ISRCTN28602629 https://doi.org/10.1186/ISRCTN28602629

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

Submission date	Recruitment status	[ ] Prospectively registered
23/01/2004	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
23/01/2004	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
11/06/2014	Oral Health	[ ] 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
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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