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Awareness of Young Women on HPV Self-Sampling Trial using Opt-in Method

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Abstract

Study Background: Recently, studies have indicated that HPV self-sampling is an effective tool, though they do not state the reasons why young women do not take the test. Our study is to determine the awareness of young women who want or do not want to use HPV self-sampling and discuss the issues for increasing the use of the test.

Methods: We conducted two mailing surveys between July 1, 2018, and September 30, 2018, in city A. City A conducted the self-sampling trial with us. Our research target group had 101 women who returned filled questionnaires out of 837 aged 25 to 29 who had not undergone cervical cancer screening the previous year. In Questionnaire 1, there were questions regarding whether or not women wanted the self-sampling and the reasons why. In Questionnaire 2 was for women's willingness to use the kits.

Results: Only 9.8% of young women wanted to use self-sampling. In Questionnaire 1 stated "free self-sampling supported from the city", "I can do it in my own time", and "I have never received HPV vaccine" as the characteristic reasons for wanted; "I have no symptom", and "I am anxious about doing the test by myself" for not wanted. In Questionnaire 2, many women who performed self-sampling felt positive. Awareness of self-sampling was low overall.

Conclusion: We clarified that young women who did not want to use self-sampling tended to have anxiety toward the diagnosis accuracy of self-sampling. Some reasons for determining this were the lack of general knowledge on cervical cancer screening and low awareness of self-sampling. Therefore, we propose that national and local governments should aid in introducing a peer support program or free self-sampling systems, to encourage more young women to take cervical cancer screening or self-sampling tests without any hesitation.

Keywords

HPV self-sampling; Awareness; Young women; Human papilloma virus; Self-sampling; Cervical cancer; Anxiety

Abbreviations

CC: Cervical Cancer; CIS: Carcinoma *in-situ*; HPV: Human Papilloma Virus; JSOG: Japan Society of Obstetrics and Gynecology

Introduction

Recently, the incidence and mortality rate from cervical cancer (CC) has increased yearly in Japanese women and it has markedly increased in the younger generation [1]. The incidence of CC excluding carcinoma-*in-situ* (CIS) in 25-29-year-old Japanese women was 3.0 (per 100,000 people) in 2016 [2], and the mortality of the women was 0.3 (per 100,000 people) in 2017 [3]. However, the rate of people attending CC screenings, a preventive measure, was 42.4% in 25-69 years old and 26.5% in 20-29-year-old Japanese women in 2016, is markedly lower than those in Western countries and similar to middle-income country rates [4]. Unfortunately, HPV vaccine coverage in young women markedly declined to 0.3% over several years in Japan [5]. Therefore, periodic attending of CC screening has become to focus in importance as a CC-preventive method.

The Japan Society of Obstetrics and Gynecology (JSOG) adopted the Bethesda diagnostic criteria instead of the diagnostic criteria based on JSOG in 2009 and revised the Japanese Guideline for Cervical Cancer Screening [6]. The new guideline for planning a domestic consensus recommended CC screening of the target age 20 to 69 years and has been added Human Papilloma Virus (HPV) testing anew. In this modified guideline, two combination methods are clinician-collected sampling combined with HPV testing, and self-sampling combined with HPV testing. If the appropriate follow up is not performed, it has a probability of lower effect than conventional cytology alone. However, the rate of Japanese women attending CC screening is low at present, and the reasons that have been included 'no time', 'bothersome', 'expensive', and 'embarrassed' [7] and there is a shortage of obstetricians and gynecologists who conduct the CC screening [8].

Nobbenhuis et al. [9] have mentioned that self-sampling HPV DNA testing seems suitable as an alternative screening tool for unscreened women. It has been shown that the diagnostic accuracy of HPV self-sampling (self-sampling) is equal to clinician-collected sampling [10-12]. Furthermore, there was no social harm or adverse events recorded in previous studies. However, there is a lack of studies that discussed awareness, preference, recognition/perception, and anxiety of women to self-sampling [13-17]. In a previous study of community-based Canadian women, there was not a significant difference of preference between a Pap smear test performed by clinicians or self-sampling, although they indicated a preference of self-sampling, due to comfort and personal feelings [18]. There are not many other studies on the reasons for why young women want to, or do not want do perform self-sampling. In a trial performed in a rural city in Hokkaido, Japan, 90.1% of subjects did not want to do self-sampling, but the reason for it was not clarified. The COMPACT study targeted women in Hokkaido, Japan, and states that high-risk HPV was detected in 16.2% of young women 20-29 years old, from 14, 642 women that were 20-69 years old, and prevalence of both cytological abnormalities and high-risk HPV declined significantly with increasing age [19]. Women's perspective toward optimal self-sampling trials, to increase the screening rate by resolving these reasons for not attending the screening and subsequently prevent CC, need to be inspected.

The objective of this study is to determine the awareness of young women who want or do not want to use self-sampling and discuss the issues for increasing the use of the test.

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Methods

Data sources

The self-sampling trial project was conducted between July 1, 2018, and September 30, 2018, in rural city A in Hokkaido, Japan, and we conducted 2 mailing questionnaires/surveys using the opt-in method as a quantitative study. City A carried out the self-sampling trial with us and sent the self-sampling kit (Home smear set plus®) to women who answered want to use the self-sampling kit on survey 1. The present study analyzed 101 women who sent back filled out questionnaires from the 837 women. All 837 of the 25-29 years old women, had not undergone a regular cervical cancer screening in city A the previous year. 837 eligible subjects were selected at random from city A's resident registration database. We decided to analyze young women aged 25-29 years old as groups are in 5-year blocks and women in this age group all had a chance to receive HPV vaccines. Also, they do not receive free coupons to get tests done like 20 to 22-year-old women, and we referred to the data investigated. In Questionnaire 1, there were questions regarding whether or not the subjects wanted to use the self-sampling and the reasons why. In Questionnaire 2 there were questions regarding whether they were willing to use the self-sampling kits.

Hokkaido Prefecture, the population of which was 5,539,539 in 2018, is located in the northernmost part of Japan and is the second-largest island in Japan, and city A, with the population less than 100,000 is located in the middle-south part of Hokkaido.

Questionnaire

Original questions of both questionnaires on surveys 1 and 2 were prepared to refer to preceding studies [20,21]. In Questionnaire 1, age, occupation, final academic background, familial medical history of cancer, presence or absence of smoking and taking a lecture on CC, histories of HPV vaccination, undergoing CC screening, the use of tampon and low-dose pill, experiences of sexual intercourse, pregnancy, delivery, and marital status were asked as attributes of the subjects. In addition, the reason for wanting or do not wanting to use self-sampling and knowledge concerning CC was surveyed. Knowledge concerning CC was divided into the following 4 fields and asked: (HPV self-sampling test; self-sampling exist, fact of similar diagnostic accuracy levels between self-sampling and clinician-collected, required time of self-sampling, ordinary price, and important points of self-sampling), (CC and HPV; the age of onset, early symptoms, the term 'HPV', the cause and root of HPV infection, and the process of HPV infection), (CC prevention method; kind of prevention methods, benefits of CC, the effect of the HPV vaccine, CC and HPV vaccine, and low risks using a condom during sexual intercourse), and (adverse reactions of HPV vaccine; main symptoms after vaccination, information of adverse reactions, unvaccinated symptoms, opinions of the reaction by Ministry of Health, Labor and Welfare, and opinions of the delayed reactions by Ministry of Health, Labor and Welfare). Each field was comprised of 5 items and each item was scored 1or 0; "I had known from before" gets 1 point, but something like "I knew firstly this time" would get 0 points.

In Questionnaire 2, in addition to the attributes of the subjects asked in Questionnaire 1, the impression of the use of the self-sampling test kit was surveyed. Multiple answers were asked regarding the reason for wanting or not wanting to use self-sampling and the reason for carrying out self-sampling. This study adopted the opt-in method for both surveys 1 and 2. Specifically, we considered no attendant decision which not returned questionnaire and self-sampling kits. And it was classified in the category of not wanting to use self-sampling.

Statistical analysis

For data analysis, the statistical analysis software SPSS for Windows Ver. 21 was used setting the significance level set to "below 5%". The p-value with two-sided. On Survey 1, the Mann-Whitney U-test, χ^2 test, and Fischer's exact test were used for comparison of the attributes between women who wanted and did not want self-sampling, the reasons for wanting and not wanting self-sampling were summarized using descriptive statistics, and the Kruskal-Wallis test was used for comparison of the scores of the 4 fields of knowledge concerning CC. On Survey 2, the attributes of the subjects and impression of the use of the self-sampling kit were summarized using descriptive statistics.

Results

Survey 1

In survey 1, 9.8% (82/837) of young women first responded to wanting self-sampling, and 90.2% (755/837) responded they did not want to do it. The rate of response to Questionnaire 1 was 14.1% (118 responded). Excluding responses containing unclear answers, the valid response rate was 85.6% (101/118). Sixty-one and 40 subjects want and do not want the self-sampling test, respectively (Figure 1).

As shown in Table 1, when the characteristics of the subjects in survey 1 were compared between the young women who want (n=61) and do not want (n=40) to use self-sampling, a significant difference was noted in 3 areas. The rates of young women who answered that "a familiar person has cancer", "I have never attended CC screening", and "I have experience of sexual intercourse" were significantly higher in the young women who want self-sampling ($p<0.001$, $p=0.03$, $p=0.02$). Figures 2 and 3 indicate the reasons for wanting and not wanting the self-sampling, respectively. In the young women who want self-sampling, the main reasons selected were "Free self-sampling supported from the city (96.7%)", "I can do it in my own time (96.7%)", "I have experience of sexual intercourse (85.2%)", "I can do it by myself (83.6%)", "I have never received HPV vaccine (77.0%)", "Self-sampling is not embarrassing (63.9%)", and "I have never attended CC screening (55.7%)". In the young women who do not want self-sampling, "I have undergone CC screening (60.0%)", "I have no symptom (57.5%)", "I am anxious about doing the test by myself (45.0%)" , "The result may not be accurate because the sample is collected by myself (45.0%)", and "Bothersome (30.0%)" were mainly selected. Table 2 shows the results, the score of CC-related knowledge in all subjects (n=101). The mean score of the 4 fields in all subjects is below half of the full score of 5. When comparing the scores of the 4 fields, the score of the field concerning (HPV self-sampling test) was significantly lower than those of the other three fields i.e. CC and HPV, CC prevention method, and adverse reactions of the HPV vaccine. When comparing the CC prevention method and adverse reactions of the HPV vaccine, the score of the former was significantly higher.

Survey 2

The response rate was 54.9% (45 responded) for the questionnaire in survey 2. Finally, 86.7% (39/45) of respondents who performed self-sampling were effective respondents in survey 2 (Figure 4). Table 3 shows the characteristics of the subjects in survey

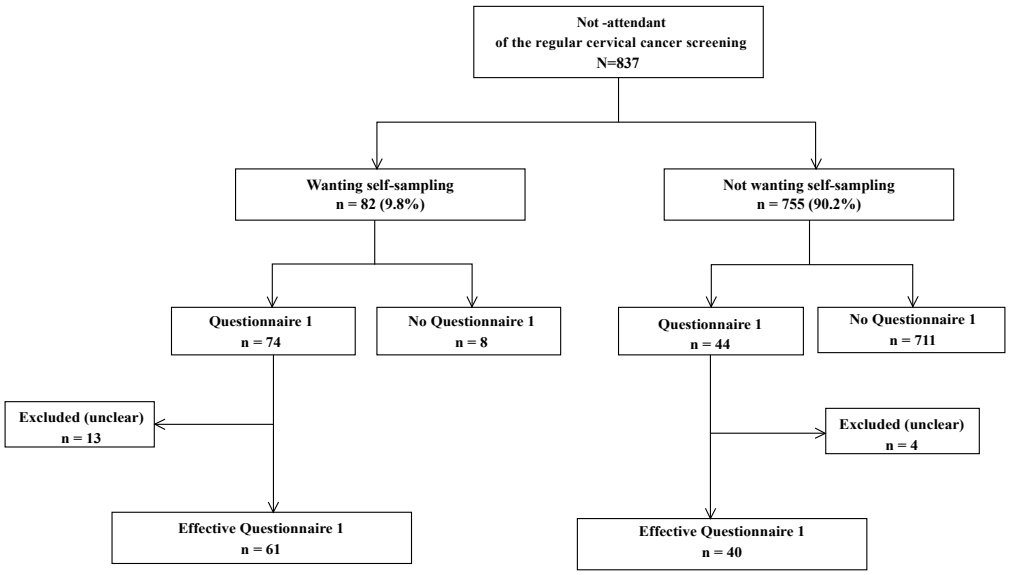

Figure 1: Flow chart of the study population in survey 1.

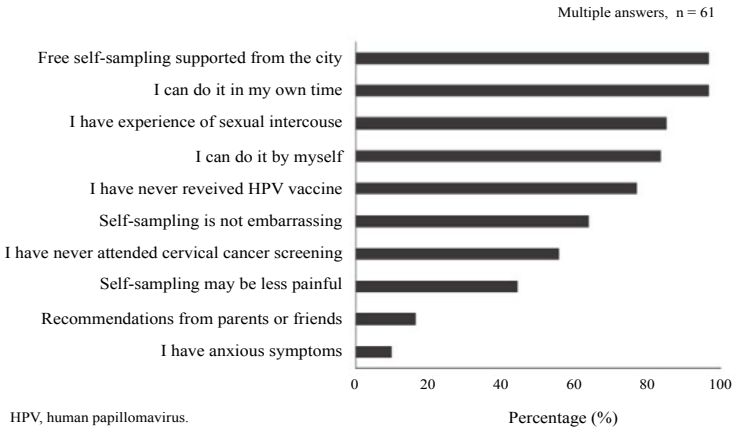

Figure 2: The reasons for wanting self-sampling.

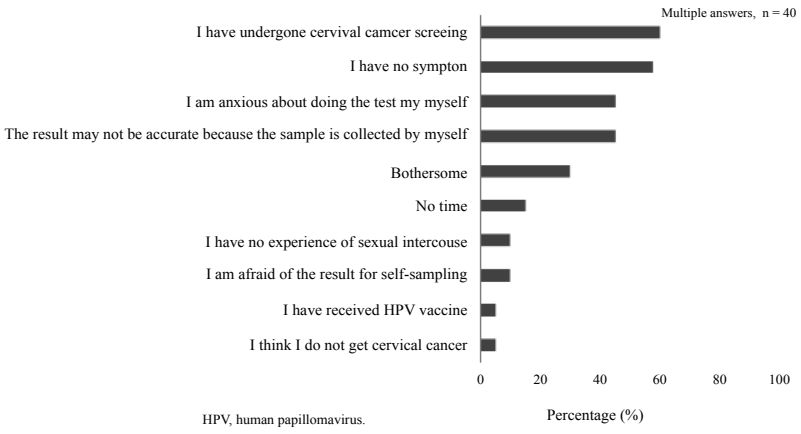

Figure 3: The reasons for not wanting self-sampling.

Table 1: Characteristics of the subjects in Questionnaire 1.

	Want (n=61)	Do not want (n=40)	p-Value
Age (mean ± SD)	26.95 ± 1.33	26.98 ± 1.07	0.88†
Occupation			
Medical workers	9	6	1.00‡
Non-medical workers	52	34	
Final academic background			
High school	15	12	0.56‡
Vocational school or junior college	28	14	
University	18	14	
Familial medical history of cancer			
Yes	40	9	<0.001‡
No	21	31	
Smoking			
Yes	11	5	0.64‡
No	50	35	
Have you taken lectures on cervical cancer?			
Yes	11	12	0.25‡
No	50	28	
Have you received HPV vaccination?			
Yes	1	3	0.30§
No	60	37	
Have you undergone cervical cancer screening?			
Yes	28	28	0.03‡
No	33	12	
Have you used a tampon?			
Yes	38	19	0.21‡
No	23	21	
Use of low dose pill			
Yes	5	6	0.34§
No	56	34	
Have you had sexual intercourse?			
Yes	61	36	0.02§
No	0	4	
Have you ever been pregnant?			
Yes	28	19	1.00‡
No	33	21	
Have you ever given birth?			
Yes	23	14	0.95‡
No	38	26	
Are you married?			
Yes	34	27	0.23‡
No	27	12	

n=101; †Mann-Whitney U test; ‡Pearson's χ^2-test; §Fischer's exact test; SD: standard deviation; HPV: Human Papilloma Virus

Table 2: Four fields on knowledge of HPV self-sampling and cervical cancer.

	Score (full score: 5 points)	
	mean ± SD	median
HPV self-sampling test	0.19 ± 0.82	0
- presence of test		
- accuracy of test		
- the required time of test		
- the cost of test		
- recommended time of test		
cervical cancer and HPV	1.69 ± 1.86	1
- age of onset		
- early symptoms		
- the term 'HPV'		
- the cause and rout of HPV infection		
- the process of HPV infection		
cervical cancer prevention method	2.05 ± 1.53*	2
- kind of prevention methods		
- benefits of CC		
- the effect of HPV vaccine		
- CC and HPV vaccine		
- low risks using condom during sexual intercourse		
Adverse reactions of HPV vaccine	1.28 ± 1.77	0
- mainly symptoms after vaccination		
- information of adverse reactions		
- unvaccinated symptoms		
- opinions of the reaction by Ministry of Health, Labor and Welfare		
- opinions of the delayed reactions by Ministry of Health, Labor and Welfare		

n=101; †Kruskal-Wallis test; $p<0.05^*$; SD: Standard Deviation; HPV: Human Papilloma Virus

2. The impressions of the use of the self-sampling kit are shown in Table 4. Thirty-four (87.2%), 36 (92.3%), 32 (82.1%), 36 (92.3%), and 37 subjects (94.9%) answered that "I could do it easily", "It took only a short time", "It was not painful", "It was not embarrassing", and "It was not uncomfortable", respectively. Thirty-eight subjects (97.4%) answered that the explanatory leaflet of self-sampling was easy to understand, the self-sampling test was easier than undergoing CC screening with sampling by a clinician, and they would consider doing the self-sampling again. Of 24 subjects who had experiences of using a tampon during menstruation, 9 (37.5%) and 10 (41.7%) answered that self-sampling is "less painful" and "the same" compared to the pain of using tampon, respectively, and 9 (37.5%) and 10 (41.7%) answered that insertion was "easier" or "the same" compared to that of using tampon, respectively (Table 5).

Discussion

Our subject sample size is low, similar to the study Nobbenhuis et al. [9] carried out, as the first study of HPV self-sampling. As found in their study, the use of the self-sampling devices is difficult (12% of subjects: 7 out of 56 women), and 23% (13 out of 56) of the women prefer the Pap smear test to self-sampling because of the reasons "no problem with gynecological examination" and "the self-sampling device is not practical". According to a previous study, the number of women who wanted to use self-sampling was 9.9%, and our result was that only 9.8% (82/837) of young women wanted to use self-sampling. Our result is similar to their result, except for a different unclear point, being the reason why women do not want to use self-sampling.

Hanley mentions that the opt-in method which confirmed the intention of wanting or not wanting to send self-sampling kits caused a low return ratio compared to the direct-mailed/opt-out method. Tranberg et al. [20] mention also that there were more women conducting self-sampling in the direct-mailed/opt-out method than women that used the opt-in method (directly mailed: 19.4%, opt-in: 8.3%). We consider that young Japanese women have to get the right information and receive education of self-sampling test or CC screenings. So they will be more willing to use the self-sampling and attend CC screenings, and not induced by direct mail/opt-out methods. Moreover, we can consider that there is a possibility to increase the number of young women who want to use self-sampling

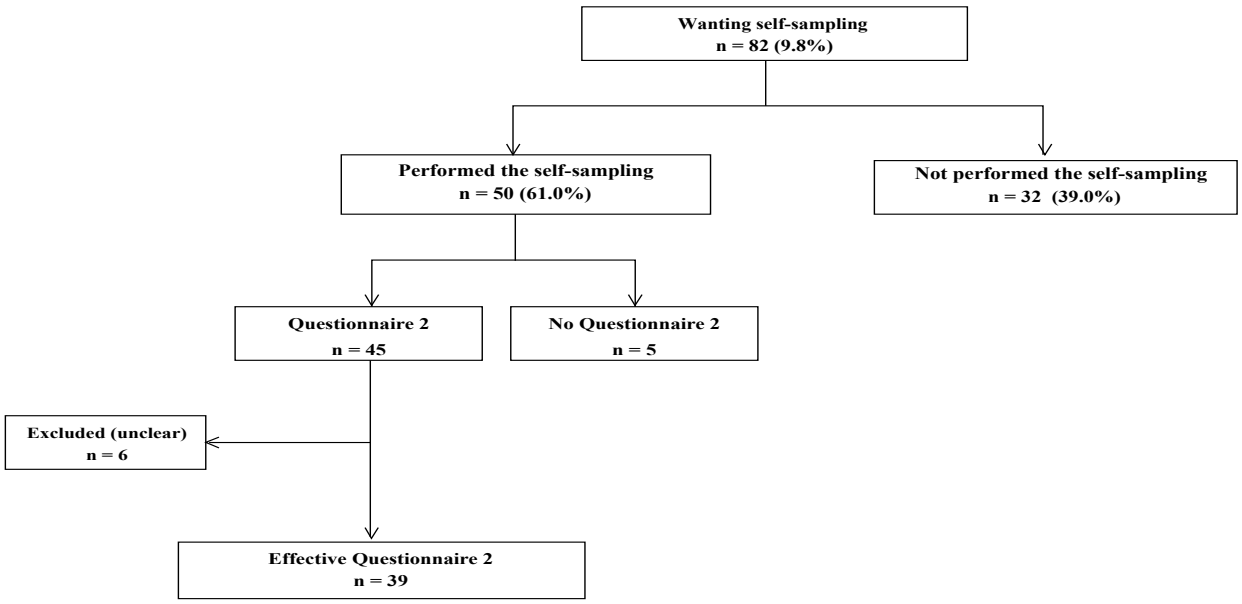

Figure 4: Flow chart of the study population in survey 2.

by doing more HPV self-sampling trials of the opt-in method that also considers the emotions of the women.

Firstly, this study clarified that the major factor to decide on wanting a self-sampling test was related to payment of the self-sampling kit (Figure 2). All tests fee was covered by city A in this study, however, for young women to continue to attend the self-sampling test, the cost was an issue. In Japan, the expense for the CC screening is an obstacle to get over. One method may be to introduce a free coupon system for all young women established by national and local governments [21]. Currently, only women 20-22 years old receive coupons for free screenings but not in all areas.

Secondary, this study shows two items not seen in previous studies [22], "I have never received HPV vaccine" and "I have never attended CC screening" (Figure 2), and they make up more than half of the answers in this research. Because young Japanese women may be reluctant to be vaccinated with concerns about adverse reactions to the HPV vaccination, they may not opt for CC screening in gynecology departments. For these reasons, the two items listed above in the survey might have been chosen more. The distribute accurate information about self-sampling and HPV vaccination as a CC prevention is very important, and we should be spreading more self-sampling information so young women can do the test by themselves in Japan.

Additionally, in this study, more than one-third of the reasons for not wanting to use self-sampling included "I have no symptom", "I am anxious about doing the test by myself", "The result may not be accurate because the sample is collected by myself", and "Bothersome" (Figure 3). We speculate that many women in this study have these reasons based on disinformation or incorrect knowledge because even if there were no symptoms, it is possible to have HPV. Although, it has already shown that the equal diagnostic accuracy between self-sampling and clinician-collected sampling [10-12], most of our study subjects lacked this general knowledge. In a study performed by Nelson et al. [23], "the results may not be accurate because the sample is collected by myself" and "I am anxious about doing the test by myself" were selected. These 2 items were also used as the reasons for not wanting self-sampling in our research. But the rate was 45.0% in our result, being higher than their rate [23]. It is worth noticing that young Japanese women not wanting self-sampling in our study had a stronger fear of self-sampling and anxiety about the accuracy of diagnosis compared to Nelson et al.'s result [23]. Although the scale is different, we consider that "Bothersome" of our results has a similar meaning to "forgot schedule an appointment (32.3%)" indicated in not-attendant women in regular screening programs of the study by Bosgraaf et al. [24].

From 2013 to the present, in Japan, the Ministry of Health, Labor and Welfare has been temporarily withholding the active recommendation for HPV vaccine on account of excessive media reports of adverse reactions, which lowered the HPV vaccination coverage rate. We propose that national and local governments should offer more subsidies and promote the self-sampling tests also peer support programs, if the Ministry of Health, Labor and Welfare will not proactively recommend HPV vaccination in the future. Because this problem must be solved as soon as possible. It is extremely important to make a new system that will make more women interested in testing and also incorporate a peer support programs into medical checkups at workplaces and schools.

There is a limitation of the number of eligible subjects due to the restricted population and the area of city A which differs from the pilot study nationwide. Also, we could not get enough subjects without donations for the self-sampling kits. In the Netherlands and Australia, providing self-sampling to women who have never attended a screening is incorporated into the national CC screening program [25,26]. Besides, Duke et al. [27] reported that the CC screening-attending rate was increased from 15.2% to 67.4% by providing self-sampling in Newfoundland, Canada. The introduction of self-sampling to women who had never undergone CC screening would lead to an increase in the screening-attending rate in Japan, as achieved in these countries.

Table 3: Characteristics of the subjects in Questionnaire 2.

	Want (n=39)
Age (mean ± SD)	26.7 ± 1.35
Occupation	
Medical workers	6 (15.4)
Non-medical workers	33 (84.6)
Final academic background	
High school	21 (53.8)
Vocational school or junior college	12 (30.8)
University	6 (15.4)
Familial medical history of cancer	
Yes	24 (61.5)
No	15 (38.5)
Smoking	
Yes	7 (17.9)
No	32 (82.1)
Have you taken lectures on cervical cancer?	
Yes	10 (25.6)
No	29 (74.4)
Have you received HPV vaccination?	
Yes	1 (2.5)
No	34 (87.2)
No remember	4 (10.3)
Have you undergone cervical cancer screening?	
Yes	19 (48.7)
No	20 (51.3)
Have you used a tampon?	
Yes	24 (61.5)
No	15 (38.5)
Use of low dose pill	
Yes	1 (2.6)
No	38 (97.4)
Have you had sexual intercourse?	
Yes	39 (100.0)
No	0
Have you ever been pregnant?	
Yes	18 (46.2)
No	21 (53.8)
Have you ever given birth?	
Yes	16 (41.0)
No	23 (59.0)
Are you married?	
Yes	20 (51.3)
No	19 (48.7)

n=39; SD: Standard Deviation; HPV: Human Papilloma Virus

Table 4: The impressions of the use of the self-sampling kit.

	n (%)
Could you do self-sampling easily?	
Yes	34 (87.2)
No	5 (12.8)
How long time did self-sampling take?	
Short time	36 (92.3)
Long time	3 (7.7)
Was self-sampling painful?	
Yes	7 (17.9)
No	32 (82.1)
Was self-sampling embarrassing?	
Yes	3 (7.7)
No	36 (92.3)
Was self-sampling uncomfortable?	
(ex. Vaginal discharge attached to your hands)	
Yes	2 (5.1)
No	37 (94.9)
Was the explanatory leaflet of self-sampling easy to understand?	
Yes	38 (97.4)
No	1 (2.6)
Which is easier for you to undergo, self-sampling or cervical cancer screening with sampling by a clinician?	
Self-sampling	38 (97.4)
cervical cancer screening by a clinician	1 (2.6)
Would you consider undergoing self-sampling again?	
Yes	38 (97.4)
No	1 (2.6)

n=39

Table 5: Feeling to use self-sampling compared with a tampon.

	n (%)
Pain	
Less painful	9 (37.5)
The same	10 (41.7)
More Painful	5 (20.8)
Easiness to insert	
Easier	9 (37.5)
The same	10 (41.7)
More difficult	5 (20.8)

n=24

Conclusion

The present study clarified that young women who did not want to use self-sampling tended to have anxiety toward the diagnosis accuracy of self-sampling and the kits. Some reasons for determining this were more subjects had a lack of general knowledge about CC screening, awareness of self-sampling was still low, and costs associated with self-sampling. In consequence, we propose that the national and local governments should aid introducing a peer support program for young women, or free self-sampling systems, to encourage more young women to take CC screening or self-sampling tests without any hesitation.

Declarations

Ethics approval and consent to participants

This study was approved by the Ethical Review Board of the Graduate School of Health Sciences, Hokkaido University (approval number: 17-114-1, approved: March 29, 2018), and the trial was

registered in a city, in Hokkaido, Japan (approved: May 23, 2018). We confirmed to informed consent by writing to all participants in this study; that can reject of participating when it does not want the self-sampling and no answer the questionnaire, and collected information kept confidential.

Availability of data and material

Our analysed data in this study is a part of a shared of cervical cancer screening as population-based in city A, in Hokkaido, Japan, and the self-sampling kits were sent to applicants of city A. Therefore, our data is not available for ethical reasons.

Competing Interests

There are no competing interests.

Author Contributions

Sayako Tada led the study design, collected data, did data coding and analysis, and drafted the manuscript. Yumi Ito contributed to the study design, collecting data, and revising the manuscript. Natsumi Nagai, Kanako Nakamura, and Kiriko Nohara reviewed it. Tadashi Sagawa contributed to the study design, interpretation of results and drafted manuscripts. All authors read and approved the final manuscript.

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