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Engagement in an e-Health Tool (ORION) predicts opioid-dependent patient likelihood of behavioural change

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Summary

Background: An eHealth computer-based tool named ORION was constructed to assist patients in the clinic to appreciate the factors responsible for risks of drug overdose. The aim of this study was to investigate the associations between risk perception of overdose, engagement in the ORION tool and willingness to alter overdose risk factors. **Methods:** 194 opioid dependent patients participated from 4 countries (UK, N=39; Germany, N=99; Italy, N=40 and Denmark, N=16). A structural equation model was fitted (AMOS version 17) to summarise the predicted associations between perceived risk and willingness to change risks of opioid overdose. The degree of engagement with the tool (time spent and number of changes to overdose risk factors) was explored. **Results:** A variety of models were fitted and the most parsimonious model provided a non-significant difference between the raw data and the specified model: Chi Sq = 16.87, df10, p = .077 chi sq/df = 1.688. The fit indices: CFI = .991, RMSEA = .066. Pre and post self-assessments of risk towards known factors linked with overdose were highly correlated. A significant path was found between engagement in the tool and the willingness to change one or more risk factors (stand. coeff. = 0.16, p = .04). In addition, the final assessment of the risk factors was associated with engagement (stand. coeff. = 0.18, p = .02). **Conclusion:** The encouragement of drug users to engage in exploring changes to their overdose risk when presented on a computer screen appears to increase willingness to change risky behaviour.

Key Words: Overdose Prevention; ORION Tool; Behaviour change; Structural Equation Modelling

1. Introduction

Drug overdose in Europe remains a significant cause of avoidable death in young adults. According to the most recent estimates from the European Monitoring Centre for Drugs and Drug Addiction [18], more than 80 million adults in EU (approx. 25%) are reported to have a lifetime use of illicit drugs, with cannabis use most frequently reported. An estimated 1.3 million Europeans were treated for use of illicit drugs in 2012 and relevant mortality rate is estimated to be 17.1 cases per million population in the EU [18]. The current scene in Europe is one where drugs

such as stimulants, synthetics, medicinal products and cannabis are becoming an increasingly prevalent problem, causing considerable concern, whereas drugs such as heroin appear to be stable if not declining in use.

DSM 5 Opioid Use Disorder [1], combining DSM-IV-TR [2] Opioid Dependence and Abuse, incorporates a wide range of illicit and prescribed drugs of the opioid class. Opioid use disorders are related to severe outcomes, including risk of overdose and premature mortality [6,30] with standardized mortality ratios up to 9.1 (CI: 8.5–9.8) [4]. In particular overdose-related mortality accounts for 0.65 (0.55–0.75)

deaths per 100 person-years, though pooled overall crude mortality rates for people who inject drugs range from 5.25 (Asia), to 2.64 (North America) and 2.31 (Western Europe) [16]. Unfortunately, people with opioid use disorders are often poorly aware of likely overdose risks [33] reporting distorted beliefs about factors associated with overdose [14] with limited knowledge and only on few factors such as polydrug/polysubstance use [48]. Furthermore, people with opioid dependence are often unaware of how to effectively prevent and respond to an overdose event, and are often unfamiliar even with the use of naloxone [21]. More importantly, overdoses seem in many cases the result of more or less deliberate risk-taking, in some cases with no knowledge about potential consequences [39]. Impaired decision making is actually a common issue for substance users, who show little regard for consequences, and often deny or are unaware that they have a problem [8].

1.1. Complex nature of non-fatal drug overdoses

Non-fatal overdoses have been found to predispose to a number of significant chronic morbidities. For example, non-fatal overdose has been associated with complications to the pulmonary [45], cardiac [30] and renal systems. Neurological damage and cognitive impairment [15] are also commonly associated with non-fatal illicit drug overdose. Some evidence has indicated that non-fatal illicit drug overdose may also predict successive risk of overdose mortality [46] suggesting that knowledge and previous experience of overdose serve only to increase the risk of drug-related deaths. Risk factors for illicit-drug overdose are complex and many. Increased risk of overdose has been associated with specific demographic factors (male gender, increased age, homelessness) [47,9], individual characteristics (individual tolerance, experience of stress, poor mental health) [6,12,27], environmental factors (imprisonment history, drug use context – alone or with more than 1 person present) [12] and importantly, those variables associated with the specific drug and drug-related behaviours (drug type, drug dose, route of administration, frequency of injection, mixing of drugs, use of other substances and CNS depressants) [7,22].

1.2. Prevention and treatment

In Europe, prevention of illicit drug overdose incidences and drug-related mortality has become a significant challenge for public health. Interventions

targeted at reducing harm from drug use are controversial in many EU countries, and overdose prevention measures such as, drug consumption rooms, peer take-home naloxone distribution, and overdose response training programmes are lacking [19]. Barriers to adequate responses, related to the setting, have to do with the legal context, police policies regarding overdoses, the scene of the overdose as well as social norms among user groups [22,43].

E-Health tools provide a way to support behavioural changes and nowadays 90% of individuals worldwide have access to the internet through mobile phone services, including vulnerable populations, such as people with substance use disorders (SUD) [38]. E-Health technology supporting behavioural treatments for SUD, encompasses a wide range of delivery formats (e.g., computer-based, smart-phones), types of intervention (e.g., brief interventions, behavioural therapy, treatment adherence tools), and has been used across various substances (e.g., opioid, cocaine, alcohol, cannabis, etc.) [31] for a wide range of populations (i.e., adults, adolescents and young adults, criminal justice populations, postpartum women), as well as in many, different settings (addiction specialty treatment programmes, schools, emergency rooms, criminal justice settings) [37].

The advantages of e-Health, appropriate for people who use opioids, include ease of access and of use across settings, delivery of information in an attractive way, personalization of intervention, enhanced confidentiality, reduction of stigmatization [40]. Furthermore, since the vast majority of people with a drug problem do not access treatment [44], e-Health tools have shown promising results, increasing rates of subjects in receipt of care [49].

Considering health and social burden related to overdoses across Europe, and based on a project purposely funded by the European Commission, a consortium of researchers from different countries developed and tested a computer-based tool named ORION to assist patients appreciating the factors responsible for risks of drug overdose [5]. The purpose of the Overdose Risk Information Project (ORION) study was to develop an overdose risk information tool. The design was to construct this as a computer-based tool which estimates individual overdose risks using a psycho-educational approach. ORION is also able to assist clinical staff and to educate opioid dependent individuals to become more aware of the level of their risk factors associated with potential fatal and non-fatal overdose. The ORION tool was based upon the premise that the patient's beliefs about the

increased likelihood of a harmful outcome can act as powerful motivators for behaviour change [10]. In the field of injecting drug-users assessments of risk have been devised to help predict health damaging behaviour [35]. The raising of risk perceptions has been shown in addictive behaviour to have a positive effect on reducing this behaviour [13]. A further development that has driven patient decision tools is the representation of numerical information [23,25]. The ORION tool was prompted to include state-of-the-art graphics to help represent risk. Hence, a system to inform patients about risks associated with a variety of important factors linked to overdose behaviour was carefully constructed [23].

The aim of this study was to investigate the associations between risk perception of overdose, engagement in the ORION tool and willingness to alter overdose risk factors, in a clinical setting across various EU member states.

2. Methods

2.1. Setting

Recruitment occurred in treatment centres for opioid dependent patients across four European countries: UK, Germany, Italy and Denmark, in both in- and out-patient healthcare settings (NHS Fife Addiction Services, UK, LVR-Hospital in Essen, Germany; Monza Regional Addiction Service, Italy; and Aarhus University Hospital, Risskov, Denmark).

2.2. Participants

Inclusion criteria were patients attending clinical services for opioid dependence, and aged between

18 to 55 years. Recruitment included consecutive male and female patients. Exclusion criteria were current psychotic symptoms, severe learning disabilities, acute intoxication and patients who were unable to give informed consent for other reasons. 194 opioid dependent patients participated in the study (UK, N=39; Germany, N=99; Italy, N=40 and Denmark, N=16). 155 patients were receiving outpatient (predominantly opioid maintenance) and 39 patients were receiving inpatient treatment for their substance misuse. The average age of participants (9 missing cases) was 38.8 (SD = 7.9) years. 86% of participants were male and 14% female (17 missing cases).

2.3. Materials

The visual design and computer programming of The Overdose Risk Information (ORION) tool software was undertaken by experts from Keele University, and was designed to reside on a PC laptop for flexible utilisation in various clinical settings. The main content contained questions about nine known risk factors for overdose. These risk factors were identified from a systematic review of the literature purposively run searching main electronic database up to March 2011, as well as discussions with clinical experts from all participating sites and countries. The experts had to validate the risk factors identified for inclusion, either on the basis of being within the control of the individual (e.g. injecting behaviour), or particularly relevant to the specific clinical settings (e.g. experience of mental health difficulties). Table 1 shows these questions, each having a possible 'Yes' or 'No' response. This gives 512 possible combinations of 'Yes' / 'No' responses across the 9 questions. Applying these combinations to gender

Table 1. Parameters in the ORION model (note 4, 6 are protective factors)

| | Revised List - Please answer the following questions with regard to the past 30 days: All questions are yes/no |
|----|--|
| 1 | Do you inject drugs? |
| 2 | Are there days when you take more than one drug (including alcohol)? |
| 3 | Have you recently been released from prison or residential rehab? |
| 4 | Are you receiving some form of treatment for taking drugs (including alcohol)? |
| 5 | Have you used drugs (including alcohol) when you were alone? |
| 6 | Have you tried to reduce your use of drugs (including alcohol)? |
| 7 | Have you had an unusually stressful life event (e.g. bereavement, relationship break-up, health problem)? |
| 8 | Are you suffering from a psychological condition (e.g. depression)? |
| 9 | Have you ever been so intoxicated that you were scared of dying? |
| | Background variables (not in questionnaire) |
| 10 | Age-group and gender: 15-24, 25-34, 35-44, 45-54/ M, F |

and age bands yields 4,096 combinations. The expert ratings from each risk factor were consequently combined using linear equations to estimate weightings of risk for entry into the internal software of the tool. The initial prototype was approved by experts at St Andrews University and then tested in external validation to ensure the delivered product was functioning and user friendly. Furthermore University of St. Andrews staff ensured quality control to the actual coding, programming and platform compatibility of the interface and focused on the experience of clinical addiction experts and behavioural scientists involved in the understanding of risk perception and how risk can be presented in a meaningful manner. The creation of the tool was developed by specialists involved in the ORION partnership [17].

2.4. Design

This study utilised a within-subjects design, whereby participants used the ORION software and answered the evaluation questions [5].

2.5. Measures

Three assessments were included in the measurement system:

1. The primary outcome variable for this study was the evaluation question: “is your drug and/or alcohol taking behaviour likely to change as a result of using this information?” This was answered using a 3 category rating: ‘Not at all’, ‘Perhaps a little’ and ‘Yes, a lot’. This was designed to assess intention to change risk factor behaviour as a result of access to the ORION tool.
2. The Overdose Risk Awareness Questionnaire consisted of 7 items and asked patients to rate the likelihood that a person will suffer a drug overdose on a zero to 10 scale of ‘no more likely’ to ‘much more likely’. This was completed by patients without close supervision on two occasions: pre- and post-clinic appointment (Cronbach alpha coefficients for pre- and post-completions were 0.84 and 0.87 respectively).
3. The behavioural response to the tool itself was recorded from the software memory for each individual respondent. The time (in seconds) and the number of changes recorded on the 9 risk factors answering scheme to change the risk estimate of overdose conse-

quence. The correlation between the number of changes made and the time spent making changes was 0.61 ($p < .01$).

2.6. Procedure

Participants were invited by a health professional to use the ORION programme [5]. The tool was adopted by four clinical teams in respective teams in Denmark, Germany, Italy and Scotland. The services selected were partners in the original ORION project who had an abiding interest in the development of new approaches to addiction services. Hence, there was support and interest by all four clinical teams to receive training and administer the tool to recruited patients. The health professional within the specialist team in each centre was available throughout the session to help with any issues arising from using the programme. They were instructed that they could use the programme to explore overdose risk factors. At the end of their session they were given a printout containing a summary of their risk factor profile.

ORION tool [5] consists of the following steps:

1. Welcome screen – describing the programme and legal disclaimer regarding overdose risk estimation.
2. Demographic information – prompting the users to enter participant number, as well as gender and age band.
3. Initial risk assessment questions – nine risk assessment questions with drop down menus allowing the users to indicate whether or not this particular risk factor applies to them.
4. First overdose risk feedback – displayed by a black marker placed along a horizontal bar ranging from low to high overdose risk, which was placed against the overdose risk of a non drug user for comparison.
5. Option to Change answers and review of modified risk – participants were given the option to review their answers and visually inspect how different answers are reflected in changes in the overdose risk feedback graphic (Figure 1). Evaluation questions – three questions about the cognitive, behavioural and affective impact the software is likely to have on the user. Each had three answer categories: not at all, a little, very much.
6. Debriefing screen – thanking the participants and explaining that the risk feedback

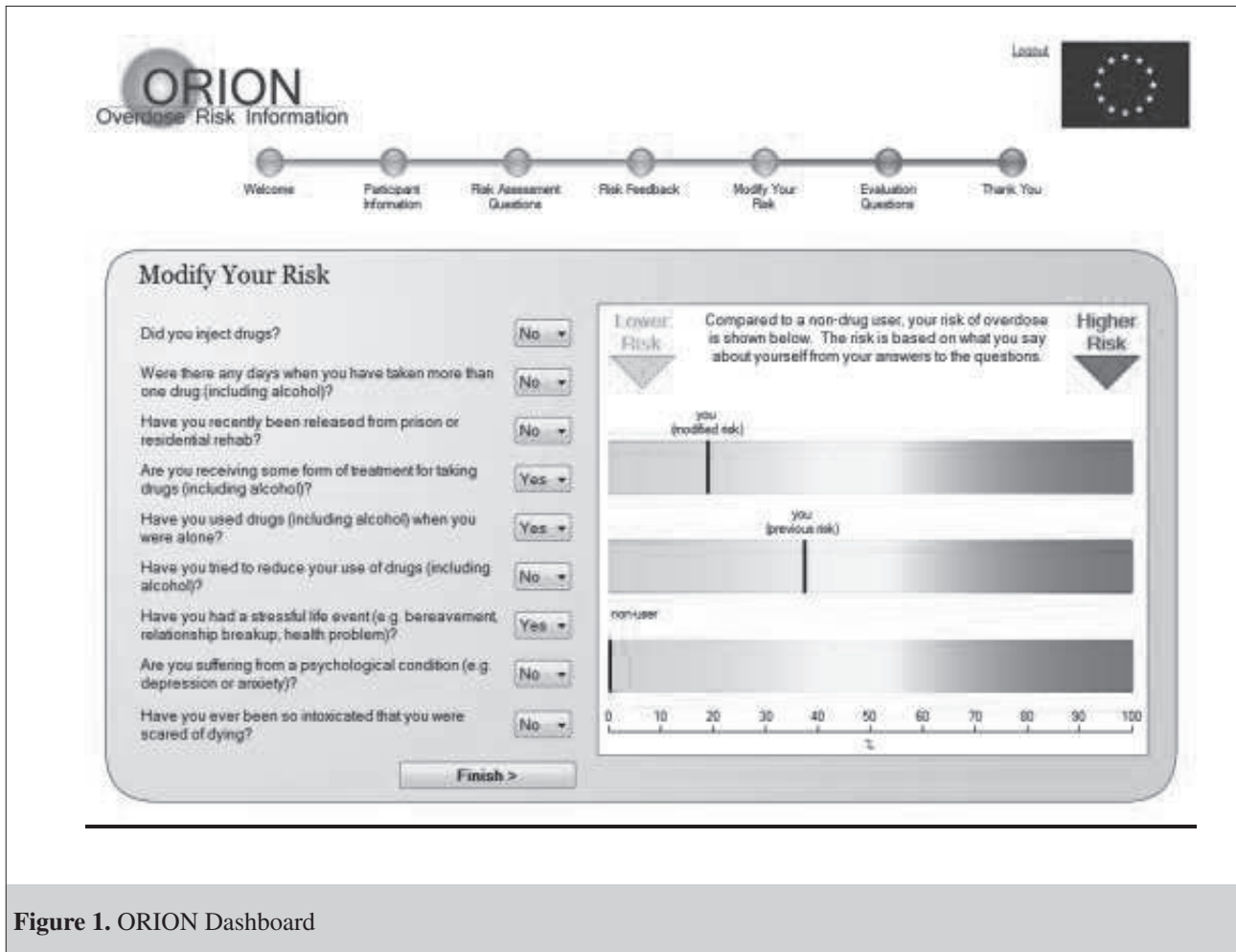


Figure 1. ORION Dashboard

can be recorded and reviewed at a later time.

The ORION tool itself recorded the participants' responses to the overdose risk questions (screen 3), whether or not participants reviewed their answers to see how this affects risk (screen 4), and which answers in particular were changed (screen 5) [5].

2.7. Statistical methods

The data were analysed with IBM SPSS Statistic v21 and AMOS Software. Latent variables were constructed for risk perception and engagement in the ORION Tool. Structural Equation Models (SEMs) [32] were constructed using the 'diagrammer' available in AMOS [3]. The risk perception questionnaire was separated into odd and even numbered questions, summed and divided by the number of items to create a common sub-scale ranging from 0-10. The advantages of 'parcelling' for this type of rating scale data for entry into SEM analyses has been well recognised [34]. These produced the pre-appointment A1 and A2 versions of the risk perception ratings for entry into the SEMs. Similarly, post-appointment versions

B1 and B2 were computed for entry. Various models were tested and compared for level of fit to the raw data. Conventional fit indices were adopted to assess elegance of the model to explain the data, including chi-square, Comparative Fit Index (CFI) and Root Mean Square Approximation of Error (RMSEA). A non-significant chi-square, a CFI >0.95, and RMSEA < 0.10 was regarded as suitable criteria for reasonable model fit [28]. The relative models were examined to provide close fit where possible without over fitting. The sample size collected was considered satisfactory for application of these models. Power analysis showed that to detect the difference between a close fitting model and just satisfactory model (RMSEA of zero versus 0.1) was possible at 88% power, alpha at 5% (df = 10) and a sample size of 190, although excessive testing was not considered suitable [36].

2.8. Research governance

Formal ethics and management approvals were secured in all four European clinical centres for the ORION protocol and its use.

Table 2: Risk perception Total Scores before and after ORION tool use

| | Pre-ORION intervention | | Post-ORION | |
|---------|------------------------|-------------|------------|------------|
| | Mean | 95% CIs | Mean | 95% CIs |
| Males | 49.6 | 46.9; 52.2 | 51.8 | 48.9; 54.6 |
| Females | 37.0 | 26.14; 47.6 | 45.6 | 34.2; 57.1 |

Within-subjects effects: Time F (1, 147) = 9.86; p = 0.002; Time by Gender F (1, 147) = 7.62; p = 0.006

3. Results

3.1. Descriptive analysis of risk factors

On average, participants had 4.5 (SD=2.2) risk factors. The most prevalent risk factors were using drugs alone (68%) and mixing drugs (58%). About half of the participants had experienced stressful events or had a psychological condition.

3.1.1. Pre-Post intervention Risk Perception scores

The maximum score for the Risk Perception measure is 70 where a high score denotes greater risk. Both pre- and post- total scores on average were higher than the mid range point of 35 (see Table 2). A test to determine whether the intervention was successful to raise awareness showed a strong positive effect, Within-subjects effects: Time F (1, 147) = 9.86; p = 0.002; although this effect was sensitive to whether the participant was male or female, Time by Gender F (1, 147) = 7.62; p = 0.006.

3.1.2. Descriptive analysis of changes to risk factors using ORION tool

Ninety-one participants made at least one change (49.2%), while 94 (50.8%) did not. The most frequently altered factor was release from prison/rehab (28%), injecting drugs (25%) and mixing drugs (23%). Among those who made changes, the average number of changes made was 4.3 (SD=3.3, range

1-22). The average time spent making changes was 64.7 seconds (SD=58.5, range 6-320).

3.1.3. Descriptive analysis of ORION tool evaluation questions

Forty-five percent indicated that they would consider changing their behaviour.

3.2. Model fitting

A variety of models were fitted and the most parsimonious model provided a non-significant difference (See Table 3) between the raw data and the specified model: Chi Sq = 16.87, df10, p = .077 chi sq/df = 1.688. The fit indices were CFI = .991, RMSEA = .066 (Table 3).

The final model (Model 2) presented in Figure 2 provides the measurement details and specification. The improvement in the chi square reduction with a single degree of freedom was borderline significance (p = 0.06). A single correlated error co-variance was added to the model to control for auto-correlation. Pre and post self-assessments of risk towards known factors linked with overdose were highly correlated (0.95). A significant path was found between engagement in the tool and the willingness to change one or more risk factors (stand. coeff. = 0.16, p = .04). In addition, the final assessment of the risk factors was associated with engagement (stand. coeff. = 0.18, p = .02).

Table 3: Model comparison between different model specifications

| | Model description to predict willingness to change risk factors | Chi sq. | df | p* | CFI | RMSEA |
|----------------|--|---------|----|------|------|-------|
| 1 | Direct effect of Risk perception, controlling for engagement with ORION Tool | 20.32 | 11 | 0.04 | 0.99 | 0.07 |
| 2 [‡] | As 1 + direct effect of engagement with ORION Tool (see Figure 2) | 16.88 | 10 | 0.08 | 0.99 | 0.07 |

* Note p level greater than 0.05 denotes no significant deviation of raw data from model specification (i.e. reasonable fit) ‡ chi square = 3.44, p = 0.06; df = degrees of freedom; CFI= Comparative Fit Index; RMSEA = Root Mean Square Approximation of Error

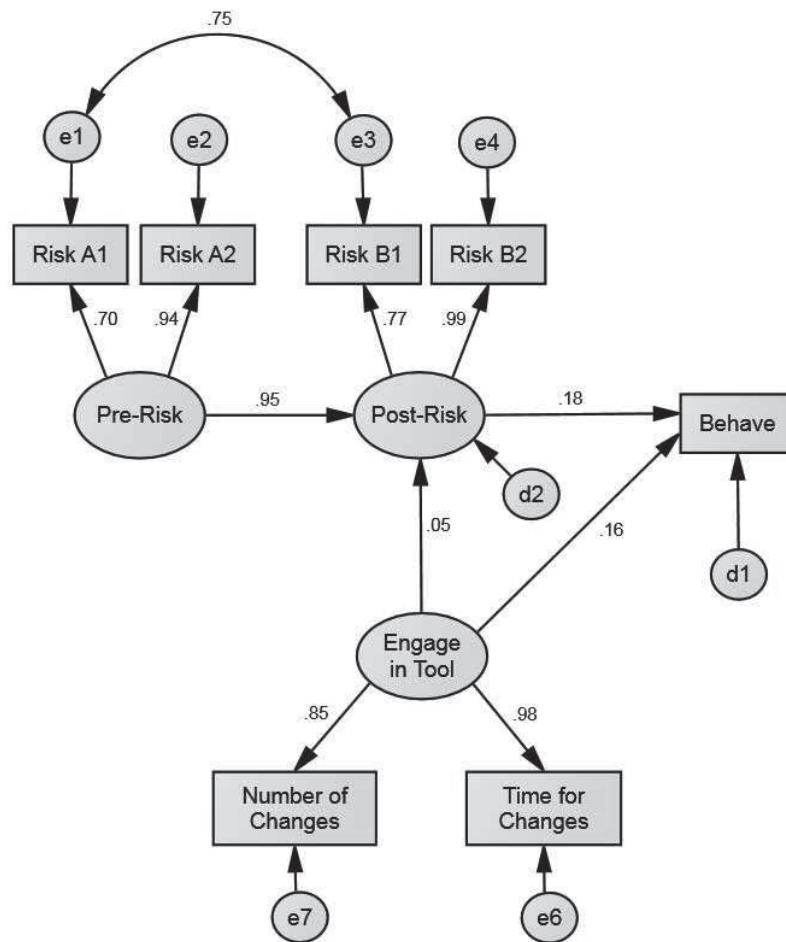


Figure 2. Structural equation model 2 showing standardised coefficients (n=159) and a single error auto-correlation

4. Discussion

The importance of attending to patient risk perception and intervening to prevent drug deaths and adverse events has been highlighted in this study. The ORION tool successfully increased risk perception of participants, especially in women. This finding is consistent with the available literature as it has been demonstrated that men in general rate their risk to alcohol, tobacco and drugs as less than women [26]. An interaction was shown between gender and the before and after measures of risk perception. Women reported an extensive heightening of risk compared to men when exposed to the ORION intervention. There may be a number of reasons for the risk perceptions not rising extensively in certain groups of participants such as men. It is known that raising risk perception may not be very successful in patients who score highly on health worry [20]. It may be that men were experiencing greater concerns about their health. This chronic status may be responsible for the tendency to

raise stress levels and this status, interestingly, was implicated in patients who discontinued their methadone programme and increased their health risks [29]. More generally this study suggests that following the monitoring of risk perception, this assessment may be more effective to encourage behavioural change if individual characteristics are taken into account such as the mediating construct often referred to as ‘readiness to change’ [24].

A further important finding from this exploration of the ORION tool is the importance of engagement in the new device within the clinical setting. It will be important for the further improvement of the tool to develop comprehensive training to assist potential users (both professional staff and service users) to highlight the risk assessment with example scenarios and give advisory instructions to assist uptake of the vitally important messages that reside within the engagement of the ORION tool. The significant association between the level of engagement, as estimated by the number of changes and time spent on the activity

of accessing the risk factors, and the assessment of likely change in risk behaviours (commonly termed intention) is a vital confirmation that elaborating personal interest in the risk factors has potential to change behaviour. The Elaboration Likelihood Model (ELM) purports to explain that stronger attitude change, and by implication intentions to change, will take place through central processes such as engaging participants to think more deeply about the information available on risks, rather than basing their views on heuristics or short-cuts in estimating risks. Hence the involvement of “high-elaboration thought in which all information is being carefully analysed” will, according to ELM, produce a stronger and more long-lasting effect [41].

Strengths and limitations

The study was successful in introducing the ORION Tool into four clinical services, each based in a different EU member state. The clinics were regional services that were designed to assist opioid dependent patients and had health service audit and commissioning governance. Hence, the addition of the ORION tool into such service settings can be considered noteworthy as a device that can be introduced into clinical practice. Behavioural data were collected successfully automatically to reveal a level of engagement in the software through the number of changes made to the answers given in the initial risk assessment and time given to make these changes. Collection of cases varied across services which was dependent on the speed of gaining ethical access, rather than a difficulty with gaining clinician support in each centre. All centres were supportive of using the intervention to discuss risk with their patients.

Inevitably, limitations exist with this field study. The investigators have focused deliberately on the creation of effective software for practical use within the service settings. It has still not been established the acceptability and effectiveness of the ORION tool across a wider set of services or the longer term introduction for routine utilisation in the health service setting. It is worth highlighting that the evaluation of the intention to change is rudimentary and requires development psychometrically. It is likely that the association has been attenuated by the fact that this dependent variable was not assessed using a multi-item set of ratings. This of course will include substantial error variance that has not been controlled for and therefore the association is likely to be stronger than indicated from the analysis of the raw data.

5. Future work

There are two issues that require development. They include a theoretical elaboration of possible underlying effects of the tool and also more pragmatic technological changes that are now required. The first issue is to explore the possibility that patients will be investing heavily in compensatory health beliefs. That is the patient is often aware of many of the risks they expose themselves to but actively process to minimise these unsettling risk beliefs by promoting the benefits of the methadone service. Patients bargain with themselves to achieve what they consider to be an appropriate balance of risk. The advantage of the ORION tool may be, with repeated use with a patient, that this balance is re-calibrated to achieve an acceptable risk level [42]. The second issue to promote is the translation of this tool to other platforms than a laptop device. The software is currently available free for download, however with greater penetration of the use of ‘smart’ mobile phone technology, the transfer to a wider source of operating systems to enable services and users greater access will assist in the utilisation of this tool and its modifications. Foremost in this development would be in the broadening of coverage to include primary care services to also increase screening and educational efforts as opportunities will arise to strengthen the messages provided in the specialist clinics [11].

The ORION eHealth tool is available free to download at ‘<http://orioneuproject.com/download-software/>’.

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Contributors

All authors were involved in the study design, had full access to the survey data and analyses, and interpreted the data, critically reviewed the manuscript and had full control, including final responsibility for the decision to submit the paper for publication.

Conflict of interest

None.

Ethics

Authors confirm that the submitted study was conducted according to the WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects. The study has IRB review/approval.

Note

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