feSTI: Evaluation of free HIV and STI testing and counselling services for young and disadvantaged populations in Lucerne and Zurich

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Departement Public & Global Health

feSTI: Evaluation of free HIV and STI testing and counselling services for young and disadvantaged populations in Lucerne and Zurich

Research legislation:	Ordinance on human research with the exception of Clinical trials (HRO) (1).
Type of Research Project:	Research project involving human subjects
Risk Categorisation:	Category A
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PROTOCOL SIGNATURE FORM

Study Title	**FeSTI: Evaluation of free HIV and STI testing and counselling services for young and disadvantaged populations in Lucerne and Zurich**

The project leader has approved the protocol version 1.1 25.11.2025 and confirms hereby to conduct the project according to the protocol, the Swiss legal requirements (1,2), the current version of the World Medical Association Declaration of Helsinki (3) and the principles and procedures for integrity in scientific research involving human beings.

The project leader has received the ICF and consider it appropriate for use.

Project leader

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GLOSSARY OF ABBREVATIONS

AIDS	*Acquired Immune Deficiency Syndrome*
ART	*Antiretroviral therapy*
BAG	*see FOPH*
BASEC	*Business Administration System for Ethical Committees*
CI	*Confidence Interval*
CH	*Switzerland*
CP	*Checkpoint Lucerne*
CRF	*Case report form*
EBPI	*Epidemiology, Biostatistics, Public Health Institute of the University of Zurich*
eCRF	*electronic case report form*
eIC	*electronic informed consent*
EK	*Ethikkomission*
FDR	*False Discovery Rate*
FOPH	*Federal Office of Public Health*
FPC	*Finite Population Correction*
GCP	*Good Clinical Practice*
HCP	*Health Care Professional*
HIV	*Human Immunodeficiency Virus*
HPV	*Human Papilloma Virus*
HRA	*Human Research Act*
HRO	*Ordinance on Human*
ICF	*Informed Consent Form*
IQR	*Interquartile Range*
KAB	*Knowledge, Attitude, and Behaviour items in questionnaires*
LMM	*Linear Mixed Models*
MED	*Minimum Detectable Effect*
MAR	*Missing At Random*
MCAR	*Missing Completely At Random*
MI	*Multiple Imputation*
MNAR	*Missing Not At Random*
MSM	*Men having Sex with Men*
OR	*Odds Ratio*
PLWH	*People living with HIV*
PPI	*Patient and Public Involvement*
PrEP	*HIV Pre-Exposure Prophylaxis*
REDCap	*Research Electronic Data Capture*
REML	*Restricted Maximum Likelihood*
S&X	*Verein Sexuelle Gesundheit Zentralschweiz*
SD	*Standard Deviation*
SE	*Standard Error*

SeGZ	*Sexuelle Gesundheit Zürich*
SHCS	*Swiss HIV Cohort Study*
STIs	*Sexually Transmitted Diseases*
UN	*United Nation*
UNAIDS	*Joint United Nation Program on HIV/AIDS*
UZH	*University of Zurich*
VCT	*Voluntary Counselling and Testing*

DEFINITIONS

Youth: Adolescents and young adults aged <25 years.

Voluntary counselling and testing (VCT): On the clients' voluntary initiative, they receive counselling and testing for Human Immunodeficiency Virus (HIV) and other sexually transmitted infections (STIs). The counselling includes an evaluation of the person's risk of HIV and STI transmission and aims to encourage behaviour which minimises the risk of acquiring HIV and other STIs (4).

1 BACKGROUND AND PROJECT RATIONALE

Switzerland has committed to achieving the UNAIDS 2030 goal of eliminating HIV(5). To this end, the National Programme for HIV and other Sexually Transmitted Infections (NAPS) addresses the two key action domains: Prevention efforts focus on ensuring that people in Switzerland are informed, aware, and empowered to act responsibly, while maintaining low-threshold access to tailored services. This includes prevention in the general population, targeted interventions for people with high-risk behaviours, and ensuring that people living with HIV (PLWH) have access to treatment and can live healthy lives. Within this framework, voluntary counselling and testing (VCT) remains a central component (6). VCT allows individuals to seek testing by their own volition, maintain anonymity, and receive professional counselling (4). In Switzerland, VCT is implemented primarily in specific VCT centres, run by a variety of different organisations from community focused NGOs to hospitals.

Despite this infrastructure, financial barriers limit access to testing. Under the current health insurance system, asymptomatic HIV and STI testing is covered by the obligatory health insurance only under a few circumstances. As a result, cost remains a significant obstacle, particularly for young people and those on low incomes. Given that Swiss people typically indicate that they started to be sexually active in their teens (16.7 years) (7) and that early detection is crucial for both individual health and public health prevention.

Recognising the need for improved access to sexual health services, the City Council of Zurich initiated action following postulates 2018/59 and 2021/432 (“Free Testing for Sexually Transmitted Infections” by Marco Denoth and Patrick Hadi Huber, February 2018). The Council approved a three-year pilot phase offering free voluntary counselling and testing (VCT) for HIV and STIs to residents under the age of 26, as well as residents > 26 years holding a KulturLegi card (an initiative of CARITAS enabling participation in cultural, educational, and sports programmes for people with critically low incomes, such as recipients of social welfare, supplementary AHV/IV benefits, or scholarships). Eligible individuals can access testing up to twice per year at two established VCT centres of Sexuelle Gesundheit Zürich (SeGZ): Checkpoint Zurich and TEST-IN Zurich. Building on this momentum, the City Council of Lucerne responded to Postulate 287 (August 2023) by Studhalter, Frey, and Abele, and approved the proposal with Resolution 810 (November 2023). This launched a three-year pilot project at Checkpoint Lucerne, operated by Sexuelle Gesundheit Zentralschweiz (S&X), which provides free HIV and STI testing and counselling for residents under 25 years of age and residents under 45 years if they hold a KulturLegi card. Both pilot projects aim to strengthen prevention and early detection of HIV and other STIs among young people and socioeconomically disadvantaged groups.

These projects aim to remove financial barriers to HIV and STI testing, particularly for those at higher risk or with limited resources, and to improve testing uptake among the sexually active population. It builds on existing service structures, ensuring professional counselling and timely access to care in the event of positive results. Importantly, it seeks to address both prevention and health equity by making testing accessible to groups for whom costs have previously been prohibitive.

Analysis of the first two years of data from the Zurich pilot (BASEC number Req-2023-00564) clearly demonstrates that the counselling component of VCT plays a critical role for the target population, particularly improving knowledge, promoting safer sex practices, and facilitating first

contact to sexual healthcare (5,6, preprints). These findings highlight the need to examine health literacy more systematically as part of the intervention's broader impact. Consequentially, the present study adopts a more comprehensive design than originally planned for the evaluation of the Zurich pilot (BASEC number Req-2023-00564), incorporating health literacy outcomes alongside epidemiological and service delivery indicators.

To date, free VCT programmes have been studied mainly in resource-limited settings, while many high-income countries already offer free or low-cost testing. Switzerland remains an exception, where testing still involves out-of-pocket costs for most asymptomatic individuals. The Zurich and Lucerne pilots therefore represent an innovative and context-specific approach with potential implications not only for the city itself, but also for other Swiss municipalities and comparable high-income settings in aiming to achieve NAPS goals and thus the UNAIDS goals.

2 PROJECT OBJECTIVES AND DESIGN

The objective of this observational study is to evaluate municipal pilot projects in Zurich and Lucerne that provide free HIV and STI testing to young people and socioeconomically disadvantaged groups. Specifically, the study aims to (i) assessing participants' satisfaction with the public health programme; (ii) assessing the implementation and operational feasibility of free VCT in municipal settings; (iii) describing demographics and epidemiological characteristics of service users; and (iv) evaluating impacts on health outcomes and health literacy. Since the inclusion criteria slightly differ between the Lucerne and Zurich project, we explicitly define them here. In the city of Lucerne projects residents up to the age of 25 years qualify by age and if they are aged between 25 and 45 years of age they qualify if the also hold a KulturLegi. In the Zurich project, people can qualify up to the age of 26 based only on their residence and age. Those older than 26 must also have a KulturLegi. However, there is no upper age limit for participation. Throughout the protocol, we will refer to participants as either "age-eligible" if they qualify by age only or "low-income-eligible" if they qualify by also holding a KulturLegi. If both groups are meant, we talk about the target population.

2.1 Hypothesis and primary objective and secondary objectives

The primary endpoint is customer satisfaction, measured as the proportion of participants who "agree" or "strongly agree" with satisfaction statements in the post-visit questionnaire.

- Null hypothesis (H_0): Customer satisfaction ≤ 80%.
- Alternative hypothesis (H_1): Customer satisfaction > 80%.

2.2 Primary and secondary endpoints

The scientific study evaluates the following primary endpoints by site unless stated otherwise:

Operational feasibility of the HIV and STI counselling and testing interventions (by site) based on customer satisfaction (post-visit questionnaire).

Secondary endpoints will be

1. Operational feasibility:
    a. Service capacity/utilisation: monthly number of completed VCT visits (operational data).
    b. Access timeliness: Median days from booking to appointment (operational booking/appointment timestamp)

    c. Workload / perceived stress of healthcare professionals (HCPs) — assessed in a possible sub-study (short survey).
2. Improved sexual health in target population (by site):
    a. Count diagnosed HIV/STI cases (operational data)
    b. Number of treated STI cases (antibiotics received at pharmacy or appointment in Maihof Praxis OR medical doctors' appointments at Checkpoint Zurich) / HIV confirmation tests / treatment start (operational data)
    c. Perception of well-being prior / post appointment over time (pre-visit and post-visit questionnaire).
3. Health literacy impact (by site):
    a. Changes in the knowledge, attitude, and behaviour questionnaire sections (KAB) before the visit (pre-visit questionnaire) and at least a week after the visit (post-visit questionnaire).
    b. Testing behaviour over time (operational data).
4. Equity of outcomes (by site):
    a. Proportion of low-income eligible participants among all participants.
    b. Coverage relative to population need, measured as the proportion above compared with the total number of KulturLegi cards issued (target: ≥5% of the eligible population reached during the study period).
    c. Descriptive comparison of positivity rates, re-testing rates, and literacy gains between low-income eligible and age-eligible groups.

2.3 Independent variables

The exposure of interest is participation in the city of Lucerne's and Zurich's pilot projects, offering free VCT. Exposure will be defined as accessing the free VCT service during the intervention period.

Independent variables and covariates to be examined include:

- **Demographics**: age (continuous, in years; also grouped young people accessing the project by age and low-income people accessing the project by holding a KulturLegi into gender, sex, as well as sexual orientation (factors), and socioeconomic status (income category, based on eligibility for the programme).
- **Epidemiological characteristics**: previous HIV/STI testing history (binary), number of tests during study period as well as number of positive / reactive tests (count), and risk factors as captured in routine anonymous testing data.

These variables will be measured using anonymous programmatic data routinely collected at the VCT sites. Age and income will determine eligibility categories; health outcomes (e.g. HIV/STI positivity rates, linkage to care where available) and self-reported measures related to health literacy (where collected) will serve as dependent variables.

Additionally, the people profiting from the free VCT, can decide to enrol in the evaluation study consisting of two self-administered questionnaires (one right before the appointment, and one ca. 1 week after the appointment).

2.4 Project design

This project is designed as a single-centre study with multiple external recruitment sites. Participants are recruited through the municipal pilot programmes in the cities of Lucerne and Zurich that offer free VCT for HIV and other STIs. The evaluation is coordinated centrally by the

University of Zurich, which is the sole research centre responsible for data management, analysis, and reporting.

Study Structure and Site Roles

The University of Zurich (UZH) oversees the design, implementation, and day-to-day conduct of the study and ensures that all activities comply with ethical and regulatory requirements. UZH holds full responsibility for study governance, data management and data protection, quality assurance, staff training and task delegation, safety reporting, and the analysis and dissemination of study results. All study data are collected, stored, managed, and analysed under the authority of UZH.

The external participating institutions contribute only as recruitment sites and operate under clearly defined, delegated responsibilities issued by the Principal Investigator at UZH. They do not function as independent study centres and do not conduct any autonomous study procedures, data management activities, or safety reporting. This structure ensures that UZH maintains full oversight and accountability for all aspects of the study.

The participating municipal testing services collaborate as implementation partners within their respective city health programmes. Their staff facilitate the recruiting process. They do not have access to research data beyond the operational data they routinely collect for service purposes, and they do not perform any analyses. All pseudonymised data are stored and managed exclusively by the UZH.

Study Design

The overall design is primarily cross-sectional, with a short-term longitudinal follow-up (participants complete questionnaires at baseline and one week after testing) (see Figure 1). This design is appropriate to (i) characterise the demographics and epidemiological profile of programme users, (ii) assess the feasibility of the service, and (iii) evaluate short-term impact on health literacy.

Study Period and Data Collection Pathways

The study period is aligned with the duration of the pilot projects (Lucerne: December 2025–November 2028; Zurich: December 2025 – May 2027). Data will be collected via two pathways:

1. **Operational data pathway**: anonymous routine data (e.g. numbers on tests performed, positivity rates) will be extracted from operational records.
2. **Evaluation pathway**: participants who provide informed consent will contribute additional data, including responses to the VCT intake questionnaire, their test results, and a follow-up feedback questionnaire approximately one week after the appointment.

This two-pathway design allows for both population-level monitoring (operational/administrative data) and more detailed assessment of feasibility and impact (evaluation data), while respecting participant autonomy and privacy.

Informed Consent and Participant Information

Study information will be provided electronically when registering for an appointment online and again at the end of the VCT intake questionnaire (see Figure 1). After filling in the questionnaire used for counselling at the testing site on either tablets provided by the centres or on their personal devices (personal survey link). Participants can give electronic informed consent (eIC)

if they wish to participate in the evaluation and fullfill the age criteria of ≥16 years (self-declaration) and if they indicate at intake that they have received the study information when booking the appointment. The email address of the study team at the UZH is given.

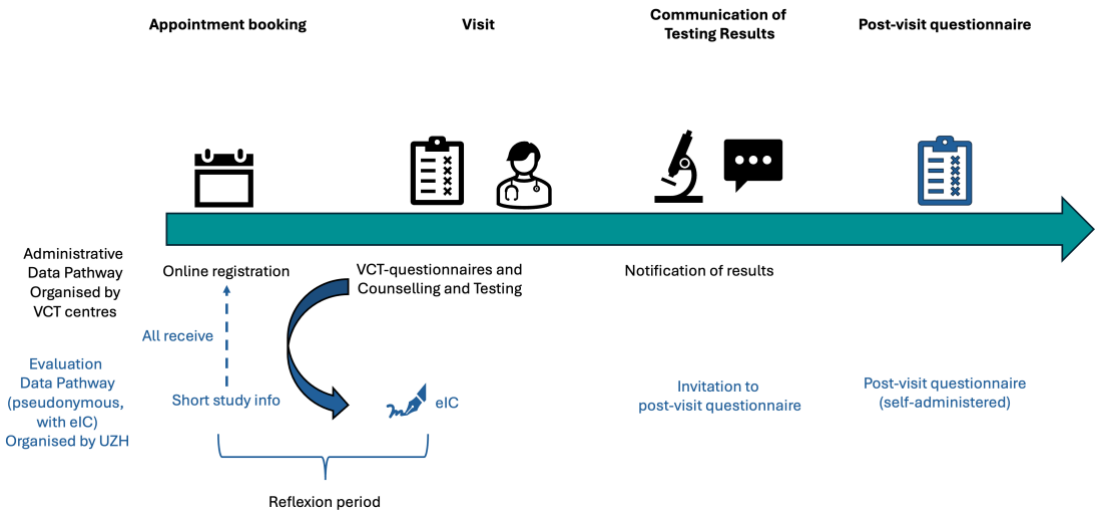

Figure 1: Study design, eIC: electronic informed consent, VCT: voluntary counselling and testing

In addition to participant-level evaluation, the project will include a short survey of HCPs involved in delivering the VCT service. This optional sub-study aims to assess workload, and implementation feasibility from the provider perspective. Including the perspectives of frontline staff complements the client-focused outcomes and helps contextualise operational feasibility.

2.5 Patient and public involvement (PPI)

The project was initiated in response to a political initiative by the “Sozialdemokratische Partei” in Zurich and the youth party of “Die Grünen” in Lucerne reflecting the priorities and interests of the target population. The regional sexual health association which is implementing the pilot is jointly run by the S&X and SeGZ, whose mission statement is to address HIV and other sexually transmitted infections from a social, psychological, preventive, medical, and political perspective. Additionally, HCPs and counsellors from the non-profit community health care centres as well as some of their clients contribute to the development of the data collection instruments by participating in cognitive debriefing of the survey material, ensuring that the questionnaires are understandable, acceptable, and relevant to users.

Thus, PPI has informed both the relevance of the research question and the usability of study procedures (survey testing with clients and counsellors). Future involvement will continue through feedback loops with the sexual health clinic, which will provide ongoing input into study implementation.

3 PROJECT POPULATION AND STUDY PROCEDURES

3.1 Project population, inclusion and exclusion criteria

The project population consists of individuals eligible for the city of Lucerne’s and Zurich’s pilot programmes offering free VCT for HIV and STIs. Eligibility for the programme is defined as:

- Residents of the City of Lucerne aged <25 years and residents of Zurich aged <26 years, regardless of income; or
- Residents aged 25–44 years (Lucerne) and or aged > 26 years (Zurich) with low income, as indicated by possession of a KulturLegi.

All visits from the pilot service during the study period will be included in the anonymous administrative dataset (see Figure 1). In this naturalistic recruitment setting, all people accessing the programme will be invited to participate in the evaluation. Participants who give informed consent will also take part in the evaluation arm of the study. This includes completion of the pre-visit and post-visit questionnaires, as well as allowing their VCT intake questionnaire and their counselling and testing data including test results to be linked to their evaluation data and used for scientific analysis.

Inclusion criteria (evaluation pathway)

- Accessing the free VCT service as part of the pilot programme.
- Residents of the city of Lucerne or Zurich and belonging to one of the eligible age- and income-defined groups.
- Provision of informed consent (via e-consent form) for participation in the evaluation (for questionnaire and follow-up components).

Exclusion criteria (evaluation pathway)

- Declining or unable to provide informed consent for the evaluation component (these individuals will still be included in the anonymous administrative dataset).
- Inability to complete the questionnaires due to language barriers (materials are currently available in German and English).
- <16 years of age (self-declaration)

Sample size

This real-world evaluation includes all service users accessing free VCT during the pilot period who provide electronic informed consent (eIC) for the evaluation. The sample size is therefore programmatically determined by service uptake rather than assigned by investigators.

Lucerne: The city funds up to 800 free consultations per year, resulting in a maximum of approximately 2,400 visits over the three-year pilot period.

Zurich: Based on observed service uptake in the first two years (6,599 visits), we anticipate a maximum of 5,000 visits during the remaining 18 months of the project.

Because some individuals may attend more than once, the number of unique participants will be slightly lower than the number of visits. Based on participation patterns from the first 24 months of the Zurich pilot (BASEC Req-2023-00594), we expect between 20% and 33% of service users to provide eIC and participate in the evaluation pathway. This corresponds to an anticipated evaluation sample of approximately $N \approx 800$ participants in Lucerne and $N \approx 1{,}000$ participants in Zurich over the respective study periods.

Customer satisfaction is the primary outcome, measured through positively worded Likert-scale items with response categories ranging from “strongly disagree” to “strongly agree.” Previous surveys at the Zurich site showed consistently high satisfaction, with more than 90% of respondents selecting “agree” or “strongly agree” across all satisfaction questions. For the present evaluation, we therefore base our sample size considerations on a conservative expected satisfaction proportion of 80%.

To estimate this proportion with ±5% precision using a one-sided 95% confidence interval, we applied the finite population correction (FPC) to account for the total number of eligible survey opportunities over the study period (i.e., the total number of visits at each site). The required sample sizes are 162 participants in Lucerne and 168 participants in Zurich (see Table 1).

Based on the expected number of consenting participants, these retention rates (23% and 17%, respectively) are sufficient to achieve the minimum required sample sizes. Experiences from the ongoing Zurich pilot, where response rates to satisfaction surveys have consistently met or exceeded these thresholds, together with published retention rates from similar community-based digital surveys (40–60%) (10–12), make us confident that the required sample sizes will be reached at both sites.

Representation of age, sex, and gender

Recruitment for the pilot project reflects the programme’s eligibility criteria (age and income) as well as the clinic’s catchment population. The service is open to all eligible residents, regardless of sex, gender identity, sexual orientation, or age, and therefore does not intentionally exclude or underrepresent any group. Participation is determined solely by eligibility criteria and not influenced by sex, gender, or other demographic characteristics. Consequently, the distribution of participants by sex, gender, and age is expected to reflect the population that actively seeks HIV/STI testing within this framework.

If certain groups appear underrepresented, this may indicate the presence of systematic barriers, such as stigma, lack of awareness, cultural factors, or structural inequalities, which limit their access to testing services. Identifying such gaps is a key component of the evaluation and will provide important insights into equity of access.

To support inclusivity, the study information as well as the evaluation questionnaires will be deliberately kept short and written in simple, accessible language. They will be developed in line with internationally recognised plain language principles (HL7 International Plain Language Standards) and “Einfache Sprache” guidelines for the German version, as well as equivalent standards for the English version. Cognitive debriefing with members of the target population have be conducted to ensure comprehensibility and cultural appropriateness, and instruments were revised based on their feedback. Readability will also be assessed using established tools such as the “Wiener Sachtextformel” (WSF) for German and, where feasible, the Flesch Reading Ease score for English.

Where participant numbers allow, analyses will be stratified by site, sex/gender, and age group to identify potential differences in access, feasibility, or health outcomes, and to ensure that findings are meaningful for all relevant subgroups.

3.2 Recruitment, screening and informed consent procedure

Recruitment

All individuals who attend the sexual health clinic to access the free VCT service are eligible for the study if they are able to give informed consent. Participants for the evaluation pathway will be invited to provide eIC at the point of service. When booking an appointment for the municipal public health projects, potential participants will automatically receive the study information (in standard German and English; simple language versions are also provided), including the purpose of the research project, the procedures involved, the expected duration, potential risks and any discomfort it may entail — along with contact details for the study team at the University of Zurich (see Appendix 1 a tabular and Appendix 2 for a detailed description of the recruitment and eIC process flow). This information is provided in electronic form together with the appointment confirmation, giving individuals ample time to consider whether they wish to participate. Upon arrival at the clinic, counsellors verify whether clients have seen the study information and answer any questions.

Each participant is informed that the participation in the research project is voluntary and that they may withdraw from the research project at any time and that withdrawal of consent will not affect his/her/their subsequent medical assistance and treatment. The participants are informed that he/she/they can ask any question. Enough time is given to the participant.

All participants complete the routine VCT questionnaire as part of the standard intake process (see Figure 1). They are then electronically asked whether they wish to participate in the evaluation. If they agree, they provide eIC and are sent the formal consent form and study information to the email address they entered. Participation is voluntary, and declining does not affect access to free testing. Individuals who do not consent contribute only to the anonymous administrative dataset used for operational monitoring.

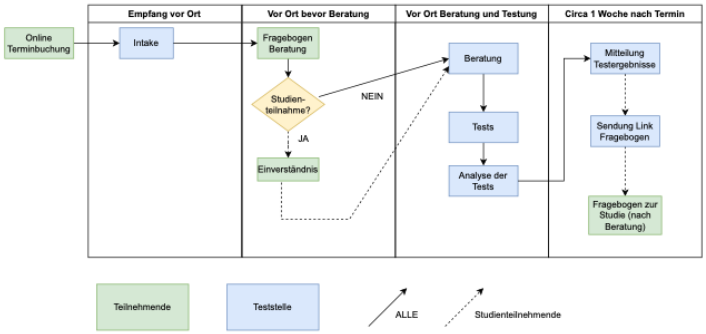

Figure 2: Data instruments according to parties completing the data entry and displaying the difference between anonymous and pseudonymous participation. eIC: electronic informed consent, REDCap: Research Electronic Data Capture, VCT: voluntary counselling and testing.

Screening and recruitment

Recruitment will take place via the booking system of the sexual health clinics operated by the regional sexual health association in the cities of Lucerne and Zurich implementing the pilot projects. All clients meeting the municipal eligibility criteria for free VCT (either by age or due to their low income) and booking a programme appointment will be systematically informed about the evaluation component before the time of their visit as part of the appointment booking process.

Recruitment procedure

- Service users will first be registered for the free testing service according to routine clinic procedures.
- Upon online appointment registration, clients will be invited to participate in the evaluation pathway. The study will be explained in written form. in standard German, both containing information describing the study aims, procedures, and data protection.
- Participation in the evaluation pathway is voluntary, and refusal does not affect access to free testing.
- People signing up for the free VCT have a reflection period to deliberate their participation in the evaluation between the appointment booking and the appointment itself.
- All service users complete the VCT-questionnaire as part of routine counselling upon arrival and intake procedure at the site (see Figure 1, Figure 2, Appendix 2).
- After completing the VCT-questionnaire, clients are invited via eIC to decide whether they wish to participate in the evaluation pathway (see Figure 1, Appendix 2).
- If they decline, the intake questionnaire is used solely for counselling purposes and their visit contributes only to the anonymous administrative dataset (operational statistics, see Figure 1).
- If they agree and provide eIC, their intake data and test results will be included in the evaluation dataset (see Figure 1). And they will be invited to participate in another survey approximately one week after the counselling and testing.

Screening procedures and informed consent

Eligibility is determined by residency, age and income, which are already part of the programme's routine documentation.

Study information will be exposed to testers when signing up for a free VCT appointment online (see Figure 1). When arriving at the appointment, the person at intake will ask if study information was seen and if there were any questions. Participants will have adequate time to consider participation and may ask questions to the counsellors, who are trained in explaining the

evaluation study. After answering the VCT-questionnaire for the appointment, they will be asked within REDCap if they are willing to participate in the evaluation. If yes, electronic informed consent (eIC) form will be opened and they can either consent or refuse to be part of the evaluation and thus sharing their data. During the consent process, participants will also be asked whether they wish to be contacted about future studies related to the programme.

3.3 Study procedures

The overall project is anticipated to run for three years, from 1 December 2025 to 30 November 2028 in Lucerne and 18 months from 1 December 2025 – 31 May 2027 in Zurich, in parallel with the municipal pilot programmes.

Participant timeline

For participants in the evaluation pathway, the individual study duration is approximately one week: it begins with the testing appointment at the sexual health clinic and ends once participants have received their test results and completed the follow-up questionnaire about one week later.

Sequence of procedures during a programme visit

1. Online appointment registration: Clients register via the clinic's booking system and self-declare their eligibility (residency, age and/or income criteria). At this point, they receive study information.
2. Arrival at clinic: Upon check-in, all clients complete the routine VCT-questionnaire.
3. Counselling and testing: A counsellor provides the consultation. Testing includes HIV, syphilis, chlamydia, and gonorrhoea, if clinically indicated. The Zurich programme also includes Hepatitis C testing if indicated. Rapid HIV test results are communicated during the appointment; other laboratory results are communicated within a few days.
4. Evaluation pathway (optional): After completing the VCT-questionnaire, clients are invited to provide eIC..
5. Follow-up: Approximately one week after the visit, participants receive a link to the post-visit self-administered questionnaire, following receipt of their test results.

eIC, as well as all data entry instruments and questionnaires are administered/recorded with Research Electronic Data Capture (REDCap).

Biological samples

The evaluation involves no additional biological sampling. It is based solely on data from routine HIV/STI tests conducted within the free testing pilot, over which the evaluation team has no influence.

Expected biases and mitigation

As this is a real-world programme evaluation, participation in the evaluation pathway is voluntary and may lead to selection bias (e.g., individuals more comfortable with surveys may be over-represented). To mitigate this, anonymous administrative data from all service users will be included, allowing comparison between participants and non-participants in the evaluation. Another potential bias is loss to follow-up for the post-visit questionnaire; a reminder and mobile-friendly survey formats will be used to reduce this risk. To mitigate the risk that mainly highly educated individuals participate in the evaluation, study information is written in simple language (English and German), and questionnaires are designed to be short and in simple language (see 3.1 Project population, inclusion and exclusion criteria).

HCP Sub-study

A brief online survey will be conducted among healthcare professionals involved in delivering the free VCT services during the pilot phase. The purpose of this sub-study is to assess perceived workload, and implementation feasibility from the provider perspective, thereby complementing client-level feasibility outcomes. Participation is voluntary, and no identifiable data will be collected. HCPs will receive study information and provide eIC before completing the survey, which consists of approximately 10–12 items and requires less than 10 minutes to complete. The survey will be administered once during the project period (approximately mid-point) and again near project completion. Survey responses will be analysed in aggregate and reported descriptively; no linkage to individual staff members or clinical performance data will occur.

3.4 Withdrawal and discontinuation

Participants may withdraw from the evaluation project at any time, without giving reasons and without affecting their access to free testing. Withdrawal may occur in two ways:

- Drop-out (e.g. not completing the post-visit questionnaire): In this case, data already collected up to the point of discontinuation are retained for analysis, but no further contact is made.
- Withdrawal of informed consent: If participants actively request withdrawal, their contact data (e-mail address/phone number) will be deleted as soon as feasible from REDCap, and no further data will be collected. Existing research data will be anonymised by deletion of direct identifiers (name, e-mail).
- After removal of contact details, the dataset is considered anonymised, in accordance with Art. 25 HRO, because no direct identifiers remain and re-identification would require disproportionate effort.

Anonymisation procedure

Contact details (specifically the e-mail address) are collected and stored only for the purpose of sending the follow-up questionnaire. If a participant withdraws consent, these contact fields are promptly deleted from REDCap.

The evaluation dataset contains only two quasi-identifiers: year of birth and postal code. These are included solely for essential analytical and eligibility purposes. In Zurich, only the first two digits of the postal code are collected, which are sufficient to confirm city residency but do not allow meaningful subgroup analyses or pose a significant re-identification risk.

In Lucerne, residency verification is more complex because the first two postal code digits are not sufficient to determine whether a participant lives within the city limits. For this reason, the full postal code must be collected. During data entry at client intake, the system is designed so that if a non-Lucerne postal code is entered, a warning notification will appear to flag potential ineligibility. The postal code is collected solely for the purpose of confirming eligibility, stored without any direct identifiers, and does not enable re-identification once contact details are removed. In both sites the postal code will not be used for any stratifications.

After removal of contact details, the dataset is considered anonymised in accordance with Art. 25 HRO, as no direct identifiers remain and re-identification would require disproportionate effort. Following anonymisation, no key exists that would allow linkage of the dataset back to individual participants. No biological material is stored beyond what is required for routine clinical care; therefore, no additional destruction procedures are necessary.

4 STATISTICS AND METHODOLOGY

4.1 Statistical analysis plan

Study Endpoints

Primary Endpoint: Customer satisfaction with the HIV and STI counselling and testing intervention, defined as the proportion of participants who complete the post-visit questionnaire and who select “agree” or “strongly agree” on satisfaction statements (administered approximately one week after the appointment). This endpoint will be assessed separately by site (Lucerne and Zurich).

Secondary Endpoint:

Operational feasibility:

- Service capacity/utilisation: monthly number of completed VCT visits (operational data)
- Access timeliness: median days from booking to appointment (operational booking/appointment timestamp)
- Workload/perceived stress of HCPs, assessed in a possible sub-study (short survey).

Improved sexual health in target population (by site):

- Count of diagnosed HIV/STI cases (operational data)
- Number of treated STI cases (antibiotics received at pharmacy or appointment in Maihofpraxis OR medical doctors' appointments at Checkpoint Zurich) / HIV confirmation tests / treatment initiation (operational data)
- Perception of well-being before and after appointment (pre-visit and post-visit questionnaire)

Health literacy impact (by site):

- Proportion of low-income eligible participants (KulturLegi holders) among all participants
- Coverage relative to population need, measured as the proportion above compared with the total number of KulturLegi cards issued in each city (target: ≥5% of the eligible population reached during the study period)
- Descriptive comparison of positivity rates, re-testing rates, and literacy gains between low-income eligible (KulturLegi) and age-eligible (general population) groups

Hypotheses

The primary endpoint is customer satisfaction, measured as the proportion of participants who “agree” or “strongly agree” with satisfaction statements in the post-visit questionnaire.

- Null hypothesis (H_0): Customer satisfaction ≤ 80%.
- Alternative hypothesis (H_1): Customer satisfaction > 80%.

This is a one-sided superiority test to determine whether satisfaction exceeds the pre-specified benchmark of 80%, based on prior data from Zurich where >90% of participants reported high satisfaction.

Sample Size Rationale

This evaluation is a real-world implementation study with programmatically determined sample size. All service users accessing free VCT services during the pilot period and providing eIC will be included. See Table 1 for expected sample.

Table 1: Minimal response rate needed to test null hypothesis.

Site	Total visits (max)	Expected eIC rate	Expected evaluation N	Required N (95% CI, ±5%)	Required retention for follow-up
Lucerne	~2,400	20–33%	20–33%	20–33%	20–33%
Zurich	~5,000	20–33%	20–33%	20–33%	20–33%

Power calculation for primary endpoint (customer satisfaction):

- **Statistical test:** One-sample binomial test (one-sided)
- **Null hypothesis proportion (p_0):** 0.80
- **Alternative hypothesis proportion (p_1):** 0.90 (based on prior Zurich data showing >90% satisfaction)
- **Effect size:** Difference in proportions = 0.10
- **Rationale for expected proportion:** Previous evaluation of VCT services at Checkpoint Zurich demonstrated satisfaction rates >90% among participants
- **Significance level (α):** 0.05 (one-sided)
- **Desired precision:** Margin of error (E) = ±0.05
- **Finite population correction:** Applied based on expected consenting sample (N=800 for Lucerne, N=1,000 for Zurich)

Sample size calculation: Using the formula for one-sample proportion with finite population correction:

$n = (Z^2\alpha \times p \times (1-p)) / E^2 \times (N / (N + n_0 - 1))$

Where:

- $Z\alpha = 1.645$ (one-sided, $\alpha=0.05$)
- $p = 0.80$ (conservative estimate)
- $E = 0.05$
- N = finite population size

Results:

- **Lucerne:** 162 participants needed for post-visit questionnaire
- **Zurich:** 168 participants needed for post-visit questionnaire

Software used: R version 4.3 with base stats package.

Justification of minimum response rates: The minimum post-visit questionnaire response rates shown above (23% for Lucerne and 17% for Zurich) represent conservative estimates required to achieve adequate statistical precision. These are not expected response rates, but rather worst-case thresholds to ensure the study remains adequately powered even under pessimistic scenarios.

Based on the study design features—including plain language questionnaires, email invitations, and HCP emphasis on the importance of participation—we anticipate achieving substantially higher response rates (potentially 30-50%). However, since this is a novel implementation study

and we lack directly comparable data for this specific design, we have planned the sample size conservatively.

Compensation for expected drop-out: The expected consent rates (33% for Lucerne, 20% for Zurich) already account for the fact that not all service users will consent to participate in the evaluation. Among those who do consent and complete the pre-visit questionnaire (N≈800 and N≈1,000), the conservative response rate assumptions (23% and 17%) provide a buffer against non-response to the post-visit questionnaire. If post-visit response rates fall substantially below these thresholds, we will report results descriptively without formal inferential testing (see Statistical Methods below).

Statistical methods:

- **Significance level:** All inferential tests will use α = 0.05. The primary endpoint will be tested using a one-sided test; all secondary endpoints and sensitivity analyses will use two-sided tests.
- **Descriptive statistics:** The primary analysis will follow an intention-to-measure approach, including all participants who provided eIC, regardless of post-visit questionnaire completion. Sensitivity analyses will compare complete-case and imputed datasets.
- **Primary endpoint:** One-sample binomial test with one-sided 95% confidence interval.
    - **Outcome definition:** Proportion of participants responding "agree" or "strongly agree" to satisfaction statements, calculated among all consenting participants (denominator = all who provided eIC).
    - **Analysis method:** The proportion will be estimated and tested against the null hypothesis value of 0.80. Analysis will be conducted separately by site.
    - **Handling of non-response:** See Section 4.2 (Missing Data) below.
    -
- **Secondary endpoints:**
    - **Operational feasibility metrics:** Descriptive statistics (counts, medians, IQRs) will be reported monthly and overall. Trends over time will be assessed using linear regression (continuous outcomes) or Poisson regression (count outcomes) with calendar time modelled as a continuous variable or using restricted cubic splines if non-linear trends are evident. If enrolment is sparse in early months, time will be grouped by quarter.
    - **Sexual health outcomes (diagnoses, treatments):** Counts and proportions will be reported descriptively. Positivity rates (proportion of participants testing positive) will be compared between subgroups (e.g., KulturLegi vs. age-eligible) using chi-square or Fisher's exact tests. Trends in positivity over time will be assessed using logistic regression. Trends over time: linear or logistic regression.
    - **Well-being and KAB changes (pre/post):**

      Statistical test: Linear mixed-effects models with random intercepts for participants

      Analysis approach:

        - Models will include time (pre vs. post) as a fixed effect
        - Estimation method: Maximum likelihood, which uses all available data under the missing-at-random (MAR) assumption

        - Covariates: Models will adjust for age, gender, income (KulturLegi status), previous testing history, education, and language preference
        - Ordinal outcomes: If KAB items are analysed as ordinal scales, proportional odds mixed models will be used
    - **Minimum sample size for inferential testing:** If fewer than 50 participants per site complete the post-visit questionnaire, we will report only descriptive statistics (means, standard deviations, and graphical displays of change) without formal hypothesis testing, as model estimation would be unstable and underpowered.
    - **Sensitivity analysis:** Complete-case paired t-tests (or Wilcoxon signed-rank tests for non-normal distributions) will be reported as a secondary analysis restricted to participants with both pre- and post-visit data.
- Equity outcomes
    - **Uptake and coverage:**
        - The proportion of KulturLegi holders among all consenting participants will be calculated
        - Coverage will be estimated as: (number of KulturLegi participants) / (total KulturLegi cards issued in the city during the study period), with the goal of reaching ≥5% of the eligible population
        - Uptake rates will be compared between KulturLegi holders and the general age-eligible population using chi-square tests
    - **Disparities in outcomes:** Positivity rates, re-testing rates, and changes in KAB scores will be compared descriptively between KulturLegi and age-eligible groups using:
        - Chi-square or Fisher's exact tests for binary outcomes (positivity, re-testing)
        - Linear mixed models with group × time interaction terms for continuous outcomes (KAB, well-being)

If sample sizes permit (n ≥50 per subgroup), interaction terms will be formally tested. Otherwise, results will be presented descriptively with effect sizes and confidence intervals to inform hypothesis generation for future studies.

Control for Confounding Factors

This is an observational evaluation study without a comparison group. To account for potential confounding in secondary analyses examining associations between participant characteristics and outcomes, multivariable models will adjust for the following variables: age, gender, income (KulturLegi status), previous testing history, education, and language preference. Calendar time will be included to account for temporal trends in service utilization and outcomes.

Multiple Testing Considerations

- **Primary endpoint:** No multiplicity adjustment is needed, as there is a single primary endpoint (satisfaction).
- **Secondary endpoints:** Results will be interpreted as exploratory and hypothesis-generating. No formal adjustment for multiple comparisons will be applied across the different secondary endpoint families (operational feasibility, sexual health, health literacy, equity), but effect sizes, confidence intervals, and p-values will be reported to aid interpretation and avoid overinterpretation of findings.

- **Subgroup and sensitivity analyses:** False discovery rate (FDR) procedures will be applied if multiple subgroup comparisons are conducted within a single endpoint (e.g., satisfaction by income, language, age groups).

Sex and Gender Analyses

Primary interest: This study does not have sex or gender differences as a primary research question. However, sex and gender are important equity dimensions that will be examined in exploratory analyses.

Planned analyses: All primary and secondary outcomes will be stratified by sex and gender where sample sizes permit. A minimum of **n=50 per subgroup** is required for formal subgroup analyses with inferential testing. Interaction terms (e.g., gender × time for KAB changes) will be included in regression models to assess differential effects.

Sample size considerations: The sample size calculation for the primary endpoint was not powered to detect sex/gender differences, as these are exploratory analyses. If subgroup sizes are insufficient for formal testing (n<50), results will be reported descriptively with effect sizes and confidence intervals and interpreted cautiously as hypothesis-generating.

Interpretation: All sex and gender analyses will be reported transparently, with clear acknowledgment of statistical power limitations and the exploratory nature of these comparisons.

Sensitivity Analyses

Sensitivity analyses for the primary endpoint and key secondary endpoints are described in detail in Section 4.2 (Missing Data) below. These include best/worst-case bounds, multiple imputation under missing-at-random assumptions, and tipping-point analyses to assess robustness to missing-not-at-random mechanisms.

Statistical Software

All analyses will be conducted using R (version 4.3 or later) with the following packages:

- Data manipulation: dplyr, tidyr
- Visualization: ggplot2
- Mixed models: lme4, nlme, ordinal
- Multiple imputation: mice
- General statistics: stats, broom

Reproducibility and Transparency

All data will be collected and managed in REDCap, ensuring secure storage, audit trails, and structured export of variables. Data exports will not include identifiers. Data cleaning, variable derivation, and statistical analyses will be conducted in R following a fully documented and reproducible workflow.

All analysis scripts, data processing code, and outputs will be maintained under version control in a private GitLab repository, allowing full traceability of changes over time and ensuring that all analyses can be replicated from raw data to final results. Access to this repository will be restricted to the study team and regulatory bodies as required.

While individual-level data cannot be shared due to sensitivity and privacy considerations, all analysis scripts and aggregated codebooks will be archived and can be made available to reviewers, or other researchers upon reasonable request.

4.2 Handling of missing data

We anticipate two types of missingness:

1. **Unit non-response:** Participants who provide eIC and complete the pre-visit questionnaire but do not complete the post-visit questionnaire (primary concern for satisfaction and KAB endpoints)
2. **Item non-response:** Missing individual items within completed questionnaires

Operational data (visit counts, diagnoses, treatments) are expected to have minimal missingness due to automated data capture systems.

General Principles

For all endpoints, we will:

- Describe the extent and patterns of missingness by site, time, and participant characteristics
- Compare baseline characteristics of responders vs. non-responders using standardized differences (Cohen's d for continuous variables, Cramer's V for categorical variables)
- Pre-specify the primary analysis approach for each endpoint (see below)
- Conduct sensitivity analyses to assess robustness of conclusions to different missing data assumptions

Primary endpoint (satisfaction):
The primary analysis will be a complete-case analysis among post-visit respondents. The estimated proportion of participants selecting “agree” or “strongly agree” will be calculated separately by site, with a one-sided 95% confidence interval and a one-sample binomial test versus $p_0 = 0.80$.

Sensitivity analyses:

1. **Best/worst-case bounds:**
    - Upper bound: assume all non-responders were satisfied
    - Lower bound: assume no non-responders were satisfied (this is equivalent to the primary analysis)
    - These bounds provide intuitive limits on possible findings
2. **Multiple imputation (MI) under missing-at-random (MAR):**
    - Method: Chained equations (predictive mean matching for ordinal satisfaction items)
    - Imputation model: includes age, gender, language, KulturLegi status, prior testing history, site, calendar month, and all available pre-visit questionnaire data
    - Number of imputations: m=20
    - Results pooled using Rubin's rules
    - This assumes that non-response can be explained by observed characteristics
3. **Missing-not-at-random (MNAR) tipping-point analysis:**
    - Non-responders will be assumed to have satisfaction probabilities that differ systematically from responders

- Method: Delta-adjustment where non-responders are assumed to be δ times as likely to be satisfied as responders (multiplicative shift on the odds scale)
- Range explored: δ = 0.5 to 1.5 (i.e., non-responders are half as likely to twice as likely to be satisfied as responders)
- Presentation: Results will be displayed graphically, showing how the estimated satisfaction proportion and 95% CI change as δ varies
- Tipping point: The value of δ at which the lower bound of the 95% CI crosses 80% will be reported, indicating how strong the departure from MAR would need to be to change the study conclusion

All sensitivity analyses will use two-sided 95% confidence intervals. Results will be presented as proportions with confidence intervals, and the robustness of conclusions to missing data assumptions will be discussed transparently in the final report.

Secondary Endpoints

KAB scores and well-being (pre/post):

Primary analysis: Linear mixed-effects models estimated by maximum likelihood. This approach uses all available data and is valid under the missing-at-random (MAR) assumption, where missingness depends on observed covariates but not on unobserved values of the outcome.

Secondary analysis: Paired complete-case analysis (paired t-tests or Wilcoxon signed-rank tests) restricted to participants with both pre- and post-visit data. This provides a comparison to the mixed model approach.

Sensitivity analyses:

- Multiple imputation for missing post-visit data using chained equations; imputation model will include baseline KAB/well-being scores, demographics, and auxiliary variables correlated with missingness
- MNAR sensitivity: Delta-adjustment imputation where non-responders are assumed to have KAB/well-being scores that differ systematically from responders (e.g., δ = -0.5 SD lower than predicted under MAR). Results will be reported to assess robustness to departures from MAR.

Operational metrics (counts, waiting times, diagnoses/treatments):

- Descriptive analyses with explicit reporting of denominators
- No imputation planned; sporadic missingness will be noted in results
- If missingness exceeds 10% for any operational metric, patterns will be investigated and described

Equity outcomes:

- Proportions and rate ratios will be calculated using complete-case data
- If non-response differs substantially between KulturLegi and age-eligible groups, sensitivity analyses will use multiple imputation aligned with the methods described above for the primary endpoint

Item-Level Missingness (Multi-Item Scales)

For multi-item scales (e.g., KAB, well-being):

- If ≤20% of items are missing for a participant, compute person-mean prorated scores (13)
- If >20% of items are missing, treat the entire scale as missing for that participant
- Internal consistency (Cronbach's α) will be reported for all scales; acceptable reliability is defined as $\alpha \geq 0.70$

Rationale for Analytical Approach

The primary analyses avoid routine imputation to maintain transparency and interpretability. Multiple imputation and MNAR sensitivity analyses are used to demonstrate the robustness of conclusions to plausible missing-data mechanisms. Best/worst-case bounds provide intuitive limits on possible findings and help communicate uncertainty to non-statistical audiences.

Prevention of Missingness

The following design features are implemented to minimize non-response to the post-visit questionnaire:

- Short, plain-language questionnaires (maximum 10 minutes to complete)
- Multiple language options (German, English)
- Healthcare professional endorsement of the evaluation during counselling
- Email invitations with clear, simple instructions
- Timing aligned with test result delivery (a natural engagement point, approximately one week post-visit)

Post-visit questionnaire response rates will be monitored continuously throughout the study. If rates fall substantially below the conservative estimates used in sample size planning (23% for Lucerne, 17% for Zurich), study procedures will be reviewed and adapted in consultation with the research team and ethics committee. Potential adaptations may include enhanced reminder systems, shortened questionnaires, or extension of the study period to reach target sample sizes.

Participant Withdrawal and Data Handling

Withdrawal during counselling (before eIC confirmation): If a participant withdraws consent during the counselling session after completing the pre-visit questionnaire but before eIC confirmation is documented, all evaluation data will be deleted by the data manager as soon as feasible. These individuals will not receive an invitation to the post-visit questionnaire. However, anonymized operational data (e.g., HIV/STI test results, treatment received) collected as part of routine clinical care will be retained, as these data are not person-identifiable and are essential for public health monitoring.

Withdrawal after confirmed eIC: If a participant explicitly withdraws consent after eIC confirmation, identifiable information will be deleted. However, anonymized operational data (e.g., HIV/STI test results, treatment received) collected as part of routine clinical care will be retained, as these data are not person-identifiable and are essential for public health monitoring.

Loss to follow-up (passive non-response): Participants who do not complete the post-visit questionnaire but do not explicitly withdraw will be retained in the analysis dataset. Their baseline (pre-visit) data will be included in analyses, and missing post-visit data will be handled as described above using the specified sensitivity analyses.

Reproducibility of Missing Data Analyses

All procedures for handling missing data—including complete-case analyses, multiple imputation specifications, and tipping-point sensitivity analyses—will be fully scripted in R and maintained under version control in GitLab alongside the rest of the data cleaning and analysis workflow. This ensures that every analytical step, including the handling of missingness and sensitivity testing, is transparent, documented, and fully reproducible from raw data export through to final results.

5 REGULATORY ASPECTS AND SAFETY

5.1 Local regulations / Declaration of Helsinki

This research project will be conducted in accordance with the protocol, the Declaration of Helsinki [3], the Human Research Act (HRA) and the Human Research Ordinance (HRO) [1] as well as other locally relevant regulations. The project leader acknowledges his responsibilities as both the project leader and the Sponsor.

5.2 Notification of safety and protective measures (HRA Art. 15, HRO Art. 20)

If, during the research project, circumstances arise which could jeopardise the safety or health of the participants or lead to a disproportionate relationship between the risks and burdens and the benefits, all the measures required to ensure protection are to be taken without delay.
The project leader and the Sponsor is promptly notified (within 24 hours) if immediate safety and protective measures must be taken during the conduct of the research project. The Ethics Committee will be notified via BASEC of these measures and of the circumstances necessitating them within 7 days.

5.3 Serious events (HRO Art. 21)

If a serious event occurs, the research project will be interrupted and the Ethics Committee notified on the circumstances via BASEC within 7 days according to HRO Art. 21[1].

5.5 Amendments

Substantial changes to the project set-up, the protocol and relevant project documents will be submitted to the Ethics Committee for approval according to HRO Art. 18 before implementation. Exceptions are measures that have to be taken immediately in order to protect the participants.

The following are considered to be substantial changes:
a. changes affecting the participants' safety and health, or their rights and obligations;
b. changes to the protocol which concern the objectives of the research project;
c. a change of research site or conducting the research project at an additional site; or
d. a change of project leader or Sponsor.

5.6 End of project

Upon project completion or discontinuation, the Ethics Committee is notified within 90 days.

[1] A serious event is defined as any adverse event where it cannot be excluded, that the event is attributable to the sampling of biological material or the collection of health-related personal data, and which:
a. requires inpatient treatment not envisaged in the protocol or extends a current hospital stay;
b. results in permanent or significant incapacity or disability; or
c. is life-threatening or results in death.

The completion of the research project is defined by the last collection of health-related personal data or the last sampling of biological material.

All biological materials collected during the free testing campaign will be processed according to protocols of local laboratories participating working with the SeGZ and S&X (standard procedure not related to the conduct of the study). All primary data will be anonymised prior to data entry and archiving

5.7 Insurance

Non-clinical/non-interventional research projects belonging to category A do not require an insurance.

6 FURTHER ASPECTS

6.1 Overall ethical considerations

Scientific and societal value:
This project addresses a clear public health need. In most high-income countries, free HIV and STI testing is widely available, but in Switzerland access is still limited, with testing generally offered only during specific campaigns or at personal cost. As a result, individuals with limited financial means, including many young people, may face significant barriers to testing. The project evaluates the feasibility, acceptability, and impact of free HIV/STI counselling and testing services, thereby generating evidence to guide future health policy and reduce health inequities. The results will have direct social value by informing sustainable models for accessible sexual health services in Switzerland and comparable settings.

Justification of study design and participant burden:
The study is observational, with minimal burden for participants. Clients are asked to complete short, self-administered questionnaires before and approximately one week after their appointment, and HCPs may complete a brief workload survey. No interventions beyond standard care are performed, and participation is entirely voluntary. Individuals who do not consent can still access all services free of charge. Likewise, HCP participation in the survey is voluntary and has no bearing on employment conditions.

Autonomy and voluntary participation:
Informed consent is obtained electronically (eIC) prior to participation. Only data from individuals who provide consent are included in the evaluation. Persons unable to understand the study information due to cognitive or mental impairment will not be included in the research but may still use the free testing services. Participation or refusal has no consequences for clinical care or service access.

Non-maleficence and data protection:
The project involves the collection of sensitive information on sexual health and related demographic data. To ensure participant safety and confidentiality, strict data protection measures are applied.

Two distinct data pathways are used. For the operational dataset, routine service data from the municipal testing programmes are provided to the research team in fully anonymous form**,** without any identifiers or possibility of linking back to individuals.

For the evaluation dataset, participants who provide eIC contribute pseudonymised data. Their names and e-mail addresses, collected solely for sending the follow-up survey link, are accessible only to the core study team at the University of Zurich. These identifiers are never included in analysis datasets. Before the study is archived, all personal identifiers are permanently deleted, after which the remaining pseudonymised data are stored securely as part of the final project backup.

All data are entered directly into REDCap, hosted on the secure LEOMED infrastructure operated by ETH Zurich and the University of Zurich. LEOMED provides encrypted storage, restricted user access, and continuous security monitoring in line with the Swiss Federal Act on Data Protection (FADP).

Researchers do not have access to local linkage keys maintained by the participating testing sites. Data are analysed and published only in aggregated form. Responses to the HCP survey are anonymous, and only summary results are shared with partners or stakeholders.

Justice:
The project's primary aim is to improve equitable access to HIV/STI testing by reducing financial and structural barriers. Evidence generated by the study will support policies and interventions targeting underserved populations. Both service users and HCPs may benefit indirectly through more accessible services and better-resourced sexual health infrastructure.

Incidental findings and surplus information:
The study does not include diagnostic procedures beyond routine clinical care. Test results are handled entirely within the standard clinical workflow of the participating services and communicated directly to clients according to clinical guidelines. No clinically relevant "surplus information" is expected to arise from the research procedures. If incidental findings were to occur, they would be managed in accordance with Swiss law and swissethics guidelines.

6.2 Risk-Benefit Assessment

The study is classified as Category A (low risk). The principal potential risk is unauthorised access to sensitive personal data. This risk is minimised through secure data capture (REDCap on LEOMED), encryption, restricted user access, audit trails, and anonymisation of data once follow-up is complete. No invasive procedures or experimental interventions are part of the study, and participation involves only brief questionnaires.

Participants do not receive direct medical benefit from study participation. However, the expected societal benefits are substantial: improved understanding of barriers to testing, better targeting of public health resources, and evidence to inform future policy on accessible sexual health services. Over the long term, these benefits could lead to increased testing uptake, earlier detection and treatment of infections, and reduced transmission of HIV/STIs. The study will also generate insights into service delivery feasibility and HCP workload, supporting sustainable programme implementation.

6.3 Rationale for the inclusion of vulnerable participants

The study includes adolescents and low-income adults, both of whom are considered vulnerable groups. These populations are included because they face disproportionate barriers to accessing HIV/STI testing — including financial constraints, lower health literacy, and higher baseline risk of undiagnosed infections — and therefore stand to benefit most from the intervention. Equivalent insights could not be obtained without their inclusion.

Adolescents are included because they are often sexually active from mid-adolescence (mean age of first sexual intercourse: 16.7 ± 0.05 years in a representative Swiss sample, 2017) and may be unaware of their HIV/STI status (7). Excluding them would significantly limit the generalisability and policy relevance of the findings. Informed consent is obtained electronically from all participants aged 16 and above, following standard ethical guidelines.

Given the low-risk nature of the study, the strong safeguards in place to protect data confidentiality, and the high potential for societal benefit, the inclusion of these groups is ethically justified and necessary to address the research questions.

7 QUALITY CONTROL AND DATA PROTECTION

7.1 Quality measures

All questionnaires developed for study purposes will be tested via consultation with content experts and cognitive debriefings to test the acceptability, reliability, and validity of items. Personal at the testing sites will be trained in data entry in REDCap, the data manager at the University of Zurich will regularly check data for plausibility. Data will be screened in R Statistical Software for impossible or illogical values, unusual patterns, and missing values. Any manual data entry of primary data will be checked by a second study staff member by choosing 10% of data entries to check at random. Project personnel with native level proficiency in the local language will be trained to conduct the qualitative interviews.

For quality assurance the Ethics Committee may visit the research sites. Direct access to the source data and all project related files and documents must be granted on such occasions.

The project leader has appropriate knowledge and skills in the areas of data security and data protection or is able to ensure compliance by calling in appropriate expertise (Art. 4 HRO).

7.2 Data recording and source data

Data capture and electronic case report forms (eCRF):
All project data, such as participant questionnaires, operational indicators, and HCP surveys, will be captured and managed using REDCap, a secure, web-based data collection and management platform that includes user authentication, role-based access controls, full audit trails, and version history. EBPI's REDCap is hosted on LEOMED No Microsoft Office tools (e.g. Excel) will be used for data entry, storage, or primary analysis. All REDCap instances are hosted on LEOMED, the high-security biomedical research platform operated by ETH Zurich and the University of Zurich. LEOMED is designed specifically for handling sensitive health data and complies with the Swiss Federal Act on Data Protection (FADP) and relevant Good Clinical Practice (GCP) guidelines. It provides encrypted data storage and transfer, strict access control policies, and continuous security monitoring in line with institutional and national standards (14).

Source data and source documents:
Source data for this study consist of:

- Participant responses to project-specific pre- and post-visit questionnaires (evaluation data).
- Operational data routinely collected as part of the VCT services (e.g. appointment dates, testing outcomes, treatment start, visit counts).
- HCP survey responses.

Source documents include original electronic records within REDCap, as well as project-specific data exports for analysis. Routine service data recorded by the VCT sites are part of the participant's clinical or administrative file but are transferred in anonymised or coded form to the project database for analysis.

Data linkage and pseudonymisation:
All individuals accessing the free VCT services are recorded in REDCap, regardless of whether they consent to participate in the evaluation. Individuals who do **not** consent to the evaluation

have their data stored anonymously in REDCap, with no identifying information. The testing sites maintain a local linkage key that connects contact information (e.g. email or phone number for appointment management) with a coded participant ID. This key is stored securely and never accessible to the research team at UZH. Without this key, REDCap data cannot be linked back to an individual. If participants in the evaluation indicate that they are interested in taking part in future studies related to the programme, their contact details and coded study ID will be retained in a secure, pseudonymised linkage file until the end of the current study. This enables any future data they provide to be linked to their existing dataset without directly identifying them. Full pseudonymisation of all data will occur once the current study is completed and no further contact is required.

Evaluation participants:
Participants who consent to the evaluation provide their name and email address during eIC in REDCap. The email address is used solely to distribute the personalised link to the post-visit questionnaire. Participants are also asked to self-report non-identifying demographic information (year of birth, postal code, sex, and gender identity). Upon completion of the post-visit survey, all identifying information is deleted, and the data are fully anonymised.

HCP sub-study (survey):
Due to the small number of HCP participants, personalised survey links will be sent to their institutional email addresses to prevent non-serious responses. Only the core UZH research team has access to de-identified, individual-level responses. All external stakeholders and collaborators will see aggregated, generalised data only. No health-related or sensitive personal data will be collected from HCPs.

Data quality and audit trail:
All data entries, modifications, and exports in REDCap are logged with timestamps and user identifiers, ensuring traceability and auditability throughout the project lifecycle. Version-controlled data cleaning and analysis scripts will be stored in a private GitLab repository to ensure reproducibility and documentation of all analytical steps.

Questionnaire administration:
All project questionnaires (pre-visit, post-visit, and HCP surveys) will be completed online in REDCap by participants either on-site (e.g. using a tablet at the testing centre) or remotely (via a personalised survey link sent by email). This process is fully documented in the study procedures and ensures that all responses are captured directly into the eCRF without intermediate paper forms.

7.3 Confidentiality and coding

Project data will be handled with uttermost discretion and is only accessible to authorized personnel who require the data to fulfil their duties within the scope of the research project. On the CRFs and other project-specific documents, participants are only identified by a unique participant number. Coding is done using a method based on the current state of the art (Art. 26 HRO).

All project data will be collected and managed using REDCap, a secure, web-based data capture platform with full audit trails, user authentication, role-based access control, and encrypted data transfer. REDCap is hosted on LEOMED, the high-security biomedical research infrastructure operated by ETH Zurich and the University of Zurich. LEOMED complies with the Swiss Federal

Act on Data Protection (FADP) and Good Clinical Practice (GCP) requirements, ensuring state-of-the-art protection against unauthorised or accidental disclosure, alteration, deletion, copying, or theft.

Participants are identified in REDCap and all project documents exclusively by a coded participant ID.

Contact information collected for distributing post-visit survey links (name and email address) is used solely for that purpose and deleted once the follow-up questionnaire is completed. At that point, the dataset is fully anonymised. All access to data and changes within REDCap are logged and traceable, and regular password-protected backups are performed to prevent data loss.

Biological material:
No biological samples are collected or stored specifically for this study. Any diagnostic samples (e.g. swabs or blood) are processed and retained by the participating testing sites as part of standard clinical care, outside the scope of this research project. The study team does not have access to these materials. Consequently, no project-specific coding, storage, shipment, or destruction procedures for biological material are required.

Data transfer:

No coded or uncoded data and no biological material will be transferred outside the participating institutions or abroad without explicit participant consent and appropriate legal agreements in place.

7.4 Retention and destruction of project data and biological material

The project leader retains all the research project data for a period of at least ten years after the completion or early termination of the research project.

Project data:

All coded project data, including REDCap exports, analysis scripts, and related documentation, will be archived on secure institutional servers of the University of Zurich for a minimum of ten (10) years following project completion or early termination, in accordance with Swiss legal requirements and good research practice. Access to archived data will remain restricted to authorised project personnel. All processing activities essential for traceability, including data creation, cleaning, analysis, and export, are documented through REDCap audit logs and version-controlled GitLab repositories.

At the end of the retention period, anonymised datasets will be securely destroyed in compliance with institutional data governance procedures, unless a separate ethics application and participant consent are obtained for further use (e.g. inclusion in a registry or secondary analyses).

Biological material:

No biological samples are collected, processed, or stored specifically for this research project. Any diagnostic specimens (e.g. swabs or blood samples) are collected, processed, and retained solely within the framework of routine clinical care at the participating testing services. These activities take place under the responsibility of the respective providers — S&X (Lucerne) and SeGZ (Zurich) — in accordance with their established clinical procedures and local public health regulations.

The study team at the University of Zurich has no operational role in counselling, testing, or sample collection, and no access to biological material. Accordingly, no project-specific procedures for coding, transport, storage, or destruction of biological material are required. All

counselling, testing, and sample collection activities form part of the municipal public health programmes implemented by the respective organisations in the cities of Zurich and Lucerne. The research project itself adds the participant and healthcare professional questionnaires to assess satisfaction, feasibility, and impact.

No biological samples are collected or analysed as part of the study.

8 FUNDING / PUBLICATION / DECLARATION OF INTEREST

Funding for the study has been provided by the cities of Lucerne and Zurich. The funding organisations have no role in the design or conduct of the study; in the collection, management, analysis, or interpretation of the data; or in the preparation of the scientific manuscripts. According to the funding agreements, both parties will be notified of any planned publications and provided the opportunity to review manuscripts up to 20 working days before submission. This review is limited to factual verification and does not grant the funders any right to alter the scientific content or prevent publication. All analyses and publications will be conducted independently by the research team, and the reporting of results will follow the STROBE guidelines (15).

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Appendix 1: Schedule of assessments

Time (weeks)	***>-1 day***	***0***	***+1 week***	***After 6 months***
Visit	*Appointment booking and study information*	*VCT appointment (visit and questionnaires)*	*Results & post visit-questionnaire*	*HCP survey on feasibility*
oral and written Information	+			
Written consent		+		
check inclusion-/ exclusion criteria		+		
Participant Characteristics		+		
Questionnaire		+	+ (post-visit)	
Sampling (HIV- and STI-Testing)		+		
Survey HCP				+

Appendix 2: Recruitment and eIC Process Flow

Appointment booking

- Individuals book appointment for free voluntary counselling and testing (VCT) through the testing sites homepage.
- Upon booking they automatically receive the study information
- The information is provided at the time of appointment booking, giving the individuals time to consider participation in the evaluation.

Arrival and questionnaires at time of appointment

- At time of service, they are asked if they have received the evaluation information and if they have question regarding the evaluation.
- They fill in the obligatory VCT questionnaire which helps the counsellor during the consultation. At the end of the VCT questionnaire they are asked electronically if they wish to participate in the evaluation component.

Electronic Informed Consent

- If they agree, they are routed to the eIC form, which again presents the study infromation. If they agree to be part of the evaluation, their data will be used and they will be sent a survey link approximately one week after the appointment
- If they do not wish to be part of the evaluation, they are done with the questionnaires and continue on to the counselling and testing. None of the steps below apply to them.