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Client-centred, caseworker-delivered smoking cessation intervention for a socially disadvantaged population.

Submission date	Recruitment status	[X] Prospectively registered
23/11/2009	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
08/12/2009	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
16/09/2015	Mental and Behavioural Disorders	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

631055

Study information

Scientific Title
A randomised controlled trial of a client-centred, caseworker-delivered smoking cessation intervention for a socially disadvantaged population.

Study objectives
Current hypothesis as of 03/09/2013:
Clients attending a non-government community social service, who have been randomly allocated to receive a smoking cessation intervention, will have 8% higher smoking cessation rates at 1 and 6 months follow-up (as measured by a. continuous abstinence and b. 24-hour validated self-reported smoking cessation), relative to those randomised to the group receiving minimal ethical care.

Previous hypothesis:
Clients attending a non-government community social service, who have been randomly allocated to receive a smoking cessation intervention, will have 8% higher smoking cessation rates at 1, 6 and 12 months follow-up (as measured by a. 24-hour validated self-reported smoking cessation and b. 7-day self-reported smoking cessation), relative to those randomised to the group receiving minimal ethical care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Pending

Study design
Randomised active-controlled parallel-group trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Smoking cessation; prevention of related health problems

Interventions
The smoking cessation (intervention) group will receive an intensive client-centred smoking cessation intervention offered by the caseworker over a minimum of 3 face-to-face visits (each 2 weeks apart) which will commence immediately following baseline survey completion, followed by at least 2 phone contacts (1 week apart). This intervention will constitute an add-on to clients' usual regular counselling visits, reducing additional costs to the Centre and to clients. If a client requires further contact, staff will provide further quitting assistance and record what they delivered on their checklist.

The control group will receive minimum ethical care.

Intervention Type
Behavioural

Primary outcome measure
Current primary outcome measures as of 03/09/2013:
There will be two primary outcome measures obtained at 1 month follow-up:
1. Self-reported quit attempts
2. continuous abstinence
There will be two primary outcome measures obtained at 6 month follow-up:
1. Continuous abstinence
2. 24-hour carbon monoxide (CO) validated self-reported smoking cessation

These follow-up time periods and measures of smoking cessation have been recommended by the Society for Research on Nicotine and Tobacco (SRNT) workgroup for measuring smoking cessation. Continuous abstinence will be defined as abstinent since the 2 week grace period following baseline assessment. Continuous abstinence will allow greater power to detect differences.

Biochemical verification of self-report: General population reports and some clinical trial based studies show that misreporting tends to be low, around 5%. Little is known regarding the misreporting rate of smoking status in this population. Thus, this study will use biochemical validation methods to ensure self-report estimates are validated. Verification will be conducted using measures of CO in expired air as recommended by the SRNT Biochemical Verification workgroup.

Previous primary outcome measures:
There will be two primary outcome measures obtained at 1, 6 and 12 month follow-up:

1. 24-hour carbon monoxide (CO) validated self-reported smoking cessation
2. 7-day self-reported smoking cessation

These follow-up time periods and measures of smoking cessation have been recommended by the Society for Research on Nicotine and Tobacco (SRNT) workgroup for measuring smoking cessation. 7-day smoking cessation will be defined as abstinent for the past 7 days at 1, 6 and 12 months respectively. 7-day point prevalence abstinence is a common and recommended cessation outcome and has the highest concurrent validity of a range of cessation measures including prolonged and continuous abstinence. Also, prolonged abstinence is not an appropriate measure for this sample given the likelihood of delayed intervention effects, high relapse rates and a focus on encouraging repeated quit attempts which should be captured through the use of longer term follow-up (12 months).

Biochemical verification of self-report: General population reports and some clinical trial based studies show that misreporting tends to be low, around 5%. Little is known regarding the misreporting rate of smoking status in this population. Thus, this study will use biochemical validation methods to ensure self-report estimates are validated. Verification will be conducted using measures of CO in expired air as recommended by the SRNT Biochemical Verification workgroup.

Secondary outcome measures
1. Sociodemographic characteristics will include:
1.1. Age
1.2. Gender
1.3. Marital status
1.4. Housing status
1.5. Income
1.6. Education
1.7. Postcode.
2. Nicotine dependence will be measured by
2.1. Heaviness of Smoking Index (HSI). HSI scores range from 0-6 and are calculated by summing the points for 1) time to first cigarette smoked after waking (in minutes) and 2) number of cigarettes smoked per day. Higher HSI scores indicate more dependence on nicotine.
2.2. 2-item short form of the Fagerstrom Tolerance Questionnaire
3. Quit attempts. A commonly used item which asks 'How many serious attempts to stop smoking have you made in the last 12 months? By serious attempt I mean you decided that you would try to make sure you never smoked again. Please include any attempt that you are currently making and please include any successful attempt made within the last year'.
4. Use of cessation aids. Clients who have made a serious quit attempt will be asked about treatments they had used in their most recent quit attempt. A single item developed by Shiffman et al will list various pharmacological, behavioural and alternative smoking cessation aids.
5. Partner smoking behaviour. One item will assess partner smoking behaviour: 'Does your partner smoke?' (response options: yes, yes but stopping with me, no ex-smoker, no never smoked, N/A).
6. Depression. A recent meta-analysis indicates that the Patient Health Questionnaire (PHQ) has sensitivity of 80% and specificity of 92% in diagnosing major depression. The two-item PHQ2 is recommended by the US Preventive Services Taskforce for depression screening and will ask 'Over the last 2 weeks have you felt down, depressed or hopeless?' and '...have you felt little interest or pleasure in doing things?'.
7. Financial stress will be measured using a scale developed by Assistant Investigator Prof Mohammad Siahpush et al and previously used as a predictor of smoking behaviour. It includes items asking 'In the last 6 months, did any of the following happen to you because of a shortage of money?' followed by 6 options.

Overall study start date
01/02/2010

Completion date
30/01/2014

Eligibility

Key inclusion criteria

1. Aged over 18 years
2. Self-reported smokers
3. Clients who attend for counselling services have a number of repeat visits that offers them opportunity for repeated exposure to the smoking cessation intervention. Eligible clients include:
3.1. Those attending the Centre for their first visit for a counselling service
3.2. Those who have attended the Centre at another time in the past, and are returning to start a new program
4. English speakers. Reading age up to year 5 will be assumed and the survey and study materials will be presented at this reading level. English-speaking clients who are unable to read at this level will be offered assistance from the research assistant (RA) to complete study consent forms and surveys.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
400

Key exclusion criteria
1. Only attending once (for example, for emergency relief)
2. Presentation with uncontrolled mental illness (as identified by the RA and confirmed by the caseworker)
3. Partner is already enrolled in the study
4. Non-English speaking

Date of first enrolment
01/02/2010

Date of final enrolment
30/01/2014

Locations

Countries of recruitment
Australia

Study participating centre
University of Newcastle
Newcastle

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Sponsor information

Organisation
Centre for Health Research and Psycho-oncology (CHeRP) (Australia)

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Sponsor type
Research organisation

Funder(s)

Funder type
Research council

Funder Name
National Health and Medical Research Council (ref: 631055)

Alternative Name(s)
NHMRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Australia

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	14/09/2015		Yes	No