

BMJ Open COBA-Cohort: a prospective cohort of HIV-negative men who have sex with men, attending community-based HIV testing services in five European countries (a study protocol)

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ABSTRACT

Introduction: Community-based voluntary counselling and testing (CBVCT) services for men who have sex with men (MSM) can reach those most-at-risk and provide an environment for gay men that is likely to be non-stigmatising. Longitudinal data on the behaviour of HIV-negative MSM are scarce in Europe. The aim of this protocol, developed during the Euro HIV Early Diagnosis And Treatment (EDAT) project, is to implement a multicentre community-based cohort of HIV-negative MSM attending 15 CBVCT services in 5 European countries.

Research objectives: (1) To describe the patterns of CBVCT use, (2) to estimate HIV incidence, and to identify determinants of (3) HIV seroconversion and (4) HIV and/or sexually transmitted infection (STI) test-seeking behaviour.

Methods and analysis: All MSM aged 18 years or over and who had a negative HIV test result are invited to participate in the COmmunity-BASed Cohort (COBA-Cohort). Study enrolment started in February 2015, and is due to continue for at least 12 months at each study site. Follow-up frequency depends on the testing recommendations in each country (at least 1 test per year). Sociodemographic data are collected at baseline; baseline and follow-up questionnaires both gather data on attitudes and perceptions, discrimination, HIV/STI testing history, sexual behaviour, condom use, and pre- and post-exposure prophylaxis. Descriptive, exploratory and multivariate analyses will be performed to address the main research objectives of this study, using appropriate statistical tests and models. These analyses will be performed on the whole cohort data and stratified by study site or country.

Ethics and dissemination: The study was approved by the Public Health authorities of each country where the study is being implemented. Findings from the COBA-Cohort study will be summarised in a report to the European Commission, and in leaflets to be distributed to study participants. Articles and

Strengths and limitations of this study

- This study is the first pan-European multicentre prospective cohort of HIV-negative men who have sex with men (MSM) enrolling participants in community-based counselling and testing services.
- The COmmunity-BASed Cohort (COBA-Cohort) is recruiting a sample of HIV-negative MSM expected to be larger than 4000 individuals, collecting HIV test results and other common data on testing patterns and sexual behaviour.
- The prospective design of the COBA-Cohort will allow causal relationships to be inferred with appropriate statistical analysis.
- Representativeness will be the main limitation of this study; the final sample will not be representative of the whole European MSM population but only of those individuals attending the participating sites.
- Long-term data collection may be limited in several sites due to scarce financial resources.

conference abstracts will be submitted to peer-reviewed journals and conferences.

INTRODUCTION

In the European Economic Area, the annual rate of HIV diagnoses has remained relatively stable since 2004, with 32 605 new cases reported in 2014 (6.4/100 000 population) when adjusted for reporting delay.¹ In those countries consistently reporting data, the proportion of new infections due to

male-to-male sexual transmission increased from 30% in 2005 to 42% in 2014, while decreasing in all other known transmission groups.¹ In Western Europe, seven countries reported an estimated HIV prevalence in MSM of more than 10% in 2012, ranging from 17.7% in France to 10.2% in Portugal.²

Although men who have sex with men (MSM) remain one of the most affected populations for HIV in Europe, direct incidence estimates are scarce because very few cohort studies have been conducted. Those incidence data that are available show that HIV is still spreading rapidly among MSM, with slightly different estimates between countries: 1.2/100 person-years (PYs) in Amsterdam (the Netherlands) in 2014,³ 3.1/100 PYs in Barcelona (Spain) in 2011⁴ and 2.8/100 PYs in Lisbon (Portugal), between 2011 and 2014.⁵

Under the current 'combination prevention' paradigm, based on behavioural, biomedical and structural interventions, improving access to and frequency of HIV testing has become one of the main strategies to improve HIV prevention in MSM. Indeed, there is strong evidence of the benefits of early diagnosis and subsequent treatment for individuals (lower mortality and morbidity, higher quality of life, improved life expectancy and overall health) and populations (both behaviour change and antiretroviral therapy reducing onward transmission risk).⁶ Although the evidence for reduced sexual risk reduction after HIV testing and counselling in those with a negative test is weaker, a recent study suggested that frequent HIV testing helps HIV-negative MSM to talk more openly about HIV status with their sexual partners, which in turn may reduce serodiscordant condomless anal intercourse.⁷

Frequent voluntary counselling and testing for HIV and other sexually transmitted infections (STIs) in MSM has been recommended for about 10 years.^{8–9} Both WHO and European Centre for Disease Prevention and Control (ECDC) recently reminded that annual HIV/STI testing for sexually active MSM is a minimum, and should be more frequent for those having condomless anal sex with multiple or anonymous partners.^{10–11} Despite these recommendations, the observed proportions of MSM tested within the previous 12 months in the European MSM Internet Survey (EMIS) ranged from 20% in Lithuania to 47% in France,^{12–13} suggesting that there is considerable scope to increase frequent HIV testing within combined prevention Public Health strategies.

Barriers to the uptake of HIV (re-)testing are well known and may exist at individual, health provider and institutional levels.⁶ MSM face additional, specific barriers to testing, such as homophobia and internalised homonegativity.^{13–17} To help overcome these barriers, many European countries have implemented or at least authorised community-based voluntary counselling and testing (CBVCT) services (as defined in the HIV-COBATEST project: HIV COMMUNITY-BASED TESTING practices in Europe¹⁸) targeting key populations,

including MSM. CBVCT services targeting MSM manage to reach those most at risk,^{19–21} probably because peer counselling is well adapted to the culture of MSM, understands their practices, and addresses homophobia and worries of rejection. Several studies have also shown that CBVCT has contributed to increasing testing frequency among MSM^{19–20} and has improved linkage to care.^{22–23}

Conducting longitudinal studies within CBVCT services is challenging because their work is focused on HIV testing and prevention activities, and the systems employed to guarantee anonymity may hinder identification of returning individuals. Although data are routinely collected by CBVCT services to monitor their testing activity, these are often underexploited and report test positivity rates rather than the proportion of users who test positive for HIV.

This study protocol thus proposes to implement a service-based cohort of HIV-negative MSM among attendees of existing CBVCT services targeting MSM, taking into account the experience of two existing cohorts of MSM in CBVCT services.^{4–24} The protocol was developed within the Euro HIV Early Diagnosis And Treatment project (Euro HIV EDAT: <https://eurohivedat.eu/>), cofunded by the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA, European Commission). Euro HIV EDAT builds on experience and expertise from the HIV-COBATEST project (study reports available at <http://cobatest.org>) in which a network of European CBVCT services was developed to share experience and improve early diagnosis in key populations such as MSM.

To the best of our knowledge, this study—the COMMUNITY-BASED COHORT (COBA-Cohort)—is the first pan-European longitudinal study involving CBVCT services sharing the same data collection tool and recruitment procedures. It is thus a unique occasion to improve the comparability of incidence data between European countries and to disentangle the observed similarities and peculiarities in the determinants of seroconversion between countries.

METHODS AND ANALYSIS

General study design

This COBA-Cohort is a pan-European prospective and multicentre cohort of HIV-negative MSM attending 1 of the 15 participating CBVCT services, led by five non-governmental organisations (NGOs): AIDES, AIDS-Fondet, Ath Checkpoint, CheckpointLX and Legebitra, from France, Denmark, Greece, Portugal and Slovenia, respectively (figure 1). The current protocol was developed, discussed and agreed on by a working group that includes the coordinating centre (Centre for Epidemiological Studies on HIV/STI of Catalonia (CEEISCAT), Barcelona, Spain), at least one representative of the previously mentioned NGOs and three representatives from external academic institutions (Institute of Tropical Medicine Antwerp in Belgium;

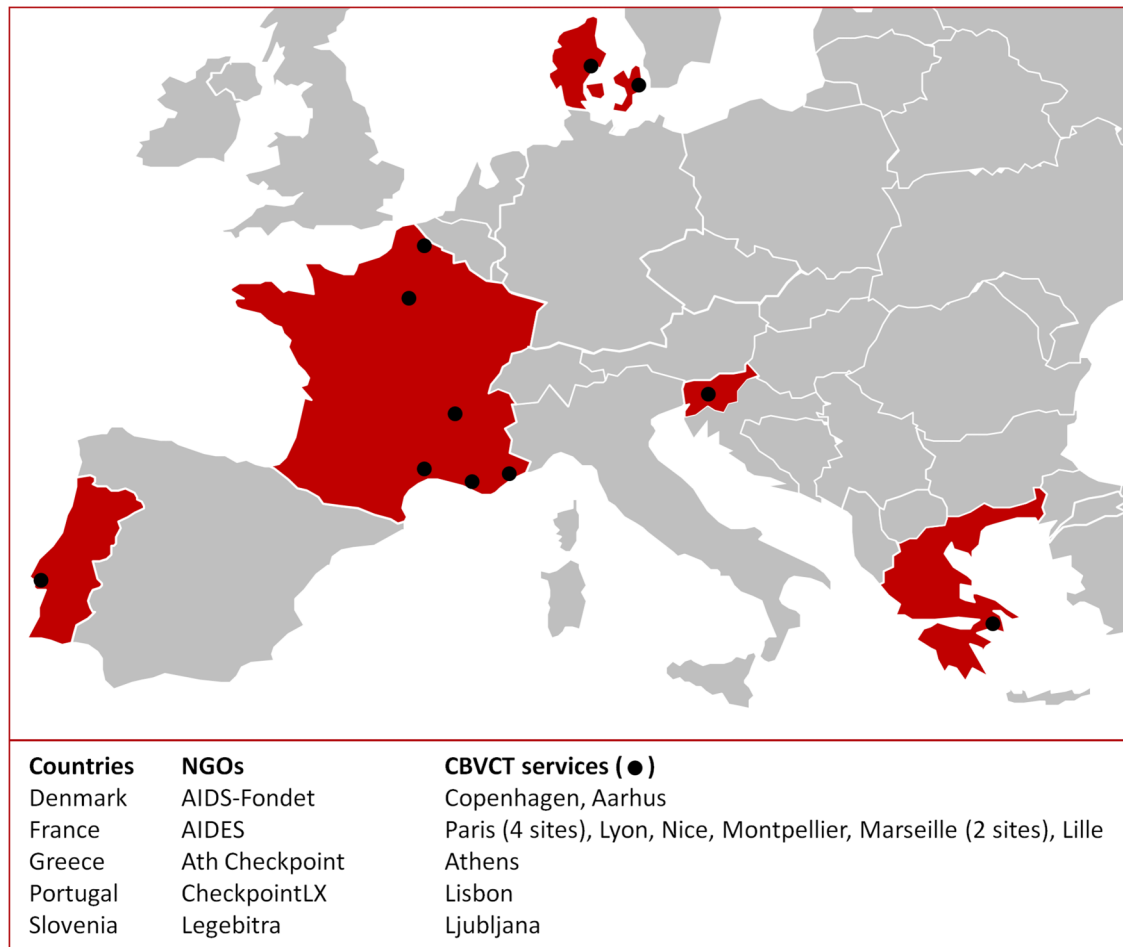


Figure 1 Community-based voluntary counselling and testing (CBVCT) services participating in the COmMunity-BASed Cohort (COBA-Cohort).

the Institute of Public Health of the University of Porto in Portugal and the Slovenian Institute of Public Health).

The main challenge in developing the protocol of the COBA-Cohort study was to harmonise the methodological procedures and tools in order to obtain comparable data, while maintaining the operative autonomy of the participating CBVCT services. This observational service-based cohort does not aim to change any of the usual procedures of the participating sites, for instance HIV testing recommendations or counselling and testing methods. The follow-up frequency of participants hence depends on the participants' willingness to return for a test.

Objectives

The main research objectives of this service-based study in MSM are (1) to describe the patterns of CBVCT use, (2) to identify determinants of HIV and/or STI test-seeking behaviour (including repeat testing), (3) to estimate the HIV incidence and (4) to identify risk factors for seroconversion.

Furthermore, determinants for sexual risk behaviour and coinfections could also be described.

Feasibility

The existence of two ongoing HIV-negative MSM cohorts in CBVCT services, at BCN Checkpoint in Barcelona⁴ and CheckpointLX in Lisbon,²⁴ demonstrates the feasibility of running a service-based pan-European cohort, enrolling and following up MSM within established CBVCT services. CheckpointLX, which is also participating in COBA-Cohort, established and runs the MSM Lisbon Cohort and was enrolling around 600 new participants per year until 2014, taking into account a 30% refusal rate.

The first sites of COBA-Cohort started enrolling participants in early 2015, and the total sample included 2313 individuals by 29 February 2016. Other start dates and interim raw data for each CBVCT service are presented in table 1. As the enrolment phase started only a few weeks before this date in several sites, the corresponding samples are still very small.

These raw data show that CheckpointLX is now recruiting many more participants per year than in previous years, and has a stable refusal rate of 30%.

In smaller centres such as Legebitra (Ljubljana, Slovenia), which performed 480 HIV tests in 2014, the refusal rate is much lower (around 11%). Apart from

Table 1 Interim enrolment data between the start and 29 February 2016 (raw data)

NGOs	CBVCT services	Start dates (mm/dd/yyyy)	Eligible men invited to participate n	Participants enrolled n	Users who declined participation* n (%)	Participants who returned at least once† n (%)
CheckpointLX (Portugal)	Lisbon	01/02/2015	1748	1219	529 (30.3)	220 (18.0)
Legebitra (Slovenia)	Ljubljana	02/09/2015	324	287	37 (11.4)	69 (24.0)
AIDS-Fondet (Denmark)	Copenhagen	04/13/2015	697	624	73 (10.5)	107 (17.1)
	Aarhus	05/07/2015	66	52	14 (21.2)	18 (34.6)
AIDES (France)	Paris 12th	01/05/2016	8	8	0 (0)	0 (0)
	Lyon	01/06/2016	16	15	1 (6.3)	1 (6.7)
	Montpellier	01/07/2016	13	12	1 (7.7)	1 (8.3)
	Paris 8th	01/13/2016	7	7	0 (0)	0 (0)
	Marseille South	01/14/2016	20	19	1 (5.0)	0 (0)
	Marseille North	01/15/2016	5	5	0 (0)	0 (0)
	Lille	01/20/2016	13	12	1 (7.7)	0 (0)
	Paris 2nd	01/21/2016	6	6	0 (0)	1 (16.7)
	Nice	01/22/2016	32	18	14 (43.8)	0 (0)
	Paris 19th	01/27/2016	9	8	1 (11.1)	0 (0)
Ath Checkpoint (Greece)	Athens	02/15/2015	33	21	12 (36.4)	0 (0)
Total	15 sites	01/02/2015	2997	2313	684 (22.8)	417 (18.0)

*May be under-reported in several sites.

†May include duplicates in several sites.

CBVCT, community-based voluntary counselling and testing; NGO, non-governmental organisation.

the personal motivation of the Slovenian CBVCT users to participate in a research study, this refusal rate may be lower than that of CheckpointLX because they can take advantage of the systematic waiting time before the test to fill in the questionnaire. Additionally, peer counselors may have more time per attendee because the annual number of tests is smaller than at the other sites.

Inclusion criteria and recruitment

Inclusion criteria are as follows: reporting any kind of sex with another man at least once in the 12 months prior to enrolment, being 18 years or older, being a resident or frequent visitor to the CBVCT service catchment area, having a negative HIV test result at enrolment and providing written consent.

All men attending the participating CBVCT services who meet the inclusion criteria during the recruitment period are offered participation in the cohort. Potential participants are given specific information about the COBA-Cohort and the implications of participation (verbal and written explanations) before giving their written informed consent. CBVCT service attendees who meet the inclusion criteria but decline participation are asked to complete a short questionnaire, to be filled in either by the attendee himself or by a counsellor during a face-to-face interview (the refusal questionnaire included the following variables: date of the current test, gender, date and country of birth, country of residence, education,

occupation, definition of sexual orientation, date of the last HIV test, main reasons for not participating).

The aim is to make the convenience sample as large as possible (expected to be larger than 4000 participants), and as representative as possible of each site (an essential pre-requisite for descriptive and analytic objectives). Within the framework of Euro HIV EDAT, the enrolment phase was due to start in January 2015 and to end in June 2016 at each site (18 months). However, the start of the cohort has been delayed in almost all sites (see table 1) due to difficulties in preparing the field-work (translations, trainings, pilots, etc) and/or in obtaining the ethics approval.

Nevertheless, all participating CBVCTs already expressed their willingness to continue the recruitment after the originally planned deadline. Those sites that started in 2015 will thus recruit for 18 months (same duration as originally planned), and the others will recruit for a total of at least 12 months.

Follow-up

Recommendations for testing frequency differ between countries and CBVCT services, but they all recommend having at least one test per year, the frequency usually varying according to the risk profile. Enrolled participants are encouraged to be retested according to these recommendations. Proactive follow-up (calls, SMS, emails, etc), which has already been implemented in several participating CBVCT services, would also be

offered to all study participants in order to improve repeat testing rates for those accepting reminders.

At each follow-up visit, participants undergo HIV testing and peer counselling, and are offered prevention supplies (condoms, lubricants, brochures, etc) by the CBVCT services. In case of a reactive test during follow-up, participants are offered a confirmation test in accordance with country diagnosis guidelines. In some of the participating CBVCT services, the confirmatory test can be conducted onsite. In others, participants are referred to a laboratory or health facility for confirmatory testing and access to standard public HIV care in their country. Linkage to care procedures in European CBVCT services are being investigated as part of another work package of the Euro HIV EDAT project.

COBA-Cohort participants will be followed up at least until the end of the study period planned in the Euro HIV EDAT project (March 2017). However, all participating CBVCT services are aware of the importance of continuing the follow-up in such a study. Some have already expressed their willingness to continue the follow-up beyond this date.

The study group is currently exploring opportunities to obtain extra funds and/or finding alternative solutions that could reduce the workload linked to participation in the COBA-Cohort. In particular, as data entry is one of the most time-consuming tasks for the participating CBVCT services, the possibility of using new technologies such as online or tablet-based self-administered questionnaires is being investigated to overcome this barrier to long-term participation.

Data collection

A common version of each questionnaire (baseline, follow-up and refusal) has been developed and agreed on by the working group. In all but one CBVCT service, questionnaires are self-administered. Participants have to fill in a sociobehavioural questionnaire at inclusion (baseline questionnaire) and a shorter version (follow-up questionnaire) every time they return to the CBVCT service.

These questionnaires collect data on the sociodemographic profile (baseline questionnaire only), general health and HIV risk, HIV testing (history, patterns, intentions and attitudes), sexual behaviour (history, type of partners, condom use, partner's serological status data, etc), STIs, and hepatitis B and C (history, testing patterns and vaccines), and pre- and post-exposure prophylaxis (awareness, use and intention to use). Several questions also gathered information about alcohol and drug use during sex (type of drugs and frequency) as well as history of injecting drug use (whether or not related to sex, including the date of the last injection).

In the baseline questionnaire, questions refer to 'the past 12 months' and 'since the last visit' in the follow-up questionnaire. Indeed, as the frequency of follow-up is not fixed (eg, visiting every 6 months), follow-up questions about participants' behaviour prior to their visits

refer to 'since the last visit' in order to cover all the exposure time between two visits. The original questionnaires were developed in English, and then translated by each NGO into their local language(s) before piloting them internally.

During each visit, CBVCT providers also collect data about the general characteristics of each participant's visit (counselling, type of test, confirmatory testing), biomedical data (test and confirmatory test results, access to the results) and linkage to care (if applicable). These indicators are mainly derived from the standardised form currently used in the European COBATEST network of CBVCT services.^{25 26}

Data management

To facilitate sharing and harmonisation of the data gathered through the self-administered questionnaires, the coordinating centre has implemented a web-based data collection tool (secured by an https connection protocol) enabling CBVCT service providers to enter the paper questionnaires online. Nevertheless, each participating CBVCT service can also use its own data collection approach. Indeed, as CheckpointLX already had its own data collection tool, its use was continued. In France, AIDES developed a tablet-based self-administered questionnaire to be filled in by the enrolled participants themselves because CBVCT service providers are not allowed to enter the participants' questionnaire data under current French ethical guidelines. Since this latter model of data collection would considerably reduce the time dedicated to COBA-Cohort in each site, the study group aims to generalise it in the coming months.

For the moment, CBVCT services using the paper questionnaires must perform regular data entry of the inclusion, follow-up and refusal questionnaires. This allows the coordinating centre to centralise the data every 6 months in order to monitor the study and perform interim analyses. In the CBVCT services using their own data collection tool, cumulative data sets in a pre-established format are sent to the coordinating centre, to be merged with the rest of the data.

According to local data protection laws and ethical guidelines, personal identifiable information of the participants (name, email address, etc) may be collected locally by the CBVCT service to remind participants to come back for a test, but such data are not entered into the central cohort database managed by the coordinating centre; each participant will only be identified by an anonymous *unique participant identifier* in the cohort database.

Statistical analysis

The study aims to recruit a convenience sample of CBVCT service users that is as representative as possible, offering participation in the study to all eligible MSM attending the participating CBVCT services during the recruitment period, and collecting basic sociodemographic data for those declining participation.

The sociodemographic profile of MSM declining to participate will be compared with that of those enrolled in the cohort study and should any significant differences be found between both groups, the final sample will be weighted to compensate for selection bias. The estimated weight to be applied will be computed as the inverse of the probability of participation on the basis of the sociodemographic data.

Descriptive analyses will then be performed on each variable in order to describe the activity and the main characteristics of the cohort (for the total cohort and separately for each CBVCT service or NGO).

Other descriptive, exploratory or multivariate analyses will be performed to address the main research objectives of this study (patterns of use of CBVCT, HIV/STI testing behaviour and sexual risk taking). χ^2 Tests will be used to compare categorical variables, and Student's t-test or Mann-Whitney U test for continuous variables, as appropriate.

The HIV incidence rate (with 95% CI) will be estimated for the total cohort and if sample size allows for each CBVCT service or NGO among participants having at least one follow-up visit. The follow-up time of participants will start at the date of the baseline visit and end at the date of HIV seroconversion or last HIV-negative test. The incidence will thus correspond to the number of HIV seroconversions (ie, a first positive HIV test after a negative HIV test in a previous visit) divided by PYs of follow-up. We will also identify factors associated with HIV seroconversion, using multivariate Cox regression models. HRs and their 95% CIs will be computed.

In longitudinal analyses, differences in the period of time between visits will be taken into account by using the appropriate statistical models (eg, generalised estimating equation and mixed-effects models).

ETHICS AND DISSEMINATION

The coordinating centre and all NGOs except Ath Checkpoint have been involved in the HIV-COBATEST,¹⁸ also funded by the European Commission. The coordinating centre and several partners of the present study have also taken part in other European projects such as SIALON^{27 28} and EMIS.¹³

The first study results will be published at the end of the Euro HIV EDAT study period (September 2017) in a report for the CHAFAEA, European Commission. This report will address all the research objectives of this study, and will be published after approval from the steering committee members and the advisory board of the Euro HIV EDAT project. A brochure based on the main study results will be published and translated into various languages in order to be distributed by the participating CBVCT services to the men who took part in the cohort.

At the end of the recruitment period, a first scientific article describing the COBA-Cohort profile will be published in a peer-reviewed journal, and other articles and conference abstracts will be submitted to international

journals and conferences to disseminate the results of specific analyses. Regular brochures for participants will provide an insight into the evolution of the cohort.

APPLICABILITY AND PERSPECTIVES

The implementation of such a cohort of HIV-negative MSM in different European countries, sharing methodology and data, should contribute to improved scientific knowledge of the uptake of community-based testing, HIV and STI testing patterns, and the trends in HIV testing and sexual behaviours over time, and from test to test in this population. It will also be an opportunity to compare the behaviour and attitudes of MSM between countries and in various contexts (including health systems), highlighting the specific characteristics of each local situation.

These data will be crucial to design better preventive interventions aiming at increasing test uptake among MSM. HIV incidence data are also very important measures that will help in identifying the specific subgroups that are even more affected by HIV. Indeed, a recent cohort study showed that it was possible to identify subgroups of MSM with a much higher incidence, even in low-incidence contexts.²⁹ The results will also contribute to increased knowledge of the care cascade in Europe, in particular in those sites where data regarding linkage to care are available.

Some of the main challenges of this pan-European multicentre prospective cohort of HIV-negative MSM are (1) to make it sustainable over time and (2) to include other CBVCT services in order to better reflect the diversity of European MSM. At the time of publication of this article, the study group was already in contact with other European CBVCT services that would be willing to join the study.

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Contributors NL, LFL, CA and JC conceived and supervised the study design. SC, BC, RF, DRC, SM, FP, PSK and—as representatives of each NGO—provided background information and feedback on the study design and its feasibility. PM, RL, IK and TP brought external expertise to the study design and tools. NL drafted the first version of the article and all the other co-authors reviewed the manuscripts. All the co-authors read and approved the final version of the manuscript.

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Competing interests None declared.

Ethics approval The current study protocol has been approved by the Ethics Committee of the Germans Trias i Pujol Hospital (Badalona, Spain) for the coordinating centre (CEEISCAT). All the NGOs have been granted ethical approval by their respective Health Authorities and are currently enrolling participants (see attachments).

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