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Contingency management for tobacco smoking during opioid addiction treatment: Implementation challenges

Short title: CM for smoking in opioid addiction

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Abstract

Introduction and Aims: Tobacco smoking prevalence in opioid addiction patients is approximately six times that of the general population, highlighting the need for novel interventions. A pilot/feasibility study was conducted to investigate whether a contingency management (CM) intervention could be added to UK standard smoking cessation treatment. The aim of this report is to describe the challenges experienced during the implementation of this CM intervention.

Design and Methods: A two-armed, randomised, pilot/feasibility study of a 5-week escalating with reset CM intervention, conducted as an adjunct to smoking cessation treatment in an outpatient drug and alcohol treatment centre.

Results: 40 participants were recruited, but only 19 attended the baseline session. Ten participants attended all treatment sessions **(**25% retention), with only one contactable at six-month follow-up. Whilst smoking cessation clinic engagement was higher than previously, implementation issues included limited operating hours of the smoking treatment clinic, ineffective biochemical verification of abstinence and overly restrictive inclusion criteria.

Discussion and Conclusions: This study highlighted the difficulty of integrating CM interventions into standard smoking cessation treatment for this population, but also the potential of CM to engage this group with smoking cessation treatment. Future research in this area should consider increasing the availability and flexibility of smoking cessation treatment, and relaxing inclusion criteria to be more reflective of the opioid-treatment-seeking population.

This study is registered on ClinicalTrials.gov (NCT03015597, https://clinicaltrials.gov/ct2/show/NCT03015597)

Keywords: Contingency Management, Smoking, Smoking Cessation, Addiction, Opioid Addiction.

Introduction

Tobacco smoking is one of the leading causes of premature death in the world (1), killing over seven million people globally each year. In the UK, smoking prevalence in the general population is under 15% (2). For those in drug addiction treatment however, this approaches 90% (3), increasing to as high as 98% in opioid addiction (4). Drug-addicted smokers have a fourfold greater rate of premature mortality than non-smokers (5) and illicit drug use is associated with a significant decrease in the efficacy of standard smoking cessation treatment (6). Individuals receiving treatment for opiate addiction have reported high levels of interest in smoking cessation (7), making them an ideal population with which to develop novel interventions.

Contingency management (CM) is a behavioural intervention based on operant conditioning, whereby changes in behaviour are brought about through positive reinforcement. To our knowledge (8), there are currently only four published studies that have investigated CM for smoking cessation in opiate addiction treatment (9–12), all conducted in the US. All studies reported significantly greater smoking abstinence in CM conditions than in control conditions at the end of treatment. However, none of these studies tested interventions compatible with standard clinical practice or smoking cessation treatment in the UK (13,14) nor included any follow-up. The purpose of the current study therefore was to investigate whether these promising findings could be maintained with a CM intervention formulated as an adjunct to standard UK smoking cessation treatment in an outpatient setting.

However, implementation of the study proved extremely challenging; to such a degree that any discussion of any results regarding efficacy would be of little utility. Instead, we provide below a very brief overview of the study methods and results, followed by a more detailed discussion of the primary issues encountered during study implementation and the lessons that can be learned from these going forward.

The Pilot Study

Participants were eligible for inclusion if they: wanted to quit smoking, were 18-65 years old, undergoing pharmacological treatment for opioid addiction, and smoked a minimum of ten cigarettes per day (15). Participants were excluded if they were currently undergoing treatment for other drugs of abuse or participating in any other research.

Participants were randomised to either an experimental (Abstinence) or control condition (Attendance), stratified on current smoking frequency

(10-20 or >20 cigarettes per day (3)). Neither patients nor research staff were blind to treatment allocation.

The standard smoking cessation treatment followed national guidelines (13,14). Treatment combines manualised behavioural support with nicotine replacement therapy (NRT), taking place over six weeks with one session per week. Smoking status is recorded at each session and biochemically verified using breath carbon monoxide (CO), with breath CO<10ppm signifying abstinence (16). At the time of the study, the smoking clinic ran for two hours each Monday afternoon and offered e-cigarettes as a novel form of NRT, on a trial basis.

The CM intervention started in week two of the smoking cessation treatment and ended in week six. It followed an escalating with reset schedule (reward values increase with each successive display of abstinence, with non-abstinence resulting in no reward and reward values resetting to the original value until the next display of abstinence). In this case, rewards started at £5, doubling each time to a maximum of £40, meaning a maximum total reward value of £115. Participants in the Abstinence condition were rewarded for providing breath CO samples <10ppm, those in the Attendance condition for submitting a breath CO sample, regardless of breath CO levels.

The study protocol provides additional detail (17).

Forty participants were recruited. Nineteen participants attended their baseline session (Abstinence 62%, Attendance 65%), ten attended all five study sessions (25%). Retention was three times higher in the Attendance condition (47%) than the Abstinence condition (15%). Only a single participant could be contacted for six-month follow-up, and reported not having smoked since end of treatment, but CO verification could not be obtained.

Implementation Issues and Recommendations for Future Studies

Smoking Clinic Operation

Although the treatment centre officially had a smoking clinic, at the study outset it transpired that it was poorly attended, necessitating the retraining of staff and relaunch. This delayed the start of the study by a number of weeks, and could have been avoided with a more diligent initial appraisal of the study centre's operations. Due to resource restraints, we were unable to record the fidelity of the smoking cessation treatment

provided. In future studies, particularly those taking place across multiple sites, we would strongly recommend that fidelity be measured, so as to allow accurate appraisal of any CM intervention effects.

Participant Retention

The 25% retention rate observed here is much lower than the 60% retention observed in other similar studies (10,11). This may be partly attributable to the large number of participants that withdrew from the study immediately after being randomised to the Abstinence condition. Another potential explanation for the poor retention may be that the smoking clinic operated for only two hours, once a week. These limited operating hours may not have fitted participants' schedules, or offered insufficient opportunity for patients with disorganised lives to engage with the smoking clinic in a meaningful way. Interestingly though, despite the poor retention, the number of participants engaged with the smoking cessation service over the four-month study recruitment period was greater than those engaged in the previous 12 months. Were the study to be replicated, we would suggest that provision of the smoking clinic be increased to multiple times per week, or a 'drop-in' style model adopted, based on prior consultation with patients. We also believe that ability of CM to engage patients with smoking cessation services merits further investigation.

Biochemical Verification of Abstinence

Part way through the study, some participants began voluntarily self-reporting smoking, despite providing breath CO readings indicative of abstinence (<10ppm). Consequently, some participants in the experimental condition were receiving rewards for abstinence whilst still smoking, negating any potential effect of the intervention to encourage cessation. Breath CO was used to verify abstinence as this is what is routinely practiced in standard smoking cessation treatment. However, this can only capture smoking in the past 12-24 hours (18). Other methods of biochemical verification are sensitive over longer periods of time; however, some cannot be used alongside NRT (e.g. cotinine testing which is a metabolite of nicotine) making them incompatible with standard smoking cessation treatment; others require lab testing (anabasine or anatabine), making them unsuitable for use in CM where intervention efficacy is dependent on the immediacy of rewards. A far stricter breath CO requirement could be used, with some research suggesting levels as low as 2-3ppm may be suitable (19). Future studies may wish to adopt this stricter cut-off level, or alternatively maintain the standard cut-off of 10 ppm, instead testing abstinence multiple times per week as in other CM interventions (9–12). For example, breath CO levels could be tested daily

as participants collect their opiate substitution medication, receiving rewards at the end of the week.

Inclusion Criteria

Inclusion of patients in treatment solely for opioid addiction proved overly restrictive, as most patients were receiving treatment for addiction to multiple drugs. Consequently, we changed the inclusion criteria to recruit participants whose primary drug of abuse was an opioid, regardless of secondary drug use. Our inability to recruit patients only receiving treatment for opioid dependence speaks to a broader issue within addictions research. Patients receiving treatment for drug addiction have highly complex needs, often using multiple different addictive substances. Moreover, up to 85% of patients in drug and alcohol treatment have co-morbid mental health problems, further complicating treatment needs (20). Focussing on only one aspect of patients' health potentially reduces the applicability of research findings when they are applied in practice. Future studies should seek to be as inclusive as possible in terms of patient demographics, so as to better represent the diversity of the patient population that the intervention is designed to serve.

Conclusion

Overall, the poor retention rate observed here demonstrates that the integration of CM interventions with standard care, at least within this particular treatment context, may be more difficult than initially envisaged. Despite the issues encountered in implementing the current intervention, there are some important lessons that can be taken forward into future studies. These include the requirement for more adequate provision of smoking cessation support, more stringent or more frequent biochemical verification of abstinence and, arguably most important, a more representative sampling strategy. However, even with these changes, CM interventions rewarding abstinence may not be the most fruitful avenue for future research in this treatment context. Rather, CM interventions for smoking cessation in opioid addiction treatment may be more effective if rewards are instead used to engage patients with smoking cessation services, as has been shown with Hepatitis B vaccination adherence (21). Regardless of the direction that future research takes, tobacco smoking remains a severely under-researched topic within the field of addictions and without a significant increase in research activity, will continue to be the most prevalent cause of mortality in this population (22).

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Declaration of Conflicting Interests

JS is a researcher and clinician in the university and NHS, and has had a long-standing working relationship, including in a leadership role, with the treatment service in which this study was conducted. He has also worked with several pharmaceutical companies to seek to identify new or improved medications, but they do not have a relationship to the study and findings reported here. For updated information see John Strang's info at http://www.kcl.ac.uk/ioppn/depts/addictions/people/hod.aspx. JS is a National Institute for Health Research (NIHR) Senior Investigator and is supported by the NIHR Biomedical Research Centre for Mental Health at South London and Maudsley NHS Foundation Trust and King's College London. AM is also a NIHR Senior Investigator. The views expressed in this article are those of the authors and not necessarily those of the NIHR or the Department of Health and Social Care.

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