An Audiovisual Intervention's Effects on Psychological Barriers toward initiating Insulin Therapy among diabetic type 2 patients: A randomized controlled trial

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Abstract

Introduction: This study evaluates the effectiveness of educational videos against patients' fixed beliefs and lack of knowledge in comparison with traditional educational methods. It investigates the effectiveness of these tools in overcoming patients' psychological barriers toward insulin therapy.

Methods: This randomized, controlled trial used the validated insulin treatment appraisal scale (ITAS) to evaluate patients' psychological barriers. An educational video and brochure were developed, each containing the same contents. The study was conducted in King Abdulaziz city housing with a total sample size of 126, divided into an intervention group (who were shown the video) and a control group (who were given the brochure). Both groups filled out the same questionnaire before the intervention, immediately after the intervention, and six weeks later.

Results: Neither educational method showed superiority to the other. Most of the questionnaire items had a nonsignificant p-value for both methods, and even when one intervention method was effective, the other method showed similar effectiveness. Conclusion: This study showed no superiority of the video over the brochure, which cost less and required less effort to produce.

Trial registration number: NCT03544645

Key words: audiovisual; diabetes type 2; educational intervention; insulin therapy; psychological insulin barriers.

Introduction

Insulin should be prescribed more frequently among type 2 diabetic patients, especially when oral medications alone are not effective anymore [1]. Despite being the most effective diabetes treatment, patients often feel reluctant to initiate insulin therapy when it is needed. Many studies relate this reluctance to reasons such as fear of disease progression, needle anxiety, feelings of guilt and failure, concerns about hypoglycemia, sense of loss of control over one's life, reduced quality of life, and the fear of being stigmatized [1-7]. All these reasons have contributed to the prevalence of uncontrolled diabetes; a survey conducted in the USA showed that the percentage of controlled diabetic patients was only 36% [8], and a 2012 study in the Al Hassa region of Saudi Arabia showed that the percentage of uncontrolled diabetic patients was 69% [9].

The impact of most of these reasons are overestimated by patients and can be overcome with an insulin analogue and a new delivery method. For example, a novo pen, which many studies have found to be less painful, is easier to carry around than traditional delivery methods and leads to less hypoglycemic events [10-12]. The fact that patients still so frequently cite the reasons above indicates that up-to-date methods are not being provided to patients, which could be accomplished through traditional educational methods such as brochures, leaflets, or face-to-face discussions [13].

A newer educational technology is educational videos, and many studies emphasize the effectiveness of this method [14-18]. In one study, a video-based lifestyle educational trial was designed for newly diagnosed type 2 diabetics, who were divided into a video education group and a control group. The video education group showed more improvement in general knowledge related to lifestyle than the control group [14]. Another study about heart failure patients revealed that patients who received video education showed less signs and symptoms of heart failure, such as edema, fatigue, and dyspnea, than another group that received only traditional education [15]. Even if we compare video education with other newer methods such as internet research, video education is more effective because patients are more likely to review all the information provided to them [16]. In addition, another study found that video intervention was one of the best methods to increase the knowledge of health issues, such as certain disease complications, in people with low literacy [17].

Furthermore, a systematic review that included 40 studies related to video intervention showed how video education was effective in three major ways: supporting the treatment decision, reducing anxiety, and supporting coping skills to increase self-care practices [18]. Since there have been no previous studies comparing the difference in effects between traditional and non-traditional education methods on diabetic patients' attitudes in Saudi Arabia, this study aims to compare the impact of audiovisual educational materials versus printed educational materials on type 2 diabetic patients' knowledge, attitudes, and practices towards insulin therapy. It does so by assessing the patients before, immediately after, and 6 weeks after the intervention.

Methods

We conducted a randomized controlled trial on type 2 diabetic patients who agreed to participate in the study after screening them for inclusion and exclusion criteria. The target population of the study was type 2 diabetic patients who had an A1c of 8 mg/dL or above, were aged 30 to 70 years, and had not yet begun insulin therapy. Patients currently experiencing pregnancy, blindness, profound vision loss, or severe mental problems such as psychosis were excluded.

The study was conducted from March to June 2017 in a community-based polyclinic located in the King Abdulaziz city housing for the National Guard in Rivadh, Saudi Arabia. This polyclinic includes primary care centers and serves about 60,000 individuals, consisting of soldiers and their families as well as the professionals who work there and their families. We developed an educational video and brochure, both of which contained the same content about knowledge, attitude, behavior, and psychological barriers toward insulin therapy. The intervention group was shown the educational video and the control group was given the brochure. Both groups filled out a questionnaire before the intervention, then immediately after the intervention filled out the same questionnaire to assess the materials' immediate effects. Six weeks later, both groups filled out the same questionnaire once more to measure the longterm effects. The immediate and long-term effects of both groups were compared to assess the materials' effects on participants' knowledge, attitudes, behaviors, and psychological barriers toward insulin therapy.

A computerized sequence in Microsoft Excel 2016 generated a randomized list of patients, allocating participants into 2 groups: an audiovisual intervention group and a printed material control group. A serially numbered opaque sealed envelope (SNOSE) contained these group assignments. The total sample size was 126 patients (63 in each group), which afforded us an 80% power to detect a difference of at least 5% in the mean knowledge percentage between the two groups, with an equal standard deviation of 10% and a significance level (α) of 5% using two proportions (z-test).

The validated insulin treatment appraisal scale (ITAS) questionnaire was used [19]. It is available on the internet free of charge, and permission to use it was obtained. The questionnaire measured the following variables: attitude, knowledge, practice, and behavior. It was translated into Arabic and pre-tested.

The educational video, which we developed and validated for this study and presented to the intervention group, aimed to address the psychological barriers mentioned in the questionnaire and tried to correct patients'

misconceptions about insulin therapy. More specifically, it aimed to overcome the barriers by briefly explaining the pathophysiology of type 2 diabetes and the ways to manage type 2 diabetes, focusing especially on the advantages, adverse effects, and misconceptions about insulin therapy. Its content was developed based on the American Diabetes Association's 2017 Standards of Medical Care in Diabetes [20]; the validation process included family physicians to ensure that the content was appropriate for the patients and medical students to ensure the quality of the design and avoid any language mistakes; it also included type 2 diabetic patients with similar inclusion and exclusion criteria of this study to ensure that the video is suitable for them in terms of language and approach. The validation paper has been published separately (27), and the video with English subtitles can be accessed from the link in the reference list [21]. For each item on the questionnaire, two p-values were measured. The first was obtained with McNemar's test, to measure the effect of each intervention individually. The second was obtained using a two-proportion z-test to compare the two interventions and determine if either was superior. Results with a p < 0.05 were considered significant. IBM SPSS Statistics 20, manufactured by IBM Corp., was used for data analysis.

Ethics

This study was sponsored and ethically approved by King Abdullah International Medical Research Center's (KAIMRC) ethic committee with ID number (SP16/235), and all patients provided written consent. It was also registered in the trial registry, clinicaltrial.gov, with a trial registration number of NCT03544645.

Results

The study included 126 diabetic patients, with no losses during the study. Patients' demographics are presented in Table 1 (next page). Table 2 shows the effects of the two intervention methods (the video and the brochure) regarding patients' fixed beliefs, namely their psychological barriers to insulin therapy (determined through 10 questions), and regarding their understanding of insulin therapy as the ideal treatment for their condition (2 questions, q6 and q7, in Table 2). The percentages in Table 2 represent the participants who agreed with the questions' statements, and each question had 3 main p-values: one for the effect of the video, one for the effect of the brochure, and the last to show any superiority in method, whether it was for the video or the brochure. The different p-values measure the reductions in barriers between before and immediately after the intervention, as well as the reduction between before and 6 weeks after the intervention.

As determined by McNemar's test, the questions related to the psychological barriers to insulin therapy (questions 1 and 3: "I am worried about starting insulin therapy" and "Taking insulin means my health will deteriorate") showed significant p-values (<0.05) for both the video and the brochure. Interestingly, questions 11 and 12 ("Taking insulin increases the risk of low blood glucose levels" and "Insulin causes weight gain") showed positive p-values for both the brochure and video, but the reductions were of negative value and, since the question was not a negative statement, these values were significant for their reverse outcomes. A reverse outcome here means that instead of decreasing the barriers, the intervention methods increased them , although these barriers were addressed directly with both methods.

There were no significant p-values for the other barriers related to insulin therapy, indicating that neither intervention was effective in this regard. However, q6 and q7 ("Taking insulin helps to prevent complications of diabetes" and "Taking insulin helps to improve my health," respectively), which were related to the benefits of insulin but not psychological barriers toward insulin therapy, showed significant p-values for both interventions.

As for the two-proportion z-tests used to compare the two interventions, most p-values were non-significant. That is, even when the video showed effectiveness, the brochure showed an equal effect; thus, neither method appeared superior to the other.

Discussion

Although both interventions had a slight effect, it was still not large enough to alter patients' fixed beliefs and behaviors. The interventions reinforced the positive ideas patients already had about the benefits of insulin therapy, but were not sufficient to break their psychological barriers to insulin therapy, such as feelings of guilt and failure, fear of disease progression, feelings of a loss of control over one's life, and the fear of being stigmatized, even though both intervention methods addressed these beliefs directly. In fact, patients' worries about hypoglycemic attacks and weight gain increased at the mere mention of them in the interventions, even though the interventions indicated that new methods could help overcome these problems. Overall, neither method was found to be superior.

A meta-analysis has shown that video interventions are effective in some settings such as breast self-examination, prostate cancer screening, sunscreen adherence, self-care in patients with heart failure, and HIV testing and treatment adherence [22]. However, this study shows that such an intervention is not effective in changing overall behaviors or attitudes, nor fixed beliefs toward insulin therapy, such as psychological barriers. Thus, the intervention's goal plays an important role in its impact.

The result of this study raises the question of whether multifaceted intervention could be more effective than one-method intervention. One study that targeted diabetic patients with multifaceted interventions, such as problembased learning sessions and educator-patient face-to-face sessions, showed improvements in their A1C and blood pressure [23]. In addition, two studies on multifaceted interventions showed improvements in drug adherence for post ACS and anti-depressant drugs using booklets, voice messages, and counseling interventions [24-25].

Table 1: Participants' Demographics

		N	%
Age (years)	<= 40	11	8.7%
	41 - 50	61	48.4%
	51 - 60	30	23.8%
	61+	24	19.0%
Sex	Male	61	48.4%
	Female	65	51.6%
Education	Illiterate	38	30.2%
	Primary school	31	24.6%
	Intermediate school	13	10.3%
	High school	32	25.4%
	College	12	9.5%
Marital status	Unmarried	10	7.9%
	Married	116	92.1%
Job	Military	47	37.3%
	Civil	12	9.5%
	House wife/unemployed	67	53.2%
Exercise	More than an hour and a half per week	43	34.1%
	Less than hour and a half per week	42	33.3%
	Do not exercise	41	32.5%
Diet	On a diet	40	31.7%
	Not on a diet	86	68.3%
Smoke	Non-smoker	96	76.2%
	Ex-smoker	15	11.9%
	Smoker	15	11.9%

I am worried about starting V insulin therapy B insulin therapy P-va Taking insulin means other V people see me as a sicker B person p-va Taking insulin means my V health will deteriorate B failed to manage my diabetes P-va with diet and tablets P-va diabetes B vith diet and tablets P-va diabetes B	Intervent V 82.5% B 85.7% p-value ** for Video vs. V 58.7% V 58.7% Prvalue 71.4% Prvalue for Video vs. 8rc V 33.3% Prvalue for Video vs. 8rc V 33.3% Prvalue for Video vs. 8rc V 73.0% Prvalue for Video vs. 8rc V 73.0% Prvalue for Video vs. 8rc V 68.3% Prvalue for Video vs. 8rc V 57.1%	Brochure Brochure Brochure	intervention 65.1% 77.8% 69.8% 69.8% 27.0% 27.0% 88.9% 76.2% 79.4%	intervention 63.5% 68.3% 50.8% 56.7% 66.7% 56.7% 25.4% 81.0% 88.9% 81.0% 81.0%	17% 8% 8% 0.1282 0% 2% 2% 16% 16% 16% 16% 16% 13% 0.5836 -5%	0.013 0.063 1.000 1.000	19% 17% 0.1282	0.008
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nighteres ligs become more a	for Vid				8% %8'	0.227	-6%	0.424
worse p-va	57.1	* *			0.2459		0.225	
Taking insulin helps to V		*	81.0%	71.4%	-24%	<0.001	-14%	0.064
prevent complications of B	49.2%		77.8%	76.2%	-29%	0.001	-27%	0.005
diabetes (reverse-worded) p-va	p-value for Video vs.	rs. Brochure			0.6293		0.1437	
Taking insulin helps to V	54.0%	*	81.0%	77.8%	-27%	<0.001	-24%	0.001
improve my health (reverse- B	49.2%	*	76.2%	74.6%	-27%	<0.001	-25%	0.002
worded) p-va	p-value for Video vs.	s. Brochure			1		0.9194	
Taking insulin makes it more V	50.8%	%	42.9%	41.3%	8%8	0.267	10%	0.238
difficult to fulfil my B	50.8%	*	52.4%	47.6%	-2%	1.000	3%6	0.815
responsibilities (at work and p-va home)	p-value for Video vs.	s. Brochure			0.001		0.1124	
Being on insulin causes family V	63.5%	*	66.7%	60.3%	-3%	0.687	3%	0.754
and friends to be more B	84.1%	8	85.7%	85.7%	-2%	1.000	-2%	1.000
	p-value for Video vs.	Brochure			0.7269		0.0001	
10 I have no problem injecting V	50.8%		52.4%	58.7%	-2%	1.000	-8%	0.302
myself in the presence of my B	46.0%		58.7%	60.3%	-13%	0.008	-14%	0.049
colleagues at my workplace p-va (reverse-worded)	p-value for Video vs. Brochure	s. Brochure			0.0303		0.3371	
11 Taking insulin increases the V	61.9%	%	77.8%	77.8%	-15.9%	0.006	-15.9%	0.031
risk of low blood glucose B	68.3%	%	87.3%	85.7%	-19.0%	0.004	-17.4%	0.019
	p-value for Video vs.	s. Brochure			0.7019		0.8491	
12 Insulin causes weight gain. V	49.2%	%	79.4%	77.8%	-30.2%	<0.001	-28.6%	<0.001
8	38.1%		79.4%	71.4%	41.3%	<0.001	-33.3%	<0.001
en-d	p-value for Video vs.	's. Brochure			0.3731		0.6798	

* McNemar test

** two proportion z-test

Reduction 1: the difference between before intervention and immediately after intervention. Reduction 2: the difference between before intervention and six weeks after. The present study had several limitations and strengths. The limitations included a sample limited to a clinic located in housing for National Guard soldiers, which may not represent the population of Riyadh as a whole. The strengths include the study's randomized approach, which helped minimize bias, as well as the high response rate, strict inclusion criteria, the consistency of the research method, the follow-up after six weeks, and and the fact that the educational video was validated by the authors of this study.

Conclusion

Audiovisual methods such as educational videos are important sources for delivering different kinds of information. This study demonstrates that these methods can be useful for delivering new information and increasing people's general knowledge, but sometimes fall short in changing people's pre-existing fixed beliefs, such as psychological barriers regarding insulin therapy.

Practice Implications

The results of the study raise the question of whether educational materials are indeed superior to doctor– patient educational sessions, which are more interactive and allow the patient to ask questions. It also suggests that a multifaceted intervention could be more effective than a one-method intervention. Future research should consider what further efforts are required to change misleading information that people believe.

Determining what new technologies should be utilized as intervention methods is a wide research field with a promising future. One such technology is social media, which is now widely accepted and has many active users. One study has demonstrated that social media can be effective as an intervention method to increase patients' physical activity [26], but further research on this subject is lacking.

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