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## **Factors associated with sexual quality of life among HIV positive men**

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## **Factors associated with sexual quality of life among HIV positive men**

1 **Abstract**

2 **Introduction:** There is a high prevalence of sexual difficulties among people living with HIV  
3 and AIDS (PLWHA), which makes it crucial to examine different dimensions of sexual quality  
4 of life (SQoL). We aimed to establish the prevalence of sexual difficulties and determine factors  
5 associated with SQoL among HIV-positive men.

6 **Methods:** Between December 2017 and December 2018, this cross-sectional study included  
7 107 heterosexual men and 474 men who have sex with men (MSM). The participants were  
8 recruited from HIV centers or via the internet in five countries (Australia, Brazil, Canada,  
9 France, and the USA). The questions related to participants' physical and mental health status,  
10 as well as HIV parameters, were self-reported. We assessed the prevalence of three common  
11 sexual difficulties (erectile difficulty, ejaculation difficulty, low sexual desire) among the  
12 participants.

13 SQoL was assessed using the newly developed PROQOL-SexLife questionnaire, comprising  
14 six dimensions (score range: 0-100) for MSM and five dimensions for heterosexual men:  
15 positive sexual perception (POP), sexual difficulties (DIS), stigma/fear (STI), Sexual practices  
16 with partner (PAR), soft sexual practices (SOF), and drug consumption (DRG). A linear mixed  
17 model was used to explore the relationship between explanatory variables (sociodemographic  
18 variables, mental health-related variables, HIV biological-related factors) and scores measured  
19 by PROQOL-SexLife dimensions, by treating countries as random effects.

20 **Results:** A majority of the participants (54.6%) indicated experiencing low sexual desire, with  
21 MSM demonstrating a notably higher susceptibility compared to heterosexual men. Amongst  
22 MSM, SQoL in the POP dimension was associated with living with a partner and healthcare  
23 satisfaction, while the STI dimension was associated with frequent condom usage,  
24 cardiovascular complications, and being single. Viagra use, anti-cholesterol treatment, and  
25 living with a partner as a mode of life were significant in the DIS dimension. Amongst  
26 heterosexual men, employment status and African origin were found to be associated with  
27 SQoL scores in the POP dimension, and alcohol consumption in the STI. The mental health-  
28 related variables, such as clinical depression, depressive symptom, and preoccupation with the  
29 risk of HIV transmission during sexual practices, were negatively associated with a better  
30 outcome of SQoL in the three dimensions (POP, DIS, STI) among MSM and in two dimensions  
31 among heterosexual men (POP and DIS).

32 **Conclusion:** The significance of psychological and stress-related factors, alongside the lack of  
33 correlation between HIV-related biological parameters (CD4 count, viral load), and SQoL,  
34 highlights the necessity of taking non-clinical determinants into account when assessing SQoL  
35 outcomes. This includes factors like the perceived quality of healthcare and the confidence in  
36 understanding transmission risks, underscoring the necessity for tailored initiatives within the  
37 HIV context.

38

39 **Introduction**

40 Sexual health, an integral component of overall health related quality of life, encompasses the  
41 possibility of having pleasurable and safe sexual experiences or the enjoyment of sexual activity  
42 of one's choice, without causing or suffering physical or mental harm [1]. However, sexual  
43 health among people living with HIV (PLHIV) is confronted with challenges, which may  
44 contribute, among other things, to constrained intimacy but also sexual function difficulties [2].  
45 Among men living with HIV, it has been reported a high prevalence of sexual function  
46 difficulties, especially erectile difficulties, which are more common (ranges from 9 to 74%)  
47 [3,4] and low sexual desire (ranges from 24 to 33%) [5,6]. These occurrences surpass not only  
48 those observed in individuals without HIV but also exceed rates found within cancer survivor  
49 groups [7]. The nature of the association between HIV and the presence of sexual difficulties,  
50 as well as the underlying reasons are subject to debate. Studies have identified multiple  
51 contributors of sexual function difficulties such as psychological (e.g. depression,  
52 psychological distress) [8] and relational factors [9] as well as HIV related stigma [10,11]. The  
53 role of antiretroviral therapy (ART) in the onset of sexual function difficulties remains  
54 controversial [12]. Troubles with sexual function have also been discovered to correlate with  
55 heightened engagement in sexual risk behaviors and reduced adherence to antiretroviral therapy  
56 (ART) [13]. These difficulties may influence sexual quality of life (SQoL).

57 In fact, SQoL refers to an individual's overall well-being and satisfaction in their sexual  
58 experiences and relationships [14]. It encompasses various aspects of a person's sexual health,  
59 including physical, emotional, and relational factors.

60 Taking a comprehensive approach to sexual health involves moving beyond a narrow focus on  
61 the mere presence of sexual difficulties as the endpoint of studies. Instead, it emphasizes  
62 studying sexual health in relation to its impact on health-related quality of life among PLHIV.  
63 To do so it is important to assess a broad range of sexual dimensions specifically related to  
64 living with HIV, representing a measure of sexual quality of life and hence relevant to sexual  
65 health. It is also vital to examine contributors of sexual quality of life dimensions, which would  
66 be useful in clinical settings where individuals with poorer sexual quality of life are offered  
67 treatment. Assessing and addressing sexual quality of life is essential in healthcare and  
68 relationship counseling to enhance individuals' overall well-being and satisfaction in their  
69 sexual lives.

70 In this study, our aim was to establish the prevalence of sexual difficulties and identify the  
71 factors associated with Sexual Quality of Life (SQoL) among HIV-positive men. The  
72 assessment of sexual quality of life dimensions was conducted using the PROQOL-Sexlife  
73 questionnaire [14]. The questionnaire provides a 6-factor structure with 22 items for self-  
74 identified men who have sex with men (MSM) and a 5-factor structure with 23 items for self-  
75 identified heterosexual men, as per the factor structures.

76 The PROQOL-Sexlife self-report questionnaire measures the following sexual quality of life  
77 dimensions: Positive sexual perception (POP), Sexual difficulties (DIS), Stigma and fear (STI),  
78 Sexual practices with partner (PAR), Soft sexual practices, refer to intimate activities including  
79 sexual dreams and masturbation, (SOF) and Drug consumption (DRG). While the drug  
80 consumption (DRG) are addressed separately among MSM, for heterosexual men, they are  
81 compiled in one unique dimension (SOF/DRG).

## 82 **Methods**

### 83 *Study participants, recruitment, and procedures:*

84 This cross sectional was carried out across multiple centers and countries among PLWHA from  
85 December 2017 to December 2018. The study spanned France, Australia, Brazil, the USA, and  
86 Canada. These countries were selected to account for differences in the health care systems,  
87 cultures and languages, treatment availability and to augment study feasibility. A convenience  
88 sample was performed among male patients attending the HIV clinic. Patients who visited the  
89 HIV clinics were invited participate to this study in Canada and Brazil, while in USA, invitation  
90 was exclusively by e-mail. In France and Australia the potential participants were invited both  
91 at the HIV clinics and by e-mail. Eligibility criteria included (1) male patient living with HIV  
92 followed-up in one of the study HIV clinics, and (2) being fluent in the official language  
93 (English, French or Portuguese). Non-inclusion criteria were (1) hospitalization and (2) having  
94 an acute infectious disease at the time of the study. Written informed consent was obtained  
95 prior to inclusion to the study. Participants' personal data were anonymized, and a 4-digit  
96 number was assigned to each participant in the clinical report form, this number was later used  
97 for gathering the missing data.

98

### 99 *Sexual quality of life (SQoL)*

100 SQoL was measured using the PRQOL-Sexlife self-report questionnaire that assesses the six  
101 and five SQoL dimensions respectively for MSM and heterosexual men using a 5-point Likert

102 scale from “never” to “all the times”. Some items in the POP dimension used a 5-point intensity  
103 scale (“very good” to “very bad”). Dimension scores transformed linearly, according to a  
104 standardized algorithm ranging from a score of 0 to 100. In the POP, DRG, STI and DIS  
105 dimensions, lower scores indicate better SQoL and higher scores are equal to poorer SQoL.  
106 Table 1 presents one question for each dimension of the PROQOL-SexLife questionnaire, with  
107 the purpose of fostering comprehension of the questionnaire.

#### 108 *Sexual function difficulties*

109 The prevalence of sexual function was evaluated through questions about the occurrence of  
110 specific difficulties such as erectile problems, ejaculatory issues, and low sexual desire over the  
111 previous four weeks. The responses were recorded on a 3-point Likert scale (not frequently,  
112 sometimes, and frequently).

#### 113 *Explanatory factors questionnaire*

114 Based on previous HIV-related research and discussion with experts at the medical centers,  
115 explanatory factors of interest were grouped into sociodemographic, clinical HIV-related,  
116 comorbidities, mental health, and health-related behaviors domains. The questionnaire was  
117 filled out at the same time as the PROQOL-Sexlife questionnaire.

118 *The sociodemographic domain* encompassed factors such as age, education, ethnicity,  
119 employment, marital status, living mode and sexual orientation.

120 *The clinical HIV-related domain:* it included the duration of HIV treatment (year), HIV  
121 treatment regimen (only for three country: Brazil, France and Canada), biological markers  
122 (CD4 count, viral load). The HIV-related parameters were reported by the patients and in clinic  
123 settings the participants were helped by a research assistant providing them the data from  
124 medical records.

125 *Comorbidities domain:* The participants were inquired about the presence of certain  
126 comorbidities, responding with “yes/no”, these comorbidities included the coinfection with  
127 viral hepatitis (HCV or HBV), diabetes, and cardiovascular complications.

128 *Mental health domain:* it was assessed by questions about, psychiatric disorders, clinical  
129 depression, presence of depressive symptoms, using anti-depressant/psychiatric treatment  
130 during the last four weeks, responding with “yes/no”. Depressive symptoms were measured  
131 by two variables: frequently feeling sad/hopeless, and lack of interest for life. Besides,  
132 participants were asked the extent of concern regarding HIV transmission during sexual

133 activities, using a 3-point Likert scale that ranged from "not preoccupied" to "very  
134 preoccupied."

135 *Health-related behaviors domain:* To comprehend the risky behaviors, we incorporated the  
136 variables of psychoactive substance use, responding with "yes/no", such as alcohol (defined as  
137 consumption of more than 2 glasses of alcoholic drinks per day or not), tobacco (defined as  
138 smoking at least one cigarette per day or not), Cocaine and Cialis/Viagra .

139 In the same theme, we were also interested in assessing the level of awareness regarding the  
140 risk of HIV transmission and the practice of condom use using a 3-point Likert scale (not  
141 frequently, sometimes, frequently). For this, we used two questions of SRQ-12 (questionnaire  
142 of understanding the risk of HIV transmission) to measure the knowledge of the risk of  
143 transmission of HIV among people living with HIV. In which, participants were asked to  
144 indicate the option that most accurately described their level of understanding of the risks  
145 associated with HIV transmission during sexual activity, using a 3-point Likert scale (aware,  
146 moderately aware, not aware).

147 Interaction with healthcare was explored with satisfaction with health care support, and  
148 communication with health providers about sexuality using a 3-point Likert scale.

#### 149 *Data analysis*

150 R was used for data management and statistical analysis (R Core Team 2013). Through  
151 descriptive analysis, the two populations of heterosexual men and MSM were compared in  
152 relation to their demographic and medical characteristics using t-student tests and chi-square  
153 test.

154 Variance inflation factors (VIF) were used to analyze the existence of potential collinearity  
155 problems ( $VIF \geq 5$ ) among the independent variables. Missing data of explanatory variables  
156 were handled with K-Nearest Neighbor method ( $K=5$ ) (package: caret). Variable selection for  
157 the final linear model was done by stepwise AIC method (package: MASS). Stepwise validation  
158 of was done using the bootstrap method (package: caret). Finally, we added country as a random  
159 effect to the retained variables to perform a linear mixed effects model to explore the  
160 relationship between the score of each dimension and explanatory variables (package: lme4)  
161 separately for MSM and heterosexual men. Variance explained by the entire model, including  
162 both fixed and random effects was calculated using Pseudo-R-squared (package: MuMIn).  
163 Participants who reported not being in a sexual relationship during the last four weeks were not  
164 included in the regression model of the PAR and DRG/SOF dimensions. As the data regarding

165 the type of HIV treatment was accessible only for participants in Brazil, France and Canada,  
166 therefore we didn't enter this factor as a variable in the model.

167 Of the 615 recruited participants, 13 were excluded based on incomplete socio demographics  
168 and 21 were removed due to a HIV negative status. After these exclusions 581 men (Australia:  
169 109; Brazil: 139; Canada: 79, France: 190; USA: 64) remained and were included in the  
170 analyses.

## 171 **Ethical consideration**

172 Potential participants were informed orally about the study, or received written information  
173 about the study, voluntariness was underscored, before consent was obtained. The project was  
174 approved by ethics committee in each of participating countries: respecting legal authorities in  
175 France, Australia, USA, Brazil, and Canada. The project was registered on clinicalTrials.gov  
176 (NCT03468673).

## 177 **Results**

### 178 *Participants' characteristics related to the explanatory factors*

179 Among 581 participants, 81.6% were MSM, the mean age (SD) was 49 ( $\pm$  11.8) years, 76.8%  
180 identified themselves as Caucasians, 55.6% were employed and 61% were single. Almost half  
181 of the participants attained university level (49.1%).

### 182 *Clinical-related variables*

183 Almost two-thirds (63.4%) of the participants reported a current CD4 count higher than 500  
184 cells/mm<sup>3</sup>, and the majority (95.2%) reported an undetectable HIV viral load. Data on HIV  
185 treatment were available in only three countries (Brazil, France and Canada) which shows that  
186 the antiretroviral most used was Integrase inhibitors (INI) (36.8%).

187 The prevalence of comorbidities, including cardiovascular diseases, HCV coinfection, HBV  
188 coinfection, diabetes, psychiatric disorders, and clinical depression, varied from 28% to 7%.  
189 The occurrence of clinical depression was noted at a significant rate of 28%.

190 In relation to the presence of depressive symptoms, slightly fewer than half of the participants  
191 noted a sense of low interest of life, while a significant number of respondents conveyed  
192 experiencing frequent feelings of sadness/hopelessness (42%).

### 193 *Health-related behaviors*

194 Regarding alcohol consumption and smoking, they were disclosed by 23% and 13% of the  
195 participants, respectively. Additionally, engaging in sexual activity without using condoms was  
196 reported by 37% of the participants. Almost half of the participants reported having been able  
197 to talk with health providers about sexuality (48.8%) or satisfied about healthcare (54.1%).

198 Compared to heterosexual men, MSM were less likely to be married, and less likely to report:  
199 smoking, cardiovascular, diabetes comorbidities, using treatment of Bactrim prophylaxis and  
200 HCV coinfection. They were more likely to report university as level of education. A higher  
201 proportion of MSM compared to the heterosexual men reported a CD4 cell counts above 500  
202 cell/mm<sup>3</sup>. It was noted that, MSM were more frequently able to talk with health providers about  
203 sexuality comparing to heterosexual men (Table 2).

#### 204 ***Prevalence of sexual difficulties***

205 The prevalence of medium to high frequency of erectile difficulty, ejaculation difficulty, and  
206 low sexual desire was respectively in 42.3%, 30.1% and 54.6% of the participants. MSM  
207 have reported more often lower level of sexual desire comparing to Heterosexual men  
208 ( $p < 0.001$ ) (Table 3).

#### 209 ***Scores of PROQOL- SexLife dimensions***

210 Taking into account that a lower score indicates a higher level of sexual quality of life, we have  
211 examined the average of the dimensions within two populations. The characteristics of  
212 PROQOL- SexLife dimensions and scores for each population are shown in table 4.

213 In MSM, the mean ( $\pm$ SD) score was ranged from 28 ( $\pm$ 22) for PAR dimension to 78 ( $\pm$ 23) for  
214 DRG dimension. While in heterosexual, it was ranged from 36 ( $\pm$ 24) for DIS dimension to 51  
215 ( $\pm$ 15) for PAR dimension. Both the MSM population and the heterosexual population exhibit  
216 similar levels of stigma and social distress in the STI dimension. The scores for this dimension  
217 are almost identical between the two groups, with 42 ( $\pm$ 23) for heterosexual individuals and 42  
218 ( $\pm$ 27) for MSM.

#### 219 ***Factors associated with PROQOL- SexLife dimensions***

220 Visual inspection of residual plots did not reveal any obvious deviations from homoscedasticity  
221 or normality except for drug consumption dimension for MSM. Variance inflation factors (VIF)  
222 indicated the absence of serious collinearity problems. The significant variables found in each  
223 linear mixed model dimension are shown in tables 5 and 6.

#### 224 ***MSM population***

225 After conducting mixed linear regression analyses, it was discovered that individuals living  
226 with a partner (as opposed to those living alone) as well as those who expressed satisfaction  
227 with their health services, were positively associated with positive perception of sexual  
228 experiences in POP dimension (better SQoL). Regarding the STI dimension, it was observed  
229 that single participants or those with cardiovascular complications were more prone to  
230 experiencing stigma and fear. Notably, frequent condom use was associated with a 9unit  
231 increase in the STI dimension compared to category of “not frequently”, as outlined in table 5.

232 Within the DIS dimension, encompassing issues such as erectile problems and low sexual  
233 desire, a negative association was found between SQoL and the use of Viagra and undergoing  
234 anti-cholesterol treatment. Moreover, living with a partner was associated with fewer instances  
235 of sexual difficulties among MSM.

236 Regarding the PAR/SOF dimension, higher scores in this domain were indicative of less  
237 frequent and less varied sexual practices. Within the PAR dimension, factors such as being  
238 HCV-positive and utilizing anti-cholesterol treatment were associated with less varied sexual  
239 practices with a partner, while satisfaction with healthcare services appeared to be positively  
240 linked with a higher frequency of sexual activities. Soft practices were more prevalent among  
241 individuals with higher education and those living with children, but less common among older  
242 men and those of Maghreb origin.

243 In the DRG dimension, specific to MSM, co-infection with HCV was found to be associated  
244 with higher values or consumption in this realm. As predicted, the consumption of Viagra also  
245 yielded significant implications.

#### 246 *Heterosexual men*

247 In POP dimension being unemployed was found to be associated with a decreased level of  
248 positive sexual perception, while having African origin was found to be associated with an  
249 increased level of positive sexual perception.

250 Looking at sexual practices with a partner dimension (PAR), consumption of Viagra was found  
251 to be associated with a reduced frequency and diversity of sexual practices with a partner  
252 while Hispanic origin was associated positively with a greater frequency and diversity of sexual  
253 practices. In STI dimension, frequent alcohol consumption was found to be linked to an  
254 elevated perception of stigma and fear (Table 6).

255 *Mental health morbidity-related factors*

256 Mental health-related factors, including a history of clinically diagnosed depression, the  
257 presence of depressive symptoms, and a preoccupation with the risk of HIV transmission during  
258 sexual activity, were negatively associated with better outcome of SQoL in the three dimensions  
259 (POP, DIS, STI) among MSM. These mental health morbidity-related variables were associated  
260 with at least 6 to 13 points decrease in SQoL among MSM. Among heterosexual men being  
261 very preoccupied with risk of HIV transmission variable was significant in POP and DIS  
262 dimension.

263 *Country effect*

264 By demonstrating the results of SQoL according to country (figure 1 & 2), we observe that the  
265 POP dimension has been skewed toward better outcome ( $\beta=-9$ ) for Brazil among MSM. The  
266 STI dimension is skewed toward slightly better outcome of SQoL for France ( $\beta=-4$ ), figure 1.  
267 By choosing country as a random effect, our model was able to show the potential intra-country  
268 differences; however, the intra-class correlation (ICC) in all dimensions did not exceed 0.15,  
269 and stayed in mild level, which implies overall small part of variation in the model is explained  
270 by country effect.

271

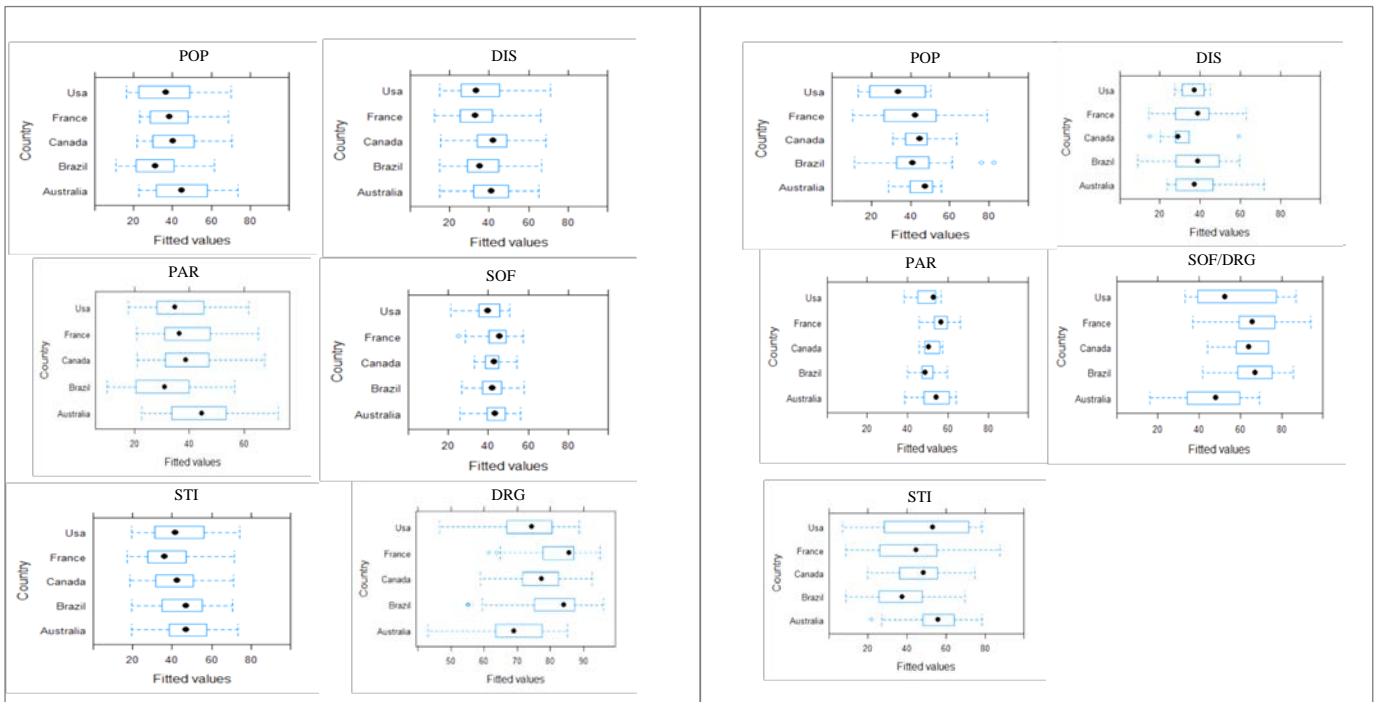


Figure 1. Variation of scores due to random effect (country) among MSM

Figure 2. Variation of scores due to random effect (country) among heterosexual men

272 **Discussion:**

273

274 The aim of this study was to establish prevalence of sexual difficulties and determine factors  
275 associated with SQoL amongst HIV-positive men. To our knowledge, this is the first study that  
276 has investigated the quality of sexual life in men living with HIV by using a gender-tailored  
277 instrument (PROQOL-SexLife).

278 The prevalence of erectile difficulty among men with HIV reported in the literature ranges from  
279 30% to 60% [15,16], while in our study, 42% of participants reported having a medium to high  
280 frequency of erectile difficulty. In our study, MSM exhibited a significantly higher prevalence  
281 of low sexual desire compared to heterosexual men. Various aspects of MSM's sexological and  
282 behavioral life could potentially influence sexual function, including sexual desire. However it  
283 is important to consider that low sexual desire is highly associated with demographic factors  
284 such as age, ethnicity, HIV parameters or type of HIV treatments (especially protease  
285 inhibitors) [17,18,19]. We have reported the prevalence of sexual difficulties in these two  
286 groups of men without controlling all the mentioned factors.

287 We observed that the patterns of contributors to PROQoL's dimensions have not been same  
288 among MSM and heterosexual men as some variables shown to be significant only among one  
289 population for a given dimension while not significant among the other population for the same  
290 dimension, for instance, unemployment was significant among heterosexual men in the POP  
291 dimension but not significant among MSM. However, we observed many similarities among  
292 two population; especially we observed a close association between impaired mental health and  
293 adverse SQoL's outcomes reported by both MSM and heterosexual men. This confirms previous  
294 findings that have also showed a significant association between sexual satisfaction of PLWHA  
295 and psychosocial factors, i.e. depression or anxiety and social factors, such as experiences of  
296 HIV related discrimination [20].

297 Feeling preoccupied with risk of HIV transmission reflects the influence of psychological  
298 distress within the context of intimate relationships. In addition to that, another source of  
299 distress among PLWHA was the fear of contracting new infections from sexual activities. This  
300 variable is one of the variables constructing the stigma and fear dimension (STI) in PROQOL-  
301 SexLife.

302 Certain studies have demonstrated that relational aspects, including intimate connections within  
303 couples, serve as robust predictors of sexual satisfaction for both heterosexual and homosexual

304 men. Factors such as feeling preoccupied with risk of HIV transmission or fear of reinfection  
305 may affect SQoL by negatively affecting intimacy [21].

306 Regarding to preventive behaviors and possible association with SQoL, we found that frequent  
307 condom use was associated with higher values of STI dimension among MSM. Considering  
308 that fear of reinfection was a constructing element in the STI dimension (as mentioned above),  
309 the observed association is comprehensible. But it could also imply that even with safer sex  
310 practices, anxiety of reinfection could still impair SQoL.

311 None of the HIV-related biological parameters in our study (CD4, viral load), in none of the  
312 study populations, appeared relevant to SQoL, which is consistent with the results reported  
313 from a large representative study in France [22]. Nonetheless, a study conducted in the United  
314 States with a male sample, as well as a separate study conducted in the UK, discovered an  
315 association between CD4 counts below 200 and the presence of sexual difficulties. [23,24]. The  
316 cumulative effect of antiviral therapy has also been discussed as a potential factor in SQoL in  
317 the literature [16]. In our study, duration of treatment has lost its significance on SQoL results  
318 after adding other HIV-related comorbidities (treatment for anti-cholesterol treatment). Other  
319 studies have found dyslipidemia as a significant risk factor for erectile difficulty symptom  
320 among HIV-positive men [25].

321 Although we have not assessed dyslipidemia directly, the prevalence of anti-cholesterol  
322 treatment was used as a proxy of dyslipidemia. In our study, being under anti-cholesterol  
323 therapy was a significant variable in DIS and PAR dimensions among MSM. Since  
324 dyslipidemia has been described as one of the side effects of highly active antiretroviral therapy  
325 on long term (HAART), this study emphasizes on cumulative side effect of antiviral therapy,  
326 specifically dyslipidemia.

327 Apart from existing health conditions and mental health, the role of socio-economic status such  
328 as unemployment, was found to be correlated with SQoL in the current study among  
329 heterosexual men. This finding aligns with results from other studies conducted among the  
330 general population [26]. However, unemployment was not significant among MSM, who had  
331 much higher rates of employment and levels of education compared to the heterosexual  
332 participants. The fact that unemployment is a marker of socioeconomic status shows the  
333 importance of controlling for these factors in future HIV studies.

334 A striking finding of our study is related to the role of satisfaction from health services on the  
335 POP dimension among MSM. Being under well support by health providers, could decrease

336 the distress and anxiety related to living with HIV. Also, the perception of receiving high quality  
337 of health services, may improve the patient's self-efficacy to cope with sexual related issues.

338 The current study had several limitations. We could not estimate the impact of type of HIV  
339 treatment as a potential factor. However, the literature results are inconsistent regarding to the  
340 association of antiretroviral therapy and sexual difficulties. Studies reported HAART as a  
341 causal factor for sexual difficulties, particularly Protease inhibitors including a large study of  
342 900 men from 10 European countries who found Protease inhibitors as a risk factor for sexual  
343 difficulties [12,27].

344 Another limitation of this study arises from the fact that the current assessment of behaviors  
345 was based on convenient sampling, thus our study is not representative of the populations of  
346 MSM and heterosexual men living with HIV in the investigated countries, which induces a non-  
347 participation bias. One of the most significant limitations of a cross sectional study design is  
348 that temporal relationships cannot be determined since explanatory elements and sexual  
349 outcomes were assessed at a single time point. In addition, our analysis is not allowing  
350 addressing causality association between SQoL outcomes and the associated factors. One of the  
351 limitations of this study is that it did not create a composite measure of sexual quality of life.  
352 Instead, it relied on individual measures or factors related to sexual well-being, which may not  
353 capture the full complexity of this multidimensional concept.

354

355 In conclusion, the considerable significance of psychological factors coupled with the lack of  
356 association with HIV-related biological parameters (CD4, viral load) in our study underscores  
357 the necessity of encompassing both clinical and non-clinical factors in order to  
358 comprehensively and accurately assess all elements of SQoL. Recognizing and addressing the  
359 factors associated with SQoL is essential for improving the overall well-being and quality of  
360 life for patients. Clinicians play a vital role in ensuring that individuals receive the support and  
361 care they need to overcome sexual challenges and lead fulfilling lives. They should conduct a  
362 comprehensive assessment that considers physical, psychological, and social aspects of a  
363 patient's life. This holistic approach can reveal underlying factors affecting SQoL life that may  
364 not be immediately apparent.

365

366

367 **Competing interest**

368 None of the authors have declared any competing interest.

369

370 **Authors 'contributions**

371 EF and DM designed the study. AA, RT, DM, JI and GJ collected the data. EF conducted the

372 main statistical analyses with assistance from BP. EL, RS, JI, IY, TF and CO provided editorial

373 support, reviewed and revised the manuscript. All the authors read and provided feedback on

374 drafts of the manuscript. All the authors contributed to the final manuscript.

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381

382 **Data Availability statement**

383 Data are available from Dr Martin Duracinsky.

384

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387

388

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473

**Table1.** Examples of the questions in the PROQOL-SexLife questionnaire (MSM and Heterosexual men)

<b>Dimension</b>	<b>Example of the statement</b>	<b>Responses</b>
<b>POP</b>	In general, my sexual life is...	very good/ good/average/not good/very bad
<b>STI</b>	I am afraid of being rejected in my sexual life	never/rarely/sometimes/most of the time/ all the time
<b>DIS</b>	I had low sexual desire	never/rarely/sometimes/most of the time/ all the time
<b>PAR</b>	during the last four weeks I had sexual activities such as oral-anal sex or oro-vaginal with a partner	never/rarely/sometimes/most of the time/ all the time
<b>SOF</b>	during last four weeks I had sexual dreams	never/rarely/sometimes/most of the time/ all the time
<b>DRG</b>	I have used alcohol or drugs to have sex	never/rarely/sometimes/most of the time/ all the time

**Table 2:** Characteristics of the study's participants (N=581)

Participants characteristics	Total (N= 581)		Heterosexual (N= 107)		MSM (N= 474)		P-value*
	N	n or(± SD or %) mean	N	n or(± SD or %) mean	N	n or(± SD or %) mean	
<b>Sociodemographic</b>							
Age, years	581	49(± 11.8)	107	48(± 12.4)	474	49(± 11.7)	0.811
University level, yes	560	275(49.1%)	106	37(34.9%)	454	238(52.4%)	<0.001
Professional activity	576		107		469		0.048
Active		320(55.6%)		50(46.7%)		270(57.6%)	
Retired		118(20.5%)		26(24.3%)		92(19.6%)	
Student		17(2.9%)		1(0.9%)		16(3.4%)	
Unemployed		121(21.0%)		30(28.0%)		91(19.4%)	
Marital status	577		107		470		<0.001
Married		190(32.9%)		51(47.7%)		139(29.5%)	
Single		352(61.0%)		42(39.2%)		310(66.0%)	
Other		35(6.1%)		14(13.1%)		21(4.5%)	
Living mode	581		107		474		<0.001
Alone		274(47.2%)		35(32.7%)		239(50.4%)	
With a partner		171(29.4%)		27(25.2%)		144(30.4%)	
Other		127(21.9%)		39(36.5%)		88(18.6%)	
With children		9(1.5%)		6(5.6%)		3(0.6%)	
Ethnicity	547		100		447		<0.001
Caucasian		420(76.8%)		58(58.0%)		362(81.0%)	
African		63(11.5%)		28(28.0%)		35(7.8%)	
Hispanic		19(3.5%)		4(4.0%)		15(3.4%)	
Asian		35(6.4%)		9(9.0%)		26(5.8%)	
Maghreb		7(1.3%)		0(0.0%)		7(1.6%)	
Aborigines		3(0.5%)		1(1.0%)		2(0.4%)	
<b>Clinical related variables</b>							
Duration of HIV treatment, years	581	13(±8.6)	107	13(±8.9)	474	13(± 8.6)	0.982
Type of HIV treatment**a	408		87		321		0.587
INI		150(36.8%)		36(41.4%)		114(35.5%)	
NNRTIs		107(26.2%)		22(25.3%)		85(26.4%)	
NRTIs		9(2.2%)		0(0.0%)		9(2.8%)	
PIs		84(20.6%)		16(18.4%)		68(21.2%)	
PIs + INI		36(8.8%)		8(9.2%)		28(8.7%)	
Others		22(5.4%)		5(5.7%)		17(5.3%)	
HIV-RNA	560		99		461		0.117
Undetectable(≤50)		533(95.2%)		91(91.9%)		442(95.9%)	
Detectable(>50)		27(4.8%)		8(8.1%)		19(4.1%)	
CD4 count, cell/mm3	511		94		417		<0.001
CD4 (0-199)		51(10.0%)		22(23.4%)		29(7.0%)	
CD4 (200-499)		136(26.6%)		22(23.4%)		114(27.3%)	
CD4 (>500)		324(63.4%)		50(53.2%)		274(65.7%)	
Co-morbidities and Mental health	581		107		474		
Diabetes, yes		54(9.3%)		16(15.0%)		38(8.0%)	0.026
Cardiovascular diseases, yes		95(16.4%)		26(24.3%)		69(14.6%)	0.014
Psychiatric disorder, yes		45(7.7%)		5(4.7%)		40(8.4%)	0.188
Clinical depression, yes		163(28.1%)		23(21.5%)		140(29.5%)	0.094
HBV coinfection, yes		73(12.6%)		16(15.0%)		57(12.0%)	0.409
HCV coinfection, yes		92(15.8%)		32(29.9%)		60(12.7%)	<0.001

Medical treatment	<b>581</b>		<b>107</b>		<b>474</b>	
Bactrim prophylaxis, yes		40(6.9%)		12(11.2%)		28(5.9%)
Anti-depressant/psychiatric treatment, yes		120(20.7%)		18(16.8%)		102(21.5%)
Anti-cholesterol, yes		80(13.8%)		17(15.9%)		63(13.3%)
<b>Depressive symptoms</b>	<b>581</b>		<b>107</b>		<b>474</b>	
Feeling sad/hopeless, yes		246(42.3%)		50(46.7%)		196(41.4%)
Low interest for life, yes		259(44.6%)		51(47.7%)		208(43.9%)
<b>Health-related behaviors</b>						
<b>Consumption behavior</b>	<b>581</b>		<b>107</b>		<b>474</b>	
Alcohol, yes		136(23.4%)		26(24.3%)		110(23.2%)
Smoking, yes		73(12.6%)		34(31.8%)		39(8.2%)
Cocaine, yes		46(7.9%)		13(12.1%)		33(7.0%)
Cialis/Viagra, yes		119(20.5%)		17(15.9%)		102(21.5%)
<b>Knowledge of risk of HIV transmission</b>	<b>580</b>		<b>106</b>		<b>474</b>	
Aware		510(87.9%)		90(84.9%)		420(88.4%)
Moderately aware		25(4.3%)		6(5.6%)		19(4.1%)
Not aware		45(7.8%)		10(9.4%)		35(7.5%)
<b>Preoccupation with risk of HIV transmission</b>	<b>575</b>		<b>104</b>		<b>471</b>	
Not preoccupied		265(46.1%)	39	(37.5%)		226(48.0%)
Moderately		231(37.0%)	42	(40.4%)		171(36.3%)
Very preoccupied		97(16.9%)	23	(22.1%)		74(15.7%)
<b>Condom use</b>	<b>575</b>		<b>106</b>		<b>471</b>	
Not frequently		213(37.0%)		42(39.2%)		171(36.3%)
Sometimes		265(46.1%)		39(36.4%)		226(48.0%)
Frequently		97(16.9%)		23(21.5%)		74(15.7%)
<b>Sexuality and health care</b>						
<b>Erectile difficulties</b>	<b>581</b>		<b>107</b>		<b>474</b>	
Not frequently		335(57.7%)		60(56.1%)		275(58.0%)
Sometimes		129(22.2%)		26(24.3%)		103(21.7%)
Frequently		117(20.1%)		21(19.6%)		96(20.3%)
<b>Ejaculatory difficulties</b>	<b>581</b>		<b>107</b>		<b>474</b>	
Not frequently		406(69.9%)		69(64.5%)		338(71.3%)
Sometimes		85(14.6%)		17(15.9%)		67(14.1%)
Frequently		90(15.5%)		21(19.6%)		69(14.6%)
<b>Low sexual desire</b>	<b>581</b>		<b>107</b>		<b>474</b>	
Not frequently		264(45.4%)		47(43.9%)		119(25.1%)
Sometimes		172(29.6%)		34(31.8%)		217(45.8%)
Frequently		145(25.0%)		26(24.3%)		138(29.1%)
<b>Able to talk with health providers about sexuality</b>	<b>580</b>		<b>106</b>		<b>474</b>	
No		164(28.2%)		42(39.6%)		122(25.7%)
Sometimes		133(22.8%)		15(14.1%)		118(24.9%)
Yes		283(48.8%)		49(46.2%)		234(49.4%)
<b>Health care satisfaction</b>	<b>576</b>		<b>106</b>		<b>470</b>	
No		156(27.0%)		35(33.0%)		121(25.7%)
Sometimes		108(18.7%)		19(17.9%)		89(18.9%)
Yes		312(54.1%)		52(49.0%)		260(55.3%)

\* Chi-square, t-student tests

\*\* INI= Integrase inhibitors, NNRTIs= Non-nucleoside reverse transcriptase inhibitors; NRTIs= Nucleoside reverse transcriptase inhibitors;

PIs= Protease inhibitors;

<sup>a</sup> only for three country: Brazil, France and Canada

**Table 4.** Characteristics of PROQOL sexlife dimensions

	<b>Dimension (abbreviation)</b>	<b>Mean of score ± SD</b>	<b>The detail of the questions and concepts constructing PROQOL-SexLife dimensions</b>
<b>MSM</b>	Positive sexual perception (POP)	41± 24	<ul style="list-style-type: none"> <li>• General evaluation of the sex life</li> <li>• Feeling that sex life give a sense of existence</li> <li>• Avoiding sexual relationship</li> <li>• Being satisfied with sex life</li> <li>• Feeling pleasure during sexual activities</li> <li>• Believing that the sexual partner is satisfied form sexual relationship</li> <li>• Having the sexual relationship during the last four weeks</li> </ul>
	Stigma and fear(STI)	42± 23	<ul style="list-style-type: none"> <li>• Having fear of being rejected in relation to sex</li> <li>• Being annoyed by the serum status in relation with emotional and romantic life</li> <li>• Having fear of being infected with another disease during sex</li> <li>• Feeling being less desirable</li> <li>• Experiencing stigma and discrimination in daily life because of sexual orientation</li> </ul>
	Sexual difficulties(DIS)	37 ± 25.7	<ul style="list-style-type: none"> <li>• Feeling less sexual desire</li> <li>• Having the erection difficulties</li> </ul>
	With partner sexual practices(PAR)	28 ± 22	<ul style="list-style-type: none"> <li>• Type of sexual activity: oral-vaginal, oral-anal</li> <li>• Type of sexual activity: anal sex</li> </ul>
	Soft practices(SOF)	42 ± 23	<ul style="list-style-type: none"> <li>• Type of sexual activity: having sexual dreams</li> <li>• Type of sexual activity: masturbation</li> </ul>
	Drug consumption(DRG)	78 ± 23	<ul style="list-style-type: none"> <li>• Taking the drugs or drinking alcohol for having the sexual activities</li> <li>• Type of sexual activity: others</li> </ul>
<b>Heterosexual men</b>	Positive sexual perception(POP)	40± 26	<ul style="list-style-type: none"> <li>• General evaluation of the sex life</li> <li>• Feeling that sex life give a sense of existence</li> <li>• Being satisfied with sex life</li> <li>• Feeling pleasure during sexual activities</li> <li>• Believing that the sexual partner is satisfied form sexual relationship</li> </ul>
	Stigma and high social distress(STI)	42± 27	<ul style="list-style-type: none"> <li>• Having fear of being rejected in relation to sex</li> <li>• Being annoyed by the serum status in relation with emotional and romantic life</li> <li>• Being afraid of infection during sex</li> <li>• Feeling being less desirable</li> </ul>
	Sexual difficulties(DIS)	36± 24	<ul style="list-style-type: none"> <li>• Feeling less sexual desire</li> <li>• Feeling hardly excited sexually</li> <li>• Having the erection difficulties</li> <li>• Avoiding sexual relationship</li> </ul>

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With partner sexual practices(PAR)	51± 15	<ul style="list-style-type: none"> <li>• Having the sexual relationship during the last four weeks</li> <li>• Type of sexual activity: preliminary</li> <li>• Type of sexual activity: oral-vaginal, oral-anal</li> <li>• Type of sexual activity: vaginal sex</li> <li>• Type of sexual activity: anal sex</li> </ul>
Soft practices(SOF/ DRG)	42± 27	<ul style="list-style-type: none"> <li>• Taking the drugs or drinking alcohol for having the sexual activities</li> <li>• Type of sexual activity: Having sexual dreams</li> <li>• Type of sexual activity: masturbation</li> </ul>

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**Table 5.** Significant factors in multivariable mixed regression among MSM

SQoL dimension			Coefficient	Standard Error	p-value
<b>Positive sexual perception (POP)</b>	Fixed Variables	Living mode: Living with a partner	-4.4	2.1	0.045
		Clinical depression: Yes	6.6	2.4	0.007
		Not preoccupied with risk of HIV transmission	-9.4	2.0	0.000
		Very preoccupied with risk of HIV transmission	13.8	2.8	0.000
		Healthcare satisfaction: Yes	-15.1	2.2	0.000
	Random effect parameters	<i>SD Intercept</i>	8.1		
		<i>ICC</i>	0.1		
		<i>R<sup>2</sup> *</i>	0.4		
<b>Stigma &amp; fear (STI)</b>	Fixed Variables	Being single	10.0	2.2	0.000
		Condom usage: frequently	9.8	2.9	0.000
		Cardiovascular: Yes	7.1	3.0	0.011
		Depressive symptom(feeling sad/hopeless): Yes	5.9	2.3	0.010
		Not preoccupied with risk of HIV transmission	-13.7	2.1	0.000
	Very preoccupied with risk of HIV transmission during sex	6.8	2.9	0.022	
	Random effect parameters	<i>SD Intercept</i>	0.0		
	<i>ICC</i>	0.0			
		<i>R<sup>2</sup></i>	0.3		
<b>Sexual difficulties (DIS)</b>	Fixed Variables	Viagra use: Yes	7.9	2.8	0.005
		Clinical depression: Yes	8.6	2.9	0.004
		Living mode: Living with a partner	-5.4	2.5	0.035
		Anti-cholesterol treatment: Yes	9.0	3.3	0.007
		Not preoccupied with risk of HIV transmission	-10.0	2.5	0.000
	Random effect parameters	<i>SD Intercept</i>	0.0		
		<i>ICC</i>	0.0		
		<i>R<sup>2</sup></i>	0.2		
<b>Sexual practices with partner (PAR)</b>	Fixed Variables	HCV-coinfection: Yes	11.7	3.7	0.002
		Anti-cholesterol treatment: Yes	8.7	3.9	0.027
		Healthcare satisfaction: Yes	-8.5	3.0	0.005
	Random effect parameters	<i>SD Intercept</i>	6.2		
	<i>ICC</i>	0.0			
		<i>R<sup>2</sup></i>	0.2		
<b>Soft sexual practices (SOF)</b>	Fixed Variables	Age group: 40-49	13.8	5.7	0.015
		Age group: 50-59	12.7	5.7	0.026
		University Education	-5.3	2.2	0.018
		Living mode: living with children	-27.0	13.8	0.048
		Origin: Maghreb	18.7	9.2	0.043
	Random effect parameters	<i>SD Intercept</i>	2.3		
	<i>ICC</i>	0.0			
		<i>R<sup>2</sup></i>	0.0		
<b>Drug consumption (DRG)</b>	Fixed Variables	Viagra use: Yes	-10.5	2.7	0.001
		HCV-positive	-10.7	3.2	0.005
	Random effect parameters	<i>SD Intercept</i>	0.0		
		<i>ICC</i>	0.1		
		<i>R<sup>2</sup></i>	0.1		

\* Pseudo-R-squared explaining the variance by the entire model, including both fixed and random effects

**Table 6.** Significant factors in multivariable mixed regressions among Heterosexual men

SQoL dimension			Coefficient	Std,Error	p-value
<b>Positive sexual perception (POP)</b>	Fixed Variables	Unemployed	12.5	6.2	0.047
		Not preoccupied with risk of HIV transmission	-11.9	5.8	0.046
		Origin: African	-17.5	6.3	0.008
	<i>Random effect parameters</i>	<i>SD Intercept</i>	0.5		
		<i>ICC</i>	0.0		
	<i>R<sup>2</sup></i>	0.3			
<b>Stigma/fear (STI)</b>	Fixed Variables	Alcohol consumption: Yes	20.0	7.1	0.007
		<i>SD Intercept</i>	0.0		
	<i>Random effect parameters</i>	<i>ICC</i>	0.0		
		<i>R<sup>2</sup></i>	0.28		
<b>Sexual difficulties (DIS)</b>	Fixed Variables	Not preoccupied with risk of HIV transmission	-12.1	6.3	0.055
		<i>SD Intercept</i>	0.0		
	<i>Random effect parameters</i>	<i>ICC</i>	0.0		
		<i>R<sup>2</sup></i>	0.2		
<b>Sexual practice with partner (PAR)</b>	Fixed Variables	Origin: Hispanic	29.3	13.7	0.040
		Viagra use: Yes	-12.4	6.0	0.047
	<i>Random effect parameters</i>	<i>SD Intercept</i>	0.0		
		<i>ICC</i>	0.0		
		<i>R<sup>2</sup></i>	0.2		