

The use of audio tapes in oral health promotion for an Urdu-speaking community

Submission date 23/01/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 23/01/2004	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 11/06/2014	Condition category Oral Health	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

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
RBF 99X23

Study information

Scientific Title

Study objectives

Primary research question: does the use of pre-recorded audio tapes encourage patients to complete their course of dental treatment?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Not Specified

Participant information sheet

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

Health condition(s) or problem(s) studied

Oral health

Interventions

1. Exposure to audio tapes
2. Standard care

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

The intervention will be considered effective if it reduces the failure rate by 20-40%. To have an 80% power of detecting such a difference as statistically significant at the 5% two-sided level

could required 107 children per group (214 in total). This service sees approximately 150 patients per month in this age group. Assuming 60% agree to take part, then to recruit 214 children will take approximately 3 months. The main outcome measure is the difference in the failure rate between the two groups (intervention and control); failures to attend for appointments will be compared by a Chi squared test. 95% confidence intervals for the differences in failures to attend for appointments between the two groups will also be calculated.

Secondary outcome measures

Not provided at time of registration

Overall study start date

27/09/1999

Completion date

01/09/2001

Eligibility

Key inclusion criteria

The age group will be 6-10

Sample size: the main outcome for determining sample size is failure rate. The current failure rate is approximately 60%.

Participant type(s)

Patient

Age group

Child

Lower age limit

6 Years

Upper age limit

10 Years

Sex

Both

Target number of participants

214

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

27/09/1999

Date of final enrolment

01/09/2001

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Community Dental Service

Sheffield

United Kingdom

S10 3TH

Sponsor information

Organisation

NHS R&D Regional Programme Register - Department of Health (UK)

Sponsor details

The Department of Health

Richmond House

79 Whitehall

London

United Kingdom

SW1A 2NL

+44 (0)20 7307 2622

dhmail@doh.gsi.org.uk

Sponsor type

Government

Website

<http://www.doh.gov.uk>

Funder(s)

Funder type

Government

Funder Name

NHS Executive Trent (UK)

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