life measurement instruments. Overall, no significant differences were found between groups. Pooling was not appropriate because the instruments measure different domains of HRQOL (Glaab et al., 2010). Only two RCTs presenting the mean change (i.e., posttest-pretest) of total and sub-dimension scores of the SGRQ were pooled (Jódar-Sánchez et al., 2013, Koff et al., 2009). In SGRQ, lower scores represent better quality of life (Jones, 2005). A statistically significant change was found in the SGRQ total score (SMD=-0.53; 95%CI=-0.97– -0.09; Z=-2.35; p=0.019; I^2=17.74%) suggesting that patients receiving home telemonitoring had a greater HRQOL after the intervention (Figure 3). This trend was not confirmed for SGRQ sub-dimensions (p>0.05; I^2=0.00%).

In terms of clinical significance (i.e., mean change ≥4units) (Jones, 2005), both groups exhibited a clinically important change in SGRQ total score in Jódar-Sánchez et al. (2013) (HTMG=10.9; CG=4.5); however, only the HTMG achieved this clinical change in Koff et al. (2009).

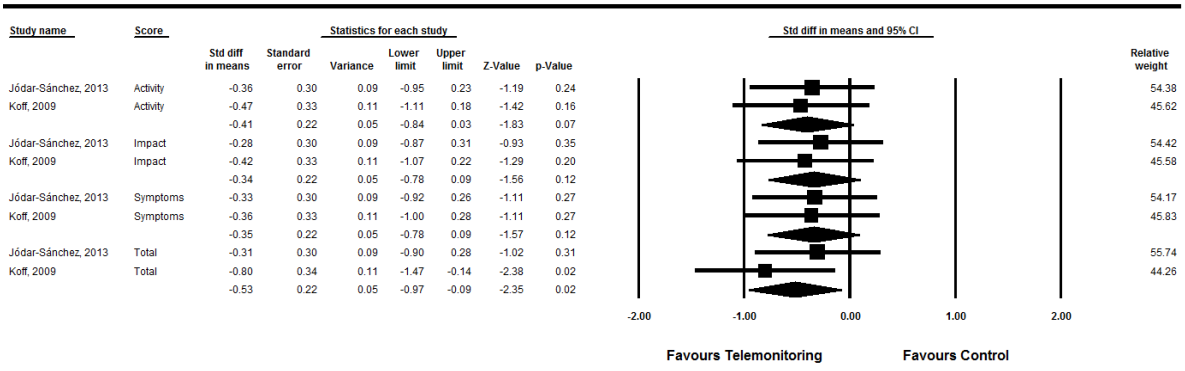

Figure 3. Mean change in quality of life of the home telemonitoring and control groups using the St. George's Respiratory Questionnaire total and sub-dimension (activity, impact and symptoms) scores (fixed-effects model). Std diff in means: standardised mean difference.

Discussion

This systematic review assessed the effectiveness of home telemonitoring in COPD. Nine studies were included, five of them published from 2011 to the present which emphasises the novelty of this type of intervention. Most studies were RCTs of good quality; however, some of them had relatively small samples. Findings suggest that, although home telemonitoring appears to have a positive effect in detecting and reducing respiratory exacerbations and improving HRQOL, there is still no clear indication that it reduces healthcare utilisation and associated costs as only hospitalisation risk was reduced in the HTMG. One NRCT (Trappenburg et al., 2008) also showed a significantly lower number of emergency department visits in the HTMG. However, this result should be interpreted with caution because of the inherent risk of bias associated with this study design. Furthermore, this positive trend was not observed in a RCT with a similar target-population and telemonitoring duration (Jódar-Sánchez et al., 2013).

Healthcare utilisation was similar in both groups, with the exception of hospitalisation rates. Some reasons may have contributed to these findings. Firstly, it was not always clear whether healthcare utilisation reported in some studies was related to respiratory exacerbations (Dinesen et al., 2012, Jódar-Sánchez et al., 2013, Paré et al., 2006, Trappenburg et al., 2008). Therefore, it is unclear if COPD-related healthcare utilisation was actually reduced. Secondly, the levels of patients' compliance with telemonitoring may also explain some of the results. As reported earlier, compliance with data transmission ranged from 40% (Antoniades et al., 2012) to 98% (Chau et al., 2012). This lower compliance found in some studies might have contributed to the failure in detecting health deterioration. Hence, the purpose of home telemonitoring, i.e., the continuous monitoring of patients' clinical data to early detect and address health deterioration, may not have been reached due to a lack of patients' compliance.

The two studies reporting the occurrence of respiratory exacerbations in both groups found that the CG had a higher number of exacerbations during the intervention, when compared to the HTMG (Pedone et al., 2013, Trappenburg et al., 2008). Two additional studies reported that the telemonitoring system was able to detect respiratory exacerbations (Jódar-Sánchez et al., 2013, Koff et al., 2009). These findings support the hypothesis that telemonitoring can be a potential way of detecting and managing COPD exacerbations in a timely manner. Advancements in physiological sensors and in information and communication technologies may, therefore, offer opportunities for providing healthcare management tools, enabling extended independent living at home for

individuals with COPD. However, there is still a lack of clarity about which parameters should be used to detect exacerbations (McKinstry, 2013). The worsening of peripheral oxygen saturation was the most frequent altered clinical finding in the detection of respiratory exacerbations (Koff et al., 2009, Pedone et al., 2013). A previous exploratory research supports these results (Hurst et al., 2010). According to Hurst and co-workers (2010), a composite measure that combines oxygen saturation and heart rate may be useful to identify an exacerbation onset. In this review, only four studies collected both measurements (Chau et al., 2012, Jódar-Sánchez et al., 2013, Lewis et al., 2010a, Lewis et al., 2010b, Pedone et al., 2013).

Studies reporting healthcare-related costs revealed a positive trend towards telemonitoring interventions, suggesting that home telemonitoring may, therefore, have the ability to produce savings in COPD management (Jaana et al., 2009). This trend may be in part related to the decreased hospitalisation rates found in the present study. According to previous research, hospitalisations represent more than one-half of the total direct costs attributable to COPD (Miller et al., 2005), mostly due to respiratory exacerbations (Toy et al., 2010). However, the small number of studies providing healthcare-related cost information and the differences in the estimation of this outcome (e.g., in the study of De San Miguel et al. (2013), hospital visit costs were based on length of stay rather than number of hospitalisations) limit the interpretation of the findings. Further work still needs to be conducted on this topic to draw final conclusions.

Findings on patients' HRQOL were inconsistent. In most studies, no significant changes after the intervention were found. Nevertheless, they used different measurement instruments which made difficult to perform comparisons. When two studies using the same questionnaire were pooled (Jódar-Sánchez et al., 2013, Koff et al., 2009), significant changes were found in favour of the HTMG. These studies also demonstrated a clinically important change in the HTMG and one found a clinical change also in the CG (Jódar-Sánchez et al., 2013). Hence, the ability of home telemonitoring to demonstrate an improvement in HRQOL beyond to that achieved with usual care remains a challenge.

Limitations

One limitation of this review concerns the exclusion of six studies written in languages other than English, Portuguese and Spanish, since they could be relevant for the scope of the review. The fact that some studies could not be integrated in the quantitative analysis due to missing or non-comparable data is another limitation. Thus, it is unknown if any of

these studies could have influenced the outcomes in the telemonitoring group. Lastly, in most cases, the number of studies included in the meta-analysis was insufficient (n<5) (Sterne et al., 2005) to measure the potential of publication bias.

Implications for research and practice

The value of home telemonitoring to reduce healthcare utilisation and improve health-related outcomes is not yet well defined. Therefore, to advocate the use of this intervention as a patient management approach and to incorporate it into practice, further work needs to be conducted. In addition, variations in compliance rates suggest that telemonitoring regimens may not be appropriate for all patients. Further research is needed to identify the types of patients most likely to benefit from these interventions. Future studies should also consider: i) including a composite measure of oxygen saturation and heart rate to early detect exacerbations; ii) using similar HRQOL measurement instruments to enable comparisons across studies; iii) reporting healthcare utilisation data in a format that can be further pooled into meta-analysis.

Conclusion

The findings provide limited evidence of the effectiveness of home telemonitoring to reduce healthcare utilisation and improve health-related outcomes in patients with COPD. Although this intervention appears to have a positive effect in reducing respiratory exacerbations and hospitalisations and improving HRQOL, there is still no clear indication that it reduces healthcare utilisation and associated costs. Further research is needed to assess the effectiveness of home telemonitoring in COPD management, as there are still few studies in this area.

Authors' contributions

All authors contributed in different processes of the systematic review. JC and AM worked on the definition of appropriate search terms, quality assessment, data extraction and analysis. JC performed the search in the electronic databases and provided a draft of the manuscript, which was critically revised by all authors. All authors read and approved the final manuscript.

Funding and Acknowledgements

Support for this study was provided by Fundação para a Ciência e Tecnologia (Ref. SFRH/BD/81328/2011), Portugal.

References

Antoniades, N. C., Rochford, P. D., Pretto, J. J., Pierce, R. J., Gogler, J., Steinkrug, J., et al. 2012. Pilot study of remote telemonitoring in COPD. *Telemed J E Health,* 18**,** 634-40.

Bolton, C. E., Waters, C. S., Peirce, S. & Elwyn, G. 2010. Insufficient evidence of benefit: a systematic review of home telemonitoring for COPD. *J Eval Clin Pract,* 17**,** 1216-22.

Chau, J. P.-C., Lee, D. T.-F., Yu, D. S.-F., Chow, A. Y.-M., Yu, W.-C., Chair, S.-Y., et al. 2012. A feasibility study to investigate the acceptability and potential effectiveness of a telecare service for older people with chronic obstructive pulmonary disease. *Int J Med Inf,* 81**,** 674-82.

De San Miguel, K., Smith, J. & Lewin, G. 2013. Telehealth Remote Monitoring for Community-Dwelling Older Adults with Chronic Obstructive Pulmonary Disease. *Telemed J E Health,* 19**,** 652-7.

Deeks, J. J., Higgins, J. P., Altman, D. G. & on behalf of the Cochrane Statistical Methods Group 2008. Analysing data and undertaking meta-analyses *In:* HIGGINS, J. P. & GREEN, S. (eds.) *Cochrane Handbook for Systematic Reviews of Interventions - Cochrane Book Series.* Chichester, UK: John Wiley & Sons.

Dinesen, B., Haesum, L. K., Soerensen, N., Nielsen, C., Grann, O., Hejlesen, O., et al. 2012. Using preventive home monitoring to reduce hospital admission rates and reduce costs: a case study of telehealth among chronic obstructive pulmonary disease patients. *J Telemed Telecare,* 18**,** 221-5.

Glaab, T., Vogelmeier, C. & Buhl, R. 2010. Outcome measures in chronic obstructive pulmonary disease (COPD): strengths and limitations. *Respir Res,* 11**,** 79.

Global Strategy for the Diagnosis Management and Prevention of COPD Global Initiative for Chronic Obstructive Lung Disease (GOLD) 2013. Available from: www.goldcopd.org/. [Accessed on February, 2013].

Hailey, D., Roine, R., Ohinmaa, A. & Dennett, L. 2011. Evidence of benefit from telerehabilitation in routine care: a systematic review. *J Telemed Telecare,* 17**,** 281-7.

Higgins, J. P. T., Thompson, S. G., Deeks, J. J. & Altman, D. G. 2003. Measuring inconsistency in meta-analyses. *BMJ,* 327**,** 557-60.

Hurst, J., Donaldson, G., Quint, J., Goldring, J., Patel, A. & Wedzicha, J. 2010. Domiciliary pulse-oximetry at exacerbation of chronic obstructive pulmonary disease: prospective pilot study. *BMC Pulm Med,* 10**,** 52.

Jaana, M., Pare, G. & Sicotte, C. 2009. Home telemonitoring for respiratory conditions: a systematic review. *Am J Manag Care,* 15**,** 313-20.

Jódar-Sánchez, F., Ortega, F., Calderon, C. P., Gomez-Suarez, C., Jordan, A., Perez, P., et al. 2013. Implementation of a telehealth programme for patients with severe chronic obstructive pulmonary disease treated with long-term oxygen therapy. *J Telemed Telecare,* 19**,** 11-7.

Jones, P. W. 2005. St. George's Respiratory Questionnaire: MCID. *COPD,* 2**,** 75-9.

Kamei, T., Yamamoto, Y., Kajii, F., Nakayama, Y. & Kawakami, C. 2013. Systematic review and meta-analysis of studies involving telehome monitoring-based telenursing for patients with chronic obstructive pulmonary disease. *JJNS*, *doi: 10.1111/j.1742-7924.2012.00228.x. Epub ahead of print: October 1, 2013.*

Koff, P. B., Jones, R. H., Cashman, J. M., Voelkel, N. F. & Vandivier, R. W. 2009. Proactive integrated care improves quality of life in patients with COPD. *Eur Respir J,* 33**,** 1031-8.

Landis, J. R. & Koch, G. G. 1977. The measurement of observer agreement for categorical data. *Biometrics,* 33**,** 159-74.

Lewis, K. E., Annandale, J. A., Warm, D. L., Hurlin, C., Lewis, M. J. & Lewis, L. 2010a. Home telemonitoring and quality of life in stable, optimised chronic obstructive pulmonary disease. *J Telemed Telecare,* 16**,** 253-9.

Lewis, K. E., Annandale, J. A., Warm, D. L., Rees, S. E., Hurlin, C., Blyth, H., et al. 2010b. Does Home Telemonitoring after Pulmonary Rehabilitation Reduce Healthcare Use in Optimized COPD? A Pilot Randomized Trial. *COPD,* 7**,** 44-50.

McKinstry, B. 2013. The use of remote monitoring technologies in managing chronic obstructive pulmonary disease. *QJM,* 106**,** 883-5.

McLean, S., Nurmatov, U., Liu, J. L., Pagliari, C., Car, J. & Sheikh, A. 2011. Telehealthcare for chronic obstructive pulmonary disease. *Cochrane Database Syst Rev***,** 7. doi: 10.1002/14651858.CD007718.pub2.

Miller, J. D., Foster, T., Boulanger, L., Chace, M., Russell, M. W., Marton, J. P., et al. 2005. Direct costs of COPD in the U.S.: an analysis of Medical Expenditure Panel Survey (MEPS) data. *COPD,* 2**,** 311-8.

Moher, D., Liberati, A., Tetzlaff, J., Altman, D. G. & The Prisma Group. 2009. Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. *PLoS Med,* 6**,** e1000097.

Murray, C. J. L. & Lopez, A. D. 2013. Measuring the Global Burden of Disease. *N Engl J Med,* 369**,** 448-57.

O'Reilly, J. F., Williams, A. E. & Rice, L. 2007. Health status impairment and costs associated with COPD exacerbation managed in hospital. *Int J Clin Pract,* 61**,** 1112-20.

Paré, G., Jaana, M. & Sicotte, C. 2007. Systematic review of home telemonitoring for chronic diseases: the evidence base. *J Am Med Inform Assoc,* 14**,** 269-77.

Paré, G., Sicotte, C., St.-Jules, D. & Gauthier, R. 2006. Cost-Minimization Analysis of a Telehomecare Program for Patients with Chronic Obstructive Pulmonary Disease. *Telemed J E Health,* 12**,** 114-21.

Pedone, C., Chiurco, D., Scarlata, S. & Antonelli Incalzi, R. 2013. Efficacy of multiparametric telemonitoring on respiratory outcomes in elderly people with COPD: a randomized controlled trial. *BMC Health Serv Res,* 13**,** 82.

Polisena, J., Tran, K., Cimon, K., Hutton, B., McGill, S., Palmer, K., et al. 2010. Home telehealth for chronic obstructive pulmonary disease: a systematic review and meta-analysis. *J Telemed Telecare,* 16**,** 120-7.

Soler-Cataluña, J. J., Martínez-García, M. Á., Román Sánchez, P., Salcedo, E., Navarro, M. & Ochando, R. 2005. Severe acute exacerbations and mortality in patients with chronic obstructive pulmonary disease. *Thorax,* 60**,** 925-31.

Sterne, J. A. C., Becker, B. J. & Egger, M. 2005. The funnel plot. *In:* ROTHSTEIN, H., SUTTON, A. & BORENSTEIN, M. (eds.) *Publication bias in meta-analysis : prevention, assessment and adjustments.* West Sussex: John Wiley & Sons.

Toy, E. L., Gallagher, K. F., Stanley, E. L., Swensen, A. R. & Duh, M. S. 2010. The economic impact of exacerbations of chronic obstructive pulmonary disease and exacerbation definition: a review. *COPD,* 7**,** 214-28.

Trappenburg, J. C. A., Niesink, A., de Weert-van Oene, G. H., van der Zeijden, H., van Snippenburg, R., Peters, A., et al. 2008. Effects of Telemonitoring in Patients with Chronic Obstructive Pulmonary Disease. *Telemed J E Health,* 14**,** 138-46.

World Health Organization (WHO) 2008. The global burden of disease: 2004 update. WHO Library Cataloguing-in-Publication Data.

Study 2 – Home telemonitoring in COPD: A systematic review of methodologies and patients' adherence

Joana Cruz
Dina Brooks
Alda Marques

International Journal of Medical Informatics, 83(4), 249–63 (2014)

Abstract

Aim: This systematic review aimed to provide a comprehensive description of the methodologies used in home telemonitoring interventions for Chronic Obstructive Pulmonary Disease (COPD) and to explore patients' adherence and satisfaction with the use of telemonitoring systems.

Methods: A literature search was performed from June to August and updated until December of 2012 on Medline, Embase, Web of Science and B-on databases using the following keywords: [tele(-)monitoring, tele(-)health, tele(-)homecare, tele(-)care, tele-home health or home monitoring] and [Chronic Obstructive Pulmonary Disease or COPD]. References of all articles were also reviewed.

Results: Seventeen articles were included, 12 of them published from 2010 to the present. The methodologies were similar in the training provided to patients and in the data collection and transmission processes. However, differences in the type of technology used, telemonitoring duration and provision of prompts/feedback, were found. Patients were generally satisfied and found the systems useful to help them manage their disease and improve healthcare provision. Nevertheless, they reported some difficulties in their use, which in some studies were related to lower compliance rates.

Conclusions: Telemonitoring interventions are a relatively new field in COPD research. Findings suggest that these interventions, although promising, present some usability problems that need to be considered in future research. These adjustments are essential before the widespreading of telemonitoring.

Keywords: adherence; chronic obstructive pulmonary disease; e-health; remote monitoring; satisfaction level; telemedicine.

Research Highlights

- Telemonitoring interventions should to be adjusted to their target population;
- Assessment of patients' acceptance of telemonitoring technology should be considered prior to its implementation;
- Future research should consider the inclusion of easy-to-use technology and more training sessions;
- Frequency of data collection/transmission should be flexible to improve adherence;
- Changes in patients' self-management behavior should be explored in future studies.

Summary Points

What is already known on the topic:

- The number of patients with COPD being managed at home is increasing to reduce health-related costs while trying to increase patients' comfort;
- Home telemonitoring is an innovative approach which facilitates patients' management at home, by exchanging information between patients and their healthcare professionals;
- There are systematic reviews available on the topic of home telemonitoring in respiratory patients and, specifically, in patients with COPD. However, they lack information about telemonitoring methodologies and patients' adherence.

What has this study added to our knowledge:

- Home telemonitoring interventions, although promising, still need to be adjusted to ensure their suitability to the target population. Assessment of patients' needs, characteristics and acceptance of the technology may facilitate patients' adherence to telemonitoring regimens;
- Future home telemonitoring interventions for COPD should consider the inclusion of easy-to-use technology and more training sessions to facilitate patients' education on the use of the technologies, and they should be flexible in frequency of data collection and transmission to improve adherence;
- The impact of telemonitoring interventions on patients' self-management behavior and satisfaction should also be explored, as well as their associations with patient outcomes and healthcare utilization.

Introduction

Chronic Obstructive Pulmonary Disease (COPD) is a highly prevalent disease worldwide (World Health Organization [WHO], 2008). As the disease progresses, patients become more susceptible to respiratory exacerbations which cause frequent hospital admissions and readmissions and, thus, have a considerable impact on patients' quality of life and healthcare costs (Casas et al., 2006, Global Strategy for the Diagnosis Management and Prevention of COPD [GOLD], 2013). This poses COPD as a public health problem of increasing concern to healthcare systems worldwide (Nici et al., 2006). A number of interventions have been developed to help patients self-manage their disease and improve their quality of life, therefore reducing pressures on healthcare resources. Recent studies have shown that the number of patients with COPD being managed at home is increasing to reduce health-related costs while trying to increase patients' comfort (Bolton et al., 2010).

Home telemonitoring is a relatively new approach (dating back to the early 1990s) which facilitates patients' management at home (Paré et al., 2007). It is defined as the use of telecommunication technologies to transmit data on patients' health status (e.g., oxygen saturation, vital signs) from home to a healthcare center (Jaana et al., 2009, Paré et al., 2007). By systematically monitoring patients' health condition, home telemonitoring can be used for a timely assessment of an acute exacerbation or as a mechanism to generate alarms to the patients and/or healthcare professionals when clinical changes that may constitute a risk to the patient occur (McKinstry, 2013). This approach aims to empower patients to manage their disease (e.g., by recognizing the early signs of exacerbations), improve patient-professional interactions and prevent unplanned hospital admissions (McKinstry, 2013, Paget et al., 2010).

Five systematic reviews are available on the topic of home telemonitoring in respiratory patients (Jaana et al., 2009) and, specifically, in patients with COPD (Bartoli et al., 2009, Bolton et al., 2010, McLean et al., 2011, Polisena et al., 2010). However, they focus on clinical outcomes (e.g., quality of life) (Polisena et al., 2010, Jaana et al., 2009, McLean et al., 2011), reduction in healthcare service utilization (Bolton et al., 2010, Jaana et al., 2009, McLean et al., 2011, Polisena et al., 2010), feasibility and use (Jaana et al., 2009), and on economic (Bolton et al., 2010, Jaana et al., 2009) and organizational (Bartoli et al., 2009) impacts of telemonitoring. None of these studies provides a comprehensive description of the telemonitoring methodologies, which is essential to enhance the design of future telemonitoring interventions and facilitate comparisons between studies.

Furthermore, optimal interventions require patients' adherence (WHO, 2003), but there is still limited information about adherence to telemonitoring in COPD research. Previous studies on telemonitoring in different health conditions have suggested that adherence is related to patients' satisfaction with the telemonitoring regimens (Kraai et al., 2011, Rahimpour et al., 2008, Sanders et al., 2012), so satisfaction should be considered when assessing patients' adherence. Thus, this systematic review aimed to: (1) provide a comprehensive description of the methodologies used in home telemonitoring for COPD; and (2) describe the current state of literature on patients' adherence and satisfaction with the use of telemonitoring systems.

Methods

Information sources and search strategy

A literature search was performed from June to August of 2012 in the medical databases Medline (1948-2012) and Embase (1974-2012) and wide-ranging scientific databases Web of Science (1970-2012) and B-on Online Knowledge Library (1999-2012). These databases were included to ensure that all relevant articles were retained. Search terms were based on a combination of the following keywords: [tele(-)monitoring or tele(-)health or tele(-)homecare or tele(-)care or tele-home health or home monitoring] and [Chronic Obstructive Pulmonary Disease or COPD]. Search was customized for each database according to their filtering specificities. Additional searches for relevant studies were performed within the bibliography of the selected articles and weekly automatic updates retrieved from the databases until December of 2012.

Eligibility criteria and study selection

This systematic review is structured according to Preferred Reporting Items for Systematic Reviews and Meta-Analyzes (PRISMA) guidelines (Liberati et al., 2009; Moher et al., 2009). Eligible studies included adult people with a diagnosis of COPD whose health condition was telemonitored at home. Home telemonitoring was defined according to the following criteria (Jaana et al., 2009, Paré et al., 2007): i) patients or their caregivers had to periodically record patients' clinical data (e.g., physiological signs or symptoms) at home; ii) these data had to be transmitted using telecommunication technologies from patients' home to a monitoring center. Studies were excluded if they: i) included patients with diseases other than COPD (i.e., the intervention was not specific to COPD

population); ii) included only regular telephone calls, video-consultation or teleconference interventions without telemonitoring clinical data; iii) involved downloading the data during healthcare visits or at the end of the study; iv) were limited to a technical description of the technology employed; vi) provided telemonitoring in other places than patients' home. Studies without information on patients' adherence and satisfaction were still retained in the review to enable a full description of the methodologies used in home telemonitoring (the first aim of the paper). In this review, the term *adherence* followed the definition proposed by the WHO (2003) and consisted of the extent to which the patient's behavior corresponds to the recommendations provided by the monitoring center regarding the use of the telemonitoring technology. The studies considered for review were randomized controlled trials (RCTs) and quasi-experimental studies; observational studies which did not include a telemonitoring intervention and case studies were excluded. Non-original articles (e.g., review papers, editorials, commentaries to articles, study protocols) and abstracts of communications or meetings were not considered suitable and, therefore, were excluded from this review although their reference list was reviewed closely. Papers without abstracts or written in languages other than English, Portuguese and Spanish were also excluded.

Study selection followed the stages recommended by the guidelines for conducting systematic reviews (Centre for Reviews and Dissemination, 2009). Initial screening of articles was based on type of publication and relevance for the scope of the review according to their title, abstract and keywords. Then, the full-text of potentially relevant articles was screened for content to decide its inclusion in the review. Studies with multiple publications were identified to avoid duplicate reports.

Data collection process

One reviewer extracted the data from the included studies and a second reviewer checked the extracted data. Disagreements were resolved by discussion between the two reviewers. Data were extracted in a structured table-format (developed prior to data collection) according to the following topics: first author's last name and year of publication, study design, country where the study was conducted, participants, type(s) of intervention(s), telemonitoring methodology, patients' adherence and satisfaction. The telemonitoring methodology data were synthesized in sub-categories: i) telemonitoring duration; ii) type of technology; iii) patients' training to use the system; iv) data collection and transmission; v) use of prompts, reminders and/or feedback and detection of health

deterioration. Patients' adherence was obtained by accessing dropout and compliance rates of patients who participated in the telemonitoring interventions. When available, reasons for non-adherence were also collected. Meta-analyzes could not be performed due to the nature of the data collected (description of methodologies) and lack of comparable outcomes to measure patients' adherence and satisfaction. Instead, a narrative synthesis was employed to synthesize the findings (Popay et al., 2006).

Quality assessment

Quality of studies was formally assessed according to the guidelines for conducting systematic reviews (Centre for Reviews and Dissemination, 2009), using a modified version of the scoring system developed by Hailey et al. (2011) to evaluate telemedicine research. This modified version was summarized in a recent systematic review on COPD (Polisena et al., 2010) and consists of 5 levels, from grade A (high quality) to E (poor quality), taking into consideration the study design and performance. For study design, scores were assigned to 4 types of study: large RCTs (≥50 subjects in each arm), small RCTs, prospective non-randomized studies and retrospective studies. For study performance, five areas of interest were considered: patient selection, description/specification of the intervention, specification and analysis of study, patient disposal and outcomes reported.

The quality of studies was independently assessed by two reviewers and inter-rater agreement calculated using the Cohen's kappa coefficient. The kappa values can be interpreted as (Landis and Koch, 1977): slight agreement (≤0.20), fair agreement (0.21–0.40), moderate agreement (0.41–0.60), substantial agreement (0.61–0.80) and almost perfect agreement (≥0.81). Disagreements between reviewers were resolved by consensus.

Results

Study selection

The database search identified 455 records. After duplicates removal, 130 records were screened for relevant content. During title, abstract and keyword screening, 109 articles were excluded due to the following reasons: non-original articles (n=55), case studies (n=3), no abstract provided (n=6), inclusion of non-COPD patients (n=17), absence of telemonitoring interventions (n=22) and other languages rather than English, Portuguese

or Spanish (n=6). The full-text of the 21 potentially relevant articles was assessed and 8 articles were excluded. Reasons for exclusion included: no telemonitoring information (n=4), laboratory testing of the system (n=2), participants with diseases other than COPD (n=1) and provision of teleconsultations alone (n=1). Automatic updates from the databases and search for relevant articles within the bibliography of selected articles retrieved 4 articles, which were also included (Figure 1). From the articles included in the analysis, eight were identified as referring to the same studies: 2 articles per study in 2 studies (Kim et al., 2012a, Kim et al., 2012b, Lewis et al., 2010a, Lewis et al., 2010b) and 4 articles pertaining to a single study (Dinesen et al., 2012, Haesum et al., 2012, Jensen et al., 2012a, Jensen et al., 2012b). In total, 17 articles on 12 studies were included, all published in English.

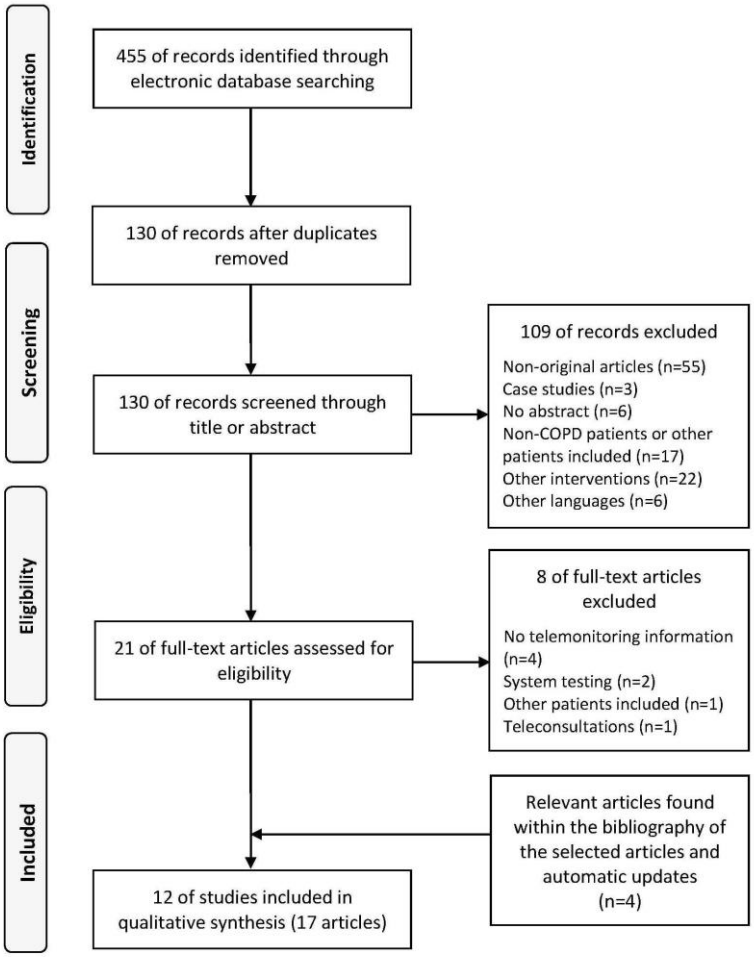

Figure 1. Flow diagram for study selection according to the preferred reporting items for systematic reviews and meta-analyzes (PRISMA) guidelines.

Study characteristics

Study characteristics are presented in Table 1. Most studies were randomized controlled trials (n=5), followed by uncontrolled before-and-after studies (n=4) and non-randomized controlled trials (n=3). Sample sizes varied from 20 to 165 patients with COPD, mostly older people. Ten studies included specifically patients in advanced stages of the disease. Most studies recruited patients during/following hospital admission or those receiving specialized care at the hospital or at home.

In 6 studies, the intervention consisted of telemonitoring clinical data plus other health care components such as: in-home nurse visits (n=1), virtual visits/consultations or regular telephone calls from the healthcare team (n=5) or provision of education (n=5).

Quality assessment

Quality levels differed across articles: 4 were rated A (high quality) (Chau et al., 2012, Dinesen et al., 2012, Haesum et al., 2012, Lewis et al., 2010b), 7 were rated B (good quality) (Antoniades et al., 2012, Koff et al., 2009, Lewis et al., 2010a, Paré et al., 2006, Ure et al., 2012, Trappenburg et al., 2008, Sund et al., 2009), 5 were rated C (fair to good quality) (Jensen et al., 2012a, Jensen et al., 2012b, Kim et al., 2012b, Kim et al., 2012a, Sicotte et al., 2011) and 1 was rated E (poor quality) (Dale et al., 2003). The articles rated as A and 3 articles rated as B (Antoniades et al., 2012, Koff et al., 2009, Lewis et al., 2010a) were referring to randomized controlled trials. Cohen's kappa coefficient revealed substantial agreement between raters (κ=0.78, p=0.001) for study quality levels.

Description of telemonitoring methodology

Telemonitoring duration

The length of the telemonitoring period ranged from 2 to 12 months (Table 1). While 8 studies defined a specific period for telemonitoring, 2 reported that the duration was defined according to patients' needs.

Table 1. Main characteristics and description of the technology used in the studies.

First author (year)	Study design	Country	Participants	Type(s) of intervention(s) or comparator(s)	Telemonitoring duration	Description of technology
Antoniades (2012)	RCT	Australia	44 patients with moderate to severe COPD and with ≥1 hospital admissions/year randomized in 2 groups: IG (n=22) and CG (n=22).	IG: home telemonitoring; CG: usual care.	12 months	Laptop computer with peripherals: blood pressure cuff and stethoscope, pulse oximeter, pneumotachograph, electrocardiogram touch plate and thermometer.
Chau (2012)	RCT	Hong Kong	53 older people with moderate to very severe COPD randomized in 2 groups: IG (n=30) and CG (n=23).	IG: home telemonitoring plus in-home nurse visits with provision of education. CG: in-home nurse visits with provision of education.	2 months (mean duration 54.36 days)	Mobile phone with a touch-screen monitor and peripheral devices: oximeter and respiratory rate sensor.
Dale (2003)	UBA	United Kingdom	55 patients with COPD.	Home telemonitoring plus additional telephone questions.	3 months	Oximeter and home weight scale.
Dinesen (2012), Haesum (2012), Jensen (2012a), Jensen (2012b)	RCT	Denmark	111 patients with severe or very severe COPD randomized in 2 groups: IG (n=60) and CG (n=51).	IG: home telemonitoring plus in-home exercises plus a monthly video meeting. CG: in-home exercises.	4 months	Telemonitor device. Other devices (not connected to the main device): weight scale, blood pressure monitor, oximeter, spirometer and step counter (in Dinesen (2012) and Haesum (2012)).
Kim (2012a), (2012b)	Non-equivalent multiple-group UBA	Korea	144 patients with COPD randomly allocated in 3 groups: IG1 (n=78), IG2 (n=36) and IG3 (n=30).	IG1: home telemonitoring; IG2: home telemonitoring plus education plus mobile phone service; IG3: home telemonitoring plus education plus video phone teleconsultation.	6 months	Integrated platform with peripherals: spirometer, oximeter and electronic stethoscope.

(*table 1 – continued*)

First author (year)	Study design	Country	Participants	Type(s) of intervention(s) or comparator(s)	Telemonitoring duration	Description of technology
Koff (2009)	RCT	United States of America	40 patients with COPD grades 3 and 4 according to the GOLD criteria.	IG: home telemonitoring plus education plus usual care. CG: usual care.	3 months	Health Buddy® device. Other devices (not connected to the main device): oximeter, pedometer and mini-spirometer.
Lewis (2010a), (2010b)	RCT	United Kingdom	40 patients with moderate to severe COPD randomized in 2 groups after undertaken pulmonary rehabilitation: IG (n=20) and CG (n=20).	IG: home telemonitoring during 26 weeks and usual care in the following 26 weeks. CG: usual care for 52 weeks.	6 months	Hand-held telemonitor (Docobo® Health HUB) to display questions and a peripheral oximeter. A manual thermometer was also provided.
Paré (2006)	NRCT	Canada	30 patients with severe COPD assigned in 2 groups: IG (n=20) and CG (n=10).	IG: home telemonitoring; CG: usual home care.	6 months	Web phone with a touch-screen monitor and a modem.
Sicotte (2011)	NRCT	Canada	46 patients with severe COPD assigned in 2 groups: IG (n=23) and CG (n=23).	IG: home telemonitoring; CG: usual home care.	Mean±SD of 146.7±72.3 days	Web phone with a touch-screen monitor.
Sund (2009)	UBA	United Kingdom	20 patients with moderate to severe COPD.	Home telemonitoring.	6 months	Mobile phone with a touch-screen and a peripheral spirometer. 2 software packages to enter data about symptoms and spirometry.
Trappenburg (2008)	NRCT	Netherlands	165 patients with moderate to severe COPD: IG (n=101) and CG (n=64).	IG: home telemonitoring plus education plus usual care; CG: usual care.	6 months	Health Buddy® device with 4 large buttons to present questions and education.
Ure (2012)	UBA		27 patients with moderate to severe COPD.	Home telemonitoring.	2 months	Touch-screen computer and peripherals: Bluetooth-linked oximeter and spirometer.

UBA - Uncontrolled before-and-after study; NRCT - non-randomized controlled trial; RCT – Randomized controlled trial; NA – no available information; COPD – chronic obstructive pulmonary disease; IG – intervention group; CG – control group; SD – standard deviation.

Technology

The telemonitoring systems were different across studies (Table 1). Some studies provided detailed information about them, including the peripheral devices that could be connected to a main device, such as: oximeters (n=5), spirometers (n=3), blood pressure monitors (n=1), thermometers (n=1), electrocardiographs (n=1), respiratory rate sensors (n=1) and/or electronic stethoscopes (n=1). The main device was frequently a mobile/web phone with an integrated touch-screen (n=4) or a touch-screen computer (n=1) that allowed patients to record data collected via the peripheral devices and/or to answer questions about their symptoms and disease management. Two studies used the same main device, which also provided patients with information about the disease and/or educational questions to answer regularly.

Patients' training

Training to use the telemonitoring systems was described in 9 studies (Table 2). Four studies reported that patients were trained in their homes during the initial home visit by a nurse working in the telemonitoring project. Patients had to demonstrate the use of the system in 3 studies and they received information about the normal clinical parameters in only 1 study. In 2 studies, ongoing support could be given according to patients' needs.

Data collection and transmission

Table 3 summarizes the clinical data collected through the telemonitoring systems. The most common parameters collected were symptoms (n=9), oxygen saturation (n=8), spirometric parameters (n=6), medication (n=6), heart rate (n=5), temperature (n=3) and weight (n=3).

Data collection process was similar across studies. Answers to symptoms and self-management questions (e.g., changes in medication, patient knowledge about COPD) were performed manually using touch-screen monitors. Regarding clinical data, it was not always clear if the information had to be inserted manually or if the process was automatic (i.e., the peripheral devices enabled automatic data transfer to the main device). Four studies required data collection at a specific time of the day and in 2 studies the data were collected more than once per day (Table 3).

Table 2. Patients' training and specificities of data transmission and management.

First author (year)	Training to use the system	Reminders, prompts and/or feedback	Data transmission	Data management	Detection of health deterioration
Antoniades (2012)	In the initial home visit. Ongoing in-home support available, if required.	On-screen prompts to complete the measurements and questionnaire.	Via a telephone line to a central server.	A nurse monitored the data on weekdays.	Significant changes triggered a contact to a physician/nurse or to the patient for further assessment.
Chau (2012)	In the initial home visit, provided by a nurse, with return demonstration.	Medication and pursed-lips breathing reminders with a feedback function.	Via a radio service to an online network platform on a base station.	A nurse monitored the data.	Immediate action taken when changes in clinical data occurred (not specified).
Dale (2003)	In the initial home visit, provided by a nurse.	NA	Via a telephone line to a clinical response center.	A nurse monitored the data on a daily basis.	Clinical changes could lead to further assessment or treatment. A physician could be contacted for decision-making.
Dinesen (2012), Haesum (2012), Jensen (2012a), Jensen (2012b)	In the initial home visit, with advice on how to exercise.	NA	Through a secure line using wireless to a healthcare center/hospital and stored in patient's database.	Healthcare professionals monitored the data.	Healthcare professionals could give advice (not specified).
Kim (2012a), (2012b)	At the hospital, with return demonstration, and then at home. Ongoing in-home support available, if required.	NA	Via a cable modem or digital subscriber lines.	NA	NA

(table 2 – continued)

First author (year)	Training to use the system	Reminders, prompts and/or feedback	Data transmission	Data management	Detection of health deterioration
Koff (2009)	In the initial home visit, provided by a nurse, with education about the normal clinical parameters.	Advice to contact the coordinator when classified as *red flags.*	Via a telephone line to the databank, each night.	The coordinator monitored the data in the following morning of data transmission.	Patients automatically stratified into 3 color-coded groups and contacted if persistent red/yellow flags appeared. A red flag or a patient call led to the contact of the primary care physician.
Lewis (2010a), (2010b)	In the initial home visit (~1h per patient).	NA	Via a free-phone landline to a central server, at 02h00 daily. Transmission failures were followed by a call or a message on the screen after 7 days (2010a) or 24h (2010b).	Healthcare professionals monitored the data.	Detection of health deterioration triggered an automatic email message to healthcare professionals, who called the patient (on weekdays).
Paré (2006)	In the initial home visit, provided by a nurse.	Alerts and advice when readings fell outside pre-set values.	Over the internet.	A nurse monitored the data on a daily basis.	Data outside pre-set values triggered an automatic alert to patients and the nurse, who contacted the patient or the physician for decision-making.
Sicotte (2011)	NA	Alerts and advice when readings fell outside pre-defined values.	Over the internet, in real time.	NA	Data outside pre-set values triggered automatic alerts to a surveillance center and a nurse called the patient.

(table 2 – continued)

First author (year)	Training to use the system	Reminders, prompts and/or feedback	Data transmission	Data management	Detection of health deterioration
Sund (2009)	In the initial home visit, with an information sheet and return demonstration. A helpline was available.	Prompts to attach the spirometer to the main device.	To research center, in real time. Transmission failures for 2 days were followed by a call.	Data monitored by the research team, based on daily time-score plots about symptoms and FEV_1.	Exacerbations automatically detected by a red line on the time-plots. Patients were called to start treatment with pre-provided medications.
Trappenburg (2008)	NA	Each answer received immediate feedback from the device: praise or encouragement to try again.	Via a telephone line to Health Hero's data center.	Respiratory nurses monitored the data on weekdays.	Data automatically stratified and color-coded. Nurses received alerts and contacted the patient and/or notified a pulmonary physician (if needed).
Ure (2012)	NA	NA	Via a secure broadband link to a call center. Transmission failures were followed by a call.	Staff monitored the data.	Staff contacted the patient or physician on weekdays according to an algorithm. Patients received an action plan and emergency supply of medication to commence as soon as an exacerbation was recognized. Physicians provided clinical care at weekends.

NA – no available information; FEV_1 – Forced expiratory volume in 1 second.

Table 3. Type and frequency of data collection.

First author (year)	Symptoms	Oxygen saturation	Spirometry	Heart rate	Temperature	Weight	Blood pressure	Respiratory rate	Medication	Other reports*	Frequency
Antoniades (2012)	●	●	●		●	●	●		●		Daily, at the same time
Chau (2012)		●		●				●			3 times/day on weekdays
Dale (2003)		●		●		●					Daily
Dinesen (2012), Haesum (2012), Jensen (2012a), Jensen (2012b)	●	●	●	●		●	●				According to prescription
Kim (2012a), (2012b)	●	●		●							Daily
Koff (2009)	●	●	●						●	●	Daily morning on weekdays
Lewis (2010a), (2010b)	●	●		●	●				●		2 times/day, at a specific period
Paré (2006)	●		●						●		Daily
Sicotte (2011)	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	Daily
Sund (2009)	●		●						●	●	Daily evening
Trappenburg (2008)	●								●	●	Daily
Ure (2012)	●	●	●		●						Daily

NA – no available information. *Other reports: lung and heart sounds (Kim et al., 2012), electrocardiogram data (Antoniades et al., 2012), number of steps in the 6-minute walking test (Koff et al., 2009) and questions regarding patients' knowledge about COPD (Koff et al., 2009, Trappenburg et al., 2008).

Data were transmitted on a daily basis in almost all studies. This process was usually performed via telephone line to a secure server, either on real time (n=2) or at a specific time of the day (n=2). Data were received in a healthcare center, call center or manufacturer center. There, healthcare professionals could monitor the data, generally on a daily basis (Table 2). In 6 studies, the information transmitted was automatically analyzed and alerts were sent to healthcare professionals and/or researchers when readings fell outside pre-established parameters. When data were not transmitted on consecutive days, patients were contacted via telephone call (n=3) or via message in the monitor screen (n=1).

Reminders, feedback and detection of health deterioration

Three studies provided reminders or prompts via the telemonitoring system to patients (Table 2). Prompts consisted of step-by-step instructions to help patients complete the measurements and/or questions or instructions to attach a peripheral to the main device. One study provided patients with a medication and pursed-lip breathing reminder.

Two types of automatic feedback could be given by the systems: feedback about blank and/or correct/incorrect answers (n=1) or alerts when readings fell outside pre-established parameters (n=3). When deterioration of health condition was detected, patients could contact the healthcare professionals (n=1) or be contacted via telephone calls (n=9). Patients' answers about their health condition could determine the next action to be taken (Table 2): contact of a physician to make a decision about treatment (n=4) or providing patients with an action plan and an emergency supply of medication to commence as soon as an exacerbation was recognized (n=2).

Patients' adherence and satisfaction

Compliance and dropout rates

Since these data were intended to inform about the adherence of patients to telemonitoring regimens, information about the control groups (if it existed) was not included.

All studies provided information on patient dropouts. From these, only 3 provided information on dropouts before intervention (Chau et al., 2012, Kim et al., 2012, Lewis et al., 2010). Reasons for withdrawal included (Chau et al., 2012): worsening of patient's

physical condition, financial-related reasons (patients did not have enough money to attend the follow-up and to afford the additional cost of recharging the batteries of the device every other day), refusal to use the belt for measuring respiratory rate in cold weather, the device was too difficult to carry around at work or the frequency of telemonitoring was too demanding (i.e., 3 times/day on weekdays).

Five of the studies which provided dropout information during the intervention period had a high number of dropouts (≥20%) and/or low compliance rates (≤80%) (Antoniades et al., 2012, Chau et al., 2012, Kim et al., 2012, Sund et al., 2009, Trappenburg et al., 2008), while 5 reported low dropout rates (Dinesen et al., 2012, Koff et al., 2009, Paré et al., 2006, Sicotte et al., 2011, Ure et al., 2012). The frequency of data transmission was related to lower compliance rates in one study. Chau et al. (2012) found that patients' compliance rates were high when data were transmitted once per day (98% for oxygen saturation and 83% for respiratory rate), but they decreased when the frequency was the recommended 3 times a day (79% and 60%, respectively).

Overall, dropout reasons were related to usability problems (n=2) (Kim et al., 2012, Sund et al., 2009) and technical problems with the system or the telephone line (n=3) (Koff et al., 2009, Sund et al., 2009, Ure et al., 2012). Other reasons not related to the telemonitoring system itself included the occurrence of respiratory exacerbations or illness (n=3) (Chau et al., 2012, Dinesen et al., 2012, Kim et al., 2012), relocation (n=2) (Antoniades et al., 2012, Trappenburg et al., 2008) and patients' death (n=4) (Antoniades et al., 2012, Lewis et al., 2010, Sicotte et al., 2011, Trappenburg et al., 2008).

Patients' satisfaction

Nine studies assessed patient satisfaction with the telemonitoring system (Table 4). Studies used quantitative scales/questionnaires (n=5), qualitative interviews (n=1) or both (n=2). Only one study did not provide information about how these data were collected. Patient satisfaction assessments were conducted face-to-face or through telephone calls. Most quantitative data were collected using non-validated scales and none of the studies used the same questionnaire. Thus, a meta-analysis could not be performed.

Overall, patients found the technology easy to learn and/or use (n=7) and useful (n=5). Most patients reported that the system improved self-management of their health condition, as they: had a better understanding of their disease, symptoms and ways to control them; were more involved in their health care; and recognized earlier the signs of

exacerbations. In the patients' perspective, the system also improved the care received from healthcare professionals. Patients felt a sense of security and reassurance when using the system because they knew their health condition was being monitored and they would be contacted if deterioration occurred (n=5). Furthermore, patients reported that the system helped them to improve communication with healthcare professionals and facilitated the access to professional advice (n=3). Levels of satisfaction were reduced regarding the medication prompt (n=2); patients did not find it useful because they already took their medication correctly.

In some studies, open-ended questions provided additional information about the difficulties felt by patients when using the systems (n=3). Patients reported the following difficulties regarding the device itself: the display screen was too small and words too small to read; the touch-screen was difficult to use due to deficits in sensation and poor fine motor control; push buttons were too small to manipulate and the button to initiate an emergency call too sensitive or the volume was difficult to adjust. In one study, patients mentioned that the mobile phone was far too technologically advanced for them and they did not know how to operate when unexpected characters were displayed. As a result, some patients needed help from their caregiver to transmit the data. Difficulties such as determining the precise area to apply the device or using the belt of the respiratory rate sensor due to dyspnea or discomfort were also described in 2 studies.

Some concerns with the system functioning were reported: the batteries of peripheral devices were of short-lived duration and needed a long time to charge, power supply connection was small and confusing (n=1) and the background noise of the computer fan caused some problems in smaller living situations (n=1). Other concerns included the uncertainty of data transmission (n=3) and the limited portability of the device (n=1). Suggestions to improve the system were given in two studies and consisted of adding a blood pressure monitor, ensuring the transmission of clinical data and giving real time feedback.

Table 4. Patients' satisfaction with the telemonitoring system.

First author (year)	Measures of patients' satisfaction	Results of patients' satisfaction
Antoniades (2012)	Non-validated questionnaire related to: ease of use of the system; adequacy of technical support; system usefulness for disease management; overall satisfaction.	- Easy-to-use system (94%); - Good technical support (100%); - Useful to manage the disease (82%); - Overall satisfaction (88%).
Chau (2012)	*Quantitative data:* Self-developed satisfaction questionnaire (1-5 Lickert scale, 5 being the highest level of satisfaction) related to: ease of use; level of confidence in using the system; acceptability; usefulness; satisfaction with nurse support.	*Quantitative data* (% or mean±SD): - Overall satisfaction (91%); - Adequate explanation (86.3%) and understanding (3.50±1.10); - Usage difficulties (2.45±0.80); - Mediation reminders (60%); - Automated healthcare advice (50%) and nurse support (100%) reassuring; - Useful to manage the disease (54.5%); - Recommend to others (3.14±089).
	Qualitative data: Open-ended comments.	*Qualitative data:* - Facilitated timely care and access to professionals to help decide on the best action; - Reminders about medication not helpful because patients remembered to take it. **Difficulties found:** - Action taken when unexpected characters were displayed (n=5); - Instability of data transmission; - Small display screen, words, push buttons and power supply; - Use of the touch screen, due to decreased sensation and fine motor control; - Emergency call button too sensitive; - Need of help from caregiver to transmit the data; - Use of the belt of respiratory rate sensor (dyspnea, cold water in the winter); - Short-lived duration batteries with long time needed to charge. **Suggestions:** add a blood pressure monitor.

(table 4 – continued)

First author (year)	Measures of patients' satisfaction	Results of patients' satisfaction
Dale (2003)	Satisfaction questionnaire approved by the local research and medical ethics committee.	- Easy-to-use equipment; - Health condition well managed; - Monitoring service reassuring (no quantitative data reported).
Kim (2012)	*Quantitative data:* Tool developed by the research team to measure attitude toward the system (4-point Lickert scale questions, from "strongly agree" to "strongly disagree"): user satisfaction; intention to use in the future; preferred cost. *Qualitative data:* Open-ended questionnaire.	*Quantitative data:* Most patients were "satisfied" or "very satisfied" with the systems. "Agree" or "strongly agree" options were higher for the topics: - Physical aspect (n=136); - Ease to use (n=129); - Treatment improvement (n=140) and communication with physician (n=139); - Recommendation to others (n=128). *Qualitative data:* **Difficulties found:** - Selection of the precise area to apply the device; - Incorrectly connection of the device or error of the server; - Learning to use the video phone and adjusting the volume; - Limited portability of the device. **Suggestions:** Ensure data transmission, give real-time feedback and include blood pressure monitors.
Koff (2009)	Questionnaire about satisfaction with individual pieces of the equipment (1-10 Lickert scale: 10 being the highest level of satisfaction).	Satisfaction was very high for all equipments (mean scores 9.6 to 8.5), except for the pedometer (4.5), which was not accurate for some patients with gait impairments.
Lewis (2010a)	NA	Most patients found it "helpful" or "very helpful" (88%); 1 patient "neither agreed nor disagreed" that it was useful; 1 patient found it "inconvenient".

(table 4 – continued)

First author (year)	Measures of patients' satisfaction	Results of patients' satisfaction
Paré (2006)	Questionnaire about satisfaction completed by telephone (4-point Lickert scale: 4 being the highest level of satisfaction) and related to: ease of use; technical support; usefulness.	**Results** (mean±SD): - Easy-to-use web phone (3.47±1.18); - Training (3.76±0.75) and vocabulary used (3.65±0.86); - Problems solved within 24h (3.57±1.09); - Sense of security (3.35±1.22); - Useful for the adoption of new practices to stabilize health condition (3.65±0.86).
Sicotte (2011)	Validated scale of patient satisfaction (5-point Lickert scale: 5 being the highest level of satisfaction). Validated scale of the benefits of telemonitoring (5-point Lickert scale, 1=very little to 5=very good).	**Overall satisfaction** (mean±SD, 4.6±0.8): - Information quality (4.6±0.5), usefulness (4.2±1.4), presentation (4.9±0.4) and understanding (4.6±0.7); - Data confidentiality and security (4.4±1.0); - Ease of use (4.8±0.4) and learning (4.4±0.9); - Frequency of use (4.9±0.3); - Technical performance (4.2±0.8); **Perceived benefits** (mean±SD): - Reassurance (4.2±1.2); - More quickly detection of health deterioration (3.6±1.3) and action when it occurred (4.1±1.3); - Medication taken as prescribed (2.5±1.7).
Ure (2012)	Face-to-face interviews about acceptability of the system, specifically: installation; training; use; disease management; benefits about care, health management, recognition of symptoms and feelings; concerns; confidentiality; communication with healthcare professionals; recommended changes.	Most patients found the system easy to use and useful: - Earlier recognition of exacerbations; - Facilitated access to professional advice; - Confidence to respond to health deterioration; - Reassurance. **Difficulties found:** - Background noise of the computer fan caused problems in smaller living situations; - Uncertainty of data transmission.

NA – No available information; SD – standard deviation.

Discussion

This systematic literature review provided a comprehensive description of the methodologies of home telemonitoring interventions in COPD and summarized the findings related to patients' adherence and satisfaction with the use of telemonitoring systems. The majority of the articles were published from 2010 to the present, suggesting that telemonitoring interventions are a relatively new field in COPD research. Protocols of the telemonitoring studies were similar in several aspects such as the training provided to patients and the process of data collection and transmission. Studies diverged on the type of technology used, telemonitoring duration, and on the provision of prompts, reminders and/or feedback. Training was usually provided in the initial home visit. However, this training may not have been enough to allow easy use of the systems, as many difficulties were encountered.

With respect to data collection, most studies lacked information about whether data had to be inserted manually or if the process was automatic, hindering study replication. Furthermore, some of these studies required data collection/transmission at a specific time of the day or more than once a day. These options were related to lower compliance rates in one study (Chau et al., 2012). The results suggest that the moment and frequency of data collection/transmission should be flexible to meet patients' preferences and specific needs. However, the optimal frequency of data collection/transmission has not yet been defined in the literature.

Information on the type of technology used was lacking in some studies. Generally, a main device was connected to one or more peripheral devices. Most studies did not provide systems with options for adjusting them to each patient, making the use of those systems difficult. Some patients identified difficulties in manipulating the devices and in viewing the information provided on screen (Chau et al., 2012). According to the review by Botsis and Hartvigsen (2008), telemonitoring systems should fulfill the following criteria: i) be easy to use; ii) operate without interruptions; and iii) provide security and confidentiality of data collected. These criteria were not fully addressed in the included studies, since patients were not always comfortable about using the technology to monitor their health condition. Furthermore, the difficulties felt by patients may have been a contributor to the high dropouts found in some studies, as suggested by Sanders and co-workers in their study exploring the factors related to the non-adherence to telemonitoring interventions (Sanders et al., 2012). To overcome these difficulties, it has been suggested that patients should receive training over a period of several days to help them learn to use the new

technology and, therefore, optimize its use (Demiris et al., 2001). As the success of a telemonitoring system depends on how well it serves the needs of the target population (Demiris et al., 2001), assessment of patients' acceptance of the system may also be useful to avoid dropouts and ensure patients' compliance. According to the American Telemedicine Association (Krupinski et al., 2006), evaluating and tailoring technology systems to specific user populations may contribute significantly to reduce *technophobia* among potential users.

Despite the usability problems, most patients reported that the system provided them with a better understanding of their disease and helped them to recognize the earlier signs of an exacerbation. These findings support the belief that telemonitoring may improve self-management of the disease (Fairbrother et al., 2012). According to Bourbeau et al. (2004), self-management refers to the various tasks that a person carries out for management of their condition, in order to control their disease and improve their well-being. By helping patients to be aware of their symptoms and act in case of exacerbations, home telemonitoring may have facilitated patients' self-management. Furthermore, patients felt secure and reassured when using the system, because they knew that they would be contacted if deterioration occurred. The worsening of symptoms associated with COPD exacerbations is usually present for days before hospital admissions (Kim et al., 2012). Thus, home telemonitoring may be a valuable tool to detect these changes sooner and allow an earlier intervention to reduce the severity of exacerbations. This is particularly important since exacerbations contribute to the deterioration of patients' clinical status (GOLD, 2013).

The results of this review showed that patients were overall satisfied with the telemonitoring systems. This is an encouraging finding, since one of the aims of home telemonitoring is to explore the potential of the monitoring services to provide a continuum of care and, therefore, patients' satisfaction must be high for successful innovations to achieve a significant change in practice patterns. However, this positive impact may be questionable and even overestimated, since the included studies used poorly constructed instruments. According to previous literature (Bolton et al., 2010), the concept of patient satisfaction is still not well defined and validated instruments are lacking.

Limitations

The present study has several limitations that need to be acknowledged. First, the study was restricted to English, Portuguese and Spanish languages. Although six records written in other languages were excluded, they could be relevant for the scope of the review. Second, this review included studies which were not specific for patients with COPD but had a sub-group of patients with this disease, and/or studies with different interventions (telemonitoring alone versus telemonitoring plus other health care components). This may have contributed to the differences found between studies. Nevertheless, this was deemed necessary to gather all information about the methodologies used in home telemonitoring for COPD. Finally, patients' satisfaction was explored regardless of clinical outcomes and healthcare utilization. Thus, it was not possible to assume that more satisfied patients were those with improved outcomes and reduced healthcare utilization.

Recommendations for future telemonitoring interventions

This review points out important methodological aspects that should be considered by researchers and healthcare professionals when developing home telemonitoring interventions for patients with COPD, and it provides recommendations for future interventions:

- The inclusion of more training sessions may facilitate patients' education on the use of the systems;
- Assessment of patients' needs, characteristics and acceptance of the telemonitoring technology should be considered prior to its implementation, as it may help adjusting the intervention to the target population;
- Studies should consider the inclusion of easy-to-use technology for patients with COPD, including those with disabilities;
- The frequency of data collection and transmission should be flexible to improve adherence to telemonitoring interventions. As the optimal frequency of data collection/transmission has not been set yet, future research should also explore this topic;
- The potential of telemonitoring interventions to change patients' self-management behavior, as well as its associations with patient outcomes and healthcare utilization, should be explored to improve the evidence on this topic;

- Patients' satisfaction with the use of systems should be further explored using more robust and validated instruments. Alternatively, a thorough qualitative analysis can be conducted to enable an in-depth understanding of patients' satisfaction and the use of that information to improve future technology designs.

Conclusion

Home telemonitoring interventions are a relatively new field in COPD research. Findings suggest that these interventions, although promising, still need to be adjusted to ensure their suitability to the target population. This study provides important recommendations for future telemonitoring interventions, such as the inclusion of additional training sessions to facilitate patients' education on the use of the systems and the assessment of patients' characteristics and acceptance of the technology prior to its implementation. These adjustments are essential before the widespreading of telemonitoring can occur. Future research should also investigate the impact of these interventions on patients' self-management behavior and satisfaction, and explore their associations with patient outcomes and healthcare utilization.

Statement on conflicts of interest

Support for this study was provided by Fundação para a Ciência e Tecnologia (FCT – Ref. SFRH/BD/81328/2011), Portugal. The authors report no conflict of interest.

References

Antoniades, N. C., Rochford, P. D., Pretto, J. J., Pierce, R. J., Gogler, J., Steinkrug, J., et al. 2012. Pilot study of remote telemonitoring in COPD. *Telemed J E Health,* 18**,** 634-40.

Bartoli, L., Zanaboni, P., Masella, C. & Ursini, N. 2009. Systematic Review of Telemedicine Services for Patients Affected by Chronic Obstructive Pulmonary Disease (COPD). *Telemed J E Health,* 15**,** 877-83.

Bolton, C. E., Waters, C. S., Peirce, S. & Elwyn, G. 2010. Insufficient evidence of benefit: a systematic review of home telemonitoring for COPD. *J Eval Clin Pract,* 17**,** 1216-22.

Botsis, T. & Hartvigsen, G. 2008. Current status and future perspectives in telecare for elderly people suffering from chronic diseases. *J Telemed Telecare,* 14**,** 195-203.

Bourbeau, J., Nault, D. & Dang-Tan, T. 2004. Self-management and behaviour modification in COPD. *Patient Educ Couns,* 52**,** 271-7.

Casas, A., Troosters, T., Garcia-Aymerich, J., Roca, J., Hernández, C., Alonso, A., et al. 2006. Integrated care prevents hospitalisations for exacerbations in COPD patients. *Eur Respir J,* 28**,** 123-30.

Centre for Reviews and Dissemination 2009. Systematic reviews: CDR's guidance for undertaking reviewsin health care. York: University of York.

Chau, J. P.-C., Lee, D. T.-F., Yu, D. S.-F., Chow, A. Y.-M., Yu, W.-C., Chair, S.-Y., et al. 2012. A feasibility study to investigate the acceptability and potential effectiveness of a telecare service for older people with chronic obstructive pulmonary disease. *Int J Med Inf,* 81**,** 674-82.

Dale, J., Connor, S. & Tolley, K. 2003. An evaluation of the west Surrey telemedicine monitoring project. *J Telemed Telecare,* 9 Suppl**,** S39-S41.

Demiris, G., Finkelstein, S. M. & Speedie, S. M. 2001. Considerations for the design of a Web-based clinical monitoring and educational system for elderly patients. *J Am Med Inform Assoc,* 8**,** 468-72.

Dinesen, B., Haesum, L. K., Soerensen, N., Nielsen, C., Grann, O., Hejlesen, O., et al. 2012. Using preventive home monitoring to reduce hospital admission rates and reduce costs: a case study of telehealth among chronic obstructive pulmonary disease patients. *J Telemed Telecare,* 18**,** 221-5.

Fairbrother, P., Pinnock, H., Hanley, J., McCloughan, L., Sheikh, A., Pagliari, C., et al. 2012. Continuity, but at what cost? The impact of telemonitoring COPD on continuities of care: a qualitative study. *Prim Care Respir J,* 21**,** 322-8.

Global Strategy for the Diagnosis Management and Prevention of COPD Global Initiative for Chronic Obstructive Lung Disease (GOLD) 2013. Available from: http://www.goldcopd.org/. [Accessed on February 11, 2013].

Haesum, L. K., Soerensen, N., Dinesen, B., Nielsen, C., Grann, O., Hejlesen, O., et al. 2012. Cost-Utility Analysis of a Telerehabilitation Program: A Case Study of COPD Patients. *Telemed J E Health,* 18**,** 688-92.

Hailey, D., Roine, R., Ohinmaa, A. & Dennett, L. 2011. Evidence of benefit from telerehabilitation in routine care: a systematic review. *J Telemed Telecare,* 17**,** 281-7.

Jaana, M., Pare, G. & Sicotte, C. 2009. Home telemonitoring for respiratory conditions: a systematic review. *Am J Manag Care,* 15**,** 313-20.

Jensen, M. H., Cichosz, S. L., Dinesen, B. & Hejlesen, O. K. 2012a. Moving prediction of exacerbation in chronic obstructive pulmonary disease for patients in telecare. *J Telemed Telecare,* 18**,** 99-103.

Jensen, M. H., Cichosz, S. L., Hejlesen, O. K., Toft, E., Nielsen, C., Grann, O., et al. 2012b. Clinical impact of home telemonitoring on patients with chronic obstructive pulmonary disease. *Telemed J E Health,* 18**,** 674-8.

Kim, J., Kim, S., Kim, H., Kim, K., Lee, C. T., Yang, S., et al. 2012a. Acceptability of the Consumer-Centric u-Health Services for Patients with Chronic Obstructive Pulmonary Disease. *Telemed J E Health,* 18**,** 329-38.

Kim, J., Kim, S., Kim, H. C., Kim, K. H., Yang, S. C., Lee, C. T., et al. 2012b. Effects of Consumer-Centered u-Health Service for the Knowledge, Skill, and Attitude of the Patients With Chronic Obstructive Pulmonary Disease. *Comput Inform Nurs*, 30, 661-71.

Koff, P. B., Jones, R. H., Cashman, J. M., Voelkel, N. F. & Vandivier, R. W. 2009. Proactive integrated care improves quality of life in patients with COPD. *Eur Respir J,* 33**,** 1031-8.

Kraai, I. H., Luttik, M. L., de Jong, R. M., Jaarsma, T. & Hillege, H. L. 2011. Heart failure patients monitored with telemedicine: patient satisfaction, a review of the literature. *J Card Fail,* 17**,** 684-90.

Krupinski, E., Dimmick, S., Grigsby, J., Mogel, G., Puskin, D., Speedie, S., et al. 2006. Research recommendations for the american telemedicine association. *Telemed J E Health,* 12**,** 579-89.

Landis, J. R. & Koch, G. G. 1977. The measurement of observer agreement for categorical data. *Biometrics,* 33**,** 159-74.

Lewis, K. E., Annandale, J. A., Warm, D. L., Hurlin, C., Lewis, M. J. & Lewis, L. 2010a. Home telemonitoring and quality of life in stable, optimised chronic obstructive pulmonary disease. *J Telemed Telecare,* 16**,** 253-9.

Lewis, K. E., Annandale, J. A., Warm, D. L., Rees, S. E., Hurlin, C., Blyth, H., et al. 2010b. Does Home Telemonitoring after Pulmonary Rehabilitation Reduce Healthcare Use in Optimized COPD? A Pilot Randomized Trial. *COPD,* 7**,** 44-50.

A. Liberati, D.G. Altman, J. Tetzlaff, C. Mulrow, P.C. Gøtzsche, J.P.A. Ioannidis, et al., 2009. The PRISMA statement for reporting systematic reviews and meta-analyses of studies that evaluate healthcare interventions: explanation and elaboration, BMJ 339, b2700.

McKinstry, B. 2013. The use of remote monitoring technologies in managing chronic obstructive pulmonary disease. *QJM,* 106**,** 883-5.

McLean, S., Nurmatov, U., Liu, J. L., Pagliari, C., Car, J. & Sheikh, A. 2011. Telehealthcare for chronic obstructive pulmonary disease. *Cochrane Database Syst Rev***,** CD007718.

Moher, D., Liberati, A., Tetzlaff, J., Altman, D. G. & The, P. G. 2009. Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. *PLoS Med,* 6**,** e1000097.

Nici, L., Donner, C., Wouters, E., Zuwallack, R., Ambrosino, N., Bourbeau, J., et al. 2006. American Thoracic Society/European Respiratory Society Statement on Pulmonary Rehabilitation. *Am J Respir Crit Care Med,* 173**,** 1390-413.

Paget, T., Jones, C., Davies, M., Evered, C. & Lewis, C. 2010. Using home telehealth to empower patients to monitor and manage long term conditions. *Nurs Times,* 106**,** 17-9.

Paré, G., Jaana, M. & Sicotte, C. 2007. Systematic review of home telemonitoring for chronic diseases: the evidence base. *J Am Med Inform Assoc,* 14**,** 269-77.

Paré, G., Sicotte, C., St.-Jules, D. & Gauthier, R. 2006. Cost-Minimization Analysis of a Telehomecare Program for Patients with Chronic Obstructive Pulmonary Disease. *Telemed J E Health,* 12**,** 114-21.

Polisena, J., Tran, K., Cimon, K., Hutton, B., McGill, S., Palmer, K., et al. 2010. Home telehealth for chronic obstructive pulmonary disease: a systematic review and meta-analysis. *J Telemed Telecare,* 16**,** 120-7.

Popay, J., Roberts, H., Sowden, A., Petticrew, M., Britten, N., Arai, L., et al. 2006. *Guidance on the conduct of narrative synthesis in systematic reviews,* UK, Lancaster University.

Rahimpour, M., Lovell, N. H., Celler, B. G. & McCormick, J. 2008. Patients' perceptions of a home telecare system. *Int J Med Inf,* 77**,** 486-98.

Sanders, C., Rogers, A., Bowen, R., Bower, P., Hirani, S., Cartwright, M., et al. 2012. Exploring barriers to participation and adoption of telehealth and telecare within the Whole System Demonstrator trial: a qualitative study. *BMC Health Serv Res,* 12**,** 220.

Sicotte, C., Paré, G., Morin, S., Potvin, J. & Moreault, M.-P. 2011. Effects of Home Telemonitoring to Support Improved Care for Chronic Obstructive Pulmonary Diseases. *Telemed J E Health,* 17**,** 95-103.

Sund, Z. M., Powell, T., Greenwood, R. & Jarad, N. A. 2009. Remote daily real-time monitoring in patients with COPD - a feasibility study using a novel device. *Respir Med,* 103**,** 1320-8.

Trappenburg, J. C. A., Niesink, A., de Weert-van Oene, G. H., van der Zeijden, H., van Snippenburg, R., Peters, A., et al. 2008. Effects of Telemonitoring in Patients with Chronic Obstructive Pulmonary Disease. *Telemed J E Health,* 14**,** 138-46.

Ure, J., Pinnock, H., Hanley, J., Kidd, G., McCall Smith, E., Tarling, A., et al. 2012. Piloting tele-monitoring in COPD: a mixed methods exploration of issues in design and implementation. *Prim Care Respir J,* 21**,** 57-64.

World Health Organization [WHO] 2003. Adherence to long-term therapies - Evidence for action. World Health Organization.

World Health Organization [WHO] 2008. The global burden of disease: 2004 update. WHO Library Cataloguing-in-Publication Data.

Chapter 4 – Accuracy of piezoelectric pedometer and accelerometer step counts

Joana Cruz
Dina Brooks
Alda Marques

The Journal of Sports Medicine and Physical Fitness. Epub ahead of print on January 21 (2016)

Abstract

Background: This study aimed to: assess step-count accuracy of a piezoeletric pedometer (Yamax PW/EX-510), when worn at different body parts, and a triaxial accelerometer (GT3X+); compare device accuracy; and identify the preferred location(s) to wear a pedometer.

Methods: Sixty-three healthy adults (45.8±20.6 years old) wore 7 pedometers (neck, lateral right and left of the waist, front right and left of the waist, front pockets of the trousers) and 1 accelerometer (over the right hip), while walking 120m at slow, self-preferred/normal and fast paces. Steps were recorded. Participants identified their preferred location(s) to wear the pedometer. Absolute percent error (APE) and Bland and Altman (BA) method were used to assess device accuracy (criterion measure: manual counts) and BA method for device comparisons.

Results: Pedometer APE was below 3% at normal and fast paces despite wearing location, but higher at slow pace (4.5–9.1%). Pedometers were more accurate at the front waist and inside the pockets. Accelerometer APE was higher than pedometer APE (P<0.05); nevertheless, limits of agreement between devices were relatively small. Preferred wearing locations were inside the front right (n=25) and left (n=20) pockets of the trousers.

Conclusion: Yamax PW/EX-510 pedometers may be preferable than GT3X+ accelerometers to count steps, as they provide more accurate results. These pedometers should be worn at the front right or left positions of the waist or inside the front pockets of the trousers.

Key words: actigraphy; dimensional measurement accuracy; exercise; walking.

Introduction

Regular physical activity (PA) is associated with important health benefits (Warburton et al., 2006) and may prevent the development and progression of chronic diseases (e.g., cardiovascular disease, chronic obstructive pulmonary disease [COPD] (Esteban et al., 2010, Warburton et al., 2006)). Thus, improving PA levels of healthy and chronic disease populations has become a public health priority (World Health Organization [WHO], 2010).

Since walking is the most common type of exercise (Hootman et al., 2001), international PA recommendations using step-count goals have been developed (Garber et al., 2011, Tudor-Locke and Bassett, 2004). One simple strategy to monitor these goals is the use of pedometers (Bravata et al., 2007). Pedometers are simple and inexpensive motion devices that count steps taken and present them on real time, providing immediate feedback to the user. They have been used as a motivational tool to improve PA behaviours and in PA screening and assessment of interventions (Bravata et al., 2007, Tudor-Locke and Bassett, 2004).

Numerous studies have evaluated the accuracy of diverse pedometers in measuring steps (Crouter et al., 2005, Crouter et al., 2003, Le Masurier et al., 2004, Melanson et al., 2004) and they concluded that accuracy was lower at slower speeds, particularly in pedometers using a spring-suspended horizontal lever arm mechanism (Crouter et al., 2005, Melanson et al., 2004). As these pedometers had to be worn in a vertical position on a belt/waistband, body composition and pedometer tilt could influence pedometer accuracy (Crouter et al., 2005). To overcome this problem, pedometers with a piezoelectric technology (e.g., Yamax PW/EX-510) were developed. These pedometers may be used in non-traditional wearing locations, e.g. inside the pockets or around the neck. Nevertheless, there are still few studies exploring the impact of wearing positions on accuracy of piezoelectric pedometers (De Cocker et al., 2012, Hasson et al., 2009, Holbrook et al., 2009). Furthermore, pedometers may have low acceptance when attached to certain body parts or clothing (de Bruin et al., 2008) or when used in certain situations (e.g., when wearing a dress) (Gardner and Campagna, 2011). This issue has been scarcely explored in previous validation studies, despite its importance to improve user acceptance (de Bruin et al., 2008).

In addition to pedometers, the use of triaxial accelerometers (e.g., GT3X+) to objectively assess PA has increased in recent years (Trost and O'Neil, 2014). Triaxial accelerometers are motion devices that measure acceleration in 3 planes during body movement (Strath

et al., 2013). Many accelerometers have also a step-count function, though most of them do not provide feedback (Bassett and John, 2010). Hence, they are intended to measure PA rather than to motivate individuals to exercise. Accelerometers are often preferred in research and clinical settings because they provide more information than pedometers, e.g. frequency, duration and intensity of PA (Strath et al., 2013). They have shown good validity with regard to activity counts and energy expenditure in healthy and chronic disease populations (Santos-Lozano et al., 2013, Van Remoortel et al., 2012); however, their step-count accuracy has not been extensively investigated, with most studies being conducted in the last 5 years (Barreira et al., 2013a, Barreira et al., 2013b, Connolly et al., 2011, Van Remoortel et al., 2012, Webber et al., 2014, Tudor-Locke et al., 2015). Assessment of accelerometer step-count accuracy along with pedometer accuracy is fundamental to enable comparisons among studies using different motion devices.

This study aimed to: (1) assess step-count accuracy of a piezoeletric pedometer (Yamax PW/EX-510), when worn at different body parts, and a triaxial accelerometer (GT3X+); (2) compare device accuracy; and (3) identify user's preferred location(s) to wear a pedometer.

Methods

Design

This prospective cross-sectional study was conducted as part of a larger study (www.clinicaltrials.gov, NCT02122614). Ethical approval was obtained from the Central Regional Health Administration (2011-02-28), Hospital Centre (34428) and National Data Protection Committee (9250/2012, 2012-11-06).

Participants

Sixty-three healthy adults volunteered to participate in the study. They were included if the following criteria were met: (1) ≥18 years old; (2) able to walk independently without a walking aid; and (3) able to understand the purpose and procedures of the study. Participants were excluded if they presented severe cardiovascular, neurological, respiratory, musculoskeletal or psychiatric disorders or severe visual/hearing impairment. Written informed consent was obtained according to the Declaration of Helsinki.

Socio-demographic and anthropometric (height, weight) data were collected to characterise the sample. The performance of the Yamax PW/EX-510 pedometer (Yamasa Tokey Keiki Corporation, Tokyo, Japan) and the GT3X+ accelerometer (ActiGraph, Pensacola, FL) was then assessed.

Instruments

The Yamax PW/EX-510 is a lightweight pedometer with a triaxial sensor and a visual display to present on real time the estimated step counts, energy expenditure, fat burn, distance and activity time. For this study, only step counts were considered. This pedometer has an 11-step filter (i.e., if a person moves less than 11 steps and take about 5s without moving, those steps are not counted) to recognise actual walking activity and a 30-day and 30-week memory function that enables the user to recall steps. The user's weight and stride length must be entered before using the pedometer.

The GT3X+ accelerometer has also an embedded triaxial sensor that detects acceleration in 3 planes. After initialisation, the device collects and stores PA data which can be further downloaded and converted into time-stamped activity counts, step counts, energy expenditure and body postures, using specific software (Actilife – ActiGraph, Pensacola, FL). The accelerometer does not have a visual display to provide the user with real-time data.

Procedures

This study followed the international recommendations for pedometer testing (Strath et al., 2013): (1) pedometers should be tested during walking at slow, moderate and fast paces; and (2) pedometer accuracy should be assessed by manually counting steps (criterion measure) over a 100- to 200-meter course and then comparing pedometer steps and manual counts. To perform the tests, participants were required to use trousers with front side pockets and flat shoes (except flip-flops). They were instructed to walk 120m in a straight 20-meter corridor while wearing 7 pedometers and 1 accelerometer. Pedometers were worn simultaneously at different body parts: 1 around the neck suspended from a lanyard; 2 attached with a belt clip at the lateral right and left (midaxillary line) sides of the waist and 2 attached at the front right and left (midclavicular line) sides; 2 in the front (right and left) pockets of the trousers. Universal belt clips were used to attach the pedometers at the waist. Before data collection, one researcher entered participant's weight and stride

length in each pedometer. Stride length was measured by asking patients to walk 10 steps in a straight corridor marked with a measuring tape and dividing the total distance per 10 (e.g., 6.0m/10 steps=0.60m). The accelerometer was worn on a waistband over the right hip, according to the manufacturer recommendations and the results from a recent study (Tudor-Locke et al., 2015). It was initialised before data collection (30Hz) using ActiLife v6.7.2.

The test (i.e., walking 120m) was performed at 3 different paces in a random order: slow, self-preferred (normal) and fast pace. For slow pace, participants were asked to walk slowly as if they were taking a walk. For normal pace, participants were instructed to walk at their usual speed. For fast pace, they were asked to walk as if they were late to an appointment. Trials were repeated twice at two proximal occasions. All trials were recorded using video-recordings. One researcher counted every step taken during trials with a digital tally counter (criterion measure) and recorded trial duration using a stopwatch. At the end of each trial, the researcher registered step counts of each pedometer. Pedometers were then set to zero for the next trial. To ensure researcher blinding, manual counts were recorded before registering pedometer steps. Only in case of doubt the researcher signalled the trial of interest and reviewed the video-recording. As the accelerometer does not provide real time data, the researcher recorded the start time of each trial to allow its identification in the data downloaded. Data were downloaded in 1-by-1s epochs using Actilife v6.7.2.

After completing the tests, participants' opinion about the most and least preferred locations to wear a pedometer was collected. They could choose up to 3 wearing locations (without order of preference).

Statistical analysis

Descriptive statistics were conducted to characterise the sample. The average walking speed (trial 1) was calculated for each pace using the equation 1:

$$\text{Speed (km/h)} = 0.120 \text{ (km)} / \text{time (h)} \quad (1)$$

where 0.120km is the total distance walked and time is the duration of each trial.

Accuracy of pedometers and accelerometer was analysed by comparing their estimated steps with manual counts (trial 1) and consistency of measurement error was assessed by comparing the results of the same device on trials 1 and 2. The absolute percent error (APE) was calculated for each device at each walking pace as follows (equation 2):

$$APE=(|device\ steps-observed\ steps|/observed\ steps)*100 \quad (2)$$

APE absolute value was used to avoid that positive and negative values cancelled each other out when calculating average APE. Values closer to zero indicated more accurate results and an APE below 3% has been considered acceptable (Crouter et al., 2003, Holbrook et al., 2009).

Normality of data was assessed with the Kolmogorov-Smirnov test. Differences in accuracy of devices were analysed with a repeated measures analysis of variance (ANOVA), for each walking pace. If a significant difference was detected ($P<0.05$), post-hoc analyses were conducted. Consistency of measurement error was assessed using paired samples t-tests. APE was used instead of step counts to account for individual variability (i.e., number of steps may vary among individuals even in a well-controlled environment).

The Bland and Altman (BA) method (Bland and Altman, 1986) was used to assess agreement between estimated steps and manual counts (trial 1). Mean of the differences and tight agreement intervals around 0 suggested more accurate results. The BA method was also used to examine agreement between pedometer- and accelerometer-estimated steps. Positive values indicated that pedometer presented higher values than accelerometer.

Data concerning participants' most and least preferred locations to wear a pedometer were converted into frequencies. When participants identified more than 1 preferred location, all answers were considered.

Statistical analyses were performed using SPSS v20.0 (IBM Corp., Armonk, NY) and GraphPad Prism v5.0 (GraphPad Inc., La Jolla, CA, USA).

Results

Participants

Participants had a mean age of 45.8±20.6 years (range 20-86) and body mass index of 25.2±4.3kg/m^2, mostly female (n=42, 66.7%). The average speed performed in slow, normal and fast paces was 3.3±0.6km/h, 4.4±0.7km/h and 5.5±0.7km/h, respectively. The number of steps recorded manually and through pedometers and accelerometer is presented in Table I.

Table I. Number of steps collected manually and through the pedometers (worn at different body parts) and the accelerometer, at 3 walking paces.

	Slow pace	Normal pace	Fast pace
Manual count (steps)	215.0±23.8	189.2±22.2	172.2±20.2
Pedometer (steps)			
Neck	196.6±37.1	185.4±19.6	168.8±18.1
Lateral right	195.3±36.0	186.8±20.7	169.9±19.1
Front right	201.5±32.3	186.8±20.6	170.1±18.7
Right pocket	202.2±31.6	187.1±20.5	170.1±18.7
Lateral left	200.6±34.5	186.2±21.1	169.4±18.6
Front left	202.4±29.9	187.0±20.9	169.9±19.5
Left pocket	206.8±20.7	186.9±19.7	170.5±19.9
Accelerometer (steps)	175.5±38.7	179.1±16.9	164.5±15.3

Device accuracy

Absolute percent error

Table II presents the APE of pedometers and accelerometer on trials 1 and 2. On trial 1, the mean APE of pedometers was below 3% at normal and fast paces, despite wearing location. The performance was poorer at slow pace (mean APE>4%). When comparing locations, accuracy was improved (i.e., mean and standard deviation were the smallest) for pedometers located at the front right and left of the waist, at all paces (Table II). Pedometers inside the pockets also showed a high performance, with the pedometer of the left pocket presenting the lowest APE at slow pace (4.5±7.7%). Despite that, differences among pedometer APE were only significant between pedometers worn around the neck and attached to the front left of the waist, the latter presenting a lower APE (1.9±2.1% vs. 1.2±1.4%, P=0.006).

The accelerometer presented a high APE, ranging from 16.8±19.4% at slow pace to 3.9±2.9% at fast pace.

Regarding consistency of measurement error, no significant differences were found between APEs of pedometers (P>0.05), irrespective of wearing location. The same results were found for the accelerometer (P>0.05, Table II).

Table II. Absolute percent error (APE) of steps registered by the pedometers worn at different body parts and the accelerometer, at 3 walking paces (results from trials 1 and 2).

	Slow pace APE (%) mean, SD		**Normal pace** APE (%) mean, SD		**Fast pace** APE (%) mean, SD	
	Trial 1	Trial 2	Trial 1	Trial 2	Trial 1	Trial 2
Pedometer						
Neck	9.0±17.2	8.8±18.1	1.9±2.1[a]	1.8±1.8	1.9±1.8	1.9±1.8
Lateral right	9.1±16.5	7.0±13.7	1.6±1.5	1.9±2.5	1.5±1.5	1.8±2.3
Front right	6.8±12.9	5.7±12.1	1.3±1.3	1.5±2.4	1.3±1.4	1.4±2.1
Right pocket	6.3±12.7	5.7±14.7	1.2±1.7	1.6±3.4	1.8±1.9	1.4±1.8
Lateral left	6.9±14.1	6.2±12.3	1.9±3.4	3.1±11.7	1.6±2.3	1.4±1.9
Front left	5.8±11.0	5.3±12.1	1.2±1.4[a]	1.3±2.3	1.4±1.9	1.2±1.7
Left pocket	4.5±7.7	3.4±9.1	1.7±2.9	1.8±2.3	1.7±1.9	1.7±2.3
Accelerometer	16.8±19.4[b]	15.7±19.4	4.6±2.6[b]	4.6±3.1	3.9±2.9[b]	3.8±3.5

[a]Differences between APE of the pedometers were significant (P=0.006). [b]Differences between the APE of all pedometers and the accelerometer on trial 1 were significant at slow pace (0.001<P<0.043), and at normal and fast paces (P<0.001). Abbreviations: APE, absolute percent error; SD, standard deviation.

Bland and Altman method

Table III presents the mean of the differences between manual counts and device-estimated steps and the LoA. An excellent level of agreement was found for all pedometers at normal and fast paces, except for the pedometer around the neck which presented poorer agreement (i.e., higher mean difference and wider LoA). At slow pace, the mean difference between manual counts and pedometer-estimated steps was high (from -6.7 to -19.8 steps) and the LoA were wide, despite wearing location. Overall, better agreement results were found for pedometers located at the front right and left of the waist and inside the pockets.

The accelerometer showed the highest mean of the differences and the widest LoA, at all walking paces (Table III).

Table III. Mean of the differences between manually-counted and device-estimated steps and limits of agreement, at 3 walking paces.

	Slow pace		**Normal pace**		**Fast pace**	
	$Mean_{diff}$ (steps)	LoA (steps)	$Mean_{diff}$ (steps)	LoA (steps)	$Mean_{diff}$ (steps)	LoA (steps)
Pedometer						
Neck	-18.5	-100.6 – 63.7	-3.8	-13.2 – 5.6	-3.4	-10.4 – 3.6
Lateral right	-19.8	-94.9 – 55.3	-2.3	-9.6 – 5.0	-2.3	-8.3 – 3.7

(*table III – continued*)

	Slow pace		Normal pace		Fast pace	
	$Mean_{diff}$ (steps)	LoA (steps)	$Mean_{diff}$ (steps)	LoA (steps)	$Mean_{diff}$ (steps)	LoA (steps)
Front right	-13.5	-71.4 – 44.4	-2.4	-8.1 – 3.3	-2.1	-7.9 – 3.7
Right pocket	-11.2	-69.3 – 46.8	-1.1	-9.2 – 6.9	-1.1	-10.3 – 8.1
Lateral left	-14.4	-75.3 – 46.4	-3.0	-16.4 – 10.4	-2.9	-11.9 – 6.2
Front left	-12.7	-61.9 – 36.5	-2.2	-8.1 – 3.7	-2.2	-9.6 – 5.1
Left pocket	-6.7	-48.4 – 35.0	-1.4	-15.6 – 12.8	-1.6	-9.5 – 6.3
Accelerometer	-38.5	-137.4 – 60.4	-9.1	-21.2 – 3.1	-6.8	-19.1 – 5.4

Abbreviations: $Mean_{diff}$, mean of the differences (i.e., observed steps – device steps); LoA, limits of agreement.

Comparison between devices

When comparing the two devices, the accelerometer presented a significantly higher APE than pedometers, regardless of wearing location ($0.001<P<0.043$, Table II). The accelerometer recorded a lower number of steps than pedometers, with the mean of the differences ranging from 19.7 to 29.2 steps at slow, 5.7 to 7.7 steps at normal, and 3.5 to 5.8 steps at fast pace (Table IV). Even though, the LoA were relatively small at normal and fast paces.

Table IV. Mean of the differences between pedometer and accelerometer step counts and limits of agreement, at 3 walking paces.

	Accelerometer					
	Slow pace		Normal pace		Fast pace	
	$Mean_{diff}$ (steps)	LoA (steps)	$Mean_{diff}$ (steps)	LoA (steps)	$Mean_{diff}$ (steps)	LoA (steps)
Pedometer						
Neck	21.6	-76.4 – 119.5	5.7	-4.2 – 15.5	3.5	-5.7 – 12.7
Lateral right	19.7	-60.7 – 100.0	6.9	-4.6 – 18.4	4.7	-7.0 – 16.2
Front right	26.6	-59.6 – 112.7	6.8	-3.6 – 17.2	4.9	-4.9 – 14.7
Right pocket	26.2	-50.8 – 103.2	7.7	-4.0 – 19.3	5.8	-7.4 – 18.9
Lateral left	26.3	-64.2 – 116.8	6.2	-8.8 – 21.1	4.1	-5.7 – 13.8
Front left	28.3	-63.1 – 119.7	7.0	-3.6 – 17.6	4.7	-5.2 – 14.5
Left pocket	29.2	-37.5 – 95.9	7.4	-4.7 – 19.4	5.4	-7.7 – 18.5

Abbreviations: $Mean_{diff}$, mean of the differences (i.e., pedometer steps – accelerometer steps); LoA, limits of agreement.

Pedometer preferred locations

According to participants' opinion, the best locations to wear the pedometer were inside the right (n=25) and left (n=20) pockets of the trousers (Figure 1). The neck was reported both as one of the most (n=17) and least (n=15) preferred locations. Other least preferred locations were the lateral right and left positions of the waist (n=21 each) and the front right and left positions of the waist (n=16 each).

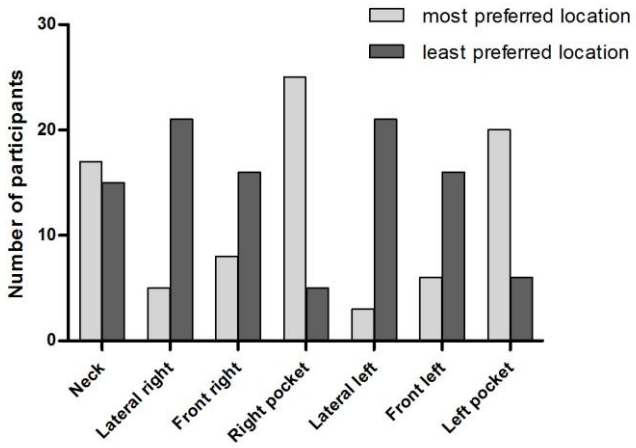

Figure 1. Participants' opinion about the most and least preferred locations to wear the pedometer (participants could choose more than 1 preferred location up to 3, without order of preference).

Discussion

Pedometers Yamax PW/EX-510 were highly accurate in quantifying steps at normal and fast walking paces, but less accurate at slow pace. Pedometers worn at the front right and left of the waist and inside the pockets of the trousers were the most accurate. The latter was also the most preferred location to wear the pedometer. The GT3X+ accelerometer underestimated the steps when compared to manually-counted and pedometer steps. Findings support the use of pedometers for measuring ambulatory activity using step counts.

Accuracy of pedometers was low at slow pace, despite wearing location. Similar results have been described in validation studies using other piezoelectric pedometers (De Cocker et al., 2012, Holbrook et al., 2009), suggesting that caution should be taken when using this type of technology in slow walking populations (e.g., older adults (Prince et al., 1997) and patients with neurological disorders (Busse et al., 2006)). Nevertheless, piezoelectric pedometers have shown lower measurement errors than those using a

spring-suspended lever arm mechanism, particularly at slower speeds (Crouter et al., 2005, Melanson et al., 2004). Thus, pedometers with a piezoelectric mechanism should be preferred particularly when used by individuals who naturally ambulate at slower speeds. In controlled conditions, a 3% is frequently considered an acceptable measurement error (Crouter et al., 2003, Holbrook et al., 2009). Other studies have suggested that a maximum error of 5% (De Cocker et al., 2012, Vincent and Sidman, 2003) or 10% (Crouter et al., 2003) can be accepted for slower speeds. In this study, the average measurement error of pedometers was approximately 4.5-9.1%, thus they may be considered fairly accurate.

Pedometers were more accurate when worn at the front right and left of the waist and inside the pockets. These results were consistent among trials. Therefore, individuals should be provided with these two wearing options when using Yamax PW/EX-510 pedometers. Since some individuals have reported difficulties in deciding where to use the pedometer in certain situations (e.g., when using clothing without pockets) (Gardner and Campagna, 2011), this finding may improve users' acceptance of pedometers. Furthermore, pockets were identified as a preferred location to wear the pedometer, thus this option may enhance pedometer use in daily living.

Pedometer worn around the neck was reported as both one of the most and least preferred locations. Although this is one of the manufacturers' recommended positions, results suggest that it may not be advisable since it was one of the locations with lower accuracy and agreement results. Reasons for these findings are not clear, however, it is possible that lack or excess of movement of the upper body during walking may have produced over- or under-oscillation of the pedometer, leading to higher measurement error. Previous validation studies using other piezoelectric pedometer brand have shown opposite findings, with pedometers around the neck providing the most accurate results (De Cocker et al., 2012, Hasson et al., 2009). This finding reinforces the need to test different pedometer models before using them, as recommended in international guidelines (Strath et al., 2013).

The GT3X+ accelerometer provided poorer accuracy and agreement results than pedometers, although differences between devices and LoA were relatively small at normal and fast paces. Previous research supports these findings. Studies conducted in specific populations (i.e., pregnant women, overweight and obese adults, older adults with/without walking aids) have shown that pedometers (either with a piezoelectric or a lever arm mechanism) present higher step-count accuracy results than the GT3X+

(Barreira et al., 2013a, Barreira et al., 2013b, Connolly et al., 2011, Webber et al., 2014), particularly when walking at slower speeds (Connolly et al., 2011, Webber et al., 2014). Therefore, caution must be taken when comparing step counts of studies that have employed different types of motion devices, since their findings may differ. Likewise, the choice of the motion device should be based on a number of factors, including:

(1) Need for PA feedback – since pedometers provide feedback to the user, they may be more appropriate in self-monitoring interventions (Strath et al., 2013, Trost and O'Neil, 2014). Conversely, if individuals must be blinded, then accelerometers may be chosen as most of them do not provide this feedback function (Bassett and John, 2010);

(2) Type of outcomes – accelerometers capture the frequency, duration and intensity of human movement, providing a more detailed analysis of daily PA (Strath et al., 2013, Trost and O'Neil, 2014). Hence, they may be valuable in PA screening or assessment of PA interventions;

(3) Cost – pedometers may be preferred to accelerometers in simple studies measuring only step counts, due to their lower cost (Strath et al., 2013) and high accuracy (as found in the present study).

Strengths and limitations

This study has several strengths that should be acknowledged. Overground walking was chosen instead of treadmill walking to reflect daily ambulatory activity. Nevertheless, it was not possible to control walking speed throughout the tests. Participants' opinion about the most and least preferred locations to wear the pedometer was a novel and important finding, as it may influence people's adherence in using pedometers on a daily basis. Finally, validation of Yamax PW/EX-510 pedometer was innovative, since previous studies validating piezoelectric pedometers have been mostly limited to Omron models (De Cocker et al., 2012, Hasson et al., 2009, Holbrook et al., 2009, Wallmann-Sperlich et al., 2015, Zhu and Lee, 2010). This pedometer has additional features that may be valuable in motivating individuals to be more physically active (e.g., 30-day and 30-week memory function). This should be further explored.

This study had also several limitations. One limitation concerns to the fact that only step counts were considered. Since both devices are able to provide additional parameters, these should be validated in future research. The context of validation tests (i.e.,

controlled conditions) was another limitation. Tests conducted under free-living conditions are warranted to fully capture the potential of motion devices to detect human activity. Lastly, all tests were performed in healthy adults which may limit the generalisability of findings. Nevertheless, previous validation studies conducted in healthy and chronic disease populations concluded that pedometer accuracy was similar between samples when walking at different speeds (Furlanetto et al., 2010, Turner et al., 2012).

Conclusions

Findings suggest that Yamax PW/EX-510 pedometers may be preferable than GT3X+ accelerometers to count steps, as they provide more accurate results. These pedometers should be worn at the front right or left positions of the waist or inside the front pockets of the trousers. The latter was considered the most preferred location to wear the pedometer.

Acknowledgements

The authors gratefully acknowledge all the volunteers for participating in the study.

Funding

This work was supported by the Fundação para a Ciência e a Tecnologia (FCT) under grant number SFRH/BD/81328/2011.

Conflicts of interest

The authors report no conflicts of interest.

References

Barreira, T. V., Brouillette, R. M., Foil, H. C., Keller, J. N. & Tudor-Locke, C. 2013a. Comparison of older adults' steps per day using NL-1000 pedometer and two GT3X+ accelerometer filters. *J Aging Phys Act,* 21**,** 402-16.

Barreira, T. V., Tudor-Locke, C., Champagne, C. M., Broyles, S. T., Johnson, W. D. & Katzmarzyk, P. T. 2013b. Comparison of GT3X accelerometer and YAMAX pedometer steps/day in a free-living sample of overweight and obese adults. *J Phys Act Health,* 10**,** 263-70.

Bassett, D. R. & John, D. 2010. Use of pedometers and accelerometers in clinical populations: validity and reliability issues. *Phys Ther Rev,* 15**,** 135-42.

Bland, M. J. & Altman, D. G. 1986. Statistical Methods for Assessing Agreement between Two Methods of Clinical Measurement. *The Lancet,* 327**,** 307-10.

Bravata, D. M., Smith-Spangler, C., Sundaram, V., Gienger, A. L., Lin, N., Lewis, R., et al. 2007. Using pedometers to increase physical activity and improve health: a systematic review. *JAMA,* 298**,** 2296-304.

Busse, M. E., Wiles, C. M. & van Deursen, R. W. M. 2006. Community walking activity in neurological disorders with leg weakness. *J Neurol Neurosurg Psychiatry,* 77**,** 359-62.

Connolly, C. P., Coe, D. P., Kendrick, J. M., Bassett, D. R., Jr. & Thompson, D. L. 2011. Accuracy of physical activity monitors in pregnant women. *Med Sci Sports Exerc,* 43**,** 1100-5.

Crouter, S. E., Schneider, P. L. & Bassett, D. R., Jr. 2005. Spring-levered versus piezo-electric pedometer accuracy in overweight and obese adults. *Med Sci Sports Exerc,* 37**,** 1673-9.

Crouter, S. E., Schneider, P. L., Karabulut, M. & Bassett, D. R., Jr. 2003. Validity of 10 electronic pedometers for measuring steps, distance, and energy cost. *Med Sci Sports Exerc,* 35**,** 1455-60.

de Bruin, E. D., Hartmann, A., Uebelhart, D., Murer, K. & Zijlstra, W. 2008. Wearable systems for monitoring mobility-related activities in older people: a systematic review. *Clin Rehabil,* 22**,** 878-95.

De Cocker, K. A., De Meyer, J., De Bourdeaudhuij, I. M. & Cardon, G. M. 2012. Non-traditional wearing positions of pedometers: Validity and reliability of the Omron HJ-203-ED pedometer under controlled and free-living conditions. *J Sci Med Sport,* 15**,** 418-24.

Esteban, C., Quintana, J. M., Aburto, M., Moraza, J., Egurrola, M., Pérez-Izquierdo, J., et al. 2010. Impact of changes in physical activity on health-related quality of life among patients with COPD. *Eur Respir J,* 36**,** 292-300.

Furlanetto, K. C., Bisca, G. W., Oldemberg, N., Sant'Anna, T. J., Morakami, F. K., Camillo, C. A., et al. 2010. Step Counting and Energy Expenditure Estimation in Patients

With Chronic Obstructive Pulmonary Disease and Healthy Elderly: Accuracy of 2 Motion Sensors. *Arch Phys Med Rehabil,* 91**,** 261-7.

Garber, C. E., Blissmer, B., Deschenes, M. R., Franklin, B. A., Lamonte, M. J., Lee, I. M., et al. 2011. American College of Sports Medicine position stand. Quantity and quality of exercise for developing and maintaining cardiorespiratory, musculoskeletal, and neuromotor fitness in apparently healthy adults: guidance for prescribing exercise. *Med Sci Sports Exerc,* 43**,** 1334-59.

Gardner, P. J. & Campagna, P. D. 2011. Pedometers as measurement tools and motivational devices: new insights for researchers and practitioners. *Health Promot Pract,* 12**,** 55-62.

Hasson, R. E., Haller, J., Pober, D. M., Staudenmayer, J. & Freedson, P. S. 2009. Validity of the Omron HJ-112 Pedometer during Treadmill Walking. *Med Sci Sports Exerc,* 41**,** 805-9.

Holbrook, E. A., Barreira, T. V. & Kang, M. 2009. Validity and Reliability of Omron Pedometers for Prescribed and Self-Paced Walking. *Med Sci Sports Exerc,* 41**,** 670-4.

Hootman, J. M., Macera, C. A., Ainsworth, B. E., Martin, M., Addy, C. L. & Blair, S. N. 2001. Association among Physical Activity Level, Cardiorespiratory Fitness, and Risk of Musculoskeletal Injury. *Am J Epidemiol,* 154**,** 251-8.

Le Masurier, G. C., Lee, S. M. & Tudor-Locke, C. 2004. Motion sensor accuracy under controlled and free-living conditions. *Med Sci Sports Exerc,* 36**,** 905-10.

Melanson, E. L., Knoll, J. R., Bell, M. L., Donahoo, W. T., Hill, J. O., Nysse, L. J., et al. 2004. Commercially available pedometers: considerations for accurate step counting. *Prev Med,* 39**,** 361-8.

Prince, F., Corriveau, H., Hébert, R. & Winter, D. A. 1997. Gait in the elderly. *Gait Posture,* 5**,** 128-35.

Santos-Lozano, A., Santin-Medeiros, F., Cardon, G., Torres-Luque, G., Bailon, R., Bergmeir, C., et al. 2013. Actigraph GT3X: validation and determination of physical activity intensity cut points. *Int J Sports Med,* 34**,** 975-82.

Strath, S. J., Kaminsky, L. A., Ainsworth, B. E., Ekelund, U., Freedson, P. S., Gary, R. A., et al. 2013. Guide to the Assessment of Physical Activity: Clinical and Research Applications: A Scientific Statement From the American Heart Association. *Circulation,* 128**,** 2259-79.

Trost, S. G. & O'Neil, M. 2014. Clinical use of objective measures of physical activity. *Br J Sports Med,* 48**,** 178-81.

Tudor-Locke, C., Barreira, T. V. & Schuna, J. M., Jr. 2015. Comparison of step outputs for waist and wrist accelerometer attachment sites. *Med Sci Sports Exerc,* 47**,** 839-42.

Tudor-Locke, C. & Bassett, D. R., Jr. 2004. How many steps/day are enough? Preliminary pedometer indices for public health. *Sports Med,* 34**,** 1-8.

Turner, L. J., Houchen, L., Williams, J. & Singh, S. J. 2012. Reliability of pedometers to measure step counts in patients with chronic respiratory disease. *J Cardiopulm Rehabil Prev,* 32**,** 284-91.

Van Remoortel, H., Giavedoni, S., Raste, Y., Burtin, C., Louvaris, Z., Gimeno-Santos, E., et al. 2012. Validity of activity monitors in health and chronic disease: a systematic review. *International Journal of Behavioral Nutrition and Physical Activity,* 9**,** 84.

Vincent, S. D. & Sidman, C. L. 2003. Determining Measurement Error in Digital Pedometers. *Measurement in Physical Education and Exercise Science,* 7**,** 19-24.

Wallmann-Sperlich, B., Froboese, I., Reed, J. L., Mathes, S. & Sperlich, B. 2015. How accurate are Omron X-HJ-304-E and Yamax SW-700/701 pedometers at different speeds and various inclinations? *J Sports Med Phys Fitness,* 55**,** 113-7.

Warburton, D. E., Nicol, C. W. & Bredin, S. S. 2006. Health benefits of physical activity: the evidence. *Can Med Assoc J,* 174**,** 801-9.

Webber, S. C., Magill, S. M., Schafer, J. L. & Wilson, K. C. 2014. GT3X+ accelerometer, Yamax pedometer and SC-StepMX pedometer step count accuracy in community-dwelling older adults. *J Aging Phys Act,* 22**,** 334-41.

World Health Organization 2010. *Global recommendations on physical activity for health,* Geneva, WHO Library Cataloguing-in-Publication Data.

Zhu, W. & Lee, M. 2010. Invariance of wearing location of Omron-BI pedometers: a validation study. *J Phys Act Health,* 7**,** 706-17.

Chapter 5 – Impact of feedback on physical activity levels of individuals with COPD during pulmonary rehabilitation: a feasibility study

Joana Cruz
Dina Brooks
Alda Marques

Chronic Respiratory Disease, 11(4):191-8 (2014)

Abstract

Objectives: This study aimed to investigate whether providing feedback on physical activity (PA) levels to patients with Chronic Obstructive Pulmonary Disease (COPD) is feasible and enhances daily PA during pulmonary rehabilitation (PR).

Methods: Patients with COPD participated in a 12-week PR program. Daily PA was measured using activity monitors on weeks 1, 7 and 12 and feedback was given in the following weeks, including: number of steps; time spent in sedentary, light and moderate-to-vigorous intensity activities; time spent standing, sitting and lying. Compliance with PA monitoring was collected. Two focus groups were conducted to obtain patients' perspectives on the use of activity monitors and feedback given. Differences in PA data were also assessed.

Results: Sixteen patients (65.63±10.57 years; FEV_1 70.31±22.74pp) completed the study. Eleven participants used the activity monitors during all monitoring days. Participants identified problems regarding the use of activity monitors and monitoring duration. Daily steps (p=0.026) and standing time (p=0.030) were improved from weeks 1–7, however, the former declined from weeks 7–12.

Conclusions: Using feedback to improve PA during PR is feasible and results in improved daily steps and standing time on week 7. The subsequent decline suggests that additional strategies may be needed to stimulate/maintain PA improvements. Further research with more robust designs is needed to investigate the impact of feedback on patients' daily PA.

Keywords: Accelerometer; Chronic Obstructive Pulmonary Disease; Exercise; Monitoring; Physical activity; Rehabilitation.

Introduction

Low levels of physical activity (PA) have been associated with increased healthcare utilization and reduced survival in patients with Chronic Obstructive Pulmonary Disease (COPD) (Garcia-Aymerich et al., 2006). Thus, improving PA levels has become one of the main goals of COPD research (Ng et al., 2012, Spruit et al., 2013).

Pulmonary rehabilitation (PR) is an evidence-based intervention which includes exercise training, education and psychosocial support (Spruit et al., 2013). The exercise training component has been shown to improve exercise capacity and reduce dyspnea (Vestbo et al., 2013); however, its effects in increasing PA levels are limited (Ng et al., 2012). A recent study showed that although a 3-month PR program increased patients' exercise capacity and quality of life, changes in daily PA were restricted to a marginal improvement in walking intensity (Pitta et al., 2008). The authors suggested that patients would likely require longer programs to increase their time spent actively (Pitta et al., 2008).

Alternatively, PA levels may be enhanced by including behavior strategies in PR programs (Spruit et al., 2013). One strategy consists of increasing patients' awareness of their actual PA levels (Troosters et al., 2010). In healthy adults, awareness of individual PA is a potential determinant of the intention to increase PA levels (Ronda et al., 2001). As patients with COPD tend to overestimate their PA levels (Pitta et al., 2005), making them aware of their actual levels may contribute to improve patients' PA. For this purpose, activity monitors can be a valuable tool because they provide objective information about PA which can be then delivered to the patient. However, the effective contribution of activity monitors to increase PA levels of patients with COPD is still unclear, with the few existing studies showing conflicting results (de Blok et al., 2006, Hospes et al., 2009, Steele et al., 2008). Differences in the devices used, PA monitoring protocols and interventions may explain in part these discrepancies, but patients' compliance with PA monitoring and their experience with the activity monitors may have contributed as well. These aspects are key elements to ensure feasibility of interventions involving PA monitoring and feedback; nevertheless, they have been understudied in COPD research (Troosters, 2009). Before the widespread utilization of this technology on a larger scale, its feasibility should be investigated. Therefore, this study aimed to investigate whether providing feedback on PA levels to patients with COPD, using activity monitors, is feasible and enhances patients' daily PA during PR.

Methods

Design

This was a feasibility study with a mixed methods design. The study received full approval from the Institutional Ethics Committee.

Participants

Patients with COPD were recruited in two primary care centers of the central region of Portugal (Aveiro). General practitioners informed eligible patients about the study and asked their willingness to participate. Inclusion criteria were: (a) being 18 years old or older; (b) having a diagnosis of COPD according to the GOLD criteria (Vestbo et al., 2013); and (c) presenting clinical stability for one month prior to the study (no hospital admissions or exacerbations). Patients were excluded if they: (a) presented severe psychiatric, neurologic or musculoskeletal conditions and/or unstable cardiovascular disease; or (b) were engaged in regular exercise before the study. Patients who agreed to participate were contacted by the researchers. Detailed information about the study was provided and written informed consent was obtained before data collection.

Intervention

The intervention was conducted between April and July and consisted of a 12-week PR program with exercise training (three times per week, 60 min/session) and psychoeducation (once per week, 90 min), plus the provision of feedback on PA levels to participants. Exercise training sessions included:

- A warm-up period (5-10 min) with range-of-motion, stretching, low-intensity aerobic exercises and breathing techniques;
- Endurance training (20 min walking) at 60-80% of the six-minute walk test (6MWT) average speed (Jenkins, 2007), with intensity adjusted to patient's fatigue/dyspnea (4-6 in the Modified Borg Scale (Spruit et al., 2013));
- Strength training (15 min) including seven exercises (two sets, 10 repetitions/set) of the major upper and lower limbs muscle groups, at 50-85% of the 10 repetition maximum (10-RM) (Nici et al., 2006). Progression was based on the two-for-two rule (American College of Sports Medicine, 2009);

- Balance training (5 min) with static and dynamic exercises organized in progressive levels of difficulty (Chodzko-Zajko et al., 2009);
- A cool-down period (10 min) similar to the warm-up.

The psychoeducation component included educational and supportive modules regarding: information about COPD; breathing and energy conservation techniques; adoption of healthy lifestyles (exercise, nutrition, sleep habits); emotion-management strategies; and community resources.

PA was monitored during the first (W1), seventh (W7) and 12th (W12) weeks of the PR program using the activity monitors GT3X+ (ActiGraph, Pensacola, FL) and feedback to participants was given in the following weeks. As these devices did not provide automatic feedback to participants, researchers analyzed the information collected and summarized it. Feedback was given by one of the health professionals conducting the PR program and lasted 15-20 minutes. Feedback about W1 and W7 was given at the end of the exercise training session of the following week (W2 and W8, respectively); feedback about W12 was given in the week following program completion. Each participant received written (graphical) and verbal information about: (a) time spent standing, sitting and lying on each day of the week; (b) a weekly average of the number of daily steps and of time engaged in sedentary, light and moderate-to-vigorous intensity activities. On W1, participants were instructed to maintain their routine to establish a baseline of their activity levels and received verbal and written instructions on how to use the device. When receiving feedback of W1, participants were informed about the recommended values of PA for healthy people (≥150 min/week or ≥30 min/day of moderate intensity activities, ≥75 min/week or ≥20 min/day of vigorous intensity activities or a combination of both, performed continuously or accumulated in bouts of at least 10 min; 7000-10,000 steps/day (Garber et al., 2011)). Although feedback was given in group, each participant received individualized recommendations to improve or maintain their PA levels regarding the time spent in moderate-to-vigorous intensity activities and number of steps per day, based on the results of the previous week. They also received general recommendations to improve daily PA and a leaflet with exercises similar to those of the exercise training component. Feedback of W7 and W12 was similar to W1.

Data collection

Participants' characteristics

Socio-demographic data were collected before the intervention to characterize the sample. Lung function was assessed with a portable spirometer (MicroLab 3500, CareFusion, Kent) according to the guidelines (Miller et al., 2005). All participants took their usual prescribed medications before performing the lung function test. COPD grade and severity (ranging from group A - low risk, less symptoms - to group D - high risk, more symptoms) were determined in accordance with the GOLD criteria (Vestbo et al., 2013). Patients' breathlessness was measured using the Modified Medical Research Council Dyspnea Scale (Doherty et al., 2006). Exercise capacity was assessed with the maximal distance walked on the 6MWT (Jenkins, 2007). Two tests were performed according to the American Thoracic Society guidelines (2002). The best performance was reported and related to the reference values (Troosters et al., 1999).

Feasibility measures

Patients' compliance with the use of activity monitors (number of days wearing the device, time per day) and reasons for non-compliance were collected. In the week following the intervention, two focus groups were conducted in Portuguese to evaluate patients' perspectives on the use of activity monitors and feedback given. Each focus group lasted approximately 30 minutes and was audio-recorded for further transcription and analysis.

Physical activity

Daily PA was assessed using the activity monitors GT3X+ (already validated in COPD population (Rabinovich et al., 2013, Van Remoortel et al., 2012)) on W1, W7 and W12 of the PR program. Participants were instructed to wear the device for seven consecutive days during waking hours (except when bathing or swimming) and informed about its correct positioning: at the waist on an elastic belt, at the anterior axillary line of the right hip. Data were then downloaded using Actilife version 6.7.2 (ActiGraph, Pensacola, FL). Since five or more days of measurement are required to reliably assess PA in COPD (Watz et al., 2009), patients with less than five days in one of the time points were excluded from PA analysis. A valid day was defined as at least 8 hours of wearing time (Demeyer et al., 2014). Daily PA was calculated using the algorithms incorporated in the software and included: (a) number of steps; (b) time spent in sedentary, light and

moderate-to-vigorous intensity activities; and (c) time spent standing, sitting and lying. Cut-points for PA intensity were defined as: sedentary (0-99 counts-per-minute [CPM]), light (100-1951 CPM) and moderate-to-vigorous intensity activities (1952-∞ CPM) (Freedson et al., 1998). Since an increase in exercise capacity might facilitate increases in PA (Zwerink et al., 2013), the 6MWT was also performed in the week following program completion to assess intervention-related differences.

Data analysis

Participants' characteristics

Descriptive statistics were used to characterize the sample. Baseline measurements of completers and dropouts were compared using independent t-tests for normally distributed data, Mann Whitney U-tests for ordinal/non-normally distributed data, and Chi-square tests for categorical data. The normality of data was investigated with the Shapiro–Wilk test. A similar analysis was conducted to compare baseline measurements of patients with complete and incomplete PA assessment (i.e., patients with seven PA monitoring days vs. those without seven monitoring days).

Feasibility measures

The number of monitoring days missed by patients and wearing time was calculated and reasons for non-compliance analyzed. Focus group analyzes were conducted by two independent researchers using the procedures suggested by Ulin (2005): (a) reading and rereading the transcripts; (b) identifying possible themes; (c) displaying the information relevant to each theme; (d) reducing the information to its essential points; and (e) identifying its core meaning. Any disagreements were resolved by consensus.

Physical activity

Differences in PA data among the three time points were assessed using a repeated-measures analysis of variance (ANOVA) and pairwise comparisons were performed whenever statistical significance ($p<0.05$) was reached. Effect sizes (ES) were computed using the eta squared (η^2), interpreted as: 0.01 small, 0.06 medium and 0.14 large effect (Cohen, 1988). Observed power was also calculated. A paired t-test was used to assess differences in the six-minute walking distance (6MWD) of participants before and after the

intervention. Analyzes were conducted using SPSS version 20.0 (IBM Corp., Armonk, NY).

Results

Participants

Twenty patients entered the study. However, four were lost due to non-COPD health-related problems (n=2), changes in work schedule (n=1) and no reasons given (n=1). Sixteen participants completed the intervention. Their baseline characteristics are presented in Table 1. There were no significant differences between completers and dropouts (p>0.05).

Table 1. Participants' characteristics (n=16).

Characteristics	
Age (years)	65.63±10.57
Male	11 (68.8%)
Educational level	
Primary education	9 (56.2%)
Secondary education	4 (25.0%)
Higher education/University	3 (18.8%)
Current occupation	
Employed	4 (25.0%)
Retired	12 (75.0%)
BMI (Kg/m^2)	30.37±4.12
FEV_1% predicted	70.31±22.74
COPD grade	
Mild	5 (31.2%)
Moderate	8 (50.0%)
Severe to very severe	3 (18.8%)
GOLD classification	
A	7 (43.8%)
B	6 (37.5%)
C	1 (6.3%)
D	2 (12.5%)
mMRC	2 [2–2.75]
6MWD (m)	466.50±81.56
6MWD% predicted	74.95±8.59

Note: The results are shown as mean±SD, n (%) or median [25^{th} percentile – 75^{th} percentile]. BMI: body mass index; FEV_1: forced expiratory volume in one second; GOLD: Global Initiative for Chronic Obstructive Lung Disease; mMRC: modified Medical Research Council Dyspnea Scale; 6MWD: six-minute walking distance.

Feasibility measures

Eleven participants (68.8%) used the activity monitors during all monitoring days. Five participants missed one day (n=1, 6.3%), two days (n=1, 6.3%) or three days or more (n=3, 18.8%) of PA monitoring in at least one of the time points. Reasons included: the monitor was uncomfortable to wear in specific situations (n=1, 6.3%); failure to attend the last week of the program due to work-related issues (n=1, 6.3%); and forgetfulness (n=3, 18.8%). No significant differences were found in the baseline characteristics of participants who had complete and incomplete PA assessments ($p>0.05$). Daily wearing time was similar over the weeks (W1=14.04±0.68h; W7=13.85±1.92h; W12=13.40±1.81h, $p=0.348$).

Five participants (out of 16 who completed the study) did not attend the focus groups due to work-related issues (n=2), schedule constraints (n=2) and no reasons given (n=1). Focus group analyzes revealed that, whilst five participants (45.5%) reported no difficulties in using the activity monitors, six participants (54.5%) felt that the device was uncomfortable due to its placement and the pressure exerted by the elastic belt:

> *"It caused some pressure and sometimes the elastic belt felt like scratching (…) It was placed in a region where there is not much fat, there is mostly bone." [P1]*

> *"I used the monitor underneath the clothes and, when I started to sweat, it felt like burning..." [P2]*

Suggestions to improve its use consisted of changing the elastic belt for another with a softer material (n=4, 36.4%), and changing the placement (e.g. attached to the thigh, chest or arm) (n=4, 36.4%) or the dimensions of the device, making it more flattened (n=2, 18.2%).

Regarding data collection, six participants (54.5%) mentioned that there were too many days of monitoring. The optimal duration for using the device would be three days (n=4, 36.4%):

> *"Sometimes it was even unnoticed, but at the end of the 3rd, 4th, 5th days it started to [bother me]. I would choose to use it only for 3 days, because this was the time that it did not really bother..." [P3]*

The feedback given to participants made them more conscious about their PA levels, as they found that it reflected the reality (n=8, 72.7%). Six participants (54.5%) reported that they had improved their active time because they were wearing the devices:

> *"Using the device made me walk more!" [P4]*

"I tried to get out of the car when I could to avoid being seated for so long." [P3]

Three participants (27.3%) referred that giving daily feedback (instead of a weekly average) would be important to allow comparisons between the activities performed on a given day and the results reported by the device:

"We should use it during the day and download [the information] at the end of it. We would try to improve, 'On this day I didn't do anything… It was Tuesday… On Tuesday, I have no chance to improve…' or 'I will try to improve!'" [P5]

Physical activity

Table 2 presents daily PA levels of patients in the three time points. Significant differences with a large effect were found for number of daily steps (p=0.026, η^2=0.306). Participants increased their steps from W1 to W7 (p=0.050), followed by a decrease on W12 (p=0.048). The mean time spent in moderate-to-vigorous intensity activities was above the 30 min/day in the three time points, however, no significant differences were found (p=0.167). No changes were observed in time spent in light intensity and sedentary activities (p=0.685 and p=0.673).

Table 2. Daily physical activity levels of participants on weeks 1, 7 and 12 of the intervention (n=13).

	Week 1	**Week 7**	**Week 12**	**p-value**	**η^2**	**Observed power**
Daily steps (number)	8,638.23±2,408.14	10,002.27±2,798.13	8,858.43±1,641.80	0.026*,[a]	0.306	0.692
Moderate-to-vigorous intensity activities (min)	36.51±27.89	41.31±26.38	31.46±20.86	0.167	0.139	0.361
Light intensity activities (min)	344.52±86.76	335.27±94.25	344.44±79.42	0.685	0.031	0.105
Sedentary activities (min)	454.14±88.56	464.77±89.34	444.54±76.18	0.673	0.035	0.107
Standing (min)	253.19±77.47	302.18±70.25	283.24±64.07	0.030*,[b]	0.254	0.668
Sitting (min)	481.15±94.69	459.06±71.32	435.54±68.41	0.260	0.115	0.274
Lying (min)	46.26±32.86	33.96±23.37	48.39±28.34	0.269	0.112	0.267

Note: The results are shown as mean±SD. *Significant at p-value<0.05. [a]Pairwise comparisons were in the borderline of statistical significance between weeks 1 and 7 (p=0.050) and significant between weeks 7 and 12 (p=0.048). [b]Pairwise comparisons were significant between weeks 1 and 7 (p=0.021).

Regarding body postures, differences were found for standing time (p=0.030, η^2=0.254). Specifically, improvements were observed between W1 and W7 (p=0.021), but not between W7 and W12 (p=0.130). No significant differences were found for time spent sitting (p=0.260) or lying (p=0.269).

Regarding exercise capacity, participants' 6MWD was significantly increased after the intervention (466.50±81.56m vs. 513.33±86.18m, p=0.001).

Discussion

This study demonstrated that using feedback to improve PA during PR is feasible and increases the number of daily steps and standing time in the short-term. Nevertheless, there are still some issues that should be further enhanced in to stimulate and/or maintain PA improvements.

Overall, participants' compliance was satisfactory and they reported a positive experience regarding the use of activity monitors. Still, some participants reported problems related to usability issues (monitor placement, pressure exerted by the elastic belt) and duration of PA monitoring. To date, a small number of studies has specifically addressed these issues; however, this may have important implications for compliance with activity monitoring (Trost et al., 2005) and should be carefully considered when planning a study. In addition, some participants occasionally forgot to wear the activity monitor. To overcome this problem, future studies should implement strategies to improve patients' compliance, as it has been recommended in the literature (Trost et al., 2005).

Participants reported that feedback made them more conscious about their PA levels and PA improvements were related to wearing the devices. This suggests that the aim of including feedback in PR was achieved, i.e., increasing patients' awareness and motivating them to improve daily PA. Nevertheless, some participants mentioned that daily feedback would have facilitated comparisons between the activities performed on a given day and the results reported by the device. Activity monitors with an automatic daily feedback function may, therefore, be valuable to meet patients' needs and expectations. Pedometers include this option, but their limited accuracy may prevent them from detecting PA changes in interventional studies (Ng et al., 2012). Future advances in sensing technologies may offer opportunities to improve PA monitoring and feedback in COPD research.

Participants improved their daily steps and standing time from W1 to W7; however, the former declined from W7 to W12. Nevertheless, a large effect was observed indicating a relevant change. These findings suggest that patients' PA levels may already be increased on W7 of PR programs, if appropriate feedback is given. However, complementary strategies may be necessary to stimulate and/or maintain PA improvements, since a decline was observed on W12. In this study, a psychoeducation session focused on promoting exercise habits in participants was carried out on W6, which could have acted as an additional motivational tool to stimulate behavior change and, thus, improve participants' PA on W7. Future research should explore the value of feedback and additional strategies (e.g. psychoeducation sessions about exercise habits) to stimulate patients' behavior change into a more active lifestyle, as this is one of the current challenges in COPD research.

Strengths and limitations

The combination of quantitative and qualitative methods of data collection is a strength of the present study, as it enabled gathering the full experience of participants with the use of activity monitors and provided important information for the design of future technologies and interventions.

The small sample size and lack of control group were limitations of the present study, which may have contributed to the insufficient power obtained in some comparisons. The absence of a control group may have acted as a confounding factor, since previous studies have shown that PR per se is able to promote increases in PA levels (Pitta et al., 2008). Further studies with more robust designs are needed to investigate the value of providing feedback on PA levels to patients with COPD during PR. In addition, patients' PA levels were collected on specific weeks of the PR program, which may compromise the comparisons with previous studies. However, this was deemed necessary to enable the provision of feedback on PA levels to participants as part of the intervention.

Most participants were in mild and moderate COPD grades, which differ from other intervention studies with PA monitoring (Pitta et al., 2008, Steele et al., 2008, de Blok et al., 2006). Nevertheless, recent literature has acknowledged that PA is already reduced in early COPD grades (Troosters et al., 2010, Watz et al., 2009) and PR is now considered a standard of care for all patients, including those at earlier grades (Spruit et al., 2013).

The fact that feedback was only given on specific time points may have limited participants' PA improvements. In addition, it was not possible to determine if PA levels

were already increased before W7. Future studies should explore the impact of more regular feedback and monitoring on patients' daily PA. Furthermore, since patients were on average sufficiently active on W1 (i.e., above the internationally recommended target of 7,000 steps per day) (Garber et al., 2011), future studies should explore whether patients who have a lower step performance at baseline are more motivated to change their daily steps during and after the intervention.

The mean time spent in moderate-to-vigorous intensity activities was above the 30 min/day in the three time points, which could suggest that patients have met the international recommendations (Garber et al., 2011). However, one recent study showed that the recommended time of moderate-to-vigorous intensity activities varies upon the selected PA analysis, i.e., bouts vs. non-bouts analysis (van Remoortel et al., 2013). In the study of van Remoortel at al. (2013), the commonly used bouts cut-point of 30 min/day was associated to a non-bouts cut-point of 80 min/day. Since the present study did not conduct a bouts analysis, it is possible that patients did not reach the international PA target for moderate-to-vigorous intensity activities. Future studies using bouts and non-bouts analysis should be conducted in order to clarify whether patients with COPD meet the international recommendations.

Despite the limitations, results from this study suggest that feedback on PA levels can be used to support patients in achieving a more active lifestyle, by helping them to self-monitor their daily PA. The costs associated to the provision of feedback were relatively small and related to the purchase of activity monitors and the time needed by health professionals to deliver feedback to the participants (15-20 min). Therefore, this seems a feasible intervention to be implemented in various health care settings. Furthermore, as lower PA levels have been related to increased healthcare utilization, poorer quality of life and reduced survival of patients with COPD (Garcia-Aymerich et al., 2006, Waschki et al., 2011, Watz et al., 2008), it is reasonable to believe that this type of intervention may lead to reduced COPD health-related costs. This should be investigated in future research.

Conclusions

Providing feedback on physical activity (PA) levels to patients with COPD is feasible and may enhance daily PA during pulmonary rehabilitation. However, additional strategies might be necessary to stimulate patients' behavior change into a more active lifestyle, as this is one of the current challenges in COPD research. Patients' experiences on the use

of activity monitors should also be assessed, as they provide valuable information to adjust PA technologies and interventions to the target population. Further research with more robust designs is needed to investigate the impact of feedback on patients' daily PA.

Acknowledgements

The authors would like to acknowledge the patients who participated in this study. A special thanks to Cristina Jácome and Raquel Gabriel for their valuable contribution in the implementation of the PR program.

Conflict of interest statement

This work was supported by the Foundation for Science and Technology (grant number SFRH/BD/81328/2011). The authors declare that there is no conflict of interest.

References

American College of Sports Medicine 2009. *ACSM's resource manual for guidelines for exercise testing and prescription,* Philadelphia, Lippincott Williams & Wilkins.

American Thoracic Society 2002. ATS Statement: Guidelines for the Six-Minute Walk Test. *Am J Respir Crit Care Med,* 166**,** 111-7.

Chodzko-Zajko, W. J., Proctor, D. N., Fiatarone Singh, M. A., Minson, C. T., Nigg, C. R., Salem, G. J., et al. 2009. Exercise and Physical Activity for Older Adults. *Med Sci Sports Exerc,* 41**,** 1510-30.

Cohen, J. 1988. *Statistical Power Analysis for the Behavioral Sciences,* New Jersey, Lawrence Erbaum Associates.

de Blok, B. M., de Greef, M. H., ten Hacken, N. H., Sprenger, S. R., Postema, K. & Wempe, J. B. 2006. The effects of a lifestyle physical activity counseling program with feedback of a pedometer during pulmonary rehabilitation in patients with COPD: a pilot study. *Patient Educ Couns,* 61**,** 48-55.

Demeyer, H., Burtin, C., Van Remoortel, H., Hornikx, M., Langer, D., Decramer, M., et al. 2014. Standardizing the analysis of physical activity in patients with copd following a pulmonary rehabilitation program. *Chest,* 146**,** 318-27.

Doherty, D. E., Belfer, M. H., Brunton, S. A., Fromer, L., Morris, C. M. & Snader, T. C. 2006. Chronic Obstructive Pulmonary Disease: Consensus Recommendations for Early Diagnosis and Treatment. *J Fam Pract,* Supplement**,** S1-S8.

Freedson, P. S., Melanson, E. & Sirard, J. 1998. Calibration of the Computer Science and Applications, Inc. accelerometer. *Med Sci Sports Exerc,* 30**,** 777-81.

Garber, C. E., Blissmer, B., Deschenes, M. R., Franklin, B. A., Lamonte, M. J., Lee, I. M., et al. 2011. American College of Sports Medicine position stand. Quantity and quality of exercise for developing and maintaining cardiorespiratory, musculoskeletal, and neuromotor fitness in apparently healthy adults: guidance for prescribing exercise. *Med Sci Sports Exerc,* 43**,** 1334-59.

Garcia-Aymerich, J., Lange, P., Benet, M., Schnohr, P. & Anto, J. M. 2006. Regular physical activity reduces hospital admission and mortality in chronic obstructive pulmonary disease: a population based cohort study. *Thorax,* 61**,** 772-8.

Hospes, G., Bossenbroek, L., Ten Hacken, N. H., van Hengel, P. & de Greef, M. H. 2009. Enhancement of daily physical activity increases physical fitness of outclinic COPD patients: results of an exercise counseling program. *Patient Educ Couns,* 75**,** 274-8.

Jenkins, S. C. 2007. 6-Minute walk test in patients with COPD: clinical applications in pulmonary rehabilitation. *Physiotherapy,* 93**,** 175-82.

Miller, M. R., Hankinson, J., Brusasco, V., Burgos, F., Casaburi, R., Coates, A., et al. 2005. Standardisation of spirometry. *Eur Respir J,* 26**,** 319-38.

Ng, L. W. C., Mackney, J., Jenkins, S. & Hill, K. 2012. Does exercise training change physical activity in people with COPD? A systematic review and meta-analysis. *Chron Respir Dis,* 9**,** 17-26.

Nici, L., Donner, C., Wouters, E., Zuwallack, R., Ambrosino, N., Bourbeau, J., et al. 2006. American Thoracic Society/European Respiratory Society Statement on Pulmonary Rehabilitation. *Am J Respir Crit Care Med,* 173**,** 1390-413.

Pitta, F., Troosters, T., Probst, V. S., Langer, D., Decramer, M. & Gosselink, R. 2008. Are patients with COPD more active after pulmonary rehabilitation? *Chest,* 134**,** 273-80.

Pitta, F., Troosters, T., Spruit, M. A., Decramer, M. & Gosselink, R. 2005. Activity monitoring for assessment of physical activities in daily life in patients with chronic obstructive pulmonary disease. *Arch Phys Med Rehabil,* 86**,** 1979-85.

Rabinovich, R. A., Louvaris, Z., Raste, Y., Langer, D., Van Remoortel, H., Giavedoni, S., et al. 2013. Validity of physical activity monitors during daily life in patients with COPD. *Eur Respir J,* 42**,** 1205-15.

Ronda, G., Van Assema, P. & Brug, J. 2001. Stages of change, psychological factors and awareness of physical activity levels in the Netherlands. *Health Promot Int,* 16**,** 305-14.

Spruit, M. A., Singh, S. J., Garvey, C., Zuwallack, R., Nici, L., Rochester, C., et al. 2013. An official American Thoracic Society/European Respiratory Society statement: key concepts and advances in pulmonary rehabilitation. *Am J Respir Crit Care Med,* 188**,** e13-e64.

Steele, B. G., Belza, B., Cain, K. C., Coppersmith, J., Lakshminarayan, S., Howard, J., et al. 2008. A randomized clinical trial of an activity and exercise adherence intervention in chronic pulmonary disease. *Arch Phys Med Rehabil,* 89**,** 404-12.

Troosters, T. 2009. Physical activity monitoring: a new outcome facing many challenges, but yielding promising results. *COPD: Journal of Chronic Obstructive Pulmonary Disease,* 6**,** 82-3.

Troosters, T., Gosselink, R. & Decramer, M. 1999. Six minute walking distance in healthy elderly subjects. *Eur Respir J,* 14**,** 270-4.

Troosters, T., Sciurba, F., Battaglia, S., Langer, D., Valluri, S. R., Martino, L., et al. 2010. Physical inactivity in patients with COPD, a controlled multi-center pilot-study. *Respir Med,* 104**,** 1005-11.

Trost, S. G., McIver, K. L. & Pate, R. R. 2005. Conducting accelerometer-based activity assessments in field-based research. *Med Sci Sports Exerc,* 37**,** S531-S543.

Ulin, P. R. 2005. *Qualitative methods in public health: a field guide for applied research* San Francisco, Jossey-Bass.

van Remoortel, H., Camillo, C. A., Langer, D., Hornikx, M., Demeyer, H., Burtin, C., et al. 2013. Moderate Intense Physical Activity Depends on Selected Metabolic Equivalent of Task (MET) Cut-Off and Type of Data Analysis. *PLoS One,* 8**,** e84365.

Van Remoortel, H., Raste, Y., Louvaris, Z., Giavedoni, S., Burtin, C., Langer, D., et al. 2012. Validity of Six Activity Monitors in Chronic Obstructive Pulmonary Disease: A Comparison with Indirect Calorimetry. *PLoS One,* 7**,** e39198.

Vestbo, J., Hurd, S. S., Agustí, A. G., Jones, P. W., Vogelmeier, C., Anzueto, A., et al. 2013. Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Pulmonary Disease. *Am J Respir Crit Care Med,* 187**,** 347-65.

Waschki, B., Kirsten, A., Holz, O., Muller, K. C., Meyer, T., Watz, H., et al. 2011. Physical activity is the strongest predictor of all-cause mortality in patients with COPD: a prospective cohort study. *Chest,* 140**,** 331-42.

Watz, H., Waschki, B., Boehme, C., Claussen, M., Meyer, T. & Magnussen, H. 2008. Extrapulmonary effects of chronic obstructive pulmonary disease on physical activity. *Am J Respir Crit Care Med,* 177**,** 743-51.

Watz, H., Waschki, B., Meyer, T. & Magnussen, H. 2009. Physical activity in patients with COPD. *Eur Respir J,* 33**,** 262-72.

Zwerink, M., van der Palen, J., van der Valk, P., Brusse-Keizer, M. & Effing, T. 2013. Relationship between daily physical activity and exercise capacity in patients with COPD. *Respir Med,* 107**,** 242-8.

Chapter 6 – Walk2Bactive: A randomised controlled trial of a physical activity-focused behavioural intervention beyond pulmonary rehabilitation in COPD

Joana Cruz
Dina Brooks
Alda Marques

Chronic Respiratory Disease, 13(1), 57–66 (2016)

Abstract

Objectives: To investigate the impact of a physical activity (PA)-focused behavioural intervention during and after pulmonary rehabilitation (PR) on PA levels (primary aim), health-related outcomes and self-efficacy (secondary aims) of patients with COPD.

Methods: 32 patients were randomly assigned to an experimental (EG) or control (CG) group. The EG received a PA-focused behavioural intervention during PR (three months) and follow-up support (three months). The CG received PR (three months). Daily PA was collected: number of steps; time spent in moderate-to-vigorous PA (MVPA), total PA and sedentary activities (SA). Secondary outcomes comprised exercise capacity, muscle strength, health-related quality of life (HRQOL) and self-efficacy. Measures were collected at baseline, three and six months.

Results: Compared with the CG, the EG improved the number of steps ($p=0.006$) and time spent in MVPA ($p=0.007$), total PA ($p=0.014$) and SA ($p=0.018$) at three months. Differences were maintained after follow-up support ($0.025 \leq p \leq 0.040$), except for SA ($p=0.781$). Exercise capacity, muscle strength and HRQOL were increased at three and six months ($p \leq 0.002$) with no between-group differences ($0.148 \leq p \leq 0.987$). No changes were observed in self-efficacy ($p=0.899$).

Conclusions: A PA-focused behavioural intervention during and after PR may improve patients' PA levels. Further research is warranted to assess the sustainability of the findings.

Clinical Trial Registration: ClinicalTrials.gov NCT02122614, URL: www.clinicaltrials.gov

Keywords: Chronic Obstructive Pulmonary Disease; Daily activity; Exercise; Monitoring; Pedometer; Social Cognitive Theory.

Introduction

Patients with Chronic Obstructive Pulmonary Disease (COPD) are markedly inactive during daily life (Pitta et al., 2005). Low physical activity (PA) levels have been associated with adverse outcomes, including hospitalisation and all-cause mortality (Waschki et al., 2011, Garcia-Rio et al., 2012); therefore, increasing patients' PA has become a desirable outcome (Spruit et al., 2013).

Pulmonary rehabilitation (PR) is the cornerstone of COPD management with well-documented effects on exercise capacity and health-related quality of life (HRQOL) (Nici et al., 2006). Hence, it would seem the ideal intervention to promote PA behaviours in patients with COPD (Spruit et al., 2013). However, previous studies assessing the impact of PR on PA levels have shown that an increase in exercise capacity does not necessarily translate into significant improvements in patients' PA (Egan et al., 2012, Mador et al., 2011, Pitta et al., 2008). Alternative methods to produce PA behaviour change within PR are therefore needed.

In the last decade, several PA-focused interventions complementary to PR have been developed (Wilson et al., 2014). Those including self-monitoring using activity monitors, behaviour change approaches and goal setting showed the most promising results (Altenburg et al., 2015, Cruz et al., 2014). However, to date, only a few randomised controlled trials have studied the effectiveness of these interventions along with PR in improving patients' PA (Altenburg et al., 2015, de Blok et al., 2006, Steele et al., 2008).

The aim of this randomised controlled trial was to investigate the impact of a PA-focused behavioural intervention during and after a PR programme on PA levels of patients with COPD. Secondary aims were to evaluate its effects on health-related outcomes and self-efficacy.

Methods

Study Design

This was a randomised controlled trial. Patients were randomly assigned to receive a PA-focused behavioural intervention during and after PR (experimental group [EG]) or PR alone (control group [CG]), using a computer-generated schedule in random blocks of two. One researcher kept the allocation sequence in sealed opaque envelopes, drew the envelopes and scheduled patients. Patients knew about the existence of two groups but

not the differences between interventions. Ethical approval was obtained from the Central Regional Health Administration (2011-02-28), Hospital Centre (34428) and National Data Protection Committee (9250/2012). Written consent was obtained from each participant. The trial was registered at ClinicalTrials.gov (NCT02122614) and was reported according to CONSORT guidelines (Schulz et al., 2010).

Participants

Patients were recruited from three primary care centres and a district hospital. Patients were included if they were: 18 years or older; diagnosed with COPD according to the GOLD criteria (Global Strategy for the Diagnosis Management and Prevention of COPD [GOLD], 2015); clinically stable in the last month (i.e., no hospital admissions or exacerbations) and able to provide informed consent. Exclusion criteria consisted of the presence of severe neurologic, musculoskeletal or psychiatric disorders, unstable cardiovascular disease or severe visual impairment, and participation in PR in the previous six months or in regular strenuous exercise.

Intervention

Patients of both groups underwent 12 weeks (three months) of PR between April and July 2014. Additionally, the EG received a PA-focused behavioural intervention (three plus three months).

Pulmonary rehabilitation

PR consisted of exercise training and psychosocial support and education sessions. Exercise training was held three times/week (60min/session) by physiotherapists with expertise in the field and comprised warm-up, aerobic training, resistance training, balance training, and cool-down (as described elsewhere (Cruz et al., 2014)). Psychosocial support and education sessions were conducted once a week (90min) by a multidisciplinary team. Topics included information about COPD, promotion of healthy lifestyles (PA, nutrition) and self-management strategies. PR programmes were conducted at different times to avoid group contamination.

PA-focused behavioural intervention

The PA-focused behavioural intervention was implemented by one physiotherapist during the PR programme (three months) and continued for three months after its completion. It was specifically designed to achieve a sustained increase in patients' PA levels and was based on the Social Cognitive Theory (SCT) (Bandura, 1986), which acknowledges the role of self-efficacy, goal setting and performance feedback as core elements of behaviour change. The present intervention incorporated these concepts by using the Health contract technique (Haber, 2010, Haber and Rhodes, 2004) and objective feedback provided by pedometers. The intervention is described in detail below.

In the first psychosocial support and education session, participants in the EG were given a piezoelectric pedometer (Yamax Power Walker EX-510) and a log diary to record daily steps in order to establish their baseline steps. These pedometers have shown good accuracy results at slow (absolute percent error [APE] 4.5-9.1%), self-preferred/normal and fast (APE<3%) speeds, particularly when worn at the front right or left sides of the waist or inside the front pockets of the trousers (Cruz et al., 2015). In the following session, participants received a Health contract (Haber, 2010), i.e., a written agreement between each patient and the physiotherapist. The physiotherapist assisted patients in completing the Health contract: they had to formulate an individualised long-term step-count goal to achieve by the end of the PR programme, based on their baseline steps and international PA recommendations (7000-10,000steps/day (Garber et al., 2011)), and identify potential facilitators (e.g., walking with family/friends, planning a daily schedule). Participants also received a calendar to register their short-term step-count goals and daily steps, which were self-monitored with the pedometer. Short-term goals were defined on a weekly basis and consisted of the previous short-term goal plus ~800 additional steps (if the goal of the previous week was met) (Moy et al., 2010) or the previous goal (if it was not met). The final aim was to achieve the long-term goal. In each psychosocial support and education session, the physiotherapist provided individual feedback on patients' performance and helped them to define the next short-term goal (~20-30min/session). In the last session, the long-term goal was reassessed. If achieved, participants were praised and asked to readjust it for the next 3 months. After PR, patients continued registering their steps in the calendar and received the physiotherapist's support on a weekly (in the first month) and fortnightly (in the second and third months) basis by telephone calls.

Measures

Participants' characteristics were assessed at baseline. Outcome measures were collected at baseline, three months (i.e., post-PR) and six months (i.e., after the PA-focused behavioural intervention).

Participants' characteristics

Sociodemographic and anthropometric data were collected using a structured questionnaire and dyspnoea using the modified Medical Research Council dyspnoea scale (mMRC) (Doherty et al., 2006). Lung function was assessed with a portable spirometer (MicroLab 3500, CareFusion, Kent) (Miller et al., 2005) and GOLD grades and exacerbation risk groups were determined (GOLD, 2015).

Primary outcome measure

Daily PA levels were assessed using activity monitors GT3X+ (ActiGraph, Pensacola, FL), already validated in COPD (Rabinovich et al., 2013, Van Remoortel et al., 2012). Participants wore the device for four consecutive weekdays during waking hours (except when bathing or swimming) (Demeyer et al., 2014). Data were downloaded using Actilife v6.10.4 (ActiGraph, Pensacola, FL). A valid day was defined as ≥8h of wearing time (Demeyer et al., 2014). Daily PA included the time spent in moderate-to-vigorous PA (MVPA, 1952–∞ counts-per-minute [CPM]), total PA (100–∞CPM) (Freedson et al., 1998) and number of steps. Time spent in MVPA was calculated considering the total time (overall MVPA) and the internationally recommended duration of ≥30min of daily MVPA, either continuous or in blocks of ≥10min (recommended MVPA) (American College of Sports Medicine, 2014). Time spent in sedentary activities (SA, 0–99CPM) was also calculated (Freedson et al., 1998).

Secondary outcome measures

Secondary outcomes comprised exercise capacity (six-minute walk test) (American Thoracic Society, 2002), quadriceps muscle strength (1 repetition maximum) (American College of Sports Medicine, 2014), HRQOL (St. George's Respiratory Questionnaire, SGRQ – 3 domains and global score) (Jones, 2005) and self-efficacy (Self-Efficacy Scale)

(Pais-Ribeiro, 1995). The questionnaires presented good internal consistency (SGRQ: 0.695≤Cronbach's α≤0.877; Self-Efficacy Scale: Cronbach's α=0.696).

Statistical analysis

Sample size was estimated using the primary outcome measure based on a pilot study (Cruz et al., 2014). It was found that 12 patients with COPD would be required in each group to provide 80% power (α=0.05) to detect significant between-group differences in MVPA (using the effect size eta squared, η^2=0.139). However, as PR programmes have a considerable dropout rate (~30%) (Fischer et al., 2009, Garrod et al., 2006), 16 patients per group were recruited. Power analyses were performed using G*Power v3.1.3 (Franz Faul, Kiel University, Germany).

Baseline characteristics were compared between groups and between completers and dropouts with independent t-tests for normally distributed data, Mann Whitney U-tests for ordinal data and Chi-square tests for categorical data. For each outcome, a mixed-model analysis of variance (ANOVA) was used to determine the effects of time and time X group interaction considering a level of significance of 0.05. Effect sizes were computed using the partial eta squared ($\eta^2_{partial}$), interpreted as: $\eta^2_{partial}$≥0.01 small, $\eta^2_{partial}$≥0.06 medium and $\eta^2_{partial}$≥0.14 large effect (Cohen, 1988). Observed power was also calculated. If interaction was significant, a simple effects analysis was performed using independent t-tests to assess between-group differences at each time point. Data were analysed using SPSS v20.0 (IBM, Armonk, NY) and GraphPad Prism v5.0 (GraphPad, La Jolla, CA).

Results

Participants

Forty patients were screened (Figure 1); however, eight were excluded for not meeting the inclusion criteria (n=5) or declining to participate (n=3). Therefore, 32 patients were allocated to the EG (n=16) or CG (n=16). Participants (27 males) had a mean age of 66.4±8.4 years and a FEV_1 of 67.1±20.1% predicted. No significant between-group differences were found in baseline characteristics (0.121≤p≤0.855, Table 1).

Twenty-six participants completed the intervention and posttest assessments and thus were included in the analysis. Baseline characteristics were not significantly different between completers and dropouts (0.143≤p≤0.817).

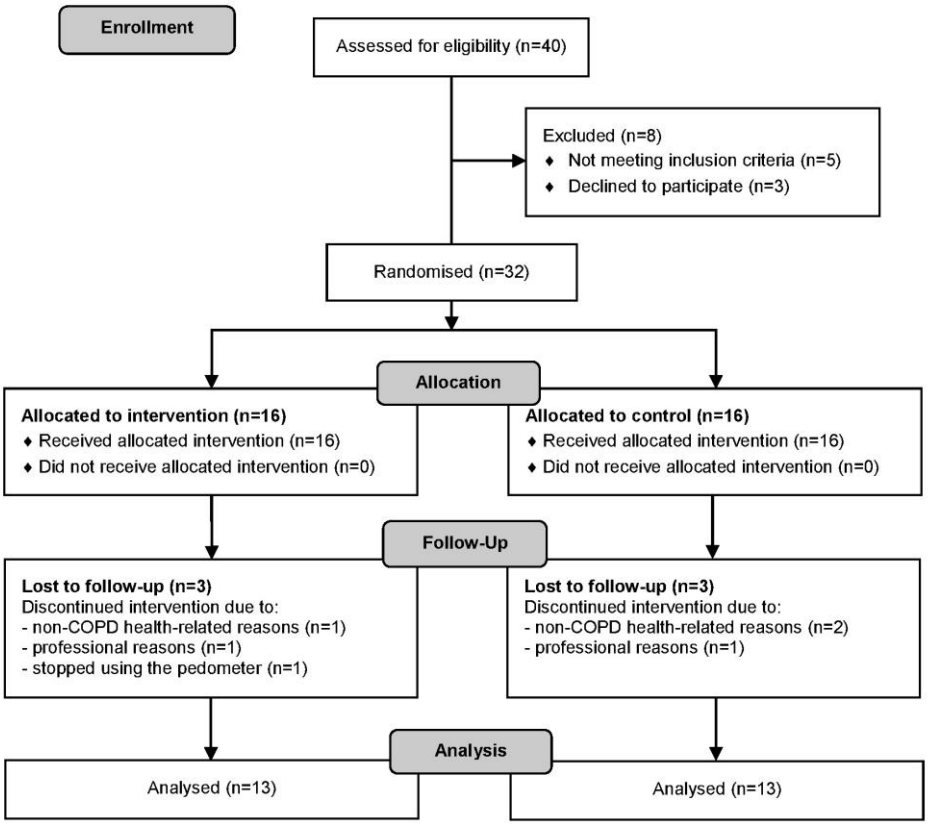

Figure 1. Flow diagram.

Table 1. Characteristics of participants from both groups (n=32).

	Experimental group (n=16)	**Control group (n=16)**	**P**
Age, years	68.8±8.2	64.1±8.2	0.121
Sex (male), n(%)	13 (81.2%)	14 (87.5%)	0.626
Current occupation, n(%)			
Retired	14 (87.5)	11 (68.8)	0.303
Employed	2 (12.5)	2 (12.5)	
Unemployed	0	3 (18.8)	
BMI, Kg/m^2	29.3±3.6	29.6±6.3	0.855
mMRC, M[IQR]	1.5 [1.0–2.0]	2.0 [1.0–2.5]	0.423
FEV_1, L	1.9±0.8	2.0±0.7	0.699
FEV_1, % predicted	65.5±21.1	68.4±19.7	0.697

(table 1 – continued)

	Experimental group (n=16)	Control group (n=16)	P
GOLD grade, n(%)			
Mild	6 (37.5)	6 (37.5)	0.623
Moderate	4 (25.0)	6 (37.5)	
Severe to very severe	6 (37.5)	4 (25.0)	
Exacerbation risk, n(%)			
A	5 (31.2)	5 (31.2)	0.776
B	4 (25.0)	6 (37.5)	
C	3 (18.1)	1 (6.2)	
D	4 (25.0)	4 (25.0)	

Data are presented as mean±standard deviation, unless otherwise indicated. Abbreviations: BMI, body mass index; FVC, forced vital capacity; FEV_1, forced expiratory volume in one second; GOLD, Global Initiative for Chronic Obstructive Lung Disease; IQR, interquartile range, M, median; mMRC, modified British Medical Research Council dyspnoea scale.

Physical activity

Figure 2 and Table 2 present the main PA findings. A significant time X group interaction was found for time spent in overall MVPA (p=0.030, $\eta^2_{partial}$=0.21, Power=0.89), recommended MVPA (p=0.012, $\eta^2_{partial}$=0.17, Power=0.78) and total PA (p=0.047, $\eta^2_{partial}$=0.12, Power=0.59) and for the number of steps (P=0.001, $\eta^2_{partial}$=0.27, Power=0.96).

Patients in the EG spent significantly more time in overall MVPA (three months: EG=57.8±32.8 min/day CG=26.7±19.6 min/day, p=0.007; six months: EG=51.6±29.4 min/day CG=28.0±26.0 min/day, p=0.040), recommended MVPA (three months: EG=23.3±28.6 min/day CG=4.3±7.3 min/day, p=0.036; six months: EG=20.3±24.2 min/day CG=3.8±7.4 min/day, p=0.033) and total PA (three months: EG=279.5±74.0 min/day CG=212.0±53.9 min/day, p=0.014; six months: EG=269.3±61.5 min/day CG=202.9±82.5 min/day, p=0.029). In addition, the EG walked on average more 4010.0 steps/day at three months (p=0.006) and 3266.7 steps/day at six months (p=0.025) than the CG (Figure 2).

A time X group interaction was also found for SA (p=0.031, $\eta^2_{partial}$=0.14, Power=0.66). At three months, the EG spent significantly less time in SA (EG=536.4±86.6 min/day CG=625.9±93.3 min/day, p=0.018). No between-group differences were found at six months (p=0.781).

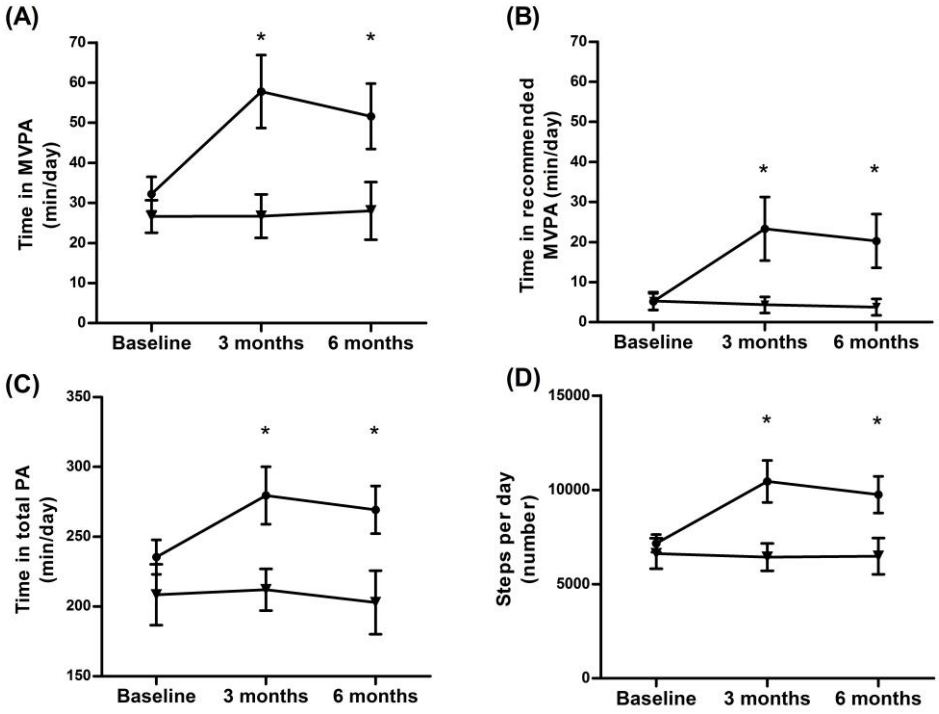

Figure 2. Physical activity (PA) levels of participants in the EG (●) and CG (▾) at baseline, 3 and 6 months. Data are presented as mean and standard error of the mean (SEM). Significant differences between groups in each time point are identified with an *. (A) Time in moderate-to-vigorous PA (MVPA); (B) Time in MVPA according to the international recommendations (i.e., ≥30min of MVPA either continuous or in blocks of ≥10min); (C) Time in total PA; (D) Number of daily steps.

Table 2. Daily physical activity (PA) levels of participants in the experimental (EG, n=13) and control (CG, n=13) groups at baseline, 3 months and 6 months.

		Baseline	3 months	6 months	P[a]	$\eta^2_{partial}$ [b]	Observed power[c]
Overall MVPA (min)	EG	32.2±15.4	57.8±32.8	51.6±29.4	0.030*	0.21	0.89
	CG	26.6±14.6	26.7±19.6	28.0±26.0			
Recommended MVPA (min)	EG	5.2±7.5	23.3±28.6	20.3±24.2	0.012*	0.17	0.78
	CG	5.3±8.2	4.3±7.3	3.8±7.4			

(table 2 – continued)

		Baseline	3 months	6 months	P[a]	$\eta^2_{partial}$ [b]	Observed power[c]
Total PA (min)	EG	235.4±44.6	279.5±74.0	269.3±61.5	0.047*	0.12	0.59
	CG	208.4±78.9	212.0±53.9	202.9±82.5			
Daily steps (number)	EG	7161.5±1708.1	10440.0±4012.9	9747.9±3511.8	0.001*	0.27	0.96
	CG	6617.1±2914.2	6430.0±2613.1	6481.3±3454.4			
Sedentary activities (min)	EG	600.2±66.1	536.4±86.6	578.8±102.8	0.031*	0.14	0.66
	CG	611.7±77.5	625.9±93.3	566.8±116.5			

Data are presented as mean±standard deviation. Significant differences are identified with an *. [a]P of Time x Group interaction; [b]Partial eta squared of Time x Group interaction; [d]Observed power of Time x Group interaction. Abbreviations: MVPA, moderate-to-vigorous physical activity; PA, physical activity.

B. Secondary outcomes

Both EG and CG experienced significant improvements in exercise capacity, muscle strength and HRQOL during the study (p≤0.002 – except for SGRQ Symptoms score, p=0.051), with no between-group differences (0.148≤p≤0.987). Self-efficacy remained constant throughout the study in both groups (p=0.899, Table 3).

Table 3. Outcome measures of patients of the experimental (EG, n=13) and control (CG, n=13) groups.

		Baseline	3 months	6 months	P[a]	P[b]	$\eta^2_{partial}$ [c]	Observed power[d]
6MWD (m)	EG	493.8±63.0	547.9±47.9	540.4±31.1	0.962	<0.001*	0.53	0.99
	CG	476.2±54.9	529.7±57.2	519.4±50.8				
Quadriceps muscle strength (kg)	EG	37.0±7.4	47.2±11.4	43.7±11.6	0.148	<0.001*	0.68	0.99
	CG	40.7±8.0	51.0±10.8	43.8±8.2				

(table 3 – continued)

		Baseline	3 months	6 months	P[a]	P[b]	$\eta^2_{partial}$ [c]	Observed power[d]
SGRQ Global score	EG	31.5±15.7	24.0±13.6	23.1±10.3	0.987	<0.001*	0.41	0.99
	CG	34.9±14.7	26.9±15.2	26.2±15.3				
SGRQ Symptoms score	EG	40.2±23.0	32.1±18.4	27.2±16.9	0.773	0.051	0.13	0.58
	CG	41.2±22.7	35.9±21.6	34.0±26.3				
SGRQ Activities score	EG	48.7±20.2	38.2±20.4	41.9±17.3	0.882	0.002*	0.25	0.92
	CG	49.2±16.7	38.8±22.2	40.0±17.3				
SGRQ Impact score	EG	18.4±13.2	13.1±11.6	10.8±7.8	0.833	<0.001*	0.36	0.99
	CG	24.8±13.8	17.5±12.8	15.7±14.0				
Self-efficacy	EG	77.0±12.0	75.3±12.7	79.5±11.4	0.068	0.899	0.05	0.07
	CG	82.4±10.4	85.7±11.1	79.6±13.0				

Data are presented as mean±standard deviation. Significant differences are identified with an *. [a]p of Time X group interaction; [b]p of Time; [c]Partial eta squared of Time; [d]Observed power of Time. Abbreviations: 6MWD, six-minute walking distance; SGRQ, St. George's Respiratory Questionnaire.

Discussion

This was the first randomised controlled trial that evaluated the impact of a PA-focused behavioural intervention comprising a Health contract and pedometer feedback on PA levels of patients with COPD during and after PR. The addition of this novel approach to PR was effective in improving patients' PA levels at three months which remained improved after follow-up support. Nevertheless, it did not produce further improvements in exercise capacity, muscle strength or HRQOL.

The addition of the PA-focused behavioural intervention to PR led to significant PA improvements in the EG which remained improved after follow-up support. Findings suggest that this intervention is feasible and enhances patients' PA levels. A previous study implementing a PA-focused intervention with goal setting and pedometer feedback during PR found only modest (non-significant) improvements in patients' daily steps (de Blok et al., 2006). Differences between studies may be explained by the different duration of the PR programme (nine weeks vs. 12 weeks) and professional support (five 30min individual sessions vs. weekly 20-30min group sessions). When that intervention was

implemented in a 3-month period, significant results were observed albeit the improvement was less pronounced than in the present study (547 steps/day vs. 3278.6 steps/day, respectively) (Altenburg et al., 2015). Disease severity and baseline PA levels may explain in part these discrepancies. Nevertheless, the type of PA-focused intervention may have also played a role, as in the present study a formal commitment was encouraged by the use of the Health contract. This technique has been applied with varied degrees of success in interventions conducted with other populations and health behaviours (Haber and Rhodes, 2004, Speelman et al., 2014, Cupples and Steslow, 2001). It has advantages over verbal communication alone, since formal commitment enhances the individual-clinician relationship and stimulates the active participation of the individual in identifying an achievable health goal and creating a behaviour change plan (Haber and Looney, 2000).

The costs associated with the addition of the PA-focused behavioural intervention to PR were relatively small and related to the purchase of pedometers and printed material (Health contract and calendar), the telephone calls and the time needed by the physiotherapist to provide support (~20-30min/session). Thus, this intervention can be implemented in various healthcare settings without the need for significant additional costs or human resources. Further research is needed to study the cost-effectiveness of this PA-focused behavioural intervention.

Despite the PA improvements found in the EG, there were no significant between-group differences in exercise capacity, muscle strength and HRQOL, similarly to a previous study (Altenburg et al., 2015). Therefore, the hypothesis that a more active lifestyle after the intervention translates into improved health-related measures could not be shown. One possible explanation is that PA improvements may not have been enough to promote changes in patients' daily life, as the minimum clinically important difference (MCID) of PA has not been established in COPD (Wilson et al., 2014). Other health-related measures which were not explored in this study but have been related to patients' PA (e.g., exacerbations (Donaldson et al., 2005, Pitta et al., 2006)) may have improved as a result of the intervention. This should be explored in further research. The fact that patients receiving the PR programme alone did not improve their PA levels despite having similar exercise capacity levels to those in the EG also supports the idea that low PA levels, as frequently found in patients with COPD, have a strong behavioural component. This means that some patients may opt to limit their PA levels rather than be restricted by their symptoms or impairments (Spruit et al., 2013).

No significant differences were found for self-efficacy over time in either group. Since self-efficacy is the main construct of the SCT (Bandura, 1986), it was expected that a SCT-based behavioural intervention would improve patients' self-efficacy. However, studies conducted in COPD have shown conflicting results regarding the relationship between PA and self-efficacy (DePew et al., 2013, Hartman et al., 2013, Steele et al., 2000), which may in part explain the non-significant findings obtained in this study. These findings may also be attributable to the use of a global self-efficacy scale instead of a specific scale to assess PA behaviour, given that self-efficacy is a task-specific domain (Sweet et al., 2012). Future research should apply a PA self-efficacy scale.

B. Limitations

Findings from the present study must be interpreted in light of the limitations. First, this was a small-scale trial, therefore, the generalisability of the results to clinical practice is limited. Nevertheless, the sample size calculation and the large effect sizes found for PA levels added strength to the results. Second, patients had high functioning levels at baseline (mean baseline step counts 6600-7200 steps/day, mean baseline 6-mintute walking distance 493.8–476.2m). Future research is warranted to explore whether patients with lower performance levels present similar results after the intervention. Third, the PA-focused behavioural intervention comprised asking patients to walk 800 additional daily steps; however, not all patients achieved the step target throughout the duration of the study (data not shown). Therefore, future research should define the step-count goals according to each patient's performance, e.g. by increasing a percentage of the total steps achieved. Fourth, all measures were administrated in a face-to-face interview conducted by the same researchers who implemented the intervention. Thus, assessor blinding was not possible. Fifth, the short- and long-term effects of the intervention were not studied, therefore the sustainability of the results could not be determined. Finally, both groups received the PR during the same timeframe and hence seasonal variations were not taken into account, although they may influence PA (Demeyer et al., 2014).

Conclusions

A PA-focused behavioural intervention during and after PR may improve patients' PA levels. Further research with larger samples and follow-up assessments is warranted to

support these preliminary findings and assess the short- and long-term impact of this intervention in COPD.

Acknowledgements

The authors would like to acknowledge the patients who participated in this study. A special thanks to Cristina Jácome, Ana Oliveira and Giovana Sposito for their valuable contribution in the implementation of the PR programme.

Funding

This work was supported by the Foundation for Science and Technology (grant number SFRH/BD/81328/2011). DB holds a Canada Research Chair.

Declaration of Conflicting Interests

The authors declare that there is no conflict of interest.

References

American Thoracic Society 2002. ATS Statement: Guidelines for the Six-Minute Walk Test. *Am J Respir Crit Care Med,* 166**,** 111-7.

Altenburg, W. A., ten Hacken, N. H. T., Bossenbroek, L., Kerstjens, H. A. M., de Greef, M. H. G. & Wempe, J. B. 2015. Short- and long-term effects of a physical activity counselling programme in COPD: A randomized controlled trial. *Respir Med,* 109**,** 112-21.

American College of Sports Medicine 2014. *ACSM's resource manual for guidelines for exercise testing and prescription,* Philadelphia, Lippincott Williams & Wilkins.

Bandura, A. 1986. *Social foundations of thought and action: a social cognitive theory,* New Jersey, Prentice Hall.

Cohen, J. 1988. *Statistical Power Analysis for the Behavioral Sciences,* New Jersey, Lawrence Erbaum Associates.

Cruz, J., Brooks, D. & Marques, A. 2014. Impact of feedback on physical activity levels of individuals with chronic obstructive pulmonary disease during pulmonary rehabilitation: A feasibility study. *Chron Respir Dis,* 11**,** 191-8.

Cruz, J., Brooks, D. & Marques, A. Accuracy of piezoelectric pedometer step counts in different wearing locations. *Eur Respir J*, 46, doi: 10.1183/13993003.congress-2015.PA4828.

Cupples, S. & Steslow, B. 2001. Use of behavioral contingency contracting with heart transplant candidates. *Prog Transplant,* 11**,** 137-44.

de Blok, B. M., de Greef, M. H., ten Hacken, N. H., Sprenger, S. R., Postema, K. & Wempe, J. B. 2006. The effects of a lifestyle physical activity counseling program with feedback of a pedometer during pulmonary rehabilitation in patients with COPD: a pilot study. *Patient Educ Couns,* 61**,** 48-55.

Demeyer, H., Burtin, C., Van Remoortel, H., Hornikx, M., Langer, D., Decramer, M., et al. 2014. Standardizing the analysis of physical activity in patients with copd following a pulmonary rehabilitation program. *Chest,* 146**,** 318-27.

DePew, Z. S., Garofoli, A. C., Novotny, P. J. & Benzo, R. P. 2013. Screening for severe physical inactivity in chronic obstructive pulmonary disease: the value of simple measures and the validation of two physical activity questionnaires. *Chron Respir Dis,* 10**,** 19-27.

Doherty, D. E., Belfer, M. H., Brunton, S. A., Fromer, L., Morris, C. M. & Snader, T. C. 2006. Chronic Obstructive Pulmonary Disease: Consensus Recommendations for Early Diagnosis and Treatment. *J Fam Pract,* Supplement**,** S1-S8.

Donaldson, G. C., Wilkinson, T. M., Hurst, J. R., Perera, W. R. & Wedzicha, J. A. 2005. Exacerbations and time spent outdoors in chronic obstructive pulmonary disease. *Am J Respir Crit Care Med,* 171**,** 446-52.

Egan, C., Deering, B. M., Blake, C., Fullen, B. M., McCormack, N. M., Spruit, M. A., et al. 2012. Short term and long term effects of pulmonary rehabilitation on physical activity in COPD. *Respir Med,* 106**,** 1671-9.

Fischer, M. J., Scharloo, M., Abbink, J. J., van 't Hul, A. J., van Ranst, D., Rudolphus, A., et al. 2009. Drop-out and attendance in pulmonary rehabilitation: The role of clinical and psychosocial variables. *Respir Med,* 103**,** 1564-71.

Freedson, P. S., Melanson, E. & Sirard, J. 1998. Calibration of the Computer Science and Applications, Inc. accelerometer. *Med Sci Sports Exerc,* 30**,** 777-81.

Garber, C. E., Blissmer, B., Deschenes, M. R., Franklin, B. A., Lamonte, M. J., Lee, I. M., et al. 2011. American College of Sports Medicine position stand. Quantity and quality of exercise for developing and maintaining cardiorespiratory, musculoskeletal, and neuromotor fitness in apparently healthy adults: guidance for prescribing exercise. *Med Sci Sports Exerc,* 43**,** 1334-59.

Garcia-Rio, F., Rojo, B., Casitas, R., Lores, V., Madero, R., Romero, D., et al. 2012. Prognostic value of the objective measurement of daily physical activity in patients with copd. *Chest,* 142**,** 338-46.

Garrod, R., Marshall, J., Barley, E. & Jones, P. W. 2006. Predictors of success and failure in pulmonary rehabilitation. *Eur Respir J,* 27**,** 788-94.

Global Strategy for the Diagnosis Management and Prevention of COPD Global Initiative for Chronic Obstructive Lung Disease (GOLD) 2015. Available from: http://www.goldcopd.org/. [Accessed on February, 2015].

Haber, D. 2010. *Health Promotion and Aging Practical Applications for Health Professionals,* New York, Springer Publishing Company.

Haber, D. & Looney, C. 2000. Health Contract Calendars: A Tool for Health Professionals With Older Adults. *The Gerontologist,* 40**,** 235-9.

Haber, D. & Rhodes, D. 2004. Health Contract With Sedentary Older Adults. *The Gerontologist,* 44**,** 827-35.

Hartman, J. E., ten Hacken, N. H. T., Boezen, H. M. & de Greef, M. H. G. 2013. Self-efficacy for physical activity and insight into its benefits are modifiable factors associated with physical activity in people with COPD: A mixed-methods study. *J Physiother,* 59**,** 117-24.

Jones, P. W. 2005. St. George's Respiratory Questionnaire: MCID. *COPD: Journal of Chronic Obstructive Pulmonary Disease,* 2**,** 75-9.

Mador, M. J., Patel, A. N. & Nadler, J. 2011. Effects of Pulmonary Rehabilitation on Activity Levels in Patients With Chronic Obstructive Pulmonary Disease. *J Cardiopulm Rehabil Prev,* 31**,** 52-9.

Miller, M. R., Hankinson, J., Brusasco, V., Burgos, F., Casaburi, R., Coates, A., et al. 2005. Standardisation of spirometry. *Eur Respir J,* 26**,** 319-38.

Moy, M. L., Janney, A. W., Nguyen, H. Q., Matthess, K. R., Cohen, M., Garshick, E., et al. 2010. Use of pedometer and Internet-mediated walking program in patients with chronic obstructive pulmonary disease. *J Rehabil Res Dev,* 47**,** 485-96.

Nici, L., Donner, C., Wouters, E., Zuwallack, R., Ambrosino, N., Bourbeau, J., et al. 2006. American Thoracic Society/European Respiratory Society Statement on Pulmonary Rehabilitation. *Am J Respir Crit Care Med,* 173**,** 1390-413.

Pais-Ribeiro, J. 1995. Adaptação de uma escala de avaliação de auto-eficácia geral. *In:* ALMEIDA, L. & RIBEIRO, I. (eds.) *Avaliação Psicológica: Formas e Contextos.* Braga: Apport.

Pitta, F., Troosters, T., Probst, V. S., Langer, D., Decramer, M. & Gosselink, R. 2008. Are patients with COPD more active after pulmonary rehabilitation? *Chest,* 134**,** 273-80.

Pitta, F., Troosters, T., Probst, V. S., Spruit, M. A., Decramer, M. & Gosselink, R. 2006. Physical activity and hospitalization for exacerbation of COPD. *Chest,* 129**,** 536-44.

Pitta, F., Troosters, T., Spruit, M. A., Probst, V. S., Decramer, M. & Gosselink, R. 2005. Characteristics of physical activities in daily life in chronic obstructive pulmonary disease. *Am J Respir Crit Care Med,* 171**,** 972-7.

Rabinovich, R. A., Louvaris, Z., Raste, Y., Langer, D., Van Remoortel, H., Giavedoni, S., et al. 2013. Validity of physical activity monitors during daily life in patients with COPD. *Eur Respir J,* 42**,** 1205-15.

Schulz, K. F., Altman, D. G. & Moher, D. 2010. CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials. *BMJ* 340, c332.

Speelman, A. D., van Nimwegen, M., Bloem, B. R. & Munneke, M. 2014. Evaluation of implementation of the ParkFit program: A multifaceted intervention aimed to promote physical activity in patients with Parkinson's disease. *Physiotherapy,* 100**,** 134-41.

Spruit, M. A., Singh, S. J., Garvey, C., Zuwallack, R., Nici, L., Rochester, C., et al. 2013. An official American Thoracic Society/European Respiratory Society statement: key concepts and advances in pulmonary rehabilitation. *Am J Respir Crit Care Med,* 188**,** e13-e64.

Steele, B. G., Belza, B., Cain, K. C., Coppersmith, J., Lakshminarayan, S., Howard, J., et al. 2008. A randomized clinical trial of an activity and exercise adherence intervention in chronic pulmonary disease. *Arch Phys Med Rehabil,* 89**,** 404-12.

Steele, B. G., Holt, L., Belza, B., Ferris, S., Lakshminaryan, S. & Buchner, D. M. 2000. Quantitating physical activity in COPD using a triaxial accelerometer. *Chest,* 117**,** 1359-67.

Sweet, S. N., Fortier, M. S., Strachan, S. M. & Blanchard, C. M. 2012. Testing and integrating self-determination theory and self-efficacy theory in a physical activity context. *Canadian Psychology/Psychologie canadienne,* 53**,** 319-27.

Van Remoortel, H., Raste, Y., Louvaris, Z., Giavedoni, S., Burtin, C., Langer, D., et al. 2012. Validity of Six Activity Monitors in Chronic Obstructive Pulmonary Disease: A Comparison with Indirect Calorimetry. *PLoS One,* 7**,** e39198.

Waschki, B., Kirsten, A., Holz, O., Muller, K. C., Meyer, T., Watz, H., et al. 2011. Physical activity is the strongest predictor of all-cause mortality in patients with COPD: a prospective cohort study. *Chest,* 140**,** 331-42.

Wilson, J. J., O'Neill, B., Collins, E. G. & Bradley, J. 2014. Interventions to Increase Physical Activity in Patients with COPD: A Comprehensive Review. *COPD: Journal of Chronic Obstructive Pulmonary Disease,* 12**,** 332-43.

Chapter 7 – General discussion

General discussion

The main aim of this Thesis was to study whether self-management interventions can support patients with Chronic Obstructive Pulmonary Disease (COPD) in their disease management and impact significantly on health-related outcomes. The body of evidence on home telemonitoring for patients with COPD was updated regarding its effectiveness, methodologies and patients' adherence and satisfaction with the telemonitoring technologies. Also, the impact of a physical activity (PA)-focused behaviour intervention combined with pulmonary rehabilitation (PR) on PA levels and health-related outcomes of patients with COPD was investigated. In this chapter, the results from the studies that have supported this Thesis are integrated and discussed in light of the most updated literature and a description of the general limitations is provided, hoping to contribute for improving knowledge in the field of self-management in COPD.

Effectiveness of home telemonitoring in COPD

The need for home care is expanding dramatically to reduce health-related costs while increasing patient involvement in their own care. Studies presented in **Chapter 3** found that there are still a limited number of studies of home telemonitoring in COPD, most of them published in the last five years which emphasises the novelty of this type of intervention. In **Study 1 of Chapter 3**, it was hypothesised that regular assessment of symptoms and/or physiological signs through home telemonitoring could help patients and healthcare providers better manage patients' clinical condition, which would be translated in improved health-related outcomes and savings in COPD management. In other chronic conditions, such as chronic heart failure, home telemonitoring was found to reduce the risk of all-cause mortality and rates of hospitalisation related to the disease (Clarke et al., 2011, Polisena et al., 2010). However, meta-analyses conducted in Study 1 showed that there is still no clear indication that home telemonitoring improves health-related outcomes and reduces healthcare utilisation in COPD, as only hospitalisation rates (but not mean number of hospitalisations) and health-related quality of life (HRQOL – measured using the St. Georges Respiratory Questionnaire) yielded significant (but small) results in favour of the home telemonitoring group. Furthermore, samples of the included studies were relatively small and the number of studies pooled for analysis was limited for each outcome. These limitations highlighted in Study 1 emphasise the idea that the role of home telemonitoring in COPD management is yet inconclusive. This study supports the current recommendations of the Global Strategy for the Diagnosis Management and

Prevention of COPD (GOLD, 2016) which refer that, given the current lack of evidence, telehealth in any of its current forms (including home telemonitoring) should not be routinely recommended in clinical practice at this time. Further research is needed to assess the effectiveness of home telemonitoring in COPD.

Other methodological limitations may also have accounted for the results found in Study 1 – these are comprehensively described in **Study 2 of Chapter 3.** One major limitation was the telemonitoring technology used across studies. Generally, it included a main device (mobile/web phone) where patients answered questions about their symptoms and disease management and/or recorded data collected via the peripheral devices. Although patients with COPD reported an overall positive attitude towards the telemonitoring technology, they also described a number of concerns regarding the user-friendliness of the devices (e.g., small screen, sensitivity of the buttons and/or touch-screen, sound volume) and the frequency of data collection/transmission (3 times/day was considered too demanding). These concerns were related to the high dropouts and low compliance rates found in some studies. Findings suggest that, even though technology may facilitate the involvement of patients in their clinical management, it may also become a barrier if they cannot easily and effectively use it to meet their needs and preferences (Broens et al., 2007, Krupinski et al., 2006b, Demiris et al., 2001). For example, older users may require larger visual displays, bigger input buttons and more automated steps than younger users (Krupinski et al., 2006b). The American Telemedicine Association (ATA) clinical guidelines (2003) highlighted the importance of assessing patients' clinical needs and functional ability to use the equipment when developing and implementing home telehealth and, specifically, home telemonitoring. None of the studies included in the systematic reviews of Chapter 3 addressed this issue prior to the implementation of home telemonitoring, although all but one (Dale et al., 2003) were published after the ATA guideline. Furthermore, as home telemonitoring requires important changes in healthcare professionals' usual practice, their acceptance of the technology should also be evaluated (Paré et al., 2007). Future research should test and tailor telemonitoring technology prior to its implementation in order to reduce *technophobia* among users (i.e., patients with COPD and healthcare professionals) and increase the chances of success (ATA, 2003, Broens et al., 2007, Krupinski et al., 2006a).

Another important limitation identified in **Study 2 of Chapter 3** was the provision of training to use the telemonitoring technology. Typically, patients' training was only conducted in the initial home visit which may not have been enough to allow the easy use of technology, as many difficulties were encountered throughout the implementation of

home telemonitoring. Previous studies on the topic of telemedicine and web-based applications have emphasised the need to provide users with repetitive training and support at the technological level (e.g., how to install and sustain the system, how to deal with errors and problem situations) (Broens et al., 2007, Demiris et al., 2001). This is particularly valuable to users at older ages (Demiris et al., 2001), such as patients with COPD included in the studies described in the systematic reviews (Chapter 3). Such training/support may improve patients' ability and motivation to use the telemonitoring technology, potentially increasing patients' adherence to the intervention. This topic has not been explored in the COPD population and thus further research is warranted.

Most patients with COPD reported that home telemonitoring provided them with a better understanding of the disease and allowed them to be aware of symptoms and recognise the earlier signs of an exacerbation (**Study 2 of Chapter 3**). These findings support the belief that home telemonitoring may hold promise for patients to self-manage their disease (Fairbrother et al., 2012). However, the impact of the intervention on behaviour change, which is the pivotal objective of self-management interventions, was not properly evaluated in studies described in the systematic reviews (Chapter 3). Evaluating the benefits of a self-management intervention solely on patients' health status and healthcare utilisation is overly narrow and may not be realistic in the short-term (Bourbeau and van der Palen, 2009). It is only after achieving behaviour change that effective self-management of the disease can be expected, thus resulting in better patient outcomes and reduction in utilisation of healthcare services (Bourbeau and van der Palen, 2009). Furthermore, details on the incorporation of behaviour change strategies were lacking in home telemonitoring interventions (Study 2 of Chapter 3), although these are essential to promote behaviour change. Future studies aiming at enhancing patient self-management through home telemonitoring should include the measurement of patients' behaviour change and its determinants (e.g., self-efficacy), and provide information on how behaviour change will be encouraged.

The diagnosis of an exacerbation relies exclusively on the clinical presentation of the patient complaining of an acute change of respiratory symptoms that is beyond normal day-to-day variation (GOLD, 2016). As this clinical presentation may vary among patients, currently there is a lack of understanding about which combination of changes in symptoms and physiological measurements indicates what is abnormal for a particular patient in order to predict exacerbations through home telemonitoring (Hardisty et al., 2011, McKinstry, 2013). Studies included in the systematic reviews presented in Chapter 3 collected various clinical parameters (e.g., symptoms, oxygen saturation, heart rate),

however, there was no consistency in which parameters should be measured to early detect exacerbations. Therefore, the insufficient evidence to support home telemonitoring may be in part attributed to the difficulty in establishing the clinical criteria necessary to detect and address health deterioration. Further research is needed to develop clinical algorithms with the most sensitive parameters to early detect COPD exacerbations. This information would be valuable to develop effective home telemonitoring interventions.

In conclusion, home telemonitoring has the potential to improve patient self-management without the need of face-to-face contact with healthcare services, thus leading to less costly interventions. This could also promote interactivity between patients, families and healthcare professionals and help decentralise healthcare by extending its access to regions where healthcare professionals are scarce (e.g., rural areas). However, evidence to support this type of intervention is still limited and further work needs to be conducted before it can be incorporated into clinical practice.

Behaviour change towards improved physical activity in COPD

Technology advancements have increased the opportunities for monitoring patients' daily PA at home. **Chapter 4** assessed the step-count accuracy of a piezoeletric pedometer (Yamax PW/EX-510) when worn at different body parts and identified users' preferences regarding its wearing location. The Yamax PW/EX-510 pedometer was highly accurate in quantifying steps at normal and fast walking paces, particularly when worn at the front right or left positions of the waist and inside the front pockets of the trousers. The latter was also identified as the preferred location to wear the device. Pedometer accuracy was lower at slow walking pace, though it was within the maximum error values considered acceptable for slower speeds (i.e., 5-10% (Crouter et al., 2003, De Cocker et al., 2012, Vincent and Sidman, 2003)). These findings suggest that the Yamax PW/EX-510 pedometer can be confidently used at the front of the waist or inside the pockets of the trousers to assess step counts in individuals who ambulate at slower speeds, such as patients with COPD (Ilgin et al., 2011). **Chapter 4** also assessed the step-count accuracy of a triaxial accelerometer (GT3X+) and compared accuracy between devices (i.e., pedometer and accelerometer). The GT3X+ accelerometer underestimated steps when compared to manually-counted and pedometer step counts, although differences between devices were relatively small at normal and fast paces. Thus, the pedometer may be more appropriate than the GT3X+ accelerometer in studies using the number of steps as the

main outcome measure. If a more detailed analysis of PA is required, the accelerometer should be used instead.

The GT3X+ accelerometer was used in **Chapter 5** to assess the feasibility of providing patients with feedback on their PA levels (i.e., number of daily steps; time spent in sedentary, light and moderate-to-vigorous (MVPA) intensity activities; time spent standing, sitting and lying) during a 12-week PR programme. Patients with COPD used the accelerometer during the first, seventh and twelfth weeks and feedback was provided in the following weeks. This exploratory study demonstrated that using feedback to improve patients' PA levels during PR was feasible and increased the number of daily steps and standing time in the short-term (week 7), although these values declined on week 12. In the discussion of Chapter 5, a number of methodological limitations were identified and recommendations were provided to enhance the design and implementation of future PA-focused interventions. Briefly, patients' experience in using the accelerometer was overall positive, however, they described problems related to the usability of the accelerometer (monitor placement, pressure exerted by the elastic belt) and monitoring duration (i.e., 7 days). Patients also suggested that daily feedback would have facilitated comparisons between the activities performed on a given day and the results reported by the device. These issues were addressed in the randomised controlled trial presented in **Chapter 6**: (1) the accelerometer was used over the right hip and the elastic belt was replaced for another with a softer material; (2) monitoring duration was reduced to four consecutive weekdays, as recently recommended (Demeyer et al., 2014a); and (3) real-time feedback on patients' PA levels was provided on a daily basis using the Yamax PW/EX-510 pedometers (experimental group). The GT3X+ accelerometer was used in both experimental and control groups to assess patients' PA levels as it provided information about changes in the quantity (i.e., time, number of steps) and intensity (e.g., moderate-to-vigorous) of PA.

The feasibility study presented in Chapter 5 also identified the need to explore the value of combining feedback with additional strategies to stimulate patients' behaviour change into a more active lifestyle. **Chapter 6** addressed this issue by implementing a PA-focused behavioural intervention during a 12-week PR programme (3 months) and 3 months after its completion. The PA-focused intervention was guided by a sound theoretical framework (Social Cognitive Theory (Bandura, 1986)) as advocated in recent literature on the topic (Leidy et al., 2014, Spruit et al., 2015). The intervention involved a formal commitment by the use of a Health contract (Haber, 2010, Haber and Rhodes, 2004) and objective feedback provided by pedometers. This novel approach provided promising results by

suggesting that a PA-focused behavioural intervention during PR improves patients' PA levels at 3 months which are sustained with follow-up support (3 months). A recent study conducted by Burtin et al. (2015) did not achieve the same results. Burtin et al. (2015) investigated the impact of adding an individual activity counselling programme to a 6-month PR on PA levels of patients with COPD (experimental group). The control group received PR and face-to-face attention (sham programme). Notably, the authors found no significant differences between groups. Divergences between the results obtained in Burtin et al. (2015) and in the study presented in Chapter 6 may be partly explained by differences in patients' disease severity (moderate to very severe COPD vs. all COPD grades) and baseline PA levels which were lower in Burtin et al. (2015). In addition, the nature of the intervention may have accounted for the differences between studies. In the study of Burtin et al. (2015), as well as in the studies of de Block et al. (2006) and Altenburg et al. (2015), the intervention consisted of individualised counselling provided to patients. In contrast, the intervention described in Chapter 6 was implemented through a Health contract which was carried out in a group format, although step-count goals were individualised to each patient. The formal commitment encouraged by the use of the Health contract may have helped patients in identifying an achievable health goal and creating a behaviour change plan (Haber and Looney, 2000). Furthermore, the group may have acted as an additional stimulus for patients to fulfil the step-count goals and thus increase their PA levels. Previous research has highlighted the importance of groups in supporting behaviour change through a sharing of experiences and social learning and by discouraging passivity (Bourbeau et al., 2004, Kaptein et al., 2014). This hypothesis should be investigated in future research.

Despite the PA improvements found after the implementation of the PA-focused behavioural intervention (Chapter 6), there were no significant between-group differences in exercise capacity, muscle strength and HRQOL. Therefore, the hypothesis that a more active lifestyle translates into improved health-related measures was not confirmed. A number of reasons may have accounted for these results. First, the mean time spent in moderate-to-vigorous physical activity was below the internationally recommended (i.e., ≥30min of daily either continuous or in blocks of ≥10min (Garber et al., 2011)). Currently, the classification of whether a patient is sufficiently physically active is based on general PA recommendations directed to healthy adults (Garber et al., 2011) and the extent to which these recommendations apply to people with varying degrees of COPD is still unknown (Watz et al., 2014). This is important to provide patients with an evidence-based tailored advice. Other possible explanation is that PA improvements may not have been

enough to promote changes in patients' daily life, as the minimum clinically important difference (MCID) has not been extensively investigated in COPD (Wilson et al., 2014). To date, there was only one study that determined the MCID for the number of daily steps in COPD, which ranged between 576 and 1181 steps depending on the distribution-based approach used (Demeyer et al., 2014b). Finally, the lack of significant between-group differences in performance-based outcomes, such as exercise capacity, supports the idea that low PA levels have a strong behavioural component. It is believed that, as a complex behaviour, PA is influenced by a combination of determinants including individual characteristics, health beliefs, exercise-associated symptoms, as well as social and environmental determinants (Sallis et al., 2006, Spruit et al., 2013). For example, it is known that climate may influence the PA levels of patients with COPD (Pitta et al., 2009, Sewell et al., 2010). Functional and psychosocial factors have also been associated with patients' PA levels (Altenburg et al., 2013, Gimeno-Santos et al., 2014, Hartman et al., 2013), although the quality of evidence is low (Gimeno-Santos et al., 2014). Other factors, such as the physical environment (e.g., neighbourhood), have been identified as important factors in PA levels in adults (Addy et al., 2004, Wendel-Vos et al., 2007), but its influence has not been studied in patients with COPD. More insight is necessary on the (modifiable) determinants of PA behaviour in patients with COPD to develop effective interventions and, ultimately, provide guidance to the international health policies and action. This is a challenging new area of research.

In conclusion, activity monitors (i.e., pedometer, accelerometers) have the potential to support patient self-management by reliably tracking, storing and providing feedback about an individual's engagement in PA. A PA-focused behavioural intervention consisting of goal setting and objective feedback from pedometers during and after a PR programme has the potential to improve patients' PA levels. Further research with larger samples and follow-up assessments is warranted to support these preliminary findings and assess the long-term impact of this intervention in COPD.

Limitations

The present Thesis has some important limitations that should be considered when interpreting the results. First, the systematic reviews presented in **Chapter 3** were restricted to studies published in English, Portuguese and Spanish. Studies published in other languages could also be relevant for the scope of these reviews. Second, the keywords used in the search strategy did not include terms such as 'smartphone', 'e-

mobile' or 'e-health', which may have reduced the number of relevant papers found. Third, the studies included in the systematic reviews were not exactly the same due to their study design (i.e., only randomised and non-randomised controlled trials entered in Study 1), therefore, a direct relationship between the outcomes and home telemonitoring methodologies could not be investigated. In addition, it was not possible to understand whether patients' satisfaction was related to improved outcomes and reduced healthcare utilisation found in some studies. Further research should explore the impact of the methodologies in the effectiveness of home telemonitoring in COPD.

In **Chapter 4**, all tests were performed in healthy adults which may limit the generalisability of the findings to patients with COPD. Nevertheless, previous validation studies conducted simultaneously in healthy and chronic disease populations concluded that pedometer accuracy was similar between samples when walking at different speeds (Furlanetto et al., 2010, Turner et al., 2012). Only step counts were considered when assessing pedometer accuracy (Chapter 4) and when using pedometers as a feedback tool (Chapter 6). The Yamax PW/EX-510 pedometers provide additional PA parameters (e.g., energy expenditure, fat burn, distance and activity time) which could also have been valuable to motivate patients with COPD increase their PA levels. Further research should assess the accuracy of Yamax PW/EX-510 pedometers in measuring these PA parameters before their use in interventions aiming to enhance PA levels. The validation tests presented in Chapter 4 were performed in controlled conditions and, thus, the potential of activity monitors (i.e., pedometers, accelerometer) to detect human activity was not fully investigated. Future studies should assess pedometer and accelerometer accuracy under free-living conditions.

Chapters 5 and 6 included small sample sizes and most participants were in mild and moderate COPD grades. Therefore, the generalisability of the results is limited. Further studies with larger samples and different COPD grades are needed to understand which patients are most likely to benefit from the PA-focused behavioural intervention. Another limitation of these Chapters concerns the inclusion of patients with relatively high functioning levels at baseline (e.g., step counts, 6-minute walking distance). Future research is warranted to explore whether patients with lower performance levels at baseline present (or not) similar results after the intervention. Outcome assessment was not blinded in Chapters 5 and 6, since all measures were administrated by the same researchers who implemented the intervention. Nonetheless, there was an attempt to standardise the order of the tests to minimise bias. Studies presented in Chapters 5 and 6 were conducted during the same timeframe and hence seasonal variations were not taken

into account, although they may influence PA (Demeyer et al., 2014a). Finally, the implementation of the PA-focused behavioural intervention described in Chapter 6 resulted in increased patients' PA levels immediately after the intervention. However, it is unknown whether these findings were sustained as the short- and long-term effects were not assessed. More research on the sustainability of the results is needed.

References

Addy, C. L., Wilson, D. K., Kirtland, K. A., Ainsworth, B. E., Sharpe, P. & Kimsey, D. 2004. Associations of Percieved Social and Physical Environmental Supports With Physical Activity and Walking Behavior. *Am J Public Health,* 94**,** 440-3.

Altenburg, W. A., Bossenbroek, L., de Greef, M. H. G., Kerstjens, H. A. M., ten Hacken, N. H. T. & Wempe, J. B. 2013. Functional and psychological variables both affect daily physical activity in COPD: A structural equations model. *Respir Med,* 107**,** 1740-7.

Altenburg, W. A., ten Hacken, N. H. T., Bossenbroek, L., Kerstjens, H. A. M., de Greef, M. H. G. & Wempe, J. B. 2015. Short- and long-term effects of a physical activity counselling programme in COPD: A randomized controlled trial. *Respir Med,* 109**,** 112-21.

American Telemedicine Association. 2003. Home Telehealth Clinical Guidelines. Available at: http://www.americantelemed.org/practice/standards/ata-standards-guidelines/home-telehealth-clinical-guidelines.

Bandura, A. 1986. *Social foundations of thought and action: a social cognitive theory,* New Jersey, Prentice Hall.

Bourbeau, J., Nault, D. & Dang-Tan, T. 2004. Self-management and behaviour modification in COPD. *Patient Educ Couns,* 52**,** 271-7.

Bourbeau, J. & van der Palen, J. 2009. Promoting effective self-management programmes to improve COPD. *Eur Respir J,* 33**,** 461-3.

Broens, T. H. F., Huis in't Veld, R. M. H. A., Vollenbroek-Hutten, M. M. R., Hermens, H. J., van Halteren, A. T. & Nieuwenhuis, L. J. M. 2007. Determinants of successful telemedicine implementations: a literature study. *J Telemed Telecare,* 13**,** 303-9.

Burtin, C., Langer, D., van Remoortel, H., Demeyer, H., Gosselink, R., Decramer, M., et al. 2015. Physical Activity Counselling during Pulmonary Rehabilitation in Patients with COPD: A Randomised Controlled Trial. *PLoS One,* 10**,** e0144989.

Clarke, M., Shah, A. & Sharma, U. 2011. Systematic review of studies on telemonitoring of patients with congestive heart failure: a meta-analysis. *J Telemed Telecare,* 17**,** 7-14.

Crouter, S. E., Schneider, P. L., Karabulut, M. & Bassett, D. R., Jr. 2003. Validity of 10 electronic pedometers for measuring steps, distance, and energy cost. *Med Sci Sports Exerc,* 35**,** 1455-60.

Dale, J., Connor, S. & Tolley, K. 2003. An evaluation of the west Surrey telemedicine monitoring project. *J Telemed Telecare,* 9 Suppl**,** S39-S41.

de Blok, B. M., de Greef, M. H., ten Hacken, N. H., Sprenger, S. R., Postema, K. & Wempe, J. B. 2006. The effects of a lifestyle physical activity counseling program with feedback of a pedometer during pulmonary rehabilitation in patients with COPD: a pilot study. *Patient Educ Couns,* 61**,** 48-55.

De Cocker, K. A., De Meyer, J., De Bourdeaudhuij, I. M. & Cardon, G. M. 2012. Non-traditional wearing positions of pedometers: Validity and reliability of the Omron HJ-203-ED pedometer under controlled and free-living conditions. *J Sci Med Sport,* 15**,** 418-24.

Demeyer, H., Burtin, C., Van Remoortel, H., Hornikx, M., Langer, D., Decramer, M., et al. 2014a. Standardizing the analysis of physical activity in patients with copd following a pulmonary rehabilitation program. *Chest,* 146**,** 318-27.

Demeyer, H., Hornikx, M., Marcal Camillo, C. A., Van Remoortel, H., Burtin, C., Langer, D., et al. 2014b. An estimation of the minimal important difference in physical activity for patients with COPD. *Eur Respir J,* 44.

Demiris, G., Finkelstein, S. M. & Speedie, S. M. 2001. Considerations for the design of a Web-based clinical monitoring and educational system for elderly patients. *J Am Med Inform Assoc,* 8**,** 468-72.

Fairbrother, P., Pinnock, H., Hanley, J., McCloughan, L., Sheikh, A., Pagliari, C., et al. 2012. Continuity, but at what cost? The impact of telemonitoring COPD on continuities of care: a qualitative study. *Prim Care Respir J,* 21**,** 322-8.

Furlanetto, K. C., Bisca, G. W., Oldemberg, N., Sant'Anna, T. J., Morakami, F. K., Camillo, C. A., et al. 2010. Step Counting and Energy Expenditure Estimation in Patients With Chronic Obstructive Pulmonary Disease and Healthy Elderly: Accuracy of 2 Motion Sensors. *Arch Phys Med Rehabil,* 91**,** 261-7.

Garber, C. E., Blissmer, B., Deschenes, M. R., Franklin, B. A., Lamonte, M. J., Lee, I. M., et al. 2011. American College of Sports Medicine position stand. Quantity and quality of exercise for developing and maintaining cardiorespiratory,

musculoskeletal, and neuromotor fitness in apparently healthy adults: guidance for prescribing exercise. *Med Sci Sports Exerc,* 43**,** 1334-59.

Gimeno-Santos, E., Frei, A., Steurer-Stey, C., de Batlle, J., Rabinovich, R. A., Raste, Y., et al. 2014. Determinants and outcomes of physical activity in patients with COPD: a systematic review. *Thorax,* 69**,** 731–9.

Global Strategy for the Diagnosis Management and Prevention of COPD 2016. Global Initiative for Chronic Obstructive Lung Disease (GOLD). Available from: http://www.goldcopd.org/. [Accessed on January, 2016].

Haber, D. 2010. *Health Promotion and Aging Practical Applications for Health Professionals,* New York, Springer Publishing Company.

Haber, D. & Looney, C. 2000. Health Contract Calendars: A Tool for Health Professionals With Older Adults. *The Gerontologist,* 40**,** 235-9.

Haber, D. & Rhodes, D. 2004. Health Contract With Sedentary Older Adults. *The Gerontologist,* 44**,** 827-35.

Hardisty, A. R., Peirce, S. C., Preece, A., Bolton, C. E., Conley, E. C., Gray, W. A., et al. 2011. Bridging two translation gaps: A new informatics research agenda for telemonitoring of chronic disease. *Int J Med Inf,* 80**,** 734-44.

Hartman, J. E., Boezen, H. M., de Greef, M. H. & ten Hacken, N. H. 2013. Physical and Psychosocial Factors Associated With Physical Activity in Patients With Chronic Obstructive Pulmonary Disease. *Arch Phys Med Rehabil,* 94**,** 2396-402.

Ilgin, D., Ozalevli, S., Kilinc, O., Sevinc, C., Cimrin, A. H. & Ucan, E. S. 2011. Gait speed as a functional capacity indicator in patients with chronic obstructive pulmonary disease. *Ann Thorac Med,* 6**,** 141-6.

Kaptein, A. A., Fischer, M. J. & Scharloo, M. 2014. Self-management in patients with COPD: theoretical context, content, outcomes, and integration into clinical care. *Int J Chron Obstruct Pulmon Dis,* 9**,** 907-17.

Krupinski, E., Dimmick, S., Grigsby, J., Mogel, G., Puskin, D., Speedie, S., et al. 2006a. Research recommendations for the american telemedicine association. *Telemedicine and e-Health,* 12**,** 579-89.

Krupinski, E., Dimmick, S., Grigsby, J., Mogel, G., Puskin, D., Speedie, S., et al. 2006b. Research recommendations for the american telemedicine association. *Telemed J E Health,* 12**,** 579-89.

Leidy, N. K., Kimel, M., Ajagbe, L., Kim, K., Hamilton, A. & Becker, K. 2014. Designing trials of behavioral interventions to increase physical activity in patients with COPD: Insights from the chronic disease literature. *Respir Med,* 108**,** 472-81.

McKinstry, B. 2013. The use of remote monitoring technologies in managing chronic obstructive pulmonary disease. *QJM,* 106**,** 883-5.

Paré, G., Jaana, M. & Sicotte, C. 2007. Systematic review of home telemonitoring for chronic diseases: the evidence base. *J Am Med Inform Assoc,* 14**,** 269-77.

Pitta, F., Breyer, M. K., Hernandes, N. A., Teixeira, D., Sant'Anna, T. J. P., Fontana, A. D., et al. 2009. Comparison of daily physical activity between COPD patients from Central Europe and South America. *Respir Med,* 103**,** 421-6.

Polisena, J., Tran, K., Cimon, K., Hutton, B., McGill, S., Palmer, K., et al. 2010. Home telemonitoring for congestive heart failure: a systematic review and meta-analysis. *J Telemed Telecare,* 16**,** 68-76.

Sallis, J. F., Cervero, R. B., Ascher, W., Henderson, K. A., Kraft, M. K. & Kerr, J. 2006. An ecological approach to creating active living communities. *Annu Rev Public Health,* 27**,** 297-322.

Sewell, L., Singh, S. J., Williams, J. E. A. & Morgan, M. D. 2010. Seasonal Variations Affect Physical Activity and Pulmonary Rehabilitation Outcomes. *J Cardiopulm Rehabil Prev,* 30**,** 329-33.

Spruit, M. A., Pitta, F., McAuley, E., ZuWallack, R. L. & Nici, L. 2015. Pulmonary Rehabilitation and Physical Activity in Patients with Chronic Obstructive Pulmonary Disease. *Am J Respir Crit Care Med,* 192**,** 924-33.

Spruit, M. A., Singh, S. J., Garvey, C., Zuwallack, R., Nici, L., Rochester, C., et al. 2013. An official American Thoracic Society/European Respiratory Society statement: key concepts and advances in pulmonary rehabilitation. *Am J Respir Crit Care Med,* 188**,** e13-e64.

Turner, L. J., Houchen, L., Williams, J. & Singh, S. J. 2012. Reliability of pedometers to measure step counts in patients with chronic respiratory disease. *J Cardiopulm Rehabil Prev,* 32**,** 284-91.

Vincent, S. D. & Sidman, C. L. 2003. Determining Measurement Error in Digital Pedometers. *Measurement in Physical Education and Exercise Science,* 7**,** 19-24.

Watz, H., Pitta, F., Rochester, C. L., Garcia-Aymerich, J., ZuWallack, R., Troosters, T., et al. 2014. An official European Respiratory Society statement on physical activity in COPD. *Eur Respir J,* 44**,** 1521-37.

Wendel-Vos, W., Droomers, M., Kremers, S., Brug, J. & Van Lenthe, F. 2007. Potential environmental determinants of physical activity in adults: a systematic review. *Obes Rev,* 8**,** 425-40.

Wilson, J. J., O'Neill, B., Collins, E. G. & Bradley, J. 2014. Interventions to Increase Physical Activity in Patients with COPD: A Comprehensive Review. *COPD: Journal of Chronic Obstructive Pulmonary Disease,* 12**,** 332-43.

Chapter 8 – Conclusions and recommendations for future research and clinical practice

Conclusions

This Thesis contributes to further understanding of the role of home telemonitoring and physical activity (PA)-focused behavioural interventions in self-management of patients with Chronic Obstructive Pulmonary Disease (COPD). Findings provide limited evidence of the effectiveness of home telemonitoring to improve health-related outcomes and reduce healthcare utilisation in patients with COPD (**Study 1 of Chapter 3**). Home telemonitoring still needs to be adjusted to ensure its suitability to the target population. **Study 2 of Chapter 3** provides important recommendations for the development and implementation of future home telemonitoring interventions. It was also concluded that activity monitors (Yamax PW/EX-510 pedometers, GT3X+ accelerometers) have the potential to support patient self-management by reliably tracking, storing and providing feedback about an individual's PA levels (**Chapter 4**). A PA-focused behavioural intervention consisting of goal setting and objective feedback during and after pulmonary rehabilitation (PR) has the potential to improve patients' PA levels (**Chapters 5 and 6**). Further research with larger samples and follow-up assessments is warranted to support these preliminary findings and assess the short- and long-term impact of this intervention in COPD.

Recommendations for future research and clinical practice

This chapter presents the main recommendations for future research as well as implications for clinical practice.

Findings from **Chapter 3** showed that there is still no robust evidence to support home telemonitoring interventions in COPD and further work needs to be conducted before it can be incorporated into clinical practice. Recommendations for future research are the following:

- Studies should be conducted with larger samples, higher methodological quality (e.g., multicentre randomised controlled trials) and longer observation periods;
- There is a need to identify clinical indicators of exacerbations and develop algorithms to help recognise deterioration of patients' health condition. This information would be valuable to develop effective home telemonitoring interventions;
- Telemonitoring technology should be tested and tailored to users (i.e., patients with COPD and healthcare professionals) prior to its implementation and more training sessions should be provided to patients in order to improve their adherence. In

addition, there is an urgent need to identify the type of patients most likely to benefit from these interventions;

- Home telemonitoring interventions should provide information on how behaviour change is encouraged;
- Assessment of patients' behaviour change and its determinants (e.g., self-efficacy) should be conducted along with the measurement of health-related and healthcare outcomes;
- Outcome measures should be similar across studies and reported in a format that can be further pooled into meta-analysis.

Self-management of PA was addressed in **Chapters 4-6**. Findings suggest that a PA-focused behavioural intervention during and after PR can be used to support patients in achieving a more active lifestyle, by helping them self-monitor their daily PA. Nevertheless, more research is needed before it can be routinely used in clinical practice, specifically:

- The intervention should be implemented in larger samples with follow-up assessments to assess its short- and long-term impact in COPD;
- It should also be explored whether patients with lower performance at baseline present (or not) PA improvements after the intervention similar to those with higher performance;
- The role of the group as an additional stimulus for patients' behaviour change should be investigated;
- It seems worthwhile to investigate whether general guidelines for the recommended minimum amount of PA for adults are also suitable for patients with COPD and lead to health-related benefits;
- The minimum clinically important difference (MCID) of PA in patients with COPD should be established;
- Finally, the (modifiable) determinants of PA behaviour in patients with COPD should be identified in order to develop more effective interventions and, ultimately, provide guidance to the international health policies and action.

Appendices

Appendix 1 – List of publications

List of publications

Publications in Peer-Reviewed Journals

Citations: 0
[IF: 0.972]

Cruz J, Brooks D, Marques A. (2016) Accuracy of piezoelectric pedometer and accelerometer step counts. *The Journal of Sports Medicine and Physical Fitness*. ePub ahead of print on January 21. PMID: 26796079

Citations: 1
[IF: 2.694]

Cruz J, Brooks D, Marques A. (2015) Walk2Bactive: a randomized controlled trial of a physical activity-focused behavioral intervention beyond pulmonary rehabilitation in COPD. *Chronic Respiratory Disease.* 13(1), 57–66.

Citations: 3
[IF: 2.308]

Cruz J, Brooks D, Marques A. (2014) Impact of feedback on physical activity levels of individuals with COPD during pulmonary rehabilitation: a feasibility study. *Chronic Respiratory Disease*, 11(4):191–8.

Accompanying editorial: Singh S. (2014) Physical activity and pulmonary rehabilitation – A competing agenda? *Chronic Respiratory Disease,* 11(4):187–9.

Citations: 23
[IF: 2.061]

Cruz J, Brooks D, Marques A. (2014) Home telemonitoring in COPD: a systematic review of methodologies and patients' adherence. International Journal of Medical Informatics, 83(4), 249–63.

Citations: 11
[IF: 2.427]

Cruz J, Brooks D, Marques A. (2013) Home telemonitoring effectiveness in COPD: a systematic review. The International Journal of Clinical Practice, 68(3):369–78.

Abstracts in Conference Proceedings

Accepted
[IF: 7.636]

Cruz J, Brooks D, Marques A. (2016) Walk2Bactive: Patients' perspectives of a physical activity-focused intervention beyond pulmonary rehabilitation in COPD. *European Respiratory Journal.* 26th European Respiratory Society (ERS) International Congress, 3-7 September, London, United Kingdom (poster discussion).

[IF: 1.712]

Cruz J, Brooks D, Marques A. (2016) Outcome changes in COPD rehabilitation: exploring the relationship between physical activity and health-related outcomes. *BMC Health Services Research*. 3rd IPLeiria International Health Congress, 6-7 May, Leiria, Portugal (oral communication).

[IF: 7.636]

Cruz J, Brooks D, Marques A. (2015) Accuracy of piezoelectric pedometer step counts in different wearing locations. *European Respiratory Journal*, 46: Suppl. 59. 25th ERS International Congress, 26-30 September, Amsterdam, Netherlands (poster discussion).

[IF: 7.636]

Cruz J, Brooks D, Marques A. (2015) Self-report vs. pedometer steps in COPD: are they similar? *European Respiratory Journal*, 46: Suppl. 59. 25th ERS International Congress, 26-30 September, Amsterdam, Netherlands (poster discussion).

[IF: 7.636]

Cruz J, Brooks D, Marques A. (2014) Does family support affect physical activity of patients with COPD? An exploratory study. *European Respiratory Journal*, 44: Suppl. 58, 4493. 24th ERS International Congress, 6-10 September, Munich, Germany (poster discussion).

[IF: 1.219]

Cruz J, Brooks D, Marques A. (2014) Physical activity estimates in COPD rehabilitation: self-reported vs. objective measures. *Revista de Saúde Pública*, 48(special issue), 137. 2nd IPLeiria International Health Congress, 9-10 May, Leiria, Portugal (oral communication).

Appendix 2 – Abstracts in Conference Proceedings

Physical activity estimates in COPD rehabilitation: self-report vs. objective measures

Joana Cruz
Dina Brooks
Alda Marques

Introduction: Self-report physical activity (PA) measures are often used to assess changes before/after chronic obstructive pulmonary disease (COPD) rehabilitation, as they are easy to employ and more feasible than objective measures. However, the ability of self-report measures to detect intervention-related changes in PA should be determined.

Objective: To examine the sensitivity of the International Physical Activity Questionnaire short-form (IPAQ-sf) to detect intervention-related changes in PA compared to accelerometry in patients with COPD.

Methods: Eleven patients with COPD (67.5±9.2yrs) participated in a 12-week pulmonary rehabilitation program. Participants wore an accelerometer (Actigraph GT3X+) for 7 consecutive days on the 1st and 12th weeks of the program and completed the IPAQ-sf. Spearman's correlation coefficients (ρ) were used to assess relationships between the results of the IPAQ-sf and the accelerometer.

Results: Both the IPAQ-sf and the accelerometer showed non-significant differences in time spent in sedentary activities [median(IQR): IPAQ=60.0(240.0) min/day; accelerometer=1.1(128.0) min/day), moderate-to-vigorous physical activities (MVPA: IPAQ=-150.0(1080.0) min/week; accelerometer=12.0(60.0)min/week) and total PA (IPAQ=-495.0(1060.0) min/week; accelerometer=-9.0(559.0) min/week) as a result of the intervention (p>0.05). Changes in sedentary activities obtained by self-report were significantly correlated to those obtained by accelerometry (ρ=0.714, p=0.014). Changes in self-reported and accelerometer-based MVPA were moderately yet non-significantly correlated (ρ=0.588, p=0.057). No significant correlations were found for total PA measured by self-report and accelerometry.

Conclusions: The IPAQ-sf showed limited correlations with accelerometer-based PA. Patients with COPD tend to under-report their PA levels. Thus, objective measures should be preferred when assessing the impact of rehabilitation interventions in patients with COPD, as these have greater potential to detect PA changes.

Keywords: accelerometer; COPD; physical activity; pulmonary rehabilitation; self-report measures

Does family support affect physical activity of patients with COPD? An exploratory study

Joana Cruz

Dina Brooks

Alda Marques

Introduction: Despite the well-recognised benefits of regular physical activity (PA) in COPD, a large number of patients are inactive. Previous research has highlighted that family support may affect PA levels of healthy people. However, the influence of family members on PA levels of patients with COPD has never been explored. **Objective:** To assess PA levels of patients with COPD and explore the influence of family members on this health behaviour.

Methods: Eighteen patients (66.2±11.7 years, FEV_1 67.2±20.7pp) and their respective family members (57.7±12.4 years) completed the Portuguese version of the International Physical Activity Questionnaire short-form (IPAQ-sf), which provides information about the amount of PA performed in the last 7 days. This was reported as Metabolic Equivalents-minutes spent per week (MET-min/wk) and sitting time per day. Descriptive statistics were conducted and a stepwise multiple linear regression analysis was used to evaluate whether family members' PA variables were associated with patients' PA.

Results: Patients spent a median of 1386.0 (interquartile range [IQR]=2255.5) MET-min/wk and family members spent 862.5 (IQR=1533.0) MET-min/wk. Self-reported sitting time was 4.0 (IQR=2.3) h/day for patients and 3.0 (IQR=3.25) h/day for family members. Family members' MET-min/wk (B=0.957, p=0.021) and sitting time (B=-10.319, p=0.015) were significant predictors of patients' MET-min/wk ($F(2,15)=6.438$, $p=0.010$; $r^2_{adjusted}=0.39$).

Conclusion: Findings suggest that family members influence the PA levels of patients with COPD. Therefore, the inclusion of the family in rehabilitation interventions might facilitate the increase of patients' PA.

European Respiratory Journal, 44: Suppl. 58, 4493 (2014)

Self-report vs. pedometer steps in COPD: are they similar?

Joana Cruz

Dina Brooks

Alda Marques

Background: Pedometers have been used as an objective measure to assess physical activity (PA) in COPD. However, in most studies, pedometer results rely on users' ability to provide accurate information using daily logs. It is important to understand if self-report steps correspond to actual steps recorded by pedometers, in order to use more confidently self-report data.

Aims: This study aimed to compare self-report steps and steps recorded by a pedometer with a memory function in patients with COPD.

Methods: Patients (n=15, 75.4±26.6yrs, FEV_1=69.9±27.6pp) were asked to use a pedometer and register their daily steps, as part of a rehabilitation programme with step goals. Patients were unaware of pedometer memory. A researcher recorded the steps stored in pedometers. A mixed-model ANOVA was used to investigate if self-report and pedometer steps differed among patients (method X patient, P<0.05), using 7 random days.

Results: Self-report and pedometer steps were significantly different among patients (P<0.001). Nevertheless, Fig. 1 shows that self-report steps were over-reported in only 3 patients (out of 15).

Conclusions: Most patients with COPD provide an accurate estimation of their PA, although differences between self-report and pedometer steps may occur. Patients' failure to recall steps or technological problems with pedometer memory may explain these differences.

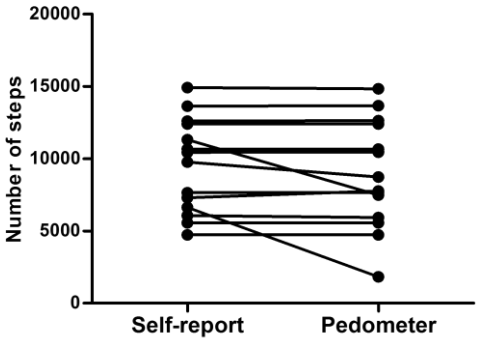

Fig 1. Comparison between self-report and pedometer steps among patients (n=15).

European Respiratory Journal, 46: Suppl. 59 (2015)

Accuracy of piezoelectric pedometer step counts in different wearing locations

Joana Cruz
Dina Brooks
Alda Marques

Background: Pedometers are simple and inexpensive devices used as a motivational tool or in rehabilitation interventions for chronic respiratory diseases. Piezoelectric pedometers may be worn at different body locations; however, their impact on pedometer accuracy has been scarcely explored. In addition, it is unknown which locations are preferred by patients, despite its importance to improve user's acceptance.

Aims: To assess the accuracy of a piezoeletric pedometer (Yamax EX-510) in counting steps, when worn at different body locations, and identify users' preferred location(s).

Methods: Sixty-three healthy adults (45.8±20.6yrs) wore 7 pedometers (neck, lateral/front right/left of the waist, pockets of the trousers), while walking 120m at slow, self-preferred (normal) and fast paces. Steps were manually counted (criterion measure) and pedometer steps were recorded. Tests were repeated twice. Participants indicated their preferred location(s) to wear a pedometer. Absolute percent error (APE) and the Bland and Altman method were used to examine device accuracy and consistency.

Results: APE was, on average, <3% at normal and fast paces despite wearing location, but higher at slow pace (4.5-9.1%). Accuracy was improved in pedometers located at the front of the waist and inside the pockets. Results were consistent ($p>0.05$). Most patients preferred to wear the pedometer inside the right (n=25) and left (n=20) pockets.

Conclusions: Yamax EX-510 pedometers can be used to monitor walking activity, as they provide accurate results even at slower speeds (considering a 10% error[1]). They should be worn at the front of the waist or inside the pockets.

[1]Crouter SE, et al. *Med Sci Sports Exerc* 2003;35(8):1455-60

European Respiratory Journal, 46: Suppl. 59 (2015)

Outcome changes in COPD rehabilitation: exploring the relationship between physical activity and health-related outcomes

Joana Cruz

Dina Brooks

Alda Marques

Introduction: Reduced physical activity(PA) levels are associated with poor health-related outcomes in patients with Chronic Obstructive Pulmonary Disease(COPD). PA-focused interventions complementary to pulmonary rehabilitation(PR) have been developed to increase patients' PA. However, it is unknown whether PA changes are related to health-related outcomes improvement. This study explored the relationship between changes in PA and health-related outcomes in patients with COPD.

Methods: Thirteen patients with COPD (65.6±10.6yrs) participated in a 12-week PR programme plus a PA-focused intervention. Daily PA was measured using accelerometers on weeks (W) 1, 7 and 12 and feedback was given to participants in the following weeks regarding: daily steps; time spent in sedentary, light and moderate-to-vigorous (MVPA) intensity activities. Exercise capacity (6-minute walk test), functional balance (Timed Up-and-Go (TUG) test) and health-related quality of life (St George's Respiratory Questionnaire (SGRQ) – Symptoms, Activities, Impact) were assessed at W1/W12. Correlations between PA data and health-related outcomes were performed at W1 and using the change scores (W12-W1).

Results: At W1, time spent in MVPA was correlated with exercise capacity (r=0.817, p=0.001) and TUG (r=-0.692, p=0.009). Changes in MVPA time were correlated with changes in TUG (r=-0.653, p=0.016) and SGRQ Symptoms (r=-0.588, p=0.035). The latter was also correlated with changes in sedentary time (r=0.760, p=0.003). No other significant correlations were found.

Conclusions: Patients with better exercise capacity and functional balance were also more physically active at W1. Nevertheless, findings suggest that intervention-related improvements in symptoms and functional balance may contribute to PA changes in a greater extent than exercise capacity. More research is needed.

Keywords: active lifestyle; activity monitoring; chronic respiratory disease; COPD

BMC Health Services Research (2016) – accepted

Walk2Bactive: Patients' perspectives of a physical activity-focused intervention beyond pulmonary rehabilitation in COPD

Joana Cruz

Dina Brooks

Alda Marques

In the last decade, several physical activity (PA)-focused interventions complementary to pulmonary rehabilitation (PR) have been developed in Chronic Obstructive Pulmonary Disease (COPD). A randomised controlled trial including self-monitoring with pedometers and goal setting showed promising results.[1] Before implementing this intervention in a larger scale, patients' perspectives should be considered as they may provide important findings for future research. This study explored patients' perspectives of a PA-focused intervention beyond PR in COPD.

13 patients with COPD completed a PA-focused intervention during PR (3 months) and follow-up support (3 months).[1] The intervention included a Health contract and calendar where patients registered step-count goals and objective feedback provided by pedometers. Two focus groups were conducted after the intervention to assess patients' perspectives of their participation (n=11, 69.2±6.9yrs, FEV_1=69.4±32.9pp).

Patients' perspectives were largely positive (n=10), except for one patient which was in the most severe COPD grade. Patients emphasised the importance of step-count goals (n=6), professional support (n=4) and social support (n=2) to motivate PA behaviour change. They reported a positive impact on their health (n=5) and lifestyle (n=4). Nevertheless, they underlined the need for on-going support (n=7) and regular PR sessions to optimise benefits (n=5).

The PA-focused intervention was valuable to patients with COPD, although regular support and PR sessions may be needed to sustain the benefits. Disease severity may be a factor of non-adherence. Future research is needed.

[1]Cruz J. et al. *Chron Respir Dis* 2016;13:57-66.

European Respiratory Journal (2016) – accepted

Appendix 3 – Ethical approval

CENTRO HOSPITALAR DO BAIXO VOUGA, E.P.E. / AVEIRO
Conselho de Administração

Avenida Artur Ravara – 3814-501 AVEIRO
Tel. 234 378 300 – Fax 234 378 395
daniela.delgado@hdaveiro.min-saude.pt
Matrícula na Conservatória do Registo Comercial
de Aveiro
Capital Social 40.284.651 € Pessoa Coletiva nº 510 123 210

Ex.ma Senhora
Prof.ª Adjunta Alda Sofia Marques
Escola Superior de Saúde da
Universidade de Aveiro
Campus Universitário de Santiago
3810-193 Aveiro

S/ Ref.ª	S/ Comunicação de	N/ Ref.ª	Aveiro,
		003428	25/07/2012

ASSUNTO: Resposta à V/ solicitação de colaboração no Projecto de Investigação

Em resposta ao V/ pedido, vimos, pelo presente, informar que se autoriza a realização do Projecto de Investigação na área da patologia respiratória crónica, especificamente da Doença Pulmonar Obstrutiva Crónica.

Com os melhores cumprimentos,

O Presidente do Conselho de Administração
do C.H.B.V., E.P.E.

(José Afonso)

Na resposta indicar o número e as referências deste documento. Em cada ofício tratar só de um assunto.

D.D.

CHBV – 347

Ministério da Saúde

ARSC ADMINISTRAÇÃO REGIONAL DE SAÚDE DO CENTRO, I.P.

DELIBERAÇÃO

Considerando que foram emitidos os devidos esclarecimentos solicitados pela Comissão de Avaliação de Pedidos de Patrocínio Científico e Autorização de Estudos da ARSCentro, I.P., para a realização do projecto "Reabilitar pessoas idosas com DPOC e suas famílias", pela Professora Alda Sofia Pires de Dias Marques e apresentados pelo ACES Baixo Vouga II, o Conselho Directivo decide autorizar a sua realização nos termos solicitados.

Coimbra, 28 de Fevereiro de 2011

O Conselho Directivo
da Administração Regional de Saúde do Centro, IP

(Dr. João Pedro Pimentel)
Presidente

(Dr. Mário Rui Ferreira)
Vice-Presidente

(Dr. Joaquim Gomes da Silva)
Vogal

(Dr.ª Regina Dias Bento)
Vogal

Alameda Júlio Henriques Apartado 1087 3001-553 Coimbra
Telefone 239 796 800 Fax 239 796 861 E-mail: secretariado.ca@arscentro.min-saude.pt

Joana Cruz

De: Maria, Damas <maria.damas@srsaveiro.min-saude.pt>
Enviado: quinta-feira, 2 de Maio de 2013 18:01
Para: Joana Cruz
Cc: Alda Marques
Assunto: RE: Pedido de extensão de autorização ética do ACES BVII para o ACES BV

Exmas. Senhores,

Relativamente ao mail infra, informamos V.Exas., que está autorizado o estudo referido, dado que sejam respeitadas as condições do ex ACeS Baixo Vouga II.
Melhores Cumprimentos

Maria Augusta Damas

Secretariado ACeS Baixo Vouga
E-mail: aces_bxvouga@srsaveiro.min-saude.pt
maria.damas@srsaveiro.min-saude.pt
-----Mensagem original-----
De: Joana Cruz [mailto:joana.cruz@ua.pt]
Enviada: quinta-feira, 2 de Maio de 2013 17:36
Para: Maria, Damas
Assunto: FW: Pedido de extensão de autorização ética do ACES BVII para o ACES BV

-----Mensagem original-----
De: Alda Marques
Enviada: quinta-feira, 11 de Abril de 2013 18:30
Para: dex-aces_bxvouga@srsaveiro.min-saude.pt; teresa.braz@srsaveiro.min-saude.pt; maria.lamas@srsaveiro.min-saude.pt
Cc: Joana Cruz
Assunto: Pedido de extensão de autorização ética do ACES BVII para o ACES BV

Ex.mo Sr. Dr. Manuel Sebe,
Na qualidade de investigadora responsável por um projeto de investigação a decorrer no ACES BV II, e necessitando de realizar intervenções em Centros de Saúde que estão abrangidos por todo o ACES do BV, venho por este meio solicitar extensão da autorização ética já concedida previamente. Queira por favor considerar os documentos em anexo para sua análise.

Melhores cumprimentos,
Alda Marques

1

Appendix 4 – Approval from the National Data Protection Committee

COMISSÃO NACIONAL
DE PROTECÇÃO DE DADOS

Despacho n.º 28 /2013

Analisado o Processo nº 9250/2012, cuja responsável pelo tratamento é a Universidade de Aveiro, a CNPD emitiu a Autorização n.º 8940/2012, no sentido de autorizar um tratamento de dados pessoais com a finalidade de elaborar um estudo observacional para caracterizar as pessoas com Doença Pulmonar Obstrutiva Crónica e as suas famílias em Portugal, com vista a desenvolver um programa de reabilitação respiratória e a monitorização no domicílio via telemedicina.

Por lapso, a finalidade redigida nas páginas 1 e 3 não está correta, pelo que, constatando-se que tal se deveu a lapso material, procede-se à retificação da mesma.

Deste modo, nos termos do tratamento que constam da Autorização n.º 8940/2012 e, onde se lê "Estudo observacional para caracterizar as pessoas com Doença Pulmonar Obstrutiva Crónica e as suas famílias em Portugal, com vista a desenvolver um programa de reabilitação respiratória e a monitorização no domicílio via telemedicina" e "Estudo observacional para analisar a pneumonia adquirida na comunidade em adultos residentes em Portugal continental", deve ler-se "Estudo observacional e intervencional para caracterizar as pessoas com Doença Pulmonar Obstrutiva Crónica e as suas famílias em Portugal, com vista a desenvolver um programa de reabilitação respiratória e a monitorização no domicílio via telemedicina".

Notifique o requerente com cópia deste despacho.

Lisboa, 25 de janeiro de 2013

A Secretária Geral

(Isabel Cristina Cruz)

Rua de São Bento, 148-3º • 1200-821 LISBOA
Tel: 213 928 400 Fax: 213 976 832
geral@cnpd.pt www.cnpd.pt

21 393 00 39
LINHA PRIVACIDADE
Dias úteis das 10 às 13 h
duvidas@cnpd.pt

Appendix 5 – Authorisation to use the Saint George's Respiratory Questionnaire

St George's
University of London

Medicine, Biomedical Sciences, Health and Social Care Sciences

Cranmer Terrace
London SW17 0RE
Switchboard
+44 (0)20 8672 9944
www.sgul.ac.uk

1 June 2015

To Whom It May Concern:

This is to confirm that St George's, University of London (St George's Hospital Medical School) has given permission for Joana Cruz, School of Health Sciences, University of Aveiro, Portugal to use the SGRQ in a study entitled *"Home-monitoring and Adherence of Patients with COPD to Long-term Rehabilitation"*.

Professor Paul Jones, PhD FRCP
Professor of Respiratory Medicine

P.W. Jones, PhD FRCP
Professor of Respiratory Medicine
Tel. ++44 (0)20 8725 5371 Fax. ++44 (0)20 8725 5955 email pjones@sgul.ac.uk

Appendix 6 – Authorisation to use the Self-Efficacy Scale

Joana Cruz

From: José Luis Pais Ribeiro <jlpr@fpce.up.pt>
Sent: quinta-feira, 28 de maio de 2015 09:46
To: Joana Cruz
Subject: RE: Escala de Avaliação da Auto-eficácia Geral - Solicitação para a utilização da escala

Cara colega

Autorizo o uso da Escala de avaliação da auto eficácia que estudei para a população portuguesa.

José Luís Pais Ribeiro
jlpr@fpce.up.pt
mobile phone: (351) 965045590
web page: http://sites.google.com/site/jpaisribeiro/
ORCID: http://orcid.org/0000-0003-2882-8056
Lattes- http://lattes.cnpq.br/1488255260017966
ResearchGate- https://www.researchgate.net/profile/Jose_Pais-Ribeiro/publications

---

De: Joana Cruz [joana.cruz@ua.pt]
Enviado: quarta-feira, 27 de Maio de 2015 10:57
Para: José Luis Pais Ribeiro
Assunto: Escala de Avaliação da Auto-eficácia Geral - Solicitação para a utilização da escala

Exmo. Sr. Professor Doutor J. Pais-Ribeiro,

Sou aluna de Doutoramento da Escola Superior de Saúde da Universidade de Aveiro (ESSUA) e estou a desenvolver o meu projeto de Doutoramento na área da doença crónica, nomeadamente na Doença Pulmonar Obstrutiva Crónica. O projeto inclui a avaliação da auto-eficácia dos doentes. Neste sentido, venho por este meio solicitar uma autorização formal para a utilização da Escala de Avaliação da Auto-eficácia Geral, adaptada para a população portuguesa pelo Sr. Professor Doutor J. Pais-Ribeiro, no projeto de investigação em questão.

Estou disponível para esclarecer eventuais questões.

Os meus melhores cumprimentos,

Joana Cruz
joana.cruz@ua.pt
+351 969 196 218
Lab 3R - Escola Superior de Saúde da Universidade de Aveiro (ESSUA)
Campus Universitário de Santiago
Agras do Crasto, Edifício 30
3810-193 Aveiro

Appendix 7 – Informed Consent

Termo de Consentimento Livre e Esclarecido

Título do Projeto: Reabilitar pessoas com Doença Pulmonar Obstrutiva Crónica

Nome do investigador principal: Alda Marques

Por favor leia e assinale com uma cruz (X) os quadrados seguintes.

1. Eu confirmo que percebi a informação que me foi dada e tive a oportunidade de questionar e de me esclarecer. ☐

2. Eu percebo que a minha participação no programa de reabilitação respiratória é voluntária e que sou livre de desistir, em qualquer altura, sem dar nenhuma explicação, sem que isso afete qualquer serviço de saúde que me é prestado. ☐

3. Eu concordo que as sessões do programa de reabilitação respiratória sejam filmadas com o objetivo de ajudar no planeamento de futuros programas de reabilitação respiratória. ☐

4. Eu compreendo que os dados recolhidos durante a investigação são confidenciais e que só os investigadores do projeto da Universidade de Aveiro têm acesso a eles. Portanto, dou autorização para que os mesmos tenham acesso a esses dados. ☐

5. Eu compreendo que os resultados do estudo podem ser publicados em Revistas Científicas e usados noutras investigações, sem que haja qualquer quebra de confidencialidade. Portanto, dou autorização para a utilização dos dados para esses fins. ☐

6. Eu concordo então em participar no estudo. ☐

_____	_____	_____
Nome da pessoa	Data	Assinatura

_____	_____	_____
Nome do Investigador(a)	Data	Assinatura