Original article

Efficacy of digitalized comprehensive educational program for patients with allergic contact dermatitis: A randomized controlled trial

Wongsiya Viarasilpa, Prattana Sittiwattanawong*

Department of Medicine, Faculty of Medicine, Thammasat University, Khlong Luang, Pathum Thani, Thailand.

Background: Allergic contact dermatitis (ACD) is an inflammatory skin disease resulting from exposure to allergen. The patient education is crucial to successful treatment and management of ACD. However, this process can be time consuming, requiring trained healthcare personnel resulting in increased workload and may be difficult in the setting of limited workforce or resource.

Objective: To assess the effect of informative digitalized video-based educational program (iDVE) on patients' quality of life, disease severity and knowledge of ACD compared to standard counselling (control).

Methods: Patients with ACD were randomized to participate in iDVE or control group. The primary outcome was the effect on patients' quality of life using dermatology life quality index (DLQI) score at initial and follow-up visits at 1-month, 3-months and 6-months. The secondary outcomes were disease severity using eczema area and severity index (EASI) score and the scoring atopic dermatitis (SCORAD) score, patients' knowledge and confidence at initial and each follow-up visits compared to control.

Results: Seventy-four patients were enrolled, of which 38 patients were allocated to iDVE group and 36 to control group. At 3-month and 6-month follow-up, there were significant changes of DLQI from baseline in iDVE compared to control group (- 7.00 ± 6.73 *vs.* - 3.56 ± 7.29, $P = 0.047$; and - 9.03 ± 7.36 *vs.* - 4.18 ± 7.51, $P = 0.01$, respectively). DLQI at 6-months in iDVE group was also significantly lower compared to control (2.47 ± 3.66 *vs.* 5.27 ± 5.85, $P = 0.023$).

Conclusion: The informative digitalized video-based educational program can significantly improve patients' quality of life and may has positive impact on disease severity and patients' knowledge regarding allergic contact dermatitis.

Keywords: Allergic contact dermatitis, education, digital, video.

Allergic contact dermatitis (ACD) is an inflammatory skin disease resulting from exposure to an allergen or multiple allergens in a patient's personal care products, home or work environment. [1-4] It is a common diagnosis affecting about 20.0% of the adult general population with prevalence varying from 4.0 to 10.0% of all dermatologic disorders depending on the population and geographic area.[2-5] ACD is generally diagnosed using a history of contact substance together with distribution of lesion. To identify and confirm causative agent of ACD, patch test is one of the most reliable test.[6] In Thailand, the rate of positive patch test in patients suspected of having ACD is up to 45.00 – 60.00%, of which, the most common allergens are nickel sulfate, cobalt chloride, potassium dichromate, p-phenylenediamine and fragrance mix. [5, 7, 8] The identification of the causative allergens in a patient diagnosed with ACD is the first step in patient management, followed by patient education, which is crucial to the successful treatment and management of the patient. [1, 9]

Patient education regarding the allergens identified through patch testing is as important as identifying the allergens themselves for successful management of ACD. It is important for patients to be educated about all allergens identified during the patch test including the information regarding where

***Correspondence to: Prattana Sittiwattanawong,** Department of Medicine, Faculty of Medicine, Thammasat University, Khlong Luang, Pathum Thani 12120, Thailand.
E-mail: prattananoon@gmail.com
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or which products the allergens can be found, relevant synonyms that might be used and how to properly avoid the allergens. Simply providing a patient with the names of any identified allergens may not be sufficient for them to effectively avoid the allergens. Thus, time must be taken for detailed patient education or it is unlikely that the ACD will improve even after identifying the allergens.[1] Educating patients about all information regarding all their causative substances is necessary; however, this process can be time consuming especially in case of patients with multiple allergic substances. It also requires trained healthcare personnel or dermatologists themselves to properly educate the patients resulting in increased workload and may be difficult in the setting of centers or hospitals with limited workforce or resource.

Thus, the comprehensive educational program using digitalized, informative, simplified and localized material regarding the allergens may provide solution to these aforementioned limitations. The objective of our study was to assess the effect of our informative digitalized video-based educational programme (iDVE) on patients' quality of life, disease severity and knowledge of ACD.

Materials and methods

This randomized controlled trial recruited patients diagnosed with ACD confirmed by patch test at dermatologic center at Thammasat University Hospital from July 2019 to July 2020. The primary outcome was assessment of the effect of the iDVE on patients' quality of life using dermatologic life quality index (DLQI) score at initial and follow-up visits at 1-month, 3-months and 6-months compared to standard counselling (control). The secondary outcome measure were: 1) the effect on disease severity using eczema area and severity index (EASI) score and the scoring of atopic dermatitis (SCORAD) score; and 2) the impact on patients' knowledge using score (% correct) of multiple-choice (MCQ) and patients' confidence using self-gauging visual analogue scale (VAS) at initial and each follow-up visits compared to control.

Patients in both groups were assessed of their knowledge regarding the substances they were allergic to using score (% correct) of MCQ. Each individual patient's MCQ consisted of 5 questions regarding general knowledge for allergic contact dermatitis plus 5 additional questions regarding knowledge of individual allergens for each substances patient allergic to. For example, if patient A was allergic to substance 1 and substance 2, his MCQ would consisted of total 15 questions including 5 questions regarding general knowledge for allergic contact dermatitis plus 5 questions regarding substance 1 plus 5 questions regarding substance 2. The number of questions patient answered correctly would then be divided by total number of questions in MCQ for each individual patient to calculate % corrected of MCQ score.

Patients' confidences in both groups were assessed using self-gauging VAS. At initial and each follow-up visits, patients were asked to gauge their confidence of their chance of being able to totally avoid the substances they were allergic to with score from 0 to 100 using VAS. 100 mean that they thought they would be able to 100.00% avoid the substance whereas, 0 would mean that they thought it is impossible for them to be able to avoid the substance.

The study has been approved by our local ethics committee, and was conducted according to the good clinical practice guideline, as well as the Declaration of Helsinki.

Randomization and allocation

After diagnosis of ACD and identification of causative allergens, patients were randomly allocated 1:1 to iDVE group or control group. Allocation was done using opaque, sealed, sequentially numbered envelopes ordered using random-block of 4 per mutation to equally allocate patients to each group. This study is single-blinded randomized controlled trial. The allocation was revealed to the patients and study coordinator, but dermatologists evaluating and treating the patient were not informed of the allocation. In each group, the patients were informed of the diagnosis and causative allergens, then assessed for initial DLQI, EASI, SCORAD and underwent pre-test MCQ evaluating baseline knowledge and confidence of avoiding the allergens.

Intervention and control

After the initial pre-test, patients in control group were given information regarding their causative allergens by the physicians and provided with paper brochure with text information regarding the allergens. The text in the brochure contained information of where the allergens can be found, relevant synonyms that might be used and how to avoid the allergens as aide-memoire.

In iDVE group, patients were assigned to the room with monitor presenting the short videos providing information regarding the causative allergens. The videos contained self-running presentations using Microsoft PowerPoint program with audio narration, of which the duration of each videos varying from about 2 to less than 5 minutes containing about 5 to less than 10 slides for each allergens. The presentations consisted of simplified localized text in Thai language with audio narration regarding information of where the allergens can be found, relevant synonyms that might be used and how to avoid the allergens with pictures of examples of common products containing the substances and illustration of the method to avoid the allergens. After watching all the video presentations of their causative allergens, the patients were then provided the digitalized brochure file depending on their preference in Portable Document Format (.pdf) or Joint Photographic Experts Group (.jpeg) of the slide presentations of their allergic substances as aide-memoire. The context of content in presentations in iDVE group was the same as in control group but differed in the method of content presentation and illustration, of which in iDVE group, the information was conveyed to the patients using video presentations with multiple media modalities, including text, pictures and audio narration compared to brochure paper with text in control group.

Patients in both groups were asked to repeat MCQ, post-test, to evaluate knowledge and confidence after counselling process. The patients were then followed-up at 1-, 3- and 6-months. In each visit, the patients were assessed for DLQI, EASI, SCORAD and underwent MCQ evaluating retaining knowledge and gauged their confidence of avoiding the allergens using VAS.

Statistical analysis

The sample size estimation was performed before study initiation taking in to account expected 10.0% drop out rate for each groups, resulting in 36 participants required for each groups. The outcomes of both groups were analysed using the intention-to-treat analysis (ITT). Comparison between mean DLQI, EASI, SCORAD, score (% correct) on MCQ and VAS of both groups were analysed by student's *t* - test. Chi-squared and Fisher's exact was used to compare the demographic characteristics. Statistically significance was defined as the $P < 0.05$.

Results

All patients with confirmed diagnosis of ACD were recruited between July 2019 and July 2020. Seventy-four patients were enrolled, of which 38 patients were allocated to iDVE group and 36 to control group. Mean age of the patients was 39.00 ± 13.00 years and majority of patients was female, consisting around 68.90% of all patients. The most common allergens were nickel, fragrance mix, carba mix, p-phenylenediamine and cobalt. The mean baseline DLQI was 10.64 ± 7.22, while mean baseline EASI and SCORAD were 6.25 ± 7.46 and 49.86 ± 17.68, respectively. Patients' initial knowledge regarding allergen using pre-test was 75.40% ± 21.93, whereas confidence at the beginning of the study measured as VAS was 28.20% ± 30.14. There was no difference in baseline characteristics between patients in iDVE and control group. Two patients in iDVE group and one patient in control group lost follow-up at 1-month follow-up and there were additional two patients in iDVE group and one patient in control group drop out at 3-month follow-up, total as 10.50% in iDVE and 5.50% in control group. There was no drop out at 6-month follow-up in both groups. The major cause of most patients drop out (3 in iDVE, and 2 in control group) was due to disruption of transportation due to emerging viral outbreak Table 1.

DLQI (dermatologic life quality index) score

As shown in Table 2, the baseline, 1-month, 3-month DLQI were not statistically different between patients in iDVE and control group (12.03 ± 7.90 *vs.* 9.17 ± 6.21, $P = 0.087$; 8.97 ± 14.01 *vs.* 6.26 ± 5.70, $P = 0.291$; 4.50 ± 5.36 *vs.* 5.65 ± 5.49, $P = 0.386$, respectively). However, at 3-months and 6-months, there were significant changes of DLQI from baseline in iDVE compared to control group (- 7.00 ± 6.73 *vs.* - 3.56 ± 7.29, $P = 0.047$; and - 9.03 ± 7.36 *vs.* - 4.18 ± 7.51, $P = 0.010$, respectively). Furthermore, DLQI at 6-month in iDVE group was also significantly lower compared to control, 2.47 ± 3.66 *vs.* 5.27 ± 5.85, $P = 0.023$.

EASI (Eczema area and severity index) score and SCORAD (the scoring of atopic dermatitis) score

Patients in iDVE group had significantly lower EASI at 1-month and 6-month compared to control (0.49 ± 0.79 *vs.* 1.39 ± 2.02, $P = 0.017$; and 0.11 ± 0.39 *vs.* 0.69 ± 1.37, $P = 0.024$, respectively).

However, there was no difference in EASI between iDVE and control group at baseline and 3-months follow-up (Table 2).

Regarding to SCORAD, there was no difference between both groups at baseline, 1-month and 3-month follow-up. However, at 6-month, the mean SCORAD of patients in iDVE group was significantly lower with significant change of SCORAD from baseline compared with control group (3.07 ± 10.20 *vs.* 11.28 ± 18.47, $P = 0.029$; and - 48.21 ± 19.48 *vs.* - 36.90 ± 22.88, $P = 0.033$, respectively) (Table 2).

Patient knowledge and confidence

Table 3 shows that patients in iDVE had no significant difference in pre-test, post-test and 1-month MCQ score compared to control. The score was significantly higher in iDVE group than control at 3-month follow-up, but there was no difference between both groups at 6-month (96.21 ± 7.09 *vs.* 90.35 ± 15.28, $P = 0.048$; and 95.65 ± 8.21 *vs.* 90.55 ± 16.74, $P = 0.122$, respectively).

There was no significant difference in patients' confidence measured by VAS between both groups at baseline. However, patients' confidences were significantly higher in iDVE compared to control group immediately after intervention, at 1-month, 3-months and 6-months follow-up (84.74 ± 13.75 *vs.* 73.19 ± 20.95, $P = 0.007$; 87.50 ± 12.56 *vs.* 75.23 ± 23.36, $P = 0.008$; 91.62 ± 9.90 *vs.* 71.26 ± 22.19, $P < 0.001$, 96.47 ± 6.46 *vs.* 71.67 ± 21.24, $P < 0.001$, respectively) (Table 3).

Table 1. Baseline characteristics of patients.

Characteristics	iDVE group (n = 38)	Control group (n = 36)	*P* - value
Age, mean ± SD	37.00 ± 13.00	40.00 ± 14.00	0.431
Gender, n (%)			1.00
Male	12 (31.60)	11 (30.60)	
Female	26 (68.40)	25 (69.40)	
Baseline DLQI, mean ± SD	12.03 ± 7.90	9.17 ± 6.21	0.087
Baseline EASI, mean ± SD	5.87 ± 5.93	6.65 ± 8.87	0.657
Baseline SCORAD, mean ± SD	51.99 ± 18.63	47.61 ± 16.58	0.289
Pre-test, mean ± SD	75.33 ± 19.88	75.56 ± 24.20	0.966
Baseline confidence, mean ± SD	22.37 ± 27.65	34.44 ± 31.78	0.085
Most commonly identified allergens, n (%)			
Nickel	20 (52.60)	16 (44.40)	0.497
Fragrance mix I	8 (21.10)	5 (13.90)	0.545
Carba mix	6 (15.80)	6 (16.70)	1.000
P-Phenylenediamine	6 (15.80)	5 (13.90)	1.000
Cobalt	5 (13.20)	9 (25.00)	0.242
Fragrance mix II	5 (13.20)	3 (8.30)	0.712
Formaldehyde	5 (13.20)	2 (5.60)	0.431
Colophonium	5 (13.20)	2 (5.60)	0.431
Methylisothiazolinone	3 (7.90)	3 (8.30)	1.00
4-tert-Butylphenolformaldehyde resin	3 (7.90)	3 (8.30)	1.00
Peru balsum	3 (7.90)	2 (5.60)	1.00
Methylisothiazolinone + Methylchloroisothiazolinone	2 (5.30)	3 (8.30)	0.67
Methyldibromo glutaronitrile	2 (5.30)	3 (8.30)	0.67
Potassium dichromate	2 (5.30)	3 (8.30)	0.67
Benzocaine	2 (5.30)	1 (2.80)	1.00

DLQI, dermatology life quality index ; EASI, eczema area and severity index; SCORAD, the scoring atopic dermatitis; SD, standard deviation

Table 2. Scores and changes of severity outcomes at 1-month, 3-month, and 6-month follow-up.

Outcomes assessment	iDVE group (n = 38)	Control group (n = 36)	*P* - value
DLQI, mean ± SD			
Baseline	12.03 ± 7.90	9.17 ± 6.21	0.087
1 month	8.97 ± 14.01	6.26 ± 5.70	0.291
Δ1M	- 2.69 ± 15.19	- 2.91 ± 7.34	0.291
3 months	4.50 ± 5.36	5.65 ± 5.49	0.386
Δ3M	- 7.00 ± 6.73	- 3.56 ± 7.29	0.047
6 months	2.47 ± 3.66	5.27 ± 5.85	0.023
Δ6M	- 9.03 ± 7.36	- 4.18 ± 7.51	0.01
EASI, mean ± SD			
Baseline	5.87 ± 5.93	6.65 ± 8.87	0.657
1 month	0.49 ± 0.79	1.39 ± 2.02	0.017
Δ1M	- 5.33 ± 6.10	- 5.42 ± 7.77	0.959
3 months	0.65 ± 1.80	1.10 ± 1.80	0.31
Δ3M	- 5.41 ± 5.53	- 5.87 ± 8.34	0.789
6 months	0.11 ± 0.39	0.69 ± 1.37	0.024
Δ6M	- 5.95 ± 6.16	- 6.46 ± 8.51	0.778
SCORAD, mean ± SD			
Baseline	51.99 ± 18.63	47.61 ± 16.58	0.289
1 month	9.83 ± 12.19	14.62 ± 14.93	0.142
Δ1M	- 41.54 ± 19.40	- 32.86 ± 18.87	0.060
3 months	8.70 ± 14.02	14.53 ± 19.15	0.158
Δ3M	- 42.57 ± 19.40	- 32.86 ± 18.87	0.06
6 months	3.07 ± 10.20	11.28 ± 18.47	0.029
Δ6M	- 48.21 ± 19.48	- 36.90 ± 22.88	0.033

Δ1M, change from baseline to 1 month; Δ3M, change from baseline to 3 months; Δ6M, change from baseline to 6 months; DLQI, dermatology life quality index; SD, standard deviation; EASI, eczema area and severity index; SCORAD, scoring atopic dermatitis

Table 3. Scores of patients' allergen knowledge and confidence assessment at 1-month, 3-month, and 6-month follow-up.

Outcomes assessment	iDVE group (n = 38)	Control group (n = 36)	*P* - value
Knowledge assessment,mean ± SD			
Pre-test	75.33 ± 19.88	75.56 ± 24.20	0.966
Post-test	95.38 ± 7.51	89.87 ± 20.63	0.138
Test 1-month	95.17 ± 9.31	90.51 ± 14.78	0.116
Test 3-month	96.21 ± 7.09	90.35 ± 15.28	0.048
Test 6-month	95.65 ± 8.21	90.55 ± 16.74	0.122
Confidence assessment,mean ± SD			
Before intervention	22.37 ± 27.65	34.44 ± 31.78	0.085
After intervention	84.74 ± 13.75	73.19 ± 20.95	0.007
After 1 month	87.50 ± 12.56	75.23 ± 23.36	0.008
After 3 months	91.62 ± 9.90	71.26 ± 22.19	< 0.001*
After 6 months	96.47 ± 6.46	71.67 ± 21.24	< 0.001*

iDVE, informative digitalized video-based educational program; SD, standard deviation

Discussion

This study has generated clinical information supporting the role of informative digitalized video based educational programme (iDVE) on improvement of patients' quality of life, disease severity and knowledge of ACD. The effect of iDVE was most consistent in term of improvement of patients' quality of life as measured by DLQI, which was the study primary objective. The DLQI of patients in iDVE group had changed significantly from baseline after 3-month with DLQI at 6-month significantly better than control. Regarding disease severity, patients in iDVE seemed to have less disease severity than control, however there were some inconsistency between the results of EASI and SCORAD. The EASI of patients in iDVE group were significantly lower at 1-month and 6-month, but not at 3-month and there were no significant change of EASI from baseline at any period of follow-up. Whereas, the SCORAD of patients in iDVE were significantly lower at 6-month and there was significant decrease of SCORAD from baseline at 6 months compared to control, of which seem to be correlated with the decrease in patients' DLQI. These discrepancy between two disease severity index scores may partly be due to different method for score calculation of each indexes, however the trend seemed to favour iDVE over control. Patient overall knowledge regarding the causative allergen even before intervention was high as mean baseline pre-test score were more than 75.0% in both groups. Since the most common causative allergens identified in our study such as nickel or fragrance were common substance that are known to general population, it was not unexpected for patients to have high baseline knowledge score. After invention, patients in both group had knowledge score increased to nearly more than 90.0%. There was no significant difference of knowledge score between two groups except for at 3-month follow-up, of which the patients in iDVE group had significant higher score than control. Even though patients' confidence scores measured by VAS were consistently significantly higher in iDVE group than control group from after intervention and every follow-up until last follow-up at 6-month; these findings could be confounded by patients' bias since patients in our study could not be blinded regarding their interventional allocation. It should be anticipated that the patients in the interventional group would gauge their confidence measured by VAS higher than patients in control group, because they had received the intervention (placebo effect). Thus patients' confidence score results in this study could not be used to assess and interpreted for superior efficacy of iDVE compared to control.

There were two main explanations for the reason why patients in iDVE group had significant better quality of life and trend toward better disease severity despite no difference in knowledge regarding the allergens. First, the influence from the video presentations with simplified localized text, pictures and audio of iDVE may have promoted more profound effect on patients' behaviour beyond knowledge recollection and retention causing more sustainable improvement of substance avoidance in patients' real lives. Because only knowledge without following actual actions of allergens avoidance would not contribute to improvement of quality of life nor disease severity. Second, since the questions in MCQ contained common "must-know" questions regarding the allergens, there may be some information that were not in MCQ questions that patients in iDVE group had better insight, recollection and retention of than in control group and the information could possibly contribute to change in patients' behaviour resulting in improvement of quality of life and disease severity.

These two explanations, though hypotheses, could be supported by the concept of working memory involving in patients' learning regarding health information materials.[10]

The working memory is the resource through which people manipulate and actively keep information available for on-line cognitive processing. Working memory is activated in nearly all complex cognitive tasks such as reading, reasoning or problem solving.[11, 12] However, working memory resources are limited and only allow individuals to process a finite amount of information at any given time.[10 - 12] Due to working memory constraints, the choice of educational media itself can also extrinsically affect cognitive load. [10, 13] Based on the Mayer's multimedia learning theory, even though the cognitive resources have a limited capacity, the working memory has multiple, distinct stores for information based on the modality through which information is presented. For example, visual and aural information are processed separately. [10, 12, 14] According to this modality principle, the use of video as a communicative modality, with dynamic images, text and audio narration, should be superior to print-based media

that require all content to be solely displayed visually to the audiences.[10] In iDVE group, patients were presented the short video presentations with text, pictures and audio providing information regarding their causative allergens. Thus the information was delivered to patients through multiple media modalities causing less working memory constraint and cognitive load resulting better understanding, recollection and retention of important information. Since detailed patient education regarding causative allergens is crucial step in management of ACD, the video based educational programme consisting of multiple media modalities should hypothetically provide significant better effect on patients' quality of life and disease severity.

The benefit of iDVE may not be limited to improvement of patients' quality of life, but it can also reduce the workload of healthcare personnel in centers or hospitals with limited resource and workforce. The iDVE consists of set of self-running video presentations with audio. The setting of these video presentations can easily be selected based on the types of substances patients are allergic to. For example, for the patients who were allergic to many substances, the healthcare personnel can then select the video presentations for each allergens for the patients and presented them via self-running presentations instead having to detailed educating each patients for each allergens by themselves which could be time consuming. Thus, the time required for the healthcare personnel to give to patient's education is just as the length of time for selecting the set of video presentations for each patient, i.e., for one patient with one allergic substance as for many patients with multiple allergic substances. The format of iDVE files is in .pptx, which can be opened by Microsoft PowerPoint program, which is a widely available and most commonly used presentation program. They can easily be distributed, uploaded, or shared via multiple channel both offline and online and can also be edited by other centers or hospitals to be suitable for their different population and geographic area.

There were limitations in our study. Despite statistical significance of outcomes measured, due to relatively small sample size in this study, these results could still be incidental or by chance, which may become insignificance with larger sample size (regression to the truth/mean hypothesis). Furthermore, mean age of the patients in our study was 39.00 ± 13.00 years with majority of patients female, consisting around 68.90% of all patients. Due to relatively younger patient population with high likelihood of high technological enable, the results in our study may not be able to be applied in some specific population group, such as elderly with limited access to technological device. Finally, some outcomes such as DLQI and confidence VAS score were relatively subjective as compared to more objective measurement such as EASI and SCORAD. These relatively subjective outcome measurements could be affected by multiple factors and bias, thus needed to be interpreted carefully and using the correlation and association with more objective outcomes to help guide interpretation.

In the future, iDVE can be presented to patients via internet channel in form of e-learning. The process can also possibly be optimized and tailored in case of patients coming in large group and having overlapped allergic substances with each other to reduce the time requiring for the educational process. In summary, iDVE could be considered for application in centers or hospitals with limited resource and workforce to help reducing the burden of healthcare personnel, i.e., giving them time to manage more severe and urgent patients or other more important or necessary matter.

Conclusion

The informative digitalized video-based educational program (iDVE) can significantly improve patients' quality of life and may have positive impact on disease severity and patients' knowledge regarding allergic contact dermatitis.

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Conflict of interest

All authors have no conflict of interest.

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