U.PORTO

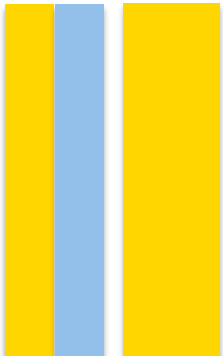
2º CICLO DE ESTUDOS
MESTRADO EM SAÚDE PÚBLICA

Access to PrEP and satisfaction among users and health professionals: results from a pilot project of a community-based provision model in Portugal

André Gonçalves Cardoso

M

2023



André Gonçalves Cardoso

Access to PrEP and satisfaction among users and health professionals: results from a pilot project of a community-based provision model in Portugal

Orientadora:

Paula Cristina Coelho Ribeiro de Meireles

Faculdade de Medicina da Universidade do Porto

Instituto de Saúde Pública da Universidade do Porto

Dissertação apresentada à Faculdade de Medicina da Universidade do Porto e Instituto de Ciências Biomédicas Abel Salazar da Universidade do Porto para obtenção do grau de mestre em Saúde Pública.

Porto | 2023

AVISOS LEGAIS

No âmbito da elaboração da presente dissertação o autor foi responsável por obter os pareceres necessários à realização da mesma, de forma a atestar a sua legalidade. Para tal, O Conselho de Administração do Centro Hospitalar Universitário do Porto, na reunião de 10 de Agosto de 2023, emitiu a seguinte deliberação no Ofício 2023.048 (039-DEFI/040-CE) : “Autorizado” para a realização do estudo acima mencionado, após a implementação das recomendações elaboradas pela Encarregada da Proteção de Dados, a realizar no Serviço de Urgência e Serviço de Infeciologia desta Instituição, tendo como Investigador Principal o Enf. André Gonçalves Cardoso, estudante de Mestrado em Saúde Pública ministrado pela Faculdade de Medicina e Instituto de Ciências Biomédicas Abel Salazar da Universidade do Porto. O estudo foi previamente analisado pela Comissão de Ética do CHUP/ICBAS, pelo Serviço de Investigação Clínica, pela Direção do Departamento de Ensino e Formação do Santo António, pela Direção de Enfermagem e pelo Presidente do Conselho de Administração, tendo obtido parecer favorável.

AGRADECIMENTOS

Demonstro um verdadeiro e profundo agradecimento a todos os envolvidos e que me acompanharam ao longo deste longo percurso que culmina com a elaboração da minha dissertação a fim de obter o grau de mestre.

Em primeira instância, agradeço à minha família, a minha mãe Emília, o meu pai Luís e o meu irmão Rafael, assim como, à minha companheira Bruna.

De seguida, agradeço aos meus amigos, camaradas e colegas de curso que sem a presença de todos eles não seria possível alcançar os meus objetivos de uma forma calorosa, inspirada e feliz.

Por fim, mas não menos importante, deixo o meu agradecimento à minha orientadora Dra. Paula Meireles pela sua dedicação e disponibilidade demonstrada na minha supervisão e orientação.

Obrigado

"If people were silent, nothing would change"

Malala Yousafzai

TABLE OF CONTENS

LIST OF ABREVIATIONS & ACRONYMS

ART Antiretroviral therapy
CBO Community Base Organization
CC+AP Community Center +Abraço Porto
CHUP Centro Hospitalar Universitário do Porto
CHUSJ Centro Hospitalar Universitário São João
ECDC European Center of Disease Prevention and Control
GAT Grupo de Ativistas em Tratamento
HGO Hospital Garcia de Orta
HIC High Income Country
HIV Human Immunodeficiency Virus
HPV Human Papilloma Virus
LMIC Low Middle-Income Country
MSM Male who have sex with Male
NHS National Health System
PEP Post Exposure Prophylaxis
PHU Public Health Unit
PNHS Portuguese National Health System
PrEP Pre-Exposure Prophylaxis
PWID People Who Inject Drugs
RCT Randomized Control Trial
STD Sexual Transmitted Diseases
STI Sexual Transmitted Infections
UK United Kingdom
USA United States of America
VHA Hepatitis A
VHB Hepatitis B
WHO World Health Organization

LIST OF TABLES

LIST OF FIGURES

RESUMO

A epidemia global provocada pelo VIH continua a ser um desafio para a saúde pública. Intervenções que visam prevenir a infeção por VIH foram implementadas usando diferentes modelos de acesso, tais como, o regime de oferta comunitária de PrEP que veio diminuir as barreiras de acesso a populações com risco elevado de infeção. Em Portugal, o projeto-piloto de PrEP em regime comunitário e descentralizado iniciou em 2021. O objetivo deste estudo foi descrever a acessibilidade e a satisfação dos indivíduos, assim como, dos profissionais de saúde nos primeiros 2 anos do projeto-piloto. Para este fim, foi realizado um estudo transversal descritivo onde participaram 93 indivíduos cisgénero masculinos em PrEP e 16 profissionais de saúde a exercer funções em serviços de PrEP. Os resultados mostraram que a maioria dos utilizadores de PrEP sentem um elevado nível de satisfação em relação ao projeto piloto e, em média, aguardaram cerca de 7 semanas pela sua primeira consulta médica. Os profissionais de saúde também se sentem satisfeitos, sendo a interferência que o projetos-piloto têm com o seu horário de trabalho o fator que provoca menor satisfação. O presente estudo demonstra que o primeiro projeto-piloto de acesso à PrEP usando um modelo de distribuição comunitário e descentralizado foi bem-sucedido. Estes resultados poderão ser importantes para o desenvolvimento de novas intervenções a fim de contribuir para a satisfação do utilizador, assim como, do profissional de saúde em serviços de PrEP.

Palavras-chave: PrEP, modelo comunitário, VIH, satisfação, acesso à PrEP

ABSTRACT

The global HIV epidemic remains a significant public health challenge. HIV prevention interventions such as PrEP have been implemented in community-based settings to address barriers in access to formal healthcare settings such as hospitals. The Portuguese pilot project of PrEP in a community-based distribution model started in 2021. The objective of this study was to describe the accessibility and satisfaction of beneficiaries as well as providers in the first two years of this novel pilot project. For this purpose, a cross-sectional study was conducted. In this study, 93 cisgender male PrEP users and 16 healthcare professionals participated. The results showed that almost all PrEP beneficiaries reported a high level of satisfaction towards this pilot project and had to wait a mean time of 7 weeks to get to their first appointment. PrEP providers were also highly satisfied, being the lowest satisfied with the interference that the pilot project took in their working schedule. This study shows that the first pilot project of PrEP access using a community-based in Portugal was successful in terms of beneficiaries and provider satisfaction. These results may be important to the development of tailored interventions in order to contribute to the satisfaction with PrEP.

Keywords: PrEP, community-based model, HIV, satisfaction, PrEP access

BACKGROUND

1. Human Immunodeficiency Virus (HIV)

According to the latest data from UNAIDS, an estimated 38 million people were living with HIV at the end of 2020, and approximately 1.5 million new HIV infections occurred worldwide in 2022 (1).

Over the last decade, significant progress has been made globally regarding HIV treatment, such as ensuring immediate access to antiretroviral therapy (ART) (2). Nevertheless, the global HIV epidemic remains a significant public health challenge (1).

Furthermore, the COVID-19 pandemic created social disruptions as the loss of income, livelihood and social changes which impacted and raised even further the inequalities among the key populations at high risk for HIV, such as men who have sex with men (MSM), sex workers and people who inject drugs (PWID). Thus, these outcomes may put at risk public health prevention measures regarding HIV (3) and intensified efforts and diversified strategies are needed to address this challenge (1). In order to achieve the WHO goal of ending the HIV epidemic by 2030 we must ensure an efficient HIV response with a range of prevention strategies that include condom use and pre-exposure prophylaxis (PrEP) (1,4).

2. Pre-Exposure Prophylaxis (PrEP)

The World Health Organization (WHO) defined PrEP as the use of an antiretroviral medication by seronegative individuals to reduce the risk of acquiring an infection by HIV (5).

This prophylactic intervention is safe and recommended as part of a comprehensive HIV prevention strategy that includes regular HIV testing and condom use (6-8). Until 2019, several randomised controlled trials (RCT) showed that taking PrEP resulted in a 97% risk reduction of acquiring HIV, regardless of risk behaviours, if taken daily or more than 4 doses a week (9-13).

One qualitative study conducted in the World Gay Parade 2017, in Madrid, showed that 63% of the participants were motivated to access PrEP services, of whom 53% justified their motivation in order to prevent themselves from HIV infection, 14% to have condomless sexual intercourses while in PrEP and 8% to feel safer while they were having sex (14). Though, until 2021, 144 countries adopted the WHO recommendations to use PrEP in their national guidelines, it may not be accessible or affordable for everyone who needs it (1,15).

Access to PrEP can be limited by a range of barriers altering the individual's ability to access this prevention tool and may contribute to disparities in PrEP uptake and adherence among different populations all over the world (16). One of the most significant barriers to PrEP access is the expensive cost of ARV medication, therefore prescription criteria must be ensured in order to reach key populations, allowing PrEP to be a cost-effective measure for HIV prevention (17). Although some countries have implemented PrEP subsidies or assistance programs to help address this barrier, not all individuals have access to such programs and need to rely on insurance coverage schemes or out-of-pocket payments (18).

A cross-sectional study in 2019, showed that Portugal and seventeen other countries (i.e., Northern Ireland, Wales, Scotland and England within the UK, Iceland, Norway, Sweden, Ukraine, Moldova, Georgia, Bosnia and Herzegovina, Croatia, Slovenia, Belgium, France, Germany, Luxembourg, the Netherlands, Greece and Spain) offered free access to PrEP in their National Health Service (NHS), provided through public expenditure or private funding (e.g., demonstration, research and/or pilot programmes) (19). Countries such as Italy, Israel, Austria, Ireland, Malta, the Czech Republic, Switzerland, Sweden, Poland and Finland partially guarantee free access to PrEP which means that their citizens are required to have some array of health insurance to have access. Countries in the Middle East and North African region, Russia and Turkey acknowledge the non-existence of formal PrEP use (19). Hence, several individuals may not know that PrEP exists or may have misconceptions about its effectiveness and safety (20). Healthcare providers may also hold biases and stereotypes about certain populations, which can lead to feelings of stigma and discrimination associated with HIV and with high-risk behaviours such as sex work or drug use (21).

Language and cultural barriers can also play a decisive role regarding access to PrEP services, particularly for individuals from non-English-speaking countries or immigrant communities (22). In 2022, the USA, Australia, France and the UK were the high-income countries (HIC) that registered the highest number of people who started to use PrEP. On the other hand, South Africa, Nigeria, Zambia and Uganda accounted for the highest PrEP uptake among low and middle-income countries (LMIC) (23).

Moreover, since 2018 PrEP uptake has progressively risen as Europe and Central Asia boosted their access and availability through formal mechanisms. This resulted from a multifaceted approach implemented by the national health services over these regions to diversify their PrEP delivery models (24,25). Currently, countries around the world can provide PrEP to their citizens through several delivery models, including, hospital-based

outpatient services, pharmacy-led initiatives, nurse-led PrEP, community-based programmes and home-based delivery services (25,26).

3. Delivery models of PrEP

Hospital-based outpatient services deliver PrEP in clinical settings such as hospitals and/or primary healthcare clinics through scheduled appointments performed by healthcare professionals such as doctors and nurses (27). This type of delivery model effectively uses the institution's logistics, infrastructure and human resources as also can provide additional knowledge or skills to their healthcare force (28). Associated with this delivery model users may find some access barriers (e.g., people who have scarce means of transportation and have time-limited availability due to living in remote or rural areas), language barriers in communicating with health professionals, privacy concerns (e.g., clinical settings usually are busy and waiting rooms are full), and struggling with feelings of stigma and discrimination (e.g., some people may not feel comfortable disclosing their identity, sexual behaviours and/or HIV risk to healthcare providers in public settings) (29,30). These barriers could halt the population with a high risk for HIV from accessing PrEP by avoiding hospital-based outpatient services (31).

Pharmacy-led initiatives comprise the provision of PrEP medication by pharmacies with or without a prescription from another healthcare provider (32). This model has some benefits, including reduced perceptions of stigmatisation and increased accessibility (e.g., PrEP users can access ARV medication easily with less time-consuming and without rigid schedules) (32). On the other hand, lack of medical oversight, limited counselling and education-based activities may create the risk of adverse health outcomes and misleading attitudes by the user of PrEP services (33). In the USA, one qualitative study that evaluated the users' satisfaction and pharmacists' acceptability of a PrEP access programme that used a pharmacy-led delivery model showed that 73% of the patients reported being very satisfied and only 2.9% of the pharmacists had experienced uncomfortable situations (34). Thus, this type of delivery model was associated with substantial rates of satisfaction and acceptance.

The European Center for Disease Prevention and Control (ECDC) defined nurse-led PrEP delivery as a type of service that allows nurses to provide ARV medication to the key population with an ongoing risk of HIV infection (35). This emerging access model allows nurses to play a central role in initial assessments, prescription, monitoring and supporting individuals using PrEP by task-sharing alongside doctors. This can boost adherence, particularly for those who may face barriers to accessing PrEP through traditional medical settings (36). Nurse-led PrEP can be implemented in non-clinic settings

such as sexually transmitted infection (STI) testing clinics, urban Public Health Units (PHU), Community-Based Organizations (CBO) and mobile HIV screening units, by nurses that can also facilitate linkage to care for those who test positive for HIV or other STI (37).

Community-based programmes have also been involved in the delivery of PrEP to individuals at high risk for HIV through fixed-location CBO and/or mobile screening units that are often based in hard-to-reach communities (38). The involvement of CBO in PrEP delivery has been shown to increase access to PrEP among key populations (e.g., MSM, sex workers and PWID) that rely on scarce support and low availability of sexual health services (39). CBO can effectively provide education and navigation services to individuals who may not otherwise have access to these services. It also works closely with healthcare providers to ensure that their users receive appropriate medical care, including monitoring for side effects of PrEP and regular STI testing (40). Other benefits include the development of trusting relationships between CBOs and their users which allows them to be more likely to seek out PrEP services as part of their HIV prevention strategy (41). However, some challenges associated with the community-based PrEP delivery model can arise as many CBOs rely on grant funding to access medical resources which can create long waiting periods and a shortage of well-trained health professionals (42). By leveraging the strengths of community organizations and working in partnership with healthcare providers, CBOs can play a critical role in reducing HIV incidence and increasing PrEP uptake and adherence (43).

Home-based delivery of PrEP has emerged as a potential solution to overcome some of the barriers to accessing PrEP in traditional healthcare settings (44). With online PrEP access, individuals can obtain ARV medication and clinical monitoring through telemedicine or web-based portals, often without needing to visit a healthcare provider physically. Home-based delivery models allow for an agile and discreet delivery to the user's dwelling, reducing time constraints, transportation, or logistical barriers (45). Further, online PrEP access can improve access to HIV prevention strategies by reducing barriers, particularly for individuals who may be uncomfortable accessing PrEP in healthcare settings due to feelings of discrimination or stigma. Telemedicine can also facilitate PrEP access for people who live in remote areas or areas with limited access to healthcare providers (46). Nonetheless, potential disadvantages such as inadequacy of in-person clinical supervision, monitoring and counselling, a lack of regulation and a curtailment regarding the quality of care can occur for some online providers. Despite these concerns, online PrEP access and home-based delivery models have shown promise in increasing access to PrEP and reducing barriers to care for underserved

populations. Thus, it is crucial to ensure that these delivery models are implemented with appropriate quality control and monitoring measures to guarantee safe and effective PrEP use (47,48).

4. PrEP in Portugal

The Portuguese National Health Service (PNHS) registered a total of 1803 new cases of HIV infection, between 2020 and 2021, where 52% of the new diagnoses corresponded to heterosexual individuals, and 27.6% were people over 50 years old. HIV infections among MSM accounted for 40% of the total newly detected HIV infections and among this population, 70% were individuals between the ages of 15 and 29 years old. The areas of Lisbon, Porto and Madeira Island were the urban areas with the highest HIV incidence rates (49).

In 2017, the PNHS published the guideline 025/2017 to provide access to PrEP to individuals at high risk for HIV infection (50). Soon after, in 2018, PNHS created an early access program to PrEP services through a hospital-based delivery model that was available to the Portuguese population (51). Individuals had to schedule an appointment in the Infectious Disease Department in order to access the PrEP program, which included different stages: triage, counselling appointments with healthcare professionals (i.e., doctors and nurses), clinical monitoring and patient follow-up (52). After one year of the PrEP early access program in Portugal, 1000 users, mostly adult MSM with a university degree, accessed PrEP (53). Mainly, this population was aware of the PrEP program due to visits to STI clinics and CBO (53).

In 2021, one study reported that before the introduction of PrEP by the PNHS people obtained their ARV medication without clinical prescription and supervision using sources such as the Internet (41%), offered in foreign countries (26%) or through friends and/or sexual partners (9%), respectively (54). After the introduction of the early access PrEP program in Portugal, the same study found that 70% of new PrEP users were using ARV through medical prescription in Portugal (54). Regarding knowledge related to PrEP in Portugal, one study found that knowledge remains low among people with a high risk for HIV infection (55).

At the end of the 2nd semester of 2021, the PNHS created a pilot project where PrEP was delivered in a community-based service through CBO alongside the main Hospitals in Porto and Lisbon. This initiative was implemented in Lisbon by *Grupo de Ativistas em Tratamento* (GAT) through *Hospital Garcia de Orta* (HGO) and in Porto by *Centro Comunitário +Abraço Porto* (CC+AP) through *Centro Hospitalar Universitário do Porto* (CHUP) and *Centro Hospitalar Universitário São João* (CHUSJ) (56-7).

5. Adherence, Retention and Satisfaction in PrEP programmes

Adherence to PrEP is critical for its effectiveness in preventing HIV transmission, as several studies have shown that high levels of adherence are associated with a >97% reduction in HIV incidence (58). Several authors reported that nurse-led PrEP in a community-based setting was associated with high levels of adherence among participants who reported feeling more comfortable discussing sexual health concerns compared to a physician in a clinical setting (59). However, further research is needed to explore the effectiveness of this model in addressing challenges regarding adherence among different settings and populations (60).

Achieving high levels of adherence in PrEP programmes can be challenging due to several factors (e.g., stigma, side effects, satisfaction and access barriers). Regular visits with users to manage side effects and offering PrEP in a variety of settings can improve adherence to PrEP programs (61).

Retention in PrEP programs is also crucial to ensure that individuals continue to receive the benefits of PrEP, including protection against HIV and access to HIV-related healthcare services. The success of PrEP programs is dependent on high levels of retention, which can be influenced by a variety of factors (62,63). PrEP programs must ensure that individuals have access to health education interventions to ensure that individuals understand the importance of adherence and continuous enrollment in the prevention of HIV programs (64,65). Partner support (e.g., partner counselling and regular STI screenings) can also be an important factor in improving retention by creating a supportive network for individuals taking PrEP (66).

In addition, a study conducted in Kenya found that individuals who received adherence counselling reported higher levels of satisfaction with their PrEP program (67). Satisfaction in PrEP programs plays an important role in the levels of retention and adherence to PrEP services (68). A study conducted in San Francisco found that individuals who reported high satisfaction with their enrolment in PrEP were more likely to have high levels of adherence (69). PrEP programs should focus on providing high-quality care, enhancing accessibility and convenience, providing comprehensive information and education, offering adherence support, and involving individuals in program planning and evaluation to improve overall PrEP user satisfaction (70).

Moreover, PrEP programs must be adequately staffed to ensure that users receive timely and appropriate care to minimize waiting times and provide flexible clinical hours to accommodate individuals' schedules (71). In 2022, one pilot programme that delivered PrEP using a community-based model in Cambodia showed a higher effectiveness compared to previous delivery models used in the country (1). This programme was

implemented by a local CBO working as an STI clinic alongside an urban PHU that provided ARV medication to key populations at the moment of their first PrEP appointment if the patients complied with established clinical safeguard guidelines (1). Another study conducted in Scotland found that individuals who accessed PrEP services with knowledge-based interventions and support engagement strategies reported equitable access which increased user satisfaction (72). Similarly, a study conducted in South Africa sought to evaluate the participants' satisfaction enrolled in a PrEP delivery service through a CBO and the results showed higher levels of satisfaction in contrast with participants who accessed PrEP services through a traditional clinic (73).

According to the ECDC, there is a deep need to create data-collecting tools to monitor and evaluate PrEP programs in their different delivery models. The ECDC guidance highlights the importance of involving key stakeholders, including affected communities, in the evaluation process (74). This involves engaging with individuals and organizations that are affected by PrEP programs, as well as involving them in the design and implementation of evaluation activities. Overall, the ECDC guidance provides a framework for evaluating PrEP programs that can be adapted to different settings and populations. By evaluating the impact of PrEP programs, it is possible to identify areas for improvement and optimize the delivery of PrEP for HIV prevention (75). Hence, we sought to study PrEP users using priority indicators (i.e., the waiting time to get access to PrEP services and subjective satisfaction) that are embedded and withheld in PrEP programs, which translates into individuals using continuously ARV medication for a period of three or more months (76).

Finally, individuals' experiences with PrEP programs can be enhanced by involving them in program planning and evaluation. Programs should solicit feedback from participants and use this feedback to improve services and enhance satisfaction. This can help individuals feel more invested in the program and increase their overall satisfaction with PrEP services (77).

OBJECTIVES

The present study aims to describe the accessibility and user satisfaction among individuals using PrEP for over three or more months in a novel pilot project which uses a community-based delivery model. This study encompasses the program implemented by Centro Comunitário +Abraço Porto (CC+AP) through Centro Hospitalar Universitário do Porto (CHUP). Thus, this study sought to answer the following research questions: "What was the level of satisfaction of PrEP beneficiaries and PrEP providers of a community-

based PrEP delivery model?" and "What was the mean waiting time between the date of PrEP request and the date of first PrEP appointment in a community-based PrEP delivery model from 2021 and 2023?".

To address the exploratory nature of this study we sought to describe PrEP users at three main levels: sociodemographic, clinical background and risk factors. Subsequently, we sought to identify and analyze (a) the level of satisfaction of PrEP users and health professionals, and (b) the waiting time between the date that the user requested to access the HIV prevention program and the date of the user's first PrEP appointment (i.e., the first stage of the community-based PrEP program).

METHODS

1. Study Design

This is a cross-sectional study concerning the first two years of the pilot project (2021 and 2022) that used a community-based model to offer PrEP in the *Centro Comunitário +Abraço do Porto* (CC+AP) to patients of the *Centro Hospitalar Universitário do Porto* (CHUP). Currently, CHUP offers PrEP in two models of distribution, hospital-based and community-based, both following the guideline 025/2017 (updated on 16th May 2018) in order to guarantee patient safety while on PrEP. The community-based PrEP model that targets individuals prone to HIV infection includes several interventions such as: (1) evaluation of the user's knowledge regarding PrEP, perceived risk of HIV infection and STD, (2) clinical monitoring, and (3) prevention measures through health education sessions and condoms distribution. At this present date, CHUP continues to collaborate with CC+AP to distribute PrEP in a community setting. The study received ethical approval from the Ethical Board of the CHUP.

2. Procedures

Between August and September of 2023, the researcher recruited participants who were enrolled in the pilot project of PrEP distribution using a community-based model of *Centro Hospitalar Universitário do Porto* (CHUP) by face-to-face invitations. This invitation to participate in the study included the provision of information regarding the study objectives, as well as briefing sessions to answer possible doubts and questions that the participants may have. Both the recruitment process, participants' invitation and interview process took place at *Centro Comunitário +Abraço Porto* (CC+AP), which is the place where PrEP users had their medical appointments. The administration of the questionnaire was completed privately and autonomously in one office of the CC+AP, in

order to ensure patient privacy. The questionnaires were available in Portuguese and English and took approximately 15 to 20 minutes to complete. The researcher provided additional explanations if the participants had information-related questions. There were no incentives or monetary compensation offered to participants for their participation.

3. Participants

In this study, participants were directly recruited at *Centro Comunitário +Abraço do Porto* (CC+AP) and *Centro Hospitalar Universitário do Porto* (CHUP). PrEP users and healthcare professionals enrolled on the pilot project of community-based, between 20th November 2021 and 30th March 2023, were invited to participate, regardless of their gender identity, sexual orientation and relational status.

We included PrEP users enrolled in the pilot project who meet the following inclusion criteria: (1) being cisgender males, (2) having a valid prescription provided by the physician, (3) having a pharmaceutical scheme of four or more doses of PrEP a week, and (4) returning to the medical appointment of the 3rd month. Exclusion criteria include: (1) two or more consecutive faults to the scheduled medical appointment. 98 PrEP users were invited to participate in the study, 95 consented to participate in this study. Questionnaires from 2 participants were excluded because they had two or more consecutive faults with the scheduled medical appointment.

Regarding the healthcare professionals, we include those who meet the following inclusion criteria: (1) working in CHUP or CC+AP, and (2) being directly enrolled on the PrEP pilot project of community-based. 16 healthcare professionals were invited to participate in the study, all participants consented to participate in this study.

4. Measures

a. Sociodemographic Questionnaire

The sociodemographic questionnaire was applied to the PrEP users' total sample and provided a sociodemographic characterization of the following variables: gender identity, age, nationality, city of residence, education categorized according to the ISCED-11, and occupation categorized according to the (ISCO-08) (78,79).

b. Clinical Questionnaire

The clinical questionnaire retrieved information from the participant's medical records that were collected during their first medical appointment in the PrEP program. Thus, it was possible to collect the following data about the participants' clinical history: relevant medical history, use of any regular medication, previous diagnosis of an STD,

and if affirmative which one (s), previous use of PrEP, and previous use of Post-Exposure Prophylaxis (PEP) and if affirmative the date when it was administered. Moreover, data regarding PrEP users' risk factors was collected such as their vaccination status for VHA, VHB and HPV, information regarding sex partners with whom they have unprotected sex, type of sexual practices and use of psychoactive substances and if affirmative what type of substance and form of consumption (Appendix D).

c. Perceived Satisfaction Questionnaire

The perceived satisfaction questionnaire aimed to collect data regarding the PrEP user's and the healthcare professionals' own satisfaction regarding the novel pilot project of PrEP provision in a community-based model. This questionnaire used a Likert scale that classified perceived satisfaction into 5 levels (0-5) and it was first used in a study that aimed to evaluate the satisfaction level of PrEP users and healthcare professionals in a PrEP service using a community-based model by The University of Nebraska (34). The main author gave permission to use the same framework in this present study. The perceived PrEP users' satisfaction questionnaire has questions regarding the level of their own satisfaction experience with the healthcare provided, information related to their own health and health education, perceived relation between healthcare professionals, the process of collecting biological samples, follow-up medical appointments, privacy concerns and the access to PrEP. The perceived satisfaction questionnaire applied to the healthcare professionals used questions regarding the level of satisfaction experienced with the comfort of the facilities, the type of healthcare provided, the working environment, colleagues' communication and interference with their work schedule (Appendix E).

d. Access to PrEP

To describe the access to PrEP in the pilot project of community-based we measured the period of waiting time, in days, that the PrEP beneficiaries experienced from the date they fulfilled their request to access the program to the date of their first medical appointment.

5. Analysis

The data obtained from the sociodemographic, clinical and perceived satisfaction questionnaires were presented using descriptive statistics of the total sample (mean, standard deviations and range) and frequency analysis (absolute and relative). Due to the small sample size, we decided to dichotomize the answers from the perceived satisfaction

questionnaire into low (1-3) and high (4-5). The analysis was conducted using the 29th version of the IBM SPSS Statistics.

6. Ethical Approval and Informed Consent

To legally implement the present study, permission was obtained by the President of the Administration Council of the *Centro Hospitalar Universitário do Porto* (CHUP) that received approval from the following departments: Ethical Board, Data Protection Officer, Clinic Investigation Service, Education and Investigation Department, Clinical Director of the Infectious Disease Department, Clinical Director of the Emergency Department and respective Nursing Chief Departments (Appendix B). Prior to the data collection, the objectives of the research project were explained to the participants as also information was provided regarding the anonymity, protection and confidentiality of the collected data. Further, recommendations from the Data Protection Officer were followed to safeguard the elaboration of the study. In the presence of the researcher, a Study Information Form and an Informed Consent Form (Appendix C) were distributed to the participants and a copy was provided to them. Subsequently, a set of assessment instruments were distributed to the participants. Hence, the questionnaires were returned directly to the researcher soon after being stored in a closet safeguarded by a lock that the key was only available to the researcher. We provided a point of contact (i.e., phone number and email) after informing the participants regarding the possibility of withdrawing from the study for a period of 6 months if they wished to.

RESULTS

1. PrEP users' characterisation

Participants ranged from 20 to 64 years old (M=31.1; SD= 8.28). Participants' nationality was distributed relatively equally between Brazilian (50.5%) and Portuguese (44.1%), other nationalities (5.4%) included participants from the USA, Netherlands, Italy and Spain. Most were living in the Porto district (89.2%), had completed a higher education course (64.4%) and were currently working (85.1%). The sociodemographic characteristics of the final sample of PrEP users are presented in Table 1.1.

Table 1

Sociodemographic characteristics of PrEP users (N=93)

Variable		All (N=93) N (%)
Nationality		
	Portuguese	41 (44.1)
	Brazilian	47 (50.5)
	Other	5 (5.4)
City of Residence		
	Porto	83 (89.2)
	Other	10 (10.8)
Education		
	Less than upper secondary education	4 (4.4)
	Upper secondary or post-secondary non-tertiary education	29 (31.2)
	Tertiary or higher education	60 (64.4)
Occupation		
	Operational and Technical	34 (36.6)
	Professional	31 (33.3)
	Supervisor and Manager	14 (15.2)
	Student	8 (8.6)
	Unemployed	6 (6.5)
Age (in years)		
	Mean (SD)	31.1 (8.28)
	Range	20-64

Regarding the clinical characteristics of PrEP users, most participants were healthy without any relevant medical history (73.1%), without known allergies (84.9%) and didn't take any regular medication (79.6%). A previous STD infection was reported by 47.3% of PrEP users. Regarding the previous use of PEP, 22.6% of participants said that they had used it and 81.7% of those used it in the past 3 years. Out of the total sample, 10.8% already had taken PrEP in the past. In regards to the participants' vaccination status, almost all had been vaccinated for Hepatitis B (92.5%), 18.33% for Hepatitis A and 9.7% for HPV. The clinical characteristics of the final sample of PrEP users are presented in Table 2.

Table 2
Clinical characteristics of PrEP users (N=93)

Variable	All (N=93) N (%)
Relevant Medical History:	
No	68 (73.1)
Yes	25 (26.9)
Relevant Medical conditions present (n=25):	
Anxiety	4 (16.0)
Asthma	4 (16.0)
Depression	5 (20.0)
Hemorrhoids	4 (16.0)
Others	8 (32.0)
Know allergies:	
No	79 (84.9)
Yes	14 (15.1)
Regular Medication:	
No	74 (79.6)
Yes	19 (20.4)
Previous Diagnosis of STD:	
No	49 (52.7)
Yes	44 (47.3)
STD Diagnosed (n=44):*	
Chlamydia	5 (5.4)
Gonorrhea	15 (16.1)
HPV	8 (8.6)
Syphilis	28 (30.1)
Others	3 (3.3)
Previous Use of PEP:	
No	72 (77.4)
Yes	21 (22.6)
Previous use of PEP in the past 3 years (n=21):	
No	4 (18.3)
Yes	17 (81.7)
Previous Use of PrEP:	
No	83 (89.2)
Yes	10 (10.8)
Vaccination:	
VHA	17 (18.3)
VHB	86 (92.5)
HPV	9 (9.7)

*.*Categories not mutually exclusive; PEP: Post-Exposure Prophylaxis; PrEP: Pre-Exposure Prophylaxis*

Relatively to the sexual behaviors of PrEP users, 7.5% reported not having and don't do unprotected/condomless sex (7.5%), and the remaining participants reported they have had condomless sex with: people they didn't know the results of STD screenings or if they had been performed (62.4%); people they know to be regularly screened for STDs and are HIV negative (25.8%); and people with whom they have confirmed to be living with HIV (4.3%). Still, regarding the individuals with whom PrEP users have condomless sex with: 45.2% of participants don't know if they have other partners: 33.5% reported their partners have other partners; 12.9% reported that don't have other partners (12.9%). Participants' sexual practices were receptive oral sex (96.8%), insertive oral sex (94.6%), receptive anal sex (86%), insertive anal sex (82.8%) and insertive vaginal sex (11.8%). The sexual behaviors of participants are presented in Table 3.

Table 3
Sexual Behaviors of PrEP users (N=93)

Variable	**All** (N=93) N (%)
The individuals with whom you have unprotected sex with:	
Not applicable because I don't have condomless sex	7 (7.5)
They have confirmed HIV infection	4 (4.3)
They are regularly screened for STDs and are HIV negative	24 (25.8)
I don't know the results of STD screenings or if they are performed	58 (62.4)
The individuals with whom you have had unprotected sex with:	
Not applicable because don't do condomless sex	6 (6.5)
Don't have other partners	12 (12.9)
Have other partners	33 (35.5)
Don't know if they have other partners	42 (45.2)
Regarding your sexual practices, you do:*	
Receptive Oral Sex	90 (96.8)
Insertive Oral Sex	88 (94.6)
Receptive Anal Sex	80 (86.0)
Insertive Anal Sex	77 (82.8)
Insertive Vaginal Sex	11 (11.8)

* *Categories not mutually exclusive; STD: Sexual Transmitted Diseases; HIV: Human Immunodeficiency Virus*

Regarding the use of drugs by PrEP users, most participants used drugs in a non-sexual context (43%), with alcohol (70.7%) and marijuana (46.1%) being the most used.

Around 27% used drugs in a sexual context and about 30% reported not using drugs. The characteristics of drug use of the participants are presented in Table 4.

Table 4
Use of Drugs of PrEP users (N=93)

Variable	All (N=93) N (%)
Use of Drugs:	
Don't use	28 (30.1)
Use mainly in non-sexual context	40 (43.0)
Use mainly in sexual context	25 (26.9)
Type of drugs:	
Alcohol	46 (70.7)
Marijuana	30 (46.1)
Cocaine	8 (12,3)
Ecstasy	4 (6.1)
LSD	3 (4.6)
Poppers	4 (6.1)
Mephedrone	4 (6.1)
MDMA	5 (7.7)
GHB	2 (3.1)
Modes of Drug Administration:	
Inhaled	14 (15.1)
Smoked	32 (34.4)
Ingested	52 (55.9)
Injected	1 (1.1)

**LSD- Lysergic acid diethylamide; MDMA- Methylenedioxymethamphetamine; GHB Gamma-hydroxybutyric acid*

Participants reported in general a high level of satisfaction in all subjects addressed. The satisfaction of PrEP users for each subject is presented in Table 5.

Table 5
Satisfaction of PrEP users, the proportion of high satisfaction (4-5)

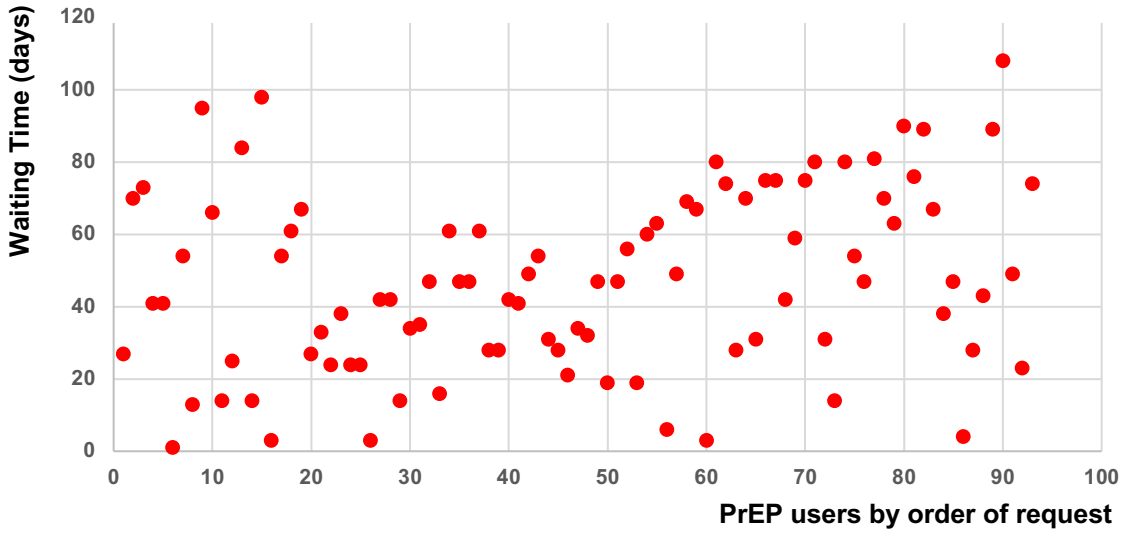
Variable	All (N=93) N (%)

Easy to access PrEP:	87 (93.5)
Waiting period to know the results of the exams performed:	88 (94.6)
Biologic products collection process:	92 (98.9)
Working relationship between the healthcare professionals:	93 (100)
Privacy of the information disclosure during appointments:	92 (98.9)
Information provided by the healthcare professionals about PrEP and/or health status:	93 (100)
Interested of healthcare professionals in participants health:	92 (98.9)
Comfort of the place where the appointments took place:	92 (98.9)

PrEP: Pre-Exposure Prophylaxis

The mean time of waiting to get access to their first medical appointment was 47.08 days (SD=25.171). The results of the number of days by the number of users enrolled on PrEP are presented in Figure 1.

Figure 1
PrEP users by order of request to get access to the PrEP program and their respective waiting time (N=93)



2. Health Professionals characterisation

Healthcare professionals included 6 nurses, 9 doctors and 1 psychologist. At the time of the study, most were working at both hospital-based and community-based PrEP services (68.8%) and their service time ranged from 4 to 324 months (M=88; SD=105.44). The professional characteristics of the healthcare professionals are presented in Table 6.

Table 6
Professional characteristics of healthcare professionals (N=16)

Variable	All (N=16) N (%)
Working setting	
Hospital-based only	1 (6.3)
Community-based only	4 (25.0)
Both	11 (68.8)
Service Time (in months)	
Mean (SD)	88 (105.44)
Range	4-324

Healthcare professionals reported a high level of satisfaction in all subjects addressed. The satisfaction of healthcare professionals is presented in Table 7.

Table 7
Satisfaction of healthcare professionals, the proportion of high satisfaction (4-5)

Variable	All (N=16) N (%)
Comfort of the patient-professional relationship:	15 (97.3)
Working relationship among professionals:	15 (97.3)
Comfort of the place where the appointments took place:	15 (97.3)
Comfort with the interventions performed:	14 (87.5)
Interference of PrEP provision with working sheduale:	11 (68.8)

DISCUSSION

The purpose of this study was to explore the satisfaction of PrEP users and healthcare professionals with the pilot project of a community-based PrEP program as well as to identify the waiting time date that the user requested to access the HIV prevention program and the date of the user's first PrEP appointment. Despite evidence demonstrating that users enrolled in PrEP programs that use a community-based model experience a higher level of perceived satisfaction, this information remained to be known in Portugal (19,53).

PrEP users' satisfaction towards the pilot project was high in all subjects addressed. The lowest levels of satisfaction were related to the ease of access to PrEP and the time that PrEP users had to wait to receive their exam results. This can be explained by the increasing waiting time they experienced to get to the first PrEP appointment. Nevertheless, for all subjects, inquired satisfaction was equal to or more than 93%. The working relationship between the healthcare professionals, the interest of healthcare professionals in PrEP users' health status, and the information provided by the healthcare professionals about PrEP and/or personal health obtained a 100% high level of satisfaction. These results are in line with other studies conducted with other populations using PrEP (34) and can be explained by to development of a trusting relationship between the community-based organizations and their users (39-41).

Regarding PrEP access, the mean time participants had to wait in order to have their first PrEP appointment was 7 weeks. In the first 2 years of the pilot project, the mean waiting time to get PrEP was lower than expected, as evidence shows that the most common waiting time is 12 weeks (80). On the other hand, the last period of the pilot project was above 12 weeks which may signal barriers in terms of PrEP access as other studies demonstrated (80).

Regarding the healthcare professionals' perceived satisfaction, the results showed a generalized high level of perceived satisfaction towards the pilot project in all subjects addressed. These results did not differ from other studies conducted with other populations of healthcare professionals working in PrEP services (34). In the matter of the interference with the healthcare professionals' working schedule, a higher proportion of participants reported a low level of satisfaction. can be explained due to the extra hours they may have spent in CC+AP which then adds to the time the healthcare professionals spend travelling from their workplace (mostly hospitals) to the CBO.

The results of this study not only show that the pilot project of community-based PrEP was well accepted by the beneficiaries but also by the healthcare professionals. High levels of satisfaction by the user play an important role in the adherence and acceptance to PrEP programs (69). The high levels of satisfaction can be explained due

to the pilot project having high-quality care with accessibility and convenience, comprehensive information and education sessions, as well as adherence support (70). Retention is also related to the satisfaction perceived by the user as higher levels translate into success of the program and higher retention of the user (68).

The inclusion of users' opinions in this study allowed us not only to analyze their satisfaction but also to understand if the pilot project was successful during the period of collected data. The inclusion of the waiting time that the beneficiaries experience from the request to their first appointment was also important to measure an indicator of accessibility and also to capture an increase in this indicator which can be an early warning of a potential barrier being posed to PrEP candidates.

To our knowledge, the present study is the first to explore and describe the satisfaction of PrEP users in Portugal, contributing to the current state of knowledge about the topic. However, several limitations of this study should be considered such as the small sample size, and the fact that the data was collected from a single health institution and a single CBO. Other limitations include the lack of diversity in terms of sociodemographic characteristics of the participants; different levels of satisfaction may be found in PrEP users from different backgrounds. social desirability may have happened which would contribute to the overestimation of satisfaction, but the fact that the questionnaire was self-administered would have minimized that effect. Finally, we have only evaluated satisfaction related to eight aspects of PrEP provision, as PrEP is scaled up other aspects may gain relevance and be evaluated.

Despite these limitations, we believe that the findings can help fill the gap in the literature regarding PrEP user satisfaction in Portugal. As well as it describes the pilot project of PrEP access using a community-based model from its first year of implementation (2021-2022). This can be valuable to healthcare professionals who work with PrEP users, public health institutions, decision-makers and governmental officers in order to have more information available and scientific knowledge when implementing policies or PrEP access programs for the Portuguese population.

Finally, we believe that future research is needed regarding PrEP users. This will enable the creation of tailored PrEP access programs for the Portuguese population and the development of interventions embedded into the program. We believe that investment in the optimization of PrEP access programs using a community-based model is needed as well as the full implementation of the program due to the high level of satisfaction experienced by the PrEP users in the pilot project. By investing in PrEP access programs with a community-based model as an HIV prevention, Portugal should be more capable of protecting the populations at high risk of HIV infection.

REFERENCES

1. UNAIDS. IN DANGER: UNAIDS Global AIDS Update 2022. Geneva: Joint United Nations Programme on HIV/ AIDS; 2022. Available at:unaids.org/en/resources/documents/2022/in-danger-global-aids-update
2. Piot P, et all. Defeating AIDS-advancing global health. UNAIDS–Lancet Commission. Lancet. 2015;386(9989):171-218. Available at: doi.org/10.1016/S0140-6736(15)60658-4
3. Iversen J, et al. COVID-19, HIV and key populations: cross-cutting issues and the need for population-specific responses. Jour Int AIDS Soc. 2020;23:25632. Available at: doi.org/10.1002/jia2.25632/full
4. World Health Organization. Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection: recommendations for a public health approach. Geneva: WHO. 2021. Available at:who.int/publications/i/item/9789241549684
5. World Health Organization. WHO Implementation tool for pre-exposure prophylaxis (PrEP) of HIV infection. Module 1: Clinical. Geneva: WHO. 2017. Available at: apps.who.int/iris/handle/10665/255889
6. World Health Organization. WHO implementation tool for pre-exposure prophylaxis (PrEP) of HIV infection. Module 13. Integrating STI services. Geneva: WHO; 2022. Available at: who.int/publications/i/item/9789240057425
7. Pilkington V, et al. How safe is TDF/FTC as PrEP? A systematic review and meta-analysis of the risk of adverse events in 13 randomised trials of PrEP. Jour Virus Erad. 2018;4:215-224. Available at:ncbi.nlm.nih.gov/pmc/articles/PMC6248833/
8. Baeten JM, Grant R. Use of antiretrovirals for HIV prevention: what do we know and what don't we know? Curr HIV/AIDS Rep. 2013;10(2):142-51. 2013. Available at:doi.org/ 10.1007/s11904-013-0157-9
9. McCormack S, et al. Pre-exposure prophylaxis to prevent the acquisition of HIV-1 infection (PROUD): effectiveness results from the pilot phase of a pragmatic open-label randomised trial. Lancet. 2016;387(10013):53-60. 2016. Available at:doi.org/10.1016/S0140-6736(15)00056-2
10. Ghou R, et al. Preexposure Prophylaxis for the Prevention of HIV. Updated Evidence Report and Systematic Review for the US Preventive Services Task Force. JAMA. 2023;330(8):746-63. 2023. Available at: doi.org/10.1001/jama.2023.9865
11. Baeten JM, et al. Antiretroviral prophylaxis for HIV prevention in heterosexual men and women. N Eng Jour Med. 2012;367(5):399-410. 2012. Available at: doi.org/10.1056/NEJMoa1108524
12. Choopanya K, et al. Antiretroviral prophylaxis for HIV infection in injecting drug users in Bangkok, Thailand (the Bangkok Tenofovir Study): a randomised, double-blind, placebo-

controlled phase 3 trial. Lancet. 2013;381(9883):2083-2090. 2013. Available at: doi.org/10.1016/S0140-6736(13)61127-7

13. Molina JM, et al. Efficacy, safety and effect on sexual behaviour of on-demand pre-exposure prophylaxis for HIV in men who have sex with men: an observational cohort study, Lancet. 2017;4(9):402-10. 2017. Available at:doi.org/10.1016/S2352-3018(17)30089-9
14. Iniesta C, et al. Awareness, knowledge, use, willingness to use and need of Pre-Exposure Prophylaxis (PrEP) during World Gay Pride 2017. PLoS ONE. 2018;13(10):0204738. 2018. Available at:doi.org/10.1371/journal.pone.0216376
15. ten Brink DC, et al. Cost-effectiveness and impact of preexposure prophylaxis to prevent HIV among men who have sex with men in Asia: A modelling study. PLoS ONE. 2022;17(5 5). Available at:doi.org/10.1371/journal.pone.0268240
16. Kornilova M, et al. Assessment of the availability of PrEP, the main barriers to implementing PrEP, and scaling up PrEP in the EECA region. Tallinn: Eurasian Coalition on Male Health. 2019. Available at:ecom.ngo/resource/files/2021/05/assessment-of-the-availability-of-prep-the-main-barriers-to-implementing-prep-and-scaling-up-prep-in-the-eeca-region.pdf
17. Mi Y, et al. Cost-Effectiveness of Pre-exposure Prophylaxis Among Men Who Have Sex With Men in China: A Systematic Review. Front. Public Health. 2022;10:809268.Available at:doi.org/10.3389/fpubh.2022.809268
18. Bonacci RA, et al. Toward Greater Pre-exposure Prophylaxis Equity: Increasing Provision and Uptake for Black and Hispanic/Latino Individuals in the U.S. American Jour Prev Med. 2021;61(5):60-72. Avaialble at: https://doi.org/10.1016/j.amepre.2021.05.027
19. Hayes R, et al. Estimating the 'PrEP Gap': how implementation and access to PrEP between countries in Europe and Central Asia in 2019. Eurosurveillance 24: 2019. Disponível em: doi.org/10.2807/1560-7917.ES.2019.24.41.1900598
20. Geldsetzer P, et al. Knowledge and attitudes about HIV pre-exposure prophylaxis: Evidence from in-depth interviews and focus group discussions with policy makers, healthcare providers, and end-users in Lesotho. PLOS Glob Pub Hea. 2022;2(10):e0000762. Available at:doi.org/10.1371/journal.pgph.0000762
21. Zhang C, et al. Understanding the Association Between PrEP Stigma and PrEP Cascade Moderated by the Intensity of HIV Testing. Resea Squa. 2022 Available at: doi.org/10.21203/rs.3.rs-1326890/v1
22. Liu Y, et al. Suboptimal Recent and Regular HIV Testing Among Black Men Who Have Sex With Men in the United States: Implications From a Meta-Analysis. Jour Acquired Immune Def Syndromes. 2019;81(2):125-33. Available at:doi.org/10.1097/qai.0000000000002013
23. Global PrEP Tracker. PrEP Watch. AVAC: Global Advocacy for HIV Prevention. 2022. Available at:data.prepwatch.org/

24. European Centre for Disease Prevention and Control. HIV testing in Europe and Central Asia. Monitoring implementation of the Dublin Declaration on Partnership to fight HIV/AIDS in Europe and Central Asia – 2021 progress report. Stockholm: ECDC; 2022. Available at: ecdc.europa.eu/sites/default/files/documents/DD_HIV_TestingBrief_May%202022-revised-final.pdf
25. Vanhamel J, et al.The current landscape of pre-exposure prophylaxis service delivery models for HIV prevention: A scoping review Pre-exposure prophylaxis (PrEP) for HIV prevention among men who have sex with men (MSM): A scoping review on PrEP service delivery and programming. BMC Hea Serv Resea. 2020;20(1). Available at:doi.org/10.1186/s12913-020-05568-w
26. Camlin C, et al. Understanding Demand for PrEP and Early Experiences of PrEP Use Among Young Adults in Rural Kenya and Uganda: A Qualitative Study. AIDS and Behavior. 2020;24(7):2149-62. doi.org/10.1007/s10461-020-02780-x
27. Marcus JL, et al. Preexposure Prophylaxis for HIV Prevention in a Large Integrated Health Care System: Adherence, Renal Safety, and Discontinuation. J Acquir Immune Defic Syndr. 2016;73(5):540-546. Available at:doi/10.1097/QAI.0000000000001129
28. Carter MR, et al. Knowledge, Attitudes, and PrEP Prescribing Practices of Health Care Providers in Philadelphia, PA. Jour Prim Car Com Hea. 2019; 10:1-6. Available at:doi.org/10.1177/2150132719878526
29. Edelman EJ, et al. Preferences for implementation of HIV pre-exposure prophylaxis (PrEP): Results from a survey of primary care providers. *Prev Med Rep*. 2020;*17*. Available at: doi.org/10.1016/j.pmedr.2019.101012
30. Babel RA, et al. Stigma, HIV Risk, and Access to HIV Prevention and Treatment Services Among Men Who have Sex with Men (MSM) in the United States: A Scoping Review. AIDS and Behavior. 2021;25:3574-604. Available at:doi.org/10.1007/s10461-021-03262-4
31. Hanshaw BD, et al. A Patient's Perspective on Privilege as a Prerequisite for PrEP. Jour Assoc of Nurses in AIDS Care: JANAC. 2021;32(4):418-22. Available at: doi.org/10.1097/jnc.0000000000000255
32. Rousseau E, et al. Novel Platforms for Biomedical HIV Prevention Delivery to Key Populations-Community Mobile Clinics, Peer-Supported, Pharmacy-Led PrEP Delivery, and the Use of Telemedicine. Curr HIV/AIDS Rep. 2021;18 (6):500-507). Available at: doi.org/10.1007/s11904-021-00578-7
33. Hopkins R, et al. Support and perceived barriers to implementing pre-exposure prophylaxis screening and dispensing in pharmacies: Examining concordance between pharmacy technicians and pharmacists. Jour Am Pharm Ass. 2021;61(1):115-120. Available at: doi.org/10.1016/j.japh.2020.10.005

34. Havens JP, et al. Acceptability and feasibility of a pharmacist-led human immunodeficiency virus pre-exposure prophylaxis program in the Midwestern United States. IDSA. Op For Infec Dise. 2019;6(10):365. 2019. Available at: doi.org/10.1093/ofid/ofz365
35. Owusu MO, et al. PrEP in the EU/EEA: PrEP service delivery, standards and monitoring Scientific Panel Meeting, Stockholm: ECDC. 2020;12-13. Available at:doi.org/10.13140/RG.2.2.14458.52160
36. O'byrne P. Nurse-led PrEP-RN clinic: A prospective cohort study exploring task-Shifting HIV prevention to public health nurses. *BMJ Op. 2021*;*11*(1). Available at: doi.org/10.1136/bmjopen-2020-040817
37. Schmidt HMA, et al. Scaling up access to HIV pre-exposure prophylaxis (PrEP): should nurses do the job? *Lancet HIV*. 2022;*9*(5):363-6.Available at:doi.org/10.1016/S2352-3018(22)00006-6
38. Reza-Paul S, et al. Community Inclusion in PrEP Demonstration Projects: Lessons for Scaling Up. Gat Op Rese. 2019;3:1504. Available at:doi.org/10.12688/gatesopenres.13042.1
39. Mudimu E, et al. Individual and community-level benefits of PrEP in western Kenya and South Africa: Implications for population prioritization of PrEP provision. PLoS ONE. 2020;15. Available at:doi.org/10.1371/journal.pone.0244761
40. Sullivan PS, et al. Getting pre-exposure prophylaxis (PrEP) to the people: Opportunities, challenges and emerging models of PrEP implementation. Sexual Health. 2018;15(6), 522-7. Available at:doi.org/10.1071/SH18103
41. Rousseau E, et al. A community-based mobile clinic model delivering PrEP for HIV prevention to adolescent girls and young women in Cape Town, South Africa. *BMC Hea Serv Rese*. 2021;*21*(1). Available at:doi.org/10.1186/s12913-021-06920-4
42. Hosek SG. HIV pre-exposure prophylaxis diffusion and implementation issues in nonclinical settings. Am Jou Prev Med. 2013;44(2). Available at:doi.org/10.1016/j.amepre.2012.09.032
43. Charreau I, et al. Community-based care in the ANRS-IPERGAY trial: the challenges of combination prevention. AIDS Edu Prev. 2019;31(3):259-72.
44. John SA, et al. Home-based pre-exposure prophylaxis (PrEP) services for gay and bisexual men: An opportunity to address barriers to PrEP uptake and persistence. PLoS ONE. 2017;12(12). Available at:doi.org/10.1371/journal.pone.0189794
45. Mayer KH, et al. Evolving Models and Ongoing Challenges for HIV Preexposure Prophylaxis Implementation in the United States. J Acquir Immune Defic Syndr. 2018;77(2):119-27. doi.org/10.1097/QAI.0000000000001579
46. Phan JM, et all. Telehealth Interventions for HIV in Low- and Middle-Income Countries. Cur HIV/AIDS Rep. 2022;19(6): 600-9. Available at:doi.org/10.1007/s11904-022-00630-0
47. Galvan FH, et al. Using social and sexual networking mobile applications to promote HIV testing, medical care and prevention services among Latino men who have sex with men in

Los Angeles County, California, USA. PLoS ONE- 2022;17. Available at:doi.org/10.1371/journal.pone.0268406

48. Kincaid RM, et al. Delivering HIV pre-exposure prophylaxis (PrEP) care online: A scoping review. 2021. Available at: doi.org/10.1101/2021.12.15.21267774
49. Ministério da Saúde/Direção-Geral da Saúde/Instituto Nacional de Saúde Doutor Ricardo Jorge. Infeção por VIH em Portugal-2022. Lisboa: DGS/INSA; 2022. Available at:insa.min-saude.pt/relatorio-infecao-por-vih-em-portugal-2022/
50. Ministério da Saúde; Direção-Geral da Saúde. Norma nº 025/2017 de 28/11/2017 atualizada a 16/05/2018. 2017. Available at: lisboa.pt/fileadmin/special_areas/lisboa_sem_sida/i024728.pdf
51. Diário da Républica Portuguesa. Decreto-Lei 131/2017. 2017. Available at: dre.pt/dre/detalhe/decreto-lei/131-2017-108280429
52. Circular Normativa Conjunta nº 02/2018 do INFARMED/ACSS/DGS/SPMS de 13 de Março de 2018, sobre o Programa de Acesso Precoce para a Profilaxia de Pré-Exposição da infeção por VIH-1 no Adulto. 2018. Available at: infarmed.pt/documents/15786/2398909/Programa+de+Acesso+Precoce+para+Profilaxia+de+Pr%C3%A9exposi%C3%A7%C3%A3o+da+infe%C3%A7%C3%A3o+por+VIH1+no+Aduto/68185369-bbc3-41c9-9f3a-4704881adbc8?version=1.0
53. Valdoleiros SR, et al. Implementação da consulta de PrEP: a experiência do Centro Hospitalar Universitário do Porto. 2018. Available at:eacs2019.newsfarma.pt/posters/311-implementa%C3%A7%C3%A3o-da-prep-em-portugal-dois-anos-de-experi%C3%AAncia-do-centro-hospitalar-universit%C3%A1rio-do-porto.html
54. Meireles P, et al. Provision of preexposure prophylaxis at the Portuguese national health service and uptake in the lisbon cohort of men who have sex with men. AIDS Behav. 2021;25:1975-83. 2021. Available at:doi.org/10.1007/s10461-020-03127-2
55. Simões D, et al. Knowledge and use of PEP and PrEP among key populations tested in community centers in Portugal. Front Pub Hea. 2021;9:673959. 2021. Available at: doi.org/10.3389/fpubh.2021.673959
56. Sistema Nacional de Saúde. Centro Hospitalar Universitário São João. CHUSJ. Portal Online. Notícias. 2021. Available at:portal-chsj.min-saude.pt/frontoffice/pages/16?news_id=1343
57. Agência de Notícias de Portugal. LUSA. 2022. Available at:lusa.pt/article/2022-02-18/35725099/projeto-piloto-junta-abra%C3%A7o-e-hospitais-do-porto-para-prevenir-infe%C3%A7%C3%A3o-vih-c-%C3%A1udio
58. Jourdain H, et al. Real-world effectiveness of pre-exposure prophylaxis in men at high risk of HIV infection in France: a nested case-control study. Lancet Pub Hea. 2022;7(6):529-536. Available at: doi.org/10.1016/S2468-2667(22)00106-2

59. Velloza J. Interventions to improve daily medication use among adolescents and young adults: What can we learn for youth pre-exposure prophylaxis services? AIDS. 2021;35(3):463-75. Available at: doi.org/10.1097/QAD.0000000000002777
60. Wanga V, et al. Uptake and impact of facility-based HIV self-testing on PrEP delivery: a pilot study among young women in Kisumu, Kenya. Jou Int AIDS Soc. 2020;23(8):25561. Available at: doi.org/10.1002/jia2.25561
61. Wang Y, et al. Evidence and implication of interventions across various socioecological levels to address pre-exposure prophylaxis uptake and adherence among men who have sex with men in the United States: a systematic review. AIDS Rese The. 2022;19(1). Available at:doi.org/10.1186/s12981-022-00456-1
62. Celum, C, et al. PrEP for HIV Prevention: Evidence, Global Scale-up, and Emerging Options. Cell Host Micro. 2020;27(4):502506. Available at: doi.org/10.1016/j.chom.2020.03.020
63. Eubanks A. Loss to Follow-Up from HIV Pre-Exposure Prophylaxis Care in Men Who Have Sex with Men in West Africa. Viruses. 2020;14(11):2380. Available at: doi.org/10.3390/v14112380
64. Eubanks A, et al. Socio-behavioral correlates of pre-exposure prophylaxis use and correct adherence in men who have sex with men in West Africa. *BMC Pub Hea*. 2022;*22*(1):1832. Available at: doi.org/10.1186/s12889-022-14211-8
65. Nieto O, et al. PrEP discontinuation among Latino/a and Black MSM and transgender women: A need for PrEP support services. *PLoS ONE*. 2020;*15*(11):024134. Available at:doi.org/10.1371/journal.pone.0241340
66. Zimmermann HM, et al. Motives for choosing, switching and stopping daily or event-driven pre-exposure prophylaxis-a qualitative analysis. Amsterdam PrEP Project team in the HIV Transmission Elimination AMsterdam Consortium (H-TEAM). *Jou Int AIDS Soc*. 2019; 22(10):25389. Available at:doi.org/10.1002/jia2.25389
67. Koss CA, et al. Uptake, engagement, and adherence to pre-exposure prophylaxis offered after population HIV testing in rural Kenya and Uganda: 72-week interim analysis of observational data from the SEARCH study. Lancet HIV. 2020;7(4):249-61. Available at: doi.org/10.1016/S2352-3018(19)30433-3
68. Siegler AJ, et al. A Review of HIV Pre-exposure Prophylaxis Streamlining Strategies. Current HIV/AIDS Reports. 2020;17(6):643-53. Available at:doi.org/10.1007/s11904-020-00528-9
69. Golub SA, et al. Preexposure prophylaxis and predicted condom use among high-risk men who have sex with men. J Acquir Imu Defic Syndr. 2010;54(5):548-55. Available at: doi.org/10.1097/QAI.0b013e3181e19a54

70. Bonacci R, et al. Toward Greater Pre-exposure Prophylaxis Equity: Increasing Provision and Uptake for Black and Hispanic/Latino Individuals in the U.S. Am Joul Prev Med. 2021;61(5):60-72. Available at: doi.org/10.1016/j.amepre.2021.05.027
71. Beckham SW, et al. Eliciting Preferences for HIV Prevention Technologies: A Systematic Review. Patient. 2021;14(2): 151-74. Available at:doi.org/10.1007/s40271-020-00486-9
72. Young I, et al. Strategies to support HIV literacy in the roll-out of pre-exposure prophylaxis in Scotland: Findings from qualitative research with clinical and community practitioners. BMJ Open. 2020;10(4):033859. Available at:doi.org/10.1136/bmjopen-2019-033849
73. Medina-Marino A, et al.The Community PrEP Study: a randomized control trial leveraging community-based platforms to improve access and adherence to pre-exposure prophylaxis to prevent HIV among adolescent girls and young women in South Africa-study protocol. Trials. 2021;22(1):489. Available at: doi.org/10.1186/s13063-021-05402-6
74. European Centre for Disease Prevention and Control. Monitoring HIV pre-exposure prophylaxis programmes in the EU/EEA. Stockholm: ECDC. 2022. Available at:ecdc.europa.eu/en/publications-data/monitoring-hiv-pre-exposure-prophylaxis-programmes-eueea
75. European Centre for Disease Prevention and Control. HIV pre-exposure prophylaxis in the EU/EEA and the UK: implementation, standards and monitoring. Operational guidance. Stockholm: ECDC. 2021. Available at:ecdc.europa.eu/sites/default/files/documents/HIV-Pre-Exposure-Prophylaxis-in-the-EU-EEA-UK.pdf
76. Parsons JT, et al. Uptake of HIV pre-exposure prophylaxis (PrEP) in a national cohort of gay and bisexual men in the United States: The Motivational PrEP Cascade. J Acquir Immune Defic Syndr. 2017;74(3):285–92. 2017. Available at: doi.org/10.1097/QAI.0000000000001251
77. Ramautarsing RA. Evaluation of a pre-exposure prophylaxis programme for men who have sex with men and transgender women in Thailand: learning through the HIV prevention cascade lens. Jou Int AIDS Soc. 2020;23(3):E25540. Available at:doi.org/10.1002/jia2.25540/full
78. UNITED NATIONS EDUCATION EDUCATIONAL, SCIENTIFIC, AND CULTURAL ORGANIZATION. International Standard Classification of Education (ISCED). Institute for Statistics. Geneve: UNESCO. 2015. Available at: circabc.europa.eu/sd/a/286ebac6-aa7c-4ada-a42b-ff2cf3a442bf/ISCED-F%202013%20-%20Detailed%20field%20descriptions.pdf
79. INTERNATIONAL LABOR OFFICE. International Standard of Occupation (ISCO). Geneve: ILO. 2012. Available at: ilo.org/public/english/bureau/stat/isco/docs/publication08.pdf
80. National AIDS Trust. Not PrEPared report: Barriers to accessing HIV prevention drugs in England.2022. Available: tht.org.uk/sites/default/files/2022-11/Not%20PrEPared%20report.pdf

APPENDIX A: Collaboration to Conduct the Study

abraço

ASSOCIAÇÃO DE APOIO A PESSOAS COM VIH/SIDA

PESSOA COLETIVA N.º 503 170 151 | REGISTO DE IPSS N.º 12/93 DO LIVRO DE INSTITUIÇÕES COM FINS DE SAÚDE

PEDIDO DE COLABORAÇÃO

O Centro Comunitário +ABRAÇO Porto, localizado na Rua da Torrinha 254D, defere com parecer positivo ao pedido de colaboração ao nível da cedência das instalações ao estudante André Gonçalves Cardoso do Mestrado em Saúde Pública para a realização da dissertação intitulada "Acesso à PrEP e satisfação entre utentes e profissionais de saúde: resultados de um projeto piloto de base comunitária em Portugal".

Porto, 13 de setembro de 2023

(Pedro Morais, Coordenador Centro Comunitário +Abraço)

Sede Largo José Luís Champalimaud n.º 4 A, 1600-110 Lisboa | Tel. 21 799 75 00
Norte Rua Vila Nova n.º 315, 4150-504 Porto | Tel. 22 375 66 55
Madeira Rua Bela de São Tiago n.º 17, 9060-420 Funchal | Tel. 29 123 67 00 | Fax. 29 123 58 00
Sul Rua Mormugão n.º 35, 2900-506 Setúbal | Tel. 26 522 88 82
E-mail geral@abraco.pt | Website www.abraco.pt

APPENDIX B: Permit to Conduct the Study

Exmo. Sr. Enf. André Gonçalves Cardoso
up202001169@med.up.pt

ASSUNTO: Trabalho Académico - Mestrado - **"AVALIAÇÃO DA CONSULTA DE PREP NO CHUP: COMPARAÇÃO DO ACESSO E NÍVEL DE SATISFAÇÃO DOS UTENTES E PROFISSIONAIS DA SAÚDE ENTRE OS MODELOS DE CONSULTA HOSPITALAR E DESCENTRALIZADA"** - N/ REF.ª 2023.048(039-DEFI/040-CE)

O Conselho de Administração do CHUdSA na reunião de 10 de agosto de 2023 emitiu a seguinte deliberação: "Autorizado" para a realização do estudo acima mencionado, após a implementação das recomendações elaboradas pela Encarregada da Proteção de Dados do Santo António, a realizar no Serviço Urgência desta Instituição e tendo como Investigador Principal o Enf. André Gonçalves Cardoso, estudante de Mestrado em Saúde Pública Ministrado pela Faculdade de Medicina e pelo ICBAS da Universidade do Porto.

O estudo foi previamente analisado pela Comissão de Ética do Santo António | ICBAS, pelo Serviço de Investigação Clínica, pela Direção do Departamento de Ensino e Formação do Santo António, pela Direção de Enfermagem e pelo Presidente do Conselho de Administração, tendo obtido parecer favorável.

Cumprimentos,

Assinado por: **Cláudia Alexandra Oliveira Santos**
Num. de Identificação: 11089889
Data: 2023.08.11 10:18:08+01'00'

CHAVE MÓVEL

CENTRO HOSPITALAR UNIVERSITÁRIO DE SANTO ANTÓNIO, E.P.E.
Largo Prof. Abel Salazar | 4099-001 Porto | Portugal | www.chusantoantonio.pt

COMISSÃO DE ÉTICA CHUdSA / ICBAS

APRECIAÇÃO E VOTAÇÃO DO PARECER

Deliberação	Data: 10 MAIO 2023	Órgão: Reunião Plenária
Título: "AVALIAÇÃO DA CONSULTA DE PREP NO CHUP: COMPARAÇÃO DO ACESSO E NÍVEL DE SATISFAÇÃO DOS UTENTES E PROFISSIONAIS DA SAÚDE ENTRE OS MODELOS DE CONSULTA HOSPITALAR E DESCENTRALIZADA"		Ref.ª: 2023.048(039-DEFI/040-CE)
Protocolo/Versão: **TA-Mestado**	Promotor: **o(a) próprio(a)**	Investigador / Local: **André Gonçalves Cardoso Serviço de SU - CHUdSA**

A Comissão de Ética CHUdSA / ICBAS, ao abrigo do disposto no Decreto-Lei n.º 80/2018, de 15 de Outubro, em reunião realizada nesta data, apreciou a fundamentação do relator sobre o pedido de parecer para a realização do **TA-Mestado** acima referenciado:

Ouvido o Relator, o processo foi votado pelos Membros da Comissão de Ética CHUdSA / ICBAS presentes:

Presidente: Prof. Doutor João Nuno Melo Beirão
Vice-Presidente: Dr.ª Paulina Aguiar

Dr. Aníbal Albuquerque, Prof.ª Doutora Carla Teixeira, Dr.ª Cármen de Carvalho, Dr.ª Fernanda Manuela Costa, Prof. Doutor José António Pinho, Prof.ª Doutora Margerida Araújo, Prof.ª Doutora Maria Strecht, Prof.ª Doutora Susana Magalhães, Mestre Virgínio Costa Ribeiro.

Resultado da votação:

PARECER FAVORÁVEL

A deliberação foi aprovada por unanimidade.

Pelo que se submete à consideração superior.

Data 10 MAIO 2023

O Presidente da Comissão de Ética CHUdSA / ICBAS

Prof. Doutor João Nuno Melo Beirão

APPENDIX C: Study Information Form and Informed Consent

AVALIAÇÃO DA CONSULTA DESCENTRALIZADA DE PREP NO CHUP: ACESSO E NÍVEL DE SATISFAÇÃO DOS UTENTES E PROFISSIONAIS DE SAÚDE

INFORMAÇÃO SOBRE A PARTICIPAÇÃO NO ESTUDO (AVALIAÇÃO DA CONSULTA DESCENTRALIZADA DE PREP NO CHUP: ACESSO E NÍVEL DE SATISFAÇÃO DOS UTENTES E PROFISSIONAIS DE SAÚDE)

*

Excelentíssimo(a) Senhor(a),

Vimos por este meio convidá-lo(a) a participar no estudo "AVALIAÇÃO DA CONSULTA DESCENTRALIZADA DE PREP NO CHUP: ACESSO E NÍVEL DE SATISFAÇÃO DOS UTENTES E PROFISSIONAIS DE SAÚDE". Para que possa tomar uma decisão informada quanto à sua participação no estudo e para que possa autorizar o tratamento dos seus dados pessoais, é importante que saiba quais objetivos, quais os riscos e inconvenientes decorrentes da sua participação no mesmo, as condições em que o mesmo é realizado e que implicações o mesmo tem para si.

É inteiramente livre de participar ou não no presente estudo. Pode, por isso, recusar-se a participar, sem que isso, de algum modo, afete o seu tratamento.

O objetivo do presente documento é transmitir-lhe, de forma transparente, todas as informações de que poderá necessitar, incluindo informação de como os seus dados pessoais, designadamente os de saúde, serão utilizados ou transmitidos a terceiros, caso opte por participar, para que possa tomar uma decisão informada relativamente à sua participação e relativamente ao tratamento dos seus dados pessoais. Agradecemos, por isso, que leia, atentamente, o presente documento, confrontando-o com as informações que lhe foram prestadas pelo investigador.

Antes de decidir se deseja ou não participar no estudo, pode colocar todas as perguntas que entender pertinentes, de forma a ficar com um conhecimento completo acerca do mesmo. No caso de não compreender alguma da informação constante deste documento ou de permanecer com dúvidas quanto à natureza do estudo e à sua participação no mesmo, deverá solicitar ao investigador responsável o esclarecimento ou a informação adicional que entenda necessário.

*

AVALIAÇÃO DA CONSULTA DESCENTRALIZADA DE PREP NO CHUP: ACESSO E NÍVEL DE SATISFAÇÃO DOS UTENTES E PROFISSIONAIS DE SAÚDE

IDENTIFICAÇÃO DO ESTUDO

NOME/TÍTULO: AVALIAÇÃO DA CONSULTA DESCENTRALIZADA DE PREP NO CHUP: ACESSO E NÍVEL DE SATISFAÇÃO DOS UTENTES E PROFISSIONAIS DE SAÚDE

NATUREZA E ALCANCE: Trata-se de estudo nacional, um centro, não interventivo, retrospetivo, transversal, com duração de 1 ano. Este estudo pretende recolher informação sobre o tempo de espera entre o pedido e acesso à primeira consulta de PrEP e o seu grau de satisfação ao nível dos cuidados de saúde prestados, educação para a saúde, interação com os profissionais, recolha de produtos biológicos, consultas de retenção, conforto do local, privacidade, prescrição e acesso à medicação. A proposta para a sua inclusão neste estudo e é feita com base no facto de já ter tido a sua primeira consulta médica, ter sido prescrita terapêutica, ter mantido uma posologia superior a quatro doses por semana e ter regressado à consulta do terceiro mês.

DURAÇÃO: 12 meses
PROMOTOR: Faculdade de Medicina da Universidade do Porto (225513600)
INVESTIGADOR PRINCIPAL: André Gonçalves Cardoso (913294380)
EQUIPA DE INVESTIGAÇÃO: André Gonçalves Cardoso (913294380)

*

1. O QUE É UM ESTUDO CLÍNICO?

Um «estudo clínico» é um estudo sistemático, conduzido no ser humano ou a partir de dados de saúde individuais, destinado a descobrir ou a verificar a distribuição ou o efeito de fatores de saúde, de estados ou resultados em saúde, de processos de saúde ou de doença, do desempenho e/ou segurança de intervenções ou serviços de saúde, através de aspetos biológicos, comportamentais, sociais ou organizacionais.
Os estudos clínicos são realizados no estrito respeito pelo princípio da dignidade da pessoa humana e dos seus direitos fundamentais.

2. QUAL É A FINALIDADE DESTE ESTUDO?

Este estudo tem como objetivo avaliar a implementação do projeto-piloto do CHUP com modelo de acesso à PrEP em regime descentralizado, ao nível do tempo de espera entre a manifestação de interesse do utente e o acesso à primeira consulta médica, assim como, ao nível da satisfação do participante e respetivos profissionais de saúde.

3. O QUE ACONTECERÁ SE DECIDIR PARTICIPAR NO ESTUDO?

Caso decida participar, os seus dados pessoais abaixo melhor identificados serão incluídos no Consentimento Informado, podendo ser analisados e estudados nos termos acima referidos, tendo em vista o princípio da minimização de dados e incluindo a pseudonimização.

4. QUE RISCOS PODE CORRER COM A PARTICIPAÇÃO NESTE ESTUDO?

Não são comtemplados riscos à participação neste estudo.

5. QUE POTENCIAIS BENEFÍCIOS PODERÃO RESULTAR DA SUA PARTICIPAÇÃO NESTE ESTUDO?

Não são comtemplados quaisquer benefícios, monetários ou outros, à participação neste estudo.

6. É OBRIGADO (A) A PARTICIPAR NESTE ESTUDO?

Não. A participação no presente estudo é livre e a decisão de não participar no mesmo não acarreta quaisquer consequências.

Por outro lado, caso opte por participar, poderá, mais tarde, e em qualquer momento, retirar o seu consentimento para a participação, sem ter de invocar qualquer justificação e sem que de tal opção advenham quaisquer consequências, bastando para o efeito o envio de uma comunicação escrita, para o endereço postal ou para o endereço eletrónico do investigador responsável.

7. QUE DADOS PESSOAIS SERÃO TRATADOS NO ÂMBITO DESTE ESTUDO?

O presente estudo integrará e permitirá tratar: (i) Dados de identificação, tais como o nome, género, data de nascimento; (ii) Dados de contacto, tais como email pessoal, (iii) Dados sociodemográficos, tais como, escolaridade, ocupação e nacionalidade, (iv) Dados de saúde, tais com antecedentes médicos, vacinação prévia, comportamentos sexuais praticados, uso de drogas e uso de PrEP ou PEP anteriormente.

8. COMO TERÃO ACESSO AOS SEUS DADOS PESSOAIS?

A equipa de investigação terá acesso aos seus dados pessoais através do processo clínico hospitalar sendo certo que este acesso é restrito à(s) finalidade(s) indicada(s) e aos membros que integram esta equipa.

9. PARA QUE FINALIDADES SERÃO TRATADOS OS SEUS DADOS PESSOAIS?

Os seus dados pessoais serão tratados apenas para as finalidades do presente estudo, tal como definido, detalhadamente, na resposta à questão 2, pelo que não está autorizada qualquer outra utilização para fins não identificados.

10. QUAL É O FUNDAMENTO LEGAL QUE PERMITE O TRATAMENTO DOS SEUS DADOS PESSOAIS?

O fundamento legal que permite o tratamento dos seus dados pessoais no âmbito do presente estudo é o seu consentimento explícito, nos termos e para os efeitos do disposto no artigo 9.º, n.º 2, alínea a) do Regulamento Geral sobre a Proteção de Dados (Regulamento (UE) 2016/679 do Parlamento Europeu e do Conselho de 27 de abril de 2016. Sem a sua autorização explícita, não poderemos tratar os seus dados pessoais para estas finalidades.

11. PODE RETIRAR O SEU CONSENTIMENTO PARA O TRATAMENTO DE DADOS PESSOAIS?

Sim, o consentimento prestado para efeitos de tratamento dos seus dados pessoais pode ser retirado a qualquer momento, sem que lhe possam ser opostas quaisquer objeções.

Se o consentimento para o tratamento de dados for retirado, todas as operações de tratamento de dados efetuadas até ao momento, com base nesse consentimento, consideram-se válidas. No entanto, o responsável pelo tratamento de dados deve interromper o tratamento de dados pessoais e, não existindo qualquer outro fundamento jurídico que justifique a conservação dos dados, deve proceder à sua eliminação. Deste modo, a retirada do consentimento para o tratamento dos seus dados pessoais implicará, necessariamente, a retirada do consentimento para a participação no estudo.

12. QUEM É (SÃO) O(S) RESPONSÁVEL(IS) PELO TRATAMENTO DOS SEUS DADOS?

O(s) Responsável(is) pelo tratamento dos seus dados pessoais incluídos no presente estudo é(são) a(s) seguinte(s) pessoa(s):

Nome: André Gonçalves Cardoso

Contactos: 913294380

Nome: Isabel Almeida
Contactos: diretura.su@chporto.min-saude.pt

Encarregado da Proteção de Dados:
Elisabete da Silva Castela
Contactos: dpo@chporto.min-saude.pt

13. OS SEUS DADOS PESSOAIS SERÃO PARTILHADOS?

NÃO

14. OS SEUS DADOS PESSOAIS SERÃO TRANSFERIDOS PARA UM PAÍS FORA DO ESPAÇO ECONÓMICO EUROPEU OU PARA UMA ORGANIZAÇÃO INTERNACIONAL?

NÃO

15. SERÃO ADOTADAS DECISÕES AUTOMATIZADAS, INCLUINDO A DEFINIÇÃO DE PERFIS?

NÃO

16. QUAIS SÃO OS SEUS DIREITOS RELATIVAMENTE AOS SEUS DADOS PESSOAIS?

Na qualidade de titular de dados pessoais, poderá, nos termos legais:

- Solicitar o acesso aos dados pessoais que lhe digam respeito;
- Solicitar a retificação dos seus dados pessoais;
- Solicitar a eliminação dos seus dados pessoais;
- Solicitar a limitação do tratamento dos seus dados pessoais;
- Solicitar a portabilidade dos seus dados pessoais;
- Opor-se ao tratamento dos seus dados pessoais ou à sujeição a decisões automatizadas;
- Retirar o seu consentimento;
- Apresentar reclamação à Comissão Nacional de Proteção de Dados.

17. COMO PODERÁ EXERCER OS SEUS DIREITOS RELATIVAMENTE AOS SEUS DADOS PESSOAIS?

Os direitos acima referidos poderão ser exercidos mediante pedido escrito dirigido ao responsável pelo tratamento de dados ou ao encarregado da proteção de dados, para os endereços eletrónicos ou para as moradas postais atrás divulgados.

18. QUAL O PRAZO DE CONSERVAÇÃO DOS SEUS DADOS?

5 ANOS

19. QUE MEDIDAS SERÃO TOMADAS PARA ASSEGURAR QUE OS SEUS DADOS UTLIZADOS NESTE ESTUDO MANTÊM-SE CONFIDENCIAIS?

- Não utilizar computadores pessoais. Quando tal não é possível, e o investigador armazena dados em computador próprio, certificar-se que os dados pessoais que têm o CHUPorto como responsável pelo tratamento são tratados com software licenciado pela instituição, e quando não é o caso, cabe ao investigador a responsabilidade de verificar a conformidade do software com os princípios de proteção de dados;
- Credenciais de acesso ao equipamento por utilizador (controlo de acesso lógico/autenticação): - senha de acesso com o mínimo de 12 caracteres, com a inclusão dos seguintes conjuntos de caracteres: letras minúsculas (a…z), letras maiúsculas (A…Z), números (0…9) e caracteres especiais (~ ! @ # $ % ^ & * ( ) _ + | ` - = \ { } [ ] : " ; ' < > ? , . /);
- Não replicar ficheiros de dados pessoais em diversos dispositivos (pens, portáteis, PCs), salvo na medida do estritamente necessário e do tempo estritamente necessário e/ou exclusivamente para garantir cópias de segurança;
- No caso de utilização de dispositivo móvel para armazenamento dos dados (risco elevado de perda e furto de dados) o mesmo deverá ser encriptado;
- Separação lógica entre a chave de encriptação e a b;
- Realização de cópias de segurança (backups);

20. QUEM PODE CONTACTAR PARA OBTER MAIS INFORMACÕES?

Irá receber uma cópia deste documento e da declaração de consentimento que prestar.

Caso tenha alguma questão acerca de qualquer aspeto relacionado com este estudo, poderá contactar o Investigador responsável ou qualquer elemento da equipa de investigação, através dos contactos facultados anteriormente.

Caso tenha alguma questão sobre o tratamento dos seus dados pessoais, poderá contactar o Encarregado da Proteção de Dados, através dos contactos facultados anteriormente.

Muito obrigado por se ter disponibilizado a ler este documento e por considerar fazer parte desta investigação.

_____ de _____ de _____

O Investigador responsável,

ANDRÉ GONÇALVES CARDOSO, MESTRANDO/ ENFERMEIRO, ISPUP,

913294380

ANEXO I

DECLARACÃO DE CONSENTIMENTO INFORMADO

DECLARAÇÃO DE CONSENTIMENTO PARA EFEITOS DE TRATAMENTO DE DADOS PESSOAIS

Eu, _____portador(a) do _____n.º _____, válido até __/__/_____, declaro que:

1. Li e compreendi a informação constante do documento de informação relativo ao estudo____ (daqui em diante designado apenas por estudo) de que esta declaração de consentimento constitui anexo. Fiquei devidamente esclarecido(a) sobre os objetivos, a natureza, o alcance, as consequências, os riscos e os benefícios da participação no estudo, bem como o direito de me retirar do mesmo a qualquer momento, sem quaisquer consequências. As dúvidas que coloquei foram esclarecidas.
2. Estou ciente de que a minha participação no estudo é voluntária e de que tenho total liberdade para retirar o meu consentimento para a minha participação em qualquer altura, sem que tenha de invocar qualquer justificação e sem que de tal opção advenham quaisquer consequências, designadamente sem que os cuidados de saúde que me são prestados ou os meus direitos sejam afetados.
3. Tomei conhecimento de que o André Gonçalves Cardoso (913294380) é o responsável pelo tratamento dos meus dados pessoais no âmbito do estudo "*Avaliação da consulta descentralizada de PrEP: acesso e nível de satisfação dos utentes e profissionais de saúde*" para as finalidades e nos termos acima referidos, e que tem como encarregado da proteção de dados *a* Elisabete da Silva Castela (dpo@chporto.min-saude.pt)
4. Fiquei conhecedor(a) das categorias dos meus dados pessoais a tratar, da sua origem, das finalidades do tratamento, do fundamento jurídico que autoriza o tratamento e do prazo de conservação.
5. Fui igualmente informado(a) de que, nos termos da legislação aplicável, poderei solicitar, a todo o tempo, o acesso aos dados pessoais que me digam respeito, bem como a sua retificação, eliminação ou a limitação do tratamento, a portabilidade dos dados, ou posso opor-me ao tratamento, mediante pedido escrito dirigido ao responsável pelo tratamento de dados ou ao encarregado da

proteção de dados, através dos seus endereços postais ou eletrónicos. Do mesmo modo, posso apresentar reclamação junto da Comissão Nacional de Proteção de Dados.

6. Fiquei ciente de que poderei retirar o meu consentimento para o tratamento dos meus dados pessoais em qualquer altura, o que não invalida, no entanto, o tratamento efetuado até essa data com base no consentimento previamente dado. Contudo, a retirada do consentimento para o tratamento dos meus dados pessoais implicará, necessariamente, a retirada do consentimento para a participação no estudo.
7. Confirmo que recebi todas as informações que me eram legalmente devidas, bem como todas aquelas que solicitei e tive oportunidade de esclarecer todas as minhas dúvidas e de solicitar os esclarecimentos que entendi adequados e pertinentes. Se no futuro me surgir alguma dúvida poderei sempre solicitar esclarecimentos ao investigador principal ou à equipa de investigação sobre os termos do presente estudo; ou solicitar ao responsável pelo tratamento de dados ou ao encarregado da proteção de dados o esclarecimento de quaisquer questões relacionadas com o tratamento dos meus dados pessoais.

Por ser a minha vontade, concordo em participar, de forma livre e esclarecida, no estudo

Sim ☐ Não ☐

Autorizo o acesso aos meus dados pessoais de saúde para efeitos do presente estudo.

Sim ☐ Não ☐

Consinto que os meus dados pessoais aqui identificados sejam tratados:

- No âmbito do estudo "*Avaliação da consulta descentralizada de PrEP: acesso e nível de satisfação dos utentes e profissionais de saúde*" para efeitos de dissertação de mestrado em Saúde Pública, nos termos definidos neste documento;

  Sim ☐ Não ☐

Autorizo a divulgação dos resultados obtidos no meio científico, desde que garantido o anonimato.

Sim ☐ Não ☐

AVALIAÇÃO DA CONSULTA DESCENTRALIZADA DE PREP NO CHUP: ACESSO E NÍVEL DE SATISFAÇÃO DOS UTENTES E PROFISSIONAIS DE SAÚDE

Entendi e foi-me explicado o documento «***INFORMAÇÃO SOBRE A PARTICIPAÇÃO NO ESTUDO "Avaliação da consulta descentralizada de PrEP: acesso e nível de satisfação dos utentes e profissionais de saúde***" a que o consentimento está anexo, e recebi uma cópia de toda a documentação, composta por cinco páginas.

_____ de _____ de _____

O Participante,

_____

APPENDIX D: Sociodemographic Questionnaire

Anexo 1 – Questionário de boas-vindas

Olá! Se estás a ler este questionário, é porque manifestaste interesse na possibilidade de realizar profilaxia pré-exposição (PrEP) para prevenção da infeção pelo vírus de imunodeficiência humana (VIH).

A PrEP é um tratamento altamente eficaz na prevenção da infeção pelo VIH, que pode estar indicado nalgumas pessoas com maior risco de infeção. Como a maioria dos medicamentos, os que compõem a PrEP são mais eficazes quando tomados de acordo com a prescrição (respeitando os intervalos entre tomas, não omitindo tomas previstas, etc.) e não são isentos de efeitos laterais e contraindicações. Felizmente, os efeitos laterais são pouco ou nada notados pela maioria das pessoas que tomam PrEP e, para garantir a tua segurança, vamos fazer uma avaliação médica regularmente. Este questionário faz parte dessa avaliação.

A análise desta informação também é relevante para avaliar e melhorar a distribuição de PrEP de base comunitária. Se quiseres contribuir com os teus dados, podes manifestar essa intenção no final do questionário.

Toda a informação aqui disponibilizada é **confidencial** e para consulta exclusivamente pelos profissionais de saúde diretamente envolvidos nos teus cuidados.

1. Identificação:
   Género (masculino, feminino, outro): _____
   Pronomes (ele, ela, elu, outro): _____
   Nome: _____
2. Idade: _____ 3. Nacionalidade: _____
4. Cidade de residência: _____
5. Contacto preferencial (telemóvel e/ou email): _____
6. Habilitações literárias (grau académico e área de especialização): _____
   _____
7. Profissão: _____
8. Antecedentes médicos de relevo? _____
   _____
9. Diagnóstico prévio de infeção sexualmente transmissível (VIH, hepatite A/B/C, sífilis, gonorreia, clamídia, herpes, outra) _____
   _____
10. Utilização prévia de profilaxia pós-exposição do VIH (sim/não, se sim, quando): _____
    _____
11. Medicação habitual: _____
    _____
12. Alergias conhecidas: _____
13. Vacinação para hepatite A, hepatite B e/ou vírus do papiloma humano (HPV)?

Por favor, seleciona as afirmações que mais se assemelham à tua realidade:

14. Quanto às pessoas com quem tens relações sexuais sem preservativo:

☐ Têm infeção confirmada pelo VIH

☐ Fazem rastreio regular de infeções sexualmente transmissíveis e **não** têm infeção pelo VIH

☐ Não sei os seus resultados de rastreios de infeções sexualmente transmissíveis ou se os realizam

☐ Não aplicável, porque não tenho relações sexuais sem preservativo

15. A(s) pessoa(s) com quem tens relações sexuais sem preservativo:

☐ Não têm outros parceiros

☐ Têm outros parceiros

☐ Não sabes se têm outros parceiros

☐ Não aplicável, porque não tenho relações sexuais sem preservativo

16. Relativamente às tuas práticas sexuais, realizas:

☐ Sexo oral recetivo

☐ Sexo oral insertivo

☐ Sexo anal recetivo

☐ Sexo anal insertivo

☐ Sexo vaginal recetivo

☐ Sexo vaginal insertivo

Outra: _____

17. Relativamente a substâncias psicoativas (álcool, canabinoides, anfetaminas, etc.):

☐ Não utilizas

☐ Utilizas em contexto não sexual

☐ Utilizas em contexto sexual

☐ Inaladas

☐ Fumadas

☐ Ingeridas

☐ Injetadas

☐ Por via vaginal

☐ Por via retal

Outra: _____

Quais?

_____

_____

Eu, _____

dou / não dou (riscar o que não interessa) consentimento para que os dados constantes deste questionário sejam analisados (após anonimização) pelos profissionais do CHUPorto e da Abraço envolvidos diretamente nos meus cuidados para fins de investigação.

Este consentimento pode ser retirado a qualquer momento. Basta informares um dos profissionais. Obrigada!

APPENDIX E: Perceived Satisfaction Questionnaire

Como classificas o teu nível de satisfação com os seguintes aspetos mencionados?

(assinala com um X a resposta que corresponde à tua experiência)

1. **A facilidade em aceder à PrEP:**

☐ muito insatisfeito ☐ insatisfeito ☐ neutro ☐ satisfeito ☐ muito satisfeito

2. **Tempo de espera pelo resultado dos exames realizados:**

☐ muito insatisfeito ☐ insatisfeito ☐ neutro ☐ satisfeito ☐ muito satisfeito

3. **O processo de colheita dos produtos biológicos (sangue e urina, zaragatoa):**

☐ muito insatisfeito ☐ insatisfeito ☐ neutro ☐ satisfeito ☐ muito satisfeito

4. **A relação de trabalho entre os vários profissionais de saúde (médico e enfermeiro):**

☐ muito insatisfeito ☐ insatisfeito ☐ neutro ☐ satisfeito ☐ muito satisfeito

5. **A privacidade das informações partilhada nas consultas:**

☐ muito insatisfeito ☐ insatisfeito ☐ neutro ☐ satisfeito ☐ muito satisfeito

6. **As informações que me foram fornecidas pelos/as profissionais de saúde acerca da medicação e/ou estado de saúde:**

☐ muito insatisfeito ☐ insatisfeito ☐ neutro ☐ satisfeito ☐ muito satisfeito

7. **O interesse dos profissionais de saúde no teu estado de saúde:**

☐ muito insatisfeito ☐ insatisfeito ☐ neutro ☐ satisfeito ☐ muito satisfeito

8. **O conforto do espaço onde as consultas foram realizadas:**

☐ muito insatisfeito ☐ insatisfeito ☐ neutro ☐ satisfeito ☐ muito satisfeito

Categoria profissional:

Tempo de serviço (anos) em infeciologia:

Prestação de Serviço em:

- consulta de PrEP hospitalar:
- consulta de PrEP descentralizada:
- ambas:

Como classifica o seu nível de satisfação com os seguintes aspetos mencionados?

(assinala com um X a resposta que corresponde à tua experiência)

1. O conforto da relação utente/profissional:

☐ muito insatisfeito ☐ insatisfeito ☐ neutro ☐ satisfeito ☐ muito satisfeito

2. O conforto da relação profissional/profissional:

☐ muito insatisfeito ☐ insatisfeito ☐ neutro ☐ satisfeito ☐ muito satisfeito

3. O conforto do espaço onde as consultas foram realizadas:

☐ muito insatisfeito ☐ insatisfeito ☐ neutro ☐ satisfeito ☐ muito satisfeito

4. O conforto na prestação dos cuidados de saúde:

☐ muito insatisfeito ☐ insatisfeito ☐ neutro ☐ satisfeito ☐ muito satisfeito

5. A interferência com o seu horário de trabalho:

☐ muito insatisfeito ☐ insatisfeito ☐ neutro ☐ satisfeito ☐ muito satisfeito

SEDE ADMINISTRATIVA

FACULDADE DE **MEDICINA**

INSTITUTO DE **CIÊNCIAS BIOMÉDICAS ABEL SALAZAR**