

An evaluation of a model system for active prevention in the general dental service.

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 checked="" type="checkbox"/> Results
Last Edited 08/12/2009	Condition category Oral Health	<input type="checkbox"/> Individual participant data

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
RDO/90/19

Study information

Scientific Title

Study objectives

A randomised, controlled trial will evaluate the benefit to child patients aged 2-5 years of a structured, practice-based dental health education package given to parents by dental health educators over a two year period.

The null hypotheses tested will be:

1. The secondment of dental health educators to general dental practices will not influence the caries incidence of 'at risk' regularly attending pre-school child patients over a two year period.
2. There will be no cost-effective health gain from the use of dental health educators in the general practice setting.
3. The parents in the test group will not increase their knowledge on the prevention of caries more than those in the control group.

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)

Other

Study type(s)

Prevention

Participant information sheet

Health condition(s) or problem(s) studied

Oral health/stomatognathic diseases

Interventions

1. Control group children given a toothbrush and toothpaste and the parents will be interviewed and given instruction in the child's oral hygiene; they will be recalled at the end of two years, re-examined and the parents interviewed again.
2. Test group children will be given three dental health education visits at the beginning and one

recall visit every 4 months for the two year study period. Children also given toothbrush and toothpaste and parents interviewed. The dental health education package will consist of detailed counselling on sugar control and the use of fluoride toothpaste for young children.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Incidence of caries

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/01/1999

Completion date

31/10/2002

Eligibility**Key inclusion criteria**

Children 2-5 years

Participant type(s)

Patient

Age group

Child

Lower age limit

2 Years

Upper age limit

5 Years

Sex

Both

Target number of participants

Not provided at time of registration

Key exclusion criteria

Does not match inclusion criteria

Date of first enrolment

01/01/1999

Date of final enrolment

31/10/2002

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

Dept of Dental Health and Medicine

Manchester

United Kingdom

M15 6FH

Sponsor information**Organisation**

Record Provided by the NHS R&D 'Time-Limited' National Programme Register - Department of Health (UK)

Sponsor details

The Department of Health

Richmond House

79 Whitehall

London

United Kingdom

SW1A 2NL

Sponsor type

Government

Website

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

Funder(s)**Funder type**

Government

Funder Name

NHS National Programme for Primary Dental Care (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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	11/10/2003		Yes	No