A randomized control trial of an asthma self-management program for adolescents in Taiwan: A study protocol

Tzu-Jung Tseng, RN PhD[a,*], Anne M. Chang, RN PhD FRCNA[b],
Chiung-Jung (Jo) Wu, RN DrHlthSc FACN[c,d,e,f]

[a] Department of Nursing, Chang Gung University of Science and Technology, No.2, Sec. W., Jiapu Rd., Puzi City, Chiayi County 61363, Taiwan, ROC
[b] Adjunct Professor, School of Nursing, Queensland University of Technology, Victoria Park Road, Kelvin Grove, Queensland, Australia
[c] Associate Professor, School of Nursing, Midwifery and Paramedicine, University of Sunshine Coast
[d] Visiting Fellow, School of Nursing, Queensland University of Technology, Brisbane, Australia
[e] Honorary Research Fellow, Royal Brisbane and Women's Hospital, Brisbane (RBWH), Australia
[f] Honorary Research Fellow, Mater Research Institute-University of Queensland (MRI-UQ), Brisbane, Australia

ARTICLE INFO

ABSTRACT

Uncontrolled asthma in adolescents can be explained by developmental changes and lack of priority for self-care activities. Limited reports on asthma self-management programs for adolescents to enhance prevention behaviors in Taiwan were found. The protocol paper presents a two-armed, randomized controlled trial aiming to test the effectiveness of a newly developed self-management program for 112 adolescents with asthma in Taiwan. The primary outcome is asthma self-efficacy. Data will be collected at baseline and the week 4. The findings of this study will determine the extent to which a self-management program for adolescents with asthma in Taiwan enhances asthma management self-efficacy, self-management activities in asthma prevention and management, and achievement of well-controlled asthma.

Trial Registration No: ACTRN12613001294741.

1. Introduction

Asthma has become one of most prevalent diseases and uncontrolled asthma has been a significant cause of death. The Global Asthma Report [1] reported approximately 334 million asthma sufferers, most of whom are between 10 and 14 years of age. Although the trend for hospital admission due to asthma and its related mortality have declined in higher-income countries, asthma prevalence continues to increase in some countries, such as Thailand and Taiwan [2]. A National Survey conducted in Taiwan demonstrated an increase of 2.6% in the prevalence of asthma among adolescents in 2005 and 7.3% in 2009 [3,4]. The data for 2009 also indicated that 11.5% of asthmatic adolescents had visited the emergency department for an asthmatic attack whiles 16.9% of adolescents with asthma reportedly ignored the symptoms of a flare up.

An effective self-management program may improve lung function and self-efficacy, decrease missed school days, and reduce activity limitations and emergency department visits [5]. Moreover, an ideal self-management program would be individually tailored for different populations; thus, a self-management program for adolescents must use age-appropriate strategies that appeal to adolescents [6].

Several studies have investigated asthma interventions programs for asthmatic children in Taiwan [7–9]. However, only one study was specifically designed for adolescents [10]. The results of these intervention programs for the enhancement of lung function and asthma control were inconsistent [7,10]. Also, there was a lack of theory-based intervention programs regarding behavior change [8,10]. Furthermore, an intervention that uses different strategies, communication styles, and encouragement to address individual needs for enhancing patients' self-care is necessary [11–13]. The impact of asthma on adolescents differs from those of other age group [6]. Therefore, the development of a specific asthma self-management program for adolescents is vital. There has been far less research on the effects of such programs on asthma prevention and management, including the monitoring of symptoms of asthma. Studies in Taiwan have stressed the importance of improving knowledge in order to promote health outcomes; however, knowledge alone is insufficient to change behaviors or provide better health outcomes [6,14], particularly among adolescents [15].

Fig. 1. Consolidated Standards of Reporting Trials (CONSORT) diagram presenting the studying enrolment both groups: intervention and control.
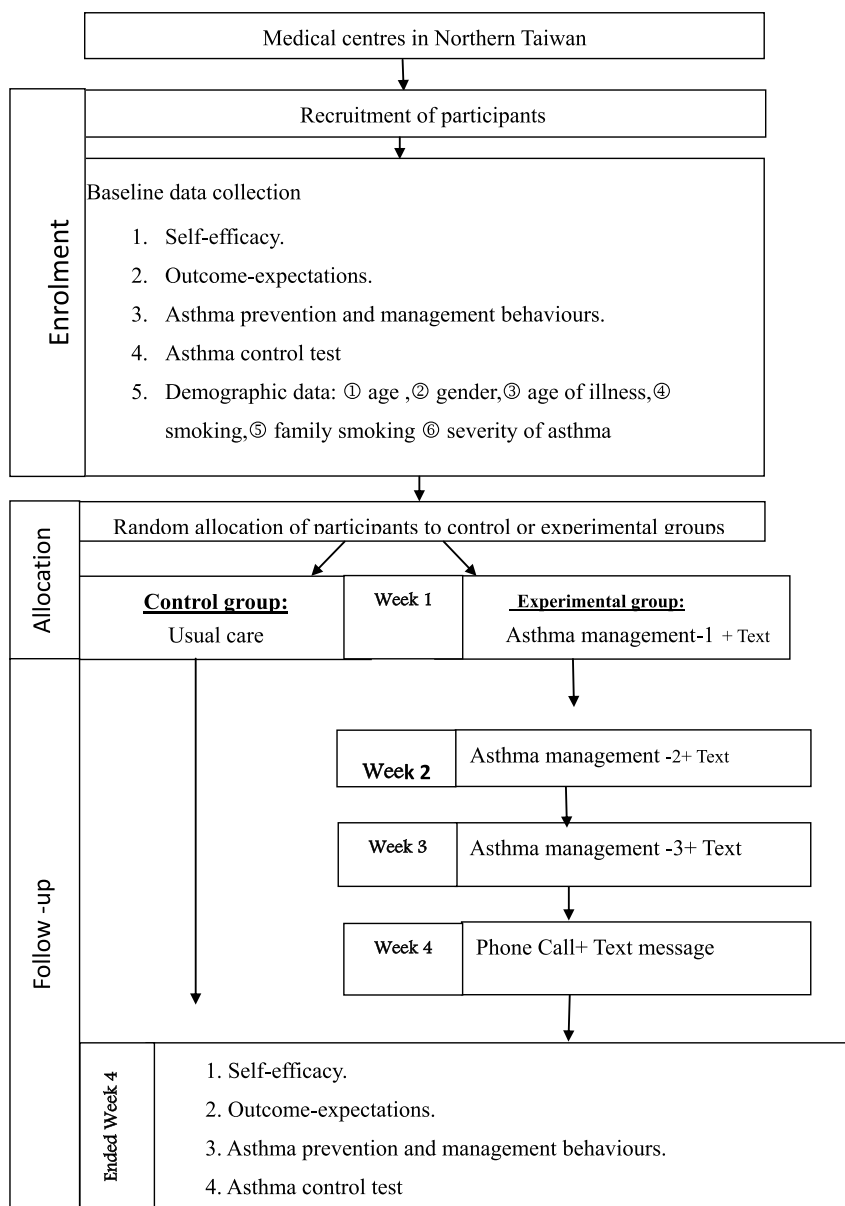

Fig. 1. Consolidated Standards of Reporting Trials (CONSORT) diagram presenting the studying enrolment both groups: intervention and control.

1.1. Study aims

The primary study aim is to develop an asthma self-management program for adolescents in Taiwan based on the self-efficacy model. The secondary aim is to assess the effectiveness of an asthma self-management program for improving asthma self-efficacy, self-management behaviors, outcome expectations, and control in adolescents.

2. Methods

2.1. Design

This two-arm, parallel-group, randomized control trial (Fig. 1) will be conducted in a pediatric clinic in the northern region of Taiwan. The control group will receive the usual asthma education by a registered nurse based on the guideline of Bureau of Health Promotion in Taiwan [8]. The usual asthma care will be provided by registered nurses at the hospital outpatient department. The participants in the experimental group will receive the newly developed asthma self-management program in addition to the usual asthma care.

2.2. Sample size

A total of 112 participants, with an anticipated attrition rate of 19.1% [16] will be recruited from the Chung Gung Medical Hospital, a 3506-bed facility that provides health services to approximately two million outpatients annually. The sample size is based on a two-tail significance level of 0.05, 80% power and at least a mean difference of 6.3 units (Standard deviation = 10.56) in the self-efficacy scores between the control and experimental groups [17].

2.3. Recruitment

The inclusion criteria are all adolescents aged 12–18years of age with asthma who attend the participating hospitals with a diagnosis of persistent moderate to severe asthma for at least 3 months as assessed by a physician, able to converse in Mandarin or Taiwanese, and with access to a mobile phone. Potential participants will be excluded if they are participating in another research or have a chronic comorbid condition.

2.4. Randomization, concealment and group allocation

Baseline data will be collected after informed consent is obtained. Computer-generated random numbers will be used by an independent statistician to allocate participants to either the intervention group or control group. Data collections will be done by a research assistant to avoid contaminations of data.

2.5. Intervention

2.5.1. Asthma self-management program for adolescents in Taiwan

The newly developed asthma self-management program will be provided by the researcher after the randomization. The content of the intervention program will be based on the four elements of the Expert Panel Report-3 (EPR-3) of the National Heart, Lung, and Blood Institute in the USA (2007). The strategies will be guided by Bandura's self-efficacy model (1997), and will consider adolescent developmental needs [18–20] including seeking support at school, and interactive communication.

The 4-week asthma self-management program will include three 30–40 min face-to-face question-and-answer sessions provided over a 3-week period, at the outpatient clinic in week 1, and in the participants' homes in weeks 2 and 3. The participants and their parents will be present at all three sessions, during which questions will be encouraged, as well as cooperation between parents and adolescents in managing asthma. At the first meeting, the researcher will provide a booklet on asthma. The researcher will also send two short text messages to the participants following the weekly face-to-face sessions to remind them to use their medication and provide encouragement and motivation. In Week 4, the participants in the experimental group will receive a phone call in addition to the text message, with the aim of identifying problems, providing support, helping to solve any problems in carrying out their asthma action plan, and revising the information already provided. After the 4-week intervention, a research assistant who is blinded to the group allocation will collect the data.

The validity of the intervention for adolescents in Taiwan was determined by experts in the field. A panel was established with members experienced in the care of patients with asthma and asked to review the content of the self-management program to determine its suitability for adolescents with asthma. Each expert rated the relevance of the content on a 5-point Likert scale, with 1 indicating totally unsuitable and irrelevant asthma care and 5 indicating totally suitable and relevant asthma cares. The score obtained ranged between 4 and 5. The content validity index for the intervention program was 100%, indicating the acceptance of the program.

2.6. Data collection

The demographic variables include gender, family smoking, the severity of asthma and the number of years since the diagnosis of asthma will be collected at baseline. The same outcome variables will be collected again by Asthma Self-Efficacy Index [16], Outcome expectancy [21], Asthma Self-Management index [16] and asthma control test [22] at the baseline and the end of week 4. As the original scales were only available in English, permission to translate the English versions into Chinese by using the translation and back-translation approach [23] were obtained. All the questionnaires were firstly using forward translation followed by back-translation (Chinese to English). The translations were then compared for equivalence with the original English version by monolingual and bilingual authors. Some items required little adjustment of the wording to ensure equivalence with the original English meaning.

Asthma self-efficacy will be measured by the Asthma Management Self-Efficacy index [16] comprising 14-items measured on a 6-point Likert scale (1 = I am sure I could not; 6 = I am very sure I could) to judge the confidence of respondents in completing the tasks. The validity if this tool was supported by factor analysis and there was sufficient reliability with a Cronbach's alpha valve of 0.84. Based on the recommendations of Bandura [14], the response scale for self-efficacy was modified to rate the degree of confidence in carrying out each of the asthma management actions on a scale of 1–10 (1 = no confidence at all, 10 = highly confident). This modification, which was approved by the original author, resulted in a total possible score ranging from 14 (low self-efficacy) to 140 (high self-efficacy).

Outcome expectancy will be measured by the treatment efficacy scale [24] and a section of the Caretaker Expectation Regarding the Management of Pediatric Asthma scale [25], with expert provided content validity for the former and established construct validity. Outcome-expectancy includes 8 items with a Cronbach's alpha valve of 0.84. The response items in the original version were measured on a 5-point scale, from 1 (not helpful) to 5 (extremely helpful). High outcome-expectation scores by adolescents with asthma indicate that they are more positive in anticipating good outcomes from engaging in the asthma self-management behaviors. As this proposed study is based on the self-efficacy theory, the researcher modified the response format, revised the content, and discussed these changes with the author via e-mail. The responses will now be rated from 1 (no confidence at all) to 10 (complete confidence), which is in accordance with the recommendation of Bandura [14]. The total score ranges from 8 (low outcome expectation) to 80 (high outcome expectation).

The outcome of asthma self-management behavior as measured using the Asthma Self-Management Indices, which test the different strategies and skills for adolescents to achieve well-controlled asthma, will be used to assess asthma self-management and prevention behaviors. Cronbach's alpha values of the Asthma Prevention Index and the Asthma Management Index are 0.71 and 0.51, respectively [16]. High scores indicate high levels of asthma prevention and management behaviors. The outcome will be measured by the Asthma Control Test (ACT) which assesses the current clinical control of asthma, preferably over a 4-week period. The contents of this test include frequency of daytime symptoms, limitation of activities, nocturnal symptoms/awakening, need for reliever or rescue treatment, and patients' feelings about their asthma control. Low scores on the ACT indicate uncontrolled asthma, whereas, high scores indicate well-controlled asthma. Internal consistency for the asthma control test was between 0.75 and 0.85 [22].

Severity of disease means levels of asthma severe. The asthma severity will be determined by frequency and intensity of asthma symptoms, including symptoms of asthma at night time and daytime, active limitation, exacerbation, and frequency of bronchodilator usage. For example, the participant who had asthma symptoms in daytime was less more 2 times a week, however, the participant awaked early morning or awakening because of symptoms of asthma three times a month. Level of severity was mild not intermittent. The severity of asthma will be measured by The Seattle Asthma Severity and Control Questionnaire (SASCQ) [26].

2.7. Data analysis

Data analyses will be undertaken using SPSS 21.0 (IBM Corp, Armonk, NY) with a significance level of 5% (two-tailed). The homogeneity between the control and experimental groups will be examined firstly. Chi-square test will be used to examine differences of categorical variables in the two groups. Test-test or Mann-Whitney U test will be used to examine participants' age and the number of years since the diagnosis of asthma years.

The dependent variables, such as self-efficacy, outcome expectancy, asthma prevention and management, as well as the Asthma Control test will be measured by the questionnaires [16,21,22]. These continuous variables will be summarized by mean and standard deviation or median with range, depending on the distributions. T-test or Mann-Whitney U test will be used to examine differences of self-efficacy,

outcome-expectancy, asthma prevention and management behaviors, and the Asthma Control Test, between the control and experimental groups. Pearson product-moment correlation coefficient or Spearman rank correlation coefficient will be used to examine the relationships among these variables. Repeated measure will be used to determine the effectiveness of the asthma self-management program to improve participants' outcomes of asthma self-efficacy, outcome expectancy, prevention and management behaviors, as well as the Asthma Control Test at Week 4.

2.8. Ethical considerations

This study has been approved by the Queensland University of Technology (QUT) Human Research Ethics Committee, Brisbane, Australia (Ethics No.140000006) and the Chang Gung Medical Foundation Institutional Review Board, Taiwan (CGMFIRB No.102–3787B). It has been prospectively registered with the Australia New Zealand Clinical Trials Registry (ACTRN12613001294741) on 11/21/2013.

3. Discussion

A randomized controlled trial is used to test the effectiveness of asthma self-management program for adolescents with asthma in Taiwan. This program was based on Bandura's self-efficacy model in improving adolescents' self-confidence and outcome expectancy in carrying out an asthma self-management program. Although numerous self-management programs have been used in the treatment of asthma, not all the programs have demonstrated effectiveness and understanding of asthma self-management behaviors in adolescents. Asthma self-management programs [16,27–30] developed for adolescents have been criticized because of their insufficient attention to adolescents' developmental needs [31], which may contribute to their lack of effectiveness in asthma self-management. The major focus in developing the asthma self-management program in the proposed study is firstly on adolescents' developmental needs. Secondly, this intervention program has been designed using Bandura's four sources of attaining self-efficacy as well as outcome-expectations, another component of Bandura's model for self-management programs. These two outcomes, in turn, will help to encourage adolescents who are willing to carrying out prevention and management behaviors for asthma symptoms thereby controlling and managing their condition. Strategies for delivering the asthma self-management program include a face-to-face meeting with age-appropriate communication styles, text-messages, and a telephone call. Also, outcome expectation, which has received minimal attention in past studies, is important for improving a person's intention to practice positive health behaviors such as the self-management of asthma by demonstrating the link between actions and outcomes. Furthermore, conducting this study in Taiwan will redress the lack of studies in this country; as many previous studies regarding asthma self-management in adolescents have been conducted in the USA. This program will contribute to the evidence base for such programs.

Declaration

None.

Competing interests

The authors declare that they have no competing interest.

Authors' contributions

TJT, AMC, and CJW contributed to the conception and design of the trail. TJT contributed to data collection and analysis, manuscript writing, as well as appraisal and editing of all revisions. CJW also contributed to data analysis, reporting, manuscript writing and appraisal and editing of the manuscript. AMC contributed to the study design and appraisal of the manuscript. All authors have reviewed and approved the final draft of this protocol paper.

Disclosure

None.

References

[1] I. Asher, N. Pearce, Global burden of asthma among children, Int. J. Tubercul. Lung Dis. 18 (2014) 1269–1278.

[2] K. Chua, S. Soh, S. Ma, B. Lee, On behalf of the Asia Pacific Association of Pediatric Allergy R, Immunology. Pediatric asthma mortality and hospitalization trends across asia Pacific relationship with asthma drug utilization patterns, World Allergy Organ. J. 2 (2009) 77–82.

[3] Health Promotion Administration, National Health Interventie Survey: Percentage Diagnosed with Asthma by Physician/nurse, (2005).

[4] Health Promotion Administration, National Health Interview Suvery : Percentage Diagnosed with Asthma by Physician/nurse, (2009).

[5] D.R. Liptzin, S.J. Szefler, Evolution of asthma self-management programs in adolescents: from the crisis plan to facebook, J. Pediatr. 179 (2016) 19–23.

[6] S. Holley, R. Morris, R. Knibb, S. Latter, C. Liossi, F. Mitchell, et al., Barriers and facilitators to asthma self-management in adolescents: a systematic review of qualitative and quantitative studies, Pediatr. Pulmonol. 52 (2017) 430–442.

[7] L.C. Chiang, J.L. Huang, K.W. Yeh, C.M. Lu, Effects of a self-management asthma educational program in Taiwan based on PRECEDE-PROCEED model for parents with asthmatic children, J. Asthma 41 (2004) 205–215.

[8] L.F. Tzeng, L.C. Chiang, K.C. Hsueh, W.F. Ma, L.S. Fu, A preliminary study to evaluate a patient-centred asthma education programme on parental control of home environment and asthma signs and symptoms in children with moderate-to-severe asthma, J. Clin. Nurs. 19 (2010) 1424–1433.

[9] H.-C. Lin, L.-C. Chiang, T.-N. Wen, K.-W. Yeh, J.-L. Huang, Development of online diary and self-management system on e-Healthcare for asthmatic children in Taiwan, Comput. Meth. Programs Biomed. 116 (2014) 299–310.

[10] S.H. Maa, Y.C. Chang, C.L. Chou, S.C. Ho, T.F. Sheng, K. Macdonald, et al., Evaluation of the feasibility of a school-based asthma management programme in Taiwan, J. Clin. Nurs. 19 (2010) 2415–2423.

[11] J. Mammen, H. Rhee, Adolescent asthma self-management: a concept analysis and operational definition, Pediatr. Allergy Immunol. Pulmonol. 25 (2012) 180–189.

[12] S.C. Cheng, A concept analysis of self-management of asthma in children, J. Nurs. 55 (2008) 73–78.

[13] S. Lindsay, S. Kingsnorth, Y. Hamdani, Barriers and facilitators of chronic illness self-management among adolescents: a review and future directions, J. Nurs. Healthcare. Chron. Illness 3 (2011) 186–208.

[14] A. Bandura, Health promotion by social cognitive means, Health Educ. Behav. 31 (2004) 143–164.

[15] C.L. Joseph, D.R. Ownby, S.L. Havstad, J. Saltzgaber, S. Considine, D. Johnson, et al., Evaluation of a web-based asthma management intervention program for urban teenagers: reaching the hard to reach, J. Adolesc. Health Official Publ. Soc. Adolesc. Med. 52 (2013) 419–426.

[16] J.M. Bruzzese, S. Kingston, B.J. Sheares, A. Cespedes, H. Sadeghi, D. Evans, Feasibility and preliminary outcomes of a school-based intervention for inner-city, ethnic minority adolescents with undiagnosed asthma, Patient Educ. Counsel. 85 (2011) 290–294.

[17] D.L. Pichora, Program Evluation: Knowledge, Attitudes, Self-efficact, Quality of Life in Adolescents with Asthma Ontario, Queen's University, 1997.

[18] L.J. Milnes, L. McGowan, M. Campbell, P. Callery, Developing an intervention to promote young people's participation in asthma review consultations with practice nurses, J. Adv. Nurs. 69 (2013) 91–101.

[19] B. Velsor-Friedrich, F. Vlasses, J. Moberley, L. Coover, Talking with teens about asthma management, J. Sch. Nurs. 20 (2004) 140–148.

[20] N. Kime, J. McKenna, L. Webster, Young people's participation in the development of a self-care intervention—a multi-site formative research study, Health Educ. Res. 28 (2013) 552–562.

[21] K. Zebracki, D. Drotar, Outcome expectancy and self-efficacy in adolescent asthma self-management, Child Health Care 33 (2004) 133–149.

[22] M. Schatz, C.A. Sorkness, J.T. Li, P. Marcus, J.J. Murray, R.A. Nathan, et al., Asthma Control Test: reliability, validity, and responsiveness in patients not previously followed by asthma specialists, J. Allergy Clin. Immunol. 117 (2006) 549–556.

[23] A.M. Chang, J.P.C. Chau, E. Holroyd, Translation of questionnaires and issues of

equivalence, J. Adv. Nurs. 29 (1999) 316–322.

[24] B. Bursch, L. Schwankovsky, J. Gilbert, R. Zeiger, Construction and validation of four childhood asthma self-management scales: parent barriers, child and parent self-efficacy, and parent belief in treatment efficacy, J. Asthma 36 (1999) 115–128.

[25] G. Holden, S.L. Wade, H. Mitchell, C. Ewart, Caretaker expectations and the management of pediatric asthma in the inner city: a scale development study, Soc. Work Res. 22 (1998) 51–59.

[26] T.S. Hallstrand, D.P. Martin, J.P. Hummel, B.L. Williams, J.P. LoGerfo, Initial test of the Seattle asthma severity and control questionnaire: a multidimensional assessment of asthma severity and control, Ann. Allergy Asthma Immunol. 103 (2009) 225–232.

[27] C.L.M. Joseph, E. Peterson, S.L. Havstad, C.C. Johnson, S. Hoerauf, S. Stringer, et al., A web-based, tailored asthma management program for urban African-American high school students, Am. J. Respir. Crit. Care Med. 175 (2007) 888–895.

[28] J. Berg, M.-J. Tichacek, R. Theodorakis, Evaluation of an educational program for adolescents with asthma, J. Sch. Nurs. 20 (2004) 29–35.

[29] S. Magzamen, B. Patel, A. Davis, J. Edelstein, I.B. Tager, Kickin' asthma: school-based asthma education in an urban community, J. Sch. Health 78 (2008) 655–665.

[30] S.F. Shaw, H.H. Marshak, D.T. Dyjack, C.M. Neish, Effects of a classroom-based asthma education curriculum on asthma knowledge, attitudes, self-efficacy, quality oflLife, and self-management behaviors among adolescents, Am. J. Health Educ. 36 (2005) 140–145.

[31] B.J. Srof, P. Taboas, B. Velsor-Friedrich, Adolescent asthma education programs for teens: review and summary, J. Pediatr. Health Care 26 (2012) 418–426.