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Focus and Scope

JMIR Research Protocols (ISSN 1929-0748) publishes peer-reviewed, openly accessible research ideas and grant proposals, study and trial protocols, reports of ongoing research, current methods and approaches. (Preliminary results from pilot studies, early results, and formative research should now be published in [JMIR Formative Research](#).) While the original focus was on the design of medical and health-related research and technology innovations, *JMIR Research Protocols* publishes research protocols, proposals, and methods *in all areas of medical and health research*.

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- Published protocols will receive a Registered Report Identifier which will facilitate publication of the subsequent results paper;

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Nico Bruining, PhD

Thoraxcenter, Department of Cardiology, Erasmus MC, Rotterdam, The Netherlands

Bio

Dr. Bruining is currently the head of the Department of Clinical and Experimental Information (CEI) processing and holds the position of assistant professor at the Erasmus MC within the Thoraxcenter. The CEI was started in 1969, and since then, it has developed and worked with computer systems to collect a variety of available cardiothoracic data such as monitoring systems and, consequently, signal processing, imaging and image analyses, databases and data exchange. Recently, many of these topics are covered in the so-called eHealth. His personal background has mostly been within interventional cardiology and cardiovascular imaging.

Research Focus

Dr. Bruining currently focuses on cardiovascular imaging and eHealth within cardiology.

Filip Drozd, PhD

Senior Researcher, National Network for Infant Mental Health, Regional Centre for Child and Adolescent Mental Health, Eastern and Southern Norway

Filip Drozd, PhD

Senior Researcher, National Network for Infant Mental Health, Regional Centre for Child and Adolescent Mental Health, Eastern and Southern Norway

Research Focus

Filip Drozd's research focus includes infant, child, and family mental health, implementation research, study protocols of RCTs, and evaluation of health information systems.

Bio

Dr. Drozd is concerned with the translation of research into practice, and the use of technology and research methods to work systematically for safer and more effective health and social services for infants, children, and their families.

Kate Eddens, PhD, MPH

Assistant Professor, Department of Health Behavior, University of Kentucky College of Public Health, USA

Bio

Dr. Eddens' research agenda focuses on increasing the reach and effectiveness of health communication strategies to connect underserved populations to cancer prevention and control services and solutions by utilizing social network analysis, word-of-mouth communication and marketing, unique social service channels, and innovative technology. She is currently developing tablet-based network data collection and visualization software that optimizes opportunities for technology to transcend issues of literacy by adapting to the user and facilitating important network connections.

Research Focus

Dr. Eddens' primary focus is in using egocentric social support and communication networks to understand how to reach people with effective information and persuade them to participate in cancer screening and prevention services. She is currently developing technology to facilitate this research and has found that showing people their social support and health communication networks has a powerful impact on how they perceive the amount of support they have in their lives. She is working towards building this as a clinical tool that can help guide the provision of social support services and resources throughout the cancer survivorship continuum as well. Other general areas of focus include social network analysis, technology development, using unique channels such as social services to reach people with cancer prevention and control information, health literacy, disparity and underserved populations, and health communication.

Peter Giacobbi Jr, PhD

Associate Professor, West Virginia University, USA

Research Focus

Peter Giacobbi Jr's research focus includes complementary and alternative medicine, behavioral medicine, and public health surveillance.

Bio

Dr. Giacobbi's work has focused primarily on behavioral interventions designed to increase exercise behavior. More recently, he has focused on multi-behavior interventions intended to simultaneously address multiple chronic disease risk factors.

Ciska Hoving, PhD

Assistant Professor, Health Communication in Health Care, Maastricht University, The Netherlands

Research Focus

Ciska Hoving's research focuses on the systematic development and testing of online lifestyle interventions and decision aids to be implemented in healthcare settings.

Bio

Dr. Hoving is an assistant professor of Health Communication in Healthcare Settings, aiming to conduct interdisciplinary research to support patients and health professionals to improve communication and self-management.

Ashish Joshi, PhD, MBBS, MPH

Associate Dean, School of Public Health, City University of New York (CUNY), USA

Research Focus

Ashish Joshi's focus includes human-centered design and development of health technology interventions, mHealth, population health dashboards, personalized health records, and health technology innovations.

Bio

Dr. Joshi is an applied population health informatics researcher of over a decade. His academic background in clinical medicine, public health, and health informatics provides him with a unique combination to connect these 3 disciplines. He has applied mobile and Internet-enabled multifaceted health technology interventions and innovations by translating research into practice in several global settings including India, the USA, Nigeria, Brazil, and Haiti. He has been funded by agencies including the US NIH, AHRQ, Department of Veteran Affairs, New York State and City Health Department, Bill and Melinda Gates Foundation, Ministry of Health, Brazil, Indian Council of Medical Research, Government of India, and several other private foundations and industries.

Arun Keepanasseril, MDS, MSc

Project Manager, Canadian Hemophilia Assessment and Resource Management System (CHARMS), McMaster University, Canada

Bio

Arun Keepanasseril is an eHealth specialist with a background in life sciences, specializing in knowledge reviews and advanced e-applications in hemophilia/bleeding disorders.

Andre Kushniruk, BA, PhD

School of Health Information Science, University of Victoria, Canada

Research Focus

Andre Kushniruk's research focuses on usability of health care information systems and technologies, methodologies, usability testing, technology-induced errors, HCI models, frameworks, and theories.

Bio

Andre Kushniruk conducts research in a number of areas including evaluation of the effects of technology, human-computer interaction and usability engineering in health care. His work is known internationally and he has published widely in the area of health informatics. He focuses on developing new methods for the evaluation of information technology and studying human-computer interaction in health care.

Christian Lovis, MD, MPH, FACMI

Professor and Chairman, Division of Medical Information Sciences, University Hospitals of Geneva (HUG), University of Geneva (UNIGE), Switzerland

Research Focus

Christian Lovis' work is mostly driven by using digitalization of data, information, and knowledge. His team's research focuses on three major fields: (1) clinical information systems: design and architecture, sustainability, and impacts; (2) data and knowledge-driven science: natural language processing, knowledge representation, semantics and interoperability, context awareness, advanced analytics, predictive, and decision support; and (3) human factors: advanced interactions, augmented reality, conversational, qualitative and quantitative evaluation, and ergonomics. Christian's own research is led by the desire to use medical information sciences to improve health, well-being, and knowledge in life sciences, with an MD thesis centered on natural language processing and large datasets to support physician's work. This is a theme that he has continued all through his career, to the big data and artificial intelligence era, to address the challenge of real-time usable integration of multisource, multimodal data with persistent semantics.

Bio

Christian Lovis is a Professor of Clinical Informatics at the University of Geneva and leads the Division of Medical Information Sciences at the Geneva University Hospitals. He is a medical doctor board certified in Internal Medicine with emphasis on Emergency Medicine and holds a Master's in Public Health from the University of Washington, WA. In parallel to medicine, he studied Medical Informatics at the University of Geneva under the supervision of Prof Jean-Raoul Scherrer. Christian developed and deployed the clinical information system at the university hospitals of Geneva, a consortium of all public in- and out-patient facilities of Geneva State, Switzerland. Christian is the author of more than 150 peer-reviewed papers in the field of Medical Informatics. He has occupied several positions in Medical Informatics organizations, such as Chair of the IMIA WG on Health Information Systems (HIS), President of the Swiss Medical Informatics, President of the European Federation of Medical Informatics, Vice-Chair of the Board of Directors of HIMSS. Christian is a Fellow of the American College of Medical Informatics and a founding member of the International Academy of Health Sciences Informatics. He has been heavily involved in the development and enforcement of the Swiss Federal Law for the Shared Patient Record.

Ilaria Montagni, PhD

Junior Researcher, Centre de Recherche Inserm - Université de Bordeaux U1219, France

Research Focus

Ilaria Montagni's focus includes digital health literacy, Internet and mental health, and health communication theories and practices.

Bio

Dr. Montagni has a PhD in epidemiology for psychiatry and psychology. She has expertise in communication in mental health and translational research for psychiatry and psychology and in Web knowledge brokering and policies for mental health.

John F Pearson, MD

Attending Anesthesiologist, Division of Clinical Informatics, Department of Anesthesia, Critical Care and Pain Medicine, Beth Israel Deaconess Medical Center & Harvard Medical School, USA

Caroline R Richardson, MD

Associate Chair of Research, Max and Buena Lichter Research Professor of Family Medicine
Co-Director, University of Michigan National Clinical Scholars Program
Department of Family Medicine, University of Michigan Medical School

Bio

Dr. Richardson is a physical activity and diabetes prevention researcher who emphasizes the importance of using low-cost and scalable approaches to promoting physical activity. She develops and tests behavioral internet-mediated interventions to increase physical activity, decrease weight, and prevent diabetes. Focusing on components of web-based interventions that are interactive and individually tailored, Dr. Richardson builds interventions that are more than just static informational websites. They incorporate objective monitoring of physical activity, individually tailored feedback and motivational messaging, and online social support to motivate and engage users. Automated, gradually incrementing and individually tailored step-count goals are assigned to participants based on program progress as they build up their endurance. Dr. Richardson was the Director of the Veterans Administration Diabetes Quality Improvement Initiative (QUERI) and conducted a multi-site implementation study of the Diabetes Prevention Program for veterans.

Dr. Richardson current serves as Associate Chair for Research Programs in the Department of Family Medicine. She currently serves as a member of the Institute for Health Policy and Innovation's Institute Leadership Team (ILT). In addition, she leads education and scholarship initiatives as Chair of the IHPI education committee and co-director of the IHPI Clinician Scholars Program (NCSP).

Travis Sanchez, PhD, MPH

Rollins School of Public Health, USA

Research Focus

Travis Sanchez's research interests include: disease surveillance evaluation, HIV/AIDS prevention, infectious disease, public health practice and sexual health/behavior

Bio

Dr. Sanchez received a Doctorate of Veterinary Medicine from the University of Georgia in 1994. After a veterinary internship at North Carolina State University, Dr. Sanchez practiced as an emergency veterinarian in the Metro Atlanta area until he returned to the Rollins School of Public Health at Emory University and received his Master of Public Health degree in International Health and Epidemiology in 2000. Dr. Sanchez began his public health career working for the Georgia Division of Public Health in the notifiable diseases epidemiology section and coordinated the state's district epidemiologist program. He came to CDC in 2001 and worked for the Surveillance Branch in the Division of HIV/AIDS Prevention and later for the newly created Behavioral and Clinical Surveillance Branch (BCSB) as a project officer for the National HIV Behavioral Surveillance System. In 2005, he became BCSB's Associate Chief for Science and served for extended periods as an Acting Team Leader and the Acting Branch Chief for BCSB. Dr. Sanchez participated in CDC's IETA program in Vietnam in 2005 and worked closely with CDC's Associate Director for Science in 2007 during a training detail. From 2008-2009 he was the Chief of the Epidemiology and Strategic Information Branch of the CDC-South Africa Office. From 2009-2011, Dr. Sanchez served as the Associate Chief for Science in the HIV Epidemiology Branch at CDC. In 2011 he took an associate professor appointment with the Rollins School of Public Health in the Department of Epidemiology.

John Torous, MD

Harvard Medical School, USA

Bio

John Torous, MD, is co-director of the digital psychiatry program at Beth Israel Deaconess Medical Center, a Harvard Medical School-affiliated teaching hospital, where he also serves as a staff psychiatrist and clinical informatics fellow. He has a background in electrical engineering and computer sciences and received an undergraduate degree in the field from UC Berkeley before attending medical school at UC San Diego. He completed his psychiatry residency at Harvard. Dr. Torous is active in investigating the potential of mobile mental health technologies for psychiatry, developing smartphone tools for clinical research, leading clinical studies of smartphone apps for diverse mental illnesses, and publishing on the research, ethical, and patient perspectives of digital psychiatry. He serves as editor-in-chief for of JMIR Mental Health, currently leads the American Psychiatric Association's work group on the evaluation of smartphone apps, and co-chairs the Massachusetts Psychiatric Society's Health Information Technology Committee. He is an assistant editor for The Harvard Review of Psychiatry and section editor for The Asian Journal of Psychiatry as well as Psychiatric Times.

John Torous, MD

Harvard Medical School, USA

Bio

John Torous, MD, is co-director of the digital psychiatry program at Beth Israel Deaconess Medical Center, a Harvard Medical School-affiliated teaching hospital, where he also serves as a staff psychiatrist and clinical informatics fellow. He has a background in electrical engineering and computer sciences and received an undergraduate degree in the field from UC Berkeley before attending medical school at UC San Diego. He completed his psychiatry residency at Harvard. Dr. Torous is active in investigating the potential of mobile mental health technologies for psychiatry, developing smartphone tools for clinical research, leading clinical studies of smartphone apps for diverse mental illnesses, and publishing on the research, ethical, and patient perspectives of digital psychiatry. He serves as editor-in-chief for of JMIR Mental Health, currently leads the American Psychiatric Association's work group on the evaluation of smartphone apps, and co-chairs the Massachusetts Psychiatric Society's Health Information Technology Committee. He is an assistant editor for The Harvard Review of Psychiatry and section editor for The Asian Journal of Psychiatry as well as Psychiatric Times.

Jing Wang, PhD, MPH, RN, FAAN

Professor and Vice Dean for Research, Hugh Roy Cullen Professor, UT Health San Antonio School of Nursing, San Antonio, TX, USA

Director, Center on Smart and Connected Health Technologies, UT Health San Antonio, San Antonio, TX, USA

Bio

Jing Wang's research uses mobile and connected technology to support seniors aging in place and to optimize behavioral lifestyle interventions and improve patient-centered outcomes in type 2 diabetes and obesity, especially among the underserved communities. Through interprofessional collaborations, her research also spans patient safety, usability evaluation on electronic health record systems, and health promotion in Mexican-American and Asian-American populations.

Research Focus

Aging in place, mobile health, connected health, telehealth, diabetes education, lifestyle interventions, living lab, self-regulation, behavior change, usability evaluation, clinical decision support, interprofessional education, patient-generated health data, patient reported outcomes.

Susan Woods, MD, MPH

President, Society for Participatory Medicine

Bio

Sue has broad healthcare experience spanning private and public sectors. Board certified in general internal medicine and health informatics. Sue is a design thinker who is passionate about effective health care communication, clinician-patient partnership and using innovative digital tools that improve care and the patient experience. She served as Director of Patient Experience for the Connected Care Office at the Veterans Health Administration, developing web and mobile apps for patients and clinicians and leading a national effort on patient generated data. Sue received her MD at Oregon Health Sciences University and public health degree at the University of Washington. Her research focuses on consumer use of health technology, health information transparency and promoting virtual care delivery. She has served on Boards at the Society for Behavioral Medicine and the Society for Participatory Medicine. Sue promotes participatory care and services that engage people and families in their health and their health care. As the founder of HiTech HiTouch, LLC, she advocates for full patient access to health records (OpenNotes), telehealth and eHealth adoption, universal broadband access and digital inclusion.

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Surveillance Systems

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Acceptance and Resistance of New Digital Technologies in Medicine: Qualitative Study

[Sabur Safi](#) , [Thomas Thiessen](#) , [Kurt JG Schmailzl](#)

JMIR Res Protoc 2018 (Dec 04); 7(12):e11072

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Non-randomized Protocols and Methods (ehealth)

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The Internet of Things in Health Care in Oxford: Protocol for Proof-of-Concept Projects

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JMIR Res Protoc 2018 (Dec 04); 7(12):e12077

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RCTs - Pilots/Feasibility Studies (non-eHealth)

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Efficacy of an Education Session by Pharmacists for Patients With Asthma: Protocol and Design of a Randomized Controlled Trial

Elida Zairina , Gesnita Nugraheni , Gusti NV Achmad , Arie Sulistyarini , Yunita Nita , Arief Bakhtiar , Muhammad Amin

JMIR Res Protoc 2018 (Dec 18); 7(12):e10210

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Serious Games for Improving Genetic Literacy and Genetic Risk Awareness in the General Public: Protocol for a Randomized Controlled Trial

Serena Oliveri , Renato Mainetti , Alessandra Gorini , Ilaria Cutica , Giulia Candiani , Nunzio Alberto Borghese , Gabriella Pravettoni

JMIR Res Protoc 2018 (Dec 18); 7(12):e189

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A Tailored Advice Tool to Prevent Injuries Among Novice Runners: Protocol for a Randomized Controlled Trial

Ellen Kemler , Vincent Goutteborge

JMIR Res Protoc 2018 (Dec 19); 7(12):e187

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Protocol

Efficacy of an Education Session by Pharmacists for Patients With Asthma: Protocol and Design of a Randomized Controlled Trial

Elida Zairina¹, PhD; Gesnita Nugraheni¹, MSc; Gusti NV Achmad¹, MSc; Arie Sulistyarni¹, MPharm; Yunita Nita¹, Dr; Arief Bakhtiar^{2,3,4}, MD; Muhammad Amin^{2,3,4}, MD, Prof Dr

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Abstract

Background: Asthma is a chronic disease that requires indefinite long-term therapy. Many approaches have been developed to enable people with asthma to live as normally as possible. In medication therapy management, pharmacists could play important roles in supporting the everyday life of asthmatic patients, such as by providing education therapy management to ensure that patients achieve optimal therapeutic outcomes. A good collaboration between health care practitioners and patients will produce a better system in terms of therapeutic management, which will lead to health care cost savings related to emergency visits. Although the Government has made various efforts to manage asthma in Indonesia, without commitment and support from both patients and health care professionals, the expected outcomes cannot be achieved.

Objective: This study aims to evaluate the effectiveness of an educational intervention provided by pharmacists compared with that of usual care.

Methods: A randomized controlled trial comparing usual care with an education session by pharmacists is underway. The intervention comprises a one-on-one education session of 60 minutes with a pharmacist comprising information regarding (1) asthma medication that has been used; (2) how to use asthma medication devices correctly; (3) asthma symptoms and how to prevent exacerbation of asthma; and (4) how to manage asthma triggers and environmental control measures. The primary outcome measure is change in asthma control, as measured using the Asthma Control Questionnaire. Secondary outcomes include changes in Asthma Quality of Life Questionnaire score, lung function, asthma-related health visits, days off from work or study, and oral corticosteroid use. Research assistants who are masked to the group allocation will collect outcome data at the baseline and every month for a 3-month period. Informed consent will be sought at enrollment and intention-to-treat analysis will be performed.

Results: This study was funded in January 2017 and ethical approval was obtained in June 2017. The enrollment was started in August 2017, and about 72 participants have been enrolled. First results are expected to be submitted for publication in 2019.

Conclusions: This is the first study to evaluate the effectiveness of a pharmacist-guided asthma education session compared with that of usual care in Indonesia. If it is proven effective, this intervention program could improve asthma self-management by patients, which may reduce risks of poorly controlled asthma. This intervention could also be implemented in addition to the current usual care for patients with asthma.

Trial Registration: Thai Clinical Trials Registry TCTR20171219001; <http://www.clinicaltrials.in.th/index.php?tp=regtrials&menu=trialssearch&smenu=fulltext&task=search&task2=view1&id=3068> (Archived by WebCite at <http://www.webcitation.org/73Ci5eKtv>)

International Registered Report Identifier (IRRID): DERR1-10.2196/10210

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KEYWORDS

asthma control; education session; pharmacist

Introduction

Asthma is a chronic disease that affects people of all ages worldwide. Uncontrolled asthma can restrict patients' daily activities and can place them at risk of death. According to the World Health Organization and Global Initiative for Asthma, as many as 300 million people worldwide, of different ages and races, are exposed to asthma; this number is predicted to increase to 400 million by 2025 [1]. Asthma is a health problem in both developed and developing countries [1-3]. Approximately 250,000 people die of asthma each year [3,4]. In 2007, asthma caused 3447 deaths in the United States—equivalent to approximately 9 people each day [5]. Death due to asthma is more common among adults than among children; it is also more common among women (2173) than among men (1274) [5]. In the United Kingdom, >10% of the adults exhibit asthma [6,7]. Although the proportion of population affected by asthma in Asian countries, including Indonesia, is lower than that in Europe or America, the proportion of elderly patients with asthma in Asian countries is quite high (1.3%-15.3%) [8]. Asthma can be controlled with appropriate therapeutic management. Patients with controlled asthma conditions can participate in normal activities and are not likely to experience fatal asthma symptoms [9].

Asthma is a chronic disease that requires indefinite long-term therapy. Various approaches are needed to optimize therapeutic treatments among asthma patients. Several studies in developed countries, such as the United States [10,11] and Australia [12-14], have showed that better health outcomes for asthma patients resulted from the following factors: adequate knowledge among asthma patients, regular monitoring of therapy, and high level of understanding among both health care professionals and patients regarding the disease management behavior. In Indonesia, asthma is one of the top 10 causes of morbidity and death, together with chronic bronchitis and emphysema [15]. In April 2007, observations in 5 provinces of Indonesia (North Sumatra, Central Java, East Java, West Kalimantan, and South Sulawesi) conducted by multiple chronic and degenerative disease subdivisions showed that, in general, asthma control efforts have not been effectively implemented; moreover, there is minimal availability of the equipment required for the diagnosis and management of asthma patients in health care facilities. In 1995, the prevalence of asthma in children was 12%; in 2008, results of the International Study of Asthma and Allergies in Childhood showed that asthma prevalence in 12-14-year-old children was 12.6% [16].

It is currently unknown how the implementation of pharmacist-guided education in asthma self-management might

affect asthma self-management in Indonesia as there has been limited research regarding the understanding and behavior of patients for the management of asthma. Therefore, the proposed study has been designed to determine the effectiveness of pharmacist-guided education for asthma patients in Indonesia. Because medications play important roles in successful management of chronic diseases, including asthma, the role of pharmacists' expertise is essential in the implementation of medication therapy management. Studies have shown that improved asthma control can be achieved if patients are involved in self-management, including self-monitoring of asthma symptoms or lung function, as well as when patients follow written asthma action plans while maintaining regular contact with their health care professionals [17].

This study aims to evaluate the efficacy of pharmacist-guided education sessions provided to patients with asthma compared with that of usual care. We hypothesize that the intervention group will demonstrate superior asthma control, as measured by changes in the Asthma Control Questionnaire (ACQ) scores, after 3 months from the baseline.

Methods

Study Setting

Participant recruitment is ongoing at the outpatient Departments of Pulmonology at Universitas Airlangga Hospital. The study has been approved by the human research ethics committee of Universitas Airlangga Hospital. All participants provide written informed consent at the time of enrollment.

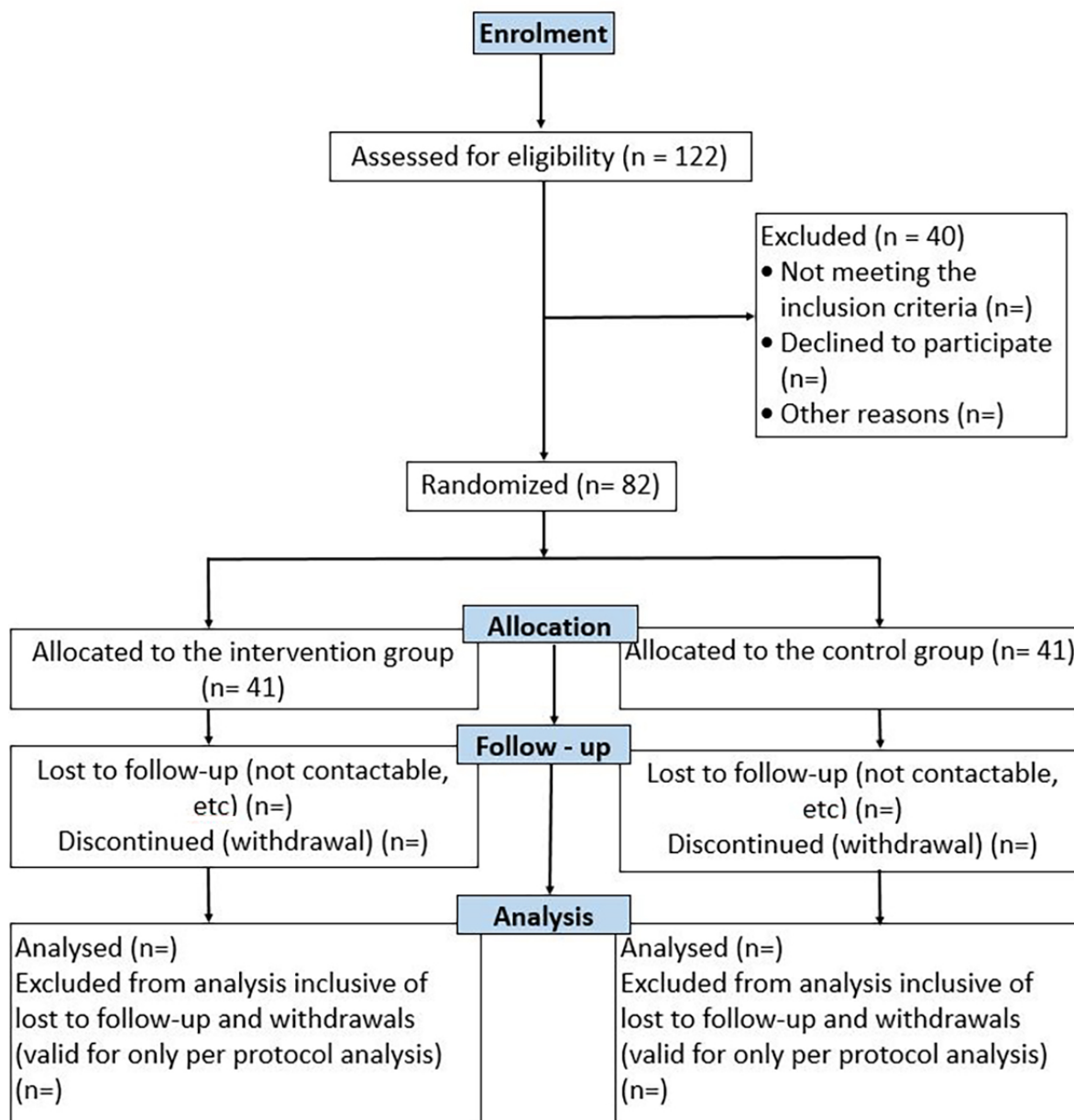
Study Design

This study is designed as a prospective, single-blinded, randomized controlled trial (Thai Clinical Trials Registry # TCTR20171219001); outcome assessors will be masked to group allocation at follow-up assessments. The flow of participants with the expected number is illustrated in Figure 1. The total duration of the study is 3-6 months, depending on the timing of the first visit and patient enrollment in the study. Both groups will be followed up for 3 months; the outcomes will be compared at 1, 2, and 3 months from the baseline to evaluate the efficacy of the intervention.

Inclusion and Exclusion Criteria

Eligibility for this trial includes patients with asthma who have used any regular medications for asthma within the previous 12 months, who are 18 years of age or older, and are able to communicate in Indonesian. Those who are unable or contraindicated to demonstrate the lung function with spirometer will be excluded.

Figure 1. Flowchart of study participants.



Trial Recruitment

The following methods of identification and recruitment of participants will be used in this study: First, the doctors will identify all patients with asthma visiting the outpatient Department of Pulmonology at Universitas Airlangga Hospital on the date of each patient’s clinic visit. The research assistants will approach potential participants and perform screening on the basis of the inclusion and exclusion criteria that were described earlier in this protocol. Then, participant explanatory statements and expression of interest forms will also be provided at the outpatient Department of Pulmonology at Universitas Airlangga Hospital, which has access to the relevant information. Potential participants will be asked to leave their contact details to allow one of the research assistants to contact them. Finally, if a patient agrees to participate, written informed consent will be sought.

Group Allocation

Recruited participants will be allocated to intervention or control group on a 1:1 basis. Allocation will be concealed using the sealed opaque envelope technique. Random blocks of 4 and 6 will be chosen, and random numbers will be generated using a random allocation software program [18] by an external researcher not involved in the study. Only this researcher will know the allocation sequence. At the time of recruitment, the researchers coordinating this study will open the numbered envelope and allocate each participant to the control (usual care) group or the intervention (education) group. The outcome assessors will be masked to participant group allocation during follow-up assessments.

Control and Intervention Group

Control: Usual Care Group

Participants allocated to the control group will receive usual medical care provided by the Department of Pulmonology and its health care professionals. This includes regular monthly visits, depending on each patient's asthma severity or complications. If, during follow-up, it becomes apparent that asthma control has deteriorated since the prior assessment (eg, using the asthma reliever ≥ 3 times per week or requiring an increased preventer dose), the participant and corresponding health professionals will be notified with the participant's permission.

Intervention: Education Group

Before the delivery of educational sessions to patients, pharmacists in this study will undergo training provided by a certified asthma educator (EZ). The trial evaluates an intervention involving pharmacists to deliver a *one-on-one* education session regarding (1) asthma medication that has been used; (2) how to use asthma medication devices correctly; (3) asthma symptoms and how to prevent exacerbation of asthma; and (4) how to manage asthma triggers and environmental control measures. A video that explains how to properly use asthma medications with a variety of devices will be shown to the intervention group. The intervention group will also be provided with an asthma booklet that explains how to correctly use asthma medication and avoid asthma triggers. One of the researchers will contact participants' health care professionals if any medication changes or unscheduled asthma-related visits are needed.

A written asthma action plan, consistent with the Global Initiative for Asthma guidelines, has been translated into the Indonesian language and will be used to design a participant-specific treatment plan based on the information obtained at the baseline. The asthma action plan contains instructions regarding which medications to take when feeling well, how to recognize worsening asthma, what to do when symptoms are worsening, and what to do in the event of an acute attack, including a first aid plan. The flow of the study is described in [Figure 2](#).

Outcome Measures

The primary outcome measure is change in asthma control, as measured by the Juniper ACQ [19]. Secondary outcomes include

changes in Juniper's Asthma Quality of Life Questionnaire score [20], lung function, Adherence to Refills and Medications Scales scores, asthma-related health visits, days off from work or study related to asthma, and oral corticosteroid use.

Data Collection and Follow-Up

ACQ scores, Juniper's Asthma Quality of Life Questionnaire scores, Adherence to Refills and Medications Scale scores, asthma-related health visits, asthma-related days off from work or study, oral corticosteroid use, and preventer or reliever use data will be collected at the baseline and at 1, 2, and 3 months from the baseline to allow comparisons. Identical data collection forms will be used for both groups. The assessors responsible for collecting outcome data at 1, 2, and 3 months will be masked to participant group allocation.

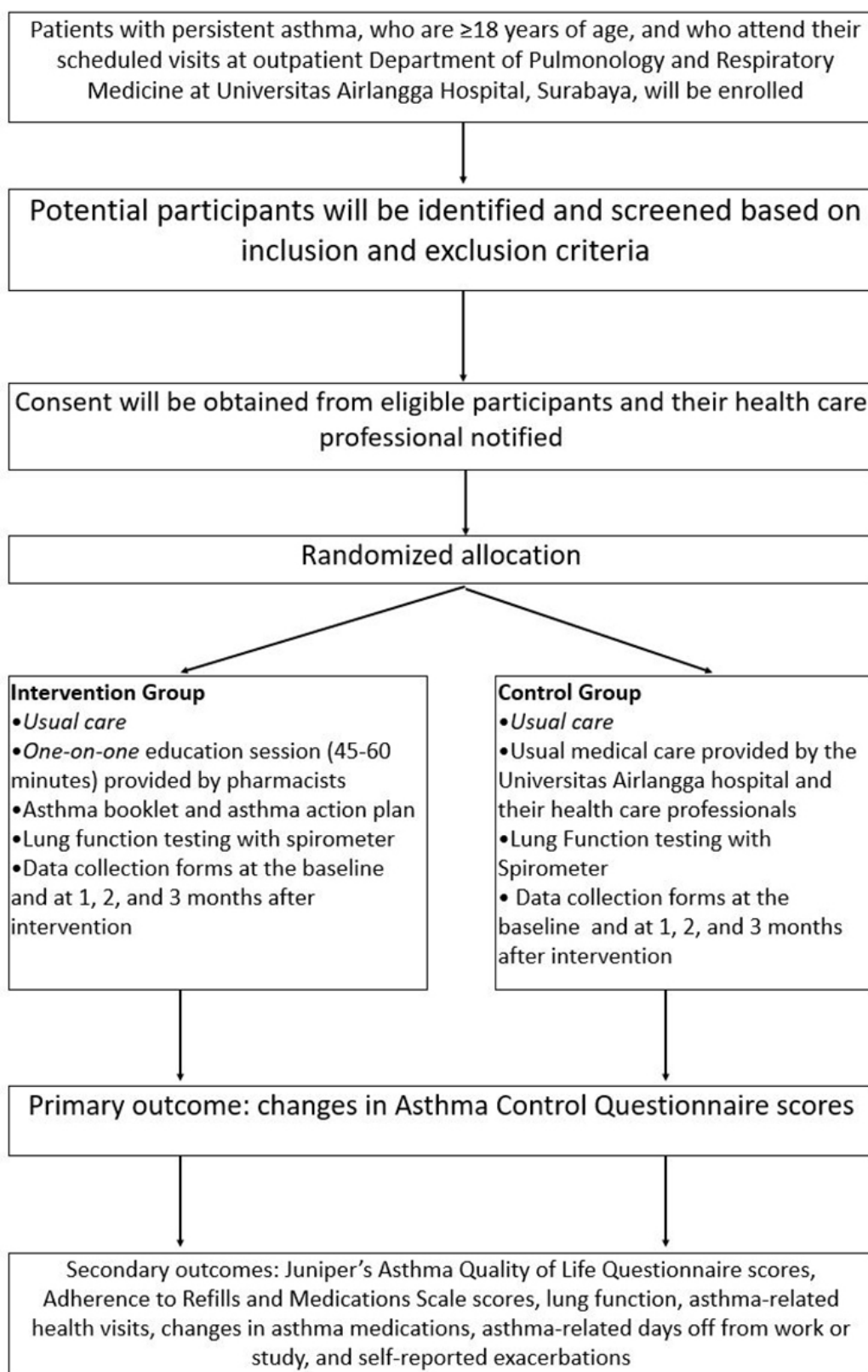
Sample Size

A sample size of 28 participants per arm using an estimated SD of 0.66 in ACQ scores will have 80% power (with 2-sided 5% significance level) to detect the minimal clinically important difference in the ACQ score of ≥ 0.5 between the groups [21,22]. To allow for 25% attrition, 41 participants will be recruited for each arm.

Data Analysis

The primary analysis will be performed in accordance with the intention-to-treat principle. The baseline characteristics of the 2 groups will be compared using Student's *t* test for normally distributed continuous variables, Mann-Whitney *U* test for nonnormally distributed continuous variables, and chi-square or Fisher's exact test (as appropriate) for categorical variables. Primary inferential analysis will be conducted using a mixed effects model for the intention-to-treat population. This model will include the treatment group and time as fixed effects, with an interaction between treatment and time to ascertain if the groups behave differently over time. Other demographic and clinical factors will be included as potential covariates in the mixed effects model. Comparisons will also be made of the following: the proportion of participants whose ACQ score improves >0.5 (minimal clinically important difference) over the study period, the proportion in whom asthma remains "not well controlled" (ACQ score ≥ 1.5), and those whose asthma is "well controlled" (ACQ score <1.5) at each time point [23]. Secondary outcomes will be summarized using descriptive statistics; analyses will be performed using the methods described above.

Figure 2. Flowchart of the study.



Results

This study was funded in January 2017 and ethical approval was obtained in June 2017. The enrollment was started in August 2017 and is currently ongoing; we plan to complete the

enrollment by December 2018. About 72 participants have been enrolled in the trial. First results are expected to be submitted for publication in 2019.

Discussion

This is the first study to evaluate the effectiveness of a pharmacist-guided asthma educational session compared with that of usual care in Indonesia. If it is proven effective, this intervention program could improve asthma self-management by patients, which may thus reduce the risk of poorly controlled asthma. This intervention could also be implemented along with the current usual care for patients with asthma. This trial is designed to evaluate an educational program for patients with asthma in order to enable better self-management for the control of their asthma. The individualized written asthma action plan designed for each patient provides clear guidelines in terms of actions to be taken in case of worsening asthma.

The proposed intervention has the potential to improve asthma outcomes by facilitating better asthma self-management. This may translate to reduced health care costs in the form of fewer asthma-related unplanned medical and emergency department

visits. If the intervention is efficacious, this could potentially influence clinical practice and health policy.

In order to improve health outcomes of asthmatic patients, solutions include regular monitoring as well as education regarding medication use and compliance. Most chronic diseases require patients to undergo therapy for an indefinite duration to meet therapeutic goals. Pharmacists have an important role in ensuring patients achieve optimal therapeutic outcomes. A pharmacist should be aware of this role, which involves providing adequate information to patients with chronic diseases. By building collaborations among health care professionals, a robust system of therapeutic management for patients with asthma will be established, enabling improvement of health outcomes and potentially reducing health care costs. Multiple efforts have been initiated by the government to manage asthma in Indonesia; however, without support and commitment from both health care professionals and community, the desired results cannot be achieved.

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Authors' Contributions

EZ conceived the project idea with input from GN, GNVA, and YN. EZ further developed the trial with input from all other authors: AB, MA, AS, GN, GNVA, and YN. EZ is managing the trial, while GN is organizing research assistant rosters. EZ wrote the first draft of this manuscript and refined it on the basis of comments and feedback from all other authors.

Conflicts of Interest

None declared.

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Abbreviations

ACQ: Asthma Control Questionnaire

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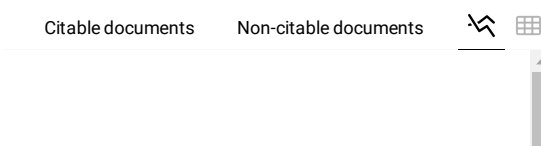
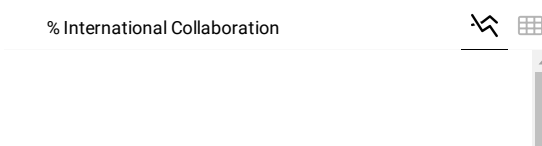
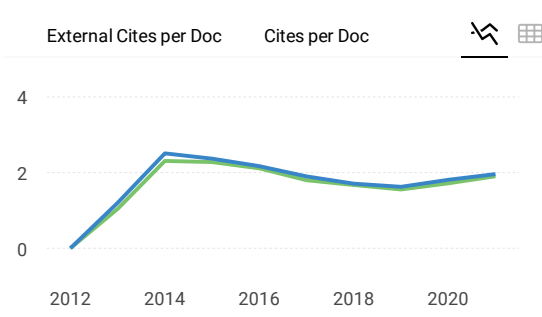
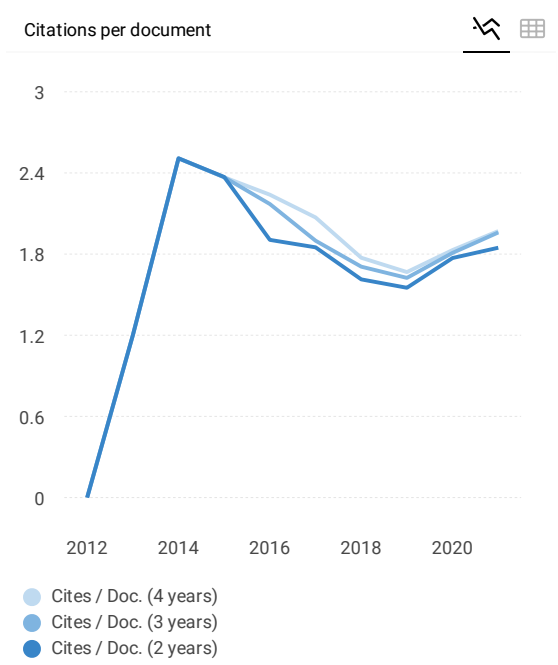
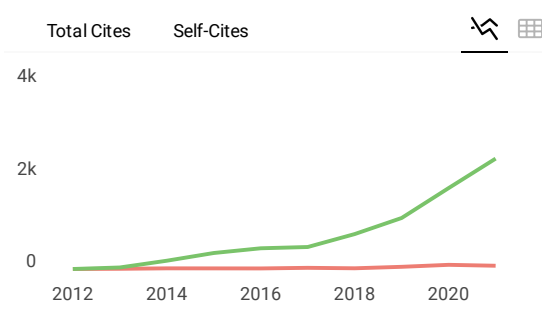
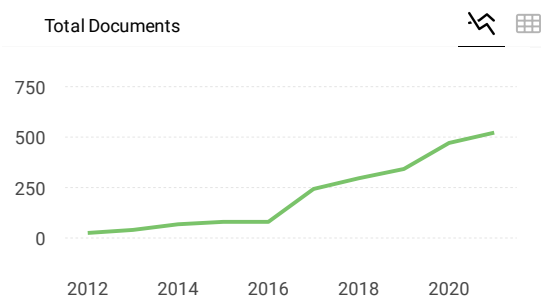
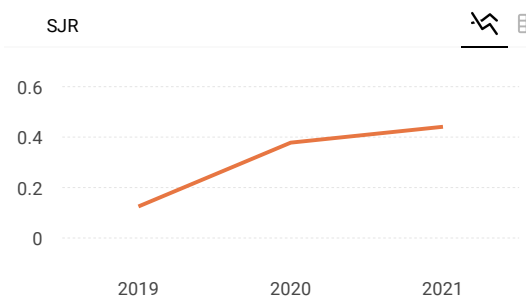
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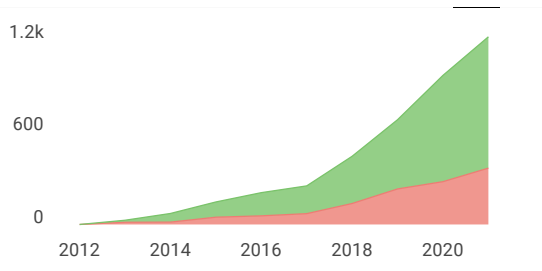
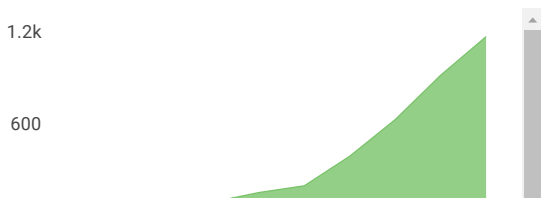
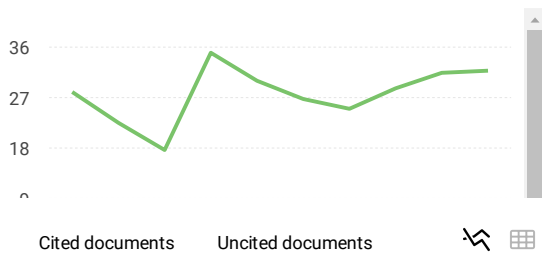
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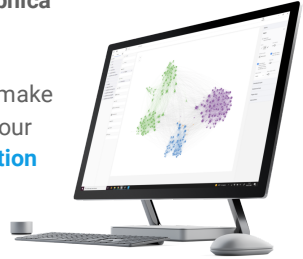
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