Ten D by Night
Dark, Dance, Disco, Dose, Drugs, Drive
Danger, Damage, Disability, Death

STUDY DESIGN MANUAL
Study Protocol
Contents:

1. **Study Design**
2. **Choice of drug test** and information on their usage
3. **Choice of alcohol test** and information on their usage
4. **Definition of the console reaction time** and information on its usage
5. **Definition of participants pathway**
6. **Production of leaflets and posters**
7. **Production of anonymous coding system**
8. **Production of questionnaire**
9. **Production of informative material for participants**
10. **Production of informed consent sheet and anonymous sheet with results**
11. **Definition of pilot study design**
1. STUDY DESIGN
Maria Lucia Specchia
Università Cattolica del Sacro Cuore (Collaborating partner)

BACKGROUND
Psychoactive substances and alcohol consumption, widespread among young people and often associated with social contexts and activities, suggests a scenario characterized by new social and substance consumption trends. Recreational drug consumption represents a complex public health issue and field of research, particularly taking into account the amount of substances used by young people \(^1\,^2\). The decision to use psychoactive substances and alcohol is influenced by different factors, including curiosity, peer pressure, ready market availability and favourable circumstances. Substance abuse is a leading cause of physical, mental health and social-economic problems for youngsters. Road accidents caused by mental impairment represent one of the main risks run by these young people \(^1\). Literature available data show psychoactive substances playing a major role in causing road accidents, but little is known about the prevalence of people taking substances, either occasionally or regularly, before driving, and about the consequences of this behaviour \(^3\).

OBJECTIVES OF THE STUDY
General objectives
The strategic objective of this project is to develop a prevention programme aimed at:

- increasing young people’s awareness of the influence of alcohol and psychoactive substances on their driving capacity (reduction of the attention level, slowness of reaction...);
- disseminating correct and effective information on the effects of both alcohol and psychoactive substances;
- defining a European approach to the prevention of road accidents correlated with alcohol and psychoactive substances consumption/abuse;
- contributing to increase the knowledge of young people’s alcohol and psychoactive substance consumption in their usual meeting places.

Specific objectives
- Estimating, in the involved territories, alcohol and psychoactive substance consumption in young people usual meeting places;
- estimating effects of alcohol and psychoactive substance consumption on driving ability and on road accident risks;
- increasing, in the involved territories, young people’s awareness of the influence of alcohol and psychoactive substance consumption on driving ability, through the dissemination of correct and effective information and the use of innovative tools (such as console for reaction times measure);
- contributing to increase the efficacy of European prevention programmes in the field of drink and drugs abuse by evaluating on the field the implementation of an innovative integrated approach;
- contributing to the reduction of the number and the seriousness of road accidents in local territories involved in the project, particularly the ones in which young people are involved, that occur during weekends.

STUDY DESIGN: cross-sectional study

STUDY DESCRIPTION
Survey team
A team of at least 5 skilled people, able to enter efficiently in contact with young people, will be organized in each of involved territories.
The team will be composed of a team leader, 1 technician (for reaction time evaluation), 2 interviewers and one hostess (steward). The team leader will be responsible for supervising the team in the field, assigning participants identification codes, supplying the interviewers with the survey materials (informed consent, questionnaires, alcohol and drug tests, forms) and giving participants gadgets. The interviewers will be responsible for subjects selection, following pre-established selection criteria, questionnaires and tests administration and results forms drawing up.

**Info points**
Information points will be installed in 15 young people’s recreational meeting places for each involved territory. Informative and awareness-raising material (project leaflets, informative sheet on substances) will be given at the entry to young people attending the disco. Communication activity will be developed by a communication expert on the field, aimed to explain to young attendees the aims and the actions of the interventions, in order to stimulate their interest in participating in the study. Young people will be recruited among population attending the disco and answering selection criteria (see “Study population” paragraph), who will accept to participate in the study.

**Questionnaire and Tests**
At the entry, **informed consent, questionnaire** (entrance questionnaire) and **alcohol test** (alcohol test 1) will be administered to respondents and **driving reaction time measurement**, by the use of the console for driving reaction time (reaction time 1), will be registered.

At the exit, **questionnaire** (exit questionnaire), **drug test** and **alcohol test** (alcohol test 2) will be administered; **driving reaction time measurement** (reaction time 2) will be registered; tests results, recorded in the special form, will be communicated and explained to respondents, in order to demonstrate
how much alcohol and psychoactive substances consumption influence their driving ability, and gadgets will be given to participants.

**Code assignment**

Respondents will be “tagged” at the entry with a non-removal ID containing an anonymous code. The unique identification code will be also recorded in the questionnaire and the tests results form (alcohol tests, driving reaction time measurements and drug test) and will be used to link entry and exit data.

<table>
<thead>
<tr>
<th>Entry</th>
<th>Exit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Informed consent</td>
<td>Exit questionnaire</td>
</tr>
<tr>
<td>Entrance questionnaire</td>
<td>Drug test</td>
</tr>
<tr>
<td>Alcohol test 1</td>
<td>Alcohol test 2</td>
</tr>
<tr>
<td>Reaction time 1</td>
<td>Reaction time 2</td>
</tr>
<tr>
<td></td>
<td>Results</td>
</tr>
</tbody>
</table>

**Study population**

The study population will be represented by 7000 drivers young people, between 16 and 24 years, attending discotheques, 2000 in Italy and 1000 in each of other involved territories. In order to obtain gender and age specific information, collected data will be stratified for gender and age classes (16-18; 19-21; 22-24 years).

At list 15 discotheques in each involved territory will be selected. In order to obtain a total sample of 7000 people, an average of 133 young people for disco in Italy and of 67 young people for disco in each of other territories will be selected.

**Choice of recreational places**

Mapping of recreational meeting places - representative of the whole territorial contexts involved, with relation to the target population - will be realized...
through the experiences already implemented by the partners on their territories and on the basis of official database information. Before starting the study, researchers will make all of the key contacts with managers and/or owners, needed to grant permission for conducting the survey.

Most of partners have already implemented prevention interventions in their territories involving young people attending recreational places, so they have constructed relationships with recreational places owners and managers. These relationships will be used to develop contact with discos to be recruited in the cross-sectional study.

Discotheques will be chosen on the basis of:

a. highest presence of young people;

b. geographical distribution, in order to cover the largest portion of territory;

c. the availability of owners to cooperate.

Discos recruitment criteria and owners and managers involvement conditions will be in detail described in the final report.

A targeted number of 44-45 young people a night in Italy and 22-23 people a night in each of other territories will be recruited. A total of 3 interventions for each disco will be foreseen. Interventions will take place during the week-end (on Wednesday and Saturday night).

**Data collection on pre-post incidentality rates**

Collected quantitative data about road accidents involving young people, with specific reference to the ones occurred during week-end nights in each involved territory, will be compared with data available at the end of the project in order to evaluate the efficacy of the intervention in the short term in reducing the number of car accidents.

Data collection fonts will be represented by official Police databases and statistics.
REFERENCES


2. CHOICE OF DRUG TESTS and information on their usage
Andrzej Kalitowicz
4-Fundacja-PL

The review of the most popular drug tests and information on their usage.
We make market research to select most popular saliva drug tests used in Europe. After that we chose four, in our opinion, the best and often used tests. Below we present information on their usage and opinions of producers.

2.1 DRUGLAB TWIST SCREEN ORALFLUIDTEST

2.1.A DRUGLAB TWIST SCREEN testing the following drugs:
Amphetamine ( AMP )
Methamphetamine ( MET )
Cocaine ( COC )
Opiates ( OPI )
Marijuana ( THC )

those 5 above mentioned drugs are available with additional either
Phencyclidine ( PCP ) or Methadone ( MTD ) or Benzodiazepine ( BZD )

Facts:
It is true that most tests cannot detect cannabis very well in saliva - oralfluid. The reason for this is that when someone smokes cannabis the mouth gets in it PARENT THC and all other cannabis compounds ( over 400 ). But the tests usually work on antibody from THC METABOLITE ( delta-9 THC carboxylic acid) but there is no metabolite in the mouth! The tests will usually not pick up THC, only the metabolite.
Product Advantage:

**DRUGLAB TWIST SCREEN is unique** because its chemistry will detect **ALL** the parent cannabinoids together!

- you collect PARENT THC with the test collector
- the test has the antibody in it that can only detect THC METABOLITE
- **BUT it contains a chemical turns the PARENT THC into the Metabolite**
- therefore the test can detect cannabis for reliable evaluation purposes within 10 minutes only!

Cut off’s:

- AMP : 50 ng / mL
- MET : 20 ng / mL
- COC: 20 ng / mL
- OPI : 40 ng / mL
- MTD: 10 ng / mL
- THC: 12 ng / mL (100 ng / mL )
- PCP: 10 ng / mL
- BZD: 10 ng / mL

No additional equipment required for test procedure and test evaluation - but we offer a reader for evaluation purposes upon customer request.

**2.1. B DRUGLAB ORALFLUID TESTS**
**ORALFLUID 6** testing for following drugs:
Amphetamines (AMP), Cocaine (COC), Cannabis (THC), Methamphetamines (MET), Opiates/Morphine/Heroin (OPI), Phencyclidine (PCP)

**ORALFLUID 6/2** testing for following drugs:
Amphetamines (AMP), Cocaine (COC), Cannabis (THC), Methamphetamines (MET), Opiates/Morphine/Heroin (OPI), Methadone (MTD)

Cut off 's:

- **AMP:** 50 ng/mL
- **COC:** 20 ng/mL
- **THC:** 12 ng/mL
- **MET:** 50 ng/mL
- **OPI:** 40 ng/mL
- **MTD:** 30 ng/mL
- **PCP:** 10 ng/mL

Package sizes: 1 x 1; 5 x 1; 25 x 1 Test
2.2 ORALINE

In drug analysis, oral fluid drug screening has certain advantages over the screening of other biological fluids such as urine and blood. Oral fluid is readily accessible, and is less likely to be adulterated. With oral fluid tests the drugs may be detected immediately after ingestion, even before they are metabolized and would show up in urine. Generally OraLine® is designed to work at a lower detection level for all test drugs than those detected in urine.
samples. OraLine® oral screening for drugs of abuse detects the presence of parent compounds and drug metabolites.

The OraLine® products use an immunochromatographic technique that provides the accuracy of an immunoassay without the need for laboratory equipment. It is designed to detect recent drug usage, and is particularly useful for screening of drug intoxication.

OraLine's® unique design makes on-site saliva drug screening simple by eliminating the need to handle potentially messy bodily fluids, embarrassing collection observation, and the possibility of sample adulteration.

- The OraLine® test is fast, accurate and affordable
- Results in just 10 minutes!
- Provides on-site rapid-results for Marijuana, Cocaine, Opiates & Methamphetamines
- Easy to administer anywhere and anytime
- Patented collection process is safe and clean
- No need for special training or expensive equipment to administer the test

Cut Off’s:
- THC: 4 ng / mL
- COC: 25 ng / mL
- MET: 50 ng/mL
- OPI: 40 ng / mL
2.3 ORATECT III
(COC, OPI, THC, AMP, mAMP, BZO)
The Oratect III, Oral Fluid Drug Screen Device is a one-step chromatographic immunoassay device for the qualitative simultaneous detection of multiple drugs. Oratect III oral fluid 6 panel saliva screen.
The New Oratect III, Oral Fluid 6 Panel Drug Screen Device introduces a blue line indicator for the sufficient collection of saliva. The presence or absence of a red line corresponding to a specific drug on the panel indicates a negative result or presumptive positive result respectively. This onsite saliva screen allows testers to obtain the rapid results they need without having the concerns of handling a urine specimen.
Detecting drug use with an Oratect III, 6 Panel oral fluid drug screen is a clean and easy drug screening technique. Oral Fluid Specimen can be collected simply while the donor is under observation, which makes it harder for the donor to tamper with the results.
Oral fluid collection (for the test purpose) is much less invasive and embarrassing than urine testing.

Features:
- Simple, rapid, non-invasive, one step procedure
- 15 Minute total collection and testing time
- Simultaneous testing for 6 drugs
- Eliminates uncomfortable gender observation
- Built-in confirmation in single device
- No instruments required
- Simple visual result
- Room temperature storage

Cut off’s:
- MET: 25ng/mL
- THC: 40 ng/mL
- COC: 20 ng/mL
- AM: 25 nm/mL
- OPI: 10 ng/mL
- BZ: 5 ng/mL
RESUME:
After the market research we have selected four most popular saliva drug tests used in Europe. We can divide drug tests for three main groups:

- **Three steps test.** First to collect the saliva with special sponge then put the sponge into the chamber (2nd) and dispense 3 drops of saliva into the sample well of the cassette, then check results, 3rd (DRUGLAB ORALFLUID TESTS)
- **Two steps test.** Collecting the saliva with special sponge then put the sponge into chamber and check results (DRUGLAB TWIST SCREEN ORALFLUIDTEST)
- **One step test.** Putting the panel into mouth and after some time check results (ORALINE, ORATECT III)

In our opinion the most important feature in the test specification is testing time, simple of making test and number of testing drugs. After our analyze we suggest to choose one of one-steps tests (ORALINE, ORATECT III). The ORALINE is testing for only 4 types of drugs, when ORATECT III is testing 6 types. But testing time in ORATECT III is 5 min longer than in ORALINE. The organizers have to decide which of this standards is more important for our project: number of drugs tested or short time of the test. In discos we would have problem to keep youngsters for around 20 minutes to make drug test, alcotest and to check reaction time. The shorter test will be much easier to make. On the other hand, using the shortest ORALINE test we can’t check if the person isn’t under influence of any other types of drugs.

**PRICES OF DRUG TESTS.**

In our opinion the best drug test which we can use in our project is The ORALINE. It is one-step test so easier to do and faster than other ones. There
are the strong sides. The weak side of The ORALINE is testing for only 4 types of drugs, but perhaps it is enough for our project. The ORALINE is the cheapest test, so we can order even 12000 tests and to be still in the budget. Below we present the examples of prices we received from the distributors of drug tests in Poland.
3. CHOICE OF ALCOHOL TESTS and information on their usage"
Daniel Vankov
5-Open Youth-BG

3.1 Ethilometer Drager 6510

Drager Alcotest 6510 is operated intuitively which makes it very easy to use both from professional and non-professional staff. It also analysis the breath very quickly, making it an ideal tool for field interventions. It is user-friendly and compact plus very easily adaptable to meet different international regulations and guidelines.

Some technical innovations

<table>
<thead>
<tr>
<th>Analytical principle</th>
<th>Electrochemical DrägerSensor in 1/4&quot; technology for alcohol analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Measurement precision</td>
<td>Standard deviation +– 0.008 mg/L or +– 1.7 % of the measurement value. The higher value applies. Drift: typically &lt; 0.6 % of the measurement value/month</td>
</tr>
<tr>
<td>READY Time</td>
<td>approx. 6 s</td>
</tr>
<tr>
<td>Recovery time</td>
<td>approx. 6 s, at 0 mg/L, depending on ambient temperature</td>
</tr>
<tr>
<td>Quick menu</td>
<td>The most important information is available at the touch of a single key</td>
</tr>
<tr>
<td>Human interface</td>
<td>All measuring functions can be carried out with one key. Navigation in the menu via 2 menu buttons</td>
</tr>
<tr>
<td>Size</td>
<td>approx. 140 mm x 70 mm x 30 mm / 5.5” x 2.8” x 1.2”</td>
</tr>
<tr>
<td>Weight</td>
<td>approx. 195 g / 0.5 lbs. incl. batteries</td>
</tr>
</tbody>
</table>
**Design**
Alcotest 6510 is very compact and able to fit even into shirt pocket. Its ergonomic design makes it equally usable both to right- and left-handed people. The separation of the grip area and the mouthpiece automatically ensures a certain distance between the hand of the operator and the mouth of the person to be tested.

**Safety and easiness to use**
Automatic sampling and calibration processes make the instrument easy to use. All measurement functions are controlled through a single key, while menu navigation is by two menu keys. The special way the mouthpieces are designed means they can be fitted quickly and securely even in poor light conditions.

**Readiness**
The applied electronics technology ensures that the instrument is ready for use in 6 seconds.

**Quick and precise analysis**
The sensor with its optimized gas dynamics measures specifically alcohol. Even at high alcohol concentrations direct gaspaths, fast pneumatic components and short reaction times of the sensor ensure the measurement result will be displayed quickly.

**Energy consumption**
The device works with two AA batteries. More than 1500 breath alcohol tests can be conducted without replacing them.
Memory
The device remembers the last 10 measurement results with their respective test numbers. These can be called up from the log by pressing the menu keys.

Mouthpiece
The shape of the mouthpiece is designed to be intuitively put in the right place. An air outlet which cannot be obstructed prevents any manipulation when the breath sample is given. A spacer on the mouthpiece prevents the test subject's lips from coming into contact with the instrument's housing, and at the same time may be used as a mouthpiece ejector.

Instrument interaction
## Basic equipment and accessories

<table>
<thead>
<tr>
<th>Item</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dräger Alcotest 6510</td>
<td>Carrying case with measuring instrument, 3 mouthpieces, hand strap, 2 batteries, brief instructions, full instructions for use</td>
</tr>
<tr>
<td>Mouthpiece (slide’n’click)</td>
<td>With saliva trap, each individually packed</td>
</tr>
<tr>
<td>Leather pouch</td>
<td>For carrying the Drager Alcotest 6510 attached to the belt, rotatable, i.e. adapts to the respective body position (standing, sitting); removable by means of rapid-action release (belt pouch remains attached to the belt)</td>
</tr>
<tr>
<td>Calibration set</td>
<td>Set for performing regular calibration (adjusting) of the equipment. With this set, the Drager Alcotest 6510 can be connected with the respective calibration equipment (wet bath calibration or dry gas calibration). Consists of 1 x mouthpiece coupling, 1 x calibration mouthpiece, 0.5 m / 20” tube</td>
</tr>
</tbody>
</table>

### Explanation

- These breathalyzers are reliable. The breathing analyses measure the quantity of alcohol present in the expired air.
- The quantity of alcohol is indicated in “promillage” (‰). The quantity authorized for the drivers is 0,5‰ or 0,2‰, depending on the countries.
- Advise of course everyone not to drink at all when they want to drive.
- In the case of a driver have an alcohol level too high, advise the attendee to choose another driver or to call a cab.
- if it appears that the driver drank too much, another passenger of the car can of course also make the test in order to determine if he/she can drive safety.
Notices

- Firmly hold the breathalyzer with the leash rolled up around your wrist. Even if the person tested wishes to hold it him/herself, you are not authorized to let him/her taking it. It is usually required for security (those machines are quite expensive).
- Ask tested attendees who smoke to extinguish their cigarette before starting to blow. If smoke would have been puffed up in the machine, an error message appears on the screen.
- Do not let blow a person who is holding a glass of alcohol in the hand from which he/she has just drunk alcohol. Even if it is about its first glass, the result will be positive. The alcohol which is still in the mouth is directly puffed up into the machine and false the results.
- In this case, ask the person to await minimum 15 min and then to come back and make the test again.

BIBLIOGRAPHY:

1. Alcotest 6510 manual
2. Alcotest 6510 brochure
4. Definition of the console reaction time and information on its usage
Lacroce Renato
1-Consepi-IT

A good definition for the "Reaction Time" can be resumed as: Perception, Recognition, Decision and Action.

The Driver must see the object, identify it as an obstacle, take a rapid decision about what is better to do and do it.

Driving at 50Km/h means covering 13,9 meters in 1 second, which is the estimated time for a driver to perceive that there is an obstacle at some point near him and start breaking.

So if the obstacle is nearer that 10 meters there's no possibility to avoid the accident.

What if the speed is higher?

More then 90 % of road accident are caused by human factor: high speed, distraction, alcohol and drugs consumption are main reason.
Reaction time has been a favorite subject of experimental psychologist since the middle of the 19th century. Psychologist have named three basic kinds of reaction time experiments:

1) simple: there is only one stimulus ad one response
2) recognition: there are some stimuli that should be responded to, and other that should get no response,
3) choice: the user must give a response that corresponds to the stimulus, such as pressing a key corresponding to a letter if the letter appears on the screen.

Outcome of any experiments is correlated to its kind indeed different studies with different instruments obtain different reaction time values. Therefore, if we decide ignore the variations of the results caused by the different type (of reaction time) of experiments, the different type of stimulus or the stimulus intensity,

there are still many factors affecting the reaction time:
- arousal
- age
- gender
- left vs right
- direct vs peripheral vision
- practice and error
- fatigue
- distraction
- warnings of impending stimulus
- alcohol
• drugs
• breathing cycle
• personality type
• exercise
• stress
• intelligence
• brain injury
• illness

With so many factors to take in regard it’s very difficult to find a single impact find the impact of every single one in case study, but in our project we can try to do a correlation with use and abuse of alcohol and drugs and especially we’ll have valid method for to explain to young driver the importance of driving using their best (in single moment) reaction time.

In our project we chose to use an special and innovative console for reaction time measurement because:
1) for estimating effects of alcohol and drugs consumption on driving ability and road accidents risk, we consider better to investigate the reaction time with driving simulator,
2) the test consists in a simple stimulus (stop signal or red traffic light) that requires a specific response (take up right foot from the pedal, move on the brake pedal and press it quickly). This is the first action that anyone need to perform when involved in road accident risky situation.
3) The immediate test results contain the reaction time and some information about its correlation with speed and space. This offers a chance to teach young driver the risk of speed and distraction.
4) Reaction time console look like a driving simulator videogame, so it can be a good reasons to incentive participation.
HOW TO

1. Explain to young driver that the console is like a proper car with automatic gear.

2. Help the subject to sit on the simulator and start the software program for reaction time measurement.

3. Show on the monitor the place where signs (traffic light or stop signal) will appear (in the center)

4. Test 0: Invite young driver to accelerate and drive on. When the first sign will appear, explain to him how to react (take up right foot from the pedal, move on the brake pedal and press it quickly. Don’t do nothing with the steering wheel) Test 0 is only a demo for understand what to do.

5. Outcome 0: Don’t explain nothing simply restart the test.

6. Test 1 (point 4 in pathway): This is the first measure of reaction time, don’t talk to young driver during test, let him drive and react, let also him accelerate freely: more high is the speed, better you can show him the risks of speeding and distraction in outcome.
7 Outcome 1: First write the reaction time result in a module, then show to the subject how many meters he had cover for the complete stopping of the car, divided in reaction time and breaking time. Always underline that in reaction time, the car doesn’t reduces its speed. If there is time, explain the correlation between km/h vs m/s, and the rules about speed and space for stop.

8 Test 2 (point 7 in pathway): Simply invite the driver to make the test in the same way as the previous. don’t talk to subject during test.

9 Outcome 2: First write reaction time result in a module, then you can show or explain, if there is time, what the young driver asks you (i.e. the space for stoping the car – braking space – depends on: tires, street condition, speed, ...)

We may use special attention in subjects that obtain bad reaction time (3 seconds or more) and ask ourselves why. There are a lot of reasons for this (distraction, alcohol, drugs, fatigue, ...) but our personal thinking isn’t a scientific strategy, so write the bad reaction time in the module and if there is time let young driver try another test only for his own satisfaction. They can try Test 1 and Test 2 more than once, but make them clear, in real life they will have just one chance.
Bibliography

5. Definition of participants’ pathway
Francisco Alonso
7-UVEG-ES

An important aspect in the field intervention of the project, for it is going to be a key aspect further on during the implementation of the pilot study, is the design of an acting protocol, that will have to keep in mind the possible incidents, experimental and sampling (of liability and validity), as well as applicable ethic rules. This protocol must view aspects such as the definition of who must implement the action, what the procedure must be and following what aim.

From the practical point of view, the final aim of this project is that the highest possible number of young people, with no distinction because of personal conditions (this is, with no bias) participate in it, in their condition both of “adopting public” and “experimental subjects”, so it will be necessary that we persuade them to collaborate in the realization of it.

We intend to reach the young in the most efficient possible way, so that they understand the project’s aims, and they gain conscience of the risks and dangers of driving under the effects of alcohol and/or other psychoactive substances. Nevertheless, we must achieve this respecting the ethic applicable rules and principles.

A factor that we must have in mind when designing an acting protocol, is that when we interact with groups of young and given the number of countries in which this action is going to be implemented, we need to think about the social, cultural and psychological differences that may exist among the different “samples”. However, we proceed to suggest a general action plan that can be adapted to its particular specific characteristics by each country.
Incentives of participation

Firstly, there is a high chance that a great number of young do not want to participate in the study, either because of fear of the authorities, of their parents/tutors or because of the simple fact of seeing their consumption habits in a study of public scope. This is why we will have to use various persuasion strategies aimed to transmit the guaranty of strict anonymity of the results. In this sense, and aiming to avoid the rejection or initial fear to participation by the young:

- We shall inform about the codification method intending to prove the total anonymousness of the results;
- We shall emphasize the key role that anonymous people have in investigations aimed to detect aspects that contribute to discontentment or contentment of our society using for it examples of real and current investigations;
- Using the emotional and rational activation, we shall emphasize on the importance of participating in a study of these characteristics establishing parallelism with other investigations that, precisely using this same method of anonymousness of their participants, have been able to detect the causes and therefore have discovered the ways by means of which solutions have been implemented blocking an enormous quantity of human suffering.
- Activating the social usefulness attitudes, we will refer to the fact that every one of us has a unique (no-one knows or can do exactly the same as we do) and active role that will contribute to improve our society;
- Activating the feelings of emotional welfare referring to how we feel when we have contributed to improving the physical or psychological state of another person or people;
- Activating the attitudes of empathy, referring to how we would feel if other people had contributed to other welfare participating in an anonymous investigation of these characteristics;
Moreover, and given that this project is not just experimental, but an intervention programme, we shall inform of the “privilege” of participating in it, given that the scope it could have won’t reach the whole population for financial limitations.

In this sense, we shall inform of the value of usefulness that it has for each participant and for everything around him (especially companions and friends). Once the intervention is finished we shall go deeper into this message, asking for the participation in diffusing this project within their equals. With this we shall achieve a greater dissemination if possible.

**Requirement of consent and information about the tests**

However, it is necessary that we require the signature or consent of the experimental subject, which is not incompatible with the anonymous nature of the test. Requiring the signature has the aim, for those who do the study, of proving that the final data come from physical people from which we have extracted the results or the legal needs for doing it (according to the specific laws of the participant countries)

For so, it is necessary that at all times information about the tests to be carried out is clear, for, if they have to sign a consent form, they must be informed of what they are signing and with what purpose.

Moreover, we must stress that the need of signing is simply a bureaucratic subject, and that no name will be associated to any result.

To make this dissociation easier, once informed, the subject can be given an identification code, known only by the subject, but allowing to follow the whole intervention.
In this way, we shall declare that, although the consent for participating in an investigation is signed, this data will not allow us to link between identity and results.

Aiming to strengthen this confidence, the consent form should include a clause indicating the anonymous nature of the test and, willing to add more credibility and confidence, it will be signed by the investigator too.

**Information about the risks in driving**

In the explanation about what the study/intervention is about, any comments about the risks of driving under the effects of alcohol and psychoactive substances should be avoided. The reason for this omission is that, in the previous mention, it could put the young in alert, which could result in a possible contamination of the following test, them being more attentive. In this case some changes could be seen from non-desirable “behaviours” (in an initial state) as those referred to the normal consumption or the grade of activation (attention, etc.) in the tests of the time reaction console.

However, from the ethic point of view, it could seem as if by omitting this information we are trying to mislead the young or manipulate them. This is why the aspects related to advise about the risks of driving under the effects of alcohol or other drugs, it would be convenient to leave them for the conclusion and explanation subsequent to the implementation of the action. With it, we will try that our explanation interferes the least in the realization of the test, obtaining more reliable results. Therefore, we would use the method called “simple blind”.

In this sense, it would be convenient saying only that the aim of the study is to identify the current patterns in the consumption of alcohol and/or psychoactive substances among the young of different societies and countries.
This aim, said in this way, even being corresponding to the one presented in the study, does not imply a necessary understanding of the study, remaining blurred the fact that it is a transnational project.

**Phases of action**

Therefore, and having detailed some of the possible problems previous to the intervention, we go on to detailing the phases to follow in it:

1. **Asking for participation:**
   a) Information about the study
   b) Guarantee of anonymousness

   If we should see any grade of distrust in any subject, or group of subjects, we will have to stress that data from the participants will not be given further than the consent form, and that a code will be relating the tests before and after the stay in the recreational place so that they can be compared but they shall not relate the test to the person who does it. Requirement of signing the consent form and information on its need.

2. **Implementation of the alcohol test**

3. **Implementation of the questionnaire**

   We shall remind that the questionnaire will be strictly anonymous, though we would appreciate the higher level of concreteness and sincerity

   **Reaction test**

4. **Period in which the young will enter the recreational place...**

5. **Drug test:**

   At this point, there is the chance that, after being the whole night in the recreational place, the young who had previously promised to collaborate with us could back out and deny participating, or simply not come back to where we are making the intervention. We call this “experimental death” and it will obviously translate into a decrease of the original sample. In this sense, and
in a preventive way we will pass the first tests to a higher level of young than the final rate that we need

6. Reaction test

7. Alcohol test
Possibly at this stage, if the alcohol levels are clearly superior to previous moments of the night, the young can deny passing an alcohol test, possibly reappearing the fears from the beginning about the data becoming public and arriving to parents or authorities, as a result of the less rationalization created by alcohol or psychoactive substances. In this case, we will insist on the anonymousness of the test, in order to avoid a higher experimental death.

8. Delivery of informative sheet

9. Final explanation
The problem that can be found in this moment is that the data of the intra-subject comparison are not determinant and consequently do not show a clear difference between driving without having consumed and driving having consumed. For it we will have some population data (that will be added as our application advances) over which we can support our conclusions. For this, we shall use, firstly, data from previous experimental studies and, further on, an average of added data of the subjects who have already passed the study.

10. Exit part of the questionnaire
11. In a complementary way we could promote some willing (and capable) drivers to drive the young home or have some elements that may help in using taxis or public transport (knowing about their location, frequency, routes, etc.)
Profile of the trainers involved

To solve the problems associated to the implementation of the intervention and maximize the positive elements of it those in charge of the application must have certain characteristics:

As for the age, the subjects will be young or not too old. As for sex, we must count necessarily on both men and women.

From the point of view of the initial formation, or that which they should complementarily receive they must have knowledge of psychology and road safety.

As for the first point, they must have knowledge about the regulational bases of the human behaviour, attitudes, change in attitudes y groups dynamics. In this way they must be prepared to refute any negative or excuse from the young, as well as detecting the perceptions and negative attitudes and therefore intervene to modify them.

From the point of view of road safety, they must have knowledge about the problematic, especially in everything referring to epidemiologic variables and human factor. In a complementary way they should have knowledge about vehicles and concretely in anything referring to their active and passive security (for questions not directly related to the programme may arise and they must be prepared to answer with the aim of increasing credibility from the source about their knowledge as a prescriptor)
Bibliography


6. Production of leaflets and posters
Giulia Manassero
3-S&T-IT
The TEN D BY NIGHT logotype is composed by different elements and it is addressed to young people with the intent to sensibilize and teach them how to have fun with responsibility.

The first element of the logotype is a car, the main symbol of independence for young people that, if wrongly used, can turn into a risky element.

The second element is a stained star, meaning night, disco and fun.

The third element in the writing TEN D BY NIGHT. Fonts used are the **DEPRESSIONIST THREE** for the words “TEN BY NIGHT” and the **Alexa** for the “d”.

The fourth and last element is the image of the ten D’s surrounding the other 3 elements. The used font is **Alexa**.

The chosen colors are blue and yellow, signifying the sky at night with stars.

- **PANTONE 655 C**
- **PANTONE 109 C**

To use the logotype in quadricromy colors, they will become:

- **100C 68M 0Y 52K**
- **0C 10M 100Y 0K**

To use the logotype in greys scale, the colors will be:

- blue will become **100% Black**
- yellow will become **30% Black**

For smaller versions of the logotype, it can be used without the 10 D’s.
TEND is a transnational project aimed to define a European approach to contribute to the reduction of car accidents often correlated to alcohol and drugs use and misuse. More than 6000 European young people will participate: LET'S JOIN THEM and EXPERIENCE our tests, FULLY ANONYMously.

IF YOU WISH TO KNOW WHERE AND WHEN YOU CAN FIND US PLEASE VISIT
WWW.TENDBYNIGHT.EU

YOU CAN TRY OUR TEST

ALCOHOL TEST
Blow in the breathalyzer and check if you’re still able to drive!

DRUG TEST
Discover how it is possible to analyze your saliva for drug use detection!

REACTION TIME CONSOLE
Test your reaction skills for braking to avoid an obstacle while driving!

AND YOU WILL RECEIVE A SPECIAL GADGET!

This material arises from Ten D By Night Project which has received funding from European Union, in the framework of the Public Health Programme. Sole responsibility for contents lies with the partnership and Executive Agency is not responsible for any use that may be made of the information contained therein.
7. Production of ANOMINOUS CODYNG SYSTEM
Robert a Siliquini
2-UniTo-IT

Studies with repeated measurements require linking together data from the same subjects at different time points. This is usually accomplished by means of personal identifiers such as name, birth date or security number. Because of ethical considerations it is often not possible to keep identified computerized health records of young people without obtaining guardian's consent or, anyway, it is not possible in our study as the volunteer participation must assure, for the legal problem related to drug assumption, the complete anonymous record linkage.

Although rules may vary between countries, consent procedures are often long, complex and may lead to a substantial dropout from the study base, with consequent loss of efficiency. However, if record linking would still be possible without the use of personal identifiers, the guardian's consent would in many cases not be mandatory. Computerized procedures making personal data anonymous have been proposed to partially solve issues of data protection in public registers, but to date there are no examples applied to field studies involving longitudinal data in the same night.

No data at all are shown by literature in order to fulfill some requirements of our study:
- guaranteeing the anonymity of the data collected also for researcher (we should avoid in any case to be compelled to supply data in case of legal problem. F.I. a car accident happens to a driver involved in the study);
- guaranteeing the record linkage between data collected at the entrance and those collected at the exit
- guaranteeing that no one but the person involved and the researcher can access to the previously collected data.

One possibility is a self generated by each participant anonymous code (for instance: the first 2 letter of your mother name+the number of your birth
day+the first letter of your best friend name, etc.) that has been already proved as efficient and sensible in a cohort of few persons as are the person we have planned to contact during a night in a recreational place. On the other hand we should take in account that this kind of info, needed to reproduce the code, cannot be so easy for a young under drug and alcohol effect making our effort completely inefficient.

Another possibility is to supply the volunteer participant with a sheet of paper with the printed code to be reproduced when leaving the recreational place in order to attend the other test and get results. In this case we do not guarantee the anonymity: if the sheet of paper is lost or stolen anyone can collect the results of another person.

Thus the method proposed is a seal with a changing code to be printed on the participants’ hand – or harm or another place in which is less possible that it disappear - (we need only an hundred of changing code: the complete code will be created by putting together place, date and printed code).

In this case, looking at the printed code on the seal, we do assure that the participant that comes is the one that attended the test at the beginning, we can link the records and we do not know anything about the participant.

Once leaving the place the participant will be ask to cancel the seal with a paper serviette and alcohol we will provide them.
Bibliography


8. Production of the questionnaire
Roberta Siliquini
2-UniTo-IT

The following questionnaire has been created in order to gather information on the subjects recruited by the study:
- socio demographical variables,
- very general anamnestic information,
- use of alcohol and psychoactive drugs (both normally, and related to the event during which the questionnaire is administered,
- driving habits,
- opinions on usefulness of the project and costumer satisfaction.

In order to arrange the questionnaire a bibliographic research on the more common scientific research websites (Pubmed and Ovid) has been performed. We took in consideration paper published from 2002.

Key and mesk words used and combined have been: questionnaire, traffic crashes, traffic accidents, young, prevention, preventive intervention, alcohol drinking, drugs, substance use, substance abuse, driving, risk, saliva, oral fluid, test, stick, effectiveness, methodology.

When explicit in the papers, the questions have been reported sometimes using the same text, sometimes modifying it: if the questions were not reported they have been inferred from variables cited in materials and methods or results.

For some aspect of interest (f.i. usefulness of intervention or satisfaction), as no paper in literature has been found, questions have been created ad hoc.

According to the recreational setting in which the questionnaire will be administered we tryed to restrain as possible its lenght, even if several are the information we need to gather.
At the beginning of the questionnaire some fields regarding the setting (date, place and kind of recreational event) are asked together with the subject code (please see chapter on coding system).

a. Entrance part

1. In order to define the demographic and social profile, further than gender, year of birth, scholarity and occupational status (variables generally present in the literature) we ask also with who the subject habitually lives and father’s scholarity (referring to European countries we think that father’s scholarity can better than the mother one indicate more precisely the cultural setting of education).
Furthermore in order to identify the culture to which the participant belongs we did not use the variable ‘race’ for two reason: firstly it is not indicative of the culture and, moreover this question could be read as offensive in some countries.
It could be more useful to ask for each one ‘ethnic group’ but his terminology is differently interpreted and can create some confusion. So we decided, in order to get some information on culture, for asking the country of birth of the participant together with the country of birth of the mother.

2. Regarding anamnestic information and health status (that we need to indagate for legal reason being this one a study carried out for scientifical reasons) we did not find any clue in the scientific literature. So on we formulate two questions on the presence of any kind of allergies and chronic diseases in order to perform a screening (even if rough) of recruitable subjects.

3. Concerning the driving habits we inserted questions about experience of the subject (age in which they got their license, frequency of driving in the last month), style of driving (numbers of speeding tickets, license
suspensions, number of crashes), how the subject organize for moving during the evening (if he drove to reach the place and if he is going to drive for leaving it)

These information, besides contribute to outline the subject profile seem useful in order to better interpret the driving tests they will undergo.

4. Regarding alcohol and drug seems interesting to indagate both usual consumptions than the specific night consumption.
The usual alcohol consumption will be investigate referring to the previous month (consumption frequency and eventual episode of binge drinking) as it is quickly reminded by the subject and enough revealing of the normal habit.
For drug consumption, on the contrary, we refer to consumption frequency during the last year in order to gather also sporadic consumption
The consumption of psychoactive substance before arriving in the recreational setting is investigate in detail both for alcohol (kind and number of drinks) and drugs (kind but not quantity because it is very difficult to define)
Finally we foresee questions aimed to investigate the willingness of subject to drink alcohol or consuming drug during the evening: we perfectly know that this answer can be influenced by the intervention but we will have an objective value through the test results.

5. The last section of the entrance part of the questionnaire foresee a series of questions related to ‘driving under substance use’.
We decided to use this expression (even if the literature often gives a more restrictive definition taking in account the specific number of hours passed between consumption and driving) for two reasons. First of all this definition calls to the awareness of the subject to be in some way altered by a substance effect, secondly in this way we do not bind the subject to too much restrictive limits that could lead to wrong information.
Moreover the questionnaire gather information about the driving habits under alcohol or drugs effect during the last month, the habits to be passenger in a
vehicle driver by a person under alcohol or drugs effect during the last month, the number of crashes under drug or alcohol effect and others. The last question of this section asks the subject to indicate how much is, in his opinion, driving under the effect of a list of substances indicated in order to have a framework of risk perception related to different substances.

b. Exit part

1. The first few number of questions is related to alcohol and drug consumption during the night and the time elapsed from the last consumption. This question is not taken from literature but can be useful to delineate the behaviour of subjects willing to drive once leaving the recreational place.

2. Than there is a question aimed to assess a possible immediate effect of the project regarding the decision to drive or not in the light of the reaction time test results.

3. The last section is aimed to delineate the degree of perceived utility of the intervention, an opinion about its feasibility and the eventual desire to have more initiatives of this kind. These questions have been created ad hoc because we did not find any models in literature.
References


INFORMATION LETTER TO INFORMED CONSENT

Before agreeing to participate in this action-research study, it is important that you read the following explanation about it.

TITLE OF THE STUDY: TEN D by Night - (Dark, Dance, Disco, Dose, Drugs, Drive, Danger, Damage, Disability, Death). Action is supported by the Public health Executive Agency acting under European Commission and involving 7 European countries.

PURPOSE OF THE STUDY: This study focuses on influence of alcohol and drug use to driving ability. The strategic aim of TEN D project is to define a European approach in order to contribute to the reduction of the number and seriousness of road accidents, in particular the ones in which young people are involved, that occur during weekends and can be correlated with the consumption of alcohol and drugs.

PROCEDURES: As a participant in this study, you will be asked to complete the following:

1. An anonymous questionnaire
2. The breath test to determine the quantity of alcohol present in the expired air
3. Saliva test to determine presence of following substances: Amphetamines, Cocaine, Marijuana, Methamphetamine, Opiate, Benzodiazepines
4. To measure the reaction time

You will do two repetitions of the driving test and alcohol test before entering disco and after. More detailed information about each of these tests is presented in the special leaflets. A specially trained staff will show and explain the test procedure on place. The maximum time requirement for these tests and questionnaire will be about 20 minutes. There will be no costs for participation in the action.

RISKS AND BENEFITS: There are not contraindications to participation in this study. During measurement for hygienic purposes you will be provided with individual hygienic mouth piece. The procedures will be simple, rapid and non-invasive, therefore it do not have any risk for your health. After measurement you will receive personal data sheet with the results of tests.
When the study will be finished, we will provide feedback to let you know about main findings of the project TEN D by Night in public web (www.tendbynight.eu). The results of this study will be used in traffic accident prevention programs targeted to young people attending recreational places and also in reducing alcohol and drug consumption.

STOPPING YOUR PARTICIPATION: You are free to choose whether or not to participate in this action. You may withdraw from this study at any time. To do so, indicate this to the researcher or one of the research assistants by saying, "I no longer wish to participate in this study".

CONFIDENTIALITY: To ensure the confidentiality of individuals’ data, each participant will be identified by a participant identification code. All records from this study will be anonymous; so far no individual identities will be used in any reports or publications resulting from the study.

PARTICIPANT FEEDBACK: After tests are completed, you will be provided with a feedback sheet that will include summary of the results.

CONTACT INFORMATION: If you have any questions about the study at any time, please contact local partner (insert name of institution) at his/her office (phone:… or e-mail)

Concerns about Your Participation: We would like to assure you that this study has been reviewed and received ethics clearance through the Ethical Committee of Ten D project (e-mail: info@tendbynight.eu). However, the final decision about participation is yours.
CONSENT FORM
I give my consent to participate in the project mentioned above on the following basis:

I have had explained to me the aims of this research project, how it will be conducted and my role in it. I am cooperating in this project on condition that:

- the information I provide will be anonymous and kept confidential,
- the information will be used only for this project,
- the measurement results will be made available to me and any published reports of this study will preserve my anonymity.

I understand that there is no obligation to take part in this study and I am free to withdraw at any time. I have been given a copy of the information/consent sheet, signed by me and by the principal researcher (name) to keep.

_______________________________Signature of volunteer

_______________________________Date

_______________________________Signature of Researcher

_______________________________Name in full

_______________________________Date

Should you have any complaints or concerns about the manner in which this project is conducted, please do not hesitate to contact the researchers in person, or you may prefer to contact TEN D by Night at the following address:

Telephone: 
Fax: 
Email: 

DRIVING AFTER ALCOHOL AND PSYCHOACTIVE SUBSTANCES CONSUMPTION OR DRIVING WHEN YOU ARE PARTICULARLY TIRED REPRESENT A RISK FOR YOU AND OTHERS, THEREFORE IN THESE CASES DON’T DRIVE!
CONSENT FORM

I give my consent to participate in the project mentioned above on the following basis:

I have had explained to me the aims of this research project, how it will be conducted and my role in it. I am cooperating in this project on condition that:

- the information I provide will be anonymous and kept confidential,
- the information will be used only for this project,
- the measurement results will be made available to me and any published reports of this study will preserve my anonymity.

I understand that there is no obligation to take part in this study and I am free to withdraw at any time. I have been given a copy of the information/consent sheet, signed by me and by the principal researcher (name) to keep.

________________________________________Signature of volunteer
________________________________________Date

________________________________________Signature of Researcher
________________________________________Name in full
________________________________________Date

Should you have any complaints or concerns about the manner in which this project is conducted, please do not hesitate to contact the researchers in person, or you may prefer to contact TEN D by Night at the following address:

Telephone: 
Fax: 
Email: 
“Ten D by Night”

1. Researcher ______________________
2. CODE ______________________

ENTRANCE QUESTIONNAIRE

Demographic data and socioeconomic status:

3. Gender    □ male    □ female

4. Year of birth __________

4.a. Birthplace (State) __________

4.b. Mother’s birthplace (State) __________

5. Living    □ alone
               □ with parents
               □ with friends / colleagues
               □ with partner / spouse
               □ other

6. Education    □ none
               □ compulsory
               □ secondary
               □ degree

6.a. Father’s highest level of education    □ none
                                             □ compulsory
                                             □ secondary
                                             □ degree

7. Employment status    □ student
                         □ having a job
                         □ in search of employment
Medications consumption:

8.a. Have you taken any medication in the last 7 days?
   □ yes   8.b. (which one / ones ? ____________________________)
   □ no

Driving:

9. Age of motorbike driving licensing _________
10. Age of car driving licensing _________
11. Driving frequency in the last month
    □ never   □ less than weekly   □ weekly   □ daily
12. Number of speeding tickets you received during lifetime
    □ none   □ less than 5   □ 5 or more
13. Licence suspensions during lifetime
    □ none   □ one   □ more than one
14. Traffic crashes as driver during lifetime
    □ none   □ one   □ more than one
15. Have you driven to come here? □ yes □ no
16. Are you going to drive upon leaving this place? □ yes □ no

Alcohol and drug use:

17. How often have you had beer / wine / distilled spirits / cocktails / alcohol pops in the past month?
    □ never
    □ once or twice in the month
    □ about once a week
    □ 3 or 4 days a week
    □ every day
18. Have you engaged in binged drinking in the past month?
    □ yes □ no
19. How often have you used each of the following substances in the past 12 months?

<table>
<thead>
<tr>
<th>Substance</th>
<th>never</th>
<th>once but not any more</th>
<th>sometime</th>
<th>several times a month</th>
<th>several times a week</th>
</tr>
</thead>
<tbody>
<tr>
<td>19.a. marijuana</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>19.b. methamphetamines (including ecstasy)</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>19.c. cocaine</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>19.d. hallucinogens (e.g. LSD, magic mushrooms)</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>19.e. amphetamines</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>19.f. benzodiazepines (e.g. tranquillizers, sleeping medicines)</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>19.g. opiates (e.g. heroin, methadone)</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
</tbody>
</table>

20. Before arriving here did you drink
20.a1. beer? □ yes 20.a2. (number of cans/bottles ____ ) □ no

20.b1. wine? □ yes 20.b2. (number of glasses ____ ) □ no

20.c1. distilled spirits? □ yes 20.c2. (number of glasses ____ ) □ no

20.d1. cocktails? □ yes 20.d2. (number of glasses ____ ) □ no

20.e1. alcohol pops? □ yes 20.e2. (number of cans/bottles ____ ) □ no

21.a. Did you use any drug before arriving here (medicinal or non-medicinal substances in the preceding 12 hours)? □ yes 21.b. specify which one / ones:
   □ marijuana  □ methamphetamines (including ecstasy)
   □ cocaine   □ hallucinogens  □ amphetamines
   □ benzodiazepines  □ opiates
   □ no

22. Are you going to drink alcohol tonight? □ yes □ no □ possibly
23. Are you going to use any drug tonight? □ yes □ no □ possibly

**Driving and substance use:**

24. In the last month have you driven
   24.a. under alcohol influence? □ yes □ no
   24.b. under drug influence? □ yes □ no

25. Have you been arrested for driving under the influence of alcohol or drugs during the past 12 months? □ yes □ no

26. In the last month have you been a passenger in a vehicle where the driver
   26.a. was under alcohol influence? □ yes □ no
   26.b. was under drug influence? □ yes □ no

27.a. Have you ever had a traffic accident while driving under the influence of alcohol and/or drugs during your lifetime?
   □ yes 27.b. (how many times? ___________ ) □ no

28.a. Have you ever been involved in a traffic accident while being driven by an alcohol- or drug-intoxicated driver?
   □ yes 28.b. (how many times? ___________ ) □ no

29. In a scale from 1 to 4, how dangerous do you think the following substances are for a driver?

<table>
<thead>
<tr>
<th></th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td>29.a. alcohol</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>29.b. marijuana</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>29.c. methamphetamines (including ecstasy)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>29.d. cocaine</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>29.e. hallucinogens (e.g. LSD, magic mushrooms)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>29.f. amphetamines</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>29.g. benzodiazepines (e.g. tranquillizers, sleeping medicines)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>29.h. opiates (e.g. heroin, methadone)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
EXIT QUESTIONNAIRE

Alcohol and drug use at the event:

30. How many alcoholic drinks did you have?
□ none □ 1 □ 2 □ 3 □ 4 □ 5 or more

31. If you had alcoholic drinks, how many hours ago did you have the last one?
□ less than 1 hour ago □ 1-2 hours ago □ 2-3 hours ago □ more than 3 hours ago

32.a. Did you use any drug during the party?
□ yes 32.b. specify which one / ones:
□ marijuana
□ methamphetamines (including ecstasy)
□ cocaine
□ hallucinogens (e.g. LSD, magic mushrooms)
□ amphetamines
□ benzodiazepines (e.g. tranquillizers, sleeping medicines)
□ opiates (e.g. heroin, methadone)
□ no

Leaving this place:

33.a. Are you going to drive this night?
□ yes, now □ yes, but later □ no

33.b. Why?__________________________________________________________

Your opinion about this preventive intervention:

34. In a scale from 1 to 4, how useful do you think this intervention is?
□ 1 □ 2 □ 3 □ 4

35.a. If we came back here next month, would you repeat these tests?
□ yes
□ no 35.b. (why? ____________________________________________
_______________________________________________________)

36. Would you like to have more initiatives like this one? □ yes □ no
37. Would you like to have a copy of the test results? □ yes □ no
TESTS RESULTS

38. Blood Alcohol concentration (g/L)
   38.a. 1° test (entrance) ________________________________
   38.b. 2° test (exit) ________________________________

39. Reaction Time (seconds)
   39.a. 1° test (entrance) ________________________________
   39.b. 2° test (exit) ________________________________

40. Drug consumption (only on exit):
   YES  NO
   40.a. ME Methamphetamine/MDMA □ □
   40.b. TH THC (Δ9-tetrahydrocannabinol) □ □
   40.c. CO Cocaine □ □
   40.d. AM Amphetamine □ □
   40.e. OP Opiate □ □
   40.f. BZ Benzodiazepine □ □

41. FIRST DRUG TEST INVALID □
## Tests Results

**Blood Alcohol Concentration (g/L)**

---

**Reaction Time (seconds)**

---

### Drug Consumption:

<table>
<thead>
<tr>
<th>Drug</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>ME Methamphetamine/MDMA</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>TH THC (Δ9-tetrahydrocannabinol)</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>CO Cocaine</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>AM Amphetamine</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>OP Opiate</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>BZ Benzodiazepine</td>
<td>□</td>
<td>□</td>
</tr>
</tbody>
</table>

**These Results Don’t Represent a Medical Certification.**

**Driving After Alcohol and Psychoactive Substances Consumption or Driving When You Are Particularly Tired Represent a Risk for You and Others, Therefore in These Cases Don’t Drive!**
9. Production of informative material for participants
Axel Duart
6-RYD-BE

Volunteers and Students
Drugs' prevention training book

HOW TO REACH YOUNG RAVERS
TEN D BY NIGHT
www.tenDbynight.eu
A. INTRODUCTION

A EUROPEAN YOUTH COOPERATION

We live in a drug using world. From our morning coffee, to the medication we use or the glass of wine or beer we have in an evening. Whilst many people use alcohol safely and responsibly, young people experiment with alcohol and drugs for the first time at younger age. We can also notice an increase in the amount and frequency of alcohol consumed. Alcohol and other drugs put young people at risk in a number of ways. If alcohol is misused, young people's health may be damaged, they may get involved in criminal activities, they may be assaulted or become involved in unplanned sexual activity.

It is worth noting though that the majority of young people still do not use illicit drugs and despite any general beliefs towards young people, there is a demand coming from this young crowd to get more information on the theme in order to become aware of the danger and make a choice responsibly. On the field of awareness actions for young people (mainly in nightlife), there is a strong interest of young people to be understood and guided by their peers on this (so far) taboo subject (e.g. not to drugs and drive).

If young people are to grow up safe in this drug using world it is important that they develop the knowledge, skills and understanding that will enable them to make positive and confident choices in relation to drugs of all kinds.

There will, however, be a minority of young people who will use drugs in a way that puts them at social, physical and emotional risk: they may use dependently or for a complex variety of reasons. These young people may go on to develop problematic drug use and it is here that YOU can make the difference.
In order to talk about prevention about alcohol and drug use, it may be worth to consider some of the factors that increase the will of drug use. It is therefore important to distinguish different kind of users: Occasionally users (once in a while, to experiment, with friends) and regular users (every weekend, every day). The reason of their consumption might be utterly different. Indeed, while the occasional users will consume to experiment some new fun, the regular users is usually addicted and do not see any other alternative than consuming (personal problems, to cope with life / society in general). It is therefore important to understand what kind of user may be in front of you and adapt your speech consequently.

Here is a list why a young user might start consuming (at a young age):

- Living in a deprived area
- Non/low attendance at school
- Criminal involvement
- Parent, siblings, friends use or misuse drugs
- Evidence of lack of consideration for their child's welfare
- in care of the Local Authority
- lives in difficult circumstances
- has learning disabilities
- Young person is being sexually exploited

Factors that encourage the diminution of drugs use: There are of course many factors which can protect a young person from engaging in drug misuse. Here are just a few of them. Please feel free to underline them during your speech if relevant:

- Good family relationships
- Good relationships with other significant adults such as teachers
- Having non-using peers
- Having one non-using parent (even if the other uses)
- Having positive role models
• Being involved in activities’ organizations such as clubs, sport, youth groups
• Work
• Inclusion within groups and good integration with peers
• Good decision making skills and high self-esteem
• Regular routines and goals in life
• Having talents and abilities (music, theater, hobbies) which are recognized
• Good "health-esteem"

C. 10 TIPS FOR TEN D

When planning drug education and policy it is vital that we cater for all the young people and young adults, acknowledging that they will have different needs and understandings of drugs issues. All the evidence shows that a community that works together to tackle drug use, with a common purpose, is an effective community. Young people's views and experiences (your experience), the stability of a positive environment, skilled teaching, appropriate support, and effective partnerships are all resources that can be very useful to make a positive difference to drug use among them.

TEN D contributes to the following outcomes for young people to be healthy, staying safe, enjoying and getting back home safely, making a positive contribution of every young people’s well-being.

10 ways to encourage young people to talk with you about drugs:

1. Be part of their lives

Make sure that you take enough time for them (but be careful that it is not your only task and that they are other people behind, waiting). Take an interest in their interests and reply with your own experience. Don’t be afraid to ask if they have used anything and what. Be frank, direct and honest, they will be more enthusiast to talk with you if they see that you do not have any taboo.
2. Listen to them

Don’t be aggressive. As you going to the person directly showing willingness to talk and listen to get their opinion, they will feel more comfortable about listening to you. Ask for their input about friends’ decisions to demonstrate that you value their opinions too. Try not to interrupt or react in a way that will stop further discussion.

3. Be a role model

When it comes to drugs, there is no such thing as “Do as I say, not as I do”. Show them that you also like to have fun but that you are responsible. Don’t underestimate the influence that your behaviour can have on them. If you look cool and positive, they will get interest in you.

4. Be honest

It is important to be informed but don’t pretend to know everything. Be prepared to say “I don’t know but I will find out”. Be honest and clear about where you stand so that your peer will find it easier to be honest with you.

5. Pick your moment

Choose the right time to discuss the topic of drugs by looking for natural opportunities as they arise. First of all introduce yourself, explain the project, talk about nightlife and alcohol, than introduce the drugs subject. Don’t be afraid, it will come easily in the conversation.

6. Be calm

Being calm and rational is also important. Don’t overreact. You should keep the lines of communication open and don’t mock your peers or lecture them. This is definitely not your role. Remember that getting angry will just close the door on further discussion.

7. Avoid conflict

It is difficult to solve a problem when there is conflict. Try to see their point of view and encourage them to understand yours. If you feel that you do not have sufficient self control, do not hesitate to ask one of your colleague to come and help you, or replace you.

8. Keep on talking
Once you’ve had a discussion, it’s important to have another. As the action will include questionnaires, breathalyzers, drugtests, and reactotest, there are many possibilities to discuss. It is for instance an open door to talk about road safety issues correlated to impaired driving.

9. Set clear boundaries

Most young people expect and appreciate some ground rules. Allowing them to take part in setting the rules encourages them to take more responsibility for sticking to them. Talk about the zero tolerance philosophy, even if you understand it is not always easy to apply (according to everyone’s background). Once you have rules, enforce them and ensure young people to understand the consequences of breaking them.

Find and agree to ways young people can act should they find themselves in a situation that exposes them to drugs. For example, let them know that you will still be at disposal if they need to, even if it is later during the night.

However, make it absolutely clear that you would rather they didn’t put themselves in a situation where they are likely to be exposed to illicit drugs.

10. Focus on the positive

Reward their “good behaviour” (e.g. “You are really smart not to take your car when you go out, there is always simple alternatives, you are right”) and emphasise those things that you think they do well. Encourage them to feel good about themselves and let them know that they deserve respect.
D. 10 JUSTIFICATIONS TO CONSUME

Here are some of the reasons young people give for using drugs and some ideas about how you might choose to respond to them.

“Someone had some and I just thought I’d try it.”
Express your concern and question their decision. Ask whether it was what they expected and talk about the risks of further use. Try and find out if they felt pressured – this may lead to better ways for them to handle a similar situation in the future. Consider using examples of your personal background.

“I always wanted to try that stuff.”
Ask what made that particular drug appealing, what they expected to get from it and if they got the expected results. E.g. “What did you think it would be like?” and “Why that drug?”. You may be able to discuss whether they have tried other drugs and do not hesitate to talk about the side-effects (depression, stomachache, headache, etc... referring to the brochure about drugs use).

“All my friends were doing it so I thought ... why not?”
Ask if they felt it was safe because their friends were using it. Ask why they thought their friends used it and whether they were aware of the risks. Discuss the dangers of experimenting with drugs. It may be useful to discuss the importance of being able to make their own responsible decisions instead of following the crowd. However it is recommended never take drugs alone, you never know where it is going to lead.
“It made me feel really good.”
Try exploring the main reason the young person took the drug. Find out how they have been feeling. Talk about less risky ways of feeling good.

“All my problems from school, home and life just went away.”
This statement is a chance to really confront other issues. You can express your concern about using drugs as a means of coping. Let them know that if there are problems, it exists a lot of healthy solutions and people who can listen to them in a professional way. Ask what can be done to make things better. Discuss whether the problems returned after the effects of the drug wore off. Express your feelings about the dangers of using drugs that will increase problem (because of addiction, depression, etc...).

“It gave me more confidence.”
Let them know that this is of concern to you and explain that they don’t need drugs to feel good about themselves. Share your own experiences. By acknowledging your own behaviour, you will increase your credibility with the young person. Consider ways in which you can help to improve the young person’s confidence and self-esteem.

“Well, do you use drugs?”
You should be prepared for this type of response if this statement applies to you. You need to be frank, honest and open with them. Most of young people are saying that drugs prevention is always organized by adults who do not know anything about the subject. This is here an opportunity to let them know that we are also young, that we like to party but that we take our responsibility (to prove adults wrong when they say that young people are irresponsible), knowing the high risks it brings. We all, once in our lifetime, had been confronted to people using drugs (friends, relatives), so even if we are not professional about the subject, we remain open and try to do something about it (e.g. with the TEN D questionnaires, better statistics will be available about consumption and therefore better prevention awareness campaign can be applied). Remember: You are an important role model.
Here is a short overview about cannabis status in order to know what is exactly stated about this very drug which is often confused in young people’s mind. Other drugs are usually clearly considered and understood as illegal, even if people are still using it.

**Cannabis for personal use: the legal status**

Despite the different legal approaches towards cannabis across the Member States, a general trend in Europe can be seen in the development of alternative measures to criminal conviction, for cases of use and possession of small quantities of cannabis for personal use without aggravating circumstances. Cannabis is now frequently distinguished from other illicit substances either in the law, by prosecutorial directive, or by the judiciary practice. In most European countries, the move has been away from custodial sentences and towards fines, cautions, probation, exemption from punishment and counselling. Examples of this trend can be found in a number of recent measures, including the removal of custodial penalties in Luxembourg in 2001 and Belgium in 2003, and reduction of custodial penalties in Greece in 2003 and the United Kingdom in 2004. Directives to police or prosecutors were issued in: Belgium in 2003 and 2005, France in 2005, and the United Kingdom in 2004 and 2006. In 2006, the Czech Republic almost established different classes for non-medicinal drugs, but that draft of the Penal Code was rejected for unrelated reasons. Despite this, the number of reported cannabis offences continues to rise in Europe. (Source: EMCDDA)
F. STARTING DISCUSSING

To engage with young people, outreach teams usually take a non-judgmental approach and, while stating that the safest option is not to take drugs at all, may also provide harm-reduction advice.

Some youth and young adults have some opportunity to obtain drugs in or near the event locations. Nightlife creates an environment that produces time out behaviour in which behavioral limits may be relaxed.

Be aware that it is their choice to consume or not. Your goal is not to make any judgment but trying to bring them some help in order to adopt a sense of responsibility towards alcohol and drugs (mainly while driving).

Watch out, it might happen that a driver appears to be negative on the results of a drugtest, even if he admits that he has consumed drugs.

If it concerns cannabis, explain him that this very test is more accurate if the driver has smoked it at maximum 1 hour before doing the test (THC samples do not remain for several hours in your saliva. It remains much longer in your urine and your blood which can also be tested by the authorities).

For all other drugs, if the participant appears to be positive, and affirm not having taken anything, explain him that it can be due to some medicines that the person has been taken earlier, to the consumption of some energy drinks, or simply to the fact that this very test is not working properly and maybe trying a new one.

Also, be aware that you are talking to your peers for whom you should not have any taboo. So please do not talk to them using scientific terms such as “psychoactive substances”, or “narcotics”, etc… Just refer to the basic vocabulary that young people frequently use, such as “drugs”. You will be therefore closer to their way of speech and gain in credibility towards them.
Finally, if you are facing someone under the influence of drugs, try to look after them, reassure them, and never try to freak them out or to wind them up.

I. INFO POINTS

More information about alcohol and drugs (prevention, alternatives, treatments, and solution, in your region) is easily available on the Internet. Just start by surfing on our TEN D By Night webpage, you’ll be linked to some good info:  www.tenDbynight.eu.

Be cool, but responsible !
And good luck !
Leaving pills behind

The best way to deal with drugs and alcohol is to deal with the underlying causes. When you’re feeling down or stressed, try talking to someone safe and secure. Support yourself and your friends.

More information about alcohol and drugs (prevention, alternatives, treatments and solutions) is easily obtained on the Internet. Just start surfing on our “TEN D By Night” webpage, you’ll find out what we do and where we’re going to.

www.tendbynight.eu

Just for you to know... 10 relevant facts!

Worldwide observations show that a large numbers of terrible accidents usually happen during weekends’ nights in which young people are often involved. Thousands of young European drivers will risk injuries and even death to drive back home after drinking, using drugs or medicines misuses.

Source: CARE database - European Commission

- Experimental studies show that use of cannabis and medicines result in impaired driving ability, varying according to dose, tolerance and delay after intake.
- Combining any of these drugs with alcohol significantly increases the risk of being involved in or responsible for a traffic accident.
- It seems that cocaine tends replacing stimulants and ecstasy as the stimulant of choice.
- Deaths mentioning ecstasy are often unexpectedly among socially integrated young people.
- Suicide is identified as a cause of drug overdose deaths in some studies among drug users. Studies estimated 29% of all drug-related deaths reported in Scotland in 2005. Drugs misuse problems contribute to suicidal behaviour.
- Studies show that, after alcohol, cannabis is the most prevalent drug among European drivers’ population.
- A French study showed that 17% of the drivers under 25 years old involved in a road accident between 2001 and 2003 had used cannabis.
- A survey carried out for Green Flag in United Kingdom, of drivers aged between 17 and 24 years, about a third knew someone who takes illegal drugs and drives regularly. One-in-five also said they were likely to take illegal drugs over the festive period; and more than half said someone they knew would take illegal drugs.
- Marijuana is almost a third had been a passenger in a car when they knew the driver had taken drugs.
- Cannabis-using drivers are most likely to be young males.
- There are general legal changes to the prosecution of drug driving, and the penalties for it have been already reduced in several countries. Illicit drugs such as cannabis are indicated by the new zero-tolerance law for drivers.

1. Alcool
- Effects: Affects personality, vision, movements, reduce inhibition.
- Risks: Impaired judgement, impaired vision, impaired coordination, impaired reaction time, impaired fatigue.
- TR: Don’t mix drugs with alcohol.

2. Cannabis
- Effects: Euphoria, relaxing mood, perception, anxiety.
- Risks: Lung cancer, respiratory disease, brain damage, paranoia.
- TR: Don’t smoke, potentially cause a fire, only driving under influence are compelling to do so.

3. Ecstasy
- Effects: Stimulation, Amplify all senses, sensitivity, emotional.
- Risks: Dehydration and hyperthermia, the comedown can be fast depression, paranoia, heart attack, high blood pressure.
- TR: Regularly drink water, Stay aside if you feel pressurized.

4. Cocaine
- Effects: Strong excitement, more self-esteem, euphoria, tremors.
- Risks: Coronary heart disease, rapid and sudden death.

5. GHB
- Effects: Strong stimulating, strong high.
- Risks: Sudden death, heart attack, coma.
- TR: Keep your glass at sight, don’t use drugs in public places.

6. Speed/ Crystal (for amphetamines)
- Effects: Strong stimulating, no more pain sensations.
- Risks: Hyperactivity, psychological/physical dependence, reproduction failure.
- TR: Watch out! Because you don’t feel any pain while on ketamine, you can seriously injure yourself without knowing it.

7. Ketamine
- Effects: Sedation, anaesthesia, no more pain sensations.
- Risks: Psychological/physical dependence, reproduction failure.
- TR: Watch out! Because you don’t feel any pain while on ketamine, you can seriously injure yourself without knowing it.

8. Magic Mushrooms
- Effects: Hallucinations, delirium, hallucinations.
- Risks: Nausea, vomiting, diarrhea, dizziness, anxiety, depression.
- TR: Keep your glass at sight, don’t use drugs in public places.

9. LSD / Acid
- Effects: Hallucinations, delirium, split-brain, high-agitation.
- Risks: Nausea, vomiting, diarrhea, dizziness, anxiety, depression.
- TR: Keep your glass at sight, don’t use drugs in public places.

10. Heroin
- Effects: Central nervous depression, depression, coma.
- Risks: Impaired judgement, impaired vision, impaired coordination, impaired reaction time, impaired fatigue.
- TR: Most dangerous drug. Do not even dare. Treatment available.

We, European kids, live in a drug using world (from our morning coffee, to the medication we use or the glass of wine or beer we have in a party). But all drugs have the potential to harm if not used carefully. The most commonly used drug is still alcohol, but the raise of other psychoactive drugs and their increasing rate of consumption must be carefully considered by you and by your friends.

Therefore in cooperation with the European Commission, several European youth organizations and Universities assembled to find out what is really happening within nightlife and collecting precise statistics about alcohol and drugs use and misuse.

The project is called TEN D by Night and aims to define a European approach to contribute to the reduction of car accidents often correlated to this issue.

Some images have been kindly provided by the European Commission within the Tendbynight Program.
10. Production of informed consent sheet and anonymous sheet with results
Anita Villerusu
8-RSU-LV

General rules for informed consent procedure
In general, public health practices and policies seek to improve the overall health of the public, a position sometimes at odds with the autonomy of the individual. To advance traditional public health goals while maximizing individual liberties and furthering social justice, public health interventions should reduce morbidity or mortality. At the same time burdens of the program must be identified and minimized. The program must be implemented fairly and must, at times, minimize pre-existing social injustices and prove acceptability to a community (1).

The Universal Declaration on Bioethics and Human Rights adopted by the United Nations Educational, Scientific, and Cultural Organisation (UNESCO) on 19 October 2005 is an important step from researcher point in the search for global minimum standards in biomedical research and clinical practice (2).

The protection of human subjects in biomedical research relies on two principal mechanisms: assessing and comparing the risks and potential benefits of proposed research, and obtaining potential subjects' informed consent (3).

The concept of voluntarism is central to an understanding of ethical considerations of research. In all cases the researcher must obtain the informed consent of each subject to participate in the research. WHO Declaration on the Promotion of Patients’ Rights in Europe stated an informed consent as a prerequisite for any medical intervention (4). Also for conducting epidemiological studies and public health activities obtaining informed consent is very important. Report of the UNESCO’s Working Group on Informed Consent is recommended for research in public health field (5).
Participants in research should be informed about the study, about their rights, and give their consent before a researcher collects data from them. Every country has its own legislation or legal cases that determine the required standard for informed consent.

In TEN D project informed consent is more than simply getting a client to sign a written consent form. This is a process of communication between a client and researcher that results in the client's authorization or agreement to undergo preventive intervention. Information will be presented to enable persons to voluntarily decide whether or not to participate as a study subject. It is a fundamental mechanism to ensure respect for persons through provision of thoughtful consent for a voluntary act.

An approved written informed consent sheet will be provided to participants before survey, and researchers must obtain signatures that indicate participants have received the informed consent document, understand their rights as participants in research, and consent to participate in the study.

There should be no exception in asking written agreement in all countries involved in the Ten D by night project field work. Some studies suggested that consent is needed even in cases when researchers doing mental health and/or substance use research tended to use money as a research incentive (6).

UNESCO Report on Informed Consent included detailed guidelines on informed consent in epidemiological studies and public health activities (5).

Informed consent sheet contains all of the following elements:

1. A statement that the study involves research, and at least a general description of the topic of the research, the procedures used, and the duration of the research.
2. A statement of the risks and/or benefits of participation.
3. A statement that participation is voluntary, and that the participant may discontinue participation at any time without penalty.
4. A statement about the extent to which a participant's data and participation will be confidential.
5. Information (names, phone numbers and/or email addresses) about how to contact the researcher(s), and a statement that participants may contact researchers with questions.

6. Information about how, when, and where participants maybe more fully informed about the nature of the research and the results of the study.

7. A statement that the study has been reviewed and approved by the Institutional Review Board.

The procedure for obtaining informed consent should be designed to inform and educate the subject population in way that they can understand. Therefore, informed consent language, especially, explanation of the study's purpose, duration, experimental procedures, alternatives, risks, and benefits must be written in "lay language", i.e. understandable to the young people being asked to participate.

Understandable language or explanation is very important element in process of creating consent forms for study. Even in biomedical research recommendations are use of plain language (7).

Inform consent sheet should be written in language that is understandable to the subject who is providing consent. In the project it will be in Italian, Polish, Spanish, French, Dutch and Bulgarian language.

The consent document will be revised after pilot study in case when deficiencies are noted in the document or process.
Reference


INFORMATION LETTER TO INFORMED CONSENT

Before agreeing to participate in this action-research study, it is important that you read the following explanation about it.

TITLE OF THE STUDY: TEN D by Night - (Dark, Dance, Disco, Dose, Drugs, Drive, Danger, Damage, Disability, Death). Action is supported by the Public health Executive Agency acting under Commission of the European Communities and involving 7 European countries.

PURPOSE OF THE STUDY: This study focuses on influence of alcohol and drug use to driving ability. The strategic aim of TEN D project is to define a European approach in order to contribute to the reduction of the number and seriousness of road accidents, in particular the ones in which young people are involved, that occur during weekends and can be correlated with the consumption of alcohol and drugs.

PROCEDURES: As a participant in this study, you will be asked to complete the following:

1. An anonymous questionnaire
2. The breath test to determine the quantity of alcohol present in the expired air.
3. Saliva test to determine presence of following substances: Amphetamines, Cocaine, Marijuana, Methamphetamine, Opiate
4. To measure the reaction time

You will do two repetitions of the driving test and alcohol test before entering disco and after. More detailed information about each of these tests is presented in the special leaflets. A specially trained staff will show and explain the test procedure on place. The maximum time requirement for these tests and questionnaire will be about 20 minutes. There will be no costs for participation in the action.

RISKS AND BENEFITS: There are not contraindications to participation in this study. During measurement for hygienic purposes you will be provided with
individual hygienic mouth piece. The procedures will be simple, rapid and non-invasive, therefore it do not have any risk for your health. After measurement you will receive personal data sheet with the results of tests.

When the study will be finished, we will provide feedback to let you know about main findings of the project TEN D by Night in public web (www.tendbynight.eu). The results of this study will be used in traffic accident prevention programs targeted to young people attending recreational places and also in reducing alcohol and drug consumption.

**STOPPING YOUR PARTICIPATION:** You are free to choose whether or not to participate in this action. You may withdraw from this study at any time. To do so, indicate this to the researcher or one of the research assistants by saying, "I no longer wish to participate in this study".

**CONFIDENTIALITY:** To ensure the confidentiality of individuals’ data, each participant will be identified by a participant identification code. All records from this study will be anonymous; so far no individual identities will be used in any reports or publications resulting from the study.

**PARTICIPANT FEEDBACK:** After tests are completed, you will be provided with a feedback sheet that will include summary of the results.

**CONTACT INFORMATION:** If you have any questions about the study at any time, please contact either Project leader *(insert name of institution)* at his/her office ( phone:... or e-mail)

**Concerns about Your Participation:** We would like to assure you that this study has been reviewed and received ethics clearance through the Office of Research Ethics.......(Phone:...; Fax:... or e-mail). However, the final decision about participation is yours.
CONSENT FORM (1)
I agree to take part in a research study TEN D by Night being conducted by (Insert researcher name) and the (Insert Name of institution).
I have made this decision based on the information I have read in the Information letter. All the procedures, any risks and benefits have been explained to me. I have had the opportunity to ask any questions and to receive any additional details I wanted about the study. If I have questions later about the study, I can ask one of the researchers (list names, departments, telephone numbers of investigators).
I understand that I may withdraw from the study at any time by telling it the researcher.
This project has been reviewed by, and received ethics clearance through, the Office of Research Ethics at................. I am aware that I may contact this office if I have any concerns or questions resulting from my involvement in this study.

_____________________________     Signature of Participant
_____________________________     Signature of researcher
_____________________________     dated at place of study
CONSENT FORM (2)

I give my consent to participate in the project mentioned above on the following basis:

I have had explained to me the aims of this research project, how it will be conducted and my role in it. I am cooperating in this project on condition that:

• the information I provide will be kept confidential,
• the information will be used only for this project, and
• the measurement results will be made available to me and any published reports of this study will preserve my anonymity.

I understand that there is no obligation to take part in this study and I am free to withdraw at any time. I have been given a copy of the information/consent sheet, signed by me and by the principal researcher (name) to keep.

_______________________________Signature of volunteer
______________________________Date

_______________________________Signature of Researcher
_______________________________Name in full
______________________________Date

Should you have any complaints or concerns about the manner in which this project is conducted, please do not hesitate to contact the researchers in person, or you may prefer to contact TEN D by Night at the following address:

Telephone:
Fax:
Email:
ALCOHOL/DRUG/REACTION TIME RESULTS SHEET

The findings will be filed in a special result sheet. One Copy of Consent form and Result sheet should be given to volunteer and other to researcher.

Date:
Identification number:
Type of test done:

Drug test: □ yes □ no
Alcohol test: □ yes □ no
Reaction time: □ yes □ no

Results of Alcohol test 1) ____ (in %)
2) ____

Results of Drug test: ___Neg ___Pos

If positive, list type of Drug:

Reaction time: 1) ________________
2) ________________

________________________

Researcher’s Signature
The quantity of alcohol is indicated in “promilles” (‰). The quantity authorized for the drivers is 0.5‰ or 0.2‰, depending on the countries and driving experience. **Advise to everyone not to drink at all when you would like to drive.**

In the case if a driver has an alcohol level too high – advice to choose another no drunk driver or to call a cab.
11. Definition of pilot study design
Francisco Alonso
7-UVEG-ES

Aims of the project

When implementing a pilot study, an aspect that must not be forgotten are the general objectives of the programme, of which some are going to be tested during this pilot study:

1. Estimating, in the involved territories, alcohol and psychoactive substance consumption in young people usual meeting places
2. Estimating effects of alcohol and psychoactive substance consumption on driving ability and on road accident risks
4. Contributing to increase the efficacy of European prevention programmes in the field of drink and drugs abuse by evaluating on the field the implementation of an innovative integrated approach

Aims of the design of the pilot study
By implementing the pilot study we intend to know to what extent the materials we have chosen (both instrumental and human) are efficient, and, in case of finding them complicated or inexact, being able of changing them before the actual implementation, the field intervention.
Furthermore, we aim to prove that the aspects raised in the manual can be fulfilled and if, at an empirical level, the investigation that has been proposed can be carried out.
On the other hand, we intend to identify the weak spots of the design in order to modify them and therefore guarantee the efficiency of the intervention on the field.
In addition, we also want to pay attention to those aspects that may have remained unattended and whose treatment may be a key point to achieving the aims proposed.

**Implementing the pilot study**

**Sample**
A sample of 30 people per territory involved will be used. With this rate we intend to overcome any possible withdrawals from the subjects involved. Our intention is to have a uniform sample of 20 people in all the countries in which the intervention will take place.

**Training and preparation of the team coordinators**
A team of at least 5 qualified people will be organised in every participating country. Each team will have a team coordinator who will receive a specialised training in Turin. Among the contents addressed to the training of the coordinators we should highlight:

1. **How to contact and communicate with young people.** In this field we must stress the effect that the age of the communicator has on the intended persuasion through the contents dealt with. Thus, it is important that the investigators are young or not of an advanced age, finding it necessary to have both men and women in our teams. Moreover, it is important to have in mind those aspects of non-verbal communication that, in a direct way, influence and determine the level of persuasion of the target group of the intervention. For this, it would be advisable that they had a basis of Psychology (aspects that regulate and modulate human behaviour, detection of negative perceptions and attitudes, group dynamics...) and, having in mind the field of application, knowledge of Road Safety (epidemiologic aspects and importance of human factors in contributing to accidents, vehicles’ active an passive security...) This will help us check if the training is adequate and in what aspects we should insist more on.
2. The correct use of the anonymous coding system. Here the objective is to guarantee the correct use of the coding system that will allow from any perspective a total anonymity of the results. Also, it will include a practical exercise where the coding system will be applied so that we can guarantee the coordinators are able to transmit efficiently the practice of this anonymous coding system. We shall use this to make sure there will be no problems with the coding system once the investigators are on the field, and any doubt can be clarified during the training.

3. Administration of the questionnaire. At this point the coordinators will have to formalise individually the questionnaires approved in order to detect and overcome any possible doubt, comprehension problems, answer alternatives, among other, so that when they come to put it into practice they will know exhaustively these instruments and will be able to solve any problem that may appear during the administration of them. Thus, we will be able to check if the questions generate problems, if the questionnaires are feasible and if we need to introduce more data or questions in order to improve the extracting of results.

4. Administration of alcohol and saliva tests. Having in mind that, in these cases, it is necessary to have a previous knowledge and practice with these instruments, we will require the help of people specialised in their use who will train and/or cooperate with the coordinators while accomplishing this task. In order to guarantee the correct use of these instruments, the coordinators will have to realize one or more practical exercises with them. This will result in a better knowledge of the instruments, avoiding problems during the subsequent field intervention.

5. Use of the console for driving reaction time measure. In this case, due to the complexity or possible problems that may appear while using this instrument, we recommend the collaboration of a trained technician specialised in the use of this type of tools. If, during the pilot study, we see there are no problems in just having the investigators and there is no need to have a technician, we could discuss about managing without these.
6. **Data collection and analysis.** Once proving the evaluation instruments have been correctly and completely filled in, the University of Turin shall proceed to the statistical analysis of the results obtained which will make the extraction of objective data possible in order to evaluate the whole process. To make this possible, all collected data shall be sent over to this entity, which will be in charge of its storage and analysis.

7. **Modification of the instruments.** In case that during the pilot study we should discover problems, flaws or other complications within the instruments, we should have in mind the possibility of changing them and testing others before the field intervention.

**Training and preparation of the investigators**

The coordinator who is trained in Turin will then, in turn and in his country, train a team of at least 5 investigators, who will act directly with the object group of the intervention that will be implemented in their territory.

The investigators will receive from the coordinator the following training.

1. **Knowledge and application of the different persuasion strategies** (both rational and emotional) which intend to form or modify attitudes, thoughts and behaviours. With this we intend to prepare those who will then interact with the participants, and, as seen before, make sure they can react in case of any doubt or problem and, in case they cannot, intensify their preparation towards the intervention.

2. **Knowledge of the importance of non-verbal communication** in the intended persuasion process.

3. **Appropriate transmission** of the key role that anonymous people have in the investigations headed to detect aspects that contribute to improve our society. Moreover, highlight the unique and active role that each person has and that, even from anonymity, contributes to a positive change in society. What is more, we shall highlight the “privilege” of participating in an international investigation whose results will be used to design intervention strategies that will contribute to decrease road accidents. This intends to form
the investigators in persuading participants to take part in the investigation, stressing that the realisation of the project is for a good cause, this is, avoiding all the results of too many road accidents.

4. **Establishment of parallelisms** with other investigations that, using the same method of anonymity of their participants, have detected causes and ways that have resulted in solutions being implemented and decreasing a great deal of human suffering. This will give more soundness to the aims depicted to the participants, and we will know to what extent we will need this to “convince” those who doubt about participating.

5. **Being able of activating feelings** of emotional welfare as a result of contributing or having contributed to improve the personal or psychological state of other people. This aspect calls on the emotional side of the participants, letting them know that what they do is going to help us in searching for solutions which will help other people by, in this case, avoiding road accidents related to alcohol or drugs.

6. **Knowing the mechanisms and strategies** to activate and facilitate empathy in others in order to favour persuasion. This is associated to the previous two points, in which we intend to get people to think what they would like others to do for them and to what extent they are prepared to help others.

**Organization of the interventions**
Contacting with the owners or managers of the youth recreational places, and organising the field activities in each territory involved. The meeting places will be chosen on the basis of highest presence of target group (young people), geographical distribution (in order to cover the largest portion of territory) and the availability of the owner to cooperate. This will help us in order to detect problems with any disco that is not open to collaboration, if the intervention is going to be possible wherever we choose, how open people are to participating...
Collected data storage
Creation of a data warehouse (informatics system for uploading and elaborating data) for data entry. An external expert in informatics will be in charge of elaborating the system for uploading data and the corresponding data warehouse, under the instructions of the University of Turin. With this, the intention is to check the usefulness of the data warehouse and how to use it, so that, by the time the intervention takes place, investigators know how to introduce and save the data collected from each action, in order for it to be analysed afterwards.

International coordination of the pilot study
Each country will be in charge of realizing the activities already commented in their own territory. In this way they will, moreover, have the chance of implicating other participants who may contribute efficiently to achieving the aims proposed.

The partner who is leader of the WP will be in charge of both coordinating the individual activities of each partner and monitoring the adaptation to the methodological protocol. The leading partner, considering their experience, will be, on the whole, a referent to any problem related with this WP that other partners may have (by means of emails)

By doing this, we will make sure the method works before getting into the action of the intervention itself and, in case it does not work, solve any problems that may arise.
Bibliography


