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Positive reinforcement targeting abstinence in substance misuse (PRAISe): Study protocol for a Cluster RCT & process evaluation of contingency management

Metrebian N.[a,*], Weaver T.[b,c], Pilling S.[d], Hellier J.[e], Byford S.[e], Shearer J.[e], Mitcheson L.[f], Astbury M.[g], Bijral P.[h], Bogdan N.[i], Bowden-Jones O.[j], Day E.[a,k], Dunn J.[l], Finch E.[f], Forshall S.[m], Glasper A.[n], Morse G.[o], Akhtar S.[j], Bajaria J.[h], Bennett C.[j], Bishop E.[d], Charles V.[a], Davey C.[m], Desai R.[a], Goodfellow C.[d], Haque F.[a], Little N.[d], McKechnie H.[b], Morris J.[m], Mosler F.[a], Mutz J.[a], Pauli R.[k], Poovendran D.[b], Slater E.[j], Strang J.[a,f]

[a] King's College London, National Addiction Centre, Institute of Psychiatry, Psychology & Neuroscience, London, UK
[b] Imperial College London, London, UK
[c] Middlesex University, London, UK
[d] University College London, London, UK
[e] King's College London, Institute of Psychiatry, Psychology & Neuroscience, London, UK
[f] South London and Maudsley NHS Foundation Trust, London, UK
[g] Dudley & Walsall Mental Health Partnership Trust, Dudley, UK
[h] Change, Grow, Live Charity, Management Offices, London, UK
[i] South Essex Partnership NHS Foundation Trust, Essex, UK
[j] Central and North West London NHS Foundation Trust, London, UK
[k] Birmingham & Solihull Mental Health NHS Foundation Trust, Birmingham, UK
[l] Camden & Islington NHS Foundation Trust, London, UK
[m] Avon & Wiltshire Mental Health Partnership NHS Trust, Bristol, UK
[n] Sussex Partnership NHS Foundation Trust, Brighton, UK
[o] Turning Point Charity, London, UK

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ABSTRACT

There are approximately 256,000 heroin and other opiate users in England of whom 155,000 are in treatment for heroin (or opiate) addiction. The majority of people in treatment receive opiate substitution treatment (OST) (methadone and buprenorphine). However, OST suffers from high attrition and persistent heroin use even whilst in treatment. Contingency management (CM) is a psychological intervention based on the principles of operant conditioning. It is delivered as an adjunct to existing evidence based treatments to amplify patient benefit and involves the systematic application of positive reinforcement (financial or material incentives) to promote behaviours consistent with treatment goals. With an international evidence base for CM, NICE recommended that CM be implemented in UK drug treatment settings alongside OST to target attendance and the reduction of illicit drug use. While there was a growing evidence base for CM, there had been no examination of its delivery in UK NHS addiction services. The PRAISe trial evaluates the feasibility, acceptability, clinical and cost effectiveness of CM in UK addiction services. It is a cluster randomised controlled effectiveness trial of CM (praise and financial incentives) targeted at either abstinence from opiates or attendance at treatment sessions versus no CM among individuals receiving OST. The trial includes an economic evaluation which explores the relative costs and cost effectiveness of the two CM intervention strategies compared to TAU and an embedded process evaluation to identify contextual factors and causal mechanisms associated with variations in outcome. This study will inform UK drug treatment policy and practice.

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* Corresponding author at: King's College London, National Addiction Centre, Institute of Psychiatry, Psychology & Neuroscience, 4 Windsor Walk, Denmark Hill, London SE5 8AA, UK.
E-mail address: nicola.metrebian@kcl.ac.uk (N. Metrebian).

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1. Background and rationale

In England in 2012 there were approximately 256,000 heroin and other opiate users, of whom 155,000 were in treatment for addiction [1]. The majority of people in treatment receive opiate substitution treatment (OST) (methadone and buprenorphine) for their addiction to heroin [1]. There is an extensive evidence-base for OST [2]. It is proven to be cost-effective and estimated to save £9.50 for every £1 spent [3]. The National Institute for Health and Care Excellence (NICE) recommends substitute prescribing as the most effective treatment, alongside psychological therapies to change behaviour. However, recovery from heroin addiction is a long term process and many heroin users relapse and OST suffers from high attrition [4].

Contingency management (CM) is a psychological intervention based on the principles of operant conditioning. It is delivered as an adjunct to existing evidence based treatments to amplify patient benefit and involves the systematic application of positive reinforcement (financial or material incentives) to promote adherence to treatment and/or patient behaviours consistent with treatment goals (e.g. reinforcing medication compliance, or abstinence from street drugs). A number of systematic reviews concluded that, when provided in combination with methadone maintenance treatment, CM can significantly increase attendance, and reduce illicit opiate use during treatment and at follow-up [5,6]. Although this evidence base came primarily from trials conducted in the USA, and has more recently been challenged [7], in 2007 NICE recommended that CM be implemented in UK drug treatment settings to target the reduction of illicit drug use and encourage attendance at treatment appointments [8,9]. However, with no track record of delivering CM in UK addiction services, there were concerns about applying CM in a UK setting [9,10]. USA and UK drug treatment provision differ greatly in treatment philosophy and service configuration. Thus it was thought that careful assessment was needed of the application, implementation, treatment process and clinical outcome of CM in the UK NHS drug treatment settings [9].

A cluster randomised trial with different CM reinforcement schedules to evaluate whether CM encouraged completion of hepatitis B vaccination scheme among opiate dependent drug users was recently undertaken by the authors [11]. Findings showed modest financial incentives (both fixed and escalating schedules) significantly increased the proportion completing hepatitis B vaccinations compared to those not receiving financial incentives. This suggests that CM can effectively promote attendance at appointments and short term behaviour change. For CM to be effective at targeting important clinical outcomes such as abstinence from non prescribed opiates research needs to demonstrate that CM can also effectively promote longer term behaviour change.

The trial described in this paper evaluates the clinical and cost effectiveness of CM (positive reinforcement through praise and financial incentives) targeted at attendance at keywork appointments and abstinence from heroin. The feasibility of conducting such a trial has been proved in the authors' previous CM cluster trial [11] which provided information on the feasibility and effectiveness of different reinforcement schedules and helped to develop and refine practice guidance and protocols for the implementation of CM. It also informed the intervention strategies and staff training delivered and evaluated in this trial. A process evaluation being conducted alongside this trial will investigate how and why CM works (or not) by examining contextual factors and causal mechanisms associated with variation in outcome.

2. Methods

2.1. Objective

The 3 arm trial will test whether the use of positive reinforcement (praise and financial incentives) targeted at (a) the provision of urine samples negative for opiates AND on-time attendance at treatment sessions will increase abstinence from street heroin when compared to a control condition (Treatment As Usual [TAU]) in which no positive reinforcement is offered among individuals receiving OST. It will also test (b) whether the use of positive reinforcement targeted at on-time attendance at treatment sessions only will increase abstinence from street heroin when compared to TAU in which no positive reinforcement is offered. What has been unclear is whether any benefit derived from CM comes from a direct effect of CM aimed at the selected target behaviour or is a benefit from CM- improved attendance at treatment sessions (and possibly consequently improved retention in treatment). The trial includes an economic evaluation which will explore the relative costs and cost effectiveness of the two CM intervention strategies compared to TAU.

Alongside the trial a process evaluation will be undertaken to identify contextual factors and causal mechanisms associated with variation in outcome to better understand how and why the intervention does or does not work and the process and impact of delivering CM on services, clinicians and service users. In addition fidelity will be assessed to established whether the intervention was delivered as intended. Process evaluations incorporating qualitative components have been advocated in the MRC framework for the evaluation of complex interventions to understand the implementation, delivery and fidelity of randomised controlled trials in health services [12, 13], and are recommended for use pre, during and post trial [14,15,16]. The process evaluation aims to (a) identify the factors that are present in UK drug services that would facilitate or hinder the implementatin of CM; (b) describe the contingency management (CM) intervention delivered during the CM urinalysis and keywork sessions and assess whether it is delivered as intended; (c) investigate whether (and how) organisational, professional and contextual factors present within the experimental study setting influences the implementation, delivery and outcome of CM in urinalysis/keyworker sessions and identify factors which might promote or impede recruitment (of sites, clinical staff and participants) to the trial.

2.2. Trial design

The trial uses a cluster randomised controlled design as individual randomisation is not feasible. Each of the drug treatment clinics will be their own cluster. Within each cluster, all participants will receive the same allocated condition, thus minimising the risk of contamination. The most common configuration of services providing OST is for one or more clinics to provide coverage to a large geographical area. There is a high probability of contamination if staff were delivering, and service users receiving, different interventions within the same clinic. Also service-users themselves constitute a local social network and individual randomisation (with CM incentives for some service-users while not for others at the same clinic) would be highly likely to encounter inter-service-user as well as inter-staff contamination. For these reasons it is not feasible for clinicians to provide, simultaneously, both the experimental and control intervention with fidelity within a single clinical setting. Also, because subjects in treatment as usual (TAU) would be denied an incentive offered to others in the same clinic, there would be a high probability of trial-induced low recruitment, poor compliance and high drop-out within the control arm. Sites (clusters) will be recruited in stages and then randomised. We will recruit participants at entry to treatment. They will be provided with 12 weekly keywork sessions and followed up at 12 and 24 weeks after trial entry.

2.2.1. Study setting

The research was originally intended to be conducted at only NHS drug treatment clinics providing OST. However, with major changes to the NHS organization of the whole addiction provider network, non-NHS treatment agencies providing OST have been additionally recruited. This reflects current addiction service provision and thus enhances the generalisability of participating sites. Thirty-three clinics (i.e. clusters) providing OST will be recruited across NHS Trusts and