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The effect of a self-care education package based on a mobile phone application (Allergy Yar) on sleepiness and medication adherence in adolescents with allergic rhinitis: Randomized Clinical Trial

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Abstract

Background

Allergic Rhinitis (AR) is an important risk factor for the exacerbation of asthma. In the case of poor control, it has a major impact on the quality of life, emotional well-being, daily activities, productivity and sleep. Therefore, this study was conducted with the aim of determining the effect of a self-care education package based on a mobile phone application on sleepiness and medication adherence in adolescents with AR.

Methods

This study is a clinical trial conducted on adolescents with AR referred to a clinic affiliated with Yasuj University of Medical Sciences (southwest of Iran) in 2024. A total of 69 eligible adolescents with AR were randomly assigned to two intervention and control groups by convenience sampling. Data were collected using a demographic information form, Epworth Sleepiness Scale (ESS), and Morisky Medication Adherence Scale (MMAS-8). The intervention group received the mobile phone software (Allergy Yar) and the control group received only usual care. The collected data were analyzed using SPSS version 26 software.

Results

Before the intervention, there was no significant difference in the ESS and MMAS-8 between groups ($p > 0.05$). However, after the intervention, a significant difference was observed in the outcomes between the intervention group and the control group ($p < 0.05$).

Conclusion

The self-care education package based on a mobile phone application was effective on sleepiness and medication adherence of adolescents with AR.

Trial registration:

https://irct.behdasht.gov.ir/ : IRCT20240424061558N1 (Registration Date: 2024-05-02)

Introduction

Allergic rhinitis (AR) is a chronic inflammatory disorder of the nasal mucosa characterized by immunoglobulin E-mediated allergic responses (1). Several risk factors have been identified, including

antibiotic use, air pollution, exposure to animals, parental smoking, and intense physical activity in adolescents (2).

The incidence of AR peaks between the second and fourth decades of life and is a known risk factor for asthma development (3). One study reported that the prevalence of AR among adolescents ranged from 4.5% to 45.1% (4). The prevalence of AR in Iran was reported to be 28% among adolescents, impacting 27% of boys and 23% of girls (5).

Although AR was previously considered a minor condition, inadequate management can significantly affect quality of life, sleep patterns, daily activities, and overall productivity, including academic and occupational performance (6). Pharmacological treatment is a primary approach to disease management, and the selection of therapy depends on factors such as the patient's preferences and capabilities, symptom severity, treatment response, and the impact on productivity and sleep (7). The impact of sleep disturbances in individuals with respiratory allergies has been emphasized by international AR and its Impact on Asthma Association (ARIA) guidelines, leading to new classification of the disease (8). Non-adherence to prescribed medications can exacerbate nocturnal symptoms and lead to further sleep disturbances (9).

Medication adherence remains an overlooked aspect of AR management, often contributing to suboptimal treatment outcomes (10). Medication adherence is an important part of patient care and is essential for achieving therapeutic goals (11). Several underlying factors influence medication non-adherence, including disease-related variables, patient characteristics, treatment regimens, and the doctor-patient relationship (12). A study revealed found that only 9.9% of patients with AR adhered fully to prescribed corticosteroids, with lower educational levels identified as a contributing factor (13). Studies indicate that failure to adhere to treatment regimens is associated with poor self-care practices (14).

Self-care encompasses actions undertaken by individuals with chronic diseases to manage their condition outside formal healthcare settings as part of their daily lives (15). Adolescence is crucial period for fostering self-care behaviors and transitioning disease management responsibilities to young patients (16). In contemporary healthcare, technological advancements have facilitated self-care strategies, with mobile devices emerging as widely adopted tools (17). Mobile health applications have the potential to empower patients, enhance engagement in disease management, transform healthcare delivery into a more patient-centered and decentralized model, and assist healthcare professionals in providing more effective treatment (18).

Despite the increasing integration of technology into healthcare, limited research has explored the role of digital interventions in AR management. A study by Menditto et al. revealed that only 11.28% of mobile application users adhered to their prescribed medications, while 69.05% exhibited non-adherence (19). Furthermore, Leger et al. reported that 73.5% of adults and 65.8% of children with AR experienced sleep disturbances (20). Similarly, Poachanukoon et al found that among children aged 6–15 years, 86.2% had persistent rhinitis, 63.1% presented with moderate to severe disease, and nasal obstruction was the

most commonly reported symptom (66.2%). Patients with AR experienced significant sleep disturbances, including snoring, sleep apnea, restlessness, night sweats, mouth breathing, dry throat, morning headaches, daytime fatigue, and difficulty waking up (21).

A study by Glattacker et al. which assessed the effectiveness of a mobile application in patients with pollen-induced AR, demonstrated improvements in quality of life, disease-related knowledge, and self-efficacy (18). A review of multiple studies highlights that adolescents with AR exhibit low medication adherence, often accompanied by sleep disturbances. Given the widespread acceptance of mobile technologies among adolescents, mobile health applications present a viable tool for enhancing disease management and treatment adherence in this population. Therefore, this study aimed to determine the effect of a self-care education package based on a mobile application (Allergy Yar) on sleepiness and medication adherence in adolescents with Allergic Rhinitis.

Methods

Design and eligibility:

This study is a clinical trial conducted on adolescents with AR referred to a clinic affiliated with Yasuj University of Medical Sciences (southwest of Iran). Sampling and data collection were conducted from May 2024 to November 2024. A total of 69 adolescents with AR were randomly assigned to either the intervention group (n = 36) or the control group (n = 33) using convenience sampling (Fig. 1). The study is registered in the Iranian Clinical Trials Registry under the code IRCT20240424061558N1 (Registration Date: 2024-05-02)

.The inclusion criteria were as follows: Age between 11 and 19 years, Diagnosis of AR, Possession of a mobile phone with access to a smartphone, Ability to read and write, Consent to participate in the study, A score of 9 or higher on the Epworth Sleepiness Scale and A score of less than 6 on the Morisky Medication Adherence Scale. The exclusion criteria included:Presence of other chronic diseases and Diagnosis of cognitive disorders.

Ethical Considerations:

This study was approved by the Research Ethics Committee of the Vice-Chancellor of Research and Technology of Yasuj University of Medical Sciences under the registration code IR.YUMS.REC.1403.008. Prior to the intervention, all participants received a detailed explanation of the study objectives, and written informed consent was obtained. Confidentiality of the collected data, voluntary participation, and the right to withdraw at any stage were emphasized throughout the study.

Measurement:

The **Demographic questionnaire** collected demographic characteristics and clinical information of adolescents and parents.

The **Epworth Sleepiness Scale (ESS)** developed by Johns, is an 8-item instrument employing a four-point Likert scale to evaluate patients' general daytime sleepiness levels (22). Sadeghniiat Haghighi et al. established the psychometric properties of the Persian version in an Iranian population, demonstrating satisfactory internal consistency (Cronbach's α = 0.79), excellent test-retest reliability (ICC = 0.84), and significant predictive validity (23).

The **Morisky Medication Adherence Scale (MMAS-8)** was originally developed by Morisky et al. to assess treatment compliance in patients with hypertension. This 8-item unidimensional instrument has since been validated for use in a variety of disease conditions. The scale is characterized by its simple and understandable items, making it particularly suitable for populations with limited health literacy(24). The Persian version of the scale demonstrated acceptable reliability, with a Cronbach's α = 0.69, and exhibited good test-retest reliability, indicating satisfactory repeatability and consistency (25).

Intervention:

In this study, the intervention group was provided with the "Allergy Yar" mobile application and instructed to install it on their smartphones. The control group received standard education and routine care. At baseline (T0), both groups completed the demographic characteristics form, the Epworth sleepiness Scale (ESS), and the Morisky Medication Adherence Scale (MMAS-8). Data collection was conducted again on Day 15 (T1) and at the end of the intervention (T2) using the same assessment tools. The intervention lasted for 30 days for each participant.

The "Allergy Yar" mobile application was developed using Android Studio and the React Native framework software. The conceptual model of the application was designed based on an object-oriented approach, incorporating scenario-based modeling and diagram visualization. The application was developed in both Persian and English and is available on the Iranian app store, Myket.

The application consists of five main sections:

1. Educational Content – Provides information on medications, AR, sleep disturbances, and medication adherence, sourced from reliable medical references.
2. Allergy Diary – Designed using a visual analog scale (VAS) to allow patients to self-report and record symptoms (26).
3. Medication Reminder – Allows users to enter prescribed medications, with a mobile phone alarm set to remind them at scheduled times.
4. Allergy Memories – A feature for users to track their allergy experiences.
5. Entertainment Section – Includes digital games to enhance user engagement and encourage continuous app usage.

Sample size calculation:

The required sample size was calculated using G Power software, considering a type I error (α) of 0.05, a 95% confidence level, a type II error (β) of 0.2, a statistical power of 80%, and an effect size of 0.7. The estimated sample size per group was 34 participants, with an additional 10% allowance for dropout, resulting in a final sample size of 74 participants.

Results

In the present study, 69 adolescents aged 11 to 19 years with AR were randomly assigned to two groups: the intervention group (n = 36) and the control group (n = 33). The mean age of participants in the intervention group was 16.55 ± 2.00 years, while in the control group, it was 15.78 ± 2.65 years, with no statistically significant difference (p = 0.17). A summary of the demographic characteristics of the participants is provided in Table 1 significant differences were observed between the two groups in terms of demographic variables (p > 0.05), indicating that the groups were comparable at baseline.

Table 1
Baseline demographic information of the study population

Demographic variable		**Mean ± std. deviation/ number(percent)**		**P value**	**Test statistic**
		test	**control**		
Age*		16.55 ± 2.00	15/78 ± 2.65	0.17	1.36
Sex**	Male	19(52.8)	18(54.5)	0.88	0.02
	Female	17(47.2)	15(45.5)		
Education***	Middle	10(27.8)	8(24.2)	0.43	1.68
	Secondary	17(47.2)	12(36.4)		
	University	9(25.0)	13(39.4)		
Family history of AR**	Yes	18(50.0)	21(63.6)	0.36	0.80
	No	18(50.0)	12(36.4)		
Family history of smoking**	Yes	26(72.2)	11(33.3)	0.003	8.96
	No	10(27.8)	22(66.7)		
Birth order***	First born	14(38.9)	17(51.5)	0.57	1.11
	Second born	18(50.0)	13(39.4)		
	Third born & more	4(11.1)	3(9.1)		

*Independent Samples T-Test, ** Fishers Exact Test, *** Chi-Square Test

Intra-group analysis revealed a statistically significant difference in the mean sleepiness score and medication adherence within the intervention group across the three time points: before the intervention, on day 15, and after the intervention ($p < 0.001$). However, in the control group, no significant differences were observed across the same time points ($p > 0.05$) (Table 2).

Table 2
Intragroup comparison of sleepiness and Medication adherence in adolescents with AR in study groups

Variable	Group		Mean ± std. deviation	Related-Samples Friedman's Two-Way Analysis	
				P value	Test statistic
Sleepiness	Intervention	T0	12.00 ± 2.04	0.001>	38.25
		T1	9.91 ± 2.39		
		T2	6.91 ± 2.44		
	Control	T0	11.51 ± 2.25	0.23	2.88
		T1	11.09 ± 1.90		
		T2	10.69 ± 2.18		
Medication adherence	Intervention	T0	2.15 ± 1.24	0.001>	56.62
		T1	5.20 ± 1.15		
		T2	6.20 ± 0.92		
	Control	T0	2.80 ± 1.64	0.93	1.36
		T1	2.75 ± 1.58		
		T2	2.56 ± 1.37		

Before the intervention, there was no statistically significant difference in the total sleepiness score and medication adherence between the two study groups ($p > 0.05$). However, on the 15th day after the intervention, the median statistical test revealed a statistically significant difference in the total sleepiness score and medication adherence between the two groups ($p < 0.001$) (Table 3).

Table 3
Intergroup comparison of sleepiness and Medication adherence in adolescents with AR in study groups

Variable	Group		Mean ± std. deviation	Effect size	Independent-Samples Median Test	
					P value	Test statistic
Sleepiness	T0	Intervention	12.00 ± 2.04	0.23	0.35	0.93
		Control	11.51 ± 2.25			
	T1	Intervention	9.91 ± 2.39	0.54	0.02	-2.23
		Control	11.09 ± 1.90			
	T2	Intervention	6.91 ± 2.44	1.62	0.001>	-6.75
		Control	10.69 ± 2.18			
Medication adherence	T0	Intervention	2.15 ± 1.24	0.45	0.06	-1.86
		Control	2.80 ± 1.64			
	T1	Intervention	5.20 ± 1.15	1.77	0.001>	7.35
		Control	2.75 ± 1.58			
	T2	Intervention	6.20 ± 0.92	3.13	0.001>	12.99
		Control	2.56 ± 1.37			

Discussion

This study aimed to determine the impact of a self-care education package based on a mobile application on sleepiness and medication adherence in adolescents with Allergic Rhinitis. The study results indicated a statistically significant difference in the mean scores of sleepiness and medication adherence in the intervention group after the intervention compared to the control group. These findings are consistent with the results of other studies.

The study by Huberty et al. on the effectiveness mindfulness meditation mobile app for the treatment of sleep-related symptoms in adults with sleep disturbance demonstrated a significant improvement in fatigue and sleepiness in the intervention group compared to the control group (27). Similarly, the study by McCloud et al. found that after the intervention, symptoms of depression and anxiety among students in the intervention group improved, indicating the efficacy of the mobile app intervention (28).

Vollert et al. assessed the effectiveness of a mobile application in improving sleep in individuals with poor sleep quality. Their results showed that the intervention group experienced greater sleep improvement than the control group (29). In another study by Arring et al. ,aimed at evaluating the impact of the mobile application "Mi Sleep Coach" on insomnia in cancer survivors, the findings

indicated high levels of adherence to the program and user satisfaction, significantly impacting insomnia severity in cancer survivors (30).

Additionally, Reilly et al. investigated the effectiveness of a self-management mobile application based on cognitive-behavioral therapy (CBT-i Coach) for insomnia in military veterans. The results revealed significant improvements in subjective sleep parameters, including reduced insomnia reports and improved sleep quality, indicating that the application effectively enhanced subjective sleep (31). Werner-Seidler et al. examined the efficacy of the mobile application "Sleep Ninja" designed for adolescent sleep problems. The main components and objectives of the application included psychoeducation, stimulus control, sleep hygiene, and sleep-related cognitive therapy. The findings demonstrated significant improvements in sleep variables, including insomnia, sleep quality, depression, and anxiety (32). The results of previous studies align with the findings of our study. This could be attributed to the effectiveness of using mobile applications; however, they differ in terms of the target group, which, in our study, consisted of adolescents with AR.

On the other hand, Kira et al. investigated the effectiveness of a classroom-based sleep education program for adolescents. The results showed an overall treatment effect on weekend sleep duration, with the intervention group sleeping longer on weekends than the control group. However, no differences were observed between the groups for sleep duration on other nights of the week, and no significant differences were found for any secondary outcomes (sleep hygiene, sleep problems, or sleep knowledge) (33). Armitage et al. examined the effectiveness of the "Peak Sleep" mobile application on sleep quality in the general adult population. Sleep quality improved over time in both groups, with no significant difference between them, suggesting no effect of the sleep program (34). The results of these studies are not consistent with the findings of our study, which could be attributed to differences in the duration of the intervention, the educational approach, and the mobile application.

Findings from various studies have indicated that allergic diseases typically occur in early childhood and, if not controlled in a timely manner, may persist into adulthood. Adolescence is a transitional period between childhood and adulthood, and effective control during this time may allow potential risk factors and a strong immune system to interact positively, thereby managing allergic diseases without recurrence (35). Furthermore, the degree of sleep disturbances is directly related to disease severity. Increased sleep disturbances result in poor sleep accompanied by daytime fatigue and sleepiness (36).

The study by Santo et al. demonstrated that patients with coronary heart disease who used medication reminder applications had better medication adherence than those receiving usual care. Additionally, the results indicated that using applications with additional features did not further enhance medication adherence (37). Johnson et al. investigated the impact of a website and an SMS-based reminder system on medication adherence and perceived self-efficacy in adolescents with asthma. Their findings showed improvements in medication adherence, perceived quality of life, and self-efficacy (38).

Additionally, Li et al. provided evidence that mobile application-based behavioral change interventions could increase medication adherence and create long-term improvements in some clinical outcomes for

adults managing multiple chronic conditions (39). Wang et al. examined the effectiveness of Short Message Service (SMS) services on medication adherence in patients with AR, demonstrating that medication adherence in the SMS group significantly improved compared to the control group (40).

Moreover, Kosse et al. assessed the effectiveness of mobile health interventions in supporting self-management and improving adherence to inhaled corticosteroids in adolescents with asthma. The results indicated that the intervention increased medication adherence among adolescents with asthma; however, no effects on asthma control or quality of life were observed (41). In another study by Kosse et al. it was found that overall, mobile applications did not significantly impact adolescents' medication adherence. However, using the pharmacist chat feature had a positive effect on adherence (42). The results of these studies are consistent with the findings of our study, and perhaps the reason for this can be attributed to the same dependent variable at the beginning of the study.

Medication reminders can help patients overcome forgetfulness. SMS-based medication reminders are increasingly being used in interventions aimed at improving medication adherence. SMS allows the immediate delivery of short text messages to individuals at any time, place, or condition, making it a relatively simple and low-cost method (43).

Factors that appear to positively influence medication adherence in adolescents include positive family functioning, close friendships, internal control, treatment with immediate benefits, parental belief in disease severity and treatment effectiveness, and empathy with the physician. Conversely, factors that negatively impact adherence include caregiver mental health issues, family conflicts, complex treatments, medications with side effects, and denial of the disease. Adolescents experiencing emotional, social, family, or mental health problems tend to struggle more with adhering to medical regimens (44).

Mobile health applications are primarily designed to enable users to adopt a healthy lifestyle and allow them to monitor and support health-related features such as step count, heart rate, and sleep quality (45). Additionally, they improve care by providing easy access to health information for patients with chronic conditions such as diabetes (46). The greatest health benefits of these devices lie in their personal, intelligent, connected, and always-available nature. Consequently, they can be utilized both in daily life and during hospital stays (47). Given this wide range of applications, the mobile health sector is viewed as a promising component for delivering comprehensive, patient-centered care, with its potential well recognized by the United Nations and the World Health Organization (48). Mobile health is a growing field that offers numerous approaches for patients to engage in self-care activities. However, many available mobile applications in the market are designed to assist users in managing a specific health or wellness activity, such as weight loss or exercise, or a specific disease like diabetes. Only a few mobile applications engage users in a variety of goal-oriented activities (49).

However, in the "Allergy Yar" application, in addition to focusing on AR, the primary goal was to reduce sleepiness and enhance medication adherence.

Limitation

Although the findings of this study suggest a reduction in sleepiness and an improvement in medication adherence among adolescents with AR, this research also had some limitations, which include the following: The periodic nature of the disease, which resulted in a prolonged sampling period, Access to the internet was a requirement for using certain features of the application (Allergy Yar), which may have limited the use of these features.

Conclusion

Based on the findings of this study, it can be concluded that the implementation of a self-care education program via a mobile application leads to statistically significant changes in sleepiness scores and medication adherence in adolescents with AR. Therefore, implementing this intervention to reduce sleepiness and improve medication adherence in adolescents with AR can help alleviate the disease burden. Additionally, due to the self-care training and features available in the "Allergy Yar" application, the forgetfulness of prescribed medication doses was reduced, leading to increased medication adherence. Consequently, this resulted in a reduction of disease symptoms and sleepiness in adolescents with AR. Given the increasing use of mobile applications and new technologies, the nursing profession must also evolve in alignment with emerging needs. Therefore, it is recommended that mobile application-based self-care education be integrated into nursing and medical care practices.

Declarations

Ethical considerations:

This study was approved by the Ethics Committee of Yasuj University of Medical Sciences (Ethics Code: IR.YUMS.REC.1403.008) on April 24, 2024. informed consent for inclusion in this research was obtained from the a adolescents with allergic rhinitis.

Consent to participate:

written and verbal informed consent for inclusion in this research was obtained from the a adolescents with allergic rhinitis.

Consent for publication:

Not applicable

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Author Contribution

H.kh and Z.K Conceptualization, Investigation and Project administrationA.A Methodology and Formal analysisH.Kh and C.S Mobile application design and developmentA.F Data curation and Validation

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Data Availability

The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

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Figures

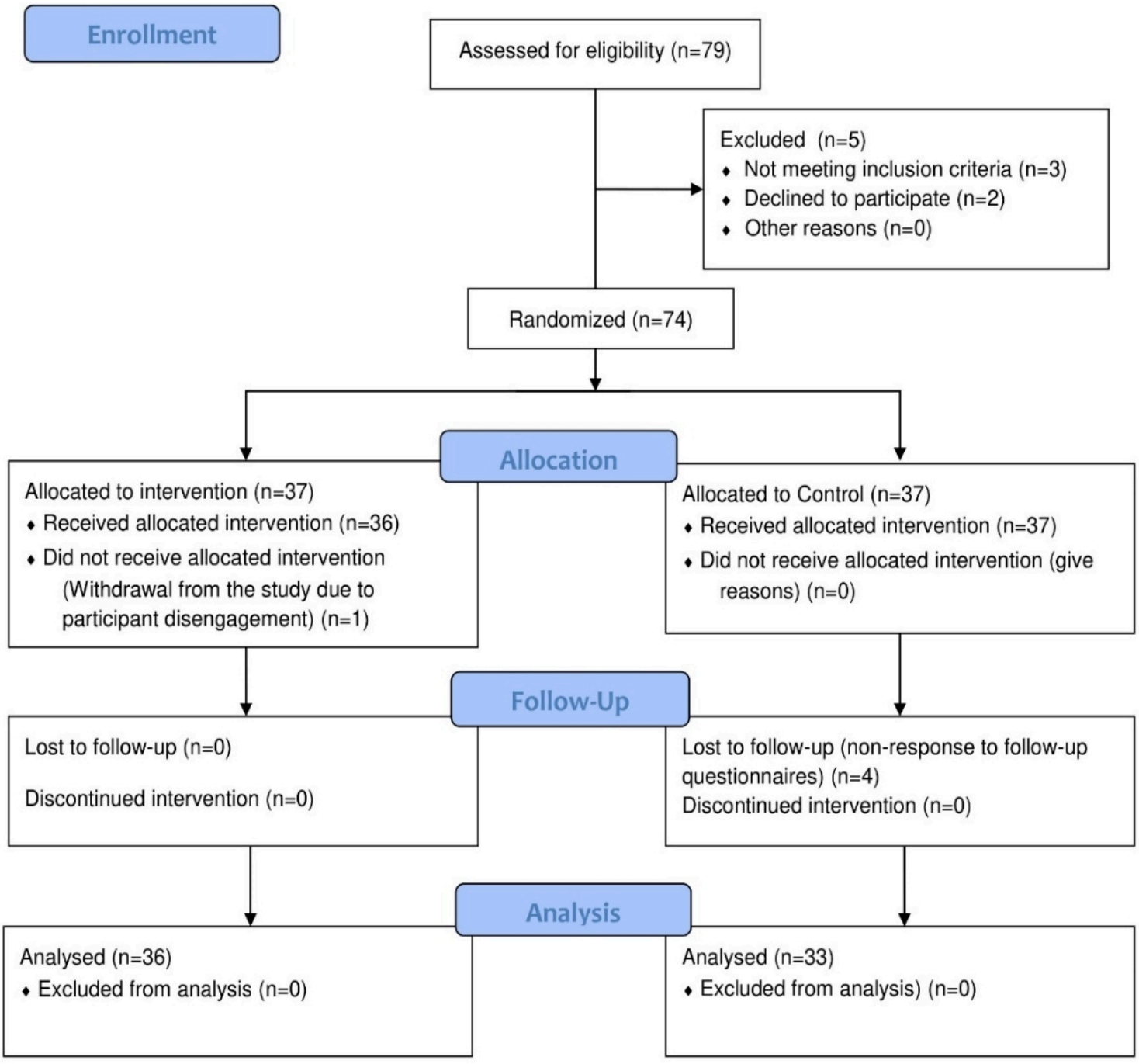


Figure 1

Flowchart of the eligibility and randomization process used for the study.