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Substance use in the Oslo nightlife setting: Study protocol for a cross section time-series using biological markers, self-reporting and qualitative data

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Complete List of Authors:	Nordfjaern, Trond; Norwegian Institute for Alcohol and Drug Research, Department of Narcotics Edland-Gryt, Marit; Norwegian Institute for Alcohol and Drug Research, Department of Narcotics Bretteville-Jensen, Anne Line; Norwegian Institute for Alcohol and Drug Research, Department of Narcotics Buvik, Kristin; Norwegian Institute for Alcohol and Drug Research, Department of Narcotics Gripenberg, Johanna; Norwegian Institute for Alcohol and Drug Research, Department of Narcotics
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STUDY PROTOCOL

Substance use in the Oslo nightlife setting: Study protocol for a cross section time-series using biological markers, self-reporting and qualitative data

Trond Nordfjærn [1*], Marit Edland-Gryt[1], Anne Line Bretteville-Jensen[1], Kristin Buvik[1] and Johanna Gripenberg[1]

* Correspondence: tn@sirus.no

[1] Norwegian Institute for Alcohol and Drug Research, Department of Narcotics, Øvre slottsgate 2 B, NO-0157, Oslo, Norway.

Abstract

Introduction: Substance use in the nightlife setting carries risks for negative consequences. The aim of this study is to investigate the prevalence of substance use as well as to investigate the characteristics of users in the Oslo nightlife context by using self-report, biological markers and qualitative data. In addition, we will examine the motives, consequences and culture surrounding substance use, and compare self-reported substance use with oral fluid test (OFT) results.

Methods and analyses: Data collection will be conducted among patrons (n = 1000) outside 12-15 premises by semi-random sampling. The patrons will be asked to anonymously complete a questionnaire, provide a breath alcohol concentration (BAC) test and an OFT. Patrons who report use of illicit substances in the previous 12 months will be asked to leave their contact information for a later semi-structured interview (n = 35). In addition, staff at licensed premises (n = 500) will be asked to participate in a survey during Responsible Beverage Service Training. Survey data will be analyzed by uni-variate and multivariate statistical methods and the oral fluid will be analyzed for a large number of substances using biochemical methods. Data collection will be repeated on a biannual basis until at least 2020, allowing for examinations of trends in substance use.

Ethics and dissemination: The study has been approved by the Regional Committee for Medical and Health Research Ethics (application 2014/192). Results will be disseminated in research journals, conferences and the media.

Discussion: We expect the study to reveal crucial information about the prevalence of substances used in the Oslo nightlife setting, and characteristics of users. We also anticipate the results to display important information about motives and consequences of nightlife substance use. The findings may facilitate joint work with the authorities and the nightlife industry to implement community-based club drug prevention programmes.

Key words: nightlife, saliva, blood alcohol level, alcohol, illicit substance, club drugs

Strengths and limitations of this study

- A rich supply of data from a high risk group in a high risk setting, including biological measures, self-reports and qualitative data
- Both cross-sectional and time series data
- Likely to yield results with high relevance for methodological development in the field
- Incorporates both nightclub patrons and staff
- Causal interpretations not possible
- Includes self-reports from intoxicated individuals

Introduction

Illicit and licit substance use in the nightclub setting is a potential public health problem that may need targeted interventions. Short-term consequences include increased risk of violence involvement, injuries, aberrant driving and risky sexual behaviour [1,2]. Adverse long-term effects may be the development of somatic or mental disease [3], occupational activity drop out (e.g. work or education) and ultimately addiction. Alcohol reduces prefrontal cortical activity and may as such increase the propensity to experiment with illicit substances. Nightclubs are common environments for adolescents and young adults to be introduced to illicit substances and to initiate use under the influence of alcohol [3]. The use of two or more substances, i.e. polysubstance use, increases the risk of negative public health effects even further [4,5].

Traditionally, the prevalence of adolescent recreational substance use has been examined by surveys conducted in schools or in the general population [e.g. 6,7]. These approaches may not have effectively reached the target population as adolescents or young adults with high recreational substance use are not necessarily present in school settings, or may fail to respond to population surveys. Young individuals with a strong propensity to use substances are likely to actively seek out the nightlife setting. Therefore it could be more feasible to reach out to these individuals in this context. Furthermore, previous surveys have tended to only include self-reporting which may be skewed towards socially desirable responses. Also, the fact that the surveys have been subject to decreasing response rates could challenge the ecological validity of results.

Recent advances in the field of substance testing allow for unobtrusive and efficient collection of oral fluid tests (OFT) to examine the presence of a range of substances, such as cocaine, amphetamines, cannabis and the new psychoactive substances (NPS) [8]. This method has

clear-cut advantages over self-reporting where both over- and underreporting is common. The present study will have a specific focus on NPS and a broad initial test repertory including a total of 122 different substances will be applied to investigate the prevalence of these substances and the 'classic' substances (e.g. cannabis, cocaine and amphetamines) among nightclub patrons.

There are relatively few studies which have combined OFT and self-reports of substance use, but some studies suggested considerable underreporting on questionnaires when compared to OFT results [e.g. 9]. Previous work on the prevalence of substance use in nightlife has also tended to focus on special events such as electronic music dance events (EMDE) [9-11] or has been carried out in specific settings, such as gay clubs [e.g. 12]. Further, few previous studies have incorporated multiple sources of data including qualitative semi-structured interviews, and the majority of previous studies were conducted at one point in time, which excludes the possibility for examinations of temporal trends in substance use. There is also a lack of research including nightclub staff into the empirical taxonomy. The present study will advance previous studies by investigating licit and illicit substance use in a large pool of different nightclubs, including both patrons outside the clubs and staff enrolled in Responsible Beverage Service (RBS) Training. We will also use multiple sources of data from self-reporting, biological and qualitative data coupled with multiple measurement waves (time-series).

Research objectives

The main aim of the current study is to examine the prevalence of substance use and the characteristics of users in the Oslo nightlife setting. We also aim to investigate motives, consequences and the culture surrounding substance use in this setting. An additional aim is to compare self-reported substance use with OFT results in order to test the validity of different methods for measuring substance use in this context. The findings are expected to

yield information that will be used to establish adequate community-based interventions in the nightlife setting.

Methods and Analysis

The present study will obtain four types of data: (1) cross-sectional survey data from nightclub patrons, (2) cross-sectional biological data from nightclub patrons, (3) cross-sectional survey data from nightclub staff, and (4) data from individual semi-structured interviews (see also Figure 1). Data collection 1-3 will be repeated bi-annually.

Procedures

Cross-sectional patron survey

Cross-sectional data will be collected from a sample of patrons close to the entrance or by the entrance of strategically selected nightclubs. In order to establish a sample that covers the broad spectrum of different nightclubs in downtown Oslo, we will obtain a complete list of licensed premises from the municipality administration. The list will be reviewed by an expert group of relevant authorities. Premises that clearly do not match the inclusion criteria will be excluded. A total of 12-15 nightclubs will be selected from the reduced list by the experts, using the following criteria: (1) popular and frequently visited nightclubs with peak hours between 23.00 p.m. and 03.00 a.m., (2) premises with geographic spread in central downtown Oslo, (3) a focus on the 'party factor', dancing and alcohol consumption and (4) premises with different profiles and patron characteristics. Similar approaches have been used to select nightclubs for studies in Europe [13], the United States [14], and Australia [15].

The data collection will be conducted by semi-random sampling of patrons (n = 1000) outside the 12-15 selected premises. Research stations are going to be located close to the selected nightclubs and an imaginary line demarking the selection point will be set. Participants are

going to be selected when they cross the line and enter the selection area. When the person is part of a group, the whole group will be asked to participate. A total of 20 research assistants will conduct the survey. They will receive training in recruitment and on the study procedures. The assistants will be divided into four groups (five people in each group) and the data collection will be conducted from 23.00 p.m. – 04.00 a.m. at Fridays and Saturdays.

The respondents will first be asked to give a breath alcohol test and thereafter be asked to complete a questionnaire and provide an OFT. The data collection process, including the OFT and breath alcohol test, will be explained to the respondents before they give their consent to participate. If requested, assistance to fill out the questionnaire will be provided. Gender and estimated age of non-respondents will be registered on a dedicated form. The questionnaire will contain a unique serial number for each respondent and the OFT samples will be given a corresponding number. The BAC level measured by a breathalyzer will be noted on each individual questionnaire. The questionnaires as well as the BAC tests, OFT procedures (n = 80) and individual interviews (n = 5) will be pilot tested among relevant user groups before data collection commences.

Cross-sectional staff survey

Nightclub staff (n = 500) at licensed premises attending RBS-training (n = 30 courses) will be asked to participate in an anonymous survey in a classroom setting. Norwegian municipalities arrange RBS-training on a regular basis, where the majority of the participants are nightclub staff. Participants will complete the survey during the RBS-training.

Time series

To establish time series data we will repeat the survey biannually until 2020 with new samples of about 600 nightclub patrons and 200 licensed premises staff using the same methods as described above.

Individual semi-structured interviews

The study will also include semi-structured individual interviews (n = 35). We will ask nightclub patrons who report use of illicit drugs in the previous 12 months, to leave their phone number to be contacted later for an individual semi-structured interview. The patrons will be contacted by the person who will conduct all the interviews, and will be able to choose where and when they wish to be interviewed. They may also decline to be interviewed if they have changed their mind. The patrons will be informed about the voluntary nature of the interviews, that they can withdraw their consent and have their data deleted at any point in time. The interviews will particularly focus on use of MDMA, ecstasy, cocaine and NPS, and informants who report use of these substances will be purposefully selected to the interviews. We will obtain consent for the interviews to be recorded. The interviews will be recorded by a digital recorder, and are expected to last for 1-2 hours. The recorded interviews will later be transcribed into text.

Assessment

Questionnaire

The patron questionnaire will contain demographic items such as gender, age, and employment status. It will also include questions about the frequency of substance use during respondents' lifetime, the last year, the last month, and the last 48 hours. The list of substances will include alcohol, cannabis, NPS, amphetamines, cocaine, LSD, heroin, ecstasy/MDMA as well as anabolic steroids. We will also include a dummy substance (MOP)

in order to examine the validity of self-reporting and extent of over-reporting. The respondents will also be questioned about the age of onset for each substance. In addition, the questionnaire will include a section to record the participants' BAC level yielded by the breathalyzer.

Oral fluid will be collected from patrons using the Orasure Intercept Oral Fluid Drug Test™. The device is composed of a sampling pad made of cotton on a plastic stick. The cotton pad is placed under the tongue for a few minutes to collect saliva. The test is thereafter transferred to a plastic tube, which contains a buffer with a preservative. The samples (plastic tube with the sampling pad) will be kept cold (2-8°C) until delivered to the analytical laboratory where they will be frozen. The sample will be analyzed for a large number of drugs using liquid chromatography with tandem mass spectrometry detection. In the pilot study we will use an extended test repertory including 122 substances covering the 'classic' substances as well as the NPS. The final test repertory will be derived from the substances detected in the pilot study and the substances from recent seizures by the Norwegian customs services. Patrons' BAC levels will be measured by using the Lion Alcolmeter™ 500, which is a high validity breathalyzer.

The survey methodology that we will use to collect data among staff at nightclubs has been developed and tested by researchers in Sweden [13]. Similar procedures and a somewhat adjusted questionnaire will be used in this study. The survey will include four sections: demographics, respondents' own alcohol and substance use experience, respondents' attitudes towards illicit substance use and observed substance use among guests at licensed premises. Both patron and staff questionnaires will be translated to English and used for respondents without proficiency in Norwegian.

Semi-structured interviews

The interview guide will aim to explore central themes regarding attitudes, motivations and experiences related to use of alcohol and illicit substances, with a particular focus on MDMA, ecstasy, cocaine and NPS. The patrons will be encouraged to speak freely, and the interview guide is prepared to make sure that important relevant topics are covered. Two core topics will be accommodated into the guide. The first topic will be motivation for illicit substance use. This section will dwell into positive and negative psychological (e.g. reducing distress and tension, enhanced positive mood), social (e.g. peer pressure and social enhancement), somatic (e.g. increased physical performance), and contextual (e.g. lack of alternative rewarding activities to substance use) factors underlying use. Open-ended questions regarding specific situations and states that may increase patrons' tendency to use illicit substances, will also be included. This component will focus particularly on shared norms, values and beliefs between the individual and peers (i.e. cultural factors), which could be relevant for the use of illicit substances. The second core topic will focus on positive and negative consequences of illicit substance use. This section includes questions related to perceived consequences of the illicit substances on mental and somatic health, social relationships, and contextual factors, such as work and educational activities.

Analyses

Univariate analyses will be used to describe the samples and to assess the prevalence of substance use. Independent samples t-tests and chi-square (χ^2) analyses will be conducted as appropriate to compare gender and age characteristics among respondents and non-respondents. Multivariate quantitative approaches, including regression analyses and Structural Equation Modelling (SEM), will be undertaken in order to assess associations between a wide-range of characteristics with substance use.

Ethics and dissemination

The study has been approved by the Regional Committee for Medical and Health Research Ethics (application No. 2014/192). The survey and biological markers will be collected anonymously, and written informed consent will be obtained for the semi-structured interviews. The results from the study will be disseminated in high quality international peer-reviewed journals, research conferences, granted reports and the media.

Discussion

Due to the potentially adverse short- and long-term effects of substance use in the nightlife setting it is crucial to obtain more knowledge about the prevalence of use and characteristics of users. Traditionally prevalence studies in this context have relied solely on the survey method. This study will investigate the use of illicit substances and alcohol in the Oslo nightlife setting using a combination of self-reporting, biological markers and qualitative data. To our knowledge this is one of the first studies that examines substance use in the nightclub setting by time series, a combination of different data collection methods, and with a large pool of nightclubs with different characteristics. Interventions have the potential to reduce the probability of somatic diseases and injuries. Interventions could also prevent young individuals from developing substance use disorders and may reduce the load in specialized treatment for substance use disorders. If the study results reflect substantial substance use in the Oslo nightlife context, the results may form the basis for community-based interventions.

Strengths and limitations

The study design has several strengths including triangulation between data sources, a large sample size reflecting the broad nightlife in central downtown Oslo, and a semi-random procedure to recruit patrons. Further, we are not aware of any nightlife studies that have utilized time series, enabling investigations of temporal trends in substance use. Our study

will also help to determine the feasibility of using biological samples for future nightlife research. Use of biological samples may reveal more accurate results than merely applying self-reporting. The use of qualitative data will allow in-depth investigations of the cultural contexts where substances are used and will provide important information about motivation and perceived consequences to be incorporated into potential interventions.

Possible limitations of this study include the cross-sectional nature of data, which does not allow for conclusions about causality or temporal relations between variables. However, we will mainly use quite stable characteristics (e.g. demographics) linked to the relevant outcomes. The fact that individuals might be intoxicated when they complete the questionnaire warrants cautious interpretations of the data, but this limitation is mitigated by the inclusion of biological measures which will yield objective data about substance use.

Implications for interventions and future policy

This study will be the first to provide data on the prevalence of substance use in the Oslo nightlife setting. It will also identify characteristics among individuals who are more likely to use high amounts of a range of substances, enabling targeted interventions. If the prevalence turns out to be substantial, the findings may facilitate collaboration work with the health authorities and the nightlife industry to establish adequate countermeasures. A general tendency in the nightlife context in Oslo has been to implement measures aimed at reducing alcohol consumption, whereas there has been less focus on illicit substance use. For example, studies have been conducted where professional actors have been trained to act influenced by alcohol to study the frequency of alcohol service to obviously intoxicated patrons [16-18]. Similar research with actors portraying to be intoxicated by illicit substances has only been conducted in Sweden [19,20]. In addition, the results can shape the basis for planning and implementing club drug prevention programs. An example of a community-based club drug

intervention in the nightlife setting is the "Clubs against Drugs" program in Sweden. This multi-component intervention combined community mobilization, training, policy work, enforcement, environmental changes, media advocacy and public relations work [3].

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

TN, ALB, MEG, and JG designed the study. KB contributed to the design of the study. TN wrote the study protocol with substantial critical input from all co-authors. All authors read and approved the final version of the manuscript.

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Figure:

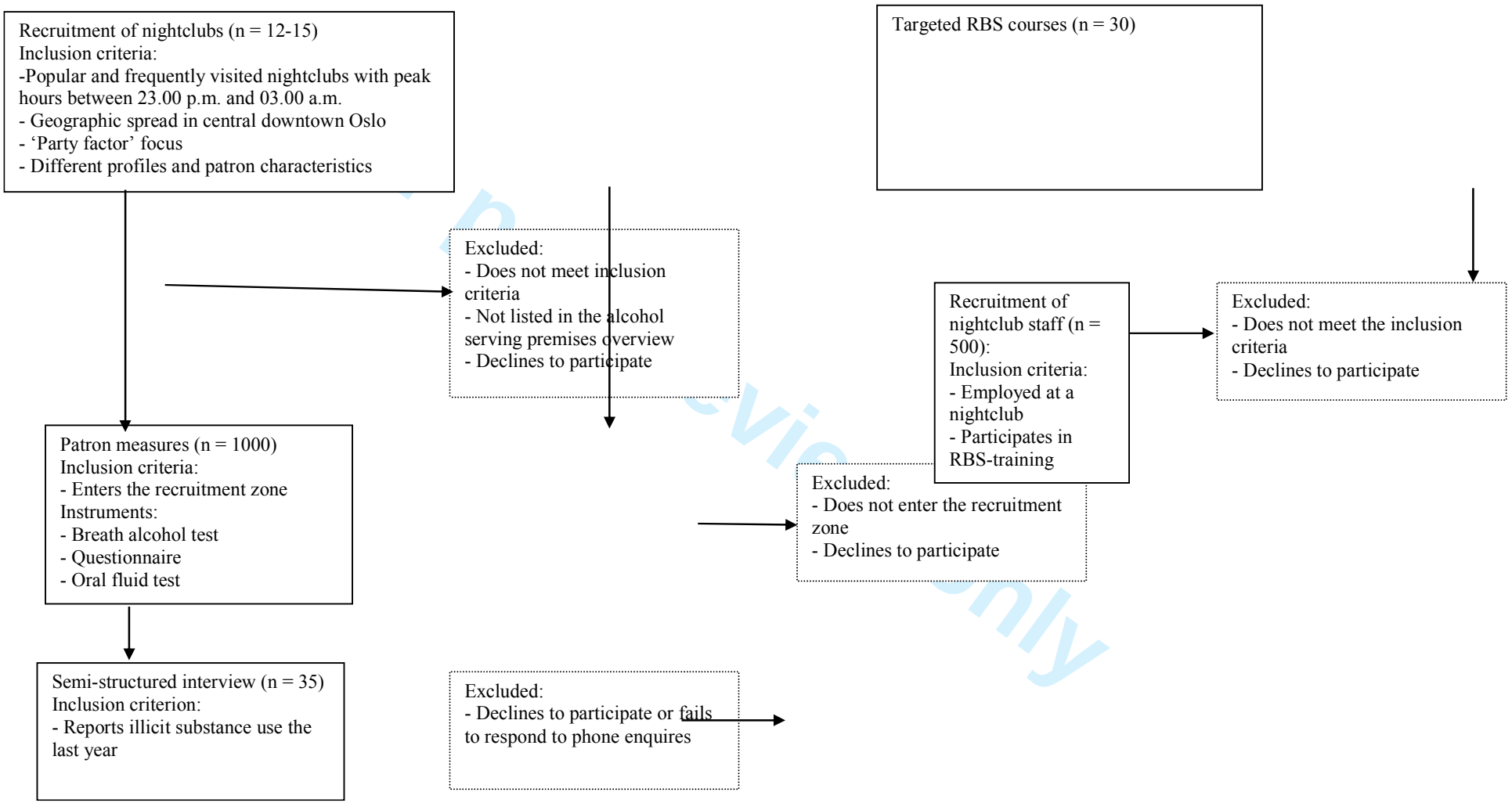

Figure 1. Flow chart of the study design

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Recreational drug use in the Oslo nightlife setting: Study protocol for a cross sectional time-series using biological markers, self-reported and qualitative data

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Keywords:	Nightlife, Blood Alcohol Level, Recreational drug use, Club drugs, licensed premises, oral fluid drug testing

STUDY PROTOCOL

Recreational drug use in the Oslo nightlife setting: Study protocol for a cross sectional time-series using biological markers, self-reported and qualitative data

Trond Nordfjærn [1*], Marit Edland-Gryt[1], Anne Line Bretteville-Jensen[1], Kristin Buvik[1] and Johanna Gripenberg[1]

* Correspondence: tn@sirus.no

[1] Norwegian Institute for Alcohol and Drug Research, Department of Narcotics, Øvre Slottsgate 2B, NO-0157, Oslo, Norway.

Abstract

Introduction: Recreational drug use in the nightlife setting carries the risk of many negative consequences, such as violence, injuries, aberrant driving and sexual risk-taking. The aim of this study is to investigate recreational drug use and user characteristics among people visiting licensed premises e.g., nightclubs and bars, by using self-reports and biological markers. Staff of licensed premises will be asked to report drug use observations. Further, by using qualitative data, we will examine the motives, consequences and culture associated with recreational drug use. An additional aim is to compare self-reported drug use with oral fluid test (OFT) results in order to validate the different measurement methods in this context.

Methods and analyses: Data collection will be conducted among patrons (n=1000) outside licensed premises. Upon consent, patrons will be asked to anonymously complete a questionnaire, a breath alcohol concentration (BAC) test and an oral fluid test (OFT). Patrons who report use of recreational drugs in the previous 12 months will be asked to leave their contact information for a subsequent qualitative in-depth interview (n=30-40). Staff from licensed premises (n=500) will be invited during Responsible Beverage Service Training to participate in an anonymous survey. Survey data will be analyzed by univariate and multivariate statistical methods and the oral fluids will be analyzed for a large number of drugs using biochemical methods. Cohen's Kappa (κ) will be used as a measure of agreement between self-reported drug use and OFT. In depth-interviews will be coded in HyperRESEARCH and analyzed using an inductive approach. Data collection will be repeated on a biannual basis until at least 2020, allowing for examination of trends in recreational drug use.

Ethics and dissemination: This study has been approved by the Regional Committee for Medical and Health Research Ethics. Results will be disseminated in research journals, conferences and the media.

Key words: nightlife, blood alcohol level, recreational drug use, club drugs, licensed premises, oral fluid drug testing

Strengths and limitations of this study

- A rich supply of data from a high-risk group in a high-risk setting, including biological measures, self-reports and in-depth qualitative data
- Both cross-sectional and time series data
- Likely to yield results with high relevance for methodological development in the field
- Provide a better understanding of the culture associated with recreational drug use
- Both patrons and staff of licensed premises
- Causal interpretations not possible
- Includes self-reports from intoxicated individuals

Introduction

Recreational drug use in the nightlife setting is potentially a public health problem that requires targeted interventions. Short-term consequences include increased risk of violence, injuries, aberrant driving and risky sexual behaviour [1,2]. Adverse long-term effects may be the development of somatic or mental disease [3], occupational activity drop out (e.g. work or education) and ultimately addiction. Alcohol reduces prefrontal cortical activity which may in turn increase the propensity to experiment with recreational drugs. Licensed premises (e.g., nightclubs, bars) are common environments for young adults to be introduced to recreational drugs and to initiate use under the influence of alcohol [3]. The concurrent use of two or more substances, i.e. polysubstance use, increases the risk of negative public health effects even further [4,5].

Traditionally, recreational drug use among young adults (i.e. individuals aged 18-30 years) has been examined by surveys conducted in schools/universities or in the general population [e.g. 6,7]. These approaches may not have effectively reached the target population because young adults with high recreational drug use are not necessarily present in school/university settings, or may fail to respond to population surveys. Young adults with a strong propensity to use drugs are likely to actively seek out the nightlife setting [3]. Therefore it could be more feasible to

reach out to these individuals in this context. Furthermore, previous surveys have tended to only include self-reported data, which are potentially skewed towards socially desirable responses. Also, the fact that response rates to surveys have been decreasing could challenge the ecological validity of results.

Recent advances in the field of drug testing allow for unobtrusive and efficient collection of oral fluid tests (OFT) to examine the presence of a range of drugs. This method has significant advantages over self-reporting, where both over- and underreporting are common. OFT can detect drugs such as cocaine, amphetamines, cannabis and the new psychoactive substances (NPS) [8]. NPS are psychoactive drugs that could represent a public health risk similar to the more traditional drugs. Some NPS are not (yet) prohibited by law in several countries [9,10]. Our study will have a specific focus on the use of NPS and a broad initial test repertory of 122 different drugs, including 'classic' drugs (e.g. cannabis, cocaine and amphetamines).

There are relatively few studies which have combined OFT and self-reports of recreational drug use. Some of these studies suggested considerable underreporting on questionnaires when compared to OFT results [e.g. 11]. Previous work regarding recreational drug use in nightlife settings has also tended to focus on special events such as electronic music dance events (EMDE) [11-13] or has been carried out in specific settings, such as gay clubs [e.g. 14]. Further, few previous studies have incorporated multiple sources of data including qualitative in-depth interviews, and the majority of previous studies were conducted at one point in time, which excludes the possibility for examinations of temporal trends in recreational drug use. There are also few studies including licensed premises staff. The present study will advance previous studies by investigating recreational drug use in a large pool of different licensed premises, including both people participating in the nightlife setting and staff enrolled in Responsible Beverage Service (RBS) Training. Thus, we will approach the phenomenon by using multiple

sources of data, i.e. self-reporting, biological and qualitative data, coupled with multiple measurement waves (time-series).

Research objectives

The main aim of our study is to examine recreational drug use and the characteristics of users in the Oslo nightlife setting. We also aim to investigate motives, consequences and the culture surrounding recreational drug use in this setting. An additional aim is to compare self-reported drug use with OFT results in order to test the validity of different methods for measuring recreational drug use in this context. The findings are expected to yield information that will be used to establish adequate community-based interventions in the nightlife setting.

Methods and Analysis

During the study we will obtain four types of data: (1) cross-sectional survey data from patrons outside licensed premises, (2) cross-sectional biological data from patrons outside licensed premises, (3) cross-sectional survey data from staff at licensed premises, and (4) data from individual qualitative in-depth interviews (see also Figure 1). Data collection 1-3 will be repeated bi-annually until 2020.

Procedures

Cross-sectional patron survey

Cross-sectional data will be collected from a sample of patrons close to the entrance of strategically selected licensed premises. A modified portal survey methodology will be used, where data will be collected once for each participant, instead of twice (upon entering and exiting licensed premises) as done in previous work [15,16]. Our aim is to increase our

knowledge about recreational drug use in the nightlife setting, rather than knowledge about drug intake inside licensed premises, which is why we have chosen this modified method.

In order to establish a sample that covers the broad spectrum of the nightlife setting in downtown Oslo, we will obtain a complete list of licensed premises from the municipality administration. The list will be reviewed by an expert group of relevant authorities. Premises that clearly do not match the inclusion criteria will be excluded. A number of licensed premises will be selected by the experts, using the following criteria: (1) popular and frequently visited licensed premises with peak hours between 11 p.m. and 3 a.m., (2) premises with geographic spread in central downtown Oslo, (3) a focus on the 'party factor', e.g., dancing and high alcohol consumption and (4) premises with different profiles and patron characteristics. A sort of "ethnographic mapping" [17,18] will also be used to ensure that the clubs match the criteria. Similar approaches have been used to select licensed premises for studies in Europe [17,19], the United States [20], and Australia [21]. For the biannual follow-up studies, the same inclusion criteria will be used to select licensed premises.

A total of 20 research assistants will conduct the data collection. They will receive training in recruitment and on the study procedures. The assistants will be divided into four groups (five people in each group) and the data collection will be conducted from 11 p.m. – 4 a.m. on Fridays and Saturdays.

Data collection stations are going to be placed close to the entrance of the selected licensed premises and an imaginary line will mark out a selection zone. As patrons cross the line, a research assistant will approach them and invite them to participate. They will offer patrons an informed consent statement, verbally and in writing. When the person is part of a group,

the whole group will be asked to participate. Previous research has found the refusal rate to be high when single people from a group are invited to participate[19].

Once patrons consent to participate in the anonymous study, they will be asked to give a breath alcohol test (BAC) and then be asked to complete a questionnaire and provide an OFT. Research assistants will help participants to fill out the questionnaire, if requested. We will record the gender and estimated age of persons who decline to participate. The questionnaire will contain a unique serial number for each respondent and the OFT samples will be given a corresponding number. The BAC level measured by a breathalyzer will be noted on each individual questionnaire. As the results from the breathalyzer will be instantly available, the participants will be informed about their BAC levels should they request it. Throughout the data collection process, the participants will be able to withdraw from the study. The questionnaires as well as the BAC tests, OFT procedures (n=80, respectively) and in-depth interviews (n=5) will be pilot tested among relevant user groups before formal data collection commences.

Cross-sectional staff survey

Staff (n=500) at licensed premises attending RBS-training (n=30 courses) will be asked to participate in an anonymous survey in a classroom setting. Norwegian municipalities arrange RBS-training on a regular basis, where the majority of the participants are staff at licensed premises. Participants will complete the survey during the RBS-training. The survey will include sections about personal characteristics, participants' observations of drug use at their work place, participants' drug use and their opinions on drug policy.

Time series

To establish time series data, we will repeat the survey biannually until 2020 using the same methods described above. That is, we will use the same criteria for selecting licensed premises and for recruiting participants. Further, we plan to keep the structure of the questionnaire unchanged although we may have to slightly adjust the questions if drug use changes.

Qualitative in-depth interviews

The study will also include individual in-depth interviews (n=30-40). We will ask study participants, who report use of recreational drugs other than alcohol within the previous 12 months, to voluntarily leave their phone number to be contacted later for an individual in-depth interview during the day. A similar method to recruit participants has previously been used elsewhere [17,18,22]. The patrons will be able to choose where and when they wish to be interviewed, though they can decline to participate at any time. They will receive a letter of confirmation, which will contain the name and contact details of the researcher. The patrons will be informed about the voluntary nature of the interviews, that they can withdraw their consent and have their data deleted at any point in time. The interviews will particularly focus on use of MDMA, ecstasy, cocaine, amphetamines and NPS, and informants who report use of these drugs will be purposefully selected to the interviews. We will obtain written consent for the interviews to be recorded. The interviews will be recorded by a digital recorder, and are expected to last for 1-2 hours. The participants will receive compensation of about 32€/300 NOK. The recorded interviews will be anonymously transcribed into text.

Assessment

Questionnaire

A questionnaire will be based upon variables found to be important in previous work [e.g. 11,12]. The patron questionnaire will contain demographic items such as gender, age, region of birth, education and employment status. It will also include questions about the frequency of recreational drug use during the respondents' lifetime, the last year, the last month, and the last 48 hours. The list of drugs will include alcohol, tobacco, cannabis, NPS (e.g. synthetic cannabis, legal highs, spice, research chemicals etc.), amphetamines, cocaine, LSD, heroin, ecstasy/MDMA as well as anabolic steroids. We will also include a dummy drug (MOP) in order to examine the validity of self-reporting and extent of over-reporting. The respondents will also be questioned about the age of onset for each drug. Further, the questionnaire will include variables such as the last year frequency of alcohol intoxication, the age of first alcohol intoxication experience and frequency of visits to licensed premises. In addition, the questionnaire will include a section to record the participants' BAC level yielded by the breathalyzer.

Oral fluid will be collected from patrons using the Orasure Intercept Oral Fluid Drug Test™. The device is composed of a sampling pad made of cotton on a plastic stick. The cotton pad is placed under the tongue for a few minutes to collect saliva. The cotton pad is then transferred to a plastic tube, which contains a buffer with a preservative. The samples will be kept cold (2-8°C) until delivered to the analytical laboratory where they will be frozen. The sample will be analyzed for a large number of drugs using liquid chromatography with tandem mass spectrometry detection.

For the pilot study we will use an extended test repertory including 122 drugs covering the 'classic' drugs as well as the NPS (see Table 1A). The list of 122 drugs was based on the

types of drugs found in Norway by the custom services as well as updated drug monitoring information. The final test repertory will be derived from the drugs detected in the pilot study and the drugs from recent seizures by the Norwegian customs services. Before new data collection waves are conducted, the oral fluid screening repertory will be critically reviewed and possibly revised. The repertory will be updated with new drugs based on seizures by police and customs as well as updated expert information about new drugs detected in Norway. Patrons' BAC levels will be measured by using the Lion Alcolmeter™ 500, which is a high validity breathalyzer.

The survey methodology that we will use to collect data from staff at licensed premises has been developed and tested by researchers in Sweden [19]. Similar procedures and a slightly modified questionnaire will be used in this study. The survey will include four sections: demographics, respondents' own alcohol and drug use experience, respondents' attitudes towards recreational drug use and observed drug use among guests at licensed premises. Both patron and staff questionnaires will be translated to English and used for respondents without proficiency in Norwegian.

Qualitative in-depth interviews

A semi-structured interview guide will be used to explore central themes regarding attitudes, motivations and experiences related to use of alcohol and recreational drugs, with a particular focus on MDMA, ecstasy, cocaine, amphetamine and NPS. The patrons will be encouraged to speak freely, and the semi-structured interview guide will ensure that two core topics are covered. The first topic will be motivation for recreational drug use. This section will delve into positive and negative psychological (e.g. reducing distress and tension, enhanced positive mood, unpleasant psychological feelings of 'coming down' from the drug), social (e.g. peer pressure and social enhancement), somatic (e.g. increased physical performance), and

contextual (e.g. lack of alternative rewarding activities to drug use) factors underlying use. Open-ended questions regarding specific situations and states that might increase a patrons' tendency to use recreational drugs will also be included. This component will focus particularly on shared norms, values and beliefs between the individual and their peers (i.e. cultural factors), which could be relevant to recreational drug use. The second core topic will focus on positive and negative consequences of recreational drug use. This section includes questions related to perceived consequences of drug use on mental and somatic health, social relationships, and work and educational activities.

Analyses

Univariate analyses will be used to describe recreational drug use and the characteristics of users. Multivariate quantitative approaches, including regression analyses, will be undertaken to assess associations between a wide range of characteristics and drug use. The Cohen's Kappa (κ) coefficient will be applied to test the correspondence between self-reported use and results from OFT. We will use time series analysis to investigate trends in drug use over time. Independent samples t-tests and chi-square (χ^2) analyses will be conducted as appropriate to compare gender and age characteristics among respondents and non-respondents.

The qualitative data will be analyzed using an inductive approach [23,24]. This means that predefined themes from the interview guide will be set aside to search for emerging themes from the interviews that the researcher had not specifically looked for. The patterns, categories and themes will be built from the "bottom-up", and organized into increasingly more abstract units of information [23]. The qualitative in-depth interviews will be analyzed after the transcribed text is coded in the HyperRESEARCH software. Some interviews will be coded by two different researchers, to ensure that the themes are coded in the same way, and to strengthen the validity in the study.

Ethics and dissemination

The study has been approved by the Regional Committee for Medical and Health Research Ethics (application No. 2014/192). The survey and biological markers will be collected anonymously, and written informed consent will be obtained for the semi-structured interviews only. The qualitative in-depth interviews will be conducted during the day, and so the participants will most likely not be under the influence of any substance when giving their written consent. Outside the licensed premises, an informed consent statement will be presented verbally and also offered in writing to all participants. Signatures will not be collected in order to maintain confidentiality. Identifying information will not be captured, and so it will not be possible for respondents to withdraw their consent after their data are collected and collated. During the process, however, the respondents will be free to retract their consent and have their response deleted.

For the qualitative in-depth interviews, ethical issues will be especially important to consider, as themes may be sensitive. It will be essential to acknowledge how the participants experience the interview situation, and at the end of the interview the researcher will always ask the participant how he or she felt about the interview experience. The participants will be given the option to see a clinical psychologist, free of charge if they wish to do so.

There are also situations in the data collection outside the lienced premises that potentially could raise ethical issues. Many of these issues have been raised and discussed in the application for the study to the Regional Committee for Medical and Health Research Ethics. One issue is the fact that many of the participants in this study will be under the influence of drugs and/or alcohol at the time we meet them outside the licenced premises. Therefore it will be important to train the research assistants in how to approach potential respondents, and how to deal with plausible situations that can occur. If the research assistants discover someone who

are extremlyintoxicated and at risk of harming him-/herself or others, they will be trained to call emergency care, such as the police or ambulance services. Each station outside licenced premises will have a team leader, and this person will have a specific responsibility for the security of the research team.

The results from the study will be disseminated in highly regarded international peer-reviewed journals, research conferences, granted reports and to the media.

Strengths and limitations

Due to the potentially adverse short- and long-term effects of drug use in the nightlife setting it is crucial to obtain more knowledge about recreational drug use and the characteristics of users. Earlier studies in this context have mostly relied on the survey method. This study will investigate the use of recreational drugs in the Oslo nightlife setting using a combination of self-reporting, biological markers and qualitative data. To our knowledge this is the first study that examines recreational drug use in the nightlife setting using this combination of different data collection methods, and recruiting participants from a large pool of licensed premises with different characteristics. The results may help derive community-based interventions to reduce use and harm.

The study design has several strengths including triangulation between data sources, and a large sample size reflecting the nightlife setting in central downtown Oslo. Our study will also help to determine the feasibility of using biological samples for future nightlife research. Use of biological samples may reveal more accurate results than self-reported data. The use of qualitative data will allow in-depth investigations of the cultural contexts where drugs are used and will provide important information about motivation and perceived consequences to be incorporated into potential interventions.

Possible limitations of this study include the cross-sectional nature of data, which does not allow for conclusions about causality or temporal relations between variables. However, we will mainly use quite stable characteristics (e.g. demographics) linked to the relevant outcomes. The fact that individuals might be intoxicated when they complete the questionnaire warrants cautious interpretation of the data. This limitation is mitigated by the inclusion of biological measures, which will yield objective data about recreational drug use.

Further, given the large number of new psychoactive substances (NPS) appearing on the illicit market, and the rapid changes in availability, it is possible that the oral fluids testing will miss some new psychoactive substances being used by the participants. As mentioned earlier, the drugs that will be tested for, will be determined by the results from the very broad spectrum of drugs used in the pilot test samples and also by the list of drugs being confiscated by police and customs in recent years. The likelihood of overlooking many NPS should be limited, as we would expect that a frequently used drug, would be confiscated by the authorities, at some point. Also, we will ask the participants to name the new psychoactive drugs they have used. The same procedure will be used in the follow-ups to ensure that the oral fluid samples are examined for the most relevant drugs.

Implications for interventions and future policy

This study will be the first to provide data on recreational drug use in the Oslo nightlife setting. It will also identify characteristics among individuals who are more likely to use large amounts of a range of drugs, enabling targeted interventions. If recreational drug use turns out to be substantial, the findings may facilitate collaboration work between the health authorities and the nightlife industry to establish adequate countermeasures. A general tendency in the nightlife context in Oslo and elsewhere has been to implement measures aimed at reducing alcohol consumption, and there has been less focus on recreational drug use. For example,

there have been studies involving professionally trained actors to act intoxicated, in order to study the frequency of alcohol service to seemingly intoxicated patrons [25-27]. Similar research for which actors pretending to be intoxicated by recreational drugs , have only been conducted in Sweden [28,29]. The results from our study will be able to provide the basis for planning and implementing drug prevention programs aimed at patrons of licensed premises.

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

TN, ALB, MEG, and JG designed the study. KB contributed to the design of the study. TN wrote the study protocol with substantial critical input from all co-authors. All authors read and approved the final version of the manuscript.

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Table 1A. Analysis repertory for the study

Drug class	Type
Amphetamines	Amphetamine
	Methamphetamine
	MDMA
	PMA
	PMMA
	2-Fluoroamphetamine (2-FA)
	3-Fluoroamphetamine (3-FA)
	4- Fluoroamphetamine (4-FA, PFA)
	4- Methylamphetamine
	4-Methylthioamphetamine
	4- Fluoromethamphetamine
	4- Methylmethamphetamine (4-MMA)
Opiates/opioids	Morphine
	Codeine
	Ethylmorphine
	Oxycodone
	Tramadol
	Tapentadol
	AH-7921
	Carfentanyl
	Fentanyl
	Methadone
	Buprenorphine
	6-MAM
Benzodiazepines	Alprazolam
	Bentazepam
	Diazepam
	Diclazepam
	Etizolam
	Flubromazepam
	Fluntirazepam
	Oxazepam
	Clonazepam
	N-desmethyldiazepam
	Nitrazepam
	Pyrazolam
Cannabis and synthetic cannabinoids	THC
	5F-Apinaca
	5F-PB-22
	AM-2201
	AM-2233
	AM-694
	HU-210
	JWH-015
	JWH-018
	JWH-019
	JWH-073
	JWH-081
	JWH-122
	JWH-200
	JWH-203
	JWH-210
	JWH-250

	JWH-251
	MAM 2201
	PB-22
	RCS-4
	RCS-4-C4
	RCS-8
	STS-135
	UR-144
	UR-144 Deg.
	URB 754
	WIN 55.212-2
	XLR-11 Deg.
	XRL-11
Cathinones	Ethylcathinone
	2-metylmetkatinon (2-MMC)
	3- methylmethcathinone (3-MMC)
	4- methylmethcathinone (4-MEC)
	Methylone (bk-MDMA, 3,4-methylenedioxy-N-methylcathinone)
	Alfa-PVP
	bk-MDDMA (dimethylone)
	MDPV (methylenedioxypyrovalerone)
	Pentedron
Phenethylamines	2C-C
	2C-I
	2C-T-2
	2C-E
	2C-T-7
	2C-P
	2C-B
	DOB
	DOI
	Bromo-DragonFLY
	25C-NBOMe
	25I-NBOMe
	Butylone (bk-MBDB)
	BDB (1,3- Benzodioxolylbutanamine)
	N,N-dimethyl-MDA
	2,5-DMA (dimethoxyamphetamine)
Aminoindanes	2-AI (2-aminoindan)
	MDAI (5,6- Methylenedioxy-2-aminoindane)
Tryptamines	Dimethyltryptamine (DMT)
	5-MeO-DMT
	alfa-methyltryptamine
Piperidines/pyrrolidines	2-DPMP (Desoxypipradrol)
	Ethylphenidate
	3,4-CTMP (2,4-Dichloromethylphenidate)
Piperazine derivatives	pFPP (p-fluorophenylpiperazine 1-(4- fluorophenylpiperazine)
	1-benzylpiperazine (BZP)
	TFMPP
	mCPP (1-(3-chlorophenyl)piperazine)
Arylalkylamines	6-APB
	5-APB
	5-IT

	6-APDB
Miscellaneous	Methoxetamine
	Xylazine
	Desomorphine
	Phenmetrazine
	Metaoxedrine (phenylephrine)
	Harmin
	Salvinorin A
	Tapentadol
	Homoamphetamine (3-amino-1-phenylbutane)
	Methiopropamine (MPA)
	Ketamine
	LSD
	Zolpidem
	Zopiclone
	Cocaine

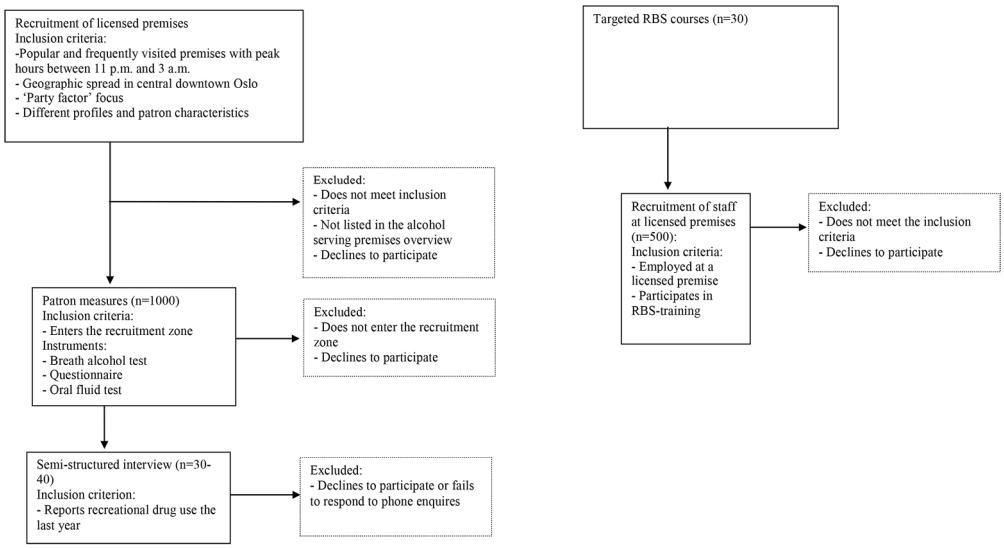

Figure 1 clean
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