Electronic-based personalised dental education for caries prevention in a disadvantaged population:
a randomised controlled study

Protocol Number OHSRC00114

Oral Health Services Research Centre
University College Cork, Ireland

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Summary

Although many studies have shown lower socioeconomic groups have a greater burden of dental disease than higher socioeconomic groups, studies have not shown the particular individual variability of caries risk within the lower socioeconomic groups. If individual variability exists, then personalised caries prevention and management are imperative. This project aims to investigate the effectiveness of an electronic-based assessment (Cariogram) and a personalised approach to caries prevention adopting personalised marketing techniques. An electronic marketing system modelled on Rapport Builder® will be developed to deliver electronic personalised educational messages for caries prevention each week to the subjects, based on their risk profile derived from the Cariogram.

To investigate the effectiveness of the approach, we will conduct an evaluator-blind randomised controlled study. Approximately 200 medical-card (proxy for low socioeconomic status) patients recruited from approximately 10 dental surgeries in Ireland will be randomly assigned to test and control groups. The caries risk profile of all subjects will be assessed using Cariogram at baseline and at six months. Once weekly for 24 weeks, the Test group will receive personalised educational text messages on caries prevention while the Control group receives non-personalised educational text messages. The average change in "chance to avoid new cavities" as measured by Cariogram before and after the intervention between the test and control groups will be compared using a two-sample two-sided t-test.

If the electronic personalised education system (EPES) for caries prevention proves successful, it represents a ground-breaking approach to reducing caries risk and building patient engagement in those with greatest need, adopting modern technologies to promote regular check-ups and better dental health. Furthermore, the concept could be adapted and applied to other lifestyle related diseases with individual variability.

Introduction

Although many studies have shown lower socioeconomic groups have a greater burden of dental disease than higher socioeconomic groups (Petersen, Bourgeois, Ogawa, Estupinan-Day, & Ndiaye, 2005), studies have not shown the particular individual variability of caries (tooth decay) risk within the lower socioeconomic groups. Caries risk may vary from person to person and may change during a person's lifetime; if individual variability exists, then personalised caries prevention and management are imperative. The literature suggests that providing caries prevention advice without reference to the individual's specific risk factors is not effective in achieving long-term behaviour change (Kay & Locker, 1998; Yevlahova & Satur, 2009).

Personalised medicine is an emerging field (Garcia, Kuska, & Somerman, 2013). This concept of personalised care could be applied to promoting changes in oral health behaviour and caries prevention. Dental caries is a preventable, prevalent and expensive disease of medical and social importance (Rugg-Gunn, 2013). The Cariogram is a validated caries risk assessment software programme (Bratthall, 1996; Petersson, 2003) (http://www.mah.se/fakulteter-och-omraden/Odontologiska-fakulteten/Avdelning-och-kansli/Cariologi/Cariogram/). The Cariogram calculates the individual's caries risk from the inputted scores of risk factors/indicators (Figure 1). Using a complex algorithm, the Cariogram determines each subject's "chance to avoid new cavities" and the proportions contributed by four risk sectors (bacteria, diet, circumstances, susceptibility) to the caries risk. A "chance to avoid new cavities" of 25% or less indicates a high caries risk according to the Cariogram manual.
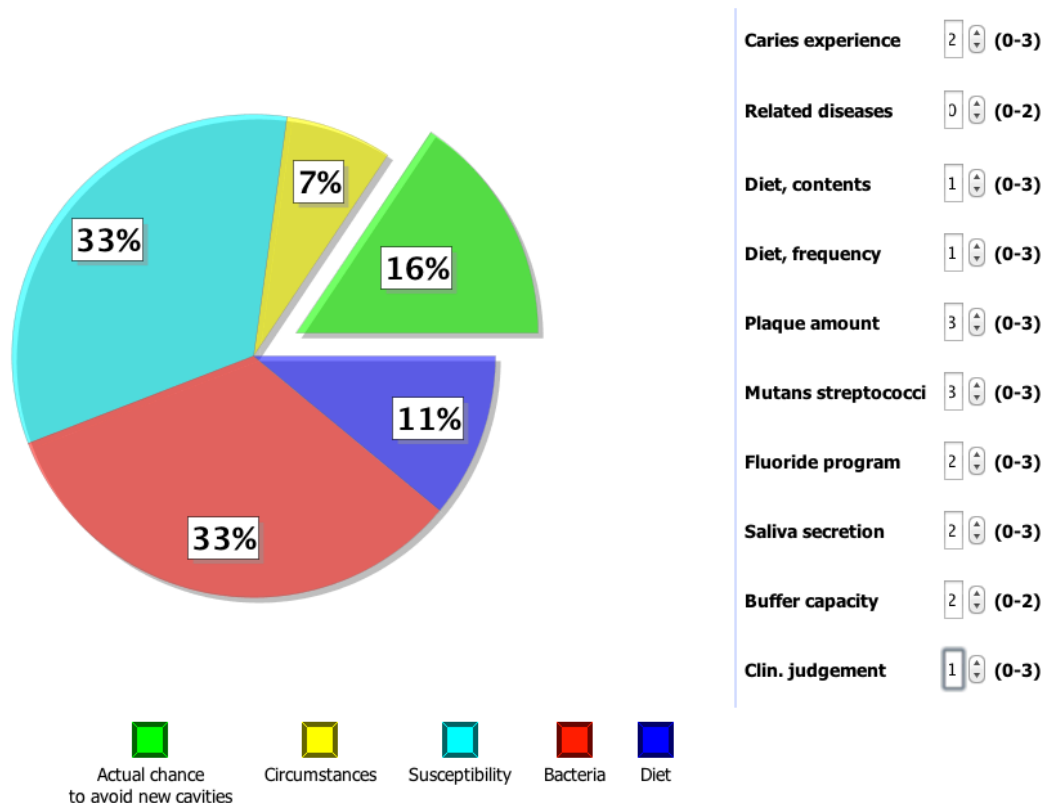
Figure 1. A Cariogram output (as it appears on computer screen). *The "chance to avoid new cavities" is but 16% which indicates this person has a high risk of developing new cavities (they are a high caries risk). The inputted scores for all risk factors and clinicians judgment are given on the right. The legend for the pie chart is displayed at the bottom. Diet contributes a lower risk (11%) compared to Bacteria (33%) and Susceptibility (33%). Therefore, providing standard dietary advice may not support this individual and is wasteful of human and financial resources. The weights of the sectors are based on Bratthall's (1996) interpretation of data from multiple sources.*

In addition to the Cariogram, an electronic personalised education system (EPES) modelled on Rapport Builder® (Oral Care Inc., Tokyo, Japan) (http://www.ocm-navi.jp/index.html) will be developed to deliver electronic personalised oral health messages to encourage the prevention of caries. The EPES will send the subjects an oral health text message, based on their risk profile that is derived from the Cariogram. To investigate the effectiveness of the approach in lower socioeconomic groups, we will conduct an evaluator-blind randomised controlled study in Cork.

Location of study

The study will be administered from the Oral Health Services Research Centre in Cork University Dental School & Hospital. Patients will be seen by their General Dental Practitioners (GDPs) in the GDP surgeries. Text messages will be sent from the UK-based Text Magic service (https://www.textmagic.com/).

Aim of study

This project aims to investigate the effectiveness of an electronic-based caries risk assessment (Cariogram) with a personalised educational approach adopting personalised marketing for caries prevention in lower socioeconomic groups.

Specific objectives

The specific objectives are:

1. To assess the influence on seven caries risk factors:
    - frequency of fermentable-carbohydrate intake (sugars)
    - amount of plaque present
    - bacterial counts
        ◇ mutans streptococci (MS)
        ◇ lactobacilli (LB)
    - use of fluorides
    - salivary flow
    - salivary buffering capacity

2. To assess whether there is an increase in patient engagement with the dentist

3. To assess the prevalence and distribution of the risk factors indicated along with past caries experience and systemic diseases and conditions such as cardiovascular

disease, diabetes and obesity

4. To assess the knowledge, behaviour and patient satisfaction relating to personalised caries prevention.

Investigator and research personnel

Role	Name	Address
Principal Investigator	Professor Finbarr Allen	Restorative Dentistry, University Dental School & Hospital, University College Cork
Co-investigator	Máiréad Harding BDS, MFGDP(UK), MDPH Senior Dental Surgeon	Oral Health Services Research Centre, University Dental School, Cork HSE South Cork ISA
Co-investigator	Makiko Nishi BEd(Japan), DDS(Japan), MDPH	Oral Health Services Research Centre, University Dental School, Cork
Laboratory Technician	Eileen MacSweeney	Oral Health Services Research Centre, University Dental School, Cork
Statistician	To be recruited	
Programmer	James Keane Undergraduate student, supervised by Dr. Sabin Tabirca	School of Computer Science and Information Technology, University College Cork

Ethics approval

This project has had the approval of the Clinical Research Ethics Committee of the Cork Teaching Hospitals.

Preparatory work

Dr. Nishi has been conducting a questionnaire survey on personalised caries prevention

in a Japanese population as her PhD project. That questionnaire has been adapted for use in this project. A Japanese non-profit organization (NPO), of which Dr. Nishi is the President, has adapted Rapport Builder® for sending oral health messages to its members. This project will work on the adapted version of Rapport Builder® (Figure 2).

Figure 2. Example of a text message to be used in this study. Simple messages are delivered weekly in a humorous manner to engage the attention of the target audience.

Hi! Prevent tooth decay by making smart & healthy food choices: foods & drinks high in sugar can lead 2 tooth decay & weight gain. Eat smart, stay healthy!

Study methodology

This project is a randomised controlled study. The null hypothesis is that no difference exists between the group receiving EPES and the group receiving non-personalised information.

The innovativeness of this project made it difficult to set the intervention interval. We considered an interval of more than six months, however we wished to maintain subject engagement and to assess the study outcomes and innovativeness. In addition, the Cariogram manual suggests re-assessment in six months for high-risk patients.

The project process is set out below (Figure 3).
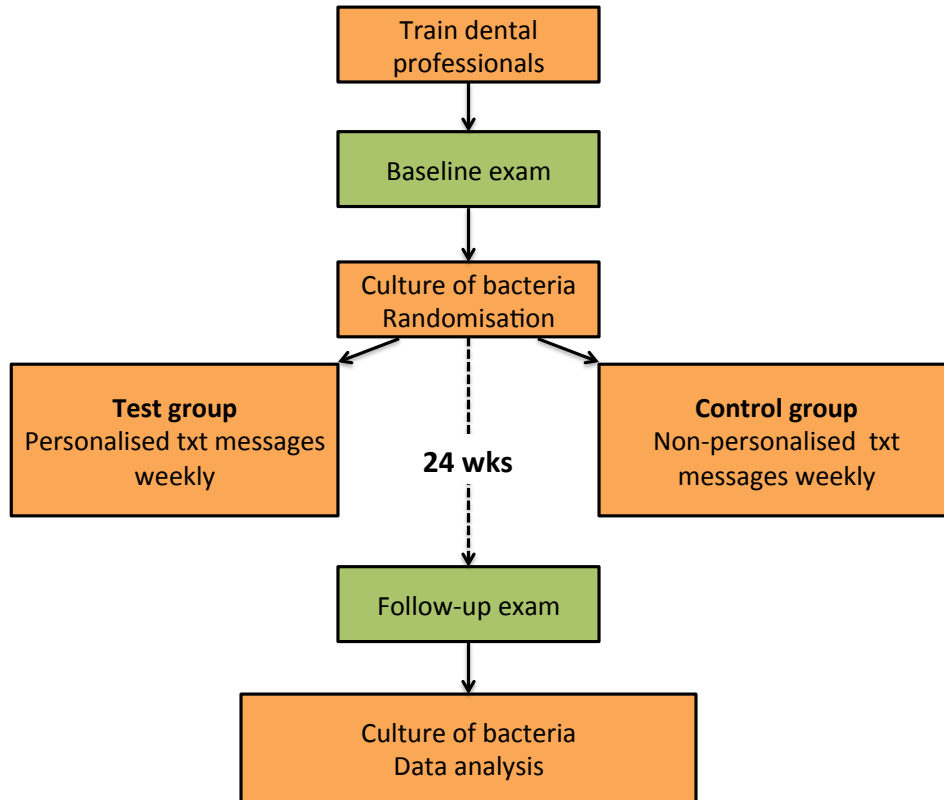
Figure 3. Process chart. Orange boxes indicate activities carried out at the Oral Health Services Research Centre (OHSRC); green boxes indicate activities at dental surgeries.

Sample size calculation

To estimate the sample size, we conducted a power calculation based on previous Cariogram studies. Where the average baseline Cariogram "chance to avoid new cavities" score is 36, with a mean between-subject standard deviation of 21.6, a sample of 64 subjects per group is required. This will provide an 80% power with a margin of error of 0.05, to detect a "chance to avoid new cavities" of at least 30% relative to the control group over the 6-month duration of the study.

To ensure adequate numbers in each group at six months to permit appropriate analysis, and minimising the risk of type II error, 100 subjects will be entered in each group at baseline.

Subject recruitment

An estimated 200 medical-card (i.e. proxy for low socioeconomic status) patients will be recruited from approximately ten general dental surgeries in Ireland. The inclusion criteria are (i) 19–70 years of age, (ii) medical-card holder, (iii) ≥ 20 teeth present, (iv) not pregnant, (v) ability to use text messaging and (vi) willingness to participate in the project.

Training module for dental professionals

Dr. Harding and Dr. Nishi explained the project protocol to the participating dental professionals , and will train them in the study procedures. Dr. Nishi has worked extensively with the Cariogram. The dental professionals are being calibrated for DMFT/DMFS and plaque index. This training is being carried out in the OHSRC.

Baseline examination

At the first appointment in the general dental surgery, the study will be explained and informed consent will be obtained prior to examination. The dental practitioner will interview the patient (fluoride use, related systemic diseases / conditions), collect saliva samples (determine salivary flow rate, salivary buffer capacity, bacteriological tests, CRT® Ivoclar Vivadent, Liechtenstein), examine (past caries experience, plaque amount) and provide a questionnaire and a dietary record form for the subject. The CRT® agar culture, history form including fluoride use and systemic diseases and oral examination form will be sent to the OHSRC within a day from the dental surgery by car.

Informed consent

If the patient meets the inclusion criteria listed above, they will be invited by the general dental surgeon to read the information sheet for patients. If they agree to participate in the project, they must sign the informed consent form.

Past caries experience

Past caries experience will be recorded for each tooth surface. Recording codes are outlined in Appendix 5 of this protocol.

Plaque amount

The Plaque Index (PI), according to Silness and Löe (1964) will be used. Recording codes are outlined in Appendix 5 of this protocol.

Fluoride use

Relevant information on fluoride use will be obtained through patient interviews. The patient will be asked:

- if the patient uses fluoridated water,
- if the patient uses fluoridated tooth paste,
- if the patient uses additional fluoride measures such as rinses and varnishes frequently,
- if the patient uses additional measures such as rinsing and varnishes, infrequently.

Related systemic diseases

The relevant information on systemic diseases will be obtained by patient interviews only. The patient will be asked whether he/she suffers from diseases / conditions such as:

- autoimmune diseases, like Sjögren's syndrome
- diabetes mellitus
- anorexia nervosa
- visually impaired
- any manual dexterity which might cause them difficulties with cleaning their teeth properly.
- any disease, which requires continuous medication that, for example, affects their saliva secretion. Details of any concomitant medications will be recorded.
- any condition requiring radiation to the head-neck region

Saliva tests

The general dental surgeon will collect saliva samples in a standardised format,

from participating patients to determine salivary flow rate, saliva buffering capacity and bacteriological testing. Details of saliva sampling procedures are outlined in Appendix 3 of this protocol.

The laboratory technician in the OHSRC will incubate and read the CRT® slides in accordance with the manufacturer's instructions.

Dietary record/Questionnaire

The patient will be provided with the 3-day dietary record and the study questionnaire, along with a stamped, addressed envelope for return of completed documents to the OHSRC.

Randomisation

The subjects will be stratified for "chance to avoid new cavities" by quartiles (0–20%, 21–40%, 41–60%, 61%–100%) and randomly allocated to Test or Control group by the statistician.

Intervention

A report of their caries risk assessment, along with their output chart as generated by Cariogram, will be sent by post to the subjects in the Test group. The subjects in the Control group will be sent only general information (not generated by Cariogram) on caries prevention, also by post. A €20 voucher will be sent to all subjects as a token of appreciation for participating in the study.

Once weekly for 24 weeks, the Test group will receive personalised oral health text messages on caries prevention while the Control group receives non-personalised text messages offering general oral healthcare advice.

Table 1 shows how to calculate numbers of text messages allocated to each risk sector for the Test group. All subjects in the Control group will receive the same six non-personalised text messages for each risk sector. All oral health messages are evidence-based (Levine and Stillman-Lowe 2009).

Table 1. How to calculate numbers of text messages of each sector. Using the example in Figure 1, over the 24 week study period, the EPES will send this patient nine text messages on bacteria (33/84), three text messages on diet (11/84), two text messages on circumstances (7/84) and nine text messages on susceptibility (33/84).

Sector (Risk Factor / Risk Indicator)	Percentage contribution calculated with the Cariogram chart (%)	Proportion contribution of each sector to the overall calculated risk (%)	Number of texts on each sector to be sent text messages
Bacteria (plaque and mutans streptococci)	33	39	9
Diet (content and frequency)	11	13	3
Circumstances (previous caries experience, co-exiating diseases)	7	8	2
Susceptibility (available fluorides, saliva properties)	33	39	9
Total of the four sectors	84	100	24
"Chance to avoid new cavities"	16		
Total of the five sectors	100		

Follow-up examination

At the second appointment, six months after the baseline examination, the same data collection procedures as at baseline (except the taking of informed consent) will be followed. After the six-month assessment, both Test and Control group subjects will be sent their baseline and follow-up output charts and their personalised caries prevention advice as generated by Cariogram, along with their reward for completing the study (€30 voucher), by post from the OHSRC.

Data analysis

Dr. Nishi will enter baseline and six-month follow-up data into the Cariogram software programme and generate Cariogram reports for each patient at each timepoint.

The data will be analysed using a statistical package (SPSS/SAS) by Dr. Nishi with the aid of a statistician. The average of "chance to avoid new cavities" as measured by Cariogram as well as the seven risk factors before and after the intervention between the test and control groups will be compared using a two-sample two-sided t-test. In addition, the measured risk factors/indicators and questionnaires results will be analysed for the third and fourth research objectives.

Infection control

Infection control in accordance with the Dental Council Ireland guidelines, (http://www.dentalcouncil.ie/g_crossinfection.php) and Cork University Dental School and Hospital will be adhered to.

Potential risks and benefits to participants

The dental examination carries no risk to the subjects and will only be undertaken with their consent and the co-operation. Standard infection control measures will be observed, as mentioned above. As there is currently no such comprehensive caries risk assessment for medical card patients in Ireland, the dental examination offers the benefit of notifying the subjects how to prevent dental caries more effectively than traditional prevention. CRT® tests are for free. At six months, the subject gets two reports of their caries risk assessments (baseline and follow-up). There will also be a total of €50 (vouchers for €20 at baseline and €30 at 6-months follow-up) reward for each patient participating in the study.

The dental practitioners will benefit by learning about caries risk assessment with Cariogram. Patients' participation in the project should make their caries management more effective in the dental surgeries and improve their motivation to visit for regular check-ups. The dental practitioners will be given full acknowledgement for their work in any publications or reports generated from the project.

If this EPES for caries prevention proves successful, it represents a ground-breaking approach to reducing caries risk and building patient engagement in those with greatest need, adopting modern technologies to promote regular check-ups and better dental health. Furthermore, the concept could be adapted and applied to other lifestyle related diseases with individual variability, such diseases are not only expensive to manage for the patient but also to treat, placing a significant burden on society.

Data Management

All personal and clinical data will be treated as confidential. Data from the clinical examination will be entered onto the paper Case Report Form, the original of which will be sent to the OHSRC. Data will be entered into an Excel spread sheet. Subject records will be retained in compliance with the requirements set out under the Dental Council. All files with patients' personalised data (full name, gender, age, address, and mobile number) will be password protected. Computers will be encrypted. The server of Rapport Builder® is protected from malware.

The study will comply with the requirements of the Data Protection Act 1988 and the Data Protection (Amendment) Act 2003; Data Protection (Access Modification) (Health) Regulations, 1989 (S.I. No.82 of 1989); Data Protection (Access Modification) (Social Work) Regulations, 1989 (S.I. No.83 of 1989); Council Directive on the Protection of Individuals with Regard to Processing of Personal Data (Directive 95/46/EC) (W).

Timetable

Subject to ethical approval, we propose commencing the training module for dental professionals and recruiting subjects in February 2015. An interim report of our research progress to the IADR will be due on July 31, 2015. The grant award will end in December 31, 2015. A final report describing the outcome of our research will be due February 29, 2016. Figure 4 shows the time frame.

Activity	2014 May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	2015 Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	2016 Jan	Feb
Prepare documents	O	O	O	O																		
Recruit and train dental professionals	O	O	O	O	O																	
Develop EPES	R	R	R	R	R	R	R	R														
Compose text messages		O	O	O	O	O	O															
Ethics approval			O	O	O			O	O													
Order saliva tests				O	O							O	O									
Recruit subjects										G	G											
Informed consent										G	G											
Baseline examination										G	G											
Randomisation												O										
Send texts												O	O	O	O	O	O	O	O			
Follow-up examination																		G				
Statistical analysis of data												O							O	O		
Send letters												O								O		
Dissemination												O		O						O		O
Report to IADR																						O

Figure 4. Time frame. *Orange cells indicate activities at OHSRC, green cells at dental surgeries and red cells at Oral Care Inc.*

List of Protocol Appendices

1. Overview of training for general dental practitioners
2. Information leaflet for recruitment of general dental practitioners
3. Instructions for participating general dental practitioners
4. Checklist for participating general dental practitioners
5. Coding for dental examinations
6. Subject Information and Informed Consent Form
7. Letters to participating subjects at baseline and follow-up
8. Case Record Form
9. Questionnaires for subjects at Baseline and follow-up
10. Dietary record form for subjects
11. Sample SMS text messages

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Rugg-Gunn, A. (2013). Dental caries: strategies to control this preventable disease. *Acta Medica Academica*, *42*(2), 117–30.

Yevlahova, D., & Satur, J. (2009). Models for individual oral health promotion and their effectiveness: a systematic review. *Australian Dental Journal*, *54*(3), 190–7.

Web links

WHO Oral Health Surveys, 5th ed, 2013
http://www.icd.org/content/publications/WHO-Oral-Health-Surveys-Basic-Methods-5th-Edition-2013.pdf

Cariogram (Manual, Download)
http://www.mah.se/fakulteter-och-omraden/Odontologiska-fakulteten/Avdelning-och-kansli/Cariologi/Cariogram/

CRT buffer® (Broacher, Instruction for use, Step by step)
http://www.ivoclarvivadent.com/en/products/prevention-care/caries-risk/crt-buffer

CRT bacteria® (Broacher, Instruction for use, Material Safety Data Sheet, Scientific Documentation, Flow chart)
http://www.ivoclarvivadent.com/en/products/prevention-care/caries-risk/crt-bacteria