

The value and cost of different forms of oral health information

Submission date 12/02/2018	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 27/03/2018	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 05/06/2024	Condition category Oral Health	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

A new system of paying NHS dentists in England is being tested which involves putting patients into Traffic Light categories: 'Red' is high risk, 'Amber' is medium risk, and 'Green' is low risk for dental disease. Currently it is not known whether dentists talk to patients about risk, whether patients find Traffic Light risk information useful, or whether this leads to improved behaviours such as toothbrushing. New camera technology (Quantitative Light-Induced Fluorescence or QLF) is also available which produces vivid images such as highlighting plaque in red. Again, it is not known whether patients appreciate this information and use it to improve brushing. The aim of this study is to find out which form of information on oral health risk patients prefer, and whether there is a difference in how they respond to the information with respect to oral health behaviours such as toothbrushing and dietary habits.

Who can participate?

NHS patients aged 18 and over who are at high/medium (red/amber) risk of poor oral health

What does the study involve?

Participants are randomly allocated to be given either: traffic Light information, QLF photographs or just verbal information by the dentist just after having their check-up. Questionnaire data is collected from patients on tablet PCs, QLF photographs are taken at their next two dental visits, and telephone interviews are undertaken 6 and 12 months later.

What are the possible benefits and risks of participating?

Not provided at time of registration

Where is the study run from?

Four NHS dental practices in the UK

When is the study starting and how long is it expected to run for?

June 2014 to October 2017

Who is funding the study?

National Institute for Health Research (UK)

Who is the main contact?

Dr Rebecca Harris

Contact information

Type(s)

Public

Contact name

Dr Rebecca Harris

ORCID ID

<http://orcid.org/0000-0002-5891-6826>

Contact details

Department of Health Services Research

Room 113, 1st Floor

Block B, Waterhouse Building

1-5 Brownlow Street

Liverpool

United Kingdom

L69 3GL

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

17265

Study information

Scientific Title

The value and cost of different forms of information on oral health status and risk given to patients following a check-up in dental practice

Study objectives

The aim of this study is to describe how patients value and respond to information on their oral health status and risk and to compare the value of three different methods for presenting information on patient's oral health and risk (verbal, paper-based traffic light rating, electronic QLF image)

Ethics approval required

Old ethics approval format

Ethics approval(s)

NRES Committee North West - Liverpool East, 26/06/2014, ref: 14/NW/1016

Study design

Both; Both; Design type: Process of Care, Other, Qualitative

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Prevention

Participant information sheet

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

Health condition(s) or problem(s) studied

Specialty: Oral and dental health, Primary sub-specialty: Other

Interventions

The trial was a three arm, parallel group, pragmatic Randomised Controlled Trial to test patients preferences and willingness to pay for information in different formats. Additionally, the trial sought to determine whether there were any clinical or behavioural differences between the three information formats being tested. Participants were randomised into one of three trial arms:

1. Verbal Only Condition: This constitutes usual care and involves a dentist providing the patient with risk information based on their individual needs verbally (also providing patients with a card with relevant oral health messages highlighted).
2. Traffic Light presentation plus verbal information: In this condition patients will be categorised according to a pre-determined RAG algorithm: Red (high-risk patient), Amber (medium risk patient) or Green (low risk patient). Patients will receive a coloured card, detailing their categorisation (as well as their RAG categorisation explanation), verbal information, and a card highlighting relevant oral health messages.
3. QLF presentation plus verbal information: In this condition, patients will receive a QLF photograph of their teeth (there are two choices of photograph, with the most salient [chosen by the dentist] being presented: either a photograph which shows mature plaque on the teeth or demineralisation of the teeth). Alongside the photograph (as well as an explanation about their photograph), patients will receive verbal information, and a card highlighting relevant oral health messages.

The intervention was given to the patients at visit 1 (V1). There were then two additional practice-based follow ups at around two/three weeks post-intervention (V2, V3) and then around six weeks post intervention. Following this, there were two further telephone follow-up points at 6 and 12 months post-intervention.

Intervention Type

Other

Primary outcome measure

Willingness-to-Pay (WTP) will be used to quantify patient's preferences for the three forms of information. WTP is recognised as representative of how consumers respond to health care decision making. WTP is measured using a contingent valuation approach (a hypothetical scenario used to elicit preferences from participants) collected at the first visit (the patient's dental check-up appointment)

Secondary outcome measures

1. Clinical communication measured by the Communication Assessment Tool (CAT), completed by patients after receiving the risk information at V1
2. Self-reported behaviour change between V1, and 6 and 12 months post-intervention:
 - 2.1. Oral hygiene is measured by self report tooth-brushing frequency, duration of tooth-brushing and frequency of interdental cleaning
 - 2.2. Use of fluoride is measured by self report fluoride toothpaste prescribed by the dentist and fluoride mouth-rinse
 - 2.3. Dietary sugar intake is measured by self report frequency of consumption of sugary foods /drinks and frequency of adding sugar to hot drinks tea/coffee
 - 2.4. Smoking is measured by self report smoking information
 - 2.5. Self-rated oral health status measured using a self report rating scale at V1 and 6 and 12 months
3. Clinical outcomes:
 - 3.1. Basic Periodontal Examination (BPE) collected by dentists concentrating on conversions between codes 1 (bleeding) and 0 (health) between V1 and V2/3
 - 3.2. Plaque Percentage Index (PPI) measured on QLF images ($\Delta R30$) – change between V1 and V2 /3
 - 3.3. Number of tooth surfaces affected by early caries – change between V1 and V2 / 3 measured on QLF images
 - 3.4. Where early carious lesions are present – change in lesion volume (ΔQ) between V1 and V2 / 3 measured on QLF images

Overall study start date

01/06/2014

Completion date

31/10/2017

Eligibility

Key inclusion criteria

1. Aged ≥ 18 years
2. High/medium (red/amber) risk of poor oral health
3. NHS patients
4. New patients or regular attenders
5. Any level of literacy

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Planned Sample Size: 400; UK Sample Size: 400

Total final enrolment

412

Key exclusion criteria

1. Less than 18 years of age
2. Vulnerable adults

Date of first enrolment

17/08/2015

Date of final enrolment

05/09/2016

Locations**Countries of recruitment**

United Kingdom

Study participating centre

Four NHS dental practices in the UK

United Kingdom

-

Sponsor information**Organisation**

University of Liverpool

Sponsor details

Research Support Office

2nd Floor, Block D, Waterhouse Building

3 Brownlow Street

Liverpool

England
United Kingdom
L69 3LG

Sponsor type
University/education

ROR
<https://ror.org/04xs57h96>

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Protocol will be published shortly. Planned publication of the results in a high-impact peer reviewed journal by October 2018.

Intention to publish date
01/10/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to issues with confidentiality and anonymity .

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	06/01/2020	08/01/2020	Yes	No
Protocol article		07/05/2018	09/08/2022	Yes	No
HRA research summary			26/07/2023	No	No
Results article		06/01/2020	05/06/2024	Yes	No