# RESEARCH

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Home-based urinary HPV self-sampling for the

detection of cervical cancer precursor lesions:

attitudes and preferences from Belgian

females participating in the CASUS study

# Abstract

**Background** Cervical cancer (CC) is the fourth most common cancer globally in females, caused by oncogenic infections with high-risk human papillomavirus (hrHPV) strains. Successful CC screening programs strongly depend on the participation rate of the target population. Nevertheless, it remains challenging to reach under screened populations. The CASUS study aimed to develop a complete CC screening solution based on first-void urine (FVU) self-sampling. Here we report on the usability perceptions and preferences from females that participated in the CASUS study by collecting FVU as a liquid biopsy.

**Methods** Females self-collected FVU samples at home the day before colposcopy using the Colli-Pee® UCM FV-5010, a FVU collection device prefilled with 3 mL of UCM preservative, collecting a total volume of 10mL. Afterwards, they completed a questionnaire expressing their usability perceptions and preferences regarding the device.

**Results** A total of 332 females (26-70y) were enrolled in the CASUS study of which 210 completed the questionnaire. Overall, 66.6% of females preferred FVU self-sampling over a physician taken cervical sample (PTS) (32.9%) for their next CC screening. Out of 159 women who reported prior experience with a urine cup, 79.2% expressed a preference for using the Colli-Pee® UCM FV-5010, while 20.8% favored the traditional urine cup. Additionally, 96.6% of females found Colli-Pee® UCM FV-5010 easy to use and 97.1% would use the device again. A total of 208 valid System Usability Score (SUS) scores were received with an average of 86.17 ± 1.03 Standard Error of Mean (SEM).

**Conclusion** The results of this study show that the majority of females in this referral cohort would prefer to self-collect a FVU sample at-home over a PTS for their next CC screening. Moreover, Colli-Pee® UCM FV-5010 was considered an easy-to-use and well-accepted self-sampling device for CC screening in a Belgian colposcopy referral population. From a future perspective, these results highlight the possibility of home-based FVU self-sampling as a liquid biopsy in CC screening where under screened populations could be approached more easily.

Trial registration The CASUS study was registered in http://www.ClinicalTrials.gov (identifier: NCT04530201).

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Keywords HPV, First-void urine, Self-sampling, Atitudes, Preferences, Cervical cancer screening, CASUS

# Introduction

#### Text box 1. Contributions to the literature

• This study provides new evidence on the preferences and usability of FVU self-sampling for CC screening.

The results of this study highlight a significant preference among women for FVU self-sampling over traditional PTS, which can enhance participation rates in cervical cancer screening programs.
By facilitating home-based FVU self-sampling, CC screening access can be improved for under-screened populations, potentially reducing

can be improved for under-screened populations, potentially redu CC incidence and mortality.

Cervical cancer (CC) is the fourth most common cancer globally among females, caused by oncogenic infections with high-risk human papillomavirus (hrHPV) strains [1, 2]. There were an estimated 604 000 new CC cases and 342 000 related deaths worldwide in 2020, with about 90% occurring in low- and middle-income countries [3]. A recent modelling study suggests that widespread coverage of both HPV vaccination and CC screening from 2020 onwards could prevent 12.5– 13.4 million new cases of CC by 2070, leading to nearelimination of CC in most countries by the end of the century [4].

Successful CC screening programs strongly depend on the participation rate of the target population. However, challenges are being faced with including hard to reach and under screened females, leading to an increased risk for CC [5]. A decade ago, the overall coverage of European CC screening programs was below 80%, ranging from 10 to 79%. In only five countries (France, England, Finland, The Netherlands, and Sweden) screening coverage was 70% or more [6]. The Belgian Center for Cancer Detection, CvKO, recently published data regarding the CC screening coverage in 2021, revealing a 64% coverage [7, 8]. Screening in most European countries is based on cytology, which requires a PTS, is challenged by low sensitivity, and knows a subjective review [9]. Several barriers have been identified that lead to reluctance towards CC screening, including lack of time and limited access to health services, physical discomfort, cultural barriers, and lack of knowledge about the benefits of CC screening [10-15].

For over 60 years, cervical cytology has been considered the gold standard for CC screening, looking for precancers or abnormal cell changes in the cervix [16–18]. Considering that the majority of cervical cancer cases are diagnosed in screening non-attendees [19], opting for HPV testing over cytology is a viable choice due to its higher sensitivity and a reduced cumulative risk of developing high-grade diseases. Randomized population-based controlled trials have demonstrated that HPV-based screening, compared to cytology-based CC screening, offers an early detection of hrHPV types and thus risk of incident CC [20, 21]. An additional advantage of CC screening using HPV assays is that these tests can be performed on self-samples. Self-sampling collection methods may include a (cervico)vaginal swab or brush, vaginal lavage, vaginal patch or a urine sample, with a particular emphasis on FVU as this is more accurate than testing on a random or midstream urine sample [22]. Recent studies have shown that hrHPV DNA testing on self-samples, compared to PTS, is equally accurate in detecting underlying CC using validated PCR-based hrHPV tests [23–26]. Furthermore, previous studies have shown that providing participants with a self-sampling kit, offering options such as a vaginal swab, brush, lavage, tampon, urine, labial padette, or a combination of these, leads to higher participation rates compared to traditional invitations for PTS and is preferred by participants. FVU offers advantages over other self-sampling methods, such as lavage, brush, or tampon-based self-sampling, due to its non-invasive nature, ease of use, and the absence of penetrating procedures, which can enhance participant comfort and increase acceptance among diverse populations [23, 27-31]. In 2018, the World Health Organization called for coordinated global action to eradicate CC, emphasizing screening for individuals aged 30–60 years, and strongly supporting the inclusion of HPV testing on self-sampling as an add-on in CC screening services [32, 33]. Approximately 99% of hrHPV infections are transient and do not lead to CC. Therefore, triage is necessary to identify only hrHPV-positive cases with clinically relevant disease to have control over referral, overtreatment, and costs [34-37]. Currently, triage relies heavily on cytology-outcomes which requires repetitive testing on PTS [38, 39]. This two-step process is associated with 25–40% loss to follow-up [40, 41]. The CASUS study aimed to develop a complete CC screening solution based on FVU self-sampling, identifying females with clinically relevant disease in need of treatment in a one-step triage manner. Here, we report usability perceptions and preferences from females participating in the CASUS study.

# Materials and methods Study population

The CASUS study (http://www.ClinicalTrials.gov iden tifier: NCT04530201) is an interventional study, which aimed to develop the first fully molecular integrated cervical cancer screening approach, based on FVU as an easily accessible and non-invasive source of biomarkers. Ethical approval for the CASUS study was provided by the Medical Ethical Committee of the University Hospital Antwerp (20/21/271, Antwerp, Belgium) on the 4th of August 2020.

At three Belgian colposcopy clinics (UZ Ghent, Ghent, Belgium; CHU de Liège, Liège, Belgium; The General Regional Hospital Heilig Hart Tienen, Tienen, Belgium), females between 26 and 70 years of age referred to colposcopy due to a (probable) hrHPV infection and/ or abnormal cervical squamous intraepithelial/glandular lesion were recruited. This recruitment took place between August 2020 and February 2022 by the medical staff of the participating colposcopy clinics when a date for a colposcopy examination was set. Hysterectomized females, females with known pregnancy, females being treated for CC in the last six months before participating in this study, females participating in another (low-) interventional study, non-consenting females, and females that were not able to understand and to sign the informed consent form were excluded. A study package, sent to the females' home address by regular mail, contained an information brochure and informed consent form, two Colli-Pee® UCM FV-5010 devices containing 3.4 mL of UCM preservative [42] and collecting a total sample of approximately 10 mL (Novosanis, Wijnegem, Belgium), instructions for use, and safety bags. The safety bags included absorbing tissues for storage of the collector tubes after FVU collection. Furthermore, along with the study package a link was provided to a digital questionnaire on the usability of the device and/or a paper version in either Dutch or French.

One day prior to the colposcopy, study participants who gave their consent self-collected two FVU samples at home using the Colli-Pee® UCM FV-5010. Participants were asked to space the two collections with a minimum of one hour. Females were asked to fill in a questionnaire at home between the two FVU collections. After collecting the FVU samples, the participant stored the collector tubes in individual plastic safety bags at room temperature with absorbing tissues. At the day of colposcopy, the participant brought the FVU samples to the colposcopy clinic and handed them over to the study team. During the colposcopy appointment, a trained physician collected a cervical sample using the Cervex-Brush (Rovers Medical Devices B.V., Oss, The Netherlands), which was subsequently transferred/preserved in ThinPrep PreservCyt solution (Hologic Inc., Bedford, Massachusetts, United States of America). This cervical sample was collected before colposcopy, during the same medical exam. Hereafter, colposcopy (with biopsy/ambulant conization if considered necessary) was performed as usual.

# **CASUS** questionnaire

The questionnaire consisted of 38 questions divided into six categories: (1) general, (2) experience prior to using Colli-Pee<sup>®</sup>, (3) experience while using Colli-Pee<sup>®</sup>, (4) experience after using Colli-Pee<sup>®</sup>, (5) feedback on the use of Colli-Pee®, and (6) feedback on the use of Colli-Pee® through a System Usability Scale (SUS) [43, 44]. The SUS questionnaire system was used to evaluate user satisfaction and consisted of 10 open-ended polarity-balanced questions with a five-point Likert scale, ranging from 1 (Strongly disagree) to 5 (Strongly agree), for responses. The SUS score, as a composite measure of the overall usability of the Colli-Pee® device, was calculated as described previously [43]. A SUS score greater than 68 is considered above average, and a SUS score greater than 80.3 indicates that the device is user-friendly and will be recommended by users. Responses regarding the experiences were gathered with an 8-point Likert scale ranging from 1 (Completely disagree) to 8 (Completely agree). The original Dutch/French questionnaire was translated to English and added as Supplement A.

# Statistical methods

Online questionnaire answers were exported from Qualtrics XM (Seattle, Washington, USA, 2020) in an Excel database. Paper questionnaire forms were encoded manually into the Excel database. A full check was done after data entry by the encoder. In addition, an independent check of a 25% random selection of the answer forms was performed by a CASUS researcher to pick-up possible data entry errors. Frequency distributions, showing the number of answers and relative percentages, were tabulated for each question followed by statistical analysis for normality with a Shapiro-Wilk test. As the proportion of missing values was small (<5%), it was decided to include the missing data in the descriptive statistics without data imputation [45]. Multiple logistic regression analysis was used to model correlations. Statistical significance was accepted when p-values < 0.05 and statistical analyses were conducted with GraphPad Prism (version 9.4.0 for Windows, GraphPad Software, San Diego, CA, USA).

### Results

### **Population characteristics**

Between the 20th of August 2020 and the 28th of February 2022, 332 females were enrolled in the CASUS study. The number of enrolled patients per colposcopy clinic was provided by the responsible gynecologists. A total of 210 questionnaires (N=210/332, 63%) from the total enrolled cohort (age 25–64 years) were obtained and analyzed. The median age of the included females was 37 years (IQR: 30–48). The distribution of the number of enrolled patients per colposcopy clinic and general characteristics of the enrolled study participants are depicted in Table 1.

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**Table 1** Characteristics of enrolled participants (*N*=210) in the CASUS study

| Characteristics                       | N   | %    |
|---------------------------------------|-----|------|
| 5-year age groups (years)             | 210 | 100  |
| 25–30                                 | 57  | 27.1 |
| 31–35                                 | 40  | 19.0 |
| 36–40                                 | 26  | 12.4 |
| 41–45                                 | 25  | 11.9 |
| 46–50                                 | 23  | 11.0 |
| 51–55                                 | 23  | 11.0 |
| 56–60                                 | 14  | 6.7  |
| 61–65                                 | 2   | 1.0  |
| Recruitment at each colposcopy clinic | 210 | 100  |
| UZ Ghent                              | 79  | 37.6 |
| CHU de Liège                          | 60  | 28.6 |
| RZ Tienen                             | 71  | 33.8 |
| Self-reported HPV vaccination status  | 210 | 100  |
| Vaccinated                            | 41  | 19.5 |
| Unvaccinated                          | 157 | 74.8 |
| Unknown                               | 11  | 5.2  |
| Missing value                         | 1   | 0.5  |
| Prior history of an oncologic disease | 210 | 100  |
| Yes                                   | 6   | 2.9  |
| No                                    | 200 | 95.2 |
| Unknown                               | 3   | 1.4  |
| Missing value                         | 1   | 0.5  |

**Table 2** Use and understanding of the instructions for use of the Colli-Pee<sup>®</sup> device (N = 210)

| Question  | Ν   | %    |
|---|-----|------|
| I used the instructions for use that came along with the device                   | 210 | 100  |
| Yes   | 174 | 82.9 |
| No  | 35  | 7    |
| Missing value   | 1   | 0.5  |
| The instructions for use were clear (for those who used the instructions for use) | 174 | 100  |
| Yes   | 170 | 97.7 |
| No  | 4   | 2.3  |

# Experiences and intentions regarding prior and future use of urinary self-samples

The level of use and understanding of the instructions for use of the FVU self-sampling device are described in Table 2. The large majority of females (N=174/210, 82.9%) indicated that they consulted the instructions for use that came along with the study package. Of those females, 97.7% (N=170/174) thought that the instructions for use of the Colli-Pee<sup>®</sup> device were clear. Some of the reasons why females found the instructions for use unclear included the following: 'The instructions didn't make it very clear what the do's and don'ts for use were', 'I have not read the instructions or can't remember doing so', 'I didn't think about using the instructions'.

Females were asked for their prior experience in selfcollecting a urine sample. Most females (N=159/210, **Table 3** Experiences and opinions on urine self-sampling (N=210)

| Question   | Ν   | %    |
|--|-----|------|
| l already took a urine sample (with a urine cup)                                     | 210 | 100  |
| Yes  | 159 | 75.7 |
| No   | 51  | 24.3 |
| Which urinary collection method do you prefer? (for those having a prior experience) | 159 | 100  |
| Colli-Pee®   | 126 | 79.2 |
| Urine cup  | 33  | 20.8 |
| I would use Colli-Pee®again to collect urine   | 210 | 100  |
| Yes  | 204 | 97.1 |
| No   | 5   | 2.4  |
| Missing value  | 1   | 0.5  |
| Colli-Pee®is easy to use   | 210 | 100  |
| Yes  | 203 | 96.6 |
| No   | 6   | 2.9  |
| Missing value  | 1   | 0.5  |

75.7%) indicated that they self-collected a urine sample before with a urine cup. Of those females, 79.2% (N=126/159) indicated that they prefer Colli-Pee<sup>®</sup> over a urine cup for urinary self-sampling (Table 3).

On a Likert-scale from 1 (strongly disagree) to 8 (strongly agree) a large amount (p < 0.0001) of females (N = 102/210, 48.6%) agreed that they had the impression it did not take them a long time before knowing how to use the device (Fig. 1A). A total of 31.9% (N = 67/210), 49.1% (N = 103/210) and 19.0% (N = 40/210) of participants indicated that it took them respectively less than 2 min. between 2 and 5 min. or more than five minutes in total (from reading the instructions to collecting the sample) to self-collect a FVU sample with Colli-Pee<sup>®</sup> (Data not shown).

Most females answered that it was clear how to use Colli-Pee<sup>°</sup> during urination (N=121/210 57.6%, p<0.01) and that they had the impression that they took the FVU sample correctly (N=143/210, 68.1%, p<0.001) (Fig. 1B, C). Participants also reported their intention to recommend the Colli-Pee<sup>°</sup> device to others whereby the majority of females indicated that they strongly agree in recommending Colli-Pee<sup>°</sup> to others (N=142/209, 67.9%, p<0.0001, 1 missing value).

Overall, 97.6% of females (N = 205/210) indicated that they would use Colli-Pee<sup>®</sup> again and 97.1% (N = 204/210) of females felt that Colli-Pee<sup>®</sup> was easy to use (Table 3).

Preferences of females regarding the sample collection method for their next CC screening are represented in Fig. 2. Overall. 66.6% (N=140/210) of females would opt a FVU self-sample taken with Colli-Pee<sup>®</sup> compared to 32.9% (N=69/210) of females who would prefer a PTS. These sample type preferences were not correlated with age, colposcopy center, self-reported HPV vaccination status, prior oncologic disease, or prior participation in

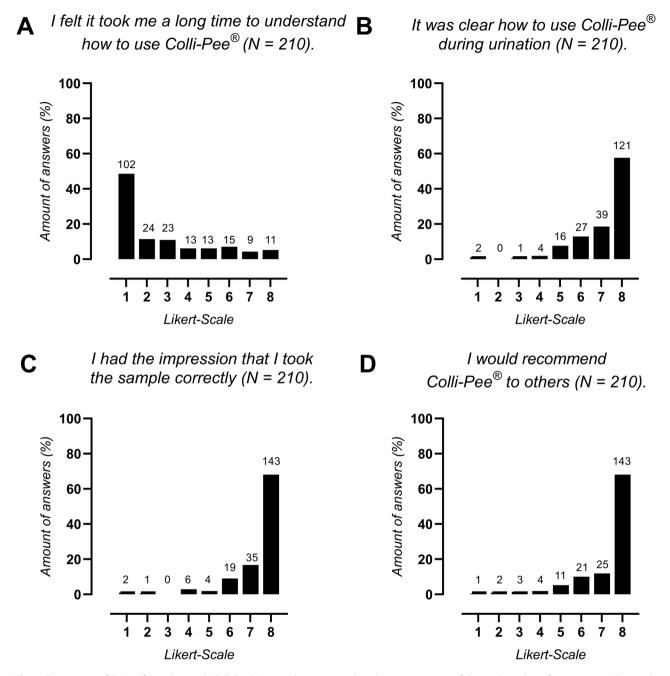


Fig. 1 Experiences of FVU self-sampling with Colli-Pee<sup>®</sup>. Bar graphs represent the relative percentage of the total number of answers to a Likert scale ranging from 1: Strongly disagree to 8: Strongly agree per statement questioned. Per Likert-Scale category. The number of answers is mentioned on top of each bar

the VALHUDES trial in which Colli-Pee<sup>®</sup> UCM FV-5020 was evaluated in a colposcopy referral population.

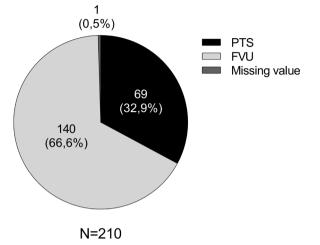
# Usability results based on SUS-scores

SUS scores are shown in Fig. 3. The color-based heatmap visualization scheme is a modified version of that recommended by Smaradottir et al. [46]. wherein white represents a positive response. grey a neutral response. and black a negative response. A total of 208 completed SUS scoring questionnaires were received with an average SUS score of  $86.17 \pm 1.03$  (out of 100), categorizing it as "excellent" [47].

# Discussion

Within the CASUS study, our objective was to gather information about the usability perceptions and preferences of female participants who self-collected a FVU sample using Colli-Pee<sup>®</sup>. Previous research demonstrated

# What sample collection method would you prefer for your next CC screening?



**Fig. 2** Preferred sample collection method for participant's next cervical cancer (CC) screening: a PTS (N=69/210). FVU (N=140/210) and missing values (N=1/210). Relative percentages are indicated between brackets

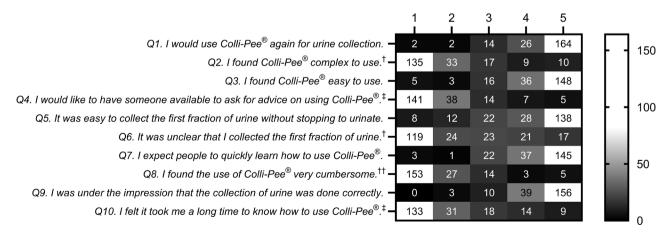
that optimized urinary HPV DNA detection includes: (i) the use of FVU; (ii) the addition of a preservative to prevent degradation of human and HPV DNA during extraction and storage and (iii) the processing of an adequate volume of whole urine [42, 48]. In our study design, we selected the Colli-Pee<sup>®</sup> UCM FV-5010 device, which is pre-filled with 3.4 mL of non-toxic and non-lytic UCM preservative. This choice was informed by our prior research, which examined the impact of different Colli-Pee<sup>®</sup> volume variants on HPV DNA detection in FVU [48]. The Colli-Pee<sup>®</sup> UCM FV-5010 design enables the immediate mixing of FVU and the UCM preservative during collection and allows a total sample collection of approximately 10mL. Our previous study evaluated the effectiveness of this UCM preservative in optimizing HPV DNA detection in FVU, demonstrating its ability to improve the collection. storage and extraction processes [42].

A total of 332 females (26-64y) were enrolled and consented their participation in the CASUS study of which 210 females completed the questionnaire. Although questionnaires were provided in both paper and digital formats, additional efforts are necessary in the future to gather comprehensive feedback from participants to obtain a complete understanding of the usability and user experience of this self-sampling device for HPV screening. Overall, 66.6% of females indicated to prefer to selfcollect a FVU sample over a PTS (32.9%) for their next CC screening. Additionally. 79.2% of females indicated to prefer the use of Colli-Pee<sup>®</sup> over a urine cup (20.8%) whereby 96.6% of females experienced Colli-Pee<sup>®</sup> as easy to use and 97.1% would use the device again.

The majority of female participants indicated that they had not previously taken part in the VALHUDES study [49], which utilized the larger Colli-Pee<sup>®</sup> UCM FV-5020 device variant prefilled with 7mL of UCM and designed to collect a total sample volume of approximately 20mL. This underscores that most participants did not have any prior bias due to their previous experience with Colli-Pee<sup>®</sup>.

Moreover, the majority of females reported using the instructions for use of the Colli-Pee<sup>®</sup> device and found them to be clear. However, some females cited reasons for finding the instructions unclear, such as: "The instructions did not clearly outline the do's and don'ts for use.", "I either have not read or cannot recall reading the instructions," and "I did not consider using the instructions."

Most females indicated that it did not take long to collect a FVU sample using Colli-Pee<sup>®</sup>, that the instructions



**Fig. 3** SUS questionnaire scores (N=208). Each row in the heatmap contains the amount of answers for each of the 10 questions (Q1 – Q10) per Likert score ranging from 1: Strongly disagree to 5: Strongly agree in each column. The color-legend of the heatmap is depicted in the separate bar graph on the right. White represents a positive response, grey a neutral response, and black a negative response.†: 4 incomplete SUS-scores, ‡: 3 incomplete SUS-scores

for use were clear. that they were confident that they took the sample correctly and that they would recommend the device to others. These findings align with previous results from the VALHUDES and Predictor's 5.1 studies where participants used the Colli-Pee<sup>®</sup> UCM FV5020 device at the colposcopy clinic compared to different vaginal self-samples and a PTS [50, 51]. In addition, the SUSscoring system was used as a composite measure of the overall usability of the Colli-Pee<sup>®</sup> device and user satisfaction and consisted of 10 open-ended polarity-balanced questions. An average SUS score  $86.17 \pm 1.03$  was calculated, categorized as "excellent".

A total of 66.6% of participants indicated they would prefer a FVU self-sample compared to a PTS (32.9%) for their next CC screening and 0.5% of females not disclosing a preferential sampling method. Similar results were previously obtained in referral populations in the EVAH [52], VALHUDES [50] and BM-SOP [53] studies featuring Colli-Pee<sup>®</sup> device variants. Nevertheless, some females showed hesitancy for a FVU sample and a preference for a PTS. Most of these females indicated that they find a PTS more reliable and a more thorough method than a FVU self-sample for CC screening, which can be combined on an annual basis during a gynecological examination. Nonetheless. a noteworthy percentage of female participants expressed that they found the usage of the Colli-Pee® to be clear (57.6%) and felt confident that they had correctly collected the FVU sample (68.1%). These results align with prior research that has investigated the Colli-Pee<sup>®</sup> device [50, 52, 54], emphasizing the non-invasive and user-friendly attributes of FVU as a liquid biopsy for CC screening. Furthermore. this suggests the potential for FVU to reduce hesitation among non-attendees.

Participants from the BM-SOP study in 2018 [53] indicated to prefer FVU collection at home over collection at the clinic or the general practitioner's office. Additionally. recent screening study in a general Japanese study population showed an improvement of CC screening participation in under-screened females when mailing HPV self-sampling kits featuring Colli-Pee<sup>®</sup> and a vaginal selfsample [55].

Concerning self-sampling for HPV testing, recent insights were obtained from a cervical cancer screening study that focused on African-American females in the Mississippi Delta. The study evaluated the efficacy of a patient-centered approach, comparing self-sampling for HPV testing at home with the existing standard of care in the U.S. public health system [56]. Aside from the increased participation rates that were perceived with a patient-centered approach for HPV self-sampling at home, the study also showed a higher cost-effectiveness when offering HPV self-sampling for CC screening in the USA [56]. Similar results were obtained in a randomized clinical trial in a health plan from Kaiser Permanente Washington, a US-based integrated health care system, where mailing HPV self-sampling kits was cost-effective for increased screening uptake relative to usual care [57]. Similarly, a UK-based research team recently assessed the cost of CC screening using self-collected FVU with Colli-Pee<sup>®</sup> or vaginal swab compared with the current strategy of PTS within the context of England's National Health Service Cervical Screening Program [58]. They found that HPV self-sampling could provide a less costly alternative to a PTS for routine HPV primary screening. More specifically, the average cost per complete screen was lowest for FVU self-sampling with Colli-Pee®, followed by vaginal self-sampling and highest for a PTS. The increase in recent and ongoing research endeavors around FVU selfsampling for HPV testing and CC screening [49, 59-61] highlights its promise as an alternative and non-invasive sampling method to extend the scope of CC screening to women who are not adequately screened.

Some limitations of our study should be addressed. First, the choice of a colposcopy setting provided sufficient statistical power to ask sensitivity questions and had minimal risk of partial verification bias inherent in screening settings. Since the females enrolled are not representative of a typical screening population, the questionnaire results should be interpreted with caution. We must also be aware that responses can be influenced to some degree towards plausible expectations and that communicated intentions do not necessarily correspond to future behavior. Additional population-based studies are recommended to assess whether home-based FVU self-sampling is effectively preferable to vaginal self-sampling and PTS. However, there are ongoing initiatives in France [61] and Belgium (NCT05996783) aimed at investigating FVU self-sampling using the Colli-Pee® device within a population-based framework.

#### Conclusion

In conclusion, the CASUS study successfully enrolled 332 females, with 210 participants providing valuable insights into their experiences with FVU self-sampling using the Colli-Pee® device. Our findings indicate a high level of user satisfaction. Moreover, the positive response to usability, as indicated by an average SUS score of 86.17, further supports the device's user-friendly nature and underscores the overall success and acceptability of Colli-Pee<sup>®</sup> in the context of FVU self-sampling for CC screening. These encouraging results not only highlight the feasibility and acceptance of Colli-Pee® but also emphasize its potential as a preferred method for future CC screening. The study participants' favorable opinions, coupled with their willingness to use Colli-Pee® again, position this device as a promising tool for future home-based FVU self-sampling as a liquid biopsy in CC

screening where under screened populations could be approached more easily.

## **Supplementary Information**

The online version contains supplementary material available at https://doi.or g/10.1186/s13690-024-01490-3.

Supplementary Material 1

#### Acknowledgements

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#### Author contributions

Conceptualization. S.V.K., G.D., S.W., J.D., V.V., K.B. Methodology. J.O.H., S.V.K., G.D., S.W., J.D., L.T., V.V., K.B., N.M., A.R.C. Formal analysis. J.O.H. Resources. J.O.H, S.V.K., G.D., S.W., J.D., L.T., V.V., K.B., N.M., A.R.C. Data curation. J.O.H. Writing—original draft preparation. J.O.H. Writing—review and editing. JO.H, S.V.K., G.D., S.W., J.D., V.V. Visualization. J.O.H Supervision. S.V.K., V.V., K.B. Project administration. J.O.H., S.V.K., V.V., K.B. Funding acquisition. S.V.K., V.V., K.B.

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#### Data availability

No datasets were generated or analysed during the current study.

#### Declarations

#### Ethics approval and consent to participate

Written informed consent for participation was obtained from all individual participants enrolled in the CASUS study. Ethical approval for the CASUS study was provided by the Medical Ethical Committee of the University Hospital Antwerp (20/21/271, Antwerp, Belgium) on the 4th of August 2020.

## **Consent for publication**

Not applicable.

#### **Competing interests**

J. O. Hendrickx, A. Rios-Cortes, N. Meers are employees of Novosanis. V.V.J. Vankerckhoven is co-founder and was board member and CEO of Novosanis until October 2022. K.C.L. Beyers is co-founder and was board member until December 2022 and CTO of Novosanis until July 2023. Novosanis was founded as a spin-off company of the University of Antwerp, Belgium and is a subsidiary of OraSure Technologies Inc. since Jan 2019. The University of Antwerp received payment for participation of S. Van Keer in an Advisory Board of Novosanis (Subsidiary of OraSure Technologies Inc. Wijnegem, Belgium).

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