

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

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Abstract

Background

The rate of young Japanese women attending Cervical Cancer screenings is still low. There is a lack of studies that discussed awareness, preference, and anxiety of women to HPV self-sampling. The aim was to clarify the awareness of young women who want and do not want HPV self-sampling toward improvement the rate of attending Cervical Cancer screenings.

Methods

We carried out the observation study by self-administered questionnaires about the awareness of HPV self-sampling with the trial in a city, in Hokkaido, Japan. The subjects were selected at random to 25-29 years old women (837 persons) residing in a city. We compared their awareness between want and do not want self-sampling. For data analysis, statistical analysis software SPSS for Windows Ver.21 was used setting the significance level at below 5%.

Results

Young women in this study who firstly responded wanting practice of self-sampling were 9.8%, and not wanting in were 90.2%. The reasons of young women that want self-sampling were “Free self-sampling supported from the city”, “I can do it in my own time”, and “I have experience of sexual intercourse”. In contrast, the reasons of do not want self-sampling were “I have no symptom”, and “I am anxious about doing the test by myself”. The awareness of HPV self-sampling was low with all subjects, and they have few the general knowledge of Cervical Cancer.

Conclusion

There is a possibility to increase the number of young women who want self-sampling by using an HPV self-sampling trial of the opt-in method that also considers the emotions of the women. Young Japanese women who do not want self-sampling, tend to have a fear and anxiety toward self-sampling, in contrast, many of the women who conducted self-sampling prefer it. This study suggests the need of new practical education for self-sampling, including HPV infection, and Cervical Cancer prevention performed by clinicians, nurses and midwives.

Background

In 2018 worldwide, Cervical Cancer (CC) ranks third for both incidence and mortality[1], following breast, and lung cancer among women. Incidence of CC is the highest in Eastern-Africa regions. High mortality areas are in the Middle/Eastern/South/Western-Africa except for Northern-Africa, secondary areas are in South-Eastern/South-Central Asia, Micronesia and the Caribbean.

Recently, the incidence of and mortality ratefrom CC has increased yearly in Japanese women and it has markedly increased in the younger generation [2]. The incidence of CC excepted of carcinoma in-situ (CIS) in 25–29 year old Japanese women was 3.0 (per 100,000 people) in 2016 [3],and the mortality of the women

was 0.3 (per 100,000 people) in 2017 [4]. However, the rate of people attending CC screenings, a preventive measure, was 42.4% in 25–69 year old and 26.5% in 20–29 year old Japanese women in 2016, being markedly lower than those in Western countries, and similar to middle income country rates [5].

Human papilloma virus (HPV) is generally known that HPV is transmitted by sexual intercourse and it is considered that CC is induced by continuous infection. There are more than 150 types of HPV and 15 types are carcinogenic, termed high-risk HPV. CC-preventive measures are the HPV vaccine and periodic screening. The effect of HPV vaccine to prevent HPV infections and cervical dysplasia has been confirmed [6], but the Ministry of Health, Labour and Welfare is temporarily withholding active recommendations of the HPV vaccination in Japan because of problematic media reports of adverse reactions, despite no medical evidence of the HPV vaccine causing the reported problems [7,8]. Accordingly, HPV vaccine coverage markedly declined to 0.3% [9] and periodic attending of CC screening has become an important CC-preventive method.

The Japan Society of Obstetrics and Gynecology (JSOG) adopted the Bethesda diagnostic criteria and revised the Japanese Guideline for Cervical Cancer Screening in 2009, instead of the diagnostic criteria based on the original JSOG classification of diagnosis [10]. Conventional population-based screening of cervical and endometrial cancer of uterine body screening was mainly of cytology alone. Clinician-collected samplings, and calculated CC screening rates of ages specified were in 5 years intervals. Recently, the modified guideline for planning a domestic consensus has recommended CC screening of the target age 20 to 69 years and been added to HIV 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. Accordingly, new studies are recommended for dissemination and implementation, also a revised program of the CC screening results. However, the rate of Japanese women attending CC screening is low at present, and the reasons that have been given include, 'no time', 'bothersome', 'expensive', and 'embarrassed' [11], in spite of the issue of low CC screening rates due to a shortage of obstetrics and gynecologist [12].

Nobbenhuis et al. [13] have mentioned that self-sampling for HPV DNA testing seems suitable as an alternative screening tool for unscreened women. Recently, it has been shown that the diagnosis accuracy of HPV self-sampling (self-sampling) is equal to clinician-collected sampling [14–16]. 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 [17–21]. In a previous study of a community-based Canadian women, there was not a significant difference of preference between a Pap smear test performed by clinician or self-sampling, although they indicated a preference of self-sampling, due to comfort and personal feelings [22]. There is no other study on the reasons of young women wanting or not wanting to 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 [23], but the reason for it was not clarified. We suppose that young Japanese women were insufficiently aware of self-sampling or have lower preference rates for self-sampling at the present. Therefore, it is required to verify women's perspective toward optimal HPV self-sampling trials to increase the screening rate by resolving these reasons for not attending the screening and subsequently prevent CC.

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

Methods

Data sources

The self-sampling trial project was conducted between July 1, 2018, and September 30, 2018, in rural a city in Hokkaido, Japan, and 2 questionnaire surveys were used as a quantitative study, performed employing postal mail using the opt-in method. 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 a city, with the population less than 100,000 is located in the middle-south area of Hokkaido.

Questionnaire

On Survey 1, Questionnaire 1 was enclosed in the invitation for the self-sampling test sent to subject by a city, and on Survey 2, Questionnaire 2 was enclosed when the self-sampling kit (Home smear set plus®) and explanatory leaflet of the kit were sent. The subjects of Survey 1 were selected at random to 25–29 years old women residing in a city. Of the subjects of Survey 1, those who wanted the self-sampling kit were the subject of Survey 2. Original questions were prepared referring to preceding studies [24,25]. 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 want and do not want self-sampling and knowledge concerning CC were surveyed. Knowledge concerning CC was divided into the following 4 fields and asked: [HPV self-sampling test; self-sampling exist, fact of same diagnosis accuracy levels between self-sampling and clinician-collected, required time of self-sampling, ordinary price, and important points of self-sampling], [CC and HPV; incidents age, symptom of cervical cancer, infection route, and maintain of HPV], [CC prevention method; 2 types of vaccine and CC, benefits of CC, required period of CC, and low risks using condom during sexual intercourse], and [adverse reactions of HPV vaccine; symptom after vaccination, problematic media reports, and statement of Ministry of Health, Labor and Welfare]. Each field was comprised of 5 items and each item was scored 1. In Questionnaire 2, in addition to the attributes of the subjects asked in Questionnaire 1, impression of the use of the self-sampling test kit was surveyed. Multiple answers were asked regarding the reason for want or not want self-sampling, and the reason for carrying out self-sampling. This study adopted the opt-in method both survey 1 and 2. Specifically, we considered no attendant decision which not returned questionnaire and self-sampling kits. And it was classified to the category of not want self-sampling.

Statistical analysis

For data analysis, statistical analysis software SPSS for Windows Ver.21 was used setting the significance level at below 5%, and 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

Young women who firstly responded wanting practice of self-sampling were 9.8% (82/837), and not wanting in were 90.2% (755/837) in survey 1. 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 (Fig. 1).

As shown in Table 1, when the attributes of the subjects in survey 1 were compared between the young women who want ($n = 61$) and do not want ($n = 40$) self-sampling, a significant difference were noted in 3 items. The rates of young women who answered that "*a familiar person has a 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 self-sampling, respectively. In the young women who wanting 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%)*", and "*I have experience of sexual intercourse (85.2%)*". In the young women who do not wanting self-sampling, "*I have undergone CC screening (60.0%)*", "*I have no symptom (57.5%)*", and "*I am anxious about doing the test by myself (45.0%)*" were mainly selected. Table 2 shows the results of comparison of 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. On comparison of the score among the 4 fields, the score of the field concerning [HPV self-sampling test] was significantly lower than those of the other three areas ([CC and HPV], [CC prevention method], and [adverse reactions of HPV vaccine]). On comparison between [CC prevention method] and [adverse reactions of HPV vaccine], the score of the former was significantly higher.

Survey 2

The Questionnaire in survey 2 response rate was 55.6% (45 responded) and the valid response rate was 86.7% (39/45). Finally, respondents who conducted of self-sampling 86.7% (39/50) were effective respondents in survey 2 (Fig. 4). The impressions of the use of the self-sampling kit are shown in Table 3. 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 comfortable*", respectively. Thirty-eight subjects (97.4%) answered that the explanatory leaflet of self-sampling was easy to understand, the test by self-sampling was easier than undergoing CC screening with sampling by a clinician,

and they would consider undergoing the self-sampling again. Of 24 subjects who had experiences of the use a tampon used during menstruation, 9 (37.5%) and 10 (41.7%) answered that self-sampling is "*less painful*" and "*the same*" compared with pain of tampon, respectively, and 9 (37.5%) and 10 (41.7%) answered that insertion was "*easier*" and "*the same*" compared with that of tampon, respectively (Table 4).

Discussion

Our sample size of subjects is low, similar to the study Nobbenhuis et al. [13]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 people out of 56 women), and 23% (13/56) of the women prefer the Pap smear test to the self-sampling because of the reasons "no problem with gynaecological examination" and "the self-sampling device is not practical". In brief, their result indicates that 77% of the participating women chose self-sampling by vaginal lavage above the Pap smear as an alternative screening tool.

According to the other previous study [23], the number women who want self-sampling is 9.9%, and their result supported our survey. 1 result that 9.8% (82/837) of young women answered to want self-sampling. Their study is similar to ours except a different unclear point, about the reason of not want self-sampling. Hanley et al. [23] mention that the opt-in method which confirmed the intention of wanting or not wanting to send self-sampling kits caused a low return ratio than with the direct-mailed/opt-out method. Tranberg et al. [26] mention also that there were much more women conducting self-sampling in the direct-mailed/opt-out method than women that used the opt-in method (direct: 9.4%, opt-in: 8.3%). Therefore, our result has a higher value in this comparative study. Our study verified the opt-in method as a trial of mailing self-sampling kits, and we got an effective return ratio. Accordingly, we think that the original questionnaire used in this study caused a slight increase in the motivation of applicants. Consequently, we can consider that there is a possibility of increasing the number of applicants who want self-sampling trial by using the opt-in method.

In addition, the following results are: "*I can do it in my own time*", "*I can do it by myself*", "*It is not embarrassing*", and "*I think that self-sampling has less pain*" (Fig. 3). These are respectively much higher than the survey conducted in the Netherlands by Bosgraaf et al. [24], and it speculates that self-sampling is easy to use and a good tool to solve the problem of non-attendance of CC screening also in Japan.

On the other hand, two items not seen in previous studies [24], "*I have not received HPV vaccine*" and "*I have never received CC screening*", make up more than half of the answers in this research. 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. Because young Japanese women are reluctant to be vaccinated with concerns about adverse reactions of the HPV vaccine and they do not undergo CC screening in gynecology departments due to the reasons mentioned above, and the two items above might be chosen more. Consequently, the self-sampling is an easy-to-use preventive method for young Japanese women who are in this situation. Moreover, it is consider to be a breakthrough tool to improve the rate of women attending CC screenings.

Our study verify that there are several issues with self-sampling, so the majority of the subjects selected are for the reasons of not wanting self-sampling, "*I have undergone CC screening*", "*I have no symptom*", and "*I am anxious about doing the test by myself*". These results imply that many women consider that the test is no longer necessary if they previously underwent the screening. Many women do not know the fact that CC is asymptomatic in its early stages, so having a suspicion and using the technique of self-sampling is good.

In a study performed by Nelson et al. [27], "*the result may not be accurate because the sample is collected by myself*" and "*I am anxious about doing the test by myself*" are selected. These 2 items are also selected as the reasons for not wanting self-sampling, but the rate was 45.0%, being higher than that in the study reported by Nelson et al. [27], clarifying that young Japanese women not wanting self-sampling had a stronger fear of self-sampling and anxiety about the accuracy compared with women in other countries, in our study.

On the other hand, receptivity by women who actually performed self-sampling is high in other countries [26], and about 90% of women who perform self-sampling also have a positive impression of the use of the self-sampling kits in our study. In addition, it is clarified that 97.4% of the subjects prefer self-sampling to sampling by a clinician and this is higher than (62.0%) in a survey performed by Winer et al. [19],clarifying that young Japanese women strongly prefer self-sampling compared with women in other countries.

Regarding the impression of the use of the self-sampling kit compared with that of a tampon used during menstruation, it is suggested that the kit is more comfortable than or comparable to a tampon. These impressions by women who actually used the self-sampling kit may serve as peer-support and material to decide on doing or not doing self-sampling for women who have never carried it out.

This time, comparing the knowledge score of [HPV self-sampling test], [CC and HPV], [CC prevention method], [adverse reactions of HPV vaccine] in our original questionnaire, and the score of [HPV self-sampling test] was significantly lower than those of the other three areas ([CC and HPV], [CC prevention method], and [adverse reactions of HPV vaccine]). We consider that the sex education in Japan is one factor connected to this. The awareness of young women with an idea thinking it is unnecessary to undergo CC screening because of no symptoms, as one of the reasons for not wanting self-sampling, has to be modified to the right recognition in sex education since early childhood. Because even if there are no symptoms, women engaged in sexual intercourse are required to undergo ordinary CC screening or self-sampling to prevent HPV infections unless they get vaccinations. From these view points, we regard that the background factor that the self-sampling is not sufficient popular, is in the fact that insufficient of correct knowledge to prevent HPV infection and the incidence of CC. To promote the right knowledge of HPV self-sampling and prevention of CC is a necessary condition due to safety and the efficacy of the self-sampling kit for young women.

Williams et al. [28] report that the lack of knowledge related to HPV and self-sampling is a barrier to wanting the test, and Crofts et al. [29] and Penaranda et al. [30] argue that the number of women who prefer self-sampling increased by educational interventions on CC and self-sampling. Moreover, it is eminently important to explain about self-sampling safely, efficacy, how to use kits, the diagnosis accuracy, and follow up system according to women's life events, with face to face instructing by clinicians, nurses and midwives as well as training from instruction booklets, DVDs, and explanatory leaflets with self-sampling kit for sustainable self-sampling. Consequently, in this study, it is clear to see there is a lack of the right knowledge in regards to the

background of self-sampling dissemination. In the future, as the enhanced awareness of young women's self-management, it is urgently to give an opportunity so they can select alternatives with confidence, either for CC screenings or self-sampling by themselves.

In this study, there is a limitation that the number of eligible subjects is restricted to the population and area of a city and it differs from the pilot study nationwide. 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 the screening is incorporated into the national CC screening program. [31,32] In addition, Duke et al. [33] reported that the CC screening-attending rate was increased from 15.2 to 67.4% by providing self-sampling in Newfoundland, Canada. Introduction of self-sampling to women who had never undergone CC screening may lead to an increase in the screening-attending rate in Japan, as achieved in these countries.

This study suggests in focus on dissemination and implementation of new practical education. To rapidly increase self-sampling in Japan, it is necessary to review sex education of the younger generation, increase correct knowledge concerning CC to mothers, and provide information on self-sampling using media rooted in daily life. The latest review mentions that no studies offered comparative data for frequency of CC screening, nor for social harm and adverse events, [34] although, the scope in our study considered the emotions of young women in their vulnerable years. Our research result is to confirm the reasons why people do not return the questionnaire and self-sampling kit. Our findings on the awareness of young women who want to do and not want to do self-sampling is useful to a program as feasible, to give support to ensure reproductive health and the rights of young women in the future.

Conclusion

There is a possibility to increase the number of young women who want self-sampling by using an HPV self-sampling trial of the opt-in method that also considers the emotions of the women. In this study, young women, who do not want self-sampling, tend to have a fear and anxiety toward self-sampling. Although, many of the young women who conducted self-sampling prefer it. In addition, almost all subjects have a lack of general knowledge on CC, and awareness of self-sampling is still low. Consequently, we suggest the need of new practical education for self-sampling, including HPV infection, and CC prevention performed by clinicians, nurses and midwives.

Abbreviations

CC: Cervical Cancer, CIS: carcinoma in-situ, HPV: Human papilloma virus, JSOG: Japan Society of Obstetrics and Gynecology,

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 written to all participants in this study; that can reject of participate when it does not want the self-sampling and no answer the questionnaire, and collected information kept confidential.

Consent for publication

Not applicable.

Availability of data and material

Our analyzed data in this study is a part of a shared of Cervical Cancer screening as population-based in a city, in Hokkaido, Japan, and the self-sampling kits were sent to applicants of a city. Therefor, our data in not available for ethical reasons.

Competing interests

There are no competing interests.

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Author Contributions

ST led the study design, collected data, did data coding and analysis, and drafted the manuscript. YI contributed to the study design, collecting data, and revising the manuscript. NN, KN and KNo reviewed it. TS contributed to the study design, interpretation of results and drafted manuscripts. All authors read and approved the final manuscript.

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Tables

Table 1. Comparison of characteristics in survey1

	Want (n = 61)	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 papillomavirus.

Figures

Table 2. Comparison 4 areas of knowledge about Cervical Cancer

	Score (full score: 5 points)	p-Value [†]
	mean \pm SD	median
HPV self-sampling test	0.19 \pm 0.82	0.0
- Cervical Cancer and HPV		< 0.001
- Preventive methods against Cervical Cancer		< 0.001
- Adverse reactions of HPV vaccine		< 0.001
Cervical Cancer and HPV	1.69 \pm 1.86	1.0
- Preventive methods against Cervical Cancer		< 0.001
- Adverse reactions of HPV vaccine		0.32
Cervical Cancer prevention method	2.05 \pm 1.53	2.0
- Adverse reactions of HPV vaccine		0.08
Adverse reactions of HPV vaccine	1.28 \pm 1.77	0.0

n=101, †Kruskal-Wallis test. SD: standard deviation, HPV: human papillomavirus.

Table 3. The impressions of the use of the self-sampling kit

	n (%)
Could you do self-sampling easily?	
Yes	34 (87.2)
No	4 (12.8)
How long time did self-sampling take?	
Short time	36 (92.3)
Long time	3 (6.7)
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	36 (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

Table4. 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

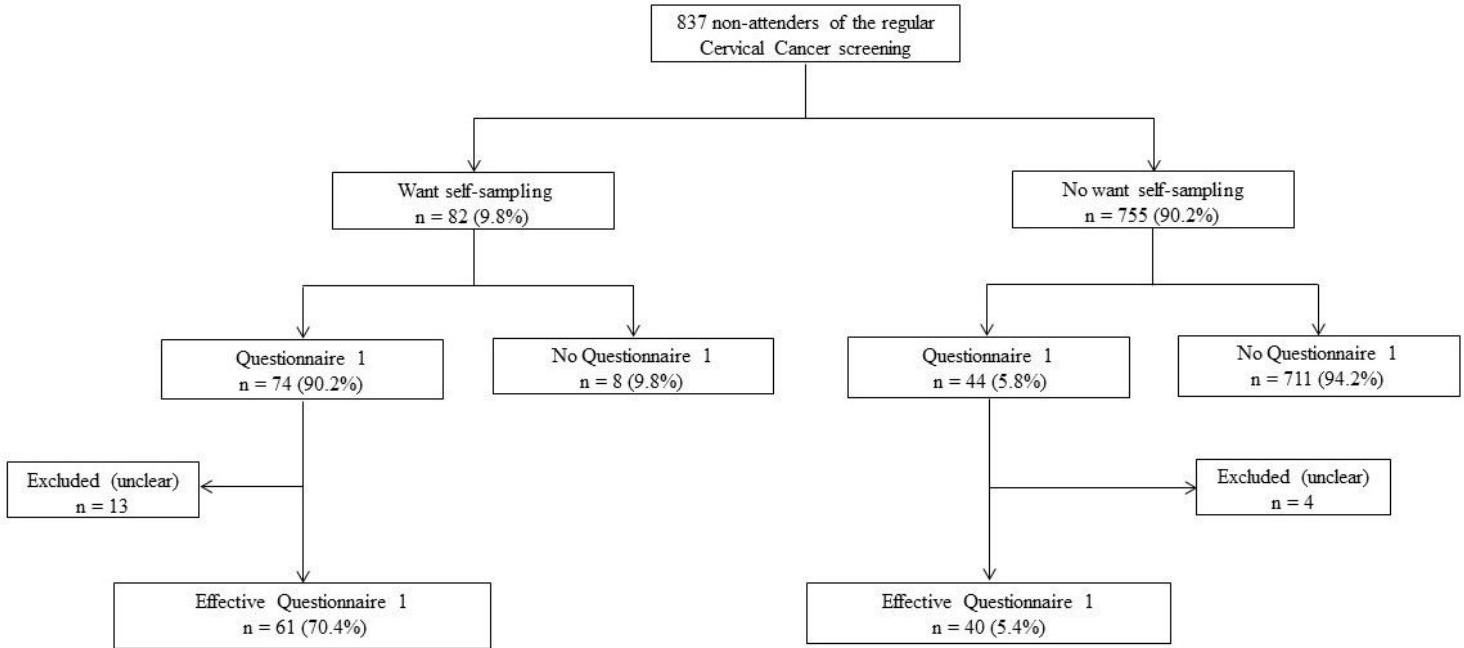


Figure 1

Flow chart of the study population in survey 1

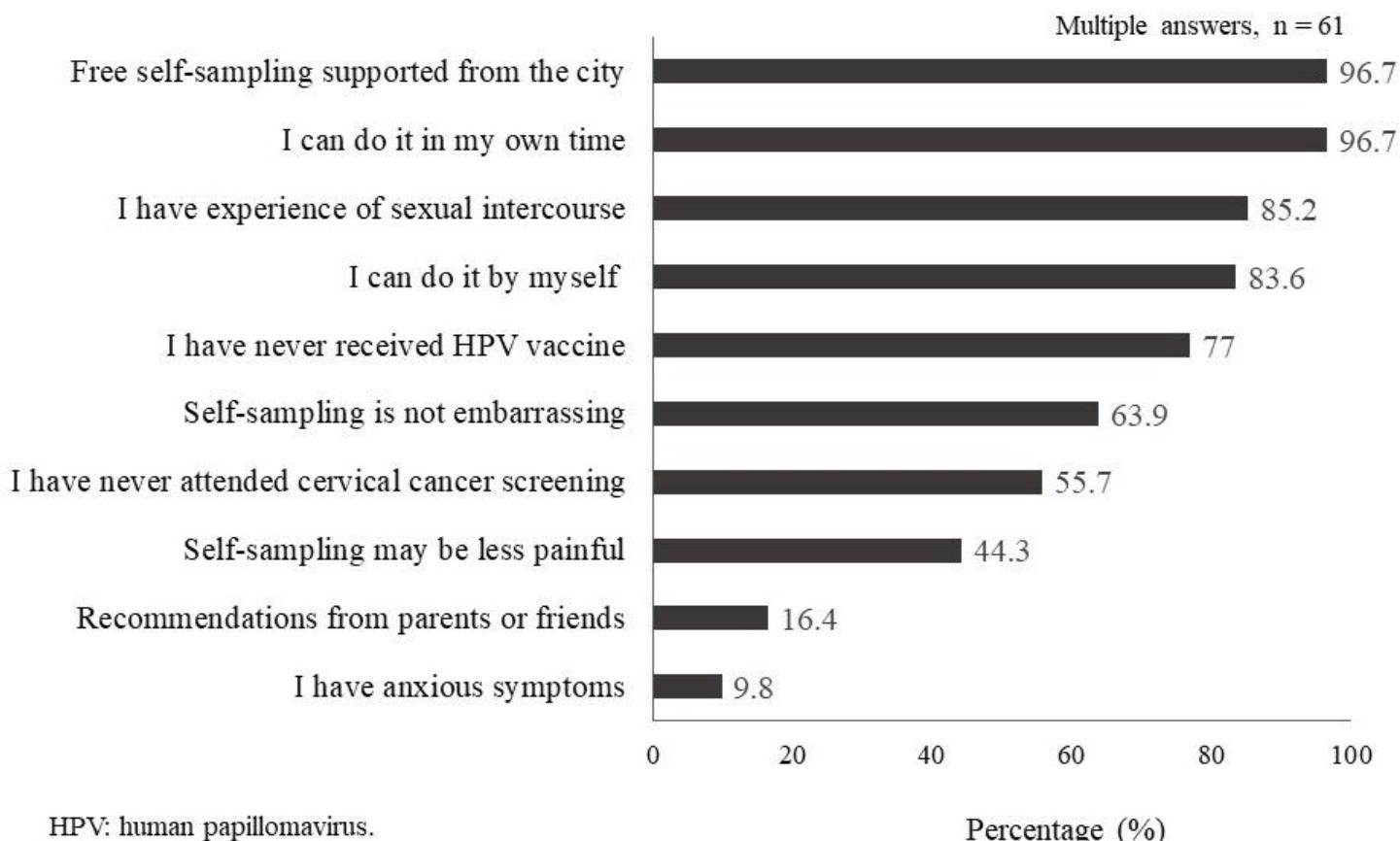


Figure 2

The reasons for wanting self-sampling

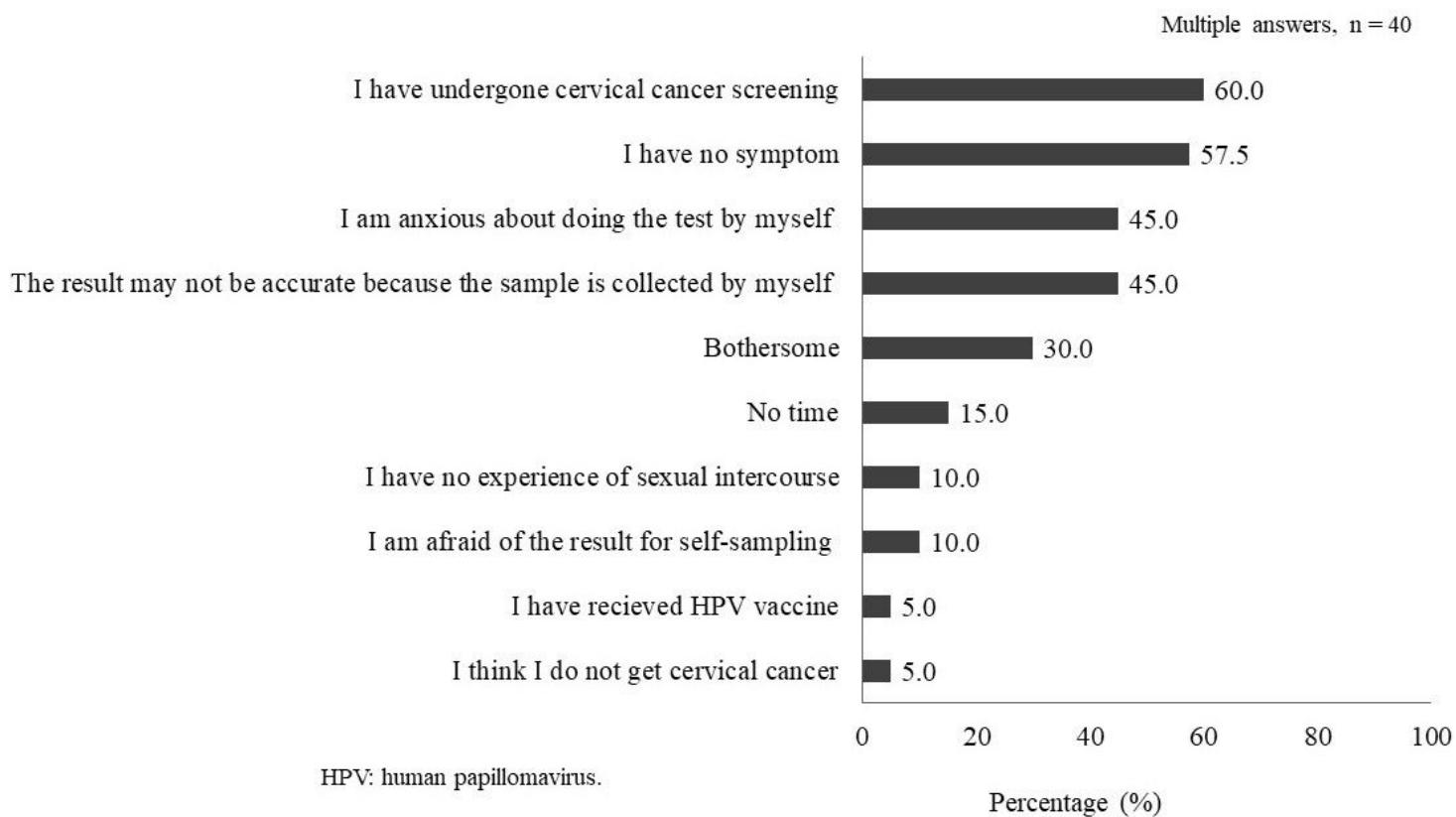


Figure 3

The reasons for not wanting self-sampling

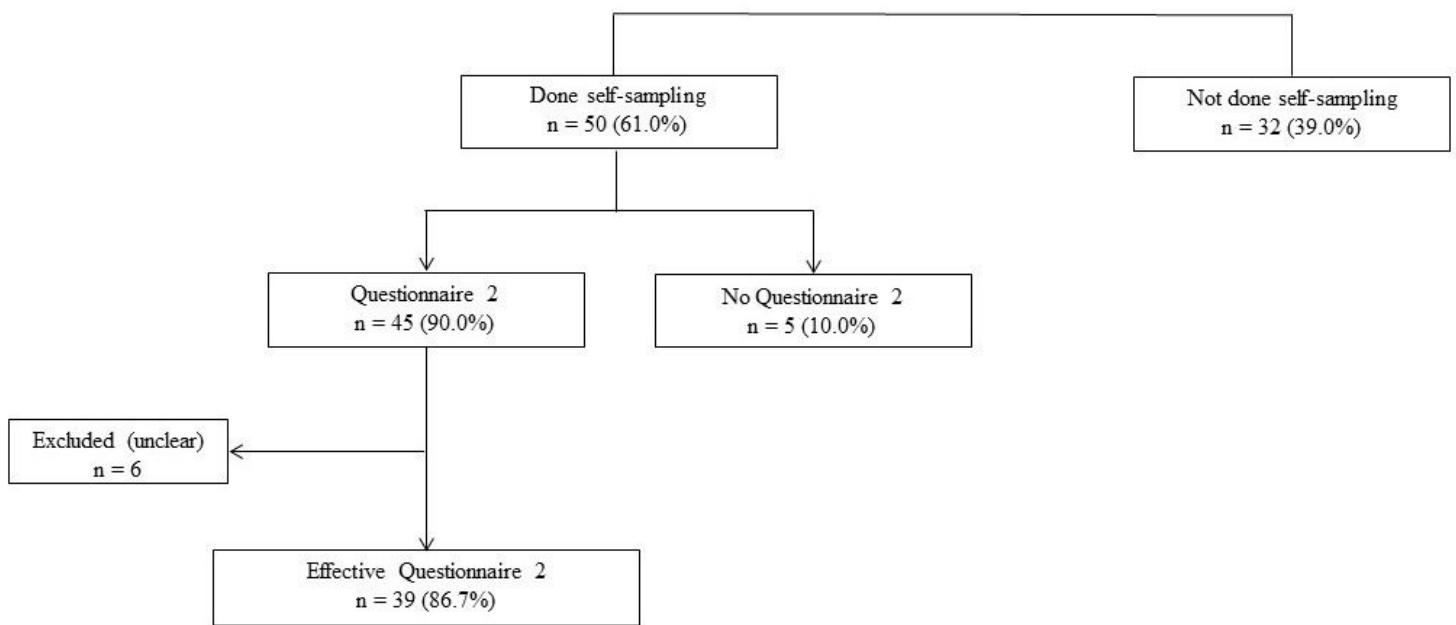


Figure 4

Flow chart of the study in survey 2