A randomised controlled trial of smoking cessation advice and nicotene replacement therapy delivered by dental hygienists in a dental setting

Submission date 07/12/2006	Recruitment status No longer recruiting	 Prospectively registered Protocol
Registration date 29/12/2006	Overall study status Completed	 [] Statistical analysis plan [X] Results
Last Edited 19/09/2007	Condition category Mental and Behavioural Disorders	Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s) Scientific

Dr Viv Binnie

Contact details

Level 8 Glasgow Dental School 378 Sauchiehall Street Glasgow United Kingdom G2 3JZ +44 (0)141 211 9802 v.binnie@dental.gla.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers N/A

Study information

Scientific Title

Study objectives

To determine the feasibility and efficacy of a smoking cessation intervention, delivered by dental hygienists in a cohort of periodontal patients attending an outpatient hospital department.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the Glasgow Dental Hospital and School Area Dental Ethics Committee in January 2001.

Study design Randomised controlled trial

Primary study design Interventional

Secondary study design Randomised controlled trial

Study setting(s) Other

Study type(s) Treatment

Participant information sheet

Health condition(s) or problem(s) studied Smoking addiction

Interventions

Intervention arm: smoking cessation advice based on the 5As (Ask, Advise, Assess, Assist, Arrange) and Nicotene Replacement Therapy (NRT) Control arm: usual care (very brief advice)

Intervention Type

Other

Phase Not Specified

Primary outcome measure

Self -reported quit rates validated by Carbon Monoxide (CO) and salivary cotinine

Secondary outcome measures

1. Changes in smoking behaviour including reduction in number of cigarettes (and change in cotinine levels), and increase in numbers of quit attempts

Overall study start date 01/04/2001

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Completion date 01/04/2004

Eligibility

Key inclusion criteria

1. Adult (more than 16 years) smokers of at least ten cigarettes

2. Informed consent

Participant type(s) Patient

Age group Adult

Sex Not Specified

Target number of participants 120

Key exclusion criteria

1. Adult (more than 16 years) smokers of less than ten cigarettes 2. Currently receiving smoking cessation therapy elsewhere

Date of first enrolment 01/04/2001

Date of final enrolment 01/04/2004

Locations

Countries of recruitment Scotland

United Kingdom

Study participating centre Level 8 Glasgow United Kingdom G2 3JZ

Sponsor information

Organisation University of Glasgow (UK)

Sponsor details University Avenue Glasgow Scotland United Kingdom G12 8QQ v.binnie@dental.gla.ac.uk

Sponsor type University/education

Website http://www.gla.ac.uk/

ROR https://ror.org/00vtgdb53

Funder(s)

Funder type University/education

Funder Name The University of Glasgow (UK) - covering the cost of cotinine analysis

Funder Name Smoking Concerns (UK) - local NHS Stop smoking body, donating NRT

Funder Name

All other costs were covered internally by NHS departments taking part in the trial

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?
<u>Results article</u>	Results	02/05/2007		Yes	No