Cyprus University of Technology

SCHOOL OF HEALTH SCIENCES

DEPARTMENT OF NURSING

Master's Thesis

Evaluation of the Psychometric Properties of the Greek version of Active Life with Asthma - ALMA (Gr-ALMA) tool

Chris Livadiotis RN, BSc, MSc©

Limassol, May 2017

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Approval Form

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ABSTPACT

Background: While the burden of asthma is high, there are problems with the delivery of care, such as under-treatment with corticosteroids. Furthermore, there is often poor asthma knowledge and self-management skills among patients with asthma. Regular asthma reviews are recommended by international guidelines to improve asthma morbidity and the quality of life of asthma patients. To facilitate these reviews in primary care practice, there is a need for structured asthma review tools.

Aim: The aim of this study was to assess the metric properties of the Greek-translated version of the Active Life with Asthma (ALMA) review, a newly developed tool to facilitate structured review and management of asthmatic patients in primary care.

Methods: This is a methodological study with a descriptive cross-sectional correlation design. A convenience sample of 156 asthmatic patients attending pulmonary clinics of three public hospitals (Nicosia, Larnaka, Limassol) as part of their consultation visit, or hospitalized at the pulmonary wards of these hospitals participated in the study. Participants provided basic socio-demographic and clinical information, and responded to the 19-item ALMA questionnaire. The construct validity of the tool was explored in exploratory factor analysis and the internal consistency of the overall scale as well as sub-scales was estimated using Cronbach's a. The test-rest reliability of the tool was assessed among 20 participants who completed the tool twice, two weeks apart. Convergence validity was assessed using the Asthma Control Questionnaire (ACQ), the most commonly used asthma control measure, and concurrent criterion validity was assessed using the MiniAQoLQ, an asthma-specific quality of life questionnaire. Finally, known-group validity was assessed based on observed differences in terms of hospitalizations or emergency visits in the past year (2 items with binary response in ALMA).

Results: Amongst the 156 participants, 95 (60.9%) were women with median age 50-65 years old. As many as 67.3% had primary or secondary level education. One in three participants reported family history of asthma. A total of 28.2% are current and 21.7% were past smokers. Exploratory factor analysis (KMO=0.83 and Bartlett test <0.001) with principal component extraction and orthogonal (varimax) rotation revealed a clear structure of three factors with little cross-loading: physical, environmental and mental domains, as in the original study. Cronbach's alpha coefficient for internal consistency for the whole scale was 0.85, while for the sub-scales, these were: environmental a= 0.69, mental a = 0.76 and

physical a = 0.85. Test-retest reliability based on the correlation between scores of 20 participants responding twice two weeks apart was r=0.92. The correlation between ALMA and ACQ was -0.70. High correlations were observed between the ACQ and all sub-scales of the ALMA with the higher correlation observed with the physical domain (r=-0.68). Statistically significantly lower asthma control scores, overall and/or at least one of the domains, were observed among older participants, those with lower educational attainment, smokers, those with reported comorbidity and those who reported being admitted to hospital or visiting the emergency department for their asthma in the past year, further confirming the known-group validity of the tool. The correlation between MiniAQoLQ and ALMA was 0.71, while a good level of consistency between the various domains of asthma control/ self-management and the corresponding aspects of quality of life was observed as indicated by the higher correlations observed between matching domains. For example, the physical domain of ALMA showed higher correlations (in the magnitude of 0.6) with the symptoms and activities aspect of quality of life, compared to the other aspects of quality of life (0.3-0.5).

Conclusion: In general, the ALMA showed good metric properties. It appears to be a reliable and valid tool which can be used as a measure for asthma control and self-management in future descriptive or intervention research studies. Unlike ACQ which focused on physical symptoms, the ALMA includes mental and environmental aspects of asthma control/ self-management. Thus, it can also be used in clinical practise as a structured review tool in the context of the systematic assessment and monitoring of asthma control and self-management as well as an educational tool for Cypriot asthmatic patients.

Keywords: Asthma, Self-management, Asthma control, metric properties, Quality of Life

ΠΕΡΙΛΗΨΗ

Εισαγωγή: Ενώ το άσθμα αποτελεί σημαντική επιβάρυνση για τους ασθενείς και τα συστήματα υγείας, συνεχίζουν να υπάρχουν σημαντικά κενά στη παροχή φροντίδας στους ασθματικούς ασθενείς, όπως η ελλιπής αντιμετώπιση του με κορτικοστεροειδή από τη μια όσο και οι ελλείπεις γνώσεις και η μειωμένη ικανότητα των ασθενών με άσθμα από την άλλη όσον αφορά στην ικανότητα τους για αυτό-φροντίδα. Οι διεθνείς κατευθυντήριες οδηγίες προτείνουν τη συστηματική και περιοδική αξιολόγηση του επιπέδου ελέγχου του άσθματος στο πλαίσιο της βελτίωσης της νοσηρότητας και της ποιότητας ζωής των ασθενών. Για τη διευκόλυνση της κλινικής αξιολόγησης του ελέγχου του άσθματος στην πρωτοβάθμια φροντίδα υγείας υπάρχει ανάγκη για δομημένα εργαλεία αξιολόγησης του βαθμού ελέγχου και της αυτοδιαχείρισης του άσθματος.

Σκοπός: Σκοπός της παρούσας μελέτης είναι η διερεύνηση των μετρικών ιδιοτήτων του εργαλείου «Ενεργός Ζωή με Άσθμα» (Active Life with Asthma - ALMA) στην ελληνική έκδοση του, το οποίο είναι ένα εργαλείο δομημένης παρακολούθησης, αξιολόγησης και διαχείρισης των ασθματικών ασθενών στην πρωτοβάθμια φροντίδα υγείας.

Υλικό-Μέθοδος: Πρόκειται για μελέτη με μεθοδολογικό χαρακτήρα με περιγραφικό σχεδιασμό συσχέτισης. Στη μελέτη έλαβαν μέρος 156 ασθενείς με διάγνωση άσθματος. Η δειγματοληψία έλαβε χώρα στις πνευμονολογικές κλινικές των τριών μεγάλων δημόσιων νοσηλευτηρίων (Λευκωσία, Λάρνακα, Λεμεσό) στο πλαίσιο της προγραμματισμένης επίσκεψης τους ή κατά την παραμονής τους στα νοσηλευτήρια λόγω έξαρσης της νόσου. Οι συμμετέχοντες συμπλήρωσαν το κύριο ερωτηματολόγιο υπό αξιολόγηση (ALMA) το οποίο αποτελείται από 19 ερωτήσεις, καθώς και σειρά κοινωνικό-δημογραφικών και κλινικών στοιχείων. Η εγκυρότητα εννοιολογικής κατασκευής ή δομής του εργαλείου διερευνήθηκε μέσω διερευνητικής παραγοντικής ανάλυσης. Η αξιοπιστία της συνολικής κλίμακας όπως και των επιμέρους διαστάσεων ως προς την εσωτερική συνοχή εκτιμήθηκε με τον συντελεστή εσωτερικής συνοχής Cronbach a. Η σταθερότητα της κλίμακας αξιολογήθηκε μέσω ελέγχου δοκιμασίας-επαναδοκιμασίας σε δείγμα 20 συμμετεχόντων οι οποίοι συμπλήρωσαν την κλίμακα δυο φορές με μεσοδιάστημα δύο εβδομάδων. Η συγκλίνουσα εγκυρότητα της κλίμακας αξιολογήθηκε ως προς την παρατηρούμενη συσχέτιση με το ερωτηματολόγιο Asthma Control Questionnaire - ACQ, το οποίο αποτελεί το πιο διαδεδομένο εργαλείο μέτρησης του ελέγχου του άσθματος ενώ η ταυτόχρονη εγκυρότητα κριτηρίου αξιολογήθηκε με βάση το MiniAQoLQ, το οποίο μετρά την ποιότητα ζωής ασθενών με άσθμα. Τέλος, η εγκυρότητα γνωστών-ομάδων αξιολογήθηκε με βάση τις παρατηρούμενες διαφορές στο

σύνολο και της επιμέρους διαστάσεις τις κλίμακας μεταξύ όσων συμμετεχόντων δήλωσαν ότι έτυχαν εισαγωγής ή επισκέφτηκαν το Τμήμα Επειγόντων Περιστατικών κατά τους τελευταίους 12 μήνες (2 αντικείμενα με δίτιμη απάντηση στη κλίμακα ALMA).

Αποτελέσματα: Από τους 156 συμμετέχοντες, 95 (60,9%) ήταν γυναίκες με μέση ηλικία 50-65 ετών. Το 67,3% των συμμετεχόντων ήταν απόφοιτοι πρωτοβάθμιας ή δευτεροβάθμιας εκπαίδευσης. Ένας στους τρεις συμμετέχοντες δήλωσαν οικογενειακό ιστορικό άσθματος. Συνολικά, το 21,7% των συμμετεχόντων δήλωσαν ότι ήταν καπνιστές στο παρελθόν ενώ το 28,2% συνεχίζουν να καπνίζουν. Στη διερευνητική παραγοντική ανάλυση (KMO = 0,83 και δοκιμή Bartlett <0,001) με ανάλυση κυριών συνιστωσών και ορθογώνια (varimax) περιστροφή αξόνων αναδείχτηκε σαφής δομή τριών παραγόντων/υπο-κλιμάκων: η σωματική, η περιβαλλοντική και η ψυχική διάσταση, όπως και στην αρχική μελέτη. Ο συντελεστής Cronbach alpha εσωτερικής συνοχής υπολογίστηκε στο 0,85 για το σύνολο της κλίμακας (17 στοιχεία) ενώ για τις υπό-κλίμακες ήταν: περιβαλλοντική διάσταση a = 0,69, ψυχική διάσταση a = 0,76 και σωματική διάσταση a = 0,85. Η αξιοπιστία δοκιμασίας-επαναδοκιμασίας με βάση τη συσχέτιση μεταξύ της συνολικής βαθμολογίας 20 συμμετεχόντων οι οποίοι συμπλήρωσαν το ερωτηματολόγιο δυο φορές ήταν r = 0,92. Ο συντελεστής συσχέτισης του Pearson μεταξύ της συνολικής βαθμολογίας στο ALMA και στο ACQ ήταν -0,70. Υψηλές συσχετίσεις παρατηρήθηκαν μεταξύ του ACQ και όλων των επιμέρους κλιμάκων του ALMA με την υψηλότερη συσχέτιση να παρατηρείτε στη κλίμακα της σωματικής διάστασης (r = -0,68). Στατιστικά σημαντική διαφορά στο επίπεδο ελέγχου του άσθματος, είτε στο σύνολο της κλίμακας είτε τουλάχιστον σε μία από τις διαστάσεις, παρατηρήθηκε αναφορικά με την ηλικία (χαμηλότερο επίπεδο ελέγχου σε άτομα μεγαλύτερης ηλικίας), σε άτομα με χαμηλότερο επίπεδο εκπαίδευσης, στους καπνιστές, σε άτομα με συννοσηρότητα και σε όσους δήλωσαν ότι έτυχαν εισαγωγής ή επισκέφτηκαν το Τμήμα Επειγόντων Περιστατικών για το άσθμα τους κατά το τελευταίο έτος, επιβεβαιώνοντας περαιτέρω την εγκυρότητα του εργαλείου. Η συσχέτιση μεταξύ MiniAQoLQ και ALMA ήταν r=0,71, ενώ παρατηρήθηκε ένα καλό επίπεδο συνέπειας μεταξύ των δυο εργαλείων, όπως αναδεικνύεται στις υψηλότερες συσχετίσεις που παρατηρήθηκαν μεταξύ των διαφόρων διαστάσεων του ελέγχου-αυτοδιαχείρισης του άσθματος και των αντίστοιχων πτυχών της ποιότητας ζωής. Για παράδειγμα, η υποκλίμακα της φυσικής διάστασης του ελέγχου-αυτοδιαχείρισης του άσθματος του ALMA είχε υψηλότερη συσχέτιση (της τάξεως του 0,6) με τη πτυχή της ποιότητας ζωής η οποία σχετίζεται με τα συμπτώματα και τη φυσική δραστηριότητα, σε σύγκριση με όλες τις άλλες

πτυχές της ποιότητας ζωής (στις οποίες ο συντελεστής συσχέτισης ήταν της τάξεως του 0,3-0,5).

Συμπεράσματα: Το ALMA έδειξε καλές μετρικές ιδιότητες και φαίνεται να είναι ένα αξιόπιστο και έγκυρο εργαλείο το οποίο μπορεί να χρησιμοποιηθεί ως εργαλείο μέτρησης του βαθμού ελέγχου και αυτοδιαχείρισης του άσθματος σε μελλοντικές περιγραφικές μελέτες ή μελέτης παρέμβασης. Σε αντίθεση με το ACQ το οποίο επικεντρώνεται στα σωματικά συμπτώματα, το ALMA περιλαμβάνει επίσης πτυχές οι οποίες εμπίπτουν στη ψυχική και περιβαλλοντική διάσταση της αυτοδιαχείρισης του άσθματος. Μπορεί επίσης να χρησιμοποιηθεί στην κλινική πρακτική ως εργαλείο δομημένης αξιολόγησης και παρακολούθησης του ελέγχου και αυτοδιαχείρησης του άσθματος, καθώς επίσης και ως εκπαιδευτικό εργαλείο για τους Κύπριους ασθματικούς ασθενείς.

Λέξεις κλειδιά: Άσθμα, Αυτοδιαχείριση, Έλεγχος άσθματος, Ψυχομετρικές ιδιότητες, Ποιότητα ζωής

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ABBREVIATIONS USED

ALMA tool: Active Life with Asthma

ACQ: Asthma Control Questionnaire

ACD: Asthma Control Diary

HRQoL: Health related quality of life

MiniAQoLQ: Mini Asthma quality of life questionnaire

1. Introduction

Historically, asthma was first described by the ancient Greek physician Hippocrates. The term derives from the Greek word asthmaino meaning panting or gasping. Since ancient times, considerable advances have been made in understanding the genetics, the epidemiology and pathophysiology of asthma, a condition that has increased in prevalence worldwide over the past 20 years (Marketos S.G et al 1982).

Asthma is now considered a major public health problem which is frequently underdiagnosed and undertreated. Globally, the prevalence of asthma is rising (Newhouse et al., 2016), as is the corresponding burden on healthcare systems (Newhouse et al., 2016) Symptom control is the primary goal of treatment. Hence, the extent to which asthma patients play an active role in the day-to-day management of their condition is directly associated with improved outcomes. However, self-management and long-term control of mild to moderate asthma is often poor and this has been linked to several factors, including, reluctance to accept diagnosis of a chronic condition, the complexity of the condition over-reliance on health professionals or often forgetfulness (Newhouse et al., 2016).

Moreover, asthma is a growing global health problem that affects all ages, ethnic groups, and population groups. Asthma is a largely uncontrolled chronic health condition with considerable financial, medical, and social burdens. Current public health estimations suggest that about 300 million people currently have asthma worldwide, and experts raise concern about the growing prevalence of asthma in the developing world. (Melen E et al., 2012). In fact, it is estimated that 250 000 people die prematurely each year as a result of asthma (Olaguibel J et al., 2012).

Almost 75% of admissions for asthma are avoidable, and potentially preventable factors are common in deaths from asthma (Lahdensuo, 1999). Self-management of asthma involves the patient making therapeutic, behavioural, and environmental adjustments in accordance with advice from healthcare professionals (Lahdensuo, 1999). Furthermore, it has been reported that at least 40% of people with asthma do not react appropriately when their symptoms worsen, and over 50% of patients admitted with acute asthma have had alarming symptoms for at least a week before admission (Lahdensuo, 1999). As many as 60% of asthmatic patients are poor at judging their dyspnoea.

The burden of asthma is experienced not only in terms of healthcare, economic and social costs but also in lost productivity and reduced participation in family life. During the past two decades, many scientific advances have improved our understanding of asthma and our ability to manage and control it effectively (E. D. Bateman et al., 2008) The proper care for patients with asthma involves the triad: systematic chronic care plans, self-management support, and appropriate medical therapy (Olagubel J et al., 2012). Patients who are able to evaluate their medical therapy are able to better control their chronic condition and symptoms exacerbations on their own.

It has been suggested that the financial costs associated with asthma care continue to increase, yet improved care with a focus on better self-management remains suboptimal. Promoting optimal self-management, including the use of asthma action plans along with regular health professional reviews, has been shown to be an effective strategy and is recommended by asthma guidelines internationally (Pinnock H., 2015).

While effective management strategies of asthma are available, unfortunately asthma remains the leading cause of morbidity and can lead to hospitalization and death in severe cases. It is a complex disorder that displays heterogeneity and variability in its clinical expression both acutely and chronically. This heterogeneity is influenced by multiple factors including age, sex, socioeconomic status, race and/or ethnicity, and gene-environment interactions. The main risk factors for death from asthma include poor asthma management, delays seeking medical assistance and psychological instability (Newhouse et al., 2016). It has been suggested that asthma mortality has even been underestimated since the standard approach in epidemiological studies is to rely on underlying cause of death coding. A study of asthma mortality trends in the USA, covering a 12 year period (1990-2002), identified that 135.668 patient's deaths were related to asthma, representing a mortality rate of 4.4 per 100.000 patients, even though only 45% of the asthma-related deaths were recorded with asthma as the underlying cause (McCoy, L et al., 2005). The reasons behind this high mortality rate are not fully understood, but poor self-care and self-management appears to play an important part. Confidential inquiries into deaths from asthma in Britain and elsewhere have shown that patients' non-compliance with medical management, inappropriate actions during acute attacks, and failure to recognize the severity of acute asthma were factors that contributed to the death (Sibbald, 1989). In fact, studies have long suggested that these issues are prevalent in all asthmatic patients and not specific to those who died. (Sibbald, 1989). Finally,

prospective hospital inpatient studies in the US and the Netherlands have shown that feelings of stigma and pessimism about asthma may produce a panic and a fearful response to the attacks. (Sibbald, 1989)

All guidelines indicate that to achieve good control, asthmatics must be educated for their treatment to decrease the symptoms on day and night, limit activity limitation, airway narrowing and thus reduce the risk of life threatening exacerbations and long term morbidity (Juniper E.F et al., 2005)

Concluding, evidence from a total of 270 RCTs confirms that supported self-management for asthma can reduce unscheduled care and improve asthma control, can be delivered effectively for diverse demographic and cultural groups, is applicable in a broad range of clinical settings, and does not significantly increase total healthcare costs (Pinnock H 2017).

2.Pathophysiology

Asthma can affect the trachea, the bronchi and the bronchioles, which form part of the lower respiratory tract. The disease causes bronchoconstriction or abnormal narrowing of the airways as a result of epithelial damage, over-production of mucus, oedema, bronchospasm and muscle damage (Kaufman G 2011).

The bronchial epithelium is a barrier to the external environment and plays a vital role in protection of the internal milieu of the lung. It functions within the epithelial mesenchymal trophic unit (EMTU) to control the local microenvironment and help maintain tissue homeostasis. However, in asthma, chronic perturbation of these homeostatic mechanisms leads to alterations in the structure of the airways, termed remodelling. Damage to the epithelium is now recognized to play a key role in driving airway remodelling (Kaufman G 2011).

Several important mediators of remodelling have been identified, most notably transforming growth factor, which is released from damaged/repairing epithelium or in response to inflammatory mediators, such as IL-13 (Maskell N et al 2009).

Patients who died of asthma show massive inflammatory infiltration of the airway at post-mortem, often with marked eosinophilia and mucus plugging (Martinoviü, 2013).

2.1 Eosinophils in asthma

An eosinophil count is a type of blood test that measures the quantity of eosinophils (a type of white blood cell) in your body. An eosinophil count is typically used to confirm a diagnosis rather than make a diagnosis. Blood and sputum eosinophilia are characteristics but not diagnostic of asthma ether atopic nether non atopic. According to the American Association of Clinical Chemistry, eosinophils are particularly involved in immune responses to infections caused by parasites and allergic reactions (Jacobsen E.A 2007).

Eosinophils have two distinct functions in your immune system. First, they destroy invading germs like viruses, bacteria, or parasites such as Giardia and pinworm. Eosinophils also create an inflammatory response (Jacobsen E.A 2007).

Inflammation is both good and bad. It helps isolate and control the immune response at the site of an infection, but it also damages the tissue around it. Allergies are immune responses that often involve chronic inflammation. Eosinophils play a significant role in the

inflammation related to allergies and asthma. They can produce mediators such as leukotriene C4 which act to contract airway smooth muscle, recruit inflammatory cells and increase mucus production.

Certainly inhaler or oral steroid treatment dramatically reduces eosinophilic inflammation in asthma. Also anti-IL-5 antibody treatment is a way that can reduce by 50% the inflammation. (Maskell N et al 2009).

2.2 T-cells, cytokines and asthma

There is increasing evidence that T cells play a central role in the pathogenesis of asthma. It is well known that T cell-derived cytokines modulate IgE production by B-lymphocytes and mediate the migration and activation of EOS and other leukocytes in asthma. However, it has been demonstrated that after bronchial allergen challenge, CD4 + T-lymphocytes are depleted in peripheral blood and sequestered in the lung (C Walker et al 1991). These cells are pivotal to specific immune responses and are activated by antigens processed and presented by cells such as dendritic cells. Furthermore, in asthmatic airways,CD4 +T cells or helper T cells appear to be activated by allergens presented by dendritic cells leading to production of a particular pattern of messenger chemicals termed cytokines (Maskell N et al 2009).T-helper-2 cytokines include interleukin IL-4 and IL-13 which turn on IgE antibody production and activate airway epithelium and IL-5 which acts to recruit and retain eosinophils to the airway (Maskell N et al 2009).T-cells producing these cytokines are the predominant cell type in asthmatic airway and strategies to block these cytokines with monoclonal antibodies or other therapies have been developed, based on expression studies in animal models (Maskell N et al 2009).

2.3 Mast cells

Mast cells are strategically placed close to blood vessels and nerves in tissue that interface with the external environment. Mast cells can react within minutes to biological, chemical or physical stimuli by the release of multiple preformed mediators that lead to enhanced vascular permeability and initial recruitment of inflammatory cells. In asthma mast cells are predominantly activated by IgE receptor cross linking. In response to activation, preformed mediators that are stored bound to proteoglycans, i.e. TNF-a IL-4, histamine, tryptase and chymaseare released (Hart P.H. 2001).

2.4 Mucus hypersecretion

Asthma causes the mucus-secreting cells in the airways to multiply and the mucous glands to expand. Increased mucus secretion contributes to the formation of viscid mucous plugs that can occlude the airways (Bradley B et alL1991).

2.5 Oedema

The capillaries in the airway walls can dilate and may leak. The consequences of microvascular leakage include increased airway secretions, impaired mucociliary clearance and oedema, which may contribute to airway narrowing and hyper-responsiveness (Hart P.H. 2001).

2.6 Bronchospasm

Bronchospasm is also a feature of asthma. It describes the sharp contraction of bronchial smooth muscle, which narrows the airways (Martinoviü, 2013).

2.7 Airway remodelling

With poorly controlled or undertreated asthma, changes in structural cells and tissues can occur in the lower respiratory tract that lead to remodelling of the airway, resulting in permanent fibrotic damage. One of the characteristic histopathological findings in the asthmatic airways is epithelial change with increased goblet cells, increased airway collagen and extracellular matrix deposition and airway smooth muscle hypertrophy. These changes are referred to as ‘airway remodelling (Maskell N et al 2009). Nevertheless, in the acute inflammatory aspects of asthma, allergen-IgE–directed processes are predominant features of airway pathology. Mast cells, Th2 lymphocytes and eosinophils are the predominant histological features. The cytokine network associated with these processes includes IL-3, IL-4, IL-5, IL-9 and IL-13 7, 8 (Martinoviü, 2013).

Mast cells are important contributors to the initiation of asthma with release of acute-phase mediators, including cysteinyl, leukotrienes, and also inflammatory cytokines, which serve to perpetuate inflammatory events in the airway. Subpopulation of lymphocytes polarized toward a Th2 profile further sustains the inflammatory process by the release of cytokines, including IL- 4, IL-5 and IL-13. These factors serve to drive inflammation (e.g., recruitment of eosinophils) and also regulate IgE production) (Martinoviü, 2013).

3.Definitions and tools for measures of interest

3.1. Asthma

Asthma is a chronic inflammatory disorder of the airways that causes recurrent episodes of wheezing, breathlessness, chest tightness, and cough, particularly at night and/or early in the mornings (Book Robbins Pathology 2013). These episodes are usually associated with widespread, but variable, airflow obstruction within the lung that is often reversible either spontaneously or with treatment (E. D. Bateman et al., 2008)The hallmarks of the disease are intermittent and reversible airway obstruction, chronic bronchial inflammation with eosinophils, bronchial smooth muscle cell hypertrophy and hyperactivity and increases mucus secretion. (Book Robbins Pathology 2013)

3.2 Self-management

According to Barlow et al, self-management is the individual ability to manage the symptoms, treatment, physical and psychosocial consequences and lifestyle changes inherent in living with a chronic disease (Tousman et al., 2011). The US Institute of Medicine defines self-management as*" the tasks that individuals must undertake to live with one or more chronic conditions. These tasks include having the confidence to deal with medical management, role management and emotional management of their conditions"*. These tasks include having the confidence to deal with medical management and emotional management of their condition. Support of patient self-management is a key component of effective chronic illness care and improved patient outcomes. Self-management support goes beyond traditional knowledge-based patient education to include processes that develop patient problem-solving skills, improve self-efficacy, and support application of knowledge in real-life situations that matter to patients (Coleman & Newton, 2005).

3.3 Health-related Quality of life

Quality of life (QoL), as a concept, broadly refers to the general well-being of individuals as well as societies. The concept of QOL has been applies to a wide range of contexts, including the fields of international development, healthcare, politics and employment (O'Leary et al., 2009). While undoubtedly a multidimensional construct with subjective meaning, it has been directly linked to health issues (health-related quality of life). This broad concept includes epidemiological, biomedical, functional, economic and cultural dimensions as well as personal preferences, perceptions and experiences which can hardly be set and measured. According to the CDC, HRQoL "encompasses those aspects of overall quality of life that can

be clearly shown to affect health—either physical or mental". In a similar, but more encompassing definition, HRQoL is thought to refer to those aspects of quality of life that directly or indirectly relate to health, and can be considered as one's subjective assessment of the physical, psychological, and social domains of health (Hand 2016). Due to the importance of being able to capture the degree to which a medical condition, and its treatment, impacts on the individual's quality of life, the inclusion of HRQoL measures in clinical studies along clinical indicators has become standard as an important additional measure of the effectiveness of therapeutic and other interventions.

HRQoL scales can be generic or disease-specific. A number of instruments have been developed to measure the health-related quality of life (HRQL) of asthmatic patients and they have been extensively used in research and clinical practice during the last decades. These include: the 32-Item-Asthma Quality of Life Questionnaire (32-item-AQLQ) (Juniper, E et al, 1993) and the Mini-Asthma Quality of Life Questionnaire (Mini-AQLQ) (Juniper, E et al 1998).

3.4 Asthma control and self-management

People living with asthma have to accommodate their long-term condition within the context of their daily life. They may need to remember to use regular medication, to keep a supply of inhalers, avoid their triggers where possible, cope with the variability of asthma and the impact this has on their and their family's daily life. Crucially, they have to recognize when their asthma is deteriorating, and make decisions about when to adjust their medication, when to use emergency treatment and when to seek professional help. Indeed, it was estimated that half of the asthmatic patients who died had not received any professional care during the fatal attack and many appeared not even to have tried to seek assistance. Only 23% had an action plan that might have advised them when and how to seek help (Sibbald, 1989).

Given the above, self-management education is considered to be a vital aspect of asthma care as patients need to be educated to control and self-manage their own asthma. Tom Creer, an asthma education researcher, used the term self-management to describe the behaviour of a person who is active in his or her self-care. It is a way of life for them and with the appropriate education, their life will be improved (Tousman et al., 2011).

With effective self-management, the patient can monitor his or her condition and make the necessary cognitive, behavioural, and emotional changes are needed to maintain a satisfactory quality of life. The goals of asthma treatment are to achieve clinical control- which implies minimal symptoms and use of reliever medication, no limitations in everyday activities, normal lung function, and no side effects medication. Nevertheless, several surveys have suggested that both patients and physicians alike overestimate the level of asthma control (Kiotseridis et al., 2012).

The effectiveness of self-management has been long linked with improving health, reducing admissions, mortality and costs. (Wilson, S et al, 1993). In fact, the evidence for supporting self-management is overwhelming. The British Thoracic Society/Scottish Intercollegiate Guideline Network (BTS/SIGN) asthma guideline cites 261 randomized controlled trials reported in 22 systematic reviews in support of its grade A recommendation that 'all people with asthma should be offered self-management education which should include a written personalized asthma action plan and be supported by regular professional review (Calderon, JC et al, 2015).

Self-management support is the process of making multilevel changes within in health care systems and the community to facilitate patient self-management (Coleman & Newton, 2005). Physician support of patient self-management is one of the key elements of a systems oriented chronic care model. Increasing evidence shows that self-management support reduces hospitalizations, emergency department use, and overall managed care costs (Pinnock, H 2015).

In 36 trials focused on adult asthma, self-management (defined here as self-monitoring coupled with medical reviews and a written action plan) produced greater reductions in nocturnal symptoms, hospitalizations, and emergency department use than usual care. Nevertheless, self-management is the least implemented and most challenging area of chronic asthma disease management even though proper asthma education should not be considered an optional extra. In order to improve asthma morbidity and improve the quality of life asthma patients, healthcare professionals have a responsibility to ensure that everyone with asthma has personalized advice to enable them to optimize how they self-manage their condition. (Pinnock, H. 2015).

In the context of improving self-management, a number of controlled trials have been conducted to measure the effectiveness of asthma education programmes. While there is evidence to suggest that these programmes improve patient knowledge, their impact on health outcomes is not as well established (Gibson et al., 2002). Thus, to facilitate regular and systematic asthma reviews in routine clinical practice, as recommended by international guidelines, there is a need for structured measurement tools which could be used both for monitoring as well as education.

Several instruments have been developed for measuring asthma control. For instance, the Asthma Control Questionnaire (ACQ) and several shorter versions of ACQ, the Asthma Control Dairy (ACD) (Juniper, E et al, 2000, Juniper, E et al, 2004) and more recently the Active life with asthma - Alma (Kiotseridis et al., 2012). The Alma questionnaire, which will be used and tested in the context of this study, is a new tool recently developed and tested in Sweden as an alternative to the older ACQ, which despite certain limitations has been extensively used internationally and often considered the gold standard. (Kiotseridis et al., 2012). A literature search was performed in PubMed, Mendeley, Scholar and Cochrane database in order to identify whether the ALMA tool had been used before. As far as we are

aware, this is the first study to use and test the metric properties of the ALMA questionnaire internationally.

4.Literature review

A number of tools have been developed to measure asthma control and self-management. The first section of this chapter, provides a narrative review of the main tools identified in the literature including the ACQ (the most commonly used among these tools) and the ALMA tool – a newly developed tool which is the focus of this study. Furthermore, there have been a number of studies with experimental or quasi-experimental design which assessed the effectiveness of several interventions aimed at improving the levels of asthma control and self-management of asthmatic patients. This literature has been extensively reviewed. For the purposes of this thesis, the literature was reviewed in order to identify published systematic reviews (not original studies) of the effectiveness of self-management, education or other type of intervention (such as action plan) programmes in improving self-management in adult asthmatic patients. A search was conducted only in the Cochrane Library using the search terms: asthma AND self-management. Eligibility criteria were defined based on PICOS: Population – adult asthma patients with no restriction on country, setting or year, Intervention – any self-management, educational or other type of intervention programmes such as chronic disease management offered to asthmatic patients with the direct aim to improve self-management and asthma control. Studies assessing the effect of active monitoring to improve self-management facilitated by a healthcare professional, such as with the use of telemonitoring, were not considered (for example, Kayleigh M Kew and Christopher J Cates. Home telemonitoring and remote feedback between clinic visits for asthma. Cochrane Database of Systematic Reviews 2016). Systematic reviews of interventional studies, preferably randomised controlled studies with a control group receiving routine/usual care (as defined in the specific setting) were considered. Due to the large volume of the literature, as well as the fact that this literature has been previously reviewed in detail, a review of original studies with primary data was not performed. The main outcome of interest was self-management. Studies measuring related constructs such as asthma control were considered but studies measuring other constructs such as clinical outcomes, quality of life or self-efficacy (for example, Isabelle Peytremann-Bridevaux Chronic disease management programmers for adults with asthma. Cochrane Database of Systematic Reviews 2015) were not considered further. The search in the Cochrane database resulted in 19 hits, of which 4 fulfilled the eligibility criteria and were considered further. This literature is presented in section 4.2.

4.1. Asthma control and self-management measurement tools

Due to the importance of periodic assessment of asthma control, several tools have been developed to quantify the level of asthma control, identify patients at risk and evaluate the effect of asthma management. Alzahrami and Becker (2016) have examined the series of tools which have been proposed. In their review they included tools that had established psychometric properties and have been extensively studied in terms of their content, methods of administration and ability to reflect the overall status of asthma control. The tools which were included in the aforementioned study are: The Asthma control test (ACT), Childhood asthma control test (cACT), Asthma control questionnaire (ACQ), Asthma therapy assessment questionnaire (ATAQ) and Lara asthma symptom scale (LASS). Each tool was evaluated in terms of its validity, reliability, accuracy and responsiveness. The authors also identify a number of limitations for each tool. Since this literature has been recently reviewed, the following section will briefly describe these tools, based on the description and conclusions of Alzahrami and Becker (2016)

The ACT is a multidimensional, validated tool used for assessing five items of asthma control in patients with asthma older than 12 years: nocturnal and daytime symptoms, use of rescue medication, effect of asthma on daily functioning and perception of asthma control over the previous 4 weeks (Nathan et al, 2004). Comparing the ACT with other asthma assessment tools, it quantifies asthma control as a continuous variable and provides a numeric value to distinguish between controlled and uncontrolled asthma. The overall validity of the instrument has been assessed more than any other asthma control assessment tools. Statistically significant associations between ACT and the AQLQ and a strong correlation between ACT and ACQ have been reported. According to GINA 2008 guidelines (Global Initiative for Asthma, 2015), an ACT score of >23 and a score of <19 indicates well-controlled asthma and uncontrolled asthma respectively.

Similarly, the Asthma Control questionnaire (ACQ) was developed by Juniper EF et al (1999) to quantify levels of asthma control defined by international guidelines and to assess the self-management of asthma. It consists of five items about asthma symptoms in the past week (night-time waking, symptoms on walking, limitation of activities, shortness of breath and wheezing) as well as sixth item which refers to the use of short-acting β2 agonists. Initially, the ACQ was developed for adult patients with asthma but later studies showed that it can also be use in children 6-17 years. Juniper et al (1999) have established the ACQ cut-

off points for controlled asthma and uncontrolled asthma including the five highest scoring symptoms, one question about b2 agonist use and another about FEV1. As the authors of the review report, studies found the ACQ to be more responsive to changes in asthma management than the 2008 GINA classification of asthma control. There have been many studies to compare the ACQ with other tools. For example, Juniper EF et al (2000) compared the measurement properties of ACQ with those of the Asthma Control Diary (ACD) in an observational study. They concluded that both were valid instruments for measuring asthma control, but the ACQ had slightly better discriminative and evaluative measurement propertied. It has since been used extensively in research studies, and it has been characterized as the gold standard questionnaire for measuring asthma control (Juniper, O'Byrne, Guyatt, Ferrie, & King, 2000).

The ATAQ tool was developed to identify individuals over 18 years with possible asthma control problems. It has also been used to assess the economic burden of uncontrolled asthma. For example, Sullivan et al (2007) reported that the costs for uncontrolled asthma, as indicated by the ATAQ score, were more than double those with scores indicating controlled asthma. Unlike the ACQ, but similarly to the ACT, the ATAQ includes self-perceptions of control. Nevertheless, it does not include any items with regards to symptom frequency, with the exception of night time awaking due to symptoms.

Another brief tool, which nevertheless is specific to children ages 4-11, is the cACT. It has been validated more than any other asthma control assessment tools for children with asthma and has been designated as a core outcome for NIH- initiated participant characterization and for observational studies. Based on the conclusions of the authors of the recent revie, the childhood asthma control test has a strong correlation with the asthma control classification based on GINA guidelines.

Finally, a tool which was developed to be used in both children as well as adults is the LASS.. The adult version of LASS is completed by the patients and the children's version by the parents of the child with asthma. It consists of 8-items that assess the frequency of several symptoms as well as the overall perception of asthma severity. Unfortunately, weak correlation was observed between LASS scores and the use of bronchodilator, visits at emergency department and hospitalization.

All these tools were designed to capture the overall level of asthma control. Whereas the ACQ and ACT are closely aligned with the 2015 GINA and NAEPP EPR-3 guidelines, neither tool assess the risk of asthma exacerbation, which is an integral part of both guidelines criteria of asthma control. According to the authors observations (Alzahrami and Becker 2016), the ACQ seems to be the preferred measure in clinical trials, even though the ACT has the most published validation data. Furthermore, many of the available tools seem to focus exclusively on the control of physical symptoms, and do not include other aspects of asthma control and self-management such as the mental domain or environmental factors (exposure to smoke, dust or pollen).

More recently, Kiotseridis et al. (2012) developed a new instrument with the main aim to provide a tool which facilitates structured asthma reviews in primary care settings. The ALMA tool includes 19 questions and has three domains (physical, psychological, environmental). The study compared the ALMA with the ACQ and found a good correlation between the two measures. The authors concluded that the ALMA is a useful tool for assessing asthma control, which is a core function of an asthma review. In fact, unlike the ACQ, the ALMA tool taps on other aspects of asthma control (mental and environmental factors), hence the authors concluded that, to quote: "The breadth of the questions in the ALMA tool and the pragmatic use in clinical practice suggest that it can form the basis of a structured review in primary care which may translate into improved outcomes".

In 2013 Jia C.E et al explored the diagnostic performances of the ACT and ACQ and statistically compared the instruments with regards to assessing asthma control. Until that time, there had not been a systematically review for the asthma control test (ACT) and asthma control questionnaire (ACQ). The ACT contains 5 questions which are related with the frequency of both asthma symptoms and the ACQ assess 7-items which includes questions about night-time waking, activity limitations, shortness of breath, wheezing, used of b2 agonist and FEV1 (Jia C.E et al 2013). The authors included studies that examined the accuracy of the ACT, ACQ or both in the assessment of asthma control. Twenty-one studies (ACT=12, ACQ=6, both=3) were included with 11.141 subjects assessed with the ACT and 12.483 assessed with the ACQ. While the ACT showed good diagnostic accuracy for the assessment of controlled asthma as well as not-controlled asthma, the ACQ appeared to have good diagnostic accuracy only for the assessment of not-well controlled asthma (Jia C. E et al 2013). The authors concluded that the ACT is preferable to the ACQ in clinical practice.

A review by Barnes P.J et al (2014) provides a summary account of the use of ACQ and the phases in which it was used as clinical endpoint. It also includes an account of the comparisons between the ACQ and other instruments. Authors identified 87 articles in which they described the use of the ACQ as an end-point in phase ii-vi trials. This tool has been used to assess the effects on asthma control of a wide range of interventions (i.e. dietary supplements). Also, it was compared with the most commonly used numerically instruments for measuring asthma, the ACT, ACSS, ATAQ, and LASS with a high degree of correlation with them (Barnes et al., 2014).Their literature review, confirmed that the ACQ has already been widely adopted as a clinical trial end-point. Both ACQ and ACT have demonstrated reliability, validity and sensitivity to changes occurring in the level of control (Barnes et al., 2014).

Another systematic review, published in 2015, looked at the effectiveness of the various treatments (i.e. inhaler corticosteroid, long-acting b-agonist) including placebo with AQLQ and ACQ questionnaires as endpoints, both of which are considered as gold standard questionnaires. Bateman E.D et al (2015) showed that scores are influenced from patient's treatment background and treatment combination. Although, these questionnaires were able to identify that new treatment medication, they have not shown significant increase in the minimal important difference (MID) when compared with placebo. Thus, the authors suggested that when these questionnaires are used to identify the effect of new treatments in asthma-self-management, it might be essential to use methods that reduce the placebo effect seen in patients receiving an inhaler corticosteroid (ICS) or long-acting b-agonist (LABA) as background treatment during clinical trials.

Pinnock & Lester (2012) have provided a commentary where they argue that while these tools, provide a useful way to address the technical aspect of measuring and assessing asthma control, the most important questions remain unanswered. Specifically, the list a series of questions with regards to the actual use of these tools in clinical practice and raise concerns, including the extent to which the use of such tools to structure the consultation might, to quote "impose a routine that potentially excludes the patient's agenda". Furthermore, they identify a clear benefit in the routine use and the development of an asthma control database, with the use of such asthma control tools, since they offer the opportunity to observe and benchmark standards of practice. However, they conclude, to quote that "Time and further research will tell whether by structuring assessment of control it is

possible to improve the quality of care provided to individual patients — and also, by routinely monitoring structured asthma reviews, raise the quality of asthma care within a healthcare community".

4.2. Studies assessing the effectiveness of self-management programmes

The effectiveness of education on self-management of asthma has been the subject of investigation for over two decades. Wilson et al (1993) assessed the morbidity and mortality due to asthma, aggravated by demonstrably poor patient self-management practices. They assessed the effectiveness of a formal patient education program in a randomized trial. They compared changes in asthma symptoms, utilization of medical services, knowledge about asthma, metered-dose inhaler (MDI) technique, and self-management behaviours for 323 adults. As a result, the self-management education programs were associated with significant improvements in control of asthma symptoms (reduced 'bother' due to asthma and increased symptom-free days).

In 2011, Tousman SA et al (2011) designed and implemented an adult asthma self-management program using a randomized control design with a total of 45 participants - 24 in the control group and 21 in the intervention group. Those in the intervention group participated in 7 weekly meetings (2 hours once a week). When compared to participants in the control condition, those individuals who participated in the intervention had significant improvements in asthma self-efficacy, asthma quality of life, and patient activation. Significant interactions also indicated that those in the intervention groups had increases in the frequencies of the following self-reported behaviours: reducing asthma triggers, reading about asthma, peak flow monitoring, exercising, and, hand washing (Tousman et al., 2011)

More recently, Newhouse N et al (2016) determined the feasibility of a randomised controlled trial (RCT) in assessing the effect of an experience- based website as a resource for the self-management of chronic asthma in England. 148 participants were randomised and took part in the study (73 intervention group). The study was single-blind RCT in 2 regions of England and both groups showed improvement in health state or management of their condition with no significant differences between arms and no adverse effects.

There have been several reviews of the effectiveness of self-management programmes for asthmatic patients in the last decade. In 2002, Gibson P.G et al (2002) reviewed studies that had assessed the results of asthma self-management programmes, when coupled with regular

health practitioner reviews, on health outcomes in adults with asthma. They had included thirty-six trials in their review, which compared self-management education with usual care. The findings suggest that self-management education reduces hospitalisations, visits at emergency department, unscheduled visits to the doctor, days off work or school, nocturnal asthma and improve the quality of life. The authors concluded that education in asthma self-management which involves self-monitoring by either peak expiratory flow or symptoms, coupled with regular medical review and a written action plan improves health outcomes for adults with asthma (Gibson et al., 2002).

More recently, Belisaro Marcano J.S et al (2013) assessed the effectiveness, cost-effectiveness and feasibility using smartphone and tablet apps to facilitate the self-management of individuals with asthma. To maximise external validity, they included only interventions using commercially available devices. In their systematic review, they included only two RCTs which both follow-up patients for at least six months with regular follow-up assessments taking place every month. Both studies evaluated the effect of a mobile phone-based asthma self-management intervention on asthma control by comparing it to traditional paper based on asthma self-management. One study allowed participants to keep daily entries of their asthma symptoms, asthma medication usage, peak flow readings and peak flow variability on their mobile phone, from which their level of asthma control was calculated remotely and displayed together with the corresponding asthma self-management recommendations. In the other study, participants recorded the same readings twice daily, and they received immediate self- management feedback in the form of a three-colour traffic light display on their phones. Participants falling into the amber zone of their action plan twice, or into the red zone once, received a phone call from an asthma nurse who enquired about the reasons for their uncontrolled asthma (Marcano Belisario, Huckvale, Greenfield, Car, & Gunn, 2013)

Overall, the results of this review were inconclusive (Marcano Belisario et al., 2013). Based on the original study's authors, one of the two studies by Ryan et al (2012) had shown that the use of a smartphone app for the delivery of an asthma self-management programme had no statistically significant effect on asthma symptom scores, asthma-related quality of life, unscheduled visits to the emergency department or frequency of hospital admissions. The other by Lui (2011) concluded that patients using an asthma self-management app had significantly higher asthma-related quality of life scores at six-month follow-up, improved

lung function (PEFR) and reduced visits to the emergency department due to asthma related complications

An important concept in asthma management is the personalized asthma action plan (PAAP) for each person. This plan includes measures of airflow limitations in adults (i.e. peak expiratory flow-PEF) and state the agreed maintenance medication. Such plans also provide clear instructions on how a person should respond to increasing symptoms with the aim of improving overall asthma control and minimising the risk of exacerbations. Evans DJW e al (2015) evaluated the effectiveness of PAAPs for adults with asthma, either alone or in combination with education on self-management. PAAP is considered as an important plan of multi-faceted, self-management education and in adults must be based on symptoms or PEF or both. PAAPs primarily serve to increase self-management of asthma by reminding people of their treatment plan and inform them about what triggers to avoid, when they need to increase their treatment, how to increase treatment, duration of increasing the treatment and when to seek medical help. Also, it is an important communication tool for patients and healthcare professionals, representing both a record and reminder of discussions between patient and clinician (Evans et al., 2015). *A summary of findings of these studies are included in a table at the end of the study* (Appendix X).

5.Aim

The overall aim of this study is to evaluate the metric properties of the Greek-translated version of the ALMA tool for self-management for asthmatic patients among Cypriot asthma patients for the first time. In addition, the study will describe the knowledge level of self-management among Cypriot asthma patients, assess any potential differences according to sociodemographic and clinical characteristics of the patients and investigate the association between self-management with QoL.

5.1 Objectives

Specifically, the objectives of the study include:

- To translate using the double forward – backward translation processes of the ALMA tool in Greek language (using English version, and not the original Sweden) and back again in English.
- To evaluate the reliability (test-retest and internal consistency) of the tool among a sample of Cypriot adult asthma patients
- To evaluate the validity of the tool among a sample of Cypriot adult asthma patients. Specifically, the construct (factorial) validity, the convergence validity (against an alternative asthma control measure), the concurrent criterion validity (against an asthma-specific quality of life measure) and known-group validity (by comparing self-management according to asthma severity indicators) will be investigated
- To describe the level of self-management and asthma - related quality of life, as well as, their association, among Cypriot adult asthma patients.
- To explore potential differences in self-management by social and clinical characteristics i.e. according to age, gender, educational attainment, medication, comorbidity, family history of asthma/atopy etc.

6.Methods

This is a methodological study (i.e. evaluation of the psychometric properties of the Greek version of the tool ALMA in the Cypriot speaking population of adult asthmatics), with a descriptive cross-sectional correlational design (i.e. assessment of the association between self-management and QoL).

6.1 Study population and sampling

Eligible participants (N=160) were patients with asthma over 18 years old, either attending the pulmonary clinics of three public hospitals (Nicosia, Larnaka, Limassol) as part of their consultation visit, or hospitalized at the pulmonary wards of these hospitals and who consent to take part. Excluded were patients under 18 years of age arriving at the emergency department or those who did not wish to participate. Since the main goal of the study was to assess the construct (factorial) validity of the 19 item ALMA tool, the study aimed for sample size of 160 complete questionnaires in order to permit the exploration into the dimensionality of the tool based on the participants' responses (i.e. 10 participants per item of the scale-part of the tool) (Sousa & Rojjanasrirat, 2011). While the common rule of thumb in validation studies suggest that anything from as little as 5 participants per tool item are sufficient to more than 20 participants per item, this is also largely dependent on the expected heterogeneity in the responses among participants which is not known in this case. The sample was a convenience consecutive sample of asthma patients in the recruitment period until a minimum required sample size achieved, which have been depended on the response rate.

6.2. Measurements tools

The instruments which were used in the study are (1) Alma, (2) ACQ and (3) MiniAQoLQ. Permissions to use these questionnaires have been received by the developers (see Appendix I). There is a Greek version of the ACQ and the MiniAQoLQ, which have been forwarded by the developers to use in the context of this study. These instruments have been extensively used in many studies across several countries (Eric D Bateman et al., n.d., 2015). For the newly developed Alma tool permission to translate and use the tool has been received by electronic communication with the authors (Kiotseridis et al., 2012). The English version (rather than the original Swedish) was used to produce the Greek version using double parallel forward and backward translation. (Sousa & Rojjanasrirat, 2011). Specifically, the main researcher and a respiratory physician translated blinded to each other the questionnaire in Greek, and the members of the Advisory Committee translated independently of each other the unified Greek version back to English. Modifications were made as necessary by consensus in order to finalise the Greek version of the tool used in this study. The readability of the tool and the need for modifications in terms of the wording or syntax of the items before finalizing it, guide us to a pilot test which was run in the pulmonary clinic, at Nicosia hospital, as part of patients' consultation visit with five asthma patients who did not take part in the study by completing the questionnaires to make sure that the questions were perceived correctly.

6.2.1 Active life with asthma (Alma)

The Active life with asthma (Alma) tool is a new tool for the management of asthmatic patients which was developed and validated in Sweden, and subsequently translated in English by the same team for the purposes of publication (Kiotseridis et al., 2012). The tool comprises of 19 items of which: a total of 16 questions mainly form the scale-part of the tool and they are provided with a four-point scale responses (often, sometimes, seldom, never). An additional 2 questions with yes/no answers and 1 question about as-needed medication are included in the questionnaire -see Appendix V for the English version an Appendix VI for the Greek-translated version). In terms of the dimensionality of the tool, exploratory factor analysis in the original study of 200 patients with doctor-diagnosed asthma suggested three sub-scales, namely, physical, psychological and environment triggers. The original study also assessed internal consistency with the Cronbach's alpha coefficient as well as test-retest reliability by sending out the questionnaire along with the ACQ, two weeks apart to

consecutive sample of patients who had earlier attended primary care for an asthma review. In the original study, the correlation between ALMA and ACQ was high (0.71). The Cronbach's alpha coefficient was 0.91 and the test-retest reliability was 0.93 (Kiotseridis et al., 2012).

6.2.2 Asthma Control Questionnaire (ACQ)

Asthma Control Questionnaire (ACQ) was first developed and validated in 1999 to measure asthma control (Victor, k et al 2011) and the primary clinical goal of asthma management as identified by international guidelines (Juniper E.F et al 2004). It includes the five highest scoring clinical symptoms: night-time waking, symptoms on waking, activity limitations, shortness of breath and wheezing, one question about b2-agonist use (see Appendix VII) and another about FEV1, which will not be used in the current study as it requires spirometry. The ACQ was tested in a 1, 5, 9-week observational study of 50 adults with symptomatic asthma and the responsiveness index was 1.35 (Juniper, E et al, 1999). A subsequent study compared the ACQ with three shortened versions of the ACQ and showed that the measurement properties were similar. Three hundred eighty-one patients remained stable between 13 and 26 weeks and the internal consistency was ≥0.82 (Juniper E et al 2004). Patients recall their experience and respond to each question using a 7-point scale. The items are equally weighted and the ACQ score is the mean of the 7- items with a theoretical range of zero (well controlled) and six (extremely poorly controlled (Juniper E et al, 1999)

6.2.3 Mini asthma quality of life questionnaire (MiniAQoLQ)

The MiniAQoLQ, was developed to measure the problems that adults with asthma experience in their day to day lives (Juniper E.F et al 1999). It consists of 15-items in four domains (symptoms, activity limitation, emotional function and environmental stimuli) and taps on the problems of adults with asthma who they might find most troublesome in their day-to-day lives. Patients respond to each question on a 7-point scale from7= 'not bothering at all' to 1='extremely bothered' (see Appendix VIII). It was developed and compared to the original, much longer, AQLQ in terms of both absolute score and measurement validity. It was tested in a 9-week observational study and showed good measurement properties. All questions are equally weighted and the overall score is calculated as the mean of the 15 items which has four domains (symptoms, activities, emotions and environmental). The MiniAQoLQ has

strong evaluative and discriminative measurement properties and the minimal important clinical difference is 0.5 on the 7-point scale (Juniper E et al, 1999).

6.2.4 Demographic, social and clinical characteristics

Sociodemographic and clinical characteristics have also been collected in order to assess potential differences in asthma control and quality of life across sub-groups. More specifically the sociodemographic characteristics have included gender, age, smoking status (pack-years), level of education, while self-reported clinical characteristics included-medication, allergies, comorbidity and family history (See Appendix IX).

6.3. Data collection

Participant recruitment was performed in the pulmonary clinics of three public hospitals in Cyprus (Nicosia, Larnaka, Limassol) as part of their consultation visit or hospitalized at the pulmonary wards of these hospitals and who consent to take part during September to December 2017. Participants were asked to complete the informed consent before taking part in the study. Participation was voluntary and anonymous. Participants' anonymity was maintained at all times. Patients with doctor-diagnosed asthma, who either visit the pulmonary clinic for a consultation or were admitted in the pulmonary ward for any reason during the recruitment period were eligible to participate. Eligible participants were identified and informed about the aims of the study by the attending nurse after the examination or during waiting time. Similarly, patients with doctor-diagnosed asthma at the pulmonary ward were informed by the ward staff about the study aim and were invited to participate. The questionnaire pack was handed out by the main researcher. The whole process took about 10-15 minutes. There was no intervention or interference with normal practice. Once completed each participant put the questionnaires in an envelope which had been provided. After data entry, the paper-form questionnaires were kept along with the consent forms in a secure office environment at the Department of Nursing, Cyprus University of Technology.

6.4. Data analysis

6.4.1 Validity

Exploratory factor analysis was used to assess the factorial (construct) validity of the Greek version of Alma and compare its dimensionality against the three domains identified in the original Swedish study. The sampling adequacy for factor analysis was assessed using the Keiser-Olkin-Meyer test and the Bartlett test of sphericity. The extraction method applied

was principal components. The number of factors to extract were assessed by using the eigenvalues criterion (>1 as per default) as well as by assessing the scree plot. Since the correlation matrix suggested relatively low correlation between factors, for easy of interpretation varimax rotation was used. Furthermore, the correlation between ALMA and ACQ (often used as the gold standard in clinical and research studies) was assessed as a means of evaluating the convergence validity of the new improved tool which covers more aspects regarding asthma control. Concurrent criterion validity had been assessed on the bases of the observed association between ALMA (asthma control) and MIniAQoLQ (quality of life). A positive but moderate correlation was expected since self-management and quality of life have been repeatedly shown to be positively correlated (higher control-better quality of life) but tap on distinct experiences of living with asthma.

6.4.2 Reliability

The internal consistency of the tool was assessed by estimating Cronbach's alpha coefficient both for the overall scale as well as the sub-scales of the tool. To assess the stability of the tool, test-retest reliability was assessed among a small sub-sample of twenty participants who completed the questionnaire twice, two weeks apart. To facilitate this, the last three digits of the person's identity card were noted at the top of the first completed questionnaires as this is required to allow matching the first and second questionnaire completed by the same person. The second questionnaire was mailed by post to each participant who were requested to return it by post in a sealed envelope noting the last three digits of their ID on the questionnaire. Test-retest reliability was calculated by using Pearson's correlation coefficient between the overall scores (test and re-test).

6.4.3 Differences by sociodemographic and clinical characteristics

Mean scores in ALMA, ACQ and MiniAQoLQ by sociodemographic and clinical characteristics were as appropriate in a series of t-test, ANOVA and Chi-square test as appropriate. In particular, differences by smoking status and severity of asthma indicators will function as a test of known-group validity of the measure.

6.4.4. Statistical Analysis

All statistical analysis was performed with the use of SPSS 20 and AMOS for windows (IBM SPSS Statistics for Windows, Ver. 20, Armonk, NY: IBM Corp). In all cases, the level of statistical significance was set to p value<0.05.

6.5. Ethical Considerations

All necessary permissions had been obtained. The Commissioner for the Protection of Personal Data had been notified accordingly and the study protocol was submitted to the Cyprus National Bioethics Committee, the Committee for the Promotion of Research of the Ministry of Health and the administration of the three participating hospitals, pulmonary clinic physicians and ward managers (See-Appendix II-IV).

All participants were informed about the aims and objective of the study and they were required to sign an informed consent form. Participation was voluntary and anonymous. The study did not involve any intervention or interference with normal ward or pulmonary clinic practice and the patient's treatment had not affect in any way if they deny participation or do not fully complete the questionnaire. The anonymous questionnaires were coded for the purposes of the statistical analysis and kept save along with the consent forms for the duration of the study and the dissemination of the findings. Only the main researcher and the advisory committee had access to the questionnaires. A report with summary data on the level of asthma control and quality of life on asthma patients will be submitted to the pulmonary clinics which participated in the study for their own use. Moreover, the final Greek translation of the ALMA tool for asthma control will be sent to the developers of the original tool (as per their request) and will be made available for use in clinical practice

7. Results

The number of participants in the final sample was N=156 (three participants did not return the questionnaires and one stopped during completing the questionnaire) who completed all three questionnaires (ALMA, ACQ, MiniAQoLQ) in full from three hospitals (Nicosia, Larnaka, Limassol). Amongst the 156 participants, 95 (60.9%) were women. The median age of the participants was 50-65 years old. As many as 55.7% of the participants were older than 50 years of age, while all other age groups were represented in the sample. Just over half of the participants (54.1%) were recruited from the Nicosia hospital. The rest were recruited from the other two hospitals, specifically 15.9% (n= 25) from Larnaka and 29.9% (n=47) from Limassol. In the absence of official statistics on the socio-demographic characteristics of asthma patients in public hospitals in Cyprus, it is not possible to assess the representativeness of the sample. In terms of gender, while there is evidence to suggest that in several countries both the prevalence as well as hospitalization for asthma in more common in women (in adults, not children), there are no similar statistics from Cyprus. The female-to-male ratio observed in this study is lower than the 2:1 commonly observed elsewhere, but it is unclear whether this reflects the gender distribution in Cyprus or it suggests more willingness among men to participate in the study. However, the distribution of the sample across the three hospitals roughly represents the population sizes of the three cities.

The socio-demographic and clinical characteristics of participants are presented in detail in Table 1. In terms of educational attainment, as many as 67.3% of the sample had primary (25.0%) or secondary level education (42.3%). One in three participants were University graduates – 20.9% (n=34) with undergraduate and 10.9% (n=17) with a postgraduate qualification. The relatively low level of educational attainment is not surprising given that more than half the sample was older than 50 years of age.

As also shown in Table 1, 28.2% (n=44) are current smokers, 21.7% (n=34) used to smoke and the majority of participants 54% (n=78) never smoked. On in three participants reported that the half a family history of asthma – 39.4% (n=62). Finally, in terms of comorbidity, approximately an equal proportion of participants responded positively and negatively (Yes= 48.7% and No= 51,3%). The most commonly reported comorbidity conditions were gastroesophageal reflux 19.7% (n=15), sinusitis 26.3% (20), nasal polyps 7.9% (n=6), allergic rhinitis 19.7% (n=15), respiratory infection 19.7% (n=15) and chronic pulmonary obstruction 6.6% (n=5).

Table 1: Socio-demographic characteristics of the participants

Variable		Frequency (N=156)	Relative Frequency (%)
Gender	Male	61	39.1%
	Female	95	60.9%
Age	18-30	29	18.5%
	30-40	20	12.8%
	40-50	20	12.8%
	50-65	57	36.5%
	65 and over	30	19.2%
Education	Primary	39	25.0%
	Secondary	66	42.3%
	Under graduate	34	21.8%
	Post graduate	17	10.9%
Smoke status	Current	44	28.2%
	Past	34	21.7%
	Never	78	54%
Family history	Yes	62	39.4%
	No	94	60.6%
Drug allergy	Yes	27	17.4%
	No	129	82.6%
Comorbidity status	Yes	76	48.7%
	No	80	51.3%
Comorb condition	Gastro. reflux	15	19.7%
	Sinusitis	20	26.3%
	Nasal polyps	6	7.9%
	Rhinitis	15	19.7%
	Res.Infection	15	19.7%
	COPD	5	6.6%
District	Nicosia	85	54.1
	Larnaka	25	15.9
	Limassol	47	29.9

In Table 2, the mean pack-years of smoking according to the smoking status of the participants is presented. Current smokers (N=44) have reported smoking on average 21 (SD 12.3) cigarettes/day over a period of 18 years on average (SD 11.4). Past smokers (N=34) reported smoking on average 25 (SD 18.6) cigarettes/day when they used to smoke, and they smoked on average for 15.4 years (SD 12.5). In total, among current and past smokers (N=78), the mean pack-years of smoking were estimated with a mean of 488 (SD 644) (equivalent, say to a pack of 20 cigarettes a day for a period of 20 years) and a range of 15 pack-years (say, equivalent to 5 cigarettes a day for 10 years) to 4000 pack-years (say, equivalent to three packs a day for 66 years).

Table 2: Smoking status and pack-years of smoking

	N	**Mean (SD)**	**Min-Max**
Current: Smoking years	N=44	18.0 (11.4)	Min=4, Max=45
Current: Smoking/day	N=44	21 (12.3)	Min: 3, Max: 43
Past: Smoking years	N=34	15.4 (12.5)	Min:2, Max:50
Past: Smoking/day	N=34	25 (18.6)	Min:4, Max:100
Current + Past: Pack-years	N=78	488 (644)	Min=15, Max=4000

Table 3: Exploratory factor analysis with all 19 items

	Factor 1 (Physical)	Factor 2 (environmental)	Factor 3 (mental)	Factor4 (HS contact)
Item1 (walk)	0.86			
Item2 (work)	0.84			
Item3 (training)	0.74			
Item4 (sleep)	0.74			
Item5(wheezing)	0.55		0.46	
Item6 (cough)	0.53			
Item7 (medicine)	0.48			
Item8 (Medicare)	0.44		0.41	
Item9 (chest tightness)	0.40			
Item10 (dust)		0.77		
Item11 (smoke)		0.74		
Item12 (cold weather)		0.69		
Item13 (cold)		0.60		
Item14(worried)			0.75	
Item15 (medicine rapid relief)			-0.74	
Item16 (affect life)			0.60	
Item17 (some things)	0.46		0.52	
Item18 (casualty ward)				0.83
Item19 (hospital)				0.82
Cronbach's a	0.86	0.69	0.73	

The internal validity measured with Cronbach's alpha for the overall scale was estimated at 0.85. An exploratory factor analysis was undertaken to investigate the dimensionality of the tool, originally including all 19 items (even though three of them are not measured on a 4-point response scale). The KMO=0.83 and Bartlett test <0.001 suggested acceptable sampling adequacy to proceed with factor extraction. As shown in Table 3, four factors were initially extracted with varimax rotation, roughly corresponding to the original sub-scales of physical (factor 1), environmental (factor 2) and mental domain (factor 3). Factor 4 loads on two items

(items 18 and 19) which are the two binary (YES/NO) items referring to hospital admissions or emergency department visits in the last year. Only factor loadings with a value of >0.39 are present in the table. The four factors retain 57% of the total variability. There was very little cross-loading, for example item 5 (I have wheezing when I breath) loaded on both factor 1 (physical) and 3 (mental), item 8 (I have asthma symptoms, despite the fact that I take my medications as prescribed by my doctor) loaded on both factor 1 (physical) and 3 (mental), and item 17 (I do not do things that I want to do because of my asthma) loaded on factors 1 (physical) and 3 (mental). It is also worth noting that item 15 (with regards to the use of rapid relief medication) loads negatively as expected because this item is reverse coded. Cronbach's alpha for the subscales were 0.86 for the physical domain, 0.69 for the environmental domain and 0.73 for the mental domain.

Specifically, Factor 2, the environmental domain, includes the 4 items, as in the original study, which refer to asthma condition as a response to environmental conditions such as (a) dust, pollen and animal fur, (b) smoke and strong odors, (c) cold weather and (d) cold symptoms. Factor 3, the mental domain includes the same 3 items as in the original study, namely "I think about my asthma and worry", "Asthma affects my life more than I would want to" and "I do not do as many things as I would like to because of my asthma". Also, in this case, item 8 "I have asthma symptoms, although I follow the medication prescribed by my doctor" and item 5 "I have wheezing when I breath " are cross-loading on factor 1 and 3 but in both cases with slightly higher loadings on factor 1. Finally, another item referring to the use of rapid relief medication loaded on factor 3 (and in fact, with a negative loading since reverse coding is used for this item). It is important to note that this item (for which a three-point scale is provided referring to the frequency of rapid relief medication use) was not included in the original study, as were none of the two items referring to hospitalization and emergency visits (factor 4 in this case). Therefore, the analysis was repeated without these items – see below. Factor 1, physical domain includes nine items, 7 of which were the same in the original (walk, work, training, sleep, wheezing, cough, chest tightness). In this case, items "I have asthma symptoms despite the fact that I take my medications as prescribed by my doctor" and "My medications cause discomfort", both of which were excluded in the original study loaded on factor 1 along with the other items that tap on physical symptoms. So in the original study authors excluded the above two items and the subscale was calculated based on 7 items than in our study which were included all the nine items. Also in the

repeated analysis Factor 3, mental domain includes 4 items 3 of them were the same in the original (worried, affect life, somethings) except the item (medicine rapid relief) which was excluded in the original study. As mentioned earlier, there was also a fourth factor 4 containing only two items – visit to the casualty ward and hospital admission (both binary items). These items were decided not to be used as separate factor. Other than the fact that there are only two items that make up this factor, and in fact binary, these items were also excluded from the original study. Nevertheless, these two items were used in the analysis to compare the overall and sub-scale scores of people who responded positively to these questions, as an additional form of known-group validity since it is assumed that self-management would be lower among people with a higher number of hospitalizations or emergency visit. A t-test was done between people who responded yes vs no in each of these two items showing a statistical significance ($p<0,05$). Future efforts may concentrate on strengthening the scale with more questions regarding contact with health services, severity and frequency of asthma exacerbations if an additional factor tapping on this domain will be formed.

Table 4: Exploratory factor analysis (with 17 items)

	Factor 1 (Physical)	Factor 2 (Environmental)	Factor 3 (Mental)
Item1 (walk)	0.86		
Item2 (work)	0.84		
Item3 (training)	0.74		
Item4 (sleep)	0.73		
Item5 (wheezing)	0.55		0.49
Item6 (cough)	0.54		
Item7 (medicine)	0.50		
Item8 (chest tightness)	0.41		
Item9 (dust)		0.77	
Item10 (smoke)		0.74	
Item11 (cold weather)		0.69	
Item12 (cold)		0.60	
Item13 (medicine rapid relief)			-0.77
Item14 (worried)			0.70
Item15 (affect life)			0.64
Item16 (some things)	0.46		0.55
Item17 (Medicare)	0.44		0.45
Cronbach's a	0.85	0.69	0.76

After repeating the factor analysis without items 18 and 19 (casualty and hospital) which were also excluded from the original study, a clear structure of three factors (with minimal cross-loading) was observed along the lines of the three domains as per the original study: physical, environmental, mental factors, explaining 54.6% of the total variance. The rotated factor loadings pattern is shown in Table 4 where only factor loadings with a value of >0.39 are shown. KMO=0.83 and Bartlett test <0.001 were also satisfactory in this case.

It was decided to retain three items ("I have asthma symptoms despite the fact that I take my medications as prescribed by my doctor" in factor 1 and "My medications cause discomfort" and "I use quick(rapid) relief medications in factor 3) even though which were excluded in

the original which only included 14 items distributed across these three scales (physical factor– 7 items (all same + one), mental factor – 3 items (all included here + two) and environmental factor – 4 items (all same)

The screen plot of the analysis including 17 items is shown in Figure 1. Cronbach's alpha coefficient for internal consistency for the whole scale was 0.85 while for the sub-scales , these were: in factor 2 – environmental (4 items) a= 0.69, in factor 3 – mental factor (5 items) a = 0.76 (and a= 0.69 if only the three items as per the original study are included) and in factor 1 - physical factor a = 0.85, and were deemed satisfactory. Finally, test-retest reliability based on 20 questionnaires was assessed using Pearson's correlation coefficient, and was estimated at r=0.92.

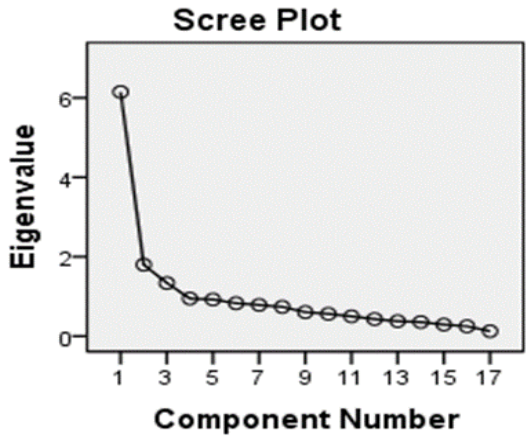


Figure 1: Scree plot for the subset of asthma control questions signalling three factors

Table 5: Relative frequencies per ALMA item (including only the 16 4-point scale items)

	Often	Sometimes	Rarely	Never
Chest tightness	8.9%	45.2%	36.9%	8.9%
Cough	19.1%	34.4%	28.7%	17.8%
Dust	51.6%	26.8%	10.8%	10.8%
Cold weather	27.4%	33.8%	22.9%	15.9%
Smoke	54.8%	19.7%	17.2%	8.3%
Cold	54.1%	29.9%	12.1%	3.2%
Worried	55.4%	22.3%	12.1%	10.2%
Affect life	22.3%	33.1%	28.7%	15.3%
Some things	20.4%	36.9%	22.9%	19.7%
Walk	35.7%	30.6%	21.0%	12.7%
Work	35.0%	29.9%	22.3%	12.7%
Training	30.6%	33.1%	16.6%	19.7%
Sleep	12.1%	34.4%	25.5%	28.0%
Wheezing	18.5%	37.6%	31.2%	12.7%
Medicare	24.2%	36.9%	26.1%	12.7%
Medicine	1.3%	17.2%	31.2%	50.3%

Table 5 shows the distribution of responses per individual item of the ALMA. In general, it appears that the higher positive responses were recorded in the items which refer to environmental conditions (smoke, dust, cold) where often more than half of the participants responded that these affect them “often”, which is not surprising both due to the high exposures experienced in Cyprus and the less control over these external factors by the individual. Relative high frequency was also observed in the case of several of the mental domain items, for example, as many as 55.4% of the participants responded that they “often think and worry about their asthma”. The least frequent negative responses were recorded for item “I have tightness in the chest” for which only 1.3% responded often and 17.2% responded sometimes. The remaining 81.5% responded rarely or never. Although, 37,6% responded for item using medication for rapid relief over two times a week 28.0% twice a week and 34,4% they never used any medication. For the item ‘emergency visit last year in

the ED' 31.2% answered as yes than 68.8% who have not visit the ED. Also, 79.6% have not admitted in the hospital last year in related with 20.4% who had admitted.

The distribution of responses per item is also presented graphically in Figure 2.

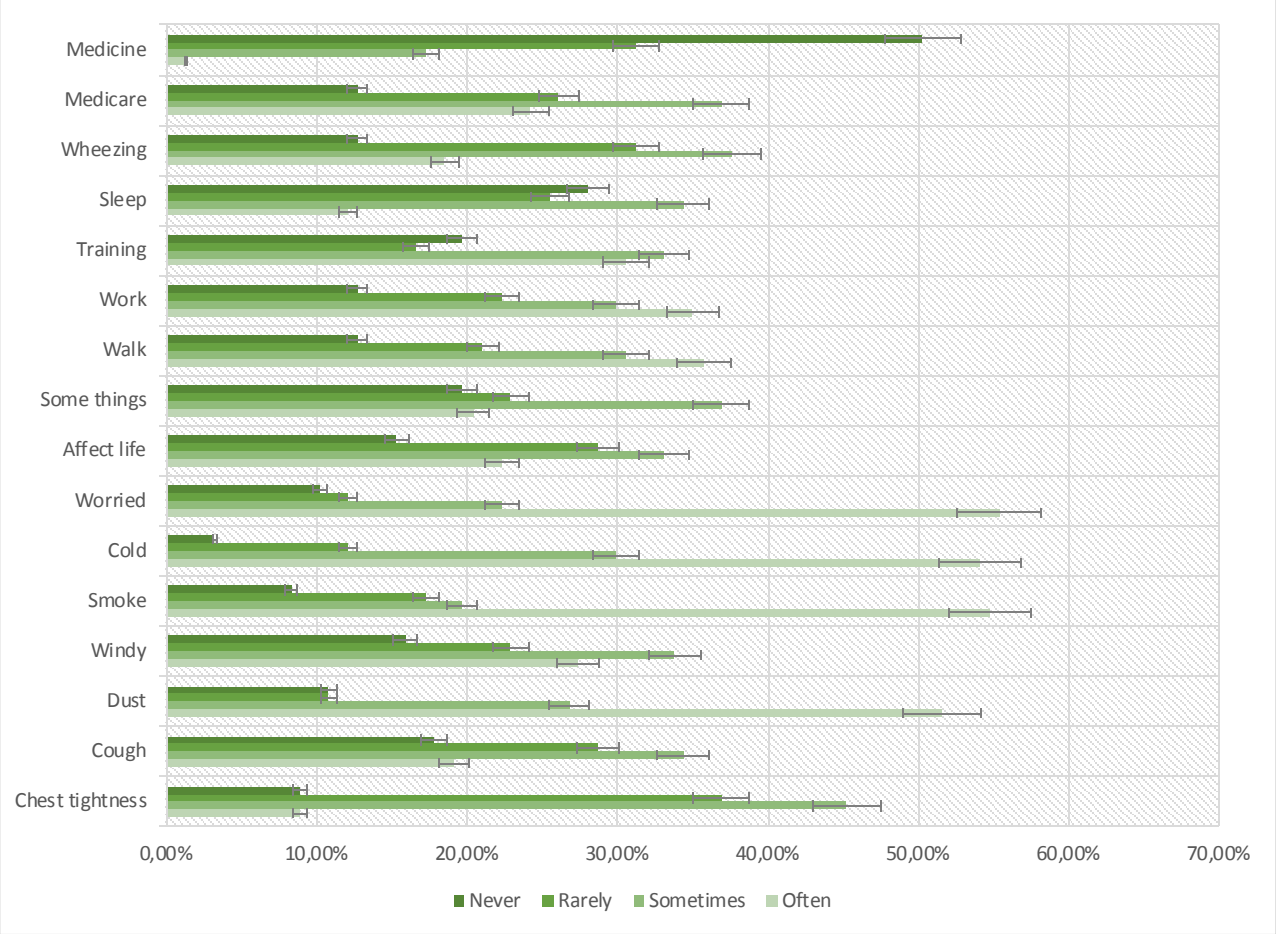
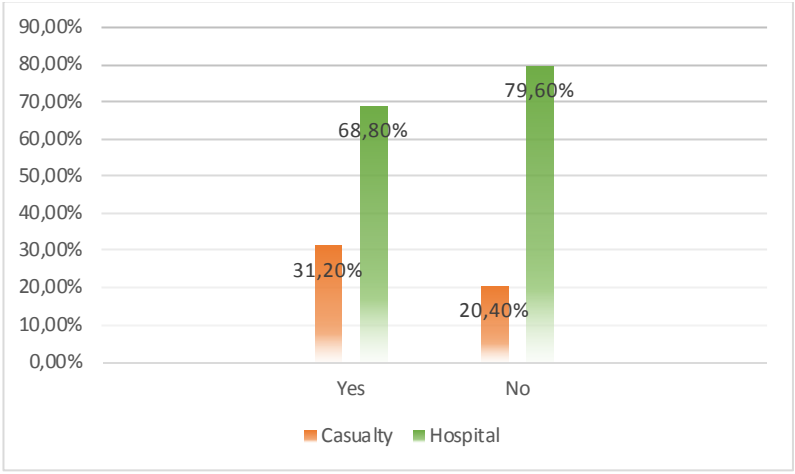


Figure 2: Results of the individual questions in the ALMA questionnaire on the participants so far registered in the database (age 18-over 65)



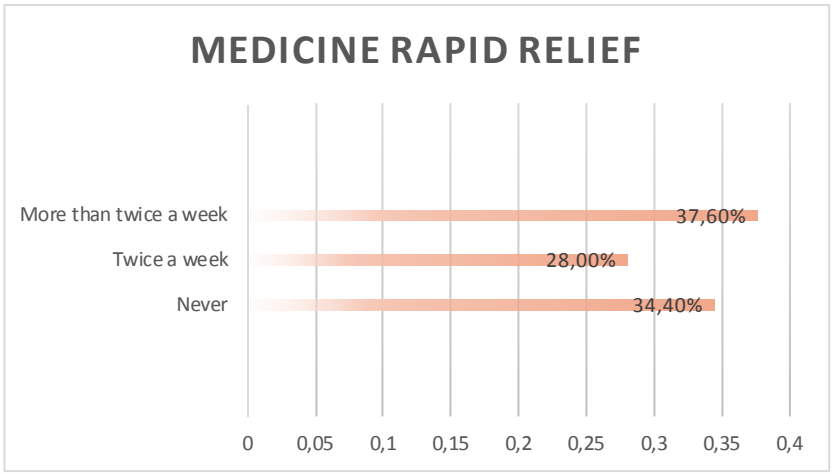


Figure 3: Results of the individual questions in the ALMA questionnaire about Casualty, Somethings and Hospital

Table 6: Differences in overall Alma score and factor sub-scale scores according to socio-demographic and clinical characteristics

	Overall Mean (SD)	**Physical Mean (SD)**	**Mental Mean (SD)**	**Environmental Mean (SD)**
Theoretical range	**17-67**	**9-27**	**4-15**	**4-16**
All participants	38.3 (10.3)	22.1 (6.0)	8.6 (3.0)	7.6 (3.6)
Emergency visits				
Yes	33.7 (8.4)	19.8 (5.3)	7.3 (2.7)	6.6 (2.3)
No	40.3 (10.4)	23.1 (6.1)	9.1 (2.9)	8.1 (4.0)
p-value	<0.001	0.001	<0.001	0.11
Admissions				
Yes	32.8 (7.7)	19.6(4.9)	6.8(2.7)	6.2(1.8)
No	39.7 (10.4)	22.7(6.1)	9.0(2.9)	8.0(3.8)
p-value	0.001	0.11	0.001	0.10
Gender				
Male	40.0 (11.0)	23.0(6.0)	8.5(2.9)	8.4(3.5)
Female	37.2 (9.7)	21.5(6.0)	8.6(3.0)	7.1(3.5)
p-value	0.10	0.11	0.89	0.32
Age				
18-30	46.2(9.0)	25.4(5.8)	11.2(2.0)	9.5(3.2)
30-40	38.4(12.0)	21.3(6.3)	9.6(3.1)	7.5(4.0)
40-50	33.4(8.2)	19.3(4.5)	7.2(2.6)	6.8(2.6)
50-65	36.4(8.6)	21.7(5.7)	8.1(2.6)	6.5(2.4)
65 and over	37.5(10.9)	22.0(6.3)	7.0(2.8)	8.5(5.0)
p-value	0.000	0.006	0.000	0.003
Education				
Primary	39.3(10.8)	23.5(6.7)	7.9(2.6)	7.9(2.9)
Secondary	35.4(10.0)	20.2(5.7)	7.9(2.9)	7.3(4.0)
Under graduate	40.6(9.0)	23.7(5.0)	9.5(3.0)	7.4(3.3)
Post graduate	42.5(10.2)	23.2(5.7)	10.6(2.8)	8.7(3.3)

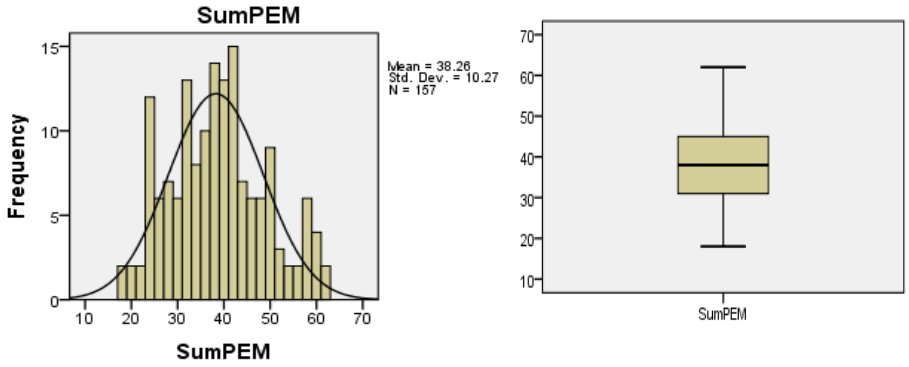
p-value	0.16	0.008	0.001	0.449
Smoke status				
Current	43.0(11.2)	22.8(6.6)	10.0(3.3)	10.2(4.3)
Past	36.9(10.5)	21.8(6.2)	8.0(2.8)	7.2(3.2)
Never	36.2(8.8)	21.8(5.5)	8.0(2.5)	6.3(2.4)
p-value	<0.001	0.368	<0.001	<0.001
Pack-years				
No smokers	35.8(8.4)	21.5(5.4))	8.0(2.5)	6.3(2.2)
<300 py (median)	41.9(9.8)	23.5(6.0)	9.9(2.6)	8.4(3.1)
>300 py (median)	39.3(13.0)	21.4(7.0)	8.1(3.7)	9.7(5.0)
p-value	0.005	0.145	0.002	<0.001
Family history				
Yes	38.5 (10.2)	21.9(6.1)	9.1(2.8)	7.5(3.0)
No	38.2 (10.4)	22.3(5.9)	8.2(3.0)	7.7(3.9)
p-value	0.85	0.71	0.78	0.77
Drug allergy				
Yes	37.3(9.0)	22.1(6.2)	8.1(2.6)	7.1(2.4)
No	38.5(10.5)	22.1(6.0)	8.7(3.0)	7.7(3.8)
p-value	0.580	0.991	0.384	0.397
Comorbidity status				
Yes	36.7(10.0)	21.4(6.0)	8.1(2.9)	7.2(3.1)
No	39.8(10.3)	22.8(5.9)	9.0(3.0)	8.0(4.0)
p-value	0.061	0.137	0.061	0.185
Comorbidity details				
Gastro. reflux	35.6(7.9)	20.6(8.5)	8.4(3.5)	6.5(2.6)
Sinusitis	35.9(10.0)	21.2(6.3)	8.1(2.9)	6.6(3.0)
Nasal polyps	33.5(7.6)	19.8(4.7)	7.6(2.2)	6.0(1.5)
Rhinitis	31.0(6.9)	18.5(4.8)	6.6(1.8)	5.8(1.2)
Res.Infection	44.0(12.3)	25.7(6.8)	8.6(2.7)	9.6(3.6)
COPD	42.0(7.4)	21.2(2.4)	10.4(3.7)	10.4(3.3)
p-value	0.007	0.036	0.187	0.001

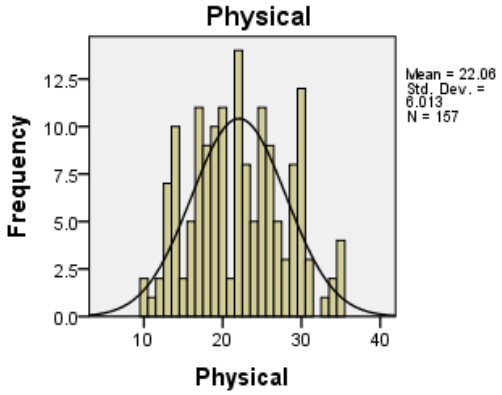
District				
Nicosia	39.5(10.2)	22.9(5.9)	8.8(3.0)	7.8(3.1)
Limassol	38.9(10.8)	21.4(5.6)	9.0(2.6)	8.3(3.5)
Larnaka	35.6(9.7)	22.0(6.0)	7.9(2.8)	6.8(2.7)
p-value	0.108	0.155	0.163	0.178

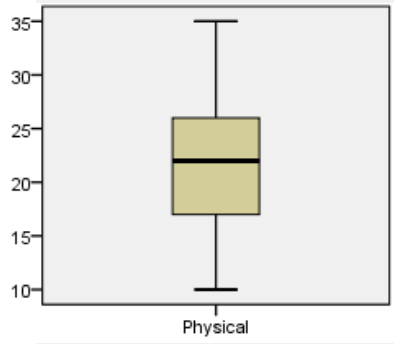
Table 6 shows the observed differences in the overall Alma score as well as the three sub-scale scores according to socio-demographic and clinical characteristics. Differences were observed by:

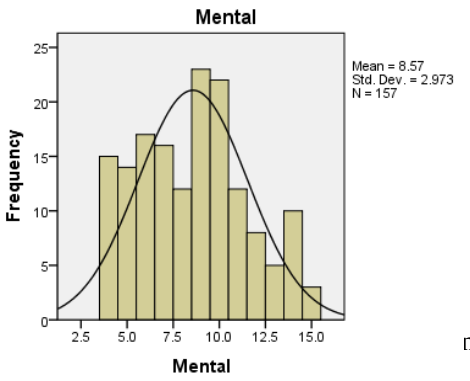
- Age: with generally better scores observed in the younger and older age-groups and worse scores in the middle age groups. Differences appear larger for the overall scale and environmental scale ($p<0.001$) but were also apparent for the physical and mental scale ($p<0.05$)
- Educational attainment: whereby better score at least for the physical and more so for the mental domains ($p<0.001$) but not for the environmental domain were observed among the group with the higher educational attainment.
- Smoke status: whereby worse scores were observed among current smokers for the environmental domain ($p<0.001$), mental domain ($p<0.001$) and overall score, but not for the physical domain. A similar pattern was observed with regards to pack-years of smoking even though the participants with the highest number of pack-years of smoking (above median) were not always scoring worse than those below the median.
- Comorbidity: where participants reporting positively tended to have lower scores, at least with regards to the physical and mental domains ($p<0.05$). While the observed differences with regards to the environmental domain and the overall score were in the same direction, these were not statistically significant at the 5% level.
- Finally, statistically significant differences were observed between participants who reported emergency visits and hospital admissions over the past year. While these differences appeared larger with regards to the overall score, physical and mental score (<0.001 in the case of emergency visits), differences in environmental domain were in the same direction, even if not statistically significant at the 5% level.
- No statistically significant differences were observed in terms of family history of asthma, drug allergies or district of sampling.

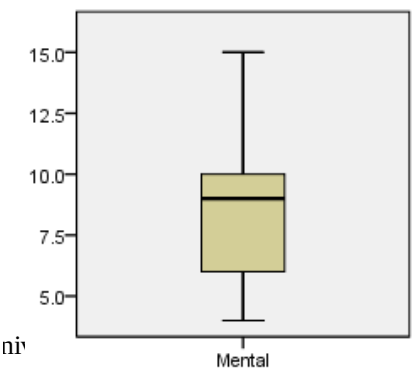
Figure 4 presents the histograms and box-plots of the distribution of the overall scores and subscale scores. In the case of the overall score, physical domain and mental domain, the distributions appear reasonably symmetrical, in contrast to the environmental domain where the distribution of scores is skewed to the right, since as also mentioned above, the majority of participants tended to respond negatively in these items.











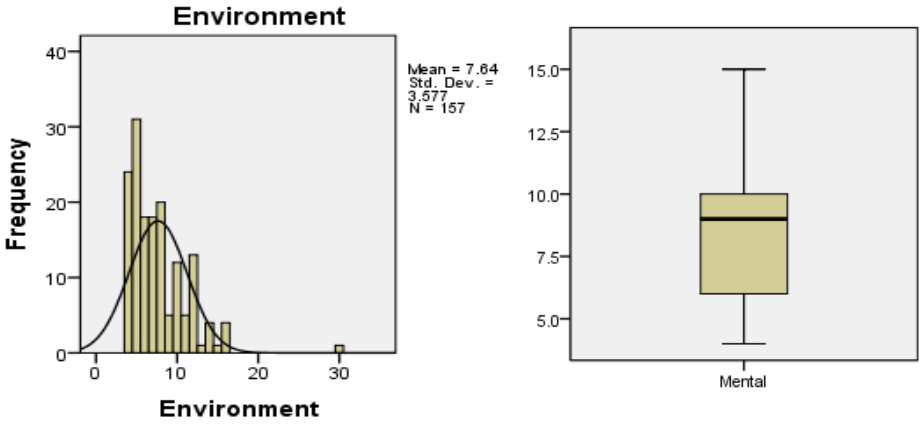


Figure 4: Histogram and box-plot for the distribution of scores for the overall scale and three subscales

Table 7: Mean of ACQ and correlation between ACQ and ALMA (overall-factors and subscales)

Cronbach's a=0.89, Mean: 1.5, SD=1.27, Min: 0, Max: 4.8

	ALMA			
	Overall	**Physical**	**Mental**	**Environmental**

ACQ	**-0.70**	**-0.68**	**-0.51**	**-0.45**

The convergence validity of the ALMA was evaluated against the ACQ scores, which is the most frequently used measure of asthma control. Cronbach's alpha coefficient for the 5-item ACQ was estimated at 0.89 and test-retest reliability using the Pearson correlation coefficient was estimated at r=0.96. The mean ACQ score was 1.5 (SD 1.27) with an observed range of 0-4.8. It should be noted that while higher scores indicate better levels of self-management in the case of ALMA, in the case of ACQ higher scores indicate worse asthma control. The correlation between ALMA and ACQ was -0.70. High correlations were observed between the ACQ and all sub-scales of the ALMA with the higher correlation observed with the physical domain (r=-0.68) as expected since the ACQ is focusing exclusively on physical symptoms. Nevertheless, moderate correlations were also observed between the ACQ and the other two domains of the ALMA - mental r=-0.51 and environmental r= -0.45.

Table 8: Differences across quartiles of ACQ scores

	Overall – Mean (SD)	Physical – Mean (SD)	Mental – Mean (SD)	Environmental – Mean (SD)
Theoretical range	17-67	9-27	4-15	4-16
ACQ quartile				
Q1: <0.5	48.1 (7.9)	27.8 (4.4)	10.6 (2.5)	9.6 (3.5)
Q2: 0.5-1.2	38.8 (8.0)	21.3 (4.2)	8.8 (2.8)	8.5 (4.7)
Q3: 1.2-2.5	35.3 (5.7)	21.3 (3.9)	7.7 (2.1)	6.2 (2.1)
Q4: >2.5	29.3 (7.5)	16.7 (4.6)	6.7 (2.7)	5.8 (2.0)
p-value	<0.001	<0.001	<0.001	<0.001

Observed differences in overall ALMA score and sub-scale scores across quartiles of participants with increasing ACQ scores (i.e. worse asthma control) are presented in Table 8. The first quartile (score <0.5) are the 25% of participants with lower scores on the ACQ, hence better asthma control. In the last quartile are the 25% of participants with the highest scores on the ACQ, hence worse asthma control. In general, a clear stepwise pattern of

decreased ALMA scores, indicating worse self-management, were observed across quartiles of participants with higher ACQ scores (indicating worse asthma control). The differences were apparent for the overall score and the three sub-scale scores, and were in all cases statistically significant ($p<0.001$).

Table 9: Descriptive statistics of MiniAQoLQ

	Mean	**SD**	**Min-Max**
Overall	68.3	21.3	18-105
Symptoms	18.6	6.4	4-28
Environment	12.0	4.7	3-21
Emotional	13.6	5.1	3-21
Activities	19.4	6.7	5-28

In terms of quality of life as measured by the AQLQ, the mean score among participants was 68.3 (SD21.3), range 18-105. For the four domains of quality of life, the mean (SD) were symptoms 18.6 (SD 6.4), environment 12.0 (SD 4.7), emotional 13.6 (SD 5.1) and activities 19.4 (SD 6.7)) as shown in table 9. By comparison across domains, lower scores were observed for the environment and emotional aspects of quality of life, compared to the physical and activities domain, which is consistent with the findings based on the ALMA sub-scales.

Table 10: Correlation between MiniAQoLQ and ALMA (overall-factors)

	ALMA			
	Overall	**Physical**	**Mental**	**Environmental**

MiniAQoLQ	0.71	0.62	0.59	0.51
Symptoms	0.64	0.63	0.48	0.40
Environment	0.63	0.47	0.46	0.63
Emotional	0.48	0.33	0.54	0.38
Activities	0.66	0.61	0.56	0.41

The correlation between MiniAQoLQ and ALMA was 0.71. High correlations were observed between the MiniAQoLQ and ALMA domains, in ranking order: physical r=0.62, r=mental 0,59 and environmental r=0.51. It also important to note that there is good level of consistency between the various domains of asthma control/self-management and the corresponding aspects of quality of life as indicated by the higher correlations observed between matching domains. For example, the physical domain of ALMA showed higher correlations (in the magnitude of 0.6) with the symptoms and activities aspect of quality of life, compared to the other aspects of quality of life (0.3-0.5). Similarly, the environmental domain of ALMA showed higher correlation with environmental-related quality of life (in the magnitude of 0.6) compared to the other aspects of quality of life (in the magnitude of 0.4).

8. Discussion

8.1. Main findings

Amongst the 156 participants, 95 (60.9%) were women with median age 50-65 years old. As many as 67.3% had primary or secondary level education. On in three participants reported family history of asthma. A total of 28.2% are current and 21.7% were past smokers. Exploratory factor analysis (KMO=0.83 and Bartlett test <0.001) revealed a clear structure of three factors: physical, environmental, mental domains. Cronbach's alpha coefficient for internal consistency for the whole scale was 0.85 while for the sub-scales, this was: environmental a= 0.69, mental a = 0.76 and physical a = 0.85. Test-retest reliability based on the correlation between scores of 20 participants responding twice two weeks apart was r=0.92. The correlation between ALMA and ACQ was -0.70. High correlations were observed between the ACQ and all sub-scales of the ALMA with the higher correlation observed with the physical domain (r=-0.68). Statistically significantly lower asthma control scores, overall and/or in at least one of the domains, were observed among older participants, those with lower educational attainment, smokers, those with reported comorbidity and those who reported being admitted to hospital or visiting the emergency department for the asthma in the past year, further confirming the known-group validity of the tool. The correlation between MiniAQoLQ and ALMA was 0.71 while a good level of consistency between the various domains of asthma control/self-management and the corresponding aspects of quality of life was observed as indicated by the higher correlations observed between matching domains. For example, the physical domain of ALMA showed higher correlations (in the magnitude of 0.6) with the symptoms and activities aspect of quality of life, compared to the other aspects of quality of life (0.3-0.5).

8.2. Strength and limitations

This is the first study to translate and evaluate the metric properties of an asthma control questionnaire among Greek-Cypriot asthmatic patients. The participants were selected from pulmonary clinics in the three largest public hospitals in Cyprus. While the sample was a convenience sample and hence the extent to which it is a representative sample of all asthmatic patients in Cyprus is not known. Nevertheless, the prime purpose of this methodological study was the evaluation of the metric properties of the tool and not the description of the level of asthma control among asthma patients in Cyprus. The sample was

heterogeneous in terms of their socio-demographic (age, education etc.) and clinical characteristics (family history, comorbidity etc.).

Another strength is the fact that, in addition to the construct validity and reliability (internal consistency and stability) of the ALMA tool, the study was designed in order to assess other aspects of the validity of the tool including its convergence validity (against ACQ, the most commonly used measure of asthma control in research and clinical practice, its concurrent criterion validity (against the MiniAQoLQ which measures quality of life in asthmatic patients) and known-group validity (according to expected differences in asthma control in terms of service utilization indicators).

There are also a number of limitations in this study, including the small sample size as a result of the time restrictions. Nevertheless, the sample size was adequate both to assess the validity and reliability of the tool as well as assess differences in asthma control according to socio-demographic and clinical characteristics. Patients response rate was high as in the majority of cases, the patients who were conducted consented to participate once the aims and purpose of the study was explained to them, thus minimising them. In order to assess the convergence validity of ALMA, the "gold standard" ACQ questionnaire was used. However, for convenience purposes, the last item of the ACQ was not included since it refers to prebronchodilator forced expiratory volume in one second (FEV1). Thus, other than self-reported measures, the study did not have any objective measures of asthma control. Nevertheless, self-reported service utilization measures were collected (as they form part of the ALMA questionnaire (admissions to hospital and emergency department visits), thus the study was able to show differences in asthma control according to these measures of asthma severity/lower control, which were in the expected direction. Finally, it should be mentioned that it became apparent during the data collection that a large number of participants were taking a new generation medication, the rolenium inhaler, which was not listed in the questionnaire. Rolenium is indicated in the regular treatment of asthma where use of a combination product (long-acting beta-2-agonist and inhaled corticosteroid). Due to the added complexity, an analysis by type of medication was not performed as originally planned.

8.3. Comparison with findings from other validation studies

As far as we are aware this is the first study which assessed the metric properties of the ALMA tool in a different language and setting. A literature review has been conducted from PubMed, Mendeley, Scholar and Cochrane database, to find out if the ALMA tool has been used in other studies for further evaluation or as a review, RCTs on asthma self-management without any results. The tool was developed in Sweden (Kiotseridis et al., 2012) for first time. In the original study the ALMA showed good-sectional validity and the correlation between ALMA and ACQ was 0.71 with a test re-test reliability r=0.93. Alike, in this study the correlation between ALMA and ACQ was -0.70. and test-retest reliability using the Pearson correlation coefficient was at r=0.96. Also, authors did not mention the Cronbach's a results of the three domains (physical, environmental, mental) and from the nineteen questions five questions (medicine rapid relief, somethings, medicare, casualty ward, hospital) were excluded for better validity in relation with this study where were the results of the three domains separately mentioned and only two questions (casualty ward, hospital) were excluded showing that it must be a fourth domain in future studies. Although, a new instrument has been created and both studies show that the ALMA it is a tool which will provides a better way of asthma control level between Cypriots and Swedish asthmatic patients.

8.4. Asthma control and self-management

Studies from different countries (USA, UK, Sweden) have shown the importance of self-management in all chronic diseases and especially for asthmatics in improving knowledge and QoL(Mancuso C et al..2010). Asthma control depends on patients acquiring information and developing self-management skills to be applied in the long term (Kumar Arvind, Gershwin Eric M 2006). It has been shown that self-management lowers the burden of illness as perceived by patients with asthma and is a safe basis for intermittent treatment with inhaled corticosteroids (Thoonen BPA et al 2003).

In a recent Cochrane review (Lahdensuo, 1999) self-management of asthma in adults was compared with usual care in 22 studies. Self-management education reduced hospital admissions (odds ratio 0.57, 95% confidence interval 0.38 to 0.88), emergency room visits (0.71, 0.57 to 0.90), unscheduled visits to the doctor (0.57, 0.40 to 0.82), days off work or off school (0.55, 0.38 to 0.79), and nocturnal asthma (0.53, 0.39 to 0.72). Self-management programmes that contained a written action plan showing patients how to act in early

exacerbations showed a greater reduction in admissions to hospital than did programmes without a plan (0.35, 0.18 to 0.68). Cost effectiveness studies of self-management programmes for asthma have shown positive results, with cost benefit ratios between 1:2.5 and 1:11 the programme with the most favourable result saved $11.22 (£7) for every $1 (£1.60) spent (Lahdensuo, 1999).

Nonetheless, there have not been any studies to date among Cypriots asthmatics, to measure their level of asthma knowledge and self-management. Anecdotal evidence suggests that many patients perceive their asthma to be mild and well controlled despite reporting frequent symptoms (Dr. Papadopoulos Consultant in Respiratory Medicine Physician-Personal contact). Also, in many cases, patients with asthma and other chronic diseases do not perceive that working out a preventative strategy is worth the time and effort involved. (Kumar Arvind, Gershwin Eric M 2006). The extent to which asthmatics in Cyprus have low adherence to treatment guidelines and poor knowledge of the disease is not known. While education and written personal management plans may be used in clinical practise in Cyprus, this is not routine practice. Information and advice for asthma is available through leaflets and subscribed from specialist doctors during or after their examination. The effectiveness of patient education and asthma management plans have not been systematically assessed. The lack of a standardized audit and review tool in the Greek language may contribute further to the lack of a standard practice as well as research in this field.

Evaluation of the newly ALMA tool and validation of the subset of asthma control questions demonstrated that the items of asthma selected cover keys in an auditable structure for primary care asthma reviews (i.e. physical restrictions, environmental, mental and healthcare utilisation). These are important aspects when assessing patients with asthma, and the use of the ALMA tool will help to structure this evaluation. A core function of an asthma review is to assess control, and as we have shown good correlation with an established instrument, the (ACQ). While the ACQ focus exclusively on physical symptoms, the inclusion of a mental and environmental domain of self-management in the ALMA tool allows for an enhanced approach in self-management, and can be used both in research studies to measure self-management of asthma patients, as well as in clinical practice as an education tool.

The breadth of the questions in the ALMA tool and the pragmatic use in clinical practise suggest that it can form the basis of a structured review in primary care which may translate

into improved outcomes. Furthermore, the good correlation with the miniAQoL indicates that it can also be useful in assessing asthma control, which is a core function of an asthma review.

Daines L et al (2016) in their study mentioned the cost of that self-management for asthma which is an effective intervention that reduces unscheduled care, and improves asthma control. To implement optimal self-management, healthcare providers should take responsibility for providing necessary skills training for clinicians and ensuring the healthcare system values and embeds self-management support.

According to Kanfer and Gaelick-Buys (1991), an effective self-management education program should help the participants develop coping strategies, the ability to assess situations and anticipate behaviour outcomes and the ability either to avoid or manage new problems. The ALMA tool also provides a useful educational complement for both patients and doctors/ healthcare Nurses with data summaries the individual level. It can also be used on a regional level to give feedback on asthma care. Also, because of the Cypriot culture there have not been any studies to date among Cypriots asthmatics, to measure their level of asthma knowledge and self-management until yet and this study has shown that there is a new tool the ALMA tool which has been translated in Greek and it is ready to be used and help people to manage their asthma in every exacerbation time. The advance nurse practitioner (ANP) role is necessary for this kind of people and eventually in Cyprus we have create this role so it will be easier for asthmatic patients to be educated and handle their life with the ANP help. Cypriot asthmatic patients must feel glad for this invent with the hope of better results for the new generation.

9. Conclusion

This study provided some first-time information about the level of self-management among Cypriot asthma patients. More importantly, it assessed the validity and reliability, and thus usefulness, of an asthma self-management tool which can subsequently be used in clinical practice for educating, reviewing and monitoring self-management among asthmatic patients.

The ALMA showed good metric properties. It appears to be a reliable and valid tool which can be used as measure for asthma control and self-management in future descriptive or intervention research studies. Unlike ACQ, which focuses exclusively on physical symptoms, the ALMA is an enhanced tool since it includes mental and environmental aspects of asthma

self-management. It can also be used in clinical practise as a structured review tool in the context of the systematic assessment and monitoring of asthma control and self-management as well as an educational tool for Cypriot asthmatic patients. Providing a tool in Greek for Greek-Cypriot asthmatics patients and health professionals alike will highlight and promote the importance of structuring management plans. The use of this tool can offer asthmatic patients a structure approach in consultation, a standardized plan treatment/management of asthma and at the same time it can be used as an educational tool.

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Appendix I: Permissions to use the tools by the developers

RE: ACQ & AQLQ Greece Greek Penny Freeman <penny@qoltech.co.uk> 7 March 2016 at 13:26

To: Chris Livadiotis <livadiotis.c87@gmail.com> Cc: Jilly Styles <jill@qoltech.co.uk>

Dear Chris,

We are happy to provide the ACQ and AQLQ Greek translations for Greece and will post these to you at the address given. If you have a postcode, please do let me know as I want to ensure the package reaches you swiftly and safely.

With best wishes

Victoria Sayer
Assistant to Jilly Styles
QOL Technologies Ltd
20 Marcuse Fields Bosham
West Sussex
P018 BNA. UK

Telephone: + (O) 572124
Facsimile: + 44 (0) 1243 573680
email:penny@qoltech.co.uk

Permission to translate and use the ALMA tool in the Greek language/Cypriot setting

Alf Tunsäter alf.tunsater@med.lu.se 12 April 2016 at 15:10
To: Nicos Middleton <nicos.middleton@cut.ac.cy>, Hampus Kiotseridis <hampus.kiotseridis@med.lu.se> Cc: Chris Livadiotis <livadiotis.c87@gmail.com>, Leif Bjermer <leif.bjermer@med.lu.se>

Dear Dr Middleton,

Thank you very much for your letter. I am sorry for this late respons. We are very glad to hear that you want to translate, use and validate ALMA. You hereby get the pernission to use the ALMA tool in accordance to your letter. We wish Chris Livadiotis good luck in his MSc research dissertation and look forward to the research findings.

Yours sincerely

Alf Tunsäter

Appendix II: Approval by the Bioethics Committee

ΚΥΠΡΙΑΚΗ ΔΗΜΟΚΡΑΤΙΑ

ΕΘΝΙΚΗ ΕΠΙΤΡΟΠΗ ΒΙΟΗΘΙΚΗΣ ΚΥΠΡΟΥ

Αρ. Φακ.: ΕΕΒΚ ΕΠ 2016.01.87

Αρ. τη2„: 22809038/039

Αρ. Φαξ: 22353878

23 Ιουνίου 2016

Κύριο Λειβαδιώτη Chris Λαχανόκηπων 32

Κάτω Δευτερά

2450 Λευκωσία

Θέμα: «Evaluation ofthe psychometric properties ofthe Greek version ofALMA (Gr-ALMA)»

Αναφέρομαι στην αίτηση σας που παραλήφθηκε στις 17 Ιουνίου 2016 για το πιο πάνω θέμα, και επιθυμώ να σας πληροφορήσω ότι από τη μελέτη του περιεχομένου των εγγράφων που έχετε καταθέσει (καλυπτική επιστολή, ερευνητική πρόταση, έντυπο συγκατάθεσης, άδειες χρήσης ερωτηματολογίων και ερωτηματολόγια), που αφορούν την πιο πάνω έρευνα, έχω τη γνώμη ότι η εν λόγω έρευνα σας δεν χρήζει περαιτέρω βιοηθικής αξιολόγησης από την Εθνική • Επιτροπή Βιοηθικής Κύπρου (ΕΕΒΚ).

2. Παραμένει περαιτέρω ευθύνη δική σας η διεξαγωγή της έρευνας με τρόπο που να διασφαλιστεί η τήρηση της εμπιστευτικότητας και ανωνυμίας των συμμετεχόντων με βάση τον περί Επεξεργασίας Δεδομένων Προσωπικού Χαρακτήρα (Προστασία του Ατόμου) Νόμο του 2001 (Ν. 138(Ι)/2001) και με τις εκάστοτε τροποποιήσεις.

3. Σας ενημερώνουμε ότι για σκοπούς καλύτερου συντονισμού και αποφυγής επανάληψης ερευνών με το ίδιο θέμα ή/και υπό εξέταση πληθυσμό μέσα σε σύντομο σχετικά χρονικό διάστημα, η ΕΕΒΚ δημοσιεύει στην ιστοσελίδα της το θέμα της έρευνας, τον φορέα και τον υπό εξέταση πληθυσμό.

4. Νοείται ότι θα εξασφαλισθούν οι απαραίτητες άδειες από το Υπουργείο Υγείας για πρόσβαση στα δημόσια νοσηλευτήρια για διεξαγωγή της εν λόγω έρευνας.

5. Σας ευχόμαστε κάθε επιτυχία στη διεξαγωγής της έρευνάς σας.

Με εκτίμηση,

Δρ. Κωνσταντίνος Ν. Φελλάς Πρόεδρος
Εθνικής Επιτροπής Βιοηθικής Κύπρου

Κέντρο Υγείας Έγκωμης, Νίκου Κρανιδιώτη, 2411 Λευκωσία,
ΗλεκτρονΙΚό Ταχυδρ0Ι-Ιξί0.• Ιστοσελίδα: www.bioethics.gov.cy

:nbc@bioethics.gov.cy

Appendix III: Approval by the MoH Research Committee

ΚΥΠΡΙΑΚΗ ΔΗΜΟΚΡΑΤΙΑ ΥΠΟΥΡΓΕΙΟ ΥΓΕΙΑΣ

Αρ. Φακ. 5.34.01.7.2Ε Αρ. Πρωτ.: 0377/2016

7 Ιουλίου 2016

Προϊστάμενη Νοσηλευτικό Λειτουργό Γενικού Νοσοκομείου Λευκωσίας
Προϊστάμενη Νοσηλευτικό Λειτουργό Γενικού Νοσοκομείου Λεμεσού
Προϊστάμενη Νοσηλευτικό Λειτουργό Γενικού Νοσοκομείου Λάρνακας

Θέμα : Άδεια για διεξαγωγή ερευνών από την Επιστημονική Επιτροπή προώθησης Ερευνών του Υπουργείου Υγείας

Έχω οδηγίες να αναφερθώ στο πιο πάνω θέμα για να σας ενημερώσω πως η Επιστημονική Επιτροπή Προώθησης Ερευνών του Υπουργείου Υγείας έχει παραχωρήσει σχετική άδεια στον κο Chris Λειβαδιώτη, Νοσηλευτικό Λειτουργό, για διεξαγωγή έρευνας με τίτλο «Η Αξιολόγηση των Ψυχομετρικών ιδιοτήτων του εργαλείου ALMA στην ελληνική έκδοση

Διευκρινίζεται πως η συλλογή των στοιχείων θα πραγματοποιείται από τον ερευνητή, στον ελεύθερο του χρόνο.

Στη διάθεση σας για οποιεσδήποτε διευκρινήσεις.

(Χριστίνα Ιωαννίδου-Ευσταθίου) (Χριστίνα Ιωαννίδου-Ευσταθίου) για
Διευθυντή Νοσηλευτικών Υπηρεσιών

Κοιν. κος Chris Λειβαδιώτη, Νοσηλευτικό Λειτουργό

Προδρόμου 1 Χίλωνος 17 Υπουργείο Υγείας, 1448 Λευκωσία τηλ: 22605740 Φαξ: 22605528

Ιστοσελίδα:http://www.moh.gov.cy

Appendix IV: Approval by the Commissioner for the protection of personal data

ΚΥΠΡΙΑΚΗ ΔΗΜΟΚΡΑΤΙΑ

Αρ. Φακ.: 3.28.435

Αρ. τηλ.: 22818303

21 Ιουνίου 2016

Κύριο Chris Λειβαδιώτη

Λαχανοκήπων 32Α

2450 Κάτω Δευτερά

Λευκωσία

ΓΡΑΦΕΙΟ ΕΠΙΤΡΟΠΟΥ ΠΡΟΣΤΑΣΙΑΣ ΔΕΔΟΜΕΝΩΝ ΠΡΟΣΩΠΙΚΟΥ ΧΑΡΑΚΤΗΡΑ

Chairmanship of Cyprus Council of Europe November 2016 - May 2017

Présidence de Chypre Conseil de l'Europe novembre 2016 — mai 2017

Γνωστοποίηση Σύστασης και Λειτουργίας Αρχείου/Έναρξης Επεξεργασίας Δεδομένων για σκοπούς έρευνας του κ. Chris Λειβαδιώτη, νοσηλευτικός λειτουργός και μεταπτυχιακός φοιτητής στο Τεχνολογικό Πανεπιστήμιο Κύπρου, με τίτλο: «Evaluation of the Psychometric Properties of the Greek version of the AIMA (Gr-ALMA», με εθελοντική συμμετοχή με απαντήσεις σε ανώνυμα ερωτηματολόγια

Αναφέρομαι στην πιο πάνω Γνωστοποίηση που υποβλήθηκε στο Γραφείο Επιτρόπου Προστασίας Δεδομένων Προσωπικού Χαρακτήρα με ημερομηνία 20.6.2016, που αφορά το πιο πάνω Αρχείο, και έχω οδηγίες να σας πληροφορήσω τα εξής:

2.1. Αφού ελήφθη υπόψη η ιδιότητα σας ως νοσηλευτικού λειτουργού που εργάζεται ΤΑΕΠ του Γενικού Νοσοκομείου Λευκωσίας, στο οποίο θα διεξαχθεί η έρευνα καθώς και σε δύο άλλα κρατικά νοσοκομεία, συνεπώς δεσμεύεστε με καθήκον εχεμύθειας από τον Κώδικα Νοσηλευτικής Δεοντολογίας,

2.2. ότι η έρευνα σας είναι μεταπτυχιακού επιπέδου και η συλλογή και επεξεργασία των δεδομένων θα πραγματοποιηθεί αποκλειστικά για ερευνητικούς σκοπούς και ότι από τα ευρήματα της ενδεχομένως θα καταδείξουν αν το εν λόγω εργαλείο είναι κατάλληλο για να χρησιμοποιηθεί από τους επαγγελματίες υγείας για την βελτίωση ζωής των ασθενών,

2.3. ότι η συμμετοχή στην έρευνα θα είναι εθελοντική και τα υποκείμενα των δεδομένων θα ενημερώνονται και θα λαμβάνετε τη συγκατάθεση τους για την επεξεργασία των προσωπικών δεδομένων τους,

2.4. ότι θα διασφαλίζεται η τήρηση της ανωνυμίας και της εμπιστευτικότητας και θα είναι δυσχερής ο εντοπισμός/ταυτοποίηση των υποκειμένων των δεδομένων (τα ερωτηματολόγια θα είναι ανώνυμα και οι ηλικίες θα ληφθούν με εύρος ετών ανά δεκαετία), και τα έντυπα συγκατάθεσης που θα λαμβάνονται θα τηρούνται ξεχωριστά από τα απαντημένα ερωτηματολόγια, και τα απαντημένα ερωτηματολόγια θα εσωκλείονται σε φάκελο και ρίπτονται σε κουτί με μορφή κάλπης,

2.5. και αφού στο σημείο «Θ» έχετε περιλάβει μέτρα ασφάλειας και προστασίας των δεδομένων, 3. έχω οδηγίες να σας πληροφορήσω ότι η Γνωστοποίηση φαίνεται να είναι σύμφωνη με τις διατάξεις του άρθρου 7(1)(2) των περί Επεξεργασίας Δεδομένων Προσωπικού Χαρακτήρα (Προστασία του Ατόμου) Νόμων του 2001 μέχρι 2012 (Ν. 138(Ι)/2001 όπως τροποποιήθηκε με τους Ν. 37(Ι)/2003 και Ν. 105(Ι)/2012), στο εξής «ο Νόμος», και, ως εκ τούτου, έχει καταχωριστεί στο Μητρώο Αρχείων και Επεξεργασιών που τηρείο Επίτροπος δυνάμει των διατάξεων των άρθρων 7(4), 23(1)(γ) και 24(1)(α) του Νόμου.

4. Το πιο πάνω Μητρώο είναι προσβάσιμο στο κοινό, σύμφωνα με το άρθρο 24(2) του Νόμου.

(Μάριος Παπαχριστοδούλου) για Επίτροπο
Προστασίας Δεδομένων Προσωπικού
Χαρακτήρα

1, 2ος Όροφος, Ι 082 ΛΕΥΚΩΣΙΑ / τ.Θ. 23378, Ι 682 ΛΕΥΚΩΣΙΑ-ΚΥΠΡΟΣ, τηλ. +35722818456, Φαξ +35722304565
E-mail: commissioner@dataprotection.gov.cy, Webesite: http://www.dataprotection.gov.cy

Appendix V: ALMA -Active Life with Asthma

Please read carefully the following 19 statements. For each statement, circle the answer that best represents your case. There are no wrong and correct answers. It is important to answer all the questions.

1	I have tightness in the chest	Often	Sometimes	Rarely	Never
2	I have severe cough even when I do not have a cold	Often	Sometimes	Rarely	Never
3	Dust, pollen and animal fur make my asthma worse	Often	Sometimes	Rarely	Never
4	When it's cold outside, my asthma worsens and I find it difficult to breath	Often	Sometimes	Rarely	Never
5	I find it difficult to breath when I am exposed to cigarette smoke and strong odours	Often	Sometimes	Rarely	Never
6	When I get a cold, my asthma worsens and I find it difficult to breath	Often	Sometimes	Rarely	Never
7	I think about my asthma and worry	Often	Sometimes	Rarely	Never
8	Asthma affects my life more than I would want to	Often	Sometimes	Rarely	Never
9	I do not do as many things as I would like to because of my asthma	Often	Sometimes	Rarely	Never
10	I cough and have difficulty breathing when I walk or get tired	Often	Sometimes	Rarely	Never
11	I cough and have difficulty breathing when I do heavy (or intense) work	Often	Sometimes	Rarely	Never
12	I cough and have difficulty breathing when I participate in sports activities	Often	Sometimes	Rarely	Never
13	During sleep, I wake up with cough and difficulty breathing	Often	Sometimes	Rarely	Never
14	I have tightness in the chest when I breath	Often	Sometimes	Rarely	Never
15	I have asthma symptoms despite the fact that I take my medications as prescribed by my doctor	Often	Sometimes	Rarely	Never

16	My medications cause discomfort	Often	Sometimes	Rarely	Never
17	During the last year, I have attended the Accidents and Emergencies department because of my asthma	Yes	No		
18	During the last year, I have been admitted to hospital because of my asthma	Yes	No		
19	I use quick(rapid) relief medications	Never	Up to twice per week	More than two times per week	

Appendix VI: Ενεργό ζωή με άσθμα (ALMA – Active Life with Asthma)

Παρακαλώ διαβάστε τις παρακάτω 19 δηλώσεις προσεκτικά. Κυκλώστε για την κάθε μια ερώτηση την απάντηση που αντιπροσωπεύει καλύτερα τη δική σας περίπτωση. Δεν υπάρχει σωστή ή λάθος απάντηση. Είναι σημαντικό να απαντήσετε σε όλες τις ερωτήσεις.

1	Έχω σφίξιμο στο στήθος.	Συχνά	Κάποιες φορές	Σπάνια	Ποτέ
2	Έχω έντονο βήχα ακόμα και όταν δεν έχω κρυολόγημα.	Συχνά	Κάποιες φορές	Σπάνια	Ποτέ
3	Η σκόνη, η γύρη ή/και το τρίχωμα των ζώων επιδεινώνει το άσθμα μου.	Συχνά	Κάποιες φορές	Σπάνια	Ποτέ
4	Όταν έξω κάνει κρύο, το άσθμα μου χειροτερεύει και δυσκολεύομαι να αναπνεύσω.	Συχνά	Κάποιες φορές	Σπάνια	Ποτέ
5	Όταν εκτίθεμαι σε καπνό του τσιγάρου ή έντονες οσμές, δυσκολεύομαι να αναπνεύσω.	Συχνά	Κάποιες φορές	Σπάνια	Ποτέ
6	Όταν κρυολογήσω, το άσθμα μου χειροτερεύει και δυσκολεύομαι να αναπνεύσω.	Συχνά	Κάποιες φορές	Σπάνια	Ποτέ
7	Σκέφτομαι και ανησυχώ για το άσθμα μου.	Συχνά	Κάποιες φορές	Σπάνια	Ποτέ
8	Το άσθμα επηρεάζει τη ζωή μου περισσότερο απ' όσο θα ήθελα.	Συχνά	Κάποιες φορές	Σπάνια	Ποτέ
9	Δεν κάνω κάποια πράγματα που θέλω να κάνω λόγω του άσθματος μου.	Συχνά	Κάποιες φορές	Σπάνια	Ποτέ
10	Όταν περπατώ ή κουραστώ, έχω βήχα και δυσκολία στην αναπνοή.	Συχνά	Κάποιες φορές	Σπάνια	Ποτέ
11	Όταν εκτελώ κάποια έντονη εργασία, έχω βήχα και δυσκολία στην αναπνοή.	Συχνά	Κάποιες φορές	Σπάνια	Ποτέ
12	Όταν συμμετέχω σε αθλητικές δραστηριότητες, έχω βήχα και δυσκολία στην αναπνοή.	Συχνά	Κάποιες φορές	Σπάνια	Ποτέ
13	Κατά τη διάρκεια του ύπνου, ξυπνώ με βήχα και δυσκολία στην αναπνοή.	Συχνά	Κάποιες φορές	Σπάνια	Ποτέ

14	Έχω σφύριγμα στο στήθος όταν αναπνέω.	Συχνά	Κάποιες φορές	Σπάνια	Ποτέ
15	Παρά το γεγονός ότι παίρνω τη φαρμακευτική αγωγή όπως την καθόρισε ο ιατρός μου εξακολουθώ να έχω συμπτώματα άσθματος.	Συχνά	Κάποιες φορές	Σπάνια	Ποτέ
16	Η φαρμακευτική αγωγή μου προκαλεί δυσφορία.	Συχνά	Κάποιες φορές	Σπάνια	Ποτέ
17	Το τελευταίο χρόνο έχω καταφύγει στο Τμήμα Επειγόντων Περιστατικών λόγω ασθματικών συμπτωμάτων.	Ναι	Όχι		
18	Το τελευταίο χρόνο, έχω εισαχθεί το νοσοκομείο λόγω ασθματικών συμπτωμάτων.	Ναι	Όχι		
19	Χρησιμοποιώ φάρμακα ταχείας ανακούφισης.	Ποτέ	Έως 2 φορές την εβδομάδα	Πάνω από 2 φορές την εβδομάδα	

Appendix VII: ACQ-Asthma Control Questionnaire

ΕΡΩΤΗΜΑΤΟΛΟΓΙΟ ΓΙΑ ΤΟΝ ΕΛΕΓΧΟ ΤΟΥ ΑΣΘΜΑΤΟΣ ©
(GREEK VERSION)

ΚΩΔΙΚΟΣ ΑΣΘΕΝΟΥΣ: _____

ΗΜΕΡΟΜΗΝΙΑ: _____

Παρακαλώ απαντήστε τις ερωτήσεις 1 – 6.

Σκεφθείτε πώς ήσαστε την ΠΕΡΑΣΜΕΝΗ ΕΒΔΟΜΑΔΑ, και βάλτε σε κύκλο τον αριθμό της απάντησης που περιγράφει καλύτερα την κατάστασή σας.

1. Γενικά, την περασμένη εβδομάδα, πόσες φορές **ξυπνούσατε από το άσθμα σας** μέσα στη νύχτα;
   0 Ποτέ
   1 Σχεδόν ποτέ
   2 Λίγες φορές
   3 Αρκετές φορές
   4 Πολλές φορές
   5 Πάρα πολλές φορές
   6 Δεν μπορούσα να κοιμηθώ λόγω του άσθματος

2. Γενικά, την περασμένη εβδομάδα, πόσο **άσχημα ήταν τα συμπτώματα του άσθματός σας όταν ξυπνούσατε** το πρωΐ;
   0 Κανένα σύμπτωμα
   1 Πολύ ελαφρά συμπτώματα
   2 Ελαφρά συμπτώματα
   3 Μέτρια συμπτώματα
   4 Αρκετά σοβαρά συμπτώματα
   5 Σοβαρά συμπτώματα
   6 Πολύ σοβαρά συμπτώματα

3. Γενικά, την περασμένη εβδομάδα, πόσο **περιορισμένες ήταν οι δραστηριότητές σας** λόγω του άσθματός σας;
   0 Καθόλου περιορισμένες
   1 Πολύ λίγο περιορισμένες
   2 Λίγο περιορισμένες
   3 Μέτρια περιορισμένες
   4 Πολύ περιορισμένες
   5 Υπερβολικά περιορισμένες
   6 Τελείως περιορισμένες

4. Γενικά, την περασμένη εβδομάδα, πόσο **λαχάνιασμα** νιώσατε λόγω του άσθματός σας;
   0 Καθόλου
   1 Πολύ λίγο
   2 Λίγο
   3 Μέτριο
   4 Αρκετό
   5 Πολύ
   6 Πάρα πολύ

παρακαλούμε γυρίστε σελίδα

ΕΡΩΤΗΜΑΤΟΛΟΓΙΟ ΓΙΑ ΤΟΝ ΕΛΕΓΧΟ ΤΟΥ ΑΣΘΜΑΤΟΣ ©
(GREEK VERSION)

ΚΩΔΙΚΟΣ ΑΣΘΕΝΟΥΣ: _____

ΗΜΕΡΟΜΗΝΙΑ: _____

5. Γενικά, την περασμένη εβδομάδα, πόσο χρόνο **είχατε σφύριγμα στο στήθος**;

0 Ποτέ
1 Σχεδόν ποτέ
2 Λίγο από το χρόνο
3 Μέτριο από το χρόνο
4 Αρκετό από το χρόνο
5 Τον περισσότερο χρόνο
6 Συνέχεια

6. Γενικά, την περασμένη εβδομάδα, πόσες **εισπνοές** κάνατε κάθε μέρα **από το φάρμακο για γρήγορη ανακούφιση** (π.χ. Ventolin,/Bricanyl);

(Αν δεν είσαστε σίγουρος/η πώς να απαντήσετε αυτή την ερώτηση, παρακαλούμε ζητήστε βοήθεια)

0 Καμιά
1 1-2 εισπνοές τις περισσότερες μέρες
2 3-4 εισπνοές τις περισσότερες μέρες
3 5-8 εισπνοές τις περισσότερες μέρες
4 9-12 εισπνοές τις περισσότερες μέρες
5 13-16 εισπνοές τις περισσότερες μέρες
6 Πάνω από 16 εισπνοές τις περισσότερες μέρες

Να συμπληρωθεί από μέλος του προσωπικού της κλινικής

7. FEV_1προ-βρογχοδιασταλτικού: .....

FEV_1 αναμενόμενο:.....

FEV_1% αναμενόμενο:.....
(καταγράψτε τις τιμές πάνω στις γραμμές με τις τελείες, και βαθμολογήστε το FEV_1% αναμενόμενο στη διπλανή στήλη)

0 > 95% αναμενόμενο
1 95 - 90%
2 89 - 80%
3 79 - 70%
4 69 - 60%
5 59 - 50%
6 < 50% αναμενόμενο

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Appendix VIII: MiniAQoLQ-Mini Asthma Quality of Life Questionnaire

ΕΡΩΤΗΜΑΤΟΛΟΓΙΟ (ΤΥΠΟΠΟΙΗΜΕΝΟ) ΠΟΙΟΤΗΤΑΣ ΖΩΗΣ ΑΣΘΜΑΤΙΚΩΝ
(GREEK VERSION)
ΣΥΜΠΛΗΡΩΝΕΤΑΙ ΑΠΟ ΤΟΝ ΑΣΘΕΝΗ

ΚΩΔΙΚΟΣ ΑΣΘΕΝΟΥΣ _____

ΗΜΕΡ/ΝΙΑ _____

Συμπληρώστε **όλες** τις ερωτήσεις τοποθετώντας σε κύκλο τον αριθμό που περιγράφει καλύτερα την κατάστασή σας **κατά τις 2 τελευταίες εβδομάδες ως αποτέλεσμα του άσθματός σας.**

ΣΕ ΓΕΝΙΚΕΣ ΓΡΑΜΜΕΣ, ΠΟΣΟ ΧΡΟΝΟ ΚΑΤΑ ΤΙΣ 2 ΤΕΛΕΥΤΑΙΕΣ ΕΒΔΟΜΑΔΕΣ:

	Συνέχεια	Τον περισσότερο χρόνο	Αρκετό από το χρόνο	Κάποιο από το χρόνο	Λίγο από το χρόνο	Σχεδόν ποτέ	Ποτέ
1. Νιώσατε ΛΑΧΑΝΙΑΣΜΑ λόγω του άσθματος;	1	2	3	4	5	6	7
2. Νιώσατε να σας ενοχλεί ή χρειάστηκε να αποφύγετε τη ΣΚΟΝΗ του περιβάλλοντος;	1	2	3	4	5	6	7
3. Νιώσατε ΘΥΜΩΜΕΝΟΣ/Η ή/και ΑΠΟΓΟΗΤΕΥΜΕΝΟΣ/Η λόγω του άσθματος;	1	2	3	4	5	6	7
4. Νιώσατε ενοχλητικό ΒΗΧΑ;	1	2	3	4	5	6	7
5. ΦΟΒΗΘΗΚΑΤΕ ΜΗΠΩΣ ΔΕΝ ΕΙΧΑΤΕ ΔΙΑΘΕΣΙΜΑ ΤΑ ΦΑΡΜΑΚΑ ΤΟΥ ΑΣΘΜΑΤΟΣ;	1	2	3	4	5	6	7
6. Αισθανθήκατε κάποιο ΣΦΙΞΙΜΟ ΣΤΟ ΣΤΗΘΟΣ ή ΒΑΡΟΣ ΣΤΟ ΣΤΗΘΟΣ;	1	2	3	4	5	6	7
7. Νιώσατε να σας ενοχλεί ή χρειάστηκε να αποφύγετε τον ΚΑΠΝΟ ΑΠΟ ΤΑ ΤΣΙΓΑΡΑ του περιβάλλοντος;	1	2	3	4	5	6	7
8. Αντιμετωπίσατε ΕΜΠΟΔΙΑ ΣΤΟ ΝΑ ΚΟΙΜΗΘΕΙΤΕ ΚΑΛΑ ΤΗ ΝΥΧΤΑ ως αποτέλεσμα του άσθματος;	1	2	3	4	5	6	7
9. Νιώσατε ΑΝΗΣΥΧΟΣ/Η ΠΟΥ ΥΠΟΦΕΡΕΤΕ ΑΠΟ ΑΣΘΜΑ;	1	2	3	4	5	6	7

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ΕΡΩΤΗΜΑΤΟΛΟΓΙΟ (ΤΥΠΟΠΟΙΗΜΕΝΟ) ΠΟΙΟΤΗΤΑΣ ΖΩΗΣ ΑΣΘΜΑΤΙΚΩΝ
(GREEK VERSION)
ΣΥΜΠΛΗΡΩΝΕΤΑΙ ΑΠΟ ΤΟΝ ΑΣΘΕΝΗ

ΚΩΔΙΚΟΣ ΑΣΘΕΝΟΥΣ _____

ΗΜΕΡ/ΝΙΑ _____

ΣΕ ΓΕΝΙΚΕΣ ΓΡΑΜΜΕΣ, **ΠΟΣΟ ΧΡΟΝΟ ΚΑΤΑ ΤΙΣ 2 ΤΕΛΕΥΤΑΙΕΣ ΕΒΔΟΜΑΔΕΣ:**

	Συνέχεια	Τον περισσότερο χρόνο	Αρκετό από το χρόνο	Κάποιο από το χρόνο	Λίγο από το χρόνο	Σχεδόν ποτέ	Ποτέ
10. Είχατε ΣΦΥΡΙΓΜΑ στο στήθος σας;	1	2	3	4	5	6	7
11. Νιώσατε ενόχληση ή χρειάστηκε να αποφύγετε να βγείτε έξω λόγω ΚΑΙΡΙΚΩΝ ΣΥΝΘΗΚΩΝ Ή ΑΤΜΟΣΦΑΙΡΙΚΗΣ ΡΥΠΑΝΣΗΣ;	1	2	3	4	5	6	7

ΠΟΣΟ **ΠΕΡΙΟΡΙΣΜΕΝΟΣ/Η** ΗΣΑΣΤΕ **ΚΑΤΑ ΤΙΣ ΤΕΛΕΥΤΑΙΕΣ 2 ΕΒΔΟΜΑΔΕΣ** ΟΣΟΝ ΑΦΟΡΑ ΤΙΣ ΔΡΑΣΤΗΡΙΟΤΗΤΕΣ ΑΥΤΕΣ **ΩΣ ΑΠΟΤΕΛΕΣΜΑ ΤΟΥ ΑΣΘΜΑΤΟΣ ΣΑΣ;**

	Τελείως περιορισμένος	Πάρα πολύ περιορισμένος	Πολύ περιορισμένος	Μέτρια περιορισμένος	Λίγο περιορισμένος	Πολύ λίγο περιορισμένος	Καθόλου περιορισμένος
12. ΔΡΑΣΤΗΡΙΟΤΗΤΕΣ ΜΕΓΑΛΗΣ ΕΝΤΑΣΗΣ (όπως η βιασύνη, η άσκηση, το γρήγορο ανέβασμα της σκάλας, η άθληση)	1	2	3	4	5	6	7
13. ΔΡΑΣΤΗΡΙΟΤΗΤΕΣ ΜΕΤΡΙΑΣ ΕΝΤΑΣΗΣ (όπως το περπάτημα, οι δουλειές του σπιτιού, η κηπουρική, τα ψώνια, το ανέβασμα της σκάλας)	1	2	3	4	5	6	7
14. ΚΟΙΝΩΝΙΚΕΣ ΔΡΑΣΤΗΡΙΟΤΗΤΕΣ (όπως η ομιλία, το παιχνίδι με τα κατοικίδια/παιδιά, η επίσκεψη σε φίλους/συγγενείς)	1	2	3	4	5	6	7

ΕΡΩΤΗΜΑΤΟΛΟΓΙΟ (ΤΥΠΟΠΟΙΗΜΕΝΟ) ΠΟΙΟΤΗΤΑΣ ΖΩΗΣ ΑΣΘΜΑΤΙΚΩΝ
(GREEK VERSION)
ΣΥΜΠΛΗΡΩΝΕΤΑΙ ΑΠΟ ΤΟΝ ΑΣΘΕΝΗ

ΚΩΔΙΚΟΣ ΑΣΘΕΝΟΥΣ _____

ΗΜΕΡ/ΝΙΑ _____

ΠΟΣΟ **ΠΕΡΙΟΡΙΣΜΕΝΟΣ/Η** ΗΣΑΣΤΕ **ΚΑΤΑ ΤΙΣ ΤΕΛΕΥΤΑΙΕΣ 2 ΕΒΔΟΜΑΔΕΣ** ΟΣΟΝ ΑΦΟΡΑ ΤΙΣ ΔΡΑΣΤΗΡΙΟΤΗΤΕΣ ΑΥΤΕΣ **ΩΣ ΑΠΟΤΕΛΕΣΜΑ ΤΟΥ ΑΣΘΜΑΤΟΣ ΣΑΣ;**

	Τελείως περιορισμένος	Πάρα πολύ περιορισμένος	Πολύ περιορισμένος	Μέτρια περιορισμένος	Λίγο περιορισμένος	Πολύ λίγο περιορισμένος	Καθόλου περιορισμένος
15. ΔΡΑΣΤΗΡΙΟΤΗΤΕΣ ΠΟΥ ΣΧΕΤΙΖΟΝΤΑΙ ΜΕ ΤΗΝ ΕΡΓΑΣΙΑ (εργασίες που έχετε να κάνετε στη δουλειά*)	1	2	3	4	5	6	7

**Εάν δεν εργάζεστε ή δεν είστε αυτοαπασχολούμενος, αυτές είναι οι εργασίες που πρέπει να κάνετε τις περισσότερες ημέρες.*

ΚΩΔΙΚΟΣ ΤΟΜΕΑ:

Συμπτώματα: 1, 4, 6, 8, 10
Περιορισμός δραστηριοτήτων: 12, 13, 14, 15
Συναισθηματική λειτουργία: 3, 5, 9
Περιβαλλοντικά ερεθίσματα: 2, 7, 11

Appendix IX: Demographic, social and clinical characteristics

1. Φύλο Άντρας ☐ Γυναίκα ☐

2. Ηλικία 18-30 ☐ 30-40 ☐ 40-50 ☐ 50-65 ☐ 65 και ☐ άνω ☐

3. Επίπεδο εκπαίδευσης :Πρωτοβάθμια

Δευτεροβάθμια ☐

Πτυχίο ☐

Μεταπτυχιακό ☐

Άλλο ……

4. Καπνίζετε ΝΑΙ ☐ ΟΧΙ ☐

4.1. Αν ΝΑΙ πόσα χρόνια καπνίζετε; ……

4.1.1. Πόσα τσιγάρα καπνίζεται τη μέρα; ……

4.2. Αν ΟΧΙ καπνίζατε στο παρελθόν ΝΑΙ ☐ ΟΧΙ ☐

4.2.1. Αν ΝΑΙ, για πόσα χρόνια συνολικά καπνίζατε;……

4.2.2.Όταν καπνίζατε, πόσα τσιγάρα καπνίζατε την ημέρα; ……

5. Κληρονομικότητα Άσθματος ΝΑΙ ☐ ΟΧΙ ☐

6. Έχετε αλλεργία σε κάποιο φάρμακο:ΝΑΙ ☐ ΟΧΙ ☐

6.1. Αν Ναι τότε σε ποιο φάρμακο; ……

7. Έχετε κάποια σύνοδα νοσήματα τα οποία επηρεάζουν το άσθμα σας; (π.χ. Γαστροοισοφαγική παλινδρόμηση, χρόνια ιγμορίτιδα, ρινικοί πολύποδες, ρινική αλλεργία, λοίμωξη αναπνευστικού, ΧΑΠ -χρόνια αποφρακτική πνευμονοπάθεια, κ.τ.λ.) ΝΑΙ ☐ ΟΧΙ ☐

7.1. Αν Ναι αναφέρεται ……

8. Παίρνετε ως φαρμακευτική αγωγή κάποιο από τα ακόλουθα φάρμακα:

VENTOLIN neb ☐

ATROVENT neb ☐

MAGNESIUM neb ☐

Beclazone εισπνεόμενο ☐

Ventolin εισπνεόμενο ☐

Medrol χάπια ☐

Prednisone χάπια ☐

Xyzal χάπι ☐

Appendix X: Table of studies

Appendix IX: Authors/Date Country	Purpose	Sample/Description	Methodology	Results
Gibson G Peter et al (2002) Australia	To assess the effects of asthma self-management programmes, when coupled with regular health practitioner review, on health outcomes in adults with asthma	Randomised trials of self-management education in adults over 16 years of age with asthma.	Systematic review. Thirty-six trials, compared self-management education with usual care.	Self-management education reduced hospitalisations, emergency room visits, unscheduled visits to the doctor, days off work or school, nocturnal asthma and quality of life.
Marcano Belisaro J.S et al (2013)	Assess the effectiveness, cost-effectiveness and feasibility of using smartphone and tablet apps to facilitate the self-management of individuals with asthma.	Two RCTs with a total of 408 participants were included. Participants with clinician-diagnosed asthma in any care setting and individuals without a diagnosis of asthma only if they were a parent to, or caregiver for a patient with asthma were included	Systematic review	Overall, the results of this review are inconclusive

Gibson P.G et al (2002)	Assess the effects of asthma self-management programmes, when coupled with regular health practitioner review, on health outcomes in adults with asthma	Thirty six trials, which compared self-management education with usual care.	Systematic review	Self-management education reduced hospitalisations, visits at emergency department, unscheduled visits to the doctor, days off work or school, nocturnal asthma and improve quality of life.
Alzahrani Y.A et al (2016) Chicago	Examines the briefly used asthma control assessment tools	The tools included are ACT, ACQ, cACT, ATAQ,LASS	Systematic review	The most commonly utilized tools are the ACT, cACT, ACQ and ATAQ.
Jia C.E et al (2012) Australia	Explored the diagnostic performances of and statistically compared the ACT and ACQ	21 studies with 11.141 subjects assessed with the ACT and 12.483 assessed with the ACQ	Systematic review and meta-analysis	The ACT is preferable to the ACQ in clinical practise and the ACQ requires further cross-validatio

Barnes P.J et al (2014)	Summary of the use of ACQ in phase II, III, VI asthma trials. Comparisons between ACQ and other instruments.	87 articles have been identified	Comprehensive and systematic review	The analysis suggest that the ACQ ia a valid and robust measure for use
Juniper EF et al (2004)Canada, Sweden	1)To examine the measurement properties of three shortened versions of the ACQ and 2) to determine whether using the shortened version would alter the results of a clinical trial	552 adults completed the ACQ at baseline and after 13 and 26 weeks of treatment	Descriptive study,	Agreement betwee the original ACQ a the reduced versio was high (intraclass correlation coefficients: 0.94-0.99)
Wilson Sandra R et al (1993)	Excess morbidity and mortality due to asthma, aggravated by demonstrably poor patient self-management practices, suggest the need for formal patient education programs.	Compared changes in asthma symptoms, utilization of medical services, knowledge about asthma, metered-dose inhaler (MDI) technique, and self-management behaviours for 323 adults	Randomize clinical trial	Compared with the usual control, the self-management education programs were associated with significant improvements in control of asthma symptoms (reduced 'bother' due to asthma and increased symptom-free days)

Comment [NM1]: This does seem right – check again, It might have been part of an RCT, but the results you are reporting here refer to a descriptive study.

Newhouse N et al (2016) England	Determine the feasibility of a randomised controlled trials (RCT) answering the effects of an experience based website as a resource for the self-management of chronic asthma	148 participants randomised (73 intervention group)	`Feasibility. Single-blind RCT in 2 regions of England	Both groups showed improvement in health state or management of their condition with no significant differences between arms. No adverse effects
Juniper EF et al (2000) London, United Kingdom	Comparing the measurement properties of the clinic-completed Asthma Control Questionnaire with those of the Asthma Control Diary	50 adults with symptomatic asthma were required to have ACQ score >0,5 at enrolment	Observational study,9 wk.	Concordance between the questionnaire and diary was high (intraclass correlation coefficient [ICC] = 0.87). Both reliability (ICC: questionnaire = 0.90; diary = 0.86) and responsiveness (responsiveness index: questionnaire = 1.06; diary = 0.90; p = 0.005) were better with the questionnaire than with the diary
Tousman SA et al 2011	Design and implement an adult asthma self-management program	45 participants- 24 in the control group and 21 in the intervention group. Those in the intervention group participated in 7 weekly meetings (2	Randomized control design	Statistically significant interactions. (cognitive, psychological, behavioural p<0,001) 1.reducing asthma triggers 2.reading about asthma 3.peak flow monitoring

		hours once a week)		4.exercising 5.hand washing