

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

Submission date 30/09/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 30/09/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 05/07/2016	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
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

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Sponsor type
Government

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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