

Dental Outreach Oral Hygiene Study

Submission date 01/10/2010	Recruitment status Stopped	☐ Prospectively registered ☐ Protocol
Registration date 06/12/2010	Overall study status Stopped	☐ Statistical analysis plan ☐ Results
Last Edited 02/09/2014	Condition category Oral Health	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol

Background and study aims

Outreach clinics provide free dental treatment delivered by final year dental students under supervision. The clinics, which have now become widespread throughout Scotland, have been constructed in areas with low NHS dental registration levels, under the direction of the NHS Action Plan for Improving Oral Health (Scottish Executive 2005). Subsequently, these clinics provide treatment for patients with high levels of disease as a result of poor oral hygiene. Dental care providers deliver oral hygiene instruction as part of a preventive care approach. However, there currently is no clear best practice on how this instruction is best delivered. There is, however, some evidence to suggest that delivery of oral hygiene instruction using a psychological framework can improve patients oral health behaviours and therefore oral health. It has also been suggested that the inclusion of biomarker information may further increase patients oral hygiene behaviours and therefore oral health. This study aims to assess the effectiveness of oral hygiene instruction delivered within a psychological framework, with the inclusion of biomarker information, on the periodontal health of dental outreach patients.

Who can participate?

Dental outreach patients over the age of 16 with at least one natural tooth.

What does the study involve?

During routine dental outreach appointments participants will complete a short questionnaire and have their gum health examined by a final year dental student. They then will be given oral hygiene instruction; the method used will be determined by the students group allocation. Participants will return at 3 and 6 months to complete a questionnaire and have their gum health examined. Participants will be enrolled in the study for 6 months. During this time they receive normal dental care on outreach which may involve gum treatment.

What are the possible benefits and risks of participating?

Participants in the study may benefit from improving their oral health. Regular effective tooth cleaning has been proven to reduce dental disease. There are no additional risks to being involved in this study as oral hygiene instruction is something which is part of usual dental care.

Where is the study run from?

Dundee Dental Hospital and School (UK).

When is the study starting and how long is it expected to run for?

The study ran from October 2010 to September 2011.

Who is funding the study?

Scottish Dental Practice Based Research Network have funded paperwork and donated researcher time to this study. Training for the study has been donated by Tayside Academic Health Science Centre.

Who is the main contact?

Dr Andrew Hall

Contact information

Type(s)

Scientific

Contact name

Dr Andrew Hall

Contact details

Department of Restorative Dentistry
Dundee Dental Hospital and School
Park Place
Dundee
United Kingdom
DD1 4HN

Additional identifiers

Protocol serial number

00000053

Study information

Scientific Title

A randomised and controlled cluster trial of 1500 patients attending dental outreach facilities affiliated with the University of Dundee, investigating whether delivery of an enhanced form of oral hygiene instruction, framed using psychological theory with the inclusion of biomarker information, can influence gingival health

Acronym

DOOHS

Study objectives

Providing tooth cleaning instruction enhanced by psychological theory and including biomarker information will improve the gingival health of dental outreach patients, compared to the providing the usual methods of tooth cleaning instruction.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Fife and Forth Valley Research Ethics Committee, ref: 10/S0501/43

Primary study design

Interventional

Study design

Randomised controlled cluster trial

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

Oral health

Interventions

Oral hygiene instruction delivery, enhanced by framing with a psychological framework including biomarker information (intervention), versus oral hygiene instruction delivered in the usual way (control).

The treatment is a one-off intervention and patients in both control and intervention arms will be followed up for 6 months.

Updated 02/09/2014: The study was stopped due to poor patient recruitment.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

To assess the effectiveness of oral hygiene instruction delivered within a psychological framework, with the inclusion of biomarker information, on the periodontal health of primary care dental outreach patients. Measured at baseline, 3 months and 6 months.

Key secondary outcome(s)

Measured at baseline, 3 months and 6 months:

1. To assess the change in reported oral hygiene behaviours after this method of oral hygiene delivery
2. To investigate the acceptability of clinical research to this new group of primary care patients and the participating students

Completion date

01/09/2011

Reason abandoned (if study stopped)

Participant recruitment issue

Eligibility

Key inclusion criteria

Dental outreach clinic patients over 16 years, with at least one natural tooth

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Patients who are pregnant
2. Patients with completely healthy gums and no dental plaque
3. Patients who have medical disorder preventing examination of the gums

Date of first enrolment

31/10/2010

Date of final enrolment

01/09/2011

Locations

Countries of recruitment

United Kingdom

Scotland

Study participating centre

Department of Restorative Dentistry

Dundee

United Kingdom

DD1 4HN

Sponsor information

Organisation

University of Dundee (UK)

ROR

<https://ror.org/03h2bxq36>

Funder(s)

Funder type

Other

Funder Name

Added 02/09/2014:

Funder Name

Scottish Dental Practice Based Research Network (UK)

Funder Name

Tayside Academic Health Science Centre (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration