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Personalised dental education for caries risk reduction in an adult population in the Republic of Ireland

Volume 1 of 1

Thesis presented by
Makiko Nishi, BEd, DDS, MDPH
orcid.org/0000-0002-6903-6277
for the degree of
Doctor of Philosophy

University College Cork
University Dental School and Hospital

Head of School: Dr Christine McCreary
Supervisors: Professor Finbarr Allen,
Professor Helen Whelton, Dr Máiréad Harding

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Original articles

This thesis is based on the following five articles, which will be referred to in the text by their roman numerals. The articles are appended at the end of the thesis.

I. Nishi M, Kumagai T, Whelton H. 2016. Access to personalised caries prevention (PCP) programmes determined by dentists: a cross-sectional study of current and potential PCP adopters in Japan and their knowledge of caries risk. J Dent Hlth. 66(4):399-407.
doi: 10.5834/jdh.66.4_399

II. Nishi M, Harding M, Kelleher V, Whelton H, Allen F. 2017. Knowledge of caries risk factors/indicators among Japanese and Irish adult patients with different socio-economic profiles: a cross-sectional study. BMC Oral Health. 17(1):55.
doi: 10.1186/s12903-017-0345-x

III. Nishi M, Harding M, Kelleher V, Cronin M, Allen F. A comprehensive caries risk assessment with the Cariogram versus patient-perceived caries risk in an adult population: a cross-sectional study. Int J Technol Assess Health Care (*prepared*).

IV. Nishi M, Harding M, Kelleher V, Cronin M, Allen F. Heterogeneity of dental caries risk within individuals among economically disadvantaged adults. Oral Health Prev Dent (*submitted*).

V. Nishi M, Harding M, Kelleher V, Cronin M, Allen F. A personalised mHealth approach based on caries risk assessment using the Cariogram: a randomised controlled study. BMC Oral Health (*submitted*).

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Article I: the Japanese Society for Oral Health
Article IV: Oral Health and Preventive Dentistry

Declaration

This is to certify that the work I am submitting is my own and has not been submitted for another degree, either at University College Cork (UCC) or elsewhere. All external references and sources are clearly acknowledged and identified within the contents. I have read and understood the regulations of University College Cork concerning plagiarism.

Author's Contribution

The author conducted all of the work in this thesis with the exception of the following:

Ms Margaret Cole, UCC provided statistical assistance for Articles I and II.
Dr Michael Cronin, UCC provided statistical assistance for Articles III–V.
'Promoting Scientific Assessment in Prevention of Tooth Decay and Gum Disease' provided assistance of administration work and data acquisition for the Japanese study.
The participant dental practitioners provided assistance of data acquisition for the Irish study.
The Oral Health Services Research Centre provided assistance of administration work and incubating and scoring CRT® bacteria (Ivoclar Vivadent, Liechtenstein) for the Irish study.
Mr James Keane, UCC former student sent mobile-phone short text messages.
Realize Mobile Communications Corp. examined the computer program for sending the mobile-phone short text messages.

Makiko Nishi

Signed: _____

Date: _____

Dedicated to the Late Professor Douglas Bratthall

"*I love it when an aria fits a singer as perfectly as a suit of well-tailored clothes.*"

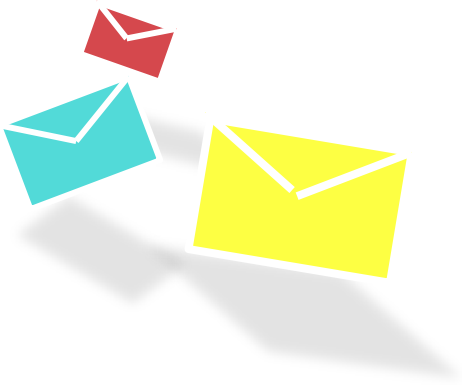
Wolfgang Amadeus Mozart (1756 – 1791)

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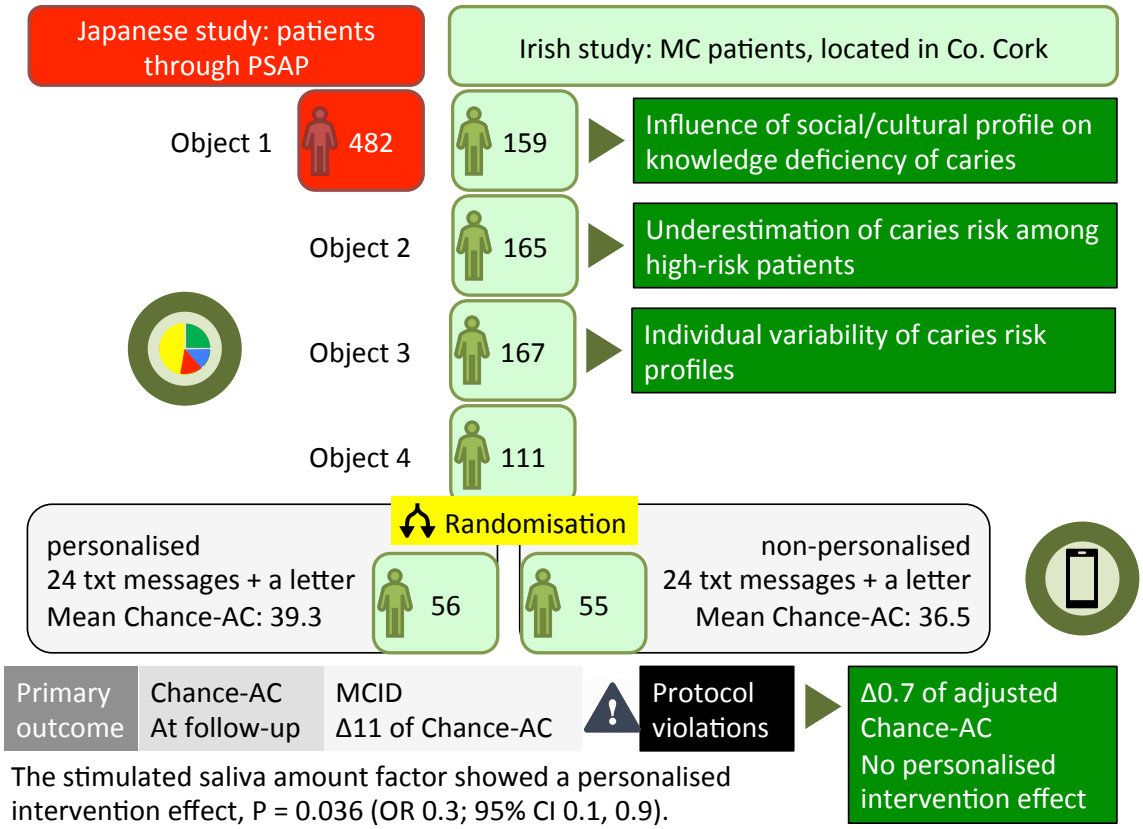


Glossary with a note on terminology used in the thesis

CAMBRA	Caries Management By Risk Assessment: a caries risk assessment mode
CFU	colony forming units
Chance-AC	chance of avoiding new cavities: the comprehensive caries risk assessment value calculated by the Cariogram, a computer-based tool
CI	confidence interval
COI	conflict of interest
CONSORT	Consolidated Standards of Reporting Trials
CPD	Continued Professional Development: process of developing and updating the knowledge and skills as a professional
CPP-ACP	Casein Phosphopeptide-Amorphous Calcium Phosphate
CRA	caries risk assessment
CRF	clinical report forms
CV	coefficient of variation
DCH	Dental Care for Health: a dental care model in Sweden
DMFS	decayed, missing and filled surfaces
DMFT	decayed, missing and filled teeth
GI	Gingival Index
ICCMS	International Caries Classification and Management System
ICDAS	International Caries Detection and Assessment System
ITT	intention-to-treat
LB	lactobacillus
MC	Medical-Card: a MC holder is entitled to a range of health services free of charge in the Republic of Ireland; proxy for economically disadvantaged status / low socio-economic status (SES)
MCID	minimal clinically important difference
mHealth	Mobile Health
MP	maintenance programme: check-ups and professional cleaning
MS	mutans streptococci
MTM	Medical Treatment Model: a dental care model

N/A	not applicable
OHI	Oral Hygiene Index
OHSRC	Oral Health Services Research Centre: an institution in University College Cork, Republic of Ireland
OR	odds ratio
PCP	personalised caries prevention: caries prevention based on CRA of individual patients
PSAP	**'**Promoting Scientific Assessment in Prevention of Tooth Decay and Gum Disease': a non-profit organisation in Japan
P4	predictive, preventive, personalised and participatory: components of a future vision of health care
Q	question number of questionnaires
RoI	Republic of Ireland
SD	standard deviation
SES	socioeconomic status
STROBE	Strengthening the Reporting of Observational Studies
UCC	University College Cork
UK	United Kingdom
USA	United States of America

Visual abstract



The stimulated saliva amount factor showed a personalised intervention effect, P = 0.036 (OR 0.3; 95% CI 0.1, 0.9).

Abstract

Background: Dental caries is a multifactorial disease and begins with an invisible, early demineralisation stage. It prevails in almost all adults. Notably, lower socioeconomic groups have a greater level of dental caries than higher socioeconomic groups. Despite being a common disease, the risk profiles for dental caries differ from individual to individual; these risk profile variations underpin personalised education measures based on individual caries risk assessment (CRA). For implementing a personalised approach, Mobile Health (mHealth; medical and public health practice supported by mobile devices) has enormous potential.

Aims / Objectives: The overall aim of this thesis was to investigate the impact on caries risk reduction of a personalised dental education approach based on individual CRA using mobile-phone short text messages in an economically disadvantaged adult population (19+ years of age) in the Republic of Ireland (RoI). The objectives were (1) to identify social/cultural influences on perceived caries risk factors/indicators in an economically disadvantaged adult population in the RoI, comparing with an adult population in Japan who are regarded to have greater knowledge of preventive dentistry (Articles I and II), (2) to evaluate the associations between 'chance of avoiding new cavities' (Chance-AC: the comprehensive CRA value calculated with the ten caries risk parameters by a computer-based CRA tool, the Cariogram) and self-perceived caries risk in an economically disadvantaged adult population in the RoI (Article III), (3) to determine individual variability of Chance-AC and seven aetiological caries risk parameters from the Cariogram's ten parameters, within individuals in an economically disadvantaged adult population in the RoI (Article IV), (4) to investigate the impact on caries risk reduction of a personalised approach, delivered via a CRA summary letter plus 24 mobile-phone short text messages based on the individual's Cariogram CRA, versus a non-personalised approach on (i) reducing Chance-AC and seven aetiological caries risk parameters and on (ii) increasing knowledge and self-perception of caries risk in an economically disadvantaged group (Article V).

Methods: Two studies were conducted: (1) a cross-sectional study with patients recruited through a non-profit organisation named 'Promoting Scientific Assessment in

Prevention of Tooth Decay and Gum Disease' (PSAP) in Japan (the Japanese study: Articles I and II), and (2) a 2-arm parallel-group, single-blinded (assessor), randomised controlled study with adult medical-card holders recruited through eight dental practices in County Cork, the RoI (the Irish study: Articles II–V). For the Japanese study, data were collected via self-administered questionnaires at the PSAP in Tokyo. For the Irish study, data were collected via interview, clinical examination, CRT® saliva tests (Ivoclar Vivadent, Liechtenstein), a 3-day food diary and self-administered questionnaires at the eight dental practices and the Oral Health Services Research Centre, University College Cork. For Objective 1, the Japanese study formed the basis of the questionnaires in the Irish study and provided supplemental data. For Objectives 1, 2 and 3, baseline data of the Irish study were used as cross-sectional studies. For Objective 4, baseline and follow-up data of the Irish study were analysed.

Results: Objective 1 (Articles I and II): The number of participants involved under Objective 1 was 482 from the Japanese study and 159 from the Irish study. There were unexpected differences in knowledge of one caries risk factor and one indicator; a higher proportion of Irish participants identified "*Not visiting the dentist for check-up and cleaning*" (odds ratio (OR) 2.655; 99% confidence interval (CI) 1.550, 4.547) and "*Not using fluoride*" (OR 1.714; 99% CI 1.049, 2.802) than did Japanese participants. Similarly, both studies revealed a lack of knowledge on saliva buffering capacity as a caries risk factor and a persistent belief that "*Not brushing teeth properly*" is a caries risk factor.

Objective 2 (Articles III): The number of patients analysed for Objective 2 was 165 from the Irish study. There was an association between Chance-AC and self-perceived caries risk in the four risk groups. The two highest risk groups according to Chance-AC were 16.0 times (95% CI 1.9, 134.2) and 18.8 times (95% CI 2.8, 124.8), respectively, more likely to perceive themselves as having high caries risk than those in the lowest risk group. On the other hand, approximately two-thirds of participants in the high-risk groups did not consider themselves as being more prone to dental decay than the average person.

Objective 3 (Article IV): The number of patients under Objective 3 was 167 from the Irish study. The average of Chance-AC (ranging from 0 to 100; lower value's indicating higher caries risk) was 64 (standard deviation (SD) = 21, coefficient of variation (CV) = 0.33), ranging from 10 to 96 with the standard 'clinical judgement'. With Score = 2 (increased risk) 'clinical judgement', the average was 39 (SD = 22, CV = 0.55), ranging from 3 to 94. The caries risk profiles among the participants were clustered into five groups: 'bacteria, saliva and diet' (having unfavourable microbiological, saliva and diet factors), 'bacteria but good saliva' (having unfavourable microbiological factors but favourable saliva factors), 'saliva' (having unfavourable saliva factors), 'diet content' (having high salivary lactobacillus counts) and 'nondescript' (having no prominent poor risk factors).

Objective 4 (Article V): The number of participants included under Objective 4 was 56 in the personalised group and 55 in the non-personalised group from the Irish study; however, as a result of protocol violations resulting from initially undetected technological challenges, 84% of the 111 participants were not sent their assigned number and combination of text messages. Intent-to-treat analysis with all participants did not show a personalised intervention effect in Chance-AC. Of the secondary outcome measures, only the stimulated saliva amount factor showed a personalised intervention effect, P = 0.036 (OR 0.3; 95% CI 0.1, 0.9). A per-protocol analysis was also performed with 21 personalised and 33 non-personalised participants having within two-message deviations and showed no significant effect in Chance-AC.

Conclusions: The results generated from this thesis confirm that understanding the influence of a population's social/cultural profile on knowledge deficiency of caries risk is important. High-risk patients tended to underestimate their caries risk and there was individual variability of caries risk profiles within the economically disadvantaged adult population in RoI. Therefore, it is plausible that caries prevention strategies for behaviour change can be personalised to account for actual and self-perceived caries risk for maximum effectiveness amongst medical card patients. Our study could not reach a definitive conclusion whether a personalised mHealth approach was more effective than a non-personalised mHealth approach with the exception that the saliva amount parameter was influenced by the personalised mHealth approach. As the participants had

insufficient knowledge on this risk factor, seeking to redress areas of unfamiliar caries risk information coupled with individual CRA may be effective. It is worth further exploring the potential of mobile-devices for individual caries risk reduction. Additionally, the lessons learned from the protocol violations are useful output for mHealth studies.

Keywords: dental caries, risk factors, risk assessment, preventive dentistry, perception, knowledge, vulnerable populations, cell phone, telemedicine

1 INTRODUCTION

1.1 Background

'Dental caries' is a technical term which dental professionals use to describe tooth destruction due to acids produced by bacteria (Pitts et al. 2017). 'Tooth decay', 'decayed tooth' and 'cavities' are terms more familiarly used for this disease by patients. In a strict sense, these familiar terms do not include invisible change before cavitation occurs on the tooth, as this stage is unlikely known by patients. However, it is important to consider the whole process of dental caries, including the invisible, early demineralisation stage, when planning prevention strategies (Hansson and Ericson 2008).

During this invisible stage, the tooth is already affected by many **aetiological risk factors** that interact with each other dynamically (Pitts et al. 2017). As early as the 1950s, it has been known that the disease is logically preventable if the aetiological factors are reduced (Rovelstad 1950). Keyes (1962) explained the relationships of the aetiological factors within three circles: diet, microflora and host. Krasse (1985) published guidelines on how to control the three groups in dental practices. Bratthall (1996) introduced a computer-based assessment tool, the Cariogram, using Keyes' and Krasse's concepts. Based on Krasse's and Bratthall's philosophy, Kumagai developed a clinical programme, the Medical Treatment Model (MTM), which, applied in his and his colleagues' practices, resulted in an overwhelming achievement of caries prevention (Kumagai 2006; Maruo et al. 2016) as Axelsson's needs-related caries preventive programme (Axelsson 2006; Axelsson et al. 2004).

However, dental caries is still one of the world's most prevalent diseases: it prevails in almost all adults (Kassebaum et al. 2015; World Health Organisation 2012), affects quality of life physically and physiologically (Bagramian et al. 2009), and financial costs to the individual and society are considerable (Meier et al. 2017). In particular, lower socioeconomic groups have a greater level of dental caries than higher socioeconomic

groups (Schwendicke et al. 2015). Global indications are that lower socioeconomic status (SES) groups:

- eat sugary food more frequently (Kuusela et al. 1999)
- brush their teeth with fluoridated tooth paste less frequently (Levin and Currie 2009)
- do not regularly visit the dentist (Gomes et al. 2008)
- have relevant systemic disease(s) (e.g. lower SES is associated with depression (Everson et al. 2002); and antidepressants reduce saliva flow (de Almeida Pdel et al. 2008)).

Therefore, SES factors are determinants of an individual's caries experience, which involve the interplay of diet, microflora and host aetiological factors.

In the Republic of Ireland (RoI), fluoridation of public tap water is mandatory at the level of 0.6–0.8 ppm under national legislation (the Fluoridation of Water Supplies Regulations 2007: S.I. No. 42 of 2007[1]), and is apparently effective and efficient for caries prevention with people on the fluoridated water supply, regardless of income level (Harding and O'Mullane 2013). As fluoridated toothpaste (1,500 ppm) is readily available in the RoI, it may be generalised that most people also benefit from fluoride use at its recommended daily maximum level. However, it remains a concern that by age 15 approximately three quarters of adolescents with fluoridated water supplies in the RoI already have experienced dental caries in their permanent dentition (Whelton et al. 2006). A more detailed examination of individual caries levels among adolescents showed that while 50% of 12-year-old children with fluoridated water supplies were caries free, from the same dataset one 12-year-old child already had 13 decayed-missing-filled teeth (DMFT) (Nishi 2007). A reason that this extreme situation can occur despite public water fluoridation is that the dentist and the patient are not controlling the particular aetiological caries risk factor(s) the patient is predisposed to.

[1] Government of Ireland. S.I. No. 42/2007 - Fluoridation of Water Supplies Regulations 2007. [accessed 7 June 2018]. http://www.irishstatutebook.ie/eli/2007/si/42/made/en/print#.

Aetiological caries risk factors are ones acting directly on the tooth surface, as shown in Keyes' circles (Keyes 1962). Aetiological caries risk factors can also be categorised into two groups: pathological and protective factors (Featherstone 2000). For assessing caries risk, not only aetiological caries risk factors but also surrounding factors – social determinants which do not directly cause dental caries but influence aetiological risk factors (see above), are often included (Pitts et al. 2017). However, the basic difference between aetiological risk factors and surrounding factors (i.e. **risk indicators**) should be kept in mind (Bratthall and Hänsel Petersson 2005; Burt 2001; Fontana and Gonzalez-Cabezas 2012). Dental professionals can advise the patient that his/her frequency of fermentable carbohydrate intake is their problem for caries prevention; however, it would make no sense for us to advise the patient that his/her education level is their problem for caries prevention.

Table 1.1 Various CRA models, methods and tools in alphabetical order

CRA models, methods and tools	References
Axelsson's needs-related caries preventive programme	Axelsson (2006); Axelsson et al. (2004)
Caries Classification System (CCS)	Young et al. (2015)
Caries Management by Risk Assessment (CAMBRA)	Featherstone et al. (2003)
Caries Management System (CMS)	Evans et al. (2008)
Caries Risk Assessment Tool (CAT)	American Academy on Pediatric Dentistry Council on Clinical Affairs (2008)
Cariogram	Bratthall et al. (2004)
Dundee Caries Risk Assessment Model (DCRAM)	MacRitchie et al. (2012)
Frisktandvård 'Dental Care for Health' (DCH)	Andås et al. (2014)
The International Caries Detection and Assessment System - International Caries Classification and Management System (ICDAS-ICCMS)	Pitts et al. (2017)
Krasse's practical guide for assessment and control	Krasse (1985)
Medical Treatment Model (MTM)	Kumagai (2006)
National University of Singapore Caries Risk Assessment (NUS-CRA) model	Gao et al. (2010)
NIH Diagnosis and management of dental caries	National Institutes of Health (2001)

Among a wide range of caries risk assessment (CRA) tools (Table 1.1), the most evidence exists for the Cariogram (Pitts et al. 2017). The Cariogram assesses ten caries risk parameters in its full form: 'caries experience', 'related diseases', 'diet contents', 'diet frequency', 'plaque amount', 'mutans streptococci', 'fluoride programme', 'saliva secretion', saliva 'buffer capacity' and 'clinical judgement' (Bratthall et al. 2004) (Figure 1.1). The Cariogram does not include social determinants among its parameters, as the impact of social determinants is included in the assessment of the aetiological risk factors measured by the Cariogram. This makes the Cariogram more universal, since in some countries, people with higher SES have more dental caries than those with lower SES (Babo Soares et al. 2016).

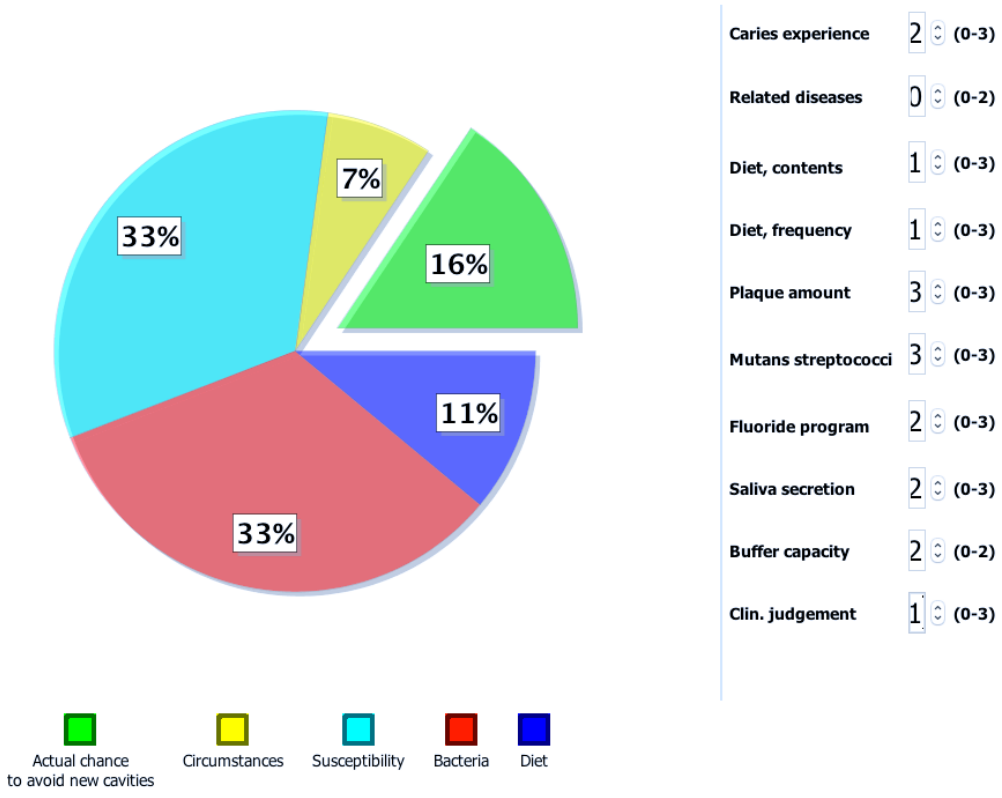


Figure 1.1 A Cariogram output (as it appears on computer screen)

The Cariogram can show how caries risk profiles differ between individuals. For example, Hänsel Petersson et al. (2002) presented a pair of real cases with the same level

of caries risk, but with different caries risk profiles using the Cariogram. Both individuals were at intermediate risk (44 of '**chance of avoiding new cavities[2]**': **Chance-AC**); one individual had unfavourable results with respect to both plaque amount and mutans streptococci (MS) levels; the other individual had unfavourable results with the diet situation but had good oral hygiene. Therefore, for these two cases, the choice of effective caries prevention measures would be different. This underpins the validity of personalised prevention approaches based on individual CRA (Pitts et al. 2017). The Cariogram offers personalised advice based on the individual caries risk to prevent the likelihood of cavities in the near future. The personalised advice identifies the parameters with a Score 2 or 3 as contributors to high risk and specifies required actions relating to those parameters (Bratthall et al. 2004; Pitts et al. 2017).

Various models of personalised, customised, tailored, individualised or stratified caries prevention exist (Table 1.1). For the sake of convenience, this thesis defines **personalised caries prevention (PCP)** as caries prevention based on CRA of individual patients. The personalised approach is linked with 'P4 medicine', with an understanding that risk levels for disease vary and no 'one size fits all' management approach is likely to prevent future disease. With its beginnings in oncology, it has been introduced as the future vision of health care and consists of four Ps: Personalised, Predictive, Preventive and Participatory (Hood and Friend 2011). The ultimate objective of 'P4 medicine' is to maximise wellness for each individual rather than to simply treat the disease (Hood and Friend 2011). 'P4 medicine' has been applied to chronic diseases, including periodontal disease (Kornman et al. 2017). The ultimate objective of 'P4 medicine' should also be set as the future vision of dental caries, with focus on the caries process rather than the outcome.

Most CRA studies have recruited children (Flink et al. 2016; Twetman and Fontana 2009). However, the burden of untreated caries is shifting from children to adults, as

[2] Approximately half of the literature use 'caries' and the rest use 'cavities' for Chance-AC. As indicated at the start of this section, this thesis adopts the strict sense of 'caries' and 'cavities'; 'caries' is a process occurring at the atomic level (Featherstone 2004; Hansson and Ericson 2008).

societies are ageing and more people keep their own teeth for longer (Kassebaum et al. 2015). Therefore, there is a gap in knowledge on effectiveness of CRA for adult populations which needs to be filled.

For conducting a personalised approach to disease prevention and management, the emerging field of **Mobile Health (mHealth)** has enormous potential (Hayes et al. 2014). mHealth is defined as *"medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDAs), and other wireless devices"* (Kay et al. 2011). Personalised mobile-phone text messages exhibited the largest effect size in a meta-analysis on efficacy of mobile-phone text messaging for health promotion (Head et al. 2013). These mobile devices allow low cost interventions and are a means of providing individual level support to health care consumers in order to increase healthy behaviour (Free et al. 2013). For example, an automated system can send thousands of personalised mobile-phone text messages by an algorithm based on patient information to the patients anywhere and anytime.

A great number of studies have examined mHealth interventions for various diseases/conditions. Four Cochrane systematic reviews have been published on educational interventions to prevent or manage a disease/condition using mobile-phone text messaging such as:

- supporting smoking cessation (Whittaker et al. 2016)
- improving contraception use (Smith et al. 2015)
- supporting the self-management of long-term illnesses (de Jongh et al. 2012)
- supporting preventive health care (Vodopivec-Jamsek et al. 2012).

These interventions with mobile devices were effective, but there are significant information gaps regarding cost-effectiveness, long-term effects, acceptability, causality, risks and patient satisfaction (de Jongh et al. 2012; Smith et al. 2015; Vodopivec-Jamsek et al. 2012). Also, the number of participants and quality of evidence were low in the review on preventive health care (Vodopivec-Jamsek et al. 2012) and most included studies were conducted in high-income countries with good tobacco control policies in

the review on smoking cessation (Whittaker et al. 2016). Therefore, further research on mHealth is still needed to draw firm conclusions for most diseases and conditions.

1.2 Overall aim

The overall aim of this thesis is **to investigate the impact on caries risk reduction of a personalised dental education approach based on individual CRA using mobile-phone short text messages in an economically disadvantaged adult population (19+ years of age) in the RoI.**

The objectives are as follows:

(1) To identify social/cultural influences on perceived caries risk factors/indicators in an economically disadvantaged adult population in the RoI, comparing with an adult population in Japan who are regarded to have greater knowledge of preventive dentistry (Articles I and II),

(2) To evaluate the associations between Chance-AC and self-perceived caries risk in an economically disadvantaged adult population in the RoI (Article III),

(3) To determine individual variability of Chance-AC and seven aetiological caries risk parameters from the Cariogram's ten parameters, within individuals in an economically disadvantaged adult population in the RoI (Article IV),

(4) To investigate the impact on caries risk reduction of a personalised approach, delivered via a CRA summary letter plus 24 mobile-phone short text messages based on the individual's Cariogram CRA, versus a non-personalised approach on (i) reducing Chance-AC and seven aetiological caries risk parameters and on (ii) increasing knowledge and self-perception of caries risk in an economically disadvantaged group (Article V).

1.3 Layout of thesis

Chapter 2 provides details and results of the literature review with respect to the overall aim of the thesis followed by a statement of the research questions and hypotheses relating to the four thesis objectives. Chapter 3 describes the participants and methodology of the five Articles comprising this thesis. Chapter 4 summarises results of the analyses according to the addressed objectives. Chapter 5 discusses the findings and limitations of this thesis. Chapter 6 provides a summary of the findings and recommendations for future research. The references upon which this thesis is grounded follow. Finally, appendices are attached.

2 LITERATURE REVIEW

In this chapter, the methodology of the systematic search of the literature will be described first. Second, existing evidence-based knowledge of the four themes underlying the overall aim of this thesis will be reviewed: (1) patients' knowledge and perception of caries risk, (2) caries risk profiles with the aetiological factors within diet, microflora and host, (3) PCP programmes and (4) mHealth approach for caries prevention. Finally, findings from the literature review will be summarised and the thesis objectives will be addressed.

2.1 Search methodology

The literature review with respect to the overall aim of the thesis was conducted, not systematically, throughout the project using PubMed[3], the Cochrane Library[4], Google Scholar[5] and Citation Information by National Institute of Informatics (CiNii: a bibliographic database service focusing on Japanese works and English works published in Japan and maintained by the National Institute of Informatics)[6]. There was no time limit included in searching the literature.

To ensure that all relevant peer-reviewed literature had been found, systematic literature searches were additionally conducted on the four underlying themes addressed by this thesis. The studies included for these systematic searches were meta-analyses,

[3] National Center for Biotechnology Information, U.S. National Library of Medicine. PubMed. [accessed 7 June 2018]. https://www.ncbi.nlm.nih.gov/pubmed/.
[4] Cochrane Library. John Wiley & Sons, Inc. [accessed 7 June 2018]. http://www.cochranelibrary.com/.
[5] Google Scholar. [accessed 7 June 2018]. https://scholar.google.com/.
[6] CiNii Articles [accessed 7 June 2018]. https://ci.nii.ac.jp/. (In Japanese)

systematic reviews, reviews and analytical studies (experimental studies and observational studies). The electronic database PubMed was searched in January 2018 with no time limits. The database search was updated in June 2018 with a custom date range beginning January 2018. The subject search used a combination of controlled vocabulary and free text terms (Appendix 1). The searches were limited to adults (19+ years of age), humans, and the English and Japanese languages. Because the four themes were all relevant to caries risk, the initial retrieval was conducted for the four themes together. Then, each theme was separately retrieved based on titles, abstracts and articles. Basically, articles not accessible to University College Cork (UCC) were excluded.

2.2 Patients' knowledge and perception of caries risk

In PubMed, 27 of the 1,425 articles which were initially searched seemed relevant to patients' knowledge or perception of caries risk based on their titles, 24 seemed relevant based on their abstracts, and eight articles were included in the final review (Figure 2.1). Articles investigating dental professionals or dental students were excluded. The updated search in June 2018 newly retrieved 62 non-duplicate articles, of which four seemed relevant based on their titles, and one article was included in the final review.

A summary of the data sources, populations, measurements and findings obtained from the systematic search are presented in Appendix 2. Apart from Articles I–III, no published investigations on patients' knowledge or perception of caries risk in an economically disadvantaged population were identified.

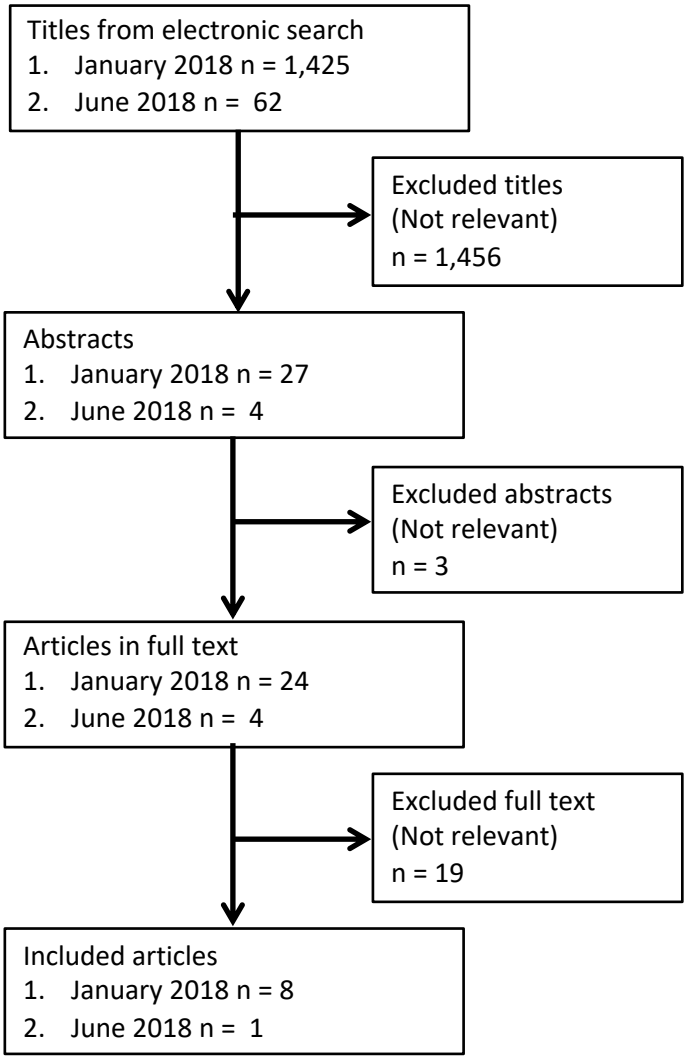


Figure 2.1 Flow chart showing numbers of included and excluded articles: patients' knowledge and perception of caries risk

Oral health knowledge does not always lead to oral preventive behaviour change (Rayant 1979), but a Chinese study indicated that those who had better dental knowledge had better toothbrushing habits (Lin et al. 2001). The survey was conducted in Guangdong Province, Southern China in 1997 and revealed generally poor oral health knowledge among adults; only 24% of the middle-aged and 11% of the elderly in rural areas were aware that sugar and sweet food were causes of dental caries. However, the subjects in the survey showed quite positive attitudes toward oral health.

Contrastingly, in a recent Norwegian study (Stein et al. 2015), 92%, 96% and 62% of the patients had knowledge of bacteria, sugar and frequent meals, respectively, as caries risk factors. Knowledge of risk factors for periodontitis and caries was a predictor variable of a health literacy score in this study. The authors also found a significant correlation between a low health literacy score and a high count of lactobacillus (LB) in saliva. As high counts of LB in saliva reflect the consumption of fermentable carbohydrates by the host over time (Bratthall et al. 2004; Nishikawara et al. 2006), Stein et al. (2015) interpret that those with low oral health literacy may not maintain their oral health as represented by their LB count.

A study on knowledge of health workers in geriatric nursing homes in France also showed that vast majority (94.7%) of the participants had knowledge of frequent sugar-rich food consumption as a caries risk factor and that 90.2% identified bacterial plaque presence as a caries risk factor (Catteau et al. 2016). In contrast, the participants lacked knowledge of mouth dryness due to head and neck radiation (correct answer: 47.8%). Nonetheless, those who had received training in maintaining oral health had more knowledge.

Some knowledge of caries risk may be controversial. Gaszynska et al. (2015) set the question statement "*If parents had a high tendency to develop caries, their children will, for hereditary reasons, have their teeth strongly affected by caries*" as false. However, more and more studies over the last decade have proven the presence of genetic factors influencing individual susceptibility to caries (Vieira et al. 2014).

Understanding what influences knowledge is important for the development of effective and efficient caries prevention strategies. A prime example would be knowledge of fluoride in Japan; many studies have consistently shown a low level of knowledge about fluoride among the Japanese public (Hirose et al. 2011; Tsurumoto et al. 1998), although it has long been considered as the single most effective factor for the prevention of dental caries (ten Cate 2013). The low level of knowledge about fluoride in Japan may be attributed to the low availability over recent decades of fluoride-containing products in Japan compared to Western countries. Until 1994, only 46% of toothpaste on the Japanese market was fluoridated (Hashizume et al. 2003). It was not until 2005 that this

market share hit 88% (Gunji et al. 2010). On the other hand, the RoI has a long history of water fluoridation dating back to the 1960's (Clarkson et al. 2003). Furthermore, the fluoridation debate in the RoI involves the public and is quite active.

Another difference in background between the RoI and Japan would be that in the RoI visiting the dentist for a dental check-up became the norm much earlier than in Japan (Table 2.1). Such cross-country comparisons allows us to inspect how differences in the social context of countries shape social determinants of health (Prus 2011).

Table 2.1 Utilisation rates of a dental check-up between two countries (%)

Year	RoI	Japan	Note	References
1979	20.0		Visiting regularly for a check-up	Clarkson and O'Mullane (1983)
1990–1991		6.5	Regular dental check-up among 60-94 year olds	Sugihara et al. (2010)
2000–2002	48.4 54.2 27.9		16–24 year olds 35–44 year olds 65+ year olds	Guiney et al. (2011)
2011		35.7	Regular check-up at least once a year	Ando et al. (2012)
2012		47.8	Probably included a simple check-up performed with other operative treatments	Ministry of Health Labour and Welfare (2014b)
2014		1.6	Dental check-up of total dental visits	Ministry of Health Labour and Welfare (2014a)
2015	69.2	91.5		Article II

Risk perception is an important aspect of many health behaviour theories that focus on individual patients, such as the health belief model, the transtheoretical model, the theory of planned behaviour, the precaution adoption process model, the wellness model, the protection motivation theory and the social cognitive theory (Bandura 1998; Chapple and Hill 2008; Glanz et al. 2008). Many studies have confirmed the association between patients' self-perceived risk and preventive health behaviours (Brewer et al. 2007; Katapodi et al. 2004; Van der Pligt 1996). However, people tend to have an optimistic

bias about their risk of developing a disease (Katapodi et al. 2004; Yang et al. 2013). In other words, some high risk patients do not have a realistic appreciation of their risk level and it remains necessary to bring their attention to their actual risk (Weinstein 1998). An understanding of the gaps between actual and perceived caries risk would be helpful in the development of caries prevention strategies to change individual behaviour for maximum effectiveness.

There were a limited number of studies on patients' perception of caries risk. Worthington et al. (1997) determined factors important in predicting the need for dental-caries-related treatment for the oncoming year. Among 31 variables, the dentist's and patient's predictions of the need for a filling were the most important. A Swedish study reported a significant correlation between the patient's oral health risk scores covering dental caries, periodontal and general risks as determined by the dentist and the patient's own perception of future oral treatment need; 45% of those assessed as high-risk patients by the dentist rated themselves as having a large future oral treatment need (Hänsel Petersson et al. 2016). Another study among Tanzanian women indicated that their self-perceived caries risk varied positively and systematically with the status of their actual risk factors/indicators (i.e. symptoms of dental caries and self-reported intake of sugary products) (Astrøm et al. 1999). The women in the Tanzanian study underestimated their comparative vulnerability regarding risk factors for poor oral health. The authors suggested finding approaches that help people gain a more accurate picture of their actual individual risk.

2.3 Caries risk profiles with aetiological factors

In PubMed, the initial search retrieved 1,425 articles; 212 of these articles seemed relevant to caries risk profiles based on their titles, 132 seemed relevant based on their abstracts and 37 articles were included in the final review (Figure 2.2). Articles not investigating the three aetiological factors (diet, microflora and host) and not showing a distribution of each risk factor were excluded. The updated search in June 2018 retrieved

62 non-duplicate articles, of which 13 seemed relevant based on their titles, and two articles were included in the final review.

A summary of the data sources, populations, investigated aetiological risk factors and findings obtained from the systematic search are presented in Appendix 3. Apart from Article IV, no investigations on individual variability in caries risk profiles within an economically disadvantaged adult population were identified.

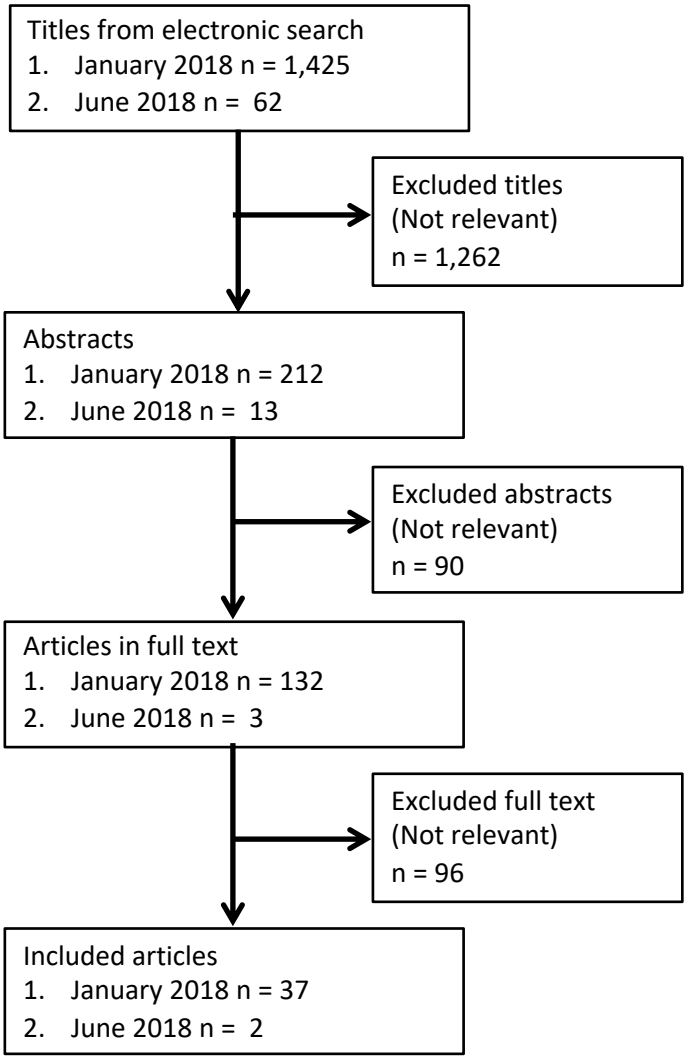


Figure 2.2 Flow chart showing numbers of included and excluded articles: caries risk profiles

Compiling a comprehensive caries risk profile based on aetiological factors for an individual is a complex process that requires taking multiple factors into account and weighting these factors together (Hänsel Petersson 2003). The tendency of recent investigations on caries risk profiles is to use the Cariogram, which was developed as a tool for educating dental students about this complex process (Bratthall and Hänsel Petersson 2005). From a wide range of CRA tools, the Cariogram has been the most used for investigations on caries risk profiles or caries prediction (Pitts et al. 2017) and is the only tool for assessing caries risk data that was validated in prospective cohort studies (Ismail et al. 2013). The advantages of this tool are as follows (Ruiz Miravet et al. 2007):

- It is an objective, quantitative method using a computer program[7] to calculate the data.
- The results can be printed out and saved.
- It gives a series of recommendations on preventive action according to caries risk. The pie chart representation with its different risk sectors (Figure 1.1) is easy for patients to understand, and thus helps to increase their motivation and their comprehension of the factors that are having or could have a negative effect on their oral health.

As Section 1.1 explains, the Cariogram estimates an individual's risk of having a new cavity in the coming year based on their scores (0–2 or 0–3) for 10 caries risk parameters (Bratthall et al. 2004). Setting apart 'clinical judgment', these risk parameters are grouped into four caries risk sectors (Table 2.2).

[7] Throughout this thesis, 'program' is used in computing contexts.

Table 2.2 Risk parameters and risk sectors of the Cariogram

Risk parameter	Score	Estimation	Risk sector
'**Caries experience**'	0–3	Past caries experience	'**Circumstances**'
'**Related diseases**'	0–2	General disease/conditions associated with caries.	
'**Diet contents**'	0–3	Cariogenicity of the food	'**Diet**'
'**Diet frequency**'	0–3	Number of meals and snacks per day	
'**Plaque amount**'	0–3	Oral hygiene	'**Bacteria**'
'**Mutans streptococci**'	0–3	Levels of MS in saliva	
'**Fluoride programme**'	0–3	What extent fluoride is available in the oral cavity over the coming period of time	'**Susceptibility**'
Stimulated '**saliva secretion**'	0–3	Amount of saliva	
Saliva '**buffer capacity**'	0–2	Capacity of saliva to buffer acids	
'**Clinical judgment**'	0–3	Opinion of dental examiner	-

The value of the four risk sectors summed and subtracted from 100 provides **Chance-AC**. This is the summary assessment of an individual's caries risk expressed by the Cariogram as a value ranging from 0 to 100. A lower Chance-AC reflects a greater probability of having a new cavity in the coming year. The three risk sectors: '**Diet**', '**Bacteria**' and '**Susceptibility**' correspond to the three circles of Keyes: diet, microflora and host, respectively. The '**Circumstances**' sector does not correspond directly to aetiological factors, but the Cariogram includes this sector to function as a caries prediction model (Bratthall and Hänsel Petersson 2005). When generating its recommendations for the prevention of the likelihood of caries in the near future, the Cariogram uses five risk groups based on the Chance-AC: 'Very high risk' (≤ 20 Chance-AC), 'High risk' (21–40 Chance-AC), 'Intermediate risk' (41–60 Chance-AC), 'Rather low risk' (61–80 Chance-AC) and 'Low risk' (> 80). This categorisation serves as a rough standard for grouping patients.

The parameter, '**clinical judgment**' is used to represent the total impression by the user of the caries situation, including social factors and the correctness of the diet situation for the individual (Bratthall et al. 2004). This adjustment does not change the relationships among the risk parameters. For adjusting systematic situations, earlier

versions of the Cariogram had ‘country/area’ and ‘group’ settings, but the latest version (version 3.0j) removed these settings for the sake of simplicity. Instead, it recommended the use of the ‘clinical judgement’ parameter for adjustment (Hänsel Petersson, G. personal communication, 16 December 2011).

The disadvantages of the Cariogram are that it is complex and time-consuming (Hänsel Petersson et al. 2013). For simplicity, the Cariogram can be used with (up to) three of its ten parameters omitted, and the substitution of pre-set values for the omitted parameters (Bratthall et al. 2004). Some studies have investigated the use of a simplified Cariogram model. Chang and Kim (2014) omitted the ‘fluoride programme’ parameter. Carta et al. (2015) omitted the ‘saliva secretion’ and ‘buffer capacity’ parameters. Lee et al. (2013) compared the full Cariogram and three simplified Cariogram models having different combinations of omitted parameters. Their finding was that two of the simplified Cariogram models, omitting the ‘diet contents’ (LB count) and ‘saliva secretion’ parameters and omitting only the ‘saliva secretion’ parameter, did not give significantly different results from the full Cariogram. Therefore, the authors concluded that the simplified Cariogram with the exclusion of the ‘diet contents’ (LB count) and ‘saliva secretion’ parameters may be used in clinical practice when a full inclusion of risk factors is not achievable, which likely means that these parameters are not given a heavy weight in the Cariogram algorithm. However, their third simplified Cariogram model, omitting only the ‘diet contents’ (LB count) parameter, showed a significant difference in Chance-AC compared to the full Cariogram. The authors did not give a clear reason for this, but the difference in the mean Chance-AC is only one or two units out of 100 between the simplified and full Cariogram, which may be considered as not clinically significant. For school children, Hänsel Petersson et al. (2010) investigated the caries predictive ability of a simplified Cariogram model and concluded that the Cariogram can still be used for caries prediction in school children, but that its predictive ability was significantly impaired by the exclusion of the saliva tests.

Less information exists on the performance of the Cariogram with adults than with children (Carta et al. 2015; Giacaman et al. 2013). The first study using the Cariogram was conducted in 2003 for Swedish elderly people (Hänsel Petersson et al. 2003). The elderly subjects were categorised into four Chance-AC groups, instead of five which is

standard for Cariogram studies. Because there was a small number of lower risk subjects, the 'Rather low risk' (61–80 Chance-AC) and 'Low risk' (81–100 Chance-AC) groups were combined. A comparison study using the same subjects (Hänsel Petersson et al. 2004) clearly illustrated how elderly people had higher risk than school children in the same country (Hänsel Petersson et al. 2002). Only 2% of the elderly subjects compared with 50% of the children subjects belonged to the 'Low risk group'; the median value of Chance-AC was 44 for the elderly subjects and 80 for the children subjects. Contributing significantly to the higher risk profiles for the adults were the unfavourable scores of the 'plaque amount', higher 'mutans streptococci' and saliva 'buffer capacity' parameters (Hänsel Petersson et al. 2004). It was also observed that the elderly subjects could be assigned fairly evenly to the four risk groups used: 26%, 17%, 36% and 21%. In other words, even though there were very few low risk subjects, there was individual variability in caries risk in the elderly population.

Other studies for adult subjects using the Cariogram are summarised in Table 2.3. There was a clear tendency for higher risk populations (i.e. lower Chance-AC) to show a higher coefficient of variation (CV) of Chance-AC, which means a greater level of dispersion around the mean (Figure 2.3). For special needs patients requiring general anaesthesia, CRA by the Cariogram showed large variance (CV = 0.80); the authors recommended that individual risk assessments could provide information for decision-making with respect to the restorative needs of these patients, as there is a wide array of treatment options for teeth greatly affected by caries in hospital-based dentistry (Chang and Kim 2014).

Table 2.3 Articles using the Cariogram for adults

Article, author, year	Country	Age group (year)	Mean (SD) Chance-AC
Al Mulla et al. (2009)	Saudi Arabia	12–29	Low caries group: 75 (16); High caries group: 42 (19)
Alian et al. (2006)	Canada	Elderly	-
Almosa et al. (2012)	Saudi Arabia	13–29	Governmental: 28 (24); Private: 61 (28)
Carta et al. (2015)	Italy	35–45	-
Celik et al. (2012)	Turkey	Young adults	-
Chang and Kim (2014)	South Korea	Adolescents & adults	27.6 (22.2)
Chang et al. (2014)	South Korea	Adolescents & adults	Intellectual disabilities: 28.1 (20.4); Non-Intellectual disabilities: 54.7 (18.4)
Daryani et al. (2014)	India	Adolescents & young adults	-
Fadel et al. (2011a)	Saudi Arabia	Mean (SD): 38.0 (15)	63 (25)
Fadel et al. (2011b)	Saudi Arabia	Means (SD): 52 (14.0), 49 (13.9)	Coronary artery disease: 31, Not coronary artery disease: 40
Giacaman et al. (2013)	Chili	Mean: 23.29 (8.66)	-
Hänsel Petersson et al. (2003)	Sweden	Elderly	41 (20.55)
Hänsel Petersson et al. (2013)	Sweden	Young adults	60.9 (22.9)
Hänsel Petersson and Twetman (2015)	Sweden	Young adults	-
Hansel Petersson et al. (2016)	Sweden	20–89	-
Hayes et al. (2017)	The RoI	> 65	-
Karabekiroglu and Unlu (2017)	Turkey	Young adults	-
Lee et al. (2013)	South Korea	Young adults	55.5 (20.3)
Mannaa et al. (2014)	Saudi Arabia	Mean (SD): 38.4 (6.4)	-
Martignon et al. (2006)	Denmark Colombia	< 40	Danish: 28.1, Colombian: 33.3
Martignon et al. (2012)	Colombia	Mean: 21 (range:16–35)	-

Article, author, year	Country	Age group (year)	Mean (SD) Chance-AC
Merdad et al. (2010)	Saudi Arabia	17–66	Endodontic: 35 (21.7); Non-endodontic: 37 (21.5)
Paris et al. (2010)	Denmark	< 40	Baseline: 60 (22); Follow-up: 64 (16)
Ruiz Miravet et al. (2007)	Spain	Young adults	77.19
Sonbul et al. (2008)	Saudi Arabia	18–56	31 (19.7)
Sonbul and Birkhed (2010)	Saudi Arabia	Mean (SD): 29 (8.8)	30.9 (19.41)
Wennerholm and Emilson (2013)	Sweden	20–73	-

SD: standard deviation.

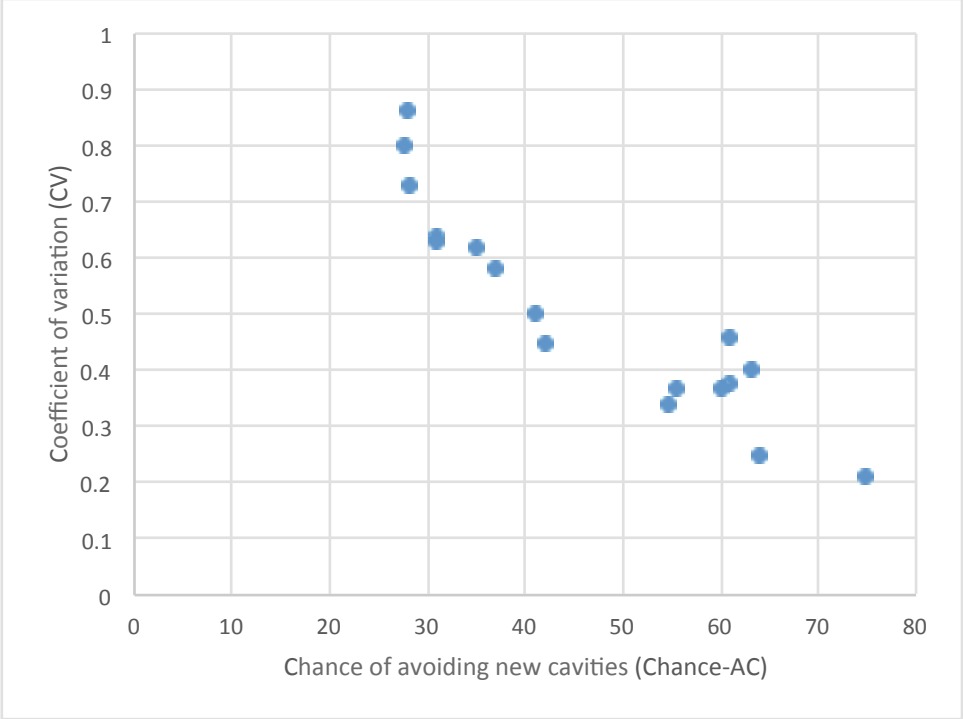


Figure 2.3 The relationship between mean Chance-AC and CV from 12 studies for adults

Al Mulla et al. (2009); Almosa et al. (2012); Chang and Kim (2014); Chang et al. (2014); Fadel et al. (2011a); Hänsel Petersson et al. (2013); Hänsel Petersson et al. (2003); Lee et al. (2013); Merdad et al. (2010); Paris et al. (2010); Sonbul et al. (2008); Sonbul and Birkhed (2010)

Of these studies, the age range and caries experience in the Merdad et al. (2010) study seemed appropriate as a reference for an Irish economically disadvantaged adult population. This study compared caries risk profiles between adults with a minimum of two root-filled teeth and adults without any root filling. Mean (standard deviation (SD)) Chance-AC was 35 (21.7) ranging from four to 80 in the endodontics group and 37 (21.5) ranging from six to 82 in the non-endodontics group. Mean (SD) age was 34.3 (12.3) years ranging from 17 to 66 in the endodontics group and 32.9 (12.8) years ranging from 18 to 66 in the non-endodontics groups. Mean (SD) decayed-missing-filled surface (DMFS) values were 49 (22) ranging from six to 97 and 34 (23) ranging from two to 118 in the endodontics and non-endodontics groups, respectively. An Irish study was also conducted in Cork city (Hayes et al. 2017). Although the age criterion was limited to over 65 years, the distribution of caries risk parameters was quite informative as a comparison to the current thesis. With the standard setting for the 'clinical judgement' parameter, the distribution of Chance-AC was 22.2%, 24.3%, 26.3%, 16.5% and 10.8% from the highest risk group to the lowest risk group among the Irish elderly people (Hayes et al. 2017).

Some studies using the Cariogram for adults specified various conditions such as patients with coronary artery disease (Fadel et al. 2011b), those with intellectual disabilities (Chang et al. 2014), special needs patients (Chang and Kim 2014), mentally challenged and visually impaired individuals (Daryani et al. 2014), orthodontic patients (Al Mulla et al. 2009; Almosa et al. 2012), periodontal disease patients (Fadel et al. 2011a) and patients with psoriasis (Fadel et al. 2013); however, no studies specified lower SES groups. A Swedish study (Hänsel Petersson et al. 2013) used socioeconomic area information as a factor to select a convenience sample; there was no analysis of risk profiles according to the socioeconomic areas.

Instead of the SES factor, a Chilean study using the Cariogram investigated a high-caries adult population (mean (SD) DMFT: 11.23 (5.23)) (Giacaman et al. 2013). Only 2% of patients were classified as low risk, and none were classified as very low risk. However, the distribution of the patients within each investigated aetiological risk parameter of the Cariogram was significantly different ($P < 0.01$). (Note that the study did not include the 'mutans streptococci' and saliva 'buffer capacity' parameters.) Therefore, individual

variability within the ‘diet contents’, ‘diet frequency’, ‘plaque amount’, ‘fluoride programme’ and ‘saliva secretion’ risk parameters was clear in this population, although Chance-AC was not highly varied in this high-caries adult population. The authors critiqued that Chance-AC appeared to be unrelated with caries experience or caries lesions in the population; this is not surprising because the Cariogram’s algorithm does not give a particularly heavy weight to the ‘caries experience’ parameter (Bratthall and Hänsel Petersson 2005). It should be noted that past caries experience and caries lesions does not always imply a current caries risk for an individual. Aetiological risk factors determine an individual’s current caries risk and the Cariogram was designed for demonstrating this.

Aside from studies using the Cariogram, Rothen et al. (2014) included SES factors such as race, education level and per capita income in their investigation. Nevertheless, these factors were only used for adjustments in the analysis of the relationship between dental caries and oral hygiene. Therefore, it is unknown if there was individual variability of caries risk profiles within lower SES in their study population. Vanobbergen et al. (2010) paid attention to oral health risk profiles unevenly spread between various social groups in the population but not within a social group. The authors indicated that socially vulnerable groups within the community can be correctly targeted with risk-based prevention and recommend that a combination of telephone coaching, mobile-phone short messaging or electronic mail be considered for dealing with lifestyle related factors in a lower SES population (Vanobbergen et al. 2010). It is interesting that vegetarians have an increased risk for caries and erosion, although vegetarians had a higher level of education than non-vegetarians; vegetarians showed better oral hygiene than non-vegetarians, but daily consumption of fruits was significantly more prevalent and topical fluoride application was less prevalent in vegetarians compared with non-vegetarians (Staufenbiel et al. 2015).

Among adults people aged 55, 65, 75 and 85 years, the older subjects had lower saliva secretion rates and more salivary counts of LB and MS than the younger ones (Fure 2004) Lundgren et al. (1997) also proved that the proportion of untreated decayed root surfaces, plaque score and the levels of LB increased significantly between the ages of 88 and 92 years and indicated a need for the development of personalised preventive

regimens for the disabled elderly. From analyses of caries risk profiles of patients after radiation therapy for head and neck cancer, Epstein et al. (1996) inferred that the lack of a statistically significant difference may be due to the multiple factors associated with caries and suggested that patient care must be personalised and that patients must be assessed at regular intervals to determine their caries risk and caries activity in order to provide guidance for the maintenance of their dentition.

For insight into the individual variability of multifactorial diseases and conditions such as asthma (Haldar et al. 2008), bruxism (Rompre et al. 2007) obesity (Green et al. 2016), tinnitus (van den Berge et al. 2017) and so on, cluster analysis has been employed. These studies show that the variability among individuals who have the disease does exist and impel us to move beyond a single classification of individuals as just the disease/condition. For example, cluster analyses in asthma patients have greatly improved the understanding of the disease and revealed the possibility of personalised curative medicine for asthma (Guilleminault et al. 2017). Some cluster analyses identified an obese phenotype and, although a systematic review on obesity and asthma concluded that the association was not straightforward (Ali and Ulrik 2013), weight reduction resulted in improving asthma control (Dias-Junior et al. 2014). Regarding dental caries, one study used a cluster analysis of past caries experience and bacteriological measurements to group schoolchildren (Sanchez-Perez et al. 2004). However, the systematic search in this thesis did not find any study using a cluster analysis of diet, microflora and host factors together for the purpose of identifying subgroups.

2.4 PCP programmes

In PubMed, 89 of the 1,425 articles from the initial search seemed relevant to PCP programmes based on their titles, 77 seemed relevant based on their abstracts, and 33 articles were included in the final review (Figure 2.4). The updated search in June 2018 retrieved 62 non-duplicate articles, of which five seemed relevant based on their titles; no articles were included in the final review.

A summary of the data sources, study designs, populations, risk assessments, prevention programmes and findings obtained from the systematic search are presented in Appendix 4. Apart from Article V (Paper 8), no investigations on PCP programmes conducted in the RoI were found. While 'Oral Health Assessment: Best practice guidance for providing an oral health assessment programme for school-aged children in Ireland' with a Caries Risk Assessment Checklist was published in 2012 (Irish Oral Health Services Guideline Initiative 2012), no such guidelines have been published for adults in the RoI.

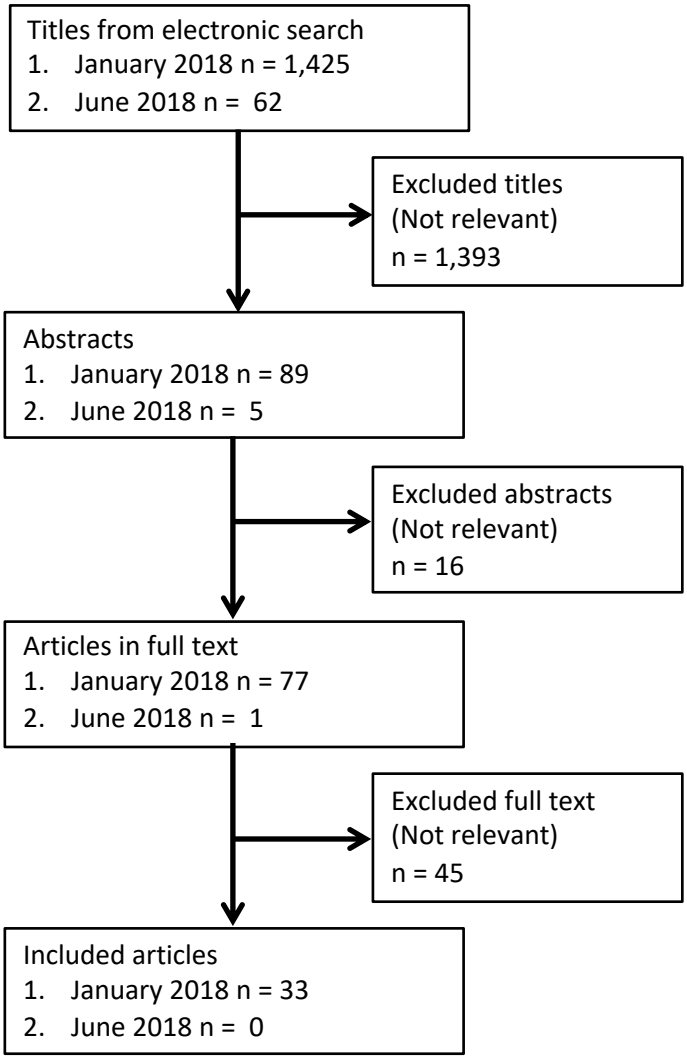


Figure 2.4 Flow chart showing numbers of included and excluded articles: PCP programmes

As noted in our literature review on caries risk profiles (Section 2.3), some articles conceptualise PCP programmes as "*a rule of thumb in daily practice, particularly in a population with high caries prevalence*" (Sonbul and Birkhed 2010), "*an essential component for the correct prevention, control and management of dental caries*" (Fontana and Gonzalez-Cabezas 2012) and "*the future standard of care for caries management in dental practice*" (Chaffee et al. 2015a). Compared to non-personalised preventive programmes, the disadvantages of PCP programmes are that it is difficult to identify high-risk patients accurately and that, even if this difficulty could be overcome, the evidence for preventive measures on high-risk individuals is still not very strong (Fontana and Gonzalez-Cabezas 2012). In the Cochrane library, there is a systematic review on personalised care planning for adults with chronic or long-term health conditions (Coulter et al. 2015). Although the authors stated that they included any long-term physical, psychological, sensory, or cognitive condition or combination of conditions affecting health being treated in any setting (primary care, secondary care, community care or residential care) in their search, dental caries was not included. Nineteen studies on diabetes, mental health problems, heart failure, kidney disease and asthma were reviewed with the conclusion that personalised care planning is a promising approach although its effects are not large.

As shown in Table 1.1, a number of different PCP programmes in dental practices have been proposed. PCP programmes commonly include (1) identifying an individual's risk profile for disease development/progression (CRA), (2) encouraging the patient to address their modifiable risk factors (for example, decrease sugar intake, improve oral hygiene, increase fluoride use/frequency at home, chewing sugar-free gum and changing medication that affects saliva secretion, quitting smoking and so on), and (3) promoting lifestyle actions that reduce cariogenic bacterial load in accordance with the individual's risk profile (Krasse 1985; Soderstrom et al. 2014).

One of the earliest programmes for adults was Axelsson's needs-related preventive programme in Sweden (Axelsson et al. 2004). The programme started in 1971. Based on the results of re-examination after six years regarding the incidence of caries and periodontal disease progression, the patients in the test group (n = 275) were stratified into three subgroups with different recall intervals as follows:

- **group R 1** (60% of patients): once every 12 months
- **group R 2** (30% of subjects): once every six months
- **group R 3** (10% of subjects): every three months.

Each patient receiving the preventive programme was given a detailed case presentation and education in self-diagnosis and self-care based on their individual need and prophylactic sessions with a dental hygienist which included plaque disclosure and professional mechanical tooth cleaning (PMTC). Over a period of 30 years, the mean numbers of new caries lesions were quite small: 0.04, 0.06 and 0.07 per year in 50–65 year olds, 66–80 year olds and 81–95 year olds in 2012, respectively. Axelsson's programme gave good results not only for dental caries but also for periodontal diseases. Preventive programmes provided in Swedish public dental clinics today are similar to Axelsson's programme (Flink et al. 2016). Most county councils in Sweden recommend that dentists use individual caries risk profiling to individualise caries treatments and recall intervals (Hänsel Petersson et al. 2013).

Furthermore, between 1991 and 1997, a new remuneration model for adults was tested in Sweden (Zickert et al. 2000). The new system was introduced to motivate both dentists and patients to apply existing knowledge. Its principle was similar to the British private capitation system, Denplan[8]. With the Swedish model, the patients paid an insurance premium depending on their risk assessment, which was based on three risk categories – case history, clinical and radiographic examinations and supplementary laboratory examinations. The results of this risk-based capitation model were a lower average number of new caries lesions and cost. Of the patients who responded to the evaluation questionnaire, almost all answered that they preferred the risk-based capitation model to the traditional fee-for-service.

[8] Denplan Limited. [accessed 7 June 2018]. https://www.denplan.co.uk/.

The success of this test led to the introduction of 'Frisktandvård' ('Dental Care for Health' (DCH)) in 2007, which is currently used as an alternative care model in public dental clinics all over Sweden (Andås et al., 2014). From the patient's electronic record, ten risk categories are assessed using a computer program. The dentist can adjust the risk categories. Dentist can adjust the risk categories. Evaluations of the DCH found that DCH patients reported themselves as being healthier, more engaged in health-promoting behaviours, satisfied with their choice and appreciative of feeling secure (Andås et al. 2014; Strand et al. 2015); DCH patients had more preventive treatment and less restorative treatment than patients with the traditional fee-for-service (Andås et al. 2014). The incidence of manifest caries[9] over six years was a 50% increase among traditional fee-for-service patients compared with DCH patients, when important background factors were controlled for (Andås and Hakeberg 2016).

However, another study among Swedish 19-year-olds found that most prevention measures were carried out in the 'some risk' group followed by the 'low-risk' group, not in the 'high risk group' (Hansel Petersson et al. 2016). The authors felt that one possible explanation for this could be because 63% of the lower risk patients had joined DCH, which might have increased the awareness and demand for preventive care among low-risk patients compared to high-risk patients. Another explanation is that patients with the greatest risk of disease are those that are least likely to attend for preventive care (e.g. unemployed young adults). This heuristic is called 'the inverse care law' (Hart 1971). James (2014) warns that genomic personalised medicine, especially that intended to prevent disease would do more harm than benefit with large-scale implementation due to 'the inverse care law' and 'inverse benefits law' (Brody and Light 2011). 'P5 medicine' which integrates a 'population perspective' into 'P4 medicine' (Hood and Friend 2011) is proposed as a balanced strategy. It is expected that implementing both

[9] Lesions clearly involving dentin, as seen on bitewing radiographs and frank cavitated lesions on other surfaces (Hedenbjork-Lager et al. 2015)

population- and individual-level interventions can best maximise health benefits, minimise harm, and avoid unnecessary healthcare costs (Khoury et al. 2012).

Soderstrom et al. (2014) investigated the effectiveness of the public dental service in a county in Sweden. They also found that the prevention programme was associated with improvements in caries risk and maintenance but that the extent to which such treatments were given to high-risk patients was low. The authors' overall conclusion is that compliance with the guidelines on caries prevention and treatment might be poor. Another important view of the authors is that while the risk scoring system, which relies mainly on caries experience, is sufficient to distinguish between low and high caries risk patients, it does not help to guide the design of individual treatment plans, unlike a system based on individually-assessed biological and behaviour risk factors.

A similar opinion was expressed by authors on CAMBRA: "*although…*" caries experience "*...is helpful, we still do not know the specific reasons behind the caries experience of this patient*" (Fontana and Gonzalez-Cabezas 2012); "*disease indicators, by themselves, give a good idea of the risk level; but they do not help the practitioner to understand why a patient has developed the disease*" (Domejean et al. 2011). The CAMBRA concept was discussed in a consensus conference of experts in California, the United States of America (USA) (Featherstone et al. 2003; Featherstone and Chaffee 2018). Twelve reviews were conducted to provide a scientific basis for CAMBRA but they were not systematic reviews. Only one review on chlorhexidine searched articles with specified key words systematically; it did not, however, assess quality of evidence (Anderson 2003). For the other 11 reviews, it is unknown whether or not the respective selections of literature reviewed were biased (Adair 2003a; 2003b; Berkowitz 2003; Bird 2003; Crall 2003; DenBesten and Berkowitz 2003; Donly 2003; Featherstone 2003; Hicks et al. 2003; Lynch and Milgrom 2003; Stewart and Hale 2003). As a result, CAMBRA recommends chlorhexidine or casein phosphopeptide-amorphous calcium phosphate (CPP-ACP), both of which are questionable for caries prevention (Raphael and Blinkhorn 2015; Walsh et al. 2015) (Ghezzi 2014).

In spite of being based on less prudent evidence than the best evidence which can be found using modern review methods, CAMBRA is still the most published caries

management programme which uses individual risk assessment for adults. The majority of these publications were reviews to introduce the model and its philosophy, with recent publications tending to be more analytical studies (Chaffee et al. 2015b; Cheng et al. 2015; Doméjean et al. 2015; Domejean et al. 2011; Teich et al. 2013). The first randomised clinical trial using a prototype of CAMBRA showed that an intervention featuring a combined antibacterial (0.12% chlorhexidine gluconate mouth rinse) and fluoride therapy significantly reduced bacterial load (Cheng et al. 2015; Featherstone et al. 2012). However, it is unknown if its effectiveness was due to the combined therapy or to fluoride alone, because the control group did not receive fluoride therapy.

The CAMBRA risk categorisation (low, moderate, high or extreme caries risk) is rather flexible, with no rigid algorithm for risk estimation (Chaffee and Featherstone 2015). Although this flexibility may puzzle users trying to discern moderate risk, a large-scale retrospective study (n = 4,468 patients with follow-up) showed evidence that the CAMBRA risk assessment could predict future caries (Chaffee et al. 2015a). Another study also showed that the risk assessment was able to categorise 2,571 patients into four risk groups and that new cavitated lesions, radiographic lesion penetration into dentine or approximal enamel lesions on X-rays were strongly associated with the risk groups. However, two concerns were (1) that only 55% of the total at-risk patients were provided with specific home care recommendations and (2) that 69% and 88% in the high-risk and extreme-risk groups, respectively, had new caries lesions at their follow-up examination at 16 ± 13 months. While compliance with the CAMBRA guidelines might not be perfect, its resulting caries incidence is still too high compared with other PCP programmes. This poses a dilemma in that the result proving predictive validity of risk assessment could also mean that CAMBRA's risk-based management did not control caries risk during the intervention.

CAMBRA is compatible with the International Caries Detection and Assessment System (ICDAS), which was created by a group of cariologists and epidemiologists in 2002 in Scotland (Ismail et al. 2007). ICDAS is a valid system for describing and measuring different degrees of severity of carious lesions (Diniz et al. 2009; Jablonski-Momeni et al. 2008). ICDAS draws the dentist's attention to early caries lesions for adequate preventive measures and for avoiding premature tooth treatment via restorations.

Recently, ICDAS has added a management system to itself, named 'ICDAS-ICCMS' (International Caries Classification and Management System) (Pitts et al. 2017). There have been no analytical studies published on the effectiveness of ICDAS-ICCMS.

The CMS model used in Australia has been investigated for a longer time than CAMBRA (Warren et al. 2016). There have been a number of published articles including a cost-effective study on the CMS (Curtis et al. 2011; Warren et al. 2010). The CMS was inspired by Axelsson et al. (Axelsson et al. 2004) and developed for use by general dental practitioners (Evans et al. 2008; Evans et al. 2016). The CMS includes a set of protocols (covering risk assessment, diagnosis, risk management, monitoring and recall) (Evans et al. 2016) and consists of ten steps (Evans et al. 2008). Diet assessment using the Usual 24-hour Snacking Questionnaire, plaque assessment using the Silness-Löe Plaque Index (Silness and Löe 1964) and saliva assessment for only stimulated saliva in two minutes are included. Final assessment of the patient is through clinical examination and a bitewing radiographic survey. Caries risk status is categorised into three groups (low, medium or high). Although there are diet, plaque and saliva assessments, risk categorisation is based only on the clinical examination and bitewing radiographic survey. At follow-up appointments, risk is also determined according to the incidence rate of new lesions and the progression status of existing lesions. This makes risk categorisation straightforward. For caries management, the diet, plaque and saliva assessments help determine the focus of patient behaviour change (oral hygiene coaching, selection of healthy diet components, and encouragement to restrict between-meal exposures to sugar-containing foods and beverages) (Evans et al. 2016). The recall protocol is to schedule for monitoring caries activity and the bitewing surveys with an interval of from three months to 24 months. The CMS seems more conservative than CAMBRA; CPP-ACP will not be included in its protocol until population clinical trials report on its efficacy.

Sbaraini and Evans (2008) followed 45 high-risk patients who received the CMS for six months. The CMS resulted in maintaining low plaque levels, decreasing gingival inflammation and reducing caries incidence and progression. In general, the patients were unable to change their dietary habits in six months. A 3-year randomised controlled trial was conducted to investigate the outcomes and cost-effectiveness of the CMS

(Curtis et al. 2008; Curtis et al. 2011; Warren et al. 2010). The overall DMFT increment among CMS patients was 21% less than in controls by intention-to-treat (ITT) (Curtis et al. 2008). Sensitivity analyses demonstrated that its cost-effectiveness improved with high-risk patients (Curtis et al. 2011). The trial was observed for another four years (Evans et al. 2016; Warren et al. 2016). The mean DMFT increment (adjusted for baseline DMFT and baseline age in years) for the CMS group was 6.13 from the clinical trial baseline to the end of the post-trial follow-up (year 7), whereas the corresponding value for the control group was 8.66 ($P < 0.0001$). Therefore, patients continued to benefit from a reduced risk of caries and experienced lower needs for restorative treatment.

In the United Kingdom (UK), evidence-based guidelines recommend assessing an individual's caries risk based on certain clinical criteria and then implementing an appropriate preventive plan (Afuakwah and Welbury 2015). Examples of such guidelines for adults are as follows:

- Scottish Dental Clinical Effectiveness Programme (SDCEP) (Scottish Dental Clinical Effectiveness Programme 2012)
- Faculty of General Dental Practice (FGDPUK) (Faculty of General Dental Practice 2016; 2018)
- Department of Health Toolkit (Public Health England 2017)
- National Institute for Health and Care Excellence (NICE) (National Institute for Health and Care Excellence 2004)
- Dundee Caries Risk Assessment Model (DCRAM) (MacRitchie et al. 2012)
- CARE tool (Keightley et al. 2012).

The national guidance on oral health assessment of adults by the Scottish Dental Clinical Effectiveness Programme (SDCEP) recommends a personal care plan that is risk-based and long-term to address the patient's individual oral health improvement and maintenance needs. (Scottish Dental Clinical Effectiveness Programme 2012) Risk is categorised into three levels (high, medium and low). For CRA, the guidance recommends using ICDAS and lists various factors to be assessed such as 'heavily

restored dentition', 'high and/or frequent sugar intake', 'low saliva flow rate' and so on. Its recommended recall intervals are as follows:

- **Low-risk**: every 2 years; consider extending the interval if there is continuing evidence of low caries activity;
- **Moderate risk:** every 12 months until no new or active lesions are apparent;
- **High risk:** every 6 months until no new or active lesions are apparent.

In the SDCEP guidance, salivary (bacterial) tests are not recommended as part of oral health assessment, but as an aid to patient motivation and education. The negative view to salivary tests as a risk assessment tool is seen in an audit project for children and adolescents (Afuakwah and Welbury 2015). In the audit, the authors investigated the delivery of risk assessment and preventive care among four dentists. At the second round, all children and adolescents (n = 513) were assessed for their caries risk (clinical evidence, dietary habits, social history, fluoride use, plaque control, saliva and medical history). There was 100% compliance with the protocol for preventive care plans, tooth brush instruction, concentration of toothpaste, diet advice, sugar-free medicines and recall intervals for all participants, while there were demonstrable variations between the categories for preventive plans incorporating fluoride varnish, fluoride supplements, fissure sealants and frequency of radiographs. The authors indicated that these differences were due to the age of patients sampled but did not mention individual risk differences. Although preventive care should be risk-based, it seems that the audit did not have the viewpoint that risk assessment is integral to preventive care. It is natural that the contents of PCP programmes differ from individual to individual; if all patients receive all components of a preventive plan, there might be over-prevention. It should be kept in mind that one purpose of PCP programmes is to reduce unnecessary effort and resources used for low-risk patients and redirect resources towards high-risk patients (Lahti et al. 2001; Twetman et al. 2013).

There is one study from Japan that investigates the effectiveness of a risk-based preventive programme for dental caries among adult patients (Ito et al. 2012). CRA included stimulated saliva flow rate, saliva buffering capacity and SM and LB levels.

The preventive treatments included education on plaque control, advice on diet, scaling and polishing and fluoride application with 9,000 ppm NaF solution. The risk-based recall visits took place between three and six months. All patients (n = 442) used a 900 ppm fluoridated toothpaste[10]. Within three years, 19.5% of the patients developed caries. In particular, patients with high levels of LB and MS had more caries lesions. These results indicate that this PCP programme can be improved with appropriate personalised intensive therapy; the authors suggested using high concentration fluoridated toothpaste and improving dietary habits. As changing dietary habits is challenging (Sbaraini and Evans 2008), more detailed consultation, for example using motivational interviewing (Harris et al. 2012), and shorter recall intervals could also be considered. Xylitol may also be used to reduce MS levels (Janakiram et al. 2017).

With a similar PCP programme to that of Ito et al. (2012), nine private dental practices participated in a multicentre study on CRA among adult patients in Japan (Arino et al. 2015). The resulting caries increment was also quite similar to that of Ito et al. (2012). The purpose of the Arino et al. (2015) study was to identify significant risk factors for the onset and accumulation of new caries in adult patients undergoing regular preventive therapy, using the same methodology as another study (Ito et al. 2011) with the same data as the Ito et al. (2011) study. It should be emphasised again that there is a dilemma when a study aims to validate risk assessments through a risk-based preventive programme (PCP programme), because a successful PCP programme should improve risk profiles during the follow-up period.

Although there is little literature in English, Kumagai's MTM (Kumagai 2006; Maruo et al. 2016) has shown effective outcomes for preventive dentistry in Japan. This model was also partly inspired by Axelsson et al. and, as mentioned in Section 1.1, incorporates the philosophy of Krasse and Bratthall.

[10] The Japanese Legislation at that time limited the maximum fluoride content up to 1,000 ppm F in toothpaste (Hirose et al. 2015).

The term ‘Medical Treatment Model’ was first introduced by Krasse and follows the following process (Krasse 2002):

(1) listen to the patient’s chief compliant,
(2) perform tests if necessary,
(3) remove the causes of the disease and reduce symptoms,
(4) monitor the treatment outcomes and prevent recurrence.

Krasse (2002) cited the example of a patient with tuberculosis: if the doctor merely cut, resected and filled with inactive material the tissues with inflammation of the tubercular patient, the doctor would be sued; while such a scenario would not occur in medical practice, in dentistry it occurs routinely. Krasse proposed that dentists should adopt the medical treatment process as outlined above when dealing with patients.

Kumagai’s MTM is similar to the PCP programme in the Japanese studies cited above (Arino et al. 2015; Ito et al. 2011; Ito et al. 2012). The difference is probably that Kumagai’s MTM bears a clear ambitious aim to keep the patient’s 28 permanent teeth sound for his/her general/oral health (Kumagai et al. 2018). As a result of motivating their patients with this aim, the outcomes among adult patients in the MTM in 2017 were similar to those of the 30-year maintenance programme by Axelsson et al. (Axelsson et al. 2004); the patients who started the MTM between 20–34 years of age and continued with the model for ≥ 21 years on average lost 0.01 tooth per year (n = 344); among 20-year-olds (n = 32), the mean DMFT was less than one (Kumagai T. symposium presentation, 7 October 2017).

2.5 mHealth approach for caries prevention

In PubMed, the initial search retrieved five articles. None of them were relevant to personalised mHealth for caries prevention. The updated search in June 2018 retrieved no articles. The bibliographic lists at the end of searched papers were also hand checked

to ensure completeness. A search using the bibliographic lists at the end of papers found 12 articles relevant to mHealth and oral health. Apart from Article V, no investigations on personalised mHealth for caries prevention were found.

The article by Ghezzi (2014) on evidence-based interventions for PCP in dentate elders concludes "*Studies in patients at risk for dental caries and vulnerable groups are needed to increase knowledge and self-care practices by communicating preventive health messages and increasing motivation*[20]". 'Vulnerable groups' here may include people in lower SES. To increase knowledge and self-care practices of such people, mHealth interventions, including mobile and other remote devices such as monitoring systems or wearable technologies, have the advantage of reaching at-risk individuals at any time or place (Naslund et al. 2015).

The earliest English article on mobile-phone short text messaging and oral health found was a randomised controlled trial to compare the effectiveness of mobile-phone short text messages and written material for the health education of mothers of young children in India (Sharma et al. 2011). For four weeks, health education was delivered via text messages to the test group (n = 72) and via pamphlets to the control group (n = 71). Outcome measures were knowledge, attitude and practices of the mothers which were assessed by questionnaires before and after the intervention. Visible plaque scores of their children were also recorded before and after the intervention. The results were that text messaging was more effective than pamphlets in improving knowledge, attitude and practices of mothers, but that the comparative reduction in plaque score between groups was not significant.

The Text2Floss Study also examined the feasibility and utility of a 7-day text messaging intervention to improve the oral health knowledge and behaviour of mothers with young children. This was also a randomised controlled trial with test (n = 60) and control (n = 69) groups. Both groups were given written material. The test group additionally received automated daily text messages. The Text2Floss platform is interactive; each day at a specific time, a text message was sent requesting a response to the query "*Did you floss yesterday?*" If the participant responds "*no*", the Text2Floss sends an additional message on oral health/oral hygiene information such as "*Did you know tooth*

decay or cavities are common, preventable problems for people of all ages?"; and if the response is "*yes*", "*Good job! Don't forget to see your dentist twice a year for professional cleanings and oral exams.*" The results of this study showed that a short 7-day text message intervention was able to increase flossing behaviour and oral health knowledge. Furthermore, text messages increased the use of mouth rinse among participants. The behaviour of the mothers with respect to their children's oral health and diet also changed. Because the intervention (one week) and follow-up (one week) were so short, long-term behaviour changes could not be evaluated. The messages linking flossing and dental caries may have also confused participants, as it remains controversial whether flossing prevents dental caries (Sambunjak et al. 2011). Another concern is that all participants were encouraged to see the dentist twice a year, regardless of their individual risks which could merit longer or shorter visit intervals.

Another mHealth study aimed to improve toothbrushing frequencies among unemployed young adults using mobile-phone short text messaging (Schluter et al. 2014). Over 10 weeks, a series of motivational text messages were sent to 171 participants; self-reported tooth brushing twice or more per day increased from 51% at baseline to 73% at week 9. This was a promising result for improving oral health self-care behaviour in a hard-to-reach group (unemployed young adults) via mobile-phones. However, it is a concern that only 26% of the participants provided valid responses at the end of the study and there were no objective measures.

A quasi-experimental controlled trial was conducted to assess the longer-term effectiveness of using mobile-phone short text messages to reinforce oral health education (Jadhav et al. 2016). The follow-up continued to six months. The subjects were 400 students from two colleges situated well apart from each other. All students were educated on the common risk factor approach (Jadhav et al. 2016) (oral hygiene practices, diet, habits such as smoking and alcohol use, stress, and trauma) through a slide presentation with audio. The colleges were then randomly allocated into test or control. For the test college group, the students were sent educational messages to reinforce their knowledge twice a week for the first three months. Students from the control college group did not receive any text messages. Follow-up examinations were given at the end of the 1st, 2nd, 3rd, and 6th month. The Mean Oral Hygiene Index (OHI)

and Gingival Index (GI) scores of the test college students were significantly less than those of the control college students after the 2nd, 3rd, and 6th month. However, after the cessation of the intervention, between the 3rd and 6th month, there was an increase in mean OHI and GI scores in the test college student group similar to the control college student group. Therefore, the effect of educational text messages may decrease over the long-term, as with other methods (Kay and Locker 1996).

Many studies have recently been published on the effect of mobile-phone text messaging on the oral hygiene of orthodontic patients (Abdaljawwad 2016; Bowen et al. 2015; Iqbal et al. 2017; Jejurikar et al. 2014; Kumar 2018; Li et al. 2016; Zotti et al. 2015). All studies show that oral hygiene status with objective measures such as plaque index, gingivitis index and white spots, improved with a text message reminder.

In recent years, smartphone-based messaging apps have gradually supplanted the use of standard phone text messaging services. The advantage of messaging apps to standard phone text messages is that it has the ability to be interactive. Zotti et al. (2015) used WhatsApp® (WhatsApp Inc., Mountain View, California, the USA) to provide chat-room-based competition for oral hygiene improvement and Li et al. (2016) used WeChat® (Tencent Ltd., Shenzhen, China) to send regular reminders and educational messages for the test group. In the Zotti et al. (2015), the test group patients shared two selfies of their teeth weekly in the chat room before and after using plaque-disclosing tablets to show their ability in maintaining oral hygiene. The moderator, after visual evaluation of the patients' photographs and level of participation in the chat room, published a ranking of the five best participants of the week. In the Li et al. (2016), educational messages were linked to articles on oral health tips and knowledge. WeChat® has functions of chatting, news reading, blogging and social networking. Service providers can deliver texts and multimedia contents to all subscribers. These applications have greater potential to be widely used in patient education and management in the future than standard phone text messaging services.

2.6 Summary of literature review

This literature review identified gaps in the research on patients' knowledge and perception of caries risk, caries risk profiles based on aetiological factors within diet, microflora and host, PCP programmes and an mHealth approach for caries prevention. Knowledge of caries risk was quite different from country to country. The social determinants of health had a strong influence on knowledge of caries risk. The association between Chance-AC (actual risk) and perceived risk for caries shows a similar tendency to that of various other diseases has certain similar tendencies among various diseases: Self-perceived caries risk was to some extent related to Chance-AC, yet people tend to have an optimistic bias about their risk of developing a disease. The Cariogram is considered a useful tool for describing complex caries risk profiles and for comparing the caries risk of different populations. Using the Cariogram's Chance-AC, it was clear that higher risk populations (i.e. Chance-AC is lower) show a higher CV of Chance-AC, which means a greater level of dispersion around the mean. For insight into the individual variability of multifactorial diseases and conditions, cluster analysis may be employed. A number of PCP programmes were developed in Sweden, the USA, Australia, the UK and Japan, with the Swedish models in the lead. The most investigated model in the research area was CAMBRA. The CMS was investigated in terms of cost-effectiveness. Generally, PCP programmes were more effective and cost-effective than traditional prevention. Of them, Axelsson's needs-related caries preventive programme and Kumagai's MTM presented overwhelming outcomes. mHealth intervention for oral health education consistently showed itself more effective than traditional education materials. However, it should be noted that the longest follow-up among the reviewed studies was only six months.

2.7 Statement of the objectives

After providing a background on dental caries, caries risk, P4 Medicine and mHealth, the overall aim of this thesis was stated in Section 1.2:

To investigate the impact on caries risk reduction of a personalised dental education approach based on individual CRA using mobile-phone short text messages in an economically disadvantaged adult population in the RoI.

2.7.1 Objectives

To meet this overall aim, this thesis pursues the following research questions and research hypotheses, and addresses four objectives in accordance with Farrugia et al.'s guidance (Farrugia et al. 2010). When statistical significance is to be tested, the null hypothesis as well as the research hypothesis is stated.

2.7.1.1 Objective 1 (Articles I and II: knowledge of caries risk)

Research question 1. *Is knowledge of caries risk in an economically disadvantaged adult population in the RoI similar or different compared with an adult population in Japan who are regarded to have greater knowledge of preventive dentistry?*

Hypothesis 1-1. An economically disadvantaged adult population in the RoI shows deficient knowledge of caries risk factors/indicators compared with an adult population in Japan who are regarded to have greater knowledge of preventive dentistry.

Null hypothesis: There is no difference in knowledge of caries risk factors/indicators between an economically disadvantaged adult population in the RoI and an adult population in Japan who are regarded to have greater knowledge of preventive dentistry.

Hypothesis 1-2. An economically disadvantaged adult population in the RoI correctly identifies fewer caries risk factors/indicators compared with an adult population in Japan who are regarded to have greater knowledge of preventive dentistry.

Null hypothesis: There is no difference in the total number of correctly identified caries risk factors/indicators between an economically disadvantaged adult population in the RoI and an adult population in Japan who are regarded to have greater knowledge of preventive dentistry.

Objective 1: To identify social/cultural influences on perceived caries risk factors/indicators in an economically disadvantaged adult population in the RoI, comparing with an adult population in Japan who are regarded to have greater knowledge of preventive dentistry (Articles I and II).

2.7.1.2 Objective 2 (Article III: self-perceived caries risk)

Research question 2. *How is self-perceived caries risk associated with actual caries risk at baseline in an economically disadvantaged adult population in the RoI?*

Hypothesis 2-1. There is an association between Chance-AC and self-perceived caries risk in an economically disadvantaged adult population in the RoI.

Null hypothesis 2-1: There is no association between Chance-AC and self-perceived caries risk in an economically disadvantaged adult population in the RoI.

Hypothesis 2-2. Those at high risk of dental caries underestimate their risk level in an economically disadvantaged adult population in the RoI.

Hypothesis 2-3. Caries risk factors/indicators (demographic factors and caries risk parameters for calculating Chance-AC) are associated with self-perceived risk in an economically disadvantaged adult population in the RoI.

Null hypothesis: There is no association between the caries risk factors/indicators and self-perceived caries risk in an economically disadvantaged adult population in the RoI.

Objective 2: To evaluate the associations between Chance-AC and self-perceived caries risk in an economically disadvantaged adult population in the RoI (Article III).

2.7.1.3 Objective 3 (Article IV: caries risk profile)

Research question 3. *What is the caries risk profile of participants at baseline in an economically disadvantaged adult population in the RoI?*

Hypothesis 3-1. Chance-AC of the Cariogram in an economically disadvantaged adult population in the RoI is lower than in general adult populations in developed countries.

Hypothesis 3-2. Each aetiological risk parameter of the Cariogram in an economically disadvantaged adult population in the RoI is different from individual to individual.

Objective 3: To determine individual variability of Chance-AC and seven aetiological caries risk parameters from the Cariogram's ten parameters, within individuals in an economically disadvantaged adult population in the RoI (Article IV).

2.7.1.4 Objective 4 (Article V: personalised mHealth for caries risk)

Research question 4. *Is a personalised dental education approach based on individual CRA using mobile-phone short text messages more effective than a non-personalised approach in reducing caries risk and in increasing knowledge and perception of caries risk in an economically disadvantaged adult population in the RoI?*

Hypothesis 4-1. A personalised dental education approach based on individual CRA using mobile-phone short text messages is more effective than a non-personalised

education approach in reducing caries risk in an economically disadvantaged adult population in the RoI.

Null hypothesis: No difference in caries risk exists between the personalised and non-personalised groups.

Hypothesis 4-2. A personalised dental education approach based on individual CRA using mobile-phone short text messages is more effective than a non-personalised approach in reducing aetiological caries risk factors in an economically disadvantaged adult population in the RoI.

Null hypothesis: No difference in number of patients with high aetiological caries risk scores exists between the personalised and non-personalised groups.

Hypothesis 4-3. A personalised dental education approach based on individual CRA is more effective than a non-personalised approach for increasing self-perceived caries risk in an economically disadvantaged adult population in the RoI at caries risk at baseline.

Null hypothesis: No difference in self-perceived caries risk exists between the personalised and non-personalised groups among high-risk participants in an economically disadvantaged adult population in the RoI.

Hypothesis 4-4. A personalised dental education approach based on individual CRA using mobile-phone short text messages is more effective than a non-personalised approach for increasing knowledge of caries risk factors/indicators in an economically disadvantaged adult population in the RoI.

Null hypothesis: There is no difference in knowledge of caries risk factors/indicators between the personalised and non-personalised groups.

Objective 4: To investigate the impact on caries risk reduction of a personalised approach, delivered via a CRA summary letter plus 24 mobile-phone short text

messages based on the individual Cariogram CRA, versus a non-personalised approach on (i) reducing Chance-AC and seven aetiological caries risk parameters and on (ii) increasing knowledge and self-perception of caries risk in an economically disadvantaged group (Article V).

3 MATERIALS and METHODS

In this chapter, the materials and methods will be discussed separately for the Japanese study (Articles I and II) and the Irish study (Articles II–V) used in this thesis. First, the materials and methods in the Japanese study will be explained in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement (von Elm et al. 2007). Second, the materials and methods in the Irish study will be explained in accordance with the Consolidated Standards of Reporting Trials (CONSORT) (Schulz et al. 2010) and CONSORT EHEALTH (Eysenbach and Group 2011) Statements. Third, primary and secondary outcomes and data analyses according to the four objectives will be set out. Finally, this chapter will be summarised in Section 3.4. Figure 3.1 illustrates the relationships between the four objectives and the two studies, which were the basis of the five articles (Roman numerals) used to address the four objectives of this thesis.

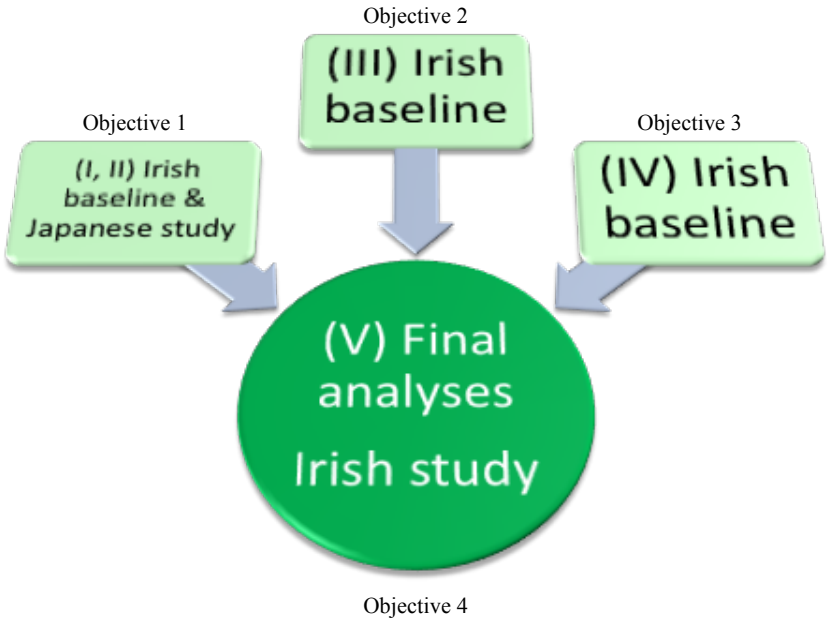


Figure 3.1 Four objectives and related studies conducted for this thesis

Roman numerals indicate article numbers.

3.1 The Japanese study (Articles I and II)

3.1.1 Study design

The Japanese study was a cross-sectional study using questionnaires which formed the basis of the questionnaires in the Irish study. The Japanese study was carried out in collaboration with a non-profit nationwide web-based organisation named 'Promoting Scientific Assessment in Prevention of Tooth Decay and Gum Disease' (PSAP). The study was conducted over a period of two years (13 May 2013 to 12 May 2015) as part of the baseline survey of a follow-up study to investigate the effectiveness of the PSAP's activities. Ethical approval for the follow-up study was granted by the Japanese Society for Oral Health (No. 24-4) on 25 March 2013.[11] The Japanese study was conducted in full accordance with the World Medical Association Declaration of Helsinki (World Medical 2001). All participants were asked to provide informed consent, which included their voluntary agreement to participation, free of coercion and undue influence, prior to taking part in the study.

3.1.1.1 PSAP

The PSAP was set-up to increase demand for patient-centred and personalised prevention of dental caries and periodontal diseases from Japanese dental practices. The activities of the PSAP are to inform the public, especially potential earlier adopters (Rogers 2003), of state-of-the-art dental prevention by means of the Internet (www.honto-no-yobou.jp/; www.facebook.com/yobousika/; twitter.com/makikonishi/), publishing books (Promoting Scientific Assessment in Prevention of Tooth Decay and Gum Disease 2013; 2014) and articles, and holding lectures.

[11] The ethics committee noted that they could not examine conflict of interest (COI) for the follow-up study investigating the effectiveness of the PSAP activities because participants were recruited through the PSAP, and suggested carrying out the follow-up study taking this in consideration. Thus, COI issues were carefully reported.

The PSAP is underpinned by the Health Belief Model (Champion and Skinner 2008) and the Diffusion of Innovation Theory (Rogers 2003). The Health Belief Model attributes the widespread failure of people to participate in programmes to prevent and detect disease to a lack of perception surrounding their susceptibility/severity of disease and/or the benefits/barriers of prevention. The first objective of the PSAP is to let health-conscious individuals (or compliers) realise the benefits of personalised prevention of dental caries and periodontal diseases in order that they make prevention a habit. Such people will practice what is beneficial to their health, if they are given correct information. The Diffusion of Innovation Theory postulates that an innovative service will not be diffused to average individuals (i.e. not health-conscious) unless health-conscious individuals first acquire it (Rogers 2003).

The PSAP is open to public membership for free and has 661 public members registered (as of 16 April 2018) since its establishment on 1 September 2010. The PSAP's financial sponsors are 151 fee-paying dental members (10,000 Japanese yen annually), two philanthropic companies (20,000 Japanese yen annually), and one corporate sponsor (Oral Care Inc., Tokyo). During the Japanese study, the PSAP website had 1,700–2,800 page views and 500–800 people visiting per month. Visitors come through Google, the URL directly, Yahoo and Facebook in descending order. The key words (in Japanese) for accessing the website are 'unknown', the PSAP's name, 'Teeth Talk' (the PSAP website's nick name) and 'preventive dentistry' in descending order. The board members of the PSAP are two dentists (including myself), one dental hygienist and one chief executive of a dental company, Oral Care Inc. PSAP operations are executed by staff members of Oral Care Inc. The administration office is located in Tokyo.

3.1.2 Participants

All fee-paying dentist members of the PSAP were asked to complete a self-administered paper questionnaire (**dentist questionnaire**) and to distribute a separate self-administered paper questionnaire (**patient questionnaire**) together with a stamped, addressed (to the PSAP) return envelope, to 20 of their patients on a first-come,

first-served basis. Patient recruitment and questionnaire collection were conducted over a two-year period from 13 May 2013 to 12 May 2015.

In order to investigate the current status of caries risk knowledge among potential opinion leaders (Flodgren et al. 2011) of PCP programmes, the target population were adults (aged 20+) who were deemed to have greater knowledge of preventive dentistry. As PCP programmes are still a new service among the Japanese people, key persons at this early phase of diffusion have greater knowledge of innovations than the rest of the population according to the Diffusion of Innovation Theory.

3.1.2.1 Fee-paying dental members

Fee-paying dental members were separated into two groups: **Group A dentists** were enrolled prior to 13 May 2013 (n = 99); **Group B dentists** were enrolled between 13 May 2013 and 12 May 2015 (n = 40).

Group A dentists were asked to complete their questionnaire on 17 January 2014. Group B dentists (n = 40) were asked to do the same upon enrolment in the PSAP. Thus, while Group A dentists had at least eight month's exposure to PSAP activities at the time of completing their questionnaire survey, Group B dentists had no exposure to PSAP activities at the time of their questionnaire survey (Figure 3.2).

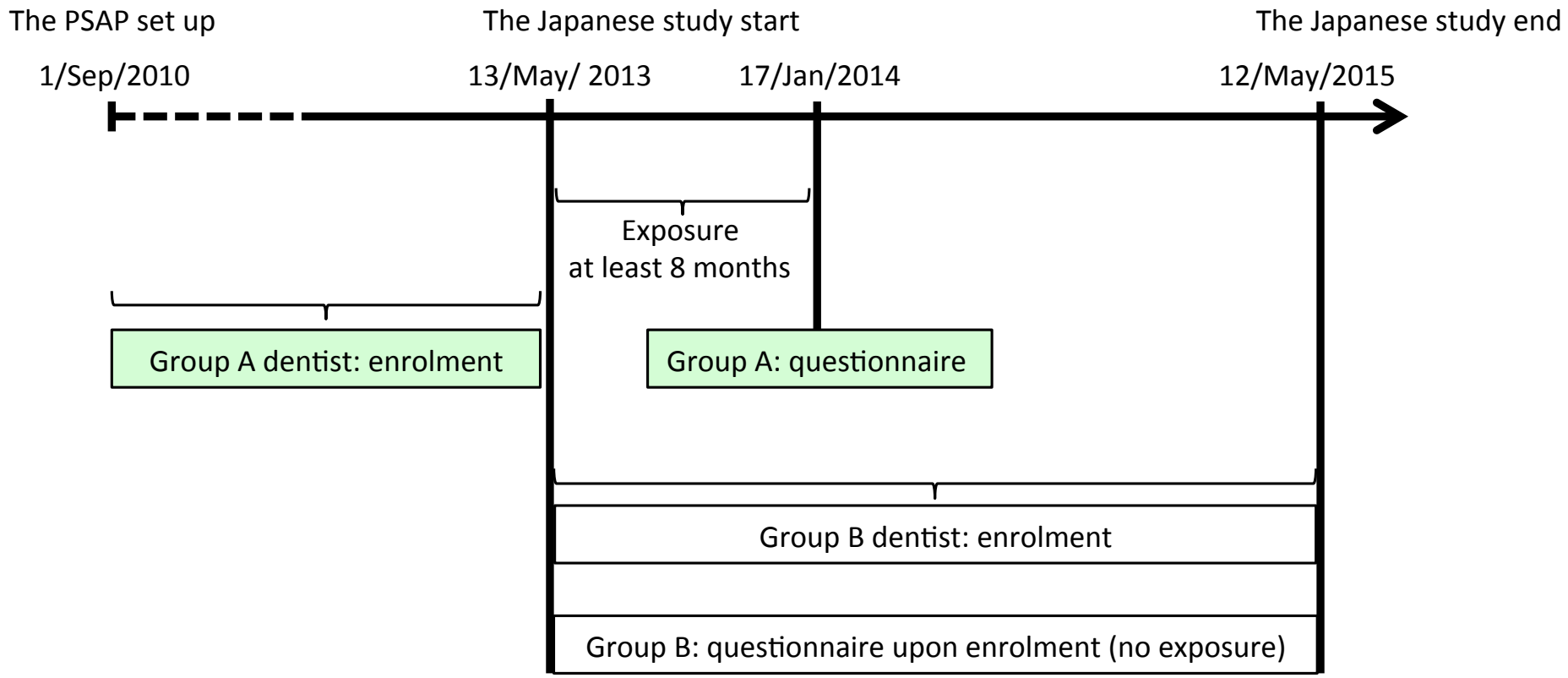


Figure 3.2 Enrolment and questionnaire distribution

3.1.2.2 Patient participants

Three patient survey groups were set as follows:

- **Group A**: patients of Group A dentists
- **Group B**: patients of Group B dentists
- **Group C**: public members of the PSAP enrolled between 13 May 2013 and 12 May 2015. Public members do not pay fees.

Although Article I included all three groups, Group C was not relevant to Objective 1 in this thesis.

The inclusion criteria for patient participants were:

(1) willingness to participate in the project
(2) 20+ years of age.

The exclusion criteria were:

(1) dental professionals (dentist, dental hygienist, dental assistant, and dental technician)
(2) Group C
(3) those who did not answer all socio-demographic factors (age, gender, whether dental professional or not) in their questionnaire.

3.1.3 Data sources/measurement

3.1.3.1 Development of questionnaires

The questionnaires for the pre-pilot study were developed in English with the help of two dentists, one psychologist, one project manager and one economist in the Oral

Health Services Research Centre (OHSRC). For the pilot study, questionnaires were formulated both in English and in Japanese. The pilot study was conducted in September 2012 of PSAP fee-paying dental members (n = 84, response: n = 24), their patients (n = 23), and public members (n = 195, response: n = 34). Since all PSAP members are Japanese speakers, the Japanese versions of the questionnaires were piloted. Based on the results of the pilot study, modifications to the **dentist questionnaire** were made and reviewed by three Japanese dentists and one Japanese dental office worker, and to the **patient questionnaire** by two non-dental Japanese speakers, the Japanese dental office worker, and one of the three Japanese dentists. Translations between Japanese and English were carried out by a Japanese/English speaker (myself) and an English speaker. Appendix 5 presents the English version of questionnaires. As with the pilot study, since all survey participants were Japanese speakers, the Japanese versions of the final questionnaires were used. Back translations were achieved only for confusing questions.

3.1.3.2 Data management and confidentiality

Both dentist and patient questionnaires were anonymous, with identification numbers which were not linked with personal information. Participant names and postal addresses were collected separately for those who were interested in receiving non-monetary incentives (oral care products: ¥280) for participating in the patient questionnaire survey. Patient participants were requested to answer their questionnaire at home to avoid undue influence from the dental practice on their answers. Both dentist and patient questionnaire data (password protected) without personal information (e.g. name, postal/email addresses) were collected and sent by the PSAP website administrator in Tokyo, Japan to myself in the OHSRC via email on 10 July 2015.

3.1.3.3 Variables

Only two questions were used from the **dentist questionnaire** in this thesis:

Question number (Q)2. Do you perform personalised caries prevention in any way? ("personalised caries prevention" means "caries prevention based on caries risk assessments according to individual patients"). Please choose only one of the following: Yes/No

Q3. What percent of individual adult patients receive personalised caries prevention in your practice? ____ %

The relevant questions in the **patient questionnaires** to this thesis were Q2, Q3, Q4, Q5, Q8, Q13, Q15, Q16 and Q17 (Appendix 5).

Since the technical term PCP might confuse participants, examples of CRAs such as "*examining contents and frequency of diet, asking about the use of fluoride, and performing saliva tests*" were given (Q5).

In dental practice settings, a PCP programme should include a routine maintenance programme (MP). MP was defined as professional check-ups and cleaning. Only participants who indicated on their questionnaire that they received both the PCP programme and MP were categorised as PCP adopters.

As for knowledge of caries risk, patient participants were asked to identify caries risk factors/indicators from eight listed items (Q3). Of the eight listed items, six came from the Cariogram (Bratthall et al. 2004). Of the two remaining listed items, "*Having naturally 'weak teeth'*" refers to a heritable weakness in enamel formation which increases individual susceptibility to caries (Vieira et al. 2014), and "*Not visiting the dentist for a dental maintenance programme (check-up and cleaning)*" was derived from a long-term study on routine MP (Axelsson et al. 2004). As all eight items are correct factors/indicators of caries risk, the more items the participant ticked, the more likely that he/she is knowledgeable about caries risk factors/indicators. If the participant ticked the item "*Other*" and specified a correct factor/indicator different from the listed

alternatives, this was given an additional point. Thus, the highest score for correct responses is nine.

In Article II, the statement question (Q6), "*The more I visit the dentist for check-up, the more teeth, I think, are drilled*" was included and participants were asked whether they agreed or not.

3.1.4 Bias

Because the Japanese study targeted adults who were deemed to have greater knowledge of preventive dentistry and participants were recruited only through the PSAP, dentist and patient participants were not considered as being representative of the general population in Japan.

3.1.5 Study size

The sample size was not calculated for the Japanese study. The number of dentist questionnaires issued by the PSAP was 139. The number of patient questionnaires issued to each PSAP dentist was limited to 20, as we did not wish to overburden participating dentists with the survey. The PSAP issued 1,980 (= 99*20, Group A dentists) and 800 (= 40*20, Group B dentists) patient questionnaires. It is unknown how many of these questionnaires were subsequently distributed by the dentists to their patients.

3.2 The Irish study (Articles II–V)

3.2.1 Study design

The design of the Irish study was a 2-arm parallel-group, single-blinded, randomised controlled clinical study with a 1:1 allocation ratio comparing personalised (test) and non-personalised (control) caries prevention advice through the medium of one letter

and 24 mobile-phone text messages. The target population was Medical-Card (MC) patients (i.e. proxy for economically disadvantaged status) in the RoI. A MC holder is entitled to free or reduced-rate medical treatment such as general physician services, prescribed drugs and medicines, public hospital services, dental, ophthalmic and aural services and appliances, and maternity and infant care service[12]. The study was conducted at the OHSRC, the Cork University Dental School and Hospital and eight dental practices in County Cork, the RoI. Ethical approval for the Irish study was granted by the Clinical Research Ethics Committee of the Cork Teaching Hospitals (ECM 4 (r) 12/08/14) on 11 August 2014. The full trial protocol is available at the OHSRC website[13]. This study is registered with the University Hospital Medical Information Network Clinical Trials Registry[14] (ID: UMIN000027253) on 10 May 2017. The Irish study was conducted in full accordance with the World Medical Association Declaration of Helsinki (World Medical Association 2001). All files including personal information were coded. Figure 3.3 presents a process chart. Coloured boxes indicate intervention activities. Table 3.1 shows the timeline of the Irish study.

[12] The Citizens Information Board. Citizens Information: Medical cards. [accessed 7 June 2018]. http://www.citizensinformation.ie/en/health/medical_cards_and_gp_visit_cards/medical_card.html.

[13] The Oral Health Services Research Centre. EPES. [accessed 7 June 2018]. https://www.ucc.ie/en/ohsrc/research/epes/.

[14] The University Hospital Medical Information Network Clinical Trials Registry. [accessed 7 June 2018]. http://www.umin.ac.jp/ctr/index.htm.

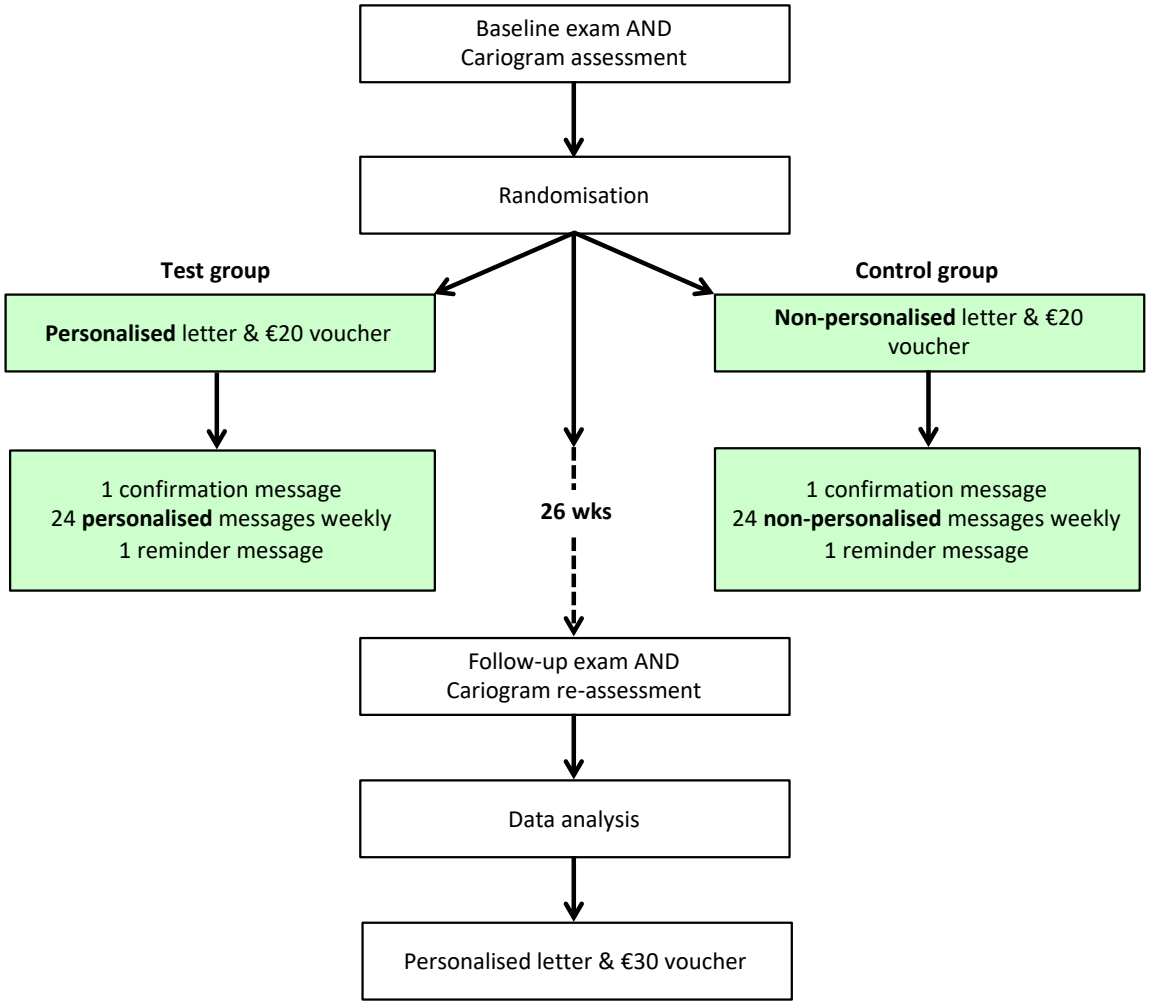


Figure 3.3 Process chart of the Irish study

Table 3.1 Timeline of the Irish study

Date	Calibration	Baseline exam	Intervention	Follow-up exam
11/02/2015	Training & Calibration 1			
18/02/2015	Training & Calibration 2			
25/02/2015		Exam start		
03/03/2015		3-day food arrival start		
01/04/2015	Training & Calibration 3			
17/04/2015		Assessment & randomisation start		
26/04/2015			Confirmation message start	
03/05/2015			Education message start	
25/05/2015	Training & Calibration 4			
27/05/2015	Training & Calibration 5			
28/09/2015		Exam finish		
14/10/2015				Exam start
23/10/2015				3-day food arrival start
28/10/2015				Assessment start
02/11/2015		3-day food arrival finish	Reminder message start	
08/11/2015		Assessment finish		
12/11/2015		Randomisation finish		
15/11/2015			Confirmation message finish	
24/04/2016			Education message finish	
08/05/2016			Reminder message finish	
19/05/2016				Exam finish
16/06/2016				3-day food arrival finish
19/07/2016				Assessment finish
16/08/2016				Assignment revealed

3.2.1.1 Baseline survey

The baseline survey started on 25 February 2015 and ended on 12 November 2015, covering a period of nine months. Recruitment was carried out over seven months to 28 September 2015. Collection of questionnaires continued until 24 November 2015. The process of the baseline survey was as follows:

In the dental practice

1. recruiting MC patients
2. informed consent (Appendix 6)
3. interview (name, gender, address, mobile number, eligibility, systemic diseases, fluoride use and smoking status)
4. saliva tests (CRT® Ivoclar Vivadent, Liechtenstein: saliva quantity, buffering capacity, LB and MS)
5. oral examination (plaque score, tooth status, coronal and root caries condition)
6. distributing the paper questionnaire (Appendix 7) and 3-day food diary (Appendix 8) with a stamped addressed return envelope to patients
7. sending the LB and MS agar cultures (CRT®), case report forms (CRF: Appendix 9) and informed consent forms to the OHSRC usually within the same day as the examination.

In the OHSRC

1. incubating the LB and MS agar cultures by the laboratory technician (The test vial was placed upright in the incubator at 37 °C for 48 hours.)
2. scoring the incubated LB (Figure 3.4) and MS (Figure 3.5) agar cultures by the laboratory technician in accordance with the manufacturer's instructions[15]
3. entering CRF data and scores of LB and MS

[15] Ivoclar Vivadent AG. CRT bacteria. [accessed 7 June 2018]. http://www.ivoclarvivadent.com/en/p/all/products/prevention-care/caries-risk/crt-bacteria.



Figure 3.4 Scoring CRT® Saliva test (LB)



Figure 3.5 Scoring CRT® Saliva test (MS)

At the MC patient's home

1. recording the 3-day food diary (Appendix 8)
2. answering the questionnaire (Appendix 7)
3. sending the 3-day food diary and the questionnaire to the OHSRC

In the OHSRC

1. assessing the 3-day food diary (Appendix 8) to evaluate average fermentable carbohydrate intake per day for each patient
2. entering data from the 3-day food diary and the questionnaire (Appendix 7)

3. assessing caries risk with the Cariogram
4. preparing thank-you letters (Appendix 10) to participants in the personalised and non-personalised groups; preparing results from the CRA to be sent to patients in the test group
5. allocation of participants to test and control group with stratified randomisation according to the CRA results
6. sending of letters and €20 vouchers to patients as a gesture of thanks

By the computer programmer

The programmer was tasked with the sending of mobile-phone text messages (Appendix 11) for 24 weeks plus an introductory message and a reminder message for the follow-up examination from 26 April 2015 to 8 May 2016.

3.2.1.2 Follow-up survey

The follow-up survey commenced on 14 October 2015 and ended on 19 July 2016, a period of nine months. The process of the follow-up survey was as follows:

In the dental practice

1. recalling the MC patients for follow-up examination
2. interview (name, gender, address, mobile number, systemic diseases, fluoride use and smoking status)
3. saliva tests (CRT®: saliva quantity, buffering capacity, salivary LB and MS)
4. oral examination (plaque score, tooth status, coronal and root caries condition)
5. distributing the paper follow-up questionnaire (Appendix 7) and 3-day food diary (Appendix 8) with a stamped addressed return envelope to their patients
6. sending the LB and MS agar cultures (CRT®), CRF (Appendix 9) to the OHSRC usually within the same day

In the OHSRC

1. incubating the LB and MS agar cultures by the laboratory technician (The test vial was placed upright in the incubator at 37 °C for 48 hours.)
2. scoring the incubated LB and MS agar cultures
3. entering CRF data and scores of LB and MS

At the MC patient's home

1. recording the 3-day food diary (Appendix 8)
2. answering the questionnaires
3. sending the 3-day food diary and the questionnaire to the OHSRC

In the OHSRC

1. assessing the 3-day food diary (Appendix 8)
2. entering data from the 3-day food diary and the questionnaire (Appendix 7)
3. assessing caries risk with the Cariogram
4. preparing the thank-you letters and the results of CRA at baseline and follow-up (Appendix 10) to be sent to the patients
5. sending the letters and €30 voucher to the patients as a gesture of thanks
6. sending the results of CRA plus their charts and personalised advice created by the Cariogram at baseline and follow-up to the dental practices and MC patients.

3.2.2 Participants

Written consent was obtained via their dental practitioner from all MC patients involved in the Irish study. All dental practitioners provided their verbal consent: as the participating dental practitioners were considered as co-researchers of the study, their consent procedure was not included in the ethics approval application.

3.2.2.1 Dental practitioners

Ten dental practitioners (volunteers) were recruited as examiners. The inclusion criteria for participating dental practitioners were (1) working in a dental practice in Cork and (2) having MC patients. All dental practices were similar in size. Dentists A and G had practices in the towns of County Cork while the others had practices in Cork city. Dentists A, F, G and I were clinical instructors in the University Dental Hospital. Dentists C, D, E, F, G and I were experienced private practitioners with his/her own dental practice. Dentist B was well-experienced in clinical trials. Dentists D, H and J received postgraduate education in the OHSRC.

Training and calibration

Prior to the recruitment of MC patients, the ten dental practitioners were trained and calibrated for the recording of two risk parameters in the Cariogram: 'caries experience' and 'plaque amount'. For recording the 'caries experience' parameter in the Cariogram, the number of coronal lesions of both caries in enamel and caries involving dentine, and the number of active root caries lesions were required inputs (Bratthall et al. 2004). The DMFS index from the Irish Adult Survey 2000-2002 was used as the reference (Whelton et al. 2007). For recording the 'plaque amount' parameter, the Silness-Löe Plaque Index (Silness and Löe 1964) is recommended in the Cariogram Manual (Bratthall et al. 2004).

Training and calibration took place in the OHSRC and the School of Dental Hygiene between on 11 February 2015 and 27 May 2015. All subjects for both the calibration training and the calibration assessments provided informed consent prior to being examined. The subjects were recruited through the restorative clinic at Cork University Dental School and Hospital. The training and calibration sessions were approved for Continued Professional Development (CPD) programme by the Dental Council of Ireland (Appendix 12). All dentists in the study were calibrated by trained examiners as follows:

- For coronal and root caries lesions: the Clinical Instructor in Restorative Dentistry in UCC
- For coronal caries lesions: the Deputy Director of the OHSRC
- For the Plaque Index: the Professor of Restorative Dentistry (Periodontology) in UCC.

The calibration training session of the eight dental practitioners (Dentists A to H) covered knowledge of epidemiology and the determinants of oral health, and research methods in dental practice including saliva collection, flow rate, and buffering capacity using CRT®.

The examiners gave the eight dental practitioners a 40-minute interactive presentation/discussion which included clinical photographs of patients. Immediately following this theory training, the examiners and the eight dental practitioners had a clinical training session with eight patient subjects. During this 3-hour-long practical training, the examiners discussed the recorded scores in detail with the eight dental practitioners until they could confidently categorise the level of caries lesions and dental plaque present.

A CPI probe, a front surface mirror size 4 head, a visible light curing unit, disposable applicator brushes and dappen dishes and a bottle (11g) of Plaque Test® (Ivoclar Vivadent, Liechtenstein) were prepared for the eight dentists and the examiners. Protective glasses were placed on each subject before the oral examination commenced.

To permit determination of the kappa statistics for reproducibility, the eight dental practitioners returned to the clinic to examine a second convenience sample one week after training. Squared weighted Kappa statistics for all sites examined were used to evaluate inter-examiner and intra-examiner reproducibility at site level using a statistical program, R (The R Core Team 2015).

At the first calibration assessment, it was revealed that inter- and intra-examiner reliability with the Silness-Löe Plaque Index using Plaque Test® was poor (0.31 to 0.54

for inter-examiner reproducibility and from 0.43 to 0.65 for intra-examiner reproducibility). Therefore, it was decided not to use Plaque Test® in the Irish study (Nishi et al. 2017). Instead, dental practitioners were instructed to record a single score from 0 to 3 as defined in the Cariogram Manual (Bratthall et al. 2004), based on their clinical impression of each subject. A previous study cited that "*the simple procedure of a quick visual assessment for the presence of readily-visible heavy plaque may be enough to provide oral health professionals with an efficient method for assessing patients 18 and older for an increased risk of dental caries*" (Rothen et al. 2014). In addition, the dental practitioners were provided with training slides that included clinical photos. Thus, the additional two dental practitioners (Dentists I and J) did not participate in the calibration assessment session for the Plaque Index.

The Kappa statistics for inter-examiner reliability ranged from 0.91–1.00 ('very good') and 0.54–0.94 ('moderate' to 'very good') for tooth status and coronal surface caries condition, respectively. For root caries, the Kappa statistics for inter-examiner reliability were 0.37–0.48 ('fair').

3.2.2.2 MC patients

Approximately four out of ten Irish people were covered by a MC in 2014 (Health Service Executive 2015b). Recruitment was through the eight dental practitioners (Dentists A to H) in County Cork.

Predetermined inclusion criteria were as follows:

- willingness to participate in the project
- 19–70 years of age
- MC holder
- ≥ 20 teeth present
- not pregnant
- ability to use text messages.

Sample size

To estimate the sample size, a power analysis was conducted based on previous Cariogram studies (Merdad et al. 2010) with a significance level of 5%, a power for that detection of 80%, a control response of 36 (Chance-AC), a standard deviation of 21.6, and a change relative to control mean of 30%; a minimum of **64 patients per group** was required (for the two-sample *t* test). It was considered that Δ11 (= 36*30%) of Chance-AC as the minimal clinically important difference (MCID).

3.2.3 Development of text messages

The mobile-phone text messages covered topics from the Cariogram's four caries risk sectors as follows:

- **'Diet'**: advice on dietary choices and reducing frequency
- **'Bacteria'**: advice on ways to reduce bacterial load
- **'Susceptibility'**: advice on fluoride use and on increasing salivary flow
- **'Circumstances'**: advice on general health and past caries experiences.

To cover all extreme cases (i.e. where the risk profile of the MC patient shows only one of the four risk sectors), more than 96 (= 24 weeks*4 risk sectors) educational text messages were created. Advice on drafting educational messages for lower socioeconomic populations such as MC patients was obtained from a dentist and researcher on dental education, dental anxiety and motivational interviewing in Sweden. A priority ranking was assigned to each message. Each message was kept within the maximum of 160 characters for a single-send text message. The draft messages were based on available evidence as follows:

- **literature** (Dental Health Foundation and Oral Health Services Research Centre 2014; Levine and Stillman-Lowe 2009)
- **public websites** (American Dental Association[16], Australian Dental Association[17], British Dental Association[18], Canadian Dental Association[19], Dental Health Foundation[20], National Health Service[21], National Institutes of Health[22], the Department of Cariology Faculty of Odontology Malmö University[23], World Health Organisation[24])
- **Cariogram Manual** (Bratthall et al. 2004)
- **educational emails** of the PSAP[25] and Rapport Builder® (Oral Care Inc., Japan)[26].

The text messages were checked and revised by one editor, one psychologist, two neuroscientists and two dentists, then piloted with three staff members in the OHSRC and one dental student. Following a trial-sending of the actual text messages to three dental students and one occupational therapist, the text messages were finalised on 26 November 2014. The text messages are presented in Appendix 11.

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[16] American Dental Association. [accessed 7 June 2018]. http://www.ada.org/en/.
[17] Australian Dental Association. [accessed 7 June 2018]. https://www.ada.org.au/.
[18] British Dental Association. [accessed 7 June 2018]. https://bda.org/.
[19] Canadian Dental Association. [accessed 7 June 2018]. https://www.cda-adc.ca/en/index.asp.
[20] Dental Health Foundation. Dental Caries (Tooth Decay). [accessed 7 June 2018]. http://www.dentalhealth.ie/dentalhealth/causes/dentalcaries.html.
[21] National Health Service. NHS Choices. [accessed 7 June 2018]. http://www.nhs.uk/pages/home.aspx.
[22] National Institutes of Health. [accessed 7 June 2018]. http://www.nih.gov/.
[23] The Department of Cariology, Faculty of Odontology, Malmö University. [accessed 7 June 2018]. https://www.mah.se/english/faculties/Faculty-of-Odontology/.
[24] World Health Organisation. [accessed 7 June 2018]. http://www.who.int/oral_health/en/.
[25] Promoting Scientific Assessment in Prevention of Tooth Decay and Gum Disease. (In Japanese) [accessed 7 June 2018]. http://www.honto-no-yobou.jp.
[26] Oral Care Inc. About Rapport Builder. [accessed 7 June 2018]. (In Japanese) https://www.ocm-navi.jp/about/about.html.

3.2.4 Intervention

Over a 24-week period, educational mobile-phone text messages were sent to each MC patient weekly. Besides the 24 educational messages, the first introductory message asked each MC patient to reply to the text as confirmation that their mobile number was correct, and the last message reminded MC patients to attend for their follow-up dental examination.

For the bulk sending of text messages (171*26 = 4,446), the programmer used a web-based text messaging service (TextMagic, the UK; www.textmagic.com) to send the 24-weekly educational text messages. A previous study using text messaging for oral health promotion sent messages on Fridays (Schluter et al. 2014), but staff in the OHSRC advised that, in the Irish context, Fridays should be avoided while Sunday evenings were the most suitable time for educational messages. We decided to send text messages between 5 and 6 pm on Sundays. The cost was £ 0.058–0.116 per message.

3.2.4.1 Personalised group

The study arms comprised personalised (test) and non-personalised (control) groups. To each MC patient in the personalised group, staff from the OHSRC posted a personalised letter that gave their Chance-AC, their Cariogram chart results and relevant advice (Appendix 10). After sending these letters, an introductory message, followed by the 24-weekly educational text messages and a final reminder message were sent.

Using the Cariogram output at baseline, the proportion contribution of each of the four risk sectors to total caries risk for each MC patient was calculated. Applying these proportions to 24 (total number of text messages to be sent), the number of text messages on each risk-sector for each MC patient was determined. Table 3.2 shows how to calculate numbers of text messages allocated to each risk sector, using the example in Figure 1.1. Over the 24-week study period, this MC patient is sent three text messages on ‘Diet’ (11/84), nine text messages on ‘Bacteria’ (33/84), nine text messages on ‘Susceptibility’ (33/84) and two text messages on ‘Circumstances’ (7/84).

Table 3.2 How to calculate numbers of text messages allocated to each risk sector

Sector	(%) to the Cariogram†	(%) to the four sectors‡	N§
'Diet'	11	13	3
'Bacteria'	33	39	9
'Susceptibility'	33	39	9
'Circumstances'	7	8	2
Total of the four sectors	84	100	24
Chance-AC	16		
Total of the five sectors	100		

†Percentage contribution calculated with the Cariogram chart. ‡Proportion contribution of each sector to the overall calculated risk. §N: Number of text messages on each sector to be sent text messages.

If, as a result of rounding, the sum of text messages to be sent was greater than 24, the number of 'Circumstances' messages was reduced as this risk-sector includes risk indicators that may not be under the control of the patient and thus less likely to be modified. If, as a result of rounding, the total number was less than 24, the number of messages in the risk-sector with the highest proportion was increased in order to highlight the highest risk-sector. If the participant had past root caries experiences, the message on root caries was always included. If the participant had a specific systemic disease, the message on that disease was always included. Otherwise, messages from each sector were selected in order of their priority ranking.

3.2.4.2 Non-personalised group

MC patients in the non-personalised group received a letter containing general information on caries prevention cited from the Dental Health Foundation website[27], with additional information extracted from the Cariogram's advices (non-personalised) in order that the letter volume (three pages of A4) was the similar to for the personalised

[27] Dental Health Foundation. Dental Caries (Tooth Decay). [accessed 7 June 2018]. http://www.dentalhealth.ie/dentalhealth/causes/dentalcaries.html.

group (Appendix 10). After sending these letters, an introductory message, the non-personalised 24-weekly educational text messages and a final reminder message were sent to the non-personalised group.

All MC patients in the non-personalised group received the same six educational messages from each of the four risk-sectors. These messages were predetermined for the group as a whole and not linked to their individual risk profiles. The text message ID numbers of the non-personalised 24 messages were 103, 104, 110, 112, 117, 122, 201, 202, 205, 206, 220, 223, 301, 303, 305, 316, 317, 324, 401, 403, 409, 414, 416 and 420 (Appendix 11).

3.2.5 Outcome measures

The outcome data were collected by means of an interview, a clinical examination, CRT® saliva tests and a self-administered questionnaire (Appendix 7) plus 3-day food diary (Appendix 8).

3.2.5.1 Caries risk assessment

Individual risk assessment was performed using the Cariogram (version 3.0j)[28].

The 'caries experience' parameter

First, DMFS was recorded both at dentinal and at the cavitated dentine level. Cavitated DMFS ($D_{3c}MFS$) and non-cavitated DMFS($D_{3vc}MFS$)[29] values were calculated from the

[28] The Cariogram (version 3.0.j). [accessed 7 June 2018]. https://www.mah.se/upload/FAKULTETER/OD/Avdelningar/Cariologi/CariogramJapaneseAndEnglish.zip.

CRF (Appendix 9). Three surfaces were counted as missing for teeth that were missing due to any reason in accordance with the Oral Health of Irish Adults 2000–2002 (Whelton et al. 2007).

The 'caries experience' parameter is a relative score with reference to local epidemiological data (Bratthall et al. 2004). The current project used the latest available Irish adult data (Whelton et al. 2007) as its reference. Table 3.3 presents the cut-off scores of the $D_{3c}MFS$ and $D_{3vc}MFS$ values from the reference data for the 25th and 75th percentiles by age group (16–24, 35–44, 65+). Cut-off scores for the 25th and 75th percentiles at ages 20-, 40- and 70-years were plotted. With the assumption that the $D_{3c}MFS$ and $D_{3vc}MFS$ values increase in a straight line according to age, straight lines between the scores at 20 and 40 years of age and between 40 and 70 years of age for the 25th and 75th percentiles were drawn. If an MC patient's $D_{3c}MFS$ index fell below the 25th percentile line, the MC patient was scored as **Score 1** (better than normal). If an MC patient's $D_{3c}MFS$ index fell above the 75th percentile line, the MC patient was scored as **Score 3** (worse than normal). If an MC patient's $D_{3c}MFS$ index lay between the 25th and 75th percentile lines, the MC patient was scored as **Score 2** (normal for age group). If the $D_{3c}MFS$ index of the MC patient fell on one of the lines, the worse score was taken. The $D_{3vc}MFS$ index was referenced in the same manner. If the MC patient had > 2 active root caries lesions or > 2 enamel lesions, the MC patient was given **Score 3**. **Score 0** means that the patient was caries free and had no restorations.

Table 3.3 Reference values

		16-24 years	35-44 years	65+ years
$D_{3c}MFS$ index	25% cut off scores	3	23	58
	75% cut off scores	18	48	96
$D_{3vc}MFS$ index	25% cut off scores	4	24	59
	75% cut off scores	19	49	96

Whelton et al. (2007)

[29] $D_{3vc}MFS$ includes non-cavitated where there was a definite shadow under the enamel, indicating the presence of dental caries that had progressed to dentine, but cavitation had not yet occurred.

The ‘related diseases’ parameter

General diseases or conditions which can directly or indirectly influence the caries process, were listed as follows (Bratthall et al. 2004):

- any autoimmune disease (e.g. 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 affect their saliva secretion
- any condition requiring radiation to the head-neck region.

Score 0 was given for patients with none of the general diseases above (no disease). **Score 1** was given if there any of the general diseases above was present (mild degree). The Cariogram Manual stated **Score 2** should be given if the patient was bedridden or may need continuous medication (severe degree, long-lasting). Because MC patients taking part in the Irish study were not bedridden and the definition of ‘long-lasting’ was unclear, **Score 2** was considered as not applicable.

The ‘diet contents’ parameter

Salivary LB count was used as an indicator of the ‘diet contents’ parameter (Bratthall et al. 2004). Although retention areas, open cavities or bad fillings could contribute to a high LB score (Bratthall et al. 2004), these conditions were not considered in the Irish study. This parameter was scored using the manufacture’s chart[30]. **Scores 0 and 1** were <

[30] Ivoclar Vivadent AG. CRT bacteria. [accessed 7 June 2018]. http://www.ivoclarvivadent.com/en/p/all/products/prevention-care/caries-risk/crt-bacteria.

10^5 colony forming units (CFU)/ml saliva. **Scores 2 and 3** were $\geq 10^5$ CFU/ml saliva. The distinction between Scores 0 and 1 and between Scores 2 and 3 were made according to the manufacture's chart. The interpretation of scores was as follows:

Score 0: very low fermentable carbohydrate
Score 1: low fermentable carbohydrate, 'non-cariogenic' diet
Score 2: moderate fermentable carbohydrate
Score 3: high intake of fermentable carbohydrate.

The 'diet frequency' parameter

On their 3-day food diary (Appendix 8), the MC participant wrote down when and what he/she had eaten and what time their bedtime was for three days[31]. The mean intake of fermentable carbohydrates per day was calculated. Dietary sugars (sucrose, glucose and fructose), cooked starches and sucralose were included in the basic count of fermentable carbohydrates. Although strictly speaking vegetables have natural sugars, they were not counted as part of fermentable carbohydrate intake because some of the educational text messages encouraged eating vegetables rather than sugary foods as snacks. Confusing food and drinks are summarised in Table 3.4.

When the MC patient did not write their bedtime and the MC patient had fermentable carbohydrates at 10 pm or later, one intake count was added. When the MC patient wrote their bedtime and had fermentable carbohydrates within one hour before bedtime, one intake count was also added. The scores for this parameter are as follows:

[31] Although the MC patients were asked to record food diary "*during three ordinary days including a weekend day*", some MC patients in the Irish study did not comply with including two ordinary days and one weekend day.

Score 0: 0–3.0 times/day (very low diet intake frequency)

Score 1: 3.3–5.0 times/day (low diet intake frequency)

Score 2: 5.3–7.0 times/day (high diet intake frequency)

Score 3: ≥ 7.3 times/day (very high diet intake frequency).

Table 3.4 Food and drinks included in or excluded from the count of fermentable carbohydrate intake

Included food and drinks	Note
Fruits except lemon	
Corns	
White pudding	
Yogurt	Unclear whether or not unsweetened
Greek yogurt	Unclear whether or not unsweetened
Port wine	
Baileys® Coffee Creamers	
Diet Coke®	Sucralose (Splenda® Brand)
Diet 7UP®	Sucralose (Splenda® Brand)
Ribena Tooth Kind®	Natural sugar from black current
Excluded food and drinks	**Note**
Lemon	
Vegetables	
Beet root	
Green beans	
Wine	
Peanuts	
Brazil nuts	
Almond	
Seeds	
Natural yogurt	
7UP free®	Aspartame and Acesulfame K

The 'plaque amount' parameter

Dental practitioners recorded a single score from 0 to 3, as defined in the Cariogram Manual (Bratthall et al. 2004), based on their clinical impression of each patient (see Section 3.1.2.1 on calibration). The scores for 'plaque amount' are as follows:

Score 0: extremely good oral hygiene
Score 1: good oral hygiene
Score 2: less than good oral hygiene
Score 3: poor oral hygiene.

The 'mutans streptococci' parameter

Like salivary LB count, salivary MS count was scored using the manufacturer's chart[32]. **Scores 0 and 1** were $< 10^5$ CFU/ml saliva. **Scores 2 and 3** were $\geq 10^5$ CFU/ml saliva. In the Irish study, Score 0 was rounded up to **Score 1** and Score 2 was rounded up to **Score 3.** See Section **5.3.1** for the reason.

The 'Fluoride programme' parameter

Relevant information on fluoride use was obtained through patient interviews. Prior to the start of the Irish study, discussion took place with other dentists familiar with fluoridation in the RoI and dentists familiar with the Cariogram in Sweden on how to score fluoride use in the Irish context. The Cariogram Manual says that Score 0 is "*Fluoride toothpaste plus constant use of additional measures - tablets or rinsings and varnishes. A 'maximum' fluoride program.*" [sic] (Bratthall et al. 2004). As mentioned in Section 1.1, the public water in the RoI is fluoridated with a target value of 0.7 ppm (the

[32] Ivoclar Vivadent AG. CRT bacteria. [accessed 7 June 2018]. http://www.ivoclarvivadent.com/en/p/all/products/prevention-care/caries-risk/crt-bacteria.

Fluoridation of Water Supplies Regulations 2007: S.I. No. 42 of 2007[33]); this was interpreted as "*constant use of additional measures to fluoride toothpaste*". The interpretation of each score is as follows:

Score 0a: use of fluoridated water, fluoridated toothpaste and additional measure on a regular basis (a 'maximum' fluoride programme)
Score 0b: use of fluoridated water, fluoridated toothpaste and additional measure on an occasional basis (a 'maximum' fluoride programme)
Score 0c: use of fluoridated water and fluoridated toothpaste (a 'maximum' fluoride programme)
Score 0d: use of fluoridated toothpaste and additional fluoride on a regular basis (a 'maximum' fluoride programme)

Score 1: use of fluoridated water

Score 2: use of fluoridated toothpaste, ***or***
Score 2: use of additional fluoride on a regular basis

Score 3: avoiding fluorides, not using fluoride toothpastes or other fluoride measures.

The 'saliva secretion' parameter

The volume of stimulated saliva collected over five minutes was collected using CRT® saliva tests. Unstimulated saliva was not measured in the Irish study. In the dental practice with a normal appointment between 9 am and 5 pm, the MC patient sat upright and stimulated salivation by chewing a paraffin pellet for five minutes. The saliva was drooled into a disposable graduated test tube through a disposable funnel during the collection period. The dentist measured the volume of the saliva in the test tube from the

[33] Government of Ireland. S.I. No. 42/2007 - Fluoridation of Water Supplies Regulations 2007. [accessed 7 June 2018]. http://www.irishstatutebook.ie/eli/2007/si/42/made/en/print#.

lowest point on the meniscus, the measurement did not include the foam, if any. The four-level scoring system is as follows:

Score 0: ≥ 1.1 ml/minute (normal saliva secretion)
Score 1: < 1.1, ≥ 0.9 ml/minute (low stimulated saliva secretion)
Score 2: < 0.9, ≥ 0.5 ml/minute (low stimulated saliva secretion)
Score 3: < 0.5 ml/minute (very low, xerostomia).

The saliva 'buffer capacity' parameter

CRT® buffer was used. Immediately after the stimulated was collected as described in the previous section, the dentist used a disposable pipette to place some of this stimulated saliva on the test strip. After five minutes, the dentist compared the colour of the test strip with the standard colour chart. The scoring system for this parameter was performed as follows:

Score 0: High (normal or good buffering capacity
Score 1: Medium (less than good buffering capacity)
Score 2: Low (low buffering capacity)

The 'clinical judgement' parameter

Just before risk assessment and randomisation were performed for the first group of MC patients, we found that the calculated average of Chance-AC was higher than expected. Possible reasons will be discussed in Section 5.3.1. Therefore, **Score 2** for the 'clinical judgement' parameter was applied. The standard score for this parameter is **Score 1** and applying **Score 2** decreases the Chance-AC. This adjustment does not change the distribution by risk sector of mobile-phone text messages to be sent.

3.2.5.2 Four risk groups

Results derived from the collected MC patient data were inputted to the Cariogram and the MC patients were categorised into four risk groups based on their Chance-AC: 'Very high risk' (≤ 20), 'High risk' (21–40), 'Intermediate risk' (41–60) and 'Low/Rather low risk' (> 60) for dental caries, in accordance with a previous study for adults (Hänsel Petersson et al. 2003).

3.2.5.3 Questionnaires

At both baseline and at follow-up, self-administered questionnaire surveys were completed by MC patients. Questionnaires were completed at home to avoid undue influence from the dental practice on their answers. The questionnaires were developed based on the English version of the patient questionnaire of the Japanese study (Section 3.1.3). World Health Organisation's Oral Heath Surveys Basic Method (World Health Organisation 2013) and the questionnaires in the Oral Health of Irish Adults 1989–1990 (O'Mullane and Whelton 1992) were also used as reference guides. Three dentists, one economist and the project manager developed the Irish study questionnaire and assessed its face validity. For the sake of simplicity, the questionnaires avoided technical language in favour of layman's terms such as 'bad' or 'weak' even though such terminology might be prone to subjective interpretations. The questionnaire was anonymous but contained the MC patient's mobile-phone number through which they could be identified; the 3-day food diary (Appendix 8) which was sent with the questionnaire (Appendix 7) contained the participant's name and phone number. The follow-up questionnaire is similar to the baseline one. The relevant questions to this thesis are as follows:

Objective 1: Article II: Q3, Q7 and Q16 at baseline
Objective 2: Article III: Q1, Q2, Q7, Q10 and Q16 at baseline
Objective 3: Article IV: Q16 at baseline
Objective 4: Article V: Q16 at baseline and Q1, Q2, Q3, Q4, Q6, Q7, Q9, Q12, Q13, Q14 and Q19 at follow-up

3.2.6 Randomisation

After consulting the statistician, the participants were stratified for Chance-AC into five groups (0–20, 21–40, 41–50, 51–60, 61–100) and randomly allocated to the personalised or non-personalised group. We combined the stratified randomisation with blocked randomisation in order to have the proportions in each stratum as balanced as possible between the personalised and non-personalised group. The statistician generated random numbers for stratified and blocked randomisation using a computer.

3.2.7 Blinding

Figure 3.6 shows the blinding of those who were involved with the CRA. The blinding procedure was as follows:

1. The laboratory technician (blinded) scored CRT® Bacteria (LB and MS) and passed myself (blinded) the results.
2. I assessed the food diary (Appendix 8) and input all parameters into the Cariogram and sent the Cariogram CRA result together with the postal address, the personalised letter and the non-personalised letter for the MC patient (Appendix 10) to the staff from the OHSRC.
3. The statistician passed the random numbers to LF.
4. The staff put the MC patient into the proper stratum and allocated the MC patient according to their random number.
5. The staff informed the programmer whether the patient was in the personalised or non-personalised group, chose the personalised letter or the non-personalised letter according to the randomisation and sent the letter with €20 voucher to the MC patient.
6. The programmer sent the MC patient 24 educational text messages over 24 weeks plus an introductory message and a reminder message of follow-up examination.

Note that dental practitioners who examined MC patients were also blinded.

3.3 Data analyses

Missing data were excluded from each analysis.

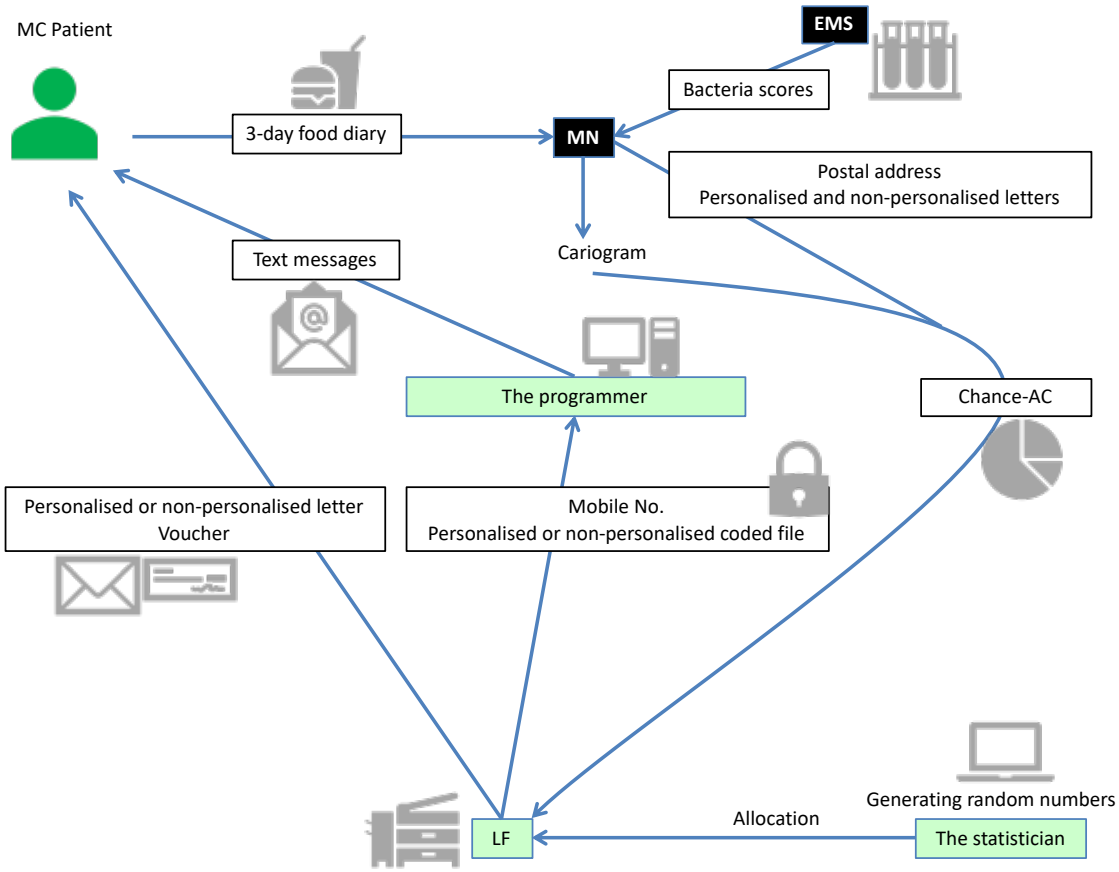


Figure 3.6 Randomisation and single-blind procedure

EMS: the laboratory technician; MN: myself; LF: the staff of the OHSRC; black boxes mean that these persons were blinded.

3.3.1 Objective 1 (Articles I and II: knowledge of caries risk)

From the dentist questionnaire, information on whether or not the dentist provided PCP and on the proportion of adult patients receiving PCP in dental practices was collected. Chi-square test and Fisher's Exact test were used to examine distribution of PCP adoption by dentists between Groups A and B; Mann-Whitney U test was used to compare percentage of adult patients receiving PCP in dental practices between Groups A and B, and to determine whether their patient samples (cluster sampling) should be combined or not.

Patients were asked to identify caries risk factors/indicators from ten (the RoI: Q3) or eight (Japan: Q3) listed items. In the Irish study, the item "*Bad eating habit*" was divided into three items: "*Consuming too much sugary foods and drinks*", "*Consuming sugary foods and drinks too often*" and "*Consuming sugary foods and drinks just before bedtime*". 'Low saliva buffering capacity' was simplified with non-technical language (Japanese study: "*Low quality of saliva*"; Irish study: "*Having saliva (spit) that does not have the right composition to protect against decay*").

Participant characteristics including age, gender, age by gender and attendance for check-ups and tooth cleaning, were summarised for the Irish and Japanese studies. Two age groups (20–39, 40+ years) were set, as the age distribution was different in the two studies. For the Japanese study, Stata's Survey data analysis method, with the dentist specified as the primary sampling unit (PSU), was employed to adjust standard errors used in the calculation of 95% confidence intervals (CIs) for intra-class correlation among responses from patients who attended the same dentist. This adjustment was not made to the 95% confidence intervals for the Irish data, due to the small number of dentists and low response level from patients of some dental practitioners. Results are presented by age group for both study groups. Percentage frequencies and 95% CI were given for the questions on knowledge of caries risk factors/indicators and for participants choosing seven caries risk factors/indicators. Means and 95% CI were presented for total number of identified risk factors/indicators excluding diet item(s). Percentage frequencies are shown for patients' opinions on the statement "*The more I visit the dentist for check-up, the more teeth, I think, are drilled.*" (Japanese study only).

The questions on diet were not included in the comparison analysis as these were framed differently in the two studies, and were compared between age groups only. A logistic regression model was fitted to each of the binary variables of the risk factors/indicators list common to both countries, with country, age and their interaction as predictors. A linear regression was fitted to the data with total number of identified risk factors/indicators excluding diet item(s) as dependent variable and country, age group and their interaction as predictors. A backward elimination process was performed for both types of regression until only significant terms remained in the model. An adjustment to standard errors was not made in these analyses due to the small number of dentists in the Irish study. The Mann-Whitney test was employed to compare ordinal responses between two age groups. The IBM SPSS Statistics Version 22 (SPSS Inc., Chicago, IL), R 3.2.3 (R Core Team, 2015[17]) and the Survey Data Analysis procedure in Stata 12.1 (Stata Corp, College Station, TX) were utilised. Two-sided significance level was set at 0.05, but the focus was on results showing a significance level less than 0.01, due to multiple testing.

3.3.2 Objective 2 (Article III: self-perceived caries risk)

From the baseline questionnaire of the Irish study, two questions on caries susceptibility were analysed:

Q1: Are you aware that some people are more prone to dental decay (cavities or caries) than others – Yes or No?

Q2: Do you think that you are more prone to dental decay than the average person – Yes or No?

Each MC holder's Chance-AC (independent variable) with self-perceived caries risk (obtained from a direct question: dependent variable) was compared with logistic regression models. Q2 was used as the direct measure of risk perception. The non-Cariogram parameters were set as follows:

- gender
- age
- education level
- smoking status
- smart phone ownership
- attendance for MP
- toothbrushing frequency
- Q1.

A logistic regression model was fitted to self-perceived caries risk (dependent variable) as follows:

(1) Each of the non-Cariogram parameters was screened using a univariate logistic regression model;
(2) If statistically significant at the 10% level, these variables were included in multivariate logistic regression models with Chance-AC;
(3) These variables were assessed again in the multivariate model and were retained only if significant at the 5% level.

A second logistic regression model was fitted wherein the non-Cariogram parameters identified in the first model were included with the Cariogram risk parameters. It was not possible to include 'related diseases' and 'fluoride programme' in this model as these variables had too few patients distributed into one or two score(s). Furthermore, categories of 'caries experience', 'plaque amount' and saliva 'buffer capacity' were merged to avoid too few data in one score. The generalised coefficients of determination for the logistic regression models were 25% and 40%, respectively. As MC patients were clustered within dentists, clustering was accounted for in the statistical analyses (Proc Surveyselect, SAS, Version 9.4, SAS Institute Inc., Cary, NC). The interpretations of the non-Cariogram parameters are presented only for the first multivariate logistic regression model.

For the 'Very high risk' and 'High risk' groups, the modifiable caries risk factors (i.e. 'diet contents', 'diet frequency', 'plaque amount', 'mutans streptococci' and 'fluoride programme')[34] with a Cariogram Score of 2 or 3 (**Higher score**) were counted and their clustering distribution by self-perceived risk was examined.

3.3.3 Objective 3 (Article IV: caries risk profile)

The CV for Chance-AC was calculated to determine individual variability of caries risk. A two-step cluster analysis method was used to explore subgroups of individuals according to seven aetiological caries risk parameters in the Cariogram ('diet contents', 'diet frequency', 'plaque amount', 'mutans streptococci', 'fluoride programme', 'saliva secretion' and saliva 'buffer capacity'). A two-step cluster is used when both continuous and categorical variables are included. All scores with the exception of the 'saliva secretion' and 'diet frequency' parameters were considered as categorical variables. For the 'saliva secretion' and 'diet frequency' parameters, original values were used as continuous variables which were standardised for the cluster analysis. The SPSS two-step clustering algorithm was used to determine the optimal number of clusters with the log-likelihood method and Bayesian Information Criterion. The silhouette measure of cohesion and separation was used for measuring the overall goodness-of-fit of the cluster structure. **Predictor importance** values indicate the relative importance of each predictor in estimating the model and do not relate to model accuracy. The cluster profiles were described, including the mean values for each cluster, and clusters were labelled accordingly. The IBM SPSS Statistics Version 22 (SPSS Inc., Chicago, IL) was utilised.

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[34] Salivary risk factors are sometimes modifiable, as the Cariogram advises those who have low saliva secretion rate to "*improve saliva secretion such as chewing sugar-free gum and changing medication that affects your saliva secretion*" and informs that "*smoking is one factor negatively affecting buffer capacity*". However, this analysis did not include salivary risk parameters in modifiable factors because there is significant heritability for salivary risk factors (Opal et al. 2015), compared to the other modifiable risk factors.

3.3.4 Objective 4 (Article V: personalised mHealth for caries risk)

The pre-specified primary outcome measure was Chance-AC (0–100) of the Cariogram at follow-up. The pre-specified secondary outcome measures were seven risk parameters as follows:

- 'diet contents'
- 'diet frequency'
- 'plaque amount'
- 'mutans streptococci'
- 'fluoride programme'
- stimulated 'saliva secretion'
- saliva 'buffer capacity'.

In addition, two questions on caries susceptibility (Q1 and Q2), knowledge of caries factors/indicators (Q3) were included.

After all text messages should have been sent, the programmer provided his logs to us on 21 May 2016. As it was discovered his logs were not accurate (manipulated), approximately one year later, **actual logs** from TextMagic were obtained on 07 June 2017. For primary analysis, all participants (n = 111) were included in the ITT approach. For the per-protocol analysis, data deviations were calculated according to the actual message log and Q13 in the follow-up questionnaire. Duplicate (and more) messages which were accidentally sent to the participant were excluded from the per-protocol analysis. Data deviations in regard to time factor were ignored for this thesis. For the seven risk parameters (secondary outcome measures), Scores 0 and 1, and Scores 2 and 3 (if any) were combined as **Lower score** and **Higher score**, respectively, in accordance with the Cariogram's advice and a previous paper (Pitts et al. 2017). The primary outcome was analysed using analysis of covariance (ANCOVA). The baseline value and age were included as covariates. Gender, dental practitioner, and the assigned group (personalised or non-personalised) were included as factors. The secondary outcomes

were analysed using logistic regression models. The baseline values and age were included as covariates. Gender and the assigned group were included as factors. Dental practitioner could not be included as the number of categories resulted in quasi-separation in logistic regression models. SAS, Version 9.4 (SAS Institute Inc., Cary, NC) was utilised.

3.4 Summary of materials and methods

Table 3.5 summarises the study design, data source, participants, outcome measures and types of analyses used for each of the four objectives, and the five articles included in this thesis. The main data source was the Irish study, which was a randomised controlled study. The participants were adult MC patients. Their baseline characteristics were examined in Articles II–IV as cross-sectional studies for Objectives 1, 2 and 3, respectively. The Japanese study was used only for Objective 1 to identify social/cultural influences on perceived caries risk factors/indicators (Articles I and II). The Japanese participants contrasted clearly with the Irish MC patients, as they were regarded to have greater knowledge of preventive dentistry. Detailed characteristics of the Japanese participants were supplemented by Article I.

For Objective 1, to compare Irish and Japanese patients, a logistic regression model and a linear regression were fitted to each of the binary variables of the risk factors/indicators and to the data with total number of identified risk factors/indicators (excluding diet items), respectively; the Mann-Whitney test was employed to compare ordinal responses between two age groups. For Objective 2, the first logistic regression model was fitted to self-perceived caries risk (dependent variable) and the second logistic regression model was fitted wherein the non-Cariogram parameters identified in the first model were included with the Cariogram risk parameters. For Objective 3, a two-step cluster analysis method was used to explore subgroups of individuals according to seven aetiological caries risk parameters in the Cariogram. For Objective 4, ANCOVA and logistic regression models were used for final analyses of the randomised

controlled study. Analyses in the other three objectives were used to deepen understanding of the final analyses.

Table 3.5 Summary of materials and methods

	Objective 1 Articles I and II	**Objective 2 Article III**	**Objective 3 Article IV**	**Objective 4 Article V**
Topic	Knowledge of caries risk	Self-perceived caries risk	Caries risk profile	Personalised mHealth
Study design	Cross-sectional study	Cross-sectional study	Cross-sectional study	Randomised controlled study
Data source	Baseline data of Irish & Japanese	Baseline data of Irish study	Baseline data of Irish study	Data of Irish study
Participants	MC & PSAP dentists' patients	MC patients	MC patients	MC patients
Outcome measures		Chance-AC	Chance-AC	Chance-AC
		Caries risk parameters	Caries risk parameters	Caries risk parameters
	Identified caries risk factors/indicators from listed items		Identified caries risk factors/indicators from listed items	Identified caries risk factors/indicators from listed items
		Question: Q2†		Question: Q2†
Analyses	Logistic regression model	Logistic regression model		Logistic regression models
	Linear regression			
	Mann-Whitney U test			
			Two-step cluster analysis	
				ANCOVA

†Q2: "*Do you think that you are more prone to dental decay than the average person – Yes or No?*"

4 RESULTS

This chapter first presents flow charts of the Japanese participants and Irish MC patients in the studies covered by this thesis. Complying with STROBE (von Elm et al. 2007), CONSORT (Schulz et al. 2010) and CONSORT EHEALTH (Eysenbach and Group 2011) statements, four sets of analyses are then presented in line with our addressed objectives (five articles) which looked at: (1) social/cultural influences on perceived caries risk factors/indicators in the Irish study compared with the Japanese study (Articles I and II) and (2) the associations between Chance-AC and self-perceived caries risk among MC patients at baseline in the Irish study (Article III), (3) individual variability of Chance-AC and seven aetiological caries risk parameters in the Cariogram within individuals among MC patients at baseline in the Irish study (Article IV) and (4) the impact of a personalised approach (delivered via a risk assessment summary letter with the Cariogram plus personalised 24 mobile-phone short text messaging based on the individual's Cariogram CRA) on (i) reducing Chance-AC and seven aetiological caries risk parameters and on (ii) increasing knowledge and self-perception of caries risk in the Irish adult population versus a non-personalised approach (Article V). Finally, findings from this chapter will be summarised to lead into Chapter 5.

4.1 Flow charts in the Japanese study (Articles I and II)

In the Japanese study, all participants were Japanese speakers. Figure 4.1 provides a flow chart of participants in the Japanese study. The PSAP issued a total of 3,142 questionnaires for distribution by dentists to their patients (Group A: n = 1,980; Group B: n = 800; Group C: n = 362). In Groups A, B and C, respectively, 459, 100 and 145 participants completed and returned the questionnaires to the PSAP. Of those who returned their questionnaire, 35, 10 and 2 participants in Groups A, B and C, respectively, did not meet the inclusion criteria and 101 from the three groups were dental professionals. These non-eligible participants were excluded. For Article I, those

who were receiving PCP programmes but not MP (n = 19), and missing data on receiving PCP programmes or MP (n = 2) were additionally excluded (11, 4 and 6 in Groups A, B and C, respectively). In total, 535 participants (389, 78 and 68 in Groups A, B and C, respectively) were analysed in Article I. Article II did not include Group C (n = 74) but included those who were receiving PCP programmes but not MP, and missing data on receiving PCP programmes or MP in Groups A and B (n = 15). In total, Article II had 482 participants (400 in Group A, 82 in Group B) from 52 dental members (40 dentists in Group A, 12 dentists in Group B) of the PSAP (Objective 1).

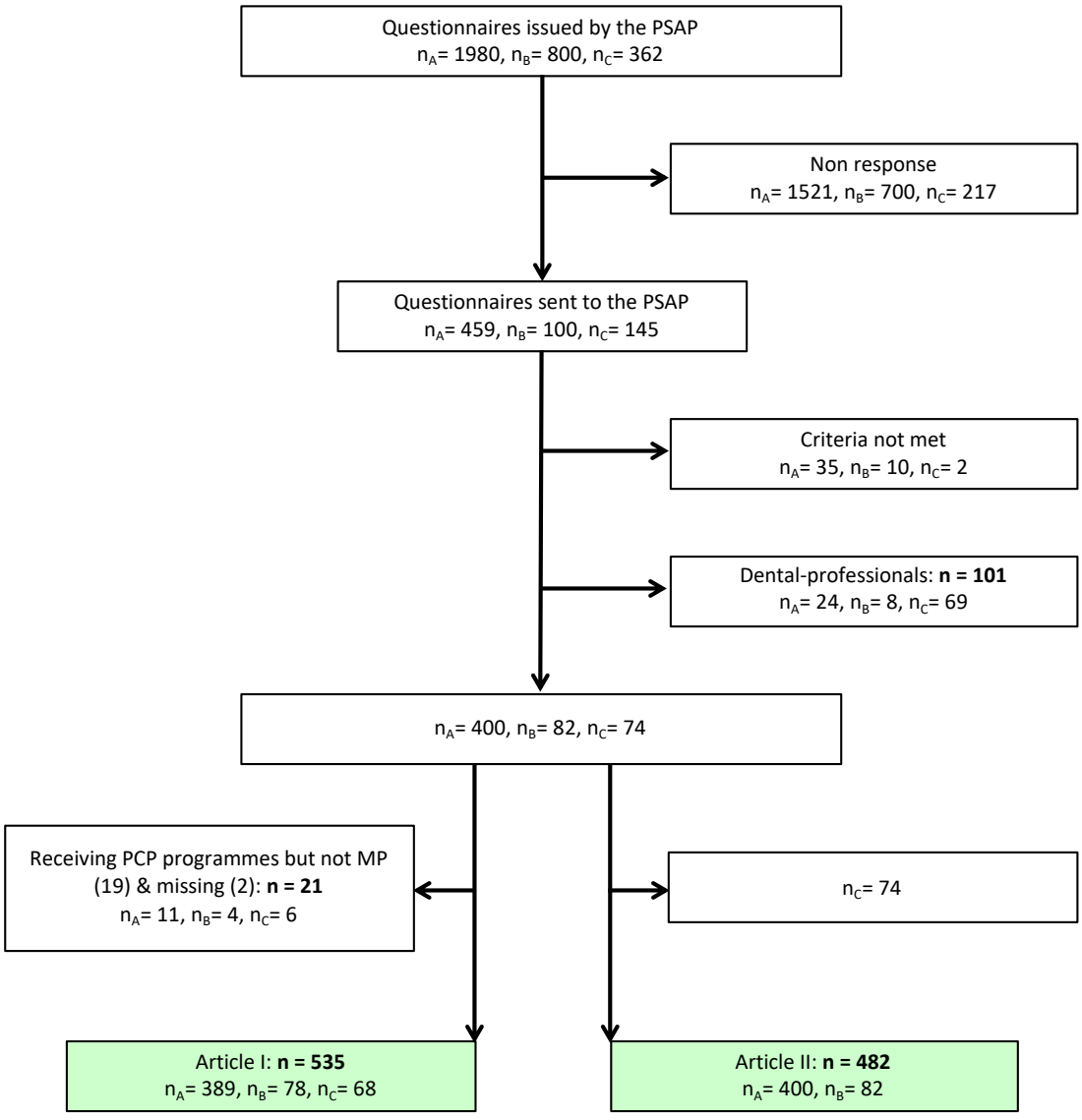


Figure 4.1 Participant flow chart of the Japanese study (Articles I and II)

n_A: number in Group A: paper questionnaire; n_B: number in Group B: paper questionnaire; n_C: number in Group C: online questionnaire

The distribution of patients (n = 389 + 78) by dental practitioners was also rather skewed in the Japanese study (Table 4.1).

Table 4.1 Number of dentists and patients per dentist in Groups A and B

		Group A	Group B	Total
Number of dentists		40	12	52
Patients per dentist	Mean (SD)	9.7 (4.8)	6.5 (4.7)	9.0 (4.9)
	Median	10	5	9.5
	Min–Max	1–18	1–14	1–18

4.2 Flow charts in the Irish study (Articles II-V)

Figure 4.2 provides a flow chart of MC patients at baseline in the Irish study. Allowing for a non-response rate of 33%, 191 patients (62 men and 129 women) were recruited during the period 25 February 2015 to 28 September 2015. Of the 191 patients recruited in the eight dental practices, 172 patients returned the 3-day food diary (Appendix 8), which is necessary for the CRA with the Cariogram. Of these 172 patients, one MC patient (aged 18 years) shared a mobile-phone with his mother who was also a participant in the Irish study. Therefore, he was excluded from the intervention, reducing the total number of MC patients to whom mobile-phone text messages were to be sent to 171. For Article IV, three MC patients < 19 years of age and one patient who was actually not a MC holder were excluded. As a result, Article IV included 167 MC patients in total (Objective 3). For Article III, further exclusions included one MC patient who did not return the questionnaire and one MC patient who did not answer Q2. Therefore, Article III included 165 MC patients in total (Objective 2). For Article II, the Irish study was compared with the Japanese study using a similar questionnaire. Those who were < 20 years of age (n = 8) were excluded in accordance with the age criteria of the Japanese study (> 19 years), and two MC patients who returned the questionnaire but not the food-diary were included. As a result, the total number of MC patients for Article II was 159 from the eight dental practices (Objective 1).

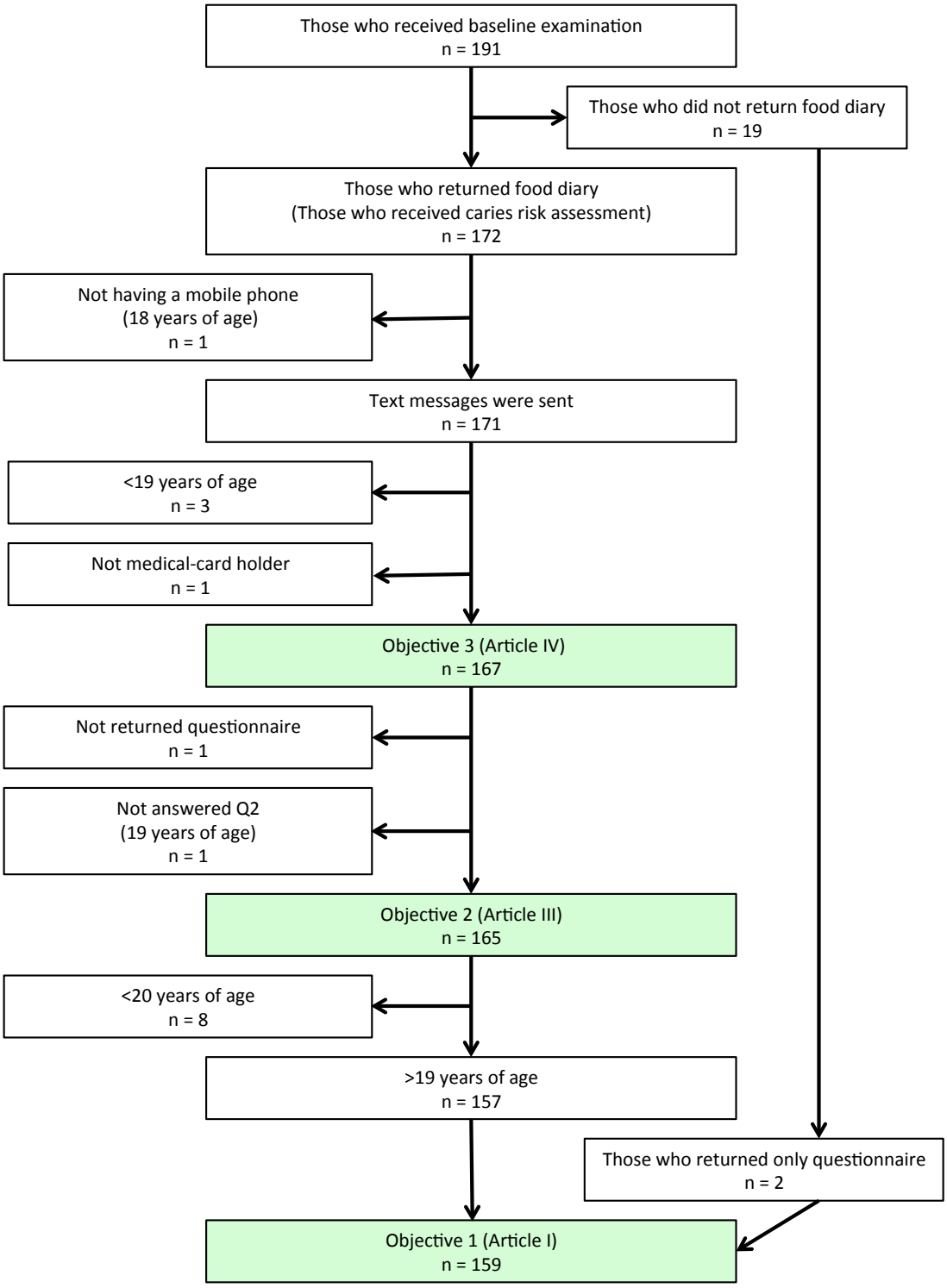


Figure 4.2 Flow chart of MC patients at baseline survey in the Irish study (Articles II–IV)

Figure 4.3 provides a flow chart of MC patients at follow-up in the Irish study. Of the 191 patients receiving the baseline examination in the eight dental practices, four MC

patients were < 19 years of age and one patient was actually not a MC holder. Therefore, 186 MC patients were eligible for inclusion in the study, of whom 167 returned the 3-day food diary and 19 did not. All five MC patients who were ***not*** eligible returned the 3-day food diary. However, one of them did not have his own mobile-phone. Therefore, 167 eligible and four non-eligible MC patients (171 MC patients in total) were to be sent mobile-phone text messages. None of the four non-eligible MC patients received follow-up examination. Of the 167 eligible MC patients, 118 received follow-up examination in six dental practices, but seven did not return the 3-day food diary. This left a total of 111 MC patients at follow-up who were assessed for caries risk and included in Article V (Objective 4). However, because the study protocol was violated during the intervention period by the programmer, both an ITT and per-protocol analyses were conducted. The 54 MC patients who were within two text message deviations from protocol were included in the per-protocol analyses.



Figure 4.3 Flow chart of MC patients at follow-up survey in the Irish study (Article V)

Distribution of patients by dental practitioners was skewed: Dentist D recruited over half the patients; Dentists I and J did not recruit any patients at all; Dentists A and F did not examine any patients at follow-up (Table 4.2).

Table 4.2 Number of MC patients by dental practitioner at baseline and at follow-up

Dental practitioner	Baseline	Follow-up
A	2	0
B	22	18
C	18	18
D	99	63
E	16	6
F	2	0
G	12	2
H	20	3
I	0	0
J	0	0
Total	191	111

4.3 Objective 1 (Articles I and II: knowledge of caries risk)

Objective 1: to identify social/cultural influences on perceived caries risk factors/indicators in an economically disadvantaged adult population in the RoI, comparing with an adult population in Japan who are regarded to have greater knowledge of preventive dentistry (Articles I and II).

4.3.1 Descriptive data

Table 4.3 provides a comparison of the number of dentists and of patients per dentist between the Irish and Japanese studies.

Table 4.3 Comparison of number of dentists and of patients per dentist between the Irish and Japanese studies in Article II

		Irish study	Japanese study
Number of dentists		8	52
Patients per dentist	Mean (SD)	19.9 (26.5)	9.3 (5.1)
	Median	13.5	9.5
	Min–Max	1–83	1–18

For the Irish study, the response rate was 85.5% (159 out of 186 eligible MC patients). For the Japanese study, the total number of dentist questionnaires returned was 30 for Group A and 16 for Group B, respectively, representing 30.3%, and 40.0% of total dentist questionnaires issued by the PSAP. From the dentist questionnaire, the percentage of dentists who said they provided PCP was 90.0% (27/30) in Group A and 75.0% (12/16) in Group B (Chi-square test, P = 0.117). Since the percentage of PCP providers was not statistically different between Groups A and B, Groups A and B were combined (Group AB).

The total number of patient questionnaires returned was 459 from 40 dental practices for Group A and 100 from 12 dental practices for Group B, representing 23.2% and 12.5%, respectively, of total patient questionnaires issued by the PSAP. Of the returned patient questionnaires, 389 participants in Group A and 78 in Group B satisfied all criteria for inclusion in Article I.

Gender distributions were similar between the Irish and Japanese studies: the male to female ratio was 3 to 7 (Table 4.4). Age distributions were rather different: the Irish study had more young participants than the Japanese study. MP attendance in the Japanese study was quite high (91.5%) compared to the Irish study (69.2%).

Table 4.4 Participants by gender, age group and attendance for MP in the Irish and Japanese studies (%)

		Irish study (n = 159)	Japanese study (n = 482)
Gender	Male	32.1	30.9
	Female	67.9	69.1
Age	20–29	22.0	8.1
	30–39	33.3	19.9
	40–49	24.5	23.4
	50–59	13.2	19.7
	60+	6.9	28.8
		n = 156	n = 481
Attendance for MP[†]	Yes	69.2	91.5
	No	30.8	8.5

[†]Three patients in the Irish study and one patient in the Japanese study did not answer the question.

4.3.2 Main results: knowledge of caries risk factors/indicators

In both the Irish and Japanese studies, common tendencies regarding knowledge of caries risk factors/indicators were observed (Table 4.5):

- more than 90% in both age groups identified "*Not brushing your teeth properly*";
- saliva buffering capacity was the least identified caries risk factor.

A higher proportion of Irish MC patients than Japanese patients identified:

- "*Not visiting the dentist for check-up and cleaning*" (odds ratio (OR) 2.655; 99% CI 1.550, 4.547; $P < 0.001$), and
- "*Not using fluoride*" (OR 1.714; 99% CI 1.049, 2.802; $P = 0.005$).

A lower proportion of Irish MC patients than Japanese patients identified:

- "*Having a reduced amount of saliva (spit) in the mouth*" (OR 0.262; 99% CI 0.159, 0.433; P < 0.001).

In the Irish study, smoking (Benedetti et al. 2013) and substance abuse (Hamamoto and Rhodus 2009) were specified under "*Other*" and considered as correct and different from the listed alternatives. In the Japanese study, heredity (Vieira et al. 2014), smoking (Benedetti et al. 2013), crooked teeth (Hafez et al. 2012) and caregivers at high caries risk (Krol 2003) were listed under the "*Other*" category and considered as correct and different from the listed alternatives. The percentages of participants choosing seven items, including "*Other*" with a correctly specified caries risk factor/indicator and excluding the diet items, were lower in the younger age group than the older age group in the Irish study (Table 4.5). The Japanese study showed the opposite tendency with the younger age group scoring higher and the older age group lower. The results of fitting the binary logistic model showed that neither age nor country were associated with the percentages of participants choosing seven items.

Table 4.5 Percentage (95% CI) of participants from Japanese (n = 482) and Irish (n = 159) studies identifying each risk factor/indicator†

Risk factor/indicator	Age group	Irish study	Japanese study
Not brushing your teeth properly	20–39	94.3 (87.2, 98.1)	94.8 (89.1, 97.6)
	40+	91.5 (82.5, 96.8)	91.6 (87.9, 94.3)
	All ages	93.1 (88.0, 96.5)	92.5 (89.6, 94.7)
Bad eating habit	20–39		65.2 (55.8, 73.5)
	40+		60.8 (54.4, 66.9)
	All ages		62.0 (56.3, 67.4)
Consuming too much sugary foods and drinks	20–39	86.4 (77.4, 92.8)	
	40+	83.1 (72.3, 91.0)	
	All ages	84.9 (78.4, 90.1)	
Consuming sugary foods and drinks too often	20–39	77.3 (67.1, 85.5)	
	40+	84.5 (74.0, 92.0)	
	All ages	80.5 (73.5, 86.4)	
Consuming sugary foods and drinks just before bedtime	20–39	61.4 (50.4, 71.6)	
	40+	76.1 (64.5, 85.4)	
	All ages	67.9 (60.1, 75.1)	
Having naturally 'weak teeth'	20–39	48.9 (38.1, 59.8)	47.4 (39.0, 56.0)
	40+	40.8 (29.3, 53.2)	59.9 (55.2, 64.6)
	All ages	45.3 (37.4, 53.4)	56.4 (51.7, 61.0)
Not visiting the dentist for check-up and cleaning	20–39	75.0 (64.6, 83.6)	50.4 (41.7, 59.1)
	40+	78.9 (67.6, 87.7)	57.3 (51.6, 62.9)
	All ages	76.7 (69.4, 83.1)	55.4 (50.5, 60.2)
Not using fluoride	20–39	37.5 (27.4, 48.5)	32.6 (22.2, 45.1)
	40+	43.7 (31.9, 56.0)	26.5 (21.0, 32.9)
	All ages	40.3 (32.6, 48.3)	28.2 (22.9, 34.2)
Having particular bacteria in the mouth that contribute to the development of dental decay	20–39	46.6 (35.9, 57.5)	60.0 (48.8, 70.3)
	40+	49.3 (37.2, 61.4)	46.4 (39.2, 53.8)
	All ages	47.8 (39.8, 55.9)	50.2 (43.0, 57.4)
Having a reduced amount of saliva (spit) in the mouth	20–39	30.7 (21.3, 41.4)	68.1 (57.8, 77.0)
	40+	33.8 (23.0, 46.0)	62.8 (55.7, 69.4)
	All ages	32.1 (24.9, 39.9)	64.3 (58.4, 69.8)
Having saliva (spit) that does not have the right composition to protect against decay	20–39	22.7 (14.5, 32.9)	32.6 (24.5, 41.9)
	40+	35.2 (24.2, 47.5)	24.5 (19.0, 30.9)
	All ages	28.3 (21.5, 36.0)	26.8 (21.7, 32.6)
% of participants choosing 7 factors/indicators excluding diet item(s)	20–39	9.1 (4.0, 17.1)	11.9 (6.7, 20.0)
	40+	12.7 (6.0, 22.7)	9.8 (6.9, 13.8)
	All ages	10.7 (6.4, 16.6)	10.4 (7.6, 14.0)

†The items were from the Irish study except "*Bad eating habit*".

The number of chosen caries risk factors/indicators was lower in the 20–39 age group of the Irish study and in the 40+ age group (mean (SD) = 3.71 (1.62)) of the Japanese study (Table 4.6). The results of fitting the linear model to the total number of correctly identified variables showed that neither age nor country were associated with total number of identified risk factors/indicators excluding diet item(s).

Table 4.6 Mean (SD) and 95% CI of the number of identified caries risk factors/indicators excluding diet item(s)

Age group	Japanese study		Irish study	
	Mean (SD)	95% CI	Mean (SD)	95% CI
20–39	3.58 (1.79)	3.20, 3.96	3.87 (1.76)	3.44, 4.31
40+	3.76 (1.95)	3.30, 4.22	3.71 (1.62)	3.54, 3.88
All ages	3.66 (1.86)	3.37, 3.95	3.75 (1.66)	3.56, 3.95

4.3.3 Other analysis

Table 4.7 presents the percentage of Japanese patient participants agreeing with the statement "*The more I visit the dentist for check-up, the more teeth, I think, are drilled*" by age group. Only a minority of participants agreed with the statement (12.6 % in the 20–39 age group; 9.9% in the 40+ age group). Number of participants with missing data was 13; all 13 (100%) were in the 40+ age group, 11 (84.6%) were female and 11 (84.6%) attended for check-ups and professional cleaning. The Mann-Whitney test showed that the ordinal responses to the statement were similar for younger (Median = 3) and older (Median = 3) age groups (U = 22593, P = 0.969).

Table 4.7 Percentage of Japanese patient participants agreeing with the statement by age group (n = 469)

Statement	20-39 years	40+ years	All age
The more I visit the dentist for check-up, the more teeth, I think, are drilled.			
Strongly/Somewhat agree	12.6	9.9	10.7
Neither agree nor disagree	41.5	45.5	44.3
Strongly/Somewhat disagree	45.9	44.6	45.0

Article I included Q2 "*Did you know that the probabilities (risk) of getting tooth-decay differ from individual to individual?*" Approximately 85% of participants in Group AB had knowledge that some people are more susceptible to caries than others.

4.4 Objective 2 (Article III: self-perceived caries risk)

Objective 2: to evaluate the associations between Chance-AC and self-perceived caries risk in an economically disadvantaged adult population in the RoI (Article III).

4.4.1 Descriptive data

The final sample numbered 165. The response rate was 88.7% (165 out of 186 eligible MC patients). The mean age was 38.5 years (SD = 12.7) and approximately two-thirds (67.9%) were women. The proportion of MC patients with third level education or higher was 35.6% (57 out of 160 respondents). The distribution of the 165 MC patients by the eight dental practitioners was 2 (1.2%), 22 (13.3%), 18 (10.9%), 86 (52.1%), 15 (9.1%), 1 (0.6%), 9 (5.5%) and 12 (7.3%) from Dentists A to H.

4.4.2 Main results

Approximately three-quarters (73.2%: 120/164) of respondents were aware that some people are more prone to dental caries than others; approximately one-quarter (28.5%: 47/165) reported that they perceived themselves to be more prone to dental caries than the average person. Table 4.8 presents associations between self-perceived caries risk and the non-Cariogram parameters excluding age; Table 4.9 presents associations between self-perceived caries risk and age.

Table 4.8 Associations between self-perceived caries risk and the non-Cariogram parameters (categorical data)

Variable		Number	% reporting self-perceived risk[‖]	P value
Gender	Male	53	22.6	
	Female	112	31.3	
		165	28.5	0.1359[†]
Education level	Primary	14	35.7	
	During second level	31	32.3	
	After second level	52	32.7	
	Third level	43	14.0	
	Postgraduate degree	14	21.4	
	Still in education	6	50.0	
		160	27.5	< 0.0001[***‡]
Smoking status	Smoker	50	44.0	
	Non-smoker	115	21.7	
		165	28.5	0.0275[*‡]
Possession of a smart phone	Yes	122	27.0	
	No	30	26.7	
		152	27.0	0.9348[†]
Attendance for MP	Yes	111	24.3	
	No	51	37.3	
		162	28.4	0.0060[**‡]
Toothbrushing frequency	Less than once/week	3	33.3	
	Less than once/day	3	33.3	
	Once/day	52	34.6	
	Twice or more/day	101	23.8	
		159	27.7	0.1194[†]
Q1[§]	Yes	120	32.5	
	No	44	18.2	
		164	28.7	0.1331[†]

[†]Univariate logistic regression model. [‡]Multivariate regression model including Chance-AC, smoking status, attendance for MP, and education level. [§]Q1: "*Do you think that you are more prone to dental decay than the average person – Yes or No?*" [‖]Q2: "*Are you aware that some people are more prone to dental decay (cavities or caries) than others – Yes or No?*" [*]P < 0.05; [**]P <0.01; [***]P < 0.001.

Table 4.9 Associations between self-perceived caries risk and age (continuous data)

Variable	Number	Mean (SD)	P value
Those perceived risk†	47	39.9 (13.2)	
Those did not perceive risk†	118	35.1 (10.7)	
	165	38.5 (12.7)	0.1226

Multivariate regression model including Chance-AC, smoking status, attendance for MP, and education level. †Q2: "*Are you aware that some people are more prone to dental decay (cavities or caries) than others – Yes or No?*"

Among the non-Cariogram parameters, there were statistically significant differences in self-perceived caries risk by education level (P < 0.01), by smoking status (P = 0.03) and by attendance for MP (P = 0.01). Non-smokers had lower odds of self-perceived caries risk being above average (OR 0.48; 95% CI 0.25, 0.92). Those who do not go to the dentist for MP had increased odds of self-perception of being at risk (OR 2.44; 95% CI 1.29, 4.61). Regarding education level, those who completed only primary education had increased odds of self-perception of being at risk relative to those who completed education at third level (OR 3.88; 95% CI 2.09, 7.19).

The association between caries risk assessed by the Cariogram and self-perceived caries risk is presented in Table 4.10. The proportion of MC patients reporting self-perceived caries risk increased in accordance with their caries risk level assessed by the Cariogram (3.2%, 31.0%, 35.8% and 35.9% in the 'Low/Rather low risk', 'Intermediate risk', 'High risk' and 'Very high risk' groups, respectively). MC patients in the 'Very high risk' and 'High risk' groups were 16.0 times (95% CI 1.9, 134.2) and 18.8 times (95% CI 2.8, 124.8), respectively, as likely to perceive themselves as having high caries risk than MC patients in the 'Low/Rather low risk' group. The 'Intermediate risk' group had increased odds of perceiving themselves as having high caries risk compared to the 'Low/Rather low risk' group (OR 11.9; 95% CI 1.4, 104.1). Most MC patients in both the 'Very high risk' group and 'High risk' group underestimated their caries risk (64.1%: 59/92).

Table 4.10 Association between caries risk assessed by the Cariogram and self-perceived caries risk

Cariogram risk group	Number	% reporting self-perceived risk[†]	P value
Very high	39	35.9	0.0105[*]
High	53	35.8	0.0023[**]
Intermediate	42	31.0	0.0252[*]
Low/Rather low	31	3.2	Reference

Multivariate regression model including Chance-AC, smoking status, attendance for MP, and education level. [†]Q2: "*Are you aware that some people are more prone to dental decay (cavities or caries) than others – Yes or No?*" [*]P < 0.05; [**]P <0.01.

Table 4.11 shows the distribution of MC patients by the Cariogram parameters and the percent reporting self-perceived caries risk. MC patients who had the worst scores for the 'caries experience' (P = 0.02), 'plaque amount' (P < 0.01) and 'saliva secretion' (P < 0.01) parameters were more likely to perceive their caries risk as high. Regarding the 'caries experience' parameter, those with Score 0 or 1 have lower odds of self-perception (being at caries risk) relative to those with Score 3 (OR 0.173; 95% CI 0.037, 0.805); those with Score 2 have reduced odds of self-perception relative to those with Score 3 (OR 0.179; 95% CI 0.050, 0.645). As for the 'plaque amount' parameter, MC patients with Score 0 or 1 have reduced odds of self-perception relative to those with Score 3 (OR 0.192; 95% CI 0.078, 0.472); MC patients with Score 2 have reduced odds of self-perception relative to those with Score 3 (OR 0.276; 95% CI 0.094, 0.808). Compared with the highest score of the 'saliva secretion' parameter, the odds ratios were 0.072 (95% CI 0.017, 0.303), 0.087 (95% CI 0.023, 0.329) and 0.130 (95% CI 0.028, 0.604) for those with Scores 0, 1 and 2, respectively. On the other hand, the 'diet contents', 'diet frequency', 'mutans streptococci' and saliva 'buffer capacity' parameters did not affect self-perceived caries risk.

Table 4.11 Distribution of the Cariogram parameters based on self-perceived caries risk (n = 165)

Parameter	Score	Number of patients	% reporting self-perceived risk[¶]	P value
'Caries experience'	0[†]	2	0	0.0187[*]
	1[†]	41	14.6	
	2	67	20.9	
	3	55	49.1	
'Related diseases'	0	158	28.5	N/A[‡]
	1	7	28.6	
'Diet contents'	0	35	20	0.9144
	1	57	28.1	
	2	45	28.9	
	3	28	39.3	
'Diet frequency'	0	23	43.5	0.4066
	1	96	27.1	
	2	39	20.5	
	3	7	42.9	
'Plaque amount'	0[†]	5	0	0.0002[***]
	1[†]	60	18.3	
	2	71	31	
	3	29	48.3	
'Mutans streptococci'	0	31		0.9162
	1	64	95[§]	25.3
	2	57		
	3	13	70[§]	32.9
'Fluoride programme'	0a	42		N/A[‡]
	0b	39	157[‖]	29.3
	0c	73		
	0d	3		
	1	1	0	
	2	7	14.3	
Stimulated **'saliva secretion'**	0	107	23.4	< 0.0001[***]
	1	16	31.3	
	2	31	32.3	
	3	11	63.6	
Saliva **'buffer capacity'**	0	110	23.6	0.146
	1[†]	48	37.5	
	2[†]	7	42.9	

Multivariate logistic regression model including the Cariogram parameters, smoking status, attendance of MP, and education level. [†]Categories merged in the logistic regression model.

[‡]N/A: not applicable as variable has too few patients to include in a logistic regression model. [§]Scores 0 and 2 were rounded to Scores 1 and 3, respectively, when entered into the Cariogram, because it seemed from the distribution that four-score classification was not appropriate. [‖]0a, 0b, 0c and 0d were considered as Score 0 when entered into the Cariogram, according to the Manual. [¶]Q2: "*Are you aware that some people are more prone to dental decay (cavities or caries) than others – Yes or No?*" [*]$P < 0.05$; [***]$P < 0.001$.

4.4.3 Other analyses

The distribution of modifiable caries risk parameters scoring 2 or 3 **(Higher score)** by self-perceived caries risk status in 'Very high risk' and 'High risk' groups is depicted in Figure 4.4. Regardless of self-perceived risk, most in these groups had two or more modifiable risk factors with Higher score (91.6% of MC patients reporting self-perceived caries risk and 84.9% of MC patients not reporting self-perceived caries risk).

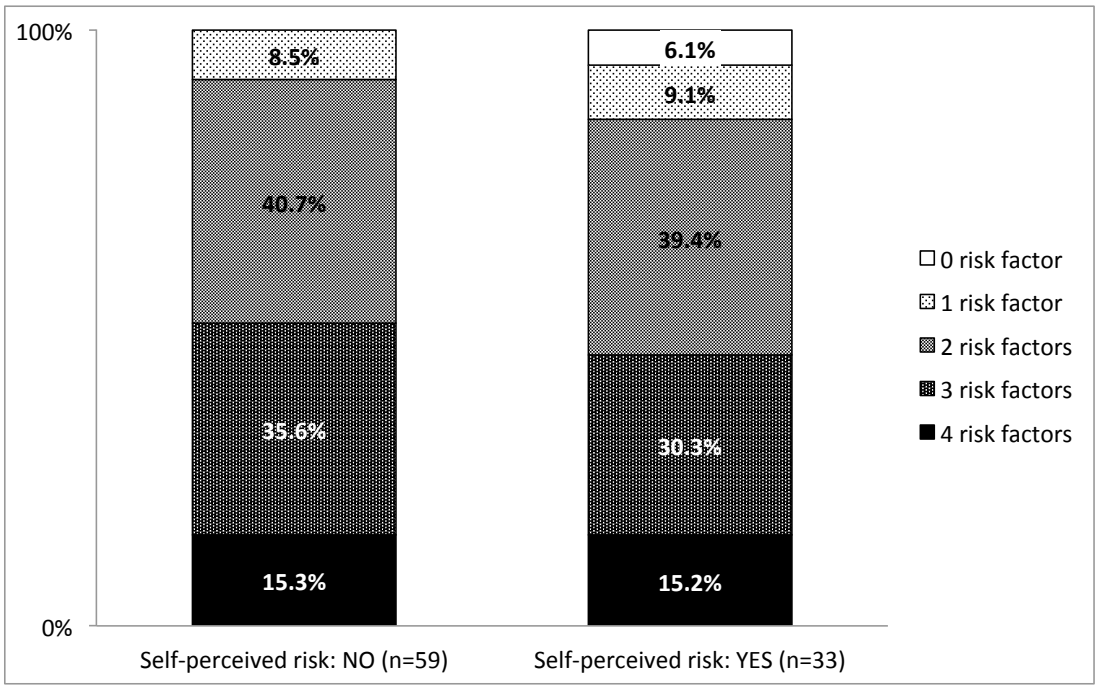


Figure 4.4 Clustering distribution of modifiable risk parameters with Score 2 or 3 by self-perceived risk among the 'Very high risk'/ 'High risk' groups.

The 'diet contents', 'diet frequency', 'plaque amount', 'mutans streptococci' and 'fluoride programme' parameters were considered modifiable.

4.5 Objective 3 (Article IV: caries risk profile)

Objective 3: to determine individual variability of Chance-AC and seven aetiological caries risk parameters from the Cariogram's ten parameters, within individuals in an economically disadvantaged adult population in the RoI (Article IV).

4.5.1 Descriptive data

Table 4.12 shows sociodemographic characteristics (n = 167). The response rate was 90% (167 out of 186 eligible MC patients). Females dominated (68.3%). The mean age was 38.4 years (SD = 12.7). The proportion of patients with third level education or higher was 35.4% (57 out of 161 respondents), which was similar to that of Irish people aged 15–64 years in 2014 (34%) (The Central Statistics Office 2015). The proportion of smokers was 31.1%. Distribution of patients by dental practitioners was 2 (1.2%), 22 (13.2%), 18 (10.8%), 87 (52.1%), 15 9.0%), 1 (0.6%), 9 (5.4%) and 13 (7.8%) from Dentists A to H.

Table 4.12 Sociodemographic characteristics (n = 167)

Variables	Number of patients
Gender: female	114
Age: mean	38.4 (SD = 12.7, min = 19, max = 69)
Education level: third level+	57[†]
Smokers	52
Smartphone ownership	124[‡]
Attendance for MP	111[§]

[†]Six patients did not answer the question. [‡]Thirteen patients did not answer the question. [§]Four patients did not answer the question.

4.5.2 Main results

Table 4.13 summaries the distribution, mean (SD) and CV of Chance-AC using both Score 1 (standard) and Score 2 (increased risk) for the 'clinical judgement' parameter. With Score 1, percentages of those who were in the four risk groups were 3.6%, 14.4%, 21.6% and 60.4% from the highest risk group to the lowest risk group. With Score 2, the percentages in the four risk groups were 24.6%, 31.7%, 25.1% and 18.6% from the highest risk group to the lowest risk group. The average of Chance-AC was 63.7 (SD = 21.1, CV = 0.33), ranging from 10 to 96 with the standard 'clinical judgement'. With Score 2, the average of Chance-AC was 39.5 (SD = 21.8, CV = 0.55), ranging from 3 to 94.

Table 4.13 Distribution (%), mean (SD) and CV of Chance-AC with Scores 1 and 2 of the 'clinical judgement' parameter (n = 167)

Chance-AC	The 'clinical judgement' parameter	
	With Score 1	With Score 2
0–20 (highest risk)	3.6	24.6
21–40	14.4	31.7
41–60	21.6	25.1
61–100 (lowest risk)	60.4	18.6
Mean (SD)	63.7 (21.1)	39.5 (21.8)
Min–Max	10–96	3–94
CV	0.33	0.55

Distribution of scores of the nine caries risk parameters (%) used by in the Cariogram is shown in Table 4.14. 'Related diseases' and 'Fluoride programme' were not diverse. For the other parameters, individual variability was apparent.

Table 4.14 Distribution of nine caries risk parameters (%) (n =167)

	Score 0	**Score 1**	**Score 2**	**Score 3**
'Caries experience'	caries free	better	normal	worse
(for age group)	1.2	24.6	40.1	34.1
'Related diseases'	no disease	mild degree	severe degree	-
	95.8	4.2	0	-
'Diet content'	$< 10^5$ CFU/ml saliva		$\geq 10^5$ CFU/ml	
(LB)	21.6	34.1	27.5	16.8
'Diet frequency'†	0–3.0	3.3–5.0	5.3–7.0	≥ 7.3
(fermentable carbohydrate, times/day)	13.8	58.1	24.0	4.2
'Plaque amount'	extremely good	good	less than good	poor
(oral hygiene)	3.0	35.9	43.7	17.4
'Mutans streptococci'	$< 10^5$ CFU/ml saliva		$\geq 10^5$ CFU/ml	
	-	57.5	-	42.5
'Fluoride programme'	maximum	water only	toothpaste only	avoid fluoride
	95.2	0.6	4.2	0
Stimulated **'saliva secretion'**‡ (ml/minute)	≥ 1.1	< 1.1, ≥ 0.9	< 0.9, ≥ 0.5	< 0.5
	64.7	9.6	18.6	7.2
Saliva **'buffer capacity'**	normal or good	less than good	low	-
	66.5	29.3	4.2	-

†The mean (SD) of the original value was 4.6 (1.3) times/day. ‡The mean (SD) of the original value was 1.5 (0.7) ml/minute.

Two-step cluster analysis identified five cluster groups. The silhouette coefficient was slightly more than 0.2 (a fair cluster solution). **Predictor importance** values were 0.83, 0.02, 0.38, 0.93, 0.02, 0.25, 1.00 for the 'diet content', 'diet frequency', 'plaque amount', 'mutans streptococci', 'fluoride programme', 'saliva secretion' and 'buffer capacity' parameters, respectively.

4.5.2.1 Cluster 1

Cluster 1 ('Bacteria, saliva and diet'; n = 26) is characterised by an unfavourable 'Bacteria' sector (high risk scores of the 'plaque amount' and 'mutans streptococci' parameters), unfavourable saliva factors (poor stimulated flow rate and high risk scores of the saliva 'buffer capacity' parameter), and an unfavourable 'Diet' sector (high risk scores for both frequency and contents of fermentable carbohydrates) (Table 4.15). While all of these patients use fluoridated toothpaste, 11.5% do not use fluoridated water. It is unknown whether they did not have access to fluoridated water or chose to avoid it. Caries experience is high compared to the average for their respective age groups. Chance-AC is low (mean (SD): 16.5 (9.6)) (Table 4.16).

4.5.2.1 Cluster 2

Cluster 2 ('Bacteria but good saliva'; n = 25) is characterised by an unfavourable level of 'Bacteria' sector (high risk scores of the 'plaque amount' and 'mutans streptococci' parameters) but distinguished by the fact that the saliva factors are good (Table 4.15). All patients in Clusters 1 and 2 have Score 3 for the 'mutans streptococci' parameter'. However, the mean (SD) saliva flow rate in Cluster 2 is higher (2.0 (0.8) ml/minute) than in any other cluster and almost all patients in Cluster 2 possess the most favourable score for the saliva 'buffer capacity' parameter.

4.5.2.2 Cluster 3

Cluster 3 ('Saliva'; n = 42) is distinguished by poor saliva factors (the 'saliva secretion' and 'buffer capacity' parameters) (Table 4.15). However, the 'plaque amount' parameter is comprehensively favourable; all patients with Score 0 for this parameter are included in this cluster.

4.5.2.3 Cluster 4

Cluster 4 ('diet content'; n = 25) is characterised by high LB counts (the 'diet contents' parameter) (Table 4.15). Almost all patients in this group have Score 2 of LB (less favourable; $\geq 10^5$ CFU/ml saliva). All patients in both Clusters 2 and 4 use fluoridated water and toothpaste.

4.5.2.4 Cluster 5

Cluster 5 ('Nondescript'; n = 49) is characterised by no prominent poor risk factors. Notably, all these patients have Score 0 for the saliva 'buffer capacity' parameter (most favourable) and Score 1 for the 'mutans streptococci' parameter (most favourable) (Table 4.15). Approximately half of this group have Scores 2 or 3 for the 'plaque amount' parameter (less favourable). Chance-AC is relatively high (mean (SD): 60.5 (18.5)) (Table 4.16).

Table 4.15 The mean (SD) score for continuous variables and score distribution (%) for categorical variables used for cluster analysis (n =167)

Parameters	Cluster 1	Cluster 2	Cluster 3	Cluster 4	Cluster 5
'Diet content'					
Score 0	11.5	0.0	28.6	4.0	40.8
Score 1	3.8	64.0	47.6	0.0	40.8
Score 2	38.5	0.0	16.7	96.0	10.2
Score 3	46.2	36.0	7.1	0.0	8.2
'Diet frequency'					
times/day	4.9 (1.1)	4.6 (1.1)	4.8 (1.5)	4.5 (1.5)	4.3 (1.2)
'Plaque amount'					
Score 0	0.0	0.0	11.9	0.0	0.0
Score 1	0.0	28.0	31.0	68.0	46.9
Score 2	92.3	36.0	42.9	0.0	44.9
Score 3	7.7	36.0	14.3	32.0	8.2
'Mutans streptococci'					
Score 1	0.0	0.0	83.3	48.0	100.0
Score 3	100.0	100.0	16.7	52.0	0.0
'Fluoride programme'					
Score 0	88.5	100.0	90.5	100.0	98.0
Score 1	0.0	0.0	2.4	0.0	0.0
Score 2	11.5	0.0	7.1	0.0	2.0
Stimulated **'saliva secretion'**					
ml/minute	1.2 (0.6)	2.0 (0.8)	1.1 (0.6)	1.5 (0.6)	1.7 (0.7)
Saliva **'buffer capacity'**					
Score 0	50.0	96.0	0.0	100.0	100.0
Score 1	38.5	0.0	92.9	0.0	0.0
Score 2	11.5	4.0	7.1	0.0	0.0

Table 4.16 The mean (SD) score for continuous variables and score distribution (%) for categorical variables NOT used for cluster analysis (n =167)

Variables	Cluster 1	Cluster 2	Cluster 3	Cluster 4	Cluster 5
Age	38.4	40.4	36.0	38.9	39.2
Mean (SD)	(11.3)	(15.2)	(11.2)	(12.2)	(13.7)
Chance-AC[†]	16.5	26.2	38.9	36.4	60.5
Mean (SD)	(9.6)	(12.4)	(16.0)	(15.9)	(18.5)
Proportion female	76.9	52.0	78.6	72.0	61.2
Proportion those with education level of third level or higher	26.9	24.0	50.0	28.0	32.6
Proportion smoker	42.3	32.0	33.3	32.0	22.4
Dental practitioner					
A	3.8	0.0	0.0	4.0	0.0
B	7.7	4.0	28.6	8.0	10.2
C	3.8	8.0	14.3	8.0	14.3
D	76.9	80.0	33.3	64.0	34.7
E	0.0	8.0	0.0	12.0	20.4
F	0.0	0.0	2.4	0.0	0.0
G	7.7	0.0	2.4	0.0	12.2
H	0.0	0.0	19.0	4.0	8.2
'Caries experience'					
Score 0	0.0	0.0	0.0	0.0	4.1
Score 1	15.4	28.0	21.4	20.0	32.7
Score 2	34.6	28.0	42.9	56.0	38.8
Score 3	50.0	44.0	35.7	24.0	24.5
'Related diseases'					
Score 0	96.2	100.0	95.2	100.0	91.8
Score 1	3.8	0.0	4.8	0.0	8.2

[†]With the increased 'clinical judgment' parameter.

4.6 Objective 4 (Article V: personalised mHealth for caries risk)

Objective 4: to investigate the impact on caries risk reduction of a personalised approach, delivered via a CRA summary letter plus 24 mobile-phone short text messages based on the individual's Cariogram CRA, versus a non-personalised approach on (i) reducing Chance-AC and seven aetiological caries risk parameters and on (ii) increasing knowledge and self-perception of caries risk in an economically disadvantaged group (Article V).

4.6.1 Recruitment

The final sample size (n = 111) was 17 patients short of the required sample size. Dropout rates were as follows:

- From the baseline examination ((191-111)/191): 41.9%
- From the baseline examination among eligible patients ((186-111)/186): 40.3%
- From included patients in Article IV ((167-111)/167): 33.5%
- From included patients in Article III ((165-111)/165): 32.7%
- From included patients in Article II ((159-111)/159): 30.2%.

The differences of subject characteristics between those who were included in Article V and those who dropped out among eligible patients (19+ years of age and MC patient, n = 186) are shown in Table 4.17. Note that these statistical analyses did not yet consider clustering by dentist. Those who completed all procedures tended to be older, with relatively fewer smokers, fewer smartphone owners and more participants with lower risk of MS than those who dropped out.

Table 4.17 The differences between those who were included in Article V and those who dropped out among eligible patients

Variables	Those who completed all procedures	Those who dropped out	P value
Number	111	75	**(Chi-square test)**
Gender: female, %	67.6	66.7	0.898
Smokers, %	23.4	46.7	0.001**
Smartphone ownership, %	77.1†	89.6‡	0.039*
MC patients with Score 0 or 1: %			
'Caries experience'	27.9	21.3	0.310
'Related diseases'	100.0	100.0	-
'Diet content'	51.4	60.0	0.245
'Plaque amount'	39.6	34.7	0.492
'Mutans streptococci'	52.3	69.3	0.020*
'Fluoride programme'	95.5	97.3	0.518
Stimulated 'saliva secretion'	76.6	70.7	0.366
Saliva 'buffer capacity'	94.6	98.7	0.152
			(t-test)
Age: mean (SD)	41.0 (12.0)	32.9 (11.9)	< 0.001***

†Six patients were missing. ‡Eight patients were missing. *P < 0.05; **P <0.01; ***P < 0.001.

The numbers of weeks between the various stages of the study were as follows:

- **baseline examination to baseline CRA:** mean (SD) = 15.0 (15.8) days, median = 9 days, range = 0–96 days;
- **baseline CRA to start of the intervention:** mean (SD) = 25.7 (10.8) days, median = 20 days, range = 11–61 days;
- **end of the intervention to follow-up examination:** mean (SD) = 31.9 (23.5) days, median = 26 days, range = 1–138 days;
- **follow-up examination to follow-up CRA:** mean (SD) = 18.3 (20.2) days, median = 10 days, range = 0–126 days.

The follow-up CRA was ended on 19 July 2016 because the dental practitioners could encourage no more patients to attend for follow-up.

4.6.2 Baseline data

The demographic characteristics of the sample are presented in Table 4.18. Dentists A and F lost all their patients at follow-up. For the six remaining dentists, the distribution of participants was greatly varied; Dentist D examined 63 of all 111 participants (57.3%).

Table 4.18 The demographic characteristics of the sample

Variable		Personalised group (n = 56)	Non-personalised group (n = 55)
Age, year	Mean (SD)	40.9 (11.3)	41.2 (12.3)
	Median	40	40
	Min–Max	19–69	19–69
Gender, %	Female	60.7	74.5
	Male	39.3	25.5
Education level, %	Less than third level	55.4	52.7
	Third level+	44.6	36.4
	Still in education	0.0	5.5
	Missing	0.0	5.5
Smoking status, %	Non-smoker	76.8	76.4
	Smoker	23.2	23.6
Smart phone, %	Non-possession	21.4	21.8
	Possession	73.2	72.7
	Missing	5.4	5.5
DMFS	Mean (SD)	32.6 (20.2)	34.9 (19.0)
	Median	33	33
	Min–Max	1–106	0–66
Dental practitioner, %	B	12.5	20
	C	16.1	16.4
	D	57.1	58.2
	E	7.1	3.6
	G	1.8	1.8
	H	5.4	0.0

4.6.3 Number of text messages

Table 4.19 shows the number of text messages from the four risk sectors both assigned and actually sent between the personalised and non-personalised groups. In total, 353 of

the assigned text messages were not actually sent: 219 and 134 text messages in the personalised and non-personalised groups, respectively.

Table 4.19 Number of assigned and actually sent text messages from the four risk-sectors between the personalised and non-personalised groups

	Risk-Sector			
	Diet	**Bacteria**	**Susceptibility**	**Circumstances**
Assigned messages				
Personalised Group				
Sum	401	504	264	175
Mean (SD)	7.2 (2.9)	9 (3.4)	4.7 (4.2)	3.1 (1.7)
Median	7	9	3	3
Min–Max	1–13	3–16	2–18	0–7
Non-personalised Group				
Sum	330	330	330	330
Mean (SD)	6.0 (0.0)	6.0 (0.0)	6.0 (0.0)	6.0 (0.0)
Median	6	6	6	6
Min–Max	6–6	6–6	6–6	6–6
Actually sent messages				
Personalised Group				
Sum	340	422	217	146
Mean (SD)	6.1 (3.0)	7.5 (3.4)	3.9 (3.2)	2.6 (1.6)
Median	6	7	3	2.5
Min–Max	0–12	0–14	0–16	0–6
Non-personalised Group				
Sum	287	313	292	294
Mean (SD)	5.2 (0.9)	5.7 (0.6)	5.3 (1.1)	5.3 (0.7)
Median	5	6	6	5
Min–Max	3–6	3–7	2–6	3–6

For Q13, two MC patients answered they did not understand 17–24 messages and another two MC patients answered they did not understand 1–8 messages. One MC patient wrote in her questionnaire that she did not receive any text messages. These MC patients were included in the ITT analysis but excluded from the per-protocol analysis.

4.6.4 Risk reduction

For the primary outcome analysis with the ITT approach, the means (SD) of Chance-AC were 46.2 (19.6) in the personalised group (n = 56) and 42.8 (22.0) in the non-personalised group (n = 55) (Table 4.20). The ANCOVA showed no statistically significant difference between the two groups (mean difference = 0.7 of Chance-AC (95% CI -5.5, 6.9), P = 0.820).

Table 4.20 ITT analysis of primary outcomes between the personalised and non-personalised groups

ITT Analysis	Personalised group (n = 56)	Non-personalised group (n = 55)	Mean difference (95% CI)	P value
Baseline				
Mean (SD)	39.3 (20.2)	36.5 (23.4)		
Median	37.5	31		
Min–Max	6–81	3–94		
Follow-up				
Mean (SD)	46.2 (19.6)	42.8 (22.0)	0.7 (-5.5, 6.9)	P = 0.820
Median	44.5	41		
Min – Max	8–83	9–93		

ANCOVA. The baseline value and age were included as covariates; gender, dental practitioners and the assigned group (personalised or non-personalised) were included as factors.

For the seven risk parameters, only the stimulated saliva amount factor showed a personalised intervention effect, P = 0.036 (OR 0.3; 95% CI 0.1, 0.9) (Table 4.21).

Table 4.21 ITT analysis of secondary outcomes (the seven risk parameters) between the personalised and non-personalised groups: percentage of MC patients with Score 0 or 1

ITT Analysis	Personalised group (n = 56)	Non-personalised group (n = 55)	OR (95% CI)	P value
'Diet frequency'				
Baseline	69.6	65.5		
Follow-up	83.9	78.2	0.8 (0.3, 2.3)	
'Diet contents'				
Baseline	48.2	54.5		
Follow-up	48.2	54.5	1.0 (0.4, 2.6)	
'Plaque amount'				
Baseline	44.6	34.5		
Follow-up	55.4	60.0	1.7 (0.7, 3.9)	
'Mutans streptococci'				
Baseline	60.7	43.6		
Follow-up	64.3	56.4	1.1 (0.4, 2.6)	
'Fluoride programme' †				
Baseline	98.2	92.7		
Follow-up	100.0	98.2		
Stimulated **'saliva secretion'**				
Baseline	80.4	72.7		
Follow-up	91.1	74.5	0.3 (0.1, 0.9)	P = 0.036*
Saliva **'buffer capacity'**				
Baseline	96.4	92.7		
Follow-up	80.4	72.7	0.8 (0.3, 2.1)	

Logistic regression models. The baseline values and age were included as covariates; gender and the assigned group (personalised or non-personalised) were included as factors. †Model fit was questionable – odds ratio estimates unreliable. *P < 0.05.

With the per-protocol analysis, there was also no statistically significant difference between the two groups (mean difference = 4.0 (95% CI -5.6, 13.5), P = 0.410) (Table 4.22).

Table 4.22 Per-protocol analysis of primary outcomes between the personalised and non-personalised groups

Per-protocol analysis	Personalised group (n = 21)	Non-personalised group (n = 33)	Mean difference (95% CI)	P value
Baseline				
Mean (SD)	36.7 (18.6)	29.4 (20.5)		
Median	37	26		
Min–Max	11–67	3–83		
Follow-up				
Mean (SD)	44.6 (18.4)	35.0 (20.6)	4.0 (-5.6, 13.5)	P = 0.410
Median	39	32		
Min–Max	16–83	9–84		

ANCOVA. The baseline value and age were included as covariates; gender, dental practitioner and the assigned group (personalised or non-personalised) were included as factors.

For the secondary outcomes, logistic regression estimates were not reliable due to the small sample size for the per-protocol analysis (Table 4.23).

Table 4.23 Per-protocol analysis of secondary outcomes between the personalised and non-personalised groups: percentage of MC patients with Score 0 or 1†

Per-protocol Analysis	Personalised group (n = 21)	Non-personalised group (n = 33)
'Diet frequency'		
Baseline	57.1	63.6
Follow-up	85.7	75.8
'Diet contents'		
Baseline	47.6	42.4
Follow-up	38.1	39.4
'Plaque amount'		
Baseline	38.1	27.3
Follow-up	57.1	54.5
'Mutans streptococci'		
Baseline	42.9	24.2
Follow-up	57.1	36.4
'Fluoride programme'		
Baseline	100.0	90.9
Follow-up	100.0	97.0
Stimulated **'saliva secretion'**		
Baseline	95.2	69.7
Follow-up	100.0	72.7
Saliva **'buffer capacity'**		
Baseline	100.0	93.9
Follow-up	85.7	81.8

†Logistic regression model fit was questionable – odds ratio estimates unreliable.

4.6.5 Knowledge of caries risk factors/indicators

For the ITT analysis, in both the personalised and non-personalised groups, more MC patients identified caries risk factors/indicators at follow-up than at baseline, with the exception of "*Not brushing your teeth properly*" and "*Consuming sugary foods and drinks too often*" (Table 4.24). No items showed a personalised intervention effect statistically.

For the per-protocol analysis, in both the personalised and non-personalised groups, more MC patients were able to identify the listed caries risk factors/indicators at follow-up than at baseline, with the exception of "*Not brushing your teeth properly*" and "*Not visiting the dentist for check-up and cleaning*" (Table 4.25). No items showed a personalised intervention effect statistically.

Table 4.24 ITT analysis of secondary outcomes (knowledge of the ten caries risk factors/indicators) between the personalised and non-personalised groups

Risk factor/indicator	Yes response by group (%)		OR (95% CI)	P value
	Personalised (n = 56)	Non-personalised (n = 55)		
Not brushing your teeth properly				
Baseline	92.9	96.4		
Follow-up	92.9	92.7	0.7 (0.1, 3.5)	0.676
Consuming too much sugary foods and drinks				
Baseline	83.9	78.2		
Follow-up	91.1	90.9	1.2 (0.2, 8.7)	0.837
Consuming sugary foods and drinks too often				
Baseline	82.1	80.0		
Follow-up	82.1	81.8	0.8 (0.2, 3.3)	0.749
Consuming sugary foods and drinks just before bedtime				
Baseline	67.9	70.9		
Follow-up	85.7	81.8	†	0.939
Having naturally 'weak teeth'				
Baseline	37.5	50.9		
Follow-up	48.2	54.5	1.1 (0.3, 4.1)	0.914
Not visiting the dentist for check-up and cleaning				
Baseline	78.6	74.5		
Follow-up	78.6	81.8	1.6 (0.4, 5.9)	0.512
Not using fluoride				
Baseline	42.9	36.4		
Follow-up	64.3	54.5	0.2 (0.0, 1.2)	0.080
Having particular bacteria in the mouth that contribute to the development of dental decay				
Baseline	46.4	49.1		
Follow-up	60.7	63.6	†	0.520
Having a reduced amount of saliva (spit) in the mouth				
Baseline	30.4	29.1		
Follow-up	53.6	41.8	0.9 (0.1, 5.7)	0.911
Having saliva (spit) that does not have the right composition to protect against decay				
Baseline	25.0	29.1		
Follow-up	57.1	47.3	1.1 (0.2, 7.3)	0.888

Logistic regression models. The baseline values and age were included as covariates; gender and the assigned group (personalised or non-personalised) were included as factors. †Estimates unreliable.

Table 4.25 Per-protocol analysis of secondary outcomes (knowledge of the ten caries risk factors/indicators) between the personalised and non-personalised groups

Risk factor/indicator	Yes response by group (%)		OR (95% CI)	P value
	Personalised (n = 21)	Non-personalised (n = 33)		
Not brushing your teeth properly				
Baseline	95.2	93.9		
Follow-up	85.7	97.0	3.7 (0.3, 48.3)	0.321
Consuming too much sugary foods and drinks				
Baseline	90.5	78.8		
Follow-up	95.2	87.9	0.4 (0.0, 5.8)	0.508
Consuming sugary foods and drinks too often				
Baseline	76.2	72.7		
Follow-up	81.0	75.8	†	0.959
Consuming sugary foods and drinks just before bedtime				
Baseline	71.4	69.7		
Follow-up	90.5	75.8	†	0.952
Having naturally 'weak teeth'				
Baseline	47.6	54.5		
Follow-up	57.1	60.6	1.1 (0.1, 9.6)	0.912
Not visiting the dentist for check-up and cleaning				
Baseline	85.7	69.7		
Follow-up	76.2	78.8	1.4 (0.2, 11.4)	0.768
Not using fluoride				
Baseline	38.1	36.4		
Follow-up	52.4	54.5	0.5 (0.1, 4.5)	0.575
Having particular bacteria in the mouth that contribute to the development of dental decay				
Baseline	38.1	42.4		
Follow-up	61.9	60.6	†	0.192
Having a reduced amount of saliva (spit) in the mouth				
Baseline	33.3	30.3		
Follow-up	57.1	42.4	0.7 (0.0, 10.3)	0.801
Having saliva (spit) that does not have the right composition to protect against decay				
Baseline	23.8	33.3		
Follow-up	61.9	51.5	1.3 (0.1, 19.9)	0.866

Logistic regression models. The baseline values and age were included as covariates; gender and the assigned group (personalised or non-personalised) were included as factors. †Estimates unreliable.

Combining the personalised and non-personalised groups, Table 4.26 presents percentage of MC patients identifying each item as a caries risk factor according to the number of actual sent text messages (0–6 messages or 7–16 messages) for the relevant risk sector: 'Diet', 'Bacteria' and 'Susceptibility'. Note that "*Having naturally 'weak teeth'*" was excluded because this item had no corresponding relevant text message and that the 'Circumstances' sector was excluded because there was no MC patient who was sent more than six text messages. Although the numbers of MC patients were small, generally speaking, more of the MC patients who were sent 7–16 text messages identified items relevant to that sector as caries risk factors than those who were sent less than seven text messages. In particular, results for items relevant to the 'Susceptibility' sector indicated that sending more text messages was clearly associated with a higher percentage of MC patients identifying the item as a caries risk factor.

Table 4.26 Percentage of MC patients identifying the item as a caries risk factor according to the number of actual sent text messages in the relevant risk sector

Risk factor/indicator	Yes response by the number of sent text messages (%)	
	0–6 messages	7–16 messages
'Diet'	**n = 85**	**n = 20**
Consuming too much sugary foods and drinks		
Baseline	80.0	84.6
Follow-up	89.4	96.2
Consuming sugary foods and drinks too often		
Baseline	80.0	84.6
Follow-up	81.2	84.6
Consuming sugary foods and drinks just before bedtime		
Baseline	70.6	65.4
Follow-up	81.2	92.3
'Bacteria'	**n = 76**	**n = 35**
Not brushing your teeth properly		
Baseline	97.4	88.6
Follow-up	93.4	91.4
Having particular bacteria in the mouth that contribute to the development of dental decay		
Baseline	48.7	45.7
Follow-up	61.8	62.9
'Susceptibility'	**n = 104**	**n = 7**
Not using fluoride		
Baseline	40.4	28.6
Follow-up	56.7	100.0
Having a reduced amount of saliva (spit) in the mouth		
Baseline	30.8	14.3
Follow-up	46.2	71.4
Having saliva (spit) that does not have the right composition to protect against decay		
Baseline	26.9	28.6
Follow-up	51.0	71.4

4.6.6 Risk perception

As the personalised text messages did not inform on individual caries risk, we considered that only the personalised letter which gave results of their caries risk assessment would have an effect on self-perceived caries risk (Appendix 11). Because

all personalised/non-personalised letters were correctly sent to all MC patients, a per-protocol analysis was not necessary for this variable.

At follow-up, almost all of the MC patients (91.8%) were aware that some people are more prone to dental caries than others. In the personalised group, the percentage increased from 63.6% to 89.1%, whereas in the non-personalised group, the percentage increased from 85.5% to 94.5% (Table 4.27). There was no personalised intervention effect, P = 0.885 (OR: estimates unreliable). This result was also substantially higher than results in Article III (73.2%; the baseline of the Irish study: n = 165) and in Article I (approximately 85%; the Japanese study: see Table 3 in the original Article I appended at the end) for the same question.

Table 4.27 Percentage of MC patients aware that some people are more prone to dental caries than others

	Yes response by group (%)		OR (95% CI)	P value
	Personalised (n = 55)	Non-personalised (n = 55)		
Baseline[†]	63.6	85.5		
Follow-up[†]	89.1	94.5	Estimates unreliable	0.885

Logistic regression models. The baseline values and age were included as covariates; gender and the assigned group (personalised or non-personalised) were included as factors. [†]One MC participant in the personalised group did not answer this question.

In the personalised group, the percentage reporting self-perceived caries risk increased from baseline to follow-up for all risk groups, i.e. 'Very high risk', 'High risk', 'Intermediate risk' and 'Low/Rather low risk' (Table 4.28). On the other hand, in the non-personalised group, the percentage reporting self-perceived caries risk dropped or remained the same in the different risk groups. Of nine MC patients with 'Low/Rather low risk' in the personalised group, only one answered that she thought that she was more prone to dental decay than the average person. Her Chance-AC was 63.

Table 4.28 Cariogram risk group at baseline and self-perceived caries risk at baseline and follow-up between the personalised and non-personalised groups

Risk group	Personalised group			Non-personalised		
	N†	% reporting self-perceived risk‡		N†	% reporting self-perceived risk‡	
		Baseline	Follow-up		Baseline	Follow-up
Very high	13	38.5	46.2	17	35.3	35.3
High	19	26.3	36.8	18	27.8	22.2
Intermediate	15	13.3	26.7	12	33.3	16.7
Low/Rather low	9	0.0	12.5§	8	0.0	0.0

†N: number of MC patients; ‡Q2: "*Are you aware that some people are more prone to dental decay (cavities or caries) than others – Yes or No?*" §One patient who did not answer Q2 was excluded.

4.6.7 Reaction to text messages in the questionnaire

For Q14 in the follow-up questionnaire, five MC patients did not answer. 100 MC patients found that receiving oral health information via text messages each week for six months was useful (94.3% of the 106 respondents). Six MC patients did not find it useful (5.7% of the 106 respondents). Of MC patients who returned the follow-up questionnaire, 34 MC patients left comments (30.6%). All comments are provided in Appendix 13. Most of the written comments were positive to receiving educational text messages on oral health.

4.6.8 Harm in the study

There was no harm or unintended effects in either group.

4.7 Summary of results

The key findings of this chapter are as follows:

- There were unexpected differences in knowledge of one caries risk factor and one indicator; a higher proportion of Irish participants identified "*Not visiting the dentist for check-up and cleaning*" and "*Not using fluoride*" than did Japanese participants.
- The Irish and Japanese studies revealed a lack of knowledge on saliva buffering capacity as a caries risk factor and a persistent belief that "*Not brushing teeth properly*" is a caries risk factor.
- There was an association between Chance-AC and self-perceived caries risk in the four risk groups for the Irish MC patients. The two highest risk groups according to Chance-AC were more likely to perceive themselves as having high caries risk than those in the lowest risk group.
- Approximately two-thirds of participants in the high-risk groups did not consider themselves as being more prone to dental decay than the average person.
- The caries risk profiles among the Irish MC patients were clustered into five groups: 'bacteria, saliva and diet' (having unfavourable microbiological, saliva and diet factors), 'bacteria but good saliva' (having unfavourable microbiological factors but favourable saliva factors), 'saliva' (having unfavourable saliva factors), 'diet content' (having high salivary lactobacillus counts) and 'nondescript' (having no prominent poor risk factors).
- Intent-to-treat analysis with all Irish MC patients did not show a personalised intervention effect on Chance-AC. Of the secondary outcome measures, only the stimulated saliva amount factor showed a personalised intervention effect. A per-protocol analysis showed no significant effect on Chance-AC.

5 DISCUSSION

This chapter will provide my interpretation of the findings and study limitations in accordance with the four objectives (five articles).

5.1 Objective 1 (Articles I and II: knowledge of caries risk)

5.1.1 Interpretation of the findings

The RoI and Japan are island countries situated on opposite sides of the Eurasian Continent. Both countries are members of the Organisation for Economic Co-operation and Development (OECD). However, their cultures are distinct and the questionnaire responses in this thesis were clearly different between the Irish and Japanese studies.

In spite of the differences, there was a persistent belief in tooth brushing as a means to reduce caries risk, despite the fact that the caries-reducing effect of tooth brushing and other self-administrated oral hygiene interventions per se (without fluoride) is doubtful (Selwitz et al. 2007). In addition, saliva's defensive role against caries is not well known in both study populations. In particular, among the Irish MC patients, the percentages of those identifying "*Having a reduced amount of saliva (spit) in the mouth*" were comparatively low in both age groups. This knowledge deficiency may present an obstacle to preventing dental caries, including root caries, when they are aged and xerostomia become common.

The results revealed that the Japanese participants, who were considered to have greater knowledge of preventive dentistry, did not always display more knowledge than the Irish MC patients, who were considered to be of low SES. In particular, the Japanese patient participants identified "*Not visiting the dentist for check-ups and tooth cleaning*" and "*Not using fluoride*" as caries risk factors/indicators less frequently than the Irish MC

patients. A possible reason for this difference is that in the RoI, visiting the dentist for MP became the norm much earlier than in Japan (Table 2.1).

The statement, "*Not visiting the dentist for a dental maintenance programme (check-ups and cleaning)*" may be regarded as a controversial risk indicator, as some dentists continue to perform unnecessary restorative intervention to early caries lesions during or after a routine check-up (Baelum et al. 2008). This may be detrimental because repetitive restorations (the 'drill, fill and bill' philosophy) result in a shorter tooth life span (Elderton 2003). This comment was made by a number of participants in the Japanese pilot study, prompting the inclusion in the final questionnaire of the statement "*The more I visit the dentist for check-up, the more teeth, I think, are drilled*" and asking participants whether they agreed or not. In the Irish questionnaire, this statement was reworded for the Irish context to "*The more I visit the dentist for check-ups, the more treatment I am given*". As the word '*treatment*' is less explicit than '*drilled*' and some patients might regard the promotion of prevention as '*treatment*', the Irish equivalent statement was not analysed. It was found that only approximately 10% of participants agreed with the statement "*The more I visit the dentist for check-up, the more teeth are drilled*". Therefore, it does not indicate that the Japanese participants meant visiting for MP was a caries risk indicator.

That Irish MC patients identified "*Not using fluoride*" more frequently than did the Japanese health-conscious participants is also interesting. It has been found that the Japanese people, including dentists, are not aware of the significant role of fluoride for caries prevention (Kakudate et al. 2015), whereas the RoI has a long history of water fluoridation (Clarkson et al. 2003) with on-going active public debates. The percentage of Japanese participants identifying this item was approximately two-thirds of the Irish percentage. However, it was surprising that only approximately 40% of the Irish MC patients identified "*Not using fluoride*" as a caries risk factor. This may be because the Irish study population were MC patients, and/or because some of them interpret fluoride not as a 'risk factor' but as a 'beneficial factor'.

Cultural beliefs and attitudes have an influence on oral health and oral health disparities (Patrick et al. 2006). One vast difference between the Irish and Japanese culture is their

native major religion – Christianity vs. Shintoism. The Japanese culture of cleanliness is partially rooted in their indigenous religion of Shintoism which equates cleanliness with purity (Horiuchi 2011); this may account for their different hygiene behaviours compared with Christian countries like the RoI. The deep-rooted Japanese belief in pursuing personal hygiene in daily life (i.e. self-care plaque control) may be a reason for their delaying the introduction of MP (i.e. professional plaque control) and the use of fluoridated products (i.e. a chemical agent).

In the Irish study only, three breakdown questions on diet (too much sugary diet, too often sugary diet, sugary diet before bedtime) were asked. The results give insight into public knowledge regarding substrate (diet) factors for caries prevention among this population. The MC patients least frequently identified "*Consuming sugary foods and drinks just before bedtime*" as a factor increasing caries risk. Considering this result with the low percentages identifying saliva as a risk factor, it would appear that the participants have little awareness of the full mechanism behind caries development. They may also believe that brushing teeth after consuming sugary foods and drinks before bedtime is sufficient to prevent tooth decay. Efforts to reduce intake of sugary foods and drinks before bedtime may also have the potential to impact general health such as weight gain, obesity and cardiometabolic diseases (Kinsey and Ormsbee 2015) under the common risk factor approach (Watt and Sheiham 2012).

5.1.2 Limitations of Articles I and II

The limitations relate to differences in the methodology between the surveys and include: sample representativeness, differences in questionnaire content and remuneration of participants in the Irish study and not in the Japanese. In particular, in the Japanese study the PSAP was the only source of recruitment, and in the Irish study Dentist D recruited more than half of all the patients. Dentist D's approach to care and education might influence patient knowledge; this might be less of a variable if the distribution of patients was more even across the dentists in the study. Therefore, generalisation of the findings is restricted. However, this study illustrates the value of

intercultural comparison in exploring knowledge and attitudes to caries risk factors/indicators and oral health.

5.2 Objective 2 (Article III: self-perceived caries risk)

5.2.1 Interpretation of the findings

Self-perceived caries risk was to some extent related to caries risk as assessed by the Cariogram amongst MC patients; however, those at high risk tended to underestimate their risk level. These findings are in line with previous self-perceived risk studies on dental caries (Astrøm et al. 1999), oral health (Hänsel Petersson et al. 2016), stroke (Yang et al. 2013), cardiovascular disease (Ko and Boo 2016) and human immunodeficiency virus infection (van der Velde et al. 1994). In the Irish study population, approximately two-thirds of patients in the 'Very high risk' and 'High risk' groups did not think that their caries risk was high. As stated for cardiovascular disease by Ko and Boo (2016), an important first step for efficiently preventing dental caries may be identifying those who underestimate their risk.

The caries risk profile created by the Cariogram can serve as a basis for dentist-patient discussion (Divaris 2016). The Cariogram advises individuals with a Chance-AC score of 20 or lower ('Very high risk') to take 'urgent actions' to lower their caries risk. In Article III, four biological caries risk factors (the 'diet contents', 'diet frequency', 'mutans streptococci' and saliva 'buffer capacity' parameters) did not affect self-perceived caries risk. This indicates that even though people may know that diet and bacteria are related to dental caries, most people may be unaware of their degree of risk from these factors.

The challenge goes beyond enhancing self-perception and motivation to modifying actual behaviour (Schüz et al. 2006). Even among those who already perceived themselves as being high caries risk in the 'Very high risk' and 'High risk' groups, the vast majority had two or more modifiable caries risk parameters (the 'diet contents',

'diet frequency', 'plaque amount', 'mutans streptococci' and 'fluoride programme' parameters) that could be improved.

It is interesting that the 'caries experience' parameter was a significant predictor of self-perceived caries risk. Patients were not informed of their 'caries experience' score before completing their questionnaire; it is also highly unlikely they had knowledge of the average caries experience for their age group (reported in the Irish Adult Survey 2000–2002 (Whelton et al. 2007). Yet, people seem to have a comparative awareness of their caries experience relative to their peers; thus, simply informing patients of the number of decayed teeth in their mouth may do little to enhance their risk perception and motivation. Rather, informing them of their personal risk factors and explaining the reasons why they have more dental caries than average may have more effect, as this information would be new to them.

Because the Irish study intervened with the caries risk of the study population, we have no evidence that the Cariogram could predict future caries incidence more accurately than self-perception or clinical judgement. Although the validity of the Cariogram was evaluated in prospective cohort studies (Ismail et al. 2013), its accuracy and predictive power may be similar in degree to past caries experience (Hänsel Petersson and Twetman 2015). For elderly patients in the RoI, the Cariogram exhibited a fair performance in predicting root caries (Hayes et al. 2017). Divaris notes that existing CRA models cannot be used to guide the design of precise personalised care (Divaris 2016). However, we employed the Cariogram based on the assumption that the model classifies patients into the four risk groups – 'Very high risk', 'High risk', 'Intermediate risk' and 'Low/Rather low risk', in agreement with most dental professionals once informed of the nine parameter scores of their patients. This assumption is based on previous research findings that the Cariogram is in agreement with the majority of dental instructors, dental students, general dentists and dental hygienists in ranking virtual patients according to Chance-AC (Bratthall 2000) and that the Cariogram is able to sort real patients into four or five risk groups that reflected actual caries outcome in prospective studies (Hänsel Petersson and Twetman 2015).

Score 2 for the 'clinical judgement' parameter was not used in the prospective cohort studies; within the current study population however, the MC patient distribution by the four risk groups were much more balanced using Score 2 rather than the standard setting (Score 1). It also seemed more appropriate to use Score 2 for the comparison with the self-perceived risk question in the current study, as the question asked for self-perception of caries susceptibility ('prone to dental decay') relative to the average person.

5.2.2 Limitations of Article III

As there is sample bias (Section 5.3.2), it may be difficult to generalise the results. Also, social or cultural factors can affect questionnaire responses. Article I showed that the proportion of individuals who believed they had high caries risk was higher among a Japanese health-oriented group than Article III did among the Irish low SES group. A survey in the USA showed that Asians have lower self-reported overall health ratings than non-Hispanic whites, despite having fewer chronic diseases (Kandula et al. 2007). Although the current study did not ask patients for their ethnicity and cultural background, the majority of participants are likely Irish, judging from their names. Kandula et al. (2007) attributed the difference to a cultural and linguistic basis in the analysed survey, but there are also genetic factors such as allelic variation between Japanese and Caucasian populations in the serotonin transporter gene-linked polymorphic region (5-HTTLPR) (Goldman et al. 2010). It has been shown that there are significant effects of 5-HTTLPR on social learning of fear, risk taking and the framing bias in decision-making (Crişan et al. 2009), and that there are significant higher levels of S-allele carriers (associated with enhanced fear) and lower levels of L-allele carriers (associated with reduced fear) in Japan (Goldman et al. 2010). Therefore, caution is required in comparing our findings with other populations, even when similar questionnaires are used. The data provide a basis for a bigger study with greater control over confounding factors.

5.3 Objective 3 (Article IV: caries risk profile)

5.3.1 Interpretation of the findings

The Chance-AC measured by the Cariogram in the Irish study was not notably lower than that of other adult populations in developed countries. Applying the increased risk score for the 'clinical judgement' parameter, the mean Chance-AC is similar to that of an Arabian study for an adult population with a similar mean age and mean DMFS (Merdad et al. 2010).

Just before risk assessment and randomisation were performed for the first group of the MC patients, it was revealed that the calculated average of Chance-AC was higher than expected. Possible reasons were as follows:

1. Almost all patients used both fluoridated water and fluoridated toothpaste, which converted to the most favourable score for the 'fluoride programme' parameter.
2. CRT® Bacteria (LB and MS) might be underscored.
3. The 3-day food diary (Appendix 8) is self-reported and might lead to underscoring.
4. The reference data used for 'caries experience' parameter was from 15 years ago.
5. The eligibility criteria (MC – proxy for low socioeconomic status – patients who have 20 or more than 20 teeth) may not adequately capture the lower socioeconomic group.

For adjusting such systematic situations, the use of the 'clinical judgement' parameter is recommended as mentioned in Section 2.3 (Hänsel Petersson, G. personal communication, 16 December 2011). The Irish study complied with this recommendation.

In another study using the Cariogram with the standard setting for the 'clinical judgement' parameter in adults aged over 65 years in the RoI (Hayes et al. 2017), the caries risk distribution looks similar to that of the Irish study when the increased risk setting, but not the standard setting, for the 'clinical judgement' parameter is applied.

The prominent difference between the Hayes et al. (2017) study and the Irish study in this thesis is that the Hayes et al. (2017) study only includes adults over 65 years of age whereas the current study includes adults aged 19–70 years. It is arguable that the different age criteria between the studies may not be that important as some of the risk parameters showed lower risk in the Hayes et al. (2017) study than in the Irish study. For example, the percentage of participants with xerostomia (< 0.7 ml saliva/minute) was actually lower in the Hayes et al. (2017) study than the Irish study (7% vs. 17%). The fundamental difference between these two studies, both conducted in the same city, actually lies in their scores for the 'fluoride programme' parameter (Table 5.1), although the percentages of those who used fluoridated water were not so different.

Table 5.1 Distribution of those who used fluoridated water, and those with Scores 0, 1, 2 and 3 for the 'fluoride programme' parameter in the Hayes et al. study (2017) and in the Irish study (%)

Source	Fluoridated water	Score 0	Score 1	Score 2	Score 3
The Hayes et al. study (2017)	69.2[†]	3.9	47.9	38.0	10.2
The Irish study (Article III)	93.3	95.2	0.6	4.2	0

[†]The figure was derived from another paper with the same participants (Hayes et al. 2016).

The distribution of MS in the Irish study showed much lower risk than shown by other studies (Hänsel Petersson et al. 2003; Hänsel Petersson et al. 2002; Merdad et al. 2010) and clinical data from two Japanese dental practices using Dentocult SM® (Oral Care Inc., Tokyo) (Table 5.2), although the Irish study population was expected to be economically disadvantaged (i.e. a high-risk group). Therefore, Score 0 was rounded up to Score 1 and Score 2 was rounded up to Score 3. The decision to apply this adjustment was made on 16 April 2015, just before risk assessment and randomisation were performed for the first MC patient. Note that the Cariogram was originally designed to use Dentocult® saliva test kits (Bratthall et al. 2004). According to the CRT® instruction, CRT® bacteria correlates with the Dentocult® system; however, CRT® MS reacts more sensitively and is able to detect even low bacterial count. Both tests have a model chart with four pictures assessing the density of CFU/ml saliva (Table 5.2).

Table 5.2 Distribution of CRT Bacteria® (MS) Score compared to other data using Dentocult SM® (%)

Data source	N[†]	Score 0	Score 1	Score 2	Score 3
CRT Bacteria® (MS)					
The Irish study	171	32	46	18	3
The Irish study (adjusted)	171	-	79	-	21
Saudi Arabian adults with endodontic treatment (Merdad et al. 2010)	100	27	25	26	22
Saudi Arabian adults without endodontic treatment (Merdad et al. 2010)	100	38	32	11	19
Dentocult SM®					
Swedish children (Hänsel Petersson et al. 2002)	392	39	16	24	21
Swedish elderly people (Hänsel Petersson et al. 2003)	148	16	22	41	22
Hiyoshi Oral Health Clinics, 2015[‡]	3,109	13	16	34	37
Takamori Dental Practice, 2013[§]	1,478	9	23	36	32

[†]N: Number of participants. [‡]Kumagai, T. personal communication, 10 April 2015. [§]Takamori, Y. personal communication, 25 May 2013.

The five subgroups have different characteristics; thus, oral health messages to each cluster should be different. For Cluster 3, emphasis may be on the 'saliva secretion' and saliva 'buffer capacity' parameters while for Cluster 2, emphasis may be on the 'plaque amount' and 'mutans streptococci' parameters and for Cluster 4, emphasis may be on the 'diet contents' parameter. For Cluster 1, all seven risk parameters are possibly combined and this group needs urgent actions to stop continuing caries incidence and recurrence.

Various diseases and conditions have been investigated in other health disciplines by cluster analyses. For example, a recent study dealt with obesity and presented six clusters of obesity (Green et al. 2016), strengthening the argument against a 'one-size-fits-all' approach. The same argument should apply to dental caries prevention among economically disadvantaged adults.

5.3.2 Limitations of Article IV

As a cluster analysis study is exploratory, Article IV does not provide firm evidence that there are five subgroups of dental caries risk profiles. Thus, generalisation to other low socioeconomic groups is not possible. However, examining individual variability and identifying subgroups among economically disadvantaged adults is helpful to recognise different risk profiles for dental caries.

The silhouette measure was barely acceptable. The range of the value is from -1 to 1. The higher the value, the more compact and separated are the clusters. With values from 0.2 to 0.5, the division of objects into clusters is considered fair. Although subgroups exist, the transitions between clusters were not clear-cut but a continuum.

The participating dental practitioners were volunteers and the numbers of participants by dental practitioners were so uneven; therefore it is a limitation that participants may correlate within dental practitioners.

The study population in the Irish study is not truly representative of the general population or even of Irish MC holders. Furthermore, using MC patients as a surrogate for low SES may not appropriately represent economically disadvantaged people in the RoI at present. Almost 39% of the Irish population were covered by a MC in 2014; eligibility has increased by 54% since 2005 (before the Irish economic downturn) (Health Service Executive 2015a). Table 5.3 summarises the other indicators between national data and Article IV (n = 167). Stricter criteria such as identifying long-term MC holders would be more appropriate but for practical reasons the current criteria were the best we could do for this study.

Table 5.3 Indicators of education level, smartphone ownership, and dental utilisation between national data and Article IV

Indicators	Article IV (%)	National data (%)	Note	References
Education level of third level or higher	35	34	Irish people aged 15–64 years in 2014	The Central Statistics Office (2015)
Smartphone ownership	80	70	An Irish survey in 2015	Behaviour & Attitudes (2015)
Attendance for MP	68	54	The Irish data in 2000/2002 among those aged 35–44 years	Guiney et al. (2011)
Smokers, C2[†] Smokers, DE[‡]	31	22.7 24.1	Lower socioeconomic groups in the RoI	Paul and David (2015)

[†]C2: skilled manual workers. [‡]D: semi-skilled and unskilled manual workers. [‡]E: unemployed.

5.4 Objective 4 (Article V: personalised mHealth for caries risk)

5.4.1 Interpretation of the findings

Article V tried to compare the effects of personalised versus non-personalised interventions via mobile-phone short text messaging on caries risk, assessed using the Cariogram, in an economically disadvantaged adult population. However, a definitive conclusion could not be reached. As the MCID was included in the 95% CI for the per-protocol analysis, replication studies will be worth conducting.

The reason for considering one- or two-message deviations as acceptable for the per-protocol analysis was that an error of less than three messages had occurred in the rounding procedure for deciding the number of text messages to be sent from each risk-sector (See Section 3.2.4.1). The reason the sample size of the personalised group (n = 21) was considerably smaller than that of the non-personalised group (n = 33) is likely because the sending of personalised combinations versus a fixed combination of text messages is more open to errors.

Time factor deviations were ignored because we found from the questionnaire that 98.2% of MC patients answered that they understood text messages they had received

and 94.3% of MC patients affirmed that receiving oral health information via text messages was useful.

The 'saliva secretion' parameter was significantly influenced in the personalised group for the ITT analysis, although the number of sent text messages with relevant information was not many. For the per-protocol analysis, all of the 21 participants had Score 0 or 1 (**Lower score**). On the other hand, we had not expected this risk parameter to be feasibly modified and had excluded it from the analysis for Objective 2 (Footnote #8). The reasoning behind this decision is that hereditary factors, which are not modifiable, significantly influence an individual's saliva secretion rate (Opal et al. 2015), compared to the other modifiable parameters: the 'diet contents', 'diet frequency', 'plaque amount', 'mutans streptococci' and 'fluoride programme' parameters. Looking at knowledge of the corresponding risk factor under Objective 1, approximately 70% of the MC patients did not know that a reduced amount of saliva is a caries risk factor at baseline. This was the second least identified caries risk factor after the saliva buffering capacity. From these results, providing information on caries risk factors/indicators they are not already familiar which would have greater impact when informing the patient of the results of his/her individual CRA. Yet, the positive change in stimulated saliva amount at the follow-up examination may not indicate a true increase of saliva amount in daily life, as participants in the personalised group may have tried drooling more saliva, possibly because they learned from their personalised letter that they did not have enough saliva, and from their text messages that it is an important factor.

One reason for the unclear difference of Chance-AC between the two groups may be the sensitive design of the current study. The non-personalised group were sent the six highest prioritised text messages for each risk-sector, which would include the messages that would also be chosen for the personalised group in accordance with the individual's risk profile. Also, in order to have the same letter volume as for the personalised group, the non-personalised letter included advice taken from the Cariogram (non-personalised) which would have overlapped with the (personalised) advice given to the personalised group (Appendix 10) As a result, unless a participant had a prominent risk profile, the interventions to the personalised participants were apt to be similar to those for the non-personalised participants. In a randomised controlled trial for smoking cessation

sending mobile-phone text messages to both test and control groups, all text messages for the test group were personalised ones related to quitting and all text messages to the control group were clearly unrelated to quitting (Free et al. 2011). In another study for weight loss, although there was some overlapping information between the test and control groups, the test group received personalised mobile-phone text messages two to five times daily plus other services whereas the control group received the print material only once a month (Patrick et al. 2009). Our study did not have such clear contrast in interventions between the test and control groups. The current study was designed with an ethical concern to provide appropriate advice to those with non-personalised intervention and with a much narrower interest that aimed to look into the effect of a personalised combination of text messages based on each individual's CRA, while keeping other conditions as equal as possible between the test and control groups. It was unfortunate that the protocol violations greatly affected our sensitive study design, which required precise, small differences between the personalised and non-personalised groups. If another control group not being sent text messages had been used, it would have been possible even with the protocol violations to validate that the mHealth intervention benefited both personalised and non-personalise group for caries risk reduction. Originally, we had considered **customer engagement** for a long-term effect (Singh 2011) as a social entrepreneur approach for behaviour change for in the study design. A service which applies this theory, Rapport Builder®, is available in Japan. Instead of the dentist, Rapport Builder® regularly sends emails to patients in order to stimulate customer engagement. As no scientific investigation has been conducted on the effect of Rapport Builder®, it is of interest whether sending emails or using some other mHealth service is more effective than short text messaging. Emails can contain limitless characters with entertainment elements, including images such as the personalised Cariogram chart. This would have been much more informative and advantageous to the personalised group. However, because when this study was designed only 57% of mobile-phone customers owned a smartphone in the RoI (Google 2013), we estimated this percentage would be even lower in a disadvantaged group and opted for short text messaging instead of emails. Since an exponential rise in smartphone use was expected in the RoI, we included the question on smartphone ownership in the CRF for a future study. The response indicated that approximately three-quarters of the

participants already had a smartphone. Therefore, services via smartphone would be the choice for mHealth today, even in a disadvantaged population in the RoI.

The vast majority of MC patients had knowledge that some people are more susceptible to caries than others at follow-up. The large imbalance in the proportion having this knowledge at baseline between the personalised group (63.6%) and the non-personalised group (85.5%) was reduced at follow-up, although the percentage remained lower in the personalised group (89.1%) than in the non-personalised group (94.5%). Because the text messages did not contain information on individual susceptibility to dental caries, it is probable that the information on the randomised controlled study that accompanied the informed consent forms (Appendix 6) influenced awareness in both groups, and that the personalised letter giving their CRA results helped to increase awareness on individual susceptibility at follow-up in the personalised group (Appendix 10).

As the text messages did not provide information on the individual's CRA results, it is probable that the personalised letter also had an effect on self-perceived caries risk. At baseline, only in the personalised group with 'Very high risk' was self-perceived caries risk greater than in the non-personalised group. At follow-up, the non-personalised group's risk perception decreased from baseline, but interestingly there was a clearer association between Chance-AC and perceived risk than at baseline although they had not yet been informed of the results of their CRA. In the personalised group, self-perceived risk increased from baseline. However, it was surprising that more than half of 'Very high risk' patients in the personalised group still did not admit they had caries risk, even though they had been directly informed that they were at 'Very high risk'.

With the exception of some commonly known risk factors/indicators which more than 80% of MC patients were able to identify at baseline, knowledge of caries risk was increased at follow-up both in the personalised and non-personalised groups. Looking at the less known risk factors/indicators, the effect of the intervention via the letter plus text messages to increase knowledge of caries risk was clear. Generally, the more text messages received on a topic, the greater the effect. Although the dentists were told not to alter their standard practice, they might have given a more time to prevention advice

when recruiting the MC patients. Therefore, the increased knowledge may not be due only to the letter and text messages.

The study was retrospectively registered, as when we had commenced the study we were adhering to the European Union's definition of a clinical trial. Almost all MC participants in the Irish study reported that receiving mobile-phone short text messages on oral health information was useful (94.3%). The percentage was quite similar to a recent study on effectiveness of mobile-phone short text messaging on controlling diabetes (Dobson et al. 2018), which found high levels of satisfaction with the text messaging educational programme: 161 (95.3%) of 169 participants reported it was useful, and 164 (97.0%) were willing to recommend the programme to other people with diabetes. Considering these results together with the positive comments from MC patients (Appendix 13), it is evident that an educational programme with an even simple technology is highly acceptable to patients.

5.4.2 Limitations of Article V

The response rate was low and may cause selection bias. Even though we gave a rather high compensation (€50) to encourage participant compliance, results showed that 79 out of 191 participants (41.4%) did not comply with the study procedure. The reasons may be as follows:

1. the study population of MC patients (low SES) is difficult to keep compliant,
2. reminder text messages were not actually sent to 15 participants (60% of them did show for the follow-up examination),
3. Dentist H changed her work place during the period of follow-up examinations.

Another limitation is that the time frame varied largely from individual to individual. The effect of educational text messages may be decreased when there are lengthy time delays, as the long-term effect of mHealth is still uncertain (Marcolino et al. 2018).

It should also be noted that a number of statistical tests were applied for Article V due to the protocol violations. However, no method was used to counteract the problem of multiple comparisons, such as the Bonferroni correction, because the study protocol was violated and the data could only be analysed to provide information for designing future research, not as a definitive study.

5.4.3 Protocol violation

There were protocol violations in the Irish study by the programmer from beginning to end of the intervention (i.e. sending of text messages). Because these activities reduced the quality and completeness of the data, it is considered that 'protocol violations' rather than 'protocol deviations' occurred, as per the definition of these terms (Bhatt 2012).

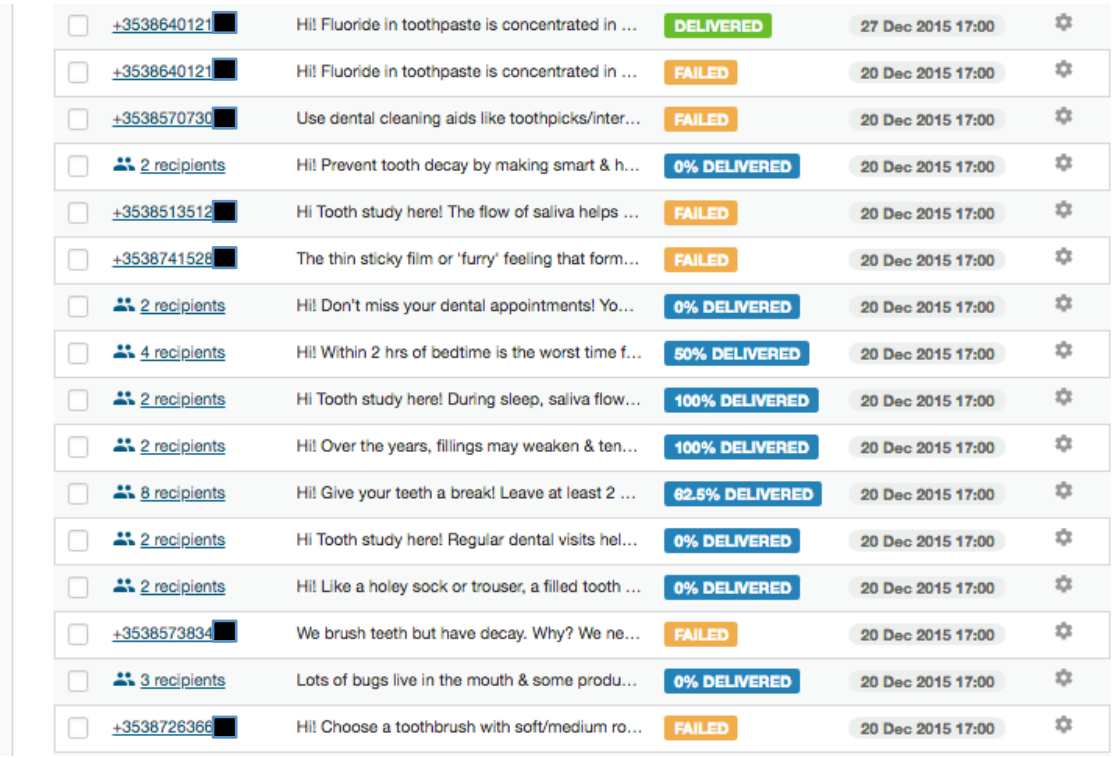
Text messages to be sent consisted of three kinds as follows:

- one introductory, confirmation message of mobile-phone number (if the patient did not reply, another message(s) was (were) sent) during week 1
- 24 educational messages from week 2 to week 25, and
- one reminder message for the follow-up examination at week 26.

The actual log issued by TextMagic revealed that among 171 MC patients who were supposed to receive text messages, 20 MC patients were not sent the confirmation massage, 148 MC patients were not sent 24 different educational messages and 15 MC patients were not sent the reminder message. There were 73 pairs of duplicate and two sets of triplicate messages sent to some MC patients. The programmer did not adhere to the decided time (between 5 and 6 pm on Sundays) when text messages should have been sent. For example, 44 pairs of different text messages were sent simultaneously; 18 text messages were sent on a different day and/or time from the decided day and/or time. For the combinations of educational messages, five MC patients were sent a largely incorrect combination of text messages, because they were wrongly allocated between the personalised and non-personalised groups by the programmer.

For the sending of text messages, MC patients were grouped into batches according to the week they were recruited. There were 30 batches (week-groups). Therefore, the programmer was supposed to send text messages for 55 weeks (= 30 + 26 - 1). Failures occurred every week; however, the failures had been ignored even though TextMagic has multiple functions to flag delivery failures (Figure 5.1). Among the 111 MC patients included in the final analysis (Objective 4: Article V), only two and nine patients in the personalised and non-personalised groups, respectively, received their educational messages as planned within the scheduled 24-week time period.

Reasons for these protocol violations may be computer program failure, non-compliance with the protocol, dereliction of duty and human errors. This section focuses on computer program failure. Describing these technological issues and making recommendations to ensure it does not happen again has merit for future studies using mHealth. Each week, the program was supposed to choose and display the appropriate text messages to be sent each MC patient. However, on the first Sunday, the program failed to send two out of 50 text messages. On the second Sunday, the program entered only 43 of 67 text messages to be sent into TextMagic and three of the 43 messages failed to send. On the third Sunday, the program entered only 37 of 72 messages to be sent by TextMagic. After the third week, one MC patient informed us on 14 May 2015 that she had not received any text messages for two weeks via email. The programmer acknowledged that his computer program did not work properly and entered text messages and mobile-phone numbers onto the TextMagic website manually. However, he continued to rely on the computer program to display the text messages to be sent.



+3538640121[redacted]	Hi! Fluoride in toothpaste is concentrated in ...	DELIVERED	27 Dec 2015 17:00
+3538640121[redacted]	Hi! Fluoride in toothpaste is concentrated in ...	FAILED	20 Dec 2015 17:00
+3538570730[redacted]	Use dental cleaning aids like toothpicks/inter...	FAILED	20 Dec 2015 17:00
2 recipients	Hi! Prevent tooth decay by making smart & h...	0% DELIVERED	20 Dec 2015 17:00
+3538513512[redacted]	Hi Tooth study here! The flow of saliva helps ...	FAILED	20 Dec 2015 17:00
+3538741528[redacted]	The thin sticky film or 'furry' feeling that form...	FAILED	20 Dec 2015 17:00
2 recipients	Hi! Don't miss your dental appointments! Yo...	0% DELIVERED	20 Dec 2015 17:00
4 recipients	Hi! Within 2 hrs of bedtime is the worst time f...	50% DELIVERED	20 Dec 2015 17:00
2 recipients	Hi Tooth study here! During sleep, saliva flow...	100% DELIVERED	20 Dec 2015 17:00
2 recipients	Hi! Over the years, fillings may weaken & ten...	100% DELIVERED	20 Dec 2015 17:00
8 recipients	Hi! Give your teeth a break! Leave at least 2 ...	62.5% DELIVERED	20 Dec 2015 17:00
2 recipients	Hi Tooth study here! Regular dental visits hel...	0% DELIVERED	20 Dec 2015 17:00
2 recipients	Hi! Like a holey sock or trouser, a filled tooth ...	0% DELIVERED	20 Dec 2015 17:00
+3538573834[redacted]	We brush teeth but have decay. Why? We ne...	FAILED	20 Dec 2015 17:00
3 recipients	Lots of bugs live in the mouth & some produ...	0% DELIVERED	20 Dec 2015 17:00
+3538726366[redacted]	Hi! Choose a toothbrush with soft/medium ro...	FAILED	20 Dec 2015 17:00

Figure 5.1 An example of the indicators to flag delivery failures on the TextMagic website

The failures of the program (which the programmer had certified) were examined by a third party (Realize Mobile Communications Corp., Tokyo), who reported that there might be repeated manual adjustments/copy & paste of data, or repeated manual sending of text messages might have added human errors to program errors but that the fundamental reason of failure was that the program did not operate and had incorrect logic.

Two bugs were found as follows:

(1) The program could not display a list of text messages to be sent.

a) Failure event

Although the program was designed to display the text messages to be sent by entering the patient's mobile-phone number, an error actually occurs and text messages were not displayed.

b) Reason

In the database (table) named "Cariogram_before_test", the column named "week_group" which the program needs does not exist.

(2) The program could not correctly determine the number of text messages to be sent to the personalised group.

a) Failure event

The 25th text messages are not sent.

b) Reason

There is an error in the termination conditions of loop processing and only 24 messages are sent.

Some bugs and glitches are inevitable in mHealth research and it is recommended to perform internal and external testing prior to the beginning of an mHealth intervention (Ben-Zeev et al. 2015). Before the intervention commenced in our research project, the programmer was instructed to test his program with 20 different real mobile numbers for a trial. It is unclear whether this test was carried out, as the TextMagic log does not show that any text message based on CRA was tried before the intervention commenced in our research project.

One important lesson for the fidelity of an intervention is the importance of having a third person monitor the intervention process. In this case, we could have allocated a third person to sign in to TextMagic and examine actual logs every week. It is also recommended to add multiple dummy recipients who monitor text messages received during the intervention period. Another lesson is to always evaluate the pros and cons when you change the situation. We had originally planned to use the services of Rapport Builder® (Oral Care Inc., Japan), which inspired the current study. However, in the interests of maintaining communications at a local level and reducing the cost, we instead decided on 23 September 2014 to develop a locally available software and enlisted as our programmer an undergraduate student for his bachelor dissertation project in the School of Computer Science and Information Technology, UCC. In hindsight, precautions should have been taken for the involvement of a relatively

inexperienced student programmer in the research team. Precautions should have included the drawing up of an official contract with technical specifications for his participation plus clear terms of reference outlining the responsibility of the student as a research team member, and the provision of appropriate training on Research Integrity[35] (Smith 2008).

On a final note, the experience of this work indicates the importance of using validated software for mHealth interventions using messaging applications (Ben-Zeev et al. 2015), the need for training staff (Smith 2006) and for monitoring the software to deliver the required intervention (Ben-Zeev et al. 2015).

5.4.3.1 Impact of the protocol violations

Although the protocol violations affected both groups, the personalised group was more affected than the non-personalised group, due to having more complicated combinations of text messages to be sent. As a result, the sensitive study design which required precise, small difference of caries risk reduction between the personalised and non-personalised groups was impacted. For the per-protocol analysis, the sample size of the personalised group decreased to 38% whereas the non-personalised group decreased to 60%. Therefore, it was more difficult to determine the effect of the personalised intervention.

However, looking at the small difference of the outcomes, even without such protocol violations, the intervention only with the different combinations of text messages (not the different contents) between the personalised and non-personalised groups might have shown a limitation of effectiveness.

[35] University College Cork. Research Integrity. [accessed 7 June 2018]. https://www.ucc.ie/en/research/support/integrity/.

6 CONCLUSIONS

This chapter will draw conclusions and make recommendations for future research. The overall aim of this thesis was **to investigate the impact on caries risk reduction of a personalised dental education approach based on individual CRA using mobile-phone short text messages in an economically disadvantaged adult population in the RoI.** Literature covering the four themes underlying the overall thesis aim was reviewed to address the four thesis objectives.

6.1 Objective 1 (Articles I and II: knowledge of caries risk)

Hypothesis 1-1 was not supported by the results of "*Not visiting the dentist for check-up and cleaning*" and "*Not using fluoride*": a higher proportion of the MC patients identified these factors compared with the Japanese patients regarded to have greater knowledge of preventive dentistry, indicating that country differences had a stronger influence on patients' knowledge than SES differences. On the other hand, the results of "*Having a reduced amount of saliva (spit) in the mouth*" supported Hypothesis 1-1: this factor was less known as a caries risk factor among the Irish MC patients. Hypothesis 1-2 was not supported by the results: there was no difference in the total number of correctly identified caries risk factors/indicators between the MC patients and the Japanese patients regarded to have greater knowledge of preventive dentistry. Furthermore, persistent belief in tooth brushing for caries prevention and lack of knowledge about saliva buffering capacity were similar tendencies both in the Irish and Japanese studies despite their different cultural and socioeconomic backgrounds. This implies that there is a general need to inform patients of the defensive role of saliva in both groups, in both countries. In addition, understanding the influence of a population's social/cultural profile on knowledge deficiency of caries risk is important, particularly when designing programmes to enhance patient knowledge.

6.2 Objective 2 (Article III: self-perceived caries risk)

Hypotheses 2-1 and 2-2 were supported by the results: there was an association between Chance-AC and self-perceived caries risk in an economically disadvantaged adult population in the RoI; however, those at high risk of dental caries underestimated their risk level in an economically disadvantaged adult population in the RoI. In addition, Hypothesis 2-3 was supported by the results: caries risk factors/indicators were associated with self-perceived risk in the population in the RoI. These findings imply that caries prevention strategies for behaviour change can be tailored according to actual and self-perceived caries risk for maximum effectiveness amongst MC patients.

6.3 Objective 3 (Article IV: caries risk profile)

Hypothesis 3-1 was not supported by the result: Chance-AC as measured by the Cariogram among MC patients in the RoI was not lower than in adult populations in developed countries. However, Hypothesis 3-2 was supported by the results: (1) there was individual variability of Chance-AC among the MC patients; and (2) individuals could be clustered into five subgroups according to seven aetiological caries risk parameters. Therefore, applying a personalised preventive approach amongst MC patients would be reasonable.

6.4 Objective 4 (Article V: personalised mHealth for caries risk)

Hypothesis 4-1 was not supported by the results: no difference in Chance-AC existed between the personalised and non-personalised groups. Hypothesis 4-2 was supported only by the result of the ‘saliva secretion’ parameter for the ITT analysis: a difference in the number of MC patients with high risk scores of the ‘saliva secretion’ parameter

exists between the personalised and non-personalised groups. Hypothesis 4-3 was not supported by the results: no difference in self-perceived caries risk exists between the personalised and non-personalised groups among the MC patients. Hypothesis 4-4 was not supported by the results: there was no difference in knowledge of caries risk factors/indicators between the personalised and non-personalised groups. However, due to the serious protocol violations, these were not definitive conclusions. It is worth further exploring the potential of mobile-devices for individual caries risk reduction.

6.5 Recommendations for future research

Among the Irish MC patients, the percentages of those identifying "*Having a reduced amount of saliva (spit) in the mouth*" were comparatively low. It is not known whether this response was influenced by their lower SES or by some other country-specific factor; a further study is necessary to confirm the reason.

Individual variability in the aetiological caries risk factors among economically disadvantaged adults has an important implication for policymakers and clinicians. Any future caries prevention efforts may as well be based on individual variability in caries risk profiles for the improvement of oral health towards the ultimate goal, **'Health for all'** (World Health Organisation 1978).

Further well-designed studies on personalised mHealth for caries prevention are necessary to prove its effectiveness. Information technology has been progressing rapidly; the more advanced mobile-devices have greater potential for individual caries prevention approaches. Not only personalised combinations of educational messages but also the contents of educational messages personalised to the individual that relates, for example, with the patient's personal information and/or results of their Cariogram and results of their baseline knowledge and perception questionnaires will be easily possible. Some smartphone instant messaging applications signal the sender when the receiver has read a message; information on whether the participant opens the message or not is

useful. Artificially intelligent chatbots will easily enable an interactive approach with participants and may give greater motivation to participants.

The insufficiency of knowledge on the saliva factor can be improved by educational text messages. A personalised letter presenting individual caries risk plus personalised text messages will significantly increase knowledge on this risk factor.

That some people are more susceptible to caries than others was successfully relayed to a vast majority of study participants via a letter plus text messages. However, even after being informed directly that they were at high caries risk via a personalised letter, most of them did not comprehend what this meant. Therefore, different strategies will be necessary to educate them of their caries risk.

For research projects based on sending text messages, it is recommended to allocate a third person who regularly monitors an actual log and to add multiple dummy recipients who monitor text messages received during the intervention period in order to rectify any failures as soon as possible. Prior to the intervention, participants should be encouraged to report any message failures.

The cost of applying mHealth for personalisation is significantly less than the cost of other approaches without information technology. Still, research on cost-effectiveness is necessary because the amount of work required for personalisation is considerably greater than for a non-personalised intervention. If a personalised strategy is proved effective, but the effectiveness is quite small compared to the time and labour required for personalisation, a non-personalised approach will be more practical.

In the Irish study, the Cariogram was used as a risk model, not a prediction model. However, even as a risk model, more accurate assessment would of course still be preferable. The development of caries risk prediction tools is still on the way; complicated interactions and different weights of multiple risk factors make risk prediction difficult. New technologies such as deep learning may be applied to create a new type of caries prediction model (Berg 2014). Such technology is able to memorise big quantities of data and improves its accuracy continuously.

Findings in this thesis will be useful to drive all the four components of 'P4 medicine' (Personalised, Predictive, Preventive and Participatory) for mHealth caries prevention in lower SES groups. Because oral health is significantly associated with general good health and quality of life, effective mHealth for caries prevention in the future is expected to contribute to the wellbeing of the individual and society to a great extent.

In summary, recommendations for caries risk interventions for an economically disadvantaged adult population in Ireland corresponding to the results of this thesis are listed as follows:

- To improve knowledge on saliva factors for caries prevention;
- To improve self-perceived caries risk among high risk patients;
- To develop personalised caries prevention strategies according to both actual and self-perceived caries risk;
- To conduct a well-designed randomised controlled study investigating the effectiveness and efficiency of mHealth for caries risk reduction.



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Appendix 1 Search strategies

Caries risk

Symbol	Concept	Search Strategy (PubMed)
C	Dental Caries	“Dental Caries"[Mesh] OR “dental, caries”[All Fields] OR “tooth, decay*”[All Fields] OR “teeth, decay*”[All Fields] OR "cavit*"[All Fields] OR “carious"[All Fields]
R	Risk	“Risk”[Mesh] OR “risk” [All Fields]
F	Filters	Filters: Humans; English; Japanese; Adult: 19+ years

All searches were performed in January 2018

PubMed: (C + R + F) = 1,425

Update searches were performed in June 2018

PubMed: (C + R + F) = 1,487

Newly retrieved articles:

1,487 - 1,425 = 62

mHealth

Symbol	Concept	Search Strategy (PubMed)
C	Dental Caries	“Dental Caries"[Mesh] OR “dental, caries”[All Fields] OR “tooth, decay*”[All Fields] OR “teeth, decay*”[All Fields] OR “cavit*”[All Fields] OR “carious"[All Fields]
M	mHealth	“Telemedicine"[Mesh] OR “Cell Phone”[Mesh] OR mHealth[All Fields] OR eHealth[All Fields] OR Telehealth[All Fields] OR “cell phone”[All Fields]
F	Filters	Filters: Humans; English; Japanese; Adult: 19+ years

All searches were performed in January 2018

PubMed: (C +R + F) = 5

Update searches were performed in June 2018

PubMed: (C +R + F) = 5

Newly retrieved articles:

5 - 5 = 0

Appendix 2 Patients' knowledge and perception of caries risk

Author, year, country	Sample, n, age (years)	Measurement	Findings
Astrøm et al. (1999), Norway and Tanzania	(1) 374 women in Norway and (2) 140 women in Tanzania Range: (1) 25 years and (2) 15–40 years; 60% was 15–25 years.	Questionnaires were conducted. The questions relevant to caries risk were as follows: (1) "*As compared to other people of your own age and gender how do you perceive your own risk of once during your lifetime having severe tooth decay gum disease? Needing dentures?*" 3 response categories (2) "*How likely or unlikely do you think it is that you some time in your lifetime will experience severe tooth decay?*" 5 response categories (2) "*As compared to neighbouring women of your own age, how do you perceive your own risk for once in your lifetime experiencing severe tooth decay?*" 5 response categories Actual risk factors/indicators were symptoms of tooth decay and intake sugary products.	The Tanzanian women made realistic judgments about the likelihood of oral health hazards occurring, taking into account own experience with actual risk factors/indicators. Both Norwegian and Tanzanian women to some extent underestimated their comparative vulnerability regarding oral health hazards. The Tanzanian women appeared to be more optimistic regarding oral health hazards than the Norwegian women.
(Catteau et al. 2016), France	99 health workers from 8 geriatric nursing homes Range: 20–59 years	Questionnaires were conducted. Participants identified the risk factors of dental caries (frequent sugar-rich food consumption, bacterial plaque presence, host susceptibility, head and neck radiotherapy and repeated intake of sweetened medical syrups) and a non-risk factor (calcium deficiency).	Sugar-rich diet and ineffective or lack of oral hygiene were correctly identified by the participants. In contrast, they lacked knowledge of mouth dryness due to head and neck radiation. Nonetheless, those who had received training in maintaining oral health had better scores.

Author, year, country	Sample, n, age (years)	Measurement	Findings
Gaszynska et al. (2015), Poland	1,380 pregnant women Range: 15–44 years	Questionnaires were conducted. The questions relevant to caries risk were as follows: "*If parents had a high tendency to develop caries, their children will, for hereditary reasons, have their teeth strongly affected by caries (false)*", "*Fluoridation of drinking water reduces the incidence of caries*" and "*Eating an apple before going to sleep is an effective substitute for washing the teeth by a child in the evening (false).*" Responses were "*true*", "*false*" or "*I don't know*".	61% of the respondents rated their knowledge and practical skills concerning care for their teeth and that of their expected child as limited, inadequate or none. A positive correlation was found between the self-assessed sufficient knowledge of the pregnant women and their oral health.
Hoeft et al. (2010), the USA	48 Mexican-American mothers of young children Mean (SD): 31 (5.6)	Face-to-face interviews were conducted. Questions were: "*Why do you think [your] child has caries?*", "*What caused those problems [caries]?*" and "*Why do you think your child does not have caries?*"	The mothers understood the key biomedical influences of sugar consumption, oral hygiene, and bottle use in caries aetiology, but had a limited depth of knowledge, especially of the mechanisms that generate carious lesions in teeth.
Lin et al. (2001), China	1,573 subjects aged 35–44 1,515 subjects aged 65–74	Knowledge of the causes of caries and periodontal disease was assessed by face-to-face structured interviews (Schwarz and Lo 1994): "*What do you think causes tooth decay/gum disease?*" and "*What do you think you can do to prevent tooth decay/gum disease?*"	More than half of the participants gave 'do not know' as the answer to the 4 questions (2 for tooth decay and 2 for gum disease). The most frequently cited causes for dental caries were sugar or sweet food, poor oral hygiene and 'Chinese explanation'. Those who had more positive oral health attitudes and better dental knowledge had better toothbrushing habits.

Author, year, country	Sample, n, age (years)	Measurement	Findings
Schwarz and Lo (1994), Hong Kong	1) 398 subjects aged 35–44 and (2) 559 subjects aged 65–74	Knowledge of the causes of caries and periodontal disease was assessed by face-to-face structured interviews: "*What do you think causes tooth decay/gum disease?*" and "*What do you think you can do to prevent tooth decay/gum disease?*"	The distribution of knowledge scores on the full 12-point scale was close to normal for the younger group, whereas the scores of the older age group were skewed heavily toward 0. Within the age groups, increased level of education and regularity of recency of dental visits were strongly associated with dental knowledge.
Stein et al. (2015), Norway	130 patients in a university dental hospital Mean: 48 ; Range: 21–80	Knowledge of bacteria, sugar and frequent meals as a caries risk factor was assessed by questionnaires.	92%, 96% and 62% of the patients had knowledge of bacteria, sugar and frequent meals as a caries risk factor, respectively. LB in saliva and knowledge of risk factors for periodontitis and caries were predictor variables for a health literacy score.
Syrjala et al. (2002), Finland	149 insulin-dependent diabetes mellitus patients Mean: 34 ;Range: 16–72	Questionnaires were conducted. One question to measure belief about outcome was relevant to knowledge of a caries risk factor. "*By brushing the teeth twice a day or more often, one can prevent decaying*" with four reply alternatives.	63.8% and 25.5% of the patients answered, 'completely true' and 'moderately true', respectively. A better dental attitude including belief about outcome was related to better diabetes adherence and fewer decayed surfaces.
Worthington et al. (1997), the UK	2,553 patients from 24 general dental practitioners ≥ 25 years	The patients were sent a postal questionnaire which included questions relating to their own predicted need for treatment during the next 12 months, knowledge of brushing teeth, and reason for cleaning teeth and preventing caries. The dentists examined the patients 12 months after their baseline dates. Throughout the 12-month period, all restorations and extractions were recorded on a specially designed form.	31 variables were identified as potential predictors for the two dependent variables 'receiving treatment' and 'receiving treatment related to caries'. Patient's prediction of the need for a filling was one of the most important variables.

Appendix 3 Caries risk profiles with aetiological factors

Author, year, country	Sample, n, age (years)	Diet	Microflora	Host	Findings
Akpata et al. (2009), Kuwait	42 patients with severe caries and 36 caries-free subjects ≥ 16 years	Daily sugar consumption Salivary LB count	The O'Leary hygiene index Salivary MS count	Stimulated salivary flow rates, Resting salivary flow rates Salivary buffering capacity	The patients with severe caries had a significantly higher frequency of sugar consumption, plaque index, LB and MS counts, as compared with those who were caries-free. No significant difference was observed in salivary flow rates or buffering capacity between the two groups of patients.
Al Mulla et al. (2009), Saudi Arabia	100 orthodontic patients Mean: 17.5 years Range: 12–29 years	The full Cariogram parameters according to its manual			Mean (SD) Chance-AC: 75 (16); CV: 0.21 in low caries group (≤ 2 DFS) and 42 (19); CV: 0.45 in high caries group (≥ 5 DFS). The low caries group displayed low values for LB and MS, and high Cariogram percent. The plaque index displayed very close significance.
Almosa et al. (2012), Saudi Arabia	(1) 45 patients in three governmental orthodontic clinics and (2) 44 patients in three private orthodontic clinics Mean: (1) 22.5 and (2) 21.2 years	The full Cariogram parameters according to its manual			Mean (SD) Chance-AC: (1) 28 (24); CV: 0.86 and (2) 61 (28); CV: 0.46. Based on the Cariogram, caries risk in the governmental clinic group was greater than in the private clinic group. The number of DMFS, plaque index, saliva buffer capacity, and counts of LB and MS were the most significant risk factors/indicators when the two groups were compared. Although the Cariogram is a practical pedagogic tool, further longitudinal validation of the Cariogram as a CRA tool in orthodontic patients is required.

Author, year, country	Sample, n, age (years)	Diet	Microflora	Host	Findings
Arino et al. (2015), Japan	732 patients from 9 private dental practices Mean (SD): 42.2 (12.5) Range: 20–64	LB count	MS count	Stimulated saliva Buffering capacity	Cariogenic bacteria are important factors for both the onset and accumulation of primary and secondary caries.
Chaffee et al. (2015a), the USA	18,004 patients in a university dental hospital Mean (SD): 47.3 (17.1) Range: 18–99	Frequent snacking (> 3x daily)	Visible heavy plaque on teeth	Stimulated saliva flow (> 1 ml/minute), fluoride toothpaste, mouth rinse, and varnish use	The CAMBRA caries risk assessment tool was used. The distribution of caries risk factors, such as recent disease history, frequent snacking, inadequate oral hygiene practices, and reduced salivary flow rate, differed sharply over the caries risk categories. CAMBRA can validly separate patients into groups with greater or lesser potential for future dental caries.
Carta et al. (2015), Italy	480 subjects randomly selected from the municipal electoral registry Mean: 40.73	Diet content and frequency from questionnaires	Salivary MS count Plaque amount and grade of oral hygiene (from clinical examination)	Fluoridation programme (from questionnaires)	The simplified Cariogram was used. More than two-thirds of the sample showed a medium risk (41–60 of Chance-AC), and most of the remaining sample showed a high risk (21–40 of Chance-AC) of future caries development. The Cariogram was able to identify caries-related factors in an adult population.
Chang and Kim (2014), South Korea	110 special needs patients with general anaesthesia Mean (SD): 23.7 (9.3)	Diet content and frequency	The Silness-Löe plaque index Salivary MS counts	Unswallowed saliva Salivary buffering capacity	The simplified Cariogram was used. The large variances existed in the data, resulting in the mean (SD) Chance-AC being 27.6 (22). (CV: 0.80)

Author, year, country	Sample, n, age (years)	Diet	Microflora	Host	Findings
Chang et al. (2014), South Korea	(1) 102 patients with intellectual disabilities and (2) 100 without intellectual disabilities in a university dental hospital (1) Mean (SD): 23.8 (9.3); Range: 13–66 (2) Mean (SD): 23.19 (3.3); Range: 15–30 years	The full Cariogram parameters according to its manual			Mean (SD) Chance-AC: (1) 28.1 (20.4); CV: 0.73 and (2) 54.7 (18.4); CV: 0.34. Those with severe intellectual disabilities had higher DMFT scores and a higher risk of developing caries risk compared to patients without intellectual disabilities. Based on the Cariogram, the diet, susceptibility, and circumstance sectors differed between the two patient groups; the bacterial sector including MS counts was the exception to this finding.
Coogan et al. (2008), South Africa	24 male and 3 female dental students Range: 20–22	LB on the teeth, the broth impression technique and in saliva A 4-day dietary record: sucrose intake and frequency, and fibre intake	A plaque index MS on the teeth by the broth impression technique and in saliva	Resting and stimulated saliva samples The buffering capacity using a modified Driezen test Lysozyme in saliva	Although the sample size was small, growth of cariogenic microorganisms on alginate impressions, saliva flow and dietary fibre predicted caries activity in most subjects.

Author, year, country	Sample, n, age (years)	Diet	Microflora	Host	Findings
Dens et al. (1996), Belgium	42 bone marrow recipients Mean: 34	Salivary LB count	Salivary MS count	Stimulated salivary flow rates and buffering capacity	A dramatic reduction of salivary flow rate was observed in all patients at 1 month after transplant, and only a partial recovery was seen after 4 months. A clear shift towards a lower buffer capacity and a higher amount of LB and MS were seen post-transplant.
Epstein et al. (1996), Canada	52 patients after radiation therapy for head and neck cancer Mean (SD): 55.2 (13.5)	Salivary LB count	Salivary MS count	Fluoride gel (5000 ppm) application Resting and stimulated saliva	Radiation dose, number of fractions, and duration of radiation had a significant inverse effect on post-radiotherapy whole resting saliva and on whole stimulated saliva. Differences in the mean caries incidence between those who reported compliance with daily fluoride application and those who did not comply were not found significant because of the large SD in the patient groups, although differences in the mean for these groups were seen.
Fadel et al. (2011a), Saudi Arabia	110 patients with periodontal disease Mean (SD): 38.0 (15)	The full Cariogram parameters according to its manual			Mean (SD) Chance-AC: 63 (25); CV: 0.40. The full Cariogram was used. There were no statistically significant differences between the three periodontal severity groups in number of root lesions or mean Chance-AC. Of the total sample, 22% displayed high caries risk (Chance-AC $\leq$ 40%). The most significant risk indicators in high caries risk patients were infrequent use of fluoride and unfavourable salivary and microbial parameters. About half of the patients were suffering from one or more systemic conditions and were taking medications for various conditions, such as asthma, hypertension, hypothyroidism and diabetes.

Author, year, country	Sample, n, age (years)	Diet	Microflora	Host	Findings
Fadel et al. (2011b), Saudi Arabia	(1) 54 patients with coronary artery disease and (2) 73 patients with no history of coronary artery disease Means (SD):(1) 52 (14.0) and (2) 49 (13.9)	The full Cariogram parameters according to its manual			Mean Chance-AC: (1) 31 and (2) 40. Significantly more participants with coronary artery disease exhibited low salivary-secretion rates than controls. A higher percentage of participants in the test group did not use any fluoride toothpaste. Salivary counts of cariogenic bacteria were notably higher in the control group than in the test group. This effect may have been of a relatively low magnitude when observing that of other parameters such as fluoride practice or counts of salivary mutans streptococci.
Fadel et al. (2013), Sweden	89 with psoriasis and 54 without psoriasis > 40 years	The full Cariogram parameters according to its manual			There were no differences in the experience or risk of dental caries in individuals with and without psoriasis. The psoriasis group had fewer remaining teeth and demonstrated a lower salivary buffering capacity.
Farsi (2008), Saudi Arabia	312 patients in a university dental hospital Ages: 6–11, n = 114; 12–17, n = 99; 18–40 older, n = 99	Salivary LB count	Oral hygiene levels using the Green and Vermillion method Salivary MS count Salivary yeast presence	Resting and stimulated saliva Salivary fluoride, pH and buffering capacity	A caries prevention strategy based on multiple screening phases that includes simple clinical assessment and a diversified pattern of tests is suggested.
Filipi et al. (2011), Czech Republic	50 gastro-oesophageal reflux disease patients	Salivary LB count	Salivary MS count The Papilla Bleeding Index	Stimulated salivary flow rates and buffering capacity	There was a low buffering capacity in 54.2% of patients and a high buffering capacity in only 8.3%. There were only four patients with high counts of MS. It is possible that because pH in the mouth of patients with active gastro-oesophageal reflux disease is so low, that metabolic activity of MS ceases.

Author, year, country	Sample, n, age (years)	Diet	Microflora	Host	Findings
Fure (2004), Sweden	200 subjects Ages 55, n = 98; 65, n = 56; 75, n = 37; 85, n = 9	24-h recall diet record The number of occasions of fermentable carbohydrate, solid or liquid intake Salivary LB count	The percentage of tooth surfaces harbouring plaque was examined. Salivary MS count	The use of fluoride in toothpaste, rinse, tablets or chewing-gums Resting and stimulated saliva samples	There is an increased risk of dental caries with age owing to unfavourable caries-related factors. The mean saliva secretion rates were lower and the overall salivary counts of LB and MS had increased in the older groups compared with the 'younger' ones.
Guivante-Nabet et al. (1999), France	117 hospitalised patients Mean (SD): 83.0 (7.8); Range: 64–102	Salivary LB count	Salivary MS count The modified Greene and Vermillion oral hygiene index	Stimulated saliva and buffering capacity	The negative relationship between saliva buffering capacity and active root caries was the strongest relationship in the study. There was an association between the type of hospitalisation (long-term care vs. rehabilitation facilities) and both stimulated saliva flow rate and plaque index.
Hänsel Petersson et al. (2003)	148 participants in a follow-up study Ages: 60, n = 69; 70, n = 51; 80, n = 28	The full Cariogram parameters according to its manual			Mean (SD) Chance-AC: 41 (20.55); CV: 0.5. The participants were assigned fairly evenly according to Chance-AC into four risk groups: 0–20 (n = 39), 21–40 (n = 25), 41–60 (n = 53) and 61–100 (n = 31). The number of new lesions (secondary caries and root surface lesions) after five years had large variations. In this study, the Cariogram was able to sort elderly individuals into risk groups that reflected their actual caries outcome after five years.

Author, year, country	Sample, n, age (years)	Diet	Microflora	Host	Findings
Hänsel Petersson et al. (2013), Sweden	1,295 patients in the Public Dental Service Age: 19	The full Cariogram parameters according to its manual			Mean (SD) Chance-AC was 60.9 (22.9); CV: 0.38. The agreement between the Cariogram and the Public Dental Service guidelines was acceptable for young adults with 'low' or 'some' risk (Chance-AC: 41–80), while the agreement was fair for those with high risk.
(Hayes et al. 2016; Hayes et al. 2017), the RoI	334 dentate older adults living independently Mean (SD): 69.11 (4.26)	The full Cariogram parameters according to its manual			69.2% of the participants used fluoridated water, 26.9% did not and 3.9% were not sure. Only 7% of the participants were categorised as xerostomic. Chance-AC into five risk groups: 0–20 (n = 74), 21–40 (n = 81), 41–60 (n = 88), 61–80 (n = 55) and 81–100 (n = 36). It is indicated that the Cariogram may be clinically useful in predicting future root caries incidence in independently living older adults.
Lee et al. (2013), South Korea	80 patients in a university dental hospital Mean: 23.0 (3.3)	The full Cariogram parameters according to its manual			The mean (SD) Chance-AC was 55.5 (20.3); CV: 0.37. All cases were assigned a score of 0 for the related general disease factor of the Cariogram model. A simplified Cariogram with the exclusion of salivary secretion rates and LB count may be used in clinical practice when a full inclusion of risk factors is not achievable. The Cariogram can be used to determine individual risk profiles of patients in need of preventive and/or restorative dentistry.
Lundgren et al. (1997), Sweden	108 subjects Ages: 88, n = 92 4 years later, 24 of the 92 were examined and 16 newly admitted 92-year-olds were added	Salivary LB count	Plaque score Salivary MS count S. mutans S. sobrinus	Stimulated saliva Buffer capacity Salivary sugar clearance time	The proportion of untreated decayed root surfaces, plaque score and the levels of LB increased significantly between the ages of 88 and 92 years.

Author, year, country	Sample, n, age (years)	Diet	Microflora	Host	Findings
Masalin (1992), Finland	232 confectionery workers	Salivary LB count Eating habits for a seven-day period	Salivary MS count	Stimulated saliva Buffer capacity	Use of xylitol-sorbitol chewing-gum and xylitol tablets was found to increase salivary flow and buffering capacity of the confectionery workers.
Merdad et al. (2010), Saudi Arabia	(1) 100 patients with 2 or more endodontically treated teeth and (2) 100 patients with no endodontically treated tooth in a university dental hospital Mean (SD): (1) 34.3 (12.3) and (2) 32.9 (12.8)	The full Cariogram parameters according to its manual			Mean (SD) Chance-AC: (1) 28.1 (20.4); CV: 0.73 and (2) 54.7 (18.4); CV: 0.34. There was no difference of caries risk between groups of individuals with multiple versus no endodontically treated teeth. Salivary MS count was significantly higher in the endodontic group compared to the control group.
Nishikawara et al. (2006), Japan	152 subjects Mean (SD): 36.1(12.6)	Salivary LB count	The O'Leary hygiene index, salivary MS count	Stimulated salivary flow rates and buffering capacity	There was a correlation between salivary LB level and flat caries for several stages of caries.
Powell et al. (1998), the USA	261 subjects Ages: < 65, n = 38; 66–70, n = 65; 71–75, n = 67; 76–80, n = 49; > 80, n = 39	Salivary LB count	Salivary MS count	Stimulated saliva, buffering capacity	Demonstrated the value of baseline DMFS and salivary variables to modelling caries incidence and introduced ethnicity as a variable useful for the study of dental caries in older adults.

Author, year, country	Sample, n, age (years)	Diet	Microflora	Host	Findings
Ravald and Hamp (1981), Sweden	31 patients referred to periodontitis. Mean (SD): 48.2 (9.1) Range: 34–73	Salivary LB count	The Plaque Control Record	Stimulated saliva Buffering capacity	Root caries development was observed for 4 years. Significant correlations were demonstrated between the initial pre-treatment score for salivary LB count and developing new root surface caries, and between low saliva secretion rate during the course of the study and root surface caries.
Ravald and Birkhed (1991), Sweden	147 patients with periodontal disease Mean (SD): 52 (10.6); Range: 30–78	Salivary LB count A dietary habit index	Salivary MS count The prevalence of dental plaque	Stimulated saliva Buffer capacity Salivary sugar clearance time	LB count, plaque index, salivary buffering capacity, dietary habit index and number of exposed root surfaces contributed significantly to the coefficient of determination.
Ravald and Birkhed (1992), Sweden	27 patients referred to periodontists. Mean (SD): 59.2 (8.2); Range: 47–79	Salivary LB count A dietary habit index	Plaque score Salivary MS count	Stimulated saliva Buffering capacity	Root caries in this population was generally a minor problem. From a long-term perspective, salivary counts of LB and MS and dietary habits seemed to be the most useful variables in the evaluation of root caries risk. However, no single variable was found to be sufficiently discriminative to predict root caries development.

Author, year, country	Sample, n, age (years)	Diet	Microflora	Host	Findings
Rothen et al. (2014), USA	1,400 patients of a network of member-dentists Ages: 9–17, n = 350; 18–64, n = 682; 65 and older, n = 368	Snacking assessed by questionnaire: between-meal carbohydrates snack (per day), sugar-added beverages (per week)	Readily-visible heavy plaque	Fluoride toothbrushing use assessed by questionnaire: frequency per day, water rinse after brushing, other fluoride products Stimulated salivary pH	The frequency of fluoride toothbrushing and the presence of readily-visible heavy plaque were the factors most strongly associated with mean caries rate. SES factors are investigated but are only used for adjustments in the analysis of the relationship between dental caries and oral hygiene.
Ruiz Miravet et al. (2007), Spain	48 first-year dentistry undergraduates	The full Cariogram parameters according to its manual			The study attempted to develop a more simplified prediction model than the Cariogram for large population groups from the predictive variables with the highest correlation to caries risk. This model was based on four variables (DMFT index, MS count, plaque index and salivary buffer capacity) and its results were close to those of the Cariogram.
Sonbul et al. (2008), Saudi Arabia	175 patients with minimum of ≥ 7 teeth with dental restorations Mean: 29.5 Range:18–56	The full Cariogram parameters according to its manual			Mean (SD) Chance-AC: 31 (19.7); CV: 0.64. Patients with several restorations were divided according to Chance-AC into four risk groups: 0–20 (n = 66), 21–40 (n = 43), 41–60 (n = 50) and 61–100 (n = 16).

Author, year, country	Sample, n, age (years)	Diet	Microflora	Host	Findings
Sonbul and Birkhed (2010), Saudi Arabia	100 patients in a university dental hospital Mean (SD): 29 (8.8)	The full Cariogram parameters according to its manual			Mean (SD) Chance-AC: 30.9 (19.41); CV: 0.63. The patients were categorized according to Chance-AC into three risk groups: 0–20 (n = 38), 21–40 (n = 28) and 41–100 (n = 34). Recurrent caries was related to the three risk groups.
Staufenbiel et al. (2015), Germany	100 vegetarians and 100 non-vegetarians Mean (SD): 41.45 (14.14); Range: 21–81 years	Patients' eating habits assessed by questionnaire: consumption of fruits and chewing gum	The O'Leary hygiene index	Topical fluoride application assessed by questionnaire: toothpaste, table salt, gel, and vanish	Vegetarians showed better oral hygiene than non-vegetarians. Daily consumption of fruits was significantly more prevalent, and topical fluoride application was less prevalent in vegetarians compared with non-vegetarians. Vegetarians have an increased risk for caries and erosion, although vegetarians had a higher level of education than non-vegetarians.
Stein et al. (2015), Norway	130 patients in a university dental hospital Mean: 48 Range: 21–80	LB count	MS count	Stimulated saliva	There was a significant correlation between low health literacy and high count of LB in saliva. Because high counts of LB in saliva reflect the consumption of simple carbohydrates by the host over time, those with low oral health literacy may not maintain their oral health as well as those with high oral health literacy.

Author, year, country	Sample, n, age (years)	Diet	Microflora	Host	Findings
Szymanska et al. (2014), Sweden	(1) 71 Crohn's disease patients who had undergone intestinal surgery, (2) 79 patients who had not and (3) 75 controls Mean (SD): (1) 50.7 (13.9), (2) 42.0 (14.4), and (3) 50.7 (13.9)	Salivary LB count Frequency of meals and consumption of sweetened drinks between meals	Salivary MS count Visible Plaque Index	Resting and stimulated saliva samples	Crohn's disease patients who had undergone surgery had higher DMFS scores compared to patients without Crohn's disease after adjusting for age, gender and smoking. Both patient groups consumed more sweetened drinks between meals, higher LB and MS levels compared to the controls.

Appendix 4 PCP programmes

Author, year, country, study design	Sample, n, age (years)	Risk assessment	Preventive programme	Findings
Anusavice (2001), the USA Review	-	Low risk, moderate risk, and high risk	Diet and oral hygiene control, monitor for new lesions at 3–12 month recall periods, professional and home flossing with 1% CHX, periodic F, monitor at 1–6 month recall periods until risk is reduced (< 2.5 x 105 CFU MS/mL)	A systematic review was conducted and suggested that assigning therapeutic regimens to individuals according to their risk levels should yield a significantly greater probability of success and better cost effectiveness than applying identical treatments to all patients independent of risk.
Arino et al. (2015), Japan Retrospective follow-up (The mean follow up time was more than 3 years.)	732 patients from 9 private dental practices Mean (SD): 42.2 (12.5); Range: 20–64	After initial treatment, the stimulated saliva flow rate, saliva buffering capacity and SM and LB levels were assessed.	The preventive treatments included education on plaque control, scaling and polishing, and fluoride application with 9,000 ppm NaF solution. All patients used a toothpaste containing 900 ppm fluoride daily. The risk-based recall visits took place between 3 and 6 months.	Within three years, 9.8% of the patients developed primary caries and 12.2% developed secondary caries.

Author, year, country, study design	Sample, n, age (years)	Risk assessment	Preventive programme	Findings
Bader et al. (2001), the USA Systematic review	27 studies (29 preventive interventions) were included in the review.	Caries-active or high caries risk classifications based on any combination of decayed, filled and/or missing primary and/or permanent surface or tooth scores, or through microbiological testing.	Fluorides, chlorhexidine, combinations of chlorhexidine and other preventive agents, an antibiotic, occlusal sealants, an alum rinse, distribution of a high risk protocol to treating dentists, chewing-gum, Adding calcium phosphate to a standard fluoride regimen.	The strength of the evidence was judged to be fair for fluoride varnishes and insufficient for all other methods. For the management of non-cavitated carious lesions, the strength of the evidence for efficacy was judged to be insufficient for all methods.
Berg (2014), the USA Review	-	Historical and environmental information to determine the risk level based upon interview data; employment of various forms of technology to assess distinct outcomes measures as determinants of risk.	Managing the disease process by mitigating risk instead of identifying the disease at a later stage when surgical restorative intervention is required.	CAMBRA was introduced.
Cunha-Cruz et al. (2015), the USA Protocol of a randomised controlled trial	82,000 subjects (0 to 21 years old) and pregnant women	Population-centred Risk- and Evidence- based Dental Interprofessional Care Team (PREDICT) will be used. For test group, risk-based preventive and caries stabilization services will be provided. For control group, preventive treatments (not risk based) will be provided.		-

Author, year, country, study design	Sample, n, age (years)	Risk assessment	Preventive programme	Findings
Curtis et al. (2008); Curtis et al. (2011); Warren et al. (2010), Australia 2-year follow-up randomised controlled trial	(1) 450 patients with standard care patients and (2) 452 patients with the CMS from 22 dental practices Mean (SD): (1) 45.8 (19.9) and (2) 43.9 (19.5)	Risk was categorised according to the CMS criteria. Risk change was categorised as 'Same', 'Improved', or 'Worse'.	Oral hygiene coaching, topical fluoride application (both professional and home care), monitoring of plaque control and treatment outcomes at each visit and recall programme tailored to caries risk status (Evans et al. 2008).	There was a significant difference in the two-year incremental DMFS score in the CMS group compared to the control group. The CMS approach appears to be cost-effective for patients at medium and high risk of developing dental caries when compared to the current standard care provided by private dental practices.
Domejean et al. (2011), the USA Retrospective follow-up, (The mean (SD) follow-up time was 16 (12.6) months.)	2,571 follow-up CAMBRA appointment patients in a pre-doctoral dental clinic A mean birth year of 1958 (median 1958; mode 1956)	The low and moderate risk determination was based on the number of protective factors and number of disease risk factors. Presence of any disease indicator automatically determines high risk. Presence of any disease indicator plus dry mouth automatically determines extreme risk.	The caries risk patients should have received preventive treatment interventions, which would have provided increased protective factors and altered their caries balance more favourably. However, only 55% of the total at-risk patients were provided with specific home care recommendations that were captured using the electronic health record.	The data have not been analysed to determine whether those who were provided with specific recommendations had less cavities. Of those assessed as high or extreme risk at baseline, the percent of patients who had new cavities at follow was 69.3% and 88%, respectively.

Author, year, country, study design	Sample, n, age (years)	Risk assessment	Preventive programme	Findings
Evans et al. (2008), Australia Review	-	Assessments of diet, plaque, and stimulated saliva. According to caries lesion status with clinical examination and bitewing radiographic survey, the patient's caries risk status is determined as low-, medium- or high-risk.	According to their caries risk, case presentation about caries lesion status, diet advice, oral hygiene instruction and coaching, managing caries lesions with professional and home topical fluoride use are provided. Diet, plaque control, fluoride exposure and treatment outcomes at each visit with individual interval (3 to 24 months) are monitored.	The Caries Management System (CMS) was developed for use by general practitioners according to a new Caries Management Policy. The policy has been adopted by the Faculty of Dentistry, University of Sydney, where learning and teaching within the new curriculum is designed to be informed by evidence-based practice.
Featherstone et al. (2003); Featherstone et al. (2007); Jenson et al. (2007); Young and Featherstone (2013); Young et al. (2007); Young et al. (2010), the USA Review	-	Caries experiences, LB and MS, visible heavy plaque, frequency of snacking, deep pits and fissures, recreational drug use, saliva flow, saliva reducing factors, exposed roots, orthodontic appliances, fluoride use, chlorhexidine, xylitol use and calcium and phosphate paste are assessed. Risk levels are low, moderate, high and extreme risk.	For the 4 risk levels, frequencies of radiographs, recall exams and saliva test (saliva flow & bacterial culture) are decided. Prescriptions of and chlorhexidine and xylitol are decided.	CAMBRA was introduced.

Author, year, country, study design	Sample, n, age (years)	Risk assessment	Preventive programme	Findings
Cheng et al. (2015); Featherstone et al. (2012), the USA, Randomised controlled trial (24-month follow-up period)	(1) 57 in test group and (2) 52 in control group Mean: (1) 39.2 ± 14.7; Range: 21–77) and (2) 40.9 ± 14.8 years; Range: 20–84	Fluoride level in saliva and salivary LB and MS counts. The patients were assigned to a low- or high-risk group.	(1) High-risk group: topical NaF gel application during the clinic visit every 6 months, daily toothbrushing with F toothpaste and daily rinsing with chlorhexidine gluconate. Low-risk group: daily toothbrushing with F toothpaste (2) oral hygiene instruction, dental cleaning and oral examination every 6 months, radiographs every 24 months and restorative treatment as needed	For mean caries increment, no statistically significant difference was observed. Caries risk reduced significantly in intervention versus control over 2 years. There was a significant difference between groups for change in MS bacterial challenge but not for LB counts or fluoride level. The test group's combined action was more effective than the action of any single variable.
Flink et al. (2016), Sweden Retrospective follow-up (The mean follow up time was > 16 years.)	(1) 88 caries-active individuals and (2) 31 caries-inactive individuals Mean (SD): (1) 39.5 (6.2) and (2) 41.0 (6.3)	(1) Those who developed manifest caries lesions in ≥ 2 teeth in the last 3 years and (2) those who had been free from manifest dental caries for ≥ 3 years.	Caries prophylaxis measures taken were recorded as 'Basic prophylaxis' including information, recommendations, performed prophylaxis and instructions, and 'Risk prophylaxis' including supplementary investigations and recommendations of risk treatment.	60% of the caries-active individuals did not experience that they became free from caries (i.e. not needing fillings). The caries-active patients had significantly more DT than caries-inactive patients over the course of the study period.

Author, year, country, study design	Sample, n, age (years)	Risk assessment	Preventive programme	Findings
Fontana and Gonzalez-Cabezas (2012), the USA Case report	63-year-old woman	A health/ dental history and a clinical examination, the subjective impression of the clinician, caries experience, socio-demographic indicators, saliva, bacteria, diet and fluoride use.	To provide frequent counselling and exposure to in–office fluoride, the recall interval was set at four months for this moderate to high-risk patient.	An objective, easy to implement, and validated risk assessment instrument is desirable and this is reflected in multiple risk assessment tools. Examples for adults include the American Dental Association's caries risk tool for adults, the CAMBRA tool for adults and the Cariogram.
Ghezzi (2014), the USA Review	-	Targeted antibacterial and fluoride therapy based on salivary microbial and fluoride levels. CAMBRA and NIH consensus were cited.		With the exception of fluoride, the current body of evidence on adjunct therapies for elderly people is too weak to establish definitive claims of effectiveness. (Chlorhexidine, xylitol, CPP-ACP, ozone and herbal liquorice)
Hansel Petersson et al. (2016), Sweden 3-year follow-up	982 patients from 8 public dental clinics Age: 19	The adult guidelines for risk assessment of oral diseases issued by the Public Dental Service. Four risk categories were used: low risk, some risk, high risk and very high risk.	The delivered preventive care to each patient was categorised into oral health information, extra fluoride therapy and professional tooth cleaning.	Most prevention measures were carried out in some risk group followed by the low-risk group. High risk and very high risk patients displayed significantly more new caries lesions and fillings than those with lower risk.

Author, year, country, study design	Sample, n, age (years)	Risk assessment	Preventive programme	Findings
Hummel and Phillips (2016), the USA Review	-	The screening assessment falls into two categories: 1) Is the person at risk for oral disease because of salivary dysfunction, poor oral hygiene or excessive exposure to sugary snacks and drinks? and 2) Is there anything to suggest early (or advanced) caries or periodontal disease?	The goals of a Population Health Management Approach are to reduce oral health risk factors through education, dietary counselling and oral hygiene training, to monitor all individuals for caries and periodontal disease, to assure that appropriate stepped therapy takes place for mild, moderate and severe caries and periodontal disease.	A Population Health Management Approach to Oral Health was introduced.
Ito et al. (2011); Ito et al. (2012), Japan Retrospective follow-up (The follow-up time was 3 years.)	442 patients from a single dental practice Range: 20–64	The stimulated saliva flow rate, saliva buffering capacity and SM and LB levels were assessed.	Preventive treatments included education on plaque control, advice on diet, scaling and polishing and fluoride application with 9,000 ppm NaF solution. All patients used a toothpaste containing 900 ppm fluoride twice a day. The risk-based recall visits took place between 3 and 6 months.	Within 3 years, 8.8% of the patients developed primary caries and 10.6% developed secondary caries.

Author, year, country, study design	Sample, n, age (years)	Risk assessment	Preventive programme	Findings
Lallam and Decup (2014), France Case report	13-year-old adolescent, 32-year-old man and 79-year-old woman	Interview (systemic factors and behavioural factors) Clinical examination (local factors)	To impact behavioural characteristics (eating and hygiene habits, smoking, drinking, drug addictions etc by giving information, explanations and advice. To change the local factors (improving biofilm removal and control and using remineralising and antiseptic molecules).	PCP approach is not covered by insurance in France. In a general dental practice, the challenge is to use this approach systematically with all patients, while taking account of the specific needs of each and every patient to provide personalised care.
Sbaraini and Evans (2008), Australia Prospective 6-momth follow-up	45 patients referred to the Caries Management Clinic ,	Only high-risk patients were included in the study; it is unknown how caries risk of the patients was assessed.	Professional applications of topical fluoride varnish, intensive coaching and monitoring of toothbrushing using 5,000ppm strength fluoride toothpaste and chlorhexidine gel. Six 2-weekly coaching sessions were held over a 3-month period.	The CMS was used. The follow-up period was only 6 months, but the CMS resulted in maintaining low plaque levels, decreasing gingival inflammation and reducing caries incidence and progression. In general, the patients were unable to change their dietary habits.
Soderstrom et al. (2014), Sweden Retrospective 7-year follow-up	(1) 200 high-risk patients and (2) 200 no/low-risk patients in the Public Dental Service Mean: (1) 46.8 and (2) 43.1	(1) ≥ 3 new caries lesions, extensive progression of several enamel lesions, lesions on non caries-prone surfaces and (2) no active enamel or dentine caries lesions	Population-based prevention plus individualised preventive and non-operative caries measures in accordance with the minimally invasive caries concept and national guidelines. The recall visits took place between 6 and 24 months.	High-risk patients continued to develop disease at a higher level than low-/no-risk patients. Preventive measures for high-risk patients were only marginally different in type and amount for low-/no-risk patients.

Author, year, country, study design	Sample, n, age (years)	Risk assessment	Preventive programme	Findings
Teich et al. (2013), the USA Prospective follow-up (The mean follow up time was 12.2 months.)	68 patients with at least moderate caries risk in a pre-doctoral clinic at one dental school Mean (SD): 57.7 (14.5)	The CAMBRA was used.		The students incorrectly used the CAMBRA guidelines and underestimated the risk in 25% of the cases. Only 44.1% received required fluoride varnish; 43% of the patients had caries at follow-up.

Author, year, country, study design	Sample, n, age (years)	Risk assessment	Preventive programme	Findings
Templeton et al. (2016), the UK Convergent mixed-methods design	196 dentists Mean (SD): 40.0 (10.9); Range: 25–65	Six behaviours were selected as key best-practice recommendations: recording risk, using risk-based recall intervals, applying fluoride varnish, placing preventive fissure sealants, demonstrating oral health maintenance and taking routine bitewing radiographs.		National guidance on oral health assessment in adults and caries prevention and management in children by the Scottish Dental Clinical Effectiveness Programme (SDCEP) and Scottish Intercollegiate Guidelines Network (SIGN) were used. Dental team members had positive attitudes toward guidance but emphasised guidance as often too long, complicated, and not universally applicable or practical. Patients identified multiple long-term benefits of preventive oral health care but were unsure about the efficacy of their self-care techniques, were anxious about dental appointments, and struggled with care of children's teeth.

Author, year, country, study design	Sample, n, age (years)	Risk assessment	Preventive programme	Findings
Warren et al. (2016), Australia Post-trial 4-year follow-up study	214 patients	Diet assessment, plaque assessment, bitewing radiographic survey and CRA	All patients were encouraged to improve their tooth brushing skills through coaching. Fluoride varnish application to non-cavitated lesions, the frequency of which is risk-determined (3-monthly applications for high risk patients and 6-monthly for medium risk patients) was instituted.	The CMS was used. If the CMS protocol is adhered to, the incremental clinical effect is sustainable over the long-term. The CMS is most cost-effective in patients with a high risk of dental caries.
Zickert et al. (2000), Sweden (1) Follow-up study (The follow up time was 6 years.) and (2) Comparison study	(1) 3,115 patients Most of the patients were < 50 years old (2) 907 patients for questionnaire (3) 100 for the capitation model of care and 100 for control	Weighting the criteria obtained from case history, clinical and radiographic examinations and supplementary laboratory examinations. The patients were assigned to a low-, medium- or high-risk group.	Basic information, an individually designed preventive programme, encouragement to try to stay free from dental caries and periodontal diseases by using self-administered home care	98% of the patients who participated in the questionnaire stated that they preferred the capitation model of care to fee-for-service. The capitation group had lower new caries lesions than the control group. The average cost per person and year was lower in the capitation patients than in the patients from the reference clinic. The capitation model stimulated both dentists and patients to apply existing prevention knowledge.

Appendix 5 Questionnaires of the Japanese study

The original questionnaires were in Japanese. Question numbers adhere to original numbers.

Dentist questionnaire (only the relevant questions to the current thesis)

Q2 Do you perform personalised caries prevention in any way? ("personalised caries prevention" means "caries prevention based on caries risk assessments according to individual patients"). Please choose only one of the following:

Yes

No

Q3 What percent of individual adult patients receive personalised caries prevention in your practice?

%

Patient questionnaire

"Caries Prevention"

1 Tooth-decay does not affect all people universally, but some get tooth-decay easily and others do not, even though they practice the same preventive methods. Did you know that the probabilities (risk) of getting tooth-decay differ from individual to individual?

Please choose **only one** of the following:

☐Yes

☐No

2 Generally speaking, what do you think is (are) the reason(s) for susceptibility (risk) of getting tooth-decay?

Please choose **all** that apply.

☐Not brushing your teeth properly

☐Bad eating habit

☐Having naturally 'weak teeth'

☐Not visiting the dentist for a dental maintenance programme (check-ups and cleaning)

☐Not using fluoride

☐Having particular bacteria in the mouth that contribute to the development of dental decay

☐Low saliva flow rate

☐Low quality of saliva

☐Other (please specify):

3 Do you think that you are at high susceptibility (risk) of getting tooth-decay?

Please choose **only one** of the following:

☐Yes

☐No

☐I do not know

4 In the dental practice where you visit, do they conduct a custom-made tooth-decay prevention and instruction programme based particularly on your tooth-decay susceptibility (risk) as determined by an assessment of your personal risk by examining contents and frequency of diet, asking use of fluorides, performing saliva tests and so on?

Please choose **only one** of the following:

☐Yes

☐No

4-2 If "Yes", would you recommend such a personalised caries prevention programme to your family or friends?

Please choose **only one** of the following:

☐Definitely would

☐Probably would

☐Neutral

☐Probably would not

☐Definitely would not

4-3 If "No", what is (are) the main reason(s) for you not receiving such a custom-made tooth-decay prevention programme?

Please choose **all** that apply.

☐Cost

☐Time

☐I did not know about them.

☐My dentist does not do.

☐They are not necessary.

☐Other

5 Do you go to the dentist for a dental maintenance programme (check-ups and cleaning)?

Please choose **only one** of the following:

☐Yes

☐No

5-2 If "Yes", would you recommend a dental maintenance programme (check-ups and cleaning) to your family and friends?

Please choose **only one** of the following:

☐Definitely would

☐Probably would

☐Neutral

☐Probably would not

☐Definitely would not

5-3 If "No", what is (are) the main reason(s) for you not attending the dentists for the dental maintenance programme?

Please choose **all** that apply.

☐Cost

☐Time

☐I did not know about them.

☐My dentist does not do.

☐I cannot find a reliable dentist.

☐They are not necessary.

☐Other

6 How strongly do you agree with these statements?

Please choose the appropriate response for each item:

	Strongly agree	**Somewhat agree**	**Neither agree nor disagree**	**Somewhat disagree**	**Strongly disagree**
Overall, I am satisfied with all aspects of my dental treatment or maintenance programme or both.	☐	☐	☐	☐	☐
Caries risk assessment should be included in the insurance system.	☐	☐	☐	☐	☐
The more I visit the dentist for check-up, the more teeth, I think, are drilled.	☐	☐	☐	☐	☐
As people are more interested in prevention than before, some dental practices use it only for advertisements and perform ineffective prevention programmes.	☐	☐	☐	☐	☐
If the general public demand strongly, dentistry will be driven to change.	☐	☐	☐	☐	☐

“Promoting Scientific Assessment in Prevention of Tooth Decay and Gum Disease (PSAP)”

7 Did you know about the PSAP?

Please choose **only one** of the following:

☐Yes

☐No

7-2 If “Yes”, how did you hear about the NPO?

Please choose **only one** of the following:

☐My dentist

☐Books, journals

☐The website

☐Social networking (Twitter, Facebook)

☐Through an acquaintance

☐Other

7-3 If "Yes", are you a member of the PSAP?

Please choose **only one** of the following:

☐Yes

☐No

8 Are you interested in activities of the PSAP?

Please choose **only one** of the following:

☐Strongly yes

☐Somewhat yes

☐Neither yes nor no

☐Somewhat no

☐Not at all

“Finally”

Gender

Please choose **only one** of the following:

☐Female

☐Male

Age

Please choose **only one** of the following:

☐19 or less than 19

☐20-29

☐30-39

☐40-49

☐50-59

☐60 or more than 60

Are you a dental professional (dentist, dental hygienist, dental assistant and dental technician)?

Please choose **only one** of the following:

☐I am not a dental professional.

☐I am a dental professional.

Today's Date

Please enter a date:

Thank you very much. Please make sure if you answer all the questions.

Please don't hesitate to give us any comment.

Appendix 6 Informed consent form of the Irish study

To be printed on OHSRC headed notepaper

Subject Information and Informed Consent Form

Protocol No: OHSRC00114 Title: Electronic-based personalised dental education for caries prevention in a disadvantaged population: a randomised controlled study

Subject Name: _____

Dentist directing the Research: Professor Finbarr Allen

You are being asked to participate in a research study. The sponsoring company for this study is Unilever, and it is supported by the International Association for Dental Research. The doctors and dentists at University College Cork study the nature of disease and attempt to develop improved methods of diagnosis and treatment. In order to decide whether or not you want to be a part of this research study, you should understand enough about its risks and benefits to make an informed judgement. This process is known as informed consent. This consent form gives detailed information about the research study, which will be discussed with you. Once you understand the study, you will be asked to sign this form if you wish to participate.

What is the purpose of the study?

Almost all adults have experienced tooth decay. However, some are more prone to tooth decay than others. This study aims to examine the effect of receiving regular oral health messages (sent by text messaging) on preventing tooth decay in adults.

What does this study involve?

- Your dentist will explain the study to you and answer any questions you might have after reading this information and consent form.
- If you decide to take part, you should sign the consent form. Your dentist will then interview you on your medical and dental history, and examine your teeth for dental decay. He/she will also measure the amount of plaque on your teeth.
- You will be asked to provide a sample of saliva (spit) for testing. The amount of saliva you produce will be measured, along with the ability of your saliva to help prevent tooth decay. The amount of decay-causing bacteria in your saliva will be determined from a sample your dentist will send to the laboratory at the Oral Health Services Research Centre.

- You will be asked to complete a questionnaire and a 3-day diet record, listing the foods and drinks you take over that time. The completed information should be returned to the Oral Health Services Research Centre in the stamped addressed envelope provided. Once we have received the documents we will reply to you by letter, enclosing some advice on avoiding dental decay plus a voucher for €20 to thank you for participating in the study.
- The project team will send a text message to you each week for 24 weeks, using computer technology. You will be randomly assigned (like tossing a coin) to one of two groups of participants in the study. Half of the participants will be sent text messages from one list of possible messages, and the other half will be sent text messages from a second list.
- After 6 months, you will return to your own dentist, who will interview and examine you and take a saliva sample, just as at your first visit. You will again be asked to complete a questionnaire and 3-day food record, and to send the completed documents to the Oral Health Services Research Centre in the stamped, addressed envelope provided.
- Once we receive the questionnaire and diet record, we will send you a thank-you letter including all of the information on your own risk of developing dental decay (calculated using a computer programme from the results of your dental examinations, saliva tests, questionnaire and food diary entries), plus a voucher (€30) to thank you for completing the study.
- **What are the possible benefits in taking part?**
  At the end of the study, you will receive a full personalised assessment of your risk of developing dental decay over the following 12 months, along with personalised advice on how to help reduce your risk of developing dental decay.
- **What are the possible risks in taking part?**
  There are no additional risks associated with the study procedures.

What are my rights in relation to this study?

You are free to refrain from participation in this study or to withdraw from the study at any time. If you do decide to withdraw from the study, your withdrawal will be

treated without prejudice. You will be informed in a timely manner, if any information becomes available that may be relevant to your willingness to continue in the study.
If you do not comply with the study procedures, you may be withdrawn from the study. The Investigator, the Ethics Committee, or the sponsors of the research may withdraw you from the study at any time without your consent if it is considered to be in your best interests or in the interests of the research.
You will be paid expenses totalling €50 if you complete the study (€20 voucher after this visit, and €30 voucher after the second visit in six months time). This payment will cover any travel expenses you may incur when travelling to your dentist's surgery.
Dental treatment and cleaning are not provided as part of the study.
Approximately 200 subjects will participate in this research study.

If you consent to take part in this study the information collected during the study will be stored by the investigator in accordance with international guidelines. For purposes of the Data Protection Act, the investigator fulfils the specified role of the Data Controller. The information may also be made available (both within and outside of the European Union) to staff from the sponsoring company, auditors and members of the Ethics Committee, for the purposes of data verification. Only the investigator and his/her clinical staff will know that the information is related to you and this information is kept separate and confidential. The results of the study may be published in the medical literature, but your identity will not be revealed.

If you would like to be part of this project, please complete the Consent form on the next page and return it to your dentist.
Pregnant women are not suitable for this study, because it would be very difficult to take part in the follow-up visit in six months time. If you are, or believe you may be pregnant, you have no need to continue. You should hand the form back telling your dentist that you do not wish to take part. Thank you for your interest.
This project was developed by the Oral Health Services Research Centre, UCC, Cork.

Agreement to Consent

The research study and the procedures associated with it have been fully explained to me. All procedures have been identified and no guarantee has been given about the possible results. I have had the opportunity to ask questions concerning any and all aspects of the project and any procedures involved. I am aware that participation is voluntary and that I may withdraw my consent at any time. I am aware that my decision not to participate or to withdraw will not restrict my access to health care services normally available to me. Confidentiality of records concerning my involvement in this project will be maintained in an appropriate manner. If the results of the research are published, my identity will remain confidential. When required by law, the Clinical Research Ethics Committee and the sponsors of the research will have direct access to my records for verification of study data and procedures, without violating confidentiality.

I understand that the investigators have such insurance as is required by law in the event of injury resulting from this research.

I, the undersigned, hereby consent to participate as a subject in the above described research study. I have received a copy of this consent form for my records. I understand that if I have any questions concerning this research, I can contact Professor Finbarr Allen at (021) 4901186. If I have any questions concerning my rights in connection with the research, I can contact the Clinical Research Ethics Committee of the Cork Teaching Hospitals at 021-4345599. If I have any queries about the study procedure I can contact Professor Finbarr Allen at (021) 4901186 during office hours.

After reading the entire consent form, if you have no further questions about giving consent, please sign where indicated.

Signature of Subject: _____

Date: _____ Time:_____

Signature of Person Taking Consent_____

Date _____ Time:_____

Appendix 7 Questionnaires of the Irish study

Baseline Questionnaire

Please complete and return this questionnaire and the 3-day diet record in the stamped addressed envelope provided.

"Caries Prevention"

1 Are you aware that some people are more prone to dental decay (cavities or caries) than others?

Please choose **only one** of the following:

○Yes

○No

2 Do you think that you are more prone to dental decay than the average person?

Please choose **only one** of the following:

○Yes

○No

3 Generally speaking, which of the following do you think would increase the risk of developing dental decay?

Please choose **all** that apply:

☐Not brushing your teeth properly

☐Consuming too much sugary foods and drinks

☐Consuming sugary foods and drinks too often

☐Consuming sugary foods and drinks just before bedtime

☐Having naturally "weak teeth"

☐Not visiting the dentist for check-up and cleaning

☐Not using fluoride

☐Having particular bacteria in the mouth that contribute to the development of dental decay

☐Having a reduced amount of saliva (spit) in the mouth

☐Having saliva (spit) that does not have the right composition to protect against decay

☐Other (please specify): _____

4 Before this research project, has your dentist ever conducted a tooth-decay risk assessment (e.g. asked you about your diet and use of fluorides, performed saliva tests etc) and provided you with a tooth-decay prevention and instruction programme based on that personalised assessment?

Please choose **only one** of the following:

○Yes Go to question 5 below

○No Go to question 6 below

5 If "Yes", would you recommend such a personalised caries prevention programme to your family or friends?

Please choose **only one** of the following:

○Strongly yes

○Somewhat yes

○Neither yes nor no

○Somewhat no

○Strongly no

6 If "No", what is the main barrier for you in accessing such a personalised caries prevention programme?

Please choose **only one** of the following:

○Cost

○Time

○I did not know about them

○My dentist does not provide such a personalised caries prevention programme based on risk assessment.

○They are not necessary

○Other

7 Do you go to the dentist for a dental maintenance programme (check-ups and cleaning)?

Please choose **only one** of the following:

○Yes Go to question 8 below

○No Go to question 9 below

8 If "Yes", would you recommend a dental maintenance programme (check-ups and cleaning) to your family and friends?

Please choose **only one** of the following:

○Strongly yes

○Somewhat yes

○Neither yes nor no

○Somewhat no

○Strongly no

9 If "No", what is the main barrier for you in attending the dentist for a dental maintenance programme (check-ups and cleaning)?

Please choose **only one** of the following:

○Cost

○Time

○I did not know about them

○My dentist does not provide a dental maintenance programme

○I cannot find a reliable dentist

○They are not necessary

○Other

10 How often do you clean your teeth?

○Never

○Less than once a week

○Less than once a day

○Once a day

○Twice or more a day

11 Do you use any of the following to clean your teeth? (include all that apply)

Toothbrush Yes○ No○

Wooden toothpicks Yes○ No○

Plastic toothpicks Yes○ No○

Thread (dental floss) Yes○ No○

Charcoal Yes○ No○

Chewstick/miswak Yes○ No○

Other Yes○ No○ Please specify .....

12 Do you use tooth paste?

○Always

○Sometimes

○Never

13 How strongly do you agree with these statements?

Please choose the appropriate response for each item:

	Strongly agree	**Somewhat agree**	**Neither agree nor disagree**	**Somewhat disagree**	**Strongly disagree**

Overall, I am satisfied with all aspects of my dental treatment and visits.	○	○	○	○	○
Personalised assessment of caries risk should be included in the public insurance system.	○	○	○	○	○
The more I visit the dentist for check-ups, the more treatment I am given.	○	○	○	○	○
If the public demand for prevention programmes is strong, dentistry can be changed from a mainly treatment-based service to a more preventive service.	○	○	○	○	○

"Finally"

14 Gender

Please specify **one** of the following:

○Female

○Male

15 Age

Please specify **one** of the following:

○19-29

○30-39

○40-49

○50-59

○60 or more than 60

16 What level of education have you completed?

○Primary

○During second level

○After second level

○Third level

○Postgraduate degree

○Still in education

17 Today's Date

Please enter today's date: _____

18 Your mobile number

Please enter here: ☐☐☐ ☐☐☐☐☐☐☐

19 Thank you very much. Please make sure that you have answered all the questions.

Please don't hesitate to give us any comments on this questionnaire:

_____

_____

Follow-up Questionnaire

Please complete and return this questionnaire and the 3-day diet record in the stamped addressed envelope provided.

"Caries Prevention"

1 Are you aware that some people are more prone to dental decay (cavities or caries) than others?

Please choose **only one** of the following:

○Yes

○No

2 Do you think that you more prone to dental decay than the average person?

Please choose **only one** of the following:

○Yes

○No

3 Generally speaking, which of the following do you think would increase the risk of developing dental decay?

Please choose **all** that apply:

☐Not brushing your teeth properly

☐Consuming too much sugary foods and drinks

☐Consuming sugary foods and drinks too often

☐Consuming sugary foods and drinks just before bedtime

☐Having naturally "weak teeth"

☐Not visiting the dentist for check-up and cleaning

☐Not using fluoride

☐Having particular bacteria in the mouth that contribute to the development of dental decay

☐Having a reduced amount of saliva (spit) in the mouth

☐Having saliva (spit) that does not have the right composition to protect against decay

☐Other (please specify): _____

You received two caries risk assessments for cavity prevention (e.g. You were asked about your diet and use of fluorides, performed saliva tests etc) in this project.

4 Would you recommend such a personalised caries risk assessment to your family or friends?

Please choose **only one** of the following:

○Strongly yes

○Somewhat yes

○Neither yes nor no

○Somewhat no

○Strongly no

5 If "No", why would you not recommend such a personalised caries risk assessment?

Please choose **only one** of the following:

○Cost

○Time

○Dentists do not provide a personalised caries risk assessment

○They are not necessary

○Other

6 Do you go to the dentist for a dental maintenance programme (check-ups and cleaning)?

Please choose **only one** of the following:

○Yes

○No

7 If "Yes", would you recommend a dental maintenance programme (check-ups and cleaning) to your family and friends?

Please choose **only one** of the following:

○Strongly yes

○Somewhat yes

○Neither yes nor no

○Somewhat no

○Strongly no

8 If "No", what is the main problem for you in attending the dentist for a dental maintenance programme?

Please choose **only one** of the following:

○Cost

○Time

○I did not know about them

○My dentist does not provide a dental maintenance programme

○I cannot find a reliable dentist

○They are not necessary

○Other

9 How often do you clean your teeth?

○Never
○Less than once a week
○Less than once a day
○Once a day
○Twice or more a day

10 Do you use any of the following to clean your teeth? (Read each item)

Toothbrush Yes○ No○
Wooden toothpicks Yes○ No○
Plastic toothpicks Yes○ No○
Thread (dental floss) Yes○ No○
Charcoal Yes○ No○
Chewstick/miswak Yes○ No○
Other Yes○ No○ Please specify .....

11 Do you use tooth paste?

○Always
○Sometimes
○Never

12 How strongly do you agree with these statements?

Please choose the appropriate response for each item:

	Strongly agree	**Somewhat agree**	**Neither agree nor disagree**	**Somewhat disagree**	**Strongly disagree**
Overall, I am satisfied with all aspects of my dental treatment and visits.	○	○	○	○	○

Personalised assessment of caries risk should be included in the public insurance system.	○	○	○	○	○
The more I visit the dentist for check-ups, the more treatment I am given	○	○	○	○	○
If the public demand for prevention programmes is strong, dentistry can be changed from a mainly treatment-based service to a more preventive service.	○	○	○	○	○

"About text messages"

13 Did you understand all of the 24 text messages you received during the project?

○Yes

○No

- ○I did not understand most of them (17 -24 text messages).
- ○I did not understand around half of them (9-16 text messages).
- ○I did not understand some of them (1-8 text messages).

14 Did you find that receiving oral health information via text messages each week for six months was useful?

○Yes
○No

"Finally"

15 Gender

Please specify **one** of the following:

○Female
○Male

16 Age

Please specify **one** of the following:

○19-29
○30-39
○40-49
○50-59
○60 or more than 60

17 Today's Date

Please enter today's date: _____

18 Your mobile number

Please enter here: _____

19 Thank you very much. Please make sure that you have answered all the questions.

Please don't hesitate to give us any comments on this questionnaire and this project:

_____

_____

Appendix 8 3-day food diary of the Irish study

3-Day Food Diary

Please record everything you eat and when you eat and go to bed during three ordinary days including a weekend day (Avoid special days like birthdays and Christmas days!).

Name _____

Mobile number _____

Example

	AM	Food/Beverage	PM	Food/Beverage
			13:00	sandwich, chips, water
Day	7:00	porriage, milk, toast, butter, jam		
Mon.			14:00	tea with sugar & milk
	11:00	tea with sugar & milk, apple	16:00	chocolates
Date			20:00	pasta (chiken, tomato, onion, basil
15				cheese)
Month			22:00	tea with sugar & milk, cake
Dec.				
			23:00	bedtime

	AM	Food/Beverage	PM	Food/Beverage
Day				
Date				
Month				
				bedtime

Appendix 9 CRFs of the Irish study

Baseline CRF

Case Report Form

Patient's full name:_____Male○ Female○

Patient's date of birth: _____

Patient's mobile number:_ ☐☐☐ ☐☐☐☐☐☐☐

Patient's tel: _____

Patient's address: _____

Dental Surgeon:_____ Dental Clinic:_____

Eligibility

Is the patient a medical-card holder?

○Yes

○No

Does the patient have at least 20 teeth?

○Yes

○No

Is the patient pregnant?

○Yes

○No

Does the patient have a mobile phone?

○Yes

○No

Does the patient have a smart phone?

○Yes

○No

Does the patient check SMS text messaging at least once a week?

○Yes

○No

History

- Systemic diseases

Does the patient suffer from:

☐ any autoimmune disease (e.g. 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 affect their saliva secretion.

Please list any medications: _____

☐ any condition requiring radiation to the head-neck region

- Is the patient a smoker?

○Yes ○No

- Fluoride use
  - Does the patient use fluoridated water?
    ○Yes
    ○No
  - Does the patient use fluoridated tooth paste?
    ○Yes
    ○No
  - Does the patient use additional fluoride measures such as rinses or vanishes on a regular basis?
    ○Yes
    ○No
  - Does the patient use additional measures such as rinses or vanishes on an occasional basis?
    ○Yes
    ○No

Saliva Tests

- **Saliva secretion**

Please enter salivary flow rate here: _____ml / 5 minutes

- Saliva sample for CRT bacteria taken

☐ Yes

☐ No If no, please state reason:

_____

- **Saliva buffer capacity**

Please compare the colour of the test field with the colour samples (pictures) after exactly 5 minutes of reaction time.

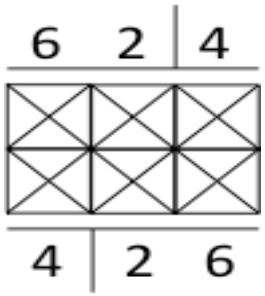
☐ High

☐ Medium

☐ Low

Clinical Examination

- **Plaque score**



Please enter plaque score here: ____

Score:

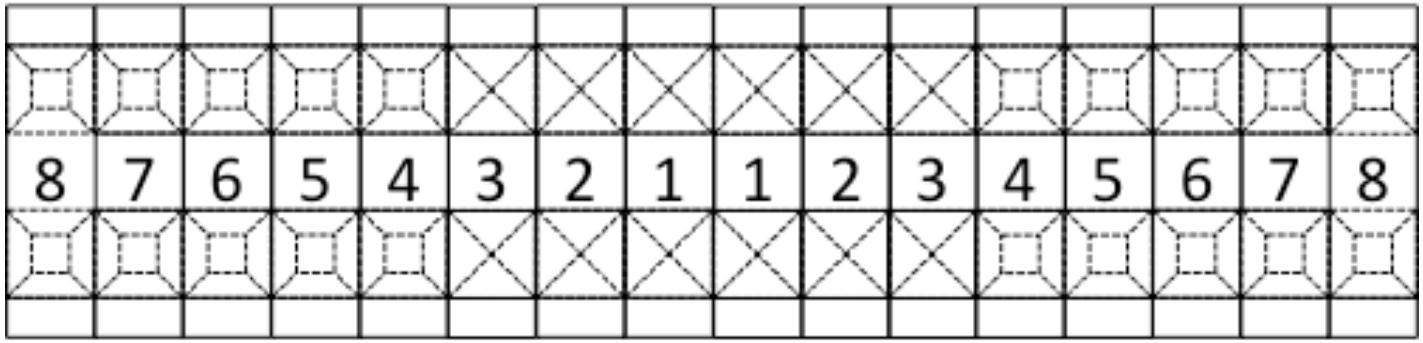
0 = Extremely good oral hygiene, Plaque Index (PI) < 0.4. No plaque, all teeth surfaces are very clean. Very 'oral hygiene conscious' patient, uses both toothbrush and inter-dental cleaning aids.

1 = Good oral hygiene, PI = 0.4–1.0. A film of plaque adhering to the free gingival margin and adjacent area of the tooth. The plaque may be seen in situ only after application of disclosing solution or by using the probe on the tooth surface.

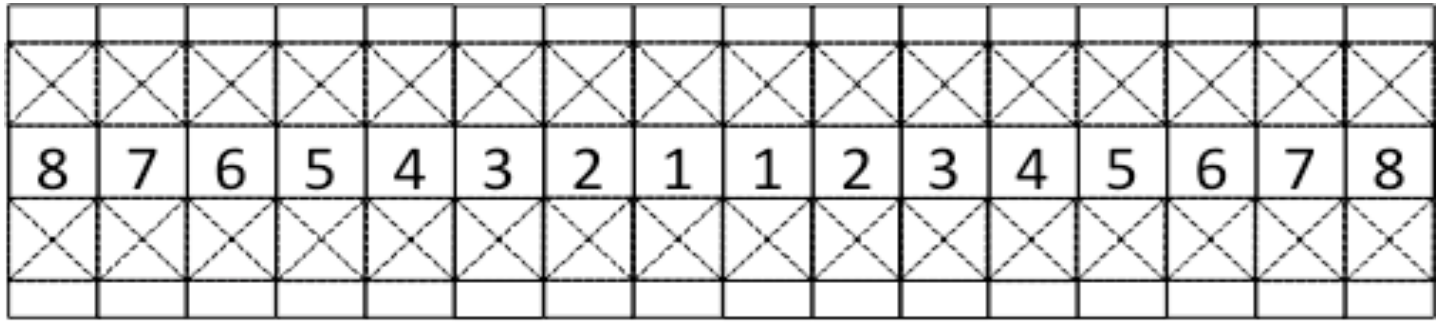
2 = Less than good oral hygiene, PI = 1.1–2.0. Moderate accumulation of soft deposits, which can be seen with the naked eye.

3 = Poor oral hygiene, PI > 2.0. Abundance of soft matter within the gingival pocket and/or on the tooth and gingival margin. The patient is not interested in cleaning the teeth or has difficulties in cleaning.

- **Dental caries CROWN**



- **Dental caries ROOT**



Please record past caries experience on the chart for each tooth surface. – Using DMFT index. In addition, the code N is recorded for visible non-cavitated or cavitated lesion limited to enamel.

Codes: Please refer to your clinical coding sheet for all codes.

Follow-up CRF

Case Report Form

Patient's full name:_____Male○ Female○

Patient's date of birth: _____

Patient's mobile number:_ ☐☐☐ ☐☐☐☐☐☐☐

Patient's tel: _____

Patient's address: _____

Dental Surgeon:_____

Checklist		Tick
1	History: at least two weeks since patient took antbiotics	
2	History: at least 12 hours since patient used an antibacterial mouthrinsing solution	
3	History: Systemic diseases and concomitant medications	
4	History: Fluoride use	
5	Salivary flow rate	
6	CRT saliva buffering capacity	
7	CRT bacteriological culture slides x 2	
8	Clinical examination: plaque	
9	Clinical examination: caries	
10	Patient has been given the dietary record form, the questionnaire and the return envelope.	
11	Informed consent, the history & oral examination form and CRT agar cultures sent to the Oral Health Services Research Centre within 24 hours.	

History

- Systemic diseases

Does the patient suffer from:

☐ any autoimmune disease (e.g. 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 affect their saliva secretion.

Please list any medications: _____

☐ any condition requiring radiation to the head-neck region

- Is the patient a smoker?

○Yes ○No

- Fluoride use
  - Does the patient use fluoridated water?
    ○Yes
    ○No
  - Does the patient use fluoridated tooth paste?
    ○Yes
    ○No
  - Does the patient use additional fluoride measures such as rinses or vanishes on a regular basis?
    ○Yes
    ○No
  - Does the patient use additional measures such as rinses or vanishes on an occasional basis?
    ○Yes
    ○No

Saliva Tests

- **Saliva secretion**

Please enter salivary flow rate here: _____ml / 5 minutes

- **Saliva buffer capacity**

Please compare the colour of the test field with the colour samples (pictures) after exactly 5 minutes of reaction time.

☐ High

☐ Medium

☐ Low

- Saliva sample for CRT bacteria taken

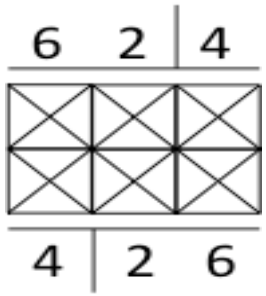
☐ Yes

☐ No If no, please state reason:

_____

Clinical Examination

- **Plaque score**



Please enter plaque score here: ___

Score:

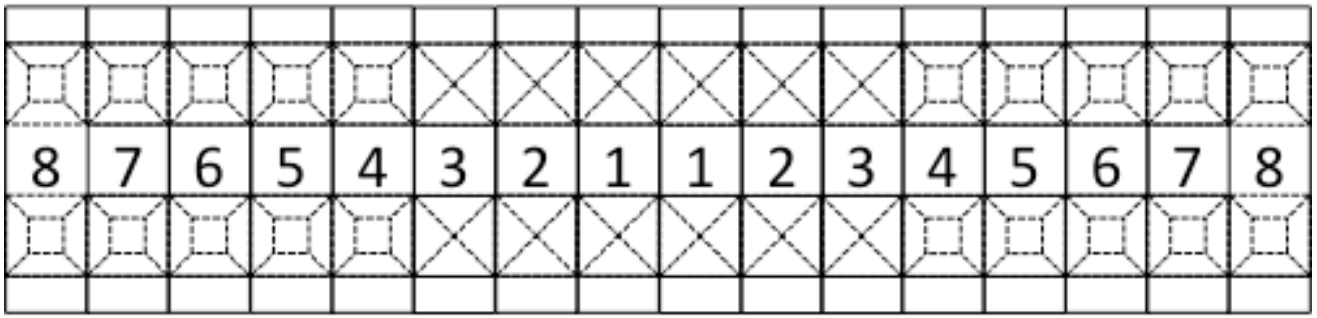
0 = Extremely good oral hygiene, Plaque Index (PI) < 0.4. No plaque, all teeth surfaces are very clean. Very 'oral hygiene conscious' patient, uses both toothbrush and inter-dental cleaning aids.

1 = Good oral hygiene, PI = 0.4–1.0. A film of plaque adhering to the free gingival margin and adjacent area of the tooth. The plaque may be seen in situ only after application of disclosing solution or by using the probe on the tooth surface.

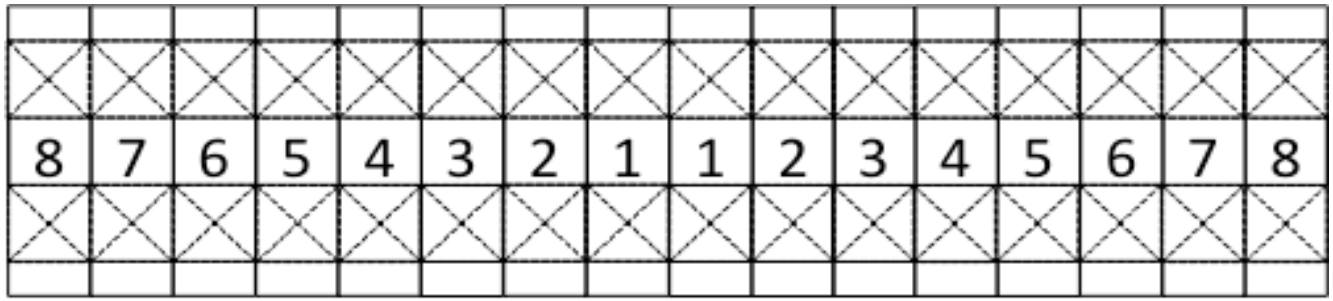
2 = Less than good oral hygiene, PI = 1.1–2.0. Moderate accumulation of soft deposits, which can be seen with the naked eye.

3 = Poor oral hygiene, PI > 2.0. Abundance of soft matter within the gingival pocket and/or on the tooth and gingival margin. The patient is not interested in cleaning the teeth or has difficulties in cleaning.

- **Dental caries CROWN**



- **Dental caries ROOT**



Please record past caries experience on the chart for each tooth surface. – Using DMFT index. In addition, the code N is recorded for visible non-cavitated or cavitated lesion limited to enamel.

Codes: Please refer to your clinical coding sheet for all codes.

Appendix 10 Thank-you letters to participants of the Irish study

Personalised letter at baseline

XXX XXX
XXXXX
XXXXX
Cork City

Today's date

Dear Ms. XXX XXX,

Thank you very much for taking part in this research project and for returning the questionnaire and 3-day diet record. As a token of our appreciation, we enclose a voucher for €20 to use as you please.

There are many factors that influence the development of tooth decay (cavities or caries). These factors include diet (what you eat, when you eat and how many times a day you eat), bacteria present in the mouth, dental plaque, fluoride use, amount and composition of saliva (spit), certain medications and medical conditions. These factors vary from person to person and it is important to know your individual risk factors in order to focus on your own personal points to prevent caries.

Using a caries risk assessment computer programme called Cariogram[1], we have assessed your risk of developing cavities within the next year. As shown in your individual Cariogram pie-chart (enclosed with this letter), your **chance of avoiding new cavities is (21)%.** The closer to 100%, the better.

Based on your individual results, we will send you personalised oral health text messages once a week for the next six months. For example, if your highest risk score is for the blue sector, your personal weak point is diet and the text messages you will receive will concentrate more on dietary advice.

[1] The Cariogram can be downloaded for free at http://www.mah.se/fakulteter-och-omraden/Odontologiska-fakulteten/Avdelning-och-kansli/Cariologi/Cariogram/

While you are participating in this study, it is very important to make sure that you read all the text messages we send you from +447624800500. Please add the number +447624800500 to your Contacts list as “Tooth Project” or “Cavity Project”.

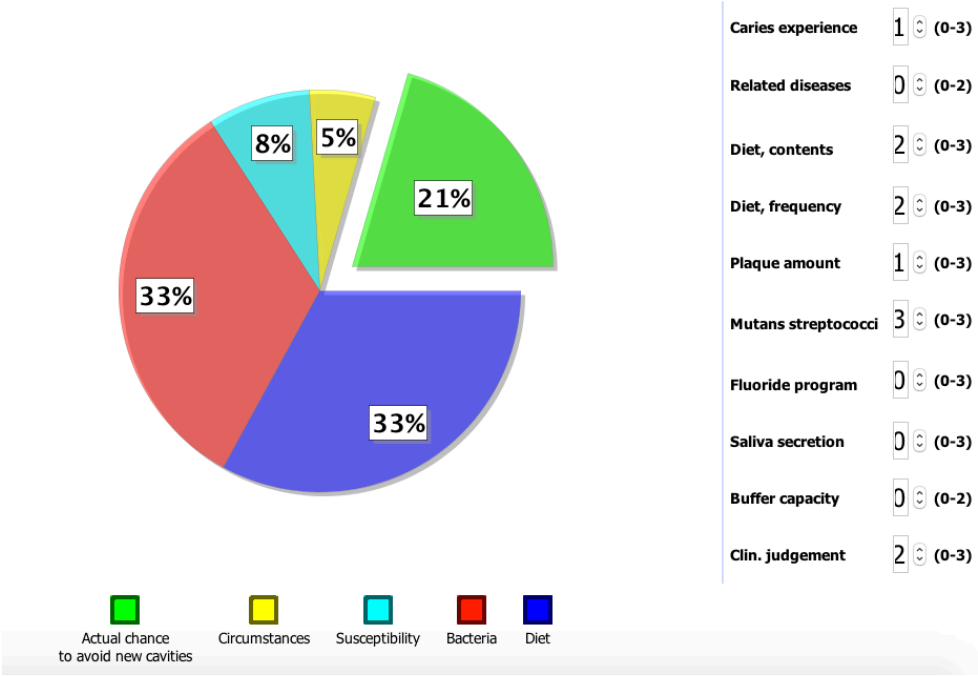
Your dentist will see you in six months to review your caries risk.

Yours sincerely,

The project team

P.S. The first message from us is *“Hi. Please send a reply to this message 2 confirm u received this test message. Hope you enjoy our messages for the next 6 mos. Regards Cavity Project Team”*. We ask that you reply to this text once only as confirmation that you’ve received it. Since our message is sent from a UK provider, you may be charged 0 to 25 cents to reply (depending on your mobile provider).

Cariogram chart for Ms. XXX XXX



The pie-chart has five sectors with different colours. The green sector represents your chance of avoiding new cavities and is 'what is left' when the risk factors have taken their share! The dark blue sector 'Diet' is risk based on a combination of diet contents and diet frequency. The red sector 'Bacteria' is risk based on a combination of the amount of dental plaque and certain bacteria (mutans streptococci). The light blue sector 'Susceptibility' is risk based on a combination of fluoride use, and saliva amount and composition. The yellow sector 'Circumstances' is risk based on a combination of past cavity experience and certain medical conditions (if present).

The bigger the green sector and the smaller the combined risk sectors, the better from a dental health point of view. A small green sector and a larger combined risk sectors means a higher risk of developing new cavities.

Cariogram's advice for you

The Cariogram indicates a High risk for tooth decay (cavities or caries). Some immediate actions are recommended.

Consider all parameters where score 2 or 3 have been added in the boxes. Which of them can most easily be changed for the better? Examples of actions in this case are:

* The Diet situation with respect to both content of fermentable carbohydrates e.g. sugars and starch (bread, potatoes, rice, flour and so on) and frequency of eating is a clear problem - a much better "dietary discipline" is needed.
* The Bacterial (bug) situation with respect to counts of "Mutans streptococci" (bugs causing tooth decay) is one of the problems. For an effective reduction of the mutans streptococci, a Chlorhexidine gel treatment session is recommended.
* The continuation of the fluoride program is encouraged.

In deciding which etiological factors to try to reduce risk of tooth decay, it is important to understand WHY the particular unfavourable factors are present. Such an approach may make it easier to assess if it is possible to improve the factor or not.

About six months after proper actions have been installed, it is recommended to make a new risk evaluation of tooth decay to make sure risk for tooth decay is decreased.

The Cariogram only expresses the over-all tooth decay risk. It does not take into account problems such as fractures of teeth or fillings, discolorations etc. which may make new fillings necessary.

Non-personalised letter at baseline

XXX XXX
XXXXX
XXXXX
Cork City

Today's date

Dear Ms. XXX XXX,

Thank you very much for taking part in this research project and for returning the questionnaire and 3-day diet record. As a token of our appreciation, we enclose a voucher for €20 to use as you please.

There are many risk factors that influence the development of tooth decay (cavities or caries). These risk factors include diet (what you eat, when you eat and how many times a day you eat), bacteria present in the mouth, dental plaque, fluoride use, amount and composition of saliva (spit), certain medications and medical conditions.
To help you understand how you can reduce your caries risk, we enclose basic information about how cavities occur and how you can prevent them. The information is taken from the Dental Health Foundation website:
http://www.dentalhealth.ie/dentalhealth/causes/dentalcaries.html.

As part of this research project, we will send you caries prevention advice in the form of text messages from +447624800500 once a week for the next six months. Please add the number +447624800500 to your Contacts list as "Tooth Project" or "Cavity Project".

Please make sure that you read all the SMS text messages we are going to send you!

Your dentist will see you in six months to review your caries risk.

Yours sincerely,

The project team

To help you understand how you can reduce your caries risk, here is some basic information about how cavities occur and how you can prevent them. The information is taken from the Dental Health Foundation website: http://www.dentalhealth.ie/dentalhealth/causes/dentalcaries.html.

When fermentable carbohydrates (mainly sucrose) in foods or drinks react with bugs (bacteria) in our mouth, acids form in the dental biofilm (plaque) on the tooth surface. The acid produced leads to a loss of calcium and phosphate from the enamel; this process is called demineralisation.

Saliva acts to dilute and neutralise the acid which causes demineralisation and is an important natural defence against cavities. Aside from buffering plaque acids and halting the demineralisation of enamel, saliva provides a reservoir of minerals adjacent to the enamel from which it can remineralise and "heal" once the acids have been neutralised. When demineralisation occurs frequently and exceeds remineralisation over many months, there is a breakdown of the enamel surface leading to a cavity. Cavities can have serious and lasting complications such as pain, tooth abscess, tooth loss, broken teeth, chewing problems and serious infection.

The prevention of dental caries can be approached as follows:

- Use fluorides

Fluoride works mainly by slowing down the process of demineralisation. It also helps to "heal" (remineralise) surfaces such as an opaque appearance. Most benefit is obtained if a low level of fluoride is constantly maintained in the mouth throughout the day. Fluoride delivered directly (or topically) to the tooth surfaces by toothpastes and rinses help to maintain fluoride levels in the mouth and provide added benefit to the fluoride delivered systemically via water fluoridation. Fluoride toothpastes are an important source of additional fluoride and should be used twice a day to help maintain a constant level of fluoride in the mouth. Daily fluoride mouthrinses are particularly useful for people who are prone to high levels of decay.

- Reduce frequent consumption of sugars

There is overwhelming evidence that frequent consumption of fermentable carbohydrate is associated with cavities. Dietary advice should be aimed at limiting the frequency of sugar intake. Foods and drinks containing "free sugars" (i.e., sugars which have been added to food plus sugars naturally present in honey, fruit juices and syrup) should be recognised and the frequency of their intake – especially between meals – reduced. Xylitol which does not casuse cavities is a good alternative for sugar.

- Other strategies
  - Improved oral hygiene and repeated professional tooth cleaning help cavity prevention.
  - Low saliva flow is a big problem for caivty prevention. If use of medicines for general disease is a cause, discuss with your physician if alternatives are available, which do not affect saliva secretion.
  - Buffer capacity is partly related to saliva secretion rate. Smoking is one factor negatively affecting buffer capacity.
  - Bad bugs increase when you have cavities. Have your dentist fix them.

P.S. The first message from us is *"Hi. Please send a reply to this message 2 confirm u received this test message. Hope you enjoy our messages for the next 6 mos. Regards Cavity Project Team"*. We ask that you reply to this text once only as confirmation that you've received it. Since our message is sent from a UK provider, you may be charged 0 to 25 cents to reply (depending on your mobile provider).

An example of letters to the patient at follow-up

4017 7314 6521 4362

UCC
University College Cork, Ireland
Coláiste na hOllscoile Corcaigh

Aonad Taighde Seirbhísí Sláinte Béil
Oral Health Services Research Centre

University Dental School and Hospital,
Wilton, Cork, Ireland.

T +353 (0)21 4901210
F +353 (0)21 4545391
http://ohsrc.ucc.ie

John [redacted]
[redacted]
Blarney,
Co. Cork.

9th February, 2016

Dear Mr. John [redacted]

Thank you very much for taking part in this research project and for returning the questionnaire and 3-day diet record. As a token of our appreciation, we enclose a voucher for €30 to use as you please.

Six months ago and just recently, we used a caries risk assessment computer programme called Cariogram[10] to assess your risk of developing cavities over the next year. Did your caries risk improve over the six months? As shown in your individual Cariogram pie-charts (enclosed with this letter), your **chance of avoiding new cavities was (15)% six months ago and is (78)% now.** The closer to 100%, the better.

The Cariogram also generated prevention advice based on your results. We enclose all results from your examinations. Your dental team may find this data useful should they wish to prescribe cavity prevention actions tailored to your specific risk profile.

Thank you again.

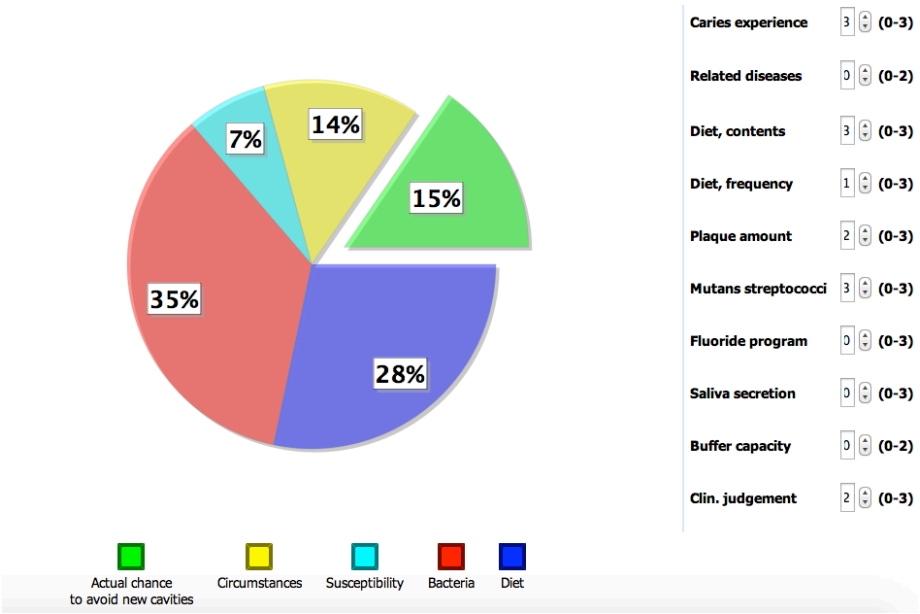
The project team

CC: Dr Liam Lynch

[10] The Cariogram can be downloaded for free at http://www.mah.se/fakulteter-och-omraden/Odontologiska-fakulteten/Avdelning-och-kansli/Cariologi/Cariogram/

Your results at baseline (18/05/2015)

Cariogram chart for Mr. John XXX



The pie-chart has five sectors with different colours. The green sector represents your chance of avoiding new cavities and is 'what is left' when the risk factors have taken their share! The dark blue sector 'Diet' is risk based on a combination of diet contents and diet frequency. The red sector 'Bacteria' is risk based on a combination of the amount of dental plaque and certain bacteria (mutans streptococci). The light blue sector 'Susceptibility' is risk based on a combination of fluoride use, and saliva amount and composition. The yellow sector 'Circumstances' is risk based on a combination of past cavity experience and certain medical conditions (if present).

The bigger the green sector and the smaller the combined risk sectors, the better from a dental health point of view. A small green sector and a larger combined risk sectors means a higher risk of developing new cavities.

Cariogram's advice for you on 18/05/2015

The Cariogram indicates a Very high risk for tooth decay (cavities or caries). Urgent actions are needed.

Consider all parameters where score 2 or 3 have been added in the boxes. Which of them can most easily be changed for the better? Examples of actions in this case are:

* The Diet with respect to its content of fermentable carbohydrates e.g. sugars and starch (bread, potatoes, rice, flour and so on) is a clear problem. It is recommended to reduce the intake of such products.
* The Bacterial (bug) situation with respect to both the "Plaque amount" and "Mutans streptococci" (bugs causing tooth decay) level has a heavy impact - both factors should be urgently controlled. Improved oral hygiene and repeated professional tooth cleaning is advised. For an effective reduction of the mutans streptococci, a Chlorhexidine gel treatment session is recommended.
* The continuation of the fluoride program is encouraged.

In deciding which etiological factors to try to reduce risk of tooth decay, it is important to understand WHY the particular unfavourable factors are present. Such an approach may make it easier to assess if it is possible to improve the factor or not.

For this High Risk case, it is important to follow up on actions taken, to make sure they have been effectively installed. It is recommended to repeat the risk evaluation for tooth decay after about six months.

The Cariogram only expresses the over-all tooth decay risk. It does not take into account problems such as fractures of teeth or fillings, discolorations etc. which may make new fillings necessary.

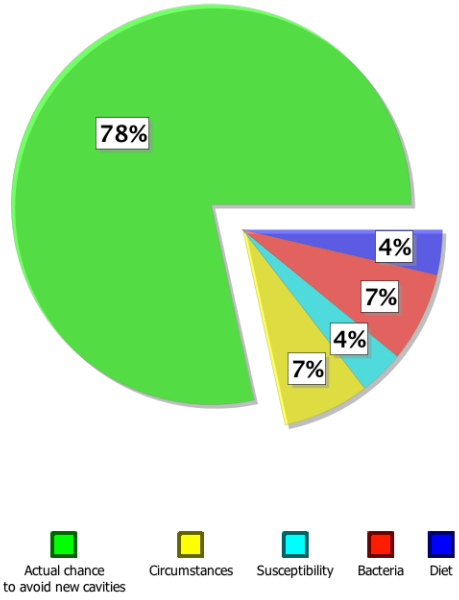
Results of examination on 18/05/2015 (only relevant to your dentist)

Mr. John XXX

DMFT	**18**
DMFS	**44**
Non-cavitated lesion	**0**
Related systemic disease	**0**
CRT ® LB	**3**
Diet frequency	**1** (Fermentable carbohydrate intake was **4.3** times/day as a mean.)
Plaque amount	**2**
CRT ® MS	**3**
Fluoride use	**0** 0: toothpaste + (water or additional measure on a regular basis) 1: toothpaste + additional measures on an occasional basis 1: water only 2: toothpaste only 3: avoiding fluorides
Saliva secretion	**0** (**8** ml/5minutes)
CRT® Buffer	**0** 0:high, 1:medium, 2:low

Your recent results (19/01/2016)

Cariogram chart for Mr. John XXX



Caries experience	3	(0-3)
Related diseases	0	(0-2)
Diet, contents	1	(0-3)
Diet, frequency	0	(0-3)
Plaque amount	1	(0-3)
Mutans streptococci	1	(0-3)
Fluoride program	0	(0-3)
Saliva secretion	0	(0-3)
Buffer capacity	0	(0-2)
Clin. judgement	2	(0-3)

The pie-chart has five sectors with different colours. The green sector represents your chance of avoiding new cavities and is 'what is left' when the risk factors have taken their share! The dark blue sector 'Diet' is risk based on a combination of diet contents and diet frequency. The red sector 'Bacteria' is risk based on a combination of the amount of dental plaque and certain bacteria (mutans streptococci). The light blue sector 'Susceptibility' is risk based on a combination of fluoride use, and saliva amount and composition. The yellow sector 'Circumstances' is risk based on a combination of past cavity experience and certain medical conditions (if present).

The bigger the green sector and the smaller the combined risk sectors, the better from a dental health point of view. A small green sector and a larger combined risk sectors means a higher risk of developing new cavities.

Cariogram's advice for you on 19/01/2016

The Cariogram indicates a rather Low risk for tooth decay (cavities or caries). Some actions could further lower the risk.
If you are interested in trying to minimize the risk even further, you should consider all parameters where scores higher than 0 or 1 have been added in the boxes!
Please take a look at the factors contributing to a positive situation for you!

* You have a good score on the "Related diseases", which means that you have none or few conditions that affect tooth decay. Tooth decay and certain diseases are linked.
* You have a good score on the "Diet frequency", which means that your dietary habit is very good.
* You have a good score on the "Fluoride programme", which means that you use fluoride very well for preventing tooth decay.
* You have a good score on the "Saliva secretion", which means that you have a healthy amount of saliva.
* You have a good score on the "Buffer capacity", which means that you have good quality of saliva.

The Cariogram only expresses the over-all tooth decay risk. It does not take into account problems such as fractures of teeth or fillings, discolorations etc. which may make new fillings necessary.

Results of examination on 19/01/2016 (only relevant to your dentist)

Mr. John XXX

DMFT	**18**
DMFS	**44**
Non-cavitated lesion	**0**
Related systemic disease	**0**
CRT ® LB	**2**
Diet frequency	**0** (Fermentable carbohydrate intake was **3.0** times/day as a mean.)
Plaque amount	**1**
CRT ® MS	**1**
Fluoride use	**0** 0: toothpaste + (water or additional measure on a regular basis) 1: toothpaste + additional measures on an occasional basis, 1: water only 2: toothpaste only 3: avoiding fluorides
Saliva secretion	**0** (**6**ml/5minutes)
CRT® Buffer	**0** 0:high, 1:medium, 2:low

To help you understand how you can reduce your caries risk, here is some basic information about how cavities occur and how you can prevent them. The information is taken from the Dental Health Foundation website: http://www.dentalhealth.ie/dentalhealth/causes/dentalcaries.html.

When fermentable carbohydrates (mainly sucrose) in foods or drinks react with bugs (bacteria) in our mouth, acids form in the dental biofilm (plaque) on the tooth surface. The acid produced leads to a loss of calcium and phosphate from the enamel; this process is called demineralisation.

Saliva acts to dilute and neutralise the acid which causes demineralisation and is an important natural defence against cavities. Aside from buffering plaque acids and halting the demineralisation of enamel, saliva provides a reservoir of minerals adjacent to the enamel from which it can remineralise and "heal" once the acids have been neutralised. When demineralisation occurs frequently and exceeds remineralisation over many months, there is a breakdown of the enamel surface leading to a cavity. Cavities can have serious and lasting complications such as pain, tooth abscess, tooth loss, broken teeth, chewing problems and serious infection.

The prevention of dental caries can be approached as follows:

- Use fluorides

Fluoride works mainly by slowing down the process of demineralisation. It also helps to "heal" (remineralise) surfaces such as an opaque appearance. Most benefit is obtained if a low level of fluoride is constantly maintained in the mouth throughout the day. Fluoride delivered directly (or topically) to the tooth surfaces by toothpastes and rinses help to maintain fluoride levels in the mouth and provide added benefit to the fluoride delivered systemically via water fluoridation. Fluoride toothpastes are an important source of additional fluoride and should be used twice a day to help maintain a constant level of fluoride in the mouth. Daily fluoride mouthrinses are particularly useful for people who are prone to high levels of decay.

- Reduce frequent consumption of sugars

There is overwhelming evidence that frequent consumption of fermentable carbohydrate is associated with cavities. Dietary advice should be aimed at limiting the frequency of sugar intake. Foods and drinks containing “free sugars” (i.e., sugars which have been added to food plus sugars naturally present in honey, fruit juices and syrup) should be recognised and the frequency of their intake – especially between meals – reduced. Xylitol which does not casuse cavities is a good alternative for sugar.

- Other strategies
  - Improved oral hygiene and repeated professional tooth cleaning help cavity prevention.
  - Low saliva flow is a big problem for caivty prevention. If use of medicines for general disease is a cause, discuss with your physician if alternatives are available, which do not affect saliva secretion.
  - Buffer capacity is partly related to saliva secretion rate. Smoking is one factor negatively affecting buffer capacity.
  - Bad bugs increase when you have cavities. Have your dentist fix them.

Appendix 11 Text messages

Abbreviation of references

DHF: the Dental Health Foundation

OHI: Oral Health in Ireland A Handbook for Health Professionals Second Edition

RB: Rapport Builder and the PSAP

C: Cariogram

ADA: American Dental Association

BDA: British Dental Association

CDA: Canadian Dental Association

NHS: the National Health Service in the UK

NIH: the National Institutes of Health in the USA

AU: Australian Dental Association

S: Scientific Basis of Dental Health Education

M: the Department of Cariology, Faculty of Odontology, Malmö University.

WHO: World Health Organisation

Non-educational messages

No.	Topic & Source / reference	Text message	Letter count
001	Confirmation	Hi. Please send a reply to this message 2 confirm u received this test message. Hope you enjoy our messages for the next 6 mos. Regards Cavity Project Team	155
999	Reminder	Hi, this is the last txt from us. Thanks for reading our messages for 25 wks! Please make an appointment at the dentist for follow-up exam. Tooth Project Team	158

1. Diet (diet content & diet frequency)

No.	Topic & Source / reference	Text message	Letter count	Priority (1st to 4th)
101	Frequency (DFH)	Hi Tooth project here! Always remember to limit the number of sugar intakes! Frequently eating / drinking sugary products causes holes in teeth!	144	1
102	Sugar in cereals (OHI)	Hi Tooth project here! Do check the sugar content of your breakfast cereals. Choose low sugar & add chopped fruits to top up their taste.	137	2
103	Before bedtime 1 (AU)	Did you know its best not 2 eat or drink after brushing at night. This way fluoride from toothpaste stays on teeth & will help strengthen them while u sleep?	157	1
104	Sugar (ADA)	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!	155	1
105	Starch (S)	Hi Tooth project here! Too much starchy foods like white bread convert to sugar in your mouth; mouth bugs convert sugar to acids; acids cause holes in teeth.	157	4
106	Xylitol (RB, S)	Hi Tooth project here! Xylitol is a sweetener that the mouth bugs cannot use to produce acid. It's a good alternative to sugar. Look for foods with xylitol.	156	3
107	Cheese (BDA, S)	Need a snack between meals? Consider cheese or yogurt without sugar! They stop acid that can breakdown tooth enamel. Their Calcium helps to resist tooth decay.	159	2

No.	Topic & Source / reference	Text message	Letter count	Priority (1st to 4th)
109	Sticky (ADA)	Sticky foods like dried fruits & jellies can damage ur teeth cos they stay on ur teeth longer. Rinse after eating such foods & brush & floss teeth carefully.	157	2
110	Snacking (BDA, S)	Hi Tooth project here! Snacking tips. Between meals choose raw vegetables, unsweetened yogurt, cheese, milk or water as snacks and stay away from sugary foods.	159	2
111	Tea with sugar (ADA, S)	Hi Tooth project here! Whenever possible choose snacks & drinks free of added sugars. Coffee & tea with no sugar added can be healthy beverage choices.	151	3
112	Fizzy drink	When u sip sugary drinks throughout the day bugs use that sugar 2 produce acids causing tooth decay! – sugary drinks are one of the worst things for ur teeth.	158	1
113	Fruit juice (ADA)	Hi Tooth project here! Frequent exposure to acidic drinks like fruit juices make teeth more likely to decay over time. Why not drink more water, instead?	153	3
113 ＋α	By the brain scientist.	Hi! It's the best to drink tap water instead of sugary drinks. Tap water may have fluoride to protect your teeth; bottle water may not have fluoride!	149	4
114	Not only sweets (BDA, S)	Hi Tooth project here! Sugars in fruits & veg are safe for teeth; Foods made from fruit or fruit juice with added sugars cause tooth decay.	139	3

No.	Topic & Source / reference	Text message	Letter count	Priority (1st to 4th)
115	Dessert (NHS, RB, S)	Hi! Enjoy ur sweet treats with meals! Eating sugars at mealtimes is safer for teeth as more saliva is produced & other foods help 2 clear sugars from ur mouth.	159	2
116	Sports drink (ADA)	Hi! Many sports & energy drinks have a lot of sugar. Check that your drink is low in sugar. Not sure? Drink water or tea without sugar instead!	143	2
117	"give teeth a rest" (Cameron A C, Widmer R P. Handbook of pediatric dentistry, 3rd ed. Mosby Elsevier, 2008.)	Hi! Give your teeth a break! Leave at least 2 hours between every meal or snack! That way your teeth have time to heal from acidic effects of food.	147	1
118	Free sugars (DHF)	Hi Tooth project here! It is better to keep foods with sugars naturally present like fruit juices & honey to main mealtimes.	124	3
119	Alcohol (NHS)	Hi Tooth project here! Did you know alcohol contains sugar and can soften and wear away the teeth? Consume alcohol in moderation!	129	4

No.	Topic & Source / reference	Text message	Letter count	Priority (1st to 4th)
120	Good food (NHS, NIH)	Hi! Ideas for a good diet 4 teeth: water, tea (no sugar), whole grains, brown bread, lean beef, poultry, fish, beans, peas, cheese, eggs, sugarless chewing gum.	160	4
121	Bad food (NHS, S)	Did u know all of these damage teeth, fizzy drinks, fruit juice, coffee,/tea with sugar, chocolate, sweets, cakes, crisps, biscuits, white bread & dried fruits?	160	4
122	Before bedtime 2 Low saliva flow (S)	Hi! Within 2 hrs of bedtime is the worst time for sugar-sweetened snacks/drinks. As we don't make much saliva during sleep, the acid attack can last many hours.	160	1
123	Mechanism of caries (DHF, S)	Acid is made in the mouth when sugary foods & drinks are eaten by the oral bacteria. The acid causes the tooth to soften. Reduce the acid and prevent decay!	156	4
124	Sugar labels Máiréad on 15/7.	Do u ever read d labels on ur food? Sugar has lots of names on food labels. It can be fructose, glucose, maltose, corn starch, high fructose corn syrup, HFCS…	158	3

2. Bacteria (plaque & MS)

No.	Topic & Source / reference	Text message	Letter count	Priority (1st to 4th)
201	Biofilm (BDA, RB)	The thin sticky film or 'furry' feeling that forms on ur teeth contains bugs, It's called a biofilm. Gunk that clogs kitchen & bathroom drains is biofilm too!	158	1
202	Brushing teeth at least twice a day (BDA, ADA, S)	Hi! Brush thoroughly w/ fluoride toothpaste 2 minutes twice a day, more often if ur dentist recommends! Small circular movements r good 2 clean ur teeth.	153	1
203	Pit and fissure on the occlusal surface (BDA, RB)	Like criminals, bugs luv 2 hide in dark places: between teeth, between gum/tooth, & at the back of ur mouth. Use floss & small toothbrush 2 crack down on bugs.	159	2
204	interproximal brush (BDA)	Use dental cleaning aids like toothpicks/interdental brushes 2 remove dental plaque from between ur teeth. Ask ur dentist/hygienist 2 show u their proper use.	158	2
205	TBI (BDA)	Hi! Don't miss your dental appointments! Your dental team will show u what areas 2 concentrate on when caring for ur teeth & how 2 brush & floss correctly.	155	1
206	professional cleaning (RB, S)	Dental plaque accumulates in all our teeth when we eat. Removal is difficult & it causes decay. Professional care by a dentist or dental hygienist may be needed	158	1

No.	Topic & Source / reference	Text message	Letter count	Priority (1st to 4th)
207	Floss (RB)	Hi Tooth project here! Flossing is easy & comfortable – Surprisingly, some monkeys in Thailand also floss, using their own hair to clean between their teeth.	157	4
208	Ireland 1 (RB)	Hi Tooth project here! Brushing twice a day is better than once a day. However, you may still leave dental plaque. That's where your dental team can help.	154	3
209	Ireland 2 (RB, S)	We brush teeth but have decay. Why? We need to floss/use a small brush head – u can't paint the house with 1 brush, change it, to get into hard to reach places.	160	3
210	Thorough brushing than more frequent cursory brushing (S)	Hi Tooth project here! A gentle thorough scrub technique is good twice a day. Brush tooth surfaces & places where the tooth meets the gum!	138	2
211	Cleaning (BDA)	Hi Tooth project here! Do you clean and floss between your teeth daily? A few small changes can make a big difference to keeping your teeth and gums healthy.	157	4
212	Plaque is not food debris, but bugs (BDA, RB)	Can u touch ur teeth w/ ur tongue, feel the white sticky stuff on ur teeth? It's called dental plaque & has billions of bugs that feed on sugars & starches.	156	3

No.	Topic & Source / reference	Text message	Letter count	Priority (1st to 4th)
213	Mutans streptococci (NHI)	Hi! 100+ bug types live in our mouth on teeth, gums, tongue etc. Some of them attach 2 teeth & produce acids & sticky dental plaque. They love sugar & acids!	157	4
214	Interdental brush	Interdental brushes r designed 2 clean btwen teeth effectively. They are much thinner than normal toothbrushes. Buy them frm ur supermarket r chemist r dentist!	160	3
215	The stickiness of the plaque (BDA)	Sticky dental plaque keeps acids produced by bugs in contact w/ teeth. After constant acid attacks, enamel covering teeth breaks down, forming a hole or cavity.	157	4
216	Small head size brush (S)	Hi! Choose a toothbrush with soft/medium round-ended nylon bristles. The head of the toothbrush should be small enough to reach into all parts of the mouth.	156	2
217(a)	Lactobacillus is easy to be removed. Filling. (M)	Hi Tooth study here! High numbers of certain decay-causing bugs can be easily reduced by: eating less sugars & starches like white bread.	137	3

No.	Topic & Source / reference	Text message	Letter count	Priority (1st to 4th)
218	Mutans streptococci is not easy to remove. (Guideline on Infant Oral Health Care, hosted on the American Academy of Paediatric Dentistry)	Hi Tooth study here! Decay-causing bugs can be transferred from adults to babies. Keep your own mouth clean & remove decay!	123	4
218 +alpha	Mutans streptococci is not easy to remove. (Guideline on Infant Oral Health Care, hosted on the American Academy of Paediatric Dentistry)	Hi Tooth study here! its important to keep babies spoons & cups separate! Licking baby's soother passes decay causing bugs on!	126	4

No.	Topic & Source / reference	Text message	Letter count	Priority (1st to 4th)
219	Plaque and acid (S)	Hi! Dental plaque covers most tooth surfaces & reforms quickly after brushing. When acid forms w/in plaque, it acts like an acid-soaked coating on ur teeth.	156	2
220	A lot of bugs in your saliva (RB, S)	Lots of bugs live in the mouth & some produce acids. Acids attack ur teeth, causing cavities. Don't leave it there! Cleaning teeth morning & night really helps.	160	1
221	Plaque accumulation (BDA)	Daily teeth cleaning is important. It removes dental plaque & prevents bugs from continuing 2 build up, feeding on d food debris left behind & causing decay.	157	3
222	When to change tooth brush (BDA)	Hi Tooth project here! Change your toothbrush every 2-3 months or sooner if the bristles look spread out or worn. Worn bristles don't clean properly.	149	2
223	When to brush your teeth (NHS)	Good morning tooth project, helping you build healthy habits! Brush your teeth before breakfast and last thing at night before you go to bed.	141	1

3. Susceptibility (fluoride & saliva secretion & saliva buffer)

No.	Topic & Source / reference	Text message	Letter count	Priority (1st to 4th)
301	Fluoride makes tooth strong. (BDA)	Hi Tooth study here! Fluoride in your toothpaste helps to strengthen and protect teeth, which can reduce tooth decay in adults and children.	140	1
302	Fluoride enhance remineraliza tion. (DHF, S)	Hi Tooth study here! Fluoride slows down the process of demineralisation, where tooth enamel loses its strength when exposed 2 acid from food & drinks.	151	2
303	Fluoride reduce conversion of sugars in to acid. (S)	Hi! Fluoride in toothpaste is concentrated in d dental plaque layer on d tooth surface & reduces d conversion of dietary sugars into acid by bugs.	146	1
304	Water fluoridation (S)	Hi Tooth study here! In Ireland, tap water has a very small amount of fluoride. It is safe & highly effective & efficient 4 reducing decay.	139	4
305	Fluoridated toothpaste (DHF, S)	Hi! Fluoride toothpastes are excellent against tooth decay. For adults choose toothpaste with 1450ppm. Don't rinse! Simply spit out excess paste 4 max benefit!	159	1
306	Fluoridated rinse (DHF)	Fluoride mouthrinses r useful 4 those who r prone 2 decay. Carry out fluoride mouthrinsing at a different time from toothbrushing 2 maximise the added benefits!	160	2

No.	Topic & Source / reference	Text message	Letter count	Priority (1st to 4th)
307	Fluoride varnish (BDA, DHF, S)	Hi! In the very early stages of decay, your dentist may apply a fluoride varnish onto the area. This can help stop further decay and help repair the tooth.	155	4
308	Balance between demineralisation and remineralisation (RB, S)	Hi! Bugs produce acids that damage teeth; saliva helps repair d damage. It's like a see-saw (⇅). If saliva wins d balance, cavities don't occur!	144	2
309	Saliva buffer and secretion varies. (S)	Hi Tooth study here! Teeth damaged by bug's waste (acids) can be slowly repaired by saliva. Let's give saliva a chance for about 2hrs!	134	4
310	Tooth resistance (S)	Lower front teeth rarely decay cos they don't have any grooves or fissures in which dental plaque can hide & they are bathed by saliva (a secret weapon).	153	3
311	Saliva glands. (OHI)	Cancer & its treatment can damage d salivary glands. Saliva is vital 2 oral health. Sugarless gum can help stimulate saliva flow if some gland function remains.	160	4
312	Medications (DHF)	Hi! Many medications (eg for high blood pressure, anxiety, allergies, diuretics/water tablets, sedatives/sleepers) have a side effect of reduced saliva flow.	157	3

No.	Topic & Source / reference	Text message	Letter count	Priority (1st to 4th)
313	Stimulate saliva (RB, S)	Hi! Saliva is very important. Chewing food encourages saliva flow. Saliva repairs tooth surfaces damaged by acids from bugs & dilutes the acids.	144	2
314	Saliva and remineralisation (DHF)	Hi! Saliva acts to dilute & neutralise the acid causing cavities & is a natural defence against decay. Saliva can "heal" once the acids have been neutralised.	158	3
315	Saliva and clearance. (S)	Saliva bathes dental plaque & helps 2 neutralise acids & wash away sugars. Enhance this action of saliva by eating vegetables, cheese or sugar-free chewing gum.	160	2
316	Saliva and sleeping time (S)	Hi Tooth study here! During sleep, saliva flow is very low & acid attacks to the tooth surface can last for many hours. Best to sleep & not eat in bed!	151	1
317	Fluoridated toothpaste (BDA, S)	Hi Tooth study here! Adults should use a toothpaste that contains at least 1450ppm of fluoride twice a day to prevent decay.	124	1
318	Fluoride in food (S, WHO)	Hi! Fluoride, in varying amounts, is freely available in nature: in fish bones, tea, salt, beer, vegetables, fruit, other crops, and also in the atmosphere!	156	3
319	Caries decline and fluoride (S)	Hi! Tooth decay declined dramatically during the last 30 years in Europe. Experts say that fluoridated toothpaste is an important reason. Fluoride is powerful!	159	3

No.	Topic & Source / reference	Text message	Letter count	Priority (1st to 4th)
320	Ask your physician to change medication (C, DHF)	Hi! Many medications have a side effect of low saliva flow (big risk to cavities). Ask your doctor or dentist for alternatives which don't affect saliva flow.	158	4
321	Chewing gum (BDA)	Chewing sugar-free gum for up to 20 minutes after a meal can help your mouth produce more saliva, which helps to cancel out any acids which have been formed.	157	2
322	Saliva secretion and buffer (C)	Hi Tooth study here! The flow of saliva helps to cancel out dental plaque acids, smoking affects saliva flow. Ur doctor or dentist can help you stop smoking.	157	3
323	Fluoride is in nature. (DHF)	Hi! Fluoride naturally occurs in some water sources. It’s derived from fluorine, the thirteenth most common element on earth, and prevents tooth decay.	151	4
324	Fluoride with a low level (DHF)	Hi Tooth study here! Drinking tap water containing fluoride helps to heal early signs of tooth decay.	101	1

4. Circumstances (past caries experience & systemic diseases)

No.	Topic & Source / reference	Text message	Letter count	Priority (1st to 4th)
401	Restoration does not cure cavities. (ADA)	Hi! Over the years, fillings may weaken & tend to fracture & leak around the edges. Visit your dentist regularly for professional cleanings & oral examination!	159	1
402	Restoration is risk. (CDA)	Hi! Fillings are not as smooth as natural teeth & can catch food & bugs at their edges. When a filling breaks, that part of the tooth is more likely to decay.	158	3
403	How long restoration lasts. (RB)	Hi! Like a holey sock or trouser, a filled tooth will get a crack or a hole sooner or later. Bugs can get in & cause pain. A sound tooth is the toughest.	153	1
404	Recall interval according to your risk (RB, S)	How often should u visit d dentist? High risk patients => 3 months; Low risk patients (no dental disease, non-smoker, infrequent sugar & alcohol) => 24 months.	159	2
405	Root caries (DHF, S)	Tooth decay can attack d roots of teeth should they become exposed by gum recession. The roots r more vulnerable than d crowns. It's more common in older adults	160	3
406	Side effect of medications (DHF)	Hi! Reduced saliva flow is a side effect of many medications (eg, for high blood pressure, anxiety, allergies/ water tablets/diuretics, sleepers/sedatives).	156	3

No.	Topic & Source / reference	Text message	Letter count	Priority (1st to 4th)
407	Auto immune disease Sjögren's syndrome (NIH)	The main symptom of Sjögren's syndrome is dry mouth. Mouth feels like full of cottonwool! Mouth has lost its protection from saliva => more decay may develop.	158	4
408	Diabetics (OHI)	Hi Tooth study here! With some illnesses tooth decay rates are higher, lets manage our dental and general health together!	122	3
409	Money and prevention (RB)	Hi Tooth study here! Regular dental visits help prevent decay. Going to the dentist for prevention regularly can make life more pleasant.	137	1
410	radiation on the head-neck region (Cancer Research UK)	Radiotherapy 2 ur mouth can make u more likely 2 get cavities. U need 2 go 4 dental checkups more often. Fluoride treatment may also help 2 protect ur teeth.	157	4
411	any handicap which might cause them difficulties in cleaning their teeth properly (BDA, C)	Some people find it hard to hold a toothbrush cos of a physical disability. Try toothbrushes with large handles and angled heads as they may be easier to use.	158	4

No.	Topic & Source / reference	Text message	Letter count	Priority (1st to 4th)
412	anorexia nervosa	Eating disorders affect oral & general health. They cause acid erosion of the surface of the teeth, dry mouth n tooth decay. Ur dentist will give you advice!	157	4
413	Decay damages (BDA)	Dental decay is caused by dental plaque acids that gradually dissolve d tooth. Decay damages ur teeth and may lead to d tooth needing to be filled or removed.	158	2
414	Effectiveness of a maintenance programme. (BDA. S)	Prevention is better than cure! Visit your dentist regularly: your dentist will spot problems earlier, helping u care for ur teeth.	131	1
415	What your dentists do for prevention (RB)	Ur dentist will look for dental plaque & clean the plaque u cannot clean & tell u how to care for ur teeth at home. Preventive dental visits are not painful.	157	3
416	Early stage and remineralisation 2 (BDA, S)	Early stages of decay (chalky white patch or ring or shadow or staining) can be healed. Follow advice of your dentist/hygienist to prevent decay starting again!	160	1
418	Fissure sealant (BDA)	'Pit & fissure sealant' fills crevices in the tooth surface creating a flat surface that is easier 2 clean. Ur dentist will discuss whether this is right 4 you.	160	2

No.	Topic & Source / reference	Text message	Letter count	Priority (1st to 4th)
419	Early lesion can be healed with proper prevention. (BDA)	Ur dentist can spot decay in its early stages, before symptoms start. Visit ur dentist regularly, as small cavities r much easier to manage than advanced decay.	160	2
420	Personalised caries prevention (RB, S)	Most people consume sugars everyday but not everyone develops decay. Ur dentist assesses ur mouth & suggests personal dental care 4 u like a personal trainer.	158	1
421	Common risk factor (DHF)	Hi! Did you know that tooth decay, gum disease, heart disease, cancer, and obesity are linked? A healthy oral diet for teeth helps with a healthy body.	151	2
422	Utility of a maintenance programme in Ireland (RB)	Hi Tooth study here! More & more people go to the dentist for keeping teeth cavity free, a beautiful smile, is priceless.	121	3
423	Price of a tooth (RB)	Hi Tooth project here! We all agree that smiles are priceless. With nice teeth, you can smile all day, look younger and enjoy your foods!	137	4
424	Susceptible sites (DHF)	Hi Tooth project here! The decay begins from a spot on the tooth surface, often hidden from sight in the grooves of teeth or between teeth. Take time to brush.	159	3

No.	Topic & Source / reference	Text message	Letter count	Priority (1st to 4th)
425	Lactobacillus is easy to be removed. Filling. (M)	Hi! Ask your dentist to fill cavities & check fillings that are hard to floss. A high number of certain decay-causing bugs can be easily reduced.	145	2

Appendix 12 Application Form for verifiable CPD points

Dental Council
An Comhairle Fiaclóireachta

APPLICATION FORM FOR VERIFIABLE CPD POINTS

To be completed by Course Organiser

Organising Group	Course Organiser	Location
University College Cork	Finbarr Allen	Oral Health Services Research Centre
Subject Matter	**Date**	**Duration**
Oral examination caries risk assessment	11 February 2015	4.0 hours

Lecturers / Course Presenters
Professor Finbarr Allen, Dr Máiréad Harding, Professor Anthony Roberts, Dr Cristina DiMata, Dr Makiko Nishi
Concise Educational Aims / Objectives
Tuition, training and calibration are required to carry out an IADR/Unilever funded research grant: "Electronic-based personalised dental education for caries prevention in a disadvantaged population: a randomised controlled study (EPES)". The aims of the training programme are to provide the dental practitioners participating in the study with knowledge of epidemiology and the determinants of oral health and research methods in dental practice. The dentists will be trained and calibrated to examine to the epidemiological standard, acquire the skills and support in caries risk assessment. The participant will understand the methods used to conduct clinical research in a primary care setting.
Anticipated Outcomes
The participant dentists understand the wider determinants of oral health and can synthesise the use of epidemiology and dental research methods including skills for the collection of epidemiological data on DMFT, incipient caries lesions, Plaque Index (by Silness and Löe) and saliva tests (CRT® Ivoclar Vivadent, Liechtenstein).
Quality Controls (outline opportunities for dentists to provide feedback)
Feedback from the participating dentists will be provided through questionnaires at the end of the tuition, training and calibration. In addition, the participants can contact to the lectureres during the study.
Details of proof of attendance/participation provided to attendees
Certificate of the course attendance is issued to the participant dentists at the end of this course.

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F&GP	Decision	Points

Issued May 2010

Appendix 13 All comments left by 34 MC patients [sic]
in the follow-up questionnaire

- Thank you for letting me take part in your project. I learnt a lot more about how to keep my teeth cleaner and stronger.
- Q12, (Overall, I am…), always really happy!
- Thank you very much for having me in your project
- I hope the results are useful
- The project made me realise how important it is to take care of your teeth, thank you!
- Very interesting and informative, thank you
- This was a very informative project. It made me realize how important fluoride is in your oral care
- Thank you
- I really liked the text messages and always read them to my husband and 4 children so they would benefit from them too.
- Good luck with your study, thanks for the text messages
- Although I gave texts only a quick glance over they stuck with me especially fizzy drinks warning. Very good idea
- I think this project would be better aimed at children. I'm aware enough to know that when I indulge in sugary food I'm not doing my teeth any favours. Children on the other hand may be more effected especially by the scarier more uncomfortable messages like the one about biofilm.
- We as a family have made big changes-no more fizzy drinks only at weekends, Brushing teeth every morning before breakfast, kids enjoyed what messages the "tooth fairy" gave them.
- Good Luck with the write up
- To be honest I did not read every text message, I read some and some stuck in my mind. I think that such information would be useful to educating school children about how their diet (sugary food stuffs) can effect their dental hygiene and health
- Really learnt a lot through texts messages and read them carefully

- Would like to opt out of futher text/SMS messages/do not give permission to use my data for anything else
- I found this project very useful and was delighted to partake in it. It has helped me to keep going with oral hygiene and reminded me via txt service
- I don't agree with the promotion of fluoride. Research has identified fluoide as a toxic chemical with severe side effects. I am awre of the benefit to teeth but the harm is alarming over a lifetime. I object to mass inocculation in water without consent. Dentistry does not make patients aware of its toxicity!
- I don't think the texts told me anything I didn't know already but they did change my brushing habits from not being bothered about brushing everyday to burshing at least once every day mainly because the texts every Sunday made me think more about my teeth, thanks.
- Thank you for the very valuable information. It has made me even more aware of the importance of looking after my teeth.
- Found text messages were too general and not specific to me as a person/individual. Also the use of text language, UR, R, distracted me from the message you were trying to put across
- The use of mobile … made me think about dental care more
- I found the text messages to be more of interesting trivia as opposed to facts but I was determined to use in order to iimprove my oral health
- Q12, (The more I visit the dentist for ….) only if necessary
- All I would like to say it that I will miss my text message every Sunday, I learned a lot and it was so interesting especially about the bugs that go into our teeth, ycuh!! Thank you.
- Thought it was a great new project. Made me go to the dentist a lot more than I normally would and I take extra care of my teeth hygiene
- I was very grateful an dmore than happy with this study and all the results of it, thank you.
- Re: Q14: In theory a very good idea but I was told very tillte that I did not already know
- I did not receive any text messages

- See note on questionnaire re: texts. Whilst toothpaste fluoride may aid in preventing tooth decay, too much fluoride can affect the overall health of the body in other ways. I do not agree with statements regarding 'fluoridated water'. If nature had intended fluoride in water it would have put it there naturally. The fluoride industry pollutes rivers & reservares with a toxin derived from aluminium. In many cases this does not benefit the body or teeth in the same way as toothpaste would.
- Reveiving the texts made me and my family more concious of brushing our teeth and made us watch what we were eating and drinking. I have since decided to get some dental work done that I otherwise may have put off for some years (bridge & orthodontics)
- I found by taking part in this trial, receiving text messages kept me on my toes regarding oral hygiene and the importance of it.
- I felt the text messages card have been more unformatwe. At times particluar text messages left me with unanswered questions.

Articles I–V

Article I

Nishi M, Kumagai T, Whelton H. 2016. Access to personalised caries prevention (PCP) programmes determined by dentists: a cross-sectional study of current and potential PCP adopters in Japan and their knowledge of caries risk. J Dent Hlth. 66(4):399-407.
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Available at: https://www.jstage.jst.go.jp/article/jdh/66/4/66_399/_pdf/-char/en

Authors' contribution

Nishi M: the conception of the Japanese study, the acquisition and analysis of data for the Japanese study, and drafting and finalising the article.

All authors contributed to design of the Japanese study, the interpretation of data and revising the article critically for important intellectual content, approved the final version of the article, and agree to be accountable for all aspects of the article in ensuring that questions related to the accuracy or integrity of any part of the article are appropriately investigated and resolved.

Relevant presentation

Nishi M, Whelton H, Kumagai T, Kelleher V, O'Mullane D. Use of caries risk assessment in dental practice: impact on dentists' management of caries lesions of different severity. The HRB Clinical Research Facility at UCC: Meeting Challenges in Patient Focused Research, Cork, 13 June 2013.

口腔衛生会誌　J Dent Hlth 66: 399–407, 2016

Original

Access to Personalised Caries Prevention (PCP) Programmes Determined by Dentists: A Cross-sectional Study of Current and Potential PCP Adopters in Japan and Their Knowledge of Caries Risk

Makiko NISHI[1], Takashi KUMAGAI[2] and Helen WHELTON[3]

Abstract: Personalised caries prevention (PCP) programmes – dental caries prevention programmes which are based on caries risk assessments (CRAs) – are still a new service among the Japanese people. According to Rogers' diffusion theory of innovation, key persons at this early phase of diffusion have greater knowledge of innovations. We hypothesised that difficulty accessing PCP programmes is hampering their widespread diffusion. The aim of this study is to investigate this hypothesis by: (1) estimating the percentage of PCP adopters, (2) summarising reasons for patients not receiving PCP programmes, and (3) determining if knowledge of caries risk is linked to access to PCP, among an adult group (aged 20+) sampled through a non-profit organisation (PSAP) whose purpose is promoting risk assessment of caries and periodontal disease. This study uses questionnaires with: patients of previously-enrolled PSAP dental members (group A: N=389), patients of newly-enrolled PSAP dental members (group B: N=78), and newly-enrolled PSAP public members (group C: N=68). The main outcome variables are PCP adoption by patients, reasons for not receiving PCP programmes, percentage of respondents choosing eight caries risk factors/indicators, and the total number of chosen risk factors/indicators. The application rate of PCP programmes was significantly lower in group C, at 27.9% (99% CI=13.4–42.5), than in group A, at 83.0% (99% CI=71.4–94.7). The principal reason given by Non-PCP adopters in group C for not receiving PCP programmes was that this service was not provided by their dentist, although they showed better results regarding knowledge of caries risk than Non-PCP adopters in group AB (combined groups A and B). Accessing a PCP programme was determined based on the services dentists provide; patients' knowledge of caries risk was not linked to PCP access. Further efforts are necessary to increase the availability of PCP programmes.

Key words: **Personalised caries prevention, Caries risk assessment, Diffusion of innovations, Access to care, Patient knowledge**

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Introduction

Dental caries prevention programmes, which are based on caries risk assessments (CRAs) and customised to individual patient needs, in other words, personalised caries prevention (PCP) programmes, have been available in dental practice settings since the 1980s[1]. In Japan, however, the national dental insurance does not cover CRA. A cross-sectional survey (2011/2012) of a nationwide network of Japanese dentists showed that only 26% of dentists in the network performed CRA for their patients[2] and only six percent stated that all of their patients received individualised caries prevention[3]. Furthermore, the uptake of regular check-ups (not necessarily based on CRA) by patients (47.8% in 2012*[1]) is lower than in some other developed countries (68.5% in Iceland in 2009[4], 57.2–81.7% in the USA in 2010[5]). These findings indicate that PCP programmes are still a new service for the Japanese people.

Innovations (new ideas, practices, or objects) have an S-shaped rate of adoption according to Rogers' diffusion theory[6]. The S-shaped diffusion curve shows that, at

[1] Oral Health Services Research Centre, Dental School, University College Cork
[2] Hiyoshi Oral Health Centre
[3] Dental Public Health and Preventive Dentistry, University of Leeds School of Dentistry

*[1] Ministry of Health, Labour and Welfare: The national health and nutrition survey Japan, 2012, http://www.mhlw.go.jp/bunya/kenkou/eiyou/dl/h24-houkoku.pdf (last accessed 20th January, 2016).

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first, a small number of individuals adopt the innovation; after a threshold is reached, it becomes impossible to halt further diffusion of the innovation; finally, the trajectory of the rate of adoption begins to level off[6]. PCP has been slow to take off in Japan, where adoption of the approach is still in the early, slow phase of the S-shaped curve. In this phase, earlier adopters are key persons. Generally speaking, they engage in more active information-seeking, have more favourable attitudes toward science and change, have greater knowledge of innovations, and have a higher socioeconomic status than later adopters[6].

In Japan, although the population interested in PCP programmes has these characteristics of earlier adopters, at present, the unavailability of PCP programmes due to the limited number of dentists performing CRA may also be hampering their diffusion. No matter what type of knowledge and attitudes patients possess, it is possible that what decides their caries prevention level may lie beyond such individual determinants and depend on the services dentists provide. We hypothesised that difficulty of accessing PCP programmes is inhibiting their widespread adoption. The aim of this study is to investigate this hypothesis by: (1) estimating the percentage of PCP patient adopters, (2) summarising reasons for not receiving PCP programmes, and (3) determining if knowledge of caries risk (i.e., percentage of respondents choosing multiple caries risk factors/indicators and total number of correct risk factors/indicators chosen) is linked to access to PCP, among an adult group (aged 20+) sampled through a non-profit organisation PSAP promoting state-of-the-art risk assessment of dental caries and periodontal disease*2.

Materials and Methods

1. Subjects

Complying with the recommendations of the STROBE statement guidelines*3, the current paper reports a cross-sectional study that includes the baseline survey of an on-going follow-up study project to investigate the effectiveness of the PSAP's activities with questionnaires since 13th May, 2013. The PSAP aims to increase demand for patient-centred and personalised prevention of dental caries and periodontal diseases from Japanese dental practices. The PSAP activities are to inform the public, especially potential earlier adopters, of state-of-the-art dental prevention by means of the Internet, publishing books, and holding lectures; this work is underpinned by behaviour change theory according to the Health Belief Model[7], which attributes the widespread failure of people to participate in programmes to prevent and detect disease to a lack of perceiving susceptibility, severity, benefits, and barriers. The PSAP is open to public membership for free and has 564 public members registered (as of 12th May, 2015) since its establishment on 1st September 2010. The PSAP's financial sponsors are 139 fee-paying dental members (10,000 Japanese yen annually), two philanthropic companies (20,000 Japanese yen annually), and one corporate sponsor (Oral Care Inc., Tokyo).

For the cross-sectional study among patients of PSAP dental fee-paying members and PSAP public members, we set three subject groups: groups A, B, and C.

1) Groups A and B

On the 17th January, 2014, we asked fee-paying dental members of the PSAP who were enrolled prior to 13th May, 2013 (group A dentists; N=99) to complete a self-administered paper questionnaire (dentist questionnaire) and to distribute a separate self-administered paper questionnaire (patient questionnaire) to 20 of their patients on a first-come basis. Similarly, fee-paying dental members who were enrolled between 13th May, 2013 and 12th May, 2015 (group B dentists; N=40) were asked to do the same upon enrolment in the PSAP. While group A dentists had at least eight month's exposure to PSAP activities at the time of their questionnaire survey, group B dentists had no exposure to PSAP activities at the time of their questionnaire survey. The PSAP issued 1,980 (=99*20) and 800 (=40*20) patient questionnaires to group A and B dentists, respectively. It is unknown how many of these questionnaires were subsequently distributed by the dentists to their patients. Patients were requested to answer the questionnaire at home to avoid undue

*2 Ha Ha Ha Talk: Promoting Scientific Assessment in Prevention of Tooth Decay and Gum Disease, http://www.honto-no-yobou.jp/ (last accessed 20th January, 2016).
*3 STROBE Statment: University of Bern, http://www.strobe-statement.org/ (last accessed 20th January, 2016).

Dentist questionnaire

2 Do you perform personalised caries prevention in any way? ("personalised caries prevention" means "caries prevention based on caries risk assessments according to individual patients"). Please choose only one of the following:
Yes
No

3 What percent age of individual adult patients receive personalised caries prevention in your practice?
%

Patient questionnaire

2 Tooth-decay does not affect all people universally, as some get tooth-decay easily and others do not, even though they practice the same preventive methods. Did you know that the probabilities (risk) of getting tooth-decay differ from individual to individual?
Yes
No

3 Generally speaking, what do you think is (are) the reason(s) for susceptibility to (risk of) tooth-decay? Please choose all that apply.
Not brushing your teeth properly
Bad eating habit
Having naturally 'weak teeth'
Not visiting the dentist for a dental maintenance programme (check-ups and cleaning)
Not using fluoride
Having particular bacteria in the mouth that contribute to the development of dental decay
Low saliva flow rate
Low quality of saliva
Other (please specify):

4 Do you think that you have a high susceptibility to (risk of) tooth-decay?
Yes
No
I do not know

5 In the dental practice where you visit, do they conduct a custom-made tooth-decay prevention and instruction programme based particularly on your tooth-decay susceptibility (risk) as determined by an assessment of your personal risk by examining contents and frequency of diet, asking about the use of fluoride, performing saliva tests, etc.
Yes
No

7 If "No", what is (are) the main reason(s) for you not receiving such a custom-made tooth-decay prevention programme? Please choose all that apply.
Cost
Time
I did not know about it.
My dentist does not provide this service.
It is not necessary.
Other:

8 Do you go to the dentist for a dental maintenance programme (check-ups and cleaning)?
Yes
No

10 If "No", what is (are) the main reason(s) for you not attending a dental maintenance programme? Please choose all that apply.
Cost
Time
I did not know about it.
My dentist does not provide this service.
I cannot find a reliable dentist.
It is not necessary.
Other

15 Sex
Male
Female

16 Age
19 or younger
20-29
30-39
40-49
50-59
60 or older

17 Are you a dental professional (dentist, dental hygienist, dental assistant, or dental technician)?
Yes
No

Fig. 1 The relevant questions in the current paper (The original questionnaire was in Japanese. Question numbers are the same as the original numbers.)

influence from the dental practice on their answers. Stamped addressed envelopes were provided with both the dentist and patient questionnaires for their return to the PSAP via post.

2) Group C

Public members of the PSAP enrolled from 13th May, 2013 to 12th May, 2015 (group C) received an email upon their enrolment inviting them to complete an on-line patient questionnaire. The number of questionnaires issued to group C by the PSAP was 362. Reminders to answer the electronic survey were sent weekly for two weeks after enrolment.

The inclusion criteria for the patient questionnaire were: (1) willingness to participate in the project and (2) >19 years of age. The exclusion criteria were: (1) dental professionals (dentist, dental hygienist, dental assistant, and dental technician) and (2) for group C, previous participation in the project as group A or B. The sample size was not calculated for the study. In total, 3,142 patient questionnaires and 139 dentist questionnaires were issued. The approach taken was that all dentists who had joined the PSAP since its foundation were asked to give a questionnaire to 20 of their patients on a first-come basis. The number of patient questionnaires issued to each dentist was limited to 20 because we did not wish to over-burden the dentists.

2. The questionnaire survey

The questionnaires for the pre-pilot study were developed with the help of staff (N=5: two dentists, one psychologist, one project manager, and one economist) in the Oral Health Services Research Centre (OHSRC), University College Cork, Ireland. A pilot study was conducted in September 2012 of PSAP fee-paying dental members (N=84, response: N=24), their patients (N=23), and public members (N=195, response: N=34). For the pilot study, the questionnaires were translated into Japanese since all PSAP members are Japanese speakers. Based on the results of the pilot study, modifications to the dentist questionnaire were made and reviewed by three Japanese dentists and one Japanese dental office worker, and to the patient questionnaire by two non-dental Japanese speakers, the Japanese dental office worker, and one of the three Japanese dentists.

The questions selected for this article are presented here (Fig. 1). Both electronic and paper questionnaires were anonymous, using identification numbers which were not linked with individual information. Nonetheless, prior to completing the questionnaire, all respondents provided informed consent which included their voluntary agreement, being free of coercion and undue influence, to participation. Respondent names and postal addresses were collected separately for those who were interested in receiving non-monetary incentives (oral care products) for participating in the patient question-

naire survey. Both dentist and patient questionnaire data (password protected) without personal information (e.g., name, postal/email addresses) were collected and sent by the PSAP website administrator in Tokyo, Japan to the researcher (MN) in the OHSRC via email on 10th July, 2015. The ethics committee of the Japanese Society for Oral Health approved this study (No. 24-4).

3. Definition of PCP

Prior to designing the current study, we defined PCP as "caries prevention based on caries risk assessments according to individual patients." Since the technical term PCP might confuse the subjects, examples of CRAs such as "examining contents and frequency of diet, asking about the use of fluoride, and performing saliva tests" were given (Q5). In dental practice settings, a PCP programme should include a routine maintenance programme (RMP) (check-ups and professional tooth cleaning)[8]. Respondents who indicated on their questionnaire that they received both the PCP programme and RMP were categorised as PCP adopters.

4. Caries risk factors/indicators

Question number 3 (Q3) asked subjects to identify caries risk factors/indicators from a list of eight items (Fig. 1). Of the eight listed items, six came from the Cariogram[9], as it is the only validated CRA tool in prospective studies[10]. Of the two remaining listed items, "Having naturally 'weak teeth' " refers to a heritable weakness in enamel formation which increases individual susceptibility to caries[11], and "Not visiting the dentist for a dental maintenance programme (check-ups and cleaning)" was derived from a long-term study on RMP[8]. As all eight items are correct factors/indicators of caries risk, the more items the respondent ticked, the more likely that he/she is knowledgeable about caries risk factors/indicators. If the respondent ticked the item "Other" and specified a correct factor/indicator different from the listed alternatives, this was given an additional point. Thus, the highest score for correct responses is nine.

5. Data analysis

The main outcome variables are PCP adoption by patients, reasons for not receiving PCP programmes, percentage of respondents choosing eight caries risk factors/indicators and total number of chosen risk factors/indicators. From the dentist questionnaire, we collected information on whether or not the dentist provided PCP and on the proportion of adult patients receiving PCP in dental practices. From the patient questionnaire, information needed for the application of the inclusion and exclusion criteria for respondents were collected. Any respondent to the patient questionnaire who did not answer all socio-demographic factors (age, sex, whether dental professional or not) was dropped from the dataset. In addition, we excluded those who received PCP programmes but not RMP (Q5=Yes, Q8=No) and those who provided no answer for either of these two questions. We determined the number of dentists for the patient respondents in groups A and B from identification numbers on the patient questionnaire. We grouped the respondent data into three age categories: 20–39, 40–59, and 60+, and examined the sex and age group distributions within groups A, B, and C. We described the responses to each question and total number of chosen risk factors/indicators in Q3 within these groups and their subgroups (PCP adopters vs. Non-PCP adopters). Missing values for each question were excluded from the analysis.

6. Statistical Analysis

Percentages and a summary of descriptive statistics were computed and presented. The significance level was set at $p<=0.01$ (two-sided) because of multiple testing. The Chi-square test of association between age, sex, and groups A, B, and C was used and Fisher's Exact test was applied when appropriate. Binary Logistic, Poisson, and Multinomial logistic regression were applied for binary, count, and categorical outcome data, respectively. Dentists who provide PCP or caries risk information to one patient are likely to offer PCP to other patients in their practice. Therefore, responses from patients who have the same dentist are likely to be similar. This intra-class correlation was taken into account when comparing groups A and B using Stata's Survey data analysis method with the dentist specified as the PSU (primary sampling unit). Group C was regarded as a simple random sample. The Odds ratio, incidence rate ratio, and relative risk ratio were reported, together with 99% confidence intervals where appropriate. The IBM SPSS Statistics Version 22 (SPSS Inc., Chicago, IL, USA) and the Survey Data Analysis procedure in STATA 12.1 (Stata Corp, College Station,

TX, USA) were utilised in the analysis.

Results

1. Provision of PCP in respondents' dental practices

The total number of patient questionnaires returned for group A was 459 from 40 dental practices, for group B it was 100 from 12 dental practices, and for group C it was 145, representing 23.2, 12.5, and 40.1%, respectively, of the total questionnaires issued by the PSAP. Of the returned questionnaires, 389 respondents in group A, 78 in group B, and 68 in group C satisfied all criteria for inclusion in this study. The number of dentist questionnaires returned was 30 for group A and 16 for group B, representing 30.3 and 40.0% of the total dentist questionnaires issued by the PSAP, respectively. From the dentist questionnaire, the percentage of dentists who said they provided PCP programmes was 90.0% (27/30) in group A and 75.0% (12/16) in group B. The corresponding percentages of dentists whose patients responded to the patient questionnaire was 89.3% (25/28) in group A and 77.8% (7/9) in group B. Of the 32 dentists whose patients responded to the patient questionnaire, eight stated that more than 90% of their patients received PCP while another eight stated that less than 35% of their patients received PCP.

2. Respondents' demographic factors

Table 1 shows the number of dentists and respondents per dentist in groups A and B, and the distribution of respondents by sex and age group in groups A, B, and C. The sample sizes were small in groups B and C, and sub-group percentages may therefore be unreliable. Group A had the highest application rate of PCP programmes, at 83.0% (99% CI=71.4–94.7), followed by group B at 59.0% (99% CI=21.8–96.1); group C had the lowest application rate, at 27.9% (99% CI=13.4–42.5). The difference between groups A and C was significant ($p<0.01$), as their 99% CI did not overlap.

3. Reasons for not receiving PCP programmes

The number of those who answered "No" to receiving PCP programmes (Q8) was 66 (17.0%), 32 (41.0%), and 49 (72.1%) for groups A, B, and C, respectively. Among them, six respondents did not give reasons. Because dentists in group B (12/16) were providing PCP programmes prior to enrolment with the PSAP, we combined groups A and B (group AB) in the summary of reasons given

Table 1 Number of dentists and respondents per dentist; respondents by gender and age group in groups A, B, and C

		Group A	Group B	Group C	Total	p-value[1]
Number of dentists		40	12	na	52	
Respondents per dentist						
	min.	1	1	na		
	avg.	9.7	6.5	na		
	max.	18	14	na		
Number of respondents		N=389	N=78	N=68	N=535	
Sex (%)	Male	31.9	23.1	42.6	32.0	0.041
	Female	68.1	76.9	57.4	68.0	
Age (%)	20–39	27.8	30.8	45.6	30.5	
	40–59	41.4	48.7	36.8	41.9	0.013
	60+	30.8	20.5	17.6	27.7	
Sex & Age						
Males		N=124	N=18	N=29	N=171	
Age (%)	20–39	21.0	44.4	34.5	25.7	
	40–59	38.7	27.8	31.0	36.3	0.203
	60+	40.3	27.8	34.5	38.0	
Females		N=265	N=60	N=39	N=364	
Age (%)	20–39	30.9	26.7	53.8	32.7	
	40–59	42.6	55.0	41.0	44.5	0.004**
	60+	26.4	18.3	5.1	22.8	
PCP adopters (%)		83.0	59.0	27.9	74.4	
	99% CI	71.4–94.7	21.8–96.1	13.4–42.5		

Group A: patients of early (more than eight months) dental members of the non-profit organisation (PSAP)
Group B: patients of newly enrolled dental members of the PSAP
Group C: newly enrolled public members of the PSAP
PCP: personalised caries prevention (including maintenance programmes)
1: Chi-square test
**: $p<=0.01$, significance level for the study

Table 2 Reasons for not receiving PCP programmes in groups AB and C

	Group AB (N=98)		Group C (N=49)		Total (N=147)	
Reason	N	(%)	N	(%)	N	(%)
Cost	8	(8.2)	3	(6.1)	11	(7.5)
Time	11	(11.2)	3	(6.1)	14	(9.5)
Do not know about PCP	67	(68.4)	22	(44.9)	89	(60.5)
Dentist does not provide PCP	11	(11.2)	26	(53.1)	37	(25.2)
Unnecessary	10	(10.2)	0	(0)	10	(6.8)
Other	5	(5.1)	0	(0)	5	(3.4)
Missing	2	(2.0)	4	(8.2)	6	(4.1)

Multiple answers allowed.
PCP: personalised caries prevention (including maintenance programmes)
N: number of Non-PCP adopters
%: percentage of Non-PCP adopters
Group AB: patients of dental members of the non-profit organisation (PSAP) in the combined groups A and B
Group C: newly enrolled public members of the PSAP

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Table 3　Comparison of knowledge of caries risk between PCP and Non-PCP adopters within groups AB and C (%)[1].

		Group AB							Group C						
		PCP adopters (N=369)	Non-PCP adopters (N=98)	OR	99% CI Lower	99% CI Upper	t-value	*p*-value	PCP adopters (N=19)	Non-PCP adopters (N=49)	OR	99% CI Lower	99% CI Upper	t-value	*p*-value
Q2	The subject knows that caries risk varies between individuals	N=365													
	Yes	86.8	83.7	1.29	0.56	2.98	0.81	0.423[2]	100	87.8	–	–	–	–	0.175[5]
Q3	Chosen caries risk factor/indicator														
	The subject chooses 8 factors/indicators	11.7	2.0	6.33	0.86	46.47	2.48	0.017[2]	36.8	20.4	2.28	0.47	11.09	1.38	0.174[6]
	Yes														
	Sum of chosen risk factors/indicators			IRR	Lower	Upper	t-value	*p*-value			IRR	Lower	Upper	t-value	*p*-value
	mean	4.57	3.74	1.22	1.05	1.42	3.51	0.001[3**]	5.47	4.69	1.17	0.84	1.63	1.220	0.225[7]
	sd	1.91	1.39						2.48	2.42					
	min. value, max. value	1, 8	1, 8						1, 8	1, 8					
Q4	The subject thinks he/she is at high caries risk			RRR	Lower	Upper	F(2,50)	*p*-value			RRR	Lower	Upper	F (2,66)	*p*-value
	Yes	58.0	50.0	1.34	0.67	2.67			31.6	49.0	4.25	0.21	85.93		
	No	21.7	26.5	0.94	0.39	2.31	0.82	0.446[4]	63.2	16.3	25.50	1.26	515.57	6.03	0.004[8**]
	Don't know	20.3	23.5					base outcome	5.3	34.7					base outcome

RMP: routine maintenance programme (check-ups and professional tooth cleaning)
PCP: personalised caries prevention (including RMP)
Group AB: patients of dental members of the non-profit organisation (PSAP)
Group C: newly enrolled public members of the PSAP
IRR: incident rate ratio
RRR: relative risk ratio
1: Numbers are shown when there was missing data.
2: Binary Logistic regression for correlated survey data with dentist as the PSU (primary smpling unit)
3: Poisson Regression for correlated survey data with dentist as the PSU
4: Multinomial logistic regression for correlated survey data with dentist as the PSU
5: Fisher's Exact test, because one cell has zero respondents.
6: Binary Logistic regression for correlated for SRS (simple random sample)
7: Poisson Regression for SRS
8: Multinomial logistic regression for SRS
**: p<=0.01, significance level for the study

for not receiving PCP programmes (Table 2). The most frequent reason given was "I did not know about them (PCP)" in group AB (68.4%) and "My dentist does not provide this service (PCP)" (53.1%) in group C.

4. Knowledge of caries risk: Comparison between PCP and Non-PCP adopters

Overall, in groups A, B, and C, there were 388 PCP adopters and 147 non-adopters. Table 3 shows a comparison of knowledge of caries risk between PCP and Non-PCP adopters within groups AB and C separately. The percentages of respondents choosing eight items including "Other" with a correctly specified caries risk factor/indicator (hereditary, smoking, crooked teeth, and caregivers at high caries risk) were 11.7 and 2.0% among PCP adopters and Non-PCP adopters, respectively in group AB, and 36.8 and 20.4% among PCP adopters and Non-PCP adopters, respectively, in group C. The number of chosen caries risk factors/indicators was higher (p=0.001) among PCP adopters (mean=4.57) compared with Non-PCP adopters (mean=3.74) (Ratio=1.22, 99% CI=1.05–1.42) for group AB. For group C, the corresponding figures were mean=5.47 and 4.69 among PCP adopters and Non-PCP adopters, respectively, and this ratio was not significantly different from 1.0. We compared knowledge of eight individual caries risk factors/indicators between PCP and Non-PCP adopters within groups AB and C separately, and will report on this elsewhere.

Discussion

The subjects of interest in this study were current and potential PCP adopters; three PSAP sources were used to survey these subjects (patients). We tried to obtain as large a sample as possible. The response rate

was low and the respondents may be biased in favour of those who have a strong interest in preventive dentistry. Indeed, the provision of PCP (or CRA) among the respondent dentists was higher (89.3 and 77.8% in groups A and B, respectively) than in another Japanese study (26%)[2]; the application of RMP among the respondent patients in the three groups was also high (95.1, 88.5, and 77.9% in groups A, B, and C, respectively) compared with the Japanese average (47.8%*1). The lower proportion of PCP adopters in group C compared with the other two groups may be due to the recruitment of group C respondents through the PSAP website rather than through PSAP dental members. Therefore, Non-PCP adopters in group C can be considered as potential PCP adopters without access to PCP services. A large number of dental professionals (N=69) participated in the excluded questionnaire survey in group C. These were excluded from the current paper, as were dental professionals who participated in the patient questionnaire in groups A (N=24) and B (N=8).

We did not compare knowledge of caries risk between groups AB and C statistically because two different methods were used for sampling patients and, thus, two different methods were used to analyse the data. Instead, we compared PCP adopters and Non-PCP adopters within group AB and within group C separately. Although almost all of the respondents knew that caries risk differs from individual to individual, the average number of caries risk factors/indicators chosen and percentage of respondents choosing all eight listed caries factors/indicators were rather low. Even this health-oriented population consider the aetiology of dental caries to be simpler than it is. These findings are important as the knowledge on caries risk of earlier adopters may influence the larger number of later adopters[6].

We identified 141 Non-PCP adopters who provided reasons for not receiving PCP programmes. These reasons provide an insight into the slow progress of PCP dissemination in Japan. Time or cost was not a frequently cited reason. The most frequently cited reason for not receiving PCP programmes in groups A and B was that they did not know about PCP. This indicates that the PSAP should encourage its dental members to inform their patients of PCP more actively. The most frequently cited reason in group C was that their dentist does not provide this service. This group showed better results regarding knowledge of caries risk than Non-PCP adopters in group AB, and were more knowledgeable about some risk factors/indicators than PCP adopters in group AB. A study on cardiovascular diseases also demonstrated that knowledge of patients and access to care had no direct link[12].

If we generalise based on these findings, most of the potential PCP adopters in Japan are not being provided with the opportunity to access PCP programmes because their dentists do not provide this service; thus, despite possessing strong characteristics of earlier adopters, such as engaging in more active information seeking, and having more favourable attitudes toward science and change, they cannot provide the impetus for the widespread diffusion of this new programme to later adopters. In addition, health disparities with regard to caries prevention may have causes other than individual-level determinants. In such scenarios, an individualistic behavioural approach to caries prevention will be ineffective and costly[13]. The PSAP approach, underpinned by behaviour change theory, takes a different angle: it aims not just to increase patients' knowledge but to increase demand for PCP from Japanese dental practices. In keeping with this more upstream and structured approach, the current paper has implications for under- and postgraduate dental education as well as continuing education in Japan. Educators need to be aware of the need for better training of dentists to provide PCP programmes and in communicating with their patients about such programmes. Furthermore, it is necessary to establish a system whereby dental practices can financially gain by providing caries prevention services based on caries risk assessments and not be economically reliant on operative procedures[14]. This is a common challenge worldwide[10].

Limitations of the current paper are that the sample size was not determined, that all the subjects were recruited through only the PSAP (sampling bias), and that the number of respondents in group C was small. Based on the results of the current paper, a larger survey with an analysis that stratifies findings based on innovativeness would be interesting. The findings will be useful for the development of effective strategies for

personalised dental education about PCP programmes.

In conclusion, accessing PCP programmes was determined by the services dentists provide, and patient knowledge was not linked to their access. Knowledge of caries risk was deficient among even this health-oriented population. Further efforts are necessary to increase the availability of PCP programmes in Japan through a social determinant approach, and to inform the general public about multiple caries risk factors and PCP programmes.

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Reprint requests *to* M. Nishi, Oral Health Services Research Centre, Dental School, University College Cork, Wilton, Cork City, Ireland.
TEL: +353-21-490-1210/FAX: +353-21-454-5391
E-mail: makikonishi@hotmail.com

Article II

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Authors' contribution

Nishi M: the conception and design of the Japanese and Irish studies, the acquisition of data for both the Japanese and Irish studies, and drafting and finalising the article.

Harding M: the design of the Irish study.

Kelleher V: the design of the Japanese and Irish studies, and drafting and finalising the article.

Whelton H: the design of the Japanese study.

Allen F: the design of the Irish study.

All authors contributed to analysis and interpretation of data and revising the manuscript critically for important intellectual content. All authors have approved the final version and agreed to be accountable for all aspects of the article.

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Knowledge of caries risk factors/indicators among Japanese and Irish adult patients with different socio-economic profiles: a cross-sectional study

Makiko Nishi[1*], Máiréad Harding[1], Virginia Kelleher[1], Helen Whelton[2] and Finbarr Allen[3]

Abstract

Background: A previous study has shown deficient knowledge of caries risk factors/indicators in a Japanese adult population regarded to have a high interest in preventive dentistry. No prior research has investigated caries risk knowledge in an Irish adult population. We hypothesise there may be *unexpected* differences or similarities in knowledge across countries with similar levels of economic development when comparing groups with different socio-economic and cultural profiles. Understanding what influences knowledge is important for the development of effective and efficient caries prevention strategies. The current paper aims to describe the knowledge of caries risk factors/indicators in two groups with different socio-economic profiles from two culturally distinct countries.

Methods: Cross-sectional surveys of adult dental patients were carried out in Japan and in the Republic of Ireland (RoI) using similar self-administered paper questionnaires. Patients were asked to identify caries risk factors/indicators from eight (Japan) or ten (RoI) listed items. The Japanese study involved 482 patients (aged ≥20 years) from 52 dental members of a nationwide web-based initiative Promoting Scientific Assessment in Prevention of Tooth Decay and Gum Disease (PSAP). The Irish study involved 159 patients (aged 20–69 years) accessing state-provided ('medical card') dental services from eight dental practices in County Cork. The two samples were compared.

Results: A higher proportion of Irish respondents identified 'Not visiting the dentist for check-up and cleaning' (OR 2.655; 99% CI 1.550, 4.547) and 'Not using fluoride' (OR 1.714; 99% CI 1.049, 2.802) than did Japanese respondents. A lower proportion of Irish respondents identified 'A reduced amount of saliva' (OR 0.262; 99% CI 0.159, 0.433) than Japanese respondents. Similarly shown in both studies were a persistent belief that 'Not brushing teeth properly' is a caries risk factor and a lack of knowledge on saliva buffering capacity as a caries risk factor.

Conclusions: Deficiencies in knowledge which should be addressed: among the Japanese group, of dental check-up/cleaning visits and of fluoride use for caries prevention; among the Irish group, of saliva quantity as a caries risk factor. In addition, in both groups, we need to inform patients of the defensive role of saliva.

Keywords: Dental caries, Risk factors, Knowledge, Fluorides, Saliva, Cross-cultural comparison, Japan, Ireland, Socioeconomic factors, Social determinants of health

* Correspondence: makikonishi@hotmail.com
[1]Oral Health Services Research Centre, University College Cork, Wilton, Cork, Ireland
Full list of author information is available at the end of the article

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Background

Dental caries has complex causes involving the interplay of host (saliva and teeth), microflora (plaque) and substrate (diet) factors [1]. A recent Japanese study of patients regarded to have a high interest in preventive dentistry revealed that knowledge among the public of these multiple factors is still lacking [2]; respondents were asked to identify caries risk factors/indicators from eight listed items (plus "Other") associated with these host, microflora, substrate factors and showed that the percentage of respondents identifying the caries risk factors/indicators correctly ranged from 2.0 to 36.8%. Since these respondents were considered to be more knowledgeable regarding caries prevention compared to the average Japanese person, this deficiency in knowledge of caries risk factors/indicators may be due to country-specific circumstances.

A prime example would be knowledge of fluoride; many studies have consistently shown a low level of knowledge about fluoride among the Japanese public [3, 4], although it has long been considered as the single most effective factor for the prevention of dental caries [5]. This may be attributed to the low availability over recent decades of fluoride-containing products in Japan compared to Western countries. Until 1994, only 46% of toothpaste on the Japanese market was fluoridated [6]; it was not until 2005 that this market share hit 88% [7]. On the other hand, the Republic of Ireland (RoI), which has a similar scale of per capita Gross Domestic Product (GDP) and health expenditure to Japan [8], has a long history of water fluoridation dating back to the 1960's [9]. Furthermore, the fluoridation debate in RoI involves the public and is quite active.

Despite having similar scales of per capita health expenditure, Japan and RoI have fundamentally different public policies on oral health. The Japanese health insurance system is universal health care that reimburses for sickness but not preventive care. In RoI, there are two dental treatment schemes: the Dental Treatment Benefit Scheme (DTBS) for employers and employees paying social insurance (Pay-Related Social Insurance (PRSI)) contributions and the Dental Treatment Services Scheme (DTSS) for medical-card holders who are means-tested. Both schemes pay for preventive care in the form of an annual oral examination in addition to covering some treatment costs. For medical card holders, treatment is limited to two fillings per calendar year, any extractions required and emergency dental treatment.

Cross-country comparisons allow us to inspect how differences in the social context of countries shape social determinants of health [10]. When comparing two countries with similar levels of economic development, such as Japan and RoI, the natural expectation is that the health-conscious population of one country would be more knowledgeable health-wise than the economically disadvantaged population of the second country. We hypothesise that there may be *unexpected* differences or similarities in knowledge between these two disparate groups across two economically similar countries. If our hypothesis holds, it becomes important to explore how a country's social/cultural profile shapes its social determinants of health and influences knowledge of caries risk. Understanding the influences on caries risk knowledge within a country is important for the development of effective and efficient strategies (especially population-based prevention strategies) for caries prevention.

The current paper aims to explore the knowledge of caries risk factors/indicators across two economically similar but culturally distinct countries by comparing two groups with different socio-economic profiles.

Methods

Two cross-sectional surveys were carried out, one in Japan, the other in RoI, using similar questionnaires on caries risk factors/indicators.

The Japanese study

The Japanese study targeted a population deemed to have a high interest in preventive dentistry, in order to investigate the current status of caries risk knowledge among potential opinion leaders [11] of personalised caries prevention programmes (i.e., based on each individual's caries risk assessment) [2]. Participants were patients of fee-paying dentist members of the nationwide web-based initiative *Promoting Scientific Assessment in Prevention of Tooth Decay and Gum Disease* (PSAP) [12], ≥20 years of age and not dental professionals (dentist, dental hygienist, dental assistant, dental technician). The PSAP, located in Tokyo, administered the Japanese study. Detailed data collection and data management procedures are described elsewhere [2]. All fee-paying dentist members of the PSAP were asked to distribute the paper questionnaires together with stamped, addressed (to the PSAP) return envelopes, to their patients on a first-come basis. The number of patient questionnaires issued to each PSAP dentist was limited to 20, as we did not wish to over-burden the dentists with the survey. A total of 2780 paper questionnaires were issued. Respondents who were dental professionals (dentist, dental hygienist, dental assistant, dental technician), <20 years of age or did not answer all socio-demographic factors (age, gender, whether dental professional or not) were excluded. Recruitment and questionnaire collection were conducted over a two-year period from May 2013 to May 2015. The ethics committee of the Japanese Society for Oral Health approved this study (No. 24–4).

The Irish study

The self-administered questionnaire survey was carried out on Irish adults aged 19–70 years who had 20 or

more teeth as part of a randomised controlled clinical study among economically disadvantaged people. As a proxy for low socioeconomic status, we selected medical-card holders, who are entitled to free General Practitioner (GP) care and other services [13]. Medical-card eligibility is based on the applicant's financial means. Approximately four out of ten Irish people were covered by a medical card in 2014 [14]. Recruitment was through eight dental practitioners in Cork, RoI. A sample size of $n = 200$ (including dropouts) was calculated for the randomised controlled clinical study. At the baseline examination, the dentists distributed the paper questionnaire and 3-day food diary with a stamped addressed return envelope to their patient. The respondents posted their completed questionnaire and food diary to the Oral Health Services Research Centre (OHSRC). After assessing their baseline data (clinical examination and 3-day food diary), we sent a €20 voucher to each respondent as a gesture of thanks. The questionnaire was anonymous but contained the respondent's mobile phone number through which they could be identified; the food diary which was sent with the questionnaire contained the respondent's name and phone number. Those who were <20 years of age were excluded, in accordance with the age criteria of the Japanese study (≥20 years). Recruitment was carried out over seven months between February and September 2015. Collection of questionnaires continued until November 2015. Ethical approval was given by the Clinical Research Ethics Committee of the Cork Teaching Hospitals (ECM 4 (r) 12/08/14).

Questionnaires

To allow comparison between different cultures, the self-administered paper questionnaires for the two study groups contained similar questions. English language versions of the questionnaires are provided as additional files (see Additional files 1 and 2). The Japanese study questionnaire was developed first; it was pre-piloted in English, piloted in Japanese and then further refined after piloting [2]. Among the listed risk factors/indicators, 'Not visiting the dentist for a dental maintenance programme (check-ups and cleaning)' may be regarded as a controversial risk indicator, as some dentists continue to perform unnecessary restorative intervention to early caries lesions during or after a routine check-up [15]. This may be detrimental because repetitive restorations (the 'drill, fill and bill' philosophy) result in a shorter tooth life span [16]. Hence, the statement 'The more I visit the dentist for check-ups, the more teeth, I think, are drilled' was included in the Japanese study and respondents were asked whether they agreed or not. The Irish questionnaire included a similar but, in keeping with the Irish context, less explicitly worded statement; thus, to avoid misinterpretation, the current study excluded the Irish statement. "Low saliva buffering capacity" was simplified with non-technical language (Japanese study: *Low quality of saliva*; Irish study: *Having saliva (spit) that does not have the right composition to protect against decay*). For the sake of simplicity, the questionnaires avoided technical language in favour of layman's terms such as 'bad' or 'weak' even though such terminology might be prone to subjective interpretations. Translations between Japanese and English were carried out by MN (Japanese and English speaker) and VK (English speaker). Based on the Japanese study questionnaire written in English, three dentists (MN, MH and FA), one economist (VK) and the project manager developed the Irish study questionnaire and assessed its face validity. Regarding the Japanese study questionnaire, face validity was assessed by two non-dental Japanese speakers, one dental office worker and one dentist. Table 1 shows the corresponding questions in both study questionnaires analysed by this paper. Both studies were conducted according to the principles outlined in the Declaration of Helsinki. Respondents completed the questionnaires at home to avoid undue influence from the dental practice on their answers. All patients provided written informed consent.

Data analysis

Respondent characteristics including age, gender, age by gender and attendance for check-up and tooth cleaning were summarised for Japanese patients of PSAP dentists and for Irish medical-card patients from dental practices in Cork. We set two age groups (20–39, 40+ years), as the age distribution was different in the two studies. For the Japanese data, Stata's Survey data analysis method, with the dentist specified as the primary sampling unit (PSU), was employed to adjust standard errors used in the calculation of 95% confidence intervals (CIs) for intra-class correlation among responses from patients who attended the same dentist. This adjustment was not made to the 95% confidence intervals for the Irish data, due to the small number of dentists and low response level from patients of some dentists. Results are presented by age group for both study groups. Percentage frequencies and 95% CI's are given for the questions on knowledge of caries risk factors/indicators and for respondents choosing seven caries risk factors/indicators. Means and 95% CI's are presented for total number of identified risk factor/indicator excluding diet item(s). Percentage frequencies are shown for patients' opinions on the statement 'The more I visit the dentist for check-ups, the more teeth, I think, are drilled.' (in the Japanese study only).

The questions on diet were not included in the comparison analysis as these were framed differently in the two studies, and were compared between age groups

Table 1 Correspondence table of questions on caries risk/indicator knowledge and other items

Question category	Japanese study[a]		Irish study
Caries risk	Generally speaking, what do you think is (are) the reason(s) for susceptibility (risk) of getting tooth-decay? Please choose all that apply.	d	Generally speaking, which of the following do you think would increase the risk of developing dental decay? Please choose all that apply.
	Not brushing your teeth properly		Not brushing your teeth properly
	Bad eating habit	e	Consuming too much sugary foods and drinks
			Consuming sugary foods and drinks too often
			Consuming sugary foods and drinks just before bedtime
	Having naturally 'weak teeth'		Having naturally "weak teeth"
	Not visiting the dentist for a dental maintenance programme (check-ups and cleaning)	d	Not visiting the dentist for check-up and cleaning
	Not using fluoride		Not using fluoride
	Having particular bacteria in the mouth that contribute to the development of dental decay		Having particular bacteria in the mouth that contribute to the development of dental decay
	Low saliva flow rate	d	Having a reduced amount of saliva (spit) in the mouth
	Low quality of saliva[c]	d	Having saliva (spit) that does not have the right composition to protect against decay[c]
	Other (please specify):		Other (please specify):
Opinion	How strongly do you agree with these statements?		
	The more I visit the dentist for check-ups, the more teeth, I think, are drilled. (Strongly agree, Somewhat agree, Neither agree nor disagree, Somewhat disagree, Strongly disagree)		
Attendance for check-up and cleaning	Do you go to the dentist for a dental maintenance programme (check-ups and cleaning)? Yes, No		Do you go to the dentist for a dental maintenance programme (check-ups and cleaning)? Yes, No
Gender	Male, Female		Male, Female[b]
Age	19 or younger than 19, 20–29, 30–39, 40–49, 50–59, 60 or older than 60	d	Age at informed consent was calculated with the date of birth[b].
Dental professionals	Are you a dental professional (dentist, dental hygienist, dental assistant and dental technician)? Yes, No		

English language versions of the questionnaires are provided as additional files (see Additional files 1 and 2)
[a]The original questionnaire was in Japanese
[b]Information was derived from the case report form which the dentist filled in
[c]Wording used for low saliva buffering capacity
[d]The questions were slightly different between the Japanese and Irish studies
[e]The question was different between the Japanese and Irish studies

only. A logistic regression model was fitted to each of the binary variables of the risk indicators list common to both countries, with country, age and their interaction as predictors. A linear regression was fitted to the data with total number of identified risk factors/indicators excluding diet item(s) as dependent variable and country, age group and their interaction as predictors. A backward elimination process was performed for both types of regression until only significant terms remained in the model. An adjustment to standard errors was not made in these analyses due to the small number of dentists in the Irish study. The Mann-Whitney test was employed to compare ordinal responses between two age groups. Missing data were excluded from the analysis. We utilised the IBM SPSS Statistics Version 22 (SPSS Inc., Chicago, IL), R 3.2.3 (R Core Team, 2015 [17]) and the Survey Data Analysis procedure in Stata 12.1 (Stata Corp, College Station, TX). Two-sided significance level was set at 0.05, but the focus was on results showing a significance level less than 0.01, due to multiple testing.

Results

Characteristics of the samples

The paper questionnaires were distributed by 52 dentists in Japan and eight dentists in RoI (Table 2). For the Japanese study, it is unknown how many paper questionnaires out of 2780 issued by the PSAP were distributed by the PSAP dentists to their patients. In total, 482 questionnaires were returned and met the inclusion criteria (Fig. 1). For the Irish study, 191 questionnaires were distributed by the eight dentists; 159

Table 2 Number of dentists and respondents per dentist

		Japanese study	Irish study
Number of dentists		*n* = 52	*n* = 8
Respondents per dentist			
	min.	1	1
	avg.	9.3	19.9
	s.d.	5.1	26.5
	max.	18	83
Number of respondents		*n* = 482	*n* = 159
Gender (%)	Male	30.9	32.1
	Female	69.1	67.9
Age (%)	20–29	8.1	22.0
	30–39	19.9	33.3
	40–49	23.4	24.5
	50–59	19.7	13.2
	60+	28.8	6.9
Gender & Age			
Males		*n* = 149	*n* = 51
Age (%)	20–29	7.4	25.5
	30–39	16.8	25.5
	40–49	15.4	27.5
	50–59	22.8	15.7
	60+	37.6	5.9
Females		*n* = 333	*n* = 108
Age (%)	20–29	8.4	20.4
	30–39	21.3	37.0
	40–49	27.0	23.1
	50–59	18.3	12.0
	60+	24.9	7.4
		n = 481	*n* = 156
Attendance for check-up and cleaning (%)			
	Yes	91.5	69.2
	No	8.5	30.8

The table shows number of dentists and respondents per dentist; respondents by gender, age group and attendance for check-up and cleaning in the Japanese and Irish studies

were returned and met the inclusion criteria (Fig. 1). Gender distributions were similar between the Japanese and Irish studies: the male to female ratio was 3 to 7. Age distributions were rather different: the Irish study had more young respondents than the Japanese study. Check-up and tooth cleaning attendance in the Japanese study was quite high (91.5%) compared to the Irish study (69.2%).

Knowledge of caries risk factors/indicators

The results of fitting the binary logistic model to each of the risk factors/indicators are presented in Table 3. In both studies, common tendencies were observed: more than 90% in both age groups identified 'Not brushing your teeth properly'; saliva buffering capacity was the least identified caries risk factor. The major differences were that 'Not visiting the dentist for check-up and cleaning' (OR 2.655; 99% CI 1.550, 4.547; $p < 0.001$) and 'Not using fluoride' (OR 1.714; 99% CI 1.049, 2.802; $p = 0.005$) were identified more frequently by the medical-card patients in RoI than by the potential opinion leaders in Japan. 'Having a reduced amount of saliva (spit) in the mouth' (OR 0.262; 99% CI 0.159, 0.433; $p < 0.001$) was identified in the Japanese study much more frequently than in the Irish study.

Respondents had the opportunity to list other caries risk factors/indicators not included in the tick box options. In the Japanese study, heredity [18], smoking [19], crooked teeth [20] and caregivers at high caries risk [21] were listed under the 'Other' category and considered as correct and different from the listed alternatives. In the Irish study, smoking [19] and substance abuse [22] were specified under 'Other' and considered as correct risk factors. The percentages of respondents choosing seven items including "Other" with a correctly specified caries risk factor/indicator and excluding the diet items were higher in the younger age group (11.9%) than the older age group (9.8%) in the Japanese study. The Irish study showed the opposite tendency with the younger age group scoring lower (9.1%) and older age group higher (12.7%). The number of chosen caries risk factors/indicators was higher in the 20–39 age group (mean = 3.87, sd = 1.76) of the Japanese study and in the 40+ age group (mean = 3.71, sd = 1.62) of the Irish study (Table 4). The results of fitting the linear model to the variable *total number correct* showed that neither age nor country were associated with total number of identified risk factor/indicator excluding diet item(s) (Table 4).

Agreement with the statement on dental visit for check-up

Table 5 presents the percentage of Japanese respondents agreeing with the statement 'The more I visit the dentist for check-ups, the more teeth are drilled' by age group. Only a minority of respondents agreed with the statement (12.6% in the 20–39 age group; 9.9% in the 40+ age group). Number of respondents with missing data was 13; all 13 (100%) were in the 40+ age group, 11 (84.6%) were female and 11 (84.6%) attended for check-up and professional cleaning. The Mann-Whitney test showed that the ordinal responses to the statement were similar for younger (Median = 3) and older (Median = 3) age groups (U = 22593, $p = 0.969$).

Discussion

To the best of our knowledge, this is the first study to compare two populations from different countries on their knowledge of caries risk. It is a unique comparison,

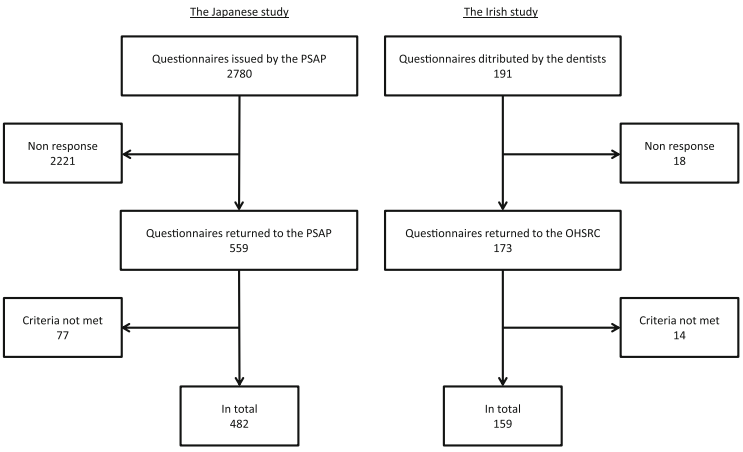


Fig. 1 Flow diagram showing numbers of patients at each stage of the Japanese and Irish studies. PSAP: Promoting Scientific Assessment in Prevention of Tooth Decay and Gum Disease. OHSRC: Oral Health Services Research Centre

as the responses were clearly different between the Japanese and Irish studies. The comparison revealed that the Japanese respondents, who were considered to have a high interest in preventive dentistry, did not always display more knowledge than the Irish respondents, who were considered to be of low socioeconomic status. In particular, the Japanese respondents identified 'Not visiting the dentist for check-up and tooth cleaning' and 'Not using fluoride' less frequently than the Irish respondents as caries risk factors/indicators. A clear reason for the great difference in the identification of dental visits for check-up and tooth cleaning as a caries risk indicator between the two studies is unknown. We checked if the Japanese respondents thought that visiting for check-ups and tooth cleaning might induce more teeth to be drilled but found that only approximately 10% of respondents agreed with the statement 'The more I visit the dentist for check-ups, the more teeth are drilled'.

A possible factor affecting the low identification of this risk factor in Japan is that the introduction of dental visits for check-up and tooth cleaning has been extremely slow in Japan, compared to the Western countries. A national survey reported that visits for dental check-up were only 1.6% of total dental visits in 2014 [23]. Another national survey reported that the uptake of check-up visits by patients during the past one year was 47.8% in 2012 [24], but probably included a simple check-up performed with other operative treatments. In both surveys, professional cleaning was not included. In the current paper, over 90% of the Japanese respondents attended for check-up and tooth cleaning. Nonetheless, they may not be aware that not receiving a check-up and tooth cleaning increases caries risk and may think that scaling (for preventing gum diseases) is the main procedure when attending for check-up and tooth cleaning.

In RoI, visiting the dentist for check-up and tooth cleaning became the norm earlier than in Japan. The earliest available survey [25] showed that in 1979, 20% of Irish adults were already visiting regularly for a check-up; the utilisation rate has since increased [26]. A topical discussion is not only how to increase utilisation, but also whether the common 'six-month' check-up for everyone is evidence-based or not [27]. In the current paper, approximately 70% of the Irish medical-card respondents received check-up and tooth cleaning. This is rather high compared to the average reported for medical-card holders by a national Irish survey (48.4% among 16–24 year olds, 54.2% among 35–44 year olds, 27.9% among 65+ year olds) [26], most likely because our participants were recruited through general dental practices and the national survey was conducted approximately 15 years ago. In addition, caution is necessary because dental practices and their patients in the current study were convenience samples.

It was expected that the Irish medical-card respondents might identify 'Not using fluoride' more frequently than the Japanese health-conscious respondents, because it has been found that the Japanese people, including dentists, are not aware of the significant role of fluoride for caries prevention [3, 4, 28], while RoI has a long history of water fluoridation [9] with on-going active public debates. The percentages of Japanese respondents identifying this item were approximately two-thirds of the Irish ones. However, it was surprising that only approximately 40% of the Irish

Table 3 Percentage (and 95% CI) of respondents from the Japanese and Irish studies identifying each risk factor/indicator[a]

Risk factor/indicator Age group	Yes response by country (%)				Odds ratio (99%CI)[b] Z, Significance level for terms in final model		
	Japanese study		Irish study		Country * Age interaction	Age	Country
Not brushing your teeth properly[c]					e	e	e
20–39	94.8	(89.1–97.6)	94.3	(87.2–98.1)			
40+	91.6	(87.9–94.3)	91.5	(82.5–96.8)			
All ages	92.5	(89.6–94.7)	93.1	(88.0–96.5)			
Bad eating habit[d]					N.A.	e	N.A.
20–39	65.2	(55.8–73.5)					
40+	60.8	(54.4–66.9)					
All ages	62.0	(56.3–67.4)					
Consuming too much sugary foods and drinks[d]					N.A.	e	N.A.
20–39			86.4	(77.4–92.8)			
40+			83.1	(72.3–91.0)			
All ages			84.9	(78.4–90.1)			
Consuming sugary foods and drinks too often[d]					N.A.	e	N.A.
20–39			77.3	(67.1–85.5)			
40+			84.5	(74.0–92.0)			
All ages			80.5	(73.5–86.4)			
Consuming sugary foods and drinks just before bedtime[d]					N.A.	2 (0.804–4.977)	N.A.
20–39			61.4	(50.4–71.6)		Z = 1.96	
40+			76.1	(64.5–85.4)		*P* = 0.050	
All ages			67.9	(60.1–75.1)			
Having naturally 'weak teeth'[c]					Z = 2.18	N.R.	N.R.
20–39	47.4	(39.0–56.0)	48.9	(38.1–59.8)	*P* = 0.029		
40+	59.9	(55.2–64.6)	40.8	(29.3–53.2)			
All ages	56.4	(51.7–61.0)	45.3	(37.4–53.4)			
Not visiting the dentist for check-up and cleaning[c]					e	e	2.655 (1.550–4.547)
20–39	50.4	(41.7–59.1)	75.0	(64.6–83.6)			Z = 4.68
40+	57.3	(51.6–62.9)	78.9	(67.6–87.7)			*P* < 0.001
All ages	55.4	(50.5–60.2)	76.7	(69.4–83.1)			
Not using fluoride[c]							
20–39	32.6	(22.2–45.1)	37.5	(27.4–48.5)	e	e	1.714 (1.049–2.802)
40+	26.5	(21.0–32.9)	43.7	(31.9–56.0)			Z = 2.82
All ages	28.2	(22.9–34.2)	40.3	(32.6–48.3)			*P* = 0.005
Having particular bacteria in the mouth that contribute to the development of dental decay[c]					e	e	e
20–39	60.0	(48.8–70.3)	46.6	(35.9–57.5)			
40+	46.4	(39.2–53.8)	49.3	(37.2–61.4)			
All ages	50.2	(43.0–57.4)	47.8	(39.8–55.9)			
Having a reduced amount of saliva (spit) in the mouth[c]					e	e	1.714 (0.159–0.433)
20–39	68.1	(57.8–77.0)	30.7	(21.3–41.4)			Z = −6.88
40+	62.8	(55.7–69.4)	33.8	(23.0–46.0)			*P* < 0.001
All ages	64.3	(58.4–69.8)	32.1	(24.9–39.9)			
Having saliva (spit) that does not have the right composition to protect against decay[c]					Z = −2.42	N.R.	N.R.

Table 3 Percentage (and 95% CI) of respondents from the Japanese and Irish studies identifying each risk factor/indicator[a] *(Continued)*

20–39	32.6	(24.5–41.9)	22.7	(14.5–32.9)	$P = 0.016$			
40+	24.5	(19.0–30.9)	35.2	(24.2–47.5)				
All ages	26.8	(21.7–32.6)	28.3	(21.5–36.0)				
% of subjects choosing 7 factors/indicators excluding diet item(s)[c]					e		e	e
20–39	11.9	(6.7–20.0)	9.1	(4.0–17.1)				
40+	9.8	(6.9–13.8)	12.7	(6.0–22.7)				
All ages	10.4	(7.6–14.0)	10.7	(6.4–16.6)				

The table includes percentage (and 95% CI) of respondents choosing seven factors/indicators excluding diet item(s) according to age groups
N.A not applicable; *N.R* not relevant when interaction term was significant, *e* eliminated from model due to non-significance
[a]The items were from the Irish study except "Bad eating habit"
[b]Odds ratio, reported for significant main effects in model and not for significant interactions
[c]Step1: full model fitted: Intercept + Age + Country + Country * Age; followed by backward elimination process
[d]Full model fitted: Intercept + Age

medical-card patients identified 'Not using fluoride' as a caries risk factor. It may be because the Irish population were medical-card patients, or/and because some of them interpret fluoride not as a 'risk factor' but as a 'beneficial factor'.

Cultural beliefs and attitudes have an influence on oral health and oral health disparities [29]. One vast difference between the Japanese and Irish culture is their native major religion – Shintoism vs. Christianity. The Japanese culture of cleanliness is partially rooted in their indigenous religion of Shintoism which equates cleanliness with purity [30]; this may account for their different hygiene behaviours compared with Christian countries like RoI. The deep-rooted Japanese belief in pursuing personal hygiene in daily life by themselves may be a reason for their delaying the introduction of dental check-ups and tooth cleaning by dental professionals and the use of fluoridated products.

Another noteworthy point is that among the Irish medical-card patients the percentages of those identifying 'Having a reduced amount of saliva (spit) in the mouth' were comparatively low in both age groups. This knowledge deficiency may present an obstacle to preventing dental caries, including root caries, when they are aged and xerostomia become common. It is not known whether this response was influenced by their lower socio-economic status or by some other country-specific factor; a further study is necessary to confirm the reason.

Common tendencies in both studies were tooth brushing being most frequently identified and saliva buffering capacity being least frequently identified as caries risk factors. In spite of the differing cultural backgrounds and socioeconomic characteristics between the groups, this study reveals a persistent belief in tooth brushing as a means to reduce caries risk, despite the fact that the caries-reducing effect of tooth brushing and other self-administrated oral hygiene interventions per se (without fluoride) is doubtful [31]. In addition, this study shows that saliva's defensive role against caries is not well known.

Although the three breakdown questions on diet (too much sugary diet, too often sugary diet, sugary diet before bedtime) were asked only in the Irish study, the results give insight into public knowledge regarding substrate (diet) factors for caries prevention among this population. The respondents least frequently identified 'Consuming sugary foods and drinks just before bedtime' as a factor increasing caries risk. Considering this result with the low percentages identifying saliva as a risk factor, it would appear that the respondents have little awareness of the full mechanism behind caries development. They may also believe that brushing teeth after consuming sugary foods and drinks before bedtime is

Table 4 Average (and 95% CI) and standard deviation of the number of identified caries risk factor/indicator

Age group	Japanese study			Irish study			Z, Significance level for terms in final model[a]		
	Average	(95% CI)	sd	Average	(95% CI)	sd	Country* Age interaction	Age	Country
20–39	3.87	(3.44–4.31)	1.76	3.58	(3.20–3.96)	1.79	e	e	e
40+	3.71	(3.54–3.88)	1.62	3.76	(3.30–4.22)	1.95			
All ages	3.75	(3.56–3.95)	1.66	3.66	(3.37–3.95)	1.86			

The results were calculated excluding diet item(s) by age group
e: eliminated from model due to non-significance
[a]Full model: Intercept + Age + Country + Country *Age

Table 5 Percentage of Japanese respondents agreeing with the statement by age group ($n = 469$)

	Age group		
Statement	20–39	40+	All ages
The more I visit the dentist for check-ups, the more teeth, I think, are drilled.			
Strongly/Somewhat agree	12.6	9.9	10.7
Neither agree nor disagree	41.5	45.5	44.3
Strongly/Somewhat disagree	45.9	44.6	45.0

sufficient to prevent tooth decay. Efforts to reduce intake of sugary foods and drinks before bedtime may also have the potential to impact general health under the common risk factor approach [32, 33].

The limitations of the current paper relate to differences in the methodology between the surveys and include: sample representativeness, differences in questionnaire content and remuneration of participants in the Irish study and not the Japanese. In particular, the PSAP was the only source of recruitment in the Japanese study and one dentist recruited more than half of the patients in the Irish study. Therefore, generalisation of the findings is restricted. However, this study illustrates the value of intercultural comparison in exploring knowledge and attitudes to risk factors and oral health. The study provides useful new insights worthy of further exploration.

Conclusions

For the risk factors/indicators 'Not visiting the dentist for check-up and cleaning' and 'Not using fluoride', a lower proportion of respondents identified these factors in the Japan study than in the Irish study, indicating that country differences had a stronger influence on patients' knowledge than socio-economic differences. 'Having a reduced amount of saliva (spit) in the mouth' was less known as a caries risk factor among the Irish group. Understanding the influence of a population's social/cultural profile on knowledge deficiency of caries risk is important, particularly when designing programmes to enhance patients' knowledge. Furthermore, persistent belief in tooth brushing for caries prevention and lack of knowledge about saliva buffering capacity were similar tendencies in both study groups despite their different cultural and socioeconomic backgrounds. This implies that there is a general need to inform patients of the defensive role of saliva in both groups from both countries.

Additional files

Additional file 1: The Japanese study questionnaire. An English-language translation of the questionnaire used in the Japanese study. (PDF 74 kb)

Additional file 2: The Irish study questionnaire. The questionnaire used in the Irish study. (PDF 81 kb)

Abbreviations

CI: Confidence interval; DTBS: Dental Treatment Benefit Scheme; DTSS: Dental Treatment Services Scheme; GDP: Gross Domestic Product; GP: General Practitioner; IADR: International Association for Dental Research; OHSRC: Oral Health Services Research Centre; OR: Odds ratio; PRSI: Pay-related social insurance; PSAP: Promoting Scientific Assessment in Prevention of Tooth Decay and Gum Disease; PSU: Primary sampling unit; RoI: Republic of Ireland

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Availability of data and materials

Data will not be made available as more articles are to be published.

Authors' contributions

For both the Japanese and Irish studies, MN contributed to conception of the studies and acquisition of data. MN and VK contributed to design of both studies, and drafted and finalised the manuscript. HW contributed to design of the Japanese study. MH and FA contributed to design of the Irish study. All authors contributed to analysis and interpretation of data and revising the manuscript critically for important intellectual content. All authors have approved the final version and agreed to be accountable for all aspects of the work.

Competing interests

MN is the chairperson of the board of the PSAP.

Consent for publication

Not applicable.

Ethics approval and consent to participate

The Japanese study was approved by the ethics committee of the Japanese Society for Oral Health (No. 24–4). For the Irish study, ethical approval was given by the Clinical Research Ethics Committee of the Cork Teaching Hospitals (ECM 4 (r) 12/08/14). All patients were informed about the survey and provided written informed consent.

Author details

[1]Oral Health Services Research Centre, University College Cork, Wilton, Cork, Ireland. [2]The School of Dentistry, University of Leeds, Leeds, UK. [3]Faculty of Dentistry, National University of Singapore, Singapore, Republic of Singapore.

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Article III

Nishi M, Harding M, Kelleher V, Cronin M, Allen F. A comprehensive caries risk assessment with the Cariogram versus patient-perceived caries risk in an adult population: a cross-sectional study. Int J Technol Assess Health Care (*prepared*).

Authors' contribution

Nishi M: the conception and design of the Irish study, the acquisition, analysis, and interpretation of data for the Irish study, drafting the work, and agreement to be accountable for all aspects of the Irish study in ensuring that questions related to the accuracy or integrity of any part of the Irish study are appropriately investigated and resolved.

Relevant presentation

Nishi M, Harding M, Cronin M, Whelton H, O'Mullane D, Kumagai T, Allen F. Actual and self-perceived risk of dental caries in disadvantaged people. The Irish Division Annual Scientific Meeting of the International Association for Dental Research (IADR), Cork 4 March 2016.

Abstract

Objective: To evaluate the associations between a comprehensive caries risk assessment and patient-perceived caries risk in an adult population.

Material and Methods: This is a cross-sectional study using data collected via interview, clinical examination, CRT® saliva tests (Ivoclar Vivadent, Liechtenstein), a self-administered questionnaire plus 3-day food diary for a randomized clinical study (UMIN-CTR ID: UMIN000027253). Eight trained and calibrated dentists recruited 191 medical-card patients, of whom 165 patients participated in this study. We compared each patient's assessed caries risk (as measured by Cariogram, a computer-based caries risk assessment model: independent variable) with self-perceived caries risk (obtained from a direct question: dependent variable) using logistic regression models.

Results: Subjects in the 'Very high risk' and 'High risk' groups were 16.0 times (95% CI: 1.9–134.2) and 18.8 times (95% CI: 2.8–124.8), respectively, more likely to perceive themselves as having high caries risk than subjects in the 'Low/Rather low risk' group. However, 64% of patients in the high risk groups did not consider themselves as being 'more prone to dental decay' than the average person.

Conclusions: Strategies for risk reduction can be tailored according to individual caries risk and self-perceived caries risk amongst medical-card holders.

Keywords: dental caries; risk factors; risk assessment; socioeconomic factors; perception

Funding details

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Disclosure statement

This research is sponsored by the IADR and Unilever and contributed to by Ivoclar Vivadent AG. Ivoclar Vivadent AG offers CRT® for student laboratory work to Cork University Dental School and Hospital in University College Cork. MN is the chairperson of the board of Promoting Scientific Assessment in Prevention of Tooth Decay and Gum Disease (Japanese non-profit organization). We have disclosed these interests fully to Taylor & Francis, and have in place an approved plan for managing any

potential conflicts arising from this arrangement.

Introduction

Risk perception is an important aspect of many health behavior theories that focus on individuals [1-3]. A number of studies have confirmed the association between patients' self-perceived risk and preventive health behaviors [4-6]. However, it is also true that people tend to have an optimistic bias about their risk of developing a disease [5, 7]. In other words, some high risk patients do not have a realistic appreciation of their risk level and it remains necessary to bring their attention to their actual risk [8].

A recent study in Sweden reported a significant correlation between patients' oral health risk scores (covering dental caries, periodontal and general risks) as determined by the dentist and patients' own perception of future oral treatment need; 45% of those assessed as high-risk patients by the dentist rated themselves as having a large future oral treatment need [9]. Another study investigating dental caries among Tanzanian women indicated that their self-perceived risk of having tooth decay varied positively and systematically with the status of their actual risk factors (i.e., symptoms of tooth decay and self-reported intake of sugary products) [10]. The subjects in the study underestimated their comparative vulnerability regarding risk factors for poor oral health. The authors suggested finding approaches that help people gain a more accurate picture of their actual individual risk.

While past caries experience alone may be as accurate as a comprehensive caries risk assessment model for predicting future caries development [11], dental caries forms through a complex interaction between host (saliva, teeth), microflora (acid-producing bacteria) and substrate (fermentable carbohydrate) factors [12] and having a comprehensive risk assessment is helpful for making individuals aware of the specific risk factors pertinent to them [11, 13]. To comprehensively account for these etiological risk factors, the Cariogram, a computer-based caries risk assessment model, was developed [14]. From a wide range of caries risk assessment tools, the Cariogram has been the most used for investigations on caries risk profiles or caries prediction [15-18], and is in agreement with the majority of dental instructors, dental students, general dentists and dental hygienists in ranking virtual patients according to 'chance of avoiding new cavities' [19, 20]. This value, which ranges from 0% to 100%, is the summary assessment of an individual's caries risk calculated by the Cariogram with 10 parameters: 'Caries experience', 'Related diseases', 'Diet contents', 'Diet frequency', 'Plaque amount', 'Mutans streptococci', 'Fluoride programme', 'Saliva secretion', 'Saliva buffer capacity' and 'Clinical judgment'.

We hypothesize that there is an association between a comprehensive caries risk assessment which considers host, microflora and substrate factors, and self-perceived caries risk, and that this association will reflect a similar tendency to that of previous studies on self-perceived risks for dental or medical conditions. The aim of this study is to evaluate the associations between a comprehensive caries risk assessment (independent variable) and patient-perceived caries risk (dependent variable), and to explore the caries risk factors/indicators that are associated with patient-perceived caries risk among Irish adult medical-card patients.

Material and Methods

Study design and setting

The data for the current cross-sectional study were obtained between February 2015 and November 2015, from the baseline examination and completed questionnaires of a randomized controlled study conducted by the Oral Health Services Research Centre (OHSRC) at the Cork University Dental School and Hospital. This study was designed to investigate the impact of a personalized caries prevention approach using educational mobile-phone short text messages based on individual risk assessment using the Cariogram (version 3.0j) among Irish adult medical-card holders. The randomized controlled study was registered in the University Hospital Medical Information Network Clinical Trial Registry (UMIN-CTR ID: UMIN000027253). The randomized controlled study and the current cross-sectional study were conducted in full accordance with the World Medical Association Declaration of Helsinki. The protocol for the randomized controlled study and the current cross-sectional study was reviewed and approved by the Clinical Research Ethics Committee of the Cork Teaching Hospitals of University College Cork (ECM 4 (r) 12/08/14) in August 2014. We obtained written consent from all patients and verbal consent from all dentists involved in the current study. As we considered participating dentists (volunteers) as co-researchers of the current study, we did not include their consent procedure in the ethics approval application.

Sample selection

Details on the recruitment of patients is described elsewhere[21]. The pre-determined inclusion criteria for the randomized controlled study were as follows: (1) willingness to participate in the project; (2) 19–70 years of age; (3) medical-card holder; (4) at least 20 teeth present; (5) not pregnant and (6) ability to use text messages. Irish medical-card holders are entitled to a range of health services free of charge; eligibility to a medical card is determined by an assessment of an applicant's financial means [22].The power analysis was conducted for the randomized controlled study based on previous Cariogram studies [23] with a significance level of 5%, a power for that detection of 80%, a control response of 36 ('chance of avoiding new cavities'), a standard deviation of 21.6, and a change relative to control mean of 30%. Allowing for a non-response rate of 33%, 191 patients (62 men and 129 women) were recruited. Of them, five patients were not eligible.

Training and calibration exercise

The inclusion criteria for participating dentists were (1) working in a dental practice in Cork, Republic of Ireland (RoI) and (2) having medical-card patients. Six participating dentists were experienced private practitioners with their own dental practice, three of whom were also clinical instructors in the University Dental Hospital and one of whom had received postgraduate education in the OHSRC.

Another two participating dentists were staff dentists in different private dental practices, one of whom had received postgraduate education in the OHSRC and the other was well-experienced in clinical trials. Prior to subject recruitment, these eight dentists were trained and calibrated to examine coronal and root surface caries condition using criteria similar to those used in the Irish Adult Oral Health Survey 2000–2002 [24]. Details on the training and calibration are described elsewhere [25]. The Kappa statistics for inter-examiner reliability ranged from 0.54–0.94 and 0.37–0.48 for coronal and root surface caries condition, respectively. We did not perform further calibration to enhance the agreement of root surface caries condition but did not use this index for caries risk assessment. We did not perform intra-examiner reliability tests for all dentists. For scoring the 'Plaque amount' parameter, the dentists were provided with training slides that included clinical photos and instructed to record a single score from 0 to 3, as defined in the Cariogram Manual[14], based on their clinical impression of each subject.

Data collection

After obtaining informed consent, the dentist interviewed the patient (gender, age, fluoride use, related systemic diseases/conditions, smoking status [26], smart phone ownership), collected stimulated saliva samples for exactly five minutes (salivary flow rate, salivary buffering capacity, bacteriological tests with CRT® saliva tests (Ivoclar Vivadent, Liechtenstein)) and carried out a clinical examination (past caries experience, plaque amount) in the private dental practice. Table 1 provides details on the interview, saliva tests and clinical examination for caries risk assessment. Smart phone ownership was asked as reference for future research projects using mobile health (mHealth), and as an indicator of socioeconomic status in the current study.

The patient was then given a self-administered questionnaire (perception of caries susceptibility ('*prone to dental decay (cavities or caries)*'[1]), educational level, tooth brushing frequency, attendance for check-ups and cleaning) and a 3-day food diary form (diet frequency) to take home, complete and return to the OHSRC via post. The CRT® agar culture together with the clinical report form were all returned by the dentist to the OHSRC, usually on the same day as the examination. The questionnaire and 3-day food diary were completed by the patient. The questionnaire was developed from the English version of the questionnaire for a previous study [27], using WHO's Oral Heath Surveys Basic Method [28] and the questionnaires used in the Oral Health of Irish Adults 1989–1990 [29] as reference guides. Details on the development of the questionnaires is also described in the paper cited above [21].

The OHSRC laboratory technician incubated and read the CRT® slides (*mutans streptococci* and *lactobacillus* levels) in accordance with the manufacturer's instructions. The 3-day food diary was used to evaluate average fermentable carbohydrate intake per day for each subject. From the returned questionnaires, two questions on caries susceptibility were analyzed:

[1] Caries, cavities and decay are used interchangeably in the current paper.

Q1: 'Are you aware that some people are more prone to dental decay (cavities or caries) than others – Yes or No?'

Q2: 'Do you think that you are more prone to dental decay than the average person – Yes or No?'

Q2 was used as the direct measure of risk perception and the 'No' answer was interpreted as that the patient could not clearly say 'Yes' and not as a clear 'No'.

The data (interview, clinical examination, CRT®, self-administered questionnaire, 3-day food diary) collected for each patient were entered by the lead researcher into the Cariogram (Table 1). Using their scores for 'chance of avoiding new cavities', patients were classified as 'Very high risk' (≤20%), 'High risk' (21%–40%), 'Intermediate risk' (41%–60%) and 'Low/Rather low risk' (>60%) for dental caries [16].

Statistical analysis

A logistic regression model was fitted to self-perceived caries risk (outcome variable) as follows. Each of the demographic/non-Cariogram parameters (gender, age, educational level, smoking status, smart phone ownership, attendance for check-ups and cleaning, toothbrushing frequency and Q1) was screened using a univariate logistic regression model. If statistically significant at the 10% level, these variables were included in multivariate logistic regression models with the Cariogram assessment expressed as 'chance of avoiding new cavities'. These variables were assessed again in the multivariate model and were retained only if significant at the 5% level. As there were several variables we could include in the regression model, we applied this strategy to reduce the number of candidate variables, so that the model would be relatively parsimonious. A second logistic regression model was fitted in which the demographic/non-Cariogram parameters identified in the first model were included with the Cariogram parameters. It was not possible to include 'Related diseases' and 'Fluoride programme' in this model as these variables had too few patients distributed into one or two score(s). Furthermore, categories of 'Caries experience', 'Plaque amount' and 'Saliva buffer capacity' were merged to avoid having too few data in one score. The generalized coefficients of determination for the logistic regression models were 25% and 40%, respectively. As patients were clustered within dentists, clustering was accounted for in the statistical analyses (Proc Surveyselect, SAS, Version 9.4, SAS Institute Inc., Cary, NC). Note that the interpretations of the demographic/non-Cariogram parameters are presented only for the first multivariate logistic regression model.

Results

Of 191 recruited medical-card patients, 186 were eligible. The response rate was 88.7% (165 out of 186 eligible patients) (Figure 1). The distribution of the 165 subjects according to eight dentists was 86

(52.1%), 22 (13.3%), 18 (10.9%), 15 (9.1%), 12 (7.3%), 9 (5.5%), 2 (1.2%) and 1 (0.6%). The mean age was 38.5 years (sd: 12.7) and approximately two-thirds (67.9%) were women. The proportion of subjects with third level educational or higher was 35.7% (Table 2). Approximately three-quarters (73.2%) were aware that some people are more prone to dental caries than others; approximately one-quarter (28.5%) reported that they perceived themselves to be more prone to dental caries than the average person. Among the demographic/non-Cariogram parameters, there were statistically significant differences in self-perceived caries risk by educational level ($p<0.01$), by smoking status ($p=0.03$) and by attendance for check-ups and cleaning ($p=0.01$). Non-smokers had lower odds of perceiving their caries risk as above average (OR=0.48, 95% CI: 0.25–0.92). Those who do not go to the dentist for check-ups and cleaning had increased odds of self-perception of being at risk (OR=2.44, 95% CI: 1.29–4.61). Regarding educational level, those who completed primary education had increased odds of self-perception of being at risk relative to those who completed education at third level (OR=3.88, 95% CI: 2.09–7.19).

The association between the Cariogram and self-perceived caries risk is presented in Table 2. Distribution of the 165 subjects by Cariogram's risk groups were 23.6% 'Very high risk', 32.1% 'High risk', 25.5% 'Intermediate risk' and 18.8% 'Low/Rather low risk' when 'Clinical Judgment' was inputted with Score 2 (caries risk worse than with the standard score). The proportion of subjects reporting self-perceived caries risk increased in accordance with their caries risk level assessed by the Cariogram (3.2%, 31.0%, 35.8% and 35.9% in the 'Low/Rather low risk', 'Intermediate risk', 'High risk' and 'Very high risk' groups, respectively). Subjects in the 'Very high risk' and 'High risk' groups were 16.0 times (95% CI: 1.9–134.2) and 18.8 times (95% CI: 2.8–124.8), respectively, as likely to perceive themselves as having high caries risk than subjects in the 'Low/Rather low risk' group. The 'Intermediate risk' group had increased odds of perceiving themselves as having high caries risk to the 'Low/Rather low risk' group (OR=11.9, 95% CI: 1.4–104.1). Most patients in both the 'Very high risk' group and 'High risk' group underestimated their caries risk as assessed by the Cariogram (64%).

Table 3 shows the distribution of subjects by caries risk parameters (Cariogram parameters) and the percent reporting self-perceived caries risk. Subjects who had the worst scores for 'Caries experience' ($p=0.02$), 'Plaque amount' ($p<0.01$) and 'Saliva secretion' ($p<0.01$) were more likely to perceive their caries risk as high. Regarding 'Caries experience', those with Score 0 or 1 have reduced odds of self-perception of being at risk relative to those with Score 3 (OR=0.173, 95% CI: 0.037–0.805); those with Score 2 have reduced odds of self-perception of being at risk relative to those with Score 3 (OR=0.179, 95% CI: 0.050–0.645). As for 'Plaque amount', those with Score 0 or 1 have reduced odds of self-perception of being at risk relative to those with Score 3 (OR=0.192, 95% CI: 0.078–0.472); those with Score 2 have reduced odds of self-perception of being at risk relative to those with Score 3 (OR=0.276, 95% CI: 0.094–0.808). Compared with the highest score of 'Saliva secretion', the odds ratios were 0.072 (95% CI: 0.017–0.303), 0.087 (95% CI: 0.023–0.329) and 0.130 (95% CI: 0.028–0.604) for those with Scores 0, 1 and 2, respectively. On the other hand, 'Diet contents', 'Diet frequency', 'Mutans streptococci' and 'Saliva buffering capacity' did not affect self-perceived caries risk.

Discussion

Self-perceived caries risk was to some extent related to caries risk as assessed by the Cariogram amongst medical-card holders; however, those at high risk tended to underestimate their risk level. These findings are in line with previous self-perceived risk studies on dental caries [10], oral health [9], stroke [7], cardiovascular disease [30] and HIV infection [31]. The Cariogram advises individuals with a 'chance of avoiding new cavities' score of 20% or lower ('Very high risk') to take 'urgent actions' to lower their caries risk. An optimistic self-perception of health may negatively affect a person's decision to adopt 'urgent actions' [30]. It is essential that the gap between actual and self-perceived caries risk in this high risk group is reduced in order that 'urgent actions' are taken.

It is interesting that 'Caries experience' was a significant predictor of self-perceived caries risk. Patients were not informed of their 'Caries experience' score before completing their questionnaire; it is also highly unlikely they had knowledge of the average caries experience for their age group (reported in the Irish Adult Survey 2000–2002 [24]). Yet, people seem to have a comparative awareness of their caries experience relative to their peers; thus, simply informing patients of the number of decayed teeth in their mouth may do little to enhance their risk perception and motivation. Rather, informing them of their personal risk factors and explaining the reasons why they have more dental caries than average may have more effect, as this information would be new to them. The caries risk profile created by caries risk assessment tools can serve as a basis for discussion [13], for example, through motivational interviews [32].

Another implication from this study for personalized caries prevention programs is that unnecessary interventions on top of general population-based strategies such as water or toothpaste fluoridation can be avoided [32]. For the 'Low/Rather low risk' group, all except one subject did not show a risk perception for dental caries. In other words, the pessimistic bias was minimum in the current study population. Thus, instead of targeting all medical-card holders, redundant examinations and interventions for those with low caries risk among medical-card holders may be reduced, allowing effort and resources to be redirected towards those at high risk.

Although the current study investigated medical-card holders as a surrogate for low socioeconomic status, they may not appropriately represent economically disadvantaged people in RoI at present. Almost 39% of the Irish population were covered by a medical card in 2014; eligibility has increased by 54% since 2005 (before the Irish economic period of austerity) [33]. Looking at the other indicators, the percentage of those having completed tertiary education in the current study was similar to that of Irish people aged 15–64 years in 2014 [34] (35.7% vs. 34.3%), smartphone ownership in the current study was higher than reported in an Irish survey in 2015 [35] (80% vs. 70%) and dental utilization of check-up and cleaning in the current study was higher than the Irish data in 2000/2002 [36] (68.5% vs. 54.2% among those aged 35–44 years). In contrast, the smoking prevalence rate (30.3%) was higher in the current subjects, compared to lower socioeconomic groups in RoI (C2, 22.7%; DE, 24.1%) [37]. Stricter criteria such as identifying long-term medical-card holders or other surrogates for low

socioeconomic status would be more appropriate but for practical reasons the current criteria were the best we could do for this study.

The current study had some limitations that should be considered. Firstly, the Cariogram's scores in the current study may be controversial. The public water in RoI is fluoridated to a target level of 0.7 ppm [38]; however, the Cariogram manual does not define levels of fluoride in water for scoring. Therefore, it is possible that overestimation of this parameter's contribution to 'chance of avoiding new cavities' can occur for the study population. Furthermore, we used CRT® instead of Dentocult® (Oral Care, Tokyo), which traditionally has been used for the Cariogram. We found a lower score distribution of 'Mutans streptococci' compared to other studies, even though we rounded up Score 0 to 1 and Score 2 to 3. 'Caries experience' could also have been scored better than the reality, because the reference data is from 16 years ago, when people's oral status was worse than the present. Considering these possible overestimations to 'chance of avoiding new cavities' as well as the accuracy of self-reported 'Diet frequency', we set Score 2 for 'Clinical judgment' (worse than the Cariogram output based on the scores entered); this does not change the weight of each risk parameter. Score 2 for 'Clinical judgment' was not used in the prospective cohort studies; within the current study population, however, the subject distribution by the four risk groups were much more balanced using Score 2 rather than the standard setting (Score 1). It also seemed more appropriate to use Score 2 for the comparison with the self-perceived risk question in the current study, as the question asked for self-perception of caries susceptibility *('prone to dental decay'*) relative to the average person. With Score 1, the distribution by risk groups was 3.6%, 13.9%, 21.2%, 61.2% in the 'Very high risk', 'High risk', 'Intermediate risk' and 'Low/Rather low risk' groups, respectively.

Secondly, eight of the 165 subjects (4.8%) answered that they were not aware some people are more prone to dental caries than others but that they thought that they are more prone to dental decay than the average person. It is possible that some subjects may not have understood the terminology of the questions properly. Also, social or cultural factors can affect the responses. A previous study among Japanese health-oriented groups using a similar questionnaire to the one used in the current study showed that the proportion of individuals who believed their caries risk to be high was higher [27]. A survey in the United States showed that Asians have lower self-reported overall health ratings than non-Hispanic whites, despite having fewer chronic diseases [39]. Although the current study did not ask subjects for their ethnicity and cultural background, the majority of participants are likely Irish, judging from their names. Therefore, caution is required in comparing our findings with those for other populations, even when similar questionnaires are used.

Finally, since the subjects were recruited for a separate randomized controlled study, the study population is not truly representative of the general population or even of Irish medical-card holders. In particular, the distribution according to dental practitioners was highly skewed. However, the findings from the current study are highly suggestive for future caries prevention strategies. This is, to our knowledge, the first study to evaluate the association between comprehensive caries risk assessed by a

risk model and self-perceived risk of dental caries, and to look at the associations between multiple biological caries risk factors and self-perceived risk of dental caries.

In conclusion, most of the 'Very high risk' and 'High risk' subjects underestimated their caries risk, but self-perceived caries risk was related to caries risk as assessed by the Cariogram within this economically disadvantaged population. These findings imply that caries prevention strategies for risk reduction can be tailored according to individual caries risk and self-perceived caries risk for maximum effectiveness amongst medical-card holders.

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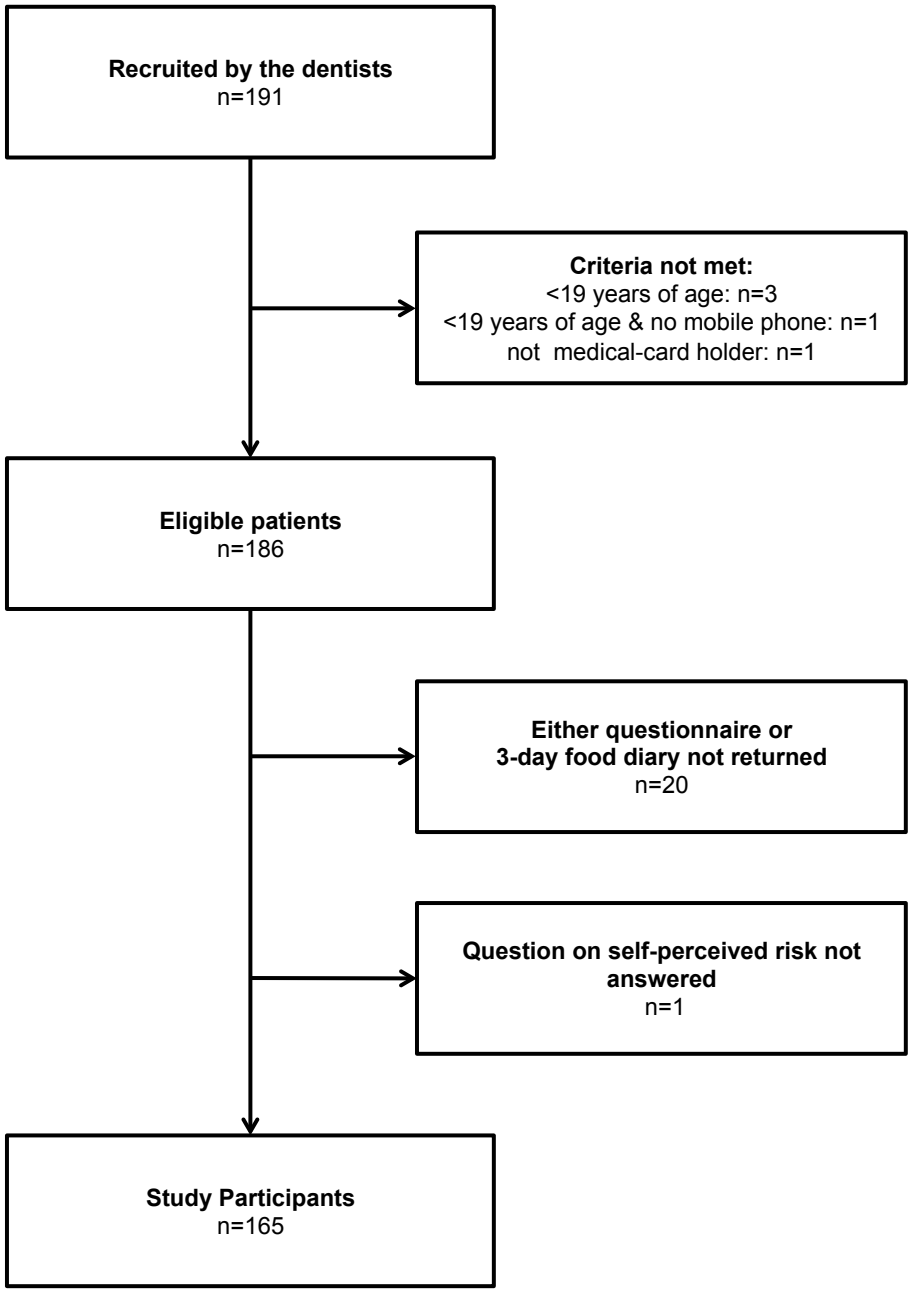
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Figure

Figure 1. Flow diagram showing numbers of patients enrolled in the study.

OHSRC, Oral Health Services Research Centre.


Recruited by the dentists
n=191
Criteria not met:
<19 years of age: n=3
<19 years of age & no mobile phone: n=1
not medical-card holder: n=1
Eligible patients
n=186
Either questionnaire or
3-day food diary not returned
n=20
Question on self-perceived risk not
answered
n=1
Study Participants
n=165

Tables

Table 1. Parameters used for assessing actual caries risk with the Cariogram.

Parameters	Cariogram scores	
Caries experience		
Data from oral examination conducted similarly to the Irish Adult Survey 2000–2002[17]. Prevalence DMFS data from the survey were used as the reference population. Three or more enamel and active root caries lesions appearing were scored '3'.	0	Caries free and no fillings
	1	Caries levels in the lower quartile of scores for age group
	2	Caries levels within the middle 50% of scores for age group
	3	Caries levels within the upper quartile of scores for age group, or having >2 enamel-caries/active-root-caries lesions
Related diseases		
Data from interviews by the dentist.	0	No disease
	1	Disease/conditions, mild degree
	2	Severe degree, long-lasting
Diet, contents		
Lactobacillus counts (CRT bacteria) were used as a measure of cariogenic diet. Score was evaluated by comparing with the corresponding photos in model chart provided with the kit.	0	$<10^5$ CFU/ml saliva
	1	
	2	$\geq 10^5$ CFU/ml saliva
	3	
Diet, frequency		
Estimation of number of fermentable carbohydrate intake per day, mean for 'normal days'; data from 3-day food diary.	0	≤3 meals per day
	1	>3 to ≤5 meals per day
	2	>5 to ≤7 meals per day
	3	>7 meals per day
Plaque amount		
Data from a clinical estimation of oral hygiene by visual overall inspection.	0	Extremely good oral hygiene
	1	Good oral hygiene
	2	Less than good oral hygiene
	3	Poor oral hygiene
Mutans streptococci		

Parameters	Cariogram scores	
Estimation of mutans streptococci level in saliva, using CRT bacteria. Score was evaluated against the corresponding four pictures in the model chart provided with the kit.	0	$<10^5$ CFU/ml saliva
	1	
	2	$\geq 10^5$ CFU/ml saliva
	3	
Fluoride programme		
Data from interviews by the dentist.	0a	Fluoridated water + fluoridated toothpaste + additional measure on a regular basis
	0b	Fluoridated water + fluoridated toothpaste + additional measure on an occasional basis
	0c	Fluoridated water + fluoridated toothpaste
	0d	Fluoridated toothpaste + additional measure on a regular basis
	1	Fluoridated water only
	2	Fluoridated toothpaste only
Saliva secretion		
Estimation of flow rate of paraffin-stimulated saliva for five minutes.	0	>=1.1ml per minute
	1	<1.1, >=0.9 ml per minute
	2	<0.9, >=0.5 ml per minute
	3	<0.5 ml per minute
Saliva buffering capacity		
Estimation of capacity of saliva to buffer acids, using CRT buffer.	0	CRT buffer blue
	1	CRT buffer green
	2	CRT buffer yellow
Clinical judgement		
Due to the overall total impression of the sample's caries situation, score 2 was used for all subjects.	2	Increased risk compared to data and results

DMFS, decayed, missing and filled surfaces.

Table 2. Associations between self-perceived caries risk and demographic parameters and actual risk group.

Variable	Number	% reporting self-perceived caries risk	P value
Gender	165	28.5	0.14[a]
Male	53	22.6	
Female	112	31.3	
Age		***mean, sd***	0.12[b]
All	165	*38.5, 12.7*	
Reporting self-perceived risk	47	*39.9, 13.2*	
Reporting no self-perceived risk	118	*35.1, 10.7*	
Educational level	160	27.5	<0.01[***b]
Primary	14	35.7	
During second level	31	32.3	
After second level	52	32.7	
Third level	43	14.0	
Postgraduate degree	14	21.4	
Still in education	6	50.0	
Smoking status	165	28.5	0.03[*b]
Smoker	50	44.0	
Non-smoker	115	21.7	
Possession of a smart phone	152	27.0	0.93[a]
Yes	122	27.0	
No	30	26.7	
Attendance for check-ups and cleaning	162	28.4	0.01[**b]
Yes	111	24.3	
No	51	37.3	
Toothbrushing frequency	159	27.7	0.12[a]
Less than once a week	3	33.3	
Less than once a day	3	33.3	
Once a day	52	34.6	
Twice or more a day	101	23.8	
Q1: Awareness that some people are more prone to caries	164	28.7	0.13[a]

Variable	Number	% reporting self-perceived caries risk	P value
Yes	120	32.5	
No	44	18.2	
Actual risk group			
Very high	39	35.9	0.01*b
High	53	35.8	<0.01**b
Intermediate	42	31.0	0.03*b
Low/Rather low	31	3.2	Reference

[a] Univariate logistic regression model.

[b] Multivariate regression model including '*chance of avoiding new cavities*', smoking status, attendance for check-ups and cleaning, and educational level.

*p<0.05; **p<0.01; ***p<0.001

Table 3. Distribution of the Cariogram parameters based on self-perceived caries risk.

Parameter and score	Number of subjects		% reporting self-perceived caries risk	P value
Caries experience				0.02*a
0†		2	0	
1†		41	14.6	
2		67	20.9	
3		55	49.1	
Related diseases				N/Ab
0		158	28.5	
1		7	28.6	
Diet, contents				0.91a
0		35	20.0	
1		57	28.1	
2		45	28.9	
3		28	39.3	
Diet, frequency				0.41a
0		23	43.5	
1		96	27.1	
2		39	20.5	
3		7	42.9	

Parameter and score	Number of subjects		% reporting self-perceived caries risk	P value
Plaque amount				0.00***[a]
0[†]		5	0	
1[†]		60	18.3	
2		71	31.0	
3		29	48.3	
Mutans streptococci				0.92[a]
0	31			
1	64	95[c]	25.3	
2	57			
3	13	70[c]	32.9	
Fluoride programme				N/A[b]
0a	42	157[d]	29.3	
0b	39			
0c	73			
0d	3			
1		1	0	
2		7	14.3	
Saliva secretion				<0.01***[a]
0		107	23.4	
1		16	31.3	
2		31	32.3	
3		11	63.6	
Saliva buffering capacity				0.15[a]
0		110	23.6	
1[†]		48	37.5	
2[†]		7	42.9	

[a]Multivariate logistic regression model including the Cariogram parameters, smoking status, attendance of check-ups and cleaning, and educational level.

[b]N/A: not applicable as variable was too sparse to include in a logistic regression model.

[c]Scores 0 and 2 were rounded to Scores 1 and 3, respectively, when entered into the Cariogram, as their distribution showed that four-score classification was not appropriate.

[d]0a, 0b, 0c and 0d were considered as Score 0 when entered into the Cariogram, in accordance with the Manual instructions.

[†]Categories merged in the logistic regression model.

*p<0.05; **p<0.01; ***p<0.001

Article IV

Nishi M, Harding M, Kelleher V, Cronin M, Allen F. Heterogeneity of dental caries risk within individuals among economically disadvantaged adults. Oral Health Prev Dent (*submitted*).

Authors' contribution

Nishi M: the conception of the Irish study, the acquisition of data for the Irish study, and drafting and finalising the article.

Kelleher V: drafting and finalising the article.

All authors contributed to design and analysis, interpretation of data and revising the manuscript critically for important intellectual content. All authors have approved the final version and agreed to be accountable for all aspects of the work.

Relevant presentation

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Oral Health and Preventive Dentistry

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Title:	Heterogeneity of dental caries risk within individuals among economically disadvantaged adults
Type:	Original Article

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Keywords

dental caries, risk factor, vulnerable populations, classification, cluster analysis

Structured abstract

Purpose: To examine heterogeneity of caries risk within individuals among economically disadvantaged adults and to explore whether it is possible to categorise them according to their principal substrate, microflora and host aetiological factors for dental caries.

Materials and Methods: From eight dental practices in Cork, Republic of Ireland, 167 patients met the study criteria and completed a comprehensive caries risk assessment (CRA) with the Cariogram, a computer-based model. The comprehensive CRA calculated by the Cariogram is based on caries risk information covering frequency of dietary intake, lactobacilli and mutans streptococci counts in saliva, plaque quantity, fluoride use, stimulated saliva flow rate (ml/min), saliva buffering capacity, past caries experience and related systemic diseases. The frequency distribution and coefficient of variation (CV) of comprehensive CRA values for the study population were examined. A two-step cluster analysis categorised the study population according to patient information inputted into the Cariogram with the exclusion of two risk indicators – past caries experience and related systemic diseases.

Results: The CVs of the comprehensive CRA values were 0.33 and 0.55 with the Cariogram's standard and increased *'clinical judgment'* parameter, respectively. The study population was clustered into five groups: 'bacteria, saliva and diet', 'bacteria but good saliva', 'saliva', 'diet content' and 'nondescript'.

Conclusion: There was heterogeneity of individual caries risk among economically disadvantaged adults. Individuals could be clustered into subgroups according to aetiological factors. These findings help to foster debate on the need for differing strategies in preventing dental caries in lower socioeconomic groups.

Introduction

Many studies have shown that lower socioeconomic status (SES) groups have a greater level of dental caries than higher SES groups.[1] Global indications are that lower SES groups eat sugary food more frequently,[2] brush their teeth less frequently with fluoridated tooth paste,[3] do not regularly visit the dentist[4] and have relevant systemic disease(s) (e.g. lower SES is associated with depression;[5] and antidepressants reduce saliva flow[6]). In other words, socioeconomic factors are determinants of an individual's caries experience, which involve the interplay of substrate, microflora and host aetiological factors.

While there has been research to indicate a relationship between SES and caries experience at population level, there are few studies investigating the individual variability of these aetiological factors within lower SES groups. Caries risk may vary from person to person and may also vary during the lifetime of the same person, even within lower SES groups. To improve caries prevention for the ultimate goal of 'Health for all',[7] such variation should be taken into account in caries prevention strategies. For example,

the promotion of sugars-intake reductions may prove successful in a specific subgroup of the lower SES group, but may ***not*** be successful in another subgroup. To compound the difficulty of effecting behaviour change in a low SES group, a prevention strategy that proves unsuccessful may act to discourage patients from complying with dental professionals' oral care messages.

Cluster analysis has been employed for insight into the heterogeneity of multidimensional diseases and conditions, such as asthma,[8] bruxism,[9] obesity,[10] tinnitus[11] and so on. These studies show that heterogeneity within individuals who have the disease and patterns of diseases or conditions do exist and impel us to move beyond a single classification of individuals as just the disease/condition. Cluster analysis is usually used for descriptive theoretical and non-inferential purposes.[12] For example, cluster analyses in asthma patients have greatly improved the understanding of the disease and revealed the possibility of personalised curative medicine for asthma.[13] Some cluster analyses identified an obese phenotype and, although a systematic review on obesity and asthma concluded that the association was not straightforward,[14] weight reduction resulted in improving asthma control.[15]

Regarding dental caries, one study used a cluster analysis of past caries experience and bacteriological measurements to group schoolchildren.[16] To the best of our knowledge, however, there has not been any study using a cluster analysis of substrate, microflora and host factors together for the purpose of identifying subgroups. Our research hypotheses are (1) that there is heterogeneity of dental caries risk within individuals in a lower socioeconomic group, and (2) that there are subgroups of individuals according to substrate, microflora and host factors. The aims of this study are (1) to examine the heterogeneity of comprehensive CRA values within individuals among economically disadvantaged adults in the Republic of Ireland (RoI) and (2) to explore whether it is possible to categorise economically disadvantaged adults according to their principal substrate, microflora and host aetiological factors for dental caries.

Materials and methods

The current cross-sectional study used baseline data of a randomised controlled clinical study (the University Hospital Medical Information Network Clinical Trial Registry ID: UMIN000027253) investigating the effectiveness of a patient education approach based on the individual's caries risk assessment among economically disadvantaged people. Prior to baseline examinations, eight participating dentists in Cork, RoI were trained and calibrated for examining tooth status, coronal surface caries condition and root surface caries condition in a procedure similar to that employed during the Irish Adult Oral Health Survey 2000–2002.[17] The dentists also acquired the skills and support for the saliva collection; flow rate, buffering capacity and bacterial count using CRT® (Ivoclar Vivadent, Liechtenstein). The Kappa statistics for inter-examiner reliability were 'very good' (0.91–1.00) for tooth status, 'moderate' to 'very good' (0.54–0.94) for coronal surface condition, and 'fair' (0.37–0.48) for root caries. For scoring plaque quantity, we employed a clinical estimation of plaque quantity by visual overall inspection according to the Cariogram manual.[18] The detailed procedure and results of the plaque calibration are described elsewhere.[19] In addition, the dental practitioners were provided with training slides that included

clinical photos.

The recruitment entry criteria were (1) willingness to participate in the project, (2) 19–70 years of age, (3) medical-card-patients (i.e. proxy for economically disadvantaged status), (4) at least 20 teeth present, (5) not pregnant and (6) ability to use text messages. Eight dental private practices in Cork recruited the patients who met the criteria during the period from February to September 2015. In the RoI, entitlement to a medical card is means-tested, and individuals of low financial means or significant medical outgoings may receive a medical card.[20] Medical-card-patients were considered as economically disadvantaged people in this study. Detailed subject recruitment and eligibility are described elsewhere.[21] The study was conducted in the Oral Health Services Research Centre (OHSRC) and in eight dental practices following approval from the Clinical Research Ethics Committee of the Cork Teaching Hospitals of University College Cork, RoI (ECM 4 (r) 12/08/14). Participating patients were informed by their dentists of the study, and provided written informed consent to participate.

The required sample size (n = 128) was calculated for the randomised controlled clinical study. To compensate for non-responses, the eight dental practitioners recruited 191 patients (62 men and 129 women) (Fig 1). Of the 191 patients who were interviewed and had a clinical examination and CRT® saliva tests, 167 medical-card-patients met the study inclusion criteria and completed their 3-day food diary. The comprehensive CRA was carried out using the Cariogram (version 3.0j), a computer-based caries risk assessment model.[18] In the Cariogram, the comprehensive CRA result for an individual is expressed as *'chance of avoiding new cavities'* from 0 (the highest risk) to 100 (the lowest risk). Necessary information for the CRA was extracted via clinical examination (past caries experience and plaque quantity), CRT® saliva tests (mutans streptococci (MS) and lactobacilli (LB) counts in saliva, stimulated saliva flow rate and saliva buffering capacity), the patient's case report form (related systemic diseases, fluoride use and age) and their 3-day food diary (diet frequency) (Table 1). In order to investigate subject characteristics, information on gender, smoking status and dental practice visited were also extracted from each patient's case report form. Other information, such as education level, was extracted from the patient questionnaire.[21]

To examine the frequency distribution of the comprehensive CRA scores, we divided *'chance of avoiding new cavities'* into four risk groups: 1–20 (highest risk), 21–40, 41–60, and 61–100 (lowest risk) in line with methods of previous literature investigating adult/elderly populations.[22, 23] *'Chance of avoiding new cavities'* was calculated with two different settings for the *'clinical judgement'* parameter: Score = 1 (standard risk) and Score = 2 (increased risk). Through the *'clinical judgement'* parameter, the Cariogram can express a somewhat lower or higher *'chance of avoiding new cavities'* without affecting the relationship among other parameters; Score = 2 makes *'chance of avoiding new cavities'* lower than the standard setting (i.e. higher risk than standard setting).

Data analyses

To examine heterogeneity of comprehensive CRA values, the coefficient of variation (CV) of *'chance of avoiding new cavities'* was calculated. A two-step cluster analysis method was used to explore subgroups

of individuals according to substrate, microflora and host factors together; two risk indicators – past caries experience and related systemic diseases, were excluded from this analysis. A two-step cluster is used when both continuous and categorical variables are included. All scores with the exception of saliva flow rate and diet frequency were considered as categorical variables. For saliva flow rate and diet frequency, we used original values as continuous variables which were standardised for the cluster analysis. We used the SPSS two-step clustering algorithm to determine the optimal number of clusters with the log-likelihood method and Bayesian Information Criterion. The silhouette measure of cohesion and separation was used for measuring the overall goodness-of-fit of the cluster structure. We described the cluster profiles, including the mean values for each cluster and labelled clusters accordingly.

Results

Of the 167 study patients, 68% were female (Table 2). Mean age was 38 years (SD = 13). The most frequent age group was 35–44 years (31%). The proportion of subjects with third level education or higher was 35% of those who answered this question (n = 161) in the questionnaire. The proportion of smokers was 31%. Figure 2 presents the distribution of *'chance of avoiding new cavities'* using both Score = 1 (standard) and Score = (increased risk) for *'clinical judgement'* Cariogram setting. With Score = 1 (standard) for *'clinical judgement'*, percentages of those who were in the four risk groups were 4%, 14%, 22% and 60% from the highest risk group to the lowest risk group. With Score = 2 (increased risk) for *'clinical judgement'*, the percentages in the four risk groups were 25%, 32%, 25% and 19% from the highest risk group to the lowest risk group. The average of *'chance of avoiding new cavities'* was 64 (SD = 21, CV = 0.33), ranging from 10 to 96 with the standard *'clinical judgement'*. With Score = 2 (increased risk) *'clinical judgement'*, the average was 39 (SD = 22, CV = 0.55), ranging from 3 to 94.

The two-step cluster analysis identified five distinct cluster groups. The silhouette coefficient was slightly more than 0.2, indicating this result is a fair cluster solution. Table 3 shows the mean characteristics of each cluster from this solution. The variables used for the cluster analysis are ranked from most important to least important predictor between groups (descending order) in each of the continuous and categorical variable categories.

Cluster 1 ('Bacteria, saliva and diet'; n = 26) is characterised by unfavourable microbiological factors (high MS counts and plaque quantity), unfavourable saliva factors (poor flow rate and buffering capacity), and unfavourable diet factors (high scores for both frequency and contents). While all of these patients use fluoridated toothpaste, 11.5% do not use fluoridated water. It is unknown whether they did not have access to fluoridated water or chose to avoid it. Caries experience is rather high compared to the average for their respective age groups. *'Chance of avoiding new cavities'* is relatively low (16.5 ± 9.6).

Cluster 2 ('Bacteria but good saliva'; n = 25) is also characterised by an unfavourable level of microbiological factors, but distinguished by the fact that the saliva factors are good. All patients in Clusters 1 and 2 have Score 3 for MS counts (the most unfavourable; $\geq 10^5$ CFU/ml saliva). However, the mean saliva flow rate in Cluster 2 is higher (2.0 ± 0.8 ml/min) than in any other cluster and almost all patients in Cluster 2 possess the most favourable score for saliva buffering capacity.

Cluster 3 ('Saliva'; n = 42) is distinguished by poor saliva buffering capacity and flow rate. However, plaque quantity is comprehensively favourable; all patients with Score 0 for this parameter are included in this cluster.

Cluster 4 ('Diet content'; n = 25) is characterised by high LB counts. Almost all patients in this group have Score 2 of LB (less favourable; $\geq 10^5$ CFU/ml saliva). All patients in both Clusters 2 and 4 use fluoridated water and toothpaste.

Cluster 5 ('Nondescript'; n = 49) is characterised by no prominent poor risk factors. Notably, all these patients have Score 0 for saliva buffering capacity (most favourable) and Score 1 for MS counts (most favourable; $< 10^5$ CFU/ml saliva). Approximately half of this group have Scores 2 or 3 for plaque quantity (less favourable). *'Chance of avoiding new cavities'* is relatively high (60.5 ± 18.5).

Discussion

The current study identified heterogeneity in the individual scores of caries risk among adult medical-card-holder patients in the RoI. First, heterogeneity was more pronounced with the increased risk *'clinical judgement'*: the CV was 0.55 and the distribution by the four risk groups was dispersed. The CVs of *'chance of avoiding new cavities'* using both the standard and the increased *'clinical judgement'* setting indicate heterogeneity in our study population. Second, a two-step cluster analysis categorised the participants into five subgroups.

Risk assessment is a subjective activity based on the view of the assessor; this also holds true for computer-based models such as the Cariogram. Therefore, it is important to sometimes adjust assessment as objectively as possible with available data. Applying the standard score for *'clinical judgement',* the distribution of *'chance of avoiding new cavities'* in the current study is similar to that of a study of Swedish school-children.[24] Applying the increased risk score for *'clinical judgement'*, the mean *'chance of avoiding new cavities'* is similar to that of an Arabian study for an adult population with a similar mean age.[25] It would appear that applying the increased *'clinical judgement'* score in our study shows more plausible results given the age, caries experience and population profile of our study participants.

Another Irish study using the Cariogram with the standard setting for *'clinical judgement'* in adults aged over 65 years presented the distribution of *'chance of avoiding new cavities'* was 22.2%, 24.3%, 26.3%, 16.5% and 10.8% from the highest risk group to the lowest risk group.[26] This distribution looks similar to our study results when the increased risk setting, but not the standard setting, *'clinical judgement'* is applied. This could be attributed to the fact that Hayes et al. (2017) includes adults over 65 years of age whereas the current study includes adults aged 19 to 70 years, and that some parameters were scored differently between the two studies. It is arguable that the different age criteria between the studies may not be that important as some of the risk parameters showed lower risk in the Hayes study[26] than in our study. For example, the percentage of xerostomic participants (< 0.7 ml saliva/min) was actually lower in the Hayes et al. study (2017) than our study (7% vs. 17%). The fundamental difference between these two studies, both conducted in the same fluoridated city, lie in their scores for

'Fluoride programme'. In the Hayes et al. study (2017), the distribution of Scores 0, 1, 2 and 3 for *'Fluoride programme'* was 3.9%, 47.9%, 38.0% and 10.2%, whereas in our study, the corresponding figures were 95.2%, 0.6%, 4.2% and 0%. As the fluoride factor has a large impact on the Cariogram algorithm for *'chance of avoiding new cavities'*,[27] the difference in how *'Fluoride programme'* is defined by each study is the likely main reason for the difference in distribution of *'chance of avoiding new cavities'* with the standard *'clinical judgement'* parameter between the two studies. In the study of Swedish schoolchildren,[24] the distribution of Scores 0, 1, 2 and 3 (0.6%, 40.0%, 59.4%, 0%, respectively) for *'Fluoride programme'* was also quite different from our study. This is also probably the main reason that the distribution of *'chance of avoiding new cavities'* with the standard *'clinical judgment'* parameter in the current study is similar to that of the Swedish study.

The Cariogram manual[18] says that Score 0 for *'Fluoride programme'* is *'Fluoride toothpaste plus constant use of additional measures - tablets or rinsings and varnishes. A* 'maximum' *fluoride program.'* Prior to the start of the current study, we discussed how to score fluoride use in the Irish context with other dentists familiar with fluoridation or the Cariogram, and decided that using fluoridated water was considered as 'constant use of additional measures'. As the city of Cork has been fluoridated since 1965,[28] and almost all toothpaste on the market contain fluoride,[29] 95.2% of our study population were given Score 0 (maximum fluoride programme) for this parameter. For adjusting such situations as fluoridation, earlier versions of the Cariogram had 'country/area' and 'group' settings, but the latest version (version 3.0j) removed these settings for the sake of simplicity. Instead, it recommended the use of the *'clinical judgement'* parameter for adjustment (Hänsel Petersson, G. personal communication, December 16, 2011). We complied with this recommendation.

The five clusters have different characteristics; thus, oral health messages to each cluster should be different. For Cluster 3, emphasis may be on saliva's role while for Cluster 2, emphasis may be on oral hygiene and for Cluster 4, emphasis may be on diet content. For Cluster 1, all aetiological (substrate, microflora and host) factors are possibly combined, resulting in the high caries experience. This group needs urgent actions to stop continuing caries incidence and recurrence.

Heterogeneity in the seven aetiological caries risk factors among economically disadvantaged adults has an important implication for policymakers and clinicians. General population-based strategies such as water or toothpaste fluoridation have been quite effective for caries prevention but they also have limitations.[30] In fact, 95.2% of our study population used fluoridated toothpaste plus either fluoridated water or regular additional fluoride. Any further efforts may as well be based on heterogeneity in caries risk profiles for the improvement of oral health towards the ultimate goal, 'Health for all'.[7] In medical research, various diseases and conditions have been investigated by cluster analyses. One of the recent studies dealt with obesity and presented six types of obesity,[10] strengthening the argument against a 'one-size-fits-all' approach. Also, with its beginnings in oncology, 'P4 medicine' has been introduced as the future vision of health care.[31] This concept consists of four Ps: Personalised, Predictive, Preventive and Participatory.[32]

One study limitation is that the silhouette measure was barely acceptable. The range of the value is from -1 to 1. The higher the value, the more compact and separated are the clusters. With values from 0.2 to 0.5,

the division of objects into clusters is considered fair. Although subgroups exist, the transitions between clusters were not clear-cut but a continuum. The participating dental practices were volunteers and the numbers of participants by dental practices were so uneven; therefore it is a limitation that participants may correlate within dental practices.

A further limitation is that the current study is exploratory and does not provide firm evidence that there are five subgroups of dental caries risk profiles. Thus, generalisation to other low socioeconomic groups is not possible. Nevertheless, examining heterogeneity and identifying subgroups among economically disadvantaged adults is helpful to recognise different risk profiles for dental caries. These findings may be useful to drive all the four components of 'P4 medicine' in economically disadvantaged groups. It would also be necessary to examine the cost-effectiveness of providing tailored caries prevention strategies.

In conclusion, our hypotheses were supported by the results: (1) There was heterogeneity of individual caries risk among economically disadvantaged adults; (2) individuals could be clustered into five subgroups according to substrate, microflora and host aetiological factors. These findings will help to foster debate among clinicians and policy makers on the need for differing strategies in preventing dental caries in lower socioeconomic groups.

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Abbreviations

CRA: caries risk assessment

CV: the coefficient of variation

SES: socioeconomic status

RoI: Republic of Ireland

OHSRC: Oral Health Services Research Centre

MS: mutans streptococci

LB: lactobacilli

Trade names

CRT® saliva tests (Ivoclar Vivadent, Liechtenstein)

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Table 1 Summary of the clinical and patient report data collected for caries risk assessment

Necessary information	Explanation
Past caries experiences (Circumstances sector)	Data of oral examination in a similar manner as used in the Irish Adult Survey 2000-2002. Prevalence DMFS data from the survey were used as the reference population. Caries free and no fillings were scored '0'. Better status than one quarter for age group was scored '1'. Status between one quarter and three quarters for age group was scored '2'. Status worse than three quarters for age group, or having >2 enamel-caries/active-root-caries lesions was scored '3'.
Related systemic diseases (Circumstances sector)	Included diseases are autoimmune disease, diabetes mellitus, anorexia nervosa, visually impaired, any manual dexterity, continuous medication that affect their saliva secretion, any condition requiring radiation to the head-neck region. No disease was scored '0'. Any disease/conditions with mild degree was scored '1'. Any disease/conditions with severe degree, long-lasting was scored '2'.
Lactobacilli (LB) (Diet sector)	LB counts (CRT bacteria) were used as a measure of cariogenic diet. Score was evaluated with the corresponding four pictures in the model chart with the kit. Scores 0 and 1 were $<10^5$ CFU/ml saliva. Scores 2 and 3 were $\geq 10^5$ CFU/ml saliva.
Diet frequency (Diet sector)	Estimation of number of fermentable carbohydrate intake per day, mean for 'normal days'; data from 3-day food diary results. <=3 meals per day was scored '0'. >3, <=5 meals per day was scored '1'. >5, <=7 meals per day was scored '2'. >7 meals per day was scored '3'.
Plaque quantity (Bacteria sector)	A clinical estimation of oral hygiene by visual overall inspection was used. Extremely good oral hygiene was scored '0'. Good oral hygiene '1'. Less than good oral hygiene '2'. Poor oral hygiene '3'.
Mutans streptococci (MS) (Bacteria sector)	MS counts (CRT bacteria) were used. Score was evaluated with the corresponding four pictures in the model chart with the kit. Scores 0 and 2 were rounded to Score 1 $<10^5$ CFU/ml saliva and Score 3 ($\geq 10^5$ CFU/ml saliva), respectively, because it seemed from the distribution that four-score classification was not appropriate.
Fluoride use (Susceptibility sector)	Estimation of to what extent fluoride is available in the oral cavity. Using fluoridated toothpaste plus either fluoridated water or regular additional fluoride was scored '0'. Using fluoridated water only was scored '1'. Using fluoridated toothpaste only was scored '2'.
Saliva flow rate (Susceptibility sector)	Estimation of flow rate of paraffin-stimulated saliva for five minutes. Score 0 was >=1.1ml per minute. Score 1 was <1.1, >=0.9 ml per minute. Score 2 was <0.9, >=0.5 ml per minute. Score 3 was <0.5 ml per minute.
Saliva buffering capacity (Susceptibility sector)	Estimation of capacity of saliva to buffer acids, using CRT buffer. CRT buffer blue was scored '0'. CRT buffer green was scored '1'. CRT buffer yellow was scored '2'.
Clinical judgement	The Cariogram expresses somewhat lower or higher *'chance of avoiding new cavities'*, not affecting the relationship among parameters according to dental examiner's 'clinical feeling'. Scored '1' is default. Scored '2' lowers 'chance of avoiding new cavities'.

Table 2 Characteristics of the study population

Variable	Number of participants
Gender	
male	53
female	114
Age	
≤24	28
25-44	38
35-44	51
45-54	29
55-64	15
≥65	6
mean (sd)	38 (± 13)
Education level*	
Primary	14
During second level	31
After second level	52
Third level	43
Postgraduate degree	14
Still in education	7
Smoking status	
Yes	52
No	115
Dental practice	
A	2
B	22
C	18
D	87
E	15
F	1
G	9
H	13
Total	167

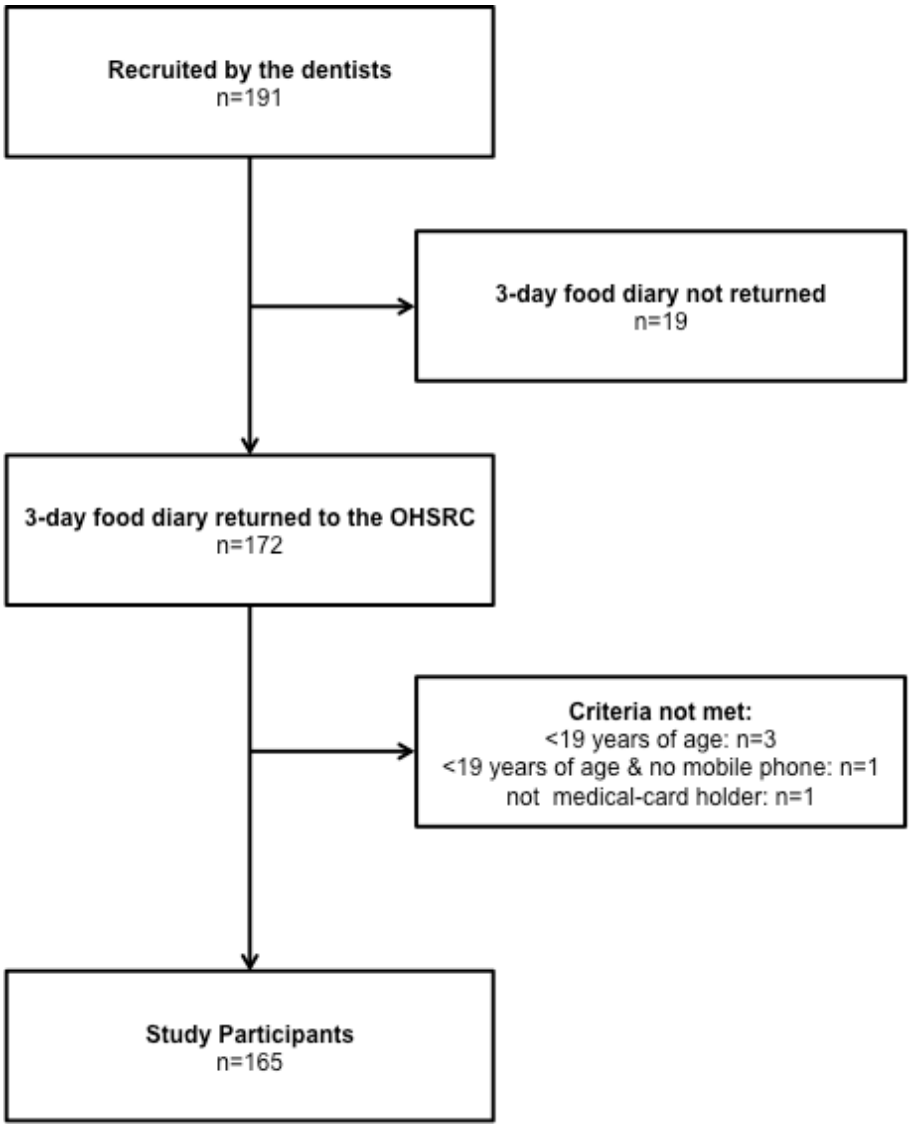
*Six patients did not answer the question.

Table 3 The mean (standard deviation) for continuous variables and score distribution (%) for categorical variables of each cluster

Variable	Unit	Predictor importance value	Clusters					All patients
			1. Bacteria, saliva, diet (N=26)	2. Bacteria but good saliva (N=25)	3. Saliva (N=42)	4. Diet content (N=25)	5. Nondescript (N=49)	(N=167)
Risk factors used for cluster analysis								
Continuous variable (mean (SD))								
Saliva flow rate	ml/min	0.25	1.2 (0.6)	2.0 (0.8)	1.1 (0.6)	1.5 (0.6)	1.7 (0.7)	1.5 (0.7)
Diet frequency	times/day	0.02	4.9 (1.1)	4.6 (1.1)	4.8 (1.5)	4.5 (1.5)	4.3 (1.2)	4.6 (1.3)
Categorical variable (%)								
Saliva buffering capacity	Score 0	1.00	50.0	96.0	0.0	100.0	100.0	66.5
	Score 1		38.5	0.0	92.9	0.0	0.0	29.3
	Score 2		11.5	4.0	7.1	0.0	0.0	4.2
Mutans streptococci	Score 1	0.93	0.0	0.0	83.3	48.0	100.0	57.5
	Score 3		100.0	100.0	16.7	52.0	0.0	42.5
Diet content (Lactobacillus)	Score 0	0.83	11.5	0.0	28.6	4.0	40.8	21.6
	Score 1		3.8	64.0	47.6	0.0	40.8	34.1
	Score 2		38.5	0.0	16.7	96.0	10.2	27.5
	Score 3		46.2	36.0	7.1	0.0	8.2	16.8
Plaque quantity	Score 0	0.38	0.0	0.0	11.9	0.0	0.0	3.0
	Score 1		0.0	28.0	31.0	68.0	46.9	35.9
	Score 2		92.3	36.0	42.9	0.0	44.9	43.7
	Score 3		7.7	36.0	14.3	32.0	8.2	17.4
Fluoride programme	Score 0	0.02	88.5	100.0	90.5	100.0	98.0	95.2
	Score 1		0.0	0.0	2.4	0.0	0.0	0.6
	Score 2		11.5	0.0	7.1	0.0	2.0	4.2
Variables not used for cluster analysis								
Continuous variable (mean (SD))								
Age	year		38.4 (11.3)	40.4 (15.2)	36 (11.2)	38.9 (12.2)	39.2 (13.7)	38.4 (12.7)
*'Chance to avoid new caries'**			16.5 (9.6)	26.2 (12.4)	38.9 (16.0)	36.4 (15.9)	60.5 (18.5)	39.5 (21.8)
Categorical variable (%)								
Proportion female			76.9	52.0	78.6	72.0	61.2	68.3
Proportion those with education level of third and more			26.9	24.0	50.0	28.0	32.6	34.1
Proportion smoker			42.3	32.0	33.3	32.0	22.4	31.1
Dental practice	A		3.8	0.0	0.0	4.0	0.0	1.2
	B		7.7	4.0	28.6	8.0	10.2	13.2
	C		3.8	8.0	14.3	8.0	14.3	10.8
	D		76.9	80.0	33.3	64.0	34.7	52.1
	E		0.0	8.0	0.0	12.0	20.4	9.0
	F		0.0	0.0	2.4	0.0	0.0	0.6
	G		7.7	0.0	2.4	0.0	12.2	5.4
	H		0.0	0.0	19.0	4.0	8.2	7.8
Caries experience	Score 0		0.0	0.0	0.0	0.0	4.1	1.2
	Score 1		15.4	28.0	21.4	20.0	32.7	24.6
	Score 2		34.6	28.0	42.9	56.0	38.8	40.1
	Score 3		50.0	44.0	35.7	24.0	24.5	34.1
Related diseases	Score 0		96.2	100.0	95.2	100.0	91.8	95.8
	Score 1		3.8	0.0	4.8	0.0	8.2	4.2

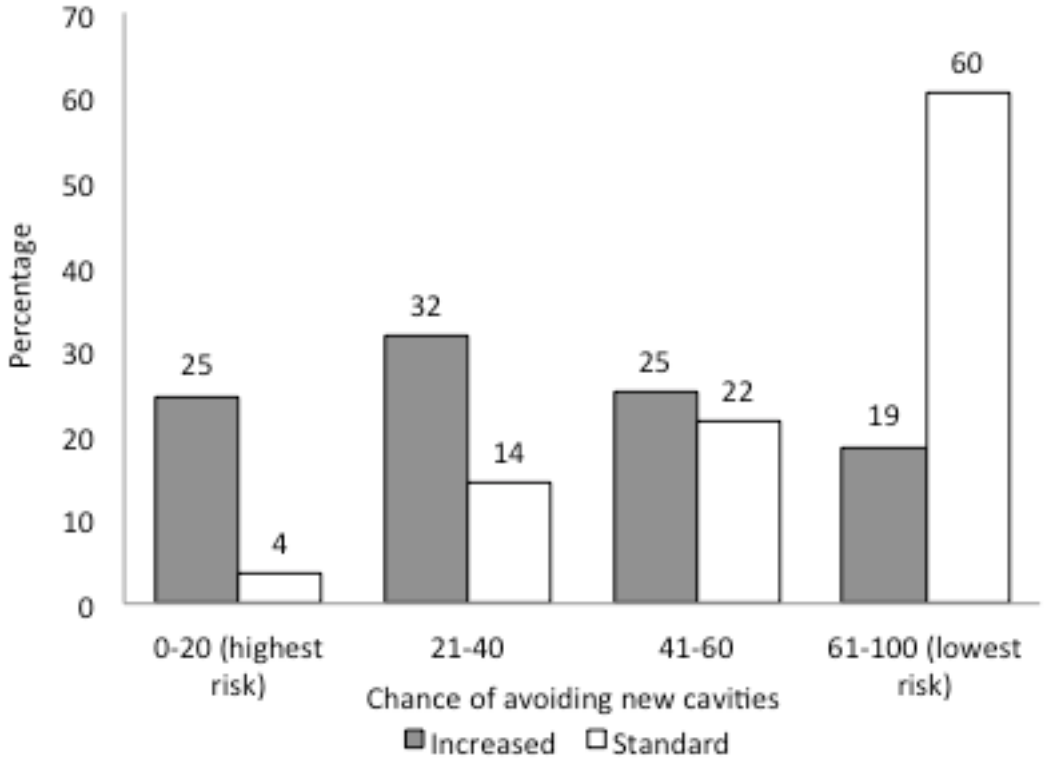
*With the increased 'clinical judgment' parameter

Fig 1 Flow diagram showing numbers of patients enrolled in the study



OHSRC: Oral Health Services Research Centre

Fig 2 Distribution of '*chance of avoiding new cavities*' with both the standard and increased *'Clinical judgement'*



Article V

Nishi M, Kelleher V, Cronin M, Allen F. A personalised mHealth approach based on caries risk assessment using the Cariogram: a randomised controlled study. BMC Oral Health (*submitted*).

Authors' contribution

Nishi M: the conception of the Irish study, the acquisition of data for the Irish study, and drafting and finalising the article.

Kelleher V: drafting and finalising the article.

Cronin M: statistical analysis.

All authors contributed to design and analysis, interpretation of data and revising the manuscript critically for important intellectual content. All authors have approved the final version and agreed to be accountable for all aspects of the work.

Relevant article and presentation

Nishi M, Roberts A, Harding M, Allen F. 2017. Brief communication: dentists' reproducibility in scoring the Plaque Index using a fluorescent colouring agent. J Ir Dent Assoc. 63(4):212-216.

Nishi M, Harding M, Allen F. Dentists reliability scoring the Plaque Index using a fluorescent colouring agent. The 21st meeting of the European Association of Dental Public Health, Budapest, 30 September 2016.

Nishi M. Personalised caries preventive programmes. One-day Seminar with Professor Kim Ekstrand and Ms Lina Kanters, Tokyo,16 July 2017. Osaka, 17 July 2017.

Nishi M. Personalised caries prevention and the future of cariology. The 12th Sakata Team Meeting entitled "Dentistry in the future - through information from different countries", Sakata, 7 October 2017.

BMC Oral Health

A personalised mHealth approach to caries risk assessment using the Cariogram in an economically disadvantaged adult population: a randomised controlled study

--Manuscript Draft--

Manuscript Number:	
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Funding Information:	International Association for Dental Research (the International Association for Dental Research Unilever Social Entrepreneur Approach to Change Oral Health Behaviour Research Award 2014) — Professor Finbarr Allen
Abstract:	Background: In the Republic of Ireland (RoI), fluoridated water has been effective and efficient for caries prevention at population level, regardless of income status; however, at individual level it still has limitations. This study aimed to investigate the impact on caries risk reduction of a personalised mobile health (mHealth) approach based on an individual's caries risk assessment (CRA) in economically disadvantaged adults in the RoI, compared to a non-personalised approach. Methods: The intervention was via a CRA summary letter plus 24 weekly personalised mobile-phone short text messages (text messages) based on the individual's CRA, compared with a non-personalised approach via a non-personalised letter and a predetermined, fixed set of 24 weekly text messages. The study was designed as a two-arm parallel-group, single-blinded (assessor), randomised controlled study in County Cork, RoI. The primary outcome was a comparison of 'chance of avoiding new cavities' calculated by the Cariogram, a computer-based CRA model, with clinical examination, interview, CRT® (Ivoclar Vivadent, Liechtenstein) and three-day food diary between the two groups at follow-up. We combined stratified randomisation with blocked randomisation for 171 participants who completed baseline. Of them, 111 completed follow-up and were analysed (56 and 55 from the personalised and non-personalised groups, respectively). Due to protocol violations, both an intent-to-treat (ITT) and per-protocol analyses were conducted. Results: The ITT analysis did not show a personalised intervention effect on 'chance of avoiding new cavities'. Of the secondary outcome measures, only the stimulated saliva flow factor showed a personalised intervention effect, p = 0.036, OR = 0.3 (95% CI = 0.1, 0.9). The per-protocol analysis with 21 personalised and 33 non-personalised participants within two-message deviations showed no significant effect on 'chance of avoiding new cavities'. Conclusions: A definitive conclusion on the effectiveness of a personalised mHealth approach could not be reached; however, as the minimal clinically important difference was included in the 95% CI for the per-protocol analysis, replication studies will be worth conducting to explore the potential of mobile-devices for individual caries risk reduction. Trial registration: University Hospital Medical Information Network Clinical Trials Registry (UMIN000027253) on 10 May 2017. The study was retrospectively registered.
Corresponding Author:	Makiko Nishi, B.Ed, D.D.S., M.D.P.H Oral Health Services Research Centre, University College Cork IRELAND
Corresponding Author Secondary Information:	
Corresponding Author's Institution:	Oral Health Services Research Centre, University College Cork
Corresponding Author's Secondary Institution:	
First Author:	Makiko Nishi, B.Ed, D.D.S., M.D.P.H

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Abstract

Background: In the Republic of Ireland (RoI), fluoridated water has been effective and efficient for caries prevention at population level, regardless of income status; however, at individual level it still has limitations. This study aimed to investigate the impact on caries risk reduction of a personalised mobile health (mHealth) approach based on an individual's caries risk assessment (CRA) in economically disadvantaged adults in the RoI, compared to a non-personalised approach.

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Trial registration: University Hospital Medical Information Network Clinical Trials Registry (UMIN000027253) on 10 May 2017. The study was retrospectively registered.

Key words: Dental Caries, Risk Factors, Vulnerable Populations, Cell Phones, Dental Health Education, Preventive Dentistry, Risk Reduction Behavior, Risk Management, Ireland, Adult

Background

The incidence of dental caries, a preventable disease [1], is strongly associated with social and economic deprivation [2]. In the Republic of Ireland (RoI), fluoridated water has been effective and efficient for caries prevention at population level, regardless of income status [3]. Although the most recent data on 15-year-olds in the RoI was collected 17 years ago, it remained a concern that by age 15 approximately three quarters of adolescents with fluoridated water supplies in the RoI have experienced dental caries [4]. To compensate for this limitation of water fluoridation, caries prevention based on an individual's caries risk assessment (CRA) could be of value to the individual [5].

Even within the lower socioeconomic groups, there are multiple caries risk factors which may vary from person to person and may change during a person's lifetime; therefore, it seems reasonable that applying a personalised preventive approach could be effective [6]. Mobile health (mHealth) has enormous potential for conducting personalised approaches to disease prevention and management [7]. Mobile devices allow low cost interventions and are a means of providing individual level support to health care consumers in order to increase healthy behaviour [8]. An automated system can send bulk personalised text messages using an algorithm based on patients' information to patients anywhere and anytime. Personalised messages exhibited the largest effect size in a meta-analysis on efficacy of text messages for health promotion [9].

In dentistry, for example, mobile-phone text messaging improved tooth brushing frequencies among unemployed young adults [10], oral health knowledge and behaviour in mothers of young children [11] and plaque removal in orthodontic patients [12]. To the best of our knowledge, no study has previously been conducted on mHealth interventions for a personalised approach based on CRA.

<Figure 1 near here>

The Cariogram, a validated computer-based CRA model [6], "*is a graphical picture illustrating in an interactive way the individual's/patient's risk for developing new caries in the future, simultaneously expressing to what extent different etiological factors of caries affect the caries risk for that particular patient.*" [13] (Fig. 1). The Cariogram calculates the four risk-sector values – 'Diet', 'Bacteria', 'Susceptibility' and 'Circumstances', based on combinations of nine risk parameters as follows: 'Diet' is

based on 'Diet contents' and 'Diet frequency'; 'Bacteria' is based on 'Plaque amount' and 'Mutans streptococci'; 'Susceptibility' is based on 'Fluoride programme', 'Saliva secretion' and 'Saliva buffer capacity'; 'Circumstances' is based on 'Caries experience' and 'Related diseases'. These nine parameters plus the 'Clinical judgement' parameter are scored 0, 1, 2 or 0, 1, 2, 3. The total of the four risk-sector values subtracted from 100 equals '*chance of avoiding new cavities*'.

The aim of this study was to investigate the impact on '*chance of avoiding new cavities*' as calculated by the Cariogram of a personalised approach in economically disadvantaged adults in the RoI via a personalised summary letter plus a personalised combination of 24 weekly mobile-phone short text messages (text messages) based on CRA. The comparison was a non-personalised approach via a non-personalised summary letter plus a predetermined, fixed set of 24 weekly text messages. The null hypothesis is that no difference would exist between the group receiving personalised information and a comparison group receiving non-personalised information.

Methods

Study design

The study design was a two-arm parallel-group, single-blinded (assessor), randomised controlled study with a 1:1 allocation ratio comparing personalised (test) and non-personalised (control) caries preventive advice. Ethical approval was granted by the Clinical Research Ethics Committee of the Cork Teaching Hospitals of University College Cork (UCC) (ECM 4 (r) 12/08/14). The study was conducted in compliance with the principles of the Declaration of Helsinki. The study protocol is available on the website of the Oral Health Services Research Centre (OHSRC) [14]. All files including personal information were coded. Detailed calibration examination and baseline procedures, subject characteristics, and data collection are described elsewhere [15, 16]. Protocol violations occurred after trial commencement; an additional file shows the protocol violations in more detail [see Additional file].

Subjects

An a priori sample size calculation was performed after systematically searching literature through PubMed on studies using the Cariogram among adults. Based on two previous studies [17, 18], we set a significance level of 5% (two-sided), a power for that detection of 80%, a control response of 36 ('*chance of avoiding new cavities*'), a standard deviation of 21.6 and a change-relative-to-control mean of 30% for the two-sample *t* test. We considered Δ11 (= 36*30%) of '*chance of avoiding new cavities*' as the minimal

clinically important difference (MCID). The required size for the study was 128 subjects randomised into two groups of 64 subjects. As it was expected that dental practitioners would have even recruitment of participants, clustering by dental practitioners was not considered for the sample calculation.

The pre-determined inclusion criteria for patient participants were (1) willingness to participate in the project, (2) 19–70 years of age, (3) medical-card holder (i.e. proxy for economically disadvantaged status), (4) at least 20 teeth present, (5) not pregnant and (6) ability to use text messages. The eight trained and calibrated dental practitioners (Dentists A to H) in County Cork, RoI, who were volunteers with an interest in practice-based research, recruited medical-card-holder patients and obtained written informed consent from each patient participant. Allowing for a non-response rate of 33%, 191 participants (62 men and 129 women) were recruited.

We combined stratified randomisation with blocked randomisation. The block size was randomly varying. After consultation with the statistician who had looked at the first group of participants' data (*n* = 52) before randomisation commenced, we decided to stratify the participants into five groups ('*chance of avoiding new cavities*' of 0–20, 21–40, 41–50, 51–60, 61–100). The statistician generated random numbers for stratified and blocked randomisation using Proc Surveyselect, SAS, Version 9.4 (SAS Institute Inc., Cary, NC). Allocation was concealed using sealed, opaque, sequentially numbered envelopes. The envelopes were handed out by an OHSRC staff (LF) who was not involved in assessing data. LF enrolled and assigned the participants under the direction of the statistician. MN prepared personalised and non-personalised letters for each participant and passed them to LF together with their '*chance of avoiding new cavities*' scores for their stratification into the five groups. LF informed the person who was to send the text messages (computer programmer) of each participant's mobile number and which group they were in. Apart from LF, the computer programmer and the participants, all involved in the research project were blinded. Participants were randomised between 17 April 2015, and 12 November 2015. After all data entry was completed, the group assignments were revealed on 16 August 2016.

Interventions

The text messages covered the four caries risk-sectors in accordance with the Cariogram output (Fig. 1). We created more than 96 (= 24 weeks * 4 risk-sectors) educational text messages, and assigned a priority ranking to each message. Each message was kept within the maximum of 160 characters. The draft messages were prepared by one dentist and were based on available evidence from literature [19, 20], public websites [21-28], the Cariogram Manual [13], and educational emails of a non-profitable organisation [29] and Rapport Builder® (Oral Care Inc., Japan) [30] The text messages were checked and

revised by one editor, one psychologist, two neuroscientists and two dentists, then piloted with three staff members in the OHSRC and one dental student. Following a trial-sending of the actual text messages to three dental students and one occupational therapist, the text messages were finalised on 26 November 2014. Examples of the text messages are presented in Table 1.

Table 1 Twelve examples of text messages on the four risk-sectors

Risk-sector	**Text messages**
Diet	"Hi! Within 2 hrs of bedtime is the worst time for sugar-sweetened snacks/drinks. As we don't make much saliva during sleep, the acid attack can last many hours."
	"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!"
	Hi! Give your teeth a break! Leave at least 2 hours between every meal or snack! That way your teeth have time to heal from acidic effects of food.
Bacteria	Hi! Brush thoroughly w/ fluoride toothpaste 2 minutes twice a day, more often if ur dentist recommends! Small circular movements r good 2 clean ur teeth.
	The thin sticky film or 'furry' feeling that forms on ur teeth contains bugs, It's called a biofilm. Gunk that clogs kitchen & bathroom drains is biofilm too!
	Lots of bugs live in the mouth & some produce acids. Acids attack ur teeth, causing cavities. Don't leave it there! Cleaning teeth morning & night really helps.
Susceptibility	Hi Tooth study here! Fluoride in your toothpaste helps to strengthen and protect teeth, which can reduce tooth decay in adults and children.
	Hi Tooth study here! Adults should use a toothpaste that contains at least 1450ppm of fluoride twice a day to prevent decay.
	Hi Tooth study here! During sleep, saliva flow is very low & acid attacks to the tooth surface can last for many hours. Best to sleep & not eat in bed!
Circumstances	Hi! Over the years, fillings may weaken & tend to fracture & leak around the edges. Visit your dentist regularly for professional cleanings & oral examination!
	Hi Tooth study here! Regular dental visits help prevent decay. Going to the dentist for prevention regularly can make life more pleasant.
	Prevention is better than cure! Visit your dentist regularly: your dentist will spot problems earlier, helping u care for ur teeth.

Using the Cariogram output at baseline, the proportion contribution of each of the four risk-sectors to total caries risk for each participant was calculated. Applying these proportions to 24 (total number of text messages to be sent), the number of text messages on each risk-sector for each participant was determined. If, as a result of rounding, the sum of text messages to be sent was greater than 24, the number of 'Circumstances' messages was reduced because this risk-sector includes unlikely changeable risk indicators. If, as a result of rounding, the total number was less than 24, the number of text messages in the risk-sector with the highest proportion was increased in order to highlight the highest risk-sector. If the participant had past root caries experience, the text message on root caries was always included. If the participant had a specific systemic disease, the text message on that disease was always included.

For the bulk sending of text messages, the computer programmer used a web-based text messaging service (TextMagic, United Kingdom) [31] to send 24 educational text messages weekly [see Additional file]. Additionally, the programmer was supposed to send a welcome message asking each participant to send a reply as confirmation that we had their correct mobile number, and a final thank-you message reminding them to attend for their follow-up examination. We decided to send text messages between 5–6 pm on Sundays as this schedule was deemed most appropriate in the RoI context.

<Figure 2 near here>

The similarity of interventions between the personalised and non-personalised groups was the sending of one letter and of 24 weekly text messages (Fig 2). As text messages were chosen by their priority ranking, the top ranking messages would have been sent to participants in both groups. If a participant was assigned into the personalised group, LF posted a personalised letter which gave their '*chance of avoiding new cavities*', their Cariogram chart results and advice relevant to their results with €20 vouchers as a gesture of thanks. The programmer was supposed to select text messages from each risk-sector in order of their priority ranking as detailed above for weekly sending to the participant. If a participant was assigned into the non-personalised group, LF posted general information on caries prevention cited from the Dental Health Foundation website [21] with additional information extracted from the Cariogram's advices (non-personalised) in order that the letter volume was the same as for the personalised group and €20 vouchers a gesture of thanks. Then, the programmer was supposed to send each participant in the non-personalised group the predetermined, fixed set of 24 weekly text messages (the same six from each of the four risk-sectors with the highest priority ranking). The interventions for each group were administered between 26 April 2015 and 8 May 2016. With the €30 voucher at follow-up, we sent all participants and their dentists the results from both their baseline and follow-up CRAs plus their charts and personalised advice created by the Cariogram

Assessments and outcomes

To input the nine parameters of the Cariogram (Fig. 1) according to its manual [13], the dental practitioners examined and re-examined the participants using the case report form (CRF) and CRT® (Ivoclar Vivadent, Liechtenstein). Participants completed their three-day food diary and study questionnaire at their homes and returned them via post to the OHSRC. The laboratory technician at the OHSRC incubated and read CRT® saliva tests. We extracted information from their CRF, CRT® saliva tests, three-day food diary and study questionnaire to score and assess the demographic factors (age, gender, smoking status, educational level, possession of smartphone and dental practice) and the Cariogram parameters (except '*Clinical judgement*').

The pre-specified primary outcome measure was '*chance of avoiding new cavities*' (0–100) from the Cariogram at follow-up. Note that a bigger '*chance of avoiding new cavities*' indicates a lower total of the four risk-sector values (lower caries risk). The pre-specified secondary outcome measures were the seven biological risk parameters out of the ten risk parameters mentioned above: 'Diet contents' (salivary lactobacillus count with CRT® saliva test), 'Diet frequency' (frequency of fermentable carbohydrate intake), 'Plaque amount', 'Mutans streptococci', 'Fluoride programme', 'Saliva secretion' and 'Saliva buffer capacity'.

This work was carried out at the OHSRC between 17 April 2015 and 8 November 2015 at baseline, and between 28 October 2015 and 19 July 2016 at follow-up. We obtained actual logs of sent text messages from TextMagic on 7 June 2017 [see Additional file]. From the follow-up questionnaire, information on how many text messages were NOT understood (17–24, 9–16 or 1–8 messages; (question number 13 (Q13)) was extracted.

Before CRA commenced, the scoring of '*Mutans streptococci*' and '*Clinical judgment*' was adjusted, as we had found a lower score distribution of '*Mutans streptococci*' and a lower risk distribution of '*chance of avoiding new cavities*' among the first 52 participants compared to previous studies [17, 18].

Statistical analyses

From the baseline CRF and questionnaire, information on participant characteristics was extracted. For the primary analysis, we included all participants (n = 111) for the intent-to-treat (ITT) approach. For the per-protocol analysis, data deviations were calculated according to the actual message log and Q13 in the follow-up questionnaire. Duplicate (or more) messages which were accidentally sent to participants were

excluded from the per-protocol analysis. Data deviations relating to time factor were ignored for the current paper. For secondary outcome measures (the seven risk parameters), Scores 0 and 1, and Scores 2 and 3 (if any) were combined as 'lower score' and 'higher score', respectively, in accordance with the Cariogram's advice and the previous paper [6]. The primary outcome was analysed using analysis of covariance (ANCOVA). The baseline value and age were included as covariates. Gender, Dental Practice and Group (personalised and non-personalised) were included as factors. The secondary outcomes were analysed using logistic regression models. The baseline values and age were included as covariates. Gender and Group (personalised and non-personalised) were included as factors. Dental Practice could not be included as the number of categories resulted in quasi-separation in logistic regression models. We set the significance level of 5% (two-sided). We utilised SAS, Version 9.4 (SAS Institute Inc., Cary, NC).

Results

<Figure 3 near here>

Figure 3 summarises the participant flow through the study. Before randomisation, one participant who did not have his own mobile-phone and 19 participants who did not return their baseline three-day food diary to the OHSRC were excluded. Of the 171 participants included in the study, 26 out of 85 in the personalised group and 28 out of 86 in the non-personalised groups did not attend their follow-up examination, and three participants in each group did not return their three-day food diary to the OHSRC. As a result, 56 and 55 participants in the personalised and non-personalised groups, respectively, were analysed. Due to unexpected protocol violations, only two and nine participants in the personalised and non-personalised groups, respectively received their planned educational messages within the scheduled 24-week time period [see Additional file]. For this reason, for the per-protocol analysis, we ignored time factor and priority ranking violations and allowed two-message deviations. In total, 21 and 33 participants were included for per-protocol analysis in the personalised and non-personalised groups, respectively.

The dental practitioners recruited the participants between 25 February 2015, and 28 September 2015 at baseline, and re-examined them between 14 October 2015 and 19 May 2016 at follow-up. The cut-off for receiving the three-day food diary and questionnaire was 02 November 2015 at baseline and 16 June 2016 at follow-up. The follow-up CRA was finished on 19 July 2016 as dentists could get no more patients to attend for follow-up.

The demographic characteristics of the sample are presented in Table 2. While there were more females than males in both groups, the proportion of females in the personalised group was lower than in the

non-personalised group. The mean number of Decayed Missing Filled Tooth Surfaces (DMFS) was similar to that of the Non-Endodontic Group in the referred study [18]. Two dental practitioners (Dentists A and F) lost all their patients at follow-up. The distribution of participants for the six remaining dentists was highly uneven. The participants at randomisation tended to be younger, with less than third level education, smokers, smartphone owners and with less DMFS than ones at follow-up.

Table 2 Demographic characteristics of the sample

Variables	**Participants at randomisation**		**Participants at follow-up**	
	Personalised (*n* = 85)	**Non-personalised (*n* = 86)**	**Personalised (*n* = 56)**	**Non-personalised (*n* = 55)**
Age, y				
Mean (SD)	38.9 (12.8)	37.3 (13.0)	40.9 (11.8)	41.2 (12.3)
Median (min. to max.)	37 (17-69)[a]	36 (18-69)[a]	40 (19-69)	40 (19-69)
Gender, *n* (%)				
Female	54 (63.5)	64 (74.4)	34 (60.7)	41 (74.5)
Educational level, *n* (%)				
Less than third level	50 (58.8)	49 (57.0)	31 (55.4)	29 (52.7)
Third level and more	31 (36.5)	28 (32.6)	25 (44.6)	20 (36.4)
Still in education	1 (1.2)	6 (7.0)	0 (0.0)	3 (5.5)
Missing	3 (3.5)	3 (3.5)	0 (0.0)	3 (5.5)
Smoking status, *n* (%)				
Non-smoker	57 (67.1)	62 (72.1)	43 (76.8)	42 (76.4)
Smoker	28 (32.9)	24 (27.9)	13 (23.2)	13 (23.6)
Smart phone, *n* (%)				
Non-possession	15 (17.6)	15 (17.4)	12 (21.4)	12 (21.8)
Possession	64 (75.3)	64 (74.4)	41 (73.2)	40 (72.7)
Missing	6 (7.1)	7 (8.1)	3 (5.4)	3 (5.5)
DMFS				
Mean (SD)	31.0 (19.4)	31.7 (18.6)	32.6 (20.2)	34.9 (19.0)
Median (min. to max.)	33 (0-106)	29.5 (0-66)	33 (1-106)	33 (0-66)
Dental practice, *n* (%)				
A	1 (1.2)	1 (1.2)	0 (0.0)	0 (0.0)
B	8 (9.4)	14 (16.3)	7 (12.5)	11 (20.0)

C	9 (10.6)	9 (10.5)	9 (16.1)	9 (16.4)
D	44 (51.8)	43 (50.0)	32 (57.1)	32 (58.2)
E	8 (9.4)	7 (8.1)	4 (7.1)	2 (3.6)
F	1 (1.2)	1 (1.2)	0 (0.0)	0 (0.0)
G	6 (7.1)	3 (3.5)	1 (1.8)	1 (1.8)
H	8 (9.4)	8 (9.3)	3 (5.4)	0 (0.0)

SD Standard deviation, DMFS Decayed missing filled tooth surfaces

[a] Since one dentist did not comply with the inclusion criteria of age, one 17-year-old patient and one 18-year-old patient were included in the personalised group and one 18-year-old patient in the non-personalised group. All of them did not complete the study. See the 'Subjects' section for the pre-determined inclusion criteria.

Table 3 shows a comparison of the number of text messages from the four risk-sectors, both assigned and actually sent, between the personalised and non-personalised groups. In Q13, two participants answered they did not understand 17–24 messages and another two participants answered they did not understand 1–8 messages. One participant wrote in the questionnaire that she did not receive any text messages.

Table 3 Assigned and actually sent text messages by each risk-sector to the personalised and non-personalised groups

Number of text messages	**Personalised Group**				**Non-personalised Group**			
	Diet	**Bacteria**	**Susceptibility**	**Circumstances**	**Diet**	**Bacteria**	**Susceptibility**	**Circumstances**
Assigned messages								
Sum	401	504	264	175	330	330	330	330
Mean	7.2	9.0	4.7	3.1	6.0	6.0	6.0	6.0
(SD)	(2.9)	(3.4)	(4.2)	(1.7)	(0.0)	(0.0)	(0.0)	(0.0)
Median	7	9	3	3	6	6	6	6
Range	1-13	3-16	2-18	0-7	6-6	6-6	6-6	6-6
Actually sent messages[a]								
Sum	340	422	217	146	287	313	292	294

Mean	6.1	7.5	3.9	2.6	5.2	5.7	5.3	5.3
(SD)	(3.0)	(3.4)	(3.2)	(1.6)	(0.9)	(0.6)	(1.1)	(0.7)
Median	6	7	3	2.5	5	6	6	5
Range	0-12	0-14	0-16	0-6	3-6	3-7	2-6	3-6

SD Standard deviation

[a]Duplicates (or more) were counted as one.

For the primary analysis, with the ITT approach, means (standard deviation) of '*chance of avoiding new cavities*' were 46.2 (± 19.6) in the personalised group (*n* = 56) and 42.8 (± 22.0) in the non-personalised group (*n* = 55) (Table 4). The ANCOVA showed no statistically significant difference between the two groups (mean difference (95% confidence interval (CI)) = 0.7 (-5.5, 6.9), *p* = 0.820). For the secondary outcome, with the ITT approach, only the stimulated saliva flow factor showed a personalised intervention effect, *p* = 0.036, odds ratio (OR) = 0.3 (95% CI = 0.1, 0.9).

<Table 4 near here>

For the per-protocol analysis, there was no statistically significant difference between the two groups (mean difference (95% CI) = 4.0 (-5.6, 13.5), *p* = 0.410) (Table 4). For the secondary outcomes, logistic regression estimates were not reliable due to the small sample size for the per-protocol analysis. There was no harm or unintended effects in either group.

<Table 5 near here>

Discussion

This study tried to compare the effects of personalised versus non-personalised interventions via text messaging on caries risk in an economically disadvantaged adult population. A definitive conclusion could not be reached. However, as the MCID was included in the 95% CI for the per-protocol analysis, replication studies will be worth conducting.

The reason for considering one- or two-message deviations as acceptable for the per-protocol analysis was that an error of less than three messages had happened in the rounding procedure for deciding the number of text messages within each risk-sector. The reason the sample size of the personalised group (*n* = 21) was considerably smaller than that of the non-personalised group (*n* = 33) is likely because the programmer continued to use the failed computer program for displaying personalised combinations of

text messages after he found that the program could not properly order to send text messages to TextMagic at the third week [see Additional file]. For the non-personalised group, the program was not used to select text messages as the non-personalised group received a predetermined, fixed set of text messages. Thus, the personalised group was more affected, being subject to multiple errors.

The stimulated saliva flow parameter was significantly influenced in the personalised group for the ITT analysis, although the number of sent text messages on the 'Susceptibility' sector was not many. For the per-protocol analysis, all of the 21 participants had the lower risk score for this parameter. In another paper using the baseline data (n = 159), we found that knowledge of saliva factors as being a caries risk was quite low in this Irish population [15]; approximately 70% of the respondents did not know that a reduced amount of saliva is a caries risk factor. From these results, providing information on risk factors/indicators they are not already familiar with would have greater impact when informing the patient of the results of his/her individual CRA. Yet, the positive change in stimulated saliva flow at the follow-up examination may not indicate a true increase of saliva flow in daily life, as participants in the personalised group may have tried spitting more saliva, possibly because they learned from their personalised letter that they did not have enough saliva, and from their text messages that it is an important factor.

One reason for the unclear difference of '*chance of avoiding new cavities*' between the two groups may be the sensitive design of the current study. The non-personalised group were sent the six highest prioritised text messages for each risk-sector, which would include the text messages that would also be chosen for the personalised group depending on their risk profile. Also, the non-personalised letter contained information from the Cariogram's advices (non-personalised) in order to have the same letter volume as the personalised group. As a result, the interventions to the personalised participants were apt to be similar to those for the non-personalised participants, unless a participant had a prominent risk profile. On the other hand, in a randomised controlled trial for smoking cessation sending mobile-phone text messages to both test and control groups, all text messages for the test group were personalised ones related to quitting and all text messages to the control group were clearly unrelated to quitting [32]. In another study for weight loss, although there was some overlapping information between the test and control groups, the test group received personalised mobile-phone text messages two to five times daily plus other services whereas the control group received the print material only once a month [33]. Our study did not have such clear contrast in interventions between the test and control groups. Instead, we designed the current study with a much narrower interest that aimed to look into an effect of a personalised combination of text messages based on individual CRA, while keeping other conditions as equal as possible between the test and control groups. While it is likely that the mHealth intervention

benefited both groups for caries risk reduction, our study design cannot fully validate this as the patients, examiners (dentists) and assessors (the laboratory technician and MN) might unconsciously wish and evaluate better at follow-up than at baseline.

In the current study, the dental practices did not routinely perform patient education based on CRA. In reality, it would be preferable that personalised patient education is performed by the dental practice and that personalised mHealth is used as an auxiliary measure to compensate and re-enforce the patient education at practice and to engage the patients. Such a service, called Rapport Builder® [30], is available in Japan and was considered in the design of this study as a social entrepreneur approach for behaviour change. Instead of the dentist, Rapport Builder® regularly sends emails to patients in order to stimulate customer engagement for a long-term effect [34]. Originally, we intended to send emails similarly to Rapport Builder®. Emails can contain limitless characters with entertainment elements, including images such as the Cariogram chart. This would have been much more informative and advantageous to the personalised group. However, because when this study was designed only 57% of mobile-phone customers owned a smartphone in the RoI [35], we estimated this percentage would be even lower in a disadvantaged group and opted for short text messaging instead. Since an exponential rise in smartphone use was expected in the RoI, we included the question on smartphone ownership in the CRF for a future study. The response indicated that approximately three-quarters of the participants already had a smartphone. Therefore, services via smartphone would be the choice for mHealth today, even in a disadvantaged population in RoI. Some smartphone instant messaging applications signal the sender when the receiver has read a message; information on whether the participant opens the message or not is useful. Artificially intelligent chatbots will easily enable an interactive approach with participants, and may give greater motivation to participants.

The current study has limitations on its generalisability. The response rate was low and may cause selection bias. Even though we gave a rather high compensation (€50) to encourage the disadvantaged population, results showed that 79 out of 191 participants (49%) did not comply with the study procedure. The reasons may be (1) that this population is difficult to keep compliant, (2) that reminder text messages for the follow-up examination were actually not sent to 15 participants (60% of them did show for the follow-up examination) [see Additional file] and (3) that Dentist H changed work place during the period of follow-up examinations. Another limitation is that the time frame varied largely from individual to individual. One-fourth of the participants posted the three-day food diaries to the OHSRC more than two months after the intervention finished. The effect of educational text messages may be decreased when there are lengthy time delays to have an effect, as the long-term effect of mHealth is still uncertain [36, 37].

Conclusions

The null hypothesis that no difference would exist between personalised and non-personalised interventions among economically disadvantaged adults was not rejected. However, it is worth exploring further the potential of mobile-devices for individual caries risk reduction.

List of abbreviations

ANCOVA: Analysis of Covariance; CI: Confidence Interval; CONSORT: Consolidated Standards of Reporting Trials; CRA: Caries Risk Assessment; CRF: Case Report Form; DMFS: Decayed Missing Filled Tooth Surfaces; ITT: Intent-to-treat; MCID: Minimal Clinically Important Difference; mHealth: Mobile Health; OHSRC: Oral Health Services Research Centre; OR: Odds Ratio; PSAP: Promoting State-of-the-Art risk assessment for the Prevention of dental caries and periodontal disease; Q: question number; RoI: Republic of Ireland; SD: Standard Deviation; UCC: University College Cork

Declarations

Ethics approval and consent to participate

Ethical approval was given by the Clinical Research Ethics Committee of the Cork Teaching Hospitals (ECM 4 (r) 12/08/14). All patients were informed about the survey and provided written informed consent.

Consent for publication

Not applicable.

Availability of data and materials

Data will not be made available as more articles are to be published.

Competing interests

MN is the chairperson of the board of a non-profitable organisation promoting risk assessments of dental caries and periodontal diseases (the PSAP) in Japan which is supported by Oral Care Inc.

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Authors' contributions

MN contributed to conception of the studies and acquisition of data. MN and VK contributed to drafting and finalising the manuscript. MC contributed to statistical analysis. All authors contributed to design and analysis, interpretation of data and revising the manuscript critically for important intellectual content. All authors have approved the final version and agreed to be accountable for all aspects of the work.

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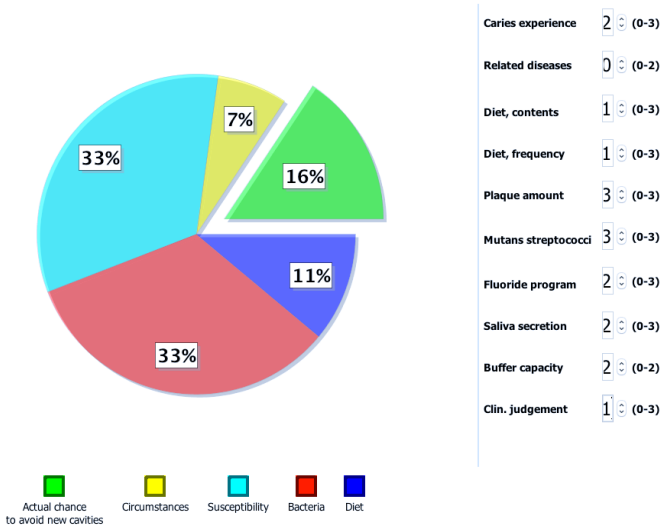
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Additional file

The protocol violations in more detail. (PDF 83kb)

Figures

Fig. 1 A Cariogram output (as it appears on computer screen)



The '*chance of avoiding new cavities*' is 16% which indicates this person has 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.

Fig. 2 Workflow diagram

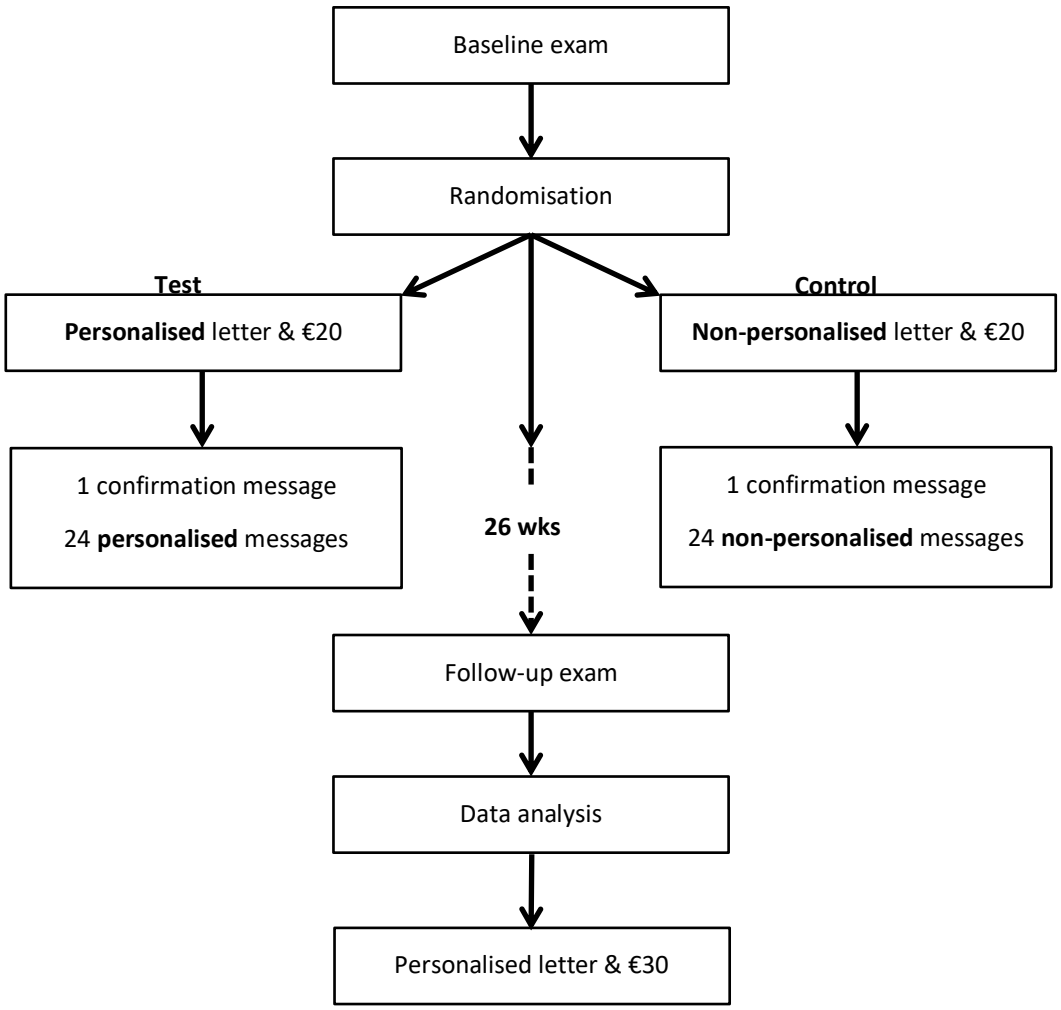
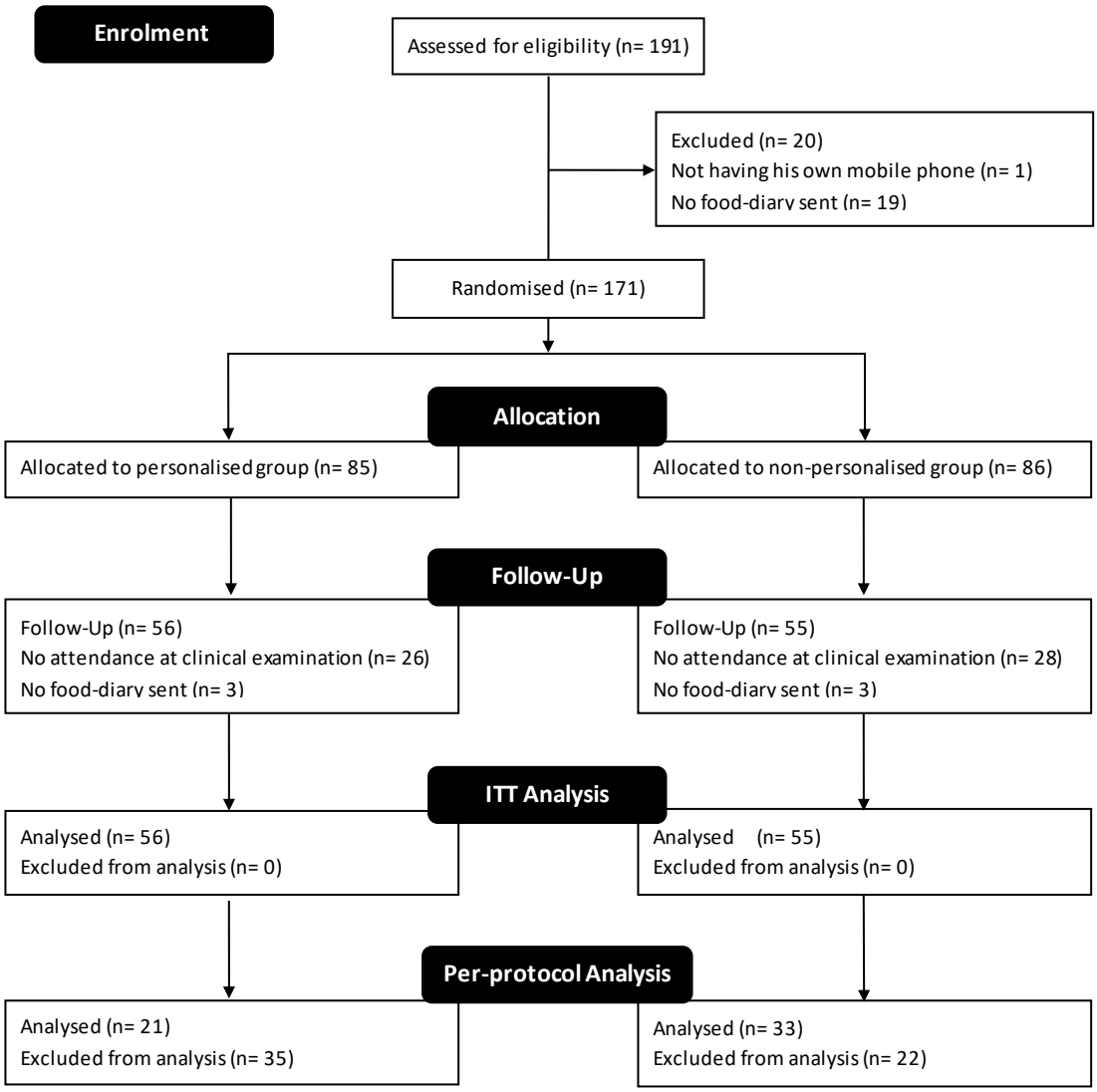


Fig. 3 Subject disposition/CONSORT flow diagram



ITT: intent-to-treat

Tables

Table 4 Intent-to-treat (ITT) analysis: primary and secondary outcomes between the personalised and non-personalised groups

ITT analysis	**Group**			
	Personalised (*n* = 56)	**Non-personalised (*n* = 55)**		***p* value**
Primary outcome			**Mean difference (95% CI)**	
Baseline				
mean (SD)	39.3 (20.2)	36.5 (23.4)		
median (min. to max.)	37.5 (6 to 81)	31.0 (3 to 94)		
Follow-up			0.7 (-5.5, 6.9)	*p* = 0.820
mean (SD)	46.2 (19.6)	42.8 (22.0)		
median (min. to max.)	44.5 (8 to 83)	41.0 (9 to 93)		
Secondary outcome (number (%) of participants with Score 0, 1)			**Odds ratio (95% CI)**	
'Diet frequency'				
Baseline	39 (69.6)	36 (65.5)		
Follow-up	47 (83.9)	43 (78.2)	0.8 (0.3, 2.3)	*p* = 0.663
'Diet contents'				
Baseline	27 (48.2)	30 (54.5)		
Follow-up	27 (48.2)	30 (54.5)	1.0 (0.4, 2.6)	*p* = 0.945
'Plaque amount'				
Baseline	25 (44.6)	19 (34.5)		
Follow-up	31 (55.4)	33 (60.0)	1.7 (0.7, 3.9)	*p* = 0.247
'Mutans streptococci'				
Baseline	34 (60.7)	24 (43.6)		
Follow-up	36 (64.3)	31 (56.4)	1.1 (0.4, 2.6)	*p* = 0.917
'Fluoride programme'[a]				
Baseline	55 (98.2)	51 (92.7)		
Follow-up	56 (100.0)	54 (98.2)		*p* = 0.941
'Saliva secretion'				

Baseline	45 (80.4)	40 (72.7)		
Follow-up	51 (91.1)	41 (74.5)	0.3 (0.1, 0.9)	$p = 0.036$*
'Saliva buffer capacity'				
Baseline	54 (96.4)	51 (92.7)		
Follow-up	45 (80.4)	40 (72.7)	0.8 (0.3, 2.1)	$p = 0.653$

*$p < 0.05$

SD Standard deviation, CI Confidential interval

[a] Model fit was questionable – odds ratio estimates unreliable.

Table 5 Per-protocol analysis: primary and secondary outcomes between the personalised and non-personalised groups

Per-protocol analysis	**Group**			***p* value**
	Personalised (*n* = 21)	**Non-personalised (*n* = 33)**		
P**rimary outcome**			**Mean difference (95% CI)**	
Baseline				
mean (SD)	36.7 (18.6)	29.4 (20.6)		
median (min. to max.)	37 (11 to 67)	26 (3 to 83)		
Follow-up				
mean (SD)	44.6 (18.4)	35.0 (20.6)	4.0 (-5.6, 13.5)	$p = 0.410$
median (min. to max.)	39 (16 to 83)	32 (9 to 84)		
Secondary outcome (number (%) of participants with Score 0, 1)[a]				
'Diet frequency'				
Baseline	12 (57.1)	21 (63.6)		
Follow-up	18 (85.7)	25 (75.8)		
'Diet contents'				
Baseline	10 (47.6)	14 (42.4)		
Follow-up	8 (38.1)	13 (39.4)		
'Plaque amount'				
Baseline	8 (38.1)	9 (27.3)		
Follow-up	12 (57.1)	18 (54.5)		

'Mutans streptococci'		
Baseline	9 (42.9)	8 (24.2)
Follow-up	12 (57.1)	12 (36.4)
'Fluoride programme'		
Baseline	21 (100.0)	30 (90.9)
Follow-up	21 (100.0)	32 (97.0)
'Saliva secretion'		
Baseline	20 (95.2)	23 (69.7)
Follow-up	21 (100.0)	24 (72.7)
'Saliva buffer capacity'		
Baseline	21 (100.0)	31 (93.9)
Follow-up	18 (85.7)	27 (81.8)

SD Standard deviation, CI Confidential interval

[a] Logistic regression estimates were not reliable due to the small sample size.

Additional file

The protocol violations in more detail

Approximately one year after the end of our study intervention, during the writing of this manuscript, we found critical protocol deviations caused by the computer programmer employed for the study and discovered that he had concealed facts in the attempt to mislead the research team of his failings. Fortunately, the web-based text messaging service which the programmer used (TextMagic, United Kingdom) [1] keeps actual logs of incoming and outgoing text messages and we were able to download this on 7 June 2017. Examination of the TextMagic log revealed the extent of deviations from project protocol. Differences in the number of text messages actually sent and the number assigned for sending by the four risk-sectors are presented in Table 3 of the main text.

Some bugs and glitches are inevitable in mobile health (mHealth) research and it is recommended to perform internal and external testing prior to the beginning of an mHealth intervention [2]. The TextMagic log shows that any text message based on caries risk assessment was tried by the programmer before intervention commenced in our research project. During the intervention, there were two chances for us to prevent further data deviations. Two participants separately gave us information on messaging inconsistencies at the beginning and in the middle of the intervention period. Although the programmer responded that the issue would be resolved for the first participant and that messages to the second participant were sent with no issue, the actual log shows that messaging failures were occurring every week from the beginning to the end of the 55-week intervention period, without being fixed. It is regrettable that we did not exploit these two opportunities to rectify any deviations, trusting instead in the programmer's expertise and integrity.

One important lesson for the fidelity of the intervention is the importance of having a third person watch the intervention process. In this case, we could have allocated a third person to sign in to TextMagic and examine actual logs every week. It is also recommended to add multiple dummy recipients who monitor text messages received during the intervention period. Another lesson is to always evaluate the pros and cons when you change the situation. We were supposed to use the services of Rapport Builder® (Oral Care Inc., Japan) [3], which inspired the current study. The merits of changing from Rapport Builder® to the student programmer in the School of Computer Science and Information Technology within our university were (1) that communication could be done locally and (2) that we could save the allocated budget to Rapport Builder®. We had had discussions about contingencies in this research project, however we never discussed the demerits of this change and precautions for the involvement of a student programmer in the research team. Precautions should have included the drawing up of an official contract with technical specifications for his participation, a clear terms of reference outlining the responsibility of the student as a research team member, and the provision of appropriate training on Good Research Practice [4].

In mHealth research, it is acceptable to ask the assistance of an IT undergraduate student as part of his/her bachelor project under supervision. However, it should be noted that this is a rather high-risk bet. The student in his/her final year may even manipulate data with his/her IT expertise without fulfilling his/her reporting obligation to his/her supervisor or realising the gravity of what they are doing. And once they have graduated, there is no sanction for their actions. Therefore, if there is a critical failure in his/her bachelor project at the last stage, it is no surprise that a student will attempt whatever is necessary for them to achieve graduation. On the

other hand, a programmer employed by a company would be held responsible for their actions and be subject to punishment and condemnation, which makes the risk of data manipulation lower. In addition, he/she and the company would suffer from a black mark on their professional reputation. Although hiring the student programmer was cheaper than contracting Rapport Builder®, the irreversible loss this change cost the current study cannot be counted.

Use of mHealth for caries prevention was a frontier topic four years ago when this project started. Thus, we had little knowledge of how to work with an IT expert, who would be at the core of the research project. Without enough IT expertise, we were naïve and treated the programmer as a sacred cow. Indeed, no one in our research team except the programmer knew that TextMagic provides various functions, which easily allows for the checking of message failures, until we had to contact TextMagic to verify discrepancies found in the programmer's log and saw these functions. Consequently, from this bitter experience we learned first-hand the vulnerability of mHealth to programmer manipulation. At the same time, rigorous detail logs are automated and easily available thanks to digital technology, which is a great advantage for mHealth research. From the TextMagic log, we could grasp exactly what was happening with the assigned 4,446 (= 26*171) text messages and analyse the factual data.

It is important to use this experience to raise the overall level of scientific integrity [5], especially for this rapidly emerging mHealth field which has huge potential [6]. To prevent the repeating message failures, which was never fixed by the student programmer, the feasibility of the computer programme designed for this study is going to be investigated by an expert as far as our budget allows. We must fulfil accountability to all people involved in this research project about protocol deviations

and the resultant findings for the integrity of the study. Especially, to the two participants mentioned above, we appreciate their feedback that became important clues in our investigation to reach closer to the truth.

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