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Journal: Journal of studies on alcohol and drugs

Year: 2013 Nov

Volume: 74

Issue: 6

Pages: 931-40

DOI: http://dx.doi.org/10.15288/jsad.2013.74.931

Need for informed consent in substance use studies – harm of bias?

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This research was supported by the Swiss National Science Foundation (33CSC0-122679)

Abstract

Objective: The aim of the study was to examine the difference between those who gave informed consent to a study on substance use and those who did not, and to analyse whether differences varied with varying non-consent rates.

Method: Cross-sectional questionnaire data on demographics, alcohol, smoking and cannabis use were obtained for 6,099 French- and 5,720 German-speaking 20-year-old Swiss males. Enrolment took place over 11 months for the Cohort Study on Substance Use Risk Factors (C-SURF). Consenters and non-consenters were asked to complete a short questionnaire. Data for nearly the entire population were available, since 94% responded. Weekly differences in consent rates were analysed. Regressions examined the associations of substance use with consent giving and consent rates, and the interaction between the two.

Results: Non-consenters had higher substance use patterns, though they were more often alcohol abstainers; differences were small and not always significant, and did not decrease as consent rates increased.

Conclusion: Substance use currently is a minor sensitive topic among young males, resulting in small differences between non-consenters and consenters. As consent rates increase, additional individuals are similar to those observed at lower consent rates. Estimates of analytical studies looking at associations of substance use with other variables will not differ at reasonable consent rates of 50-80%. Descriptive prevalence studies may be biased, but only at very low rates of consent.

Word count: 224

Keywords: informed consent; non-consent bias; consent rate; substance use; young men

Introduction

The need for informed consent due to ethical requirements has become the norm for scientific publications (Coughlin, 2006; Janssen, 2003), but little is known about the potential bias introduced by exclusion of non-consenters with regards to substance use outcomes. It has been suggested that the process of consenting can bias medical research, e.g., in the area of cardiovascular disease (Al-Shahi et al., 2005; Junghans et al., 2005), or cancer research (Neumark et al., 2001). Studies examining consent bias in the substance use field have mixed results, showing either a higher prevalence of smokers or heavy alcohol users among consenters versus non-consenters (Korkeila et al., 2001; Pullen et al., 1992) or no associations with alcohol (Wild et al., 2001). Much of the literature focuses on non-respondents. Since non-consenters are part of a wider group of non-respondents (e.g., silent refusal may occur if someone initially gives consent but does not respond later on), we have to draw a theoretical framework mostly from non-response studies that may provide indications for non-consenting as well.

In research on sensitive topics, some investigators have found low response rates and high non-response bias (Tourangeau and Yan, 2007). Substance use is generally considered a sensitive topic (Bradburn and Sudman, 1979; Singer, 1978), however, substance use studies on non-response also yield inconsistent results. For alcohol use, some reports showed a higher prevalence of abstainers (Lahaut et al., 2002; Lahaut et al., 2003; Torvik et al., 2012), a lower prevalence of heavy episodic drinking and lower frequency of drinking (Cranford et al., 2008), or hazardous and heavy drinking (Hill et al., 1997; Lemmens et al., 1988) among non-respondents compared with respondents. In contrast, other studies found higher alcohol use in non-respondents than in respondents. For example, drinking alcohol or heavy episodic drinking once a week or more (Wild et al., 2001), moderate and high alcohol consumption

(Torvik et al., 2012), as well as heavy drinking (Goldberg et al., 2006) was positively associated with non-response in a follow-up study. Similarly, lifetime prevalence of alcohol dependence (Heath et al., 2001), prevalence and frequency of alcohol use, heavy episodic drinking, risky use, maximum quantity of drinks consumed in one occasion, as well as frequency of drunkenness was higher in non-respondents than in respondents (McCoy et al., 2009; Zhao et al., 2009). Other studies also found no significant differences between respondents and non-respondents in alcohol use variables (Cunradi et al., 2005; Gmel, 2000; Korkeila et al., 2001; Kypri et al., 2004; Strote et al., 2002; Trinkoff and Storr, 1997; Ullman and Newcomb, 1998).

For tobacco use, most of the existing studies showed higher smoking rates in non-respondents than in respondents (Boström et al., 1993; Cunradi et al., 2005; Goldberg et al., 2006; Hill et al., 1997; Korkeila et al., 2001; McCoy et al., 2009; Smith and Nutbeam, 1990; Torvik et al., 2012; Woodruff et al., 2000). To our knowledge, no one has reported an opposite pattern, but two studies failed to find any significant association of tobacco use with non-response (Strote et al., 2002; Ullman and Newcomb, 1998).

Few studies have examined the association of cannabis use with non-response. Zhao and colleagues (2009) found a higher prevalence of lifetime and 12 months prevalence of cannabis users among non-respondents than in respondents, while Ullman and Newcomb (1998) found no significant differences.

Taken together, these results demonstrate that non-respondents more often are heavier substance users than respondents are, although the difference is not systematic, especially for alcohol use where the opposite pattern has been observed. The absence of clear patterns may

result from differences between studies. Research was conducted in various countries that have potentially different substance use norms (e.g., North America, France, Switzerland, Finland, New Zealand, Norway, Sweden, Wales, Netherlands) and in population with different characteristics (community, military, student, or nursing samples) that may also be related to non-response. For example, in sample of undergraduate students, Cranford et al. (2008) showed that non-respondents reported less use of alcohol, but also reported more hours spent on class preparation than did respondents. Therefore, good students who do not drink very much may decline survey participation in order to reserve time for schoolwork. There are also differences in sample sizes (ranging from 310–53,835 individuals) that may influence the statistical significances that are found. Moreover, there was great variability in response rates across studies, ranging from 40–82%, which may explain differences in findings. Studies with high response rates may mostly miss the heaviest users and therefore show large differences between respondents and non-respondents, whereas studies with low response rates may have reasons other than substance use for non-response. Therefore, most of the non-respondents are similar to the respondents, mitigating overall differences. All of these reasons may contribute to the lack of consistent results for respondents versus non-respondents in substance use research. No common denominator has been identified to distinguish between studies showing under-, similar- or over-reporting of substance use by non-respondents compared to respondents.

Mainly, three distinct approaches have been used to study non-response bias: a) follow-up of non-respondents using very short questionnaires to compare answers with regular respondents (e.g., Cranford et al., 2008); b) comparison of baseline characteristics of respondents and sample dropouts at a later follow-up (e.g., Gmel, 2000); or c) comparison between early and late survey respondents (e.g., Lahaut et al., 2002). This last approach uses late respondents as

a proxy for non-respondents because it assumes that late respondents would be non-respondents if data collection had stopped earlier. All three methods have some caveats. Data are obtained at different times when non-respondents are followed up, and in the end, only a small proportion of initial non-respondents reply. Similarly, when comparing early with late respondents, the "true" non-respondents (i.e., the most reluctant) are still not included. Finally, designs comparing baseline characteristics of respondents and non-respondents to those followed up cannot evaluate the initial non-respondents at baseline. Consequently, all three approaches miss true non-respondents who may never respond or even give consent to study participation.

Therefore, research on potential biases of non-responding or non-consenting is complicated because information about subjects in these categories is not often available (Biemer and Lyberg, 2003). The primary aim of the present study is to examine differences between consenters and non-consenters on substance use outcomes using a design attempting to overcome these limitations. A near-census of young army conscripts was asked over the course of a year to participate in a cohort study. At the same time, a five-minute substance use questionnaire was distributed among both consenters and non-consenters and resulted in a 94% response rate. This allows an examination of the differences in substance use outcomes between those who consented and (nearly) all those who did not.

It should be noted that the difference between respondents and non-respondents is only one component of non-response bias. Non-response bias is the difference between the sample estimate (based on respondents) and the total population estimate (based on respondents and non-respondents). Its magnitude is the product of the non-response rate times the difference between respondents and non-respondents (Biemer and Lyberg, 2003). A common

assumption is that when the non-response rate goes down, the pool of respondents becomes more representative of the total survey population and thus lowers non-response bias. However, this assumption has been challenged because increases in non-response rates have not necessarily altered survey estimates (Groves and Peytcheva, 2008; Keeter et al., 2000; Merkle and Edelman, 2002).

If the cause of non-response is closely related to the survey variables, non-response is selective, and increasing the response rate has only a limited effect on non-response bias. Lack of interest in the topic and sensitivity of items are some of the reasons why individuals do not respond (Groves et al., 2004; Tourangeau and Yan, 2007). Individuals will usually respond if the survey topic is salient enough and not too sensitive. Thus, efforts in increasing response rates may yield survey estimates that remain more or less the same, and only the difference between respondents and non-respondents becomes larger. This could be the case, if the heavier users remain non-respondents, and the mostly moderate users among former non-respondents are included when increasing response rates. Thus, the sample of respondents does not become more representative, but the difference between them and the remaining non-respondents becomes greater.

Increasing response rates reduces non-response bias only if the cause of non-response is not too strongly related to the main survey variables (Groves, 2006; Groves and Peytcheva, 2008). In this case non-respondents refuse participation not for topic sensitivity itself, but for other reasons that are indirectly related to the topic of the survey (e.g., having little time, being unreachable, inconvenient contact times). Since non-participation is not directly caused by the survey variables, initial non-respondents are less reluctant to be converted and the initial difference between respondents and non-respondents will be diminished by the increase

in response rates. As a consequence, the response bias will also be diminished and the sample of respondents then becomes more representative.

Currently, the association of non-response rates with non-response bias is of increasing importance, because survey response rates have decreased considerably in the last decades (de Leeuw and de Heer, 2002; Tolonen et al., 2006). De Leeuw and de Heer (2002) showed an average increase in non-response rates of 0.5 % per year that is generally attributed to individual privacy concerns, restricted time resources and perceived burdens experienced during previous research (Fuchs et al., 2013; Haunberger, 2011; Stocké and Langfeldt, 2004). Therefore, it becomes more difficult to achieve high response rates in survey designs. At the same time, the "gold standards" of survey methodology (Alreck and Settle, 1995; Babbie, 2007) usually urge researchers to minimize non-response rates to avoid the risk of bias. Researchers have to invest more money and greater effort to attain high response rates to meet this goal, although the significance of the relation of response rates with the magnitude of non-response bias is questionable. High response rates are certainly valuable, but very high response rates (around 80% or more) may not be achievable with the resources at hand. The question then becomes whether allocating research money to increase response rates (e.g., from 60% to 70%) is cost-effective, or whether the funds could be used to create better survey designs, including questions that might increase the representativeness of responses from participants.

The secondary aim of this study is to examine whether consent rates are significantly related to the magnitude of the non-response bias. Enrolment of participants was conducted on a weekly basis over a one-year period and the weekly consent rates were recorded.

Although testing the association of consent rates with non-response bias was not the main goal of the study, the data obtained constitute a unique opportunity to examine this question.

The present study tested two main hypotheses regarding non-consent bias:

a. Because of topic sensitivity, non-consenters are more likely to be heavier users than are consenters.
b. Differences between consenters and non-consenters will remain essentially the same and the magnitude of non-consent bias will be lowered only slightly with increasing consent rates, because the cause of non-consenting is related to the survey variables.

Method

Enrolment Procedure, Information and Consent

Switzerland has a mandatory army recruitment process; virtually all young men around age 20 are processed to determine their eligibility for military or, civil or no service. Since there is no pre-selection for army conscription, virtually a census of the Swiss male population in this age group was eligible for inclusion in this research.

Data were collected during the enrolment phase of the Cohort Study on Substance Use Risk Factors (C-SURF). Research staff informed the conscripts that the study was a longitudinal substance use survey designed to evaluate the trajectories of substance use patterns from late adolescence to adulthood and to identify the protective and the risk factors associated with changes in usage over time and invited them to participate, then gave them a printed information sheet and a consent form. Conscripts were fully informed about the procedure (to complete two electronic or paper one-hour questionnaires over an 18-month period), the

incentives (30 Swiss francs for completing one questionnaire and a bonus of 30 Swiss francs for finishing both), the confidentiality, and the right to withdraw from the study at any time without penalty.

A five-minute questionnaire containing items on demography, alcohol, tobacco and cannabis use was given to all conscripts during study enrolment in the army recruitment centres. Consent was not required for this, because these questionnaires were anonymous for non-consenters to the cohort study and the conscripts were informed that they could withdraw at any time, in accordance with the principles of the Helsinki Declaration. The Ethics Committee for Clinical Research at the Lausanne University Medical School approved C-SURF (Protocol No. 15/07). The present study compares consenters and non-consenters to the full cohort study only on the measures contained in the five-minute questionnaire.

Setting and Participants

Enrolment took place on a weekly basis between August 23, 2010 and July 31, 2011, in two of the six army recruitment centres located in Lausanne (French-speaking) and Windisch (German-speaking). These two centres serve 15 of the 26 cantons in Switzerland, including all of the French-speaking cantons.

Altogether, 7,011 French-speaking men showed up in the recruitment centre in Lausanne. Among them, 627 (8.9%) were never seen by the research staff because they were acutely ill (not chronically) or were randomly selected to participate in another study (CH-X; Mohler-Kuo et al., 2006). These dropouts were random and should not influence the findings. Of the 6,384 informed conscripts (91.1%), 4,430 (69.4%) gave written consent to participate in the cohort study and 6,099 (95.5%) filled in the five-minute questionnaire, independent of

consenting for the cohort study, yielding 4,429 consenters and 1,670 non-consenters among French-speaking conscripts.

Altogether, 7,382 German-speaking men attended the recruitment centre in Windisch. Among them, 1,202 (16.3%) were never seen by the research staff because they were ill or not informed about the study by the military staff, due to administrative procedures. These dropouts were random and not related to the study. Of the 6,180 (83.7%) informed individuals, 2,602 (42.1%) gave written consent to participate in C-SURF and 5,720 (92.5%) filled in the short questionnaire, yielding 2,598 consenters and 3,122 non-consenters among German-speaking conscripts.

Measures

Alcohol use. Alcohol use was assessed with three questions: usual quantity, frequency of use and frequency of risky single occasion drinking (RSOD, or occasions with at least six standard drinks). Drinking frequency was evaluated with an open-ended question about the average number of days per week on which alcohol is usually consumed. Non-weekly users were given choices of “2-3 times a month” (coded 0.73 days/week), “once a month or less” (coded 0.12 days/week), or never (coded zero days/week). Quantity was evaluated with an open-ended question for number of standard drinks on drinking days. Pictures of standard drinks containing approximately 10-12 grams of pure alcohol were provided. Number of drinking days times usual number of drinks on drinking days yielded volume. Drinking status differentiated between abstainers and drinkers. At-risk volume drinking was defined as 21 or more drinks per week (approximately 231 grams of pure alcohol), close to the 196 grams (14 drinks per week containing 14 grams) definition proposed by the National Institute on Alcohol Abuse and Alcoholism (NIAAA, 1995). At-risk RSOD was defined as having at least one occasion monthly.

Smoking. Participants were asked whether they smoked, even occasionally. Smoking status differentiated between non-smokers and occasional or daily smokers. Smokers were asked whether they smoked daily or occasionally, and daily smokers reported the number of cigarettes used every day.

Cannabis use. Frequency of cannabis use in the past 12 months was measured with categories of "never" (coded zero days/week), "once a month or less often" (coded 0.12 days/week), "2-4 times a month" (coded 0.69 days/week), "2-3 times a week" (coded 2.5 days/week), and "4 times or more often a week" (coded 4 days/ week). At-risk cannabis use was defined as smoking at least twice a week.

Covariates. Highest completed education consisted of three categories of schooling: primary (9 years), secondary (about 12 years), and tertiary (13 years or more). Urbanicity distinguished between those living in urban (>10,000 inhabitants) or rural (<10,000 inhabitants) areas. The season during which the questionnaire was completed was also computed along with the weekly response rates for the five-minute questionnaire.

Design and Statistical Analysis

Basic descriptive characteristics (i.e., highest completed education, urbanicity, season of recruitment) of consenters and non-consenters were computed separately for the two linguistic regions. For our primary objective of examining differences between consenters and non-consenters on substance use outcomes, regression models were conducted, separately for the two linguistic regions. Logistic regressions were used for dichotomous outcomes and ordinary least square regression models for continuous outcomes. Since the distribution of drinking

volume was highly skewed, a logarithmic transformation was applied. An unadjusted model compared consenters to non-consenters and an adjusted model compared consenters to non-consenters, using covariates that are potentially related to being a consenter or a non-consenter. Covariates were highest completed education, urbanicity, season of recruitment and response rates for the five-minute questionnaire.

Since weekly consent rates were obtained, differences between consenters and non-consenters at varying rates of consenting could be analysed to determine whether increasing consent rates are related to the magnitude of non-consent bias. A full interaction model of consenting, consent rate and consenting x consent rate, adjusted for covariates, was conducted separately for the two linguistic regions. Response rates for the five-minute questionnaire and the consent rates were centred at the mean separately for German- and French-speaking conscripts; otherwise, the intercept and coefficient of consenting would end up with values at an implausible zero response and consent rate. Since the same weekly consent rate was assigned to conscripts enrolled during the same week (conscripts nested within weeks), the complex sampling commands in STATA were used and week of enrolment was introduced as the primary sampling unit in the regressions to take into account possible violations of the assumption of independence in the models. In order to prevent increase in probabilities of false negatives (Rothman, 1990) and to facilitate the comparison with previous studies, the significance threshold was not adjust for multiple comparisons and was set at $p < .05$. For readers interested in multiple adjustment comparisons, Bonferroni adjusted significance threshold for 10 dependent variables comparisons is $p < .005$.

To estimate the magnitude of non-consent bias at different consent rates, two indices of non-consent bias were computed, following the formula of Biemer and Lyberg (2003). First, the

non-consent bias, defined as $Bias = \frac{N_{nc}}{N_{tot}} \times (\bar{Y}_c - \bar{Y}_{nc})$, where $\frac{N_{nc}}{N_{tot}}$ is the non-consent rate, and $(\bar{Y}_c - \bar{Y}_{nc})$ the difference in means between consenters and non-consenters, reflects the difference between the full population estimate (based on both consenters and non-consenters) and the sample estimate (based on the consenters only). Second, the relative non-consent bias, defined as the non-consent bias divided by the total population estimate, reflects the difference between consenters and the full sample as a percentage of the sample estimate. Thus it allows a comparison of the size of bias across the different outcomes.

Results

Among French-speaking participants, weekly consent rates ranged from 50.54% to 82.59%. In all, 69.39% of the French-speaking conscripts gave their consent. Among the German-speaking conscripts, the mean consent rate was 42.13%, and varied between 21.62% and 63.54%. Despite differences in consent rates between the linguistic regions, among German-speaking conscripts more than 92% of those informed of the study aims completed the five-minute questionnaire, as did more than 95% of the French-speaking conscripts.

Characteristics of consenters and non-consenters are presented in Table 1. Differences were found for highest achieved education (significant only for German speakers) and season of enrolment (significant only for French speakers). French-speaking conscripts enrolled in winter and autumn were more often non-consenters, whereas those enrolled in spring and summer were more often consenters. German-speaking consenters more often reported primary and high school, and less often secondary school, as their highest achieved education than did non-consenters.

Please insert Table 1 about here

Despite some significant results due to the large sample size, no extreme differences were observed on substance use outcomes between consenters and non-consenters (see Table 2). Unadjusted regression coefficients indicate that non-consenters had generally higher substance use patterns than consenters did, with a higher prevalence of monthly RSOD (not significant for French-speaking conscripts), risky volume drinking, smokers, daily smokers, and using cannabis more than once a week. Non-consenters also reported higher weekly drinking volume, number of weekly cannabis use and cigarettes smoked than consenters did. Thus, the magnitude and direction of effects were approximately the same between German- and French-speaking consenters and non-consenters, even though the consent rate was much higher among French-speaking conscripts. For alcohol abstention, an opposite pattern was found, with a higher prevalence of abstainers among non-consenters than among consenters (not significant for French-speaking conscripts). Adjusting for covariates did not substantively change any of the effects, except within the German-speaking sample, where the unadjusted significant effect (p = .046) for abstention from alcohol use became non-significant (p= .090), as did daily smoking (unadjusted p = .034; adjusted p = .051).

Please insert Table 2 about here

The full interaction model examined whether associations of consent rate with substance use outcomes differ between consenters and non-consenters, and is presented in Table 3. The consent rate parameter reflects the relation between consent rate and outcome for consenters, whereas the interaction of consent rate and consenting indicates the deviation of consent rate-outcome association in non-consenters as compared to that of consenters. If the interaction is

close to zero both consenters and non-consenters change on the outcome measure at the same rate, i.e., the difference between consenters and non-consenters remains unchanged with increasing consent rates.

Except for being alcohol abstainers, number of cigarettes smoked daily and >1x/week cannabis use among French-speaking conscripts, variations in consent rate were not significantly associated with outcomes among consenters. There was no significant effect for the consent x consent rate interaction term, indicating no significant difference in slopes between consenters and non-consenters.

Please insert Table 3 about here

In Table 4, outcomes for the total population of non-consenters and consenters, as well as the corresponding biases and relative biases are shown, based on the full interaction model of Table 3 at total (consenters and non-consenters) average values for covariates. Relative biases of more than 10% were found only for consent rates of 50% or lower, mainly in the German-speaking sample having even lower consent rates (with the single exception of >= 21 drinks/week in French-speaking conscripts). In models with significant effects of consenting (non-shadowed in Table 4), bias decreased with increasing consent rates (in bold). Only for three substance use variables (non-smokers, daily smokers and cannabis non-users among French-speaking conscripts) did bias increase with increasing consent rates.

Please insert Table 4 about here

Discussion

The present study examines differences in substance use outcomes between consenters and non-consenters in a substance use survey. A unique advantage is that more than 94% of the informed participants filled out a five-minute questionnaire on substance use, thus constituting a near-census on which consenters can be compared with non-consenters. A second advantage is the enrolment of consenting participants over the course of one year, allowing a comparison of weeks having both low and high consent rates to determine whether non-consent bias varied as a function of non-consent rates.

There were overall substance use differences between non-consenters and consenters. As hypothesized, non-consenters commonly showed higher substance use patterns, pointing to the sensitivity of the topic. This suggests that the need for informed consent required by the ethical standards of research may introduce an underestimation of substance use outcomes. Similar findings of biases introduced through consenting procedures have been found in the medical literature (Al-Shahi et al., 2005; Junghans et al., 2005; Neumark et al., 2001). To our knowledge, this is one of the first studies looking at the effects of consenting on substance use outcomes.

However, it is not clear whether this bias is arising from the consent requirement itself or whether it is related to a more general feature, i.e., the sensitivity of the topic. Indeed, substance use is often considered to be a sensitive topic, and this sensitivity is often associated with both higher non-response rates and non-response bias (Bradburn and Sudman, 1979; Tourangeau and Yan, 2007). Although the current literature on substance use is somewhat mixed, some studies supported our findings that non-respondents are heavier drinkers (e.g., McCoy et al., 2009; Wild et al., 2001), more often smokers (e.g., Goldberg et al., 2006; Korkeila et al., 2001), and more likely to be cannabis users (Zhao et al., 2009). Requiring consent may strengthen the negative effect of topic sensitivity on non-response bias. Overall,

in the present study differences between consenters and non-consenters were not large and were non-significant for many variables. This may mean that the process of consenting may not add much additional bias over that of topic sensitivity, and also that topic sensitivity (at least among young men) is not a major factor in the reporting of substance use.

Three additional findings may support the view that asking for consent does not add a substantive additional bias. First, there were large differences in consent rates between German- and French-speaking conscripts, pointing to aspects other than substance use patterns influencing non-consent (e.g., cultural factors). Although we do not have scientific evidence, a common view in Switzerland is that germanophones are more difficult to convince to sign contracts, but then more closely stick to them, whereas francophones have a more laissez-faire attitude in entering into agreements, but break them more easily. Some research has shown that a major barrier to consent giving is that informed consents are seen as contracts, or formal agreements between participants and researchers, not as prerequisites of participation (Murphy et al., 2009). These cultural differences in viewing informed consent statements as binding contracts versus informal initial agreements may explain the differences in consent rates in our study. It also points out the possibility that factors other than topic sensitivity are more relevant, and that findings among participants may not be severely biased regarding substance use. Second, there were also seasonal variations in consent rates; the lowest were in winter, which could mean that a general sense of well-being that is higher in warmer months may affect participation, and is not related to the sensitivity of topics.

Third, the difference between consenters and non-consenters did not increase with increasing consent rates. This is commonly interpreted to mean that not only “good” or “bad” subjects were additionally included in the increasing pool of consenters, but that both were included.

The hypothetical extremes of non-response theory assume that for sensitive topics with increasing response rates the difference between respondents and non-respondents increases, and decreases for non-sensitive topics. The variations in estimates with varying consent rates were quite small and therefore are probably reflective of topics that were neither highly sensitive nor non-sensitive.

We interpret our findings to mean that analyses determining associations between substance use and other variables are not overly influenced by consent rates, because the composition of consenters does not dramatically change. In other words, the potential bias in associations is not exaggerated or minimized by low or high consent rates, at least not within a reasonable range of consent rates. Similar findings have been obtained in research on response rates, challenging the view that increased response rates alter survey estimates (Groves and Peytcheva, 2008; Keeter et al., 2000; Merkle and Edelman, 2002). Therefore, given that response rates in general are diminishing (de Leeuw and de Heer, 2002), to make extraordinary or extreme efforts to improve these rates would unnecessarily increase survey costs. Instead, funds might be more efficiently used to improve the quality of responses from participants.

However, a rather stable difference between consenters and non-consenters at varying consent rates does not mean that there is no effect of these rates on bias. Non-consent bias is the difference between consenters and non-consenters multiplied by the non-consent rate (Biemer and Lyberg, 2003). Thus, if there is a (stable) difference between the two, bias decreases as consent rates increase.

Decreasing bias was found mostly among German-speaking conscripts having low consent rates. However, differences in relative bias were rather small in the French-speaking sample

(commonly <10% and mostly <5%) at consent rates of 50-80%. This may mean that a reasonable consent rate or response rate is needed, but that a substantial gain in sample representativeness may only be achieved if the top 20% of non-participants could be included. Currently, this appears to be an unrealistic goal.

One limitation of the present study is that not many variables other than substance use were available to explain differences between consenters and non-consenters. In addition, the environment of compliance within the recruitment centres may overshadow differences between consenters and non-consenters; conscripts may feel more obligated or pressured to participate, despite clear information that the study is independent of the army recruitment procedures and carries no penalty for refusing. However, this would not explain the difference between German- and French-speaking conscripts. In addition, although the five-minute questionnaire response rate was high (94%), it was not perfect and differences between consenters and non-consenters might have been larger if the remaining 6% had participated. The study is also restricted to young men only and cannot be generalized to both sexes or to older individuals. Finally, the study was conducted over the course of a year; other factors may have confounded both the substance use and the consent rates.

In conclusion, substance use surveys among this age group apparently are not heavily influenced by requiring consent and (within reasonable ranges) variations in consent rates have little impact on differences between consenters and non-consenters. Therefore, analytical studies of associations will still reach the same conclusions, provided consent rates are in a reasonable or customary range. Nevertheless, descriptive epidemiological studies (e.g., those focusing on prevalence rates) may be subject to bias, and higher consent or response rates are

recommended. The impact on bias is probably substantive only at very low consent rates that are mainly below 50%.

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Table 1. Participant characteristics by linguistic region and consent status

	French-speaking			German-speaking		
	consent	no consent	p-value	consent	no consent	p-value
Education						
% primary (9 years)	48.6	49.3	.072	75.5	73.4	<.001
% secondary vocational (12 years)	24.9	26.8		14.6	19.0	
% tertiary vocational and higher (e.g. university; 13 years or more)	26.5	23.8		9.9	7.6	
Urbanicity						
% urban (vs rural)	50.0	50.7	.633	31.8	31.2	.611
Season of enrolment						
% Winter	28.2	30.8	<.001	30.9	31.2	.067
% Spring	25.1	22.9		27.2	29.3	
% Summer	21.6	16.2		25.8	23.0	
% Autumn	25.1	30.2		16.2	16.5	

Note. All tests were Chi-squared tests..

Table 2. Means and prevalence of substance use outcomes by linguistic region and consent status and regression model for non-consenting

	Prevalence and means		Unadjusted model for no consent vs. consent			Adjusted model for no consent vs. consent		
	Consent	No consent	β	SE	*p*	β	SE	*p*
French-speaking								
Alcohol								
% Abstainers	10.9	12.5	0.15	0.09	.089	0.14	0.09	.130
% >= monthly RSOD, among drinkers	48.4	50.3	0.08	0.06	.222	0.08	0.06	.197
% >= 21 drinks/week, among drinkers	6.6	9.4	0.39	0.11	<.001	0.38	0.11	.001
# of drinks/week, among drinkers*$	1.40 (1.30)	1.47 (1.37)	0.07	0.04	.087	0.07	0.04	.076
Tobacco								
% Non-smokers	58.8	52.9	-0.24	0.06	<.001	-0.23	0.06	<.001
% Daily smokers, among smokers	71.0	78.1	0.38	0.10	<.001	0.39	0.10	<.001
# of cigarettes/day, among daily smokers*	13.14 (7.39)	13.94 (7.48)	0.80	0.36	.028	0.83	0.36	.022
Cannabis								
% Non-users	62.4	59.9	-0.10	0.06	.077	-0.11	0.06	.071
% > 1x/week, among cannabis users	34.2	41.4	0.31	0.09	.001	0.30	0.10	.001
# of use days/week, among cannabis users*	1.37 (1.61)	1.64 (1.70)	0.28	0.08	<.001	0.27	0.08	<.001
German-speaking								
Alcohol								
% Abstainers	6.6	8.0	0.21	0.10	.046	0.18	0.10	.090
% >= monthly RSOD, among drinkers	44.1	47.4	0.13	0.06	.018	0.13	0.06	.019
% >= 21 drinks/week, among drinkers	4.9	7.8	0.50	0.12	<.001	0.49	0.12	<.001
# of drinks/week, among drinkers*$	1.35 (1.33)	1.36 (1.40)	0.01	0.04	.826	0.01	0.04	.770
Tobacco								
% Non-smokers	58.0	50.3	-0.31	0.05	<.001	-0.31	0.05	<.001
% Daily smokers, among smokers	64.7	68.6	0.18	0.08	.034	0.17	0.09	.051
# of cigarettes/day, among daily smokers*	12.85 (6.67)	14.00 (7.23)	1.15	0.34	.001	1.20	0.34	.001
Cannabis								
% Non-users	65.9	65.6	-0.01	0.06	.837	-0.04	0.06	.458
% > 1x/week, among cannabis users	26.5	34.0	0.36	0.10	<.001	0.33	0.10	.001
# of use days/week, among cannabis users*	1.09 (1.47)	1.35 (1.59)	0.26	0.07	<.001	0.24	0.07	.001

Note. * Models use ordinary least square multiple regression models; $ number of drinks/week were logarithmized due to skewness of variable.

Consenting was coded 0; non-consenting was coded 1

Table 3 Multiple regression models of consenting and consent rate on substance use outcomes.

	Consent			Consent rate			Consent * consent rate		
	β_1	SE	*p*	β_2	SE	*p*	β_3	SE	*p*
French-speaking									
Alcohol									
Abstainers	0.127	0.078	.109	-1.242	0.514	.021	0.973	1.049	.360
>= monthly RSOD, among drinkers	0.073	0.059	.223	-0.466	0.485	.343	0.213	0.765	.782
>= 21 drinks/week, among drinkers	0.382	0.133	.007	-0.608	1.162	.604	0.798	1.510	.600
# of drinks/week, among drinkers*$	0.077	0.047	.107	-0.353	0.418	.405	0.671	0.574	.250
Tobacco									
Non-smokers	-0.264	0.068	.000	-0.471	0.391	.236	-1.160	0.739	.125
Daily smokers, among smokers	0.408	0.112	.001	-0.733	0.605	.233	1.985	1.183	.102
# of cigarettes/day, among daily smokers*	0.855	0.316	.010	4.160	1.846	.030	-3.624	3.733	.338
Cannabis									
Non-users	-0.130	0.061	.040	-0.217	0.491	.661	-0.850	0.780	.283
> 1x/week, among cannabis users	0.338	0.094	.001	1.734	0.825	.042	-0.216	1.078	.842
# of use days/week, among cannabis users*	0.290	0.073	.000	1.082	0.548	.056	-0.037	0.783	.963
German-speaking									
Alcohol									
Abstainers	0.228	0.126	.077	2.018	1.043	.059	-1.213	1.582	.447
>= monthly RSOD, among drinkers	0.133	0.051	.013	0.521	0.515	.316	-1.015	0.634	.116
>= 21 drinks/week, among drinkers	0.475	0.146	.002	0.735	1.155	.528	-2.495	1.735	.157
# of drinks/week, among drinkers*$	0.007	0.039	.850	0.063	0.421	.882	-0.384	0.476	.423
Tobacco									
Non-smokers	-0.304	0.051	.000	-0.222	0.489	.652	1.100	0.596	.072
Daily smokers, among smokers	0.153	0.077	.053	-1.196	0.670	.081	1.843	1.037	.082
# of cigarettes/day, among daily smokers*	1.196	0.363	.002	-0.180	3.646	.961	0.361	4.108	.930
Cannabis									
Non-users	-0.023	0.060	.700	0.716	0.437	.108	-0.258	0.638	.688
> 1x/week, among cannabis users	0.327	0.117	.008	0.770	0.894	.394	-1.572	1.444	.282
# of use days/week, among cannabis users*	0.236	0.078	.004	0.391	0.543	.475	-0.893	0.939	.347

Note. * Models use ordinary least square multiple regression models; $ number of drinks/week were logarithmized due to skewness of variable. Consenting was coded 0; non-consenting was coded 1

Table 4. Estimated* population totals (consenters and non-consenters), biases and relative biases based on the full interaction model of consent status, consent rate and interaction between consent status and consent rate

		French-speaking consent rate			German-speaking consent rate		
		50%	65%	80%	20%	40%	60%
Alcohol							
Abstainers	Population total*	12.6%	11.3%	9.7%	**6.1%**	**7.0%**	**8.8%**
	Bias	0.3%	-0.3%	-0.4%	**-2.0%**	**-1.0%**	**0.0%**
	Relative bias	2.7%	-2.6%	-4.4%	**-32.5%**	**-13.8%**	**-0.4%**
>= monthly RSOD, among drinkers	Population total*	51.1%	49.5%	47.7%	**48.2%**	**45.9%**	**45.7%**
	Bias	-0.4%	-0.6%	-0.5%	**-7.08%**	**-2.31%**	**0.48%**
	Relative bias	-0.8%	-1.1%	-1.0%	**-14.7%**	**-5.0%**	**1.0%**
>= 21 drinks/week, among drinkers	Population total*	7.9%	7.4%	6.6%	**9.3%**	**6.5%**	**5.4%**
	Bias	-0.8%	-0.9%	-0.6%	**-5.2%**	**-1.8%**	**-0.1%**
	Relative bias	-10.4%	-11.6%	-9.7%	**-56.2%**	**-27.9%**	**-1.1%**
# of drinks/week, among drinkers*[$]	Population total*	1.45	1.44	1.40	1.41	1.35	1.33
	Bias	0.03	-0.02	-0.03	-0.07	-0.01	0.02
	Relative bias	1.9%	-1.1%	-2.1%	-5.3%	-0.7%	1.8%
Tobacco							
Non-smokers	Population total*	60.7%	57.6%	55.8%	**48.5%**	**53.4%**	**56.2%**
	Bias	0.5%	1.8%	1.9%	**10.8%**	**4.9%**	**1.1%**
	Relative bias	0.7%	3.2%	3.4%	**22.4%**	**9.1%**	**1.9%**
Daily smokers, among smokers	Population total*	74.5%	74.3%	72.2%	66.9%	67.6%	64.9%
	Bias	-0.2%	-2.1%	-2.2%	4.4%	-1.5%	-4.3%
	Relative bias	-0.3%	-2.8%	-3.1%	6.6%	-2.2%	-6.6%
# of cigarettes/day among daily smokers	Population total*	**13.09**	**13.31**	**13.67**	**13.75**	**13.54**	**13.29**
	Bias	**-0.79**	**-0.35**	**-0.09**	**-0.89**	**-0.71**	**-0.50**
	Relative bias	**-6.1%**	**-2.7%**	**-0.7%**	**-6.5%**	**-5.3%**	**-3.8%**
Cannabis							
Non-users	Population total*	63.9%	62.0%	60.9%	63.1%	65.5%	68.3%
	Bias	-0.4%	0.8%	1.1%	-0.6%	0.2%	0.6%
	Relative bias	-0.6%	1.2%	1.7%	-1.0%	0.4%	0.9%
> 1x/week, among cannabis users	Population total*	**30.5%**	**34.7%**	**39.3%**	**34.4%**	**30.5%**	**29.5%**
	Bias	**-4.0%**	**-2.8%**	**-1.5%**	**-11.2%**	**-4.5%**	**-0.4%**
	Relative bias	**-13.2%**	**-8.1%**	**-3.9%**	**-32.6%**	**-14.8%**	**-1.3%**
# of use days/week, among cannabis users	Population total*	**1.30**	**1.41**	**1.53**	**1.36**	**1.24**	**1.20**
	Bias	**-0.14**	**-0.10**	**-0.05**	**-0.34**	**-0.15**	**-0.03**
	Relative bias	**-11.4%**	**-7.2%**	**-3.7%**	**-25.6%**	**-12.4%**	**-2.6%**

Note. Shaded areas: no significant effects for consenting (see Table 3). Bold: monotonic decrease in bias. [$] number of drinks/week were logarithmized due to skewness of variable. * models were evaluated at total (consenters and non-consenters) averages of adjustment variables urbanicity, season, education, short questionnaire rate.