

Influence of an educational videotape on attitudes toward participating in cohort studies

—Results of a randomized controlled trial

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Objective This study was conducted to examine whether an educational videotape might change peoples' attitudes toward participating in future cohort studies by a prospective randomized controlled trial.

Methods The participants were recruited from the residents of Kamogawa-city (139 at a health promotion festival, 54 from a nursery care study class, 53 from an elderly class, and 9 individuals who had not attended a health checkup for more than 10 years). All participants were randomized into a control group and an intervention group, and were asked to fill out a questionnaire designed to evaluate attitudes toward participating in future cohort studies. Those in the intervention group, however, were also asked to watch a videotape, produced by the authors to explain the objectives, significance, and security policies of a cohort study planned to be conducted in the same city, before completing the questionnaire.

Results In the intervention group, 44% (54/123) showed a positive attitude to future participation, while the figure was only 25% (31/122) in the control group (Cochran-Mantel-Haenszel χ^2 : $P=0.0025$).

Conclusion The videotape proved to be a useful tool for informing the general public about the nature of cohort studies and to increasing probable participation.

Key words : cohort study, educational intervention using videotape, informed consent, randomized controlled trial

I. Introduction

Article 16 of the Act of The National Health Promotion Act, implemented in 2003¹⁾ says “more effort should be expended to understand the correlation of lifestyle and lifestyle-related diseases”, and the director of the Department of Health Promotion²⁾ added a notice indicating that “various different kinds of research and study should be promoted”. This included epidemiological studies, especially cohort studies, as a means of evaluating public health and its relationship to lifestyle-related diseases.

New ethical guidelines implemented in 2002 for epidemiological studies³⁾ virtually call for researchers conducting any cohort studies, including those during annual health checkup programs, to obtain written informed consent from each participant^{4~6)}. Most cohort studies in Japan, however, have been

conducted by researchers belonging to universities or research institutions in conjunction with annual health checkup programs managed by local governments^{4,5)} without written informed consent, so that the participants often have not realized that an epidemiological study was being conducted or that they were actually participating^{7,8)}.

Under the new guidelines, researchers are required to explain the purpose and objectives of any cohort study so that cooperation and agreement of the participants is based on complete information and understanding. The participants, on the other hand, are required to understand why the study is being done, why they are being asked to participate, and what they will be asked to do. The potential participants have the right to decide whether they want to take part in the study or not, that is, they have the right to refuse. Unfortunately, many potential participants have been confused by these new circumstances, which require researchers to invest significant amounts of time, money, and manpower⁵⁾.

Cohort studies differ from clinical trials in defining study populations in a number of ways. In clini-

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cal trials, (internal) validity is ensured by a process of random allocation. In cohort studies without random sampling, however, validity can be ensured only by having a large number of participants, while also avoiding restriction of participant selection as much as possible. Therefore, for a cohort study to be successful, the researchers must first be able to obtain a high rate of written informed consent for participation.

This situation requires creativity and enormous effort. If the researchers err in providing appropriate information to the potential participants during the process of obtaining informed consent, the risk of losing cooperation is serious and could possibly lead to termination of the entire study.

As a tool for providing information to potential participants and educating them as to autonomy, videotapes or other visual media appear to have promise. Prospective studies using videotape programs for educational purposes in the public health arena, however, were very few before 2003; only four such studies were identified in a MEDLINE search^{9~12}) and we found only one in the Japanese literature¹³). The studies were centered on a specific disease or preventive measures, such as use of poliovirus vaccines⁹), physical activitise for preventive medicine¹⁰), smoking prevention¹¹), mammography screening¹²) and diabetes¹³). None dealt with use of a videotape program specifically for educational intervention in a cohort study. Therefore, the present designed as the first of its kind for this purpose.

The study examined use of an original educational videotape, produced by the authors, as a method for information distribution in preparation for conducting of a cohort study. General awareness of epidemiological studies and lifestyle-related diseases was evaluated before intervention by videotape. A prospective randomized controlled trial was have conducted to examine whether viewing the videotape might change peoples' attitude toward participating in future cohort studies. Factors influencing participation were also explored by comparatively between the videotape intervention group and the control group.

II. Methods

The study was conducted from September through November 2003, when a large scale cohort study named the "Otassha-study" was being planned in Kamogawa-city, located in the southeast part of Chiba prefecture and with a total population of 30,327 in 2003. Potential participants (subjects) were recruited by the investigator (M. Ishii) from all (about 500) individuals attending an annual health

promotion festival held in Kamogawa-city on September 15th. At the entrance of the gymnasium where the festival was held, the investigator provided a first questionnaire (Q#1, see appendix) to each individual and asked them to complete the sheet at the site. Then the investigator requested informed consent for the subsequent videotape intervention study. This was obtained with the name and private address from each of 139 participants. Q#1 was designed to evaluate levels of recognition and understanding of the terms "epidemiological study" (Q#1-1) and "lifestyle-related diseases" (Q#1-2). Q#1 also included questions regarding preventive medicine, names of lifestyle-related diseases, and interest in the media but the responses to these questions are not reported here.

Participants were randomized into two groups by the permuted block design with block size 2 using random allocations generated by the SAS/PLAN procedure. One group (the intervention/videotape group) was sent an educational videotape, along with a second questionnaire (Q#2, see Appendix), and instructed to watch the videotape before completing Q#2. The other group (the control group) was sent only Q#2 without the videotape. Q#2 was designed to evaluate the level of cooperation toward participating in future coming cohort studies (Q#2-1) and to identify factors that would influence participation (Q#2-2). Q#2 in the videotape group also included two questions regarding whether the participant watched the videotape and it's utility (Q#2-3, 4).

The 20-minute long educational videotape was produced by the investigators mainly based on an interview with the principal investigator (S.Mizushima) in charge of the "Otassha-study" prior to the implementation of the study. The "Otassha-study" is a large-scale cohort study conducted in 2004 for exploring the general health level of the middle-aged and elderly citizens in two cities in Chiba prefecture, Kamogawa and Amatsu-Kominato. The purpose of the videotape was to explain the objectives, significance and security policies of the study to the targeted citizens. (See the Appendix for a more complete listing of the videotape contents. A DVD of the videotape is available by request to the investigator.)

In order to increase the number of participants in the study, additional subjects were selected by the public health nurse (K.Nakamura) in charge of the "Otassha-study". The nurse asked for cooperation from the following 3 groups with an explanation of the study:

- 1) Nursery care class attendants (about 100 people), who were basically interested in health and dealing with family health problems.

- 2) Individuals from a health care class (named “SHIRAKABA”, about 130 people) composed of healthy elderly adults, averaging 81 years old.
- 3) Kamogawa residents (about 100–200 people) who are targeted for the “Otassha-study” and had been refusing to attend annual health checkups or other events for more than 10 years. (They were termed “HIKIKOMORI” by the public nurse because of their attitudes.)

The investigator (M.Ishii) visited Kamogawa-city Welfare Center, at the time when the nursery class and the “SHIRAKABA” meeting were being held. Some 54 of a nursery care class and 53 of “SHIRAKABA” submitted written informed consent to participate in the study after the investigator’s explanation of its purpose. For the “HIKIKOMORI”, selection was by the public health nurse. She telephoned 30 people of at random and as a consequence 9 individuals agreed to cooperate in the study. Those 9 individuals were the maximum who could be persuaded with availability visiting interviews by the investigator accompanied by the public health nurse, within a 2 day limited research period.

All these additional participants were randomized by the same method as described above and the same procedures were followed.

III. Statistical considerations

The primary endpoint for this study was the response regarding cooperation in cohort studies (Q#2-1) and no adjustment for multiplicity was done because the analysis of influential factors (Q#2-2) was exploratory. The minimum required number of participants was set 200 in order to assure 80% power (type I error=0.05: two-sided) for a difference of more than 20% in positive responses to Q#2-1 irrespective of the proportion in the control group

The control group and the videotape group were compared by Cochran-Mantel-Haenszel (CMH) type statistics with adjustment for four strata effects. Proportions were compared by the Mantel-Haenszel χ^2 test, and ordered responses by the extended Mantel χ^2 test. All statistical analyses were performed using SAS version 9.1.

IV. Ethical considerations

The authors are fully aware that researchers should conduct studies following appropriate guidelines. The type of study performed is, however, not covered by the “HELSINKI Declaration” nor the Japanese “Ethical Guidelines for Epidemiological

Research” and there have been and are no explicit rules for ethical judgment of such research in the institute (University of Tokyo), to which the authors belong, at the time of initiation of this study. Under these circumstances, we decided to leave a fair ethical judgment of the study on the people in the third place after due consideration of the significance of the intervention for the Kamogawa-residents, the chance of autonomous decisions by the participants and respect of privacy. There are some regional ethical committees to examine cohort study or social research conducted in the region but Kamogawa-city regional ethical committee was not ready at the time of our intervention. Therefore, the authors asked a conference of administrative officials of Kamogawa-city (the general manager, the section head and the public health nurse in charge of the “Otassha-study”). They came to the conclusion that this study would be considered as accompanying health-administrative research before the “Otassha-study” and, therefore, no formal ethical examination by a third party was considered. Therefore, the authors were permitted to conduct the research after obtaining direct informed consent from the participants.

V. Results

Answers to Q#1 were obtained from 255 participants (Table 1). The intervention (videotape) group and the control group were well balanced as regards sex and age as well as the responses in Q#1-1 and 2. Recognition of the term “epidemiological study” was low, while recognition of the term “lifestyle-related diseases” was much higher; 94% (237/253) of participants replied “never heard” or “heard but do not now the meaning” of the term “epidemiological study”, while 28% (70/252) replied “never heard” or “heard but do not now the meaning” of the term “lifestyle-related diseases”. The nursery class attendants, in particular, showed a high level of recognition of the term “lifestyle-related diseases”; 72% of them said they could name a specific disease.

Answers to Q#2 were obtained from 243 participants (Table 2). Effects of the intervention were shown in all except the “HIKIKOMORI” group. In the participants at the annual health promotion festival, the proportions of subjects who answered “positive” (response categories 1–3) to the question Q#2-1 were 43% and 29% in intervention and control groups, respectively ($P=0.081$, trend $P=0.007$). In the nursery care class, those figures are 58% and 33% ($P=0.075$, trend $P=0.030$). In the elderly class, those figures are 39% and 15% ($P=0.051$ trend $P=0.74$). The four strata-adjusted CMH-test showed a significantly high “positive”

Table 1. Comparison of recognition “life-style diseases” and “epidemiological study” (Results of Questionnaire #1 n = 255)

Videotape intervention	Demographic factor of study subjects									
	Participants of the health promotion		Nursery care class		Eldery class		“HIKIKOMORI”		All groups	
	[yes]	[no]	[yes]	[no]	[yes]	[no]	[yes]	[no]	[yes]	[no]
Number of subjects	139	54	53	9	255					
Age average (SD)	[71] 70.0(9.2)	[26] 65.4(9.9)	[26] 81.1(5.1)	[4] 64.1(12.5)	[127] 71.1(10.4)	[28] 65.5(8.4)	[27] 82.3(5.4)	[5] 63.8(10.9)	[127] 71.5(10.7)	[128] 71.5(10.7)
Sex men : women	54 : 85	8 : 46	3 : 50	6 : 3	71 : 184	[69, 7(9.7)]	[79, 8(4.7)]	[63, 8(10.9)]	[70, 8(10.1)]	[71, 5(10.7)]
Question Have you ever heard of the term “life-style related diseases”? (Q.#1-4)	[31 : 40]	[23 : 45]	[3 : 23]	[5 : 23]	[3 : 23]	[0 : 27]	[3 : 1]	[3 : 2]	[40 : 87]	[31 : 97]
Never	12(8.7%)	1(1.9%)	8(15.4%)	3(33.3%)	24(9.5%)					
Heard of the term but do not know what it means	[5; 7.1%]	[7; 10.3%]	[4; 15.4%]	[1; 3.7%]	[1; 25%]	[4; 15.4%]	[1; 25%]	[2; 40%]	[10; 7.9%]	[14; 11.1%]
Heard of the term but can not name a specific disease	[47; 67.1%]	[38; 55.9%]	[16; 59.3%]	[0; 0%]	46(18.3%)	[4; 15.3%]	[5; 18.5%]	[2; 50%]	[23; 18.3%]	[23; 18.2%]
Understand term and can name a specific disease	[6; 8.6%]	[9; 13.2%]	[7; 26.9%]	[3; 11.5%]	37(14.7%)	[5(9.4%)]	[8; 30.8%]	[1; 20%]	[17; 13.5%]	[20; 15.9%]
Question Have you ever heard of the term “epidemiological study/research”? (Q.#1-2)	[48; 68.6%]	[43; 63.2%]	[19; 73.1%]	[19; 70.4%]	145(57.5%)	[38(71.7%)]	[8; 30.8%]	[1; 20%]	[76; 60.3%]	[69; 54.8%]
Never	40(29.0%)	13(24.5%)	35(66.0%)	8(88.9%)	96(37.9%)					
Heard of the term but do not know what it means	[17; 24.2%]	[23; 33.8%]	[16; 61.5%]	[4; 100%]	[42; 33.3%]	[5; 19.2%]	[8; 29.6%]	[4; 80%]	[42; 33.3%]	[54; 42.5%]
Understand the term and can explain what it means	[47; 67.1%]	[38; 55.9%]	[16; 59.3%]	[0; 0%]	135(53.4%)	[35(66.0%)]	[15(28.3%)]	[0; 0%]	[74; 58.7%]	[61; 48.0%]
Have previously participated in a study	[4; 5.7%]	[4; 5.9%]	[0; 0%]	[1; 3.7%]	[6; 4.8%]	[4(7.5%)]	[1(1.9%)]	[1; 20%]	[14(5.5%)]	[8; 6.3%]
	[2; 2.9%]	[3; 4.4%]	[2; 7.7%]	[1; 3.7%]	[4; 3.2%]	[1(1.9%)]	[2(3.8%)]	[0; 0%]	[8(3.2%)]	[4; 3.1%]

Note: Figures in [] denote the statistics/numbers in the intervention or the control group.

Table 2. Cooperative attitude toward the epidemiological study

Question	Participants of the health promotion festival (n = 130)		Nursery care class (n = 53)		Elderly class (n = 53)		“HIKIKOMORI” (n = 9)		All groups (n = 245)	
	Yes (n = 67)	No (n = 63)	Yes (n = 26)	No (n = 27)	Yes (n = 26)	No (n = 27)	Yes (n = 4)	No (n = 5)	Yes (n = 123)	No (n = 122)
(Results of Questionnaire #2 n = 245)										
Videotape intervention										
Will you cooperate if asked to participate in future medical research? (Q#2-1)										
1 I will cooperate	9(13.4%)	1(1.6%)	4(15.4%)	0(0%)	3(11.5%)	2(7.4%)	0(0%)	0(0%)	16(13.0%)	3(2.5%)
2 I think I will	12(17.9%)	10(15.9%)	7(26.9%)	6(22.2%)	4(15.4%)	0(0%)	0(0%)	0(0%)	23(18.7%)	16(13.1%)
3 Most of the time I will	8(11.9%)	7(11.1%)	4(15.4%)	3(11.1%)	3(11.5%)	2(7.4%)	0(0%)	0(0%)	15(12.2%)	12(9.8%)
4 Depends on the content I will cooperate	27(40.3%)	32(50.8%)	9(34.8%)	15(55.6%)	8(30.8%)	19(70.4%)	0(0%)	2(40%)	44(35.8%)	68(55.7%)
5 I will not cooperate if the content is bad	3(4.5%)	1(1.6%)	0(0%)	1(3.7%)	4(15.4%)	1(3.7%)	1(25%)	1(20%)	8(6.5%)	4(3.3%)
6 Most of the time I will not cooperate	2(3.0%)	4(6.4%)	1(3.9%)	1(3.7%)	0(0%)	0(0%)	1(25%)	0(0%)	4(3.3%)	5(4.1%)
7 I know I will not cooperate no matter what	2(3.0%)	7(11.1%)	0(0%)	1(3.7%)	2(7.7%)	0(0%)	2(50%)	2(40%)	6(4.9%)	10(8.2%)
8 I decline to answer	4(6.0%)	1(1.6%)	1(3.9%)	0(0%)	2(7.7%)	3(11.1%)	0(0%)	0(0%)	7(5.7%)	4(3.3%)
proportion with a positive attitude*1	$\chi^2(P)$		$\chi^2(P)$		$\chi^2(P)$		$\chi^2(P)$		CMH- $\chi^2(P)$	
trend*2	3.0(0.081)		3.2(0.075)		3.8(0.051)		*		9.2(0.0025)	
	7.3(0.007)		4.7(0.030)		0.1(0.74)		1.0(0.33)		9.0(0.0028)	

*1 Responses 1-3 are classified to “positive” while 4-8 negative (Degrees of Freedom = 1).

*2 χ^2 is calculated from Mantel trend test of responses 1-7 (Degrees of Freedom = 1).

proportion ($P=0.0025$) and a significant trend ($P=0.0028$) in the intervention group.

Of the 10 factors in Q#2-2, significant differences were shown between the control group and the intervention group for “monetary reward” (CMH trend: $P=0.013$) and “security of personal information” ($P=0.021$); attitudes of people in the intervention group were more in favor of voluntary participation in cohort studies, that is, people in the intervention group laid less weight on monetary reward and security of personal information.

Seventy percent of the intervention group submitted comments on the video program; 75% said they could watch the video program at home (Q#2-3), and 69% said video was a convenient tool to learn the purpose and objectives of the study (Q#2-4).

VI. Discussion

In the present study, recognition of the term “epidemiological study” was low, while recognition of the term “lifestyle-related diseases” was much higher; 94% (237/253) of participants answered “never heard of” or “heard of but do not now the meaning” with regard to the former, while only 28% (70/252) gave the same answers to the latter. Some participants confused the term “epidemiology” with the “art of divination” which are homonyms in Japanese, both pronounced “EKIGAKU”. One of the reasons why the “lifestyle-related disease” is so familiar is in its naming; it had been formerly called “adult diseases” and was changed to “lifestyle-related diseases” recently in the media. It is more descriptive and therefore much easier to understand in everyday language.

The intervention using the videotape resulted in a statistically significant difference (CMH χ^2 : $P=0.0025$) between the intervention (videotape) group and the control group in attitudes to future cohort studies; 44% (54/123) in the intervention group showed a positive attitude towards future participation in cohort studies, in contrast to only 25% (31/122) in the control group. We speculate that particularly high levels of cooperation in the nursery class attendants are because these individuals deal with specific health problems in their families or relatives and they are relatively young as compared to the other groups and may better understand the meaning and significance of epidemiological studies.

The participant selection process with the three target populations (participants of the health promotion, a nurse care class and an elderly class) was designed to avoid any operational bias, although these willing to the part might be supposed to have more interest in health promotion than the general

public. Because of the limited research period, the number of “HIKIKOMORI” interviewed was small ($n=9$) and in this case the selection process may have been strongly biased towards selecting persons with more favorable views on health research. The randomized results, however, do not appear to lack internal validity. Generalization of the results to the general public is not warranted especially regarding the “HIKIKOMORI”; we are planning to conduct a new study to examine effects of campaigns on the general public regarding participation in health checkup programs.

It is still unknown whether the positive result of an increased cooperative attitude seen in this study was actually reflected in the participation rate of the “Otassha-study” held in 2004. The main reason for incomplete follow-up is administrative difficulty in tracking participation records. New research to determine actual levels of cooperation after videotape (or mass-media) intervention is being planned as described above.

Because of the small number of participants in the HIKIKOMORI group (9 people), comparison of their responses with those of the other groups is difficult. However, interviews conducted by the investigator (M.Ishii) revealed that these individuals shared some interesting characteristics. Common features included a phobia toward physicians and a strong revulsion toward doctors' diagnoses. This is not because HIKIKOMORI are not interested in their health; in fact, they feel anxiety about their health in the future. Regardless, HIKIKOMORI were hesitant about participating in a cohort study. Some also said there was confusion between participating in a cohort study and seeing a doctor for a certain disease. The interview also revealed that the major reason given by HIKIKOMORI for not participating in annual health checkup programs was time constraints due to running their own businesses. Therefore, for future cohort studies, we should consider various options to increase the number of participants, including accommodating the lifestyle of the potential participants. For example, visiting or conducting an interview at a time convenient for the participants is an option.

Of the 10 potentially influential factors, significantly different attitudes were observed between the videotape group and the control group with regard to monetary reward” (CMH trend: $P=0.013$) and “security of personal information” (CMH trend: $P=0.021$); people in the videotape group laid less weight on monetary reward and security of personal information for participating in future cohort studies. This could be explained by effects of the videotape, especially in generating in

the chief researcher of the “Otassha-study”, who appeared in the videotape and himself explained the purpose of the cohort study and stressed the significance of its performance in the specific local area. Also, the security policies of “Otassha-study” were explained through the interview by the investigator in the videotape. Without appropriate security policies and procedures, epidemiological studies could lose public trust and “fall from grace”. One possibility for public education on this issue is for responsible investigators or data managers, who are directly involved in data management, to give presentations directly to local residents so that potential participants understand the data management and security system. Such presentations should cover the following items: general policies, flow of original data, data-storage, anonymizing and linkage processes, publication and future utilization policies.

The US ethical guidelines for American population-based studies call for researchers to discuss the study with local representatives before the research is started¹⁴⁾. Discussion should include the objectives of the study, its timing and the type of analysis/statistics to be performed, etc. This type of communication can help prevent both negative reactions and opinions about the study from developing¹⁵⁾. Similar guidelines for information delivery should be developed in Japan.

The results of this study and our past experience show that the Japanese people are not familiar with the term “epidemiological study”. In such a situation, educational intervention by videotape or other media may be effective for making the concepts and significance of epidemiological studies more familiar to people; familiarization would reduce groundless anxiety. As this study showed, educational intervention by videotape (and probably other media) will also contribute to improve cooperative attitudes toward cohort studies, and it will possibly increase participation in cohort studies. Determinate of effective intervention, such as type of media, timing, frequency and intensity as well as contents should be explored in future with measurement of the outcomes.

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Appendix

Contents of the videotape:

Introduction showing scenery of annual festival at Kamogawa-city
 People filling out Q#1
 Tokyo University Campus and introduction of chief researcher
 Interview of the chief researcher, explaining the purpose of the research, etc
 Introduction to epidemiological studies
 Explanation of the "Otassha-study" by the chief researcher
 Appeal for cooperation and participation in the "Otassha-study"
 Questions and answers further explaining the "Otassha-study"
 Epilogue including other information on epidemiological research and health control

Questionnaire #1

Select the best answer from 1 to 4.

- Have you ever heard of the term epidemiological study or epidemiological research?
 1. I have never heard of this term.
 2. I have heard of this term but do not know what it means.
 3. I understand the term and can explain what it means.
 4. I have previously participated in an epidemiological study.
- Have you ever heard of the term lifestyle-related diseases?
 1. I have never heard of this term.
 2. I have heard of this term but do not know what it means.
 3. I understand the term but cannot name a specific lifestyle-related disease.
 4. I understand the term and can name a lifestyle-related disease (please write the name) _____

Questionnaire #2

- Will you cooperate if asked to participate in future medical research? Select the best answer from the following list.
 1. I will cooperate.
 2. I will probably cooperate.

3. I will cooperate most of the time.
4. I will cooperate depending on the content.
5. I will not cooperate depending on the content.
6. I will probably not cooperate.
7. I will not cooperate no matter what.
8. I decline to answer.

- Using the following scale of 1 to 4, please rate how much influence each of the factors listed below would have on your decision to participate in future medical research:

1 = Major influence on my decision

2 = Fair influence on my decision

3 = Little influence on my decision

4 = No influence on my decision

○ Monetary reward for participation: 1 2 3 4

○ Return of my individual results of research examinations: 1 2 3 4

○ Security of my personal information: 1 2 3 4

○ Length of time required for the research:

1 2 3 4

○ Participation of neighbors or friends: 1 2 3 4

○ Type of institution responsible for the research:

1 2 3 4

○ Type of samples I am asked to give for the research: 1 2 3 4

○ Contribution of the research to medical advancement: 1 2 3 4

○ My physical condition on the research day:

1 2 3 4

○ My family members' physical condition on the research day: 1 2 3 4

- Was the videotape a good tool for you to use?

1. I cannot watch a videotape at home.

2. I can watch a videotape at home.

3. I watched the videotape and read the covering letter.

4. I watched the videotape only to answer the questionnaire.

5. I read the covering letter but did not watch the videotape.

6. I did not watch the videotape or read the covering letter.

- Do you think a videotape is a good tool to help you understand the research? Select all that apply.

1. The videotape is a very good tool.

2. I am unaccustomed to the videotape cartridge.

3. I do not have time to watch a videotape at home.

4. The videotape is not a good tool to help me understand research.