Psychosocial INTerventions for Alcohol use among problem drug users (PINTA): protocol for a feasibility study in primary care

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Abstract

Background

Alcohol use is an important issue among problem drug users. Although screening and brief intervention are effective in reducing problem alcohol use in primary care, no research has examined this issue among problem drug users.

Objectives

To determine if a complex intervention, incorporating screening and brief intervention for problem alcohol use among problem drug users, is feasible and acceptable in practice and effective in reducing the proportion of patients with problem alcohol use.

Methods

PINTA is a pilot feasibility study of a complex intervention comprising screening and brief intervention for problem alcohol use among problem drug users with cluster randomisation at the level of general practice, integrated qualitative process evaluation, and involving general practices in two socioeconomically deprived regions.

Participants: Practices (N=16) will be eligible to participate if they are registered to prescribe methadone and/or at least 10 patients of the practice are currently receiving addiction-treatment. Patient inclusion criteria are: aged 18 or over and receiving addiction treatment / care (e.g. methadone) or known to be a problem drug user.

Interventions: A complex intervention, supporting screening and brief intervention for problem alcohol use among problem drug users (experimental group) compared to an 'assessment only' control group. A delayed intervention being available to 'control' practices after follow up.

Outcome: Primary outcomes are feasibility and acceptability of the intervention to patients and professionals. Secondary outcome is the effectiveness of the intervention on care process (documented rates of screening and brief intervention) and outcome (proportion of patients with problem alcohol use at the follow up).

Randomisation: Stratified random sampling of general practices based on level of training in providing addiction-related care and geographical area.

Blinding: Single-blinded; GPs and practice staff, researchers and trainers will not be blinded, but patients and remote randomisers will.

Discussion

This is the first study to examine feasibility and acceptability of primary care based complex intervention to enhance alcohol screening and brief intervention among problem drug users. Results will inform future research among this high-risk population and guide policy and service development locally and internationally.

Keywords

Complex intervention, Screening, Brief intervention, Alcohol, Methadone maintenance, Primary health care, General practice, Substance-related disorders

Introduction

Problem alcohol use is associated with adverse health and economic outcomes, all the more so among problem drug users (e.g. individuals currently using illicit drugs, or trying to abstain from other illicit drugs such as benzodiazepines, cocaine or heroin) [1, 2]. Such alcohol use may decrease in response to psychosocial interventions whose benefits have been demonstrated in general adult populations. For example, a comprehensive review by Raistrick et al presented data on the effectiveness of many such interventions, including screening, further assessment, brief interventions and alcohol-focussed specialist treatment [3].

Primary care may have an important role in addressing problem alcohol use among problem drug users. Its potential impact on screening for alcohol problems and providing appropriate interventions in the general population has been described [4], although a recently published randomised trial indicates that more intensive primary care based interventions provide little by way of additional benefit to patient information alone[5]. Internationally, screening and brief interventions (SBI) are recommended as a treatment of choice for reducing alcohol use among problem drinkers in primary care [6, 7], but they have not been tested in people who are addicted to other substances and who attend primary care [8]. It is important to address this issue in this patient group because of serious complications associated with problem alcohol use in this population: i.e. potential to increase the likelihood of a relapse to problem drug use, medical / psychological complications, liver disease, etc. [1, 2].

Similar to other evidence-based interventions, the evidence on SBIs translates into practice slowly [9-11], and the findings from implementation studies are contradictory. For example,

while a systematic review of interventions focused on increasing the use of screening and brief intervention for hazardous alcohol consumption in primary care recommended complex, multi-component strategies [12], a recent trial concluded that such a 'tailored, multi-faceted programme aimed at improving GP management of alcohol consumption' failed to show an effect and proved difficult to implement[13]. This also contradicts the conclusions of a recent paper, that 'real world evidence supports theory' of SBIs [14].

More impetus to this contradictory debate has been added by recent implementation studies and a controlled trial among problem drug users in secondary care, which demonstrated feasibility of implementing screening and brief interventions among problem drug users in secondary care but suggested a controlled pilot study was necessary to establish key parameters for a similar evaluation in primary care [15-17]. This study is designed to examine these issues.

Previous work in Ireland and how it relates to complex intervention theory

This protocol builds on our on-going programme of research which indicates (opiate) addiction treatment should also incorporate interventions that address problem use of alcohol and other illicit substances. For example, a national cross sectional study reported 35% of patients attending GPs for methadone treatment also had problem alcohol use [18] while findings from a subsequent qualitative study highlight the need for a complex intervention to address this problem in primary care [19].

The UK Medical Research Council (MRC) 'Framework for the Development and Evaluation of Complex Interventions for Randomised Controlled Trials (RCT)' [20] , which suggests core phases to the development of complex health services interventions, informed the development of the intervention under study .

(1) Preclinical phase: Theory and problem identification

- A national prevalence study showed problem alcohol use among was high (35%) among patients attending general practice for methadone maintenance[18]

- A review of scientific evidence found no studies examining this issue in primary care but research in secondary / community care settings suggests this type of intervention can be effective among problem drug users[21]

(2) Phase 1: Modelling

Development of a complex intervention / clinical guidelines informed by:

- Cochrane Systematic review on 'Psychosocial interventions for problem alcohol use in illicit drug users'[8]

- Qualitative interviews with healthcare providers and patients, which found that barriers to implementation of alcohol intervention for drug users in primary care include: Patient factors, Healthcare professional factors and Structural issues; the implementation strategies should utilize educational and support systems [19]

- Clinical guidelines, informed by the findings of qualitative interviews, expert opinion through a Delphi-facilitated expert consensus process and a Cochrane Systematic

Review[8], advocate screening and brief intervention (SBI) for problem alcohol use among problem drug users.

(3) Phase 2: Exploratory study

- A pilot study in addiction clinics showed that SBIs are effective in reducing alcohol consumption among opiate dependent patients[16]
- Current proposal to establish the acceptability and effectiveness of the intervention by conducting a feasibility study in primary care.

This protocol reflects the development and piloting phases of the MRC 'Framework for design and evaluation of complex interventions to improve health' [20, 22]. The study will provide key parameters regarding the feasibility and acceptability of the intervention to patients and practitioners. As such, this research is essential to inform the design and conduct of a larger cluster randomised controlled trial.

Specific objectives:

- To develop a complex-intervention which will enhance screening and brief intervention for problem alcohol use among problem drug users in primary care;
- To establish the feasibility and acceptability of this intervention in practice, by
  - Conducting a pilot study (with randomisation at the level of practice);
  - Exploring the feasibility and acceptability of the intervention under study and related research procedures to GPs, practice nurses and patients;
  - Exploring the fidelity of the interventions as delivered in practice;

- To inform the subsequent design of a definitive cluster randomised controlled trial, by

    o Describing the optimum configuration of the complex intervention;

    o Estimating the key parameters in such a trial (i.e., practice / patient recruitment and retention rates, intraclass correlation coefficient for primary outcome measures and the likely effect of intervention under study on these measures).

Methods

Overview of study design

Pilot feasibility study of a complex intervention to promote screening and brief intervention for problem alcohol use among problem drug users, with cluster randomisation at the level of general practice, and integrated qualitative process evaluation, involving general practice in two regions.

Study population

Recruitment and random selection of practices

The following practices will be invited to participate, given written information on the study and asked to indicate their interest in participating:

- All practices in two regions – Health Services Executive (HSE) Midwest and Dublin Mid-Leinster regions, and

- All practices who have been involved in previous related research with our group [18, 23-29]

- General practices in the study regions who are affiliated with two of Ireland's six medical schools [30, 31]

Practices will be eligible to participate if they are registered to prescribe methadone, and/or have at least 10 patients currently receiving addiction-related care.

Of those who confirm their *interest* in the study and who are eligible to participate, a stratified random sampling technique will be used to select 16 practices.

Sampled GPs will be contacted about their participation, given further information on the study (e.g., what their involvement will entail) and consulted about patient recruitment. The research team will telephone those not replying. Each practice will be visited by the principal investigator / lead researcher and provided with information about the research programme.

To ensure comparability between intervention and control groups for key practice characteristics, a restricted allocation involving stratified approach to randomisation will be adopted. Prior to randomisation, those GPs who express an interest in participating will be grouped according to level of training in providing addiction related care (level 1, 2), geographical location (Dublin/ Midwest), with 16 randomly selected using an independent remote randomisation service.

To prescribe methadone, GPs are subject to clinical audit and must complete special training, with GPs providing methadone treatment for 15 or more patients subject to more regular audit and advanced training. GPs who prescribe methadone for less than 15 patients are referred to as 'level one GPs,' and those prescribing for 15 or more as 'level two' GPs. Initiation of methadone therapy, treatment of patients with more complex medical and psychosocial needs (including alcohol dependence) and unstable drug use is only permitted by specialist addiction treatment services or by 'level two' GPs. A more complex, difficult cohort of patients attends level two

GPs and this might have implications for the success of the intervention. Therefore, it will be introduced in the data analysis as a potential confounder.

Identification and recruitment of patients

Before introducing the complex intervention, each participating practice will engage in an intensive, two-week period of patient recruitment, an approach we found most effective in previous qualitative work with this population [19].This two-week period will be supported by a member of the research team and will aim to: a) establish a 'disease' register of patients, b) obtain contact details for and informed consent from eligible patients, c) review the clinical records of patients who consent to participate in the study and d) collect baseline data, including patient demographics and current care process / outcome measures from clinical records. Patients will be eligible to participate if they are: aged 18 or over, receiving addiction treatment /care (e.g., methadone), or known problem drug user, and attending a participating general practice for general medical care. They will be excluded from the study if they have language difficulties (i.e., unable to speak, read and write English sufficiently well to complete study questionnaires), are acutely intoxicated, and / or are cognitively impaired (including severe mental health illness) to the extent that they are unable to provide informed consent to participate.
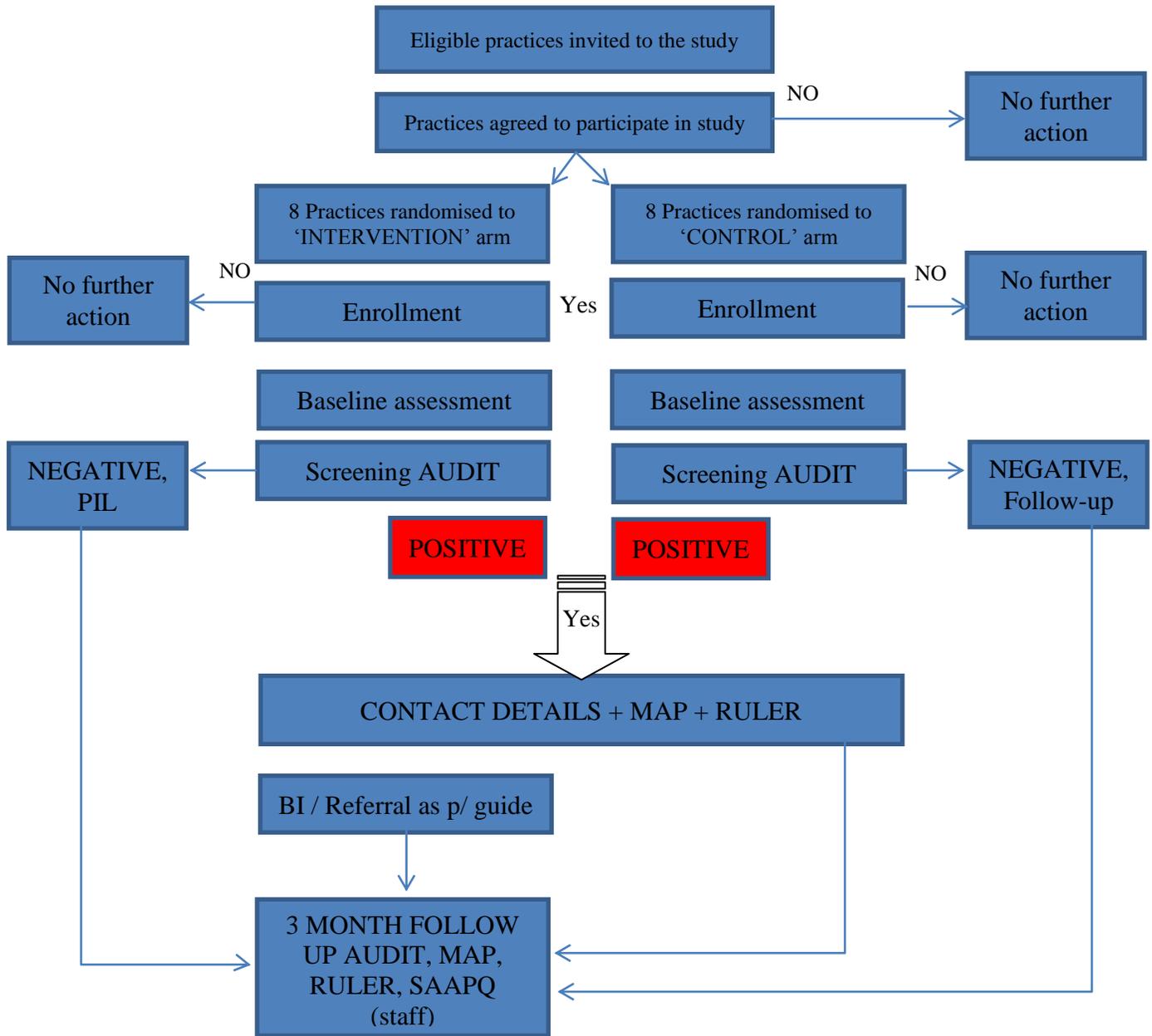
Systematic random sampling of patients in participating practices is difficult in studies among this population [25]. Hence, a standardised non-probability sampling framework will be used to identify *consecutive* patients from each practice on whom data will be collected for the purpose

of the study. Potential patient selection bias will be assessed in the exploratory data analysis, by comparing the socio-demographics of the included patients with all patients, who were identified as problem drug users, in each practice.

Patients who consult a GP taking part in the study, and who in the clinical opinion of the GP are eligible for the study (see inclusion criteria above), will be given written information on the study. Those interested in participating will be invited to meet a researcher who will be at the practice during the recruitment period. At this meeting, interested patients will be given further information on the study and will have an opportunity to ask the researcher questions. If they consent to participate, patients will be asked to sign a consent form and to complete a self-/ interviewer-administered questionnaire that includes problem alcohol use and other outcome measures, if necessary with the assistance of the researcher at T1 (i.e., Time 1, at baseline) and T2 (i.e., Time 2, at three months follow up). This applies to patients in both intervention and control groups.

Following completion of the self-/ interviewer-administered questionnaire with the researcher, patients in the intervention practices will be screened for problem alcohol use and delivered the brief intervention by their GP/ practice team (at their earliest convenience). Patients in the control arm will receive the 'Less is more' leaflet (A guide to rethinking your drinking, Health Service Executive, 2008) from the researcher. A "thank you" letter will be sent to all GPs and patients within two weeks of receiving completed study instruments/ intervention. A reminder letter will be sent to all GPs and patients five weeks before the follow-up assessments informing them of the anticipated time/date of their appraisal. Participant flow and follow up is outlined in the CONSORT diagram [32], Figure 1.

Figure 1 CONSORT diagram - Participant flow and follow up.

| Eligible practices invited to the study |

| Practices agreed to participate in study | NO → | No further action |

8 Practices randomised to 'INTERVENTION' arm

8 Practices randomised to 'CONTROL' arm

NO ← | No further action | | Enrollment | Yes | Enrollment | → NO | No further action |

| Baseline assessment | | Baseline assessment |

| NEGATIVE, PIL | ← | Screening AUDIT | | Screening AUDIT | → | NEGATIVE, Follow-up |

POSITIVE   **POSITIVE**

Yes

| CONTACT DETAILS + MAP + RULER |

| BI / Referral as p/ guide |

| 3 MONTH FOLLOW UP AUDIT, MAP, RULER, SAAPQ (staff) |

Power calculations and sample size estimates

The goals of this study are to examine feasibility, acceptability and effectiveness of the complex intervention. With respect to the feasibility component, the study aims to achieve the following rates of recruitment/ consent, participation and retention, as observed in previous studies cited below:

- 20% recruitment rate defined as number of invited GPs who confirm their interest in the study [19],

- 75% participation rate, *i.e.,* number of participants allocated to the intervention arm who will receive/ complete screening and brief intervention [5],

- 75% retention/ follow-up rate [5].

Based on the recommendations for good practice in pilot studies [33, 34], we estimate that 160 patients (attending 16 general practices) will be adequate to calculate the actual recruitment and retention rates (*i.e., feasibility*) for a sample of patients recruited in primary care and provide data on *acceptability* of study processes and outcome measures which will inform a future definitive trial. This pilot study is not powered to determine effectiveness of SBI on reduction of alcohol consumption among problem drug users. The proportion of patients who reduce their alcohol consumption will be used to predict the sample size and length of follow up for a future definitive RCT.

Intervention

A staggered intervention design will be adopted, whereby participating practices randomised to the intervention arm of the study will be provided with the complex intervention for the duration

of the study period, while practices randomised to the control arm of the study will provide usual care to patients for the duration of the study and provided with the complex intervention thereafter (i.e. delayed intervention). Such an approach was successfully used in our previous cluster randomised controlled study to improve screening for hepatitis C among problem drug users attending general practice in Ireland [25].

Control intervention

All practices (control and intervention arms) will be required to:

- Establish a 'disease' register of 'problem drug users' before study onset;

- Identify potential participants for the study;

- Recruit participants for the study / obtain informed consent;

- Enable interview with a member of the research team (telephone or in-person) to determine problem alcohol and other drug use, demographic details at baseline and at three months follow up;

- Facilitate data collection (including morbidity, primary / secondary care utilisation) from clinical records by researchers;

- €50 per patient recruited to study (paid to the GP upon receipt of completed data)[35].

We consider the above engagement with practices as close to 'usual care' as possible while still allowing evaluation of the complex intervention. To enable the development of a practice register of people with problem drug use, clinical records and prescribing information will be reviewed. For those practices who use electronic patient records, an International Classification of Primary Care (ICPC) disease code (P19) will be assigned to those patients who meet the

criteria of Europe's Monitoring Centre for Drugs and Drug Addiction (EMCDDA) for 'Problem Drug Use'. For those practices that use paper records, this register will be developed in hard copy.

Experimental intervention

A complex intervention will be delivered to practices assigned to the intervention arm and this will be delivered at two levels, practice level and patient level.

Practice level:

i. CME / CPD accredited education delivered both internally (practice-based academic detailing) and externally (seminar)

ii. Dissemination of clinical guidelines

iii. Other resources to facilitate implementation at practice level (e.g., contact details / referral information for local services)

All practices will participate in the external education (seminar). Internal education (practice-based academic detailing) will be offered on as needed basis, depending on practice resources and experience with SBI[36]. Academic detailing and support will be available to practices during the three months study period. The number and duration of these visits will be used to predict the level of support for a future definitive RCT.

Patient level: Delivery of SBI (10-15 minutes) to patients.

Data collection

At baseline, demographic details and data on primary/secondary outcome measures will be
collected by reviewing clinical records and by patients completing study instruments.

At follow up, data will again be collected by reviewing clinical records and by patients
completing study instruments. Participants will be invited to complete a follow up interview with
a researcher to include primary / secondary outcome measures. A purposive sample of patients in
the 'intervention' arm will be interviewed regarding their experience of problem alcohol use
related care in the preceding three months.

Quantitative data will be collected at baseline (T1) and at three months follow up (T2):

- Review of clinical records (T1, T2),

- Self or interviewer - administered questionnaires and semi-structured interviews
  (patients, T1, T2),

- Self-administered questionnaires, incl. open-ended questions (practitioners, T2).

Outcome measures

Table 1 summarises the key data being collected during the study.

**Table 1 Primary and secondary outcome measures to be used at the baseline and /or
follow-up examinations**

Aim / Target group	Patient measures	Staff and organisation measures	System measures
1) Feasibility	Indirect (review of clinical records): • Socio-demographic characteristics and general medical morbidity (i.e. clinical records review	Self-administered baseline questionnaire to include: • Practice / professional details, • Experience of training, • Adherence to intervention guide / manual assessed with	Indirect (review of clin records): • Current and previou with regards to scre intervention for pr alcohol use among

	using a structured instrument previously developed previously[24]) at *baseline*	the NIH 'Behaviour Change Framework'[37] (includes five intervention adherence strategies: Intervention design, Training procedures, Delivery of intervention, Receipt of intervention, and Enactment of SBI skills) *at follow up* • SAAPPQ questionnaire – see below	problem drug users • Numbers of patient a) screened for alco offered a brief inter received the brief in d) referred to a spe *follow up*
2) *Acceptability*	• Patients' experience of intervention: semi-structured interviews at *follow up* (via telephone or face to face)	Postal survey to include: • Shortened Alcohol and Alcohol Problems Perception Questionnaire (SAAPPQ)[38] at *baseline* and *follow up* • Healthcare professionals' experience of the intervention: Free text in questionnaires at *follow up* eliciting information on staff attitudes towards alcohol screening and brief intervention; previous practice of alcohol screening and brief intervention; preparedness to undertake these activities; the training required to implement screening and brief intervention; the suitability of each site to provide SBI[35].	Postal survey examinin • perceived barriers of implementation Ireland.
3) *Effectiveness*	Direct (interview at baseline and follow up): • AUDIT [39] • Other drug use (e.g., Maudsley Addiction Profile [40]) • Motivation to change risky behaviour (e.g., Readiness ruler [41]).		Indirect (review of clin records): • Results of chemical alcohol and drugs (breathalyser or urin be also retrieved us practice records to report measures.

a) Staff and organisation measures:

Healthcare professionals at participating practices will be asked to complete a self-administered questionnaire which will elicit data on:

- *Practice / professional details*

- *Experience of training*

- *Intervention fidelity.* The NIH 'Behaviour Change Framework' [37].

- *Shortened Alcohol and Alcohol Problems Perceptions Questionnaire (SAAPQ).*

b) System measures:

1) total number of patients screened for alcohol problems (and method of screening), 2) the number screening positive,

4) the number receiving any alcohol intervention (including referral),

3) results of chemical tests for alcohol and drugs (e.g., breathalyser or urine tests) conducted by GPs will be also retrieved using the practice records (T2) to verify self-report measures.

c) Patient measures:

- *Indirect examination*,

- *Direct examination.* At baseline and follow up, the study battery will include the following:

AUDIT- Alcohol use disorders identification test (10 items), developed by the World Health Organisation to identify a continuum of problem alcohol use [21, 39].

Maudsley Addiction Profile (MAP) a brief, structured questionnaire for treatment outcome research, which measures problems in four areas: substance use, health risk behaviour, physical and psychological health, and personal/social functioning [18, 40].

Readiness Ruler will assess patient's motivational state regarding changing their drinking behaviour [42].

Financial incentives

Participating practices will be offered €50 per patient to compensate for the extra administration work as in a similar trial [35]. We consider this a conservative level of remuneration given the additional work involved for participating practices [43].

Data analysis

Descriptive statistics will be estimated with respect to key feasibility variables:

- Baseline:
    - Practice recruitment rate
    - Prevalence of problem drug use at participating practices
    - Patient recruitment rate
    - Baseline prevalence of problem alcohol use among problem drug users
- Intervention: process and fidelity evaluation of pilot educational intervention;
- Outcome:
    - Practice / patient retention rates
    - Prevalence of problem alcohol use among problem drug users

      o   Confounding factors, e.g. practice busyness or person who did SBI

SPSS v20 and R software will be used for analysis by the HRB Centre for Support and Training in Analysis and Research.

Qualitative evaluation

A parallel qualitative evaluation will also be conducted with patients and healthcare professionals:

With regard to healthcare professionals, open-ended questions eliciting information on staff attitudes towards alcohol screening and brief intervention; previous practice of alcohol screening and brief intervention; preparedness to undertake these activities; the training required to implement screening and brief intervention; the suitability of each site to provide SBI; and other barriers to effective implementation[35].

With regard to patients, among a 20% purposive sample (estimated N=16) of patients in the intervention practices, we will also explore patients' satisfaction with and experience of intervention and problem alcohol use related care in the preceding 3-6 months. Interviews will be done by researcher via telephone, postal questionnaire or in person. Prior to the interviews, the participant will be informed of the interview purpose, the interview procedure and the use of the findings. The participant will then be invited to sign an additional consent form and the interview will commence.

Qualitative data analysis will be systematic and organised in order to easily locate information within the data set when tracing results, providing examples in context[44]. The qualitative research software Nvivo v8 will be used to facilitate the coding. Thematic analysis will be used to analyse qualitative data. This approach has many benefits for studies such as this which are interpretive in nature, as it is a 'method for identifying, analysing and reporting patterns (themes) within data'[44].

Ethical considerations

Ethical approval has been obtained from the Research Ethics Committee of the Irish College of General Practitioners (Protocol Reference: Cullen, November 29th, 2012). Research carried out on humans in this study is in compliance with the Helsinki Declaration. The protocol follows the CHECKLIST of items to consider for inclusion in a report of a pilot studies[45], adopted from the CONSORT statement [32, 46].

A two-stage procedure to obtain informed patient consent to participate in the study will be used during the study. Patients who consult a GP taking part in the study, and who in the clinical opinion of the GP are eligible for the study, will be given written information on the study (brief study information sheet). Those interested in participating will be invited to meet a researcher who will be at the practice during the recruitment period. At this meeting, interested patients will be given further information on the study and will have an opportunity to ask the researcher questions. When all issues have been explained to the person's satisfaction, he or she will be asked to indicate consent to participate in the study by signing a consent form and this procedure will be witnessed by a third party. The standard patient consent form for participation in non-clinical trials, developed by the Research Ethics Committee of the Irish College of General Practitioners, will be used in the study. Participation in the study will be on a voluntary basis. No

inducements to participate will be offered to patients, and refusal to participate will not compromise patient care.

Potential adverse effects of the intervention will be explored in the qualitative interviews with patients and practitioners.

Discussion

The PINTA is the first study to examine the feasibility and acceptability of alcohol screening and brief intervention for problem alcohol use among problem drug users attending primary care. It will provide key data which will enhance scientific understanding of interventions that prevent risk behaviours, inform policy and service development and contribute to health and social gain locally and internationally.

The project team involves academic, clinical, policy experts responsible for planning/delivery of addiction care/primary care and international experts on optimum primary care delivery to at-risk populations / primary care alcohol treatment.

The proposed work will build on our recently completed project which has identified problem alcohol use as a common finding among patients on methadone and subsequent programme of research which has explored and documented existing practices with respect to alcohol interventions among this group. This information is used, in conjunction with scientific evidence, to develop clinical guidelines regarding screening and treatment for problem alcohol use, and then consult it with patients / healthcare professionals.

At the end of this research, the feasibility of a clinical intervention, informed by international best practice and local barriers, will be evaluated in areas of high need. This intervention is likely to consist of a training and support programme and clinical guidelines. By involving service users and service providers in their development phase, acceptability and feasibility will be enhanced. The research methodology also gives a voice to a group of service users not normally at the centre of how interventions are tested.

This feasibility study may inform clinical practice by providing initial indications as to whether psychosocial interventions for problem alcohol use are feasible, acceptable and also effective among problem drug users attending primary care. It will also inform future research on the topic by providing key parameters for the design of a future cluster randomised controlled trial.

Feasibility study status
Protocol development

Competing interests
The authors declare that they have no competing interests.

Authors' contributions
JK is lead researcher on the study. WC is Principal investigator, conceived the study. JK and WC led preparation of the manuscript with a core group of authors. All authors read and approved the final manuscript of this manuscript.

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