ISRCTN26423417 https://doi.org/10.1186/ISRCTN26423417

A study investigating patient decision making in the light of 'evidence'

Submission date	Recruitment status	[ ] Prospectively registered
30/09/2005	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
30/09/2005	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
05/07/2016	Oral Health	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof T Newton

Contact details
Department of Dental Public Health
18th Floor Guy's Tower
Guy's Hospital
London
United Kingdom
SE5 9RS
+44 (0)20 7955 4031
tim.newton@kcl.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0116149179

Study information

Scientific Title
A study investigating patient decision making in the light of 'evidence'

Study objectives
In this study we intend to determine, on what basis patients make decisions about whether or not to have dental treatment carried out, when faced with information from two sources. The aim of the study will be to identify the relative effects of research evidence and clinical evidence on patient decision making.

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)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Oral Health

Interventions
The study will take place in the waiting areas of King's College Dental Hospital. All participants will be asked to give their consent to participating in a study examining patient decision making about whether or not to have dental treatment carried out, when faced with information from two sources.

The experimental design will be a two-factor independent group design. The two factors will be the type of information given to patients, informed by the clinician's judgement and the research evidence. Each factor will have two levels: strong evidence for and strong evidence against. The participant will be randomly assigned to one of the four combinations of the two variables. Participants will be given a cover letter explaining the purpose of the study,

demographic questions and a case vignette. The participants will be asked to complete the vignettes, making judgements and decisions about treatment and use of information given. Additionally participants' will be asked to rate their oral health using a standardised scale (Atchison and Dolan, 1990)

The scenario will be identical in each vignette. Each vignette will describe a visit to their dentist for treatment of a large hole in one of their back teeth. The nature and purpose of the visit will be identical in each vignette. The first paragraph will describe our study. The second paragraph will describe the context of the visit to the dentist. The next paragraph will describe the strength of research evidence available. The fourth paragraph will describe the dentist's clinical judgement of the possible outcome. The two factors will be manipulated to express two levels of each variable; the evidence strongly supports the intervention, the evidence strongly suggests no effect. The four vignettes will correspond with all four factorial combinations of the two factors. Participants will be asked to read their vignette. After reading their vignette they will be asked to indicate their decision about possible treatment based on the information they will have been given in the vignette and their confidence in the decision.

The vignettes were reviewed as a result of the Research Ethics Committee's comments given on 27th February 2004. In response to these comments, the vignettes were reviewed by three dentists and subsequent modifications were made to encompass the need for clinical reality.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
The outcome variable will be the proportion of patients to undergo the treatment described in the vignette.
The outcome measures will be assessed by:
1. Patients' willingness to engage in treatment with the binary of unwilling/willing
2. Patients' confidence

Secondary outcome measures
No secondary outcome measures

Overall study start date
15/06/2004

Completion date
30/09/2004

Eligibility

Key inclusion criteria
1. Patients from the waiting areas of King's College Dental Hospital
2. Gave consent

Participant type(s)

Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
Not provided at time of registration

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
15/06/2004

Date of final enrolment
30/09/2004

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Guy's Hospital
London
United Kingdom
SE5 9RS

Sponsor information

Organisation
Department of Health

Sponsor details
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.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
Kings College Hospital NHS Trust R&D Consortium (UK)

Funder Name
NHS R&D support funding (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