Universidade Nova de Lisboa
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Best Practices in drug demand reduction: beyond promotion,

how to measure the impact?

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*To Emanuele , Nuno, Maria
and Domingos: the source of
my renewable energy.*

Abstract

Drug related problems remain an important burden for public health. Prevention is considered key even under very different political orientation.

Effective preventive interventions need to rely on supportive policies, sound evidence and effective implementation. The present project touches on all these three dimensions providing an analysis of the world regional, the European and the European National drug strategies on prevention of drug related problems and the way in which these shape the quality assurance systems in the European Member States.

Prevention is often associated with provision of information about the risks through, for example media campaigns. We assessed the evidence-base for media campaign interventions to prevent the use of illicit drugs and the emerging role of web and text based interventions to discourage tobacco smoking.

We critically commented on the process at the base of evidence dissemination, e.g. the development of guidelines, and we proposed that various study designs should be used to summarize the evidence in support of interventions aimed at changing behaviours. We concluded with a review of the classical epidemiological study designs to discuss strength and weaknesses of evaluating prevention and we investigated how often a method to include evidence from various study designs is used in the systematic reviews of evidence to promote behavioural changes with the aim of providing acceptable and feasible recommendations.

This work represents a comprehensive and pragmatic analysis aimed at contributing to a common understanding of the terminology and processes of evidence-based prevention interventions with the objective of facilitating the adoption of effective preventive intervention for drug related problems, and to promote an informed debate about the methods to evaluate interventions.

Keywords

Drug Strategies, Evidence-base, Prevention, Illicit Drugs

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Abbreviations

CDC= Centre for Disease and Epidemiology Control;

EMCDDA= European Monitoring Centre for Drugs and Drug Addiction;

EU= European Union;

UNODC = United Nations Office on Drugs and Crime

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1. Introduction

The drug phenomenon: old story new facts

Historically in all cultures human beings have used mind-altering substances [1]. These spanned from alcohol to opium, tobacco, cannabis and chocolate. Nevertheless in recent periods the use of some substances has been recognized as a problem for societies and public health [2].

For example, the United Nations Office on Drugs and Crime estimated that more than 29 million people among those who use drugs suffer from disorders related to the use of drugs [2] ; and 207,400 drug-related deaths corresponding to 43.5 deaths per million people aged 15-64 were caused by illicit drugs in 2014.

In terms of drug consumption, the number of those having used illicit drugs at least once in their life was estimated in 2014 to be a quarter of a billion or 1 in 20 people aged 15 to 64 [3].

This picture clarifies the importance of prevention as a way to diminish the burden posed to treatment and harm reduction, and, more importantly in this particular historical moment, to face the possible increase in prevalence of use due to the changes occurring in the legal status of illicit drugs.

In addition prevention is an area where health promotion and crime prevention can find a balanced approach as indicated for example by the European Drug Strategy (2013-2010).

Evidence-based and appropriate prevention interventions can reduce the availability of illegal drugs, enhance the protective factors against drug related problems and reinforce individual capacity for dealing with potentially drug use triggering factors.

Drugs, licit and illicit, do they differ for public health?

Substances producing forms of addiction can be easily found in our societies and these include coffee, sugar and salt, among others [5]. Nevertheless our understanding of the term drug is to some extent unique. In medicine drug refers to any substance with the potential to prevent or cure disease or enhance physical or mental welfare. In

pharmacology, it means any chemical agent that alters the biochemical or physiological processes of tissues or organisms.

In the context of international drug control organisations, "drug" means any of the substances listed in Schedule I and II of the 1961 Single Convention on Narcotic Drugs, whether natural or synthetic.

Drugs conventions are international treaties mutually supportive and complementary(see table 1). An important purpose of the first two treaties is to codify internationally applicable control measures in order to ensure the availability of narcotic drugs and psychotropic substances for medical and scientific purposes, and to prevent their diversion into illicit channels. They also include general provisions on trafficking and drug abuse.

Tab. 1 International convention on drugs

1961 UN single convention on narcotic drugs as amended by the 1972 protocol
1971 Convention on psychotropic substances
1988 Un Convention against illicit traffic in narcotic drugs and psychotropic substances

The first international drug convention, the International Opium Convention of The Hague, was signed in 1912 entering into force 3 years later in 1915. The peace treaty of Versailles contained a clause which required all its signatories to adhere to the International Opium Convention of The Hague. This convention was aimed at curbing the shipments of narcotic drugs not meant to be used for medical purposes.

Beginning with 1920, international drug control became part of the tasks performed by the League of Nations. Under its auspices, three main conventions were developed (1925 Convention, 1931 Convention and 1936 Convention). These provided the framework for the practical operations of the international drug control system and by the end of the World War II, drug control came under the auspices of the United Nations. This brought about several protocols among them the 1953 Opium Protocol.

The distinction between licit and illicit drugs is far from intuitive. For example some of the substances that are now listed in the table of controlled substances were commonly used for medical purposes until recently. This is the case for cocaine and some of the opium-based formulations.

In this regard the United Nations Office on Drugs and Crime stated that only use of the substance can be considered licit or illicit whereas the substances per se would not have any good or bad connotations.

Illicit drugs refer to drugs which are under international control (and which may or may not have licit medical purposes) but which are produced, trafficked and/or consumed illicitly.

The legal status of substances has an indirect influence on the health of the actual or potential consumers. In fact illegal substances have to be elaborated and smuggled clandestinely into the countries and this implies lack of hygiene in the production processes and risky practices during transport. Raw material is processed in clandestine laboratories controlled by organized crime associations, and the substances are hidden into human or animal bodies to pass the boarders [6]. In addition the adulteration of the illicit substance with unknown and inappropriate substances that can be infected or toxic are some of the known risky practices.

On the other hand prevention interventions that proved to be effective in regulating the production, transportation and retail of legal substances like tobacco and alcohol cannot be applied to illegal substances.

For example some of the environmental approaches such as prohibition of underage selling, taxation and restriction of use in public places, which proved to be helpful in the prevention of smoking and alcohol use, cannot be used in the context of illicit drugs [7].

Of course, on the other hand the illegality of substances is a possible deterrent for many people and in particular the youngest. In fact it has been noted that the appearance of many and diversified new psychoactive substances in particular in some European Countries is linked to the need to react to or anticipate a legal ban [8]. In conclusion, although unquestionable that – as the UNODC commented – substances per se are not legal or illegal but it is rather their use that can be legal or illegal the legality of substances indirectly influences their risk for health.

In the next paragraph we will expand the discussion on the new psychoactive substances, their characteristics and some of the challenges they pose. Although

prevention interventions generally don't distinguish between different substances (legal, illegal, hard or soft [9]) the new psychoactive substances represent a particular case requiring some brief explanation.

New psychoactive substances or Legal Highs
New psychoactive substances have been appearing on the market posing in first instances some legal challenges [10]. This is because the current legal system simply was unprepared to provide responses to this phenomenon [11].

For example the criminal law needs to be specific in defining offences thus requiring that a law must clearly list all substances under its control. In the past, the discovery of a new 'drug' required that, after an assessment of the threat to public health this was added to the national list of controlled substances. Nowadays this process is complicated by the appearance of many substances at the same time with little evidence of health risks. The producers of these substances keep modifying them making the creation of the lists an impossible goal.

The phenomenon although not extended is of concern for at least two reasons, first of all because little is known about these substances and second because they are most used among very young generations in recreational settings with few but sometimes lethal consequences. In addition the new psychoactive substances can be associated with different patterns of use and with new or different subgroups that need to be studied.

In the European Union, a system for assessing the risk of new substances is in place and risk assessments are regularly conducted by the EMCDDA [12] This system is based on expert judgement to assess the likelihood that use of a new psychoactive substance will spread [12]. This judgement is based on a comparison of the characteristics and accessibility of the new psychoactive substance and the setting in which it is used with the characteristics, accessibility and setting of use of other well-known substances.

Whether, as before mentioned, the legal status of substances affect the composition of those substances and the contexts in which they are consumed as well as the legal and social consequences of their consumption, quite often the principles of preventive

interventions remain effective across varied type of drugs whose use they aim at preventing.

In the following chapter we will review how the current concept of prevention has evolved across the last century.

Prevention: evolution of the concept and relation with Epidemiology

The English American Dictionary reads "Prevention is the act or practice of stopping something bad from happening: the act of preventing something"[13].

The modern concept of preventive interventions for behavioural change in favour of a healthier lifestyle and for the protection of health seems to be historically linked to the epidemiological shift from infectious to chronic diseases as the leading cause of death in the higher income Countries [14]. To describe the evolution of epidemiology, scientists have identified four stages of the epidemiologic transitions [14]. First came the age of pestilence and famine, with high death rates due to endemic diseases, chronic under-nutrition or malnutrition, and periodic pestilences (for example during the XIV century). In this period in Western Europe waves of bubonic plague harvested the population with an estimated twenty four to thirty million deaths [15].

The subsequent stage of the epidemiologic transition has been defined as the age of declining pandemics, and the major causes of death remained predominantly endemic infectious diseases. Surprisingly the epidemiologists who drafted this storyline omitted the war as a human originated cause of death. Nevertheless it has to be considered that, for the Second World War only, the estimates of the death toll are about 72,000,000 individuals including soldiers and civilians, the figures for the First World War estimates were around twenty million deaths.

The current epidemiological stage is considered to be mainly of degenerative and chronic diseases but a new branch exist that deals with prevention and action in natural and human created disasters such as wars, conflicts, terrorism, climate change-induced natural disasters and other natural disasters [16], that are beyond the scope of the present work.

The trend towards chronic and degenerative conditions was handled in some countries by public entities being set up to prevent and monitor diseases in their populations. One example is the Centre for Disease Control and Prevention (CDC), in the US, that starting from 1988 devoted a branch to chronic diseases (see graph below).

Table 1

LEADING CAUSES OF DEATH IN THE UNITED STATES, 1900 AND 1990

1900	1990
Pneumonia-Influenza-Bronchitis	Heart Disease
Tuberculosis	Cancer
Diarrhea and Enteritis	Stroke
Heart Disease	Injuries

SOURCE: Brownson, R. C., Remington, P. L. and Davis, J. R., eds., 1993. *Chronic Disease Epidemiology and Control.* Washington, D.C.: American Public Health Association.

The increasing importance of Chronic diseases induced the epidemiologists to focus on their complex and interrelated causes [17]. These diseases have been the object of study of long term cohort studies such as the Framingham Heart Study[1], the Seven Countries Study[2], and the British Doctors Study[3]. The contribution of these studies was to clarify the role of cigarette smoking, diet, physical inactivity, and high blood pressure to the major causes of death. Establishing the behavioural causes of many of the chronic diseases affecting humans added to the definition of man-made diseases because they are heavily influenced by the life-style of individuals and communities. Habits like smoking were found to be strongly correlated with a number of diseases as the milestone Framingham study [18] has been proving for the last six decades.

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[1] https://www.framinghamheartstudy.org/;
[2] http://www.sevencountriesstudy.com/;
[3] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC437141/pdf/bmj32801529.pdf

The epidemiologist Geoffrey Rose in a seminal article on diseases among individuals and populations [19] grouped prevention of medical conditions into two main approaches, the individual based and the population based. According to Rose the distinction originates from observation of differences between the determinants of diseases in the individuals and the determinants of incidence of diseases in population. Where in the first case genetic predisposition has a role in the second the environment is key. In terms of consequences for public health, Rose elaborated the *prevention paradox* that is useful to recall here because of the role that this has in the selection of preventive approaches. According to Rose high risk individuals -although having high probability of diseases - generate overall a limited number of cases in the population because they belong to a small number of individuals, by contrast low level risk individuals that have low individual probability of diseases but represent a much larger group, generate more cases at population level. The example chosen by the epidemiologist to clarify the concept is about Down syndrome and maternal age.

The risk of giving birth to a baby with Down syndrome is higher among mothers older than 40 years of age; nevertheless – at least in the 80s – the number of mothers having babies at over 40 was small in comparison with the bigger number of younger mothers. Therefore the few cases among the younger mothers were overall more than the more frequent cases among the small group of older mothers.

The implications of this paradox for health prevention interventions that Geoffrey Rose drew where in favour of population based strategies involving health education and aiming at changing what is perceived as "normal", for example reducing the number of people smoking. The concept of "normality" introduced by Rose was confirmed by experimental research in particular for young people who appear to be particularly sensitive to what constitute *normative beliefs* [20] when making decisions about their behaviour.

According to the Society for Prevention Research "Theories of human development are used to design interventions (programs and policies) that target the reduction of risk and the enhancement of protective factors at the individual, familial, peer, community, and environmental levels. The terms preventive interventions and interventions are interchangeable and are used to encompass preventive programs and policies.

Prevention science is the foundation for health education and health promotion as well as preventive interventions"[21, page 3]. Prevention can target individuals or populations. When it is addressed to populations it includes public health measures; the perspective of this thesis is the public health perspective.

Models of prevention interventions are graphically displayed below
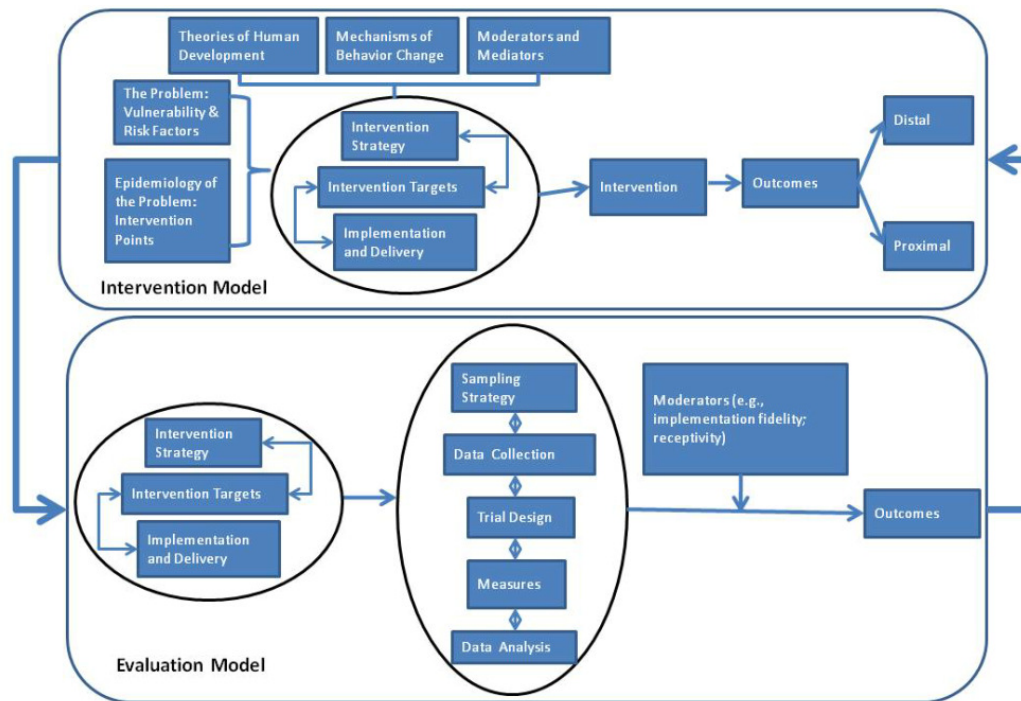
Although there is a behavioural part in the prevention model of infective diseases as well, the focus of this work is on the role of behaviour in the chronic human-generated diseases. Health education in behavioural contents for smoking and diet including alcohol consumption, were triggered by the clarifying role of the major cohort studies such as the Framingham study [22] proving the causal relation between behaviour and insurgence of diseases. Drugs addiction follows a similar pattern to smoking addiction in which the objective of prevention is to reduce the consumption of drugs. In the area of drug addiction, prevention is supposed to be able to potentially modify drugs use and related behaviours like crime, violence, and risk taking [23].

Prevention is also considered key to avoid, delay or reduce the use of drugs in the

population. The role of prevention in drug demand reduction is likely to become even more prominent in the light of the changes that are occurring on the legal status of some traditionally illicit drugs, such as cannabis, for example [24] and with the increased availability of varied types of drugs such as the so called *new psychoactive substances*. Prevention can constitute the framework in which drugs related interventions – independently from the specific substance and its legal status - will be seen as integrated and holistic including supply reduction and drug demand reduction in a balanced approach as it is invoked as central in many innovative political declarations [25].

The effects of such preventive interventions can go far beyond health improvement in the populations [26]. For example, from an economic perspective prevention is seen as an investment that provides return in terms of life time and savings in future health and social costs.

Nevertheless, data on the actual implementation of prevention intervention at European level and beyond are scarce and those available indicate that many prevention interventions focus only on some aspects of prevention, such as awareness rising and provision of information on the risks related to the use of drugs. For example, huge investments have been allocated to media campaigns for the prevention of illicit drug use among young people.

The evidence in support of prevention intervention increasingly points to the importance of holistic approaches involving many stakeholders and targeting risk and protective factors in parallel. In particular, environmental prevention is based on a public health approach that addresses the host (the individuals), the agent (the exposure to risks) and the environment (the community where the individuals live)[27]. From this perspective, in order to prevent drug use and related harms, there must be synergy [28] between the interventions that aim to reduce the population's exposure to drugs, and those that aim to promote a healthy lifestyle and a safe environment.

Environmental prevention can include strategies addressing the macro level (for example, supranational or governmental legislation), the mid-level (for example, municipal regulations) and the micro level (for example, programmes involving families and groups of peers). Preventing drug use and related harms is widely intended as the

first line of interventions to protect the population and promote security and health. For this reason, it is anticipated that it will have a key role in every strategy and future planning of global interventions on drugs [29]. The contribution of an integrated vision on the evidence and the policies as tentatively provided by the present project, will be crucial.

Central elements for a wide adoption of evidence-based interventions in Prevention are drug strategies, availability of systematic reviewing of the scientific evidence in support of interventions and availability of guidelines and quality standards, the three core elements around which the present work is organized.

In some Countries, namely in Portugal [30], the possesion and consumption of drugs have been decriminalized. To some extent the decriminalization of drugs can be seen as a prevention intervention aimed at reducing the harmful effects of the possession and consumption of drugs that are due to their illegal status. Decriminalization is different from "legalization" and from regulation of drugs, which are also occurring in some countries [31].

In the decriminalization framework the drugs, their use and possession remain illegal but the consequences do not lie in the penal system. The consequences can be administrative and, in the case of Portugal, for example, a health commission is asked to assess the health condition of the person found in possession of drugs and the measures to be applied. These vary from health counselling to referral to a treatment centre or to a harm reduction facility [30].

Sometimes confounded with decriminalization is the concept of depenalization referring to "the removal of criminal status from a certain behaviour or action. This does not imply that the behaviour is legal, but rather that non-criminal penalties can be applied. It is important to note that these measures are applied to personal possession and not to drug supply.

The concept of Supply reduction in the European Union
The European Monitoring Centre for Drugs and Drug Addiction defines supply reduction as: "the set of activities undertaken by the EU and its Member States to restrict the availability of illicit drugs. This encompasses legal measures and operational cooperation in policing and border control aimed at detecting and disrupting the cultivation, production, shipment, distribution and sale of illicit drugs and the profits derived from these activities, both inside and outside the EU.

The maintenance of a free, just and secure environment for the citizens includes the disruption of supply routes for illicit commodities (e.g. drugs) and illicit markets for their sale [11, page 2].
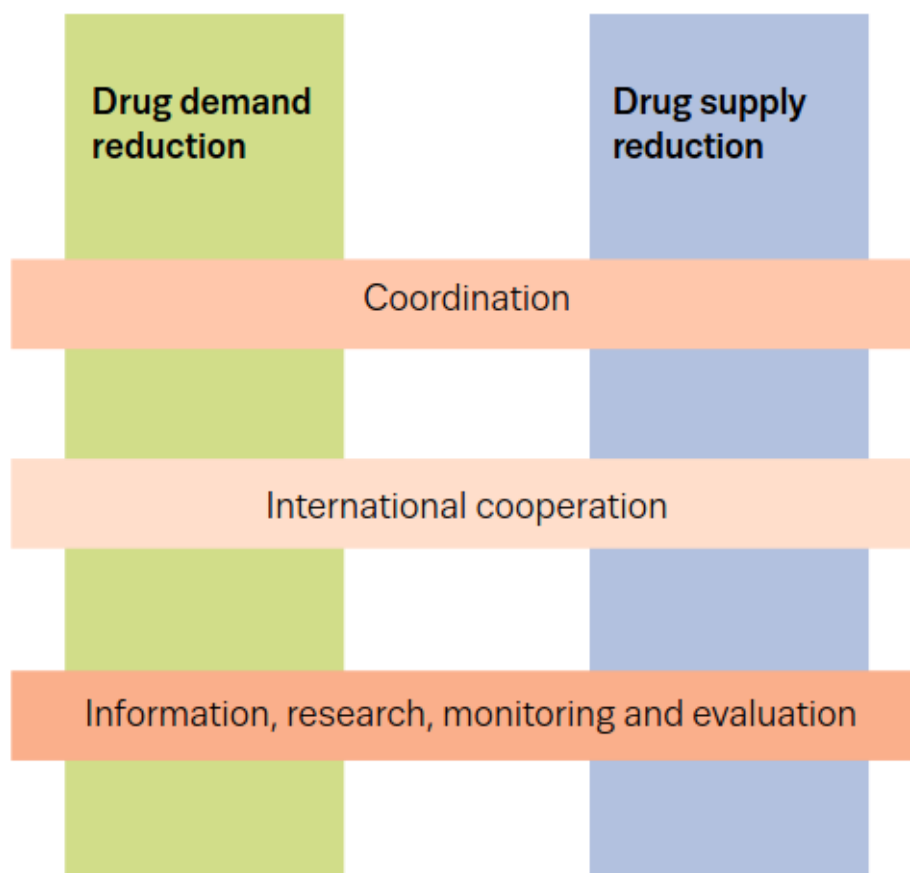
Supply reduction in Europe is regulated by a network of institutions and by a combination of varied policies, whose description is out of the scope of the present work. The focus here is on the interlink between activities related to supply reduction and those aimed at prevention, and more broadly with the demand reduction activities, which is the innovative characteristic of the European Union Drug Strategy[25].

It has been noted that in spite of the innovative approach promoted by the European Union through the introduction of a balanced approach between supply reduction and demand reduction, the terminology seems to reflect a specific economic paradigm.

Demand and supply are terms commonly used to describe micro-economic transactions, and the choice of these terms might indicate that more work is needed to frame the use of drugs into a public health approach rather than a market approach.

The figure below displays graphically the relations between the pillars and cross cutting topics in the European Union Drug Strategy.

EU drugs strategies are built on two pillars and three cross-cutting themes

Drug demand reduction

Drug supply reduction

Coordination

International cooperation

Information, research, monitoring and evaluation

Definition of drug demand reduction

Drug demand reduction consists of the compendium of activities aimed at distracting people from consuming drugs listed in the international drug control conventions (i.e. the illicit drugs). These interventions are typically defined as prevention, treatment, harm reduction and social reintegration and they should overall contribute to a reduction of prevalence of drugs and their harmful effect for individuals and society.

The term *drug demand reduction* has been coined by the international organizations and it is to some extent a political term. Imagining the illicit drugs problem as a market with a demand and a supply, the two pillars of a response to this problem should be to disrupt the supply and to discourage the demand.

The reality is more complex and the boundaries of demand reduction are flexible. As an example prevention and namely the environmental approaches to prevention cross those boundaries encompassing at the same time activities aimed at supply reduction or regulation (as is the case for the licit drugs such as tobacco and alcohol) at least at the micro level, along with activities aimed at diverting the attention from the consumption of psychoactive substances.

Also within the interventions normally considered belonging to Drug Demand Reduction, the traditional distinctions among Prevention, Treatment, Harm Reduction and Social reintegration tend to be obsolete and sometimes arguable.

Taking as an example another chronic disease like hypertension, it is apparent that treatment has a preventive effect on heart attacks but it has also a harm reduction effect on the kidneys. The boundaries between what constitutes treatment, what prevention and what harm reduction are less strong. Patients with hypertension are advised to avoid adding salt to food. Nevertheless they are not stigmatized if from time to time they break their diet and medicines are readily prescribed to control possible peaks of hypertension. Interventions are provided in a pragmatic way to defend the health capital of a specific individual (or society) considering their stage of disease and life condition. Drug addiction is affected by many ideologically influenced positions and judgements over the good and the bad that certainly have delayed progress towards pragmatic solutions, and - on the contrary – kept many professionals engaged in sterile and factious debates [32].

Of course a broader perception of what constitute prevention and the suggestion to reduce the boundaries among types of interventions does not imply confusion of roles at practice level. Clearly those in charge of treatment should be appropriately trained health carers and those providing preventive interventions should be trained as needed. The approach we are here proposing has more to do with a problem-oriented approach where cooperation is given priority to fragmentation and pragmatism to ideology.

The major political position in favour of a holistic view that overcomes the fragmentation of interventions and the related waste of resources is the so called *"balanced approach"*. Some international political debates have introduced the

concept of "Integrated, Comprehensive and balanced approach" indicating the need to combat the problems deriving from the market and the use of illicit drugs in an holistic way harmonizing the interventions aimed at supply reduction with those targeted at drug demand reduction. In particular the *Manifesto* of the balanced approach (echoed by other political documents) is the European Union Drug Strategy 2013-2010.

Drug Strategies: the vision in drug policies

Drug strategies and action plans are policy documents that establish visions, setting far-reaching objectives and describing future actions to address drug-related problems [33].

Drug strategies exist at regional level and national level.

Most regional drug strategies were developed between 1998 and 2009, under the influence of the United Nations' (UN) political declarations and plans of action that were published at that time [34,35]. The UN's declarations and plans of action created a systematic and structured approach to drug policy and prompted UN member states to create comprehensive and balanced national drug strategies that also involved regional mechanisms of cooperation. The existing intergovernmental (regional) drug plans and strategies involve countries from the Americas, Africa, the European Union and a number of Asian countries. These strategic documents express the official will of countries in these regions to tackle security and social problems caused by the drugs phenomenon, and influence the priorities and possibly the resources made available for achieving regional goals.

European National Drug Strategies and the European drug strategy

The definition of Drugs policy is the responsibility of the EU national authorities, which are best placed to make those choices that suit the local culture and socio-economic conditions. Nevertheless because drugs are a transnational threat, and EU countries cannot tackle it effectively on their own [36].
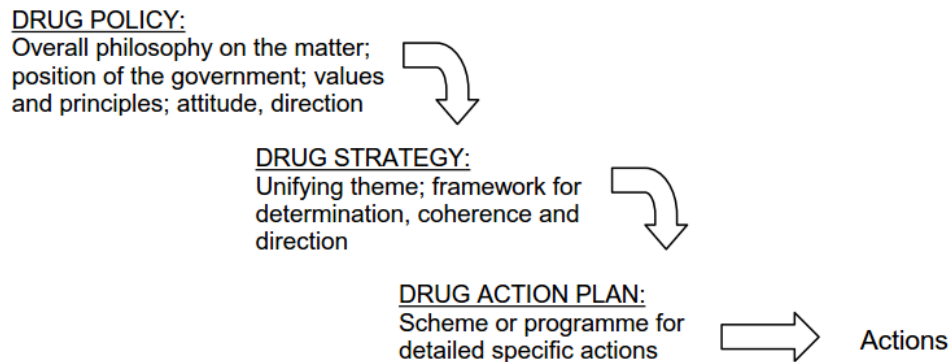
Appropriately addressing illicit drugs requires a long-term, integrated and multidisciplinary approach, which joins together public health, social and education policies, law enforcement and external action in a coherent policy.

In a synthesis of the – at the time – emerging drug strategies, Ballotta [37] gave working definitions of policies, strategies and action plans, aimed at depicting the European developments. These definitions are helpful in framing the present analysis and will be reported below.

National drug policy – containing the overall philosophy, principles, actors, actions and initiatives of the government in the field of drugs, not necessarily formalised in documents or plans.

National drug strategy –refer to the set of instruments or mechanisms aimed at directing drug policy principles towards objectives. The strategy might not necessarily appear in written format, however in the time of the present work, the majority of the European Union Member States have a written Drug Strategy. These documents may be adopted by the government itself and, in some cases, by the national parliament.

National drug action plan – is the instrument (a document) aimed at implementing and delivering the principles of the strategy, in which objectives, targets, resources and responsibilities would be detailed and identified in order to be achieved within a set timeframe.

DRUG POLICY:
Overall philosophy on the matter; position of the government; values and principles; attitude, direction

DRUG STRATEGY:
Unifying theme; framework for determination, coherence and direction

DRUG ACTION PLAN:
Scheme or programme for detailed specific actions → Actions

Source: EMCDDA 2002

The present piece of work focus on the European National Drug Strategies, at the time at which we are writing there are 30 of them (Including those of Norway and Turkey).

Evidence based drug strategies are expected to promote a holistic approach to prevention allowing for the involvement and synergies of all the relevant actors and stakeholders. At different levels of detail those strategic documents guide and influence the actions at macro-regional level (such as for Europe) and at National level.

The European Union Drug Strategy (2013–20) is the ninth strategic document on illicit drugs endorsed by EU Member States since 1990 and reflects their current drug policy position and aspirations, identifying common objectives to "reduce drug demand, dependence, related health and social harms, and supply". The Drug Strategy is accompanied by two action plans valid for four years each and translating the strategic priorities into specific actions with a timetable, responsible parties, indicators and assessment sources.

The Drug Strategy is structured around two policy areas: drug demand reduction and drug supply reduction; and three cross-cutting themes: coordination; international cooperation; and information, research, monitoring and evaluation.

Including 16 objectives and 54 actions, the European Drug Strategy spans across these five pillars, and includes the keyword of much relevance for the present work: "supporting evidence-based decision making".

The strategic document in fact stresses the need for an empirical and evidence-based approach to drugs policy. It expands the main principles on which international drugs policies are based by adding the principle of evidence-based decision-making to the integrated and balanced approach enshrined in the 2009 UN political declaration on drugs. The strategy outlines a model for EU drugs policy that is: integrated, combining all aspects of drugs activities; balanced, concentrating equally on demand and supply reduction measures; and evidence-based, drawing on scientific findings. It aims for an improved understanding of the impact of drug policy measures, the adoption of quality standards and best practices in drug demand reduction alongside the implementation of key indicators to measure success in the area of drug supply reduction. The strategy provides Member States with a forum for open debate about the effectiveness of demand reduction measures and, increasingly, supply reduction measures, and explicitly supports drug monitoring and collection of data on best practices.

Evidence-base and evidence based policies

Both the international and the national drug strategies have progressively claimed to be or be willing to be *evidence-based*. Quite often they do not clarify what they mean by being evidence-based as this concept entered the common language as self-explanatory.

The concept of "evidence-base" was developed in the Medical field by David Sackett (November 17, 1934 – May 13, 2015), an American-Canadian medical doctor who pioneered evidence-based medicine. Founder of the first department of clinical epidemiology in Canada at McMaster University, and the Oxford Centre for Evidence-Based Medicine, David Sackett defined evidence-based medicine as the "conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients. The practice of evidence-based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research" [38, page 71].

"Primum non nocere" – first of all do not harm – the phrase attributed to the Hippocratic Oath, states health intervention should first of all avoid harm. With this inspirational aim the pioneers of evidence-based medicine noted the concerning discrepancies between research results and medical practice, which would have cost human lives [39]. According to them, the timely application to practice of the results from clinical research would have saved many lives and reduced subsequent costs to the society [40].

For example, experimental studies proving the effectiveness of systemic gluco-corticosteroids administered to pregnant women at risk of preterm delivery to reduce respiratory distress syndrome in new-born babies were available already in the 1970s, but it took almost 20 years before this intervention became common practice [41] and the possible effect of the delay in the adoption of this practice was that a significant number of premature babies probably suffered and needed more expensive treatment than was necessary, or possibly died [42].

These types of considerations contributed to the spontaneous creation of a movement for the systematic collection of scientific results for dissemination outside the restricted circles of researchers and academics became known worldwide at the beginning of the 1990s [43] and was boosted by the foundation of the Cochrane Collaboration, an

international organization aimed at helping "healthcare providers, policy-makers, patients, their advocates and carers, make well-informed decisions about health care, by preparing, updating, and promoting the accessibility of Cochrane Reviews" [44] web-page.

In 1998 an editorial group specifically devoted to drugs and alcohol was founded with its base in Rome [45], and since then around 70 reviews on the various interventions (including prevention) for drug and alcohol problems have been published and regularly updated.

The availability of research on the effectiveness of interventions for drug problems has dramatically increased over the last years, even though important gaps still remain to be bridged with evidence [46,47]. The availability of studies and of systematic reviews nurtured the production of clinical guidelines as a major tool for the dissemination and application of evidence in practice. For example, a recent survey for the identification of treatment guidelines in Europe identified more than 140 sets of guidelines for the treatment of drug addiction [48].

Documents on recommendations for practice
The guidelines are key tools for the translation of study results into recommendations for practice. They have been defined as: 'statements that include recommendations intended to optimise patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options'[49]

The idea of having documents informing decision-making on the base of scientific evidence was promptly captured by public policy in particular by the international organizations as a sound scientific base to improve relevant outcomes.

Evidence-informed health policymaking is an approach to policy decisions that aims to ensure that decision-making is well-informed by the best available research evidence. It is characterised by the systematic and transparent access to, and appraisal of, evidence as an input into the policymaking process. The overall process of policymaking is not assumed to be systematic and transparent; however, within the overall process of policymaking, systematic processes are used to ensure that relevant research is identified, appraised and used appropriately. These processes are transparent in order to

ensure that others can examine what research evidence was used to inform policy decisions, as well as the judgements made about the evidence and its implications. Evidence-informed policymaking helps policymakers gain an understanding of these processes [50,51].

Evidence-based policy has been invoked in many contexts especially those linked to health including prevention of illicit drug use. According to the United Nations Economic Commission for Europe, for example, "Evidence-based policy has been defined as an approach which "helps people make well informed decisions about policies, programmes and projects by putting the best available evidence at the heart of policy development and implementation"[52, page 1].[4]

Nowadays the relation between evidence based policies and the instruments for the implementation of evidence-based interventions and policies is bi-directional. In fact policies are - or want to be - based on systematic reviews of evidence and guidelines and at the same time they can call for more research, synthesis of research and guidelines publication and dissemination.

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[4] United Nations Statistical Commission and Economic Commission For Europe Conference of European Statisticians Http://Www.Unece.org/Fileadmin/Dam/Stats/Documents/2008/05/Dissemination/Wp.10.E.Pdf

The framework for knowledge translation
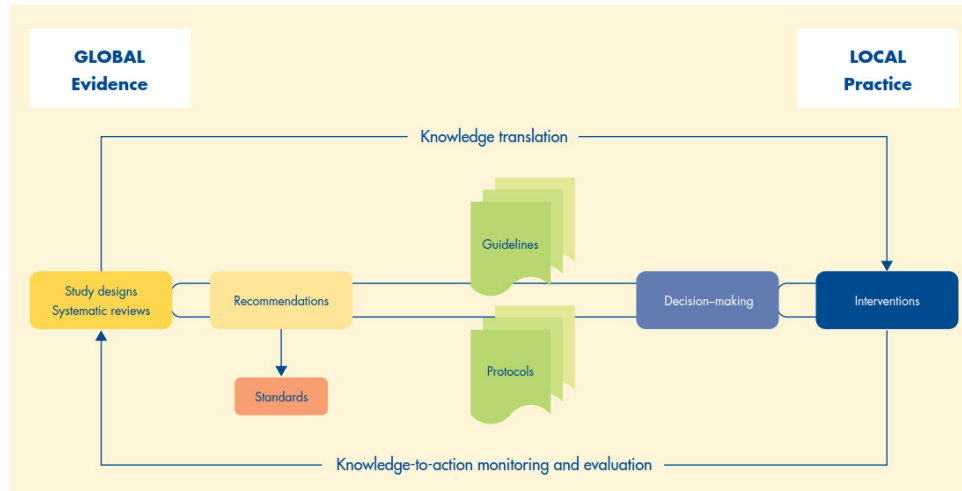
Systematic reviews are studies of studies which identify, critically assess and synthetize the experimental – but not only those- studies of evidence [53]. In this way systematic reviews are invaluable instruments to clarify the effectiveness of interventions in the light of previous research and to highlight uncertainties and identify gaps for further investigation.

Trustworthy guidelines should be based on a systematic evidence review, developed by a panel of multidisciplinary experts, provide a clear explanation of the logical relationships between alternative care options and health outcomes, and provide ratings of both the quality of evidence and the strength of the recommendations.

In the context of the present project we decided to consider altogether drug strategies, systematic reviews and guideline developments to highlight the virtuous circle linking these three pillars of effective interventions. Once these are aligned they can make an impact but a lot of harmonization among the views and actions of different stakeholders is required and this can be a challenge.

How to measure the impact of dissemination interventions?
Epidemiology is one of the sciences at the base of the evidence-based approach in health care and in prevention. Traditionally epidemiology has considered *evaluation* for aetiological hypothesis whereas social sciences and in particular education and

psychology have considered evaluation as a way to measure effectiveness of interventions [54].

With the widespread consensus on the need to base health policy on evidence these two instances have converged and the methods born in the realm of epidemiology have been applied to the study of the effectiveness of health and social interventions. An example is the creation of the Campbell Collaboration that applied the same methods of the Cochrane Collaboration to social and behavioural interventions in education, crime and justice, and social welfare.

The first review conducted by the Campbell Collaboration (which was founded in 2000) addressed a prevention program in the crime and justice system called "scared straight" that was commonly delivered to young people in the United States with similar experiences in Australia, the UK, in Germany and in Norway [55]. The program entailed juvenile delinquents or children at risk of deviance being brought to visit prisons. The review included 9 randomized controlled trials that had evaluated the interventions and concluded that the intervention was harmful or ineffective in reducing the delinquent behaviours in young people at risk.

After about twenty years of activities by the Cochrane and the Campbell Collaborations and the success of methods of systematic reviews, to assess the effectiveness of interventions, open questions remain about the success of the dissemination practices and the level of implementation.

Overall the problem is whether the existence of a body of evidence is sufficient to convince the decision makers to adopt evidence based-interventions. Implementation science has highlighted that efforts are needed to promote the effective adoption of evidence-based-interventions.

For example, randomized controlled studies are conceived to minimize the role of context and improve internal and external validity (or the generalizability of interventions to different context). Nevertheless this aspect that constitutes a strong argument for studying the medical and pharmacological interventions, has been criticized by implementation science. This critique has argued that context has a central role in the implementation and its evaluation and it should not be minimized: on the

contrary. Pawson and Tilley [56] proposed a framework where dissemination interventions are evaluated in relation to how (process) for whom (specific individuals) and in which context the interventions can work. The objective of this approach is to fully consider the context in which the interventions are delivered, considering that this has an impact on the implementation and the results.

Contribution of this piece of research

The present project contributes to a wider adoption of evidence-based prevention interventions for drug related problems by analysing the policy framework, the evidence-base, the dissemination and implementation tools, and the methodology for evaluation studies.

Four main pillars were considered: policy documents, systematic reviews of effectiveness, processes to produce recommendations and evaluation studies, in an analyses leading to 6 studies published in peer-reviewed Journals (one is published in two articles).

First we identified the role that prevention of use of illicit drugs has in the regional drug strategies to identify whether these can encourage the adoption of comprehensive environmental comprehensive approaches (Ferri et al, 2015: study 1, p.60). We then provided a brief overview of the quality assurance systems for drug demand reduction – including prevention - as deduced from the analysis of the European and national drug strategies (Ferri et al, 2016: study 2 p.65) and we assessed the evidence in support of a widely adopted prevention intervention through media campaign to prevent use of illicit drugs among young people (Ferri et al, 2013; Allara et al, 2015: study 3 p.40). We also explored how e-health interventions can be effective in addressing addiction to legal substances such as tobacco (Crocamo et al, 2017: study 4 p.76). We then decided to use the opportunity of an invited commentary from one of the Scientific Journals with higher impact factor in the addiction area (the Addiction Journal) to publish the results of an analysis of the process considered the gold standard for evidence based recommendations and promote a discussion (Ferri and Dias, 2015: study 5 p.73). To conclude, study six analyses the study designs that are generally considered for the evaluation of prevention interventions and discusses their feasibility and the contribution that different designs and level of complexity can bring to the knowledge

needed to deliver evidence-based prevention interventions. The study also assessed whether a methodology to integrate results from different study designs is used in the systematic reviews of evidence for preventive interventions aimed at changing behaviours.

I am the author of the systematic review and meta-analysis on which the publication 4 (Allara et al, 2015) is based (publication 3), (cfr with the note in the publication: "This article is based on a Cochrane Review published in the Cochrane Database of Systematic Reviews (CDSR) 2013, Issue 6, DOI: 0.1002/14651858.CD009287.pub2 (see http://www.thecochranelibrary.com for information). Cochrane Reviews are regularly updated as new evidence emerges and in response to feedback, and the CDSR should be consulted for the most recent version of the review."

My contribution in publication 5 (Crocamo et al, 2017) consisted on the methodological orientation on how to perform the search for the studies to be included and for their quality assessment. I also indicated how to extract the data to be included in the meta-analysis and how to interpret the results.

I conceived, designed and conducted the study for Publication 6 with the intention of responding to the knowledge needs of those performing evaluation of interventions in particular in prevention.

2. Objectives

2. Objectives

The present project is aimed at contributing to the implementation of evidence-based prevention interventions in Europe by analysing the policy base; the available evidence and the methodological tools.

Specific objectives:

Specific objective: To identify and describe how prevention is perceived and addressed in the regional drug strategies around the world;

Paper 1: Perception and address of prevention in the regional drug strategies (Ferri et al, 2015)

Specific objective: To identify how the indications of European Union drug strategy are reflected in the European National Drug Strategies and implemented in the Countries;

Paper 2: Quality assurance systems in the European Countries: an overview (Ferri et al, 2016)

Specific objective: To Assess the evidence base for a widely adopted prevention intervention

Paper 3: identify and critically appraise the studies on media campaigns for the prevention of illicit drug use among young people Study 3 (Ferri et al, 2013; Allara et al, 2015);

Specific objective: identify evidence in support of interventions for legal substances.

Paper 4: identify and critically appraise the studies on web and text based interventions for smoking cessation (Crocamo et al, 2017).

Specific objective: To identify the methodological gaps affecting the adoption of evidence based prevention interventions, in practice.

Paper 5: Time, consensus and implementation: challenges for knowledge exchange Ferri and Dias, 2015)

Specific objective: To review the available epidemiological study designs in order to identify which ones are feasible and acceptable to provide evidence on the evaluation of prevention interventions?

Paper 6 (in submission with Public Health Research and Practice): Study designs for prevention interventions' evaluation: feasibility and acceptability (Ferri et al).

3. Methods

3. Methods

In order to identify and comment on the perception of prevention in the regional drug strategy, (Study 1: Ferri et al, 2015), we performed a search on the websites of the intergovernmental organisations that have adopted a drug strategy or action plan on drugs, hand-searching reference lists of retrieved documents. In addition, proactively contacted the intergovernmental organisations to cross-check available information. The inclusion criteria required that documents were: (i) officially endorsed by heads of states and governments within supranational organisations of countries belonging to the same geographical area and (ii) published in the period 2009–2014. We included only documents available in the English Language.

The exclusion criteria were: documents related to cooperative projects that involved several regional and international actors; bilateral agreements in the drugs field; other strategic documents, such as regional security or health plans that were not specifically related to drugs.

The textual analysis was conducted by reading the documents and identifying relevant keywords (i.e. reducing exposure to illicit drugs, promoting healthy lifestyle and a safer environment). Each keyword was analysed in the context in which it was mentioned and summarised in a thematic table.

The overview of the quality assurance systems (Study 2, Ferri at al, 2016) was based on a search in the website of the European Monitoring Centre for Drugs of Drug Addiction (conducted in May 2015) to identify the European national drug strategies. Inclusion criteria required that the strategy was available in an official format in English Language; documents in national (non-English) languages
only were excluded. We performed an interpretative textual analysis [58] for all the quotes to pre-specified keywords.

Consultation was held with the European National experts on the systems in place for quality assurance. In November 2015, we consulted the EMCDDA's National Focal Points via a pre-filled workbook containing the information we extracted from the National Drug Strategies and from the EMCDDA structured Questionnaires on best practices
(http://www.emcdda.europa.eu/responses/data-collection).

We asked relevant officers to check and – where needed – to add comments on the contents. Furthermore, additional open questions addressed the organisation and functioning of best practice promotion that was pre-filled with information from a biannual EMCDDA questionnaire on quality assurance (Standard Questionnaire 27pII). This item explored information on national guidelines and national quality standards, the organisations in charge of producing them, the topic (prevention treatment or harm reduction) and the methodology adopted to develop such guidelines. A final open question was about accreditation systems and /or educational systems specific to drugs-related problems. By February 2016, we had received 27 complete responses.

The assessment of the evidence base for a widely adopted prevention intervention was performed by means of a Cochrane Systematic review of evidence (Study 4: Ferri et al 2012, Allara et al 2015).

To identify the studies to be included in the meta-analysis we searched the Cochrane Central Register of Controlled Trials (CENTRAL, The Cochrane Library 2013, Issue 1), including the Cochrane Drugs and Alcohol Group's Specialised Register; MEDLINE through PubMed (from 1966 to 29 January 2013); EMBASE (from 1974 to 30 January 2013) and ProQuest Dissertations & Theses A&I (from 1861 to 3 February 2013).

Selection criteria included: Cluster-randomised controlled trials, prospective and retrospective cohort studies, interrupted time series and controlled before and after studies evaluating the effectiveness of mass media campaigns in influencing drug use, intention to use or the attitude of young people under the age of 26 towards illicit drugs. Data collection and analysis were performed using the standard methodological procedures of The Cochrane Collaboration.

In order to identify and assess the evidence in support of interventions for legal substances (study 4 Crocamo et al, 2017) we conducted a systematic review and meta-analysis of studies found through PubMed, Embase and PsycInfo and references of relevant papers. The studies were evaluated according to their risk of bias

following standard Cochrane methods. In addition, we considered the heterogeneity of studies for inclusion in the meta-analysis and we performed a meta-regression to test if candidate covariates moderate the overall effect.

In order to discuss which aspects of the guidelines development process can impact the effective adoption of evidence-based interventions, we took treatment as an example. Treatment is the area where the methodology for the production of evidence in support of recommendations for practice, is the most advanced.

In an invited commentary by a reference journal (Ferri and Dias, 2015) we discussed three topics we consider important for a wide implementation of evidence-based interventions. We analysed the steps indicated by the AGREE II and the GRADE working group for the development of evidence-based clinical guidelines and we focused on time (to carry on evidence synthesis and drafting of recommendations); consensus (the external validity of the internal consensus expressed by the guidelines panels) and implementation, the actual application of recommendations for practice.

In conclusion, in order to draw recommendations on how to overcome some limitations of the typical evaluation studies, we searched the Cochrane database of reviews for prevention interventions aimed at changing behaviours and we identified the study designs included. We then searched the main European databases of the evaluated practices to investigate the study designs considered for the evaluation and we explored the extent to which a method for the combination of different study designs to synthetize the available evidence is widely used (Ferri et al, study 6 in submission).

4. Results

4. Results

This PhD programme is composed of six studies and six publications. These are aimed at analysing the policy premises at international and European level for the adoption of evidence-based prevention, reviewing the evidence in support of some interventions for illegal and legal substances and identifying limitations of the gold standard method for the dissemination and implementation of evidence-based interventions. We also revised the methods to design evaluation studies keeping into consideration the feasibility and acceptability of evaluation methods. These studies follows in the next part of the present thesis.

Paper 1: Regional Drug Strategies: how is prevention addressed and perceived?

SHORT REPORT

A review of regional drug strategies across the world: How is prevention perceived and addressed?

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Abstract

Regional drug strategies and action plans are intergovernmental policy documents that address drug-related problems. This article analyses six of these strategies, involving 148 countries in four continents. We focus in particular on how the prevention of drug-related problems is described, and if a comprehensive approach (such as environmental prevention) is used. All the documents include prevention as one of their key priorities, and three of them provide a comprehensive framework for preventive strategies that incorporates environmental interventions. The European Union drugs strategy explicitly mentions environmental prevention intervention as one of the mutually reinforcing measures for drug demand reduction. Several factors could benefit from wider adoption of an environmental prevention approach. Two of these, both prominent issues, are: the need to promote integration and synergy in efforts to reduce people's exposure to illicit drugs and the demand for drugs; and the change in the legal status of some traditionally illicit drugs that is occurring in some regions. In terms of the new legal status of some drugs, while it is not yet clear what the possible effects are of the availability and prevalence of use of those substances, prevention is expected to remain an important strategy. The "global strategies" approach can be an important endorsement in achieving wide recognition and the adoption of environmental prevention strategies in drug policy.

Introduction

Regional drug strategies and action plans are policy documents that establish visions, setting far-reaching objectives and describing future actions to address drug-related problems [European Monitoring Centre for Drugs and Drug Addiction (EMCDDA), 2014]. Most regional drug strategies were developed between 1998 and 2009, under the influence of the United Nations' (UN) political declarations and plans of action that were published at that time (UNGASS, 1988; UN, 2009). The UN's declarations and plans of action created a systematic and structured approach to drug policy and prompted UN member states to create comprehensive and balanced national drug strategies that also involved regional mechanisms of cooperation.

The existing intergovernmental (regional) drug plans and strategies involve countries from the Americas, Africa, the European Union and a number of Asian countries. These strategic documents express the official will of countries in these regions to tackle security and social problems caused by the drugs phenomenon, and influence the priorities and possibly the resources made available for achieving regional goals.

Preventing drug use and related harms is widely intended as the first line of intervention to protect the population and promote security and health. For this reason, it is anticipated that it will have a key role in every strategic and planning document on drugs (Pompidou Group, 2011). Environmental prevention is based on a public health approach that incorporates the host (the individuals), the agent (the exposure to risks) and the environment (the community where the individuals live) (Asma et al., 2004). From this perspective, in order to prevent drug use and related harms, there must be synergy (Burkhart, 2011) between the interventions that aim to reduce the population's exposure to drugs, and those that aim to promote a healthy lifestyle and a safe environment. Environmental prevention can include strategies addressing the macro level (e.g. supranational or governmental legislation), the mid-level (e.g. municipal regulations) and the micro level (e.g. programmes involving families and groups of peers).

In this article, we analyse and describe how regional drug strategies' approaches to prevention fit into the global approach to drugs, and we discuss how these highly relevant

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Table 1. Number and type of documents included in the analysis.

Title	Organisation	Function
AU plan of action on drug control 2013–2017	African Union (AU)	Implementation of strategy
Political declaration on the prevention of drug abuse, illicit drug trafficking and organised crime in West Africa (Abuja Declaration, 2008)		
Regional action plan to address the growing problem of illicit drug trafficking, organised crime and drug abuse 2008–2011 (ECOWAS)	Economic Community of West African States	Strategy and implementation
Hemispheric drug strategy 2011–2015		
Plan of action 2011–2015	Organization of American States (OAS)	Strategy and implementation
ASEAN work plan on combating illicit drug production, trafficking and use 2009–2015	Association of Southeast Asian Nations (ASEAN)	Implementation of strategy
Counter narcotic strategy of the Shanghai Cooperation Organisation Member States 2011–2016	Shanghai Cooperation Organisation (SCO)	Strategy
EU drugs strategy 2013–2020		
EU drugs action plan 2013–2016	European Union (EU)	Strategy and implementation

policy documents can enhance the profile, the role and the recognition of environmental prevention methods in drug policies.

Objectives

To describe how prevention is portrayed in the different drug strategies, identifying the actions that aim to (i) reduce exposure to drugs, (ii) promote a healthy lifestyle and (iii) create a safer environment; and to analyse whether and how these documents incorporate an environmental prevention approach.

Methods

A systematic review of drug strategies and action plans from across the world, and textual comparative analysis.

Search strategy

We identified the intergovernmental organisations with multi-sectorial purposes that have adopted a drug strategy or action plan on drugs, hand-searching reference lists of retrieved documents. One of the authors (D.B.) proactively contacted the intergovernmental organisations to cross-check available information.

Inclusion criteria required that documents were: (i) officially endorsed by heads of states and governments within supranational organisations of countries belonging to the same geographical area and (ii) published in the period 2009–2014. In addition, we included only documents available in the English language.

The exclusion criteria were: documents related to cooperative projects that involved several regional and international actors; bilateral agreements in the drugs field; other strategic documents, such as regional security or health plans that were not specifically related to drugs.

Textual analysis

The textual analysis was mainly performed by reading the documents and identifying relevant keywords (i.e. reducing exposure to illicit drugs, promoting healthy lifestyle and a safer environment). Each keyword was analysed in the context

in which it was mentioned and summarised in a thematic table (Table 1).

Results

The search strategy identified 17 documents, nine of which met the inclusion criteria; these nine documents referred to six regional drug strategies (Table 2). The documents covered four regions (Africa, America, Asia and Europe) and 148 countries. The organisations involved in the strategies were: the African Union (AU) and the Economic Community of West African States (ECOWAS); the Organization of American States (OAS); the Association of Southeast Asian Nations (ASEAN); the Shanghai Cooperation Organisation (SCO) and the European Union (EU).

The textual analysis revealed that prevention was mentioned in all the documents analysed, mainly as an activity related to drug demand reduction. Nonetheless, we observed some differences in the way in which prevention was perceived and addressed.

Reducing exposure to drugs

All the strategies identified the activities that aimed to reduce exposure to drugs as ''reduction of drug supply''. The objectives, such as strengthening law enforcement, increasing intelligence exchange and improving border controls, appeared consistent across the documents. We found that regions took a largely uniform approach, with law enforcement measures and methods to tackle drug trafficking and drug-related crime being generally very similar between continents.

However, in the area of supply reduction there was a noticeable difference in attitudes towards the final objective, as revealed by the terms used and the establishment of clear deadlines.

Both African plans (AU, 2013; ECOWAS, 2014) identified the need to harmonise legislation in the area of drug trafficking. The AU plan stressed that coordination, collaboration and capacity building should be increased in order to make law enforcement more efficient, and that actions to address drug trafficking and related organised crime should be harmonised. Increasing regional cooperation against drug

Table 2. Dimensions of prevention in the different drug plans.

| Document and organisation | Prevention | | | Measuring instruments |
	Reducing exposure to illicit drugs	Promoting healthy lifestyle	Promoting safer environment	
OAS plan of action 2011–2015 Organization of American States	Comprehensive and balanced approach to reduce supply of drugs	High-risk and general population (media campaign)	Reducing driving under the influence of drugs and drug-related accidents in the workplace	Setting of measurable objectives
ECOWAS action plan 2008–2011 Economic Community of West African States	Political attention and more resources to reduce drug trafficking	Multimedia campaign	Not found	Not found
AU plan of action on drug control 2013–2017 African Union	Coordination and law enforcement against drug trafficking and related crime	Multicomponent approaches	Evidence-based public awareness and community involvement carried out covering the prevention of drug use, trafficking and related offences	Implementation of quality standards
ASEAN work plan on combating illicit drug production trafficking and use 2009–2015 Association of Southeast Asian Nations	Drug-free region by 2015	High-risk groups	Not found	Not found
SCO counter narcotic strategy 2011–2016 Shanghai Cooperation Organisation	Drastic reduction in illicit trafficking by 2017	Young people (media campaigns in schools)	Not found	Not found
EU drugs action plan 2013–2016 European Union	Measurable reduction in the availability of illicit drugs by 2020	High-risk groups	Drug demand reduction consists of a range of equally important and mutually reinforcing measures, including prevention (environmental, universal, selective and indicated), early detection and intervention, risk and harm reduction, treatment, rehabilitation, social reintegration and recovery	Implementation of quality standards

trafficking was also one of the main objectives of the ECOWAS plan (ECOWAS, 2014), which stressed the need to attract political attention and devote more resources to this increasingly worrying phenomenon. In the OAS plan (OAS, 2011), the first objective was to improve comprehensive and balanced measures that aim to reduce drugs supply, through the use of intelligence, based on monitoring and the evaluation of findings.

The ASEAN plan (ASEAN, 2009) aimed to achieve a drug-free region by 2015. Experts in the region agreed the definition of ''drug free'', i.e. an insignificant quantity of illicit crops will remain and there will be very little manufacturing and trafficking of drugs.

A drug-free situation was also anticipated in the SCO plan (SCO, 2011), which called for a drastic reduction in the illicit trafficking of narcotics and precursors by 2017. Both the SCO plan and the ASEAN plan aimed to implement, albeit with a tighter deadline, the 2009 UN political declaration and plan of

action, which set 2019 as a target date for states to eliminate or significantly and measurably reduce the illicit cultivation, production and trafficking of, and demand for, illicit drugs.

An intelligence-led approach was also the backbone of drug supply measures in Europe. The EU drugs strategy 2013–2020 (EU, 2012) set the objective of contributing to a measurable reduction in the availability of illicit drugs by using an intelligence-led approach to identifying the criminal organisations causing the most harm or posing the most serious threat, making them priority targets. Although no target date for achievement was stated, 2020 should be considered the end point when progress will be evaluated.

Promoting a healthy lifestyle (main target population and actions)

The drug strategies of ASEAN (ASEAN, 2009), the AU (AU, 2013) and the EU (EU, 2012) focused on identifying and

providing evidence-based prevention interventions to at-risk groups (Carra, Bartoli, Brambilla, Crocamo, & Clerici, 2014), whilst those from ECOWAS and SCO (ECOWAS, 2014; SCO, 2011) relied mainly on information provision to promote behavioural changes. The strategy by OAS (OAS, 2011) mentioned both approaches.

The ASEAN plan stated that prevention interventions, including those that aim to reduce the spread of HIV/AIDS, should involve experts, the media and civil society, and should be targeted at high-risk groups. The AU approach linked drug use prevention (and treatment) to several qualitative concepts: comprehensiveness, accessibility, evidence-based and ethically oriented towards human rights. It framed minimum quality standards for settings in the area of prevention throughout the continent. According to the EU strategy and plan, prevention is best achieved by interventions tailored for a target group, prioritising both at-risk groups and risk factors, and introducing the concept of quality standards.

The strategy by ECOWAS called for multimedia campaigns to inform and educate through media publicity about the dangers of drugs and integration of drug abuse counselling in healthcare services. The SCO plan was to use education and information campaigns, delivered by the mass media or during leisure activities, to prevent drug use, especially by young people. It advised that anti-drugs education should be included in extracurricular activities for young people.

Finally, the OAS promoted the implementation of measurable objectives and evidence-based programmes, targeted at specific populations, and invited member states to disseminate information on the risks of drugs via the mass media and the Internet.

Promoting a safer environment

Actions to address the environment in which the risks occur were clearly indicated in three of the analysed documents (the OAS, AU and EU drug strategies). The OAS strategy, for example, stressed the need to involve the family, the community and the workplace in multifaceted programmes to reduce accidents resulting from driving under the influence of drugs and drug-related accidents in the workplace. The AU plan called for community involvement in programmes on prevention, trafficking and offences related to drug use.

The EU drug strategy went further, being the only one that explicitly mentioned the environmental prevention approach among the mutually reinforcing interventions that contribute to drug demand reduction, along with detection and early intervention, risk and harm reduction, treatment and rehabilitation, social reintegration and recovery.

Discussion

Prevention interventions were mentioned in the entire regional drug strategies analysed. The combination of the three core elements of prevention, i.e. reducing exposure to drugs, promoting a healthy lifestyle and creating a safer environment, were explicitly mentioned in three strategies that also target high-risks groups, referring to evidence-based interventions and setting instruments for measuring progress.

Recent evidence in the field of prevention (Faggiano et al., 2014) has reduced interest in isolated intervention [e.g. stand-alone media campaigns (Ferri, Allara, Bo, Gasparrini, & Faggiano, 2013)] in favour of multicomponent interventions encompassing reduction in exposure to drugs, enhancement of the motivation of the individuals to embrace a healthy lifestyle and improvement of the micro-environment (Burkhart, 2011). However, in Europe, many programmes, continue to be based on information provision, awareness-raising counselling, approaches where the evidence of effectiveness is scarce (EMCDDA, 2014). Examples of successful multicomponent interventions have been implemented in nightlife settings (Miller, Holder, & Voas, 2009) and in the community (Steketee et al., 2013). The main characteristic of these projects is a comprehensive and synergic approach that includes all the stakeholders in the communities where the individuals live and the drug use may occur.

These stakeholders may include the law enforcement system, schools and health and social services.

In the regional strategies analysed the influence of this increased availability of evidence in the field of prevention is clearly seen, in particular in the EU, AU and OAS strategies.

Conclusion

Following the UN's political declaration and plans of action on drugs (1998 and 2009) many countries jointly launched regional strategic documents. The totality of those documents highlights the importance of a preventive approach to the drugs phenomenon. The interventions mentioned in the strategic documents encompass those aimed at reducing exposure to drugs, promoting healthier lifestyles and creating a safer environment.

The increase in available evidence in support of prevention indicates that environmental prevention approaches are effective not only with the target population but also in promoting synergies and integration among the many stakeholders involved. Some of the strategies we analysed, such as the EU drugs strategy, clearly referred to environmental prevention, and two other strategies referred to similar holistic approaches.

In 2009 the countries meeting under the auspices of the Commission on Narcotic Drugs (CND, 2009) agreed to tackle drug problems in the context of comprehensive, complementary and multi-sectorial drug demand reduction strategies, reaffirming their commitment to working towards the goal of universal access to comprehensive prevention. The countries set 2019 as the target year to achieve this commitment (UN, 2009:11).

Regional drug strategies, supporting and promoting such holistic approaches, are working towards the UN drug policy goals for 2019.

Declaration of interest

The authors report that they have no conflicts of interest.

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Paper 2: Quality assurance in drug demand reduction in European countries: an overview

Quality assurance in drug demand reduction in European countries: an overview

Marica Ferri, Sonia Dias, Alessandra Bo, Danilo Ballotta, Roland Simon & Giuseppe Carrá

Quality assurance in drug demand reduction in European countries: an overview

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Abstract

Background: The EMCDDA, through its network of National Focal Points, collects information on the quality assurance systems for drugs-related interventions across European countries. European National Drug Strategies include recommendations for systems and approaches for the assurance of the quality of interventions.
Methods: We searched National Drug Strategies for elements related to quality assurance in drug demand reduction and summarised information through questionnaires administered to the EMCDDA Network of National Focal Points.
Results: In total, 15 National Drug Strategies and 60 questionnaires were analysed. Almost all the strategies include quality-related topics. Frequently, the Ministry of Health leads quality assurance although sometimes jointly with the Ministries of Education, Labour, Family and Social Welfare. Accreditation systems are common, but implemented in different ways. Training and education are widely provided, for the vast majority of countries, consisting of short-term training to keep professionals updated. Guidelines and Standards are gathering momentum as the major tools for the implementation of evidence-based recommendations and are usually available across countries.
Conclusions: Although the evidence base for interventions in drug demand reduction is becoming available and accepted, attention needs to be given to implementation issues. The European countries are rapidly moving towards paying greater attention to the quality of interventions.

Background

There has been increasing consolidation of the evidence base for interventions in drug demand reduction since leading organisations such as the Cochrane Collaboration started considering the evidence base for interventions in substance-related disorders and publishing and keeping up-to-date numerous systematic reviews and relevant guidelines (Davoli et al., 2015). Nowadays, decision-makers have a choice of tools for evidence-informed programmes and it appears increasingly clear that the way in which evidence-based interventions are implemented is crucial to success. The implementation process also aims at using or integrating evidence-based interventions within a setting (Rabin, Brownson, Haire-Joshu, Kreuter, & Weaver, 2008) and targets specific recipients to reach planned outcomes. In other words, decision-makers have realised that efforts should be made not only in the selection of interventions provided – in terms of proofs of effectiveness (what), but also on the ways in which these interventions are implemented (how) to reach the expected impact (Sloboda & Petras, 2014, pp. 293–307).

The importance of implementation on the impact of interventions has been stressed by comparing it to a multiplier of interventions effect. If implementation equals zero, the overall effect of that intervention will also be zero (Duda, Riopelle, & Brown, 2014). In particular, quality assurance systems in health and social care are meant to ensure appropriate implementation and delivery of interventions and this is perceived as crucial nowadays when scarce resources need to be allocated to the most effective interventions, in order to maximise their impact (Ferri & Bo, 2012). Nonetheless, quality assurance systems require coordination at system, organisation, programme and practice levels (Fixsen, Naoom, Blase, Friedman, & Wallace, 2005), supported by policies facilitating synergies among stakeholders. There have been some attempts to encourage such coordination at European as well as national levels.

In the drug addiction field in Europe, the European Drug Strategy (2013–2020) is the ninth strategic document on illicit drugs endorsed by European Union (EU) Member States since 1990, presenting their current drug policy position and aspirations (Ballotta, 2015; Ferri, Ballotta, Carrá, & Dias, 2015). The Drug Strategy sets common objectives to reduce drug demand, dependence, related health and social harms, and supply.

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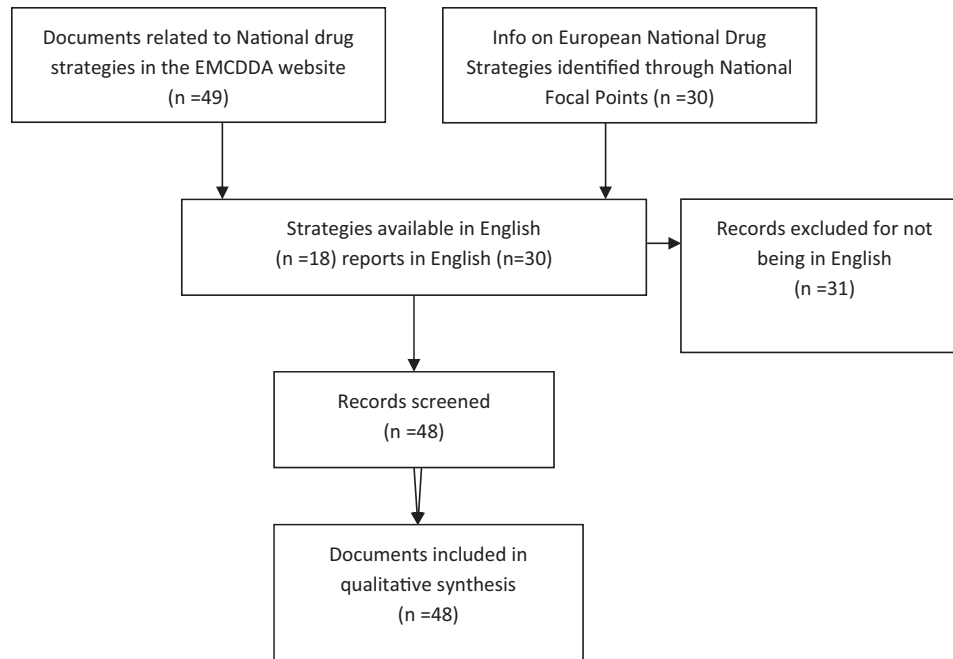
Figure 1. Sources of information on European National Drug Strategies.

At a national level, European drug strategies are instruments or mechanisms aimed at directing drug policy principles towards objectives (Ballotta & D'Arrigo, 2002). It has been observed that after the publication of the first European Drug Strategy in 2000, there has been a growing tendency to codify in official documents, the principles to be achieved by the government in the drugs field (EMCDDA, 2014). These documents have been adopted by governments and, in some cases, by the national parliaments, and can be accompanied by National Drug Action Plans.

Based on the principle of subsidiarity, National Drug Strategies are independently set by each member state. Notwithstanding, the European Union Drug Strategy and action plan indicate the Member States as responsible parties in about 47 out of 51 actions. As of May 2015, 28 Member States have national strategies or similar policies in place (Figure 1), and consistently, most of the National Strategies refer to the most recent European Union Drug Strategy. A description of the mechanisms of consultation in the EU is beyond the scope of the present study, but it is worth bearing in mind that the National Drug Coordinators are present in most of the organisations involved in the development of the European Union Drug Strategy so that a bidirectional relation between national and European Strategies is expected (Edwards & Gallá, 2014).

The stated aim of the Strategy is to contribute to reducing drug demand and supply in the EU along with reducing health and social risks and harms caused by drugs and their use, through an ''integrated, balanced and evidence-based approach'' (Council of European Union, 2012a, p. 1). In particular, the quality of interventions is contextualised with the need for improvement of the services provided, their coverage and diversification.

The tool that is identified for supporting the implementation of evidence-based interventions is based on the quality standards, that are included in the action plan of the EU drug strategy (2013–2016), objective 3 (Embed coordinated, best practice and quality approaches in drug demand reduction) and specified as an action inviting the Council, the Working Party on Drugs, the Member States and the Commission, along with the European Monitoring Centre for Drugs and Drug Addiction, to ''Agree and commence the implementation of EU minimum quality standards, that help bridge the gap between science and practice'' (Council of European Union, 2012b, p. 5). Reference to some EU-funded projects is made in this action that is aimed at achieving consensus on the standards to be adopted.

Projects to promote the development and adoption of quality standards were primarily introduced in the area of prevention through a shared project funded in 2009 and developed since, producing various tools for professionals (Brotherhood & Sumnall, 2011). These standards were aimed at guiding professionals along the process of designing and delivering high-quality drug prevention. In particular, they outlined the steps needed to plan, implement and evaluate drug prevention activities. In addition, in 2011, a further initiative, this time enlarging the standards to all the dimensions of drug demand reduction interventions, was launched by the European Commission (Schaub, Uchtenhagen, & EQUS Expert Group, 2013). This took into account existing experiences across European countries and beyond, including previous projects, and suggested 33 minimum standards for drug prevention, 22 for drug treatment or rehabilitation and 16 for harm reduction, respectively. The standards developed in the Donabedian's (2005) three-level framework (structure, process and outcomes) were tested through rounds of consultations with experts based in 24 European countries. As a result, and based on evidence accumulated in these initiatives, exchange of knowledge

among the European countries with relevant experiences dramatically improved.

In September 2015, relevant initiatives undertaken by the Greek, the Italian and the Latvian European Presidencies resulted in the Council of European Union adopting a Council Conclusion on 16 Quality Standards in Prevention, Harm Reduction, Treatment and Social Reintegration (Council of the European Union, 2015). The standards were selected by a panel of experts and the Civil Society Forum who had been invited by the Italian Presidency to identify a reduced number of standards from a wide range of documents including the Standards on Prevention by United Nations Office on Drugs and Crime (UNODC) (UNODC, 2015) and the Standards by UNODC and WHO on Treatment (UNODC, 2012). The 16 quality standards represent an aspirational set of minimum quality benchmarks for interventions, leaving it up to each individual country to take the initiative on how to achieve them through the use of their own tools and systems already in place. Nevertheless, the newly adopted standards are a major advancement in the drugs field at EU level, bringing together expert knowledge and political decision-making across 28 countries (EMCDDA, 2016a). In fact, the standards reinforce the willingness to base interventions on evidence and to provide staff with appropriate training, sharing best practices and promoting knowledge exchange.

The quality assurance system comprises of the bulk of evidence and relevant quality tools, the production of research in support of effective interventions; the guidelines where existing evidence is summarised and stated in the shape of recommendations for practices, and the standards (setting aspirations to be achieved). Additionally, elements for staff training and accreditations systems for professionals and services can be provided. Although none of these components as such can significantly impact the level and quality of interventions, the policy system can facilitate and promote synergies and integration aiming at better interventions and outcomes. However, relevant references on quality assurance for drug demand reduction interventions in the different European National Drug Strategies reveal both differences and similarities among the systems in place (EMCDDA, 2016a), thus precluding a comprehensive overview, which is needed in order to facilitate best practices and knowledge exchange.

With a view to remedying these limitations, we aimed to provide a systematic and comprehensive picture of quality assurance related references in the European National Drug Strategies, describing characteristics of relevant systems in place across European Member States. The following sections provide a description of the methods used, the results and finally, a discussion of the state of play in the quality assurance systems for drug demand reduction interventions in Europe.

Methods

Most of the keywords used in this article are widely and commonly used in everyday language. Nevertheless, as noted above, meanings vary across different documents and it is likely that terms are differently interpreted. For this reason, we provide a concise glossary of working definitions.

Box 1: Working definitions of keywords.

Best practice

This is a common definition related to effective actions. A search on Pubmed showed the success of such a keyword that grew from one citation in 1959 (on transliteration from Russian published in Science) to 7150 citations available in 2015. The EMCDDA convened a group of experts to agree on a definition of best practice as: ''the best application of the available evidence to current activities'' (Ferri & Bo, 2012).

Evidence base

The term is widely accepted to mean a scientific approach to decision-making. Evidence base was firstly discussed in the medical field, and elaborated as ''the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients'' (Sackett, Rosenberg, Grey, & Haynes, 1996). With regard to drug-related topics, it is used to indicate the inclusion of scientific results to inform decisions on interventions.

Guidelines and standards

Guidelines have been defined as ''statements that include recommendations intended to optimise patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options'' (Institute of Medicine, 2011). Quality standards are principles and sets of rules based on evidence (Brunsson & Jacobsson, 2000), used to implement the interventions recommended in guidelines. They can refer to content issues, processes or to structural aspects.

Training and education

Training and education are key elements for the dissemination of evidence and for the implementation of recommendations (e.g. included in Guidelines and Standards) into the practice of service provisions. Adult education and the promotion of a life-long learning workforce are considered one of the core elements of quality assurance systems.

Quality assurance systems

Quality assurance is defined in the dictionary (Merriam Webster, 2016) as ''the activity of checking goods or services to make sure that they are good''. According to the World Health Organisation's working definition of quality of health systems (WHO, 2006), the first pre-requisite is effectiveness in delivering evidence-based interventions. In order to be effective, quality assurance in the drug demand reduction field needs to involve various actors, roles and responsibilities. These should include the policy level, the services provisions and the community, and the target population. Quality assurance systems can include benchmarking, that is the comparison of service processes and performance to best practices from other services including dimensions such as quality, time and cost.

Accreditation

Accreditation is the process by which an institution delivering a service is independently assessed for quality against pre-defined criteria and standards, which are set by the accrediting body. For the drug-related field, accreditation may include a requirement for treatment services, harm reduction or prevention programmes to receive public funding (Archibald & Rankin, 2013).

Evaluation

Evaluation is the systematic and objective assessment of an on-going or completed project, programme or policy, its design, implementation and results (OECD, 2010). Evaluation assists organisations, programmes, projects to verify achievements and set objectives. In the area of quality assurance, evaluation may be based on pre-defined standards. Evaluation is needed to check the requisites for accreditation (EMCDDA and CICAD-OAS, 2010).

Systematic search of the European National Strategies

We searched the website of the European Monitoring Centre for Drugs of Drug Addiction in May 2015 and located 30 National Strategies. Inclusion criteria required that the strategy was available in an official format in English Language; documents in national (non-English) languages only were excluded. We performed an interpretative textual analysis (McKee, 2003) for all the quotes to keywords

Table 1. Quality assurance: references drug strategies and national organisations.

Keywords in the National Drug Strategy	Evidence based	Quality assurance	Best practice	Evaluation
Number of countries	$N = 20$	$N = 10$	$N = 13$	$N = 19$
Countries	BE, DK, DE, EE, IE, ES, FR, LT, LU, HU, NL, PL, PT, RO, SI, SK, SE, UK, HR, TR	LU, HU, MT, AT, PT, RO, SI, FI, SE, UK	BE, DK, DE, EL, IT, LT, HU, MT, PT, FI, SE, UK, HR	BE, CZ, DK, EE, GR, ES, FR, IT, LT, LU, HU, AT, PL, PT, RO, SI, FI, SE, UK, HR
Entities in charge of quality assurance at national level	Ministry of Health	Ministry of Education, Justice, Human Capacity	Labour, Family and Social Welfare	Other organisations
Number of countries	$N = 14$	$N = 2$	$N = 4$	$N = 11$
Countries (categories are not mutually exclusive)	CZ, DK, DE, EE, LT, LU, NL, PL, PT, AT, SK, FI, UK, HR	HU, HR	MT, RO, SK, HR	BE, EE, CZ, GR, ES, FR, IT, LV, SE, HR, TR

related to quality assurance and systems and/or processes (Table 1).

Consultation with the National Focal Points on the systems in place for quality assurance

In November 2015, we consulted the EMCDDA's National Focal Points via a pre-filled *workbook* containing the information we extracted from the National Strategies and from the EMCDDA structured Questionnaires on best practices (http://www.emcdda.europa.eu/responses/data-collection). We asked relevant officers to check and – where needed – to add comments on the contents.

Furthermore, additional open questions addressed the *organisation and functioning of best practice promotion* that was pre-filled with information from a biannual EMCDDA questionnaire on quality assurance (Standard Questionnaire 27pII). This item explored information on national guidelines and national quality standards, the organisations in charge of producing them, the topic (prevention treatment or harm reduction) and the methodology adopted to develop such guidelines. A final open question was about *accreditation systems and or educational systems* specific to drugs-related problems. By February 2016, we had received 27 complete responses.

Results

National Strategies

We retrieved 49 documents from 30 European countries. In all, 18 strategies were available in English (from Croatia, Czech Republic, France, Germany, Hungary, Ireland, Malta, Norway, The Netherlands, Portugal, Slovakia, Spain, Sweden, Turkey, the UK [England, Northern Ireland, Scotland and Wales]). Five of these had been published after the most updated European Union Drug Strategy, namely the strategies of France (2013–2017), Slovakia (2014–2020), Hungary (2013–2017), Turkey (2013–2015) and Norway (2014) (see Figure 1 for flowchart).

National Drug Strategies: references to quality assurance and organisations in charge

The analysis of the National strategies revealed that almost all the countries mention quality assurance related topics among

the main objectives. A number of strategies aim at basing demand reduction intervention on evidence and at taking care of quality of interventions through dissemination of best practices. The textual analysis of the strategies (or of extracts translated from the strategies that were not available in English) reported ''evidence-base'' and ''evaluation'' as present in the documents from 20 countries, and ''best practice'' in 13, respectively. Quality assurance was mentioned by 10 countries. Nevertheless, the analysis of the sub-sample of 18 strategies available in English suggested that these terms are used in different ways. The term most consistently used with the same meaning seems to be evidence-based, which appears associated with approaches, methods and methodology and/or with interventions and programmes. In some cases, quality assurance is associated with systems and accreditation, about quality standards, but in other cases it refers to data quality, measurements and evaluation. Best practice, not surprisingly, is associated with several different concepts, including treatment, education, dissemination and knowledge sharing, professional practices, outcomes and programme evaluation, research and communication. Evaluation is commonly linked with strategy evaluation, monitoring and evaluation, evaluation and research, internal and external evaluation of programmes and services.

The type and the level of integration of bodies in charge of the provision and monitoring of interventions vary. The Ministry of Health is indicated as responsible or involved in the quality assurance system in almost half of the countries; other relevant Ministries mentioned are Labour, Family and Social Welfare, Justice, Education and the Economy.

About 40% of the countries have a dedicated organisation that is responsible for addressing drugs issues. These may be placed at governmental level as it is the case for Czech Republic, Estonia, France, Italy, Sweden and Croatia, or based in research centres and scientific societies as in Spain, Belgium and Turkey, or finally, can be active at municipal level as in Latvia or at service level as in Greece.

Quality assurance processes and outputs

In terms of processes and outputs to ensure the quality of interventions, two-thirds of countries have some form of accreditation systems. This can be aimed at accrediting the health services in general but also influence, sometimes

Table 2. Quality assurance processes and outputs.

Quality assurance mechanisms	Accreditation	Training and education		Standards and guidelines
		In academic environment	Continuing education	
Number of countries	$N = 19$	$N = 7$	$N = 14$	$N = 20$
Countries	HR, FR, CZ, DK, DE, EE, HU, IT, LT, LU, NL, AT, PL, PT, RO, SK, ES, SE, UK	CZ, DE, DK, EE, LU, NL, RO	BE, GR, ES, IE, IT, LT, LU, AT, PL, PT, FI, SE, TK, FR	BE, CZ, DK, EE, LT, LU, HU, MT, DE, AT, PL, PT, RO, SK, FI, SE, UK, HR, IE, TK

No info: BG, CY, NO.
AT: Austria; BE: Belgium; CZ: Czech Republic; DE: Germany; DK: Denmark; EE: Estonia; ES: Spain; FI: Finland; FR: France; GR: Greece; HR: Croatia; HU: Hungary; IE: Ireland; IT: Italy; LT: Lithuania; LU: Luxembourg; MT: Malta; NL: The Netherlands; PL: Poland; RO: Romania; SE: Sweden; SK: Slovakia; TK: Turkey; UK: United Kingdom.

minimally, the drug services. In some cases, specific criteria for treatment of drug dependence are in place. In other cases, accreditation covers only one aspect of demand reduction interventions, such as the prevention sector. Responsibility for the accreditation system is often placed with a public national body; in a few cases it is placed at the municipality level or operates through the health and social insurances companies. Some countries like the Czech Republic, Poland, Romania, the UK and Belgium pioneered or adopted quality criteria based on best practices, for example with the introduction of quality standards for the treatment services and or for the prevention intervention providers.

For example, since 2006 the Czech Republic has progressively introduced standards to ensure the quality of centres, facilities and programmes, namely, the Certification Standards of the Government Council for Drug Policy Coordination. The certification process entails the ascertainment of compliance with these standards. The standards include inter-agency instruments and effort covering health and social services. Part of these sets of standards are the Standards for Quality in Social Services of the Ministry of Labour and Social Affairs and the standards for primary drug prevention programmes developed by the Ministry of Education, Youth, and Sports (EMCDDA, 2016b). In the field of addiction, the Health Ministry's standards exist for substitution treatment. Slightly more recently, in Poland the Minister of Health approved the accreditation standards for providing health care services for residential drug treatment units by implementing an accreditation system. In parallel, the National Bureau for Drug Prevention in collaboration with the State Agency for Preventing Alcohol-related Problems and the Centre for Monitoring Quality in Health Care initiated actions aimed to develop guidelines on how to conduct accreditation audits (EMCDDA, 2016b).

Training and education for intervention providers are also commonly available across countries, with two-thirds of them mentioning delivery of some form of training. The type of training ranges from specific university programmes (e.g. in Germany and in Czech Republic) to, more commonly, specific courses offered in the realm of health or social welfare university programmes. Often some type of vocational training for those working in the health services, in prevention and in harm reduction areas, is offered (Table 2).

Finally, many countries mention the availability of published practice guidelines and documents including standards although the details of these guidelines and standards differ substantially. Guidelines can be numerous, produced by national agencies, or initiated by scientific professional societies and insurances companies, and in some cases, delegated to non-governmental organisations (NGOs). In particular, standards are now becoming more commonly available as a way to implement recommendations included in practice guidelines. A typical example is the standards set by the Care Quality Commission in the UK for treatment services that address residential rehabilitation units as well as community-based services (CQC, 2015). Implementation of Standards can be voluntary but in some examples it is a prerequisite to participate in programmes that are funded by public taxation (Table 2).

Discussion and conclusion

The European Drug Strategy (Council of European Union, 2012a, 2012b) calls for an evidence-based approach to drug demand reduction. The European countries echo this approach in their national strategies and invest their public bodies with the responsibility for implementation.

Europe is a region where the majority of countries have a National Drug Strategy (Ballotta, 2015). Evidence-based interventions for drug demand reduction are mentioned in all the documents, often with indication of specific measures to inform decision-making and control the quality of interventions. The strategies are not only aspirational, since they also indicate responsibilities and functions. In at least 19 countries, the Ministry of Health is responsible for the quality assurance system often in collaboration with other Ministries such as Social Affairs (sometimes called Social Policy or Social Protection, Labour and Family), Ministry of Education, Ministry of Economy, Ministry of Justice and Ministry of Human Capacity. These entities work jointly with other levels such as regional and municipal organisations in a variety of ways; in a few cases, NGOs and professional organisations are delegated some of the functions.

Forms of accreditation for delivering drug demand reduction interventions are present in the great majority of countries, with the exception of a few for which we were unable to retrieve information. Nevertheless, the level and type of accreditations vary greatly. They can include general accreditation for health services, specific accreditation for drug demand reduction interventions and in some cases

accreditation of services based on standards developed at national level (as for example in the Czech Republic and Poland).

Training and education for professionals working in the demand reduction field are also widely available, in the form of university programmes devoted to addiction medicine, as it is the case for Germany and Czech Republic, or short-term postgraduate ones for social and health workers. In a number of cases, training includes continuing education on specific topics related to health and social professionals. Examples are VAD (Vereniging voor Alcohol – en andere Drugproblemen) in Belgium (officially recognised by the Flemish government to deliver education for professionals working in the field of demand reduction) which offers a broad range of topics in prevention, treatment, harm reduction and early intervention. In Greece, KETHEA (Therapy Centres for Dependent individuals) provides training seminars for drug demand reduction practitioners and, in collaboration with the University of San Diego in California, offers training on management and planning in the area of drug addiction. In France, training is provided to law enforcement officers on the prevention of violence related to alcohol in various settings (mainly schools, but also occupational settings, common tourist sites and more).

Finally, in the last decades, the availability of Guidelines for the implementation of evidence-based recommendations has greatly increased. Guidelines are more common than standards and both these kinds of instruments are a result of aspirations to achieve evidence based and reproducible interventions for drugs demand reduction (Carrà, Bartoli, Brambilla, Crocamo, & Clerici, 2015).

Thus, across countries, the process of accreditation is common and guidelines and standards are becoming popular tools for the implementation of evidence-based recommendations, but there is still considerable diversity in how quality standards are delivered as well as in forms of training and education.

Despite efforts put in place at European and national levels to focus on quality improvement, it is still difficult to assess whether – even in the presence of a common language – there is a shared understanding of methods and objectives. This seems true even for the understanding of the basic keyword *evidence* that is sometimes taken as a self-evident ''truth'' (Ioannidis, 2016) rather than a process for a pragmatic and continuing integration of scientific results into decision-making. This integration of cumulative knowledge should aim to match practice-generated questions with scientific- and experience-generated results to provide pragmatic answers, rather than merely to satisfy scientific curiosity. Those using evidence to inform decisions, and their advisors, should be able to critically appraise studies for their contribution to common knowledge rather than on the boldness of their conclusions. At the moment, we do not have the means to assess if this pragmatic approach exists with regard to quality assurance in drug demand reduction across European countries.

Clarifications are also needed to help disentangle the use and possible contribution of the common guiding documents (Ferri & Bo, 2012). Practice guidelines should represent the translation of scientific results into recommendations for actions. They are better placed in the toolkit of practitioners

and subject to continuous updating with new knowledge, rather than being placed among laws and decrees depending on political decisions. Quality standards are aspirational and indicate willingness to provide harmonised recommendations that need to be operationalised at local level and evaluated.

Finally, the presence of all these tools and virtuous processes called quality assurance systems do not guarantee positive results. A monitoring and evaluation system needs to be operant and able to quickly capture emerging trends in order to (a) set the objectives; (b) select the appropriate interventions and (c) evaluate the results.

Although more detailed information is needed to draw a clearer picture of the interventions implemented at national and regional levels, and to understand what is behind the general categories we created for the present preliminary description, it seems that Europe is quickly moving forward and creating all the ingredients necessary to improve the quality of interventions. However, the combination of these ingredients into an effective harmonised quality system is still to come. Hopefully, this will be based on future research measuring the effectiveness of these quality assurance systems and their impact on the health of target populations.

Declaration of interest

The work was conducted at EMCDDA and the authors have no conflicts of interest to declare.

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Paper 3: Media Campaign for the prevention of illicit drug use among young people

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Media campaigns for the prevention of illicit drug use in young people (Review)

Ferri M, Allara E, Bo A, Gasparrini A, Faggiano F

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T A B L E   O F   C O N T E N T S

[Intervention Review]

Media campaigns for the prevention of illicit drug use in young people

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ABSTRACT

Background

Substance-specific mass media campaigns which address young people are widely used to prevent illicit drug use. They aim to reduce use and raise awareness of the problem.

Objectives

To assess the effectiveness of mass media campaigns in preventing or reducing the use of or intention to use illicit drugs amongst young people.

Search methods

We searched the Cochrane Central Register of Controlled Trials (CENTRAL, *The Cochrane Library* 2013, Issue 1), including the Cochrane Drugs and Alcohol Group's Specialised Register; MEDLINE through PubMed (from 1966 to 29 January 2013); EMBASE (from 1974 to 30 January 2013) and ProQuest Dissertations & Theses A&I (from 1861 to 3 February 2013).

Selection criteria

Cluster-randomised controlled trials, prospective and retrospective cohort studies, interrupted time series and controlled before and after studies evaluating the effectiveness of mass media campaigns in influencing drug use, intention to use or the attitude of young people under the age of 26 towards illicit drugs.

Data collection and analysis

We used the standard methodological procedures of The Cochrane Collaboration.

Main results

We included 23 studies involving 188,934 young people, conducted in the USA, Canada and Australia between 1991 and 2012. Twelve studies were randomised controlled trials (RCT), two were prospective cohort studies (PCS), one study was both a RCT and a PCS, six were interrupted time series and two were controlled before and after (CBA) studies. The RCTs had an overall low risk of bias, along

with the ITS (apart from the dimension 'formal test of trend'), and the PCS had overall good quality, apart from the description of loss to follow-up by exposure.

Self reported or biomarker-assessed illicit drug use was measured with an array of published and unpublished scales making comparisons difficult. Pooled results of five RCTs (N = 5470) show no effect of media campaign intervention (standardised mean difference (SMD) -0.02; 95% confidence interval (CI) -0.15 to 0.12).

We also pooled five ITS studies (N = 26,405) focusing specifically on methamphetamine use. Out of four pooled estimates (two endpoints measured in two age groups), there was evidence of a reduction only in past-year prevalence of methamphetamine use among 12 to 17 years old.

A further five studies (designs = one RCT with PCS, two PCS, two ITS, one CBA, N = 151,508), which could not be included in meta-analyses, reported a drug use outcome with varied results including a clear iatrogenic effect in one case and reduction of use in another.

Authors' conclusions

Overall the available evidence does not allow conclusions about the effect of media campaigns on illicit drug use among young people. We conclude that further studies are needed.

PLAIN LANGUAGE SUMMARY

Do media campaigns prevent young people from using illicit drugs?

Media campaigns to prevent illicit drug use are a widespread intervention. We reviewed 23 studies of different designs involving 188,934 young people and conducted in the United States, Canada and Australia. The studies tested different interventions and used several questionnaires to interview the young people about the effects of having participated in the studies brought to them. As a result it was very difficult to reach conclusions and for this reason we are highlighting the need for further studies.

BACKGROUND

Health promotion, mass media campaigns are initiatives typically undertaken by national authorities which use communication media to disseminate information about, for example, health or threats to it and to persuade people to adopt behavioural changes. Mass media campaigns are implemented via television and radio broadcasts, newspaper or magazine advertisements, billboards and road posters. They can also use colourful advertisements and brochures available for travellers on buses and the metro and, more recently, a broad range of available technology including the Internet, mobile phone short messages and email lists. Media campaigns can be of short or longer duration and sometimes they encompass several consequent rounds of delivery. They can be standalone interventions or be integrated into complex social marketing programmes.

Mass media campaigns for the prevention of illicit drug use are very common worldwide but only few campaigns have been formally evaluated (Wammes 2007). Furthermore, most of those evalua-

tions (Rossi 2003) assessed only the process (in terms of understanding, retention and appeal of the messages) and the very few that assessed outcomes (in terms of behaviours of use) often found weak or counterproductive effects.

Description of the condition

Initiation of use of all substances typically occurs during the teens or early years of adulthood (ESPAD 2011; UNODC 2012). Since the neurological or psychological factors that may influence how and whether addiction develops are unknown, "even occasional drug use can inadvertently lead to addiction" (Leshner 1997; Leshner 1999). Indeed, research has found that drug use leading to dependence usually starts in adolescence (Camí 2003; McLelland 2000; Swendsen 2009).

Since the neurological and social mechanisms of dependence are similar for all addictive substances, a common view, therefore, is that prevention should focus on an age group (teenagers) rather

than specific substances (Ashton 2003; Leshner 1997; Nestler 1997; Wise 1998).

Description of the intervention

The mass media (TV, Internet, radio, newspapers, billboards) have increasingly been used as a way of delivering preventive health messages. They have the potential to modify the knowledge or attitudes of a large proportion of the community (Redman 1990). They also have the potential to reach large populations of suscepti-

ble individuals and groups that may be difficult to access through more traditional approaches. In addition, in terms of the per capita cost of prevention messages, they are relatively inexpensive (Brinn 2010).

This review is limited to mass media campaigns that aim to prevent the uptake of illicit drug use (both in general or that of specific substances) or to reduce or stop the use of illicit drugs. It excludes mass media campaigns that aim to promote safer or less harmful use of drugs.

The following table summarises the main characteristics of most mass media campaign.

Category	Objective	Target audience	Details
Information campaign	Warning	General or youth population	Information about the dangers and risks of a range of illicit substances
	Empowerment	General population, especially parents	Information about how to contribute to drug prevention through your own behaviour
			Information about where and how to seek support, counselling and treatment regarding illicit drug use, especially for your children
		Youth population	Information about where and how to seek support, counselling and treatment regarding illicit drug use
	Support	General population	Information about existing prevention interventions or programmes in communities, in schools or for families in order to strengthen community involvement and support for them
Social marketing campaign	Correct erroneous normative beliefs	General or youth population	Declared purpose is to correct erroneous normative beliefs about the extent and acceptance of drug use in peer populations ("you're not weird if you don't use because 80% of your peers don't either")
	Setting or clarifying social and legal norms	General or youth population	Declared purpose is to deglamorise and demystify drug use and related behaviour (e.g. drug driv-

			ing) and to explain the rationale of community norms and control measures
	Setting positive role models or social norms	General or youth population	Declared purpose is to promote non-drug-use-related prototypes of lifestyles, behaviour and personality

How the intervention might work

Most campaigns are based on a limited number of theoretical models, such as the health belief model (lack of knowledge about health harms may lead to drug use), the theory of planned behaviour (drug use is a rational decision due to attitude toward drugs, perceived social norms and perceived control over drugs) and the social norms theory (overrated perception of prevalence among peers may lead to drug use). In summary, the theories most frequently used as base for anti-drugs mass media campaigns are:

• **Health belief model**. This model (Glanz 2002) is based on the concept that the perceived susceptibility to and the severity of the disease and the perceived benefits of action to avoid disease are the key factors in motivating a positive health action. So, based on some elements of the model, the provision of factual information about the negative effects and dangers of drugs should deter use or prevent substance abuse by creating negative attitudes towards drug use.

Intervention based on this theory: information campaign

• **Theory of reasoned action/theory of planned behavior**. The theory of reasoned action/theory of planned behaviour (Ajzen 1991) proposes that an individual's behavioural intentions have three constituent parts: the individual's attitude towards the behaviour, the social norms as perceived by the individual and the perceived control over the behaviour. Individuals may weight these differently in assessing their behavioural intentions. According to this model, drug use is a consequence of a rational decision (intention), which is based on the belief about drug use, the social norms towards drug use and the belief about control over the behaviour.

Intervention based on this theory: social marketing campaigns with the objective of setting or clarifying social and legal norms as well as information campaigns

• **Social norms theory**. This theory (Perkins 1986) states that "our behaviour is influenced by incorrect perceptions of how other members of our social groups think and act" (Berkowitz 2004, p. 5). Campaigns based on this theory, which are also referred to as 'normative education', challenge the

misconception that many adults and most adolescents use drugs. For example, students are provided with information on the prevalence - from either national or local surveys - of drug use among their peers so that they can compare their own estimates of drug use with the actual prevalence.

• Related to this is the **Super-Peer Theory** (Strasburger 2008). The Super-Peer Theory postulates that media portrayal of drug use (or casual sex or violence) influences the susceptible teens.

Intervention based on this theory: social marketing campaigns that aim to correct erroneous normative beliefs

• **Social learning theory**. The social learning theory (Bandura 1977) postulates that personality is an interaction between environment, behaviours and the psychological processes of an individual. Also referred to as observational learning, the theory of social learning places an emphasis on observing and modelling other people's behaviours, attitudes and emotional reaction.

Intervention based on this theory: social marketing campaigns setting positive role models or social norms

Why it is important to do this review

Bühler and Kröger (Bühler 2006) conclude their review of reviews with the recommendation to use media campaigns only as supporting measures and not as a single strategy alone, whereas Hawks 2002, in line with the review of reviews by the Health Development Agency (HDA) (McGrath 2006), concludes that "the use of the mass media on its own, particularly in the presence of other countervailing influences, has not been found to be an effective way of reducing different types of psychoactive substance use. It has however been found to raise information levels and to lend support to policy initiatives".

Despite concerns in reviews about poor effectiveness and possible harm of anti-drug prevention activities (Faggiano 2008), media campaigns are still very popular worldwide and in European Union member states (EMCDDA 2009).

An assessment of both positive and negative (iatrogenic) effects is important for ethical reasons as well, because mass media campaigns - unlike other social or health interventions - are imposed on populations that have neither asked for nor explicitly consented to the intervention (Sumnall 2007). A systematic review of all the studies assessing media campaign interventions aimed at preventing illicit drug use in young people is therefore necessary in order to inform future strategies and to help design campaigns that avoid harm. Such a review will also contribute to the identification of further areas for research.

OBJECTIVES

To assess the effectiveness of mass media campaigns in preventing or reducing the use of or intention to use illicit drugs amongst young people.

METHODS

Criteria for considering studies for this review

Types of studies

Any study that evaluates the effectiveness of mass media campaigns in influencing drug use, intention to use or the attitude of young people towards illicit drugs.
1. Randomised controlled trials in which the unit of randomisation is an individual or a cluster (the school, community or geographical region)
2. Controlled trials without randomisation allocating schools, communities or geographical regions
3. Prospective and retrospective cohort studies
4. Interrupted time series
5. Controlled before and after studies

Types of participants

Young people under the age of 26.

Types of interventions

Experimental intervention

The following definition was adopted by a similar Cochrane review (Brinn 2010): "Mass media is defined here as channels of communication such as television, radio, newspapers, billboards, posters, leaflets or booklets intended to reach large numbers of

people and which are not dependent on person to person contact". To be included in the review, a study needs to assess a mass media campaign explicitly aimed at influencing people's drug use, intention to use or attitude towards illicit drugs use.

Control intervention

1) No intervention; 2) other types of communication interventions such as school-based drug abuse prevention programmes (Faggiano 2008); 3) community-based prevention programmes; 4) lower exposure to intervention; 5) time before exposure to intervention.

Types of outcome measures

Primary outcomes

1. Self reported or biomarker-assessed illicit drug use

Secondary outcomes

1. Intentions not to use/to reduce use/to stop use
2. Attitudes towards illicit drug use
3. Knowledge about the effects of illicit drugs on health
4. Understanding of intended message and objectives
5. Perceptions (including perceptions of peer norms and perceptions about illicit drug use)
6. Adverse effects induced by the campaign (reactance, i.e. a reaction to contradict the prevailing norms of rules and positive descriptive norms, i.e. increased perception that drug use in peer population is common, normal or acceptable)

Search methods for identification of studies

Electronic searches

We obtained relevant trials from the following sources:
1. Cochrane Central Register of Controlled Trials (CENTRAL, *The Cochrane Library* 2013, Issue 1) which includes the Cochrane Drugs and Alcohol Group's Specialised Register;
2. MEDLINE through PubMed (freely accessible at http://www.ncbi.nlm.nih.gov/pubmed/) (from 1966 to 29 January 2013);
3. EMBASE (from 1974 to 30 January 2013);
4. ProQuest Dissertations & Theses A&I (from 1861 to 3 February 2013).
We compiled detailed search strategies for each database searched. These were based on the search strategy developed for PubMed but revised appropriately for each database to take account of differences in controlled vocabulary and syntax rules.

The search strategy for:

1. CENTRAL is shown in Appendix 1;
2. PubMed is shown in Appendix 2;
3. EMBASE is shown in Appendix 3;
4. ProQuest Dissertations & Theses A&I was: *(media campaigns OR mass media) AND illicit drug* AND preventi*.*

We searched for ongoing clinical trials and unpublished studies on the following Internet sites:

1. http://www.controlled-trials.com;
2. http://apps.who.int/trialsearch/;
3. http://clinicaltrials.gov/;
4. https://eudract.emea.europa.eu/.

Searching other resources

We also searched other sources to identify relevant studies. We assessed conference proceedings that were likely to contain relevant material and contacted the authors. We contacted investigators or experts in the field to seek information on unpublished or incomplete trials. We also reviewed EMCDDA National Focal Points Annual National Reports for any description of relevant studies conducted in Europe.

We used the first studies identified as fulfilling the inclusion criteria to inspect the MeSH terms and to integrate the search strategies. Moreover, we used the "related articles" function of PubMed in a "capture-recapture method" to validate the inclusiveness of the search strategy.

We did not apply any language restriction.

Data collection and analysis

Selection of studies

Two review authors (EA and MF) inspected the search hits by reading the titles and the abstracts. We obtained each potentially relevant study identified in the search in full text and at least two review authors assessed studies for inclusion independently. In case of doubts as to whether a study should have been included, this was resolved by discussion between the review authors. We collated and assessed multiple publications as one study.

Data extraction and management

Two review authors (EA and AB) independently extracted data and input relevant information into Review Manager (Review Manager 2012) for meta-analysis. Two review authors (MF and FF) assessed the theoretical background of the campaigns. We discussed and solved every step by consensus. We produced a narrative synthesis of the key findings along with a meta-analysis of studies which used appropriate measures.

Assessment of risk of bias in included studies

Four review authors (EA, AB, MF and FF) performed quality assessments independently. We discussed and solved any disagreement by consensus. We uploaded final assessments into Review Manager. In order to obtain more information on the criteria for reducing risk of bias, we contacted the authors of most of the studies.

To assess RCTs we followed the criteria recommended by the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). The recommended approach for assessing risk of bias in studies included in Cochrane Reviews is a two-part tool, addressing seven specific domains, namely sequence generation and allocation concealment (selection bias), blinding of participants and providers (performance bias) blinding of outcome assessor (detection bias), incomplete outcome data (attrition bias) selective outcome reporting (reporting bias) and other source of bias. The first part of the tool involves describing what was reported to have happened in the study. The second part of the tool involves assigning a judgement relating to the risk of bias for that entry, in terms of low, high or unclear risk. The domains of sequence generation and allocation concealment (avoidance of selection bias) were addressed in the tool by a single entry for each study. Blinding of participants might not be applicable for this type of intervention, and we therefore considered blinding of personnel and outcome assessors (avoidance of performance bias and detection bias). We considered a study to have low risk of bias if the data were obtained with an anonymous questionnaire or administered by computer. We considered incomplete outcome data (avoidance of attrition bias) for all outcomes.

For ITS studies we used the tools developed by the Effective Practice and Organization of Care (EPOC) Group (Appendix 4). For cohort studies we used the SIGN Quality Criteria described in Appendix 5.

Measures of treatment effect

We intended to analyse dichotomous outcomes (such as intention to use or actual use of illicit substances) by calculating the risk ratio (RR) or odds ratio (OR) for each trial and express the uncertainty in each result with their 95% confidence intervals. We only found continuous outcome measures which we analysed by calculating the standardised mean difference (SMD) with its corresponding 95% confidence intervals.

Unit of analysis issues

In the case of cluster-randomised trials the unit of analysis is either the school or the town. We stated at protocol level that in this case we would have taken into account the criteria for assessing bias in cluster-randomised trials as described in the *Cochrane Handbook*. We inflated each arm's standard deviation for two studies (Slater 2006; Newton 2010) by multiplying it by the study design effect,

a coefficient which takes into account the average cluster size and the study intra-class correlation.

Dealing with missing data

Where needed, we contacted the authors of the studies for integration of any possible missing data.

Assessment of heterogeneity

The presence of heterogeneity between the trials was tested using the I^2 statistic and the Chi^2 test. A P value of the I^2 statistic higher than 0.50 and a P value of the Chi^2 test lower than 0.10 suggests that there is some evidence of heterogeneity.

Assessment of reporting biases

We intended to use funnel plots (plots of the effect estimate from each study against the standard error) to assess the potential for bias related to the size of the trials, which could indicate possible publication bias. In fact we did not reach the minimum number of (10) studies included in the meta-analysis which is suggested as sufficient for conducting a funnel plot (Higgins 2011).

Data synthesis

We intended to carry out a meta-analysis by combining RR/OR or the SMD where possible. We performed a meta-analysis of the RCTs using a random-effect model in order to take into consideration the heterogeneity among studies.

For the studies evaluating the Meth Project (Colorado Meth 2011; Georgia Meth 2011; Hawaii Meth 2011; Idaho Meth 2010; Wyoming Meth 2011) we performed a separate meta-analysis. An interrupted time series (ITS) design was applied for estimating the differences in prevalence of methamphetamine use before and after the Meth Project intervention, adjusting for any underlying temporal trend. Statistical models were based on multilevel mixed effects logistic regression, with State as a random intercept modelling baseline log odds of methamphetamine use to vary randomly across states. The relatively few data points did not allow exploring of more complex models, e.g. the temporal trend could not be assumed to vary randomly across states. The fixed part of the final model assumes (i) a different baseline by age group, but similar among states; (ii) a linear temporal trend homogeneous across states; (iii) an effect of the intervention differing by age group but constant across time and occurring immediately after the intervention. The model may be written as $\text{logit}(\text{use}_{ij}) = \beta_0 + u_{0j} + \beta_1 \text{time}_i + \beta_2 \text{interv}_i + \beta_3 \text{age}_i + \beta_4 \text{age} \times \text{interv}_i + \epsilon_{ij}$, with use

as prevalence of methamphetamine use, time as a continuous variable, intervention and age as two-level categorical variables and J indicating state. The exponentiated coefficient β_2 is interpretable as the ratio between the odds of using methamphetamine after (numerator) and before (denominator) the intervention (Gilmour 2006). The model was fitted separately for past-month and past-year use of methamphetamine. Data points regarding lifetime use of methamphetamine were not analysed.

Subgroup analysis and investigation of heterogeneity

We intended to perform stratified meta-analysis in order to assess the differential effect of the campaigns based on different theoretical approaches. However the impact of media campaigns may be mediated by the sub-cultural environment and, in particular, by the attitude towards substance use in a given culture. Therefore, at protocol level it was anticipated that subsets of studies were to be analysed by characteristics of target participants (regional location, users versus non-users etc.) whenever possible. Studies could also be compared by type of campaign, based on different theoretical approaches. We did not reach the number of studies sufficient to perform any type of sub-set analysis.

Sensitivity analysis

To incorporate the assessment of risk of bias in the review process we first plotted the intervention effect estimates against the assessment of risk of bias. We subsequently inspected the results stratified for risk of bias and we did not find significant associations between measure of effect and risk of bias. We therefore decided to not include the 'Risk of bias' assessment in the meta-analysis and to discuss it narratively in the results section. The items considered in the sensitivity analysis were the random sequence, blinding of personnel and outcome assessors, and selective reporting.
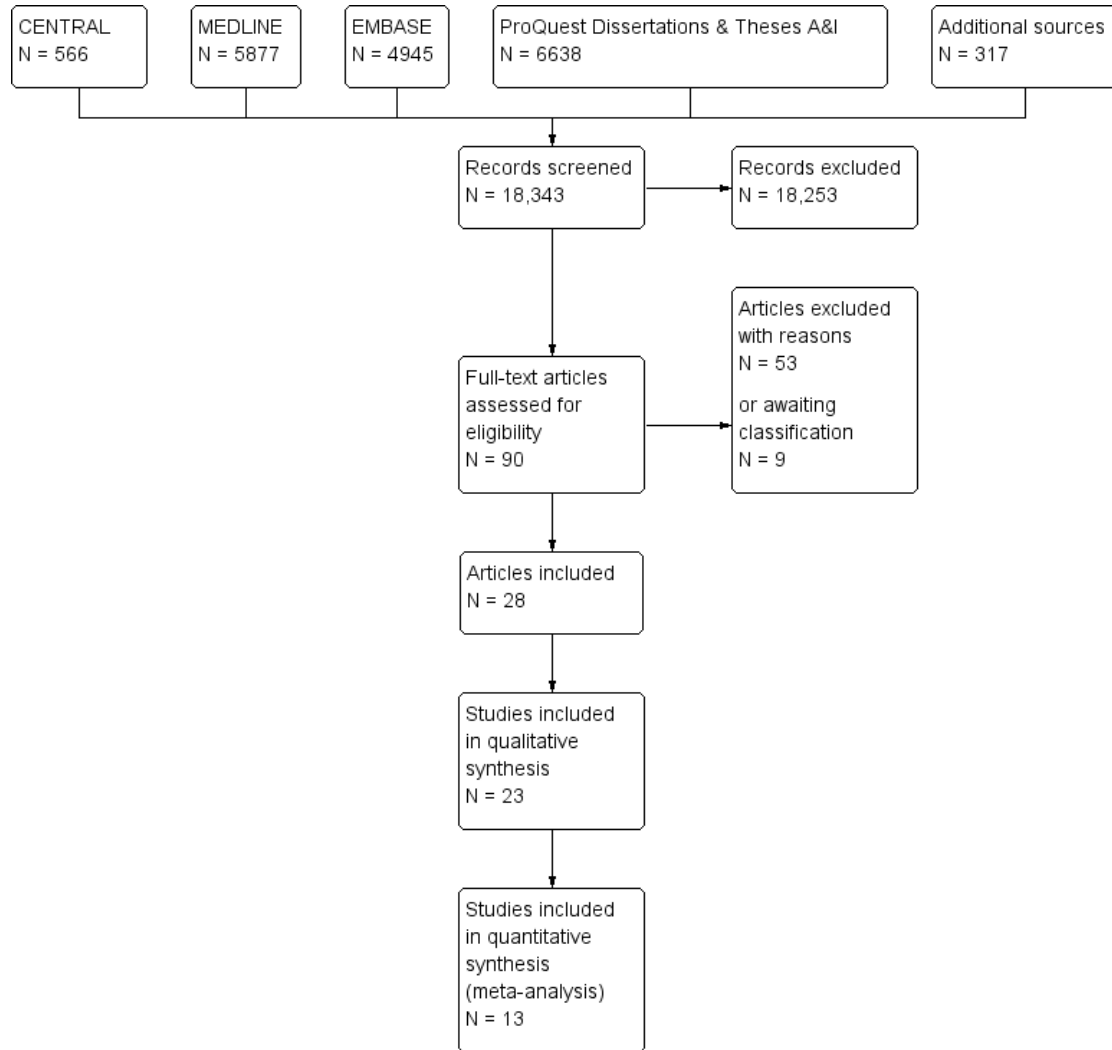
R E S U L T S

Description of studies

See: Characteristics of included studies, Characteristics of excluded studies and Characteristics of studies awaiting classification.

Results of the search

The study flow chart is presented in Figure 1.

Figure 1. Study flow diagram. Please note that some studies include more than one article. This explains why there are 23 included studies out of 28 included articles.

Search sources

On 29 January 2013 we performed a PubMed (MEDLINE) search as described in Appendix 2, which identified 5877 records. On 30 January 2013 we searched CENTRAL which returned 566 results and EMBASE which gave 4945 records. On 3 February 2013 we also performed a ProQuest 'Dissertations & Theses A&I' search which returned 6638 records.

We also obtained additional records (N = 317) from one single paper (Hornik 2006) using PubMed's 'Similar articles' feature, and from papers extracted from 10 reviews (Battjes 1985; Berberian 1976; Hailey 2008; Kumpfer 2008; Romer 1994; Romer 1995; Schilling 1990; Stephenson 2003b; Wakefield 2010; Werb 2011),

three reports (EMCDDA 2010; Know the Score 2007; NCI 2008) and three book chapters (Crano 2001; Flay 1983; Moskowitz 1983).

Screening

We independently screened records from each source search, i.e. no automatic removal of duplicates was used because of the risk of false-positive duplicates. Therefore, we screened 18,343 titles and abstracts. Of them, we excluded 18,253 records (99.5%) as obviously irrelevant.

Full-text analysis

We examined the full-text articles of the remaining 90 records. Of them, 62 records were either excluded (N = 53) due to ineligibility of intervention type, participant age and reported outcome, or set in a pending status (N = 9) due to missing information. We contacted authors whenever possible.

Twenty-eight records corresponded to 23 unique studies which were included in this review. A subset of 13 studies (eight RCTs and five ITS) could also be included in meta-analyses, mostly thanks to personal communication with some authors who provided us with unpublished data and additional reports.

Included studies

Study design

Out of 23 unique studies, 12 were randomised controlled trials (RCT) (Czyzewska 2007; Fang 2010; Fishbein 2002; Kelly 1992; Lee 2010; Newton 2010; Palmgreen 1991; Polansky 1999; Schwinn 2010; Slater 2011; Yzer 2003; Zhao 2006), two were prospective cohort studies (PCS) (Hornik 2006; Scheier 2010), one study was both a RCT and a PCS (Slater 2011), six were ITS (Carpenter 2011; Colorado Meth 2011; Hawaii Meth 2011; Idaho Meth 2010; Palmgreen 2001; Wyoming Meth 2011) and two were before and after (CBA) studies (Georgia Meth 2011; Miller 2000).

Population

No study enrolled subjects younger than 10 years old. Twenty-one studies included subjects older than 10 and younger than 20 years old. Two studies included subjects older than 20 years old and younger than this review's limit of 26 years old; one of them included only people older than 20 (Miller 2000) and one people aged 18 to 22 (Palmgreen 1991).

Three studies included only girls (Fang 2010; Kelly 1992; Schwinn 2010). The others did not specify any sex-related selection criteria. Two studies focused on specific ethnic or racial groups: one on Mexican-American boys and girls (Polansky 1999) and one on Asian-American girls (Fang 2010). The remaining studies did not use ethnicity, racial or socioeconomic characteristics to define the selection criteria.

Intervention

Mass media components

Eight studies evaluated standalone TV/radio commercials (Czyzewska 2007; Fishbein 2002; Kelly 1992; Palmgreen 1991; Palmgreen 2001; Polansky 1999; Yzer 2003; Zhao 2006) and four studies evaluated standalone Internet-based interventions (Fang 2010; Lee 2010; Newton 2010; Schwinn 2010). Eleven studies evaluated multi-component interventions, three regarding TV/radio and printed advertising (Miller 2000; Slater 2006; Slater 2011) and eight regarding TV/radio commercials, printed advertisements and Internet advertising (Carpenter 2011; Hornik 2006; Scheier 2010 and the five Meth Projects). No study evaluated interventions using standalone printed advertising.

Three studies added a school-based drug prevention curriculum (Slater 2006; Slater 2011) or a combination of peer education, computer resources, campus policy and campus-wide events (Miller 2000) to the mass media component(s).

Setting

Eleven studies were conducted in only one setting: eight studies in a school/college setting (Czyzewska 2007; Fishbein 2002; Kelly 1992; Lee 2010; Miller 2000; Newton 2010; Polansky 1999; Yzer 2003), two in a community setting (Fang 2010; Schwinn 2010) and one in a national/statewide setting (Palmgreen 2001).

Twelve studies were conducted in multiple settings: three in school and community settings (Palmgreen 1991; Slater 2006; Zhao 2006), eight in community and national settings (Carpenter 2011; Hornik 2006; Scheier 2010 and the five Meth Projects), while one (Slater 2011) reported evaluations of two similar but distinct interventions - one implemented in a school and community setting and one aired to the whole nation.

Comparison group

Fourteen studies compared one or more mass media interventions with no intervention (Fang 2010; Fishbein 2002; Lee 2010; Miller 2000; Palmgreen 2001; Schwinn 2010; Slater 2006; Yzer 2003; Zhao 2006 and the five Meth projects). Four studies compared higher to lower exposure to a mass media intervention (Carpenter 2011; Hornik 2006; Scheier 2010; Slater 2011). Five studies compared anti-drug advertisements with another intervention (Czyzewska 2007; Kelly 1992; Newton 2010; Palmgreen 1991; Polansky 1999). Two studies (Palmgreen 1991; Yzer 2003) had different intervention arms comparing either another intervention or no intervention. For details of control interventions see the table Characteristics of included studies.

The following table summarises the interventions evaluated and the exposure of the comparison groups, as well as the theories underlying the interventions.

Studies	Explicit underpinning theory	Intervention			Comparison group		
		Internet-based intervention	PSA (public service - TV/ radio) advertisements	Printed advertisement	No intervention	Lower exposure to intervention	Other intervention/different combination of same intervention
Palmgreen 1991	Influence of sensation-seeking on drug use		X				X
Kelly 1992	Role of discussion on attitudes and opinions		X				X
Polansky 1999	Decision theory		X				X
Miller 2000	Self regulation theory		X	X	X		
Palmgreen 2001	Influence of sensation-seeking on drug use		X		X		
Fishbein 2002	Beliefs, norms or self efficacy		X		X		
Yzer 2003	Theories of behavioral change: persuasion effects		X		X		X
Slater 2006	Social-ecological framework (norms and expectations influence drug use)		X	X	X		
Zhao 2006	Normative beliefs		X		X		

(*Continued*)

Study	Theory						
Czyzewska 2007	Reactance theory		X				X
Hornik 2006	Unclear	X	X	X		X	
Scheier 2010	Social marketing	X	X	X		X	
Schwinn 2010	Social learning theory	X			X		
Lee 2010	Readiness to change	X			X		
Fang 2010	Family-oriented	X			X		
Newton 2010	Social influence approach	X					X
Idaho Meth 2010 / Colorado Meth 2011 / Georgia Meth 2011 / Hawaii Meth 2011 / Wyoming Meth 2011	Perception of risk and perception of social disapproval are correlated with drug consumption	X	X	X	X		
Slater 2011	Autonomy and aspiration perceptions as mediators marijuana use		X	X		X	
Carpenter 2011	Unclear; evaluated many heterogeneous mass media campaigns	X	X	X		X	

Outcome

The sum of studies described in this paragraph exceeds the number of included studies because many studies measured more than one outcome.

Sixteen studies measured the effect of mass media campaigns on illicit drugs use. Thirty-six studies reported the following secondary outcomes (seven were without primary outcomes):

- seven studies: intentions not to use/to reduce use/to stop use;
- 15 studies: attitudes towards illicit drug use;
- two studies: knowledge about the effects of illicit drugs on health;
- one study: understanding of intended message and objectives;
- 11 studies: perceptions (including perceptions of peer norms and perceptions about illicit drug use).

Country

Twenty-one studies were conducted in the USA, one in the USA and Canada (Schwinn 2010), and one in Australia (Newton 2010).

Duration

No follow-up was described, or was applicable, for seven studies (Carpenter 2011; Czyzewska 2007; Fishbein 2002; Palmgreen

1991; Polansky 1999; Yzer 2003; Zhao 2006). Follow-up was shorter than 12 months for four studies (Fang 2010; Kelly 1992; Lee 2010; Schwinn 2010), and longer than or equal to 12 months for the remaining 12 studies.

Excluded studies

Several thousand studies were excluded after screening their title and abstract because they did not meet the inclusion criteria. Fifty-three studies required closer scrutiny and are listed in the Characteristics of excluded studies table.

Four were excluded because the population studied did not meet the inclusion criteria; nine studies included interventions different from our inclusion criteria The remainder were excluded because the study design did not met the inclusion criteria.

Risk of bias in included studies

Randomised controlled trials (RCTs)

Approximately half of the included studies are randomised and quasi-randomised controlled trials. One of them is a mixed RCT-cohort study (Slater 2011). The results of their 'Risk of bias' assessments are presented in Figure 2 and Figure 3 and described in detail in Table 1.

Figure 2. Randomised controlled trial 'Risk of bias' graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.
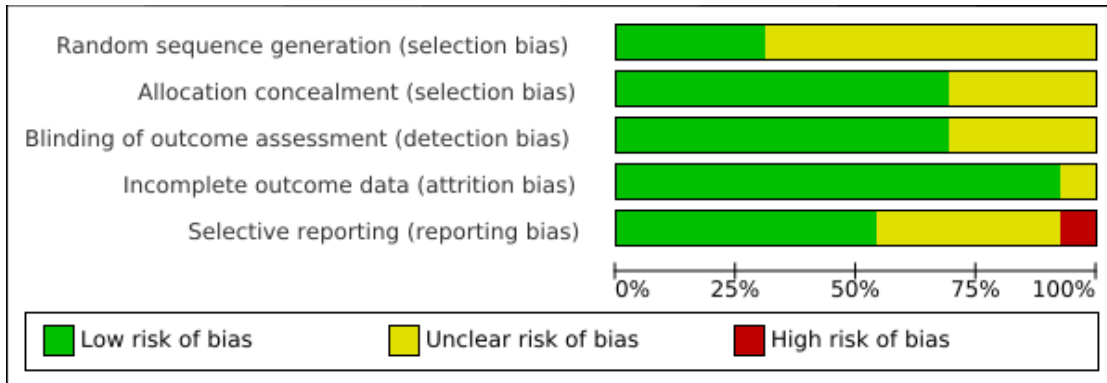
Figure 3. Randomised controlled trial 'Risk of bias' summary: review authors' judgements about each risk of bias item for each included study.

Overall the quality of the included RCTs is acceptable: the stronger dimension is the consideration of risk of attrition bias (incomplete data addressed in the discussion) and the weaker dimension the risk of selection bias (unclear description of method for randomisation). More than half of the studies were clearly free of selective outcome reporting. In one case (Schwinn 2010) there was a clear indication of potential high risk of reporting bias.

Other potential sources of bias

Ecological factors are likely to interfere with the effect of a media campaign. These factors can include exposures to other media campaigns (advertisements), films or mass media debates directly addressing illicit drugs or other factors acting indirectly (for example, a popular singer who dies from an overdose).

Interrupted time series (ITS) and before and after studies (CBA)

Six studies are ITS and two studies are CBA. The results of their 'Risk of bias' assessments are presented in Figure 4 and Figure 5.

Figure 4. Interrupted time series 'Risk of bias' graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.
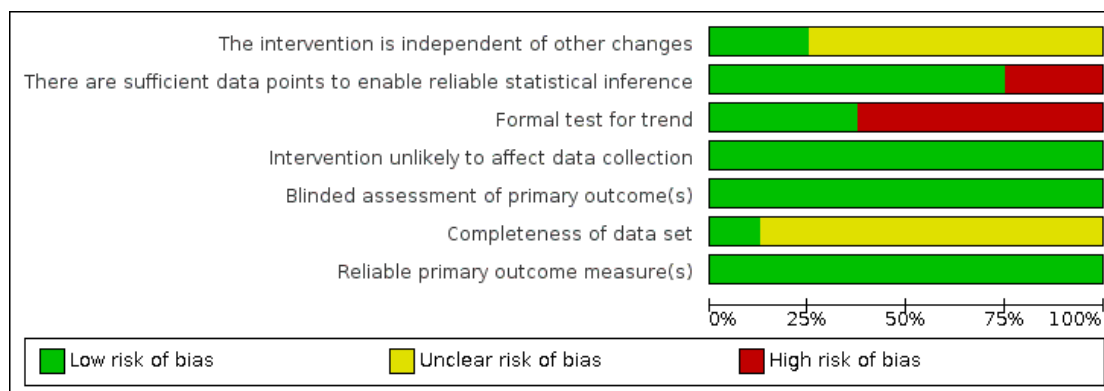
Figure 5. Interrupted time series 'Risk of bias' summary: review authors' judgements about each risk of bias item for each included study.

Overall the studies reported sufficient data points to enable reliable statistical inferences; they also had good strategies to ensure anonymous or computer-administered questionnaires and to ensure that interventions did not affect data collection. The reliability of primary outcome measures was also satisfactory for all the studies. The weaker points were the lack of a formal test for trends and the unclear completeness of the data sets for many studies.

Prospective cohort studies (PCS)

Three studies are cohort studies and one of them is a mixed RCT-cohort study (Slater 2011). The results of their 'Risk of bias' assessments are presented in Table 2, Figure 6 and Figure 7.

Figure 6. Prospective cohort studies 'Risk of bias' graph: review authors' judgements about each risk of bias item presented as percentages across all included studies
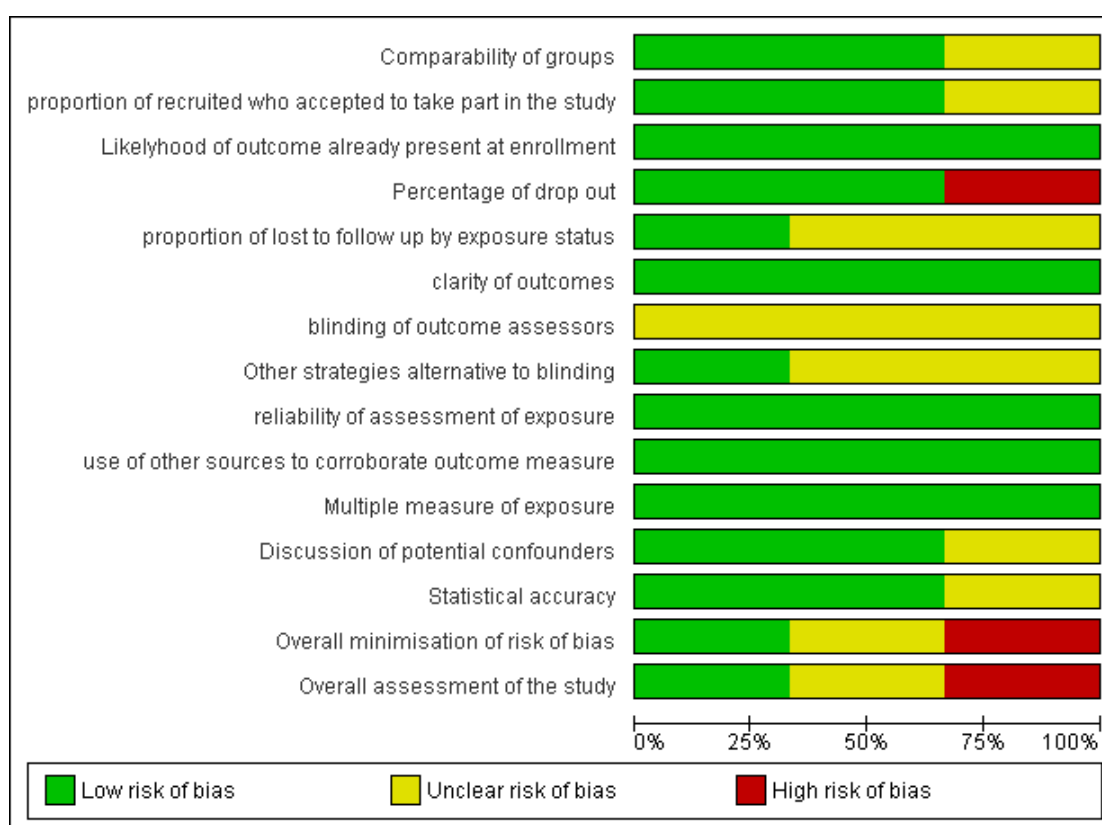
Figure 7. Prospective cohort studies 'Risk of bias' summary: review authors' judgements about each risk of bias item for each included study.

Overall, all PCS addressed an appropriate and clearly focused question. In two studies subjects were selected with proper procedures in order to make them comparable in all respects. The same two studies indicated how many of the people asked to take part actually participated in the study. One study (Slater 2011) failed to address these issues. Attrition was 35% in two studies and 42.9% in Slater 2011. Comparison between participants and those lost to follow-up was made only in Scheier 2010.

Assessment

The outcomes were clearly defined in all studies. Blinding to exposure status was not applicable for any of the studies. In one study (Hornik 2006) there was some recognition that knowledge of exposure status could have influenced the assessment of the outcomes. In all studies the measure of assessment of exposure was reliable: evidence from other sources was used to demonstrate that the method of outcome assessment was valid and reliable, and exposure level or prognostic factor was assessed more than once.

Confounding

The main potential confounders were adequately identified and taken into account in two studies (Hornik 2006; Slater 2011).

Statistical analysis

Confidence intervals were provided in two studies. One study reported only P values (Scheier 2010).

Overall assessment of the study

One study did very well in addressing the risk of bias or confounding (Hornik 2006), one did quite well (Slater 2011) and one did not adjust for potential confounders (Scheier 2010).

Effects of interventions

Primary outcomes

Self reported or biomarker-assessed illicit drug use

This primary outcome is measured in 15 studies: five randomised controlled trials (RCT) + one RCT and prospective cohort study; two prospective cohort studies; six interrupted time series (ITS) and one controlled before and after (CBA) study.

The five RCTs (Fang 2010; Lee 2010; Newton 2010; Schwinn 2010; Slater 2006) enrolled 5470 young people and were included in a meta-analysis (see Figure 8). Their pooled results show no effect of media campaign intervention (standardised mean difference (SMD) - 0.02; 95% confidence interval (CI) -0.15 to 0.12, heterogeneity P = 0.02) (Analysis 1.1). Youngsters exposed to a media campaign tend to use, on average, fewer illicit substances measured through an array of published and unpublished scales including the American Drug and Alcohol Survey (Centers for Disease Control and Prevention), Youth Risk Behavior Survey, Australian National Drug Strategy Household Survey and Global Appraisal of Individual Needs-I (see Table 3).

Figure 8. Forest plot of comparison: 1 Mass media versus no mass media intervention (RCT), outcome: 1.1 Drug use.
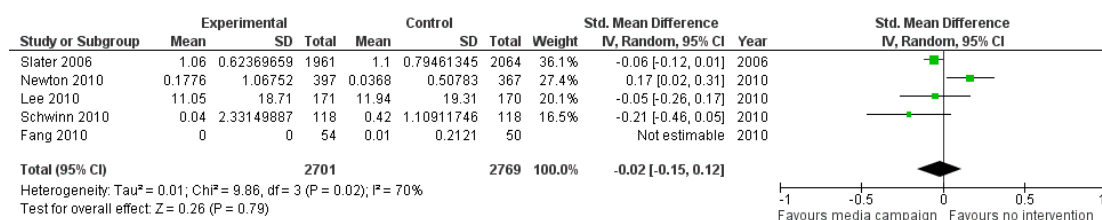
Several time points of use were available in the different studies, but we chose the six-month follow-up as a standard comparable across studies. To do this we have used both published and unpublished data kindly provided by the authors. Among the six-month assessments, Slater 2006 and Schwinn 2010 measured use in the past 30 days, Lee 2010 measured use in the past three months and Newton 2010 frequency of use in the past 12 months.

The pooled result shows no effect of the intervention, with overall significant heterogeneity among studies (P < 0.05); this can be partially explained by the results of Newton 2010 which showed a reduction of use in the control group.

The theoretical background for the five studies was varied, with two studies based on the social learning theory (Schwinn 2010) and the social ecological framework (Slater 2006) providing the better results, whereas the study based on the social influence approach (Newton 2010) favoured the control group.

Five ITS (Colorado Meth 2011; Georgia Meth 2011; Hawaii Meth 2011; Idaho Meth 2010; Wyoming Meth 2011, N = 26,405) evaluated the Meth Project intervention in five US states. In every study the first year reports pre-campaign figures. Observed and predicted overall and state-specific probabilities were plotted against time for both past-month (Figure 9) and past-year (Figure 10) use of methamphetamine. Among study participants aged 12 to 17 years old there was no evidence of an effect on past-month prevalence of methamphetamine (odds ratio (OR) 1.16, 95% CI 0.63 to 2.13) and evidence of a reduction in past-year prevalence (OR 0.59; 95% CI 0.42 to 0.84). Among participants aged between 18 and 24 years old there was no evidence of an effect for past-month (OR 0.72; 95% CI 0.16 to 3.20) or past-year (OR 0.91; 95% CI 0.43 to 1.94) prevalence of methamphetamine.

Figure 9. Observed and predicted probabilities of past-month methamphetamine use in the Meth Project studies
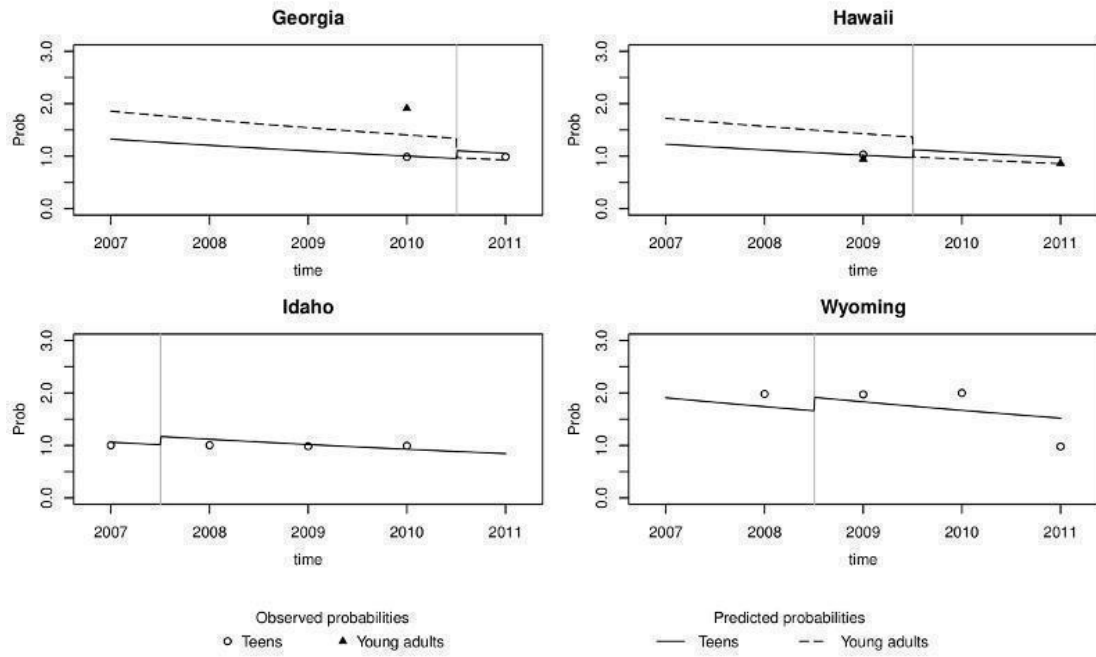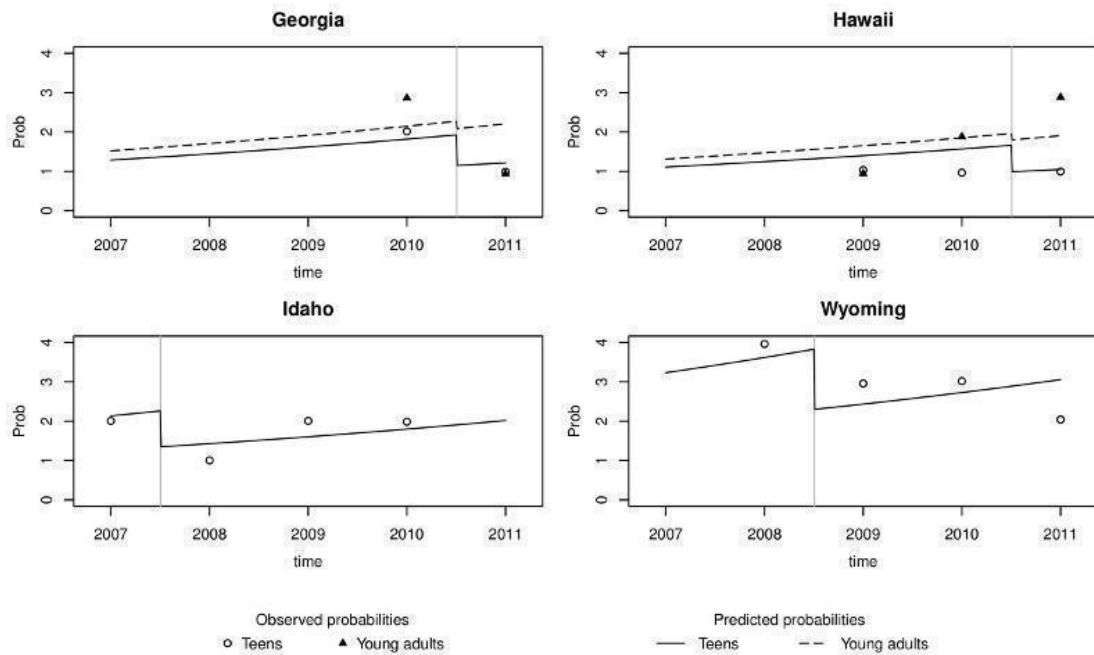
Figure 10. Observed and predicted probabilities of past-year methamphetamine use in the Meth Project studies

Due to the intrinsic methodological limitations of ITS studies and the impossibility of conducting more sophisticated analyses (e.g. by adjusting for potential confounders), these findings should be considered with caution.

Slater 2011, the only RCT that included a prospective cohort study(the reason why it was not included in the meta-analysis) found evidence that a community-level campaign, adjusted for the effect of a school-level campaign, reduced marijuana uptake compared to no intervention (estimate -0.511; P = 0.026).

Two prospective cohort studies (N = 10,632) found results ranging from non-significantly effective to a significant iatrogenic effect. Namely, Scheier 2010 found that over time young participants in the experimental arms reported increasingly more awareness and recalled increasingly more campaign messages, and also a concomitant but not statistically significant decrease in their reported levels of marijuana use. Hornik 2006 measured past-year marijuana use after exposure to a national media campaign as a function of exposure to a specific advertisement at a prior round and found an increase in use (odds ratio (OR) 1.21; 95% CI 1.19 to 1.65), controlled for considered confounders.

One ITS(Palmgreen 2001) was included in the meta-analysis because the author we contacted for this review suggested presenting the data as in the original papers. In this 32-month study, high sensation-seekers exhibited a significant upward trend in 30-day

marijuana use before exposure to the campaign and a significant downward trend after exposure. This finding was reported in both the communities involved in the study (Knox County Time Series (P = 0.001) and the Fayette County Time Series (P = 0.003 and P = 0.001 after campaign 1 and 2, respectively)).

One ITS(Carpenter 2011) analysed the relationship between exposure to the 'Above the Influence' campaign in 210 US media markets and adolescent marijuana use from 2006 to 2008. The study showed lower rates of past-month (adjusted odds ratio (AOR)0.67; 95% CI 0.52 to 0.87) and lifetime (AOR 0.76; 95% CI 0.62 to 0.93) marijuana use among girls in grade eight. For boys in grade eight and both girls and boys in grades 10 and 12 there was no evidence of an association between the campaign and a reduction in marijuana use.

The only controlled before and after (CBA) study (Miller 2000) found a modest increase in drug use in the control campus, paralleled by a modest decrease in drug use in the experimental campus, without statistical significance.
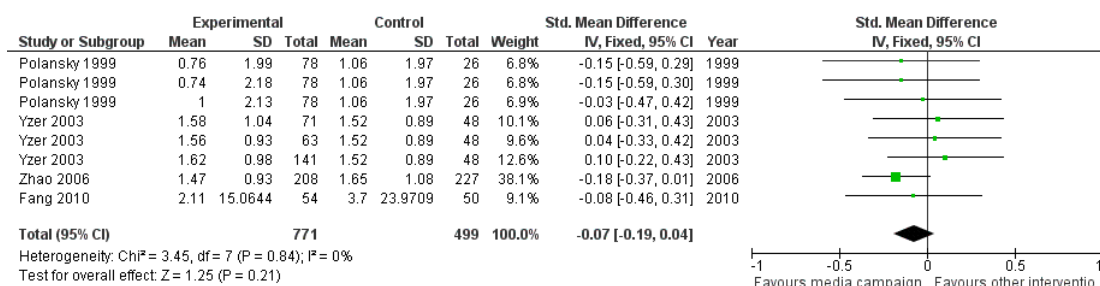
Secondary outcomes

Intentions not to use/to reduce use/to stop use

This outcome was measured by four RCTs, which found a non-statistically significant effect in favour of media campaigns, and one prospective cohort study which, on the other hand, found a possible iatrogenic effect.

Four RCTs (Fang 2010; Polansky 1999; Yzer 2003; Zhao 2006) involving 1270 students were included in the meta-analysis (see Figure 11) and the pooled analysis shows that there is no effect (SMD -0.07; 95% CI -0.19 to 0.04) (Analysis 1.2). Intentions to use drugs were measured with several unpublished scales and the Drug Attitude Scale (see Table 3 for a brief description of the scales used).

Figure 11. Forest plot of comparison: 1 Mass media versus no mass media intervention (RCT), outcome: 1.2 Intention to use drugs.

Study or Subgroup	Experimental Mean	SD	Total	Control Mean	SD	Total	Weight	Std. Mean Difference IV, Fixed, 95% CI	Year
Polansky 1999	0.76	1.99	78	1.06	1.97	26	6.8%	-0.15 [-0.59, 0.29]	1999
Polansky 1999	0.74	2.18	78	1.06	1.97	26	6.8%	-0.15 [-0.59, 0.30]	1999
Polansky 1999	1	2.13	78	1.06	1.97	26	6.9%	-0.03 [-0.47, 0.42]	1999
Yzer 2003	1.58	1.04	71	1.52	0.89	48	10.1%	0.06 [-0.31, 0.43]	2003
Yzer 2003	1.56	0.93	63	1.52	0.89	48	9.6%	0.04 [-0.33, 0.42]	2003
Yzer 2003	1.62	0.98	141	1.52	0.89	48	12.6%	0.10 [-0.22, 0.43]	2003
Zhao 2006	1.47	0.93	208	1.65	1.08	227	38.1%	-0.18 [-0.37, 0.01]	2006
Fang 2010	2.11	15.0644	54	3.7	23.9709	50	9.1%	-0.08 [-0.46, 0.31]	2010
Total (95% CI)			**771**			**499**	**100.0%**	**-0.07 [-0.19, 0.04]**	

Heterogeneity: Chi² = 3.45, df = 7 (P = 0.84); I² = 0%
Test for overall effect: Z = 1.25 (P = 0.21)

Favours media campaign Favours other interventio

Hornik 2008 was not included in the meta-analysis because its study design (prospective cohort study) was not comparable with that adopted by the others (randomised controlled trial). The study found that at one round a higher level of exposition was associated with more intention to use marijuana (expressed as less intention to avoid marijuana use(y= -0.07; 95% CI -0.13 to -0.01).

Attitudes towards illicit drug use

Fourteen studies including 37,172 youngsters considered this outcome which was measured specifically by eight RCTs, one prospective cohort study and five ITS. No meta-analysis was possible and results have been described narratively. Overall, no conclusions can be drawn on the basis of the available studies.

Eight RCTs showed mixed results with four studies giving positive results and four uncertain results. For example, Palmgreen 1991 found that media campaign messages specifically targeting high sensation-seekers were more effective than controls in increasing negative attitude towards drug use. In Kelly 1992 the exposed group showed a change in attitude towards drugs. In Polansky 1999 ninth-grade students exposed to media advertisement showed more ability to resist peer pressure to use drugs than

the control group. In Czyzewska 2007 the anti-marijuana advertisements group showed a tendency to more negative implicit attitudes to marijuana than the control whereas Newton 2010 showed that at the 12-month follow-up no differences between groups persisted for alcohol expectancies, cannabis attitudes or alcohol- and cannabis-related harms. The advertisements studied by Yzer 2003 targeted the belief that marijuana is a gateway to use of stronger drugs. Nevertheless results did not support this as no clear persuasion was found for any of the ad sequences. In comparison to the control condition, adolescents in the explicit gateway condition tended to agree less with the gateway message and displayed weaker correlations between anti-marijuana beliefs and their attitude towards marijuana use. Schwinn 2010 measured drug resistance/refusal skills; however they did not report results. Zhao 2006 did not find any significant effect on individual measures of attitude change.

Hornik 2006 found a small but significant increase in anti-marijuana beliefs and attitudes in students exposed to media campaigns even though this was not accompanied by significant parallel gains in intentions not to use, social norms or self efficacy.

Heterogeneous results were reported in the five included Meth

Project studies. In Wyoming Meth 2011 more teens disapproved of experimental meth use (i.e. trying meth once or twice) in 2008 than 2011, and both experimental and regular use of heroin, marijuana and cocaine. In Colorado Meth 2011 disapproval of experimental use of marijuana decreased but disapproval of regular use increased from 2009 to 2011. In Georgia Meth 2011 most 12 to 17-year-olds disapproved of experimental use of meth, heroin and cocaine in 2011 than in 2010. In Hawaii Meth 2011 more 12 to 17-year-olds disapproved experimental use of meth in 2009 than in 2011. Most 18 to 24-year-olds disapproved of experimental and regular use of meth and experimental use of heroin and cocaine. In Idaho Meth 2010 more teens disapproved of experimental and regular use of meth, heroin and cocaine in 2007 than in 2010.

Knowledge about the effects of illicit drugs on health

One RCT measured this outcome, finding a possible association between the effectiveness of the campaign and message on individual characteristics. One study shows significant improvement in knowledge about the target substance in the experimental group. Lee 2010 found an association between contemplation for change and marijuana use at three-month follow-up. Intervention participants who were higher in contemplation for change showed a significant decrease in marijuana use. Nevertheless, this result was not confirmed at six months follow-up. Newton 2010 showed that at the 12-month follow-up, significant improvements in alcohol and cannabis knowledge in students in the intervention group compared to the control group were present.

Understanding of intended message and objectives

Only one RCT addressed this outcome:Fishbein 2002 which adopted a measure of perceived effectiveness of a media campaign.

Perceptions (including perception of peer norms and perception of risks of use of illicit drugs)

This outcome was measured by 11 studies (N = 40,243): four RCTs, one prospective cohort study, one CBA and five ITS. Only one of the four included RCTs found a significant effect in favour of media campaigns in changing towards a negative perception of marijuana use (Zhao 2006). The remainder found weaker results apparently in favour of interventions. Fishbein 2002 adopted a measure of perceived effectiveness of media campaign based on realism, learning and emotional responses, all considered highly correlated with effective messages. Zhao 2006 found that students exposed to media campaign messages showed changes towards a negative perception about the consequences of marijuana use. Schwinn 2010 measured the normative belief among participants and found a change in the experimental group which was not maintained at six months follow-up. As already mentioned Yzer 2003 targeted the belief that marijuana is a gateway to stronger drugs. Results did not support this and no clear

persuasion was found for any of the ad sequences. In comparison to the control condition, adolescents in the explicit gateway condition tended to agree less with the gateway message and displayed weaker correlations between anti-marijuana beliefs and their attitude toward marijuana use.

Hornik 2006, the only prospective cohort study investigating this outcome, found a small but significant increase in anti-marijuana beliefs and attitudes in students exposed to media campaigns yet this was not accompanied by significant parallel gains in intentions not to use, social norms or self efficacy

The only CBA(Miller 2000) found that the students enrolled in the experimental arm showed significantly higher perceived risks from substance use

Results differed considerably across the five included Meth Project studies. In Wyoming Meth 2011 perception of ease to acquire any of the examined drugs (meth, heroin, marijuana and cocaine) decreased from 2008 to 2011. More teens agreed with all of the 14 perceived risks attributed to meth and more teens disagreed with six out of the nine perceived benefits attributed to meth. In Colorado Meth 2011 more teens in 2011 than in 2009 agreed with nine of the 14 items concerning risks attributed to meth. In Georgia Meth 2011 perception of ease to acquire cocaine and heroin decreased from 2010 to 2011 among 12 to 17-year-olds. More teens agreed with all of the 14 perceived risks attributed to meth, and fewer teens agreed with five of the nine perceived benefits attributed to meth. Among 18 to 24-year olds, more young adults agreed with seven of the 14 perceived risks attributed to meth, and fewer young adults agreed with six of the nine perceived benefits attributed to meth. In Hawaii Meth 2011 perception of ease to acquire heroin decreased from 2009 to 2011 among 12 to 17-year-olds. The percentage of those who see a "great risk" in taking meth, heroin and cocaine decreased by around 10 points. More teens agree with 13 of the 14 perceived risks attributed to meth. Among 18 to 24-year-olds a reduction of perceived ease to acquire marijuana and cocaine was also described. In such an age group the percentage of those who see a "great risk" in taking meth, heroin and cocaine decreased by around 15 points. More young adults agreed with all of the 14 perceived risks attributed to meth and fewer young adults agreed with five of nine perceived benefits of meth. In Idaho Meth 2010 perception of risk in trying meth, heroin and cocaine once or twice increased from 2007 to 2010. More teens agreed with all of the 14 perceived risks attributed to meth and fewer teens agreed with all of the nine perceived benefits attributed to meth.

Adverse effects

- Reactance (i.e. a reaction to contradict the prevailing norms of rules)

Fishbein 2002 found that six out of 16 studied Public Service Advertisements (PSA) were judged by the young participants as not effective. In other words, adolescents viewing these six PSAs

reported that they and their friends would be more likely to try or to use drugs, and would feel less confident about how to deal with situations involving drugs. Specifically negative correlations were found for the advertisement tackling marijuana (r = -0.52), those not specifying a drug or talking about drugs in general, also tended to be judged as ineffective, although this relationship was not significant (r = -0.23). PSAs describing the "just say no" message tended to be judged as less effective (r = -0.29). Yzer 2003 found that adolescents exposed to the "Gateway" message (explicitly saying that marijuana use led to use of hard drugs) considered this message less effective and were (although not statistically significantly) more positive towards marijuana use, while Hornik 2006 found a possible presence of pro-marijuana effects in at least two analyses out of 10 in terms of intention to use and initiation.

- Positive descriptive norms (i.e. increased perception that drug use in peer population is common, normal or acceptable)

Palmgreen 2001 found a reinforcing effect of the media campaign on pro-marijuana beliefs (particularly for occasional use).

DISCUSSION

Summary of main results

The studies included in this review tested an array of different interventions including national campaigns, public service advertisements, television messages, video tapes and Internet-based campaigns and the effects were measured by means of unpublished and published scales administered to the participating adolescents. Hence the first issue is the comparability of results.

Overall 15 studies measured the effects on the use of drugs of nine campaigns of which four used the Internet, one was performed in school setting and four were TV broadcasting campaigns (the Meth Project was assessed by five studies and the National Youth Anti-Drug Media Campaign (NYADMC) was assessed at different stages by five studies).

The outcomes on the use of drugs of five randomised controlled trials (RCTs) (four on Internet-based interventions and one on TV/radio broadcasting) have been pooled, resulting in no effect of mass media campaigns (standardised mean difference (SMD) -0.02; 95% confidence interval (CI) -0.15 to 0.12), with statistically significant heterogeneity (P = 0.02). The four studies including Internet-based interventions gave contrasting results about drug use (some showed that the intervention reduced the use of drugs and some showed that the intervention could favour use), whereas the study on the national campaigns found a reduction in use in the experimental group.

The study evaluating the school media campaign found a non-significant reduction in drug use in the experimental group.

The studies evaluating the Meth Project on methamphetamine were included in a separate meta-analysis, the pooled results of

which showed a significant reduction in the past-year use of methamphetamine.

Five studies evaluated different phases of the NYADMC. The preliminary study showed positive results in favour of the campaign, the two studies evaluating the 1st phase showed an opposite effect, with a significant increase in drug use in the more robust study, and the two studies evaluating the 2nd phase showed positive results in favour of the campaign.

There are a series of observational studies, generally cohort studies or interrupted time series (ITS), which can be classified as field trials and evaluate the effectiveness of the multimedia-TV campaigns intervention in its context. They show contrasting results, from weakly effective, as for the Meth Project campaign, to clearly harmful, as one form (Hornik 2006) reported statistically significant results in favour of the control group, showing an increase in marijuana use of 20% in those more exposed to the campaign compared to those less exposed. The multistage evaluation of the NYADMC campaign conducted to positive results.

Looking at the secondary outcomes, the RCTs included in the meta-analysis showed non-significant results in favour of the groups exposed to the campaign for intention to use, an outcome considered a proxy for future behavior (Litchfield 2006; Olds 2005). One observational study (Hornik 2006) found a possible reinforcing effect of media campaign exposure on intention to use, especially cannabis.

Summing up the available evidence from RCTs shows that media campaigns based on the Internet are not effective in reducing the use of drugs, whereas the evidence from observational studies shows that there are some positive effects in reducing last-year prevalence in younger people. A study based on independent data collection gave overall positive results for girls and showed no effectiveness in boys in terms of marijuana use.

Overall completeness and applicability of evidence

The objective of this review was to measure the effect of media campaigns on influencing drug use among young people. The studies we included only partially answer the question and they are hardly comparable. In fact the studies focused on a variety of interventions and used several different scales to measure the outcomes. It was therefore not possible to have results on all the typologies of campaign listed in the introduction section, and any attempt to compare effects is limited.

A second threat to the applicability of results is the nature of the studies: the RCTs are always carried out in an experimental context such as, for example, schools in which the students randomised to the intervention arm are exposed to the media message, or the trials enrolling volunteers on the Internet, a very selected population. This appears to measure efficacy and not effectiveness of the intervention, given that subjects are out of the context in which they would be exposed in the real world. The other studies, called

field studies, measure the effect in a real context, but are limited in numbers, overall methodological quality and are actually focused on two campaigns.

Furthermore, all the studies were conducted in the USA, apart from two in Canada and Australia, and as a consequence the generalisability to other geographical and social contexts, such as Europe, remains unclear.

Quality of the evidence

We included 23 studies on very different interventions, the effects of which were measured with several scales. The methodological quality of the included studies was hard to assess as many dimensions were unclear in the relevant publications. Nevertheless, when the dimensions were reported the quality of the studies was acceptable. In many cases further information was obtained by contacting the study authors. The main limitation of the evidence available is the lack of comparability of some measures of outcomes and, more importantly, the unclear causal relationship between the campaign size and its effect. This lack of clarity reduces the generalisability of results, i.e. it is still unclear which part of a campaign should be reproduced to achieve which results.

Potential biases in the review process

The inclusion of studies which are different from randomised controlled trials complicates the identification and retrieval of the studies, due to a less structured indexing of studies in different databases, and lack of devoted registries and unique identification of studies. We therefore acknowledge that we might have missed some studies. Nevertheless, an accurate cross-check of all the reference lists and contacts with the principal investigators in the field may have reduced this risk.

The assessment of study quality relied on study design-specific checklists, yet for many publications the majority of the information we used assess and score the quality criteria was unclear. We therefore contacted many authors to ask for clarification, but in the case of the older studies it was not possible to retrieve additional information.

Agreements and disagreements with other studies or reviews

Werb and colleagues (Werb 2011) performed a systematic review of all the studies assessing public service announcements (eight studies) including meta-analyses for two outcomes: intention to use and and mean use of illicit drugs. In spite of different inclusion criteria (as we also included non-PSA interventions) and criteria for analysis, we reached similar conclusions. Furthermore, Wakefield 2010, in their broader analysis of media campaigns aiming to change health behaviour, address the media campaign effect

on illicit drugs use with five studies, concluding that the relevant evidence is inconclusive.

AUTHORS' CONCLUSIONS

Implications for practice

The effectiveness of media campaigns to prevent illicit drug use among young people is not clearly supported, with some evidence of iatrogenic effects. Therefore it is recommended that such campaigns should only be provided in the context of rigorous, well-designed and well-powered evaluation studies.

Implications for research

The great majority of the studies are conducted in the United States, thus more worldwide studies should be carried out. Moreover, validated and standardised tools to measure the outcome are recommended to allow comparability and generalisability of results. As the actual evidence suggests some effectiveness in specific populations (younger and female, for example) we need to focus better on investigation of the components of media campaigns which are effective in specific populations.

For this reason, beyond the general methodological recommendations, we suggest a strategy to make the best use of available resources and study designs. Our suggestions initially consider general improvement of methods:

- field evaluation studies should adopt, whenever possible, a cohort design;

- studies should be conducted in different countries and contexts;

- validated, comparable and standard tools should be used for the measurement of effects;

- the separate testing of specific media campaign components for their efficacy should be carried out by pilot randomised controlled trials in specific populations;

- future studies should ensure consistency among hypothesis testing, study design and measures of outcomes.

In general, whenever possible, interrupted time series studies, using independent and current data collection (such as the one by Carpenter 2011), should be conducted to assess the overall effects of any anti-drug media campaign.

Until the development of this research is ensured, we should not exclude the possibility of a campaign having iatrogenic effects.

ACKNOWLEDGEMENTS

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* *Indicates the major publication for the study*

CHARACTERISTICS OF STUDIES

Characteristics of included studies *[ordered by study ID]*

Carpenter 2011

Methods	Study design: interrupted time series study Sampling: systematic sampling (schools are selected within geographic areas that are determined by the sampling section of the University of Michigan Survey Research Center, page 949) Comparison group(s): pre-intervention surveys Follow-up duration: n/a Study time span: 2006 to 2008 (approximately 36 months)
Participants	130,245 youths from 8th to 12th grade (13- to 18-year-old)
Interventions	All media for 210 media markets for 2006 to 2008, after the introduction of the Above the Influence campaign
Outcomes	- Past 30-day marijuana use - Lifetime marijuana use - Past-month alcohol consumption
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not applicable
Allocation concealment (selection bias)	Unclear risk	Not applicable
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Not reported
Selective reporting (reporting bias)	Unclear risk	No information regarding potential reporting bias

Colorado Meth 2011

Methods	Study design: interrupted time series study Sampling: n/a Comparison group(s): pre-intervention survey Follow-up duration: n/a Study time span: March 2009 to April 2011 (26 months)
Participants	1803 youths (600 + 601 + 602)
Interventions	Meth Project (USA), a "messaging campaign, supported by community outreach, and public policy initiatives". The campaign comprises "television, radio, print, billboard, and Internet advertising"
Outcomes	• Past-month use of methamphetamine • Attitudes on methamphetamine and other drugs • Perceptions concerning methamphetamine and other drugs • Information sources and advertising awareness • Statewide Meth Project awareness and perceptions
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not applicable
Allocation concealment (selection bias)	Unclear risk	Not applicable
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Anonymous questionnaires
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Not reported
Selective reporting (reporting bias)	Unclear risk	No information regarding potential reporting bias

Czyzewska 2007

Methods	Study design: randomised controlled trial Sampling: not specified Comparison group(s): 4 = 2 anti-tobacco advertisements x 2 orders of advertisements (i. e. explicit attitudes towards tobacco or marijuana) Follow-up duration: not applicable Study time span: not specified
Participants	229 college students aged 18 to 19 years
Interventions	15 advertisement embedded in a 15-minute science programme (USA). 10 advertisements were youth directed, 5 were non-youth directed. Each programme comprised of 90-second science film segments, 30-second youth-directed ad, 30-second non-youth-directed ad, then again another 30-second youth-directed ad. There were 4 versions of recorded programme corresponding to 4 experimental conditions: 2 types of advertisements (i.e. anti-tobacco or anti-marijuana) x 2 orders of advertisements (i.e. explicit attitudes towards tobacco or marijuana)
Outcomes	• Implicit and explicit attitude towards tobacco • Implicit and explicit attitude towards marijuana
Notes	Implicit attitudes were assessed through the Implicit Association Test (IAT)

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	p. 117 "They were randomly assigned to experimental conditions", but randomisation details are not reported
Allocation concealment (selection bias)	Low risk	Although full allocation concealment is not possible for this kind of study, there is low risk of selection bias because researchers administering the intervention were unlikely to know the children. See p. 117: "Two groups of 18- to 19-year-old college students were exposed to either anti-tobacco or anti-marijuana advertisements followed by implicit and explicit tests of attitudes to both, marijuana and tobacco"
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Anonymous questionnaire p. 119 "Next to a computer, each person had a survey with a pre-recorded ID number on it"
Incomplete outcome data (attrition bias) All outcomes	Low risk	All participants completed the test (being a post-only design); p. 117 "Two groups of 18- to 19-year-old college students were

Czyzewska 2007   *(Continued)*

		exposed to either anti-tobacco or anti-marijuana advertisements followed by implicit and explicit tests of attitudes to both, marijuana and tobacco"
Selective reporting (reporting bias)	Unclear risk	No study protocol was mentioned

Fang 2010

Methods	Study design: randomised controlled trial Sampling: random sampling (through online advertisement and community service agencies) Comparison group(s): no intervention Follow-up duration: 6.25 months Study time span: September 2007 to ~December 2008 (~16 months)
Participants	108 Asian-American girls aged 10 to 14 with private access to a computer, and their mothers
Interventions	Internet-based prevention programme (USA) guided by family interaction theory and aiming to prevent girls' substance use through enhancing mother-daughter interactions. 9 sessions: mother-daughter relationship, conflict management, substance use opportunities, body image, mood management, stress management, problem solving, social influences, self efficacy. The programme was not designed expressly for Asian-Americans
Outcomes	- Past 30-day use of - alcohol - cigarettes - marijuana - prescription drugs - Intention to use any of the above in the future - Depression - Other variables - Self efficacy - Refusal skills - Mother-daughter closeness - Mother-daughter communication - Maternal monitoring - Family rules against substance use
Notes	Only 1 post-test survey. Unclear whether the intervention focused on a single substance or many

Risk of bias

Bias	Authors' judgement	Support for judgement

Random sequence generation (selection bias)	Unclear risk	p. 530 "Mother-daughter dyads were randomly assigned to intervention (n = 56) and control arms (n = 52)", but randomisation details are not reported
Allocation concealment (selection bias)	Low risk	Although full allocation concealment is not possible for this kind of study, there is low risk of selection bias because researchers administering the intervention were unlikely to know the children. See p. 530: "Delivered by voice-over narration, animated graphics, and games, session content involved skill demonstrations and interactive exercises that required the joint participation of mothers and daughters."
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Online questionnaire p. 530 "Girls and mothers had separate and unique log-in names and passwords, and each completed a pretest and posttest survey online"
Incomplete outcome data (attrition bias) All outcomes	Low risk	Low number of missing outcome data; missing data balanced in numbers across study groups p. 530 "Mother-daughter dyads were randomly assigned to intervention (n = 56) and control arms (n = 52)" "Two mother-daughter dyads attrited from each arm, and 104 dyads (54 intervention and 50 control) successfully completed both pretest and posttest measures"
Selective reporting (reporting bias)	Unclear risk	p. 530 "The study protocol was approved by Columbia University's Institutional Review Board"

Fishbein 2002

Methods	Study design: randomised controlled trial Sampling: systematic random sampling (letters from each included middle/high school) Comparison group(s): 5 experimental (6 advertisements each, embedded in a 24-minute documentary) + versus no intervention (documentary only) condition Follow-up duration: not applicable Study time span: not specified
Participants	3608 youths aged 11 to 18 years (grades 4 to 12), median age 15 years

Fishbein 2002   *(Continued)*

Interventions	30 public service announcements produced by the Partnership for a Drug Free America (USA)
Outcomes	30 dependent variables (5 scores for each of the 6 PSAs) - Perceived PSA effectiveness and realism - Negative and positive emotional response - Amount learned (understanding of intended message and on) 5 scores resulting from mean of the 6 PSA scores - Total perceived PSA effectiveness and realism - Total negative and positive emotional response - Total amount learned (understanding of intended message and on) - Perceptions: - Perceived danger of engaging in risky behaviours - Perceived harmfulness of engaging in risky behaviours - Social norms
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No mention of the sequence generation in the article (methods section p. 239)
Allocation concealment (selection bias)	Unclear risk	No mention of the sequence generation in the article (methods section p. 239)
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Anonymous questionnaire p. 240 "Confidentiality and anonymity were emphasized in the instructions, both in written and audio-video form"
Incomplete outcome data (attrition bias) All outcomes	Low risk	Apparently almost all the sample exposed to interventions were included in the final analysis (and filled out the questionnaires) . But no mention of the number originally enrolled, mention of some drop-outs apparently unlinked to outcomes but no absolute numbers reported
Selective reporting (reporting bias)	Low risk	Protocol not available but we do not suspect selective reporting

Georgia Meth 2011

Methods	Study design: before and after study Sampling: 4-stage probability sampling Comparison group(s): pre-intervention survey Follow-up duration: n/a Study time span: November 2009 to April 2011 (18 months)
Participants	4454 youths (2432 + 2022)
Interventions	Meth Project (USA), a "messaging campaign, supported by community outreach, and public policy initiatives". The campaign comprises "television, radio, print, billboard, and Internet advertising"
Outcomes	• Past-month use of methamphetamine • Attitudes towards methamphetamine and other drugs • Perceptions concerning methamphetamine and other drugs • Information sources and advertising awareness • Statewide Meth Project awareness and perceptions
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not applicable
Allocation concealment (selection bias)	Unclear risk	Not applicable
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Anonymous questionnaires
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Not reported
Selective reporting (reporting bias)	Unclear risk	No information regarding potential reporting bias

Hawaii Meth 2011

Methods	Study design: interrupted time series study Sampling: 4-stage probability sampling Comparison group(s): pre-intervention survey Follow-up duration: n/a Study time span: March 2009 to March 2011 (25 months)
Participants	3305 youths (1065 + 1035 + 1205)

Hawaii Meth 2011   (*Continued*)

Interventions	Meth Project (USA), a "messaging campaign, supported by community outreach, and public policy initiatives". The campaign comprises "television, radio, print, billboard, and Internet advertising"
Outcomes	- Past-month use of methamphetamine - Attitudes on methamphetamine and other drugs - Perceptions concerning methamphetamine and other drugs - Information sources and advertising awareness - Statewide Meth Project awareness and perceptions
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not applicable
Allocation concealment (selection bias)	Unclear risk	Not applicable
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Anonymous questionnaires
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Not reported
Selective reporting (reporting bias)	Unclear risk	No information regarding potential reporting bias

Hornik 2006

Methods	Study design: prospective cohort study Sampling: systematic sampling (4-stage, geographic) Comparison group(s): lower exposure to intervention Follow-up duration: November 1999 to June 2004 (56 months) Study time span: September 1999 to June 2004 (58 months). Up to 4 observations per each of the 3 cohorts. Interviews were carried out at home
Participants	8117 youths aged 12.5 to 18 years in the first round
Interventions	The National Youth Anti-Drug Media Campaign (USA) was a comprehensive social marketing campaign aimed at youths aged 9 to 18 years and disseminated though television, radio, websites, magazines, movie theatres and others. The campaign established partnership with civic, professional and community groups and outreach programs with the media, entertainment and sport industries

Hornik 2006 (*Continued*)

Outcomes	- Lifetime, past-year and past 30-day use of marijuana - Intention to use marijuana - Attitudes towards marijuana and self efficacy to resist use of marijuana - Perceptions and social norms about marijuana
Notes	NIDA report 'Evaluation of the National Youth Anti-Drug Media Campaign: 2004 Report of Findings. June 2006', on which this article is based, was also used to retrieve information for this meta-analysis

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not applicable
Allocation concealment (selection bias)	Unclear risk	Not applicable
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Anonymous and administered via computer p. 2230 (Hornik 2008) "NSPY questionnaires were administered on laptop computers brought into the respondents' homes. The interviewer recorded answers for the opening sections, but for most of the interview, to protect privacy, respondents heard pre-recorded categories of questions and answer through headphones and responded via touch screen selection on the computer. Interviews could be conducted in English or Spanish"
Incomplete outcome data (attrition bias) All outcomes	Low risk	"The overall response rate among youths for the first round was 65%, with 86% to 93% of still eligible youths interviewed in subsequent rounds", page 2230 in Evaluation of the National Youth Anti-Drug Media Campaign: 2004 Report of Findings, page 2-12, table 2-A "Completed interviews by wave"
Selective reporting (reporting bias)	Low risk	No protocol available but the we do not suspect selective reporting bias

Idaho Meth 2010

Methods	Study design: interrupted time series study
	Sampling: 4-stage probability sampling
	Comparison group(s): pre-intervention survey
	Follow-up duration: n/a
	Study time span: September 2007 to December 2010 (40 months)
Participants	11,143 youths (3091 + 2590 + 2641 + 2821)
Interventions	Meth Project (USA), a "messaging campaign, supported by community outreach, and public policy initiatives". The campaign comprises "television, radio, print, billboard, and Internet advertising"
Outcomes	- Past-month use of methamphetamine - Attitudes towards methamphetamine and other drugs - Perceptions concerning methamphetamine and other drugs - Informations sources and advertising awareness - Statewide Meth Project awareness and perceptions
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not applicable
Allocation concealment (selection bias)	Unclear risk	Not applicable
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Anonymous questionnaires
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Not reported
Selective reporting (reporting bias)	Unclear risk	No information regarding potential reporting bias

Kelly 1992

Methods	Study design: randomised controlled trial.
	Sampling: not specified.
	Comparison group(s):
	• control group (no anti-drug PSA and no group discussion).
	• experimental group 1 (anti-drug PSA without group discussion)
	• experimental group 2 (anti-drug PSA with group discussion)
	Follow-up duration: 1.5 months (6 weeks).
	Study time span: not specified, at least 1.5 months.
Participants	79 female college students, primarily 18 to 19 years old
Interventions	Anti-drug messages (USA) selected from the library of the Media Advertising Partnership for a Drug-Free America and centred on drugs and alcohol
Outcomes	• Attitudes towards marijuana
	• Attitudes towards cocaine
	• Attitudes towards crack
	• Attitude towards getting drunk
Notes	Pre-test, post-test and 6-week follow-up means are provided. Standard deviations are not provided

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not reported p.80 "Subjects were randomly divided into a total of 9 discussion groups."
Allocation concealment (selection bias)	Unclear risk	Not reported Baseline comparisons reported
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Blinding of outcome assessors not reported
Incomplete outcome data (attrition bias) All outcomes	Low risk	No missing data and clear reporting of sample size both of the intervention and control group
Selective reporting (reporting bias)	Low risk	No study protocol available but clear reporting of main study hypothesis and direct correlation between main topics investigated in the experiment and reported outcomes TOPICAL EXPERIMENTAL AREAS: p. 79 "two topical areas chosen for the study were (1) the age at which parents

Kelly 1992   (*Continued*)

		should talk to their children about dangers of drugs, (2) how much responsibility one has, if any, for another's drug use" OUTCOMES: p. 80 "three questions asking at what age children should be spoken to about marijuana, cocaine and crack" p. 81 "one question asked subjects to rate their agreement on a 5 point Likert scale with the statement "whether or not I get drunk is nobody's business". Similar question were asked regarding use of marijuana, cocaine and crack"

Lee 2010

Methods	Study design: randomised controlled trial Sampling: random sampling (letters and email sent to ~4000 college students at a "large public university in the Northwest United States") Comparison group(s): no intervention (no feedback or information, students were asked to complete web-based assessments) Follow-up duration: 6 months Study time span: June 2005 to not specified (at least 6 months because a 6-month follow-up was performed)
Participants	341 college students aged 17 to 19 with any use of marijuana in the 3 months before study
Interventions	Internet-based personalised feedback intervention (USA). Participants were presented with feedback about their marijuana use, perceived and actual descriptive norms about marijuana use, and perceived pros and cons of using marijuana. Skills and training tips for avoiding marijuana and making changes in use were provided, as well as limited alcohol feedback. Perceived high-risk contexts and alternative activities around campus and in the communities were provided
Outcomes	• Past 90-day use of marijuana • Contemplation to change marijuana use (intention) • Consequences of marijuana use (knowledge) • Family history of drug problem
Notes	Baseline survey, then 3- and 6-month follow-ups

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-based p. 267, "Students were randomly assigned

Lee 2010 *(Continued)*

		to a personalized feedback intervention (PFI) or control condition based on their screening responses (prior to baseline), using a stratified randomization procedure to produce groups with equivalent use rates at randomization"
Allocation concealment (selection bias)	Low risk	Although full allocation concealment is not possible for this kind of study, there is low risk of selection bias because researchers administering the intervention were unlikely to know the children. See p. 268: "Students in the intervention group received individual personalized feedback based on baseline information. On completion of the baseline survey, PFI participants could immediately view feedback online and could choose to print feedback to their own printer. Participants could return to view feedback on the web for 3 months"
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Computer-administered questionnaire (p. 266-7)
Incomplete outcome data (attrition bias) All outcomes	Low risk	p. 268 "All analyses are based on intent-to-treat, regardless of whether participants viewed their feedback"
Selective reporting (reporting bias)	Unclear risk	p. 267 "All study procedures were approved by the university IRB and a federal Certificate of Confidentiality was obtained from the National Institutes of Health"

Miller 2000

Methods	Study design: before and after study Sampling: random sampling Comparison group(s): no intervention (other campus with no intervention) Follow-up duration: 1 year Study time span: 1988-9, for 1.5 years
Participants	1024 college students at baseline (median age 25 in the intervention group, 22 in the control group), 865 at 1-year follow-up
Interventions	The Campuswide Alcohol and Drug Abuse Prevention Program (CADAPP; USA), based on self regulation theory. The campaign made use of printed materials, videotapes, speakers, peer-education, computer resources, campus policy, campus wide events. Other components of CADAPP targeted particular at-risk segments: free and confiden-

Miller 2000   (*Continued*)

	tial psychological 'drinker's checkup', list of drug/alcohol referral services available in the community, free psychological help for concerned family members and friends, alcohol self control training for on-campus fraternities
Outcomes	- Frequency of use of 10 types of drugs including cannabis and cocaine - Past 30-day alcohol consumption - Perception of risk related to alcohol and other drugs use - Problems related to alcohol and other drug use
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not applicable
Allocation concealment (selection bias)	Unclear risk	Not applicable
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Anonymous questionnaire p. 746 "Impact of CADAPP was measured through anonymous surveys of students on each campus [..]"
Incomplete outcome data (attrition bias) All outcomes	Low risk	p. 751 "At baseline (fall) assessment, 1, 400 surveys were distributed to enrolled UNM students, a sample of approximately 6% selected randomly by the university's computerized mailing list program. Of these, 567 surveys were returned and usable (41%). At the control campus, 1,080 surveys were distributed to a random sample of students, 457 of whom returned them (42. 3%). [..] The return rates were 431 (31%) at UNM and 434 (34%) at NMSU"
Selective reporting (reporting bias)	Unclear risk	No information regarding potential reporting bias

Newton 2010

Methods	Study design: randomised controlled trial Sampling: cluster sampling Comparison group(s): other type of communication interventions (usual health classes) Follow-up duration: 12 months Study time span: March 2007 to November 2008 (21 months)
Participants	764 13-year-old students from 10 Australian independent secondary schools (intervention branch: N = 397, 5 schools; control branch: N = 367, 5 schools). Students who enrol in independent schools come predominantly from high socioeconomic backgrounds
Interventions	Climate Schools course (Australia) is an Internet-based intervention founded on the social influence approach, derived from Bandura's social learning theory. The course delivered 2 sets of 6 40-minute lessons, each including 15 to 20-minute Internet-based lesson completed individually and 20 to 25-minute teacher-delivered activities. During the Internet-based part, students followed a cartoon storyline of teenagers experiencing real-life situations and problems with alcohol and cannabis
Outcomes	• Use of alcohol (number of drinks per week) and cannabis (times per week) • Alcohol and cannabis knowledge • Alcohol and cannabis attitudes • Alcohol- and cannabis-related harms
Notes	Assessment: baseline, immediately post, and 6 and 12 months following completion of the intervention Hybrid intervention: both school- and Internet-based

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	p. 750 "The 10 participating schools were assigned randomly using an online randomization system (www.randomizer.org) to either the control condition (usual drug education) or the intervention condition (the Climate Schools: Alcohol and Cannabis course)"
Allocation concealment (selection bias)	Low risk	Although full allocation concealment is not possible for this kind of study, there is low risk of selection bias because researchers administering the intervention were unlikely to know the children. See p. 750 "The Climate Schools: Alcohol and Cannabis course comprised the delivery of two sets of six 40-minute lessons. The Climate Schools: Alcohol module was delivered immediately after the baseline assessment, and the Climate Schools: Alco-

Newton 2010 (*Continued*)

		hol and Cannabis module was delivered 6 months later in the same school year. Each lesson included a 15-20-minute Internet-based lesson completed individually, where students followed a cartoon storyline of teenagers experiencing real-life situations and problems with alcohol and cannabis. The second part of each lesson was a predetermined activity delivered by the teacher to reinforce the information taught in the cartoons. Intervention group teachers were provided with a programme manual but no additional training."
Blinding of outcome assessment (detection bias) All outcomes	Low risk	p. 751 "A self-report questionnaire was completed online by all students in a classroom setting, where anonymity and confidentiality were assured"
Incomplete outcome data (attrition bias) All outcomes	Low risk	Similar attrition % over the 2 study groups (figure 1, page 754) p. 754 "Compared to students who were present at baseline and any follow-up occasion, students present only at baseline had significantly higher alcohol-related knowledge [7.66 versus 7.48 (of 16); $F(1, 758)$ = 4.88, $P < 0.05$]. There were no significant differences on any other alcohol or cannabis outcome measures, nor was there evidence of differential attrition"
Selective reporting (reporting bias)	Unclear risk	No study protocol was mentioned

Palmgreen 1991

Methods	Study design: randomised controlled trial. Sampling: random sampling (students were recruited from a variety of sources, including driver's licence listings, recruitment advertisements in local newspapers and shopper weekly, etc) Comparison group(s): 2 experimental viewing conditions • one public service announcements (PSA) aimed at high sensation-seekers (HSSs) • one PSA aimed at low sensation-seekers (LSSs) Follow-up duration: not applicable Study time span: not specified, at least 1 day
Participants	207 18- to 22-year-old youths

Palmgreen 1991   (*Continued*)

Interventions	2 national-quality 30-second embedded PSAs, one aimed at HSS and the other at LSS (USA)
Outcomes	- Attitude toward drug use - Intention to call a support hotline
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not clearly reported p. 221 "LSSs ad HSSs were randomly assigned to one of the experimental conditions or the control group"
Allocation concealment (selection bias)	Unclear risk	Not reported No baseline comparisons reported
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Blinding of outcome assessors not reported
Incomplete outcome data (attrition bias) All outcomes	Low risk	No missing data and clear reporting of sample size both of the intervention and control group
Selective reporting (reporting bias)	Low risk	No study protocol available but clear reporting of main study hypothesis (p. 219) and outcomes measures

Palmgreen 2001

Methods	Study design: interrupted time series study Sampling: systematic sampling (geographical and grade stratification from enrolment lists of 7th to 10th graders in spring 1996) Comparison group(s): pre-intervention surveys Follow-up duration: n/a Study time span: March 1996 to December 1998 (34 months)
Participants	6371 youths from 7th to 10th grade (12- to 17-year-olds), 3174 from Fayette County and 3197 youths from Knox County
Interventions	3 anti-marijuana public service announcements televised from January through April 1997 and from January through April 1998 in Fayette and Knox Counties (USA). These advertisements were based on the SENTAR (sensation-seeking targeting) prevention approach

Palmgreen 2001   (*Continued*)

Outcomes	• Past 30-day use of marijuana
Notes	The 2 samples differed significantly on some independent (e.g. perceived peer and family drug use, delinquency) and dependent (use of marijuana) variables, although demographic and sensation-seeking variables were consistent between the 2 samples

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not applicable
Allocation concealment (selection bias)	Unclear risk	Not applicable
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Anonymous questionnaire p. 293 "Interviews were private and anonymous, with self-administration of drug and alcohol items via laptop computer"
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Not reported
Selective reporting (reporting bias)	Unclear risk	No information regarding potential reporting bias

Polansky 1999

Methods	Study design: randomised controlled trial Sampling: systematic sampling (gender, classroom) Comparison group(s): 2 × 2 × 4 design (replication × gender × treatment) Follow-up duration: not specified Study time span: not specified
Participants	312 7th through to 9th graders from a rural south-western Mexican-American community
Interventions	3 substance abuse prevention videotapes (USA) derived from different theoretical frameworks: information-based programming, social skills approach and assertiveness training (a subset of social skills approach)
Outcomes	• Attitudes towards drugs • Use of drugs • Other: knowledge of videotape content and disposition to select socially appropriate responses

Polansky 1999   (*Continued*)

Notes	
Risk of bias	

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomisation procedure not clearly reported p. 189 "…and then randomly assigned to one of the four treatment and control conditions"
Allocation concealment (selection bias)	Unclear risk	Not reported No baseline comparisons reported
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Anonymous questionnaire p. 191 "to permit collating pre-post protocols while preserving respondent anonymity, the students devised an identification code that they placed on all materials"
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Unclear reporting of the size of both the intervention and control group Moreover unclear whether the final number of students (312) is the initial sample or is the final number of just those who answered (i.e. after drop-out) Abstract "participants were 312 students" p. 189 "153 seventh and eighth grade student responses and 159 ninth-grader responses were analysed"
Selective reporting (reporting bias)	Low risk	No study protocol available but all outcome measures expected (per hypothesis p. 188) have been reported, including those not statistically significant (p. 192/194)

Scheier 2010

Methods	Study design: prospective cohort study Sampling: systematic sampling (representative of major racial groups) Comparison group(s): lower exposure to intervention Follow-up duration: 48 months Study time span: April 1999 to March 2003 (48 months)
Participants	2515 youth aged 12 to 18 interviewed by the National Survey of Parents and Youth (NSPY)

Scheier 2010 (*Continued*)

Interventions	The National Youth Anti-Drug Media Campaign (USA), already described in Hornik 2006
Outcomes	- Past 12-month episodes of drunkenness or cannabis intoxication - Past 30-day binge drinking (5 or more drinks in a row) - Past 30-day use of cigarettes
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not applicable
Allocation concealment (selection bias)	Unclear risk	Not applicable
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Anonymous and computer-administered questionnaire p. 248 "Assessment of alcohol and drug use relied on an Anonymous Computer Assisted Self-report Interview (ACASI)"
Incomplete outcome data (attrition bias) All outcomes	Low risk	Same as Hornik 2008 ("The overall response rate among youths for the first round was 65%, with 86% to 93% of still eligible youths interviewed in subsequent rounds", page 2230 Evaluation of the National Youth Anti-Drug Media Campaign: 2004 Report of Findings, page 2-12, table 2-A "Completed interviews by wave")
Selective reporting (reporting bias)	Unclear risk	Not applicable

Schwinn 2010

Methods	Study design: randomised controlled trial Sampling: random sampling Comparison group(s): no intervention Follow-up duration: 6 months Study time span: at least 8 months (not directly specified, but pretest was administered 6 weeks before intervention and last follow-up was assessed after 6 months)
Participants	236 girls aged 13 to 14 from 42 US states and 4 Canadian provinces, recruited through the youth-oriented website Kiwibox.com™

Schwinn 2010 *(Continued)*

Interventions	Internet-based gender-specific intervention (USA, Canada) composed by 12 sessions. This intervention is a pilot test of a gender-specific intervention based on the social learning theory and employs a social competence and skill building strategy. High interaction
Outcomes	• Past 30-day alcohol, cigarette, marijuana, poly drug and total substance use • Mediator variables ○ Decision-making skills ○ Goal-setting skills ○ Drug resistance/refusal skills ○ Stress management ○ Social skills ○ Self esteem ○ Body esteem ○ Self efficacy
Notes	Baseline and 6-month follow-up

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	p. 26 "After study enrolment, girls were randomly assigned to the intervention or control arm"
Allocation concealment (selection bias)	Low risk	Although full allocation concealment is not possible for this kind of study, there is low risk of selection bias because researchers administering the intervention were unlikely to know the children. See p. 26 "After completing online pretest measures, intervention girls were immediately directed to the first program session. Control girls were thanked for their time and reminded that they would be notified when the next survey was available."
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Computer-administered questionnaire p. 26 "After completing online pretest measures, intervention girls were immediately directed to the first program session. [..] Immediately following completion of the last program module, girls in the intervention group completed the post-test"
Incomplete outcome data (attrition bias) All outcomes	Low risk	p. 28 "Differential attrition was assessed across the three measurement occasions using the same variables analysed in baseline

Schwinn 2010 *(Continued)*

		equivalency. Pretest to posttest attrition was 6.8%; the attrition rates for girls in intervention and control groups did not differ, X2 (1) = 1.74, p>0.05. At final follow-up, attrition was 9%; again, rates did not differ by study group, X2 (1) = 0.84, p>0.05"
Selective reporting (reporting bias)	High risk	Protocol not mentioned. Subjective outcomes were not described in full but only as predictors of objective outcomes (substance use)

Slater 2006

Methods	Study design: quasi-randomised controlled trial (assignment to media condition was random; assignment to school condition was not fully random because of problem of staff scheduling in 7 of the 16 communities) Sampling: randomised cluster sampling (treatment and control communities were extracted from 4 major regions of the US) Comparison group(s): no intervention (8 intervention versus 8 non-intervention communities) Follow-up duration: 24 months Study time span: Autumn 1999 to Spring 2003 (~42 months; but intervention lasted 24 months for each community, entry to the in project was different in different communities)
Participants	4216 6th- and 7th-grade students; mean age at baseline was 12.2 years
Interventions	The 'Be Under Your Own Influence' programme (USA) is a school- and community-based media effort on marijuana, alcohol and tobacco uptake. The programme emphasised "non-use as an expression of personal identity and the consistency of non-use with youth aspiration". The school-based intervention was research-based All Stars™ (13 sessions in the first year + 7 booster sessions in the second year); the community intervention was composed of workshops held by trained project staff
Outcomes	- Lifetime and past 30-day use of marijuana - Lifetime and past 30-day episodes of alcohol intoxication - Lifetime and current smoking of cigarettes
Notes	This intervention ran concurrently with the Office of National Drug Policy's national anti-drug campaign (Hornik 2006; Scheier 2010), but their simultaneous effect was not assessed in this study
Risk of bias	
Bias	**Authors' judgement** **Support for judgement**

Slater 2006 *(Continued)*

Random sequence generation (selection bias)	Unclear risk	Matching procedure described but no specification of random sequence generation
Allocation concealment (selection bias)	Low risk	Although full allocation concealment is not possible for this kind of study, there is low risk of selection bias because researchers administering the intervention were unlikely to know the children
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Blinding of outcome assessors not reported
Incomplete outcome data (attrition bias) All outcomes	Low risk	Missing data have been imputed using appropriate methods (p. 161)
Selective reporting (reporting bias)	Low risk	No protocol available but the we do not suspect selective reporting bias

Slater 2011

Methods	Study design: randomised controlled trial with a nested prospective cohort study Sampling: systematic sampling (schools were recruited based on National Center for Educational Statistics district listings) Comparison group(s): 4 groups, each including 10 schools and each comprising low to high exposure to the ONDCP campaign • Be Under Your Own Influence (BUYOI) intervention both at school and in the community • BUYOI intervention at school but not in the community • BUYOI intervention in the community but not at school • no BUYOI intervention neither at school nor in the community Follow-up duration: 24 months Study time span: Autumn 2005 to Spring 2009 (~42 months)
Participants	3236 students, mean age 12.4 ± 0.6 years
Interventions	The Office of National Drug Control Policy's (ONDCP) 'Above the Influence' media campaign (USA) and a school- and community-based mass media intervention, 'Be Under Your Own Influence' (BUYOI; USA). They both started in 2005 and ran concurrently • The ONDCP's campaign is the rebranded version of the national anti-drug campaign launched in 1998 (Hornik 2006; Palmgreen 2007; Scheier 2010). This version, like the original one, used televised ads supplemented by printed ads (e.g. posters) • The BUYOI campaign is a replication and extension of a campaign launched in 1999 (Slater 2006). This campaign employed only printed ads and was implemented both in schools and communities Although the ONDCP's campaign used far more creative executions given its funding

Slater 2011 (*Continued*)

	levels, both campaigns were similar in concept, i.e. both linked substance use with autonomy and aspiration threats
Outcomes	- Attitudes: autonomy and aspiration inconsistent with marijuana use - Lifetime, past 90-day and past 30-day use of marijuana
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Page 15 "Random assignment used a group-matching procedure: NCES data on community demographics and location were used to generate possible randomization schemes in which major demographics and location were balanced to the degree possible across experimental conditions and one of the acceptable schemes was randomly selected."
Allocation concealment (selection bias)	Low risk	Although full allocation concealment is not possible for this kind of study, there is low risk of selection bias because researchers administering the intervention were unlikely to know the children
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	It is unclear who administered the questionnaires and whether they were anonymous
Incomplete outcome data (attrition bias) All outcomes	Low risk	Reasons for missing outcome data unlikely to be related to true outcome
Selective reporting (reporting bias)	Low risk	No protocol available but the we do not suspect selective reporting

Wyoming Meth 2011

Methods	Study design: interrupted time series study Sampling: 4-stage probability sampling Comparison group(s): pre-intervention survey Follow-up duration: n/a Study time span: April 2008 to May 2011 (34 months)
Participants	5700 youths (909 + 913 + 2652 + 1226)

Wyoming Meth 2011   (*Continued*)

Interventions	Meth Project (USA), a "messaging campaign, supported by community outreach, and public policy initiatives". The campaign comprises "television, radio, print, billboard, and Internet advertising"
Outcomes	- Past-month use of methamphetamine - Attitudes towards methamphetamine and other drugs - Perceptions concerning methamphetamine and other drugs - Informations sources and advertising awareness - Statewide Meth Project awareness and perceptions
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not applicable
Allocation concealment (selection bias)	Unclear risk	Not applicable
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Anonymous questionnaires
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Not reported
Selective reporting (reporting bias)	Unclear risk	No information regarding potential reporting bias

Yzer 2003

Methods	Study design: randomised controlled trial Sampling: random sampling (from middle and high schools) Comparison group(s): - no intervention (documentary with no advertisements) - gateway condition (explicit: 4 anti-hard drug followed by a teenage girl's testimonial about how her trial use of marijuana led to using hard drugs) - implicit gateway condition (2 anti-marijuana and 2 anti-hard drugs advertisements without explicit reference to the gateway concept) - hard drugs condition (same advertisements of gateway condition, but not followed by testimonials) Follow-up duration: not applicable (post-only design) Study time span: March 2000 to not specified
Participants	418 students of middle/high schools in urban Philadelphia, mean age 14 ± 1.89 years

Yzer 2003 (*Continued*)

Interventions	Anti-marijuana and anti-hard drugs advertisements embedded in a documentary video (USA)
Outcomes	• Intention to use marijuana in the next 12 months • Attitude towards marijuana • Perceptions about marijuana
Notes	Similar to Zhao 2006, many of the authors wrote both papers

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Participants were randomly assigned to 1 of the 4 experimental conditions, and the stimuli were randomly presented using a randomisation feature in MediaLab software. (Personal communication with the author)
Allocation concealment (selection bias)	Low risk	Participants did not know which condition they were assigned to, and thus did not know which stimuli they and participants in other conditions were exposed to. (Personal communication with the author)
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Anonymous questionnaire p. 135 "All videos and the questionnaire were programmed onto a laptop computer using an interactive program that allows random ordering of questions and videos within blocks"
Incomplete outcome data (attrition bias) All outcomes	Low risk	There were no missing data. (Personal communication with the author)
Selective reporting (reporting bias)	Low risk	No protocol available but the we do not suspect selective reporting bias

Zhao 2006

Methods	Study design: randomised controlled trial Sampling: not specified (informational letters to parents in the 2 school-based studies, mall-intercept of lists held by market researchers for the mall-based study) Comparison group(s): no intervention (documentary about television production, without the embedded anti-marijuana advertisements) Follow-up duration: not applicable (post-only design) Study time span: not specified
Participants	435 youths whose mean age was 15.2 ± 1.88 years
Interventions	3 anti-marijuana advertisements (USA) addressing normative beliefs. The advertisements were embedded and randomly included in a video documentary about television production
Outcomes	• Behavioural beliefs towards marijuana (perceptions) • Intention to use marijuana • Social norms on marijuana (perceptions)
Notes	Results were based on combined data from 3 studies done at different points in time, but "identical in terms of methodology, procedures, experimental conditions, ad the structure of the outcome questionnaire". However, whereas study 1 and 2 were collected at middle and high schools, study 3 was conducted at various malls around the country

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	p. 190 "Participants were randomly assigned to condition", but randomisation details are not reported
Allocation concealment (selection bias)	Low risk	Although full allocation concealment is not possible for this kind of study, there is low risk of selection bias because researchers administering the intervention were unlikely to know the children. See p. 190: "The experimental group saw the three advertisements that challenged undesirable normative beliefs about marijuana use (see Table 1 for a description of the messages). The advertisements were embedded and randomly rotated in a video documentary about television production. The control group was not exposed to any anti-marijuana messages but saw the same documentary as the experimental group"

Zhao 2006 *(Continued)*

Blinding of outcome assessment (detection bias) All outcomes	Low risk	Computer-administered questionnaire p. 191 "The instrument (including the video clips) was programmed onto laptop computers using an interactive program called MediaLab (Jarvis, 1998), which allows random ordering of blocks of questions and videos within the questionnaire"
Incomplete outcome data (attrition bias) All outcomes	Low risk	All participants completed the test (being a post-only design); p. 190 "All three studies used the same between-subjects, post-only design, with one experimental condition and one control condition"
Selective reporting (reporting bias)	Unclear risk	No study protocol was mentioned

n/a: not applicable
PSA: public service announcement

Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
Alemi 1996	Target population is pregnant women who already use or used cocaine
An 2007	This intervention aims to promote inquiry of prescription medicines/treatments, not to hinder use of illicit drugs
Andrews 1995	The purpose of the campaign was to promote public awareness of the link between addiction and child maltreatment, not to prevent addiction
Barber 1990	Target population mean age is 40
Beaudoin 2007	Presented outcomes are not included among those of this review
Beck 2008	Overview of drugs prevalence and school-based prevention interventions in France. Some information about therapeutic interventions, but no information about mass media prevention interventions
Belenko 2009	This study analyses data from the National Survey of Parents and Youth, which was not designed to provide quality information about exposure to anti- or pro-drug websites. This study aims to find factors (e.g. gender, parent-reported income, prior exposure to drugs) associated with viewing of drug websites, not to assess whether viewing of anti-drug websites can influence outcomes included in the protocol of this review

(Continued)

Black 1994	This study aims to assess consistency of data collected with 2 different sampling methods
Brannon 1989	None of the evaluated outcomes (i.e. participation, satisfaction and perceived efficacy of programme) met the inclusion criteria for this review
Chambers 2005	Not a mass media intervention
Chiauzzi 2008	This study assesses the effectiveness of an online stress management tool. Outcomes do not include substance use, intention to use or any other outcome relevant to this review
Collins 1991	This paper aims to prevent alcohol abuse
Cook 1999	Review of books and media, not of studies
David 2006	Evaluated intervention is adolescent discussion about anti-drug advertisements, not advertisements themselves
DeJong 1999	This paper raises concern about the Office of National Drug Control Policy (ONDCP)'s National Youth Anti-Drug Media Campaign without reporting results of its effectiveness assessment
Di Noia 2003	The majority of recruited professionals were older than 26 and the assessed outcomes are not among those needed for inclusion
Donohew 2000	The aim of the study is to understand the relationship between mediators (sensation-seeking and decision-making processes) and alcohol and risky sexual behaviours in adolescents
Epstein 1999	Survey with control group but without pre-intervention questionnaire
Erceg-Hurn 2008	It is not possible to compare different years due to the different methodology used in surveys (see also commentary paper Erceg-Hurn 2008)
Everett 1995	This study does not evaluate intervention effectiveness but matching between HSV/LSV interventions and HSV/LSV subjects
Flay 2000	Reviews of mainly anti-tobacco media-, school- and community-based interventions
Hannon 2000	Narrative review of key African American community values and provides recommendations as to how this information might be incorporated into the development of anti-drug messages and materials targeted at African Americans
Harrington 2003	This study does not evaluate intervention effectiveness but matching between HSV/LSV interventions and HSV/LSV subjects
Helme 2007	Intervention was an anti-smoking campaign
Johnson 1990	The mass media intervention was administered to both study groups
Jordan 2005	This study design (survey) does not allow us to evaluate intervention effectiveness

Kang 2009	This study is an evaluation of the perceived effectiveness of specific elements of the interventions, not the effectiveness of whole interventions on outcome variables included in the protocol for this review
Know the Score 2007	For the 2 cocaine reports: the 4 study waves differed slightly but in many respects (age and working status of respondents, survey locations and, more importantly, survey questions) For the 2 heroin reports: respondent age is not fully comparable across study waves. Additionally, participants in waves 1 and 3 were older than 25
Lorch 1994	No pretest drug-related measure was taken. This study aims to predict responses to PSA and drug use by different sensation-seeking profiles
Lubman 2007	Narrative review on substance addiction prevention. Data were not presented here
Marsiglia 2009	This study evaluates a school-based intervention which has no media-related component
Myers 2006	Not a prevention intervention. It does not include illicit drug-related outcomes
Palmgreen 2007	This study does not evaluate intervention effectiveness but matching between the intervention and HSV/LSV subjects
Pentz 1990	The fffect of the mass media component could not be disentangled from other components
Ramirez 1999	Description of theoretical basis, development and implementation of 'Mirame!/Look at Me!' media- and school-based programme for substance abuse among Hispanic youth. However, the programme's effectiveness was not assessed
Reis 1994	Survey. This study design does not allow us to evaluate intervention effectiveness
Ruggiero 2006	Participants are older than 26
Schmeling 1980	Intervention targets prescription drug abusers
Siegel 2008	No blank control, one group focusing on physical harms of inhalant use, the other focusing on social harms
Skinner 1995a	The outcome (perceived persuasiveness) is not among the outcome measures included in our protocol
Sloboda 2006	This book does not include data on studies evaluating mass media programmes
Spitzer 2010	Outcomes concern 'values' and therefore do not meet the inclusion criteria
Stephenson 2002	The aim of this study was to find predictors of exposure from an anti-marijuana media campaign, not to evaluate the effectiveness of the campaign
Stephenson 2002a	CBA study aiming to link perceived message sensation value and viewer's reaction to an anti-heroin PSA
Stephenson 2003	Survey with control group aiming to evaluate sensation-seeking as a moderating variable

Stephenson 2005	This study analyses the content of ads but does not assess their effectiveness
Stevens 1996	School-based intervention with added community activities
Stryker 2003	Ecological study about the impact of media coverage of the negative consequences of marijuana use. This study does not assess the effectiveness of a single prevention intervention
Sussman 1987	Survey with a control group but without a pre-intervention questionnaire
Tait 2010	Systematic review on Internet-based interventions for the treatment of alcohol misuse
Taylor 1984	Outcomes in the pilot study (the statewide intervention was not evaluated) were knowledge, attitudes and behaviours about friendships and human relationships, not substance use/misuse
Varshavsky 2003	Qualitative content analysis of a national campaign
Werch 2010	Not a mass media intervention

CBA: controlled before and after (study)
PSA: public service announcement
HSV: high sensation value
LSV: low sensation value

Characteristics of studies awaiting assessment *[ordered by study ID]*

Block 2002

Methods	
Participants	
Interventions	
Outcomes	
Notes	We contacted authors for results and are waiting for a response

Duncan 2000

Methods	
Participants	
Interventions	

Duncan 2000 (*Continued*)

Outcomes	
Notes	We contacted authors for results and are waiting for a response

Flay 1986

Methods	
Participants	
Interventions	
Outcomes	
Notes	We were unable to retrieve the paper's full text

Longshore 2006

Methods	
Participants	
Interventions	
Outcomes	
Notes	We contacted authors for results and are waiting for a response

Marsch 2007

Methods	
Participants	
Interventions	
Outcomes	
Notes	We were unable to retrieve the paper's full text

Moore 2011

Methods	
Participants	
Interventions	
Outcomes	
Notes	We were unable to retrieve the paper's full text

Moreno 2009

Methods	
Participants	
Interventions	
Outcomes	
Notes	We contacted authors for results and are waiting for a response

Skinner 1995

Methods	
Participants	
Interventions	
Outcomes	
Notes	We were unable to retrieve the paper's full text

Williams 2005

Methods	
Participants	
Interventions	
Outcomes	
Notes	We contacted authors for results and are waiting for a response

DATA AND ANALYSES

Comparison 1. Mass media versus no mass media intervention (RCT)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Drug use	5	5470	Std. Mean Difference (IV, Random, 95% CI)	-0.02 [-0.15, 0.12]
2 Intention to use drugs	4	1270	Std. Mean Difference (IV, Fixed, 95% CI)	-0.07 [-0.19, 0.04]

Analysis 1.1. Comparison 1 Mass media versus no mass media intervention (RCT), Outcome 1 Drug use.

Review: Media campaigns for the prevention of illicit drug use in young people

Comparison: 1 Mass media versus no mass media intervention (RCT)

Outcome: 1 Drug use

Study or subgroup	N	Mean(SD)	N	Mean(SD)	Std. Mean Difference IV,Random,95% CI	Weight	Std. Mean Difference IV,Random,95% CI
Slater 2006	1961	1.06 (0.6236966)	2064	1.1 (0.7946134)		36.1 %	-0.06 [-0.12, 0.01]
Newton 2010	397	0.1776 (1.06752)	367	0.04 (0.50783)		27.4 %	0.17 [0.02, 0.31]
Lee 2010	171	11.05 (18.71)	170	11.94 (19.31)		20.1 %	-0.05 [-0.26, 0.17]
Schwinn 2010	118	0.04 (2.3314989)	118	0.42 (1.1091175)		16.5 %	-0.21 [-0.46, 0.05]
Fang 2010	54	0 (0)	50	0.01 (0.2121)			Not estimable
Total (95% CI)	**2701**		**2769**			**100.0 %**	**-0.02 [-0.15, 0.12]**

Heterogeneity: Tau² = 0.01; Chi² = 9.86, df = 3 (P = 0.02); I² =70%

Test for overall effect: Z = 0.26 (P = 0.79)

Test for subgroup differences: Not applicable

```
        -1   -0.5    0    0.5    1
   Favours media campaign   Favours no intervention
```

Review: Media campaigns for the prevention of illicit drug use in young people

Comparison: 1 Mass media versus no mass media intervention (RCT)

Outcome: 2 Intention to use drugs

Study or subgroup	Experimental		Control		Std. Mean Difference IV,Fixed,95% CI	Weight	Std. Mean Difference IV,Fixed,95% CI
	N	Mean(SD)	N	Mean(SD)			
Polansky 1999	78	0.76 (1.99)	26	1.06 (1.97)		6.8 %	-0.15 [-0.59, 0.29]
Polansky 1999	78	0.74 (2.18)	26	1.06 (1.97)		6.8 %	-0.15 [-0.59, 0.30]
Polansky 1999	78	1 (2.13)	26	1.06 (1.97)		6.9 %	-0.03 [-0.47, 0.42]
Yzer 2003	71	1.58 (1.04)	48	1.52 (0.89)		10.1 %	0.06 [-0.31, 0.43]
Yzer 2003	63	1.56 (0.93)	48	1.52 (0.89)		9.6 %	0.04 [-0.33, 0.42]
Yzer 2003	141	1.62 (0.98)	48	1.52 (0.89)		12.6 %	0.10 [-0.22, 0.43]
Zhao 2006	208	1.47 (0.93)	227	1.65 (1.08)		38.1 %	-0.18 [-0.37, 0.01]
Fang 2010	54	2.11 (15.0644)	50	3.7 (23.9709)		9.1 %	-0.08 [-0.46, 0.31]
Total (95% CI)	**771**		**499**			**100.0 %**	**-0.07 [-0.19, 0.04]**

Heterogeneity: Chi² = 3.45, df = 7 (P = 0.84); I² =0.0%

Test for overall effect: Z = 1.25 (P = 0.21)

Test for subgroup differences: Not applicable

```
        -1    -0.5    0    0.5    1
   Favours media campaign    Favours other interventio
```

ADDITIONAL TABLES

Table 1.   'Risk of bias' assessment of interrupted time series studies

Miller 2000

Criterion	Score	Notes
a) Protection against secular changes		
The intervention is independent of other changes	Done	"The usual environmental influences such as prices, taxes, state regulations, campus policies, and enforcement did not change substantially during the study period. Neither was there any reason to expect that students on the two campuses would respond differentially to anonymous surveys. The only obvious difference between the two campuses that might be expected to affect substance use differentially was the implementation of the prevention

		program at UNM", page 756
There are sufficient data points to enable reliable statistical inference	Not done	2 data points (before and after)
Formal test for trend. Complete this section if authors have used ANOVA modelling	Done	
b) Protection against detection bias		
Intervention unlikely to affect data collection	Done	"All questionnaires were completed anonymously. To encourage participation, those who returned the survey (by mail) were entered into a lottery for cash prizes by separating a numbered ticket, returning one part with the completed survey and retaining the other half. Winning numbers were announced through the campus newspaper, the Daily Lobo. As an additional incentive for the follow-up survey, respondents were invited to participate in a contest to guess the actual levels of alcohol/drug use on campus, as revealed by the first survey", page 750
Blinded assessment of primary outcome(s)	Done	Anonymous surveys, page 750
c) Completeness of data set	Done	"At baseline (fall) assessment, 1,400 surveys were distributed to enrolled UNM students, a sample of approximately 6% selected randomly by the university s computerized mailing list program. Of these, 567 surveys were returned and usable (41%). At the control campus, 1,080 surveys were distributed to a random sample of students, 457 of whom returned them (42.3%). [..] The return rates were 431 (31%) at UNM and 434 (34%) at NMSU", page 751
d) Reliable primary outcome measure(s)	Done	"Use measures (14 items) included a frequency (number of drinking days per 30) and quantity index of drinking (number of standard drinks consumed per drinking occasion; range: 0-15) that were multiplied to form a single quantity frequency measure (number of drinks per month) [..]", page 750 "Problem measures included 14 indicators of alcohol dependence and adverse consequences of heavy drinking or illicit drug use in the prior year. [..]", page 750 "Risk assessment included 13 items regarding the extent to which students perceived risk or consequences related to alcohol or other drug use [..]", page 750

Palmgreen 2001 (includes Stephenson 1999)

Criterion	Score	Notes
a) Protection against secular changes		

Table 1. 'Risk of bias' assessment of interrupted time series studies   *(Continued)*

The intervention is independent of other changes	Unclear	
There are sufficient data points to enable reliable statistical inference	Done	32 data points
Formal test for trend. Complete this section if authors have used ANOVA modelling	Done	ANOVA modelling was used. See from page 186 on
b) Protection against detection bias		
Intervention unlikely to affect data collection	Done	Methodology of data collection is not reported to have changed across data points
Blinded assessment of primary outcome(s)	Done	Anonymous computer-administered questionnaire (p. 293)
c) Completeness of data set	Unclear	
d) Reliable primary outcome measure(s)	Done	30-day use of marijuana, attitudes, beliefs, intentions

Idaho Meth 2010, Colorado Meth 2011, Georgia Meth 2011, Hawaii Meth 2011 and Wyoming Meth 2011

Criterion	Score	Notes
a) Protection against secular changes		
The intervention is independent of other changes	Unclear	
There are sufficient data points to enable reliable statistical inference	Done	Data points for each study ranged from 2 to 4 including only one baseline survey. However, overall, there are a sufficient number of observations
Formal test for trend. Complete this section if authors have used ANOVA modelling	Not done	
b) Protection against detection bias		
Intervention unlikely to affect data collection	Done	Despite some slight changes, methodology of data collection is consistent across studies and across data points
Blinded assessment of primary outcome(s)	Done	Anonymous questionnaires
c) Completeness of data set	Unclear	Not applicable
d) Reliable primary outcome measure(s)	Done	Past-month use of marijuana, attitudes, perceptions

Carpenter 2011

Criterion	Score	Notes
a) Protection against secular changes		
The intervention is independent of other changes	Done	Adjustment by many individual and market variables (page 949)
There are sufficient data points to enable reliable statistical inference	Not done	3 data points (page 949)
Formal test for trend. Complete this section if authors have used ANOVA modelling	Done	"multivariate logistic regression" (page 949)
b) Protection against detection bias		
Intervention unlikely to affect data collection	Done	Ads were broadcasted independently on the surveys
Blinded assessment of primary outcome(s)	Done	Monitoring the Future (MTF) surveys used anonymous questionnaires
c) Completeness of data set	Unclear	
d) Reliable primary outcome measure(s)	Done	Past-month and lifetime marijuana use (page 951)

Table 2. 'Risk of bias' assessment of cohort studies (Hornik 2006, Scheier 2010, Slater 2011)

Hornik 2006

Criterion	Score/Info	Notes
In a well-conducted cohort study:		
The study addresses an appropriate and clearly focused question	Well covered	"We examined the cognitive and behavioral effects of the National Youth Anti-Drug Media Campaign on youths aged 12.5 to 18 years and report core evaluation results", abstract
Selection of subjects		
The 2 groups being studied are selected from source populations that are comparable in all respects other than the factor under investigation	Well covered	"The sample was selected to provide an efficient and nearly unbiased cross-section of US youths and their parents. Respondents

		were selected through a stratified 4-stage probability sample design: 90 primary sampling units-typically county size-were selected at the first stage, geographical segments were selected within the sampled primary sampling units at the second stage, households were selected within the sampled segments at the third stage, and then, at the final stage, 1 or 2 youths were selected within each sampled household, as well as 1 parent in that household.", page 2229-30
The study indicates how many of the people asked to take part did so, in each of the groups being studied	Well covered	Evaluation of the National Youth Anti-Drug Media Campaign: 2004 Report of Findings, Appendix A, page A-6, table A-1 and page A-11 tables A-8 to A-10
The likelihood that some eligible subjects might have the outcome at the time of enrolment is assessed and taken into account in the analysis	Well covered	"Analyses were restricted to youths who were nonusers of marijuana at the current round (for cross-sectional analyses) or at the previous round (for lagged analyses).", page 2232
What percentage of individuals or clusters recruited into each arm of the study dropped out before the study was completed	35%	"The overall response rate among youths for the first round was 65%, with 86% to 93% of still eligible youths interviewed in subsequent rounds.", page 2230 Evaluation of the National Youth Anti-Drug Media Campaign: 2004 Report of Findings, page 2-12, table 2-A "Completed interviews by wave"
Comparison is made between full participants and those lost to follow-up, by exposure status	Not reported	
Assessment		
The outcomes are clearly defined	Well covered	"For 3 reasons, all drug-related measures reported here relate to marijuana use. [..] Four measures or indices represented the following constructs: (1) marijuana intentions, (2) marijuana beliefs and attitudes, (3) social norms, and (4) self-efficacy to resist use.", page 2230
The assessment of outcome is made blind to exposure status	Not applicable	Blinding to exposure status was not applicable for this study

Where blinding was not possible, there is some recognition that knowledge of exposure status could have influenced the assessment of outcome	Well covered	"A measure of general exposure to antidrug advertising was derived from responses to questions about advertising recall for each medium or media grouping: television and radio, print, movie theatres or videos, and outdoor advertising.", page 2230
The measure of assessment of exposure is reliable	Well covered	"For 3 reasons, all drug-related measures reported here relate to marijuana use.", page 2230
Evidence from other sources is used to demonstrate that the method of outcome assessment is valid and reliable	Well covered	"For 3 reasons, all drug-related measures reported here relate to marijuana use. First, marijuana is by far the illicit drug most heavily used by youths. Second, for other drugs, the low levels of use meant that the NSPY sample sizes were not large enough to detect meaningful changes in use with adequate power. Third, to the extent that the campaign did target a specific drug, it was almost always marijuana. [..] The cognitive measures were developed on the basis of 2 health behavior theories, the theory of reasoned action and social cognitive theory", page 2230
Exposure level or prognostic factor is assessed more than once	Well covered	"3 nationally representative cohorts of US youths aged 9 to 18 years were surveyed at home 4 times.", abstract
Confounding		
The main potential confounders are identified and taken into account in the design and analysis	Well covered	"Potential confounder measures. The analyses employed propensity scoring for confounder control by weighting adjustments, 9-14 incorporating a wide range of standard demographic variables and variables known to be related to youths' drug use or thought likely to be related to exposure to antidrug messages. Propensity scores were developed for the general and specific exposure measures. More than 150 variables were considered possible confounders.", page 2231
Statistical analysis		
Have confidence intervals been provided?	Well covered	Tables 1-4, pages 2233-4

Table 2. 'Risk of bias' assessment of cohort studies (Hornik 2006, Scheier 2010, Slater 2011) *(Continued)*

Overall assessment of the study		
How well was the study done to minimise the risk of bias or confounding, and to establish a causal relationship between exposure and effect? *Code* ++,+, or −	++	Propensity scoring from 150 confounders, page 2231
Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the exposure being investigated?	Yes	This study includes very good control for possible confounders
Are the results of this study directly applicable to the patient group targeted in this guideline?	Unclear	Results are applicable to US youth; it is unclear whether they are generalisable outside the US
Description of the study		
Do we know who the study was funded by?	Public Funds (NIDA), Government (Congress)	"Research for and preparation of this article were supported by the National Institute on Drug Abuse (grants 3-N01-DA085063-002 and 1-R03-DA-020893-01). The evaluation of the National Youth Anti-Drug Media Campaign was funded by Congress as part of the original appropriation for the campaign. The White House Office of National Drug Control Policy directly supervised the campaign. The National Institute on Drug Abuse supervised the evaluation; Westat, with the Annenberg School for Communication at the University of Pennsylvania as a subcontractor, received the contract. All authors were funded for this evaluation and other projects by the National Institute on Drug Abuse.", page 2235
How many centres are patients recruited from?	USA as a whole	"90 primary sampling units-typically county size-were selected at the first stage, geographical segments were selected within the sampled primary sampling units at the second stage, households were selected within the sampled segments at the third stage, and then, at the final stage, 1 or 2 youths were selected within each sampled household, as well as 1 parent in that house-

		hold.", page 2230
From which countries are patients selected? (Select all those involved. Note additional countries after 'Other')	USA	
What is the social setting (i.e. type of environment in which they live) of patients in the study?	Mixed	"More than 150 variables were considered possible confounders. [..] They include [..] urban-rural residency; [..]", page 2231
What criteria are used to decide who should be INCLUDED in the study?	4-stage selection	"Respondents were selected through a stratified 4-stage probability sample design: 90 primary sampling units-typically county size-were selected at the first stage, geographical segments were selected within the sampled primary sampling units at the second stage, households were selected within the sampled segments at the third stage, and then, at the final stage, 1 or 2 youths were selected within each sampled household, as well as 1 parent in that household.", page 2229-30
What criteria are used to decide who should be EXCLUDED from the study?	Youth living in boarding schools and college dormitories	"As mentioned previously, youth residing in group quarters were not eligible for selection in any of the three recruitment waves. Thus, youth living in boarding schools and college dormitories were excluded from the scope of the survey. This exclusion was made because it was felt that dormitory residents could not be easily interviewed at their parents' homes and that their experiences were so", Report, A-10
What intervention or risk factor is investigated in the study? (Include dosage where appropriate)	The National Youth Anti-Drug Media Campaign	
What comparisons are made in the study (i.e. what alternative treatments are used to compare the intervention/exposure with). Include dosage where appropriate	Lower exposure versus higher exposure to anti-drug campaign	"The analyses reported here were based on 3 types of measures: recalled exposure to antidrug messages aired by the campaign and other sources; cognitions and behavior related to marijuana, as outcomes; and individual and household characteristics, including a wide range of variables known to be related to drug cognitions and use and to exposure to antidrug messages.", page 2230

What methods were used to randomise patients, blind patients or investigators, and to conceal the randomisation process from investigators?	Randomisation: not applicable, but propensity scoring was employed Blinding of patients: not applicable Blinding of investigators: not reported Randomisation concealment: not applicable	
How long did the active phase of the study last?	September 1999 to June 2004 (58 months)	
How long were patients followed up for, during and after the study?	November 1999 to June 2004 (56 months) .	
List the key characteristics of the patient population. Note if there are any significant differences between different arms of the trial	Representative of US youths aged 9 to 18	"The sample was selected to provide an efficient and nearly unbiased cross-section of US youths and their parents", page 2229
Record the basic data for each arm of the study. If there are more than 4 arms, note data for subsequent arms at the bottom of the page		Tables 1-4, pages 2233-4
Record the basic data for each IMPORTANT outcome in the study. If there are more than 4, note data for additional outcomes at the bottom of the page		Tables 1-4, pages 2233-4
Notes. Summarise the authors' conclusions. Add any comments on your own assessment of the study, and the extent to which it answers your question	Through June 2004, the campaign is unlikely to have had favourable effects on youths and may have had delayed unfavourable effects The evaluation challenges the usefulness of the campaign	

Scheier 2010

Criterion	Score/Info	Notes
In a well-conducted cohort study:		
The study addresses an appropriate and clearly focused question	Well covered	"In this study, we examined whether awareness (recall) of the National Youth Anti-Drug Media Campaign (NYADMC) benefited youth by attenuating their drug use. ", abstract
Selection of subjects		

The 2 groups being studied are selected from source populations that are comparable in all respects other than the factor under investigation	Well covered	Same as Hornik 2008 ("The sample was selected to provide an efficient and nearly unbiased cross-section of US youths and their parents. Respondents were selected through a stratified 4-stage probability sample design: 90 primary sampling units- typically county size-were selected at the first stage, geographical segments were selected within the sampled primary sampling units at the second stage, households were selected within the sampled segments at the third stage, and then, at the final stage, 1 or 2 youths were selected within each sampled household, as well as 1 parent in that household.", page 2229-30)
The study indicates how many of the people asked to take part did so, in each of the groups being studied	Well covered	Same as Hornik 2008 (Evaluation of the National Youth Anti-Drug Media Campaign: 2004 Report of Findings, Appendix A, page A-6, table A-1 and page A-11 tables A-8 to A-10)
The likelihood that some eligible subjects might have the outcome at the time of enrolment is assessed and taken into account in the analysis	Well covered	Same questionnaire was administered at baseline and at follow-up. "National Survey of Parents and Youth (NSPY) [..] could be used to assess youths' awareness of the campaign messages and monitor any corresponding changes in drug use trends.", page 241-2
What percentage of individuals or clusters recruited into each arm of the study dropped out before the study was completed	35%	Same as Hornik 2008 ("The overall response rate among youths for the first round was 65%, with 86% to 93% of still eligible youths interviewed in subsequent rounds ", page 2230 Evaluation of the National Youth Anti-Drug Media Campaign: 2004 Report of Findings, page 2-12, table 2-A "Completed interviews by wave")
Comparison is made between full participants and those lost to follow-up, by exposure status	Well covered	"Attrition analyses were structured to determine whether certain factors operate systematically to cause dropout from the study. Proportional analyses using the v2 test were used for cross tabulation of binary measures and logistic regression modelling to examine the optimal predictors of retention (coded '1' stay and '0' dropout). We

		used the WesVar software program to estimate logistic regression models of panel attrition. This statistical modelling program enables us to adjust (through poststratification) the sample variance estimators for the undersampling of primary sampling units and correct any bias in parameter estimates related directly to the complex sampling design (using replicate variance estimators to adjust standard errors for design effects) Proportional tests indicated that panel youth were significantly more likely to be female, smoke more cigarettes, drink alcohol, and smoke marijuana (all v2 proportional tests significant at the p .0001) compared with dropout youth. Given the large number of variables possibly related to retention status, logistic models were run separately for five individual domains (demographics, campaign awareness, drug use, school-related factors, and psychosocial risk).7 Following tests of the individual domains, we culled only significant predictors and tested these in a combined model predicting retention. The final model indicated that retained youth were less at risk for marijuana use (unstandardized b = -3.51, p<= .0001, OR =.03), engaged in more antisocial behavior (evidencing suppression: [b = .23, p <=.0001, OR = 1.26]), spent fewer hours listening to the radio on a daily basis (b =-.09, p <=.01, OR = .91), and were more likely to have attended school in the past year (b = 1.05, p<= .01, OR = 2.87) compared with their dropout counterparts. Using the Cox-Snell likelihood pseudo-R2 statistic, the model accounted for 12% of the variance in retention status, F(14,87) = 12.127, p <=.0001.", page 250
Assessment		
The outcomes are clearly defined	Well covered	"Assessment of alcohol and drug use relied on an Anonymous Computer Assisted Self-report Interview (ACASI). Two alcohol use items6 assessed being drunk or high ("How many times were you drunk or very high from alcohol in the last 12 months?") with

		response categories ranging from "I don't use alcohol" (0) through "40 or more occasions" (7); and heavy alcohol use based on a measure of binge drinking ("How many days have you had five or more drinks in the last 30 days?") with response categories ranging from "I don't drink" (0) through "10 or more times" (6). Cigarette use was assessed with a single item ("How many cigarettes smoked a day during the last 30 days?") with response categories ranging from "None" (0) through "More than 35 per day, about 2 packs or more" (7). A single frequency item assessed marijuana involvement ("How many times have you used marijuana in the last 12 months?") with response categories ranging from "I have never used marijuana" (0) through "40 or more occasions" (6).", page 248
The assessment of outcome is made blind to exposure status	Not applicable	Blinding to exposure status was not applicable for this study
Where blinding was not possible, there is some recognition that knowledge of exposure status could have influenced the assessment of outcome	Not reported	
The measure of assessment of exposure is reliable	Well covered	"Turning to the campaign awareness parameters, we see two findings worth noting. First, growth in campaign awareness is positive for the earlier years (12 to 14), except for television viewing behavior, which had a slope not significantly different from zero. As these youth became older (14 to 18), their awareness declined for every media venue except specific recall (videos shown on laptops) and radio listening behavior. Also, the magnitude of the slope terms were considerably larger at the younger age for recall of stories about drugs and youth, brand awareness, specific recall, and radio listening but larger in magnitude for television (declining) as these youth transitioned to high school.", page 253 "Figure 2 graphically presents a generic template for testing the bivariate cohort growth models. Again, two slope trends are posited to capture the different rates of

		growth for youth when they were younger versus when they were older, and this is repeated for both drug use (D) and awareness (A) measures.", page 253
Evidence from other sources is used to demonstrate that the method of outcome assessment is valid and reliable	Well covered	"Assessment of alcohol and drug use relied on an Anonymous Computer Assisted Self-report Interview (ACASI). Two alcohol use items6 assessed being drunk or high ("How many times were you drunk or very high from alcohol in the last 12 months?") with response categories ranging from "I don't use alcohol" (0) through "40 or more occasions" (7); and heavy alcohol use based on a measure of binge drinking ("How many days have you had five or more drinks in the last 30 days?") with response categories ranging from "I don't drink" (0) through "10 or more times" (6). Cigarette use was assessed with a single item ("How many cigarettes smoked a day during the last 30 days?") with response categories ranging from "None" (0) through "More than 35 per day, about 2 packs or more" (7). A single frequency item assessed marijuana involvement ("How many times have you used marijuana in the last 12 months?") with response categories ranging from "I have never used marijuana" (0) through "40 or more occasions" (6).", page 248
Exposure level or prognostic factor is assessed more than once	Well covered	Yes: 4 rounds of data collection. Table 1, page 249
Confounding		
The main potential confounders are identified and taken into account in the design and analysis	Not reported	
Statistical analysis		
Have confidence intervals been provided?	No	Page 264
Overall assessment of the study		
How well was the study done to minimise the risk of bias or confounding, and to establish a causal relationship between expo-	-	"...there was no "intervention" to speak of, but rather the campaign took shape as a naturalistic observational study conducted

sure and effect? *Code* ++, +, or −		at a particular point in time with no clear demarcation from various historical influences that could affect patterns of reported drug use", page 264
Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the exposure being investigated?	No, because no adjustment for confounders was reported	
Are the results of this study directly applicable to the patient group targeted in this guideline?	Unclear	Results are applicable to US youth; it is unclear whether they are generalisable outside the US
Description of the study		
Do we know who the study was funded by?	No	
How many centres are patients recruited from?	USA as a whole	Same as Hornik 2008 ("90 primary sampling units-typically county size-were selected at the first stage, geographical segments were selected within the sampled primary sampling units at the second stage, households were selected within the sampled segments at the third stage, and then, at the final stage, 1 or 2 youths were selected within each sampled household, as well as 1 parent in that household.", page 2230)
From which countries are patients selected? (Select all those involved. Note additional countries after 'Other')	USA	
What is the social setting (i.e. type of environment in which they live) of patients in the study?	Mixed	Same as Hornik 2008 ("More than 150 variables were considered possible confounders. [..] They include [..] urban-rural residency; [..]", page 2231)
What criteria are used to decide who should be INCLUDED in the study?	4-stage selection	Same as Hornik 2008 ("Respondents were selected through a stratified 4-stage probability sample design: 90 primary sampling units-typically county size-were selected at the first stage, geographical segments were selected within the sampled primary sampling units at the second stage, households were selected within the sampled segments at the third stage, and then, at the final

		stage, 1 or 2 youths were selected within each sampled household, as well as 1 parent in that household.", page 2229-30)
What criteria are used to decide who should be EXCLUDED from the study?	Youth living in boarding schools and college dormitories	Same as Hornik 2008 ("As mentioned previously, youth residing in group quarters were not eligible for selection in any of the three recruitment waves. Thus, youth living in boarding schools and college dormitories were excluded from the scope of the survey. This exclusion was made because it was felt that dormitory residents could not be easily interviewed at their parents' homes and that their experiences were so", Report, Appendix A, A-10)
What intervention or risk factor is investigated in the study? (Include dosage where appropriate)	The National Youth Anti-Drug Media Campaign	"...there was no "intervention" to speak of, but rather the campaign took shape as a naturalistic observational study conducted at a particular point in time with no clear demarcation from various historical influences that could affect patterns of reported drug use", page 264
What comparisons are made in the study (i.e. what alternative treatments are used to compare the intervention/exposure with). Include dosage where appropriate	Exposure versus drug use	Varius models, e.g. see page 256
What methods were used to randomise patients, blind patients or investigators, and to conceal the randomisation process from investigators?	Randomisation: not applicable Blinding of patients: not applicable Blinding of investigators: not reported Randomisation concealment: not applicable	
How long did the active phase of the study last?	September 1999 to June 2004 (58 months)	
How long were patients followed up for, during and after the study?	November 1999 to June 2004 (56 months)	
List the key characteristics of the patient population. Note if there are any significant differences between different arms of the trial	Representative of US youths aged 9 to 18	Same as Hornik 2008 ("The sample was selected to provide an efficient and nearly unbiased cross-section of US youths and their parents", page 2229)
Record the basic data for each arm of the study. If there are more than 4 arms, note data for subsequent arms at the bottom of the page	Table 2, page 251	

Table 2. 'Risk of bias' assessment of cohort studies (Hornik 2006, Scheier 2010, Slater 2011)   *(Continued)*

Record the basic data for each IMPORTANT outcome in the study. If there are more than 4, note data for additional outcomes at the bottom of the page	Tables 3-4-5, pages 252-7	
Notes. Summarise the authors' conclusions. Add any comments on your own assessment of the study, and the extent to which it answers your question	When they were younger, these youth accelerated their drug use and reported increasing amounts of campaign awareness. When they were older, [..] no effects for marijuana were significant but trended in the direction of increased awareness associated with declining drug use	"Behavior change is guided by the Theory of Reasoned Action (TRA: Ajzen & Fishbein, 1973, 1977) and draws also from social persuasion (McGuire, 1961, 1966, 1968) and communication theories (Hovland, Janis, & Kelley, 1953). According to the TRA, the influence of attitudes (i.e. , subjective evaluations of behavior consequences) and beliefs (subjective norms and behavioral outcomes or expectancies) on behavior is mediated through intentions (i. e., future intent to engage the behavior) . In other words, youth form impressions of whether drugs are good or bad, and they combine this information with normative beliefs (whether their close friends approve of drug use) and behavioral expectations (perceived benefits and negative consequences of drug use) toward drug use. These steps are necessary but not sufficient conditions, as the final decision to use drugs is guided by their behavioral willingness or intentions.", page 242 "To date, analyses of the media campaign efficacy have used traditional linear regression or correlation techniques to examine campaign effects. While this tactic has been useful to delineate the basic statistical associations between campaign awareness and drug use, a major weakness of this approach is that it fails to provide a developmental perspective and incorporate systematic features of change in either awareness or drug use.[..] Growth modelling is clearly a more definitive way to address the question of change and increasingly has been advocated as a means to assess prevention effects that unfold over time (Brown, Catalano, Fleming, Haggerty, & Abbott, 2005; Mason, Kosterman, Hawkins, Haggerty, & Spoth, 2003; Park et al., 2000; Taylor, Graham, Cumsille, & Hansen, 2000). [..] The age

		mixture within each round makes it imperative to estimate growth using age-cohort models", page 242-3

Slater 2011

Criterion	Score/Info	Notes
In a well-conducted cohort study:		
The study addresses an appropriate and clearly focused question	Well covered	"...(a) provide two simultaneous tests of autonomy and aspiration perceptions as mediators of impact on marijuana use as a consequence of exposure to each of these campaigns, b) conduct the first independent assessment of the ONDCP media campaign, which did not have a formal independent evaluation in place during the years of this study, and c) assess the simultaneous impact of a national campaign and a similar community/in-school effort.", page 12-13
Selection of subjects		
The 2 groups being studied are selected from source populations that are comparable in all respects other than the factor under investigation	Not reported	"3,236 students participated in at least one survey, with 48% males, 52% females and a mean age at baseline of 12.4 years (SD = 0.6); 75% were European-American, 11.5% African-American, and 13.5% of other racial backgrounds. One-quarter of the youth were of Hispanic ethnicity.", page 15
The study indicates how many of the people asked to take part did so, in each of the groups being studied	Poorly addressed	Only average: "The average rate of student participation in each school was 32% of total student enrolment, lower than the prior study because of stricter IRB requirements being imposed on recruitment procedures. 57.1% of respondents provided data at all four measurement occasions; 27.2% provided data on three, 9.4% provided data on two and 5.3% provided data on just one of the measurement occasions. Missed surveys appear to be a matter more of absenteeism or slips in getting students to survey sessions, than of panel mortality; 84.5% of participants filled out the wave 1 survey,

		86.2% wave 2, 86.1% wave 3, and 81.3% wave 4.", page 15
The likelihood that some eligible subjects might have the outcome at the time of enrolment is assessed and taken into account in the analysis	Well covered	"Lifetime use of marijuana was measured at each measurement wave [..]", page 15
What percentage of individuals or clusters recruited into each arm of the study dropped out before the study was completed	42.9%	"The average rate of student participation in each school was 32% of total student enrolment, lower than the prior study because of stricter IRB requirements being imposed on recruitment procedures. 57.1% of respondents provided data at all four measurement occasions; 27.2% provided data on three, 9.4% provided data on two and 5.3% provided data on just one of the measurement occasions. Missed surveys appear to be a matter more of absenteeism or slips in getting students to survey sessions, than of panel mortality; 84.5% of participants filled out the wave 1 survey, 86.2% wave 2, 86.1% wave 3, and 81.3% wave 4.", page 15
Comparison is made between full participants and those lost to follow-up, by exposure status	Not reported	
Assessment		
The outcomes are clearly defined	Well covered	"Autonomy and Aspirations Inconsistent With Marijuana Use Autonomy inconsistent with marijuana use was measured using responses to four items following the phrase "Not using marijuana": 1) is a way to be true to myself; 2) is an important part of who I am; 3) is a way of being in control of my life; and 4) is a way of showing my own independence, where responses ranged from 1 = definitely disagree to 4 = definitely agree. Similarly, aspirations inconsistent with marijuana use were measured using the responses to three items following the phrase "Using marijuana would: 1) keep me from doing the things I want to; 2) mess up my plans for when I am older; and 3) get in the way of what is important to me." Because responses to each

		scale's items were heavily skewed, with 82% of respondents selecting "definitely agree" for all aspiration items and 84% of respondents selecting "definitely agree" for all autonomy items, each scale was dichotomized such that a "1" was assigned if all responses to the scale items were "definitely agree" and a "0" otherwise. The Cronbach's alpha values (Cronbach 1951) for each dichotomized measure were .9 or greater at each of the four waves Marijuana Use Lifetime use of marijuana was measured at each measurement wave using four questions: "How old were you the first time you used marijuana?", "How often in the last month have you used marijuana?", "How often in the last 3 months have you used marijuana?", and "Have you ever tried marijuana? (pot, grass, hash, etc.)?" If a subject responded affirmatively to any one question (or indicated an age when they first used marijuana), lifetime marijuana use was scored a "1", while an indication of never using marijuana resulted in a score of "0". The reliability for the scale was above 0.7 for the first two measurement occasions, .64 on the third occasion, and .69 at the fourth occasion.", page 15
The assessment of outcome is made blind to exposure status	Not applicable	Blinding to exposure status was not applicable for this study
Where blinding was not possible, there is some recognition that knowledge of exposure status could have influenced the assessment of outcome	Not reported	
The measure of assessment of exposure is reliable	Well covered	p. 15
Evidence from other sources is used to demonstrate that the method of outcome assessment is valid and reliable	Well covered	= 1.7
Exposure level or prognostic factor is assessed more than once	Well covered	4 waves, page 17
Confounding		

The main potential confounders are identified and taken into account in the design and analysis	Adequately addresses	p. 16
Statistical analysis		
Have confidence intervals been provided?	Well covered	Standard errors, e.g. Table 1 and 2, p. 18
Overall assessment of the study		
How well was the study done to minimise the risk of bias or confounding, and to establish a causal relationship between exposure and effect? *Code* ++, +, or −	+	
Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the exposure being investigated?	Fairly: selectivity (do no know if representative); no propensity scoring for national media campaign	
Are the results of this study directly applicable to the patient group targeted in this guideline?	Unclear	Results are applicable to US youth; it is unclear whether they are generalisable outside the US
Description of the study		
Do we know who the study was funded by?	Public Funds (NIDA)	"This research was supported by grant DA12360 from the National Institute on Drug Abuse (NIDA) to the first author.", page 12
How many centres are patients recruited from?	20 communities	
From which countries are patients selected? (Select all those involved. Note additional countries after 'Other')	USA	
What is the social setting (i.e. type of environment in which they live) of patients in the study?	Mixed	p. 14
What criteria are used to decide who should be INCLUDED in the study?	IRB requirements	"The average rate of student participation in each school was 32% of total student enrolment, lower than the prior study because of stricter IRB requirements being imposed

		on recruitment procedures", page 15
What criteria are used to decide who should be EXCLUDED from the study?	Exaggerators	"Students who responded that they had tried all drugs listed including one that had been invented were considered exaggerators and were excluded from analyses; there were no more than 0.4% of such exaggerators in any given wave of data collection.", page 15
What intervention or risk factor is investigated in the study? (Include dosage where appropriate)	(a) school- and community-based media intervention 'Be Under Your Influence' and (b) national anti-drug media campaign 'Above the Influence'	p. 12
What comparisons are made in the study (i.e. what alternative treatments are used to compare the intervention/exposure with). Include dosage where appropriate	Exposure versus drug use/aspirations/autonomy; exposure x time versus drug use/ aspirations/autonomy	
What methods were used to randomise patients, blind patients or investigators, and to conceal the randomisation process from investigators?	Randomisation: not applicable for mass media campaign, but done for 'Be Under Your Own Influence' school- and community-based media intervention	
How long did the active phase of the study last?	Autumn 2005 to Spring 2009 (~42 months)	
How long were patients followed up for, during and after the study?	24 months	
List the key characteristics of the patient population. Note if there are any significant differences between different arms of the trial	48% males, 52% females and a mean age at baseline of 12.4 years (SD = 0.6); 75% were European-American, 11.5% African-American, and 13.5% of other racial backgrounds One-quarter of the youth were of Hispanic ethnicity	p. 15
Record the basic data for each arm of the study. If there are more than 4 arms, note data for subsequent arms at the bottom of the page		Table 1 and 2, page 18
Record the basic data for each IMPORTANT outcome in the study. If there are more than 4, note data for additional outcomes at the bottom of the page		Table 1 and 2, page 18

Table 2. 'Risk of bias' assessment of cohort studies (Hornik 2006, Scheier 2010, Slater 2011)   *(Continued)*

Notes. Summarise the authors' conclusions. Add any comments on your own assessment of the study, and the extent to which it answers your question	Results indicate that earlier effects of the 'Be Under Your Own Influence' intervention replicated only in part and that the most plausible explanation of the weaker effects is high exposure to the similar but more extensive ONDCP 'Above the Influence' national campaign. Self reported exposure to the ONDCP campaign predicted reduced marijuana use, and analyses partially support indirect effects of the 2 campaigns via aspirations and autonomy	

SD: standard deviation

IRB= Institutional Review Board, is a committee that has been formally designated to approve, monitor, and review biomedical and behavioral research involving humans

Table 3. Measurement scales used in included studies

Study	Was a specific scale developed? (Yes/no/unclear)	Measurement scale(s) used	Reference	Was the scale adapted? (Yes/no/unclear)
Palmgreen 1991	No	Sensation seeking Scale, Form V	Zuckerman, M (1979) . Sensation seeking: beyond the optimal level of arousal. Hillsdale, NJ: Lawrence Erlbaum Associates, Inc	No
	No	Instruments used in a continuing survey of young people by the Institute for Social Research at the University of Michigan (NB to measure levels of use of illicit drugs)	Johnston LD, Bachman JG, O'Malley PM (1982). Monitoring the future: questionnaire responses from the nations' high school seniors, 1981. Ann Arbor: University of Michigan, Survey Response Centre, Institute for Social Research	Yes
	Yes	Behavioural Intention Index p. 221 "immediately after the second viewing of the PSA, subjects were asked "If you wanted information about alterna-	n/a	n/a

Table 3. Measurement scales used in included studies *(Continued)*

		tives to drug use, how likely it is, on a scale of 1 to 5, that you would call na 800 hotline?"		
	Yes	Attitude towards drug use p. 222 "After behavioural intention was measured, subjects were asked to indicate on a scale of 1 to 5 how they felt about their personal use of drugs in relation to each of six adjectives word pairs."	n/a	n/a
Kelly 1992	Unclear	Not mentioned	n/a	n/a
Polansky 1999	No	Drug Attitude Scale (12 items on a Likert scale)	Swisher JD, Horan JJ (1973). The Pennsylvania State University Evaluation Scales. In LA Abrams, E Garfield & JD Swisher (eds). Accountability in drug education: a model for evaluation (pp 87-99). Washington, DC: Drug Abuse Council	Unclear (: in the text is mentioned "updated version" but no further clarification)
	No	Tentative Drug Use Scale (10 items scale)	Horan JJ, Williams JM (1975). The tentative drug use scale: a quick and relatively problem free outcome measure for drug abuse prevention projects. Journal of Drug education; 5: 381-4	No
	Yes	Help-Seeking Questionnaire and Knowledge Questionnaire p. 190 "two 10-items achievement rests were developed for this study"	n/a	n/a

Table 3. Measurement scales used in included studies (*Continued*)

	No	Drug Conformity Scale (16 questions reflecting varying levels of assertive competency)	Horan JJ, Williams JM (1982) . Longitudinal study of assertion training as a drug abuse prevention strategy. American Educational Research Journal; 19: 341-51	No
Palmgreen 2001 (Stephenson 1999)	Yes	Beliefs 12 marijuana-related beliefs about occasional use of marijuana and 12 belief items about regular marijuana use were assessed on a 4-point scale with the response options of disagree strongly, disagree somewhat, agree somewhat and agree strongly	n/a	n/a
	Yes	Attitudes Seven marijuana-related attitudes about occasional use and 7 items about regular use were assessed on a 4-point scale, with the response options of disagree strongly, disagree somewhat, agree somewhat and agree strongly	n/a	n/a
	Yes	Intentions Participants were asked their intent to engage in experimental or regular marijuana use in the future. With 2 items on a 3-point scale with the response options probably will not, probably will and definitely will	n/a	n/a
Miller 2000	Yes	Use Recent drug use was measured by asking respondents about the fre-	n/a	n/a

Table 3.   Measurement scales used in included studies   (*Continued*)

		quency and recency with which they used 10 types of drugs (using commonly recognised names): cannabis, cocaine, other stimulants, tranquillisers, sedative-hypnotics, hallucinogens, opioids, phencyclidine, amyl and butyl nitrates and inhalants such as glue, paint or gasoline (4- point scale ranging from 1 = never to 4 = at least once in the past month)		
	Yes	Risks perception Risk assessment included 13 items regarding the extent to which students perceived risk or consequences related to alcohol or other drug use. Personal risk for alcohol and other drug problems was judged relative to students' perceptions of "most people" (ranging from 1 = higher than most people to 3 = lower than most people)	n/a	n/a
Palmgreen 2001	No	Brief Sensation Seeking Scale	Hoyle RH, Stephenson MT. The sensation seeking scale for adolescents. In: Lennox RD, Scott-Lennox JA, Cutler BL, eds. Applied Psychometrics for Health Outcomes Research. Chapel Hill, NC: Health Statistics Lab.	No
Fishbein 2002	Yes	Specifically developed instrument p. 241 "the instrument for the study consisted	n/a	n/a

Table 3.   Measurement scales used in included studies   *(Continued)*

		of questionnaire with 3 parts." First: demographic questions Second: series of questions on realism/content/recall of intervention Third: assessment of the respondent perceptions of the danger and harmful effects of engaging in 8 risky behaviours - perceived danger = 1 item per behaviour on yes/no basis - perceived harmfulness = 1 item per behaviour on a 5-point scale - perceived norms = 1 item per behaviour on a 5-point scale		
Yzer 2003	Yes	A specific questionnaire was developed for the study. Available upon request by the authors (p. 135) Intention to use marijuana: 1 to 2 (depending on the first answer) items using a 4-point scale Attitude: 4 items using a 7-point scale Outcome beliefs: 36 items using a 5-point scale	n/a	n/a
Slater 2006	No	Selected items from the American Drug and Alcohol Survey Alcohol lifetime score: 3 items Smoking lifetime score: 3 items Marijuana lifetime score: 5 items	American Drug and Alcohol Survey, with permission by the Rocky Mountain Behavioural Science Institute	No

Table 3. Measurement scales used in included studies *(Continued)*

Zhao 2006	Yes	Intentions not to use/to reduce use/to stop use	n/a	No
	Unclear	Attitudes towards illicit drug use: 7-point scale from -3 (bad/foolish/...) to +3 (good/wise/...)	n/a	n/a
	Yes	Perceptions (including perceptions of peer norms and perceptions about illicit drug use): 5-point scales from -2 to +2. "Although we did some analyses at the level of individual beliefs, we generally used two types of belief clusters in our analyses"	n/a	No
Czyzewska 2007	Unclear	Declared intention to use marijuana		n/a
	Unclear	Attitudes towards illicit drug use (pre-test explicit attitudes): 10-point Likert scales		n/a
	Yes	Attitudes towards illicit drug use (post-test implicit attitudes): IAT test. "Two computerized Implicit Association Tests (IAT) were designed to assess implicit attitudes to tobacco and marijuana. [..] The only difference to the standard IAT procedure was the extended number of practice trials to 40 in order to reduce the typical effect of order in which the combined categorization tasks are performed"	See Table 1 for IAT test content Scale was adapted from: Greenwald AG, McGhee DE, Schwartz JLK (1998). Measuring individual differences in social cognition: The Implicit Association Test. Journal of Personality and Social Psychology; 74: 1464-80 With updates from: Greenwald AG, Nosek BA, Banaij MR (2003). Understanding and using the Implicit Association Test: An improved scoring algorithm. Jour-	Yes

Table 3. Measurement scales used in included studies *(Continued)*

			nal of Personality and Social Psychology; 85(2):197-216	
	Unclear	Attitudes towards illicit drug use (post-test explicit attitudes): 3 sets of 7 5-point scales (= 21 5-point scales)		n/a
Hornik 2006	No	National Survey of Parents and Youth (NSPY). 3 types of measures: recalled exposure to anti-drug messages aired by the campaign and other sources; cognitions and behavior related to marijuana, as outcomes; and individual and household characteristics, including a wide range of variables known to be related to drug cognitions and use and to exposure to anti-drug messages	http://archives. drugabuse.gov/ initiatives/westat/	No
Scheier 2010	Yes	Alcohol and Drug Use Assessment of alcohol and drug use relied on an Anonymous Computer Assisted Self-report Interview (ACASI)	n/a	n/a
Fang 2010	No	Occasions of use in the past 30 days ± standard error, SE	None, but it is a standard question in this field	No
	Unclear	Intentions not to use/to reduce use/to stop use: 5-point scales; higher scores are better. No additional information		Unclear
Lee 2010	No	90-day marijuana use: "items were adapted from the Global Appraisal of Individual Needs-I"	Dennis ML, Titus JC, Diamond G, Donaldson J, Godley SH, Tims FM. The CYT Steering Committee (2002)	Yes

Table 3. Measurement scales used in included studies   (*Continued*)

			. The cannabis youth treatment (CYT) experiment: Rationale, study design and analysis plans. Addiction; 97 (Suppl 1): 16-34	
	No	Intentions not to use/to reduce use/to stop use: 4-point score (higher = more "contemplation"). "Contemplation to change marijuana use was assessed with four items (alpha = 0.79) adapted from the Readiness to Change Questionnaire (RTCQ)"	Heather N, Gold R, Rollnick S (1991). Readiness to change questionnaire: User's manual. (Tech. Rep. 15). Kensington, Australia: National Drug and Alcohol Research Center, University of New South Wales	Yes
	No	Knowledge about the effects of illicit drugs on health: negative consequences due to marijuana use. 5-point score (from 0 = never to 4 = more than 10 times). "Consequences of marijuana use were assessed using the Rutgers Merijuana Problem Index (RMPI)"	White HR, Labouvie EW, Papadaratsakis V (2005). Changes in substance use during the transition to adulthood: A comparison of college students and their non-college age peers. Journal of Drug Issues; 35: 281-306	Unclear
Newton 2010	No	Frequency of cannabis use: times per week ± SE in the past 12 months "Cannabis use was assessed from a questionnaire in the 2007 National Drug Strategy Household Survey (NDSHS) that identified the frequency of use of cannabis [1]."	Australian Institute of Health and Welfare. 2007 National Drug Strategy Household Survey: First Results. Canberra: AIHW; 2008	Yes
	No	Attitudes towards illicit drug use: score ± SE "Attitudes towards cannabis were measured by four items from the Life Skills	National Health Promotion Associates (NHPA) Incorporated. Life Skills Training Questionnaire-	Unclear

Table 3. Measurement scales used in included studies (*Continued*)

		Training Questionnaire [37], which has acceptable internal consistency (a = 0.86)."	Middle School. New York: NHPA; 2004	
	No	Knowledge about the effects of illicit drugs on health: score ± SE "The cannabis knowledge questionnaire was adapted from the Cannabis Quiz and included 16 items [33]."	Bleeker A, Malcolm A. The Cannabis Quiz. Sydney: Manly Drug Education and Counselling Centre; 2001	Yes
	No	Knowledge about the effects of illicit drugs on health: score ± SE "Cannabis harms were assessed with six questions derived from the Adolescent Cannabis Problems Questionnaire (test-retest reliability, r = 0.91) [35]."	Martin G, Copeland J, Gilmour S, Gates P, Swift W. The adolescent cannabis problems questionnaire (CPQ-A): psychometric properties. Addictive Behaviors 2006; 31: 2238-48	No
Schwinn 2010	No	Past 30-day drug use (marijuana): occasions of use (0 to 40) "...adapted from the CDC's Youth Risk Behavior Survey (YRBS; Centers for Disease Control and Prevention 2005), asked girls to report how many times in the past month and week they used alcohol, cigarettes, marijuana, cocaine, inhalants, methamphetamines, and ecstasy. Response options ranged from "0 times" to "40 or more times." Test-retest reliability for YRBS items is 0.82 to 0.95 (Centers for Disease Control and Prevention 2004)"	Centers for Disease Control and Prevention. (2005). Youth Risk Behavior Survey. Retrieved February 20, 2009, from http://www.cdc.gov/healthyyouth/yrbs/	Yes

Table 3. Measurement scales used in included studies *(Continued)*

	No	Past 30-day drug use, poly drug use (cigarettes, marijuana cocaine, inhalants, met., ectasy): 7-point score (0 to 6). Same as above	Same as above	Yes
	No	Past 30-day drug use, total substance (= poly drug use + alcohol): 8-point score (0 to 7). Same as above	Same as above	Yes
Idaho Meth 2010; Colorado Meth 2011; Georgia Meth 2011; Hawaii Meth 2011; Wyoming Meth 2011	No	Past-year and past-month use of methamphetamine: "Have used meth in past year"; "Have used meth in past month"	n/a	Unclear
	Unclear	Attitudes towards illicit drug use: "Please indicate how much you approve or disapprove of the following activities." (Strongly disapprove, strongly/somewhat approve)	n/a	Unclear
	Unclear	Perceptions (including perceptions of peer norms and perceptions about illicit drug use: binary and categorical questions, such as "How difficult, or easy, do you think it would be for you to get each of the following types of drugs?" (easy, difficult) and "Please indicate how much risk, if any, you think there is involved in each of the following activities." (Great risk, great/moderate risk, little/no risk)	n/a	Unclear

Table 3. Measurement scales used in included studies (*Continued*)

Slater 2011	Yes	Description of study measures and survey components (p. 15) Autonomy inconsistent with marijuana use: 4 items on a 4-point scale Aspirations inconsistent with marijuana use: 3 items on a 4-point scale Lifetime marijuana use: 4 items Exposure to ONDCP's campaign: 1 item on a 3-point scale	n/a	n/a
Carpenter 2011	No	Lifetime marijuana use	n/a	Unclear
	No	Past-month marijuana use	n/a	Unclear
	No	Alcohol use	n/a	Unclear

IAT: Implicit Association Test
n/a: not applicable
ONDCP: Office of National Drug Control Policy
SE: standard error

APPENDICES

Appendix 1. CENTRAL search strategy

ID	Search	Hits
#1	MeSH descriptor: [Substance-Related Disorders] explode all trees	10,355
#2	((stimulant* or polydrug* or drug* or substance) near/3 (abuse* or abusing or consumption or addict* or disorder* or intoxicat* or misus* or use*)):ti,ab	14,750

#3	(abuse* or abusing or consumption or addict* or disorder* or intoxicat* or misus* or use*):ti,ab	198,966
#4	MeSH descriptor: [Narcotics] explode all trees	681
#5	heroin:ti,ab	762
#6	MeSH descriptor: [Street Drugs] explode all trees	196
#7	MeSH descriptor: [Amphetamine] explode all trees	632
#8	(amphetamine* or dextroamphetamine* or methamphetamine or Methylamphetamine*):ti,ab,kw (Word variations have been searched)	1442
#9	(ecstasy or MDMA or hallucinogen*):ti,ab,kw (Word variations have been searched)	234
#10	MeSH descriptor: [Cocaine] explode all trees	576
#11	(crack or cocaine):ti,ab,kw (Word variations have been searched)	1953
#12	MeSH descriptor: [Cannabis] explode all trees	245
#13	(cannabis or marijuana or marihuana or Hashish):ti,ab,kw (Word variations have been searched)	1158
#14	(Lysergic next Acid):ti,ab,kw	76
#15	LSD:ti,ab,kw (Word variations have been searched)	131
#16	(benzodiazepine* or barbiturate* or ketamine or solvent or inhalant):ti,ab,kw (Word variations have been searched)	6370
#17	(benzodiazepine* or barbiturate* or ketamine or solvent or inhalant):ti,ab,kw (Word variations have been searched)	6370
#18	#4 or #5 or #6 or #7 or #8 or #9 or #10 or #11 or #12 or #13 or #14 or #15 or #16 or #17	11,919
#19	#3 and #18	6547
#20	#1 or #2 or #19	26,077
#21	MeSH descriptor: [Mass Media] explode all trees	1337
#22	MeSH descriptor: [Internet] explode all trees	1248

#23	MeSH descriptor: [Videotape Recording] explode all trees	790
#24	"Tv":ti,ab,kw (Word variations have been searched)	386
#25	(media or communication* or audiovisual or telecommunication* or radio or television or internet or campaign* or advert* or twitter or facebook) (Word variations have been searched)	27,766
#26	#21 or #22 or #23 or #24 or #25	28,828
#27	MeSH descriptor: [Adolescent] explode all trees	68,885
#28	adolescen* or preadolescen* or child* or teen* or youth* or young or kid* or juvenile* or minors or boy* or girl*:ti,ab,kw (Word variations have been searched)	157,753
#29	#27 or #28	157,753
#30	#20 and #26 and #29	566

Appendix 2. PubMed (MEDLINE) search strategy

Search	Query	Items found
#16	Search (((#3) AND #4) AND #11) AND #15	5877
#15	Search ((#12) OR #13) OR #14	3,041,802
#14	Search adolescen*[tiab] OR preadolescen*[tiab] OR child*[tiab] OR teen*[tiab] OR youth*[tiab] OR young[tiab] OR kid*[tiab] OR juvenile*[tiab] OR minors[tiab] OR boy*[tiab] OR girl*[tiab]	1,662,519
#13	Search "Child"[Mesh]	1,457,004
#12	Search "Adolescent"[Mesh]	1,498,465
#11	Search ((((#5) OR #7) OR #8) OR #9) OR #10	797,788
#10	Search media[tiab] OR Communication*[tiab] OR audiovisual[tw] OR telecommunication*[tw] OR Educat*[tiab] OR radio[tw] OR television[tw] OR TV[tiab] OR internet[tw] OR campaign*[tw] OR advert*[tw] OR twitter[tw] OR facebook[tw] OR "instant messaging"[tw]	751,996

(Continued)

#9	Search "Telecommunications"[Mesh]	54,815
#8	Search Videotape Recording[Mesh]	9970
#7	Search "Internet"[Mesh]	43,359
#5	Search "Mass Media"[Mesh]	37,325
#4	Search "heroin"[Mesh] OR heroin[tiab] OR "Street Drugs"[Mesh] OR "Designer Drugs"[Mesh] OR "Crack Cocaine"[Mesh] OR "Lysergic Acid Diethylamide"[Mesh] OR drug*[tiab] OR polydrug[tiab] OR substance[tiab] OR hallucinogen*[tw] OR cocaine[tw] OR amphetamine*[tw] OR "lysergic acid diethylamide"[tw] OR LSD [tiab] OR ketamine[tw] OR cannabis[tw] OR marihuana[tw] OR marijuana[tiab] OR hashish[tw] OR steroid*[tw] OR morphine[tiab] OR ecstasy[tw] OR MDMA[tw] OR benzodiazepine[tw]	1,136,251
#3	Search (#1) OR #2	1,812,638
#2	Search abus*[tiab] OR consumption[tiab] OR misus*[tiab] OR use*[tiab] OR addict*[tiab] OR disorder*[tiab]	1,570,344
#1	Search "Substance-Related disorders"[Mesh]	344,574

Appendix 3. EMBASE search strategy

ID	Query
#1	'substance abuse'/exp
#2	'drug abuse'/exp
#3	abus*:ab,ti OR consumption:ab,ti OR misus*:ab,ti OR use*:ab,ti OR addict*:ab,ti OR disorder*:ab,ti
#4	#1 OR #2 OR #3
#5	heroin:ab,ti OR drug*:ab,ti OR polydrug:ab,ti OR substance:ab,ti OR hallucinogen*:ab,ti OR cocaine:ab,ti OR amphetamine*:ab,ti OR 'lysergic acid diethylamide':ab,ti OR lsd:ab,ti OR ketamine:ab,ti OR cannabis:ab,ti OR marihuana:ab,ti OR marijuana:ab,ti OR hashish:ab,ti OR steroid*:ab,ti OR morphine:ab,ti OR ecstasy:ab,ti OR mdma:ab,ti OR benzodiazepine:ab,ti
#6	'diamorphine'/exp

#7	'designer drug'/exp
#8	'street drug'/exp
#9	'cocaine'/exp
#10	'cannabis smoking'/exp
#11	#5 OR #6 OR #7 OR #8 OR #9 OR #10
#12	'mass medium'/exp
#13	'internet'/exp
#14	'videorecording'/exp
#15	'telecommunication'/exp
#16	media:ab,ti OR communication*:ab,ti OR audiovisual:ab,ti OR telecommunication*:ab,ti OR educat*:ab,ti OR radio:ab,ti OR television:ab,ti OR tv:ab,ti OR internet:ab,ti OR campaign*:ab,ti OR advert*:ab,ti OR twitter:ab,ti OR facebook:ab,ti
#17	#12 OR #13 OR #14 OR #15 OR #16
#18	'adolescent'/exp
#19	'child'/exp
#20	adolescen*:ab,ti OR preadolescen*:ab,ti OR child*:ab,ti OR teen*:ab,ti OR youth*:ab,ti OR young:ab,ti OR kid*:ab,ti OR juvenile*:ab,ti OR minors:ab,ti OR boy*:ab,ti OR girl*:ab,ti
#21	#18 OR #19 OR #20
#22	#4 AND #11 AND #17 AND #21 AND [embase]/lim

Appendix 4. EPOC criteria for quality assessment of interrupted time series

The following seven standard criteria should be used to assess the methodological quality of ITS designs included in EPOC reviews. Each criterion is scored DONE, NOT CLEAR or NOT DONE. The results of the quality assessment for each study are reported in the Characteristics of included studies table in RevMan. Examples can be obtained from the EPOC Group Co-ordinator.

Criterion	Score		
	DONE	**NOT CLEAR**	**NOT DONE**
a) Protection against secular changes			
The intervention is independent of other changes	If the intervention occurred independent of other changes over time	If not specified (will be treated as NOT DONE if information cannot be obtained from the authors)	If reported that intervention was not independent of other changes in time
There are sufficient data points to enable reliable statistical inference	(a) If at least 20 points are recorded before the intervention AND the authors have done a traditional time series analysis (ARIMA model)	If not specified in paper, e.g. number of discrete data points not mentioned in text or tables (will be treated as NOT DONE if information cannot be obtained from the authors)	If any of the above conditions are unmet
	OR (b) If at least 3 points are recorded pre and post intervention AND the authors have done a repeated measures analysis		
	OR (c) If at least 3 points are recorded pre and post intervention AND the authors have used ANOVA or multiple t-tests AND there are at least 30 observations per data point		
Formal test for trend. Complete this section if authors have used ANOVA modelling	If formal test for change in trend using appropriate method is reported (e.g. see Cook & Campbell 1979)	If not specified in the paper (will be treated as NOT DONE if information cannot be obtained from the authors)	If formal test for change in trend has not been done
b) Protection against detection bias			
Intervention unlikely to affect data collection	If the investigators report that the intervention itself was unlikely to affect data collection (for example, sources and methods of data collection were the same before and after the intervention)	If not reported (will be treated as NOT DONE if information cannot be obtained from the authors)	If the intervention itself was likely to affect data collection (for example, any change in source or method of data collection reported)
Blinded assessment of primary outcome(s)*	If the authors state explicitly that the primary outcome variables were assessed blindly OR the outcome variables are objective, e.g. length of hospital stay,	If not specified (will be treated as NOT DONE if information cannot be obtained from the authors)	If the outcomes were not assessed blindly

(Continued)

	drug levels as assessed by a standardised test		
c) Completeness of data set	If data set covers 80% to 100% of the total number of participants or episodes of care in the study	If not specified (will be treated as NOT DONE if information cannot be obtained from the authors)	If data set covers less than 80% of the total number of participants or episodes of care in the study
*d) Reliable primary outcome measure(s)***	If 2 or more raters with at least 90% agreement or kappa greater than or equal to 0.8 OR the outcome is obtained from some automated system, e.g. length of hospital stay, drug levels as assessed by a standardised test	If reliability is not reported for outcome measures that are obtained by chart extraction or collected by an individual (will be treated as NOT DONE if information cannot be obtained from the authors)	If agreement is less than 90% or kappa is less than 0.8

*Primary outcome(s) are those variables that correspond to the primary hypothesis or question as defined by the authors. In the event that some of the primary outcome variables were assessed in a blind fashion and others were not, score each separately.

**In the event that some outcome variables were assessed in a reliable fashion and others were not, score each separately.

Appendix 5. Quality Criteria for Cohort Controlled Studies (SIGN)

SIGN	Methodology Checklist 3: Cohort studies
Study identification (*include author, title, year of publication, journal title, pages*)	

Guideline topic:	Key Question No:	Reviewer:

Before completing this checklist, consider:

1.Is the paper really a cohort study? If in doubt, check the study design algorithm available from SIGN and make sure you have the correct checklist

2.Is the paper relevant to key question? Analyse using PICO (Patient or Population Intervention Comparison Outcome). IF NO REJECT (give reason below). IF YES complete the checklist

Reason for rejection: 1. Paper not relevant to key question ⌐   2. Other reason ⌐   (please specify):
Please note that a retrospective study (i.e. a database or chart study) cannot be rated higher than +

Section 1: Internal validity

In a well-conducted cohort study:	**Does this study do it?**	
1.1	The study addresses an appropriate and clearly focused question.[i]	Yes ⌐ Can't say ¬	No ⌐

Selection of subjects			
1.2	The 2 groups being studied are selected from source populations that are comparable in all respects other than the factor under investigation.[ii]	Yes ▫ Can't say ▫	No ▫ Does not apply ▫
1.3	The study indicates how many of the people asked to take part did so, in each of the groups being studied.[iii]	Yes ▫	No ▫ Does not apply ▫
1.4	The likelihood that some eligible subjects might have the outcome at the time of enrolment is assessed and taken into account in the analysis.[iv]	Yes ▫ Can't say ▫	No ▫ Does not apply ▫
1.5	What percentage of individuals or clusters recruited into each arm of the study dropped out before the study was completed. [v]		
1.6	Comparison is made between full participants and those lost to follow-up, by exposure status.[vi]	Yes ▫ Can't say ▫	No ▫ Does not apply ▫

ASSESSMENT			
1.7	The outcomes are clearly defined.[i]	Yes ▫ Can't say ▫	No ▫
1.8	The assessment of outcome is made blind to exposure status. If the study is retrospective this may not be applicable.[ii]	Yes ▫ Can't say ▫	No ▫ Does not apply ▫
1.9	Where blinding was not possible, there is some recognition that knowledge of exposure status could have influenced the assessment of outcome. [iii]	Yes ▫ Can't say ▫	No ▫ ▫
1.10	The method of assessment of exposure is reliable.[iv]	Yes ▫ Can't say ▫	No ▫
1.11	Evidence from other sources is used to demonstrate that	Yes ▫ Can't say ▫	No ▫ Does not apply ▫

	the method of outcome assessment is valid and reliable.[v]		
1.12	Exposure level or prognostic factor is assessed more than once.[vi]	Yes ☐ Can't say ☐	No ☐ Does not apply ☐
CONFOUNDING			
1.13	The main potential confounders are identified and taken into account in the design and analysis.[vii]	Yes ☐ Can't say ☐	No ☐
STATISTICAL ANALYSIS			
1.14	Have confidence intervals been provided?[viii]	Yes ☐	No ☐
Section 2: OVERALL ASSESSMENT OF THE STUDY			
2.1	How well was the study done to minimise the risk of bias or confounding?[ix]	High quality (++) ☐ Acceptable (+) ☐ Unacceptable - reject 0	
2.2	Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, how strong do you think the association between exposure and outcome is?		
2.3	Are the results of this study directly applicable to the patient group targeted in this guideline?	Yes ☐	No ☐
2.4	**Notes.** Summarise the authors' conclusions. Add any comments on your own assessment of the study, and the extent to which it answers your question and mention any areas of uncertainty raised above		

[i] This relates to the risk of **detection bias**.* Once enrolled in the study, participants should be followed until specified end points or outcomes are reached. In a study of the effect of exercise on the death rates from heart disease in middle aged men, for example, participants might be followed up until death, or until reaching a predefined age. **If outcomes and the criteria used for measuring them are not clearly defined, the study should be rejected.**

[ii] This relates to the risk of **detection bias.*** If the assessor is blinded to which participants received the exposure, and which did not, the prospects of unbiased results are significantly increased. Studies in which this is done should be rated more highly than those where it is not done, or not done adequately.

[iii] This relates to the risk of **detection bias.*** Blinding is not possible in many cohort studies. In order to asses the extent of any bias that may be present, it may be helpful to compare process measures used on the participant groups - e.g. frequency of observations, who carried out the observations, the degree of detail and completeness of observations. If these process measures are comparable between the groups, the results may be regarded with more confidence.

[iv] This relates to the risk of **detection bias.*** A well-conducted study should indicate how the degree of exposure or presence of prognostic factors or markers was assessed. Whatever measures are used must be sufficient to establish clearly that participants have or have not received the exposure under investigation and the extent of such exposure, or that they do or do not possess a particular prognostic marker or factor. Clearly described, reliable measures should increase the confidence in the quality of the study

[v] This relates to the risk of **detection bias.*** The primary outcome measures used should be clearly stated in the study. **If the outcome measures are not stated, or the study bases its main conclusions on secondary outcomes, the study should be rejected.** Where outcome measures require any degree of subjectivity, some evidence should be provided that the measures used are reliable and have been validated prior to their use in the study.

[vi] This relates to the risk of **detection bias.*** Confidence in data quality should be increased if exposure level is measured more than once in the course of the study. Independent assessment by more than one investigator is preferable.

[vii] Confounding is the distortion of a link between exposure and outcome by another factor that is associated with both exposure and outcome. The possible presence of confounding factors is one of the principal reasons why observational studies are not more highly rated as a source of evidence. The report of the study should indicate which potential confounders have been considered, and how they have been assessed or allowed for in the analysis. Clinical judgement should be applied to consider whether all likely confounders have been considered. If the measures used to address confounding are considered inadequate, the study should be downgraded or rejected, depending on how serious the risk of confounding is considered to be. **A study that does not address the possibility of confounding should be rejected.**

[viii] Confidence limits are the preferred method for indicating the precision of statistical results, and can be used to differentiate between an inconclusive study and a study that shows no effect. Studies that report a single value with no assessment of precision should be treated with extreme caution.

[ix] Rate the overall methodological quality of the study, using the following as a guide: **High quality** (++): Majority of criteria met. Little or no risk of bias. Results unlikely to be changed by further research. **Acceptable** (+): Most criteria met. Some flaws in the study with an associated risk of bias. Conclusions may change in the light of further studies. **Low quality** (0): Either most criteria not met, or significant flaws relating to key aspects of study design. Conclusions likely to change in the light of further studies.

CONTRIBUTIONS OF AUTHORS

Marica Ferri and Fabrizio Faggiano conceived the systematic review and overviewed study inclusion and exclusion, methodological assessment of studies, and wrote the review. Marica Ferri and Elias Allara selected the studies for inclusion. Alessandra Bo and Elias Allara extracted the data from the studies and contributed to writing the review; Elias Allara contacted the trial authors for further information. Along with Alessandra Bo, Elias Allara input data for meta-analysis into Review Manager. Antonio Gasparrini and Elias Allara did the meta-analysis of interrupted time series studies.

Marica Ferri, Fabrizio Faggiano, Elias Allara and Alessandra Bo regularly discussed each step of review process and equally participated in each decision regarding the studies and the analysis.

Marica Ferri, Gregor Burkhart and Fabrizio Faggiano conceived the protocol, Elias Allara and Alessandra Bo performed the preliminary search strategy and participated in writing the protocol. Anna V Gyarmathy provided input to the protocol for the theories description and editing of the text.

DECLARATIONS OF INTEREST

None of the authors report conflict of interest.

SOURCES OF SUPPORT

Internal sources

- European Monitoring Centre for Drugs and Drug Addiction, Portugal.

The authors were allowed to use their working time, the offices and the working resources (computers, printers, internet access) to conduct the systematic review.

External sources

- No sources of support supplied

INDEX TERMS

Medical Subject Headings (MeSH)

*Mass Media; *Street Drugs; Australia; Canada; Health Promotion [*methods]; Prospective Studies; Randomized Controlled Trials as Topic; Retrospective Studies; Substance-Related Disorders [*prevention & control]; United States

MeSH check words

Humans

Paper 4: Are mass-media campaigns effective in preventing drug use? A Cochrane systematic review and meta-analysis

BMJ Open

Are mass-media campaigns effective in preventing drug use? A Cochrane systematic review and meta-analysis

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ABSTRACT

Objective: To determine whether there is evidence that mass-media campaigns can be effective in reducing illicit drug consumption and the intent to consume.

Design: Systematic review of randomised and non-randomised studies.

Methods: We searched four electronic databases (MEDLINE, EMBASE, ProQuest Dissertations & Theses A&I and CENTRAL) and further explored seven additional resources to obtain both published and unpublished materials. We appraised the quality of included studies using standardised tools. We carried out meta-analyses of randomised controlled trials and a pooled analysis of interrupted time-series and controlled before-and-after studies.

Results: We identified 19 studies comprising 184 811 participants. Pooled analyses and narrative synthesis provided mixed evidence of effectiveness. Eight interventions evaluated with randomised controlled trials leaned towards no evidence of an effect, both on drug use (standardised mean difference (SMD) −0.02; 95% CI −0.15 to 0.12) and the intention to use drugs (SMD −0.07; 95% CI −0.19 to 0.04). Four campaigns provided some evidence of beneficial effects in preventing drug use and two interventions provided evidence of iatrogenic effects.

Conclusions: Studies were considerably heterogeneous in type of mass-media intervention, outcome measures, underlying theory, comparison groups and design. Such factors can contribute to explaining the observed variability in results. Owing to the risk of adverse effects, caution is needed in disseminating mass-media campaigns tackling drug use. Large studies conducted with appropriate methodology are warranted to consolidate the evidence base.

INTRODUCTION

Mass-media campaigns are a powerful means for disseminating health promotion messages. A wide and diverse audience can be reached through television commercials, the Internet, mobile phones, newspapers and

Strengths and limitations of this study

- This systematic review is based on an expanded evidence base of both published and unpublished findings and aims to determine whether mass-media campaigns can be effective in preventing the use of or intention to use illicit drugs.
- Pooled analyses of eight mass-media interventions provide no evidence of an effect on drug use or intention to use illicit drugs. Four interventions provide evidence of beneficial effects. Two interventions provide evidence of iatrogenic effects.
- Owing to the paucity and inconsistency of available evidence, we cannot draw general conclusions as to whether mass-media interventions are effective in preventing the use of or intention to use illicit drugs.
- This review provides an insight into research gaps around the impact of mass-media drug prevention interventions and can serve to highlight that new campaigns should be implemented in the framework of rigorous evaluation studies, in order to avoid dissemination of interventions that are ineffective or have unintended effects.

roadside advertising hoardings. In the field of drug addiction and dependence, advertisements may contribute to shaping patterns of drug use and the intention to use drugs, as well as modifying mediators such as awareness, knowledge and attitudes about drugs.

However, ethical and economic considerations are often raised. Mass-media campaigns—unlike other health interventions—are imposed on populations that have not consented to their implementation.[1] This is a considerable ethical issue in modern, person-centred public health, where taking decisions shared with the public is essential for promoting behaviour change. Second, mass-media campaigns can be very expensive, especially when implemented at the national or state level. Large-scale purchasing of

public service announcement time during popular shows and broad dissemination via printed media are often accessible only to governmental institutions. For example, the first and second versions of the US Office of National Drug Control Policy's National Youth Anti-Drug Media Campaign cost 2.7 billion dollars over more than 10 years.[2] Although such campaigns underwent careful evaluation, most mass-media interventions are not developed in compliance with the classical circle of public health, which consists in designing interventions based on evidence and in evaluating their impact.

A systematic review of the studies assessing media campaigns aiming to prevent use of illicit drugs can inform future strategies and help design effective campaigns. The objective of this review is to assess the effectiveness of mass-media campaigns in preventing or reducing drug use or the intention to use illicit drugs among young people.

METHODS

We conducted this systematic review in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA)[3] statement and with the procedures specified in a previously published protocol.[4] As described in detail previously,[4] we systematically searched four electronic databases: MEDLINE (1966 to 29 January 2013), EMBASE (1974 to 30 January 2013), ProQuest Dissertations and Theses A&I (1861 to 3 February 2013) and CENTRAL (2013, Issue 1). Search strategies are available as supplementary files (see online supplementary appendix 1). We further explored seven additional resources to obtain both published and unpublished materials: four websites of registered studies (ie, http://www.controlled-trials.com, http://apps.who.int/trialsearch/, http://clinicaltrials.gov/, https://eudract.emea.europa.eu/), references embedded in book chapters, references included in the annual national reports written by EMCDDA national focal points and any publications recommended by prominent researchers in the field. We did not set any constraints, such as language or time, to our search.

Selection criteria

As described in detail previously,[4] we considered studies involving participants under the age of 26 and evaluating mass-media campaigns explicitly aimed at influencing the use or intention to use illicit drugs.[5] The following were deemed acceptable comparison groups: (1) no intervention; (2) community-based or school-based drug prevention programmes; (3) lower exposure to intervention; (4) time before exposure to intervention. We included randomised controlled trials (RCTs), cohort studies, interrupted time-series (ITS) studies and controlled before and after (CBA) studies providing evidence on drug use or intention not to use, to reduce use or to stop use of illicit drugs.

Two authors independently inspected search hits by reading titles and abstracts and assessed studies for inclusion. Any disagreement was solved by consensus. Multiple publications pertaining to the same study were collated as one single study.

Quality Appraisal

Four authors independently performed quality assessments, and any disagreement was solved by consensus. We contacted study authors whenever information was missing or unclear.

We used standardised assessment tools for each study design—details are available as supplementary materials (see online supplementary appendix 2). For RCTs, we used the Cochrane Collaboration Risk of Bias assessment tool.[6] For cohort studies, we followed the Scottish Intercollegiate Guidelines Network (SIGN) Quality Criteria.[7] For ITS and CBA studies, we used the tool recommended by the Cochrane Effective Practice and Organisation of Care Group.[8]

Statistical analysis

As for RCTs, we performed a random effects meta-analysis to estimate the pooled effect of mass-media interventions on drug use while accounting for between-study heterogeneity, as described in detail previously.[4] We carried out a fixed effects meta-analysis to estimate the pooled intervention effect on intention to use drugs. We tested between-study heterogeneity using the χ^2 test and the I^2 statistic. A p value lower than 0.10 in the χ^2 test and an I^2 statistic higher than 50% suggested evidence of heterogeneity. Since most studies assessed their outcome variables with different scales, we used standardised mean difference (SMD) as the summary measure of choice. SMDs were used for both drug use and intention to use drugs and were calculated by dividing the difference in mean outcome between groups by the SD of outcome between participants.[6] SMDs and their SEs were then pooled in a meta-analysis performed with RevMan.[9] For two clustered RCTs,[10 11] we inflated SEs to account for within-cluster correlations.[6]

We pooled the effect estimates of the Meth Project studies using mixed effects logistic regression.[12–16] An ITS design was applied for estimating the differences in prevalence of methamphetamine use before and after the Meth Project intervention, adjusting for any underlying temporal trend. We fitted the following model: $logit(use_{ij}) = \beta_0 + u_{0j} + \beta_1 time_i + \beta_2 age_i + \beta_3 interv_i + \beta_4 age \times interv_i$, in which use was prevalence of methamphetamine use, time was a continuous variable, age and intervention were two-level categorical variables, u_{0j} was a random intercept and we allowed log odds of methamphetamine use to vary randomly by each jth state.[17] The relatively few data points did not allow exploration of more complex models, for example, the temporal trend could not be assumed to vary randomly across states.

RESULTS

Out of 18 343 titles and abstracts, we selected 24 papers corresponding to 19 individual studies (figure 1).

Study Characteristics

Overall, 184 811 participants were included, with most studies comprising participants who were aged between 10 and 19 years (table 1). Although most studies included both boys and girls, two studies focused on girls.[18 19] One study considered Asian-Americans as the only ethnic group eligible for inclusion,[18] while the other study did not focus on any specific ethnic groups. Seventeen studies were conducted in the USA, one in the USA and Canada,[19] and one in Australia.[11]

Eleven studies (58%) evaluated multicomponent interventions, 3 regarding radio/television and printed advertising,[10 20 21] and 8 regarding radio and television commercials, printed advertisements and Internet advertising.[2 12–16 22 23] Eight studies evaluated standalone interventions, four consisting in radio and television commercials,[24–27] and four in Internet-based interventions.[11 18 19 28] The included studies in this review were grounded in a wide range of underlying theories (table 1).

Comparison groups varied considerably across studies. For thirteen studies (68%), the comparison group consisted in no exposure to any intervention. Four studies compared high exposure versus low exposure to the same mass media intervention.[2 21–23] For one study, the comparison group consisted in the standard drug education curriculum.[11] One study had four study arms consisting either in another intervention or no intervention.[26]

Eight studies were conducted in an experimental setting by explicitly inviting participants and these studies were randomised controlled trials (RCTs).[10 11 18 19 25–28] Ten studies were conducted in a field setting without explicitly inviting participants, as would usually happen with most mass-media campaigns. Of them, 2 were cohort studies,[22 23] 6 were ITS[2 12 14–16 24] and 2 were CBA studies.[13 20] One study had a double design as it was conducted in an experimental setting with an RCT design, and in a field setting with a cohort design.[21] When specified, follow-up varied from 6 months[19 28] to 4.7 years.[22]

Study quality

On the whole, the quality of the RCTs is acceptable (table 2). As described in detail previously,[4] the strongest domain appears to be the risk of attrition bias and the weakest domain the risk of selection bias (unclear description of the randomisation procedure). In one paper, findings of secondary outcomes were reported only as a predictor of the primary outcome, and the paper concerned was deemed at high risk for reporting bias.[19]

Figure 1 PRISMA flow diagram. Adapted from a previous publication.[4]
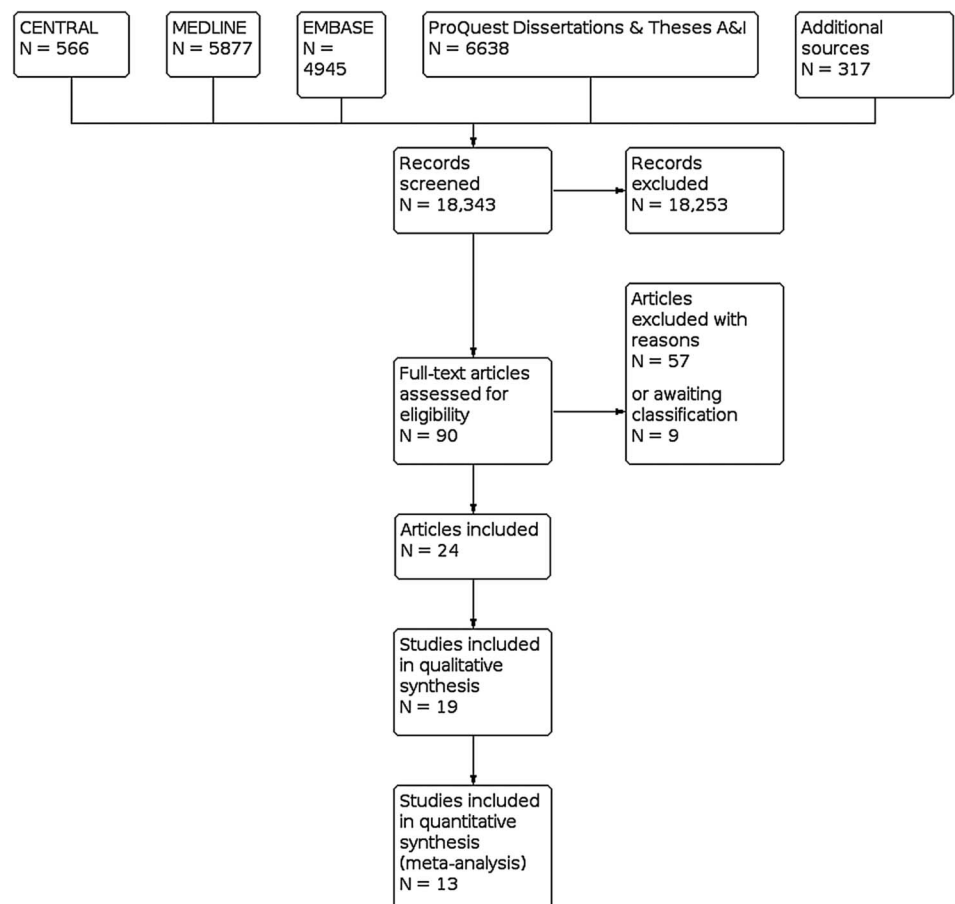
Table 1 Characteristics of included studies

Study	Underpinning theory	Design (goal)	Intervention	Comparison	Primary outcome	Secondary outcome(s)	Analysis sample	Follow-up (total time) (months)
Polansky et al 1999[25]	Decision theory	RCT (E)	PSA	Other	–	Intention to use; attitudes; knowledge and disposition to select socially appropriate responses	312	NA (NS)
Miller et al 2000[20]	Self-regulation theory	CBA (F)	PSA; printed	No intervention	Use of drugs (incl. cannabis and cocaine)	Risk perception; problems related to drug use	1024	12 (18)
Palmgreen et al 2001[24]	Influence of sensation-seeking on drug use	ITS (F)	PSA	No intervention	Past 30-day use of marijuana	–	6371	NA (32)
Yzer et al 2003[26]	Theories of behavioural change: persuasion effects	RCT (E)	PSA	No intervention; other	–	Intention to use marijuana; attitude; perceptions about marijuana	418	NA (NS)
Slater et al 2006[10]	Social-ecological framework (norms and expectations influence drug use)	RCT (E)	PSA; printed	No intervention	Lifetime and past 30-day use of marijuana	–	4216	24 (42)
Zhao et al 2006[27]	Normative beliefs	RCT (E)	PSA	No intervention	–	Intention to use; beliefs towards marijuana; social norms	435	NS (NS)
Hornik 2006[22]	Unclear	Cohort (F)	PSA; printed; internet	Lower exposure	Lifetime, past year, and past 30-day use of marijuana	Intention to use; attitudes and self-efficacy; perceptions and social norms	8117	56 (58)
Scheier and Grenard 2010[23]	Social marketing	Cohort (F)	PSA; printed; internet	Lower exposure	Past 12-month cannabis intoxications	–	2515	NA (48)
Schwinn et al 2010[19]	Social learning theory	RCT (E)	Internet	No intervention	Past 30-day substance use	–	236	6 (NS)
Lee et al 2010[28]	Readiness to change	RCT (E)	Internet	No intervention	Past 90-day use of marijuana	Intention to change marijuana use; consequences	341	6 (NS)
Fang et al 2010[18]	Family-oriented	RCT (E)	Internet	No intervention	Past 30-day use of marijuana	Intention to use marijuana	216	6.25 (16)
Newton et al 2010[11]	Social influence approach	RCT (E)	Internet	Other	Use of cannabis	Cannabis knowledge; attitudes; related harms	724	12 (21)
Meth Project studies[12–16]	Perception of risk and perception of social disapproval are correlated with drug consumption	4 ITS and 1 CBA (F)	PSA; printed; internet	No intervention	Past 30-day use of methamphetamine	Attitudes on methamphetamine and other drugs; perceptions; information sources and advertising awareness;	26 405	NA (Colorado 26; Georgia 18; Hawaii 25; Idaho 40; Wyoming 34)
Slater et al 2011[21]	Autonomy and aspiration perceptions as mediators of marijuana use	RCT (E); Cohort (F)	PSA; printed	Lower exposure	Lifetime, past 90-day and past 30-day use of marijuana	Autonomy and aspiration inconsistent with marijuana use	3236	24 (42)
Carpenter and Pechmann 2011[2]	Unclear; evaluated many heterogeneous mass-media campaigns	ITS (F)	PSA; printed; internet	Lower exposure	Past 30-day and lifetime use of marijuana	–	130 245	NA (36)

CBA, controlled before and after; Cohort, prospective cohort; E, experimental/efficacy setting; F, field/effectiveness setting; ITS, interrupted time-series; Lower exposure, lower exposure to same intervention; NA, not applicable; NS, not specified; Other, other intervention or different combination of same intervention; PSA, public service announcement (eg, television/radio); RCT, randomised controlled trial.

Table 2 Risk of bias of included studies

Design	Study	Random sequence generation	Allocation concealment	Blinding of outcome assessment	Attrition	Selective reporting	Comparability of groups	Acceptance among recruited	Attrition by exposure status	Strategies alternative to blinding	Discussion of potential confounders	Statistical accuracy	Overall risk of bias (cohort)	Sufficient data points for inference
RCT	Polansky et al 1999[25]													
	Yzer et al 2003[26]													
	Slater et al 2006[10]													
	Zhao et al 2006[27]													
	Schwinn et al 2010[19]													
	Lee et al 2010[28]													
	Fang et al 2010[18]													
	Newton et al 2010[11]													
Cohort	Slater et al 2011[21]*,†													
	Hornik et al 2006[22]*													
	Scheier and Grenard 2010[23]*													
ITS	Palmgreen et al 2001[24]‡													
	Carpenter and Pechmann 2011[2]‡													
	4 Meth Project studies[12][14–16]‡													
CBA	1 Meth Project study[13]‡													
	Miller et al 2000[20]‡													

Study quality was appraised with three different tools depending on study design. Redundant or similar items were collapsed. The 'the intervention was independent of other changes' item of the ITS checklist was considered equivalent to the 'discussion of potential confounder' item for cohort studies, the 'formal test for trend' ITS item was considered equivalent to the 'statistical accuracy' item for cohort studies and the 'completeness of data set' ITS item was considered equivalent to the 'attrition' item for RCT and cohort studies.
*All cohort studies had low risk of bias for the following items: 'likelihood of outcome already present at enrolment', 'clarity of outcome', 'reliability of assessment of exposure', 'use of other sources to corroborate outcome measure', and 'multiple measure of exposure'.
†Slater 2011 is a mixed RCT-cohort study.
‡All ITS studies and the CBA study had low risk of bias for the following items: 'intervention unlikely to affect data collection', and 'reliable primary outcome measure(s)'.
■, high risk of bias; □, low risk of bias; ▨, unclear risk of bias; CBA, controlled before and after; Cohort, prospective cohort; ITS, interrupted time-series; RCT, randomised controlled trial; White, not applicable.

All cohort studies focused on a clear and appropriate question. Subgroup comparisons between participants and dropouts were carried out in only one study.[23] The same study, however, failed to control for potential confounders.

The proportion of participants with no missing data was reported in only one controlled CBA study.[20] Potential confounders were accounted for in only one ITS study[2] and one CBA study.[20] A formal test of trend was not performed in the five Meth Project studies.[12–16] One ITS study[2] and the two CBA studies[13 20] had three or less data points, which are generally considered insufficient for drawing reliable conclusions with regard to intervention effectiveness.

EFFECTS OF MASS-MEDIA CAMPAIGNS
Use of illicit drugs
Experimental studies

Pooled analyses of five RCTs[10 11 18 19 28] comprising n=5470 subjects showed no evidence (p=0.79) of an effect of mass-media campaigns in modifying use of illicit drugs (standardised mean difference (SMD) −0.02; 95% CI −0.15 to 0.12; figure 2 and table 3). There was some evidence (p=0.020) of heterogeneity between studies.

The RCT part of a mixed RCT-cohort study (n=3236) found evidence of effectiveness (p=0.026) for a media-community intervention (OR 0.60; 95% CI 0.38 to 0.94; table 3).[21]

Field studies

Two studies found that the Office of National Drug Control Policy (ONDCP) National Youth Anti-Drug Media Campaign (first version) increased use of illicit drugs among adolescents (table 3). One study (n=3529)

reported a significant increase in past year-use of marijuana (OR 1.21; 95% CI 1.19 to 1.65).[22] The other study (n=2515) found some evidence ('p<0.05') of an iatrogenic effect among those aged 15–18 (mean change=0.144), while there was no evidence ('p>0.05') of an effect among those aged 13–14 (mean change=−0.022).[23]

The revamped version of the same ONDCP campaign, Above the Influence, was found effective in a mixed RCT-cohort study (n=3236), whose cohort part found strong evidence (p<0.001) of effectiveness (OR 0.26; 95% CI 0.19 to 0.35).[21] On a similar note were the findings of an ITS study (n=130 245) which evaluated Above the Influence and found evidence of reductions in marijuana use in the past month (OR 0.67; 95% CI 0.52 to 0.87) among eighth-grade girls.[2]

The pooled findings of the five Meth Project studies (n=26 273) suggested no evidence of a change in past-month use of methamphetamine among subjects aged 12–17 (OR 1.16; 95% CI 0.83 to 1.61), nor among those aged 18–24 (OR 1.63; 95% CI 0.70 to 3.79) (figure 3A and table 3). There was, however, evidence (p=0.001) of a reduction in past-year use of methamphetamine among those aged 12–17 (OR 0.59; 95% CI 0.43 to 0.81), while there was no evidence of a similar effect among those aged 18–24 (OR 0.70; 95% CI 0.34 to 1.45; figure 3B and table 3).

One ITS (n=6371) showed evidence of effectiveness for past 30-day use of marijuana among high sensation seekers (p=0.001 for the Fayette sample, p=0.001 for the first campaign in the Knox sample, p=0.002 for the second campaign in the Knox sample).[24]

One CBA study found an increase in use of LSD ('p<0.001'; table 3) while no evidence ('p>0.05') of differences was found for marijuana, cocaine, amphetamine and heroin.[20]
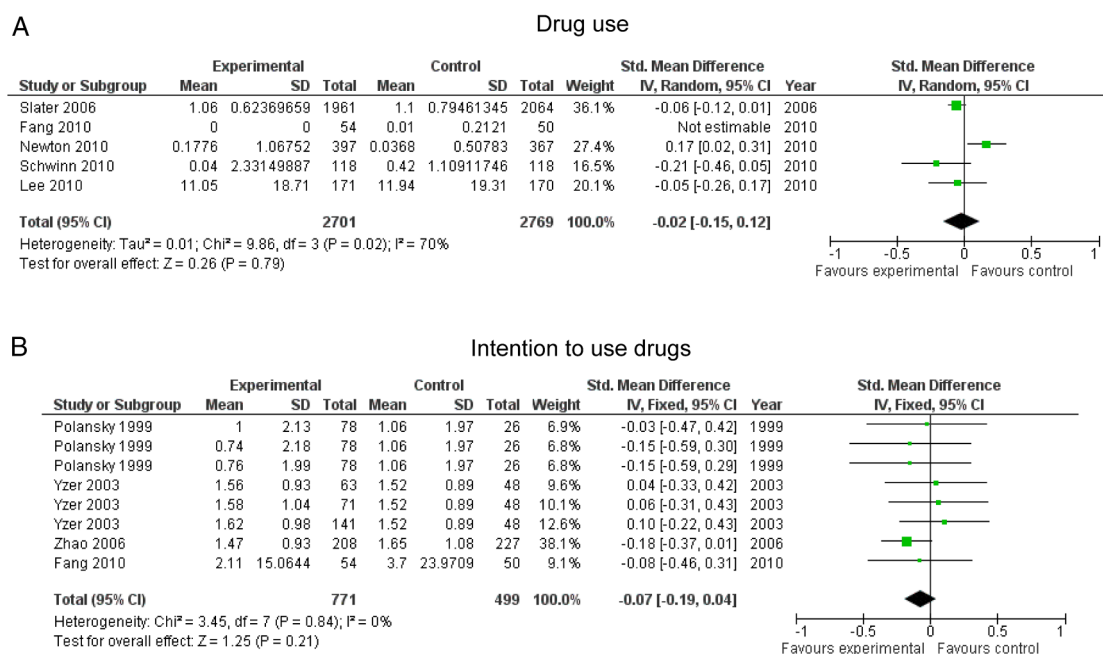

Figure 2 Pooling of randomised controlled trials. Adapted from a previous publication.[4]

Table 3 Main findings for use or intention to use illicit drugs

Pooling	Outcome	Design	References	Subgroups	Number of subjects exp vs ctrl†	Effect measure	Effect size (95% CI) or effect direction (p-value)‡	Heterogeneity p-value¶
Pooled analyses	Use of illicit drugs	RCT	Slater et al 2006;[10] Fang et al 2010;[18] Newton et al 2010;[11] Schwinn et al 2010;[19] Lee et al 2010[28]	–	2701 vs 2769	SMD, random effects	−0.02 (−0.15 to 0.12)	**0.020***
	Intention to use illicit drugs	RCT	Polansky et al 1999;[25] Yzer et al 2003;[26] Zhao et al 2006;[27] Fang et al 2010[18]	–	771 vs 499	SMD, fixed effects	−0.07 (−0.19 to 0.04)	0.840
	Past-month use of methamphetamine	4 ITS and 1 CBA	Meth Project studies[12–16]	age 12–17	14 865 vs 7497	OR, random effects	1.16 (0.83 to 1.61)	–
				age 18–24	347 vs 632	OR, random effects	1.63 (0.70 to 3.79)	–
	Past-year use of methamphetamine	4 ITS and 1 CBA	Meth Project studies[12–16]	age 12–17	17 105 vs 7497	OR, random effects	**0.59 (0.43 to 0.81)****	–
				age 18–24	1039 vs 632	OR, random effects	0.70 (0.34 to 1.45)	–
Single studies	Lifetime, past 90-day, or past-30-day use of marijuana	RCT (community-media)	Slater et al 2011[21]	–	NA (3236)	OR, random effects	**0.60 (0.38 to 0.94)***	–
		Cohort (mass-media)		–		OR, random effects	**0.26 (0.19 to 0.35)*****	–
	Past-year use of marijuana	Cohort	Hornik 2006[22]	–	NA (3529)	OR, fixed effects	**1.21 (1.19 to 1.65)***	–
	Intention to use marijuana			–	NA (2915)	OR, fixed effects	**0.89 (0.79 to 1.00)§**	–
	Past 12-month episodes of cannabis intoxication	Cohort	Scheier and Grenard et al 2010[23]	age 13–14	NA (2515)	mean difference, SEM	−0.022	–
				age 15–18		mean difference, SEM	**0.144***	–
	Past 30-day use of marijuana among high-sensation seekers	ITS	Palmgreen et al 2001[24]	Fayette	NA (3174)	test for slope	**↓ (p=0.001)**	–
				Knox, first campaign	NA (3197)	test for slope	**↓ (p=0.001)**	–
				Knox, second campaign		test for slope	**↓ (p=0.002)**	–
	Past 30-day use of marijuana (girls, 8th grade)	ITS	Carpenter and Pechmann 2011[2]	–	NA (130 245)	OR, fixed effects	**0.67 (0.52 to 0.87)****	–
	Frequency of use of 10 types of drugs	CBA	Miller et al 2000[20]	–	567 vs 431	mean difference, ANOVA	**for LSD: ↑ (p<0.001)** for marijuana, cocaine, amphetamine, and heroin: 'no longer significant' differences	–

§p<0.10 *p<0.05 **p<0.01 ***p<0.001.
†NA=breakdowns of students exposed to the interventions were not available. Number of analysed subjects is between brackets.
‡Whenever the effect size was not reported, ↓=decreased use or intention to use, and ↑=increased use or intention to use.
¶Heterogeneity test for meta-analyses of RCTs.
ANOVA, analysis of variance; CBA, controlled before and after; Cohort, prospective cohort; ITS, interrupted time-series; RCT, randomised controlled trial; SEM, structural equation modelling; SMD, standardised mean difference.
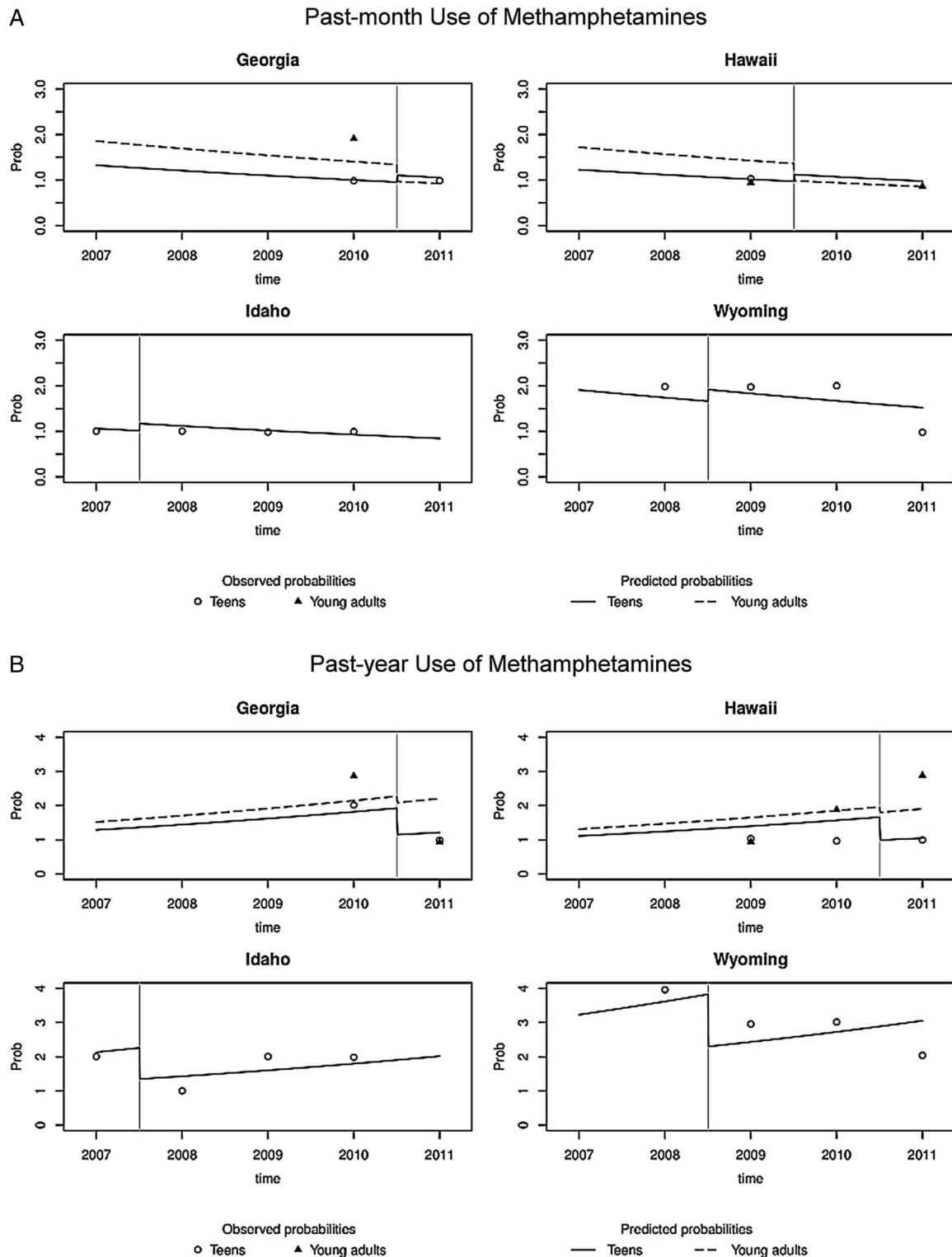
Figure 3 Pooling of the meth project interrupted time-series studies: predicted and observed probabilities. Adapted from a previous publication.[4]

Intention to use drugs
Experimental studies
In one meta-analysis of four randomised controlled studies involving 1270 participants, there was no evidence of an effect (p=0.21) of media campaigns in changing intention to use drugs (SMD −0.07; 95% CI −0.19 to 0.04; figure 2 and table 3).[18 25–27] There was no evidence (p=0.840) of heterogeneity across studies.

Field studies
One study (n=2915) found some evidence (p=0.053) of a reduction in intentions to use marijuana (OR 0.89;

95% CI 0.79 to 1.00; table 3) for the first version of the ONDCP's media campaign.[22]

DISCUSSION

Mass-media campaigns are commonly used throughout the world to tackle a broad array of preventable risk factors or injuries. Such campaigns are seldom evaluated, thus making it difficult to inform policymakers regarding their effectiveness and sustainability. In this panorama of overall uncertainty, mass-media campaigns tackling tobacco and traffic accidents are noteworthy exceptions as they have been evaluated more frequently and have shown some evidence for benefit.[29] In our attempt to summarise evidence on the effectiveness of mass-media campaigns targeting illicit drugs, we included 19 studies evaluating a number of heterogeneous interventions. We grouped interventions according to whether they were evaluated with studies conducted in experimental settings in which participants were aware of being exposed to media interventions, or were assessed with studies carried out in a field environment which are more likely to show the real-life effects of large national media campaigns, but are also more prone to risk of bias.

Findings appear to vary considerably according to the type of intervention and study design. Pooled analyses of eight interventions evaluated in an experimental setting provided no evidence of beneficial effects for use or intention to use illicit drugs, an indicator of possible future behaviour.[30 31] Four interventions evaluated with eight field studies revealed some evidence of beneficial effects: (1) the revamped campaign by the Office of National Drug Control Policy (ONDCP) called Above the Influence, which was found effective in one study and effective among eighth-grade girls in another study; (2) the Be Under Your Own Influence media-community intervention; (3) the Meth Project campaign, which was found effective on past-year methamphetamine use, although only among adolescents aged 12–17 years; and (4) the US televised antimarijuana campaigns broadcast in Fayette County (Lexington), Kentucky and in Knox County (Knoxville), Tennessee, which were found to be effective on high-sensation seekers. Two mass media campaigns showed clear iatrogenic effects, most notably, the first version of the ONDCP's media campaign My Anti Drug, which was evaluated by two studies and was found to increase use of marijuana. An adverse effect was also found for a media-community intervention evaluated by a CBA study which provided evidence of increased frequency of LSD use.

No characteristic emerged clearly as a core feature of successful or unsuccessful campaigns, either regarding their explicit or implicit theoretical background or their communication strategies. However, it is worth noting that two out of the four interventions providing evidence of effectiveness, the ONDCP's Above the Influence national campaign and the Be Under Your Own

Influence media-community intervention promoted non-use of drugs as a way to support the goals of autonomy and achievement of competence, both of which have been conceptualised as innate psychological needs that persist over the lifespan.[21] Among the interventions which provided evidence of harmful effects, the first version of the ONDCP's media campaign My Anti Drug was based on a social marketing approach which emphasised resistance skills, self-efficacy, normative education and negative consequences of drug use.[32] These mediators are suspected to have increased the perception of prevalence of drug use in the target population.[33]

An important reason for the weak evidence obtained by this review is the large variation in mass-media intervention type and study design. Similar interventions were often evaluated with different study designs while different interventions were sometimes evaluated with the same study design. Pooled analyses could thus be undertaken only for a few similar interventions evaluated with the same study design, and such small sets of pooled studies did not allow sensitivity analyses to be carried out. We did not set any time or language constraints to our search, accepted all types of controlled study designs and obtained unpublished data by establishing direct contact with the authors of the original papers. Unfortunately, owing to the paucity and inconsistency of available evidence, we cannot draw general conclusions as to whether media campaigns are effective in preventing the use or the intention to use illicit drugs. This observation is in line with the findings of similar reviews that used more restrictive inclusion criteria.[29 34]

The evidence base accrued so far on media campaigns targeting illicit drugs allows us to make at least two remarks. First, such campaigns can be evaluated—a fact that is often questioned in several parts of the world—and properly conducted evaluation studies can provide benefits to both research and practice. Second, in the worst-case scenario, media campaigns can be both ineffective and harmful. Contrary to common belief, antidrug media campaigns may be damaging and their dissemination is ethically unacceptable without a prior assessment of their effects.[35 36] New campaigns should be implemented in the framework of rigorous evaluation studies, ideally in field settings with cohort or ITS study designs. A better understanding of which media interventions work best is likely to result in a more effective prevention of drug use and increased efficiency in the management of public resources.

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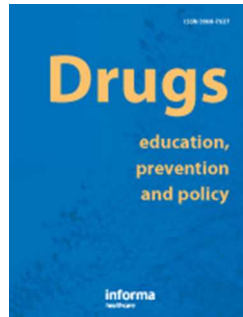
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Web- and text-based interventions for smoking cessation: meta-analysis and meta-regression

Abstract

Background In the past decade, several smoking cessation interventions have been developed and implemented through information and communication technology (ICT). Evidence suggests they might be suitable for large-scale public health interventions, based on updated communication media characteristics in terms of interplay between technology and graphical user interface, reaching high numbers of individuals.

Objectives We aimed at estimating Web/text-based interventions effectiveness as compared with approaches routinely used for general population, i.e., smoking assessment or non-electronic self-help materials.

Methods A systematic review and meta-analysis was performed searching through PubMed, Embase and PsycInfo and references of relevant papers. Heterogeneity and risk of bias were evaluated following standard methods. In addition, we performed meta-regression analyses testing if candidate covariates moderate the overall effect.

Results Slight but significant effectiveness was found for eHealth interventions over control conditions (RR=1.28, 95%CI: 1.14-1.45). Meta-regressions showed similar findings for Web- and text-based interventions. The effect seemed moderated by the follow-up period, being higher at 3 months and lower at 6/7 months-follow-up.

Conclusions Our results outline moderate effectiveness of Web/text-based interventions. However, a paucity of properly controlled studies and lack of information on several effect modifiers still hamper the development and implementation of smoking cessation interventions through ICT.

Keywords: tobacco; eHealth; smoking cessation

Web- and text-based interventions for smoking cessation: meta-analysis and meta-regression

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Web- and text-based interventions for smoking cessation: meta-analysis and meta-regression

INTRODUCTION

In the last twenty years, several smoking cessation interventions have been developed to be implemented, through information and communication technology (ICT) (Balmford et al., 2013; WHO, 2016). These efforts have been driven by two widely acknowledged factors, i.e., the epidemiological relevance of tobacco smoking and the capability of the new communication technologies to instantly deliver information. The World Health Organization defined tobacco smoking as 'one of the biggest public health threats the world has ever faced', with about 1 billion tobacco smokers in the world, causing 6 million deaths per year (WHO, 2015) for several non-communicable and communicable diseases, respectively (e.g., coronary heart conditions, stroke and lung cancer (CDC, 2015), and tuberculosis (WHO, 2009)). This holds true despite tobacco smoking being considered the most preventable cause of death and diseases (WHO, 2014).

Primary and secondary prevention programmes for tobacco smoking need to reach a high number of individuals (CDC, 2014), prompting a growing interest in new ICT interventions. In 2015 there were more than 7 billion mobile phone subscriptions worldwide, up from less than 1 billion in 2000, and more than 80% of people in developed countries, and 35% in developing ones, use the internet (ITU, 2015). Moreover, as regards preventive programmes, ICT-based implementation approaches seem highly cost-effective, since the cost of hosting a website with up to 600,000 visitors, and treating 8,000 of them each year, might be comparable to the cost of running a smoking cessation clinic capable of treating about 600 smokers in the same time period (Etter, 2005; Balhara & Verma, 2014).

Thus, several ICT interventions aimed at treating tobacco addiction, both as stand-alone approaches and nested within more complex programmes, have been developed (Cummins et al., 2012; Sheffer et al., 2012; Peng & Schoech, 2013). Along with traditional programmes based on phone counselling "quitlines", these interventions are based on Internet/text-messaging services, and seem promising in order to reach the highest number of users with relatively low costs and organizational efforts (Civljak et al., 2013). This seems due to the intrinsic absence of any waiting list, ease of use in terms of time and places, and guaranteed privacy for users (Gulliver et al., 2015; Skov-Ettrup et al., 2014).

Furthermore, individual attitudes towards electronic devices have been constantly changing over time (Bock et al., 2004; Simmons et al., 2013). Indeed, people are more inclined to surf the web in search of health information since these are able to provide individualized and interactive information in a way that influences individual decision-making processes about their own health care (Bock et al., 2004; Haug et al., 2013).

Previous meta-analyses showed that ICT interventions, including those based on web and mobile phones, might have health benefits (Graham et al, 2016; Whittaker et al., 2016; Gulliver et al., 2015; Orr & King 2015; Civljak et al., 2013; Whittaker et al., 2012; Myung et al., 2009). Promising results have also been found for digital interventions dealing with cannabis users in non-clinical settings (Hoch et al., 2016), suggesting that these applications can help people with substance use problems. However, relevant ICT interventions are becoming more complex in terms of mode of delivery (Webb et al., 2010). Indeed, they integrate interactive webpages, online chat groups, newsletters, and text-messaging services that work both automatically and on demand, often tailored to patients' clinical situation and empowerment (Ludden et al., 2015; Riva et al., 2014). Thus, a timely meta-analytic approach should take into account specific characteristics in terms of technological (Web- and text-based) and content variability. Moreover, the effect of potential modifiers on the overall effectiveness estimate should also be appropriately considered. In particular, the kind of device used for the intervention (e.g., mobile phone or personal computer), intensity and duration of the intervention, target population, and follow-up period, should all be examined in order to identify the most appropriate characteristics for effective interventions.

With a view to addressing these limitations, we conducted a systematic review and meta-analysis of relevant research to provide an estimate of the effectiveness of web- and text-based interventions in achieving smoking abstinence, as compared with appropriate control conditions, taking into account relevant factors that could influence the overall estimate.

METHODS

We performed a systematic review and meta-analysis following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) Checklist (Liberati et al., 2009). The protocol was

registered in PROSPERO (International prospective register of systematic reviews) database

(Registration code: CRD42014014561; record date: 10.29.2014).

Data Sources and Search strategy

We systematically searched for clinical trials published in the English language, between January 2005

and November 2015, PubMed, Embase and PsycInfo, as well as references of analogous meta-

analyses and reviews retrieved by our search. The search phrase combined keywords related to both

study design and interventions of interest: random*, control*, smok*, tobacco, internet, web,

computer, online, smartphone*, phone*, mobile, text, SMS, app, apps. Full search strategies are

detailed in supplementary file #1.

Eligibility criteria

We included clinical trials testing the effectiveness of web- or text-based interventions for smoking

cessation, with a randomised or quasi-randomised approach, and a control condition with no treatment

or distribution of self-help material, or with minimal amount of counseling if provided to both

experimental and control arms.

Since a very small effect was previously found for self-help materials as compared to no intervention

(Hartmann-Boyce et al., 2014), these were considered appropriate to be included as a control

condition.

We focused specifically on web- and text-based ICTs interventions for smoking cessation, avoiding

high content variability and low levels of adherence of smartphone apps (Graham et al., 2016; Abroms

et al., 2013). Thus, we excluded studies dealing with mobile apps interventions for smoking cessation,

since these seem to commonly fall short of providing tailored feedback and often need to be improved

by better integration with clinical practice and evidence-based guidelines (Hoeppner et al., 2016;

Abroms et al., 2013).

Effectiveness was measured as 7-day point prevalence tobacco abstinence (7-day PPA). This is one of

the most common measures used in the field, since it is closely related to prolonged abstinence with

satisfactory accuracy in terms of consistency, magnitude of effectiveness estimate and correlation

(Hughes et al., 2010).

We included studies with data available on 7-day PPA, and with early outcome assessment after the

intervention completion (follow-up of at least 3, and not more than 7, months). Because of reduced

comparability with interventions targeting non-comorbid smokers (McNeill, 2001; Robson and Potts,

2014), we excluded interventions developed for unhealthy special populations (e.g., for individuals

suffering from mental disorders or physical comorbidities) (Carrà et al., 2015a; Carrà et al., 2006), and

clinical trials using web-based approaches for both intervention and control conditions (e.g., Herbec et

al., 2014).

Data collection

Two authors (C.C. and D.C.) independently performed the preliminary screening based on titles and

abstracts, to include potentially relevant studies. After the first screening, articles were retrieved in full

text to assess their eligibility according to our inclusion/exclusion criteria. Moreover, reference lists of

relevant systematic reviews and meta-analyses detected by our screening were hand-searched, and

relevant studies added to our pool, when appropriate (Horsley et al., 2011). We developed a sheet for

extracting main information from each study, including year of publication; study location; inclusion

criteria; sample size; participants' characteristics; type of intervention, durations of intervention and

follow-up; allowed concurrent treatment. In order to check relevant studies' eligibility, full texts were

retrieved. Two authors (D.C. and C.C.) independently conducted data extraction, and discordances

were resolved by consensus with other authors.

Quality of evidence and Risk of bias assessment in individual studies

In order to rate the quality of evidence estimating our key outcome, i.e., effectiveness of web- and

text-based interventions in achieving abstinence, we followed the GRADE approach (Grades of

Recommendation, Assessment, Development and Evaluation) (Schünemann et al., 2008). We

evaluated evidence as high, moderate, low, or very low, according to standard items.

In addition, we used the standard Cochrane Collaboration's tool (Higgins et al., 2011) in order to

assess risk of bias of selection, performance and detection, attrition, reporting, and other biases.

Selection bias was assessed evaluating appropriateness of random sequence generation and allocation

concealment. Due to the nature of explored interventions, standard double-blind design could not be

guaranteed (Harris et al., 2006). On the other hand, performance and detection biases were evaluated

checking if blinding of personnel and outcome assessors was guaranteed. Attrition bias was

ascertained assessing proportions and balance of withdrawals from the included studies between

groups, leading to incomplete outcome data, and strategies implemented to deal with this issue. We

considered at low risk of bias those studies using full ('as randomised') or modified (excluding only

participants dropping out before receiving treatment) intention-to-treat (ITT) analyses for key outcome

(Gupta, 2011). Reporting bias was evaluated checking if, a previously registered study protocol with

sufficient agreement with the final manuscript was available, along with data on effectiveness of web-

and text-based interventions in achieving abstinence.

Finally, we assessed potential sources of indirectness (Schünemann et al., 2008). We took into account

if other treatment differences, potentially influencing clinical response, were nested within

interventions for smoking cessation.

Two authors (F.B. and C.C.) independently assessed the risk of bias. Differences in the evaluation

were resolved by consensus with other authors (G.C. and M.F.). Graphical summaries of risk of bias

were produced using RevMan (version 5.2, 2014; The Cochrane Collaboration, The Nordic Cochrane

Centre, Copenhagen).

Data analyses

A meta-analysis was carried out to estimate the combined effectiveness estimate for index, text- or

web-based, interventions as compared with control conditions, in order to increase power and

precision of the available studies (Jain et al., 2012). Since a certain degree of heterogeneity was

expected, due to the novelty value of relevant interventions, we carried out the meta-analyses using a

pre-defined random-effects model according to Mantel-Haenszel method (Deeks et al., 2008). We

estimated pooled intention-to-treat (ITT) risk ratio (RR) with relevant 95% CI for 7-day PPA. We used

the last reported appropriate 7-day PPA observation for studies including multiple follow-up observations.

Statistical heterogeneity among trials was evaluated with the I^2 index. An estimate for the proportion of overall variation attributable to between-trial heterogeneity was provided as percentage. Values of 25%, 50% and 75% were assumed to indicate low, moderate and high levels of heterogeneity (Higgins et al., 2003). Publication bias was also evaluated, using the Harbord's bias coefficient with 95% CI and two-sided p-value (Harbord et al., 2006).

Furthermore, we used suitable meta-regression analyses to test, independently, explanatory variables that might influence the overall pooled estimate, allowing the evaluation of its strength and consistency, as selected from previous research (e.g., Graham et al., 2016). We considered the moderating effect of both continuous and categorical relevant potential effect modifiers. In particular, we took into account type of intervention (Web- vs. Text-based), sample mean age, males proportion, follow-up and intervention duration, sources of sampled individuals, role of concurrent treatments (i.e., allowed or not). Data analyses were carried out using Stata statistical software package (version 13.1; StataCorp, College Station, Texas).

RESULTS

Study selection

The search identified 5351 records from PubMed, Embase and PsycInfo. After exclusion of duplicates and screening of titles and abstracts, we selected 245 potentially relevant trials and 25 meta-analyses, whose hand-searched references brought 15 additional trials. Among these, a final pool of nine trials met our inclusion criteria. The PRISMA flow diagram for identification, screening, eligibility evaluation, and inclusion of relevant studies is shown in **Figure 1**.

Figure 1 about here

Study characteristics

Studies included in this meta-analysis have been conducted in seven different countries, i.e., two in

China (Chan et al., 2015; Shi et al., 2013) and the USA (Abroms et al., 2008; Swartz et al., 2006),

respectively; and one each in Australia (Borland et al., 2013), the Netherlands (Smit et al., 2012),

Switzerland (Haug et al., 2013), Turkey (Ybarra et al., 2012), and the U.K. (Free et al., 2011). The

studies varied in size between 83 and 5,792 subjects. Five studies recruited individuals from general

population (Borland et al., 2013; Chan et al., 2015; Free et al., 2011; Smit et al., 2012; Ybarra et al.,

2012), whereas four included subjects from healthy special populations, i.e., workers (Swartz et al.,

2006), or students (Abroms et al., 2008; Haug et al., 2013; Shi et al., 2013). Five trials tested text-

based interventions (Chan et al., 2015; Free et al., 2011; Haug et al., 2013; Shi et al., 2013; Ybarra et

al., 2012), three web-based ones (Abroms et al., 2008; Smit et al., 2012; Swartz et al., 2006), and one

trial (Borland et al., 2013) both types of interventions. Among included studies duration of

interventions varied between 6 weeks and 12 months. Of the nine trials included, three (Shi et al.,

2013; Swartz et al., 2006; Ybarra et al., 2012) and five (Abroms et al., 2008; Chan et al., 2015; Free et

al; 2011; Haug et al., 2013; Smit et al., 2012) had a three- and six-month follow-up, respectively. One

study (Borland et al., 2013) had follow-up duration of seven months. Finally, the majority of included

studies allowed or encouraged additional care for smoking cessation, whereas in other two studies

(Chan et al., 2015; Shi et al., 2013) the use of concurrent treatments was an exclusion criterion.

Detailed characteristics of included studies are reported in **Table 1**.

Risk of bias

Graphical assessments of the risk of bias are reported in online **Fig. S1**.

Selection bias. Almost all studies (Borland et al., 2013; Chan et al., 2015; Free et al., 2011; Haug et

al.,2013; Shi et al., 2013; Smit et al., 2012; Swartz et al., 2006) clearly described appropriate methods

for 'random sequence generation' process, with a computer-based number generator, whereas in other

two studies methods were unclear (Abroms et al., 2008) or no information on random sequence

generation procedures was provided (Ybarra et al., 2012). On the other hand, appropriate methods for

'allocation concealment' were described in all studies.

Detection bias. In six studies (Smit et al., 2012; Swartz et al., 2006; Borland et al., 2013; Chan et al., 2015; Free et al., 2011; Haug et al., 2013) blinding of outcome assessors was satisfactorily guaranteed, though in one (Abroms et al., 2008) procedures were not entirely clear. As a whole, we thus considered the risk of detection bias as low.

Attrition bias. All studies adopted approaches dealing with attrition bias, using ITT data.

Reporting bias. All studies provided complete data on key outcome, and no risk of reporting bias was found. Moreover, six studies had an available study protocol located in main trial registries or previous publications.

Effect of interventions on seven-day abstinence

Included trials involved a total of 6,122 and 4,964 individuals for index interventions and control conditions, respectively. The meta-analysis showed a pooled RR for 7-day PPA of 1.28 (95% CI: 1.14 to 1.45; p<0.001) for web- or text-based interventions, using ITT data (**Figure 2**). Heterogeneity among trials was low ($I^2 = 17\%$), and no risk for publication bias was found (bias coefficient 0.557, 95%CI -0.829 to 1.944; p=0.373).

Figure 2 about here

Meta-regression analyses, presented in Table 2, and including separate models for potential effect modifiers, showed that duration of follow-up significantly influenced the overall estimate (coefficient -0.927 with 95%CI -1.586 to -0.269; p=0.014). In particular, likelihood of 7-day PPA, in people treated with index interventions as compared with control conditions, was higher in studies with shorter follow-up duration. None of the remaining available candidate covariates (Web- vs. Text-based intervention, sample mean age, gender, duration of intervention, population, allowed concurrent treatment), significantly moderated the effect.

DISCUSSION

Summary of evidence

This meta-analysis included nine recent trials testing Web- or text-based interventions for smoking cessation, involving 11,086 subjects. Three main findings add key evidence on effectiveness of these eHealth interventions for smoking cessation.

First, we found a slight but statistically significant effect of text/web-based interventions on seven-day point prevalence for tobacco abstinence, as compared with control conditions. Those who received the eHealth intervention had a 28% increase in probability of maintaining a seven-day tobacco abstinence, supporting relevant effectiveness. We found a low level of statistical heterogeneity, which means there is low variability in place among included studies in terms of effects attributable to the intervention. No risk of publication bias was reported, which may have been favoured by the novelty value of the topic. The apparent effectiveness of text/web-based interventions may be explained by their ability to support participants' willingness to declare themselves ready to quit (Swartz et al., 2006).

Second, although our overall findings are consistent with previous, relevant, meta-analyses (Myung et al., 2009; Whittaker et al., 2012 Civljak et al., 2013; Graham et al., 2016; Whittaker et al., 2016), these did not focus on potential effect modifiers. In our meta-analysis, we could uncover also the relationship between various clinical and methodological characteristics (as explanatory variables) and the size of the effect of the Web- or text-based interventions for smoking cessation, using appropriate random effects meta-regression analyses taking into account both within-trial variances of treatment effects, and residual between-trial heterogeneity. As potential sources of heterogeneity we investigated a set of covariates from the literature, including type of intervention (Web- vs. text-based, durations of both follow-up and intervention, potential concurrent treatment, along with mean age, male proportion and involvement of special populations). These characteristics did not seem to significantly influence the pooled estimate for the intervention effectiveness, except for follow-up duration. The follow-up duration might have a significant burden on the overall effect, being maximum at early stage (3-months) and decreasing at longer follow-up stages, eventually showing no effectiveness.

Third, although we could not directly compare the relative effectiveness of Web- and text-based interventions, we found similar effect sizes, suggesting no substantial differences in treatment effectiveness as compared with control conditions. Therefore, we were able to provide a global

measure of the overall effectiveness of Web- and text-based interventions in order to plan due large-scale interventions.

Quality of evidence and limitations

Despite early promising findings, the quality of evidence of included studies on web- and text-based interventions for smoking cessation should be considered at most 'low', following GRADE standard items. Although no selection, detection, attrition, and reporting biases were found for included studies, we could uncover at least two factors downgrading quality of evidence from the current meta-analysis. First, reported effect sizes, though consistent, were accompanied by a great uncertainty with wide confidence intervals, due to the relatively small sample size of some studies. Moreover, studies producing the biggest effects were also those with the smallest sample sizes (e.g., Abroms et al., 2008). The exploratory nature of these studies (e.g., designed to determine the feasibility of an innovative program) could partly explain this. However, in our analysis no evidence of small-study effects was found by using the appropriate Harbord's test.

Further issues downgrading evidence include both some potential indirectness, in terms of comparability of different treatments for smoking cessation, and a differential attrition in treatment and control groups. Only two studies explicitly excluded people currently following other forms of smoking cessation programmes (Chan et al., 2015; Shi et al., 2013). On the other hand, the majority of studies (Abroms et al., 2008; Borland et al., 2013; Free et al., 2011; Smit et al., 2012; Swarts et al., 2006; Ybarra et al., 2012) included people allowed, and sometimes encouraged, to be treated with a wide range of programmes for smoking cessation (e.g., nicotine replacement therapy, bupropion or varenicline, telephone helpline) (Balmford et al., 2013).In another study (Haug et al., 2013) this information was not provided.

This seems consistent with routine health care delivery, in which concurrent treatments for smoking cessation are simultaneously offered. Unfortunately, data on concurrent pharmacological treatments were not reported in all included studies, and we could not appropriately evaluate their relative effect on smoking cessation. Thus, although our meta-regression analyses did not show any influence of concurrent treatments on 7-day PPA overall estimate, the contribution of potential medications

remains ultimately unknown, and we cannot exclude that the estimate for eHealth intervention

effectiveness was inflated by an indirectness-related bias.

Furthermore, some limitations in terms of generalizability of our results should be also taken into

account. We carried out random effects meta-regressions with nine studies, although meta-regression

analyses generally should not be performed including less than ten studies (Deeks et al., 2008) for

power considerations. However, we choose to take into account clinically meaningful characteristics

as regards effects on the estimate attributable to the intervention (e.g., Web- vs. text-, durations of both

follow-up and interventions, concurrent treatment, mean age, male proportion, and inclusion of special

populations), rather than providing a conclusive list of potential effectiveness moderators.

Nevertheless, since low variability was noticed for some of these (e.g., whether other cessation

treatments were allowable), further research is needed.

Implications for research and practice

Our findings suggest that text- and web-based interventions are effective in smoking cessation with a

slight, though significant, effect on abstinence rates. Given the modest size of the effect, further

clarifications are needed from future research. First, it seems important to identify users who may be

more adequate for these eHealth interventions, but also novel approaches tailored for specific

populations, since the device type may be as important as contents of the interventions, with different

outcomes on different populations (Borland et al., 2013; Ybarra et al., 2012). Second, we could detect

a slight short-term effect, which might result in a cumulative effect over time. Poor medium- and long-

term effectiveness of these interventions in their present form suggest the need of including regular

feedback and repeated administrations, implementing new formats to be tested in terms of usability

and effectiveness. Considering decreasing effectiveness at a longer follow-up, there might be the need

to provide repeated eHealth tobacco-cessation interventions, in order to maintain sustained abstinence,

even more since relapsed smokers show interest in trying to quit smoking again in the near future (Fu

et al., 2006). Previous evidence showed a meaningful relationship between the number of feedbacks

and smoking abstinence similar to a dose–response effect (Smit et al., 2012). Similar interventions

have been developed and evaluated assessing their ability to facilitate changes in health behaviours

related to chronic diseases and health promotion, including physical activity promotion, healthy diet, and mammography screening (Kosma et al., 2005; Haerens et al., 2007; Prochaska et al., 2005; Krebs et al., 2010). All these interventions' effects decreased over time, eventually showing no effectiveness at long-term follow-up, although obviously relapses are more likely at later follow-ups, regardless of treatment modality. However, it seems that in most eHealth interventions study participants are not engaged with the programme when they might need it most, but only at fixed points in time with a decrease in self-effectiveness, and an increase in positive smoking outcome expectancies and in negative effect over time (Shiffman et al., 2007). Thus, there is the need to boost administrations integrating ecological momentary assessment with real-time data collection, enabling the adaptation of intervention content and appearance, following changes in individual attitudes towards electronic devices, motivational characteristics, and decision-making process (Smit et al., 2012). Furthermore, there may be the need to tailor tools in order to attract participants such as ex-smokers in the long-term period to prevent relapse (Smit et al., 2012), since they are more likely to feel engaged when the programme provides relevant feedbacks at the right time, increasing information relevance (Krebs et al., 2010). Finally, information on adherence and clinical effectiveness, such as perception of own tobacco consumption, and motivation to quit smoking, should be collected and taken into account since these might influence the individual response to the intervention (Zeng et al., 2015). For example, similar eHealth interventions have been recently developed, considering factors known to influence tobacco addiction at least among women such as fear of weight gain, lack of social support, stress, depressed mood and menstrual symptomatology (Giacobbi Jr. et al., 2016).

CONCLUSION

There is a growing interest in taking advantage of ICT in clinical practice (Cunningham, 2016). Consistently, many studies have explored the use of eHealth tools (text- or web-based interventions and mobile apps) in order to prevent relevant unhealthy behaviours in the addiction field (McClure et al., 2013; Gustafson et al., 2014; Wood et al., 2014; Carrà et al., 2015b). Evidence-based eHealth interventions rely on personalized individual engagement for informed decision-making, providing encouraging results also for people not seeking treatment (Carrà et al., 2016). Given the high societal

cost of tobacco smoking, these interventions have become crucial in public health initiatives. Our

findings show that stand-alone Web- and text-based interventions are promising for treating tobacco

addiction, but firm evidence cannot be drawn so far. Despite the rigorous approach followed in this

meta-analysis, our findings should be interpreted with caution given both the small number of trials

meeting inclusion criteria, and reported quality issues. Thus, further randomized controlled trials are

needed, dealing also with adherence and clinical effectiveness issues, on different types of eHealth

interventions, and adequately powered for more complex evaluations such as multiple treatment meta-

analyses.

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Table 1. Characteristics of included studies

Study	Country	Participants (N)	Sample mean age (SD), yrs.	Gender (% male)	Type of intervention (N)	Control condition (N)	Duration of intervention	7-day PPA follow-up*	Concurrent treatment
Abroms et al., 2008	USA	Undergraduate students[d] (N=83)	19.8 (1.3)	54%	Web-based (N=48)	Self-help material (N=35)	6 months	6 months	Allowed
Borland et al., 2013	Australia	General pop.[a] (N=1987)	42.1 (range 18–80)	N/A	Text-based (N=756) Web-based (N=809)	information on available assistance (N=422)	1 month	7 months	Allowed, encouraged
Chan et al., 2015	China (Hong Kong)	General pop.[a] (N=665)	N/A	82%	Text-based (N=335)	Booklet (N=330)	2 months	6 months	Not allowed
Free et al., 2011	UK	General pop.[b] (N=5792)	36.8 (11.05)	55%	Text-based (N=2911)	study participation messages (N=2881)	31 weeks	6 months	Allowed
Haug et al., 2013	Switzerland	Vocational high school students[c] (N=755)	18.2 (2.4)	48%	Text-based (N=372)	Assessment (N=383)	3 months	6 months	N/A
Shi et al., 2013	China (Shangai)	Vocational high school students[c] (N=179)	17.3 (1.0)	96%	Text-based (N=92)	Pamphlet (N=87)	12 weeks	3 months	Not allowed
Smit et al., 2012	The Netherlands	General pop.[a] (N=1123)	49.5 (32.5)	48%	Web-based (N=552)	Assessment (N=571)	6 months	6 months	Allowed, encouraged when cigarettes per day ≥ 10
Swartz et al., 2006	USA	Workers[a] (N=351)	N/A	48%	Web-based (N=171)	Waiting list (N=180)	90 days	90 days	Allowed, information provided within the intervention.
Ybarra et al., 2012	Turkey	General pop.[a] (N=151)	35.9 (9.9)	61%	Text-based (N=76)	Brochure (N=75)	6 weeks	3 months	Allowed, encouraged when cigarettes per day ≥ 10

SD=standard deviation; N/A =information not available. All studies involved current smokers or at least quitters in the previous two weeks (Borland et al, 2013)
*after study inclusion; [a] age≥ 18 years; [b] age≥ 16 years; [c] aged 16-19 years; [d] aged 18-23 years

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Table 2. Meta-regression analyses: 7-day PPA and potential effect modifiers

Variable	Number of studies included	Coefficient	P
Type of interventions [a]	8	0.376	0.326
Mean age	7	-0.012	0.297
Males proportion	8	-0.008	0.509
Follow up [b]	8	-0.927	0.014
Duration of intervention	9	-0.132	0.251
Special populations [c]	9	0.521	0.096
Concurrent treatment [d]	8	0.281	0.508

Comparisons for dichotomous variables: [a] web- vs. text-based interventions; [b] 6 vs. 3 months follow up; [c] students/workers vs. general population; [d] allowed concomitant treatment vs. not allowed

Web- and text-based interventions for smoking cessation: meta-analysis and meta-regression

Figure captions

Figure 1. PRISMA Flow diagram of data collection and selection of relevant studies

Figure 2. Pooled analysis for Web- and text-based intervention effectiveness on 7-day PPA

Figure S1. Risk of bias assessment

Figure 1 – PRISMA Flow diagram of data collection and selection of relevant studies

N=**5351** records identified through databases searching

Duplicate records removed (N=1997)

N=**3354** single records

Screening of titles and abstracts

N=**245** potentially relevant trials

N=**25** meta-analyses

N=**15** potentially relevant trials

N=**260** full text articles assessed for eligibility

N=251 trials excluded:
27 because not RCTs or quasi-RCTs
39 for inadequate comparison
38 for inadequate outcome
101 for inadequate interventions
18 with unhealthy special populations
28 for other reasons (e.g., lack of data, secondary analyses of other studies, mere protocol descriptions)

N=**9** trials included in the meta-analysis

Study	RR (95% CI)
Abroms et al., 2008	1.75 (0.68, 4.52)
Borland et al., 2013	1.12 (0.91, 1.39)
Chan et al., 2015	1.01 (0.75, 1.37)
Free et al., 2011	1.32 (1.20, 1.46)
Haug et al., 2013	1.43 (0.88, 2.31)
Shi et al., 2013	1.76 (0.74, 4.20)
Smit et al., 2012	1.37 (0.89, 2.10)
Swartz et al., 2006	2.46 (1.16, 5.21)
Ybarra et al., 2012	2.47 (0.81, 7.52)
Overall (I–squared = 16.9%, p = 0.292)	1.28 (1.14, 1.45)

.68   1   7.52

Forest Plot

196x140mm (300 x 300 DPI)

Figure S1. Risk of bias assessment

	1. Random sequence generation	2. Allocation concealment	3. Blinding of outcome assessors	4. Complete outcome data
Abroms et al., 2008	(?)	(+)	(?)	(+)
Borland et al., 2013	(+)	(+)	(+)	(+)
Chan et al., 2015	(+)	(+)	(+)	(+)
Free et al., 2011	(+)	(+)	(+)	(+)
Haug et al., 2013	(+)	(+)	(+)	(+)
Shi et al., 2013	(+)	(+)	(-)	(+)
Smit et al., 2012	(+)	(+)	(+)	(+)
Swartz et al., 2006	(+)	(+)	(+)	(+)
Ybarra et al., 2012	(?)	(+)	(-)	(+)

Web- and text-based interventions for smoking cessation: meta-analysis and meta-regression

Supplementary file 1 - Search phrase for data collection

((((random*[Title/Abstract]) OR control*[Title/Abstract])) AND ((smok*[Title/Abstract]) OR tobacco[Title/Abstract])) AND (((((((((((((internet[Title/Abstract]) OR web[Title/Abstract]) OR computer[Title/Abstract]) OR online[Title/Abstract]) OR offline[Title/Abstract]) OR smartphone*[Title/Abstract]) OR phone*[Title/Abstract]) OR mobile[Title/Abstract]) OR text[Title/Abstract]) OR sms[Title/Abstract]) OR quitline*[Title/Abstract]) OR "app"[Title/Abstract]) OR "apps"[Title/Abstract])

This search phrase was used for Pubmed. Similar search phrases were used in Psycinfo and Embase. Filters were used to select only articles published in English between January 2005 and November 2015.

Paper 6: Time, consensus and implementation: challenges for effective knowledge exchange

noted that value-based decisions may be unavoidable in specific circumstances. In reviewing the evidence for WHO recommendations for mental disorders [8], for example, it was found that for strategies aimed at improving community attitudes towards people with mental, neurological and substance use conditions, the evidence base was very poor and indirect. Nevertheless, because of strong values and the importance of improving community attitudes, panel members made a recommendation to consider the planning and implementation of activities such as anti-stigma campaigns. It should be emphasized that the added value of GRADE in these circumstances is that it is required to report transparently that some recommendations are based on strong values and weak evidence. This adaptation and contextualization of the evidence has been highlighted recently as a crucial aspect when putting the principles of evidence-based medicines into practice, and has been called real evidence-based medicine [9].

In the field of mental, neurological and substance use disorders the greatest benefit in the next decade will derive from providing better care based on current knowledge [10]. In order to convert this forecast into action, Cochrane reviews should be increasingly designed in partnership with selected stakeholders [11], giving priority to those who have been implementing activities and programmes for scaling-up care for disorders of high priority, especially for the LAMICs.

Declaration of interests

None. As Director of a WHO Collaborating Centre, Corrado Barbui has been providing methodological support to the WHO in the development of evidence-based recommendations using the GRADE approach. Corrado Barbui is also one of the Editors of the Cochrane Collaboration Depression, Anxiety and Neurosis (CCDAN) group.

Keywords Cochrane reviews, GRADE methodology, implementation, observational studies, randomized clinical trials, WHO guidelines.

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TIME, CONSENSUS AND IMPLEMENTATION: CHALLENGES FOR EFFECTIVE KNOWLEDGE EXCHANGE

The necessity of allocating available, and often scarce, resources to effective interventions [1] has increased awareness of the importance of having a sound evidence base to inform decision-making. For example, the European Union Drug Strategy and Action Plans and regional drug strategies call for the implementation of evidence-based policies [2].

These developments present an opportunity for the adoption of evidence-based guidelines such as those mentioned by Davoli *et al.* [3] and published by the World Health Organization (WHO). In addition, they put pressure on the organizations that disseminate systematic reviews and guidelines to promote knowledge exchange and enable informed decision-making [4]. Nevertheless, important obstacles remain to be solved before the Cochrane and Grading of Recommendations, Assessment, Development and Evaluations (GRADE) method for developing

evidence-based guidelines becomes the gold standard for guidelines in the field of drug addiction.

These obstacles pertain to three main dimensions, which will be discussed below: (1) time, (2) consensus and (3) implementation.

Time

No matter how fast and adequate is the identification, assessment and synthesis of evidence, it will never catch up with the new demand for knowledge.

The time allowed for decision-making, at individual or at political level, is short compared with the time required for accurate systematic reviewing and recommendation development. This is especially true for emerging problems such as new psychoactive substances and new patterns of drug use where, even in the absence of consolidated evidence, decisions need to be taken quickly [5].

The handbook of the Cochrane Collaboration [6] states that it generally takes 12 months to conduct a systematic review. If, in practice, this is a theoretical quantity, because systematic reviews require longer efforts, for decision-making this is an incommensurable time (for example, the rotating Presidencies of the Council of the European Union have a 6-month time-span [7]). In order to enable informed decision-making, it is necessary to invest in rapid methods to identify and assess the available evidence and to communicate the uncertainties and knowledge gaps.

Consensus

The guidelines development panels ensure consensus among participants by disclosing conflicts of interest, assessing the level of the evidence and determining the strength of the recommendations.

These panels are composed of methodologists performing systematic reviewing and clinicians with practical knowledge derived from contact with patients. The first group of professionals assess and synthesize the evidence (and assign the level of confidence in the available evidence) and the second group of professionals endorse the level of evidence. Finally, together they draft the recommendations and determine the strength [3: Table 4].

In order to reach a final agreement on the recommendations, some negotiations take place within the panel. These negotiations are a crucial aspect of the translation of evidence into recommendations for practice.

The question is whether or not these negotiations have a rational base. In other words, do the methodologists determine the impact of evidence-informed treatment on real patients? Do the clinicians believe that the statistical inferences from a meta-analysis apply to their patients? Recent research from other fields of knowledge has raised

doubts concerning the rationality of decisions by experts [8] that are worth considering.

Implementation

The third critical element in the Cochrane and GRADE methodology for developing guidelines in drug addiction is the implementation aspect.

The tables of evidence proposed by the GRADE Working Group to synthesize the results of systematic reviews are extremely complicated and are difficult to apply in practice. Research shows that most guidelines have little impact in practice [9] and, apparently, one of the main obstacles to implementation is lack of clarity. Methods to ensure implementability of guidelines [10] should be incorporated into the development process, ensuring that they do not extend the production time.

The Cochrane GRADE method is a step forward for guidelines development in the addiction field, but challenges remain for enabling evidence-informed decision-making.

Declaration of interests

None.

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RESPONSE TO COMMENTARIES

The authors of the two commentaries [1,2] raise interesting issues about the role of Cochrane Systematic Reviews in informing international guidelines, and give us the opportunity to describe some of the ongoing efforts of Cochrane to address these challenges. For this reason, we invited Cochrane's Editor-in-Chief to join us in preparing our response.

The first challenge is the mismatch between what Cochrane can offer and what the World Health Organization (WHO) actually needs; the author underlined that: 'for some questions, and for several outcomes that are key for guideline developers, no data are available from Cochrane reviews'. This is indeed true, but whether a Cochrane Review can draw useful conclusions depends upon results from primary studies being available and sufficient. One of the most frequent mismatches between the wishes of guidelines providers and what can be produced in Cochrane Reviews relates to the breadth of the PICO (Population, Intervention, Comparison, Outcomes) elements covered. It is frequently the case that guideline producers require greater breadth (e.g. multiple subgroups) than the evidence can cover without threatening its validity.

The lack of well-conducted primary studies addressing relevant questions and outcomes is therefore a concern, therefore every Cochrane Review includes an 'implication for research' section which focuses on future research needs, in terms of outcomes and participants, but also setting priorities and identifying areas of uncertainty.

We acknowledge that an issue of prioritization also exists for Cochrane Reviews themselves. A major effort has been made in recent years to ensure that Cochrane Reviews address the questions and uncertainties of most importance to decision-makers. Cochrane has also developed a partnership with the Guidelines International Network. Through this, we seek to work actively with guidelines producers to ensure that Cochrane Reviews meet the producers' needs to the greatest extent possible.

The second challenge relates to the fact that most Cochrane Reviews include only randomized trials, although there are Cochrane groups that have always included non-randomized studies routinely. We recognize that for some outcomes, in particular those that are rare or delayed in onset, or both, the opportunity of evaluating the evidence from non-randomized studies is crucial to guide decisions. This raises additional challenges, including those of retrieving relevant studies, and evaluating the risk and direction of bias in such studies. Cochrane contributors, including the leadership of the Cochrane Drugs and Alcohol Group, have recently been engaged in an important project to develop a risk of bias tool for non-randomized studies.

The third challenge relates to the comprehensiveness of the search; Barbui states that: 'if Cochrane reviews systematically miss a proportion of evidence from low or middle income countries (LMICs), then their relevance in informing WHO recommendations, which are especially focused on the needs of LMICs, cannot be expected to be very high'. All Cochrane editorial teams include information specialists who develop expertise in locating and retrieving reports from high-quality studies in their discipline, and many of these hand-search relevant journals to identify such studies. However, we are not complacent. We would be pleased to benefit from the expertise of those who are familiar with the literature based in LMICs, and welcome a collaborative approach.

The fourth concern, raised by Ferri, relates to the need of 'negotiation among panel members in order to reach a final agreement on the recommendations'. We agree that health-care decision-making is complex. The GRADE working group has put a major effort into making this process more explicit and transparent [3].

The DECIDE (Developing and Evaluating Communication strategies to support Informed Decisions and practice based on Evidence) project, a GRADE (Grading of Recommendations Assessment, Development and Evaluation) working group initiative funded by the European Union, has developed Evidence to Decision (EtD) frameworks for different types of decisions and recommendations. The purpose of EtD frameworks is to help panels to use evidence in a structured and transparent way to reach decisions about clinical recommendations, coverage and health system and public health interventions. The EtD frameworks have been developed to make explicit judgements about benefits and harms of the options, values, resource use, equity, acceptability and feasibility [4].

Paper 7: Study designs for prevention responses' evaluation: feasibility and acceptability

Study designs for prevention responses' evaluation: feasibility and acceptability

What do we mean by evaluation of prevention interventions for behavioural change? (submitted)

Marica Ferri, Franz Trautmann, Gregor Burkhart, Sonia Dias, Holger Schunemann, Giuseppe Carrá, Fabrizio Faggiano

Introduction

Policy documents in Europe and beyond are increasingly demanding evidence-based interventions, supported by practice guidelines and quality standards [1] and implicitly call for evaluated interventions.

This is also a requirement for interventions aimed at preventing the onset or changing risky behaviours, like for example tobacco smoking, sedentarity, alcohol abuse, high energy intake diet.

Some researchers have been calling the attention on the risks of providing preventive interventions especially to young people, that are not supported by a sound evidence and suggested that a trusted databank of proved preventive interventions should be created [2] and its use made mandatory. These authors propose that similarly to medicine approval systems, prevention interventions should be evaluated in four sequential phases. The first one should evaluate the effect of single components interventions on short term outcomes through an experimental or observational study; the second and third phases should test more of the single components interventions together assessing the effects of these multicomponent interventions with scientifically robust study designs (ideally randomized controlled studies). The four and last phase should then assess the effectiveness of those interventions, approved through the initial phases, in a real world context.

The Society for Prevention Science set a number of standards to be met before an intervention can be considered scientifically based [3]. These standards encompass the disciplines and the methodologies that should be incorporated in order to scientifically support prevention interventions. These disciplines include epidemiology, statistics, sociology, and neuroscience. Furthermore the research design and its methods and measurements have to reflect the underlying intervention theories, ensure minimization of errors, and consider contextualization. Prevention researchers – continues the report, rely on statistical techniques developed for prevention research or drawn from other fields, including epidemiology [3].

Nevertheless, a question that has been posed is if traditional epidemiological study designs conceived for appraising evidence about prevention and treatment in clinical practice fits to evaluative research on public health [4]. The idea at the base of evaluation is that interventions should have an expected impact i.e. there is a causal relation between the provision of the intervention and the outcomes. Causality in Epidemiology has been considered to study aetiology; but the evaluation of interventions was conceived in the social sciences like education

and psychology [5] . The differences between these two groups of disciplines complicated the development of a common understanding on which evidence is needed to enable decision making. Evaluation of prevention research should answer questions about the effectiveness of an intervention for whom and in which cultural and social context [6] .

One of the arguments discussed in the evaluation of preventive interventions is that the relations among interventions and outcome measures should be supported by sound theories [7]. Theories in public health may play the role of plausibility in the causal model of epidemiology. In the Bradford-Hill model of causation [8]nine points of view are discussed to hypothesise the causal model and these involve: strength of association, consistency of observations, specificity and temporality of events. The latter four dimensions being related with the credibility of the observations. The subsequent three elements in the Bradford Hill's list are biological gradient, plausibility and coherence. Three elements that seem to play a similar role as the theories play in the explanation of human behaviour and reactions in the evaluation of public health interventions.

The most powerful study design to assess the effectiveness of intervention (or the causality between exposition to an intervention and change in the outcomes) is the Randomized Controlled Trial (RCT), where the participants in the study constitute a homogeneous group who is randomly assigned to experimental or control interventions. Even though it is recognized that RCTs are the strongest study design to assess the effectiveness of interventions, they may not be feasible in the evaluation of some prevention interventions [6] .

RCTs and systematic reviews of RCTs are at the top of the pyramid representing the strength of evidence [9] and the observational studies occupy a lower place. Nevertheless in the field of health promotion, many consider the interventions evaluated in randomized controlled trials simply not transferable to other populations, mainly because the effects that can be obtained in experimental conditions cannot be replicated in real contexts. In addition, also those field workers that are convinced about the importance of scientific evaluation may face a number of practical obstacles in their attempts to implement it.

The evaluation of interventions should be able to disentangle the ability to detect the effect from the effect of the intervention itself. In other words evaluation should distinguish unsuccessful interventions from unsuccessful implementations [4].

Typically, prevention interventions are multi-component, pragmatic and context dependent [4]. As a consequence, good evaluation studies should be comprehensive enough to capture all these dimensions but not at the detriment of feasibility and affordability. An evaluation study requiring more resources than the intervention to be evaluated would be paradoxical.

The discussion around the types of study design that are helpful for the evaluation of interventions may have a direct impact on the diffusion of prevention programmes. Indeed the quality and type of evaluation studies are at the base of selection criteria for several databases of best practices addressing commissioners, professionals and potential implementers [10] .

Cochran (1965) [11]defined an observational study to be an empirical investigation in which the "objective is to elucidate cause-and-effect relationships [in settings in which] it is not feasible to use controlled experimentation, in the sense of being able to impose the procedures or

treatments whose effects it is desired to discover, or to assign subjects at random to different procedures" (p. 234).

The tension between the need for rigorous evaluation and the feasibility and credibility of evaluation results has been the focus of the reflections around the realist evaluation methods.

The realist evaluation method was introduced at the end of the nineties by two English authors, Richard Pawson and Nick Tilly (1997) [12]. This system was accepted in various disciplines including philosophy [13], law [14] , psychology [15] , economics[16] sociology [17] and management studies [18]. The approach proposed by the two methodologists is difficult to represent in brief. It starts with a good criticism of the simplification of the evidence base approach and its experimental designs providing black and white answers, and proposes a method to capture the complexity of reality. The promising objective is to be able to say what works for whom in which circumstances. Virtually all the research techniques are then involved in the evaluation that aims at capturing the complexity. It is imaginable that considerable time and resources are allocated to this extensive evaluation for which results the authors realistically say that "it should be possible to detect something about the conditions and circumstances in which the intervention is mounted which allow for and make sense of the observed process and outcome" [12] (Pawson and Tilly, 2004 page: 16).

Let the discussion about the generalizability of the results obtained with the realistic approach and the pressure of time on the decision-makers that may not allow for the detailed evaluation method proposed, alone, the issue of the combination of several study designs to make sense of complexity remains crucial across several approaches.

A response to this need has been proposed by an international group of methodologists. The mission of the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) working group is to help resolve the confusion among the different systems of rating evidence and recommendations[19].

The GRADE working group is an international network of top level experts in evidence-based medicine and beyond, who decided to try to overcome the limitations of several existing methods to score the quality of evidence to support evaluation. The GRADE methods have been applied by many organizations to produce guidelines including into interventions aimed at influencing behaviours [20] .

Furthermore, recently, in the realm of a European funded project (DECIDE) the GRADE methodology has been applied to the inclusion of qualitative studies [21]. With the GRADE methods the study assessors consider the matching between research questions and study designs along with the quality of individual study designs according to design-specific quality criteria.

The GRADE system is relevant for the Evaluation of Prevention interventions because it allows the inclusion of several study designs, according to the questions they answer and to the methodological quality. In other words the GRADE system mitigates the inflexibility of the pyramid of study quality that poses the randomized controlled studies at the top and any other study designs at a lower level, irrespectively of the questions they are called to answer.

Schunneman and colleagues [19]clarified how the GRADE system for grading the evidence includes and completes the causality criteria by Bradford Hill. In some cases, the authors of GRADE recognize that observational studies may provide more relevant information than RCTs, for long term follow-ups, for example.

The present article analyses some of the most influential databases of prevention programs in order to identify the study designs that are indicated in the inclusion criteria and therefore considered gold standard for evaluation. We will then see how often these study designs are including in the systematic reviews of evidence on preventive interventions for behavioural change and we will explore how often the GRADE method is used to integrate different study designs into the systematic reviews.

Objectives

To identify the study designs that are considered gold standard in the evaluation of prevention interventions aimed at behavioural change;

To discuss strengths and weaknesses of those study designs and,

To explore how often the GRADE method to integrate different study designs is used in the systematic reviews of evidence of preventive interventions to change behaviours.

Methods

In order to identify the study designs that are considered gold standard for evaluation of prevention interventions aimed at behavioural change, we:

a) searched the Cochrane Library (online version May 2016) for the systematic reviews with "prevention" in the title and at least one behavioural primary outcome;

b) perused four European databases of evaluated prevention program for behavioural changes;

In order to discuss the methodological strengths and weaknesses of the different study designs for the purpose of evaluation of prevention interventions aimed at behavioural changes:

a) we represented in a tabular format examples of relevant research questions with matching study designs and their strengths and weaknesses according to the GRADE [22] (Schunnemann 2010) criteria when available.

In order to explore how often the GRADE method to integrate different study designs is used in Cochrane systematic reviews of evidence of preventive interventions to change behaviours:

a) we checked whether the Cochrane systematic reviews on preventive interventions for behavioural change used the GRADE system to summarise the evidence.

Results

Study designs that are considered gold standard in the evaluation of prevention interventions aimed at behavioural change:

Cochrane reviews:

In the Cochrane Library, we identified 954 systematic reviews of prevention interventions of which 109 had a behavioural primary outcome. After exclusion of protocols and withdrawn reviews (18) we included 91 systematic reviews, 47 of which included only randomized controlled trials and 54 various combinations of different study designs like Cluster-Randomized Trials (C-RTCs), Controlled Clinical Trials (CCT); controlled before and after studies (CBA); interrupted time series (ITS) (table 1).

Table. 1 Systematic reviews on preventive interventions to change behaviours by study design and use of GRADE

Screened	Excluded	Included	Study designs considered	GRADE	
				yes	no
954	853 Protocols or reviews withrawn: 18	101	RCTs=47	20	27
			RCTs+ CCTs+ C-RCTs= 11	4	7
			RCTs+CCTs+CBA+ITS= 17	8	9
			RCTs+QuasiRCTs=11	4	7
			RCTs+Non-RCTs+CBA=3	0	3
			RCTs+CBA=4	1	3
			RCTs+QuasiRCTS+Cross-over studies=1	1	0
			Trials Controlled studies =7	0	7
			TOT=101	38	63

We also identified four European databases of evaluated prevention interventions for behavioural changes and we analysed the inclusion criteria for the type of studies requested in the evaluation (table. 2) are similar with RCTs as a first choice followed by other study designs.

Table 2. Inclusion criteria of four European Databases of evaluated prevention programs

Name, region	Scope	Inclusion criteria	Study designs	Web-address
Center for the Analysis of Youth Transition, UK	Young people and education	Seven level of evidence, at the top > than 1 RCT with positive results[22].	RCTs, controlled studies, before and after, correlation, expert opinions and descriptions of activities.	http://cayt.mentor-adepis.org/
Grüne Liste Prävention, DE	Adolescent problem behaviour	Three levels of evidence, at the top RCT, then Quasi Experimental Studies, pre-post assessment and norm reference studies[23	RCTs, Quasi Experimental Designs, Pre-post assessment, benchmark/norm and theory of change studies.	http://www.gruene-liste-praevention.de/nano.cms/datenbank/information
Prevencion baseada en la evidencia, ES	Drug addiction		RCTs, Quasi-RCTs; controlled studies	http://www.prevencionbasadaenlaevidencia.net/
EDDRA – European Monitoring Centre for Drugs and Drug Addiction EU	Drug Addiction		Various study designs	http://www.emcdda.europa.eu/themes/best-practice/examples

In order to discuss the methodological strengths and weaknesses of the different study designs for the purpose of evaluation of prevention interventions aimed at behavioural changes:

a) we represented in a tabular format examples of relevant research questions with matching study designs and their strengths and weaknesses according to the GRADE (19) criteria when available.

Table 3. Matching study designs with research questions

Study design	Example of prevention interventions	Strenghts	Factors determining limitation of evidence (GRADE) [7]	Factors increasing the confidence in the evidence (GRADE)	Considerations on the overall availability of evidence	Example of studies in prevention
RCT	Prevention programs delivered at individual or family level	Causal relation between interventions and outcomes	Lack of allocation concealment or blinding, Incomplete accounting of patients and outcome events, selective reporting or limitations like use of non-validate outcomes measures.	Results from more than one big sample RCTs with large effect size.	Preceeded by an ITS to test transferability. Followed by cohort studies to test implementation in non-experimental conditions	"Unplugged," a European school-based program for substance use prevention among adolescents: overview of results from the EU-Dap trial. (24)
C-RCT	Community based prevention interventions	Reduce risk of contamination between groups (who receive the interventions influence who does not)	Recruitment bias, analysis have to consider inter-cluster effect and the unit of analysis has to be the cluster (rather than the individuals)	Results from more than one big sample C-RCTs with large effect size.	Preceeded by an ITS to test transferability. Followed by cohort studies to test implementation in non-experimental conditions	A community based primary prevention programme for type 2 diabetes integrating identification and lifestyle intervention for prevention: the Let's Prevent Diabetes cluster randomised controlled trial. (25)
Cohort study	Prevention programs in the school	Allows to observe long term effects in rela conditions	Eligibility criteria (inclusion of control population); Measurement of both exposure and outcome; Failure to adequately control confounding; Incomplete or inadequately short follow-up.	Large effect size with no suspect for confounding factors.	To observe long term effects of programmes already assessed with a RCT or a C-RCT	Adherence to hand hygiene protocol by clinicians and medical students at Queen Elizabeth Central Hospital, Blantyre-Malawi (26)
Geographical comparisons	Multi-component community-based interventions; media campaigns	Consider complex interventions as a whole	Ecological fallacy	Availability of studies conducted in more places, adequate considerations of limitations	To study programs already assessed with a RCT or a C-RCT	Efficacy of a secondary adolescent pregnancy prevention program: an ecological study before, during and after

						implementation of the Second Chance Club.(27)
Study designs not considered in the GRADE system						
B&A	Multi-component community-based interventions; media campaigns	Considers effects of interventions over the time	pre and post intervention periods for study and control sites have to be the same; study and control sites have to be comparable with respect to dominant reimbursement system, level of care, setting of care and academic status	NA	Use of a control population	A theorybased motivational approach for reducing alcohol/drug problems in college. (28)
ITS	Multi-component community-based interventions; media campaigns	Considers effects of interventions over the time	intervention occurred at a clearly defined point in time; 3 or more data points before and 3 or more data points recorded after the intervention are available.	NA	Sufficient number of time points Use of a control population	Personal influence and the effects of the National Youth Anti-DrugMedia Campaign. (29)

Randomized controlled trials in the evaluation of prevention intervention **expand the limitations from GRADE with examples.**

Randomized controlled trials (RCT) become the synonymous of evidence –based after the movement for evidence based medicine, inspired by Archibald Cochrane [30] and initiated by David Sackett [9]. However, this assumption is not completely correct and it has been questioned by EBM movements such as GRADE. Evidence is facts and these facts can come from any source. The question is how confident one can be in the ability of the results in being generalisable. In practice randomized controlled studies are powerful study designs because they enable to isolate the effect of the interventions [31] and to control for the interfering factors.

RCT are feasible in the medical field and they are currently the gold standard for pharmacological and health technology studies. Examples of RCTs exist also in Prevention [32] nevertheless the application of RCTs for evaluating prevention interventions is challenging for several reasons including resources and methodological issues. For example contaminations between intervention and control groups can dilute the intervention effect in the evaluation of a typical prevention program aimed at changing behaviour by providing education.

Cluster Randomized Trials (C-RCT) share the same methodology of RCTs with one essential difference: the unit of randomization is not the individual but rather a cluster. In the evaluation of Prevention interventions this can be an entire region [33], or a school. Statistically speaking this study design creates one additional difficulty because of the risk of an entire cluster leaving the study and reducing dramatically the power of the study.

RCTs and C-RCTs for the evaluation of prevention interventions aimed at behaviour changes share also the same criticism on the generalizability of results. Some authors recommend RCTs for evaluation of prevention as a second line study design, after a pre-post single group study proved that the measuring instruments can capture the complexity of interventions [4].

Cohort studies and quasi-randomised trials

In cohort studies people are recruited according to their level of exposition to some intervention and followed-up across the time. Cohort can also be retrospective (the information is collected retrospectively in regard to the enrolment). Cohort studies are also resource intensive as the RCTs and the C-RCTs but they have the great advantage of providing information in a non-experimental environment, in this sense they are not subject to the same criticisms as the RCTs. Nevertheless the cohort studies are at higher risk of bias in comparison with RCTs because the causal relation between the exposure and the outcome cannot exclude the interference of characteristics of the two groups of individuals. Prospective cohort studies have been used to evaluate prevention intervention for example to assess media campaign effects (29).

Interrupted Times Series (ITS) and Controlled Before After (CBA) Studies

These two study designs are similar in their idea as both monitor some indicators before and then after the provision of the intervention to be evaluated. The measures are compared between a group that receives the intervention and a control group that does not. The Interrupted Time Series design performs observations at multiple time points before and after an intervention (the

'interruption'). The design attempts to detect whether the intervention has had an effect significantly greater than any underlying trend over time.

These study designs have been used for example in the evaluation of media campaign interventions (34). In some cases they were based on data produced independently (35.). The main limitation of this study design is the lack of control for intervening factors (for example the exposure to an unexpected media campaign –(36).

Are systematic reviews in prevention interventions aimed at behavioural change using the GRADE system to integrate evidence from different study designs?

GRADE system can potentially include in a the summary of evidence, various study designs (a part from the B&A and the ITS), it should potentially be included in the systematic review of evidence. We used the sample of reviews on preventive interventions of behavioural change, to explore how often the GRADE synthesis of evidence tables is used. Of the 101 reviews enclosed 38 included a GRADE table of evidence and 63 did not. GRADE is present more often in the reviews based mainly on RCTs (20/47) followed by the reviews including various study designs (8/17).

Discussion

There is common understanding that preventive interventions aimed at changing behaviour should be based on sound evidence, nevertheless there is no consensus on how the evidence should be gathered. One proposal is to have a central and possibly public source of evaluation studies disseminating and making the results available on large scale.

On which study designs the evaluation of preventive interventions should be based is being discussed. One point of consensus among the different actors, (for example the society for the study of prevention, the Cochrane and Campbell collaborations and the realist evaluation approach) is that several study designs should be included in the synthesis of evidence for prevention interventions aimed at behavioural change.

Each study design contributes differently to the knowledge on effectiveness of preventive interventions to change behaviours. RCTs try to disentangle the effect of the interventions from the confounding effect of the context in order to maximise generalizability. Cohort studies aim at assessing effects over longer time including the effect of context as the B&A and ITS design do. In different proportions and combinations these study designs are included in the Cochrane systematic reviews of evidence for preventive interventions aimed at changing behaviours. All these study designs are considered also by the databases of evaluated preventive interventions.

One advanced method to systematically include evidence from different study design is the one proposed by the GRADE working group. At the moment less than 40% of the relevant Cochrane systematic reviews use the GRADE synthesis of evidence tables. The Cochrane reviews do not include a reason for not having used a GRADE tables, nevertheless some considerations can be drawn. The inclusion of a GRADE table can be impossible with studies providing incomparable data, reviews without studies included, and or reviews that have been published before the availability of the GRADE table and not been updated, reviews that do not include a meta-analysis.

Conclusions

Our paper realised that there is consensus on the fact that preventive interventions aimed at changing behaviours must be based on evidence; nevertheless on which study designs the evaluation of evidence should be based is more controversial.

The main database of systematic reviews of prevention interventions and the databases of evaluated interventions both point to the inclusion of several study designs including RCTs, C-RCTs, CCTs, ITS and B&A studies.

The GRADE system allows for integration of several study designs into a synthesis of evidence and it is used in systematic review of evidence on prevention interventions for behavioural change. Nevertheless its use seems to be limited to a minority of reviews. The reasons for the limited use should be further investigated and addressed.

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5. Discussion and conclusions

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Discussion

At a time in which the global market is affecting the pattern of drug use through the appearance of new psychoactive drugs miming the effects of the old ones but trying to elude the international conventions and the national laws and when internet and social networks can become platforms to disseminate drugs, the efforts to counteract the negative effects of drugs need to be integrated to include drug demand and supply reduction.

Prevention defined in a broad sense can become the framework under which the integrated balanced approach supported in some regional strategies such as the European Union Drug Strategy, is operationalized.

Our analysis of the Regional and European National Drug Strategies to identify the political support for a wider adoption of an evidence based approach to prevention showed that there is the political will to implement evidence based prevention interventions. We revealed that the policy documents at European level allow for a wide implementation of evidence-based prevention intended in a broad sense (including demand reduction and supply reduction in a balanced way). We also noticed that in European Countries the quality of interventions is considered and systems are in place to continuously improve it. Notwithstanding, knowledge exchange to improve common understanding should be further promoted.

In Europe, most of the countries have some kind of quality assurance system in place. This can include training of professionals, adoption of guidelines and standards and accreditation systems. These systems are varied and sometimes interpretations of the same concepts differ, suggesting a need for further knowledge exchange and harmonization.

Prevention is still associated with provision of information on the risks of drug use, and the use of large-scale media campaigns to reach a high number of individuals may look like an opportunity. Our meta-analysis of studies revealed that media campaigns to prevent or reduce the use of drugs among young people are not effective. On the other

hand the use of web and text based interventions appeared promising with respect to reducing the consumption of the legal drug tobacco. The difference in the effect of similar interventions when aimed at legal versus illegal substances leaves an open question deserving more investigation. Is it possible that tobacco smokers are a larger group including various levels of dependence and that they can benefit from text and web-based interventions, whereas the illicit drugs consumers are a hidden population where only the most severely dependent are captured by studies. In addition because illegal, some drugs can be more attractive for the sensation seekers for whom information on risks is simply not interesting.

After over twenty years since its introduction, the evidence base movement is mature and evidence is available in many fields including in the field of drug demand reduction, where a Cochrane specific editorial group has been active since 1998. Nevertheless implementation of evidence-based recommendations is not yet fully achieved. The availability of evidence-based recommendations does not automatically translate into their implementation. Even the gold standard method for guidelines development, that is adopted by the World Health Organization, shows some limitations that should be addressed before it is widely adopted.

Another commonly mentioned obstacle to the implementation of evidence-based interventions is the criticism that many voice regarding the adequacy of the experimental approach to represent the complexity of reality. Many practitioners believe that randomized controlled trials and meta-analysis based on them are not sufficient to capture the complexity of situations in which health and social interventions occur. The argument is that the experimental approach tends to consider the context as a confounder whereas it constitutes the central aspects influencing the interventions and the results. This limitation seems grounded in reality and we sought possible solutions through the integration of several studies into synthesis of evidence for actions.

It seems that independently from the philosophical approach, different study designs should be applied in parallel to capture different snapshots of the complexity.

Our analysis of systematic reviews of preventive interventions aimed at behavioural changes and the search for the databases of evaluated interventions for preventive

interventions, confirmed the inclusion of various study designs aimed at changing behaviours. Nevertheless it seems that rather than being pulled together these different study designs are then narratively described separately (only a minor proportion of reviews for behaviour change include a GRADE table), we believe that the reasons for this rare utilization should be investigated and addressed.

The present investigation was aimed at identifying strategies to measure the impact of evidence- based interventions in Europe. Nevertheless, during the preliminary work it become apparent that a common understanding of the basic concepts of evidence-base and comparable data to measure the impact were not available and we refined our work towards the study of the policy and methodological premises to move forward with the creation of a European monitoring and evaluation system for the impact of evidence-based interventions.

The legal status of drugs may be at the base of differences in effectiveness of media based interventions for prevention and for discouraging use of psychoactive substances and this aspect deserves more attention especially in an historical moment in which forms of regulation of cannabis, for example, are being implemented in several countries across the world. The social undesirability of illicit drugs use, contributes to keep the community of drugs user a hidden population, the only ones we follow-up through our studies are those that seek treatment and this can represent a minority of drug users with the most severe problems and in need for treatment. If drugs were regulated and made available on the market a higher number of consumers will be visible and this will surely affect our knowledge on drug use and its consequences. Are we prepared for this? Is our knowledge sufficient to face new scenarios?

On the methodological side, the discussion on the weaknesses of the experimental approach for gathering evidence for action, in particular in preventive interventions aimed at changing behaviours, leads various researchers to reflect on the best way to handle the complexity. The alternatives proposed so far, including the realist approach, seem able to capture the complexity at the expense of generalizability but they may have a role in process evaluation of evidence-based interventions.

The present investigation has many limitations. For example the analysis of the policy documents is limited to those available in English and for the European National strategies it is complemented by abstracts in English provided by the National Focal Points. This means that the content analysis was completely missing and with it the understanding of the terminology used in the national languages. In addition, the systematic reviews of evidence included meta-analysis of primary studies but we did not analyse why the intervention failed (media campaign for prevention of illicit drugs use) or resulted as promising (text and web based interventions). In order to draw hypothesis on the reasons for failure or success we would have needed qualitative analysis of behaviours and this was not feasible within this context.

A similar limitation applies to the analysis of the process for the production of evidence-based treatment guidelines. We discussed some hypothesis that could only be tested by interviewing decision-makers, guidelines panellists and practitioners asking them for examples and possible solutions.

The last paper explores study designs and methods with the intention of including them into a synthesis of evidence in support of prevention programmes. But this remains in the realm of speculation because we do not have empirical evidence from long term observational studies following up the effects of preventive intervention in some communities.

In comparison with other health and social problems, knowledge on impact of interventions for illicit drugs is in its infancy. If we compare it with the available knowledge on cancer prevention and treatment over the last three decades, we observe a huge difference. Thanks to the introduction of the population registries of cancers developed by the International Agency for the Research on Cancer (IARC) it is possible to know for each category of diagnosis how much the waiting times from diagnosis to treatment has been reduced and how much the survival time has increased. For Europe the multiannual project EUROCARE, provides comparable data on survival rates. We can see that cancers that were lethal a few decades ago are now commonly treated and the percentage of those surviving at 5 years from the diagnosis is rocketing (for example in Italy 87% for breast cancer and 91 % for prostate cancer).

When it comes to illicit drugs treatment we don't have European data collection on outcomes of treatment, there is not even agreement on what should be the outcomes of a successful treatment. We only have estimates of the number of people entering treatment, we do not know how long they stay and the reasons for conclusions.

The efficacy of interventions is becoming clearer thanks to efforts of the Cochrane and the Campbell collaborations. It is now time to invest in population based observational studies. In case the numbers of drugs users is too small to justify cohort studies we should design European level multi-scope studies about health behaviours including drugs use. We need to know in which conditions people use drugs how and when they seek treatment, what are the effects of treatment. What makes treatment successful: abstinence? Stabilization? Social reintegration? Scenarios are rapidly changing; we need to build strong roots for our knowledge. There is no point in counting drug users in treatment if we don't make sense of the information and we don't use these numbers to improve their life, and to reduce social harm.

We will not have support from pharmaceutical industries (drugs users are not an appealing target group) but the pioneers of the Framingham studies not only did not have support from the pharmaceutical industry, they also had the fierce opposition of the tobacco industry; nonetheless they went on and in the end they changed the reality.

Conclusions

In conclusion of this work we get back to our question: Best Practices in drug demand reduction: beyond promotion, how to measure the impact?
In order to have a measurable impact, best practices or evidence-based interventions, need to be appropriately implemented. Effective implementations need a facilitating policy framework (as for example the drug strategies), national mechanisms for the quality control of interventions, a sound evidence-base and dissemination tools. In addition quality is not a static concept so that interventions need to be appropriately evaluated.
The present PhD revealed that most of the prerequisites for the implementation and monitoring of best practices in drug demand reduction, are available in Europe.

For example the world's macro-regional drug strategies do not prevent the adoption of environmental prevention strategies and, on the contrary, at least some of them, clearly indicate that comprehensive approaches that involve various stakeholders and address in a balanced way the reduction of illegal drugs in the environment and the provision of interventions for the promotion of health. We therefore consider that they represent a premise to enhance the adoption of evidence-based environmental prevention interventions. Focusing at the European national level, the national drug strategies show that quality assurance is high in priority on national agendas and it is also operationalized even though in different ways. Efforts should be put into knowledge exchange in order to harmonize the understanding and advance towards an improvement of quality of interventions, within the context of the resources and priorities set at national context.

Preventive interventions based on provision of information through media campaigns for reducing illicit drug use are not supported by evidence but web-based and text messages interventions look promising for the reduction of a licit substance use, like tobacco. A hypothesis worth testing is the relation between the legal status of a substance and its consumers' characteristics. Is it likely that legal substances are used by a larger number of people including those for whom quitting with the help of digital and e-interventions, is an option.

The translation of the evidence-base for interventions into recommendations for practice, needs a substantial process. This lengthy process includes several activities such as the identification of questions, gathering and appraisal of the available evidence, finding consensus among representatives of the practitioners (the guidelines development panel) on the interpretation and translation of evidence into statements (the recommendations). This process has been undertaken in the case of implementing evidence based treatment.. This does not come as a surprise because it is in the medical field that clinical guidelines based on evidence have been developed so far. We studied an application of the GRADE methodology for the treatment of opioid dependence and we highlighted possible bottlenecks and barriers for implementations of evidence-based interventions. We also highlighted that there is agreement on the need to evaluate preventive interventions. Evaluation of interventions is what it is pereceived as the evidence-base for prevention. We explored various databases of evidence-based

programmes and we realised that various study designs are considered as constituting good evidence. We therefore explored the use of a robust methodology to integrate results from various study designs and we realise that only a few Cochrane systematic reviews of prevention interventions aimed at changing behaviours apply this method to use various study designs.

6. References

6. References

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