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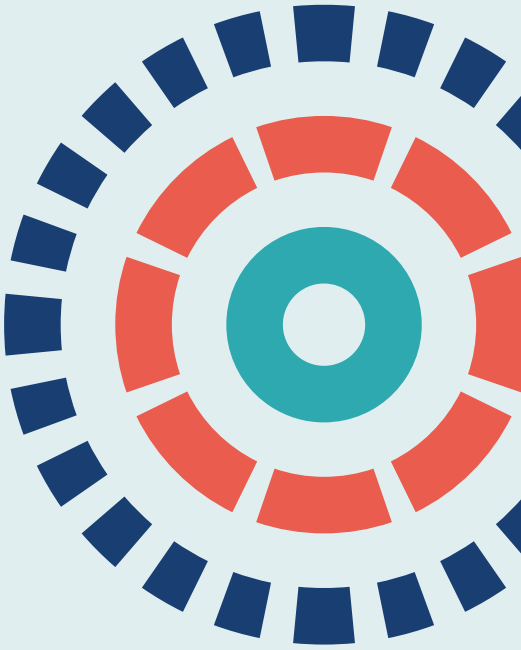

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Risk-based, 6-monthly and 24-monthly dental check-ups for adults: the INTERVAL three-arm RCT

Jan E Clarkson,[1*†] Nigel B Pitts,[2†] Beatriz Goulao,[3] Dwayne Boyers,[4] Craig R Ramsay,[3] Ruth Floate,[1] Hazel J Braid,[1] Patrick A Fee,[1] Fiona S Ord,[1] Helen V Worthington,[5] Marjon van der Pol,[4] Linda Young,[6] Ruth Freeman,[1] Jill Gouick,[1] Gerald M Humphris,[7] Fiona E Mitchell,[1] Alison M McDonald,[3] John DT Norrie,[3] Kirsty Sim,[1] Gail Douglas[8] and David Ricketts[1]

[1]Dental Health Services Research Unit, University of Dundee, Dundee, UK
[2]Faculty of Dentistry, Oral & Craniofacial Sciences, King's College London, London, UK
[3]Health Services Research Unit, University of Aberdeen, Aberdeen, UK
[4]Health Economics Research Unit, University of Aberdeen, Aberdeen, UK
[5]School of Dentistry, University of Manchester, Manchester, UK
[6]Dental Directorate, NHS Education for Scotland, Edinburgh, UK
[7]School of Medicine, University of St Andrews, St Andrews, UK
[8]School of Dentistry, University of Leeds, Leeds, UK

*Corresponding author
†Co-clinical investigator

Declared competing interests of authors: Nigel B Pitts consults for Colgate (Colgate-Palmolive Company, New York, NY, USA) and GlaxoSmithKline plc (Brentford, UK) (toothpaste manufacturers) and was also a co-applicant on the National Institute for Health Research (NIHR) Health Technology Assessment (HTA) Improving the Quality of Dentistry trial of dental scale and polish. Craig R Ramsay is a member of the NIHR HTA General Board. John DT Norrie reports grants from the University of Aberdeen and grants from the University of Edinburgh during the conduct of the study, and declares membership of the following NIHR boards: CPR decision making committee, HTA Commissioning Board, HTA Commissioning Sub-Board (Expression of Interest), HTA Funding Boards Policy Group, HTA General Board, HTA Post-Board funding teleconference, NIHR Clinical Trials Unit Standing Advisory Committee, NIHR HTA and Efficacy and Mechanism Evaluation Editorial Board and the Pre-exposure Prophylaxis Impact Review Panel. Gail Douglas reports that she is employed full time by the University of Leeds; 1 day of her time is bought out by Public Health England to assist with academic input to the dental epidemiology programme for England. She is also currently President of the British Association for the Study of Community Dentistry, a professional organisation principally for those working in the field of dental public health or allied areas.

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This report

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Abstract

Risk-based, 6-monthly and 24-monthly dental check-ups for adults: the INTERVAL three-arm RCT

Jan E Clarkson,[1*†] Nigel B Pitts,[2†] Beatriz Goulao,[3] Dwayne Boyers,[4] Craig R Ramsay,[3] Ruth Floate,[1] Hazel J Braid,[1] Patrick A Fee,[1] Fiona S Ord,[1] Helen V Worthington,[5] Marjon van der Pol,[4] Linda Young,[6] Ruth Freeman,[1] Jill Gouick,[1] Gerald M Humphris,[7] Fiona E Mitchell,[1] Alison M McDonald,[3] John DT Norrie,[3] Kirsty Sim,[1] Gail Douglas[8] and David Ricketts[1]

[1]Dental Health Services Research Unit, University of Dundee, Dundee, UK
[2]Faculty of Dentistry, Oral & Craniofacial Sciences, King's College London, London, UK
[3]Health Services Research Unit, University of Aberdeen, Aberdeen, UK
[4]Health Economics Research Unit, University of Aberdeen, Aberdeen, UK
[5]School of Dentistry, University of Manchester, Manchester, UK
[6]Dental Directorate, NHS Education for Scotland, Edinburgh, UK
[7]School of Medicine, University of St Andrews, St Andrews, UK
[8]School of Dentistry, University of Leeds, Leeds, UK

*Corresponding author p.fee@dundee.ac.uk
†Co-clinical investigator

Background: Traditionally, patients are encouraged to attend dental recall appointments at regular 6-month intervals, irrespective of their risk of developing dental disease. Stakeholders lack evidence of the relative effectiveness and cost-effectiveness of different recall strategies and the optimal recall interval for maintenance of oral health.

Objectives: To test effectiveness and assess the cost–benefit of different dental recall intervals over a 4-year period.

Design: Multicentre, parallel-group, randomised controlled trial with blinded clinical outcome assessment at 4 years and a within-trial cost–benefit analysis. NHS and participant perspective costs were combined with benefits estimated from a general population discrete choice experiment. A two-stratum trial design was used, with participants randomised to the 24-month interval if the recruiting dentist considered them clinically suitable. Participants ineligible for 24-month recall were randomised to a risk-based or 6-month recall interval.

Setting: UK primary care dental practices.

Participants: Adult, dentate, NHS patients who had visited their dentist in the previous 2 years.

Interventions: Participants were randomised to attend for a dental check-up at one of three dental recall intervals: 6-month, risk-based or 24-month recall.

Main outcomes: Clinical – gingival bleeding on probing; patient – oral health-related quality of life; economic – three analysis frameworks: (1) incremental cost per quality-adjusted life-year gained, (2) incremental net (societal) benefit and (3) incremental net (dental health) benefit.

Results: A total of 2372 participants were recruited from 51 dental practices; 648 participants were eligible for the 24-month recall stratum and 1724 participants were ineligible. There was no evidence of a significant difference in the mean percentage of sites with gingival bleeding between intervention arms in any comparison. For the eligible for 24-month recall stratum: the 24-month ($n = 138$) versus 6-month group ($n = 135$) had an adjusted mean difference of −0.91 (95% confidence interval −5.02 to 3.20); the risk-based ($n = 143$) versus 6-month group had an adjusted mean difference of −0.98 (95% confidence interval −5.05 to 3.09); the 24-month versus risk-based group had an adjusted mean difference of 0.07 (95% confidence interval −3.99 to 4.12). For the overall sample, the risk-based ($n = 749$) versus 6-month ($n = 737$) adjusted mean difference was 0.78 (95% confidence interval −1.17 to 2.72). There was no evidence of a difference in oral health-related quality of life between intervention arms in any comparison. For the economic evaluation, under framework 1 (cost per quality-adjusted life-year) the results were highly uncertain, and it was not possible to identify the optimal recall strategy. Under framework 2 (net societal benefit), 6-month recalls were the most efficient strategy with a probability of positive net benefit ranging from 78% to 100% across the eligible and combined strata, with findings driven by the high value placed on more frequent recall services in the discrete choice experiment. Under framework 3 (net dental health benefit), 24-month recalls were the most likely strategy to deliver positive net (dental health) benefit among those eligible for 24-month recall, with a probability of positive net benefit ranging from 65% to 99%. For the combined group, the optimal strategy was less clear. Risk-based recalls were more likely to be the most efficient recall strategy in scenarios where the costing perspective was widened to include participant-incurred costs, and in the Scottish subgroup.

Limitations: Information regarding factors considered by dentists to inform the risk-based interval and the interaction with patients to determine risk and agree the interval were not collected.

Conclusions: Over a 4-year period, we found no evidence of a difference in oral health for participants allocated to a 6-month or a risk-based recall interval, nor between a 24-month, 6-month or risk-based recall interval for participants eligible for a 24-month recall. However, people greatly value and are willing to pay for frequent dental check-ups; therefore, the most efficient recall strategy depends on the scope of the cost and benefit valuation that decision-makers wish to consider.

Future work: Assessment of the impact of risk assessment tools in informing risk-based interval decision-making and techniques for communicating a variable recall interval to patients.

Trial registration: Current Controlled Trials ISRCTN95933794.

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List of abbreviations

AIC	Akaike information criterion
ASC	alternative specific constant
BSO	Business Services Organisation
CBA	cost–benefit analysis
CBAC	cost–benefit acceptability curve
CEAC	cost-effectiveness acceptability curve
ChaRT	Centre for Healthcare Randomised Trials
CI	confidence interval
CONSORT	Consolidated Standards of Reporting Trials
CPD	continuing professional development
CUA	cost–utility analysis
DCE	discrete choice experiment
DMC	Data Monitoring Committee
EQ-5D-3L	EuroQol-5 Dimensions, three-level version
GDS	general dental service
GP	general practitioner
HTA	Health Technology Assessment
ICDAS	International Caries Detection and Assessment System
ICER	incremental cost-effectiveness ratio
INB	incremental net benefit
INTERVAL	Investigation of NICE Technologies for Enabling Risk-Variable-Adjusted-Length
IQuaD	Improving the Quality of Dentistry
ISD	Information Services Division
MDAS	Modified Dental Anxiety Scale
NHSBSA	NHS Business Services Authority
NICE	National Institute for Health and Care Excellence
NIHR	National Institute for Health Research
OHIP-14	Oral Health Impact Profile-14
OHRQoL	oral health-related quality of life
PAD	patient attendance data
PBC	perceived behavioural control
PCRF	patient case report form
PI	periodontal instrumentation
QALY	quality-adjusted life-year
RCT	randomised controlled trial
SD	standard deviation
SDCEP	Scottish Dental Clinical Effectiveness Programme
TOD	Trial Office in Dundee
TMC	Trial Management Committee
TSC	Trial Steering Committee
UDA	unit of dental activity
UNC15	University of North Carolina-15
WTP	willingness to pay

Plain English summary

Traditionally, dentists have encouraged both patients at low risk and patients at high risk of developing dental disease to attend their dental practices for regular 6-month 'check-ups'. There is, however, little evidence available for either patients or dentists to use when deciding on the best dental recall interval (i.e. time between dental check-ups) for maintaining oral health.

In this study, we wanted to find out, for adult patients who regularly attend the dentist, what interval of time between dental check-ups maintains optimum oral health and represents value for money. A total of 2372 adults who regularly attended 51 different dental practices across Scotland, Northern Ireland, England and Wales were involved. Patients aged 18 years or over who received all or part of their care as NHS patients were randomly allocated to groups to receive a check-up either every 6 months, at an individualised recall interval based on their own risk of oral disease (risk-based recall), or every 24 months (if considered at low risk by their dentist). The recruited adults completed questionnaires at their first trial appointment and then every year of the 4-year study. Their attendance at recall appointments was recorded and they received a clinical assessment taken by study staff at the end of their involvement at year 4.

After 4 years, there was no evidence of a difference in the oral health of patients allocated to a 6-month or variable risk-based recall interval. For patients considered by their dentists to be suitable for a 24-month recall interval, there was no difference between those in the 24-month, 6-month or risk-based recall intervals. However, people greatly value and are willing to pay for frequent dental check-ups. The recall strategy that offers the best value for money to patients and the NHS, therefore, depends on what people and decision-makers wish to value within a health-care system.

Scientific summary

Background

Traditionally, patients have been encouraged to attend dental recall appointments at regular intervals of 6 months between appointments, irrespective of the individual's risk of developing dental disease.

This recommendation of a 6-month recall interval has become established practice in primary dental care in many countries; however, there is a weak evidence base underpinning this recommendation. There has been a longstanding international debate regarding the clinical effectiveness and cost-effectiveness of recall intervals for routine dental check-up examinations. The need for primary research has been highlighted in the Health Technology Assessment Group's systematic review of routine dental check-ups, which found little evidence to support or refute the practice of encouraging 6-month dental check-ups in adults. The more recent Cochrane review on recall interval found only one trial, which was assessed as having a high risk of bias, with 185 participants and concluded that there was insufficient evidence to draw any conclusions regarding the potential beneficial or harmful effects of altering the recall interval between dental check-ups. The limited evidence from recent observational studies also supports the need for research. Many Clinical Commissioning Groups in England are now seeking to secure adherence to the National Institute for Health and Care Excellence recall interval guideline as part of their clinical governance responsibilities when commissioning dental primary care services. However, the lack of direct evidence behind differing recall strategies complicates the adoption process, while uncertainty remains within Clinical Commissioning Groups and among dentists as to how best to implement the guidance in practice. There is, therefore, an urgent need to assess the relative effectiveness and value for money of different dental recall intervals in a robust, sufficiently powered randomised controlled trial in primary dental care.

The trial protocol was published in BMC Oral Health [Clarkson JE, Pitts NB, Bonetti, D, Boyers D, Braid H, Elford R, *et al.* INTERVAL (investigation of NICE technologies for enabling risk-variable-adjusted-length) dental recalls trial: a multicentre randomised controlled trial investigating the best dental recall interval for optimum, cost-effective maintenance of oral health in dentate adults attending dental primary care. *BMC Oral Health* 2018;**18**:135].

Objectives

The aim of this trial was to compare the effectiveness and cost–benefit of dental check-ups at different recall intervals (fixed-period 6-month recall, risk-based recall or fixed-period 24-month recall) for maintaining optimum oral health in dentate adults attending general dental practices.

The primary objectives were to compare the three recall strategies on:

- gingival bleeding on probing
- oral health-related quality of life
- value for money in terms of (1) cost per quality-adjusted life-year gained, (2) incremental net (societal) benefit and (3) incremental net (dental health) benefits.

The secondary objectives were to compare the three recall strategies on:

- periodontal probing depths
- dental caries

- calculus
- preventative and interventive dental treatment
- patient anxiety
- patient satisfaction with care
- oral health knowledge, attitudes and behaviours, and to explore dentists' attitudes towards dental recall intervals
- NHS and patient participant perspective costs
- determining the general population's willingness to pay.

Methods

Design

The Investigation of NICE Technologies for Enabling Risk-Variable-Adjusted-Length (INTERVAL) trial was a UK-wide, multicentre, parallel-group, randomised controlled trial with blinded outcome assessment at 4-year follow-up.

To test the effect of dental recall interval, patient participants were randomised to one of three recall intervals: a fixed-period 24-month recall interval, a risk-variable-adjusted-length recall interval (risk-based recall) based on the National Institute for Health and Care Excellence guideline, and a fixed-period 6-month recall interval.

A two-stratum trial design was proposed to overcome potential ethical considerations and dental clinician and/or participant concerns. Participants were randomised to the fixed-period 24-month recall interval only if the recruiting dentist considered them clinically suitable. Participants who were not considered suitable for 24-month period recall were randomised to either a risk-based recall or a 6-month recall interval.

Setting

The trial sought to recruit general dental practitioners/practices from across the UK, representing a cross-section of practitioners in terms of urban/rural areas, community-level sociodemographics, and fluoridated or non-fluoridated communities.

Dentist participants

Inclusion criteria

- NHS provider for adult patients.
- Primary care provider: salaried service, corporate and independent operators.
- Willing to follow trial protocol.

Exclusion criteria

- Providing only private dental services to adults.
- Unwilling to follow trial protocol.

Patient participants

Inclusion criteria

Adult patients (≥ 18 years) who:

- were dentate
- had visited their dentist in the previous 2 years
- received their dental care in part or fully as an NHS patient, including dental examination.

Exclusion criteria

- Patients with a medical condition indicating increased risk of bleeding.
- Immunocompromised patients.

Interventions

The trial interventions recall intervals were a fixed-period 24-month recall interval, a risk-variable-adjusted-length recall interval based on the National Institute for Health and Care Excellence guideline, and a fixed-period 6-month recall interval.

Patient participants allocated to the fixed-period 24-month recall interval and the fixed-period 6-month recall interval groups were invited to attend their dentist at the scheduled time intervals for a routine dental check-up. The content of this check-up remained as per current practice. A recognised definition of a routine NHS dental check-up is clinical examination, advice, charting including monitoring of periodontal status and report. Patient participants allocated to the risk-based recall interval group were allocated recall appointments at time intervals determined by the evidence-based process outlined in the 2004 National Institute for Health and Care Excellence guideline on dental recall. The National Institute for Health and Care Excellence guideline was developed using extensive consensus methods and the limited evidence available. The recommendation was that the recall interval range for adults should vary from 3 to 24 months, depending on the likely risk of development or progression of dental disease.

Outcome measures

All primary and secondary outcomes were measured at the 4-year follow-up time point.

Primary outcomes

- Clinical: gingival bleeding on probing.
- Patient centred: oral health-related quality of life (Oral Health Impact Profile-14).

Secondary outcomes

Clinical:

- dental caries
- periodontal probing depth
- calculus
- preventative and interventive care.

Patient centred:

- dental anxiety
- oral health-related knowledge, attitudes and behaviours
- generic quality of life measured using the EuroQol-5 Dimensions, three-level version
- use of and reason for use of dental services
- satisfaction with care.

Economic outcomes

- NHS costs.
- Patient-incurred costs.
- General population preferences, willingness to pay calculated from a discrete choice experiment to value service delivery and outcomes.

- Incremental net benefits (willingness to pay minus costs) measured as societal net benefit (willingness to pay for health and non-health aspects), and dental health net benefit (willingness to pay for health outcomes, bleeding on brushing and caries experience only).
- Quality-adjusted life-years.
- Incremental cost per quality-adjusted life-year.

Service provider measures

- Dentist attitude towards dental recall intervals.

Clinical outcomes were assessed at 4 years post randomisation by trained outcome assessors who were blinded to participant allocation. Patient-centred outcomes were measured at baseline and annually via self-administered postal questionnaires over the 4-year follow-up period. Our sample size calculations indicated that we needed to randomise 705 participants to stratum 1 (235 in each arm) and 1030 to stratum 2 (515 in each arm). The primary analysis used an intention-to-treat framework and all participants with available data remained in their allocated groups. Outcomes collected at year 4 were analysed using a generalised linear model with a random effect for dental practice; outcomes collected at years 1, 2, 3 and 4 were analysed using a mixed-effects model with two random effects: participant and practice. All analyses were adjusted for the protocol minimisation variables.

Economic evaluation

The economic analysis was conducted using different perspectives of benefits (quality-adjusted life-years, willingness to pay for dental health outcomes, willingness to pay for dental recall and associated outcomes) and costs [NHS (dental, sourced from the routine claims data), NHS (dental and other services, such as primary and secondary medical care), and societal (including NHS and participant perspective costs)]. The preferred perspective depends on normative views of what benefits should be maximised with the NHS dental budget and what costs should be minimised.

Routinely collected dental claims data were linked to trial data to determine the costs of NHS provided dental care [from both an NHS and participant (including participant co-payments)] perspective. Additional participant costs, including travel costs and the opportunity cost of time spent attending dental appointments, were collected from participant self-reported questionnaires.

Quality-adjusted life-years were calculated based on participant responses to the EuroQol-5 Dimensions, three-level version, valued using UK general population tariffs. A discrete choice experiment administered to a nationally representative online sample of the UK general population was used to calculate willingness to pay for health outcomes (bleeding on brushing and caries experience) and service delivery (frequency of recall). The discrete choice experiment data were analysed using logistic regression to model preferences as a function of the attributes. Missing costs and benefits data from the trial were imputed using multiple imputation methods. All analyses were conducted following intention to treat.

The economic evaluation results were reported using three alternative perspectives on the scope of benefits to be included in the evaluation. Framework 1 reported the results of a cost–utility analysis as incremental cost per quality-adjusted life-year. Framework 2 used willingness-to-pay tariffs from the discrete choice experiment, mapped to the trial interventions (value of recall frequency) plus health outcomes (value of bleeding on brushing and caries experience) to calculate net (societal) benefit, whereas framework 3 used willingness-to-pay tariffs mapped to health outcomes only to calculate net (dental health) benefit. Within each evaluation framework, we considered a range of different scenario analyses, including different perspectives of costs (costs to the NHS dental budget, costs to the wider NHS budget and costs to both patient participants and the NHS), different methodological assumptions (around discounting and mapping the discrete choice experiment results to the trial outcomes) and regional-specific subgroup analyses.

Uncertainty in the data was described using cost–benefit acceptability curves and scatterplots of incremental costs and benefits, with the probability of each strategy being the optimal recall strategy reported at a willingness to pay of £20,000 per quality-adjusted life-year (framework 1) and a benefit-to-cost ratio = 1 (frameworks 2 and 3) for all scenario analyses considered.

Results

A total of 2372 participants were recruited, with 648 participants considered eligible to be randomised to the 24-month recall arm and, therefore, randomised to one of the three intervention arms. A total of 1724 participants were considered ineligible to be randomised to the 24-month recall arm and were, therefore, randomised to the 6-month recall or risk-based recall arm.

There were no important differences or imbalances across randomised groups in each of the eligibility strata. All participants were, in general, satisfied with the dental services received and had low dental anxiety and a good knowledge about the frequency and duration of brushing; however, they were less informed about what to do after brushing (i.e. spit but not rinse). Overall, participants in the ineligible for 24-month recall stratum were older, self-reported to attend the dentist more regularly and had a higher Oral Health Impact Profile-14 levels than those in the eligible stratum.

The primary clinical outcome, mean gingival bleeding on probing, was collected at the 4-year clinical follow-up. Overall, 64% of participants attended their appointment and 71% of participants completed a year 4 patient questionnaire, in the eligible for 24-month recall stratum. In the ineligible stratum, 70% of participants attended the clinical appointment and 76% of participants replied to the year 4 patient questionnaire. For the primary outcome, the adjusted difference between interventions was < 1% and the confidence intervals excluded the possibility of a 7.5% difference between groups. There was no evidence of a significant difference between the groups in any comparison: the 24-month recall group versus the 6-month recall group had an adjusted mean difference of −0.91 (95% confidence interval −5.02 to 3.20; *p*-value = 0.66); the risk-based group versus the 6-month recall group had an adjusted difference of −0.98 (95% confidence interval −5.05 to 3.09; *p*-value = 0.64); the 24-month recall group versus the risk-based group had an adjusted mean difference of 0.07 (95% confidence interval −3.99 to 4.12; *p*-value = 0.97). There was also no evidence of a significant difference between the recall arms for any of the secondary clinical outcomes in any comparison in either eligibility stratum.

The primary patient-centred outcome, oral health-related quality of life, was measured at the 4-year follow-up time point, as well as at baseline and annually throughout the follow-up period, through patient questionnaires. There was no evidence of a difference across any comparison: the 24-month recall group versus the 6-month recall group had an effect size of −0.24 (95% confidence interval −1.55 to 1.07; *p*-value = 0.72); the risk-based group versus the 6-month recall group had an effect size of −0.61 (95% confidence interval −1.93 to 0.71; *p*-value = 0.37); the 24-month recall group versus the risk-based group had an effect size of 0.37 (95% confidence interval −0.95 to 1.69; *p*-value = 0.58). Overall, there were no important differences between the groups across all secondary patient-reported outcomes in either eligibility stratum.

The economic evaluation results are described under each analysis framework below. Scenario analyses that affected the overall conclusions are emphasised.

- Framework 1 (maximising generic health benefit) used the results of the cost–utility analysis to assess the most efficient strategy in terms of maximising generic health outcomes (i.e. EuroQol-5 Dimensions-based quality-adjusted life-years). There was substantial uncertainty surrounding the optimal recall strategy across all analyses undertaken. This is due to concerns regarding the quality-adjusted life-year's sensitivity to capture any potential benefits of dental care interventions.

The cost-effectiveness acceptability curves and scatterplots of the cost-effectiveness plane illustrate the residual uncertainty, rendering it difficult to draw clear conclusions about the most efficient use of resources using this metric; for example, in the combined analysis across both trial strata, no strategy achieved a probability of cost-effectiveness > 70% at a threshold value of society's willingness to pay for a quality-adjusted life-year gain of £20,000. The probability of cost-effectiveness was higher for the 24-month recall strategy in the analysis restricted to the eligible for 24-month recall stratum because of the potential for cost savings from longer recall intervals.

- Framework 2 (maximising societal well-being): the discrete choice experiment provided important information on the valuation of dental health outcomes. The general population was willing to pay to avoid progressive levels of dental decay and bleeding gums. It also highly valued and was willing to pay for more frequent dental recalls. Taking the broadest perspective of benefits, including all components of value to the general population (incorporating both health and non-health sources of utility), generates a high probability that 6-month recalls are net beneficial. This finding is consistent across the full range of sensitivity analyses undertaken. This conclusion is influenced by the high value that the general population attaches to the 6-month recall service attribute in the discrete choice experiment.
- Framework 3 (maximising dental health benefits) evaluated the most efficient dental recall strategy in terms of maximising dental health benefit (i.e. through the discrete choice experiment valuation of bleeding and caries outcomes). For the stratum deemed eligible for 24-month recalls, differences in costs to the total NHS dental budget (across the UK) are not statistically significantly different across the randomised arms; however, substantial cost savings can be achieved from longer recall intervals when considering the combined cost burden to both patients and the NHS. These savings can be achieved without adversely affecting dental health outcomes. Twenty-four-month recall is the most likely optimal strategy, for those eligible, with a probability of positive net dental health benefit ranging between 65% and 99% across the full range of sensitivity analyses conducted. For the trial population as a whole (including both the eligible and ineligible for 24-month recall strata), there is substantial uncertainty regarding the most efficient strategy to maximise dental health benefit. Risk-based recalls were more likely to generate positive net dental health benefit in Scotland than in England, and when a wider perspective of the costing analysis was considered.

Conclusions

The INTERVAL trial involving regular adult NHS dental attenders has shown that a variable risk-based recall interval is not detrimental to oral health and is acceptable to patients and dentists with the potential for cost savings. Over a 4-year period, we found no difference in oral health for patient participants allocated to a 6-month or a variable risk-based recall interval. Nor did we find a difference between the recall intervals of 24 months, 6 months and risk based for the 30% of adults considered suitable to be recalled at 24 months by their dentist. Economic evaluation results based on incremental cost per quality-adjusted life-year were highly uncertain, perhaps because of a lack of sensitivity of the EuroQol-5 Dimensions to capture variation in dental health outcomes. Taking a dental health-care perspective of benefits, where dental health outcomes only are valued (bleeding on brushing and caries experience), for those eligible for a 24-month recall, 24-month recalls generated the highest probability of positive incremental net benefit. Taking a broader, societal perspective of benefits, and including the value placed on more frequent recall services in the discrete choice experiment, 6-month recalls had the highest probability of positive incremental net benefit.

Trial registration

This trial is registered as ISRCTN95933794.

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Chapter 1 Introduction

Introduction

The subsequent chapters of this monograph describe the INTERVAL (Investigation of NICE Technologies for Enabling Risk-Variable-Adjusted-Length) Dental Recalls Trial, a National Institute for Health Research (NIHR) Health Technology Assessment (HTA) programme-funded trial testing of the effectiveness and cost–benefit of dental check-ups at different recall intervals. The trial protocol has been published.[1]

The reason for the trial

Background

Traditionally, patients have been encouraged to attend dental recall appointments at regular intervals of 6 months between appointments – irrespective of the individual's risk of developing dental disease, the principal function of the dental recall being prevention and early detection of oral disease, in particular dental caries (tooth decay) and periodontal disease.[2] The traditional clinical rationale, developed at times of higher caries levels and progression rates, was the early detection of caries lesions while they were small in order to restore them before lesion progression resulted in extensive destruction of tooth tissue. This has evolved to a modern philosophy that seeks to detect small lesions at an early stage in order to provide preventative interventions prior to lesion cavitation. The preventative advice provided at recall examinations varies between practitioners and, indeed, between a practitioner's individual patients and may incorporate instruction on appropriate oral hygiene practices and dietary advice for the prevention of dental disease, as well as advice aimed at modifying risk factors for oral disease such as smoking cessation advice and alcohol-related health advice. The dental recall examination may, therefore, be understood as having a dual function as a primary preventative (the prevention of oral disease before it occurs) and a secondary preventative (limiting the progression and effect of oral diseases at an early stage through early diagnosis) measure. The evolution of implementing the change from surgical to preventative treatment philosophies has been, and continues to be, complex and slow.

The recommendation of a 6-month recall interval has become established practice in primary dental care in many countries[3–7] and has probably been a cornerstone of dental practice since it was mentioned by Pierre Fauchard in 1746.[8] There has been a longstanding international debate regarding the clinical effectiveness and cost-effectiveness of different recall intervals for routine dental check-up examinations,[2,3,5,9–16] particularly in the light of changes in the epidemiology of dental diseases and in the interests of careful resource management.[9,17–19] This debate has been fuelled by conflicting evidence from observational studies on the effects of regular attendance and by the subsequent diverging interpretations of that conflicting evidence.[20]

Epidemiology and pathogenesis

Periodontal disease is an inflammatory disease of the soft and hard tooth-supporting tissues. Periodontal diseases comprise gingivitis and periodontitis. Gingivitis is a reversible condition characterised by gingival redness and oedema, and absence of periodontal attachment loss.[21] The 2017 world workshop and classification system gives clear definition of a gingivitis site and a gingivitis case (patient).[21] A patient can be defined as a 'gingivitis case' when bleeding on probing at > 30% of sites is evident at a minimum of 10% of sites.[21] Bleeding at between 10% and 30% of sites is defined as localised gingivitis and bleeding on probing at > 30% of sites is generalised gingivitis. Gingival health is defined as bleeding on probing at < 10% of sites. Gingivitis is a pre requisite for periodontitis and is also a risk indicator for dental caries progression.

Periodontitis is the irreversible destruction of the tooth-supporting periodontal structures (periodontal ligament, cementum and alveolar bone) due to inflammation.[22] Periodontitis is characterised by periodontal pocket formation and gingival recession. In addition, tooth mobility and migration may occur as a result, as well as dentine hypersensitivity of the exposed root surface, root caries and, ultimately, tooth loss.

Gingivitis and periodontitis are a continuum of the same inflammatory disease process,[23] with evidence that gingivitis is a risk factor for periodontitis,[24] and that absence of gingival bleeding is a reliable predictor for the maintenance of periodontal health.[25] However, it is not currently possible to predict progression from gingivitis to periodontitis at either the individual or the site-specific level. Accumulation of microbial dental plaque is the primary aetiological factor for gingivitis and periodontitis, as well as dental caries.[26–28] Disease progression is also known to be affected by genetic factors (host defence mechanism), calculus, smoking and systemic comorbidities, including type 2 diabetes.[29–32]

Despite the largely preventable nature of periodontal disease, it is considered the most common disease of mankind,[33] remains the major cause of poor oral health globally and is the primary cause of tooth loss in older adults.[22,34] Global estimates of gingivitis range from 50% to 90% of populations.[35–37] Severe periodontitis is the sixth most prevalent human disease globally, with a prevalence of 11.2%,[38] which appears to be rapidly increasing.[33]

Dental caries is a multifactorial chronic oral disease that affects most populations globally and is considered the most important global oral health burden.[39] Dental caries results from production of organic acids by acidogenic bacteria within dental plaque (a biofilm formed on the tooth surface soon after tooth cleaning). Dental caries is considered a consequence of an ecological shift in the balance of the normally beneficial oral microbiota driven by a change in lifestyle and in the oral environment.[40] Organic acids can cause mineral loss from the tooth surface by removing calcium and phosphate ions from surface apatite crystals (demineralisation). In favourable conditions, a reversal of this process is possible (remineralisation). The development of a carious lesion is a dynamic process that may progress, halt or reverse. Progression of the carious lesion occurs where the demineralisation process prevails over remineralisation. Carious lesions can range from early non-detectable mineral loss restricted to enamel, through lesions that extend into dentine without any surface cavitations, to cavitated lesions visible as holes in the teeth. Progression rates of carious lesions appear to be more rapid in dentine than in enamel, with variable rates between individuals as well as between lesions within an individual.[41,42] Dental caries and its consequences are considered the most important burden of oral health, affecting up to 100% of adults in most countries.[43] It is not just a disease of children, but appears to occur at a relatively constant rate throughout the life course.[44]

Where gingival recession has migrated apical to the amelocemental junction, the exposed root surface of the tooth may be susceptible to root caries. Like coronal caries, the main aetiological factor for the initiation and progression of root caries is the presence of a cariogenic biofilm and fermentable carbohydrates. Owing to the lower level of mineralisation of dentine, a smaller decrease in pH will induce demineralisation of the root surface.[45] As with coronal caries, the formation of root caries is a dynamic process of demineralisation and remineralisation, with progression of caries occurring where the balance of factors favours demineralisation.[46] Importantly, and unlike caries in enamel, coronal dentine and root caries both involve not only demineralisation but also collagen degradation,[47] resulting in a demineralisation process that is approximately twice as rapid on enamel.[48]

Root caries, like other forms of the disease, can be associated with pain, discomfort and tooth loss,[49,50] which has the most significant impact on the oral health-related quality of life (OHRQoL) of the elderly.[51,52] Although a well-recognised disease, its prevalence is increasing as populations age and retain more of their natural teeth into older life.[47,53,54] There is a wide range in the reported global prevalence of root caries for diverse populations ranging from 29% to 89%.[55]

Individuals and dental care professionals have different roles to play in the prevention and control of periodontal diseases and dental caries. Consistent removal of the intraoral plaque biofilm by means of personal tooth brushing and interdental cleaning is considered the foundation of successful primary prevention of periodontal disease and dental caries.[56,57] The dental care professionals' role in primary prevention involves assessment of an individual's risk of developing oral disease and tailoring preventative advice, including oral hygiene and dietary advice based on this risk assessment, although the evidence relating to the beneficial effects of chairside provision of dental health education advice is conflicting.[58,59]

In 2004, the National Institute for Health and Care Excellence (NICE) published a guideline entitled *Dental Recall: Recall Interval Between Routine Dental Examinations*,[60] following a remit received from the Department of Health and Social Care and the Welsh Assembly Government. Within this guideline, the role of the oral health review, or dental check-up, in providing primary prevention and secondary prevention is highlighted. Subsequently, in 2011, the Scottish Dental Clinical Effectiveness Programme (SDCEP) published their guidance on oral health assessment and review. The SDCEP guidance was based on and was a tool to assist implementation of the NICE recommendations.[61]

Given that the global burden of oral disease is not shared evenly, the risk of developing oral disease between patients is clearly variable. It has, therefore, been suggested that the preventative needs of patients are also variable and that intervals between oral health reviews should be appropriate for the needs of individual patients.

Dental check-ups at 6-month intervals have been customary in the general dental service (GDS) in the UK since the inception of the NHS. Although a recall interval of 6 months is not explicitly recommended by the NHS, this practice is implicitly recognised by NHS regulations that have remunerated dental practitioners for providing a dental check-up at 6-month intervals for decades, and, since 2006, the dental check-up has been free in Scotland. It has been argued that a 6-month dental recall policy is too rigid and that recall intervals should match the individual needs of patients more closely – needs that may change over time. Analysis of dental attendance patterns in NHS primary dental care using the Dental Practice Board's longitudinal data demonstrates an attendance pattern that is variable, with many patients attending less frequently than every 6 months.[59] Data from the Information Services Division (ISD) in Scotland show that the vast majority of Scottish adults did not attend NHS primary care dental services on an annual basis, with only 23% attending at least once per year in each of the previous 6 years, and 21% not attending at all in the past 6 years.[62]

In addition, it has been consistently observed that caries experience is generally more extensive in lower socioeconomic status groups,[63] reinforcing the case for patient-specific recall intervals, based on an assessment of the patient's risk of oral disease.[3,60,64] Evidence from the Dutch health system suggests that there is an increase in general dentists moving away from recalling all patients at the same interval in favour of applying an individualised recall interval, resulting in more frequent screening for periodontal disease than with those dentists using a fixed-period recall protocol.[65]

One of the persistent arguments in favour of maintaining 6-month dental check-ups is that dentists may miss the opportunity to diagnose oral cancer lesions at an early stage in patients who attend at longer recall intervals. The incidence of oral cavity cancer in the UK is highest in Scotland, at 10.0 per 100,000 males,[66] and has been relatively stable in Scotland since 2000 but rising in England and Wales. However, it has been reported that 53.7% of patients diagnosed with oral cancer had not attended an NHS primary care dentist in the 2 years preceding diagnosis,[67] thus radically decreasing the opportunity for early detection. From these data it is estimated that a dentist potentially encounters one case of oral cancer every 10 years.[67] Brocklehurst and Speight[68] reviewed the pros and cons of a national screening programme for mouth cancer, concluding that studies into mouth cancer screening have provided evidence to satisfy only 5 of the 20 criteria required by the UK Screening Committee, with no evidence of a test effective in the detection of oral lesions in the context of a screening programme,[69] and that

more research is needed to develop diagnostic tests more specific than conventional oral examination.[68] The authors also report that screening programmes have not resulted in a demonstrable reduction in mortality, apart from in high-risk groups, in which there is some evidence that screening may be effective and cost-effective.[68] Instead of asserting the need for shorter intervals between dental recall appointments, these papers[67–69] highlight the need for oral health services to develop strategies to reach out to populations that do not attend primary care dental services regularly, instruct patients about high-risk habits including alcohol and tobacco use, and better network with other primary care services.

Evidence base

The recommendations in the NICE guideline on dental recall[60] are designed to aid dentists in assigning individualised recall intervals to patients based on their risk of developing oral disease. The Guideline Development Group produced a checklist for use by dentists when assessing risk, including specific risk factors for consideration.[60] The guideline recommends an adjustable recall interval for adults, ranging from a minimum of 3 months to a maximum interval of 24 months between recall appointments for patients who have repeatedly demonstrated an ability to maintain oral health. The guideline panel recommended that the recall interval be regularly assessed, discussed and agreed based on each individual's oral health risk profile and amended accordingly. The Guideline Development Group considered a balance of benefits and harms related to caries, periodontal disease and also oral mucosal lesions in making its recommendations. The recommendations are, however, based on low-quality evidence and the clinical experience of the Guideline Development Group. This lack of evidence has complicated the implementation of this guideline for dentists and health service commissioners.

Although the concept of assigning risk-based recall intervals has gained increasing standing internationally, the clinical effectiveness of this recall protocol is not supported by scientific evidence from clinical trials. Furthermore, there remains significant variation in professional recommendations within and between countries regarding the maximum time interval between dental check-ups that can reasonably be assigned for patients at low risk of oral disease. This can be considered inevitable given that many guideline recommendations regarding this issue have been informed primarily by professional consensus and are subject to variation in interpretation.[70]

There is also a paucity of reliable scientific evidence to support the effectiveness of routine dental checks of differing recall frequencies in adults. The scientific basis for the 6-month dental examination was questioned more than 30 years ago.[2] Since then, systematic reviews investigating this key question have reported limited evidence of poor overall quality, which is insufficient to reach any conclusions regarding the potential beneficial and harmful effects of varying recall intervals between dental check-ups, and concluding that there is no evidence to support or refute the practice of encouraging patients to attend for dental check-ups at 6-month intervals.[71,72] The NICE guideline on dental recall reiterated the need for research in this area to examine the effects of varying dental recall intervals on oral health.[59] The NICE guideline also concluded that the research base was severely lacking in terms of determination of the optimal dental recall intervals on the basis of cost-effectiveness.[60]

There is, therefore, an urgent need to assess the relative effectiveness and cost-effectiveness of different dental recall intervals in a robust, sufficiently powered randomised control trial (RCT) in primary dental care.

The questions addressed by the INTERVAL trial

Aim

The aim of this trial was to compare the effectiveness and cost–benefit of dental check-ups at different recall intervals (fixed-period 6-month recall, risk-based recall or fixed-period 24-month recall) for maintaining optimum oral health in dentate adults attending general dental practice.

Objectives

The primary objectives were to compare the three recall strategies on:

- gingival bleeding on probing
- oral health-related quality of life
- value for money in terms of (1) cost per quality-adjusted life-year (QALY) gained, (2) incremental net (societal) benefit and (3) incremental net (dental health) benefits.

The secondary objectives were to compare the three recall strategies on:

- periodontal probing depths
- dental caries
- calculus
- preventative and interventive dental treatment
- patient anxiety
- patient satisfaction with care
- oral health knowledge, attitudes and behaviours and to explore dentists' attitudes towards dental recall intervals.[10]

Chapter 2 Trial design and methods

Study design

The trial was a UK-wide [England (London, Manchester, Birmingham, North East), Wales (Cardiff), Northern Ireland (Belfast, County Down) and Scotland] multicentre, parallel-group, RCT with blinded outcome assessment at 4-year follow-up.

The trial interventions were three recall intervals – a fixed-period 24-month recall interval, a risk-variable adjusted-length recall interval (risk-based recall) based on the NICE guideline[60] and a fixed-period 6-month recall interval.

A two-stratum trial design was proposed to overcome potential ethical considerations and dental clinician and/or participant concerns. Participants were randomised to the fixed-period 24-month recall interval only if the recruiting dentist considered them clinically suitable.

Randomisation was organised within the two strata (*Figure 1*):

1. For those participants considered suitable for a fixed-period 24-month recall (stratum 1), randomisation was to one of three groups:

    i. Fixed-period 24-month recall versus risk-variable-adjusted-length recall (risk-based recall) versus fixed-period 6-month recall.

2. For those participants not considered suitable for a fixed-period 24-month recall (stratum 2), randomisation was to one of two groups:

    i. Risk-variable-adjusted-length recall (risk-based recall) versus fixed-period 6-month recall.

An economic evaluation to determine the cost-effectiveness of different recall intervals and to compare NHS and patient-incurred costs and benefits is included in *Chapter 5*.

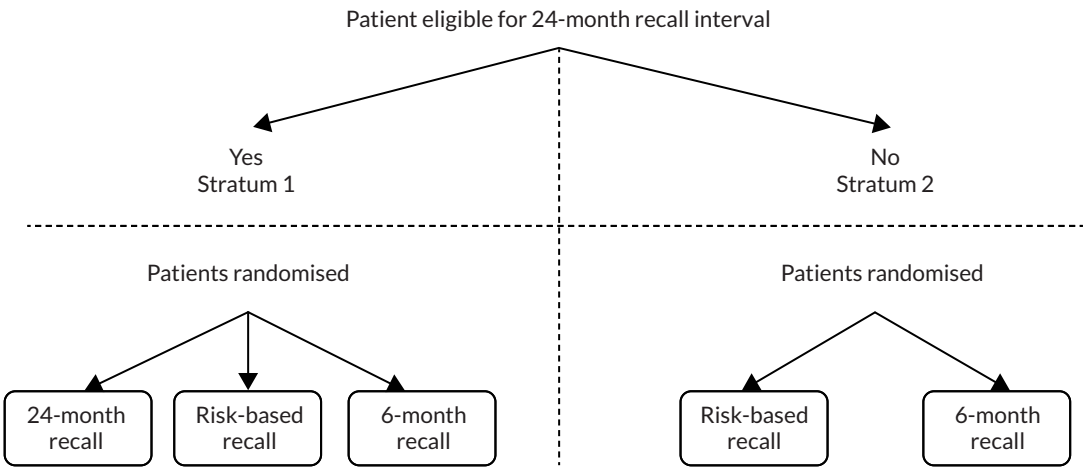


FIGURE 1 Study design.

Ethics approval and protocol amendments

Favourable ethical opinions were granted for the INTERVAL Dental Recalls Trial by the Fife and Forth Valley Research Ethics Committee (feasibility study Research Ethics Committee reference number 09/S0501/1; main study Research Ethics Committee reference number 09/S0501/1).

The trial was registered with the International Standard Randomisation Controlled Trial Register (ISRCTN), reference number 95933794.

Amendments to the protocol were made after recruitment of practices and participants, and on conclusion of the feasibility study. These included an increase of more than one dentist per practice able to participate in consenting, recruiting, randomising and establishing risk-based recall intervals for participants in the risk-based arm and the assistance of dental postgraduate research networks to identify and recruit potential dentists and identify and approach potential participants.

Additional amendments, notified to the funder, included an increase in the number of practices recruited and increased numbers of participants per practice, extension of the recruitment period, changes of Trial Steering Committee (TSC) and Data Monitoring Committee (DMC) members, lengthening from 3 to 4 months plus or minus the 4-year anniversary of participant randomisation for final year assessments, and adaptions to study administrative processes. All changes were in accordance with approved contract variations.

Recruitment and consent of dental practices

The trial sought to recruit general dental practitioners/practices from across the UK (i.e. England, Wales, Northern Ireland and Scotland), representing a cross-section of practitioners in terms of urban/rural areas, community-level sociodemographics and fluoridated or non-fluoridated communities.

Dentists were recruited through local postgraduate dental research networks, by advertising in professional dental publications and through presentations at dental conferences and dental events. Trial information and recruitment evenings were organised in Birmingham and Cardiff and across Scotland.

The Trial Office in Dundee (TOD) sent potential dentist participants a personalised invitation letter for the dentist and their staff to attend a local information and recruitment session, at which the reasons for and design of the trial and practice involvement were described. Dental professionals were given the opportunity to discuss participation with the trial team. For dentists and teams that could not attend, information packs about the trial were posted/e-mailed from the TOD.

Trial team members telephoned dental practices to follow up the notes of interest of involvement. A site briefing/training session was arranged with the dentist, practice staff and TOD staff (see *Training of dentists*). Following the site briefing, dentists who were interested in the trial were asked to provide written consent to participate, a signed declaration agreeing to adhere to the trial protocol and a completed clinician beliefs questionnaire (see the NIHR project web page for details: www.journalslibrary.nihr.ac.uk/programmes/hta/063599/#/documentation; accessed October 2020). Original signed and dated dentist consent forms and declarations were held securely as a part of the trial site file at the TOD. Copies were made and returned to dentists.

Inclusion/exclusion criteria: dental practices

The inclusion criteria were:

- NHS provider for adult patients
- primary care provider: salaried service, corporate and independent operators
- willingness to follow trial protocol.

The exclusion criteria were:

- providing only private dental services to adults
- unwilling to follow trial protocol.

Recruitment and consent of participants

Recruitment of patient participants was achieved through standard procedures and agreements for primary care research in the four nations. In some areas of England, Wales and Northern Ireland, regional Clinical Local Research Networks assisted dental practice staff to identify eligible patients and facilitate an approach by including information about the trial in the appointment letter for their routine dental examination. In Scotland, co-ordinators from the Scottish Primary Care Research Network, when invited, provided a similar service. The appointment letter included an invitation to participate, the patient information leaflet and the baseline patient and cost questionnaires (see the project web page for copies of questionnaires: www.journalslibrary.nihr.ac.uk/programmes/hta/063599/#/documentation).

In instances where the Clinical Local Research Networks and Scottish Primary Care Research Network were not available at an agreeable time, or practices did not request or require assistance, practice staff undertook the duties of identifying and contacting eligible patients and inviting them to participate in the trial using the same paperwork.

At the routine appointment, discussion about the trial was held between the dentist and patient. If agreeable, potential participants were screened for suitability prior to their routine dental examination. Patients who contacted the practice to advise that they were not interested in taking part in the trial were reassured that they would still receive a dental examination appointment with their dentist as per practice policy.

There are a variety of patient recall appointment management strategies utilised within dental practices across the UK. Some dental practices arrange routine examination appointments for their patients up to 6 months or a year in advance. Some practices send letters, e-mail, telephone or text reminders to their patients when their routine dental examinations are due, asking them to contact the dental practice to make an appointment, whereas other practices pre-allocate the date and time of appointments and ask patients to contact the practice if the appointment is not suitable. The INTERVAL Dental Recalls Trial utilised a flexible and pragmatic participant recruitment strategy that aimed to be suitable for each practice's usual recall procedure.

Eligibility of those who expressed an interest in taking part was confirmed against the trial inclusion and exclusion criteria. The dentist confirmed consent with those eligible and willing to participate in the trial. A signed participant consent form was obtained in triplicate. The participant retained a copy, the practice retained a copy in the patient's notes in the site file, and the original copy was sent to the TOD.

Following consent, the dentist clinically examined the participant to establish suitability for randomisation to the 24-month arm (see *Randomisation*). If participants had not completed the questionnaires provided with the appointment letter, they were asked to complete the baseline questionnaire and cost questionnaire in the waiting room of the dental practice before placing them in a sealed opaque envelope and returning them to practice staff. Questionnaires were returned to the TOD by the dental practice in a sealed envelope.

The TOD staff did not have access to any participant data prior to the participants consenting to take part in the trial.

Inclusion/exclusion criteria: participants

The inclusion criteria were adult patients (≥ 18 years of age) who:

- were dentate
- had visited their dentist in the previous 2 years
- received their dental care in part or fully as an NHS patient, including dental examination.

The exclusion criteria were:

- patients who had a medical condition indicating increased risk of bleeding
- immunocompromised patients.

Participants whose medical condition changed during the follow-up period were not prohibited from continuing in the trial. Provision was made for dentists to record changes and rationale to the length of the recall interval, on the patient attendance data (PAD) form, but such participants remained within the allocated stratum.

Training of dentists

In England, Wales, Northern Ireland and Scotland, the process of training recruited dentists took the same format.

Training in trial procedures

Trial staff visited the practice by arrangement for a 1- to 2-hour site briefing/training session at an agreed and convenient time, attended by the participating dentist and practice staff. After a brief review of the trial aim and objectives, trial procedures were described and discussed.

Recruited dentists were defined as local investigators within the dental practice, and were responsible for recruiting, consenting and protecting the personal data of trial participants within the dental practice. Local Investigators signed an agreement to conduct the trial in compliance with applicable legislation including (1) the *International Conference on Harmonisation Good Clinical Practice guideline*[73] and (2) the Department of Health and Social Care's *Research Governance Framework for Health and Social Care* (April 2005)[74] or the Scottish Executive Health Department's *Research Governance for Health and Community Care* (2nd edition 2006),[75] whichever was relevant.

Dentists and practice staff were advised at the trial briefing/training and in monthly practice newsletters that the International Conference on Harmonisation Good Clinical Practice guideline training was available in their local area and that attendance at these sessions could be arranged through the TOD. The TOD also signposted to the online NIHR Introduction to Good Clinical Practice e-learning (primary care) module.[76]

Training in determining risk-based recall intervals

Following the site briefing/training session, each dentist was sent a link to an online training package. The online training package presented risk-based recall interval determination according to the NICE guideline,[60] with written instruction, audio and video components, examples and test assessments. It described a systematic approach dentists could follow to consider setting and review of individualised patient recall intervals and to enable discussion and explanation between patient and dentist of the risk-based recall interval. Dentists were instructed to complete this training before screening any potential patient participants for the trial, and reminders via letter, e-mail, telephone and trial newsletter requested that dentists complete it on an annual basis during follow-up.

On completion of the online training package, and before being awarded with a certificate of training and 2 hours continuing professional development (CPD), dentists were required to complete an evaluation form that asked users to measure to what extent they felt that the training programme met the learning objectives, and how easy it was to access and understand. They were also asked to suggest improvements regarding content, design, navigability and length.

Feedback from users was mixed; some found it difficult to access and to navigate, whereas others found it user-friendly and were reassured that they could use the tool with patients. Some users found the content appropriate, easy to understand and a good support for participating in the trial, whereas others found some aspects to be basic to a practising dentist or felt that it could be shortened for the experienced practitioner.

For additional reference on risk-based interval determination, practices in England, Wales and Northern Ireland were provided with a link to the NICE guideline *Dental Recall: Recall Interval Between Routine Dental Examinations*.[60] Practices in Scotland were supplied with an electronic link and hard copy of the SDCEP Oral Health Assessment and Review (OHAR) guidance.[60,61] Both documents contained templates for checklists to record variables identified as potential modifying factors (risk variables) that influence the setting of recall intervals (see *Trial interventions* for more detail on risk-based templates).

Clinical outcome assessor training

The clinical outcome training was delivered by trial collaborators with expertise and experience of training assessors in periodontal and caries measures. The clinical outcome assessors and scribes for this trial were qualified, General Dental Council-registered dentists, dental hygienists/therapists and dental nurses employed by the trial.

The emphasis of the training was consistency of the examination process and agreement of scoring criteria. Following the didactic face-to-face and online training, the outcome assessors, with their research nurse, examined 15 patient volunteers in a clinical setting similar to that of a dental practice. The cohort of patient volunteers were similar in age and dental attendance behaviour to those recruited to the trial. The clinical outcome assessments were conducted at Dundee Dental Hospital and School, and each participant was examined by all outcome assessors.

The processes of clinical outcome assessment were agreed in advance, including the order of outcome measure assessment, time allocation, sequence around the mouth and moisture control. The primary clinical outcome of gingival bleeding on probing is a measure of gingival inflammation. It is described as 'gingival inflammation/bleeding on probing' in the study protocol;[1] for clarity within this report it will be described as gingival bleeding on probing, the definition and outcome measurement remaining the same as outlined in the protocol. This clinical outcome does not allow for repeat assessment; therefore, neither intra-assessor nor interassessor reliability measurements were possible. Training[77] for the primary outcome involved face-to-face discussion with the assessors and scribes about the assessment technique and

scoring criteria. Prior to the assessment of the cohort of volunteer patients by the outcome assessment teams, a slide presentation developed for training in commercial clinical trials was presented by a periodontal clinical trial expert, and this was supplemented with group discussion about clinical photographs and clinical cases. Periodontal training included positioning, angulation of instrument and pressure of the University of North Carolina-15 (UNC15) periodontal probe, to ensure a standardised approach by the outcome assessors. Periodontal probing depths were recorded at six sites on erupted teeth using a probing force of approximately 25 g.

Training in caries assessment consisted of several components that have been developed and used in other clinical trials and epidemiological studies. This included an online training programme for the International Caries Detection and Assessment System (ICDAS), a half-day of slide presentations and discussions of the ICDAS codes and protocol for the clinical examination. The assessor training included both theoretical aspects and discussions regarding patient participants within the clinical trial setting. Practical training included simulation of the assessment protocol on extracted carious teeth representing carious lesions at all stages of lesion progression included in the ICDAS scale, as well as clinical assessment of a cohort of volunteers similar to the trial population, who had been specifically recruited for trial assessor training. All training in the use of ICDAS was completed under the supervision of a trial collaborator experienced in the use of ICDAS in clinical research.

The caries detection elements of the ICDAS criteria are now well tested and are advocated for general use as well as for use in the clinical trials and in dental epidemiology.[78,79] The ICDAS criteria measure both early stages of caries and more advanced stages of caries. For early caries, ICDAS measures the surface changes and potential histological depth of carious lesions by relying on surface characteristics related to the optical properties of sound and demineralised enamel prior to cavitation. Advanced stages are recorded when cavitation is evident. The trial utilised a modified ICDAS as clinical data were collected only on the caries experience. Restorations and non-carious tooth loss were not recorded.

The intensive face-to-face and online training was provided a month before the first trial outcome assessment to provide sufficient time for additional training if required. The training was repeated mid-way through the INTERVAL trial clinical outcome assessment period, to reinforce standardisation in the process and clinical measures. Throughout the clinical outcome collection period, the assessment team met regularly to confirm the outcome assessment processes and data collection methods to achieve the highest level of standardisation possible.

Randomisation

Eligible and consenting patient participants were clinically examined by their dentist to determine suitability for randomisation to the 24-month recall arm (yes/no). The decision that a patient was eligible for a 24-month recall was based on routine clinical examination and risk assessment. Dentists were instructed not to apply the detailed risk-based variable assessment unless randomised to the risk-based arm in either stratum.

There were separate, identical algorithms in the trial design for the two strata. Eligible participants were randomised in equal numbers within each of the two strata according to a minimisation algorithm including:

- dentist
- participant age (18–40 years/$\geq$ 40 years)
- filled teeth ($n \leq 8$/$n > 8$)
- absence of gingival bleeding on probing (yes/no)
- exempt from dental charges (yes/no).

Random allocation occurred via telephone, after the decision by the dentists about the patient's suitability for a 24-month recall. The trial utilised the automated central randomisation service at

the Centre for Healthcare Randomised Trials (CHaRT), University of Aberdeen, which had 24-hour telephone access. The service prompted dental practice staff to enter and confirm details by entering numbers (i.e. 1 = yes, 0 = no) on the telephone touch pad.

The dentist communicated the allocation outcome and confirmed trial details with the participant. Participants randomised to a fixed-period recall interval, either 24 or 6 months, were managed according to routine practice regarding the practice recall management system. For participants randomised to receive a risk-based recall, further history taking, examination and assessments were undertaken, if required, to determine the appropriate variable risk-based recall interval. This was discussed and agreed with the patient participant prior to the recall interval being entered into the routine practice management system (see NICE guideline[60]).

Owing to the nature of the interventions, it was not possible to blind participants and dentists to allocated recall intervals. TOD staff received an e-mail notification when a successful randomisation had taken place, providing practice and participant ID numbers, and trial arm allocation. Following randomisation, dental practice staff were asked to send the original signed patient consent form, baseline patient questionnaire and cost questionnaire, and screening/patient case report form (PCRF) to the TOD.

Trial interventions

The trial interventions recall intervals were a fixed-period 24-month recall interval, a risk-variable-adjusted-length recall interval based on the NICE guideline[60] and a fixed-period 6-month recall interval.

Fixed-period recall intervals (24 months, 6 months)

Patient participants allocated to the fixed-period 24-month recall interval and the fixed 6-month recall interval groups attended their dentist at the scheduled time intervals for a routine dental check-up. The content of this check-up remained as per current practice. A recognised definition of a routine NHS dental check-up is clinical examination, advice, charting including monitoring of periodontal status and report.[71]

Risk-variable-adjusted-length recall interval (National Institute for Health and Care Excellence guideline)

Patient participants allocated to the risk-based recall interval group attended their dentist at time intervals determined by the evidence-based process outlined in the 2004 NICE guideline on dental recall.[60] The essential steps of the procedure and the risk factors collected at recall examinations are outlined (from the guideline) in *Figure 2*.

The recommended steps in establishing the appropriate recall interval were:

1. Consider the age range – in the case of this trial, all patients were adults of ≥ 18 years.
2. Consider risk variables – identification of the pertinent risk and protective factors present for each patient from both the checklist and a comprehensive oral health assessment, leading to the evaluation of the impact of these factors in the context of the patient's past levels of oral health and current disease experience, and then consideration of a likely range of recall intervals.
3. Integrate prediction of recall need – use of all the information obtained by the dental team in order to predict the potential level of threat to maintaining oral health and controlling disease for this patient and, from this, judge the most appropriate next recall interval.
4. Discuss with patient – to explicitly discuss the recommended recall interval with the patient, explain the influencing factors in setting the recall and record the agreed interval (or any reason given by a patient in disagreement).
5. Review – at each check-up review (oral health review), the appropriateness of the preceding interval is reviewed by the dentist and patient and the recall interval is reset according to the experience from the last period along with any change in the risk and protective variables identified at re-examination.

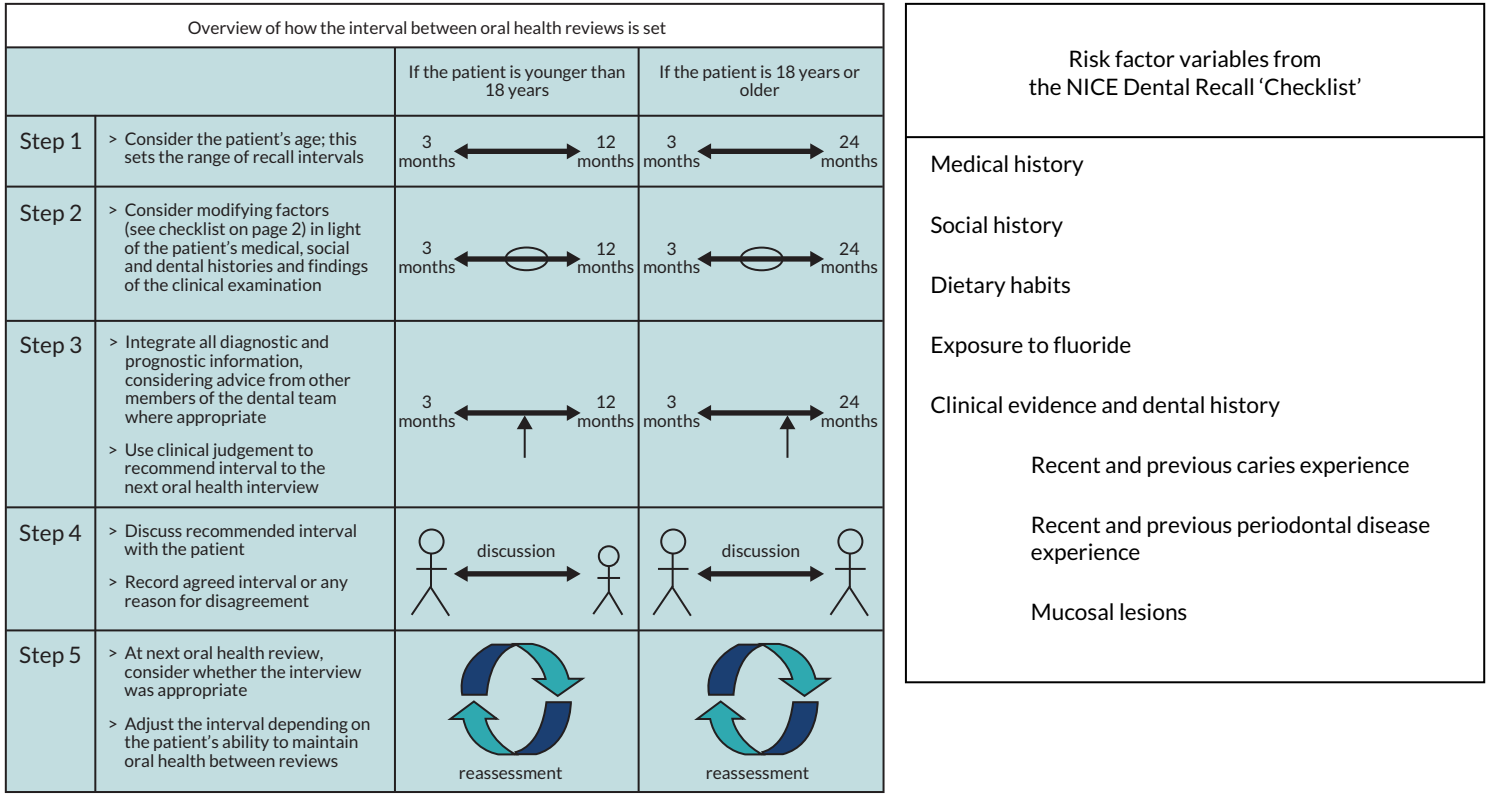


FIGURE 2 The NICE risk-based dental recall procedure and risk factors. Reproduced with permission. © NICE 2004 *Dental Recall – Recall Interval Between Routine Dental Examinations*. Available from www.nice.org.uk/guidance/cg19/evidence/full-guideline-pdf-193348909.[80] All rights reserved. Subject to Notice of rights. NICE guidance is prepared for the National Health Service in England. All NICE guidance is subject to regular review and may be updated or withdrawn. NICE accepts no responsibility for the use of its content in this product/publication.

The frequency of recall interval appropriate for an individual patient depends on the likelihood that specific diseases or conditions may develop or progress beyond the control of secondary prevention. The selection of an appropriate recall interval for a patient is a multifaceted clinical decision that involves judgement and cannot be decided mechanistically.

The NICE guideline[60] was developed using extensive consensus methods and the limited evidence available. The recommendation was that the recall interval range for adults should vary from 3 to 24 months according to risk.

The NICE guideline checklist[60] was intended to be used as a guide to assist the dentist in setting an appropriate recall interval. It is not an exhaustive list of all factors that may influence the choice of a recall interval for a patient. There is insufficient evidence to assign a 'weight' to individual factors in the checklist and dentists must use their clinical judgement to weigh the risk and protective factors for each patient. The same checklist is in the SDCEP *Oral Health Assessment and Review* guidance[61] and, therefore, for dentists across the UK guidance is consistent with the content of the trial training material including the online resource.

It was anticipated that by taking a comprehensive history and carrying out a comprehensive oral health assessment the dentist would be better informed to provide an accurate risk assessment and more appropriate preventative and interventive treatment recommendations including advice.

It was envisaged that, once trained, the time taken to complete this process would be 20 minutes for the first risk-setting visit and 15 minutes for subsequent recall examinations (oral health reviews).

Outcome measures

All primary and secondary outcome measures were measured at 4 years' follow-up and are outlined below.

Primary outcomes

Clinical:

- gingival bleeding on probing.

Patient centred:

- OHRQoL [Oral Health Impact Profile-14 (OHIP-14)].[81]

Secondary outcomes

Clinical:

- dental caries
- periodontal probing depth
- calculus
- preventative and interventive care.

Patient centred:

- dental anxiety[82]
- oral health-related knowledge, attitudes and behaviours
- generic quality of life, measured using the EuroQol-5 Dimensions, three-level version (EQ-5D-3L)
- use of, and reason for use of, dental services
- satisfaction with care.

Economic outcomes

- NHS costs.
- Patient-incurred costs.
- General population preferences, willingness to pay (WTP) calculated from a discrete choice experiment (DCE) to value service delivery and outcomes.
- Incremental net benefits (INBs) (WTP minus costs), measured as societal net benefit (WTP for health and non-health aspects) and dental health net benefit (WTP for health outcomes, bleeding on brushing and caries experience only).
- Generic quality of life, measured using the EQ-5D-3L.
- QALYs.
- Incremental cost per QALY.

(See *Chapter 3* for further details.)

Service provider measures

- Dentist attitude towards dental recall strategies.

Post hoc outcomes

- Self-reported bleeding.

Measurement of clinical outcomes

Clinical outcomes were assessed at 4 years post randomisation ± 4 months by trained outcome assessors who were blinded to allocation. The blinding of the outcome assessors was achieved by non-disclosure of the practice or patient to the allocated recall interval. The flexibility around the 4-year anniversary was to accommodate participant and practice factors influencing the convenience of attending the outcome assessment visit. Each tooth was examined, except third molars, unless a second molar was absent and the third molar tooth had drifted mesially to occupy the second molar position. The periodontal examination was performed first and the sequence of assessment was gingival bleeding on probing, periodontal probing depths and calculus. Teeth then were cleaned with a manual toothbrush by the outcome assessor and an ICDAS caries examination was carried out. More details on clinical data collection are outlined below.

Periodontal

Gingival bleeding on probing was measured according to the Gingival Index of Löe[83] by running a colour-coded UNC15 periodontal probe circumferentially around each tooth just within the gingival sulcus or pocket. After 30 seconds, bleeding was recorded as being present or absent on the buccal and lingual surfaces. The primary outcome was calculated by adding all the sites where bleeding was observed and dividing it by the number of sites (twice the number of teeth) and was presented as a percentage.

Periodontal probing depth was measured using a colour-coded UNC15 periodontal probe. Clinical probing depths were measured for all teeth at six sites per tooth (mesiobuccal, midbuccal, distobuccal, mesiolingual/palatal, midlingual/palatal and distolingual/palatal). Clinical probing depth was calculated as the mean of the six sites measured per tooth and is presented in millimetres.

Calculus was detected using a colour-coded UNC15 periodontal probe as being present or not. Calculus was calculated by adding all the sites where calculus was observed and dividing it by the number of teeth and presented as a percentage.

Caries
We measured caries at the enamel and dentine threshold using ICDAS. After manual tooth brushing by the outcome assessor, an examination of clean and wet/dry teeth (according to ICDAS procedure) was performed. Examination was aided by a ball-ended explorer used to remove any remaining plaque and debris and to check for surface contour, minor cavitation or sealants. All surfaces of all teeth were examined and the status of each recorded in terms of caries detection. A score between 0 and 6 was recorded for each surface.

Preventative and interventive care
Practice-reported data were collected throughout the 4-year trial including recall appointments on the PAD forms completed by practice staff. The PAD form was used to collect data on intended recall appointment dates, actual date of appointment, any rescheduling, length of time of appointment, any further treatment required as an outcome of the recall and, if known, the reason why a participant had not adhered to the recall interval. It also captured the expected date of the next recall appointment, after taking into account any course of treatment that might be required.

NHS routine data reported details of the treatment provided under the NHS during the trial period and was accessed through the routinely collected data in all participating regions in the UK, NHS Business Services Authority (NHSBSA) England and Wales, Business Services Organisation (BSO) Northern Ireland and ISD Scotland. Further details are provided in *Chapter 3*.

Measurement of patient-centred outcomes
Patient-centred outcomes were measured at 4 years and also collected annually, including at baseline, through a self-administered questionnaire.

Annual questionnaires were mailed to participants from the TOD on the anniversary of their randomisation. A Freepost envelope was included for ease of return. If the questionnaire had not been returned within 4 weeks, a reminder letter and another copy of the questionnaire were sent to the participants.

The full details of the calculations used to generate each patient-centred outcome are shown in *Appendix 1*, *Table 26*. We used the relevant publication to inform the calculation of validated scores, such as OHIP-14 and the dental anxiety scale.

Oral health-related quality of life
Quality of life was measured using OHIP-14.[81] The OHIP-14 is a 14-question oral health-specific patient-centred measure referring to symptoms in the past 12 months. The questions are scored from 0 (never) to 4 (very often) and summed to produce a score ranging from 0 to 56, with 56 being the worst outcome.

Dental anxiety
Patient dental anxiety status was measured using recognised and validated psychological inventories [Modified Dental Anxiety Scale (MDAS)].[82,84] Five questions relating to different dental treatments and situations were posed. The answers are scored on a scale from not anxious (rated as 1) to extremely anxious (rated as 5). The range of the summed total of five items was 5–25.

Oral health knowledge, attitudes and behaviours
The questions for measuring patient-centred belief outcomes and beliefs [attitude and perceived behavioural control (PBC)] outcomes were derived from social cognitive theory and the theory of planned behaviour.[85,86]

Oral health knowledge outcome
Knowledge was measured using four questions related to oral health (frequency of brushing, duration of brushing, frequency of flossing and frequency of interdental brush usage). The best value between

flossing and interdental brush usage was used as a measure of interdental cleaning knowledge. Each response varied from 0 to 3, with a score of 3 being the highest level of knowledge. The responses were summed to produce a total score ranging from 0 to 9, with 9 being the best outcome.

Oral health beliefs (attitude and perceived behavioural control) outcomes

Oral health-related attitude was measured using a 7-point scale varying from 1 to 7 (strongly disagree to strongly agree) and the higher the score, the better (i.e. the more positive) the attitude. The scale comprised seven questions and the final score was the average of the individual item scores.

Perceived behaviour control was measured using a 7-point scale varying from 1 to 7 (strongly disagree to strongly agree) with higher scores indicating more perceived behaviour control. The scale comprised four questions and the final score was the average of the individual item scores.

Oral health behaviours

Patient-reported oral health behaviour outcomes were measured using four questions (frequency of brushing, duration of brushing, frequency of flossing and frequency of interdental brush usage). Each response ranged from 0 to 3, with a score of 3 being the best possible behaviour. The best value between flossing and interdental brushes was used as a measure of interdental cleaning behaviour. The responses for each question were summed to produce a total score ranging from 0 to 9, with 9 being the best outcome.

Use of and reason for use of dental services

A question within the annual patient questionnaire asked participants to record the number of times they had attended the dental practice and the type of treatment received (NHS, private or combination), and their payment cost of this treatment. Questions were also asked about frequency and treatment data on non-scheduled attendance at services for dental problems (e.g. hospital accident and emergency, hospital outpatients or general medical practitioners).

Satisfaction with care was a score averaging 12 items, each varying on a scale of 1 to 7 (strongly disagree to strongly agree) and the higher the score, the more satisfied participants were with care. The satisfaction measure was developed with dental patients in Scotland.

Service provider measures

Dentists were asked to complete a clinician belief questionnaire at baseline prior to the online risk-based training and randomisation of participants.

The questionnaire collected data on the dentist's professional history and profile, practice profile, professional engagement and factors such as decision-making, confidence and workplace stress. The majority of questions ($n = 21$) related to their attitude towards dental recall interval, ease of its determination and the consequence for patients. A 7-item scale was developed from 1 (strongly disagree) to 7 (strongly agree). Full details of the calculations used to generate dentist belief outcomes are shown in *Appendix 1*, *Table 27*.

Post hoc outcome

Self-reported bleeding was included as a post hoc outcome and measured via patient questionnaire at 4 years post randomisation. It was measured by asking patients 'Have you had bleeding from your gums when brushing your teeth?' The answer could vary from 0 (never) to 4 (very often).

Demographic characteristics

Participant demographic characteristics were collected at baseline and annually using a self-administered postal questionnaire. The demographic characteristics included the most recent visit to the dental practice, type of attender (regular/non-regular), type of toothbrush (manual/electric) and smoking status. Participants also provided details on difficulty of travelling to the dental practice, which was scored from 1 to 7 on a Likert scale, where the higher the score, the easier participants found travelling to their dentist.

Demographic characteristics are presented by year and randomised group, using either mean, standard deviation (SD) or *n* (%) as appropriate.

Fidelity measures

Dental practice compliance with the protocol was monitored through face-to-face practice visits by a member of the trial office team, regular telephone contact from the TOD to practices and an audit of six participants per practice at the mid-point in the trial. The PAD forms were reviewed as part of the audit and a judgement was made on whether or not they were compliant with the allocated recall interval. Dentists were also reminded to complete the online risk-based variable training package annually to reinforce the review needed for the participants randomised to a variable risk-based recall.

The audit of six participants (two participants from each of the three recall intervals or three each from risk-based and 6 months if no participants had been allocated to 24 months) was conducted with each practice to check if participants had been contacted to attend an appointment according to their allocated treatment group. If $\geq$ 50% of these random six participants had not been contacted or invited to attend, this triggered a telephone call to the practice to check the trial processes and, if required, a visit to review protocol.

All practices received at least one face-to-face visit. This was to ensure practice compliance with the protocol and confirm staff understanding of their role. It provided a valuable opportunity to answer any queries the practice staff had and to build and maintain a rapport to ensure a smooth transition into the follow-up phase of the trial. Practice staff were encouraged to flag INTERVAL participants in their electronic system as an aide-mémoire to following up participants.

Regular telephone calls were made by TOD administration staff to designated main contacts in practices during the course of follow-up to keep practice staff on board and on track, to provide an opportunity to discuss queries and for TOD staff to seek updates on PAD forms where necessary. Practices were encouraged to contact the TOD for guidance on any aspect of the trial.

An INTERVAL-branded site folder was prepared for each practice containing copies of their completed screening log/PCRFs and participant consent forms, and a section in which to file copies of completed PAD forms.

The TOD e-mailed and posted monthly newsletters to practices to remind dentists and staff of procedures and processes for recruitment and training, and trial updates.

Number of check-ups received (routine data and patient attendance data forms)

The PAD forms were used to collect information on intended and actual appointment dates. The information about the first intended appointment date per recall group was used to assess dentists' intended compliance with the protocol.

Routine treatment data were obtained from the NHSBSA in England and ISD in Scotland for the time period 2010 to 2018.[62] The routine data provided information about the number of dental recalls received throughout the trial by counting the number of claims for treatment made by dentists for each participant.

Data collection

Baseline

Dentists were asked to complete the baseline clinician belief questionnaire after consenting to participate in the trial.

Patient-centred outcomes were collected at baseline using a self-administered questionnaire. Questionnaires were returned to the TOD by the dental practice in a sealed envelope.

Ongoing

Recall appointment dates and times and further treatment information were collected by practices on PAD forms. Routine NHS treatment data were obtained from national-level dental claims data held by the ISD (Scotland), NHSBSA (England) and BSO (Northern Ireland).

Annual follow-up

Patient-centred outcomes were collected annually using self-administered postal questionnaires.

The annual follow-up questionnaire combined questions on patient-centred outcomes, OHRQoL (OHIP-14), generic health (collected using the EQ-5D-3L), dental anxiety, oral health-related knowledge, attitudes and behaviours, use of dental services and satisfaction with care.

Questions collecting descriptive measures were also included in this questionnaire. The annual patient questionnaire also included questions for the health economic analysis, relating to patient-incurred dental costs, and patient attendance at general NHS services (e.g. hospital accident and emergency) for dental-related problems. Questionnaires were issued annually to participants at their home address from the TOD with a covering letter and a Freepost envelope for return of the completed questionnaire.

Those participants who failed to return their questionnaire within 4 weeks were sent a reminder, a further copy of the questionnaire and a Freepost envelope.

On the second anniversary of their recruitment to the trial, participants were sent a £15 gift voucher for their participation in the trial.

Final/fourth-year follow-up

Dentists completed the end-of-trial clinician belief questionnaire after all clinical assessments had been completed in their practice.

Patient-centred outcomes were collected at 4-year follow-up using the annual patient questionnaire. To maximise return, the final questionnaire was sent to participants at least 6 weeks before the date of their final year clinical assessment appointment, with a reminder sent 2 weeks before the appointment. Participants who had not returned a questionnaire by the time of their follow-up assessment appointment were asked to complete the questionnaire at that appointment prior to being assessed. A summary of the data collection items and time point is presented in *Figure 3*.

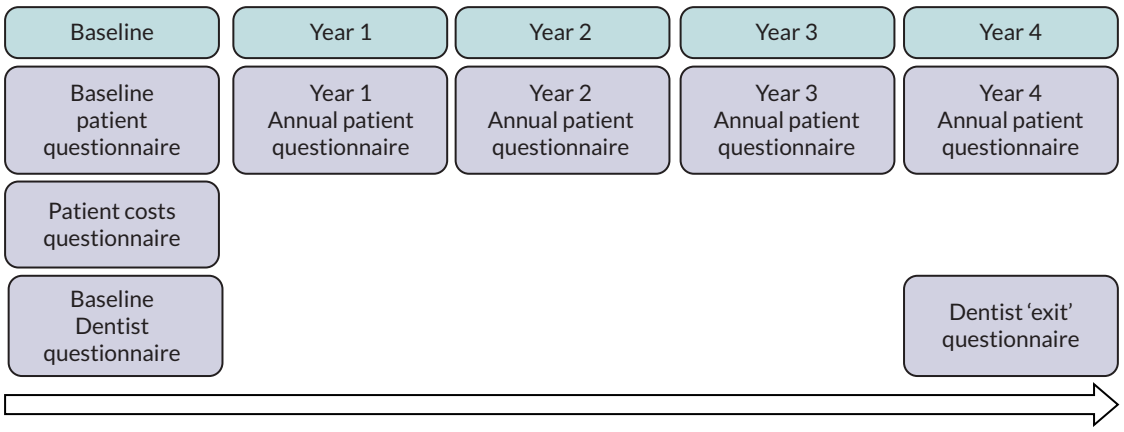


FIGURE 3 Data collection schedule summary.

All participants were invited to attend a trial final-year clinical assessment appointment by their dental practice either at the time of their routine check-up or as a separate appointment. A brief medical history was undertaken about bleeding disorders or immunocompromised disorders. The assessor also confirmed continuing consent with the participants. Gingival bleeding on probing scores, periodontal probing depths, calculus and caries detection were measured by the assessors and recorded on a clinical chart by the dental research nurse, who was a member of the trial team.

Participants who could not attend were contacted and given the option of attending at least one other day or time. Patients who were no longer registered at the practice were offered the opportunity to return to the practice (with practice permission) for an assessment examination, or at another INTERVAL practice (if appropriate) or at a suitable satellite location.

All participants who attended the follow-up assessment received a letter of appreciation for their participation in the trial, details of where the trial results would be published and a final £15 gift voucher in recognition of their contribution. Letters and vouchers were subsequently posted, where possible, to participants who did not attend a follow-up assessment.

Sample size

An exploratory trial in a similar population reported that 35% of gingival sites were bleeding on probing (SD 25%).[87] The Cochrane review of periodontal instrumentation (PI) suggested that 6-month PI versus no PI reduces bleeding sites by 15%.[88] The recall interval was expected to produce an effect lower than this given that the majority of participants in all arms would still receive PI at some time during follow-up. Assuming that either risk-based versus 24-month recall or 6-month versus 24-month recall could reduce/increase the percentage of sites bleeding by 7.5%, the study with 235 participants in each arm could detect such a difference with 90% power at 5% significance, and, likewise, detect a difference of 0.3 of the SD of the OHIP-14 score or any other global measure of OHRQoL. For the caries clinical outcome, assuming a SD of 3.5, the study with 235 participants per arm would detect a shift in white spot lesions (from 3.3 to 4.2) at 80% power and 5% significance.[79] We combined the two strata, without introducing bias, to estimate this comparison. We anticipated smaller effect sizes for the 6-month versus risk-based recall comparison than 6-month versus 24-month recall given that many of the participants in the risk-based group would be seen more frequently than 24 months. A study with 750 participants in each arm could detect a difference in bleeding scores of 4.5% with at least 90% power and a 5% significance level,[89] and likewise detect a difference of 0.17 of the SD of the OHIP-14 score. For the caries clinical outcome, assuming a SD of 3.5, a study with 750 participants per arm could detect a 20% relative shift in white spot lesions from 3.3 to 3.9 at 90% power and 5% significance.[79] Although there was no reason to be concerned about contamination effects in this trial or clustering by dentist, the sample size was conservatively estimated such that if contamination occurred with 15% of the control participants or the intracluster correlation was 0.03, the study would still have 80% power to detect the hypothesised changes in the bleeding score. Our sample size calculations indicated that we needed to randomise 705 participants to stratum 1 (235 in each arm) and 1030 to stratum 2 (515 in each arm).

Contamination effects

There were no obvious mechanisms for contamination to occur in this trial. Our experience of simultaneously conducting an educational cluster and patient randomised trial in dentistry suggested that contamination occurred in at most 15% of participants (if any);[89] therefore, fewer participants are required to perform a patient randomised trial than a cluster randomised trial.[90] There is no perceived direct influence of skill on the patient outcomes and, even if that were hypothesised, the intracluster correlation would be very low (< 0.03).

The sample size has been conservatively estimated such that, if contamination occurred with 15% of the control participants or the intracluster correlation was 0.03, the study would still have 80% power to detect the hypothesised changes in the bleeding score.

Statistical analyses of outcomes

Baseline data were explored to better understand dentists' decision-making process when allocating participants to different strata (eligible to be randomised to 24-month recall vs. not eligible). The primary analysis used an intention-to-treat framework and all participants with available data remained in their allocated groups. The participant outcomes listed above were compared between 24-month, risk-based and 6-month recall groups (for the stratum eligible for a 24-month recall) and risk-based versus 6-month recall (for the stratum ineligible for a 24-month recall). Outcomes collected at year 4 (clinical outcomes, behaviour, knowledge and PBC scores) were analysed using a generalised linear model with a random effect for dental practice. Outcomes collected at years 1, 2, 3 and 4 were analysed using a mixed-effects model with two random effects: participant and practice. A time by treatment interaction term was included in the models. The appropriate effect sizes and 95% confidence intervals were derived. All analyses were adjusted for the protocol minimisation variables [age, dentist, filled teeth (≤ 8 or > 8) and absence of gingival bleeding on probing]. Stata 15 (StataCorp LP, College Station, TX, USA) was used to undertake the analysis.

Missing data

Missing items in scales were dealt with as recommended in the literature by their authors, when recommendations were available. Otherwise, a complete-case approach was used where, in the presence of any missing items in a patient's score, the score was considered missing. Continuous missing data at baseline were imputed for modelling purposes as recommended in the literature,[91] and categorical missing data at baseline used the missing indicator method.[92] The primary intention-to-treat analysis was on observed data.

Sensitivity analysis

We explored differences between responders and non-responders to inform our missing data model. As a sensitivity analysis, missing primary outcome data were imputed using a predictive mean matching multiple imputation approach.[92]

Subgroup analysis

A pre-planned subgroup analysis explored the effect modification of age (< 45 years, 45–64 years, ≥ 65 years) and social class (exempt from payment and not exempt from payment) by including a subgroup-by-treatment interaction term in the primary clinical outcome model described in *Statistical analyses of outcomes*. Further pre-planned subgroup analyses included residence in a fluoridated area, and dentist characteristics were included in the protocol; however, there were too few participants (2%) in fluoridated areas to make a subgroup analysis meaningful. The dentist characteristics subgroup analysis was an error in the protocol. A post hoc subgroup analysis by country was also included.

Trial oversight

The University of Dundee acted as the sponsor for the study. The trial was co-ordinated from the TOD in the Dental Health Services Research Unit, Dundee, which provided day-to-day support for

the dental practices and outcome assessors/research nurses. The TOD was responsible for issuing and collecting trial documentation from practices and participants (including annual questionnaires and reminders) and co-ordination of participant follow-up. The TOD was also responsible for the entry of collected data into the database, including screening logs/PCRFs, PAD forms, baseline, costs and annual patient questionnaires, baseline and follow-up dentist questionnaires and clinical data from outcome assessments. Clinical data were entered by the dentally qualified assessment team.

CHaRT, in the Health Services Research Unit, University of Aberdeen, provided the database applications and information technology programming for the trial, and hosted the randomisation system, provided experienced trial management guidance, and took responsibility for all statistical aspects of the trial (including interim reports to the TSC and the DMC).

Trial Operational Committee meetings were held weekly and attended by Co-Chief Investigators, the Trial Manager and key TOD staff.

The Operational Management Committee met monthly, chaired by one of the Co-Chief Investigators, and comprised co-investigators in TOD and CHaRT.

The Trial Management Committee (TMC) met approximately annually, chaired by the Co-Chief Investigators, and comprised co-investigators, key members of the TOD and CHaRT and a lay representative.

The TSC comprised an independent chairperson and two further independent members, plus a member of the public acting as a lay patient representative. The TSC met approximately annually.

The DMC comprised an independent chairperson and two further independent members. The DMC met approximately annually.

Patient and public involvement

Prior to the start of the trial, advice on the design and conduct of the study was sought from members of the public partnership groups and from similar patient groups in other parts of the UK sourced under guidance from INVOLVE (UK National Advisory group).

These independent public partnership groups comprise volunteers who work in partnership with NHS Tayside and aim to provide a conduit for the views of people about their local services.

Patient advisors were a valuable resource at the outset of the trial and helped to ensure good conduct and patient-friendly practice throughout the duration of the trial. Patient advisors were involved with the trial design and provided invaluable feedback on trial recruitment and communication strategies. Patient advisors also contributed to the content and layout of trial invitation, trial newsletters and the design of patient participant questionnaires. This ensured that trial participants could understand and easily complete these materials.

As quality of life was a primary outcome of the trial, patient advisors' input to the proposed questionnaire design was essential. Qualitative work with patients was carried out to ensure that the outcome measures were patient centred.

Lay representatives on the TSC and TMC actively contributed to trial oversight, processes and procedures, including helping to interpret the trial findings, preparation of the monograph and assisting with the review of the *Plain English summary*.

Chapter 3 Health economics methods

Introduction

In this chapter we report the methods used to conduct the within-trial health economic analysis comparing different dental recall strategies as follows: eligible for 24-month recall – 24-month versus risk-based versus 6-month recall; and ineligible for 24-month recall – risk-based versus 6-month recall. All analyses are completed according to the intention to treat principle at 4 years' follow-up. The health economic analysis compares the costs and benefits of different dental care recall strategies. The results are presented using different perspectives. Economic evaluations to inform UK health-care decision-making, for example through NICE, typically take the form of cost–utility (i.e. cost per QALY) analyses, reporting incremental cost-effectiveness ratios (ICERs). However, in the context of dentistry, there are concerns that generic EQ-5D-3L-based QALYs lack the sensitivity to capture the processes and outcomes of care that are of value to patients and decision-makers.[93] Furthermore, it is argued that the time dimension embedded in QALY calculations may underestimate the impact of acute health effects such as painful caries.[94,95]

Similarly, from a cost point of view, dentistry is unique within health care as the majority of patients pay a contribution towards their NHS care. It is, therefore, crucial to consider both the costs falling directly on the NHS dental budget and the impact on patients in terms of co-charges for NHS care and the opportunity cost of time and travel to dental care appointments when making recommendations about the most efficient dental recall strategy.

For these reasons, it is necessary to consider different frameworks of evaluation that (a) are sensitive to changes in important dental health outcomes such as bleeding or caries, (b) value outcomes that are relevant to service users and (c) capture the full cost burden to both patients and the NHS of different recall strategies. Providing results from a range of perspectives of benefits and cost is essential to equip decision-makers with all the relevant information necessary to reach informed decisions about the efficient allocation of scarce dental care resources.

In terms of the benefits, the scopes are WTP for dental recall interval and associated outcomes [cost–benefit analysis, including all benefits (health and non-health) that are important to individuals], QALYs and WTP for dental health outcomes (caries and self-reported bleeding gums). The preferred analysis depends on what outcome a decision-maker wishes to maximise: social welfare, QALYs or (WTP for) defined dental health (caries and bleeding). In terms of costs, the perspectives are NHS dental budget, NHS total budget and societal perspective (NHS and participant).

Resource use and costs

Resource use and cost data are collected from an NHS and dental patient participant perspective. NHS costs include provision of dental care services (obtained from data linkage to routinely collected claims data) and costs of attending non-dental health professionals for dental problems (obtained from participant questionnaires). Patient participant costs include co-payments for dental care, purchase of dental care products, and the travel costs and the opportunity cost of time spent attending dental appointments obtained from a combination of routinely collected data and participant self-reported questionnaires.

NHS dental costs

Resource use and costs associated with the use of NHS dental services are obtained through data linkage for each randomised trial participant to national-level dental claims data held by the ISD (Scotland), NHSBSA (England) and BSO (Northern Ireland). For the 13 participants recruited from a single Welsh practice, resource use is obtained from practice note data extraction. The actual cost to the NHS of providing treatments, the split of cost burden between the NHS and the patient, and the level of granularity of data available for analysis is dependent on different remuneration systems and contracting arrangements in place for payment of NHS dental care across different UK countries. For example, dentists in Scotland and Northern Ireland are reimbursed on the basis of fee for service, whereas in England contract payments are based on banded categories of treatment complexity. This means that there is a greater granularity of data available for Scotland and Northern Ireland to inform resource use and costing. There are also differences in patient co-charges for dental check-ups ranging from £0.00 (Scotland) to £19.70 (England), which have implications for the interpretation of NHS versus patient perspective costs across the regions. *Tables 1* and *2* describe the NHS and patient breakdown of treatment charges across the UK regions for fee-paying adults. All cost data are reported in 2016/17 values based on the regional dental payment contracts. Regional specific variation in the dental payment systems is discussed in the following paragraphs.

Use of NHS dental services: England and Wales (activity-based treatment bands)

In England, dental payment contracts are negotiated at either a national (GDS contracts) level or a local (personal dental service contracts) level. GDS contracts are the most common across England, accounting for approximately 85% of negotiated contracts, and are used to inform the costing analysis.[98] Under GDS arrangements, each dental practice is contracted to provide a prespecified quantity of NHS care, measured in a currency called units of dental activity (UDAs). All dental treatments are classified into four treatment bands based on treatment complexity, with more complex treatment bands attracting a greater number of UDAs.

TABLE 1 Treatment charges for dental care in England and Wales

England and Wales activity-based banding[96,97]							
				England (2016/17 charges)[a,b]		Wales (2016/17 charges)[a,b]	
Band	Number of UDAs	UDA unit value	Band treatment value	Patient charge	NHS charge	Patient charge	NHS charge[c]
1 (e.g. check-up/X-ray/advice/PI)	1	£25	£25	£19.70	£5.30	£13.50	£6.20
2 (band 1 treatments + fillings, extractions, root canal treatments)	3	£25	£75	£53.90	£21.10	£43.00	£10.90
3 (band 1 and 2 work + crowns, dentures and bridges)	12	£25	£300	£233.70	£66.30	£185.00	£48.70
Urgent	1.2	£25	£30	£19.70	£10.30	£13.50	£6.20

UDA, unit of dental activity.

a In England and Wales, a number of services do not fall into any of the patient charge bands in their own right, but are awarded UDAs when provided outwith other banded treatments. The number of UDAs for such treatments is as follows: arrest of bleeding = 1.2 UDA, bridge repair = 1.2 UDA, denture repair = 1.2 UDA, issue of prescriptions = 0 UDA and removal of sutures = 1 UDA. These treatments incur £0 charge to the patient.

b Exceptions and exemptions apply to treatment across all regions where patients do not pay any of the cost (e.g. receiving income support, < 18 years, in full-time education, pregnant or given birth in last 12 months, receiving pension credit, universal credit, tax credit exemptions). Patient charges relate to 2016/17 values.

c Assumes that the value of a UDA in Wales is the same as in England (i.e. ≈ £25).

TABLE 2 Treatment charges for dental care in Scotland and Northern Ireland

Scotland/Northern Ireland[a]		
Treatment	**Patient charge (2016/17 charges)**	**NHS charge (2016/17 charges)**
Check-ups and case assessments	Scotland: 0% of full cost	Scotland: 100% of full cost
	Northern Ireland: 80% of full cost	Northern Ireland: 20% of full cost
Other treatments	80% of full cost	20% of full cost
Maximum charge per course of treatment	Scotland: £384.00	Unlimited
	Northern Ireland: unlimited	

a Exceptions and exemptions apply to treatment across all regions where patients do not pay any of the cost (e.g. receiving income support, < 18 years, in full-time education, pregnant or given birth in last 12 months, receiving pension credit, universal credit, tax credit exemptions). Patient charges are based on regional and time-specific statements of dental remuneration, inflated to 2016/17 values.

The value of a UDA may vary across dental practices, depending on contract negotiations, population-level general health and dental health in a catchment area and area deprivation. A value of £25 per UDA is used for the analysis, based on the Steele report in 2009[99] and maintaining consistency with NICE public health guidance on oral health promotion[100] and the published Improving the Quality of Dentistry (IQuaD) study.[101] If patients are exempt from paying treatment charges, the NHS covers the full value of treatment. It should be noted that, in England and Wales, dental check-ups without further treatment requirement incur a band 1 charge.

Routine data downloads for England were taken on 4 May 2018. NHSBSA data are often entered, cleaned and processed towards the end of the financial year, meaning that the quality of the data is probably high for all claims starting prior to the end of March 2018. Some participants [$n = 43/1031$ (4.2%)] were recruited to the trial after April 2014. Routine data for resource consumed by these participants may be missing for the 3-month period from April to June 2018; however, this applies to a very small proportion of participants over a very short time frame, so such missing data are unlikely to bias the costing analysis. For the remainder of the linked participants in England, the routine data capture a complete, and accurate, record of all primary NHS dental care received for the full 4-year duration of follow-up in the trial.

Use of NHS dental services: Scotland and Northern Ireland

The remuneration systems are similar in Scotland and Northern Ireland. Dentists are paid on a fee-for-service basis, with payment attached to over 300 different treatment codes. Payment contracts are updated and refined on a regular basis. Costing data for this report are sourced from the statements of dental remuneration in Scotland and Northern Ireland, with all treatment costs inflated to 2016/17 values using an online tool.[102] Dental check-ups are free of charge to the patient in Scotland. In Northern Ireland, the patient pays a co-charge of £6.74 (2016/17 statements of dental remuneration), which is approximately 80% of the total check-up value. For other items of service (e.g. scale and polish, fillings and extractions), patients in Scotland and Northern Ireland pay approximately 80% of the item of service value, unless they are exempt from payment charges. The payment mechanism in Scotland and in Northern Ireland means that there is a high level of detail available to inform the costing analysis.

Routine data downloads were taken on 15 May 2018 (Scotland) and 29 August 2018 (Northern Ireland). Communication with ISD and BSO indicates that the routine data are an accurate and complete representation of all treatment and resource use up until 3 months prior to the data download. On this basis, we are confident that the routine data are a complete representation of all primary dental care contacts for 1157/1188 (97.4%) participants with known robustness of data quality for 990/1188 (83%)

participants for the full duration of follow-up; however, any biases are likely to be small in magnitude because of the short period of time in which the data exist, but the quality cannot be guaranteed. For Northern Ireland, all data are a complete and accurate reflection of the full record for all patients over the 4-year follow-up.

Costing of NHS dental services

Costs to the NHS are calculated for each individual trial participant as the region-specific total treatment value minus any patient charge contributions. For patients who are exempt from paying dental charges (e.g. those on a low income), the full value is assigned to the NHS. Exemption status is, therefore, an important determinant of NHS perspective costs, and the analysis tests for any differences in status across the randomised groups.

The costing analysis excludes any treatment claims relating to or originating from examinations at the baseline trial visit. To do this, all treatment claims with a start date prior to 3 months (specifically 90 days) post randomisation are excluded. This ensures that any treatment costs are driven by the decision to randomise patients to different recall intervals and not driven by unrelated treatment need identified on entry to the trial. In addition, all treatment claims with a start date occurring more than 4 years post randomisation are excluded. Some final outcome assessments may have occurred prior to 4 years post randomisation. The outcome assessment data were not routinely passed to the participant's dental practice, and it is not anticipated that having the assessment early had a significant impact on costs. However, to ensure that the analysis does not create any bias by identifying treatment need at the final outcome assessment, the proportion of respondents for whom this occurred is compared across trial arms. If differences are identified, these are controlled for in the cost regression analyses.

Costs are reported from both an NHS and a societal perspective (NHS + patient participant). All costing is reported in 2016/17 Great British pounds and costs occurring beyond the first year of follow-up are discounted at a rate of 3.5% per annum.[103,104]

Costs of other NHS services during follow-up

Information about the use of other NHS services related to dental health was obtained from participant-completed annual postal questionnaires. NHS resource use falling outside the dental budget included secondary care visits (hospital inpatient admission, outpatient consultations, day case procedures, and accident and emergency attendances) together with general practitioner (GP) appointments and contact with out-of-hours services such as NHS 24 (Scotland), NHS Direct (England/Wales) or NIdirect (Northern Ireland). The following approach was used to deal with instrument and item non-response as well as inconsistent reporting on the participant-completed questionnaires:

- Where an instrument was not returned, data were treated as missing, and non-dental NHS costs were imputed using multiple imputation.
- Where respondents ticked 'No' to an item of resource use, but entered a number of contacts, it was assumed that no resource use was incurred.
- Where respondents stated that they attended hospital inpatient services for problems related to their teeth but provided no further information, it was conservatively assumed that such responses should be treated as day case admissions. National data show that the majority of hospital admissions in the UK for dental problems are day-case procedures.[104]
- Where respondents stated that they attended secondary care, and provided information regarding the reasons for attendance, these reasons were assessed for their link to dental care, and if clearly not related to dental care, were excluded from analysis.

The reported rates of contact with secondary care (e.g. inpatient/outpatient) were compared with average attendance rates obtained from ISD/Hospital Episode Statistics to determine their face validity.[104] It would be anticipated that, in a general dental population, as included in the trial, the rates of admission should be similar to national-level data.

Participant costs

Three sources of participant cost are included in the analysis: (a) participant co-charges for NHS dental care, (b) direct out-of-pocket expenses for private dental care and (c) the opportunity cost of participant's (and any companion's/carer's) time spent attending dental appointments.

Co-payments for NHS dental care

Routine dental claims data were used to determine participant perspective charges for each treatment provided to each trial participant. These were estimated based on treatment banding and exemption status. In England, explicit recording of the patient charge is not necessarily required for NHS payment and this may explain why, in some cases, the English data set indicates £0 co-payment despite the patient not having any exemptions indicated, or the patient charges are missing. This is likely to be an administration error and it is, therefore, assumed that the practice collected the appropriate patient charge.

Self-purchased dental care products

Participants reported whether or not and how frequently they used/replaced electric toothbrushes, electric toothbrush heads and manual toothbrushes. The cost of a new electric toothbrush was obtained from participant-reported data in each annual questionnaire. Costs of manual toothbrushes and replacement heads for electric brushes were assumed to be the cheapest available prices for commonly used toothbrush products using an online search of multiple retail stores conducted on 20 September 2018. The unit costs sourced are £8.48 [pack of four Oral-B electric heads (Procter & Gamble, Cincinnati, OH, USA), sourced from Superdrug (Superdrug Stores plc, Croydon, UK) online] and £2 [manual Colgate 360 (Colgate–Palmolive Company, New York, NY, USA), sourced from Boots (Boots UK Limited, Beeston, UK)], adjusted back to 2016 values to account for inflation and to ensure a common year of currency for all costs.

Private dental care costs

Participants reported the total cost of out-of-pocket spending on private dental care in each annual questionnaire. Reported data are summed across each questionnaire to obtain the full cost of private dental care over the trial time horizon and data are described descriptively as mean (SD) and median (interquartile range) to demonstrate the impact of a small number of high-cost items (e.g. dental implants) on the cost analysis.

Costs of time and travel

There is a direct cost to the participant for travelling to every dental appointment and an opportunity cost of their time (and their companion's/carer's time, if accompanied) spent travelling when they are away from their usual activities (e.g. work, leisure time and child care). Routine dental claims are used to identify the number of attendances for NHS dental treatment. It is conservatively assumed that each unique treatment's start/acceptance date (rather than each item of service claimed in Scotland/Northern Ireland) relates to a single dental visit. This approach probably underestimates the true participant perspective costs if more than one visit was required for a course of treatment. The unit time and travel cost to participants and companions of a return journey to the dental practice is calculated using data provided by respondents in the baseline questionnaire, using a subset of questions obtained from a standardised patient costs questionnaire.[105] The cost of a visit is assumed to remain constant at the individual level across the time horizon of the trial to avoid overburdening respondents with multiple similar questions in each annual questionnaire. Unit costs of travel and the opportunity cost of time commitment of travelling to and attending dental appointments are detailed in *Table 3*. The total opportunity cost of time and travel is obtained by multiplying the number of treatment courses by the unit opportunity cost of time and travel for each participant.

TABLE 3 Unit costs for the opportunity costs of time and travel

Activity	Assumptions made	Unit cost	Reference
Paid work	Median UK gross weekly wage: £550; 39.1 hours per week	£14.07	Office for National Statistics; *Annual Survey of Hours and Earnings*, 2017[106]
Transport	Cost per mile[a]	£0.45	HM Revenue & Customs (approved mileage rate, 2016/17)[107]
Caring for a relative or friend	Median gross weekly pay: £341; 39.2 hours per week[b]	£8.70	NHS Pay Review Body report 2016, page 17[108]
Leisure activities	Value of non-working time[c]	£7.79	*Transport Analysis Guidance (TAG) Data Book*, July 2017[109]
Child care	Assumed as paid work	£14.07	Office for National Statistics; *Annual Survey of Hours and Earnings*, 2017[106]
Voluntary work	Assumed as paid work	£14.07	Office for National Statistics; *Annual Survey of Hours and Earnings*, 2017[106]
Unemployed	Value of non-working time	£7.79	*Transport Analysis Guidance (TAG) Data Book*, July 2017[109]
Retired	Value of non-working time	£7.79	*Transport Analysis Guidance (TAG) Data Book*, July 2017[109]
Parking	Participant's individual costs	Various	Participant questionnaires
Housework	Cost of housework in the NHS, assumed annual salary £21,000 gross, 2012 values inflated to 2016/17	£10.56	NHS pay review body, 2016[108]

a Based on government-approved travel mileage reimbursement for use of own vehicles.
b Caring, leisure and other service occupations.
c Transport Analysis Guidance data report, based on values of non-working time (£ per hour, 2010 prices, inflated to 2016/17 values) based on the average of inflated prices for commuting and other time (£10.69 + £4.88)/2 = £7.79.

Statistical analysis and reporting of cost data

Cost models are estimated using generalised linear models, specifying a log link function and gamma family to account for a skewed distribution with a minimum of zero cost, and a long tail reflecting a small proportion of participants with high costs. The chosen family (gamma) is based on the results of a modified Park test, and the chosen link function is based on a combination of Akaike information criterion (AIC) score and *p*-values from the Pearson correlation test, the Pregibon link test and the modified Hosmer–Lemeshow test[110,111] obtained using the *glmdiag* program for Stata. Costing models are adjusted for the trial minimisation variables, region and baseline EQ-5D-3L score, and a random effect for centre to control for practice-specific variation in treatment decisions. For the comparison of treatment options across all trial participants, a fixed effect is included to account for randomised stratum in the trial. The cost models are estimated using Stata's *meglm* command. Recycled predictions of the coefficient on randomised treatment determine the incremental costs compared with standard care (currently 6-month recall). Two sets of results are reported. First, results are reported for all data comparing risk-based recall with 6-month recall. Second, a three-way comparison is presented for those participants randomised to the stratum of participants who are eligible for 24-month recall. Costs associated with risk-based and 24-month recall are compared against each other, and with the assumed standard care (i.e. 6-month recall).

Descriptive statistics for cost data (mean, SD, *N*) are reported for all resource use items from both an NHS and a patient participant perspective based on complete-case data for information. NHS perspective costs to the dental budget are relatively complete because of a high match rate across the regions between the routine dental claims data and the recruited trial population. However, participant perspective costs (based on questionnaire response data) are subject to significant missing data.

For the statistical analysis of costs, the mechanism of data missingness was investigated using logistical regression analysis, where the dependent binary variable (missing or not) was regressed on sociodemographic characteristics (age, gender), minimisation variables, region, baseline EQ-5D-3L utility score, and baseline measures of clinical outcome. Statistically significant explanatory variables were assumed to indicate that data were missing at random as opposed to missing completely at random. Best practice was applied, imputing data using multiple imputation of missing data following Stata's *MI* procedure.[112] Missing cost data are imputed by component of cost (e.g. dental product costs) for each questionnaire, using predictive mean matching (average of five closest values), accounting for the repeated measures nature of the costs from the annual participant questionnaires. $M = 5$ imputed data sets are used to ensure the stability of results, and the data sets were combined using Rubin's rules to obtain a single estimate of costs.[113] All data imputation models account for randomised group and adjust for explanatory variables as described above.

Benefits

Three different measures of benefit are included in the economic evaluation as alternative analyses. The analyses differ in terms of the scope and definition of the benefits included. Benefits are considered as (a) WTP for both dental recall frequency and associated dental health outcomes to inform a cost–benefit analysis (CBA) that includes all perceived benefits, health and non-health, to the general population, (b) QALYs to inform a cost–utility analysis (CUA) and (c) WTP for dental health outcomes, specifically ICDAS and bleeding gums on brushing, where the utility of dental health outcomes is measured in terms of WTP. The preferred analysis depends on what outcome a decision-maker wishes to maximise: social welfare, QALYs or (WTP for) dental health outcomes. All benefits are valued using general population preferences.

Willingness to pay: discrete choice experiment

Willingness to pay is calculated based on responses to an online DCE conducted with a nationally representative sample of the UK population, with oversampling in Scotland to determine any subgroup effects on preferences driven by different, regional-specific payment systems. A DCE is a survey designed to elicit respondents' preferences through the choices they make between different hypothetical goods or services. In the context of this study, respondents make choices between different packages of dental care that vary in terms of their recall frequency, health outcomes (bleeding gums when brushing and caries experience over a 4-year period, as informed by ICDAS classification groups) and cost. Each package comes at an annual cost over 4 years, reflecting the trial's time horizon.

Discrete choice experiments assume that a treatment or service's value depends on its component attributes and the levels of those attributes. By including the price proxy within the DCE (i.e. the annual cost of each dental package), we can obtain a monetary valuation for any given dental recall package. These WTP estimates are used as a measure of benefit within the CBA, and can be used to value all outcomes or a subset of those outcomes (e.g. health related only). The DCE received ethics approval from the College Ethics Review Board at the University of Aberdeen (ref: 2015/12/1278). The main considerations for the DCE design are as follows.

Discrete choice experiment selection of attributes and levels

The trial protocol sets the primary research question, and the DCE therefore seeks to value general population preferences for different frequencies of dental recall (24 month, 12 month, 6 month, or risk based). The selection of outcome attributes and levels was partially determined by the trial (e.g. valuing avoidance of caries), but the selection of outcomes for valuation was also based on engagement with key stakeholders (in formal and informal discussion), literature review and primary qualitative (focus group) work with members of the general population to derive a set of attributes and levels meaningful and important to respondents. It became clear from the focus group work that respondents would have difficulty valuing and understanding the primary clinical trial outcome (gingival bleeding on probing).

The DCE attribute for bleeding is, therefore, bleeding on brushing (this is mapped to a post hoc trial outcome that asks respondents to report on the frequency of bleeding when they brush their teeth). The final list of attributes and levels included in the DCE is provided in *Table 4* and an example choice set can be found in *Figure 4*.

Discrete choice experiment experimental design

A pivoted, segmented design was generated using Ngene™ experimental design software (ChoiceMetrics Pty Ltd, Sydney, NSW, Australia) to select the combination of treatment descriptions, and to create the choice sets, which minimised the design's D-error. First, respondents were assigned to one of three segments (good, moderate or poor dental health) based on their self-reported dental health as measured using stated caries experience and bleeding frequency.

The opt-out scenario described the implications of choosing the 'no dental check-up' package (i.e. receiving none of the services within the package and at no cost). Outcome attributes in the reference case were tailored to each segment, reflecting a modest reduction in the outcome attributes if no dental package was selected. The levels of the outcome attributes were then pivoted around these baseline (opt-out) levels, to ensure that only realistic choice tasks were presented to respondents. The pivoting ensured that respondents were not presented with situations in which their health could get worse by opting into one of the dental packages.

The DCE has a single five-level attribute with three four-level attributes, resulting in 320 ($5^1 \times 4^3$) possible combinations and $(320 \times 319)/2 = 5040$ unique choice sets. The resultant chosen main effects D-optimal design consisted of 24 choices, split equally across three blocks of eight choices. Two further choice tasks were added to test for consistency and dominance to each block of choices, meaning that each respondent completed a total of 10 choice tasks. The responses to the internal validity choice tasks were not included in the analysis models. The experimental design was based on vague priors, specifying only the expected coefficient sign for outcome attributes and null priors for the recall frequency attribute.

Discrete choice experiment questionnaire development

There are three sections to the survey. Section 1 asks about respondents' experiences of dental care, current dental health, how often they attend their dental practice and by whom they are treated. Responses to dental health questions are used to inform the pivoting of the design as described in

TABLE 4 Attributes and levels included in the DCE

Attributes	Levels
You have a dental check-up	Every 2 years Every year Every 6 months It varies depending on your risk
In 4 years' time, your gums will bleed	Never Hardly ever Occasionally Fairly often Very often
Over the next 4 years, you will have	No dental decay Early dental decay Moderate dental decay Advanced dental decay
The annual cost to you	£20 per year (total cost: £80 over 4 years) £50 per year (total cost: £200 over 4 years) £100 per year (total cost: £400 over 4 years) £200 per year (total cost: £800 over 4 years)

Please compare the dental packages offered, and tick which package, if any, you would choose

	Dental Check-up Package A	Dental Check-up Package B	No Dental Check-ups
You have a dental check-up:	Every 2 years	Every 6 months	None
In four years' time your gums will bleed	Never	Occasionally	Very often
Over the next 4 years, you will have	Moderate dental decay	No dental decay	Advanced dental decay
The cost to you	£100 per year (Total cost: £400 over 4 years)	£200 per year (Total cost: £800 over 4 years)	£0 per year (Total cost: £0 over 4 years)
	☐	☐	☐

FIGURE 4 Example choice task. Note: the example choice set shown in *Figure 4* is for a respondent categorised as having moderate dental health. If this hypothetical respondent chose dental check-up package B, they would be willing to pay £200 per year for that package.

Discrete choice experiment experimental design. Section 2 asks the respondents to complete the DCE, and section 3 concludes the survey with a series of demographic and attitudinal questions that may help explain choices. In addition, there are debriefing questions about ease of understanding, realism and appropriateness of the choice task questions, as well as questions designed to understand respondents' experiences of taking online surveys more generally. The questionnaire was designed using Qualtrics (Qualtrics, Provo, UT, USA) online survey design platform.

Discrete choice experiment data collection

Data were collected using Qualtrics online panels. Data collection for the DCE was conducted in parallel with the trial follow-up period and responses to the survey were provided between 7 July and 5 August 2016. The survey was nationally representative, with population census quotas sought for age (among adult population), sex and region. We oversampled in Scotland ($n = 183$) to enable regional-specific subgroup analysis split by contract type (UDA, England/Wales; fee for service, Scotland/Northern Ireland). At the pilot stage, 30% of responses were sought from non-regular attenders (defined as not having seen the dentist in the previous 2 years),[114] but it was not possible to achieve this target and, instead, a relaxed quote of 10% was sought for the main data collection phase. All responses were anonymised and respondents could leave the survey at any time and did not need to provide a reason for doing so. Those who completed the survey were reimbursed in a manner determined by the survey panel.

Discrete choice experiment data analysis

The DCE data are analysed using best practice methods and followed random utility maximisation theory.[115] In brief, all data are analysed using a mixed logit model, specifically an error components logit model, allowing for multiple choices per respondent. The observable, individual specific systematic component of the utility function (V_{njt}) for individual n, choosing dental check-up package j, in each choice task t is specified as a linear additive function of the attributes and levels presented to the respondents:

$$\begin{aligned} V_{njt} = {} & \alpha + \beta_1 Recall_{annual} + \beta_2 Recall_{six-monthly} + \beta_3 Recall_{risk-based} + + \beta_4 Bleed_{hardly-ever} + \beta_5 Bleed_{occasional} \\ & + \beta_6 Bleed_{fairly\ often} + \beta_7 Bleed_{very\ often} + \beta_8 Decay_{early} + \beta_9 Decay_{moderate} + \beta_{10} Decay_{advanced} + \beta_{11} Annual\ Cost, \end{aligned} \quad (1)$$

where α is the alternative specific constant (ASC), included as a random (normally distributed) parameter in the model. The ASC accounts for latent or unobserved utility associated with choosing any package, regardless of the attribute levels, and β represents the marginal utilities associated with the attributes and levels.

All categorical variables are effects coded where the β coefficients represent the effect of a unit change in an attribute level (away from the grand mean) on utility. The advantage of effects coding is that the reference level of an attribute is uncorrelated with the ASC. The reference categories for the effects coded attributes are 24-month recall, never bleeding and having teeth that have no decay. The utility of the reference category, relative to the grand mean of the attributes, is obtained as the negative sum of the estimated coefficients for that attribute. The coefficient on cost indicates the marginal change in utility for a £1 increase in annual cost. The error term is split into two, where μn is the individual specific random effect and ϵj, the unobserved component of the error term, is independent Type I extreme value distributed. The final model is estimated using the maximum simulated likelihood method, with 200 Halton draws.

The marginal WTP of an attribute level is equal to the negative of the marginal rate of substitution between that level and the cost attribute. For the purposes of result reporting, confidence intervals (CIs) are based on the delta method, calculated using Stata's *nlcom* command which computes point estimates and CIs for potentially non-linear combinations of parameter estimates, implemented after running the corresponding error components logit models.

The models are re-estimated separately using interaction terms for several predetermined subgroups, including (1) sex; (2) region, to determine if system of reimbursement, and patient co-charge (£0 in Scotland) has an impact on preferences; (3) smoking status, to determine if current or previous smokers' preferences differ from the overall group; (4) household income, to determine if lower ability to pay (annual income < £20,800) has an impact on preferences; (5) experience of dental check-ups (attending at least every 6 months); and (6) experience of dental decay, to determine if having experience of dental decay has an impact on preferences for its avoidance. The impact of subgroups on main attribute-level effects is assessed by the significance of interaction terms between subgroup identifier and attribute level coefficient. Likelihood ratio tests are used to test the joint significance of the interaction terms.

Estimating benefits (willingness to pay) for each trial participant

Benefits in terms of WTP, are calculated for each trial participant by mapping the WTP tariffs obtained from the DCE to the trial outcomes. Following an intention-to-treat principle, WTP values are attached to the services provided (i.e. the number of check-ups received at a trial participant level, regardless of randomised group). This means that the tariff for risk-based recall in the DCE was not directly assigned to the trial interventions. This is in line with an intention-to-treat approach, but it is possible that patients attach value directly to being allocated to a risk-based interval; therefore, sensitivity analysis explores a per protocol approach to attaching DCE WTP values to trial interventions. For check-up frequencies observed in the trial that extend beyond the valuation scope of the DCE (e.g. four check-ups per year), a stepwise linear utility function is used to extrapolate the WTP tariffs predicted using the DCE. WTP tariffs were assigned directly to the health outcome attributes observed in the trial (i.e. self-reported bleeding on brushing and caries experience). Caries experience is defined as a composite of treated caries assumed equal to the number of fillings provided over the follow-up phase in addition to the untreated caries detected at the final outcome assessment. The marginal WTP tariffs attached to each service and outcome are summed to obtain a total WTP measure of benefit. Two different measures are presented: (A) total WTP calculated as the sum of marginal WTPs for mapped health outcomes only (i.e. caries and bleeding), generating a dental health perspective of benefits, and (B) total WTP calculated as A + the marginal WTP attached to service frequency, generating a broader and more holistic measure of benefit for use in the CBA.

Quality-adjusted life-years

The EQ-5D-3L is used to capture generic health-related quality of life in the trial. Respondents complete the EQ-5D-3L at baseline and in each annual follow-up questionnaire. Responses to the EQ-5D-3L are then valued using UK general population tariffs, estimated using the time trade-off method.[116] The valuation generates a utility score for each EQ-5D-3L response on a scale of −0.564 (worst possible health state) to 1 (best possible health state). QALYs are then calculated using an area under the curve approach with linear extrapolation between the annual data collection time points. Any respondents who died over the course of the trial are assigned a zero utility score from the follow-up time point after death to the end of the trial follow-up.

Statistical analysis of benefits data

The approach for the analysis of benefits data is similar for calculations of both WTP and QALYs. All benefits, regardless of measurement approach, are discounted at a rate of 3.5% per annum in line with NICE guidance.[103] Total WTP and QALY data are both analysed using a generalised linear regression model, adjusting for minimisation covariates, region and baseline EQ-5D-3L utility score, and include a random effect for centre. For the comparison of all data in a single model, a fixed effect for stratum is added. For each benefit measure, models are estimated using Stata's *meglm* command with a Gaussian family and identify link. The chosen family (Gaussian) is based on the results of a modified Park test, and the chosen link function is based on a combination of AIC score, and *p*-values from the Pearson correlation test, the Pregibon link test and the modified Hosmer–Lemeshow test.

Missing data exist for benefits because participants may not have attended their final year clinical assessment appointment or may not have returned questionnaires detailing experience of bleeding on brushing. As with costs, the mechanism of missingness was explored using logistical regression models to determine any predictors of missingness. Presence of significant explanatory variables was taken as an indication that data were missing at random and could not be assumed missing completely at random, and so multiple imputation would be required. Missing data are imputed using Stata's *MI* procedure[112,117] (by randomised group) using predictive mean matching (five closest values), and accounting for minimisation variables and baseline EQ-5D-3L utility score. $M = 5$ imputed data sets are used and results obtained from the combined data using Rubin's rules.[113]

Economic evaluation

Cost–benefit analysis

The CBA compares the costs and benefits of alternative policies of dental recall against standard care (currently 6-month scheduled recall). Both costs and benefits are measured in monetary terms and net benefits can, therefore, be directly estimated (benefits minus cost). The INBs indicate whether moving from standard care to an alternative policy increases or decreases overall societal welfare. The imputed data sets are used to estimate net benefits and INBs. Net benefit is calculated for each participant in the trial according to *Equation 2*:

$$\text{Net benefit} = \text{total benefits} - \text{total costs}. \quad (2)$$

Cost–utility analysis: generic

This analysis is based on the cost of achieving changes in generic health profile, as measured using the EQ-5D-3L, and uses QALYs as the measure of benefits. An incremental comparison of costs and QALYs between each recall strategy is reported, and ICERs are calculated as the mean difference in costs divided by the mean difference in QALYs. The ICER can then be compared with a threshold value of WTP for a QALY gained, as is commonly considered by NICE. If the ICER is < £20,000 to £30,000 per QALY gained, an intervention is typically considered to be an efficient use of resources. In cases where there are additional costs but QALY losses, an intervention is said to be 'dominated' and is less likely to provide good value for money.

Dental health-specific evaluation

Quality-adjusted life-years are unlikely to be sufficiently sensitive to capture changes in dental health; therefore, an 'alternative' analysis is conducted using WTP for dental health outcomes (based on a composite measure of caries experience as measured using ICDAS/fillings received and self-reported bleeding gums on brushing) as the measure of benefit. INBs are estimated as described in the CBA.

Statistical analysis of costs and benefits together

For each analysis framework, data are analysed using multiple imputation of missing data, and regression analyses as described in the preceding sections. The point estimate of INB, or incremental cost per QALY gained, is obtained by dividing the treatment coefficient on costs by the treatment coefficient on benefits regressions. This is done for each cost perspective (NHS dental perspective, NHS perspective and societal perspective). The results should be considered in the light of the uncertainty surrounding the point estimate. Uncertainty is illustrated using scatterplots of costs and benefits (WTP or QALYs) on the cost-effectiveness (benefit) plane and cost-effectiveness (benefit) acceptability curves. The cost-effectiveness acceptability curves (CEACs)/cost–benefit acceptability curves (CBACs) and scatterplots are obtained using 1000 bootstraps of the corresponding analysis models, with imputation included within each bootstrapped loop where required, following the guidance outlined in Brand 2019.[118]

For the CBA, the CBACs illustrate the probability that INB is positive at various threshold values of the benefit–cost ratio. A positive INB would be associated with a benefit–cost ratio > 1. The higher the benefit–cost ratio, the more likely the intervention is to be cost-beneficial (i.e. an efficient use of resources). For the CUA, CEACs illustrate the probability that each intervention is the optimal (most efficient) strategy at increasing threshold values of society's WTP for a QALY gained. These analyses illustrate the impact of sampling uncertainty on the results, but it is also necessary to consider uncertainty driven by key analysis assumptions. The range of deterministic and scenario analyses carried out are described, with a justification for each, in *Table 5*.

TABLE 5 Scenario analyses considered

Topic	Scenarios considered	Justification for approach
Impact of costing perspective on results		
Costing perspective	Costs are considered from an NHS dental care perspective, based on NHS payment for dental care obtained from routine claims data	To determine the direct impact of different recall frequencies on the NHS dental budget
Costing perspective	Costs are considered from both an NHS dental care perspective and a broader NHS health-care perspective including costs falling outwith the dental budget (e.g. hospital attendance, GP care and out-of-hours service contacts)	To determine the impact of a narrow vs. wider perspective of NHS-incurred costs on results
Costing perspective	Costs are considered from an NHS dental care, a broader NHS health-care perspective and include all patient participant-incurred costs (including costs directly associated with attendance at NHS dental appointments and all other private dental care)	To determine the impact of different recall strategies on costs from both the NHS perspective and the patient perspective To more fully understand the impact on patients of attendance for dental visits
Costing perspective	Costs are considered from both an NHS dental care perspective and including patient participant perspective costs directly associated with attendance at dental appointments	An even wider perspective of costs, including all NHS and participant perspective costs related to dentistry
Methodological issues		
Reference analysis: multiple imputation, 3.5% discount rate for costs and benefits, WTP mapped to caries experience (routine data) + untreated caries (trial outcome), ITT analysis, based on all UK regions combined		
Discounting of costs and benefits	Assume undiscounted costs and benefits	Standard exploration of methodological uncertainty
Imputation	Complete cases	
Mapping of WTP to trial outcomes	Exploring the impact of mapping WTP for caries avoidance to clinical trial outcome (untreated caries) only	The clinical outcome assessment captures untreated caries, but not caries experience for participants when they obtained fillings over the trial follow-up. Sensitivity analysis (untreated caries only) may underestimate value of caries experience, but may be more robust given that it is unclear from routine data if fillings are provided for caries (or replacements/trauma)

continued

TABLE 5 Scenario analyses considered (*continued*)

Topic	Scenarios considered	Justification for approach
ITT vs. per protocol analysis	ITT analysis values the number of services received in the CBA. The 'per protocol' analysis attaches WTP tariffs from the DCE to randomised arms, regardless of services delivered	Analysis conducted to explore the impact of explicit valuation of risk-based recall on the CBA results
UK vs. regional analyses	Region-specific analyses for Scotland and England	Regional-specific analyses conducted to determine if the payment system for dentistry (e.g. fee for service and free check-ups for patients in Scotland) has an impact on cost-effectiveness results. This analysis additionally includes regional-specific subgroup WTP tariffs from the DCE applied to trial participant services and outcomes (by region)

ITT, intention to treat.

Chapter 4 Trial results and clinical effectiveness

Introduction

This chapter describes the study groups at trial entry, followed by a description of the interventions received, the results at the annual follow-up points and a statistical analysis of the primary and secondary outcomes. Randomised groups are presented separately dependent on eligibility stratum: whether the patient participant was eligible or not to be randomised to a 24-month recall. If the participant was eligible, three treatment options were available and are presented in this chapter (i.e. risk-based recall, 24-month recall and 6-month recall). If the participant was not eligible to be recruited to the 24-month recall stratum, two randomised groups are presented (risk-based recall and 6-month recall).

Recruitment to the study

Participants were recruited between July 2010 and July 2014. Data were closed to follow-up on 13 August 2018. The flow of participants for each INTERVAL eligibility stratum is shown separately in *Figure 5* (eligible to be randomised to 24-month recall) and *Figure 6* (ineligible to be randomised to 24-month recall), with information on primary outcome collection at the different follow-up time points in the form of a Consolidated Standards of Reporting Trials (CONSORT) flow diagram.

Participants

Participants were recruited from 51 practices (see *Appendix 1*, *Table 28*). A total of 2372 participants were recruited to the trial. Of the 648 participants recruited to the 24-month recall stratum, 217 were allocated to risk-based recall, 216 to 24-month recall and 215 to 6-month recall. Of the 1724 participants

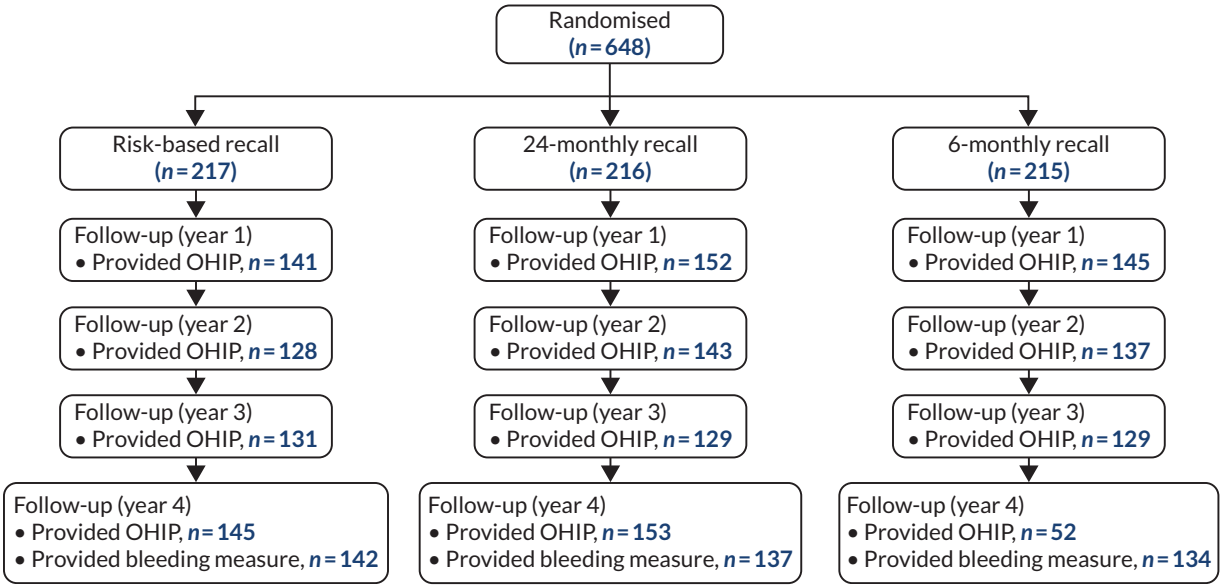


FIGURE 5 The CONSORT flow diagram for participants eligible for the 24-month recall stratum.

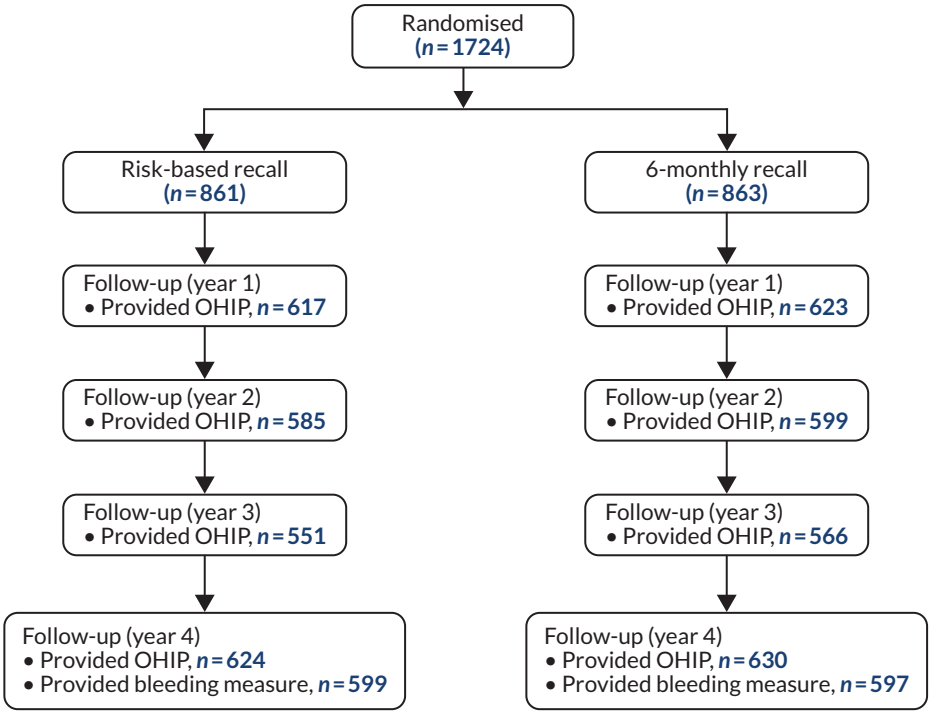


FIGURE 6 The CONSORT flow diagram for participants ineligible for the 24-month recall stratum.

ineligible for 24-month recall stratum, 861 were allocated to risk-based recall and 863 were allocated to 6-month recall. In total, 1078 participants received a risk-based recall and 1078 received a 6-month recall. Half of all participants (1188) were recruited from Scotland, 1031 were recruited from England and Wales (43%) and 153 were recruited from Northern Ireland (7%).

Description of the groups at trial entry

Participant characteristics

Sociodemographic factors and dental characteristics

Participants and sociodemographic characteristics are shown in *Table 6*. The average age of participants was 45 years (participants in the eligible for 24-month recall stratum were younger, on average by around 4 years, than those ineligible for 24-month recall); the majority were women (around 55%) and regular attenders, although there was a difference between the eligible for 24-month recall stratum (around 74% self-reported having been to the dentist in the last year) and the ineligible stratum (around 86% had been to the dentist in the last year). Approximately 15% of participants self-identified as smokers in the last 12 months. Fifty-five per cent of the participants used manual dental brushes. Participants found it easy to travel to the dentist (on average scoring 6 out of 7, where 7 is the easiest to travel). Randomised groups were balanced on the sociodemographic factors and dental characteristics collected.

Participants' dental behaviour at baseline

Most participants (around 70%) brushed twice a day or more often and believed that this is what they should do (around 86%). Around 56% of the participants reported taking 2 minutes or longer to brush. Around one-quarter of the participants reported that they spit but do not rinse, and one-third reported that they believed that is what they should do (*Table 7*).

TABLE 6 Participant characteristics at baseline by randomised group

Participant characteristic	Eligible for 24-month recall			Ineligible for 24-month recall	
	Risk based	24 month	6 month	Risk based	6 month
Randomised, *n* (%)	217 (100.0)	216 (100.0)	215 (100.0)	861 (100.0)	863 (100.0)
Baseline questionnaire returned, *n* (%)	181 (83.4)	186 (86.1)	187 (87.0)	810 (94.1)	803 (93.0)
Age (years), mean (SD), *n*	43.3 (15.1), 217	44.2 (15.2), 216	43.5 (14.5), 215	49.3 (14.1), 861	50.1 (15.3), 863
Gender, *n* (%)					
Male	87 (40.1)	100 (46.3)	94 (43.7)	356 (41.3)	366 (42.4)
Female	128 (59.0)	115 (53.2)	121 (56.3)	498 (57.8)	491 (56.9)
Missing	2 (0.9)	1 (0.5)	0 (0.0)	7 (0.8)	6 (0.7)
Smoking status, *n* (%)					
Smoked in the last 12 months	32 (14.7)	27 (12.5)	32 (14.9)	145 (16.8)	130 (15.1)
Missing	38 (17.5)	32 (14.8)	30 (14.0)	53 (6.2)	69 (8.0)
Time since previous visit to dentist, *n* (%)					
< 1 year	165 (76.0)	157 (72.7)	165 (76.7)	737 (85.6)	741 (85.9)
1–2 years	13 (6.0)	24 (11.1)	16 (7.4)	62 (7.2)	51 (5.9)
> 2 years	1 (0.5)	4 (1.9)	4 (1.9)	4 (0.5)	0 (0.0)
Missing	38 (17.5)	31 (14.4)	30 (14.0)	58 (6.7)	71 (8.2)
Patient status, *n* (%)					
NHS	152 (70.0)	154 (71.3)	155 (72.1)	695 (80.7)	677 (78.4)
Private	8 (3.7)	12 (5.6)	7 (3.3)	33 (3.8)	32 (3.7)
Combination	12 (5.5)	8 (3.7)	14 (6.5)	54 (6.3)	56 (6.5)
Missing	45 (20.7)	42 (19.4)	39 (18.1)	79 (9.2)	98 (11.4)
Type of toothbrush, *n* (%)					
Manual	114 (52.5)	131 (60.6)	113 (52.6)	489 (56.8)	496 (57.5)
Electric	64 (29.5)	53 (24.5)	74 (34.4)	318 (36.9)	298 (34.5)
Missing	39 (18.0)	32 (14.8)	28 (13.0)	54 (6.3)	69 (8.0)
Regular attender: self-report	158 (72.8)	163 (75.5)	168 (78.1)	740 (85.9)	735 (85.2)
Missing	39 (18.0)	31 (14.4)	28 (13.0)	60 (7.0)	71 (8.2)
Difficulty travelling to dentist, mean (SD), *n*	6.4 (1.2), 179	6.5 (1.2), 186	6.4 (1.2), 186	6.4 (1.2), 805	6.3 (1.2), 791

Patients' reported outcomes

The baseline patient-reported outcomes summary is shown in *Table 8*. More details about individual questions that produced the scales are given in *Appendix 1*, *Table 26*. OHIP-14 score, the patient-reported primary outcome, was, on average, low, indicating good OHRQoL in both strata. OHIP-14 was around 4.5 in the eligible for 24-month recall stratum and 5.9 in the ineligible stratum, on a scale that goes up to 56 for worst quality of life. Participants were, in general, satisfied with their dental services

TABLE 7 Participants' oral health-related behaviour at baseline by randomised group

	Eligible for 24-month recall			Ineligible for 24-month recall	
Oral health-related behaviour	Risk based	24 month	6 month	Risk based	6 month
Frequency of brushing*, n *(%)					
Less than once per day	0 (0.0)	1 (0.5)	5 (2.3)	9 (1.0)	11 (1.3)
Once per day	33 (15.2)	42 (19.4)	42 (19.5)	151 (17.5)	116 (13.4)
Twice per day	123 (56.7)	128 (59.3)	132 (61.4)	560 (65.0)	587 (68.0)
More than twice per day	23 (10.6)	15 (6.9)	8 (3.7)	82 (9.5)	80 (9.3)
Missing	38 (17.5)	30 (13.9)	28 (13.0)	59 (6.9)	69 (8.0)
Duration of brushing*, n *(%)					
< 1 minute	9 (4.1)	3 (1.4)	10 (4.7)	24 (2.8)	25 (2.9)
1 to 2 minutes	56 (25.8)	55 (25.5)	62 (28.8)	252 (29.3)	254 (29.4)
2 minutes	87 (40.1)	99 (45.8)	79 (36.7)	362 (42.0)	383 (44.4)
> 2 minutes	26 (12.0)	29 (13.4)	36 (16.7)	163 (18.9)	132 (15.3)
Missing	39 (18.0)	30 (13.9)	28 (13.0)	60 (7.0)	69 (8.0)
After brushing*, n *(%)					
Rinse with water	78 (35.9)	100 (46.3)	97 (45.1)	432 (50.2)	435 (50.4)
Rinse with mouthwash	37 (17.1)	33 (15.3)	26 (12.1)	154 (17.9)	165 (19.1)
Spit not rinse	64 (29.5)	53 (24.5)	64 (29.8)	213 (24.7)	190 (22.0)
Missing	38 (17.5)	30 (13.9)	28 (13.0)	62 (7.2)	73 (8.5)

TABLE 8 Patient-reported outcomes at baseline by randomised group

	Eligible for 24-month recall, mean (SD), *n*			Ineligible for 24-month recalll, mean (SD), *n*	
Patient-reported outcome	Risk based	24 month	6 month	Risk based	6 month
Attitude (score from 1 to 7)	4.2 (0.8), 178	4.3 (0.9), 186	4.1 (0.7), 187	4.1 (0.9), 806	4.0 (0.9), 795
Satisfaction (score from 1 to 7)	5.2 (0.8), 147	5.2 (0.8), 153	5.2 (0.7), 158	5.3 (0.6), 703	5.3 (0.6), 701
OHIP-14 (score from 0 to 56)	4.5 (7.0), 175	4.7 (6.4), 183	4.4 (6.1), 182	5.8 (6.9), 778	6.1 (7.7), 778
Overall anxiety (score from 5 to 25)	10.4 (4.6), 176	10.7 (4.4), 186	10.5 (4.5), 185	10.2 (4.5), 801	10.1 (4.5), 798

(giving, on average, a score of 5 out of 7 on the satisfaction scale, where 7 is maximum satisfaction with the service). Their anxiety was on average around 10 points, on a scale ranging from 5 to 25, where 25 is the maximum anxiety.

Baseline overview

Overall, participants in the ineligible for 24-month recall stratum were older, self-reported to attend the dentist more regularly and had higher OHIP-14 scores than those in the eligible stratum. Participants were, in general, satisfied with the dental services received and had low dental anxiety and a good knowledge about the frequency and duration of brushing; however, they were less informed about what to do after brushing (i.e. spit, but not rinse). There were no important differences or imbalances across randomised groups in each of the eligibility strata. *Appendix 1*, *Tables 29–37*, display all baseline tables

by country: Scotland, England and Northern Ireland. Average age is similar across countries, as is the proportion of regular smokers. The percentage of regular attenders was higher in Scotland than in England in the stratum eligible for the 24-month recall (85% vs. 70%). Around 80% of the participants in Scotland reported that they were fully NHS; in England, around 72% of patients eligible for a 24-month recall were fully NHS, as were 80% of patients in the ineligible for a 24-month recall stratum. In Northern Ireland, around one-third of patients in the eligible for a 24-month recall stratum were fully NHS, as were 65% of the ineligible patients. Patient-reported outcomes and behaviour and knowledge questions produced similar results across countries, except for 'What do you do after brushing?' or 'What should you do after brushing?' (i.e. spit, not rinse). In Scotland, around 35% of participants spit but do not rinse and around 45% of participants know that this should be the case. In England, around 14% of participants reported that they spit but do not rinse and around 16% of participants said that they know that this should be the case. In Northern Ireland, around 16% of participants in the eligible for 24-month recall stratum spit but do not rinse or think that they should do that whereas in the ineligible stratum this value is around 50% for both questions.

Trial follow-up

Description of the intervention

Using routine data from Scotland, England and Northern Ireland, the number of routine check-ups reported during the trial is presented in *Table 9*. Participants eligible for 24-month recall, and who had a clinical outcome assessment, had on average 3.7 check-ups in the risk-based group, 2.5 in the 24-month recall group and 5.1 in the 6-month recall group. Participants who were ineligible for the 24-month recall, and who had a clinical outcome assessment, had 5.0 check-ups on average during the trial in the risk-based group and 5.4 check-ups in the 6-month group.

Once a participant had been randomised, dentists were asked to record the date of their first intended appointment, which took account of any expected course of treatment. Participants in the eligible for 24-month recall stratum were assigned recall appointments that were intended to be at, on average, 13 months (risk-based recall), 24 months (24-month recall) and 7 months (6-month recall). Participants in the ineligible for 24-month recall stratum were advised by clinicians to wait 9 months until their first appointment if in the risk-based group and 8.5 months if in the 6-month recall group. *Appendix 1*, *Tables 38–40*, presents the description of the intervention by country. Participants from England and Northern Ireland had, on average, more check-ups than Scottish participants, but the discrepancy between randomised groups was similar across countries.

TABLE 9 Description of the intervention (from participants with a clinical follow-up)

	Eligible for 24-month recall			Ineligible for 24-month recall	
Intervention	Risk based ($n = 137$)	24 month ($n = 128$)	6 month ($n = 128$)	Risk based ($n = 582$)	6 month ($n = 578$)
Check-ups received					
0	1 (0.7)	8 (5.8)	0 (0.0)	1 (0.2)	0 (0.0)
1	15 (10.5)	50 (36.2)	7 (5.2)	14 (2.3)	7 (1.2)
2	27 (18.9)	22 (15.9)	9 (6.7)	44 (7.3)	30 (5.0)
3 or more	94 (65.7)	48 (34.8)	112 (83.0)	523 (86.3)	541 (89.9)
Missing	6 (4.2)	10 (7.2)	7 (5.2)	24 (4.0)	24 (4.0)
Number of check-ups, mean (SD), *n*	3.7 (1.9), 137	2.5 (2.2), 128	5.1 (3.7), 128	5.0 (2.3), 582	5.4 (2.0), 578

Overall, there was a clear difference in terms of number of check-ups received between the different randomised groups in the eligible for 24-month recall stratum. The number of check-ups received in the risk-based and 6-month recall was similar in the ineligible for 24-month recall stratum: there was a higher number of check-ups in the risk-based group of the ineligible stratum than of the eligible stratum. In terms of clinicians' intentions at the beginning of the trial, there is a similar pattern on the PAD forms: a clear separation in time between randomisation and first intended appointment between randomised groups. However, participants ineligible for a 24-month recall had a similar interval between randomisation and first intended appointment across the different groups.

Attendance at 4-year clinical examination and questionnaire returns

The primary clinical outcome was collected at the 4-year clinical follow-up. Overall, around 64% and 71% of the participants attended their appointment and replied to the year 4 questionnaire, respectively, in the eligible for 24-month recall stratum. In the ineligible stratum, 70% of participants attended the clinical appointment and 76% replied to the year 4 questionnaire (*Table 10*). For most participants (around 89% of the participants randomised), reasons for non-attendance were unknown. When a reason was obtained from the practices, the most common reason for non-attendance was inability to contact the patient (around 9%). This finding was similar across groups and in both strata. The mean follow-up time was 122 months with a SD of 6.2 months. Approximately 71% of participants in the eligible for 24-month recall stratum and 76% of participants in the ineligible for 24-month recall stratum returned their year 4 questionnaire.

Participants' characteristics at 4 years

Participants' characteristics at 4 years are shown in *Table 11*. A lower percentage of participants reported smoking in the last 12 months at year 4 than at baseline (12% vs. 15% approximately). The majority of participants stated that they had been to dentist in the last year (around 90%); however, there were important differences between groups. The group randomised to 24-month recall had a lower percentage of participants that reported that they had attended in the last year (76%) and a significantly higher percentage of participants reporting that the time since their previous visit was between 1 and 2 years. Around the same percentage of participants across groups reported that they used the NHS (70%) and used a manual toothbrush (50%). Most of the participants reported to be regular attenders across the groups with similar percentages in the 6-month recall groups for both strata and in the risk-based group in the ineligible stratum (around 90%). Around 84% of the participants in the risk-based group eligible for a 24-month recall and in the 24-month recall stratum reported the same. Participants, overall, found travelling to the dentist easy and with similar scores to baseline (6 out of 7 on a Likert scale, where 7 is the easiest to travel). Participant characteristics at years 1, 2 and 3 are presented in *Appendix 1*, *Tables 41–43*. Participant behaviour and knowledge related to oral health at years 1, 2, 3 and 4 are presented in *Appendix 1*, *Tables 44–47*.

TABLE 10 Attendance rates

	Eligible for 24-month recall, *n* (%)			Ineligible for 24-month recall, *n* (%)	
Time point	Risk based (*N* = 217)	24 month (*N* = 215)	6 month (*N* = 216)	Risk based (*N* = 861)	6 month (*N* = 863)
Attended clinical follow-up	143 (65.9)	138 (63.9)	135 (62.8)	606 (70.4)	602 (69.8)
Baseline	181 (83.4)	186 (86.1)	187 (87.0)	810 (94.1)	803 (93.0)
Year 1	145 (66.8)	155 (71.8)	152 (70.7)	638 (74.1)	640 (74.2)
Year 2	135 (62.2)	144 (66.7)	142 (66.0)	610 (70.8)	619 (71.7)
Year 3	134 (61.8)	131 (60.6)	134 (62.3)	571 (66.3)	584 (67.7)
Year 4	151 (69.6)	153 (70.8)	156 (72.6)	650 (75.5)	655 (75.9)

TABLE 11 Participant characteristics at year 4 by randomised group

Participant characteristic	Eligible for 24-month recall			Ineligible for 24-month recall	
	Risk based	24 month	6 month	Risk based	6 month
Number randomised	217	215	216	861	863
Replied to year 4 questionnaire	151 (100.0)	153 (100.0)	156 (100.0)	650 (100.0)	655 (100.0)
Smoked in the last 12 months	18 (11.9)	18 (11.8)	19 (12.2)	86 (13.2)	74 (11.3)
Missing	1 (0.7)	0 (0.0)	1 (0.6)	6 (0.9)	5 (0.8)
Time since previous visit to dentist					
< 1 year	130 (86.1)	116 (75.8)	143 (91.7)	604 (92.9)	621 (94.8)
1–2 years	19 (12.6)	32 (20.9)	8 (5.1)	33 (5.1)	28 (4.3)
> 2 years	2 (1.3)	4 (2.6)	3 (1.9)	5 (0.8)	2 (0.3)
Missing	0 (0)	1 (0.7)	2 (1.3)	8 (1.2)	4 (0.6)
Patient status					
NHS	104 (68.9)	94 (61.4)	105 (67.3)	460 (70.8)	469 (71.6)
Private	8 (5.3)	5 (3.3)	3 (1.9)	17 (2.6)	22 (3.4)
Combination	16 (10.6)	16 (10.5)	23 (14.7)	92 (14.2)	92 (14.0)
Missing	23 (15.2)	38 (24.8)	25 (16.0)	81 (12.5)	72 (11.0)
Type of toothbrush					
Manual	72 (47.7)	86 (56.2)	82 (52.6)	328 (50.5)	339 (51.8)
Electric	73 (48.3)	54 (35.3)	69 (44.2)	275 (42.3)	274 (41.8)
Both	6 (4.0)	13 (8.5)	4 (2.6)	42 (6.5)	36 (5.5)
Missing	0 (0.0)	0 (0.0)	1 (0.6)	5 (0.8)	6 (0.9)
Regular attender: self-report	128 (84.8)	127 (83.0)	142 (91.0)	612 (94.2)	614 (93.7)
Missing	0 (0.0)	1 (0.7)	1 (0.6)	7 (1.1)	5 (0.8)
Difficulty travelling to dentist, mean (SD), *n*	6.2 (1.4), 151	6.4 (1.1), 151	6.3 (1.2), 154	6.3 (1.3), 644	6.3 (1.3), 646

Clinical outcomes

Table 12 summarises the clinical outcomes mean per stratum and per randomised group. On average, participants had 34% of sites bleeding and 37% of surfaces with calculus across the randomised groups in both the eligible and the ineligible stratum. The average number of teeth was around 24. Moderate lesions were the most serious carious lesion found in about 65% of the participants. The ineligible stratum had a slightly higher percentage of participants with extensive caries (14%) than the eligible stratum (18%). Around 15–23% of participants had root caries. Around half of the participants presented generalised gingivitis according to the 2017 World Workshop on the Classification of Periodontal and Peri-implant Diseases.[119] In *Appendix 1*, *Table 48* presents the same clinical outcomes combining risk-based and 6-monthly groups from the eligible and ineligible strata.

Statistical analyses

Primary clinical outcome (gingival bleeding)

The treatment effects for the primary clinical outcome and secondary outcomes can be found in *Table 13*. Three treatment comparisons are presented for the eligible for 24-month recall stratum: 24-month recall versus 6-month recall; risk-based recall versus 6-month recall and 24-month recall versus risk-based recall.

TABLE 12 Clinical measures at 4 years by eligibility stratum and randomised group

	Eligible for 24-month recall			Ineligible for 24-month recall	
Clinical outcomes	**Risk based**	**24 month**	**6 month**	**Risk based**	**6 month**
Attended clinical follow-up, *n*	143	138	135	606	602
***Primary clinical outcome, mean (SD),* n**					
Gingival bleeding: mean percentage of sites bleeding	35.6 (19.1), 142	34.4 (20.1), 137	35.6 (21.7), 134	33.4 (22.2), 599	32.8 (22.1), 597
***Secondary clinical outcomes, mean (SD),* n**					
Calculus: mean proportion of surfaces with calculus	34.1 (26.0), 142	38.2 (28.3), 138	37.4 (24.9), 133	37.3 (27.8), 604	38.0 (27.8), 600
Mean pocket depth (mm)	2.2 (0.5), 142	2.1 (0.3), 137	2.1 (0.4), 133	2.2 (0.4), 594	2.2 (0.4), 594
Number of teeth	24.2 (4.8), 143	24.0 (4.5), 138	24.8 (4.0), 135	23.9 (4.6), 606	23.3 (5.2), 602
Most advanced carious lesion per person,* n *(%)					
Sound surfaces (ICDAS 0)	1 (0.7)	1 (0.7)	0 (0.0)	3 (0.5)	8 (1.3)
Initial lesions (ICDAS 1–2)	22 (15.4)	28 (20.3)	33 (24.4)	100 (16.5)	107 (17.8)
Moderate lesions (ICDAS 3–4)	98 (68.5)	87 (63.0)	87 (64.4)	393 (64.9)	376 (2.5)
Extensive caries or treatment needed (ICDAS 5–6)	20 (14.0)	22 (15.9)	13 (9.6)	110 (18.2)	107 (17.8)
Missing	2 (1.4)	0 (0.0)	2 (1.5)	0 (0.0)	4 (0.7)
***Mean number of surfaces with caries, mean (SD),* n**					
Any caries	15.5 (9.8), 143	14.1 (7.9), 138	14.7 (8.4), 135	14.7 (8.9), 606	14.7 (9.2), 602
Initial lesions	12.4 (8.8), 143	11.7 (7.4), 138	12.4 (7.5), 135	11.2 (7.5), 606	11.3 (7.8), 602
Moderate lesions	2.8 (2.5), 143	2.1 (1.9), 138	2.2 (2.2), 135	3.1 (3.1), 606	3.0 (3.0), 602
Extensive caries or treatment needed	0.30 (0.9), 143	0.28 (0.85), 138	0.16 (0.60), 135	0.43 (1.5), 606	0.36 (1.3), 602
Root caries,* n *(%)					
Yes	26 (18.2)	21 (15.2)	17 (12.6)	121 (20.0)	137 (22.8)
No	99 (69.2)	101 (73.2)	99 (73.3)	417 (68.8)	390 (64.8)
Missing	18 (12.6)	16 (11.6)	19 (14.1)	68 (11.2)	75 (12.5)
Gingivitis severity,*[a] n *(%)					
No gingivitis (< 10% sites bleeding)	10 (7.0)	14 (10.1)	18 (13.3)	100 (16.5)	96 (15.9)
Localised gingivitis (10–30% sites bleeding)	58 (40.9)	50 (36.5)	42 (31.3)	183 (30.2)	201 (33.4)
Generalised gingivitis (more than 30% sites bleeding)	74 (52.1)	73 (53.3)	74 (55.2)	316 (52.1)	300 (49.8)
Missing	1 (0.7)	1 (0.7)	1 (0.7)	7 (1.2)	5 (0.8)

a Gingivitis severity classified using the 2017 World Workshop on the Classification of Periodontal and Peri-implant Diseases and Conditions.[119]

Values are mean (SD), *n*, unless indicated otherwise.

TABLE 13 Treatment effects for clinical outcomes

Outcome	Comparison	Effect size (95% CI); *p*-value
Eligible for 24-month recall stratum		
Primary clinical outcome		
Gingival bleeding: mean percentage of sites bleeding	24 month vs. 6 month	−0.91 (−5.02 to 3.20); 0.66
	Risk based vs. 6 month	−0.98 (−5.05 to 3.09); 0.64
	24 month vs. risk based	0.07 (−3.99 to 4.12); 0.97
Secondary clinical outcomes		
Calculus: mean proportion of surfaces with calculus	24 month vs. 6 month	0.19 (−5.46 to 5.83); 0.95
	Risk based vs. 6 month	−2.92 (−8.52 to 2.67); 0.31
	24 month vs. risk based	3.11 (−2.45 to 8.67); 0.27
Mean pocket depth (mm)	24 month vs. 6 month	−0.03 (−0.12 to 0.06); 0.51
	Risk based vs. 6 month	0.07 (−0.02 to 0.15); 0.14
	24 month vs. risk based	−0.10 (−0.18 to −0.01); 0.03
Most serious level of caries found per person	Risk based vs. 6 month	1.58 (0.96 to 2.62); 0.07
	24 month vs. 6 month	1.38 (0.83 to 2.29); 0.22
	24 month vs. risk based	0.87 (0.53 to 1.44); 0.59
Root caries	24 month vs. risk based	0.86 (0.40 to 1.83); 0.70
	Risk based vs. 6 month	1.69 (0.75 to 3.78); 0.20
	24 month vs. 6 month	1.45 (0.64 to 3.32); 0.37
Overall sample (eligible and ineligible for 24-month recall stratum)		
Primary clinical outcome		
Gingival bleeding: mean percentage of sites bleeding	Risk based vs. 6 month	0.78 (−1.17 to 2.72); 0.43
Secondary clinical outcomes		
Calculus: mean proportion of surfaces with calculus	Risk based vs. 6 month	−1.30 (−3.68 to 1.08); 0.29
Mean pocket depth (mm)	Risk based vs. 6 month	0.03 (−0.01 to 0.07); 0.14
Most serious level of caries found per person	Risk based vs. 6 month	1.18 (0.96 to 1.46); 0.12
Root caries	Risk based vs. 6 month	0.86 (0.64 to 1.14); 0.29

Notes
Effect size represents mean difference for continuous outcomes and odds ratio for categorical or binary outcomes (most serious level of caries found per person; root caries). The odds ratio interpretation is for a one unit increase in the outcome (e.g. most serious level of caries), the odds for cases in a group that is $> x$ vs. $\leq x$ are the proportional odds times larger. For example, when comparing risk-based recall with 6-month recall for the overall sample (both strata), the proportional odds ratio is 1.18. That means that the odds of having extensive caries vs. having the combined initial and medium lesions are 1.18 times higher in the risk-based group than in the 6-month recall group. The models are adjusted for protocol minimisation variables and have a random effect for centre.

For the primary outcome, the adjusted difference between interventions was < 1% and the CIs excluded the possibility of a 7.5% difference between groups. There was no evidence of a significant difference between the groups in any comparison: the 24-month group versus 6-month group had an adjusted mean difference of −0.91 (95% CI −5.02 to 3.20; *p*-value = 0.66); the risk-based versus 6-month recall had an adjusted difference of −0.98 (95% CI −5.05 to 3.09; *p*-value = 0.64); and the 24-month versus risk-based recall had an adjusted mean difference of 0.07 (95% CI −3.99 to 4.12; *p*-value = 0.97).
For the overall sample (combining eligible and ineligible strata), one comparison is presented for each outcome: risk-based recall versus 6-month recall. The adjusted mean difference between the groups was 0.78 (95% CI −1.17 to 2.72; *p*-value = 0.43).

Sensitivity analysis

We used multiple imputation for the primary clinical outcome (gingival bleeding). The treatment effects for the eligible for 24-month recall stratum were as follows: 6-month recall versus risk-based recall −0.05 (95% CI −4.9 to 4.8, $p = 0.98$); 24-month recall versus risk-based recall −1.34 (95% CI −5.8 to 3.1, $p = 0.55$); 24-month recall versus 6-month recall −1.3 (95% CI −6.5 to 3.9, $p = 0.62$). For the ineligible for 24-month recall stratum, the treatment effects were as follows: 6-month recall versus risk-based recall 0.57 (95% CI −1.5 to 2.6, $p = 0.58$). The sensitivity analyses did not change the interpretation of the results.

Secondary clinical outcomes

The remaining treatment effects for secondary clinical outcomes are also presented in *Table 13*. There was no evidence of a significant difference between the groups in any comparison in either eligibility stratum. The clinical outcomes are presented by country in *Appendix 1*, *Tables 49–51*.

Patient-reported outcomes at 4 years

Table 14 shows the patient-reported outcomes at 4 years. Participants in the eligible for 24-month recall group had lower OHIP-14 scores than ineligible participants, as observed at baseline. Participants remained positive about dental services, with a high level of satisfaction on average (around 5 out of 7, where 7 represents the maximum satisfaction with the service). Anxiety levels remained similar, and on average around 10 out of 25 on the MDAS, ranging from 5 to 25 (maximum anxiety). Outcomes measured only at 4 years included PBC, attitude, oral health behaviour and knowledge. The first two ranged from 1 to 7 (where 7 means maximum PBC and most positive attitude); participants had, on average, a score of 4.8 for PBC and 4.2 for attitude.

Patient-reported outcomes means and standard errors per year and per stratum are presented in *Figures 7–10*. Overall, the scores remained unchanged during the trial and are similar across groups. Patient-reported outcomes by year and stratum are presented in *Appendix 1*, *Tables 54–56*.

TABLE 14 Patient-reported outcomes at 4 years

	Eligible for 24-month recall			Ineligible for 24-month recall	
Patient-reported outcome	**Risk based**	**24 month**	**6 month**	**Risk based**	**6 month**
***Primary patient-reported outcome, mean (SD),* n**					
OHIP-14 (score 0–56)	4.1 (5.7), 145	4.8 (6.4), 153	4.8 (6.2), 152	5.5 (6.8), 624	5.8 (8.3), 630
***Secondary patient-reported outcomes, mean (SD),* n**					
Satisfaction (score 1–7)	5.2 (0.7), 151	5.0 (0.7), 153	5.1 (0.7), 155	5.3 (0.6), 647	5.2 (0.6), 654
Dental anxiety (score 5–25; MDAS)	10.5 (4.5), 150	10.9 (4.7), 153	11.0 (4.8), 155	10.3 (4.5), 645	10.5 (4.7), 649
Perceived behaviour control (score 1–7)	4.8 (1.4), 149	4.6 (1.4), 153	4.5 (1.5), 155	4.7 (1.5), 647	4.7 (1.4), 654
Attitude (score 1–7)	4.3 (0.9), 151	4.3 (0.9), 153	4.1 (0.8), 155	4.1 (0.9), 647	4.1 (0.8), 654
Behaviour (score 1–9)	5.2 (1.8), 151	4.9 (1.7), 153	5.3 (1.6), 155	5.5 (1.7), 648	5.4 (1.7), 654
Knowledge (score 1–9)	6.5 (1.5), 150	6.6 (1.3), 153	6.8 (1.2), 155	6.6 (1.4), 648	6.7 (1.4), 651
Self-reported bleeding (score 1–5)	2.0 (1.0), 148	2.0 (0.9), 151	2.2 (1.0), 154	2.1 (1.0), 590	2.1 (1.0), 603
EQ-5D-3L utility (score −0.594 to 1)	0.893 (0.208), 145	0.884 (0.209), 151	0.856 (0.268), 157	0.866 (0.230), 637	0.867 (0.237), 645

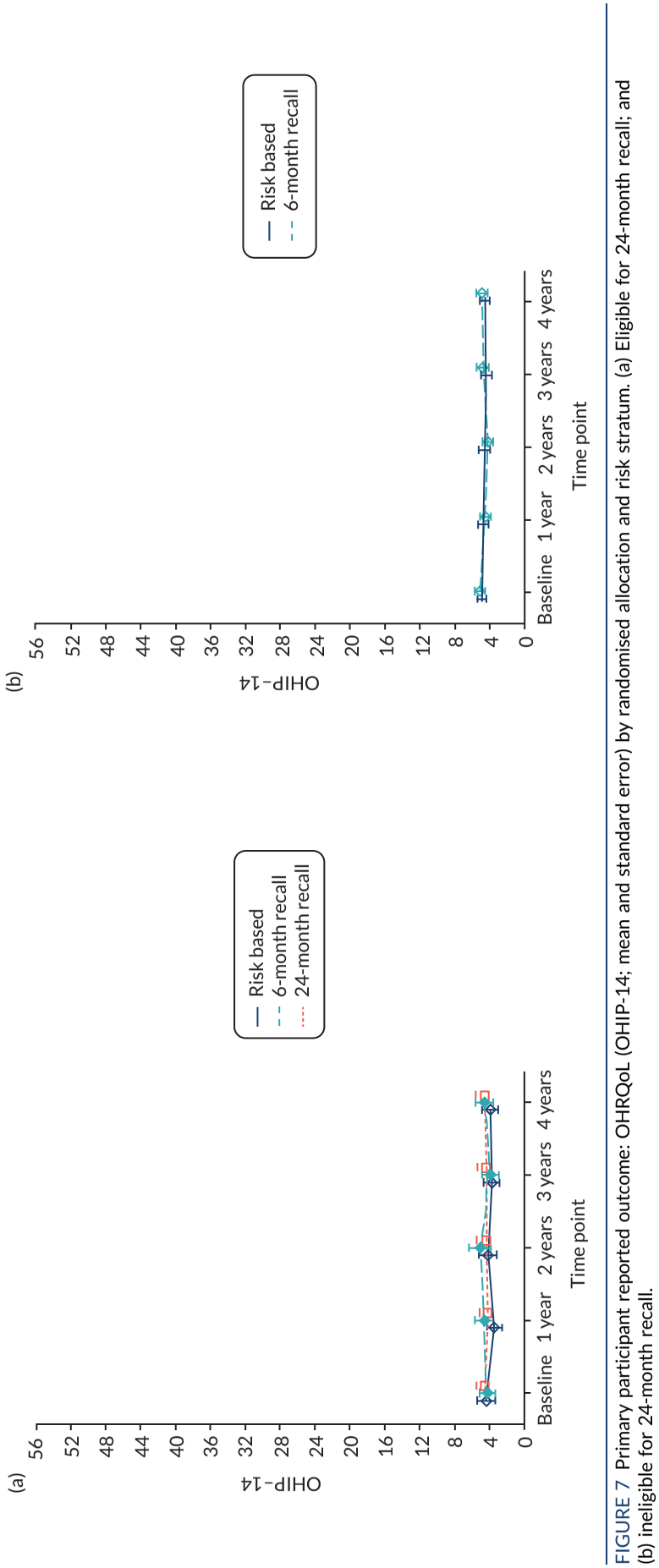


FIGURE 7 Primary participant reported outcome: OHRQoL (OHIP-14; mean and standard error) by randomised allocation and risk stratum. (a) Eligible for 24-month recall; and (b) ineligible for 24-month recall.

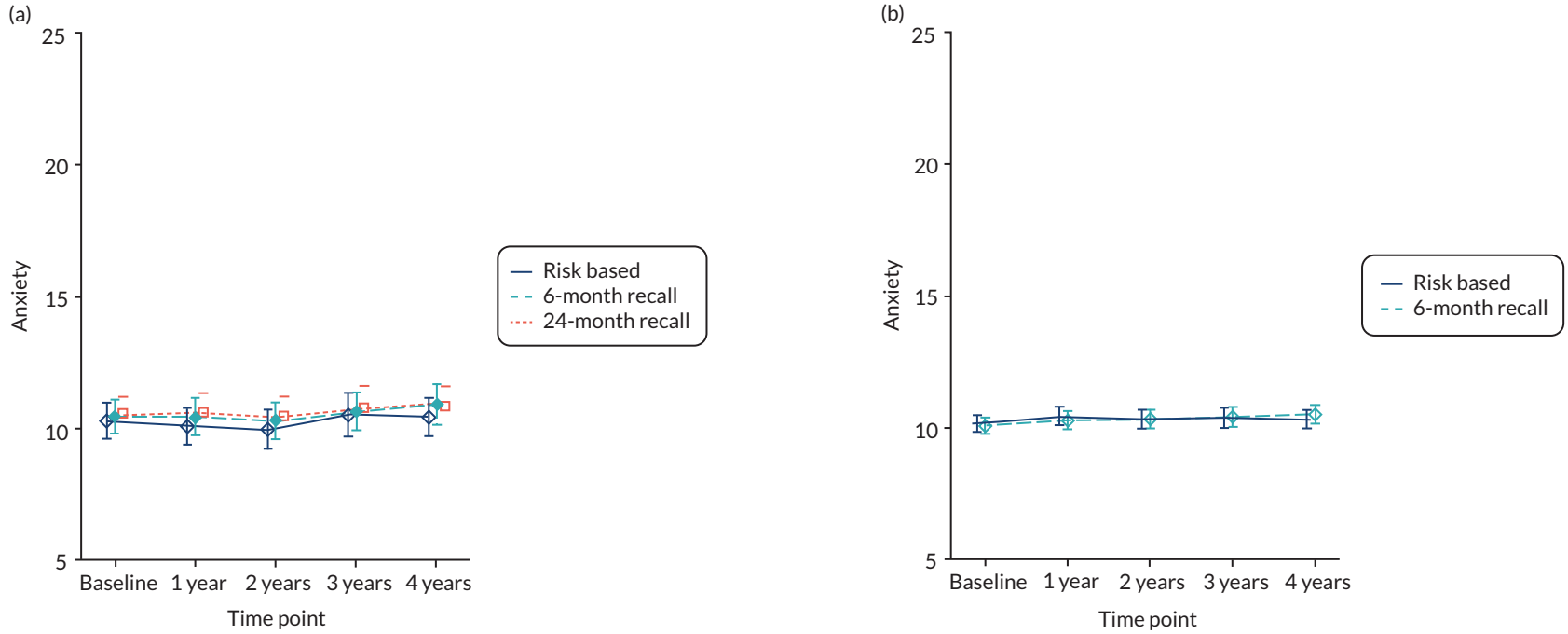


FIGURE 8 Anxiety (mean and standard error) by randomised allocation and risk stratum. (a) Eligible for 24-month recall; and (b) ineligible for 24-month recall.

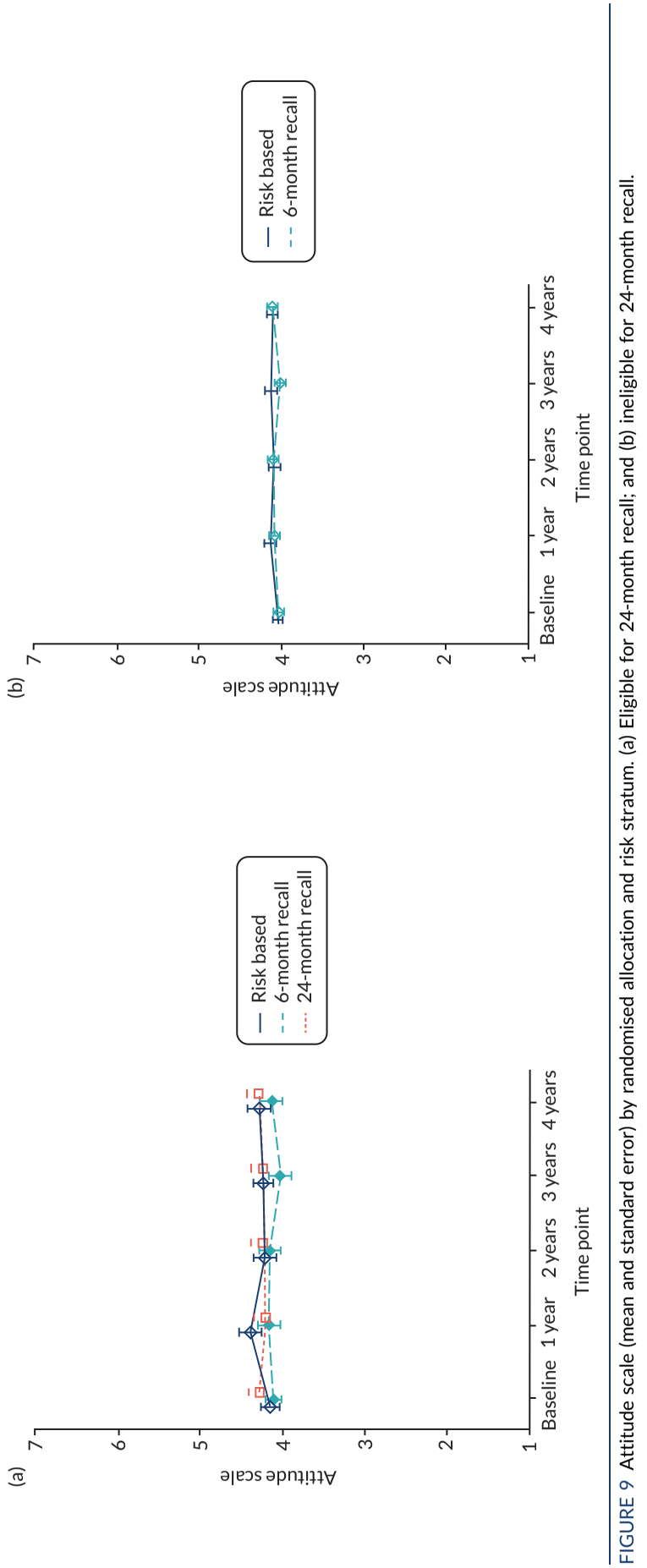


FIGURE 9 Attitude scale (mean and standard error) by randomised allocation and risk stratum. (a) Eligible for 24-month recall; and (b) ineligible for 24-month recall.

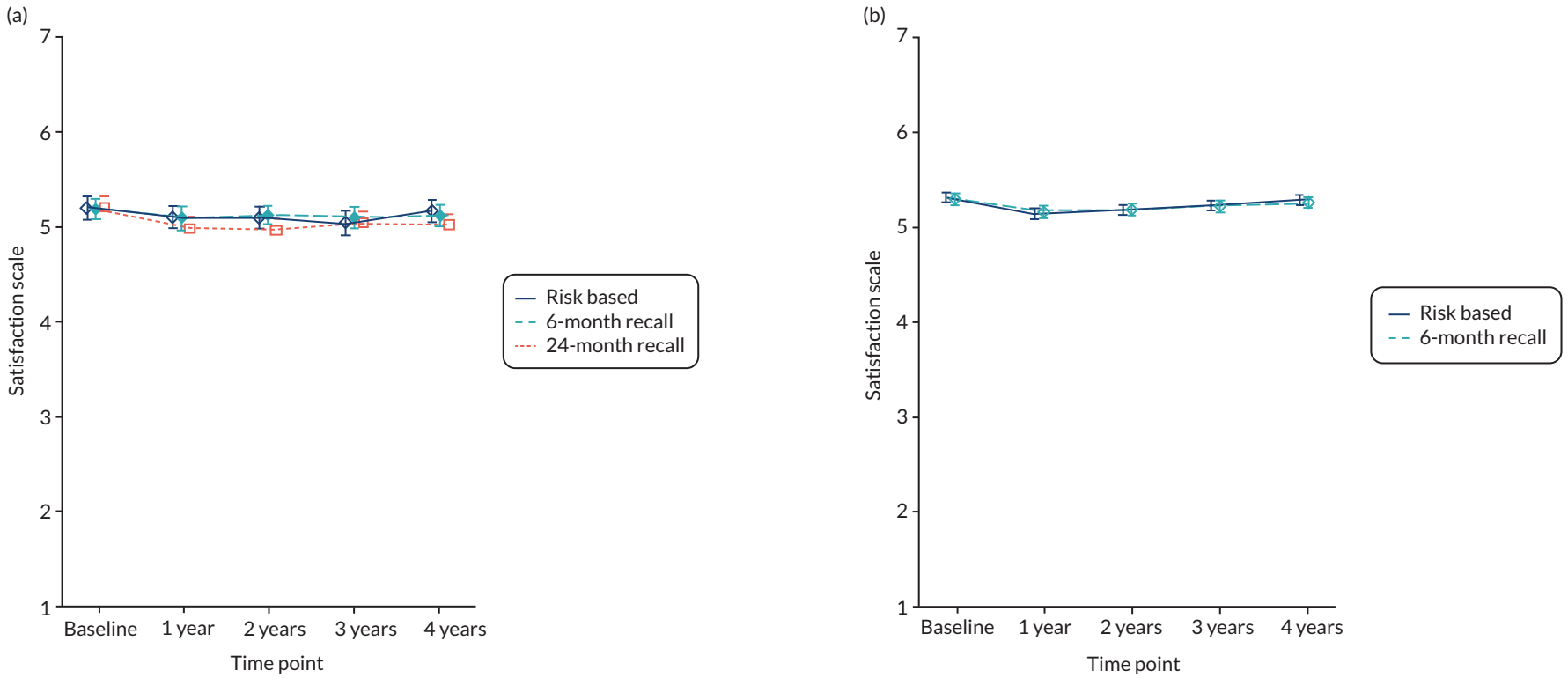


FIGURE 10 Satisfaction scale (mean and standard error) by randomised allocation and risk stratum. (a) Eligible for 24-month recall; and (b) ineligible for 24-month recall.

Statistical analyses of patient-reported outcomes

Table 15 presents the treatment effects for the patient-reported outcomes. There was no evidence of a difference across comparisons for oral health impacts (OHIP-14), the patient-reported primary outcome, with adjusted treatment differences smaller than one-quarter of a SD. Overall, there were no important differences between the groups across all the patient-reported outcomes and in the eligible for 24-month recall stratum and overall samples (eligible and ineligible strata).

TABLE 15 Treatment effects for patient-reported outcomes

Outcome/status	Comparator	Effect size (95% CI); *p*-value
Eligible for 24-month recall stratum		
Primary patient-reported outcome		
OHIP-14	Risk based vs. 6 month	−0.61 (−1.93 to 0.71); 0.37
	24 month vs. 6 month	−0.24 (−1.55 to 1.07); 0.72
	24 month vs. risk based	0.37 (−0.95 to 1.69); 0.58
Secondary patient-reported outcomes		
Anxiety	Risk based vs. 6 month	−0.31 (−1.22 to 0.61); 0.51
	24 month vs. 6 month	0.02 (−0.90 to 0.93); 0.97
	24 month vs. risk based	0.32 (−0.60 to 1.24); 0.49
Attitude	Risk based vs. 6 month	0.15 (−0.03 to 0.32); 0.11
	24 month vs. 6 month	0.17 (−0.01 to 0.35); 0.06
	24 month vs. risk based	0.02 (−0.15 to 0.20); 0.79
Behaviour	Risk based vs. 6 month	0.01 (−0.02 to 0.04); 0.53
	24 month vs. 6 month	0.00 (−0.03 to 0.03); 0.89
	24 month vs. risk based	−0.01 (−0.04 to 0.02); 0.62
Knowledge	Risk based vs. 6 month	−0.03 (−0.06 to 0.01); 0.10
	24 month vs. 6 month	−0.01 (−0.05 to 0.02); 0.42
	24 month vs. risk based	0.01 (−0.02 to 0.05); 0.41
PBC	Risk based vs. 6 month	0.30 (−0.02 to 0.61); 0.06
	24 month vs. 6 month	0.09 (−0.22 to 0.40); 0.59
	24 month vs. risk based	−0.21 (−0.52 to 0.10); 0.19
Satisfaction	Risk based vs. 6 month	0.05 (−0.10 to 0.20); 0.51
	24 month vs. 6 month	−0.11 (−0.26 to 0.04); 0.16
	24 month vs. risk based	−0.16 (−0.31 to −0.01); 0.04
Self-reported bleeding	Risk based vs. 6 month	−0.16 (−0.37 to 0.06); 0.15
	24 month vs. 6 month	−0.22 (−0.43 to −0.01); 0.04
	24 month vs. risk based	−0.06 (−0.28 to 0.15); 0.57
EQ-5D-3L	Risk based vs. 6 month	0.032 (−0.013 to 0.076); 0.165
	24 month vs. 6 month	0.024 (−0.021 to 0.069); 0.290
	24 month vs. risk based	−0.008 (−0.053 to 0.037); 0.741

continued

TABLE 15 Treatment effects for patient-reported outcomes (*continued*)

Outcome/status	Comparator	Effect size (95% CI); *p*-value
Overall sample (eligible and ineligible for 24-month recall)		
Primary patient-reported outcome		
OHIP-14	Risk based vs. 6 month	−0.35 (−1.02 to 0.32); 0.30
Secondary patient-reported outcomes		
Anxiety	Risk based vs. 6 month	−0.11 (−0.52 to 0.29); 0.59
Attitude	Risk based vs. 6 month	0.04 (−0.04 to 0.11); 0.38
Behaviour	Risk based vs. 6 month	0.00 (−0.01 to 0.02); 0.52
Knowledge	Risk based vs. 6 month	−0.01 (−0.03 to 0.00); 0.15
PBC	Risk based vs. 6 month	0.06 (−0.08 to 0.20); 0.38
Satisfaction	Risk based vs. 6 month	0.03 (−0.03 to 0.09); 0.31
Self-reported bleeding	Risk based vs. 6 month	−0.02 (−0.12 to 0.08); 0.72
EQ-5D-3L	Risk based vs. 6 month	0.008 (−0.012 to 0.029); 0.432

Notes
Effect size represents mean difference. The models are adjusted for protocol minimisation variables and have a random effect for centre. For all variables except behaviour, knowledge, PBC and self-reported bleeding, the mixed-effects model also has a random effect for participant and an interaction time*treatment effect. The effect size presented corresponds to the treatment effect at 4 years.

Subgroup analyses

Bleeding on probing outcome

Figures 11 and *12* show the means and 99% CIs for the differences in bleeding at 4 years in the subgroups for recall frequency and strata, respectively. There was no evidence of treatment heterogeneity by age category or by payment for treatment at the 1% level (see *Appendix 1*, *Table 52*). There was also no evidence of treatment heterogeneity for country in the overall sample (eligible for 24-month recall stratum and ineligible for 24-month recall stratum); however, in the eligible for a 24-month recall stratum, participants in England who were randomised to a 6-month recall showed a significant improvement compared with those randomised to a risk-based recall (mean difference 4.98, 95% CI 1.14 to 8.83; $p < 0.001$).

Caries outcome (post hoc subgroup analyses)

Figures 13 and *14* show the odds ratios and 99% CIs for caries at 4 years, comparing by recall frequency and by stratum. For this purpose, caries were grouped into two categories: sound surfaces/initial lesions ($n = 303$) versus moderate or serious lesions ($n = 1313$). There was no evidence of treatment heterogeneity by age category, country or payment for treatment at the 1% level; in the overall sample in England, patients randomised to 6-month recall were less likely to have serious carious lesions than those randomised to risk-based recall (odds ratio 1.66, 95% CI 0.98 to 2.81; $p = 0.01$). Interaction coefficients are shown in *Appendix 1*, *Table 53*.

Service providers' measures

Baseline

Table 16 provides dentists' and practices' characteristics at baseline, for dentists who replied to both the baseline questionnaire and the follow-up questionnaire (out of the 68 responders, 49 replied to both questionnaires, 16 to the baseline questionnaire only and three to the follow-up questionnaire only). Most practices had one dentist responding. About 55% of the respondents were male, had a

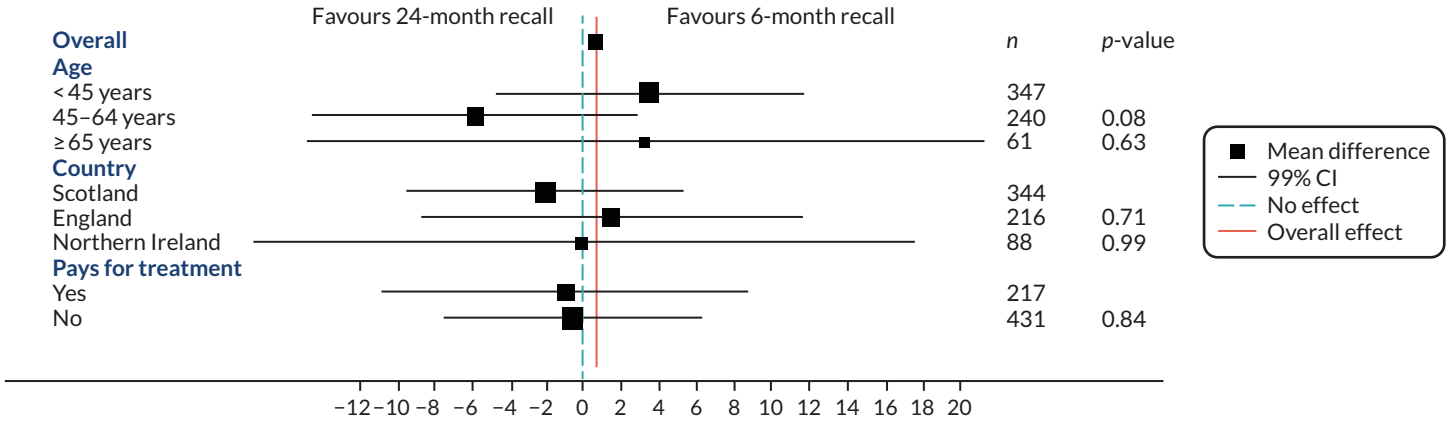


FIGURE 11 Subgroup results for recall allocation in the eligible for 24-month recall stratum for bleeding on probing: difference between arms by subgroup.

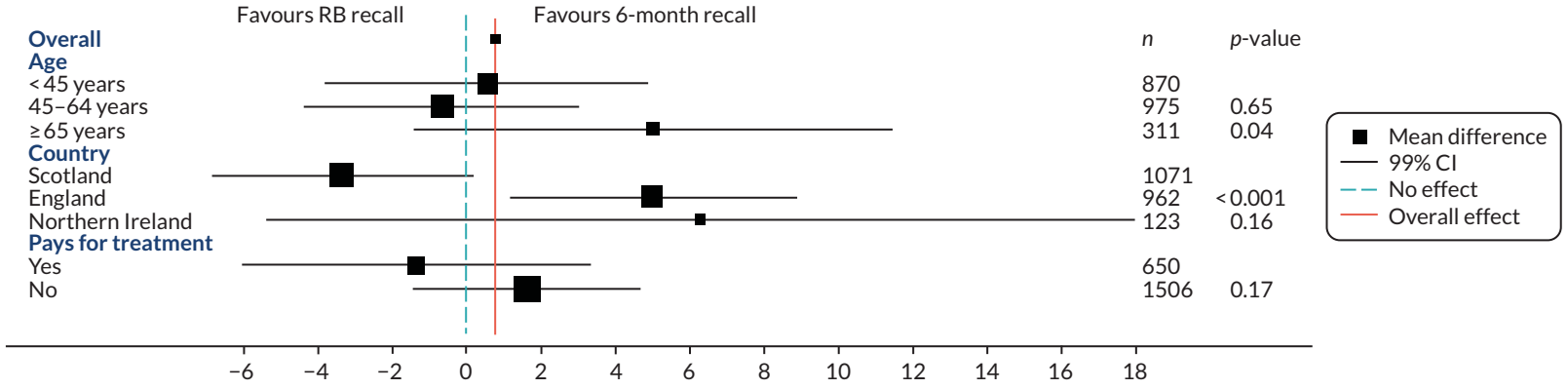


FIGURE 12 Subgroup results for recall allocation in the overall sample (eligible and ineligible strata) for bleeding on probing: difference between arms by subgroup. RB, risk-based.

FIGURE 13 Subgroup results for recall allocation in the eligible for 24-month recall stratum for caries: odds ratio by subgroup (CIs with cap have been truncated to fit the plot). RB, risk based.

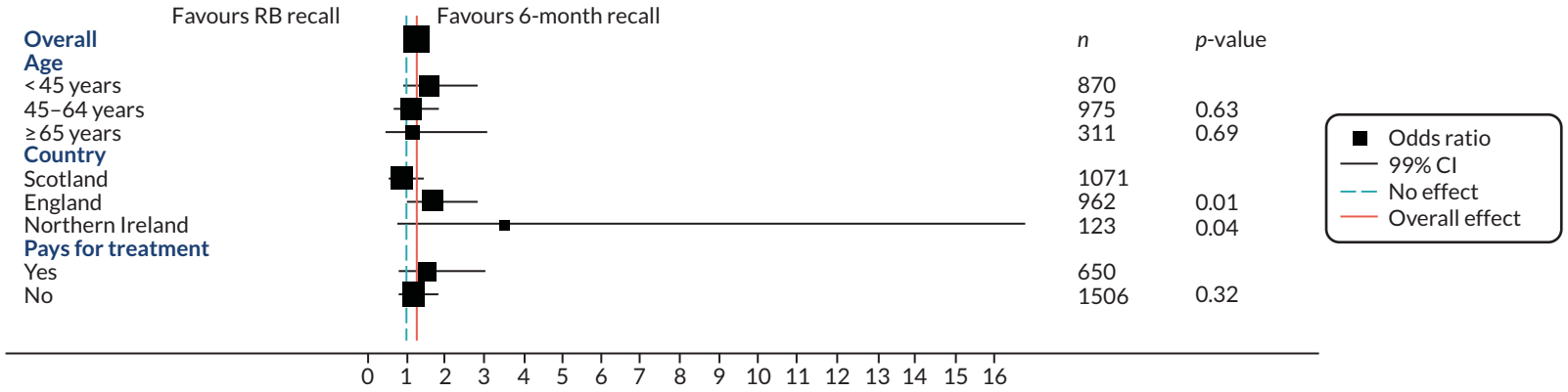


FIGURE 14 Subgroup results for recall allocation in the overall sample (eligible and ineligible strata) for caries: odds ratio by subgroup. RB, risk based.

TABLE 16 Dentists'/practices' characteristics at baseline

Characteristic	Median (percentile 25 – percentile 75), count or *n* (%)
Number of dentist respondents	49
Gender	
Male	27 (55.1)
Female	21 (42.9)
Missing	1 (2.0)
How long have you been qualified as a dentist?	16.0 (10.0–23.0), 49
Within this practice are you	
Principal/practice owner	34 (69.4)
Associate	10 (20.4)
Other	5 (10.2)
What is your approximate total practice list size?	5000.0 (2400.0–8000.0), 41
Do you consider your practice to be rural/remote?	
Yes	5 (10.2)
No	42 (85.7)
Missing	2 (4.1)
How many other members of the dental team in the practice are dentists?	3.0 (2.0–4.0), 46
How many other members of the dental team in the practice are nurses?	5.0 (3.0–6.0), 46
How many other members of the dental team in the practice are hygienists?	1.0 (0.0–1.0), 25
Is your practice	
NHS patients only	16 (32.7)
Mixture of NHS and private	32 (65.3)
Missing	1 (2.0)
Before this study, how did you usually set your patient recall appointments?	
Routinely, every 6 months	29 (59.2)
Other	15 (30.6)
Missing	5 (10.2)

median of 16 years being qualified as a dentist and 69% were principal dentists or practice owners. The median practice list size was 5000 with considerable variability. Most of the dentists considered their practices to be non-rural (86%). There was a median of three other dentists working in the practice and five nurses. Most of the practices had a mixture of NHS and private patients (65%).

Follow-up

Table 17 presents dentists' beliefs at baseline and at follow-up, and their change from baseline. Dentists' attitudes regarding a 24-month recall improved, as did their attitude regarding a 6-month recall. Overall, their general attitude about the patients' ability to assess risk and perceived ability to assess risk decreased from baseline. However, dentists who deemed at least one patient eligible for the 24-month recall ($n = 40$) increased slightly in their perceived ability to judge risk, whereas those who did not consider any patient eligible for a 24-month recall ($n = 6$) decreased their perceived ability. *Appendix 1*, *Table 57*, presents more details about dentists' beliefs by whether or not the dentist deemed at least one of their patients eligible for a 24-month recall.

TABLE 17 Dentists' beliefs at baseline and follow-up and change from baseline

Dentists' beliefs	Baseline, mean (SD), *n*	Follow-up, mean (SD), *n*	Change from baseline (follow-up–baseline), mean (SD), *n*
Attitude regarding a 24-month recall	3.8 (1.2), 46	4.4 (1.2), 48	0.6 (1.1), 45
Attitude regarding a 6-month recall	3.7 (1.0), 46	4.0 (1.2), 48	0.2 (0.9), 45
General attitude to the patient's ability to maintain self-care	4.6 (1.1), 46	4.0 (1.1), 48	–0.6 (1.4), 45
Perceived ability to assess risk	4.1 (0.9), 46	4.1 (1.1), 48	–0.1 (1.2), 45

Chapter 5 Health economics results

Introduction

This chapter reports the results of the within-trial health economic analysis (4-year follow-up). Descriptive statistics for resource use, costs and outcomes (QALYs, WTP) are presented separately by randomised stratum as follows: [eligible for 24-month recall (24 month; risk based; 6 month) and ineligible for 24-month recall (risk based; 6 month)] using complete-case data. The chapter then reports the findings of the online general population DCE. The economic evaluation results, combining incremental costs and benefits, are then reported under the three different evaluation frameworks (see *Chapter 3*) based on multiple imputation of missing data. A range of alternative scenario analyses are provided to investigate the impact of different costing perspectives and methodological issues on the results.

Resource use and costs

Resource use and costs are reported for NHS dental care, NHS other care and participants. This section details descriptive statistics from complete-case data. The reader is referred to *Appendix 2*, *Table 59*, for descriptive statistics based on multiple imputation of missing data.

Costs of NHS dental services

NHS dental care costs are based on routinely collected dental claims in the four different UK regions. Data were successfully linked for $n = 1121/1188$ (94%), $n = 932/1031$ (90%), $n = 143/153$ (93%) and collected from practice notes for 13/13 (100%) participants in Scotland, England, Northern Ireland and Wales, respectively. Given the high linkage rate, missing dental claims data were not considered to have an important impact on cost. Overall, $n = 552/2209$ (25%) participants with dental claims data were exempt from payment of dental charges for the majority of treatment claims. The proportion of participants exempt from charges was evenly balanced across the randomised groups. For the ineligible for 24-month recall stratum, 186/861 (22%) and 161/863 (19%) were exempt in the risk-based and 6-month recall groups, respectively. For the stratum where participants were eligible for 24-month recall, 74/217 (34%), 57/215 (27%) and 74/216 (34%) were exempt from charges in the risk-based, 6-month and 24-month recall groups, respectively. There are no statistically significant differences in the proportions exempt across groups, providing reassurance that any treatment effects on NHS costs are not biased by eligibility for fully funded NHS care. *Table 18* reports details of treatment claims and costs to the dental budgets of the respective regions.

Resource use data are reported separately for check-ups, fillings and extractions (for the UK as a whole and at a regional level). Participants ineligible for 24-month recall incurred greater resource use than the eligible stratum. The average number of check-ups for respondents in the risk-based group was closer to the 6-month group in the ineligible stratum, but approximately mid-way between the 6-month and 24-month group in the eligible stratum. This indicates the likelihood of greater need for more frequent checks in the risk-based group in the ineligible stratum. A similar pattern of greater treatment consumption in the ineligible than the eligible stratum is also observed for other treatments such as fillings and extractions, and appears consistent across the regions.

Other NHS resource use and costs (descriptive data)

Table 18 also indicates the resource use and costs associated with care for dental health problems provided by services other than dental practices (e.g. GP consultations, inpatient admissions, outpatient consultations and accident and emergency admissions). Emergency dental consultations

TABLE 18 NHS-provided dental care

	Ineligible												Eligible															
	Risk based						6 month						Risk based						6 month						24 month			
	Resource use			Cost			Resource use			Cost			Resource use			Cost			Resource use			Cost			Resource use			Cost		
Category	Mean	SD	*n*	Mean	SD	*n*	Mean	SD	*n*	Mean	SD	*n*	Mean	SD	*n*	Mean	SD	*n*	Mean	SD	*n*	Mean	SD	*n*	Mean	SD	*n*	Mean	SD	*n*
UK-wide data: total NHS dental costs																														
Check-ups	4.53	2.48	800	–	–	–	4.84	2.23	804	–	–	–	3.44	2.14	201	–	–	–	4.32	3.42	201	–	–	–	2.38	2.19	203	–	–	–
Fillings	1.63	1.95	800	–	–	–	1.48	1.90	804	–	–	–	1.21	1.93	201	–	–	–	1.29	1.71	201	–	–	–	1.14	1.69	203	–	–	–
Extractions	0.22	0.54	800	–	–	–	0.20	0.54	804	–	–	–	0.07	0.26	201	–	–	–	0.21	0.70	201	–	–	–	0.17	0.47	203	–	–	–
Dental budget costs	–	–	–	£130	£188	800	–	–	–	£113	£149	804	–	–	–	£97	£174	201	–	–	–	£96	£214	201	–	–	–	£80	£146	203
UK-wide data: other NHS resource use																														
GP consultations	0.76	1.76	371	£29	£66	371	0.80	1.58	393	£30	£60	393	0.94	1.51	69	£36	£57	69	0.73	1.36	80	£27	£51	80	0.81	1.99	77	£30	£75	77
Inpatient admissions	1.61	12.51	432	£7	£67	425	1.10	10.33	455	£9	£78	450	0.01	0.11	85	£8	£74	85	1.04	10.05	97	£14	£97	96	2.98	16.97	100	£7	£71	97
Outpatient consultations	0.03	0.29	374	£5	£42	374	0.08	0.52	400	£12	£77	400	0.01	0.12	69	£2	£18	69	0.05	0.22	82	£7	£30	82	0.03	0.16	78	£3	£22	78
Accident and emergency attendances	0.01	0.10	376	£1	£13	376	0.01	0.07	399	£1	£10	399	0.00	0.00	68	£0	£0	68	0.01	0.11	82	£1	£13	82	0.00	0.00	78	£0	£0	78
Total (other NHS resource use)				£34	£96	331				£46	£116	355				£49	£106	55				£50	£112	69				£24	£49	66
Total NHS costs (dental + other)				£136	£164	323				£147	£209	347				£114	£130	54				£131	£169	69				£90	£143	66

	Ineligible												Eligible															
	Risk based						6 month						Risk based						6 month						24 month			
	Resource use			Cost			Resource use			Cost			Resource use			Cost			Resource use			Cost			Resource use			Cost		
Category	Mean	SD	*n*	Mean	SD	*n*	Mean	SD	*n*	Mean	SD	*n*	Mean	SD	*n*	Mean	SD	*n*	Mean	SD	*n*	Mean	SD	*n*	Mean	SD	*n*	Mean	SD	*n*
NHS dental costs: Scotland																														
Diagnosis	4.75	2.31	393	£34	£16	393	5.22	2.16	400	£38	£14	400	3.79	2.38	107	£27	£17	107	4.87	2.19	111	£36	£15	111	3.10	2.84	110	£21	£20	110
Check-ups (1A 1B 1C)	3.59	1.69	393	–	–	–	4.09	1.59	400	–	–	–	2.82	1.78	107	–	–	–	3.88	1.62	111	–	–	–	2.10	2.05	110	–	–	–
Periodontal	3.06	2.56	393	£15	£26	393	3.10	2.52	400	£14	£20	400	2.47	2.85	107	£15	£26	107	2.80	2.38	111	£14	£24	111	1.64	2.11	110	£10	£22	110
Conservative	2.08	2.57	393	£20	£44	393	2.20	2.98	400	£20	£59	400	1.71	2.66	107	£28	£69	107	1.86	2.25	111	£22	£67	111	1.64	2.72	110	£21	£71	110
Fillings (14A, 14C1, 14C2)	1.47	1.92	393	–	–	–	1.58	2.18	400	–	–	–	1.25	2.15	107	–	–	–	1.35	1.64	111	–	–	–	1.20	1.77	110	–	–	–
Surgical	0.45	1.09	393	£2	£7	393	0.39	1.03	400	£1	£4	400	0.16	0.53	107	£0	£2	107	0.32	0.87	111	£1	£7	111	0.45	1.07	110	£2	£6	110
Extractions (21/22)	0.22	0.52	393	–	–	–	0.19	0.49	400	–	–	–	0.07	0.26	107	–	–	–	0.14	0.40	111	–	–	–	0.22	0.51	110	–	–	–
Prosthesis	0.25	0.79	393	£7	£29	393	0.26	0.85	400	£5	£24	400	0.34	1.25	107	£8	£40	107	0.11	0.51	111	£3	£22	111	0.13	0.47	110	£4	£20	110
Orthodontic	0.00	0.00	393	£0	£0	393	0.00	0.05	400	£0	£1	400	0.00	0.00	107	£0	£0	107	0.00	0.00	111	£0	£0	111	0.00	0.00	110	£0	£0	110
Other	1.09	2.52	393	£1	£5	393	0.81	1.69	400	£1	£4	400	1.65	4.15	107	£2	£7	107	1.07	2.37	111	£1	£4	111	1.06	2.42	110	£2	£6	110
Total Scotland				£79	£85	393				£79	£79	400				£80	£130	107				£77	£98	111				£59	£114	110
NHS dental costs: Northern Ireland																														
Diagnosis	6.33	2.60	30	£17	£19	30	7.33	2.63	30	£19	£14	30	4.54	2.94	28	£13	£15	28	4.96	3.00	26	£16	£19	26	3.79	2.78	29	£16	£17	29
Check-ups (101/111)	5.07	1.80	30	–	–	–	5.83	2.00	30	–	–	–	3.46	2.15	28	–	–	–	3.92	2.62	26	–	–	–	2.93	2.03	29	–	–	–
Periodontal	3.33	2.54	30	£15	£20	30	4.80	2.30	30	£23	£19	30	2.21	2.23	28	£12	£20	28	2.23	2.07	26	£14	£20	26	2.34	2.04	29	£20	£25	29
Conservative	3.10	3.57	30	£53	£129	30	2.93	4.31	30	£43	£85	30	2.29	3.02	28	£32	£61	28	2.42	2.93	26	£28	£46	26	2.48	3.18	29	£35	£70	29
Fillings (1401–04; 1421; 1426)	2.20	2.31	30	–	–	–	1.57	2.11	30	–	–	–	1.57	1.83	28	–	–	–	1.69	1.95	26	–	–	–	1.76	2.01	29	–	–	–

continued

TABLE 18 NHS-provided dental care (*continued*)

	Ineligible												Eligible															
	Risk based						6 month						Risk based						6 month						24 month			
	Resource use			Cost			Resource use			Cost			Resource use			Cost			Resource use			Cost			Resource use			Cost		
Category	Mean	SD	*n*	Mean	SD	*n*	Mean	SD	*n*	Mean	SD	*n*	Mean	SD	*n*	Mean	SD	*n*	Mean	SD	*n*	Mean	SD	*n*	Mean	SD	*n*	Mean	SD	*n*
Surgical	0.53	1.17	30	£5	£23	30	0.40	0.77	30	£2	£5	30	0.14	0.45	28	£1	£3	28	0.35	0.75	26	£3	£11	26	0.10	0.41	29	£2	£9	29
Extractions (2101)	0.20	0.48	30	–	–	–	0.13	0.35	30	–	–	–	0.04	0.19	28	–	–	–	0.15	0.37	26	–	–	–	0.03	0.19	29	–	–	–
Prosthesis	0.20	0.76	30	£5	£16	30	0.17	0.53	30	£4	£14	30	0.00	0.00	28	£0	£0	28	0.00	0.00	26	£0	£0	26	0.41	1.38	29	£10	£30	29
Orthodontic	0.00	0.00	30	£0	£0	30	0.00	0.00	30	£0	£0	30	0.00	0.00	28	£0	£0	28	0.00	0.00	26	£0	£0	26	0.00	0.00	29	£0	£0	29
Other	0.20	0.48	30	£1	£3	30	0.83	1.09	30	£2	£4	30	0.32	0.98	28	£1	£2	28	0.27	0.60	26	£1	£2	26	0.21	0.49	29	£1	£2	29
Total Northern Ireland	–	–	–	£96	£186	30	–	–	–	£94	£117	30	–	–	–	£58	£83	28	–	–	–	£62	£88	26	–	–	–	£85	£120	29
NHS dental costs: England/Wales																														
Band 1	3.37	2.39	377	£29	£28	377	3.87	2.57	374	£30	£33	374	3.17	1.98	66	£25	£24	66	3.86	3.01	64	£30	£38	64	1.56	1.45	64	£14	£20	64
Check-up	5.46	2.83	377	–	–	–	5.56	2.54	374	–	–	–	4.44	2.32	66	–	–	–	5.23	5.34	64	–	–	–	2.61	2.45	64	–	–	–
Band 2	1.95	2.04	377	£76	£106	377	1.52	1.58	374	£52	£75	374	1.20	1.60	66	£55	£98	66	1.30	2.29	64	£54	£146	64	1.05	1.88	64	£56	£132	64
Fillings	1.75	1.94	377	–	–	–	1.37	1.53	374	–	–	–	1.00	1.56	66	–	–	–	1.02	1.72	64	–	–	–	0.75	1.27	64	–	–	–
Extractions	0.23	0.58	377	–	–	–	0.23	0.59	374	–	–	–	0.09	0.29	66	–	–	–	0.34	1.10	64	–	–	–	0.14	0.47	64	–	–	–
Band 3	0.40	0.78	377	£68	£172	377	0.37	0.76	374	£56	£143	374	0.26	0.69	66	£49	£173	66	0.22	0.55	64	£45	£143	64	0.17	0.42	64	£32	£88	64
Band: urgent	0.46	0.92	377	£13	£26	377	0.40	0.82	374	£11	£23	374	0.36	0.74	66	£10	£21	66	0.42	1.97	64	£12	£56	64	0.41	1.05	64	£12	£30	64
Band: free	0.02	0.32	377	£1	£9	377	0.03	0.22	374	£1	£6	374	0.00	0.00	66	£0	£0	66	0.02	0.13	64	£0	£4	64	0.00	0.00	64	£0	£0	64
Band: other	0.01	0.12	377	£0	£1	377	0.01	0.07	374	£0	£0	374	0.00	0.00	66	£0	£0	66	0.02	0.13	64	£0	£0	64	0.02	0.13	64	£0	£0	64
Total England and Wales	–	–	–	£187	£243	377	–	–	–	£151	£194	374	–	–	–	£140	£244	66	–	–	–	£141	£350	64	–	–	–	£114	£195	64

Black text indicates broad treatment categories. Light blue text indicates specific treatments within those categories. For example, the number of conservative treatments that were fillings.
Specific treatment codes from the respective statements of dental remuneration in Scotland and Northern Ireland are provided in brackets.

(with community dental practices) are included in the dental budget and, therefore, will have been picked up through the routine data linkage. There are no obvious differences in the use of non-dental NHS services for dental problems across the randomised groups; however, it should be noted that complete data regarding use of non-dental NHS services for dental problems are available for only 37% of participants ($n = 876/2372$). A total of 385 (16%) randomised participants (between 15% and 20% across the groups) returned no questionnaires, and so have provided no resource use data regarding the use of non-dental services for dental problems. Missing data for the costs associated with the use of other (non-dental) NHS services appear to be evenly distributed across the randomised groups, and additional logistical regression analyses do not indicate that the probability of missingness is significantly predicted by any patient characteristics or dental health outcomes. An assumption of missing completely at random is therefore plausible; however, given the high proportion of missing data, multiple imputation is undertaken to complete the data set and improve the precision of the results.

Participant costs (descriptive statistics)

Table 19 reports participant cost data, specifically payment of dental co-charges, consumer out-of-pocket expenditure on dental care (electric toothbrushes, heads and other private treatment) and the opportunity cost of time and travel incurred while attending dental appointments.

It was possible to ascertain opportunity costs of time and travel, and co-charges for NHS dental care for 90% (2128/2372) of participants following the assumptions detailed in *Chapter 3*. However, data completion was poor for annual questionnaires asking about private care costs, and purchase of dental products such as electric and manual toothbrushes. As a result, total complete-case participant costs across all items and questionnaires were calculable for only 8% (182/2372) of the sample. Missing participant cost data do not appear to be driven by randomised group or patient characteristics; however, multiple imputation is still required to complete the data set, given the significant proportions of missing data.

Benefits

Benefits are assessed in this study using a DCE with the general population to obtain WTP tariffs to map to clinical trial outcomes (see *Chapter 3*) and services received and in terms of EQ-5D-3L-based QALYs.

Quality-adjusted life-years

Table 20 details descriptive statistics for the EQ-5D-3L and calculated QALYs from the trial. Across all time points, full EQ-5D-3L profile response data were available for only 35% (836/2372) of the randomised trial population. However, there were only 151 (6%) members of the trial population missing all EQ-5D-3L time points (including baseline). Missing data were evenly distributed across the randomised groups. Additional regression analysis found no evidence that missingness was determined by any participant characteristics or dental health outcomes. QALY data were, therefore, assumed to be missing at random.

Respondents were generally in good health, with greater than 3.5 undiscounted QALYs gained over 4-year time horizon across the randomised arms and strata.

TABLE 19 Participant costs

	Ineligible						Eligible								
	Risk based			6 month			Risk based			6 month			24 month		
	Cost			Cost			Cost			Cost			Cost		
Category	Mean	SD	*n*	Mean	SD	*n*	Mean	SD	*n*	Mean	SD	*n*	Mean	SD	*n*
Costs directly associated with attendance for NHS dental care															
Participant co-charges	£108	£129	800	£115	£128	804	£71	£101	201	£77	£85	201	£51	£82	203
Scotland	£84	£101	393	£89	£97	400	£57	£90	107	£65	£73	111	£51	£85	110
England/Wales	£131	£151	377	£140	£148	374	£87	£103	66	£99	£98	64	£49	£73	64
Northern Ireland	£117	£104	30	£138	£142	30	£86	£129	28	£77	£89	26	£60	£91	29
Opportunity cost of time and travel	£98	£50	775	£99	£44	787	£76	£51	191	£88	£65	191	£59	£43	184
Scotland	£92	£47	383	£95	£45	396	£71	£57	103	£84	£41	109	£60	£44	99
England/Wales	£104	£52	362	£102	£42	362	£83	£41	63	£96	£100	59	£56	£42	57
Northern Ireland	£107	£53	30	£122	£48	29	£79	£51	25	£81	£42	23	£61	£41	28
Total costs (co-charges plus opportunity costs) of attending NHS dental care	£209	£159	775	£216	£154	787	£150	£128	191	£169	£125	191	£116	£111	184
Other participant-incurred costs															
Private dental care	£109	£842	388	£99	£828	403	£23	£77	71	£13	£54	79	£95	£745	81
Electric toothbrushes	£39	£56	204	£41	£54	204	£38	£50	35	£40	£74	45	£24	£31	38
Brush heads	£16	£11	217	£15	£11	228	£18	£10	39	£15	£11	44	£13	£11	44
Manual brushes	£19	£10	283	£20	£10	297	£20	£10	47	£22	£10	56	£22	£10	64
Total (all participant costs)	£430	£581	76	£420	£724	70	£278	£104	12	£232	£167	16	£188	£213	8
Total cost of attending NHS appointments	£343	£261	775	£332	£224	787	£252	£237	191	£269	£291	191	£204	£212	184

TABLE 20 EQ-5D-3L-based QALYs

	Ineligible for 24-month recall						Eligible for 24-month recall								
	Risk based			6 month			Risk based			6 month			24 month		
Timepoint	Mean	SD	*n*	Mean	SD	*n*	Mean	SD	*n*	Mean	SD	*n*	Mean	SD	*n*
Undiscounted QALYs															
Baseline	0.898	0.208	602	0.903	0.196	590	0.931	0.135	134	0.891	0.235	140	0.927	0.172	140
1 year	0.882	0.207	613	0.889	0.204	620	0.902	0.187	140	0.872	0.224	148	0.920	0.174	149
2 years	0.874	0.217	597	0.881	0.226	603	0.887	0.225	133	0.887	0.201	143	0.891	0.195	142
3 years	0.878	0.217	561	0.872	0.226	574	0.889	0.235	129	0.863	0.264	137	0.907	0.174	124
4 years	0.866	0.230	637	0.867	0.237	645	0.893	0.208	145	0.856	0.268	157	0.884	0.209	151
QALY	3.523	0.715	310	3.491	0.801	319	3.507	0.761	65	3.483	0.906	71	3.522	0.781	71
Discounted QALYs															
Baseline	0.898	0.208	602	0.903	0.196	590	0.931	0.135	134	0.891	0.235	140	0.927	0.172	140
1 year	0.882	0.207	613	0.889	0.204	620	0.902	0.187	140	0.872	0.224	148	0.920	0.174	149
2 years	0.845	0.210	597	0.851	0.219	603	0.857	0.217	133	0.857	0.195	143	0.861	0.189	142
3 years	0.820	0.202	561	0.814	0.211	574	0.830	0.220	129	0.806	0.246	137	0.847	0.162	124
4 years	0.781	0.207	637	0.782	0.213	645	0.805	0.188	145	0.772	0.242	157	0.797	0.188	151
QALY	3.392	0.688	310	3.363	0.769	319	3.378	0.728	65	3.355	0.871	71	3.392	0.751	71

Discrete choice experiment results

Sample characteristics

The online DCE was completed by 597 respondents sampled from the general population. The median survey completion time was 16.03 minutes (interquartile range 11.85–21.98 minutes; minimum 3.95 minutes, maximum 1640.10 minutes). *Table 21* compares the sociodemographic characteristics and dental health experiences of the sample with the same characteristics in the general population. The sample was generally a good representation of the UK general population and satisfactorily matched the sought quotas for the survey. There is, however, over-representation of respondents from Scotland relative to the general population. These respondents were purposely oversampled to enable subgroup analysis of preferences across the UK regions and, in particular, to detect any impact of free check-ups in Scotland on preferences; therefore, it is less appropriate to compare the survey sample against the general population on regional distribution. Respondents were generally more regular attenders than the general population, and it is possible that the decision to participate in the survey was driven by this in part. Despite multiple invitations to the survey panel seeking at least 10% of our sample with their last attendance > 2 years ago, this was not achievable, and only 4% of the sample had their last dental check-up more than 2 years prior to completing the DCE.

TABLE 21 Characteristics of the DCE sample

Characteristic		General population[a]	DCE sample, *n* (%)[b] (*N* = 597)
Sociodemographic characteristics			
Age (years), mean (SD)[a,c]		≈47	49.54 (16.60)
Sex[a,c]	Male	49%	292 (49)
	Female	51%	305 (51)
Country of residence[c]	England	84%	392 (66)
	Scotland	8%	183 (31)
	Wales	5%	13 (2)
	Northern Ireland	3%	9 (2)
Smoker status[d]	Yes	18%	128 (21)
	No	59%	355 (59)
	Previous	23%	114 (19)
Annual gross income[e]	Low	54%	248 (42)
	Medium	37%	189 (32)
	High	8%	92 (15)
	Refused to answer	*N/A*	*62 (10)*
	Left blank	*N/A*	*6 (1)*
Educational attainment[c]	SVQ (level 1/2)	29%	210 (35)
	SVQ (level 3)	12%	83 (14)
	Degree	27%	151 (15)
	Professional	6%	64 (11)
	Apprentice	4%	12 (2)
	None	22%	77 (13)
Employment[c]	Employed	61%	328 (55)
	Unemployed	4%	27 (5)
	Retired	14%	143 (24)
	Student	9%	13 (2)
	Other	11%	86 (14)

TABLE 21 Characteristics of the DCE sample (*continued*)

Characteristic		General population[a]	DCE sample, *n* (%)[b] (*N* = 597)
Self-reported dental health[f]	Very poor	1%	11 (2)
	Poor	6%	45 (8)
	Fair	21%	201 (34)
	Good	47%	260 (44)
	Very good	24%	80 (13)
Self-reported general health[c]	Very poor	1%	11 (2)
	Poor	4%	44 (7)
	Fair	13%	175 (29)
	Good	34%	268 (45)
	Very good	47%	99 (17)
Dental health category[g]	Good	N/A	340 (57)
	Moderate		221 (37)
	Poor		36 (6)
Experiences of dental care			
Registered with dental practice	Yes	NR[h]	576 (96)
	No		17 (3)
	Do not know		4 (1)
Usual method of payment for dental care[i]	Co-charge/mix	45%	276 (46)
	NHS	23%	110 (18)
	Out of pocket		131 (22)
	Treatment plan		62 (10)
	Insurance		6 (1)
	Any private treatment	*27%*	*199 (33)*
	Never	2%	2 (0)
	Other	3%	10 (2)
Time since last check-up[i]	< 6 months		450 (75)
	6–12 months		106 (18)
	< 1 year	*69%*	*556 (93)*
	1–2 years	10%	*20 (3)*
	2–5 years	8%	8 (1)
	> 5 years	12%	9 (2)
	Never	1%	4 (1)

N/A, not applicable; NR, not reported; SVQ, Scottish Vocational Qualification.

a Data reported for a subset of the general population aged ≥ 16 years, *n* = 39,432,606 (Office for National Statistics[120]).

b Percentages are rounded to the nearest whole number so may not always add to 100%.

c Data source is 2011 census for England and Wales (Office for National Statistics[120]).

d Smoking status sourced from Office for National Statistics.[121]

e Income categories are low, < £20,800; medium, £20,800–41,600; and high, > £41,600. UK population data reflect average income of a single person household, as survey asked about individual (not household) income. The source is the UK family resources survey (UK DWP, 2017).[122] To enable comparison with general population, item non-response is excluded from the sample percentage calculations.

f Data sourced from the UK adult dental health survey (Steele and O'Sullivan[114]).

g Dental health categories reflect allocation to segments in the experimental design. See *Chapter 3, Discrete choice experiment experimental design*, for further details. No equivalent general population data exist.

h No data available at a population level.

i Source of data is the UK adult dental health survey (Steele and O'Sullivan[114]).

The entries in italic relate to subtotals. For example, *Any private treatment* is the sum of entries for out of pocket, treatment plan and insurance.

Respondents are generally in good dental health, with only 6% of the sample assigned to the poorest segment of dental health in the DCE design. The smaller sample in this segment means that the DCE has less power to detect significant preferences for the worst levels of dental health outcomes (bleeding very often and advanced decay).

Preferences for dental care

The results of the error components model describing preferences estimated from the effects coded DCE and calculated WTP tariffs for mapping to the trial interventions and outcomes are reported in *Table 22*.

TABLE 22 The DCE model results and WTP

	Preference coefficient		WTP	
Attribute level	**Coefficient**	**SD**	**Coefficient**	**95% CI**
ASC	1.484***	1.675***	£252.67	£210.65 to £294.69
24-month recall[a,b]	−0.423***		−£71.95[b]	−£86.33 to −£57.57
Annual recall[b]	−0.015		−£2.61[b]	−£15.10 to £9.88
6-month recall[b]	0.348***		£59.32[b]	£46.35 to £72.29
Risk-based recall[b,c]	0.089**		£15.24[c]	£2.91 to £27.57
Bleed never[a]	0.208***		£35.37	£16.36 to £54.37
Bleed hardly ever	0.099**		£16.82	£1.05 to £32.58
Bleed occasionally	0.089**		£15.23	£1.55 to £28.91
Bleed fairly often	−0.127**		−£21.70	−£40.60 to −£2.79
Bleed very often	−0.268***		−£45.71	−£79.85 to −£11.58
Decay none[a]	0.565***		£96.21	£77.57 to £114.84
Decay early	0.058*		£9.91	−£1.91 to £21.74
Decay moderate	−0.241***		−£41.02	−£53.08 to −£28.95
Decay advanced	−0.382***		−£65.11	−£83.70 to −£46.51
Annual cost	−0.006***			
Number of observations	14,328			
Number of respondents	597			
Log-likelihood (null)	−4578			
Log-likelihood (model)	−3856			
AIC	7739			
BIC	7837			
AIC/N	0.54			
BIC/N	0.55			

*$p < 0.1$, **$p < 0.05$, ***$p < 0.01$.

BIC, Bayesian information criterion; N in AIC/N and BIC/N refers to the number of observations.

a Indicates reference level. It should be noted that DCE results and WTP values are based on effects coded data, and so all coefficients for any given attribute are relative to the grand mean for the attribute, hence the reason for example that annual recall is not significant.

b Values presented for 2-yearly, annual and 6-month recall from the DCE are mapped to trial outcome count data for two, four and eight check-ups (from routine data), respectively. Intervening values, not directly predicted by the DCE are obtained by stepwise linear prediction up to 8 check-ups, and logarithmic extrapolation function beyond 8. The resultant functions used to map WTP to trial outcomes are as follows [where y = WTP and x = number of check-ups]: (a) if $x \leq 4$; $y = 34.671x - 141.29$; (b) if $5 > x \leq 8$; $y = 15.481x - 64.531$; if $x > 8$; $y = 94.689\ln(x) - 136.35$.

c As the analysis is primarily based on intention to treat and number of check-ups received (rather than randomised allocation), it was not possible to map the WTP for risk-based recall directly to the trial outcomes. The information is, however, still relevant as it provides an indication of the general population's preference for this service as described in the DCE.

The ASC is both positive and statistically significant. This indicates that the general population prefers any dental check-up package to none. The SD of the constant is also significant, suggesting that there is significant preference heterogeneity among the sample for this parameter. This indicates that the strength of preference for opting into a dental check-up package varies across the sample. Overall, 57% (339/597) of respondents always opted in, compared with only 6% (35/597) who always opted out. Preferences for dental recall frequency, decay, bleeding on brushing, and cost are as expected. Respondents prefer to have more frequent recalls, prefer to avoid dental decay, prefer no bleeding gums and prefer cheaper dental care packages. The WTP estimates appear to have good face validity, and findings are in line with those expected after completion of the preparatory qualitative work. Additionally, the WTP tariffs obtained for bleeding gums closely match those obtained in a previously conducted DCE for the IQuaD study,[101] indicating a high level of benefit transferability.

The WTP tariffs can be interpreted as follows: the estimated tariffs are the general population's WTP for each attribute level (e.g. 6-month recall) controlling for variation in all other attributes included in the DCE. In terms of understanding the impact of the WTP results for mapping to the trial outcomes, the difference in WTP across levels within an attribute represent the general population's value for moving from one state of the world to another. Consider dental decay: the DCE results show that the general population is willing to pay, on average, £161.32 per year, over a 4-year period, to avoid moving from a state of no dental decay (WTP tariff: +£96.21) to a state of advanced dental decay (WTP tariff: −£65.11).

Discrete choice experiment subgroup analyses

Subgroup analyses are conducted by using interaction effects to examine the impact of subgroup membership (gender, region, smoking status, employment status, income, experienced check-up frequency and experience of dental decay) on preferences. In general, subgroup membership influences overall preference patterns (as indicated by significant likelihood ratio tests). Many of the interaction effects are expected and serve to verify the face validity of the analysis results. For example, those who are in employment and have higher incomes are less sensitive to changes in the cost attribute. Those with experience of dental decay have stronger preferences to keep their teeth decay free and avoid more advanced levels of decay. Those who regularly attend the dentist every 6 months are more likely to prefer 6-month recalls, and are more likely to accept more expensive dental care packages. Smoking status and region do not appear to have any meaningful impact on preferences for any of the individual attribute levels; however, female participants in the sample placed less emphasis on differences in dental decay than the sample as a whole. Full details of subgroup analysis results are provided in *Appendix 2*, *Table 58*.

Total monetary measures of benefit (discrete choice experiment results mapped to trial outcomes)

The WTP tariffs obtained from the DCE analysis are mapped to the corresponding services received in the trial and observed trial outcomes, to enable a CBA to be completed. Total benefits (complete-case data) across randomised arms and strata are reported in *Table 23*. The impact of plausible alternative assumptions for mapping DCE results to trial outcomes (as described in *Chapter 3*) is highlighted in light blue.

Including WTP for health benefit (caries experience + bleeding on brushing) only in the definition of total benefits (see *Table 23*, WTP for health outcomes, analysis number 8) shows little evidence of difference across groups in either stratum. This is based on attaching WTP to avoid caries to both fillings received and untreated caries as measured at the final trial outcome assessment appointment. Amending the definition of caries applied for the mapping of WTP to trial outcomes (i.e. including or excluding fillings from the measurement of caries experience) impacts on mean WTP, but does not substantially alter conclusions across the randomised arms in either stratum.

TABLE 23 Total monetary benefits (WTP) combining DCE and trial interventions and outcomes

		Eligible									Ineligible					
		Risk based			6 month			24 month			Risk based			6 month		
Number	Description	Mean	SD	*n*	Mean	SD	*n*	Mean	SD	*n*	Mean	SD	*n*	Mean	SD	*n*
WTP tariffs mapped to individual trial outcomes (including sensitivity analyses)[a]																
1.	Constant	£948	£0	217	£948	£0	215	£948	£0	216	£948	£0	861	£948	£0	863
Recall																
2.	Recall ITT	−£122	£198	201	−£56	£206	201	−£236	£211	203	−£30	£195	800	£1	£175	804
3.	SA1 recall PP[b]	£54	£0	217	£211	£0	215	−£256	£0	216	£54	£0	861	£211	£0	863
4.	Bleeding on brushing	£71	£57	147	£61	£55	154	£71	£47	151	£67	£54	589	£67	£58	601
Caries																
5.	Untreated caries + fillings assume moderate[c,d]	−£140	£66	186	−£131	£65	178	−£138	£73	175	−£149	£56	767	−£144	£66	757
6.	SA2 untreated caries only[e]	−£127	£87	141	−£110	£87	133	−£120	£95	138	−£130	£88	607	−£123	£99	599
7.	SA3 untreated + fillings assume extensive[d,f]	−£186	£82	186	−£186	£87	178	−£189	£89	175	−£203	£68	767	−£198	£79	757
WTP for health outcomes																
8. (4 + 5)	Health (bleeding on brushing + untreated caries + fillings assume moderate)	−£71	£84	140	−£65	£86	142	−£68	£91	137	−£83	£81	561	−£78	£86	568
9. (4 + 6)	Health (bleeding on brushing + untreated caries only)	−£58	£100	126	−£45	£99	128	−£53	£106	126	−£62	£104	517	−£57	£108	517
10. (4 + 7)	Health (bleeding on brushing + untreated caries + fillings assume extensive)	−£109	£98	140	−£114	£103	142	−£113	£106	137	−£131	£90	561	−£127	£95	568

		Eligible									Ineligible					
		Risk based			6 month			24 month			Risk based			6 month		
Number	Description	Mean	SD	*n*	Mean	SD	*n*	Mean	SD	*n*	Mean	SD	*n*	Mean	SD	*n*
WTP overall																
11. (1 + 2 + 4 + 5)	Total WTP ITT (bleeding + untreated caries + fillings assume moderate)	£780	£207	137	£871	£207	140	£659	£219	135	£870	£181	550	£902	£186	553
12. (1 + 2 + 4 + 6)	Total WTP ITT (bleeding on brushing + untreated caries only)	£794	£212	125	£901	£213	126	£661	£224	124	£893	£190	506	£929	£194	504
13. (1 + 2 + 4 + 7)	Total WTP ITT (bleeding on brushing + untreated caries + fillings assume extensive)	£742	£207	137	£822	£209	140	£614	£207	135	£822	£175	550	£854	£186	553

ITT, intention to treat; PP, per protocol; SA, scenario analysis

a All WTP tariffs are discounted at an annual rate of 3.5% in line with current NICE guidance for the methods of technology appraisal.[103]

b This is a per protocol attachment of WTP to trial arms, assuming that participants remain in their allocated recall group and are valuing the offer of a service, rather than the service received and for which the patient attended.

c Assumes that if a filling was reported, that at least one of those fillings was for treatment of a moderate carious lesion (this is a more conservative assumption that assumes dentists are more likely to treat less severe carious lesions that might not, for example, include patients experiencing pain). To obtain a measure of caries experience, the most severe level of caries [i.e. filled (assuming moderate) or untreated] was used to assign the WTP tariff.

d Combined measures of untreated caries and fillings (assumed to reflect treatment of caries) is our preferred measure as it better reflects the impact on patient's experience of health states (not necessarily captured in a single follow-up visit) and is more congruent with the way in which the DCE question was framed. However, not all fillings will be for carious lesions and this may introduce a bias if fillings not for caries (e.g. replacement fillings) are more likely in one randomised group than another. The magnitude of any bias is likely to be small because the literature shows that only a small proportion of fillings provided are replacements.[123]

e Untreated caries are based on the clinical follow-up examination only and ignore those who have not returned for an examination, for whom a large number of data are available from the routine records.

f Assumes that, if a filling was reported, that at least one of those fillings was for extensive caries. To obtain a measure of caries experience, the most severe level of caries [i.e. filled (assuming extensive) or untreated] was used to assign the WTP tariff.

Light blue text refers to the impact of scenario analyses around the base-case approach on results.

However, substantial cross-group differences are observed when expanding the valuation space to include WTP for the service received (and all the perceived benefits associated with more frequent check-ups). Applying the high valuation of more frequent check-ups to the number of check-ups received in the trial generates substantial differences in WTP across the randomised arms from this wider, societal perspective.

Economic evaluation results

This section combines costs and benefits data, using multiple imputation of missing data, under three evaluation frameworks: (1) cost per QALY gained, (2) INB (intervention receipt + dental health benefits) and (3) INB (dental health outcomes: bleeding gums and caries experience).

Economic evaluation results for risk-based versus 6-month recall (whole trial population)

Table 24 reports the results and *Figures 15–17* illustrate the joint uncertainty in costs and benefits for the comparison of risk-based versus 6-month recall using the data set pooled across strata. The figures illustrate joint uncertainty in costs and benefits using scatterplots of the cost-effectiveness (benefit) plane and cost-effectiveness (benefit) acceptability curves for each analysis framework. The preferred recall strategy is highlighted in each of the analyses in *Table 24* for ease of reading.

For the comparison of risk-based versus 6-month recall, there was no evidence of a difference in total costs to the dental budget, QALYs gained or dental health outcomes. On the balance of probabilities, 6-month recall has a greater chance of being the most efficient strategy when considering costs from only a dental health budget perspective. There is substantial uncertainty in this conclusion for the CUA and cost per monetary valuation of dental outcomes, with a much higher chance of net benefit associated with 6-month recall when adopting a societal approach to benefit valuation in the CBA. The results for the CUA and CBA remain robust to the range of deterministic sensitivity analyses undertaken. The results of the incremental cost per unit of (monetary) health benefit (i.e. framework 3) are generally robust, with two exceptions:

1. Including participant costs of attending dental appointments (i.e. the opportunity cost of time and travel, and the co-charge payments incurred) reduces the cost-effectiveness case for 6-monthly recalls. In this scenario, there is no evidence to suggest that 6-month recall is an efficient use of resources when society is only willing to pay for health benefits; however, broadening the costing perspective does not change the findings from the CBA that 6-monthly recalls have the greatest probability of maximising societal net benefit.
2. The most efficient recall strategy when measuring benefits in terms of WTP for dental health (bleeding and caries) outcomes is sensitive to the UK region analysed. Considering data from Scotland (fee for service) only suggests a substantially higher chance that risk-based recall is associated with positive net (dental health) benefits, whereas in England (treatment banding), 6-month recall is the most likely net beneficial strategy. There are two reasons for these divergent region-specific results. First, in England there are more band 2 treatments (specifically fillings) provided in the risk-based group (ineligible stratum only), generating higher costs relative to 6-month recall than in Scotland. Second, the larger number of fillings is also counted on the benefits side (as a negative) in the WTP calculation in England; therefore, the combined effect of these drivers is a substantial difference in the probability of each strategy being an efficient use of resources across the regions (simultaneously accounting for the joint uncertainty in both costs and dental health benefits).

Economic evaluation results for risk-based versus 6-month versus 24-month recall (stratum eligible for 24-month recall)

Table 25 and *Figures 18–20* report the corresponding findings from the three-way comparison of risk-based versus 6-month versus 24-month recall for those deemed eligible for 24-month recall.

TABLE 24 Economic evaluation results (risk based vs. 6 months)

Analysis	Framework 1: CUA			Framework 2: CBA		Framework 3: WTP (dental outcomes)		Probability of being the most efficient recall strategy			
	Incremental cost: mean difference, risk based vs. 6 month (95% CI)	Incremental QALY: mean difference, risk based vs. 6 month (95% CI)	ICER (£/QALY)	Incremental benefits: mean difference, risk based vs. 6 month (95% CI)	INB	Incremental benefits: mean difference, risk based vs. 6 month (95% CI)	INB	Recall strategy	CUA (@ £20,000 per QALY)	CBA (@ benefit/cost = 1)	WTP (dental outcomes) (@ benefit/cost = 1)
Costing perspective: NHS dental	+£1.82 (−£6.66 to +£10.30)	−0.006 (−0.042 to +0.031)	Dominated	−£39.39 (−£58.40 to −£20.38)	−£41.21	−£4.05 (−£11.76 to +£3.66)	−£5.87	Risk based	30%	0%	17%
								6 month	70%	100%	83%
Costing perspective: NHS all	−£1.32 (−£19.22 to +£16.58)	−0.006 (−0.042 to +0.031)	£220	−£39.39 (−£58.40 to −£20.38)	−£38.07	−£4.05 (−£11.76 to +£3.66)	−£2.73	Risk based	31%	0%	34%
								6 month	69%	100%	66%
Costing perspective: NHS + participant-incurred costs	−£13.02 (−£68.09 to +£42.05)	−0.006 (−0.042 to +0.031)	£2170	−£39.39 (−£58.40 to −£20.38)	−£26.37	−£4.05 (−£11.76 to +£3.66)	+£8.97	Risk based	32%	22%	69%
								6 month	68%	78%	31%
Costing perspective: direct costs to NHS and participants of attending NHS dental care	−£2.87 (−£20.31 to +£14.57)	−0.006 (−0.042 to +0.031)	£478	−£39.39 (−£58.40 to −£20.38)	−£36.52	−£4.05 (−£11.76 to +£3.66)	−£1.18	Risk based	30%	0%	51%
								6 month	70%	100%	49%
Map WTP for caries outcome to untreated caries only	+£1.82 (−£6.66 to +£10.30)	−0.006 (−0.042 to +0.031)	Dominated	−£41.79 (−£61.10 to −£22.49)	−£43.61	−£6.45 (−£17.07 to +£4.17)	−£8.27	Risk based	30%	0%	12%
								6 month	70%	100%	88%
WTP mapped to trial outcomes using per protocol analysis	+£1.82 (−£6.66 to +£10.30)	−0.006 (−0.042 to +0.031)	Dominated	−£171.66 (−£159.92 to −£183.41)	−£176.48	−£6.45 (−£17.07 to +£4.17)	−£8.27	Risk based	30%	0%	17%
								6 month	70%	100%	83%
Scotland only	−£3.57 (−£12.61 to +£5.48)	−0.008 (−0.057 to +0.041)	£446	−£65.54 (−£99.29 to −£31.78)	−£61.97	+£6.52 (−£10.72 to +£23.77)	+£10.09	Risk based	37%	0%	91%
								6 month	63%	100%	9%
England only	+£11.42 (−£3.91 to +£26.74)	−0.003 (−0.058 to +0.052)	Dominated	−£23.18 (−£48.03 to +£1.67)	−£34.60	−£13.21 (−£23.95 to −£2.46)	−£24.63	Risk based	35%	0%	1%
								6 month	65%	100%	99%

continued

TABLE 24 Economic evaluation results (risk based vs. 6 months) (*continued*)

		Framework 1: CUA		Framework 2: CBA		Framework 3: WTP (dental outcomes)		Probability of being the most efficient recall strategy			
Analysis	Incremental cost: mean difference, risk based vs. 6 month (95% CI)	Incremental QALY: mean difference, risk based vs. 6 month (95% CI)	ICER (£/QALY)	Incremental benefits: mean difference, risk based vs. 6 month (95% CI)	INB	Incremental benefits: mean difference, risk based vs. 6 month (95% CI)	INB	Recall strategy	CUA (@ £20,000 per QALY)	CBA (@ benefit/cost = 1)	WTP (dental outcomes) (@ benefit/cost = 1)
Undiscounted costs and benefits	+£1.74 (−£7.23 to +£10.70)	−0.007 (−0.064 to +0.050)	Dominated	−£11.83 (−£17.12 to −£6.54)	−£13.57	−£1.15 (−3.58 to +£1.28)	−£2.89	Risk based	31%	0%	25%
								6 month	69%	100%	75%
Complete-case analysis[a]	CUA: −£1.48 (−£13.01 to +£10.05)	−0.022 (−0.067 to + 0.020)	£67.27	−£53.43 (−£83.25 to −£23.61)	−£46.00	−£4.42 (−£14.19 to +£5.35)	+£2.58	Risk based	25%	0%	62%
								6 month	75%	100%	38%
	CBA: −£7.00 (−£20.90 to +£6.89)										
	WTP (dental): −£7.00 (−£20.90 to +£6.89)										

a For the complete-case analysis, number of observations was as follows: CUA ($n = 742$); CBA ($n = 961$); WTP dental health framework ($n = 961$).
Note that the estimates of incremental costs and benefits are obtained from mixed-effects regression using *MI* estimate. Ratios are calculated parametrically and the probability of cost–benefit is obtained through bootstrapped loops of the chosen multiple imputation model ($n = 2000$ repetitions with $m = 5$ imputed data sets). All analyses are reported on the multiply imputed data set unless otherwise stated. All models are based on the combined trial sample randomised to 6 month or risk based, with adjustment for stratum. Purple shaded text indicates the most efficient strategy for each comparison in each analysis framework.

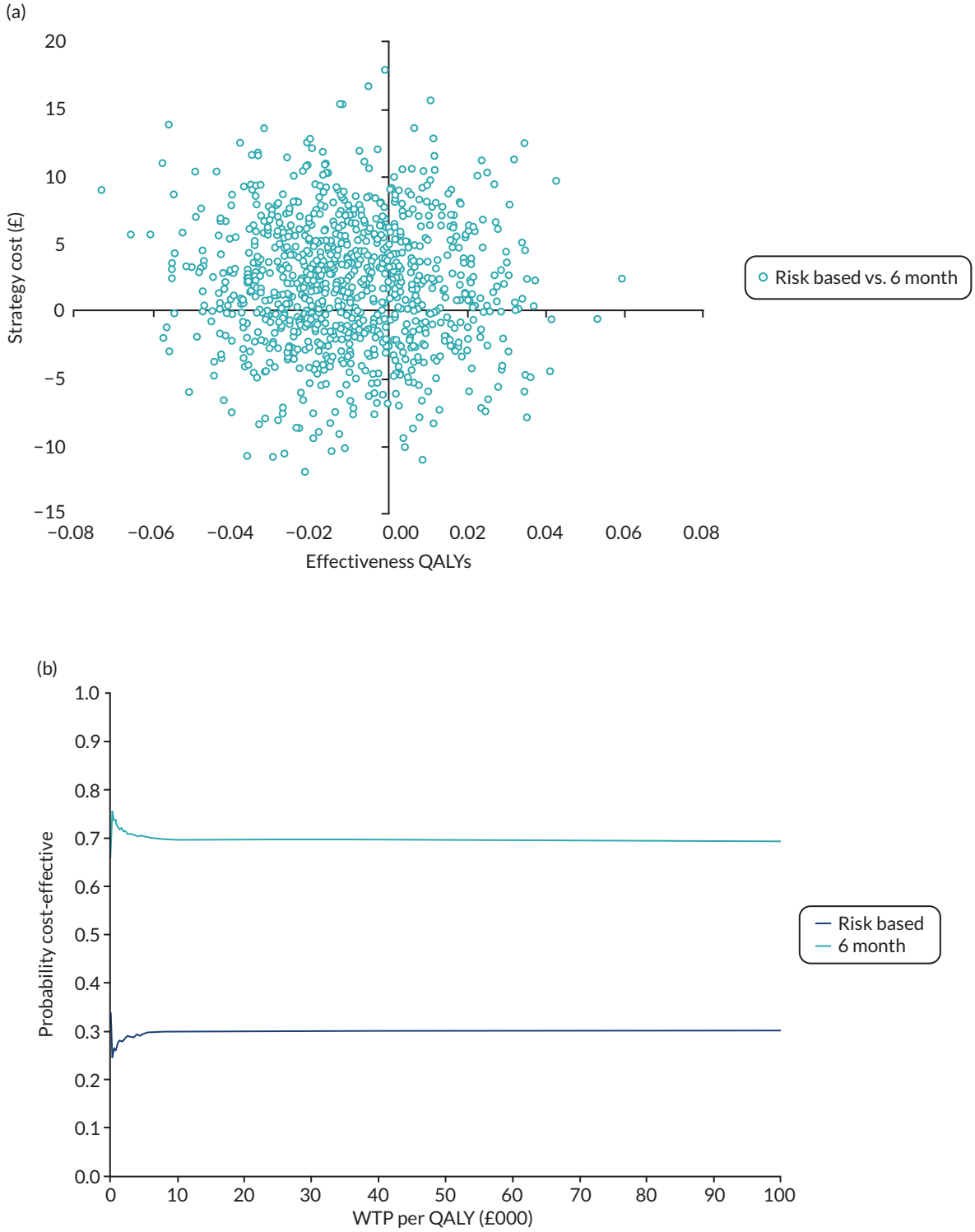


FIGURE 15 Risk-based vs. 6-month recall (CUA): (a) scatterplot of incremental costs and incremental QALYs; and (b) CEAC.

For the analysis of trial data for those eligible for the 24-month recall, the 24-month interval is the least costly interval overall, and is significantly less costly than 6-month recall. For the CUA and WTP for dental outcomes frameworks, there is a 59% and a 86% probability that 24-month recall is the most efficient strategy when considering costs to the dental budget, driven by the potential for cost-savings without adversely affecting health outcomes (generic or dental). However, as DCE respondents highly value more frequent check-ups, the wider societal measure of benefit (CBA) remains favourable to 6-month recall.

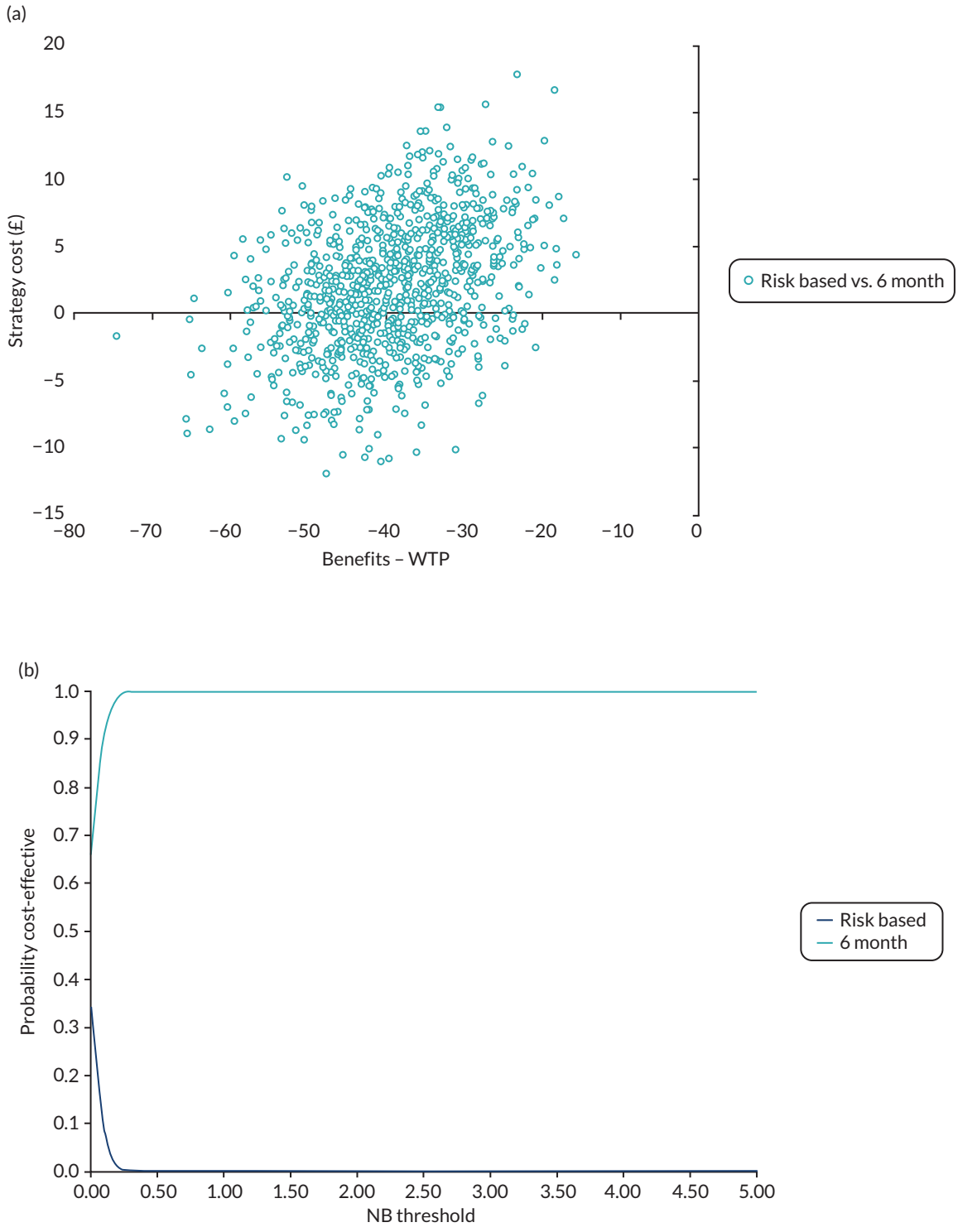


FIGURE 16 Risk-based vs. 6-month recall (CBA): (a) scatterplot of incremental costs and incremental benefits (WTP); and (b) CBAC. NB, net benefit.

In the eligible stratum, analysis frameworks focused on generic health (CUA) and dental health (WTP for dental outcomes) and both indicate that 24-month recall is the most likely recall strategy to deliver an efficient use of resources. The conclusion remains robust to the range of scenario analyses undertaken; however, broadening the scope of benefit valuation to include society's WTP for services received, the optimal treatment decision would remain 6-month recalls. For the CBA, sensitivity analyses remain robust to this conclusion.

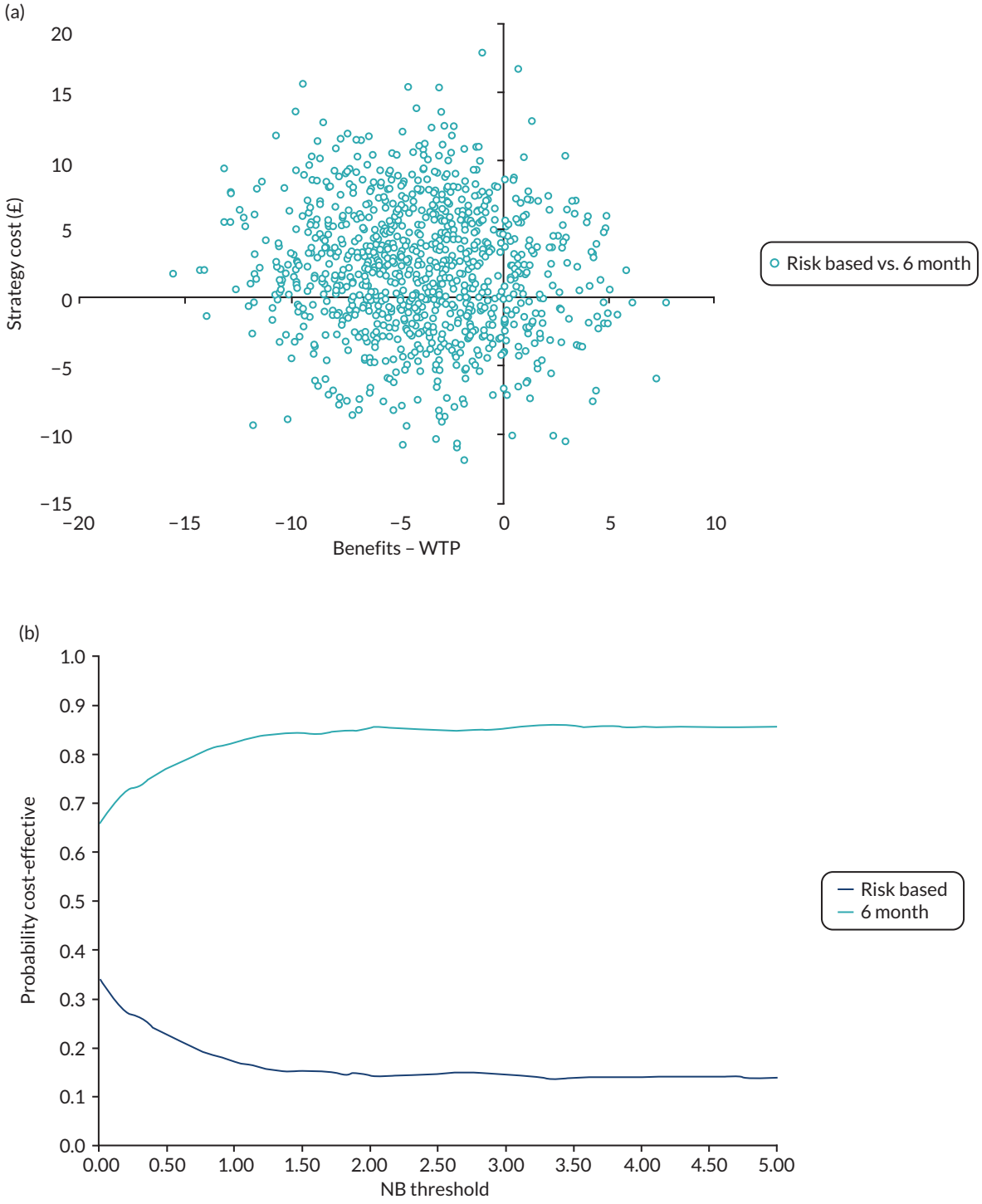


FIGURE 17 Risk-based vs. 6-month recall (WTP for dental health outcomes): (a) scatterplot of incremental costs and incremental benefits (WTP); and (b) CBAC. NB, net benefit.

In summary, for those eligible for longer recall intervals, 24-month recall is, on average, the least costly interval for both the NHS and patients, and delivers significant cost savings when combining all costs of attending dental appointments (NHS and patient incurred). These cost savings are achieved with no meaningful differences in generic or dental health outcomes. From these perspectives, 24-month recall is the most likely strategy to generate positive net benefit; however, the general population places a significant value on more frequent dental checks, despite their additional cost and lack of clinical benefit. Taking a more holistic view of benefits, 6-month recall generates the greatest net benefits despite the potential for additional patient and NHS costs.

TABLE 25 Economic evaluation results (participants eligible for 24-month recall)

			Framework 1: CUA		Framework 2: CBA		Framework 3: WTP (dental outcomes)		Probability of being the most efficient recall strategy[a]			
Analysis	Comparison	Incremental cost, mean difference (95% CI)	Incremental QALY, mean difference (95% CI)	ICER	Incremental benefits, mean difference (95% CI)	INB	Incremental benefits, mean difference (95% CI)	INB	Recall strategy	CUA P (C/E) @ £20,000	CBA P (C/B) @ BCR = 1	WTP (dental health) P (C/B) @ BCR = 1[a]
Costing perspective: NHS dental	24 month vs. risk based	−£6.46 (−£18.03 to +£5.11)	+0.007 (−0.102 to +0.117)	Dominant	−£109.22 (−£151.34 to −£67.09)	−£102.76	+£0.57 (−£18.28 to +£19.43)	£7.03	Risk based	16%	0%	12%
	24 month vs. 6 month	−£12.32 (−£30.94 to +£6.29)	+0.021 (−0.052 to +0.095)	Dominant	−£172.43 (−£241.82 to −£103.04)	−£160.11	−£1.22 (−£20.62 to +£18.18)	£11.10	6 month	25%	100%	3%
	Risk based vs. 6 month	−£5.86 (−£21.85 to +£10.12)	+0.014 (−0.082 to +0.110)	Dominant	−£63.21 (−£110.24 to −£16.18)	−£57.35	−£1.80 (−£19.72 to +£16.13)	£4.06	24 month	59%	0%	86%
Costing perspective: NHS all	24 month vs. risk based	−£3.61 (−£40.11 to +£32.89)	+0.007 (−0.102 to +0.117)	Dominant	−£109.22 (−£151.34 to −£67.09)	−£105.61	+£0.57 (−£18.28 to +£19.43)	£4.18	Risk based	17%	0%	20%
	24 month vs. 6 month	−£9.33 (−£50.44 to +£31.77)	+0.021 (−0.052 to +0.095)	Dominant	−£172.43 (−£241.82 to −£103.04)	−£163.10	−£1.22 (−£20.62 to +£18.18)	£8.11	6 month	25%	100%	10%
	Risk based vs. 6 month	−£5.73 (−£43.81 to +£32.35)	+0.014 (−0.082 to +0.110)	Dominant	−£63.21 (−£110.24 to −£16.18)	−£57.48	−£1.80 (−£19.72 to +£16.13)	£3.93	24 month	59%	0%	70%
Costing perspective: NHS + participant–incurred costs	24 month vs. risk based	−£37.92 (−£178.37 to +£102.53)	+0.007 (−0.102 to +0.117)	Dominant	−£109.22 (−£151.34 to −£67.09)	−£71.30	+£0.57 (−£18.28 to +£19.43)	£38.49	Risk based	17%	6%	26%
	24 month vs. 6 month	−£25.22 (−£126.33 to +£75.89)	+0.021 (−0.052 to +0.095)	Dominant	−£172.43 (−£241.82 to −£103.04)	−£147.21	−£1.22 (−£20.62 to +£18.18)	£24.00	6 month	25%	94%	9%
	Risk based vs. 6 month	+£12.70 (−£120.90 to +£146.31)	+0.014 (−0.082 to +0.110)	£907	−£63.21 (−£110.24 to −£16.18)	−£75.91	−£1.80 (−£19.72 to +£16.13)	−£14.50	24 month	59%	0%	65%
Costing perspective: direct costs to NHS and participants of attending NHS dental care	24 month vs. risk based	−£41.84 (−£64.87 to −£18.82)	+0.007 (−0.102 to +0.117)	Dominant	−£109.22 (−£151.34 to −£67.09)	−£67.38	+£0.57 (−£18.28 to +£19.43)	£42.41	Risk based	16%	1%	1%
	24 month vs. 6 month	−£57.82 (−£106.55 to −£9.09)	+0.021 (−0.052 to +0.095)	Dominant	−£172.43 (−£241.82 to −£103.04)	−£114.61	−£1.22 (−£20.62 to +£18.18)	£56.60	6 month	23%	99%	0%
	Risk based vs. 6 month	−£15.98 (−£58.60 to +£26.64)	+0.014 (−0.082 to +0.110)	Dominant	−£63.21 (−£110.24 to −£16.18)	−£47.23	−£1.80 (−£19.72 to +£16.13)	£14.18	24 month	62%	0%	99%
Map WTP for caries outcome to untreated caries only	24 month vs. risk based	−£6.46 (−£18.03 to +£5.11)	+0.007 (−0.102 to +0.117)	Dominant	−£108.03 (−£153.00 to −£63.07)	−£101.57	+£1.76 (−£23.33 to +£26.84)	£8.22	Risk based	17%	0%	8%
	24 month vs. 6 month	−£12.32 (−£30.94 to +£6.29)	+0.021 (−0.052 to +0.095)	Dominant	−£174.98 (−£248.18 to −£101.78)	−£162.66	−£3.78 (−£27.71 to +£20.16)	£8.54	6 month	26%	100%	5%
	Risk based vs. 6 month	−£5.86 (−£21.85 to +£10.12)	+0.014 (−0.082 to +0.110)	Dominant	−£66.95 (−£118.77 to −£15.13)	−£61.09	−£5.53 (−£32.39 to +£21.23)	£0.33	24 month	57%	0%	88%

			Framework 1: CUA		Framework 2: CBA		Framework 3: WTP (dental outcomes)		Probability of being the most efficient recall strategy[a]			
Analysis	Comparison	Incremental cost, mean difference (95% CI)	Incremental QALY, mean difference (95% CI)	ICER	Incremental benefits, mean difference (95% CI)	INB	Incremental benefits, mean difference (95% CI)	INB	Recall strategy	CUA P (C/E) @ £20,000	CBA P (C/B) @ BCR = 1	WTP (dental health) P (C/B) @ BCR = 1[a]
WTP mapped to trial outcomes using per protocol analysis	24 month vs. risk based	−£6.46 (−£18.03 to +£5.11)	+0.007 (−0.102 to +0.117)	Dominant	−£304.53 (−£345.87 to −£263.20)	−£298.07	+£0.57 (−£18.28 to +£19.43)	£7.03	Risk based	16%	0%	12%
	24 month vs. 6 month	−£12.32 (−£30.94 to +£6.29)	+0.021 (−0.052 to +0.095)	Dominant	−£468.59(−£511.45 to −£425.72)	−£456.27	−£1.22 (−£20.62 to +£18.18)	£11.10	6 month	25%	100%	3%
	Risk based vs. 6 month	−£5.86 (−£21.85 to +£10.12)	+0.014 (−0.082 to +0.110)	Dominant	−£164.06 (−£196.36 to −£131.76)	−£158.20	−£1.80 (−£19.72 to +£16.13)	£4.06	24 month	59%	0%	86%
Scotland only	24 month vs. risk based	−£9.98 (−£17.44 to −£2.51)	+0.000 (−0.163 to +0.163)	Dominant	−£126.67 (−£184.99 to −£68.35)	−£116.69	−£11.92 (−£55.69 to +£31.86)	−£1.94	Risk based	34%	0%	30%
	24 month vs. 6 month	−£16.27 (−34.02 to +£1.48)	−0.000 (−0.095 to +0.095)	£162,700	−£229.56 (−£332.09 to −£127.03)	−£213.29	+£6.34 (−£33.22 to +£45.89)	£22.61	6 month	43%	100%	0%
	Risk based vs. 6 month	−£6.30 (−£25.79 to +£13.20)	−0.001 (−0.154 to +0.153)	£6,300	−£102.89 (−£196.35 to −£9.44)	−£96.59	+£18.26 (−£24.47 to +£60.98)	£24.56	24 month	23%	0%	70%
England only	24 month vs. risk based	−£9.62 (−£40.96 to +£21.72)	+0.048 (−0.098 to +0.194)		−£131.30 (−£190.82 to −£71.79)	−£121.68	+£12.51 (−£15.94 to +£40.95)	£22.13	Risk based	5%	22%	10%
	24 month vs. 6 month	−£15.67 (−£47.99 to +£16.64)	+0.063 (−0.064 to +0.190)	Dominant	−£170.20 (−£269.40 to −£70.99)	−£154.53	−£4.14 (−£36.90 to +£28.63)	£11.53	6 month	10%	78%	14%
	Risk based vs. 6 month	−£6.05 (−£31.95 to +£19.85)	+0.015 (−0.156 to +0.187)	Dominant	−£38.89 (−£111.66 to +£33.88)	−£32.84	−£16.64 (−£48.90 to +£15.62)	−£10.59	24 month	86%	0%	76%
Undiscounted costs and benefits	24 month vs. risk based	−£6.43 (−£18.23 to +£5.38)	+0.023 (−0.071 to +0.118)	Dominant	−£31.38 (−£43.57 to −£19.19)	−£24.95	+£0.91 (−£3.81 to +£5.62)	+£7.34	Risk based	17%	16%	15%
	24 month vs. 6 month	−£13.97 (−£33.15 to +£5.20)	+0.002 (−0.089 to +0.094)	Dominant	−£48.81 (−£68.23 to −£29.40)	−£34.84	+£1.21 (−£4.53 to +£6.95)	+£15.18	6 month	29%	84%	2%
	Risk based vs. 6 month	−£7.55 (−£24.51 to £9.42)	−0.021 (−0.109 to +0.067)	£359.52	−£17.43 (−£30.76 to −£4.10)	−£9.88	+£0.30 (−£5.19 to +£5.79)	+£7.85	24 month	54%	0%	83%

continued

TABLE 25 Economic evaluation results (participants eligible for 24-month recall) (*continued*)

			Framework 1: CUA		Framework 2: CBA		Framework 3: WTP (dental outcomes)		Probability of being the most efficient recall strategy[a]			
Analysis	Comparison	Incremental cost, mean difference (95% CI)	Incremental QALY, mean difference (95% CI)	ICER	Incremental benefits, mean difference (95% CI)	INB	Incremental benefits, mean difference (95% CI)	INB	Recall strategy	CUA P (C/E) @ £20,000	CBA P (C/B) @ BCR = 1	WTP (dental health) P (C/B) @ BCR = 1[a]
Complete–case analysis[b]	24 month vs. risk based	CUA:–£10.58 (–£31.51 to +£10.35) CBA: –£15.23 (–£36.23 to +£5.77) WTP (dental):–£15.23 (–£36.23 to +£5.77)	+0.036 (–0.101 to +0.173)	Dominant	–£111.63 (–£171.69 to –£51.56)	–£96.40	+£4.95 (–£19.78 to +£29.67)	+£20.18	Risk based	6%	0%	11%
	24 month vs. 6 month	CUA: –£14.49 (–£36.47 to +£7.50) CBA: –£26.45 (–£59.45 to +£6.54) WTP (dental): –£26.45 (–£59.45 to +£6.54)	–0.048 (–0.152 to +0.056)	£301.88	–£218.40 (–£305.18 to –£131.62)	–£191.95	–£3.02 (–£30.36 to +£24.32)	+£23.43	6 month	76%	100%	8%
	Risk based vs. 6 month	CUA: –£3.91 (–£25.54 to +£17.73) CBA: –£11.22 (–£45.81 to + 23.36) WTP (dental): –£26.45 (–£59.45 to +£6.54)	–0.084 (–0.210 to +0.042)	£46.45	–£106.77 (–£173.03 to –£40.52)	–£95.55	–£7.97 (–£31.22 to +£15.28)	+£18.48	24 month	17%	0%	81%

a Percentages are rounded to the nearest whole number for presentation in the table, and may, therefore, occasionally sum to 0.99 or 1.01.
b For the complete-case analysis, number of observations was as follows: CUA ($n = 202$), CBA ($n = 285$), WTP dental health framework ($n = 285$).
BCR, benefit–cost ratio; P (C/B), probability of positive net benefit at a BCR = 1; P (C/E), probability of cost-effectiveness.

Notes

Estimates of incremental costs and benefits are obtained from mixed-effects regression using *MI* estimate. Ratios are calculated parametrically and the probability of cost–benefit is obtained through bootstrapped loops of the chosen multiple imputation model ($n = 2000$ repetitions with $M = 5$ imputed data sets). All analyses are reported on the multiply imputed data set unless otherwise stated. Purple shaded text indicates the most efficient strategy for each comparison in each analysis framework.

In this case, the ICER is reported for an intervention in the south-west quadrant of the cost-effectiveness plane; therefore, a lower value of the ICER indicates that the cost savings achieved for the risk-based intervention are not sufficient to justify a QALY loss. In such scenarios, lower ICERs indicate that an intervention is less cost-effective than its comparator.

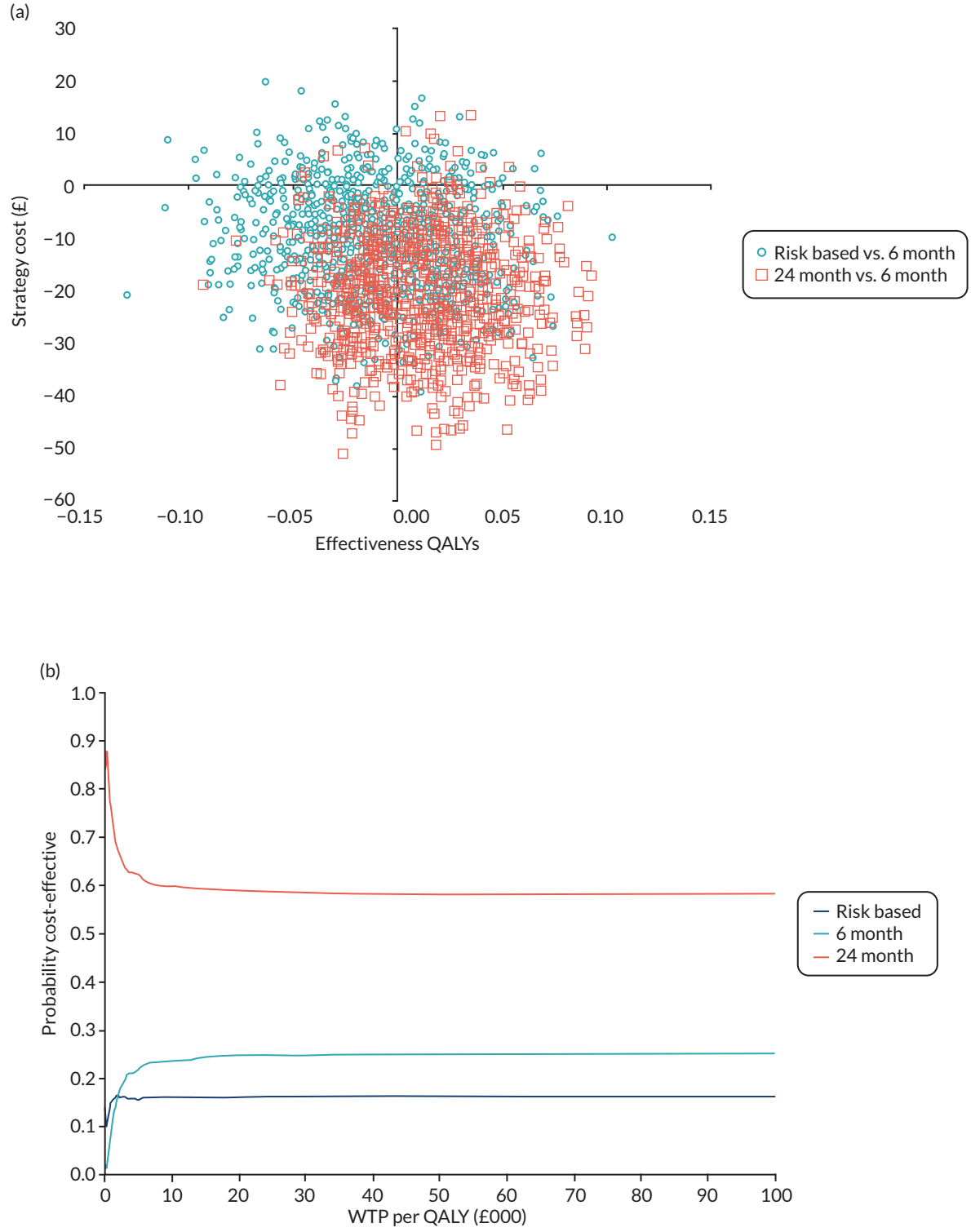


FIGURE 18 Eligible for 24-month recall: (a) scatterplot of incremental costs and incremental QALYs; and (b) CEAC, for risk-based vs. 6-month recall (CUA).

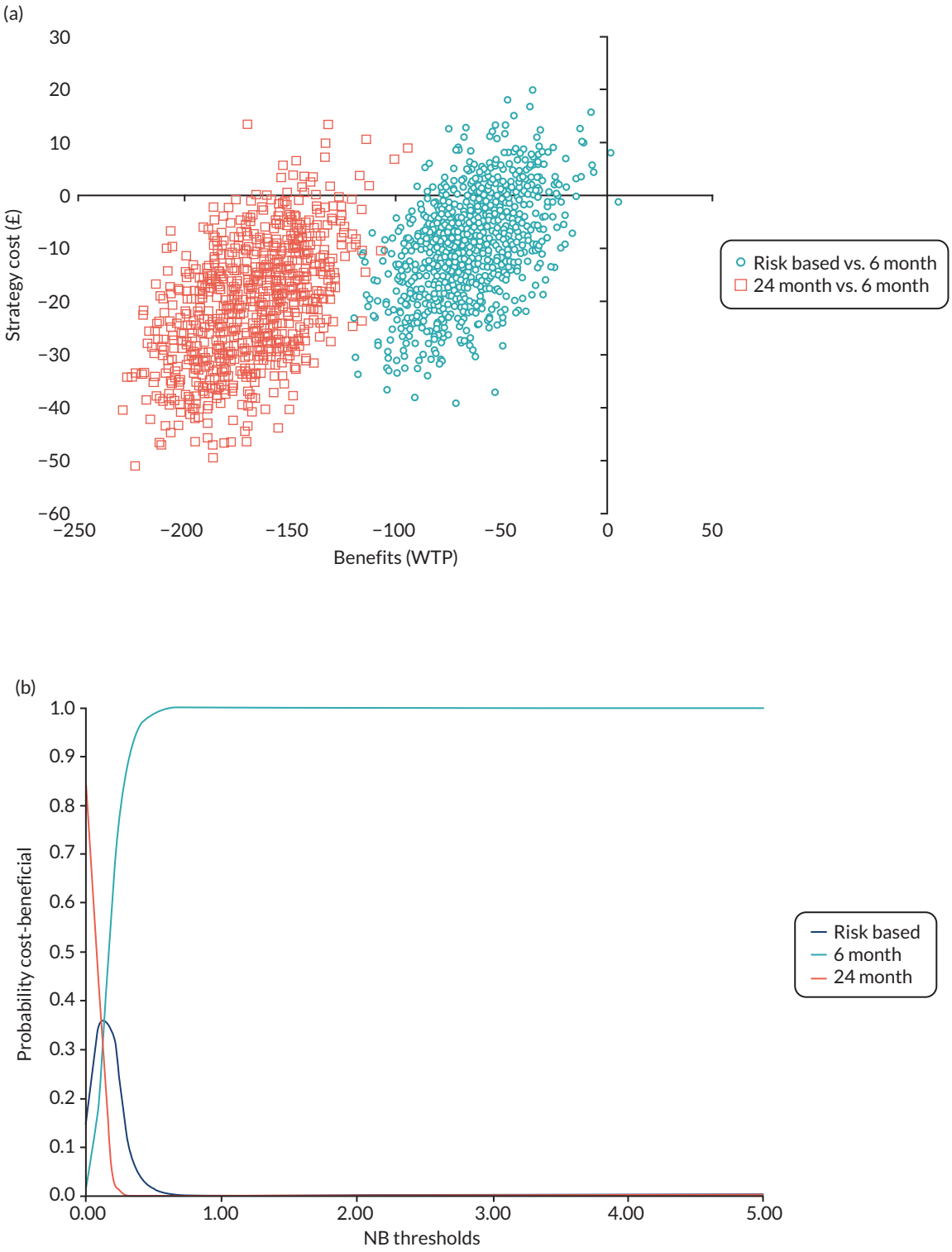


FIGURE 19 Eligible for 24-month recall: (a) scatterplot of incremental costs and incremental benefits (WTP); and (b) CBAC, for risk-based vs. 6-month recall (CBA). NB, net benefit.

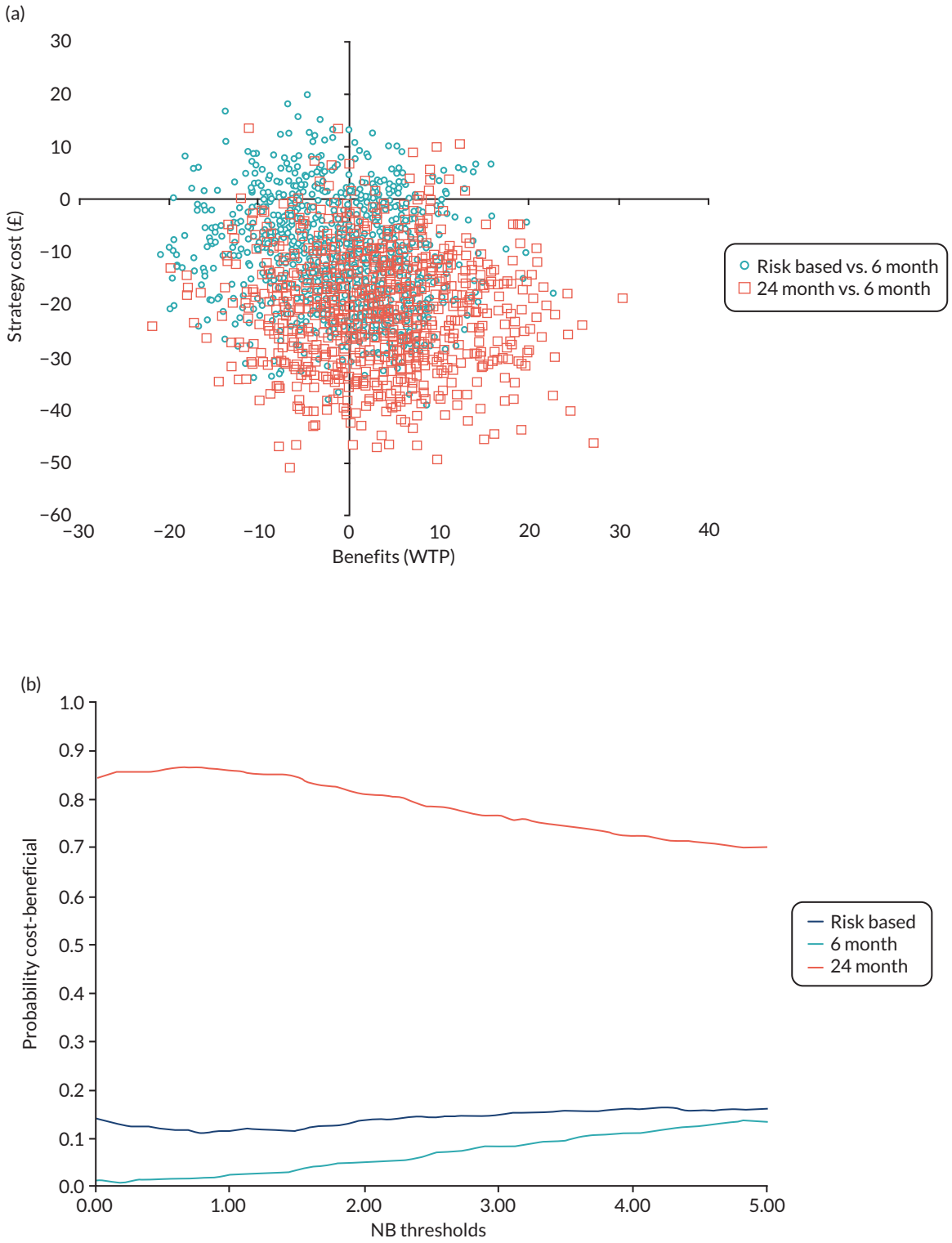


FIGURE 20 Eligible for 24-month recall: (a) scatterplot of incremental costs and incremental benefits (WTP); and (b) CBAC, for risk-based vs. 6-month recall (WTP for dental health outcomes). NB, net benefit.

Chapter 6 Discussion and conclusions

The INTERVAL trial involving regular adult NHS dental attenders has shown that a variable risk-based recall interval is not detrimental to oral health and is acceptable to patients and dentists with the potential for cost savings. Over a 4-year period, we found no difference in oral health between patient participants allocated to a 6-month or a variable risk-based interval. Nor did we find a difference between the intervals of 24-month, 6-month and risk-based recall for the 30% of adults considered suitable to be recalled at 24 months by their dentist. However, people greatly value and are willing to pay for frequent dental check-ups.

To our knowledge, this is the first national, multicentre, pragmatic RCT in a primary care setting to evaluate the clinical and patient-centred outcomes as well as the cost–benefit of different recall intervals. The INTERVAL trial investigated the implementation of a risk-variable approach to recall as recommended in the NICE guideline on dental recall.[60] The guideline takes account of the effect of dental checks on people's well-being, general health and preventative habits; caries incidence and avoiding restorations; periodontal health and avoiding tooth loss; and avoiding pain and anxiety. It aims to improve or maintain patients' quality of life and reduce morbidity associated with oral and dental disease. This guideline was initially published in 2004 and most recently reviewed in 2018, confirming that there was no emerging evidence to change the recommendations. Challenges to assumed routines of dental practice, such as the 6-month dental recall and the benefit of regular scale and polish, were voiced as early as 1970.[2,124] The mantra of a 6-month recall has been in existence for decades, and trying to establish the scientific basis for a 6-month or a variable risk-based recall interval was the reason for this trial. Assessment of the cost-effectiveness of different recall intervals was also considered important given the associated patient and NHS costs. Contemporary health care supports a patient-centred, appropriate, preventative and compassionate approach, and a dental recall visit is the opportunity for oral disease to be diagnosed early and for preventative advice and therapy to be provided. The aim of this RCT in primary care dental practice was to provide evidence for the benefit or harm of dental check-ups at different recall intervals on maintaining oral health.

The primary clinical outcome, gingival bleeding on probing, is a measure of gingivitis, a recognised precursor of periodontitis, caused by plaque retention, and is reversible with effective plaque removal. This outcome was chosen because it is an indicator of general oral health status, measurable and responsive to changes in oral self-care behaviour leading to either an improvement or a deterioration. At follow-up, on average, 35% of sites were bleeding on probing, which is similar to values reported in other studies, including the IQuaD study.[21,119] The prevalence of gingivitis confirmed that the trial interventions had the opportunity to have an impact on maintaining oral health, and that we could detect a beneficial or harmful effect. The intervention in INTERVAL was a check-up or recall appointment, which would include oral assessment, disease diagnosis and preventative/oral self-care advice, therefore, with the potential to have an impact on maintaining oral health. Around half of the participants had generalised gingivitis, as defined by the 2017 World Workshop on the Classification of Periodontal and Peri-implant Diseases and Conditions (> 30% sites bleeding) and only around 10% had clinical gingival health. Our findings challenge the usefulness of the new classification, since it does not seem to be sensitive enough to distinguish diseased from non-diseased individuals in a healthy sample.

At the 4-year follow-up, for adults allocated by their dentist to the 24-month eligible stratum (therefore, at low risk and suitable for a dental recall of 24 months), there was no evidence of a clinically meaningful or statistically significant difference in gingival bleeding on probing between those randomised to a recall interval of 24 months, risk based or 6 months (24-month vs. 6-month recall −0.91, 95% CI −5.02 to 3.20, $p = 0.66$; risk-based vs. 6-month recall −0.98, 95% CI −5.05 to 3.09, $p = 0.64$; 24-month vs. risk-based recall 0.07, −3.99 to 4.12, $p = 0.97$). Similarly, there was no evidence of a difference between the overall group of participants randomised to a variable risk-based or 6-month recall (0.78 95% CI −1.17 to 2.72; $p = 0.43$).

We are confident in the finding of no clinical benefit of 6-month recall over a variable risk-based interval, including for those assessed by the dentist as being eligible because of low risk for a 24-month recall, because the adjusted mean bleeding difference between interventions was < 1% and the 95% CIs were small enough to exclude the prespecified clinically important difference in bleeding of 7.5% and 4.5%. INTERVAL did not find a difference in patient-reported generic or oral health-related quality of life between any group, and the participants were satisfied being allocated to a recall interval based on risk.

No evidence of a difference was found in any of the secondary clinical outcomes measured between the three recall intervals for those eligible for 24-month recall or the overall 6-month and risk-based recall groups. The clinical secondary outcomes were periodontal probing depth, caries on coronal surfaces measured at three levels (i.e. initial, moderate and extensive) and the presence of root surface caries, calculus, dental treatment. Patient-centred outcomes included patient anxiety, patient satisfaction with care and patient oral health knowledge, attitudes and behaviours. The range of outcomes measured in INTERVAL was comprehensive, encompassing the important and relevant clinical and patient-centred outcomes. The absence of evidence of a difference between the three recall strategies, therefore, indicates that a variable risk-based recall interval can be supported as it is not detrimental to oral health.

All participants were assessed by their dentists at trial entry to determine whether or not they were suitable for a 24-month recall, and the 30% of participants considered to be eligible were randomised to a 24-month, risk-based or 6-month recall interval. All other participants were randomised to be recalled at a variable interval determined by risk or at 6 months. Dental practices were asked to recall their participants in keeping with their randomised allocation; however, this could be changed if the dentist considered it necessary or if requested by the patient participant because of concerns about their oral health. The pragmatic nature of the trial meant that scheduling of dental appointments and, therefore, the interval between them varied, as they do in routine dental practice because of either practice factors or patient factors. Prior to and since the publication of the NICE dental recall guidelines,[60] common practice is to provide a scale and polish or PI at the same time as a dental recall visit. The instruction to participants was not to alter the frequency of this treatment and not to delay in making an appointment if they needed to see the dentist. However, towards the end of the trial follow-up period, dentists were instructed to provide any planned scale and polish following the collection of clinical outcomes by blinded assessors.

At the start of INTERVAL, dentists' attitudes towards a risk-based approach to recall interval varied. Prior to randomising, all participant dentists were provided with training in the process of the NICE allocation of a variable recall interval. In addition to face-to-face training, it included an interactive online resource that dentists were asked to review as required and repeat annually. The online training included clinical scenarios to demonstrate the range of factors that should be assessed and considered prior to deciding the risk-based recall interval. It was designed to embed the process by taking the clinician through the stages of consideration of modifying factors of risk, integrating this with clinical information and making a clinical judgement of a suitable recall interval, discussing this with the patient and reviewing the interval at subsequent check-ups. The online training was designed to be compliant with CPD requirements and, after completion, a form could be printed to record verifiable CPD.

Oral health-related quality of life was assessed using the validated OHIP-14 measure, which has been widely used as a measure of OHRQoL. Participants deemed eligible to be allocated to a 24-month recall had, on average, a better OHRQoL score than those deemed ineligible. Participants deemed ineligible were also more likely to identify themselves as regular attenders. This suggests that dentists reliably assessed patients' risks and had done so already, which is in line with their confidence to assess patients' risks. Similarly, dentists reported that they intended to schedule appointments every 12 months for participants allocated to the risk-based arm in the eligible for 24-month recall stratum, and every 9 months in the ineligible for 24-month recall stratum. National routine data suggest that, in the NHS, the most frequent interval between check-up visits is 9 months, and this reflects the experience of the participants randomised to 6-month visits.

At 4 years, there was a clear separation in the number of check-ups received by the 30% of participants in the 24-month recall stratum: those randomised to the 24-month recall interval had half the number of check-ups of those in the 6-month interval group, and those allocated to a risk-based interval experienced a frequency between the two (24 month = 2.4, 6 month = 4.3 and risk based = 3.4 check-ups). There was a twofold difference in the number of check-up visits between groups of participants who were considered eligible for a 24-month recall. For participants randomised to a risk-based interval who had been considered suitable for a 24-month recall, the decision made by the dentist when applying the risk assessment framework was to allocate an interval of around 12 months. This was closer to the actual recall attendance of the 6-month group than those randomised to be seen at 24-month intervals.

For the 70% of INTERVAL participants who at baseline were considered not eligible for a 24-month recall interval, compared with those who were eligible, both the 6-month and risk-based groups were seen more frequently than the corresponding groups. Having the eligible for 24-month recall stratum allowed us to demonstrate the ability of dentists to assess risk as evidenced by the different number of check-ups for the risk-based groups between strata. At baseline the mean OHRQoL (OHIP-14) score was higher in the ineligible group, indicating that the dentists reliably judged these patients to be at higher risk when scheduling check-ups more frequently. The difference in the number of check-ups during the 4 years was small, 0.3 from routine claims data. National routine data suggest that, in the NHS, the most frequent interval between check-up visits is 9 months, and this reflects the experience of the participants randomised to 6-month visits. From the practice data and the monitoring of allocated recall interval, dentists intended to schedule appointments according to group; however, as INTERVAL was a pragmatic trial, the patient participants were able to amend visit dates in accordance with their need for a convenient appointment time.

The economic analysis was conducted using different perspectives of benefits (QALYs, WTP for dental health outcomes, WTP for dental recall and associated outcomes) and costs (NHS dental, sourced from the routine claims data; NHS dental and other services, such as primary and secondary medical care; and societal, including NHS and participant perspective costs). The preferred perspective depends on normative views of what benefits should be maximised with the NHS dental budget and what costs should be minimised.

The comparison of risk-based recall with 6-month recall is based on data across both trial strata, to which patients who are ineligible for 24-month recall contribute the majority of data. Using evaluation frameworks that maximise generic or dental health, there is substantial uncertainty regarding the most efficient recall strategy. In general, 6-month recall has a higher probability of cost-effectiveness, but the certainty around this conclusion tends to decrease as a wider perspective of participant-incurred costs is included. The results are sensitive to country-level subgroups, with risk-based recall having a higher probability of cost-effectiveness in a Scottish setting. As the general population places a high value on 6-month recall, expanding the valuation space to include all societal benefits (i.e. WTP for different recall intervals) leads to a high probability that 6-month recall has the greatest net benefits in a societal CBA framework. This conclusion is robust to sensitivity analyses undertaken.

Only participants who were deemed eligible for 24-month recall were randomised to the three-way comparison of 6-month versus risk-based versus 24-month recall, and so were more likely to be deemed at low risk of dental problems. The 24-month recall strategy is the least costly strategy to the NHS and generates significant cost savings compared with both 6-month and risk-based recall when also considering the opportunity cost of time and travel, and patient co-charges associated with attending the dental practice more regularly. When adopting either a generic or a dental health maximisation perspective, 24-month recall is likely to be the most efficient strategy; however, when taking a broader perspective of benefits, and incorporating the general population's valuation of recall intervals, these cost savings are offset by the perceived benefit of more frequent recall. In all cases where a wider perspective of benefits is included in the CBA, 6-month recall remains the strategy with the greatest likelihood of positive net benefits and this conclusion is robust to sensitivity analyses undertaken.

In summary, the recall strategy generating the greatest value for money is dependent on eligibility for 24-month recall and the decision-maker's views on the scope of costs and benefits that should be valued in the economic evaluation.

Framework 1 (maximising generic health benefit) used the results of the CUA to assess the most cost-effective strategy in terms of maximising generic health outcomes (i.e. EQ-5D-3L-based QALYs). There was substantial uncertainty surrounding the optimal recall strategy across all analyses undertaken. This is a result of concerns regarding the QALY's sensitivity to capture any potential benefits of dental care interventions. The CEACs and scatterplots of the cost-effectiveness plane illustrate the residual uncertainty, rendering it difficult to draw clear cost-effectiveness conclusions using this metric; for example, in the combined analysis across both trial strata, no strategy achieved a probability of cost-effectiveness > 70% at a threshold value of society's WTP for a QALY gain of £20,000. The probability of cost-effectiveness was higher for the 24-month recall strategy in the analysis restricted to the eligible for 24-month recall stratum because of the potential for cost savings from longer recall intervals.

Framework 2 (maximising societal well-being), taking the broadest perspective of benefits, including all components of value to the general population (incorporating both health and non-health sources of utility), generates a high probability that 6-month recalls are net beneficial. This finding is consistent across the full range of sensitivity analyses undertaken. This conclusion is influenced by the high value that the general population attaches to the 6-month recall service attribute in the DCE.

The DCE provided important information on the valuation of dental health outcomes; however, it is unclear why the general population places such a high value on service provision, controlling for health outcomes. The high WTP values attached to more frequent dental recall services was the main driver of results favouring 6-month recall in the wider-perspective CBA. Policy-makers may require further insights into the source of value attached to interventions in order to make informed decisions using a CBA framework, and further research is required to identify these sources of value. Some hypotheses for the high valuation of 6-month check-ups might include:

- Status quo bias, where respondents place a high value on services they usually receive.
- Omitted variable bias may occur if respondents place a value on some perceived outcomes that were not included in the DCE, such as increased likelihood of detection of oral cancers, or an assumption that check-ups come with scale and polish and associated aesthetic benefits.
- Supplier-induced demand where the population feel that they need to see the dentist every 6 months because that is the expert advice they have received over a long period of time (even if it is not evidence based).
- Reassurance provided by a consultation with a health professional.

Further work is required to more completely understand what it is that respondents explicitly value about 6-month recalls.

Framework 3 (maximising dental health benefits) evaluated the most efficient dental recall strategy in terms of maximising dental health benefit (i.e. through the DCE valuation of bleeding and caries outcomes). For the group deemed eligible for 24-month recalls, differences in costs to the total NHS dental budget (across the UK) are not statistically significantly different across the randomised arms; however, substantial cost savings can be achieved from longer recall intervals when considering the combined cost burden to both patients and the NHS. These savings can be achieved without adversely affecting dental health outcomes. A 24-month recall has the greatest probability of positive net dental health benefit, ranging between 65% and 99% across the full range of sensitivity analyses conducted.

For the trial population as a whole (including both eligible and ineligible for 24-month recall strata), there is substantial uncertainty regarding the most efficient strategy to maximise dental health benefit. Risk-based recalls were more likely to generate positive net dental health benefit in Scotland than in England, and when a wider perspective of the costing analysis was considered.

Comparison with other randomised clinical trials and studies

The Cochrane systematic review of dental recall, which was updated in 2013,[72] reported insufficient evidence to determine the effect of different recall intervals, with only one study included.[125] The trial population of the only included study[125] comprised children or adolescents aged 3, 16 or 18 years at trial entry. Wang *et al.*[125] included 185 patients and compared recall intervals of 12 months and 24 months over a 24-month follow-up period for the outcomes caries, as measured by decayed, missing and filled surfaces of primary teeth (dmfs) increment, and decayed, missing and filled surfaces of permanent teeth (DMFS) increment, and total time taken for examination and treatment. The authors of the Cochrane review concluded that a very low-quality body of evidence from one RCT was insufficient to reach any conclusions regarding the potential beneficial and harmful effects of varying recall intervals between dental check-ups. The Cochrane review *Recall intervals for oral health in primary care patients* was updated in 2020 by authors of the INTERVAL trial monograph, incorporating results from this study.[126] The updated search of 17 January 2020 identified the INTERVAL trial as the only new study eligible to be included in the updated review and the only trial to include patient participants > 18 years at trial entry. Given that different outcomes were reported in the two studies included in the updated Cochrane review, it was not possible to synthesise the data. The forest plots from the INTERVAL trial data are included to present the treatment effects across trial arm comparisons for the INTERVAL trial-reported outcomes (*Figures 21–23*).

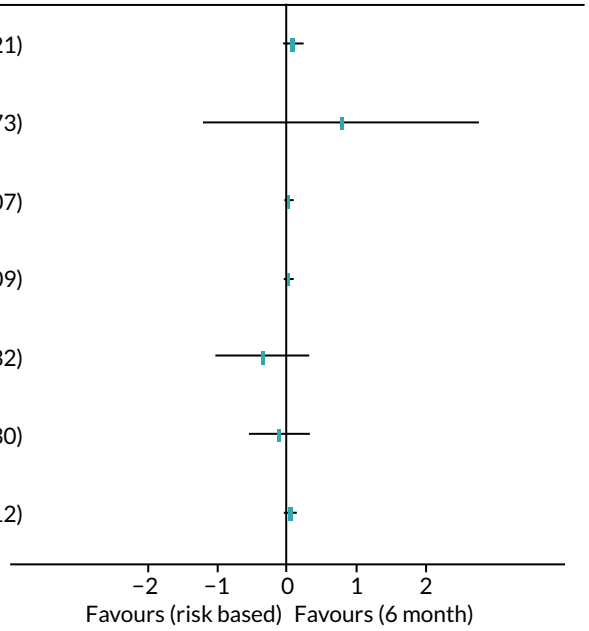
To our knowledge, this is the first RCT to fully integrate costs and benefits of different dental recall intervals and, therefore, provides the best available evidence on the short-term cost-effectiveness of different recall strategies proposed in the NICE guidance.[127] The NICE guidance was informed by a HTA report that developed a lifetime decision model to assess the cost-effectiveness of 3-, 6-, 12-, 18-, 24- and 36-month recall from a UK NHS perspective.[71] The report found that the incremental cost per decayed, missing, filled (DMF)-free tooth gained increased as recall intervals were narrowed; however, given that there is no evidence or precedence regarding society's WTP for a DMF-free tooth gained, the results are difficult to interpret. Furthermore, the scope of costs was limited, and included only check-ups and treatment for decay, omitting any other dental treatments that may be triggered by recall. Finally, the results are of limited value to current decision-making as the payment system for dentistry has been updated in England and Wales, since this review was carried out, to the current banding system. To our knowledge, there are no other studies directly relevant to the cost-effectiveness of routine dental checks or oral health reviews in a UK setting.

Strengths

The INTERVAL trial was a pragmatic trial in primary care dental practice designed to provide evidence for the clinical and cost-effectiveness of variable recall intervals. The traditional view and 'mantra' of 6-month check-ups still exists among the majority of patients and dental professionals despite the introduction of recommendations decades ago for a risk-based and variable approach to reviewing patients.[3] The design of INTERVAL was complex and unique in order to answer the commissioning brief. A strength of the design was being able to compare three recall intervals and demonstrate the ability of dentists to distinguish between high- and low-risk routine dental attenders. INTERVAL included outcomes that were relevant and important to patients, clinicians and policy-makers. The design enabled and ensured that the most robust measures were collected including independent clinical assessments and access to national routine data.

(a)

Study or subgroup	Risk based Mean	SD	Total	6 month Mean	SD	Total	Mean difference IV, fixed, 95% CI
Mean number of surfaces with extensive caries							
INTERVAL unpublished	0.4052	1.2771	747	0.3252	1.2771	736	0.08 (−0.05 to 0.21)
Gingival bleeding: percentage of sites							
INTERVAL unpublished	33.4	19.0854	741	32.62	19.0854	731	0.78 (−1.17 to 2.73)
Probing pocket depth (mm)							
INTERVAL unpublished	2.2	0.3915	741	2.17	0.3915	731	0.03 (−0.01 to 0.07)
Patient satisfaction with care (1–7 scale where higher score is better)							
INTERVAL unpublished	5.3	0.6136	798	5.27	0.6136	809	0.03 (−0.03 to 0.09)
Patient OHIP–14 (0–56 scale where lower score is better)							
INTERVAL unpublished	5.236	6.7311	769	5.586	6 .7311	782	−0.35 (−1.02 to 0.32)
Patient anxiety (5–25 scale where low score is lower anxiety)							
INTERVAL unpublished	10.3377	4.1824	795	10.4477	4.1824	804	−0.11 (−0.52 to 0.30)
Patient attitude to oral health (1–7 scale where high score is better attitude)							
INTERVAL unpublished	4.1378	0.8181	798	4.0978	0.8181	809	0.04 (−0.04 to 0.12)



(b)

Study or subgroup	Risk based Events	Total	6 month Events	Total	Risk ratio M–H, fixed, 95% CI
Prevalence of extensive caries					
INTERVAL unpublished	130	747	120	736	1.07 (0.85 to 1.34)

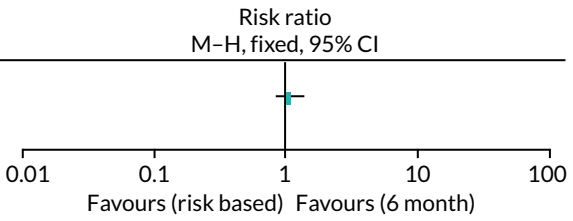
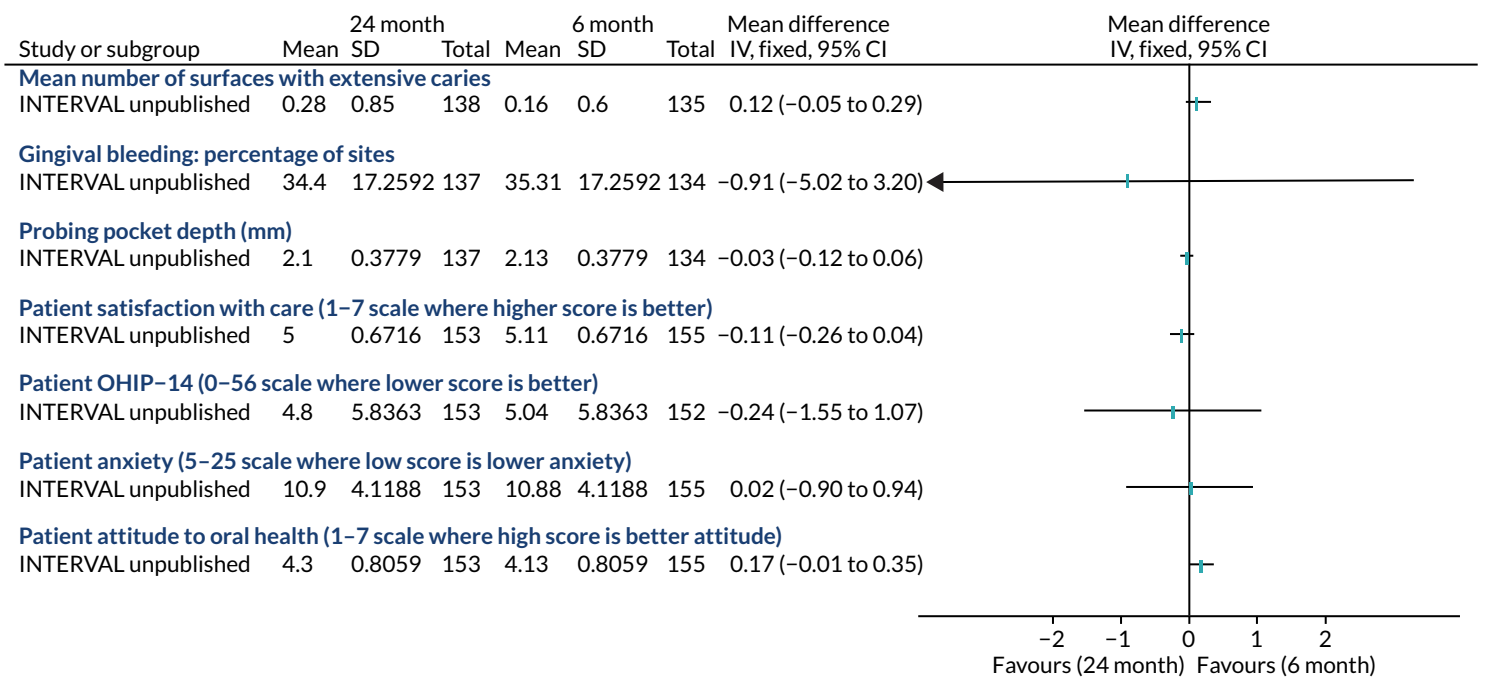


FIGURE 21 Forest plot for (a) the continuous outcomes; and (b) the outcome prevalence of extensive caries: risk-based vs. 6-month recall. M–H, Mantel–Haenszel.

(a)



(b)

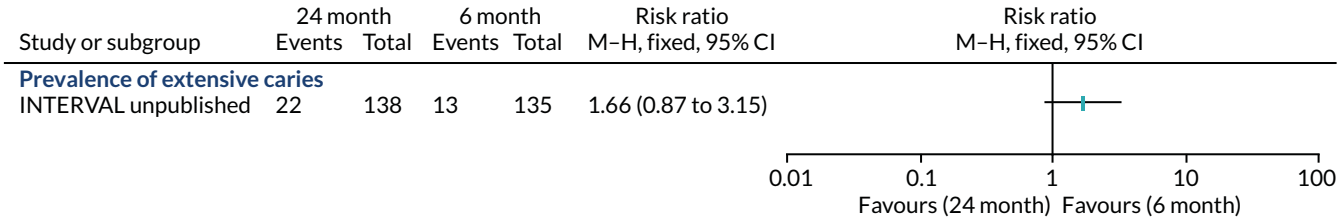
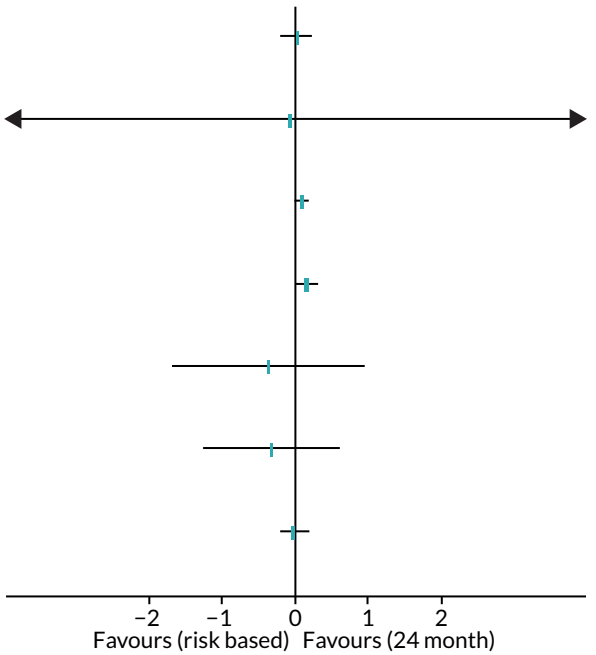


FIGURE 22 Forest plot for (a) the continuous outcomes; and (b) the outcome prevalence of extensive caries: 24-month vs. 6-month recall.

(a)

Study or subgroup	Risk based Mean	SD	Total	24 month Mean	SD	Total	Mean difference IV, fixed, 95% CI
Mean number of surfaces with extensive caries							
INTERVAL unpublished	0.3	0.9	143	0.28	0.85	138	0.02 (−0.18 to 0.22)
Gingival bleeding: percentage of sites							
INTERVAL unpublished	35.6	17.1573	142	35.67	17.1573	134	−0.07 (−4.12 to 3.98)
Probing pocket depth (mm)							
INTERVAL unpublished	2.2	0.3834	142	2.1	0.3834	137	0.10 (0.01 to 0.19)
Patient satisfaction with care (1–7 scale where higher score is better)							
INTERVAL unpublished	5.2	0.6672	151	5.04	0.6672	153	0.16 (0.01 to 0.31)
Patient OHIP–14 (0–56 scale where lower score is better)							
INTERVAL unpublished	4.1	5.811	145	4.47	5.811	153	−0.37 (−1.69 to 0.95)
Patient anxiety (5–25 scale where low score is lower anxiety)							
INTERVAL unpublished	10.5	4.0852	150	10.82	4.0852	153	−0.32 (−1.24 to 0.60)
Patient attitude to oral health (1–7 scale where higher score is better attitude)							
INTERVAL unpublished	4.3	0.8006	151	4.32	0.8006	153	−0.02 (−0.20 to 0.16)



(b)

Study or subgroup	Risk based Events	Total	24 month Events	Total	Risk ratio M–H, fixed, 95% CI
Prevalence of extensive caries					
INTERVAL unpublished	20	143	22	138	0.88 (0.50 to 1.53)

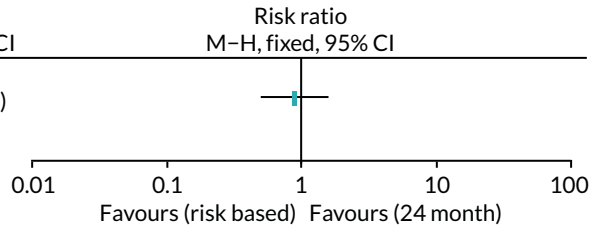


FIGURE 23 Forest plot for (a) the continuous outcomes; and (b) the outcome prevalence of extensive caries: risk-based vs. 24-month recall. M–H, Mantel–Haenszel.

Surprisingly, there have been few high-quality studies comparing different recall intervals, whether fixed or variable, according to risk. This is at a time when NHS resources are constrained, and there are demands for realistic and patient-centred care across health care. The published studies evaluating different recall intervals have involved few providers and most are in specialist settings that evaluate the impact of complex interventions usually directed at preventing caries in high-risk children. The only other trial undertaken was in a population of children and adolescents who received regular dental care in a public dental clinic in Norway from one dentist and one dental hygienist.[125] The trial inclusion criteria were less pragmatic than in INTERVAL, with individuals considered at high risk of dental caries excluded from the study. The commissioned call that INTERVAL answered presented a complex question that required a novel trial design. The strength of the design was to include two strata to avoid allocating participants to a 24-month recall for whom it was not clinically appropriate. A misinterpretation of INTERVAL may come about if the design is not understood. A significant strength is that dentists in INTERVAL applied their professional and clinical judgement before allocating a patient participant to the stratum that included randomisation to 24-month recall.

A strength of INTERVAL was that it was a pragmatic trial allowing the dentists and patient participants to respond to changes in circumstance. Changes in circumstance could have been logistics for allocating a recall appointment, or not attending as scheduled because of holidays, or responses to change in clinical condition. We predicted that the participants allocated to a 6-month recall would be most likely to attend at 9 months, thereby taking into account the added duration of any course of treatment following the previous check-up date and adjustments for the logistics or general life. A strength of INTERVAL is that dentists did implement a different recall interval for the patient participants randomised to the risk-based group in both strata of the trial. This overcame a potential risk at the outset that we might not observe a difference in the number of check-ups experienced; however, a surprising observation was that the time interval for the risk-based group was so close to the 6-month recall group. In addition, for patients whom dentists felt were suitable not to be seen, unless needed, for 24 months, dentists allocated a risk-based recall interval in between 6 months and 24 months, which was, however, not closer to the latter. A further strength of INTERVAL is that because of its pragmatic nature it has demonstrated that dentists can accurately and reliably assess risk as shown by the difference in the recall behaviours of the two strata.

The strengths of the INTERVAL trial include the recruitment and retention of a large number of centres ($n = 51$) and, to our knowledge, is the first dental trial to involve all the nations of the UK. As the nations operate in different contractual systems, INTERVAL provides insight to the potential impact that the system has on clinical decision-making and practice systems. The dental practices represent a wide range of geographical locations including remote and rural settings, and a range of characteristics including the number of dentists (average three), and whether or not they were a training practice, or employed at least one hygienist (70%). INTERVAL was not powered to detect differences across contractual systems and the numbers from Northern Ireland are too small to make any conclusions, although there appears to be a difference in the determination of risk-based recall interval for dentists in England and Scotland.

Recruitment and retention in trials is a frequent challenge, but an achievement for the INTERVAL trial was the recruitment of 2372 of the potentially eligible patients, and their retention with provision of data at 4 years from 1765 participants with 69% providing clinical data. This may be as a result of the participants being routine dental attenders and, hence, interested in dental health, and it was possibly their first invitation to participate in research. The randomised groups in both strata were balanced/similar at baseline and the reasons for loss to follow-up were related to inability of the practice to contact its patients; therefore, we were confident in the robustness of the results regardless of the missing data. The dental behaviour and clinical characteristics of the participants mean that the findings of the INTERVAL trial are generalisable to regular dental attenders across the UK in the NHS, and, therefore, also in similar third-party funding systems. Applying a risk-based determination of recall interval is advocated in many dental health-care systems and hence the findings of INTERVAL have relevance internationally.

The INTERVAL trial found no evidence of a difference in oral health from a risk-based recall interval compared with the traditional 6-month check-up. This also applied to patient participants whom the dentist assessed as low risk and suitable for a check-up at 24 months. For this group, the INTERVAL trial found no evidence of a difference between 24-month, risk-based or 6-month recall. The results were robust to sensitivity analyses exploring the impact of missing data.

The pragmatic design of the trial did not prevent fidelity to the interventions with separation in the frequency of dental check-ups between groups. We have evidence of intervention fidelity though monitoring intended check-up appointments. Dentists participated in training and were asked to revisit the e-learning tool, although compliance was variable. Conducting the trial in a primary care NHS setting with a design that involved minimal requirements for the dental practices, blind outcome assessment and access to routine data are strengths. The process undertaken to inform the determination of a risk-based recall was not independently observed (i.e. information collection, assessment and consultation with the patient); however, we believe the dentists performed this intervention as instructed in a way with which they were confident. The evidence from the dentist experience questionnaire supports the view that dentists who randomised participants to the 24-month stratum increased in confidence and were more likely to adopt/maintain that behaviour. In contrast to those who did not, their concern/anxiety increased by the end of the trial.

There was no evidence that different recall intervals made a difference to measures of patient quality of life, anxiety and satisfaction with care. The strength of INTERVAL was that these measures were collected annually during the 4 years of the trial. The reaction of some to them being considered suitable to have a recall interval of 24 months was an indication of confidence in their ability to maintain their oral health.

The health economic analysis is based on best practice methodology for conducting economic evaluation alongside RCTs. The analysis provides the only evidence that is relevant to decision-making in the UK NHS regarding the most efficient dental recall interval, and is based on the current, most up-to-date payment systems across the UK regions. The analysis is novel in implementing a CBA considering both WTP for dental health outcomes and wider societal benefits. The use of a DCE to capture the value placed on both the trial interventions and important dental health outcomes by the general population is a distinct advantage and overcomes the problems with interpreting economic evaluation results from other studies. The approach ensures consistency of methodology with recent economic evaluations of routine dental interventions (e.g. the IQuaD study[101]). A further advantage of CBA is the simultaneous valuation of multiple dental health outcomes within a single outcome measure (i.e. bleeding gums and dental decay), representing an important advantage over more traditional, single outcome measure cost-effectiveness studies (e.g. decayed teeth only) typically conducted in dentistry.

In terms of the within-trial analysis, we used best practice methodology, incorporating the most advanced recommendations for analysis with the appropriate use of missing data models to minimise the potential for bias.

Limitations

The INTERVAL trial experienced challenges throughout its course, some of which were anticipated and others of which could not have been predicted. Recruitment of dentists and participants was a challenge which was overcome, but this led to a considerable delay in the trial. The lack of research-experienced practices and the fact that the dentists were responsible for recruiting and obtaining consent from patient participants had an impact on our ability to reliably predict recruitment. INTERVAL was the first in a series of trials that the research team have been involved with, and experience has shown that a weakness was not having the research nurses supporting practices in person at dedicated recruitment sessions to overcome this. We did not collect information on the total number of routine patients approached as practices operated a process that complemented their practice management system; therefore, the reasons why patients chose not to participate in INTERVAL are unknown.

We experienced delays in analysis due to challenges encountered obtaining routine data. The process and mechanisms for establishing permission for access to routine data did not exist for England and Wales. Retrieving the routine data delayed analysis; the reasons for this included there not being a system for information retrieval or sharing of dental data at NHS services in England and Northern Ireland prior to INTERVAL.

A weakness was not collecting information on what factors were considered to inform the risk-based interval and the interaction with the patient to both determine risk and negotiate the interval. A possible weakness was the choice of the primary outcome as gingival bleeding on probing for which calibration is not possible. The rationale for this decision was that it is a measurable and modifiable outcome that indicates oral health in general. INTERVAL evaluated different recall intervals on maintaining oral health and no difference in this disease measure would reflect the absence of either improvement or deterioration. The other clinical outcomes were recorded, but the team's experience and previous research confirmed that the progression of caries and periodontal disease was going to be too slow in this population.

INTERVAL had a drop-out rate of 25–30% in the questionnaire data and 30–37% in attendance at appointments, a higher value than expected at the design stage of the trial. However, the 95% CIs for risk-based versus 6-month recall and risk-based versus 24-month recall precluded our predefined clinical minimally important differences in gingival bleeding of 4.5% and 7.5%, respectively. In addition, the drop-out rates were balanced between the arms, and sensitivity analyses using multiple imputation showed that the results were robust.

The analysis is based on 4-year outcomes from the trial. It is important to extrapolate trial results over a longer-term time horizon in order to fully capture all the costs and outcomes associated with different interventions. This was outwith the scope of the current study. There is no evidence from the trial to suggest differences in caries experience or bleeding across the different recall intervals, and it is therefore unlikely that a decision model would lead to different conclusions regarding the most efficient allocation of resources. There is a lack of good-quality information in dentistry to inform decision analysis models, for example estimates of long-term baseline transition probabilities to determine the life course of a tooth through different stages (well, decayed, root canal treatment required, missing). Further research is urgently required to bridge this gap in the evidence base and determine the economic value of long-term caries prevention.

There are different payment systems across the different UK regions. Dental check-ups are free of charge in the fee-for-service system in Scotland, there are patient co-payments in the Northern Ireland fee-for-service system, whereas England and Wales adopt a treatment banding approach. The method of payment and the cross-region variation raise three specific issues for the economic evaluation:

1. The payment for dental care services is not necessarily a true reflection of the opportunity cost of the resource required to deliver dental services. Owing to the practical barriers to conducting a detailed micro-costing exercise, and the vast number of different possible treatments in primary dental practice, we were not able to directly elicit opportunity costs in this study.
2. The different payment systems across the regions, and the process of submitting dental claims means that the resource use data collected from the practices varies substantially, which limits comparability. The quality of the data, in particular the detailed treatment information (e.g. check-ups and fillings) obtained from the routine claims data, could also potentially vary across countries.
3. The different systems may induce different provider and consumer behaviours, and different regional-specific incentives make direct comparability of results across the regions difficult. However, results are unlikely to be biased at the average UK level because the proportion of practices randomising to each group was approximately equal across the different regions.

Clinical assessment

Overcoming the practical challenge of arranging the final clinical assessment visits for participants at 51 dental practices across the four nations of the UK relied on trust, respect and partnership working between the research team and the general dental practices involved. Patient participants volunteered around 30 minutes of their time for the clinical assessment by one of the blinded assessment teams. The attendance of 1624 participants for their clinical assessments demonstrates their interest, commitment and the value placed on seeking evidence for routine oral health care and the role of practice-based dental research. The robust training undertaken prior to data collection and throughout the assessment period ensured consistency between assessors. The fact that calibration was not possible does not limit the findings, and we believe that no more could have been done to ensure reliable measures.

Patient and public involvement and engagement

Prior to the start of the trial, advice on the design and conduct of the study was sought from members of the Public Partnership Groups and from similar patient groups in other parts of the UK sourced under guidance from INVOLVE.

These independent public partnership groups comprise volunteers who work in partnership with NHS Tayside and aim to provide a conduit for the views of people about their local services.

Patient advisors were a valuable resource at the outset of the trial and they helped to ensure good conduct and patient-friendly practice throughout the duration of the trial. Patient advisors were involved with the trial design and provided invaluable feedback on trial recruitment and communication strategies. Patient advisors also contributed to the content and layout of the trial invitation, trial newsletters and the design of patient participant questionnaires. This ensured that trial participants could understand and easily complete these materials. This input was obtained remotely and from individuals. In future studies, we would recommend working with a group with some face-to-face interaction.

As quality of life was a primary outcome of the trial, patient advisors' input to the proposed questionnaire design was essential. Qualitative work with patients was carried out to ensure that the outcome measures were patient-centred.

Lay representatives on the TSC and TMC actively contributed to trial oversight, processes and procedures, including helping to interpret the trial findings, preparation of the monograph, and assisting with the review of the *Plain English summary*.

The results were discussed with the four Chief Dental Officers of the UK to enable early consideration of the implications for policy and practice.

Generalisability

The INTERVAL trial was designed pragmatically to investigate the effectiveness and cost–benefits of three different recall intervals. The 51 recruiting dental practices were situated in England, Wales, Northern Ireland and Scotland. On average, participating dentists had been qualified for 16 years and had an approximate total list size of 5000 patients. The average number of dentists in their practices was three and approximately 70% of practices employed at least one hygienist.

As at 30 September 2018, 94% of the adult population in Scotland were registered with an NHS dentist. Of these, 67% had attended their dentist at least once in the previous 2 years. The Adult Dental Health Survey 2009[114] reported that over half of the population in England, Wales and Northern Ireland had attended a dental practice within the last 3 years. The INTERVAL trial recruited 2372 patient participants who were regular attenders and had attended the dentist at least once in the previous 2 years, with 43% recruited in England and Wales, 7% in Northern Ireland and 50% in Scotland.[128]

At baseline, the average age of participants was 45 years, 55% were female, 15% identified as smokers and 55% used manual toothbrushes.

We are confident that the practices and participants recruited are a true representation of adults who attend NHS dental practices across the UK.

Recommendation for research

Further research is required to:

- enhance and support the communication of a variable risk-based recall interval to patients and the dental team, and the co-development of risk assessment tools
- develop recall interval quality management and improvement tools
- understand the role of risk-based recall and risk management of adults who are irregular dental attenders
- better understand public perceptions of the value of 6-month fixed-period recall intervals to help elucidate barriers to and facilitators of change
- inform methods for long-term decision modelling in dentistry utilising long-term dental cohort data where possible
- better utilise routine claims data sets, including tooth-level treatment data, to create cohorts of data to follow and predict individuals' health and to understand and improve care pathways in dentistry.

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Recruitment sites

We would like to thank the staff and participants of the following dental practices:

Aesthetics Dental & Implant Surgery, Amblecote Dental Care, Anita Belbin Dental Surgery, Bayview Dental Practice, Bridge Dental Centre, Brightons & Polmont Dental Practice, Brunswick Dental Practice, Bute Dental Surgery, Castle House Dental Practice, Chong Kwan Dental Centre, Church Road Dental Care, Colin C Yule & Associates, Collegiate Dental Practice, Cottam's Dental, Implant & Orthodontic Practice, Craigmillar Dental Centre, Discovery Dental Care, Dunbar Dental Practice, Eastside Dental Practice, Green Lane Dental Surgery, Hazel House Dental Surgery, Horizon Dental Clinic (Blyth), Horizon Dental Clinic (Monkseaton), Kelvingrove Dental Care Ltd, Kingsway Dental Practice, Lochshell Dental Clinic, Loughside Dental Practice, M&S Dental Care, Montgomery Street Dental Care, Montrose Dental Practice, Mount Florida Dental, My Dental Care, N13 Dental Clinic, Nairn Dental Clinic, Number One Surgery, Park View Family Dental, PCK Wee Dental Surgery, PG Lawson & Associates, Platt & Common, Roseville Dental Practice, Salmon Lane Dental Care, Shotley Bridge Dental Care, Six Gables Dental Practice, Smiledent Dental Practice, Southside Dental Care, St Leonard's Dental Practice, Walmley Dental Practice, Windsor Dental Practice (Manchester), Windsor Dental Practice (Salford), Woodside Dental Practice and Young Smile Dental Care.

Independent members of the Trial Steering Committee

Robert Elford, Trevor Johnson, Edwina Kidd (former chairperson), the late James Steele (chairperson) and Elizabeth Treasure (chairperson).

Members of the Trial Management Committee

Tony Anderson, Debbie Bonetti, Trevor Burke, Philip Dolan, Mark Forrest, Ronald Gorter, Richard Herbert, Penny Hodge, Dirk Mettes, Wendy McCombes, Ian Needleman, Margaret Ross and Debbie White.

Independent members of the Data Monitoring Committee

Martin Chalkley, Chris Deery and Simon Gates (chairperson).

Ethics approval

Ethics approval for the trial was given by the Fife and Forth Valley Research Ethics Committee on 13 January 2009 and 20 September 2011 (Research Ethics Committee reference 09/SO501/1).

The trial was registered with the ISRCTN (reference number ISRCTN95933794).

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The University of Dundee agreed to act as sponsor for the research and the study was adopted by the Scottish Dental Practice Based Research Network and the relevant local research networks in England, Wales and Northern Ireland.

Service support was provided by a central subvention from the NIHR and the local primary care trusts and health boards.

Contributions of authors

Jan E Clarkson (https://orcid.org/0000-0001-5940-2926) (Professor and Joint Chief Investigator) contributed to the conception and design of the trial, the conduct of the trial, the recruitment of dentists, the interpretation of the results, and the drafting, editing and approval of the monograph.

Nigel B Pitts (https://orcid.org/0000-0001-6184-4213) (Professor and Joint Chief Investigator) contributed to the conception and design of the trial, the conduct of the trial, the recruitment of dentists, the interpretation of results, and the drafting, editing and approval of the monograph.

Beatriz Goulao (https://orcid.org/0000-0003-1490-7183) (Statistician) developed the statistical analysis plan, led the statistical analyses, contributed to the interpretation of the data, made a significant contribution to the drafting of *Chapter 4*, and reviewed and approved the monograph.

Dwayne Boyers (https://orcid.org/0000-0002-9786-8118) (Health Economist) conducted the economic analysis, contributed to the interpretation of the data, drafted *Chapters 3* and *5*, and reviewed and approved the monograph.

Craig R Ramsay (https://orcid.org/0000-0003-4043-7349) (Professor) contributed to the conception and design of the trial, the conduct of the trial, oversaw trial methods, the interpretation of the results, and the drafting, editing and approval of the monograph.

Ruth Floate (https://orcid.org/0000-0003-2424-4643) (Trial Manager) was responsible for the day-to-day management of the trial, contributed to the interpretation of results, and the drafting and editing of the monograph.

Hazel J Braid (https://orcid.org/0000-0002-2062-8546) (Trial Administrator) was responsible for the day-to-day management of the trial, contributed to the interpretation of results, and the drafting and editing of the monograph.

Patrick A Fee (https://orcid.org/0000-0002-7188-3416) (Clinical Research Fellow) was responsible for the conduct of the trial, contributed to the collection of clinical outcomes, the interpretation of results, and the drafting and editing of the monograph.

Fiona S Ord (https://orcid.org/0000-0002-9901-7739) (Research Hygienist) was responsible for the recruitment of participants, contributed to the collection of clinical outcomes, and contributed to the drafting and editing of the monograph.

Helen V Worthington (https://orcid.org/0000-0002-4851-7469) (Professor and Triallist) contributed to the design of the trial, the interpretation of results and reviewing and approving the monograph.

Marjon van der Pol (https://orcid.org/0000-0003-0636-1184) (Professor) contributed to the conception and design of the health economics analysis, oversaw health economic methods, and contributed to editing the monograph.

Linda Young (https://orcid.org/0000-0002-6004-3374) (Research Manager and Economist) contributed to the design of the trial, the interpretation of results, and drafting and editing of the monograph.

Ruth Freeman (https://orcid.org/0000-0002-8733-1253) (Professor) contributed to the design of the trial, the interpretation of results, and reviewing and approving the monograph.

Jill Gouick (https://orcid.org/0000-0002-1456-8241) (Research Dental Nurse) was responsible for the collection of clinical outcomes, and contributed to reviewing and approving the monograph.

Gerald M Humphris (https://orcid.org/0000-0002-4601-8834) (Professor) contributed to the design of the trial, the interpretation of results, and reviewing and approving the monograph.

Fiona E Mitchell (https://orcid.org/0000-0002-7922-0676) (Research Dental Nurse) was responsible for the collection of clinical outcomes, and contributed to reviewing and approving the monograph.

Alison M McDonald (https://orcid.org/0000-0002-0256-2889) (Senior Trials Manager) was responsible for overseeing management of the trial and contributed to the interpretation of data, and to reviewing and approving the monograph.

John DT Norrie (https://orcid.org/0000-0001-9823-9252) (Professor and Triallist) contributed to the design of the trial, the interpretation of the data, and reviewing and approving the monograph.

Kirsty Sim (https://orcid.org/0000-0002-2365-5013) (Research Hygienist) was responsible for the collection of clinical outcomes, and contributed to reviewing and approving the monograph.

Gail Douglas (https://orcid.org/0000-0002-0531-3909) (Professor) contributed to the design of the trial, the interpretation of results, and reviewing and approving the monograph.

David Ricketts (https://orcid.org/0000-0002-9851-1778) (Professor) contributed to the design of the trial, the interpretation of results, and reviewing and approving the monograph.

Publication

Clarkson JE, Pitts NB, Bonetti D, Boyers D, Braid H, Elford R, *et al.* INTERVAL (investigation of NICE technologies for enabling risk-variable-adjusted-length) dental recalls trial: a multicentre randomised controlled trial investigating the best dental recall interval for optimum, cost-effective maintenance of oral health in dentate adults attending dental primary care. *BMC Oral Health* 2018;**18**:135.

Data-sharing statement

All available data can be obtained by contacting the corresponding author.

Patient data

This work uses data provided by patients and collected by the NHS as part of their care and support. Using patient data is vital to improve health and care for everyone. There is huge potential to make better use of information from people's patient records, to understand more about disease, develop new treatments, monitor safety and plan NHS services. Patient data should be kept safe and secure, to protect everyone's privacy, and it's important that there are safeguards to make sure that it is stored and used responsibly. Everyone should be able to find out about how patient data are used. #datasaveslives You can find out more about the background to this citation here: https://understandingpatientdata.org.uk/data-citation.

References

1. Clarkson JE, Pitts NB, Bonetti D, Boyers D, Braid H, Elford R, *et al.* INTERVAL (investigation of NICE technologies for enabling risk-variable-adjusted-length) dental recalls trial: a multicentre randomised controlled trial investigating the best dental recall interval for optimum, cost-effective maintenance of oral health in dentate adults attending dental primary care. *BMC Oral Health* 2018;**18**:135. https://doi.org/10.1186/s12903-018-0587-2
2. Sheiham A. Is there a scientific basis for six-monthly dental examinations? *Lancet* 1977;**310**:442–4. https://doi.org/10.1016/S0140-6736(77)90620-1
3. Clarkson JE, Amaechi BT, Ngo H, Bonetti D. Recall, reassessment and monitoring. *Monogr Oral Sci* 2009;**21**:188–98. https://doi.org/10.1159/000224223
4. Frame PS, Sawai R, Bowen WH, Meyerowitz C. Preventive dentistry: practitioners' recommendations for low-risk patients compared with scientific evidence and practice guidelines. *Am J Prev Med* 2000;**18**:159–62. https://doi.org/10.1016/S0749-3797(99)00138-5
5. Kay EJ. How often should we go to the dentist? *BMJ* 1999;**319**:204–5. https://doi.org/10.1136/bmj.319.7204.204
6. Patel S, Bay RC, Glick M. A systematic review of dental recall intervals and incidence of dental caries. *J Am Dent Assoc* 2010;**141**:527–39. https://doi.org/10.14219/jada.archive.2010.0225
7. Gussy MG, Bracksley S, Boxall A. *How Often Should You Have Dental Visits?* Deakin, ACT: Deeble Institute; 2013.
8. Fauchard P, Lindsay L. *The Surgeon Dentist: Or, Treatise on the Teeth. In Which is Seen the Means Used to Keep Them Clean and Healthy, of Beautifying Them, of Repairing Their Loss and Remedies for their Diseases and Those of the Gums and for Accidents Which May Befall the Other Parts in Their Vicinity. With Observations and Reflexions on Several Special Cases*. London: Butterworth & Co.; 1946.
9. Sheiham A. Routine check-ups. *Br Dent J* 2000;**189**:181. https://doi.org/10.1038/sj.bdj.4800718a
10. Routine six-monthly checks for dental disease? *Drug Ther Bull* 1985;**23**:69–72.
11. Elderton RJ. Routine six-monthly checks for dental disease? *Br Dent J* 1985;**159**:277. https://doi.org/10.1038/sj.bdj.4805706
12. Lock S. Getting the balance right. *Br Med J* 1986;**292**:428–9. https://doi.org/10.1136/bmj.292.6518.428
13. Perlus J. Determining recall frequency. A controversial issue. *Ont Dent* 1994;**71**:31–5.
14. Renson T. The six-monthly dental examination. *Dent Update* 1977;**4**:421–3.
15. Renson T. The professor, the newspaper and the six-monthly check-up. *Prim Dent Care* 2000;**7**:91. https://doi.org/10.1308/135576100322694141
16. Sheiham A. Is the six-monthly dental examination generally necessary? *Br Dent J* 1980;**148**:94. https://doi.org/10.1038/sj.bdj.4804393
17. Taylor G. Modernising NHS dentistry-implementing the NHS plan. *Community Dent Health* 2000;**17**:207–9.
18. Pitts NB. NHS Dentistry: Options for Change in context – a personal overview of a landmark document and what it could mean for the future of dental services. *Br Dent J* 2003;**195**:631–5. https://doi.org/10.1038/sj.bdj.4810779

19. Tan EH, Batchelor P, Sheiham A. A reassessment of recall frequency intervals for screening in low caries incidence populations. *Int Dent J* 2006;**56**:277–82. https://doi.org/10.1111/j.1875-595x.2006.tb00101.x

20. Leake JL, Birch S, Main PA, Ho E. Is regular visiting associated with lower costs? Analyzing service utilization patterns in the first nations population in Canada. *J Public Health Dent* 2006;**66**:116–22. https://doi.org/10.1111/j.1752-7325.2006.tb02566.x

21. Trombelli L, Farina R, Silva CO, Tatakis DN. Plaque-induced gingivitis: case definition and diagnostic considerations. *J Periodontol* 2018;**89**(Suppl. 1):46–73. https://doi.org/10.1002/JPER.17-0576

22. Papapanou PN. Epidemiology of periodontal diseases: an update. *J Int Acad Periodontol* 1999;**1**:110.

23. Papapanou PN, Sanz M, Buduneli N, Dietrich T, Feres M, Fine DH, *et al.* Periodontitis: consensus report of workgroup 2 of the 2017 World Workshop on the classification of periodontal and peri-implant diseases and conditions. *J Clin Periodont* 2018;**45**:S162–70.

24. Schätzle M, Löe H, Bürgin W, Ånerud Å, Boysen H, Lang NP. Clinical course of chronic periodontitis. Der klinische Verlauf chronischer Parodontitis: I. Die Rolle der Gingivitis. L'évolution clinique de la parodontite chronique. I. Le rôle de la gingivite. *J Clin Periodontol* 2003;**30**:887–901. https://doi.org/10.1034/j.1600-051X.2003.00414.x

25. Lang NP, Adler R, Joss A, Nyman S. Absence of bleeding on probing. An indicator of periodontal stability. *J Clin Periodontol* 1990;**17**:714–21. https://doi.org/10.1111/j.1600-051x.1990.tb01059.x

26. Loe H, Theilade E, Jensen SB. Experimental gingivitis in man. *J Periodontol* 1965;**36**:177–87. https://doi.org/10.1902/jop.1965.36.3.177

27. Theilade E. The non-specific theory in microbial etiology of inflammatory periodontal diseases. *J Clin Periodontol* 1986;**13**:905–11. https://doi.org/10.1111/j.1600-051x.1986.tb01425.x

28. Ekstrand KR, Bruun G, Bruun M. Plaque and gingival status as indicators for caries progression on approximal surfaces. *Caries Res* 1998;**32**:41–5. https://doi.org/10.1159/000016428

29. Linden GJ, Lyons A, Scannapieco FA. Periodontal systemic associations: review of the evidence. *J Clin Periodontol* 2013;**40**(Suppl. 14):8–19. https://doi.org/10.1111/jcpe.12064

30. Schenkein HA, Loos BG. Inflammatory mechanisms linking periodontal diseases to cardiovascular diseases. *J Clin Periodontol* 2013;**40**(Suppl. 14):51–69. https://doi.org/10.1111/jcpe.12060

31. Chapple IL, Genco R, Working group 2 of joint EFP/AAP workshop. Diabetes and periodontal diseases: consensus report of the Joint EFP/AAP Workshop on Periodontitis and Systemic Diseases. *J Clin Periodontol* 2013;**40**(Suppl. 14):106–12. https://doi.org/10.1111/jcpe.12077

32. Tonetti MS, Van Dyke TE, working group 1 of the joint EFP/AAP workshop*. Periodontitis and atherosclerotic cardiovascular disease: consensus report of the Joint EFP/AAP Workshop on Periodontitis and Systemic Diseases. *J Periodontol* 2013;**84**(Suppl. 4S):24–9. https://doi.org/10.1902/jop.2013.1340019

33. Tonetti MS, Jepsen S, Jin L, Otomo-Corgel J. Impact of the global burden of periodontal diseases on health, nutrition and wellbeing of mankind: a call for global action. *J Clin Periodontol* 2017;**44**:456–62. https://doi.org/10.1111/jcpe.12732

34. Petersen PE, Ogawa H. The global burden of periodontal disease: towards integration with chronic disease prevention and control. *Periodontol 2000* 2012;**60**:15–39. https://doi.org/10.1111/j.1600-0757.2011.00425.x

35. Albandar JM. Periodontal diseases in North America. *Periodontol 2000* 2002;**29**:31–69. https://doi.org/10.1034/j.1600-0757.2002.290103.x

36. Corbet EF. Periodontal diseases in Asians. *J Int Acad Periodontol* 2006;**8**:136.

37. Sheiham A, Smales FC, Cushing AM, Cowell CR. Changes in periodontal health in a cohort of British workers over a 14-year period. *Br Dent J* 1986;**160**:125–7. https://doi.org/10.1038/sj.bdj.4805788

38. Kassebaum NJ, Bernabe E, Dahiya M, Bhandari B, Murray CJL, Marcenes W. Global burden of severe periodontitis in 1990-2010: a systematic review and metaregression. *J Dent Res* 2014;**93**:1045–53. https://doi.org/10.1177/0022034514552491

39. Petersen PE. Sociobehavioural risk factors in dental caries – international perspectives. *Community Dent Oral Epidemiol* 2005;**33**:274–9. https://doi.org/10.1111/j.1600-0528.2005.00235.x

40. Pitts NB, Zero DT, Marsh PD, Ekstrand K, Weintraub JA, Ramos-Gomez F, *et al.* Dental caries. *Nat Rev Dis Primers* 2017;**3**:1–16. https://doi.org/10.1038/nrdp.2017.30

41. Mejàre I, Källest l C, Stenlund H. Incidence and progression of approximal caries from 11 to 22 years of age in Sweden: a prospective radiographic study. *Caries Res* 1999;**33**:93–100. https://doi.org/10.1159/000016502

42. Pine CM, ten Bosch JJ. Dynamics of and diagnostic methods for detecting small carious lesions. *Caries Res* 1996;**30**:381–8. https://doi.org/10.1159/000262348

43. Petersen PE, Bourgeois D, Ogawa H, Estupinan-Day S, Ndiaye C. The global burden of oral diseases and risks to oral health. *Bull World Health Organ* 2005;**83**:661–9.

44. Broadbent JM, Thomson WM, Poulton R. Trajectory patterns of dental caries experience in the permanent dentition to the fourth decade of life. *J Dent Res* 2008;**87**:69–72. https://doi.org/10.1177/154405910808700112

45. Bignozzi I, Crea A, Capri D, Littarru C, Lajolo C, Tatakis DN. Root caries: a periodontal perspective. *J Periodontal Res* 2014;**49**:143–63. https://doi.org/10.1111/jre.12094

46. Pretty IA, Ellwood RP. The caries continuum: opportunities to detect, treat and monitor the re-mineralization of early caries lesions. *J Dent* 2013;**41**(Suppl. 2):12–21. https://doi.org/10.1016/j.jdent.2010.04.003

47. Takahashi N, Nyvad B. Ecological hypothesis of dentin and root caries. *Caries Res* 2016;**50**:422–31. https://doi.org/10.1159/000447309

48. Featherstone JD. Fluoride, remineralization and root caries. *Am J Dent* 1994;**7**:271–4.

49. Slade GD, Gansky SA, Spencer AJ. Two-year incidence of tooth loss among South Australians aged 60+ years. *Community Dent Oral Epidemiol* 1997;**25**:429–37. https://doi.org/10.1111/j.1600-0528.1997.tb01734.x

50. Fure S, Zickert I. Incidence of tooth loss and dental caries in 60-, 70- and 80-year-old Swedish individuals. *Community Dent Oral Epidemiol* 1997;**25**:137–42. https://doi.org/10.1111/j.1600-0528.1997.tb00911.x

51. Slade GD, Spencer AJ, Locker D, Hunt RJ, Strauss RP, Beck JD. Variations in the social impact of oral conditions among older adults in South Australia, Ontario, and North Carolina. *J Dent Res* 1996;**75**:1439–50. https://doi.org/10.1177/00220345960750070301

52. Slade GD, Spencer AJ, Roberts-Thomson K. Tooth loss and chewing capacity among older adults in Adelaide. *Aust N Z J Public Health* 1996;**20**:76–82. https://doi.org/10.1111/j.1467-842X.1996.tb01341.x

53. Curzon ME, Preston AJ. Risk groups: nursing bottle caries/caries in the elderly. *Caries Res* 2004;**38**(Suppl. 1):24–33. https://doi.org/10.1159/000074359

54. Lamster IB, Asadourian L, Del Carmen T, Friedman PK. The aging mouth: differentiating normal aging from disease. *Periodontol 2000* 2016;**72**:96–107. https://doi.org/10.1111/prd.12131

55. Gluzman R, Katz RV, Frey BJ, McGowan R. Prevention of root caries: a literature review of primary and secondary preventive agents. *Spec Care Dentist* 2013;**33**:133–40. https://doi.org/10.1111/j.1754-4505.2012.00318.x

56. Tonetti MS, Chapple ILC, Jepsen S, Sanz M. Primary and secondary prevention of periodontal and peri-implant diseases. *J Clin Periodontol* 2015;**42**:S1–4. https://doi.org/10.1111/jcpe.12382

57. Axelsson P, Nyström B, Lindhe J. The long-term effect of a plaque control program on tooth mortality, caries and periodontal disease in adults. Results after 30 years of maintenance. *J Clin Periodontol* 2004;**31**:749–57. https://doi.org/10.1111/j.1600-051X.2004.00563.x

58. Kay E, Locker D. A systematic review of the effectiveness of health promotion aimed at improving oral health. *Community Dent Health* 1998;**15**:132–44.

59. Soldani FA, Lamont T, Jones K, Young L, Walsh T, Lala R, Clarkson JE. One-to-one oral hygiene advice provided in a dental setting for oral health. *Cochrane Database Syst Rev* 2018;**10**:CD007447. https://doi.org/10.1002/14651858.CD007447.pub2

60. National Collaborating Centre for Acute Care (UK). *Dental Recall: Recall Interval Between Routine Dental Examinations*. London: National Collaborating Centre for Acute Care (UK); 2004.

61. Scottish Dental Clinical Effectiveness Programme. *Oral Health Assessment and Review: Dental Clinical Guidance*. Dundee: Scottish Dental Clinical Effectiveness Programme (SDCEP); 2012.

62. Richards D. Are risk-based dental recalls risky? *Evid Based Dent* 2018;**19**:98–9. https://doi.org/10.1038/sj.ebd.6401353

63. Burt BA. *Dentistry, Dental Practice and the Community*. 6th edn. St Louis, MO: Elsevier; 2005.

64. Deep P. Screening for common oral diseases. *J Can Dent Assoc* 2000;**66**:298.

65. Mettes TG, van der Sanden WJ, Mulder J, Wensing M, Grol RP, Plasschaert AJ. Predictors of recall assignment decisions by general dental practitioners performing routine oral examinations. *Eur J Oral Sci* 2006;**114**:396–402. https://doi.org/10.1111/j.1600-0722.2006.00396.x

66. Conway DI, Purkayastha M, Chestnutt IG. The changing epidemiology of oral cancer: definitions, trends, and risk factors. *Br Dent J* 2018;**225**:867–73. https://doi.org/10.1038/sj.bdj.2018.922

67. Purkayastha M, McMahon AD, Gibson J, Conway DI. Is detecting oral cancer in general dental practices a realistic expectation? A population-based study using population linked data in Scotland. *Br Dent J* 2018;**225**:241–6. https://doi.org/10.1038/sj.bdj.2018.544

68. Brocklehurst PR, Speight PM. Screening for mouth cancer: the pros and cons of a national programme. *Br Dent J* 2018;**225**:815–19. https://doi.org/10.1038/sj.bdj.2018.918

69. Lingen MW, Kalmar JR, Karrison T, Speight PM. Critical evaluation of diagnostic aids for the detection of oral cancer. *Oral Oncol* 2008;**44**:10–22. https://doi.org/10.1016/j.oraloncology.2007.06.011

70. Tomar SL. There is weak evidence that a single, universal dental recall interval schedule reduces caries incidence. *J Evid Based Dent Pract* 2011;**11**:89–91. https://doi.org/10.1016/j.jebdp.2011.03.006

71. Davenport C, Elley K, Salas C, Taylor-Weetman CL, Fry-Smith A, Bryan S, Taylor R. The clinical effectiveness and cost-effectiveness of routine dental checks: a systematic review and economic evaluation. *Health Technol Assess* 2003;**7**(7). https://doi.org/10.3310/hta7070

72. Riley P, Worthington HV, Clarkson JE, Beirne PV. Recall intervals for oral health in primary care patients. *Cochrane Database Syst Rev* 2013;**12**:CD004346. https://doi.org/10.1002/14651858.CD004346.pub4

73. Dixon J. The international conference on harmonization good clinical practice guideline. *Qual Assur* 1998;**6**:65–74. https://doi.org/10.1080/105294199277860

74. Department of Health and Social Care (DHSC). *Research Governance Framework for Health and Social Care: Second Edition*. London: DHSC; 2005.

75. Scottish Executive Health Department. *Research Governance Framework for Health and Community Care*. 2nd edn. Edinburgh: Scottish Executive Health Department; 2006.

76. NIHR. *Good Clinical Practice*. URL: www.nihr.ac.uk/health-and-care-professionals/learning-and-support/good-clinical-practice.htm (accessed November 2013).

77. Hefti AF, Preshaw PM. Examiner alignment and assessment in clinical periodontal research. *Periodontol 2000* 2012;**59**:41–60. https://doi.org/10.1111/j.1600-0757.2011.00436.x

78. Ismail AI. Coordinating ICDAS Committee. *Rationale and Evidence for the International Caries Detection and Assessment System (ICDAS II)*. Stookey G (ed). Indianapolis, IN: Proceedings of the 7th Indiana Conference; 2005. pp. 161–222.

79. Chesters RK, Pitts NB, Matuliene G, Kvedariene A, Huntington E, Bendinskaite R, *et al.* An abbreviated caries clinical trial design validated over 24 months. *J Dent Res* 2002;**81**:637–40. https://doi.org/10.1177/154405910208100912

80. NICE. *Dental Recall – Recall Interval Between Routine Dental Examinations*. URL: www.nice.org.uk/guidance/cg19/evidence/full-guideline-pdf-193348909 (accessed October 2020).

81. Slade GD. Derivation and validation of a short-form oral health impact profile. *Community Dent Oral Epidemiol* 1997;**25**:284–90. https://doi.org/10.1111/j.1600-0528.1997.tb00941.x

82. Humphris GM, Morrison T, Lindsay SJ. The Modified Dental Anxiety Scale: validation and United Kingdom norms. *Community Dent Health* 1995;**12**:143–50.

83. Löe H. The Gingival Index, the Plaque Index and the Retention Index Systems. *J Periodontol* 1967;**38**:610–16. https://doi.org/10.1902/jop.1967.38.6.610

84. Humphris GM, Freeman R, Campbell J, Tuutti H, D'Souza V. Further evidence for the reliability and validity of the Modified Dental Anxiety Scale. *Int Dent J* 2000;**50**:367–70. https://doi.org/10.1111/j.1875-595x.2000.tb00570.x

85. Bandura A. Health promotion from the perspective of social cognitive theory. *Psychology Health* 1998;**13**:623–49. https://doi.org/10.1080/08870449808407422

86. Gollwitzer PM. Implementation intentions – strong effects of simple plans. *Am Psychologist* 1999;**54**:493–503. https://doi.org/10.1037/0003-066X.54.7.493

87. Clarkson JE, Young L, Ramsay CR, Bonner BC, Bonetti D. How to influence patient oral hygiene behavior effectively. *J Dent Res* 2009;**88**:933–7. https://doi.org/10.1177/0022034509345627

88. Worthington HV, Clarkson JE, Bryan G, Beirne PV. Routine scale and polish for periodontal health in adults. *Cochrane Database Syst Rev* 2013;**2013**:CD004625. https://doi.org/10.1002/14651858.CD004625.pub4

89. Clarkson JE. *The Effectiveness of Enhanced Oral Health Advice and Instruction Upon Patient Oral Hygiene, Knowledge, and Self-reported Behaviour*. Edinburgh: Chief Scientist Office; 2005.

90. Keogh-Brown MR, Bachmann MO, Shepstone L, Hewitt C, Howe A, Ramsay CR, *et al.* Contamination in trials of educational interventions. *Health Technol Assess* 2007;**11**(43). https://doi.org/10.3310/hta11430

91. White IR, Thompson SG. Adjusting for partially missing baseline measurements in randomized trials. *Stat Med* 2005;**24**:993–1007. https://doi.org/10.1002/sim.1981

92. Sullivan TR, White IR, Salter AB, Ryan P, Lee KJ. Should multiple imputation be the method of choice for handling missing data in randomized trials? *Stat Methods Med Res* 2018;**27**:2610–26. https://doi.org/10.1177/0962280216683570

93. Kastenbom L, Falsen A, Larsson P, Sunnegårdh-Grönberg K, Davidson T. Costs and health-related quality of life in relation to caries. *BMC Oral Health* 2019;**19**:187. https://doi.org/10.1186/s12903-019-0874-6

94. Bala MV, Zarkin GA. Are QALYs an appropriate measure for valuing morbidity in acute diseases? *Health Econ* 2000;**9**:177–80. https://doi.org/10.1002/(SICI)1099-1050(200003)9:2<177::AID-HEC497>3.0.CO;2-2

95. Birch S, Ismail AI. Patient preferences and the measurement of utilities in the evaluation of dental technologies. *J Dent Res* 2002;**81**:446–50. https://doi.org/10.1177/154405910208100702

96. Statistics for Wales. *NHS Dental Statistics in Wales: 2016–17*. Cardiff: Welsh Government; 2017.

97. NHS Digital. *A Guide to NHS Dental Publications*. Leeds: NHS Digital; 2017.

98. Business Services Authority. *NHS Payments to Dentists*. URL: www.nhsbsa.nhs.uk/dental-data/nhs-payments-dentists (accessed 19 July 2019).

99. Department of Health and Social Care. *NHS Dental Services in England. An Independent Review Led by Professor Jimmy Steele*. London: Department of Health and Social Care; 2009. URL: https://webarchive.nationalarchives.gov.uk/20130124050405/www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_101180.pdf (accessed 1 June 2019).

100. Lord J, Longworth L, Singh J, Onyimadu O, Fricke J, Bayliss S, *et al. Oral Health Guidance – Economic Analysis of Oral Health Promotion Approaches for Dental Teams*. Birmingham: Birmingham and Brunel Consortium External Assessment Centre; 2015.

101. Ramsay CR, Clarkson JE, Duncan A, Lamont TJ, Heasman PA, Boyers D, *et al.* Improving the Quality of Dentistry (IQuaD): a cluster factorial randomised controlled trial comparing the effectiveness and cost–benefit of oral hygiene advice and/or periodontal instrumentation with routine care for the prevention and management of periodontal disease in dentate adults attending dental primary care. *Health Technol Assess* 2018;**22**(38). https://doi.org/10.3310/hta22380

102. Campbell and Cochrane Economics Methods Group (CCEMG) and the Evidence for Policy and Practice Information and Coordinating Centre (EPPI-Centre). *CCEMG – EPPI-Centre Cost Converter v.1.4*. URL: https://eppi.ioe.ac.uk/costconversion/ (accessed April 2019).

103. National Institute for Health and Care Excellence (NICE). *Guide to the Methods of Technology Appraisal 2013*. London: NICE; 2013.

104. Department of Health and Social Care (DHSC). *NHS Reference Costs 201718*. London: DHSC; 2018. URL: https://improvement.nhs.uk/resources/reference-costs/#rc1718 (accessed July 2019).

105. Thompson S, Wordsworth S. *An Annotated Cost Questionnaire for Completion by Patients. Heru Discussion Paper No (03/01)*. Health Economics Research Unit, University of Aberdeen, Aberdeen. 2001. URL: www.abdn.ac.uk/heru/documents/BP/HERU_Discussion_paper_03-01.pdf (accessed February 2019).

106. Office for National Statistics. *Annual Survey of Hours and Earnings: 2017 Provisional and 2016 Revised Results*. URL: www.ons.gov.uk/employmentandlabourmarket/peopleinwork/earningsandworkinghours/bulletins/annualsurveyofhoursandearnings/2017provisionaland2016revisedresults (accessed September 2019).

107. HM Revenue & Customs. *Travel – Mileage and Fuel Rates and Allowances*. URL: www.gov.uk/government/publications/rates-and-allowances-travel-mileage-and-fuel-allowances/travel-mileage-and-fuel-rates-and-allowances (accessed May 2019).

108. NHS Pay Review Body, Cope J. *NHS Pay Review Body Twenty-Ninth Report 2016*. London: Her Majesty's Government; 2016.

109. Department for Transport. *Transport Analysis Guidance (TAG) Data Book* version 1.8. London: Department for Transport; 2017.

110. Health Services Research Unit. *Statistical Analysis of Costs – Stata Programs*. URL: www.uphs.upenn.edu/dgimhsr/stat-cstanal.htm (accessed July 2019).

111. Glick HA, Doshi JA, Sonnad SS, Polsky D. *Economic Evaluation in Clinical Trials*. 2nd edn. Oxford: Oxford University Press; 2014.

112. Gomes M, Díaz-Ordaz K, Grieve R, Kenward MG. Multiple imputation methods for handling missing data in cost-effectiveness analyses that use data from hierarchical studies: an application to cluster randomized trials. *Med Decis Making* 2013;**33**:1051–63. https://doi.org/10.1177/0272989X13492203

113. Rubin DB. *Multiple Imputation for Nonresponse in Surveys*. Hoboken, NJ: Wiley; 2009.

114. Steele J, O'Sullivan I. *Executive Summary: Adult Dental Health Survey 2009*. Leeds: NHS Digital; 2011.

115. McFadden D. Conditional Logit Analysis of Qualitative Choice Behaviour. In Zarembka P, editor. *Frontiers in Econometrics*. New York, NY: Academic Press; 1973. pp. 105–42.

116. Dolan P. Modeling valuations for EuroQol health states. *Med Care* 1997;**35**:1095–108. https://doi.org/10.1097/00005650-199711000-00002

117. Faria R, Gomes M, Epstein D, White IR. A guide to handling missing data in cost-effectiveness analysis conducted within randomised controlled trials. *PharmacoEconomics* 2014;**32**:1157–70. https://doi.org/10.1007/s40273-014-0193-3

118. Brand J, van Buuren S, le Cessie S, van den Hout W. Combining multiple imputation and bootstrap in the analysis of cost-effectiveness trial data. *Stat Med* 2019;**38**:210–20. https://doi.org/10.1002/sim.7956

119. Chapple ILC, Mealey BL, Van Dyke TE, Bartold PM, Dommisch H, Eickholz P, *et al.* Periodontal health and gingival diseases and conditions on an intact and a reduced periodontium: consensus report of workgroup 1 of the 2017 World Workshop on the Classification of Periodontal and Peri-Implant Diseases and Conditions. *J Clin Periodontol* 2018;**45**(Suppl. 20):68–77. https://doi.org/10.1111/jcpe.12940

120. Office for National Statistics. *Census Data Catalogue*. 2011. URL: www.ons.gov.uk/census/2011census/2011censusdata/2011censusdatacatalogue (accessed June 2019).

121. Office for National Statistics. *Adult Smoking Habits in Great Britain, 2013*. URL: https://www.ons.gov.uk/peoplepopulationandcommunity/healthandsocialcare/healthandlifeexpectancies/compendium/opinionsandlifestylesurvey/2015-03-19/adultsmokinghabitsingreatbritain2013 (accessed 1 June 2019).

122. UK Government Department for Work and Pensions. *Family Resources Survey 2016/17*. URL: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/692771/family-resources-survey-2016-17.pdf (accessed 1 June 2019).

123. Kirsch J, Tchorz J, Hellwig E, Tauböck TT, Attin T, Hannig C. Decision criteria for replacement of fillings: a retrospective study. *Clin Exp Dent Res* 2016;**2**:121–8. https://doi.org/10.1002/cre2.30

124. Hettiarachchi RM, Kularatna S, Downes MJ, Byrnes J, Kroon J, Lalloo R, *et al*. The cost-effectiveness of oral health interventions: a systematic review of cost-utility analyses. *Community Dent Oral Epidemiol* 2018;**46**:118–24. https://doi.org/10.1111/cdoe.12336

125. Wang N, Marstrander P, Holst D, Ovrum L, Dahle T. Extending recall intervals – effect on resource consumption and dental health. *Community Dent Oral Epidemiol* 1992;**20**:122–4. https://doi.org/10.1111/j.1600-0528.1992.tb01544.x

126. Fee PA, Riley P, Worthington HV, Clarkson JE, Boyers D, Beirne PV. Recall intervals for oral health in primary care patients. *Cochrane Database Syst Rev* 2020;**10**:CD004346.

127. Beirne P. *Dental Recall: Recall Interval Between Routine Dental Examinations*. London: National Collaborating Centre for Acute Care UK; 2004.

128. Information Services Scotland. *Dental Statistics – NHS Registration and Participation – Statistics up to 30 September 2018*. Edinburgh: Information Services Division; 2019.

Appendix 1 Clinical effectiveness outcomes

TABLE 26 Patient-reported outcomes calculation

Outcomes	Questions	Scoring
Behaviour	Section 2 Q1, Q3, Q9, Q11	Sum of the questions[a]
Knowledge	Section 2 Q2, Q4, Q10, Q12	Sum of the questions[a]
Attitude	Section 3 Q1 to Q7	Mean of all questions
PBC	Section 3 Q8 to Q11	Mean of all questions
Satisfaction with care	Section 3 Q12 to Q23	Mean of all questions

a The best value between flossing and interdental brushes was used as a measure of interdental cleaning behaviour.

TABLE 27 Dentist belief questionnaire outcomes calculation

Outcomes	Description	Questions	Scoring
Attitude to the 6-month interval	Attitude to the 6-month interval. Higher scores represent a positive attitude towards the 6-month interval	Q1, Q4, Q5, Q7, Q8, Q9, Q10, Q12, Q13, Q15, Q16, Q18	Mean of all questions
Attitude to the 24-month interval	Attitude to the 24-month interval. Higher scores represent a positive attitude towards the 24-month interval	Q3, Q14, Q17, Q19	Mean of all questions
General attitude	General attitude to the patient's ability to maintain self-care. Higher scores represent a positive attitude	Q2, Q6, Q11	Mean of all questions
PBC	Perceived ability to assess risk. Higher scores represent greater PBC	Q20, Q21 (a) to (c)	Mean of all questions

TABLE 28 Recruitment by centre

	Strata		
Centre name	Ineligible 24-month recall	Eligible 24-month recall	Total
Six Gables Dental Practice, Cardiff	6	7	13
Craigmillar Dental Centre, Edinburgh	1	8	9
Colin C Yule & Associates, Forfar	1	59	60
Roseville Dental Practice, West Midlands	2	19	21
Cottam's Dental, Implant & Orthodontic Practice, Birmingham	26	1	27
Walmley Dental Practice, Sutton Coldfield	18	12	30
Amblecote Dental Care, West Midlands	48	14	62
M&S Dental Care, Fort William	3	44	47
Southside Dental Care, Edinburgh	0	54	54
Kingsway Dental Practice, Dundee	38	38	76
Brightons Dental Surgery, Falkirk	14	38	52

continued

TABLE 28 Recruitment by centre (*continued*)

Centre name	Strata		Total
	Ineligible 24-month recall	Eligible 24-month recall	
Montrose Dental Care, Montrose	5	47	52
Bayview Dental Practice, Banff	6	16	22
Young Smile Dental Care, Alford	38	17	55
Mount Florida Dental Care, Glasgow	40	15	55
Horizon Dental Clinic, Monkseaton	0	6	6
Horizon Dental Clinic, Blyth	0	4	4
Green Lane Dental, Birmingham	23	40	63
Aesthetics Dental and Implant Surgery, Birmingham	16	23	39
Platt & Common, Stirling	3	6	9
Chong Kwan Dental Centre, Dunfermline	0	79	79
Brunswick Dental Practice, Newcastle	4	75	79
Hazel House Dental Surgery, Inverness	11	5	16
Castle House Dental Practice, Inverness	10	30	40
PCK Wee Dental Surgery, London	1	110	111
Family Dental Care, London	1	5	6
Smiledent Dental Practice, London	4	33	37
Ballynahinch Dental Care, Belfast	47	2	49
Loughside Dental Practice, Belfast	30	22	52
Church Road Dental Care, Belfast	11	41	52
Anita Belbin Dental Surgery, Glasgow	2	50	52
N13 Dental Clinic, London	3	51	54
Mr I Lightfoot, Newcastle	0	28	28
Shotley Bridge Dental Care, Newcastle	6	44	50
Discovery Dental Care, Dundee	28	26	54
Nairn Dental Clinic, Inverness	15	41	56
My Dental Care, London	5	35	40
Salmon Lane Dental Care, London	3	49	52
Eastside Dental Practice, London	15	52	67
Bridge Dental Centre, London	4	52	56
Park View Family Dental, Newcastle	16	130	146
Dunbar Dental Practice, Dunbar	67	28	95
St Leonards Dental Practice, Glasgow	3	49	52
Woodside Dental Practice, Glasgow	4	11	15
Lochshell Dental Clinic, Wick	21	11	32
Bute Dental Surgery, Bute	14	39	53
Windsor Dental Practice, Salford	4	19	23
Windsor Dental Practice, Manchester	4	1	5
Kelvingrove Dental Care Ltd, Glasgow	0	100	100
Montgomery Street Dental Practice, Edinburgh	20	33	53
Collegiate Dental Practice, Manchester	7	5	12

TABLE 29 Participant characteristics at baseline in Scotland by randomised group

	Eligible 24-month recall			Ineligible 24-month recall	
Characteristic	**Risk based**	**24 month**	**6 month**	**Risk based**	**6 month**
Randomised, *n* (%)	111 (100.0)	117 (100.0)	116 (100.0)	419 (100.0)	425 (100.0)
Baseline questionnaire returned, *n* (%)	102 (91.9)	109 (93.2)	108 (93.1)	391 (93.3)	387 (91.1)
Age, mean (SD), *n*	42.4 (14.6), 111	47.2 (15.4), 117	46.6 (14.7), 116	49.1 (13.4), 419	49.9 (14.3), 425
Female participants, *n* (%)	70 (63.1)	66 (56.4)	66 (56.9)	245 (58.5)	248 (58.4)
Regular smoker, *n* (%)	19 (17.1)	18 (15.4)	17 (14.7)	88 (21.0)	60 (14.1)
Time since previous visit to dentist, *n* (%)					
< 1 year	96 (86.5)	96 (82.1)	100 (86.2)	370 (88.3)	366 (86.1)
1–2 years	4 (3.6)	13 (11.1)	7 (6.0)	18 (4.3)	16 (3.8)
> 2 years	1 (0.9)	–	1 (0.9)	–	–
Patient status, *n* (%)					
NHS	89 (80.2)	97 (82.9)	93 (80.2)	347 (82.8)	325 (76.5)
Private	2 (1.8)	5 (4.3)	2 (1.7)	12 (2.9)	13 (3.1)
Combination	4 (3.6)	2 (1.7)	6 (5.2)	17 (4.1)	29 (6.8)
Type of toothbrush, *n* (%)					
Manual	65 (58.6)	76 (65.0)	60 (51.7)	232 (55.4)	234 (55.1)
Electric	35 (31.5)	32 (27.4)	48 (41.4)	158 (37.7)	150 (35.3)
Regular attender: self-report, *n* (%)	92 (82.9)	102 (87.2)	101 (87.1)	373 (89.0)	359 (84.5)
Difficulty travelling to dentist, mean (SD), *n*	6.5 (1.2), 101	6.6 (1.0), 109	6.4 (1.2), 107	6.4 (1.1), 389	6.3 (1.2), 383

TABLE 30 Participant characteristics at baseline in England by randomised group

	Eligible 24-month recall			Ineligible 24-month recall	
Characteristic	Risk based	24 month	6 month	Risk based	6 month
Randomised, *n* (%)	75 (100.0)	69 (100.0)	72 (100.0)	410 (100.0)	405 (100.0)
Baseline questionnaire returned, *n* (%)	62 (82.7)	61 (88.4)	64 (88.9)	391 (95.4)	386 (95.3)
Age, mean (SD), *n*	43.9 (14.6), 75	39.8 (14.3), 69	40.0 (13.1), 72	49.8 (14.6), 410	50.7 (16.1), 405
Female participants, *n* (%)	45 (60.0)	40 (58.0)	43 (59.7)	236 (57.6)	221 (54.6)
Regular smokers, *n* (%)	9 (12.0)	7 (10.1)	12 (16.7)	53 (12.9)	65 (16.0)
Time since previous visit to dentist, *n* (%)					
< 1 year	54 (72.0)	47 (68.1)	51 (70.8)	342 (83.4)	345 (85.2)
1–2 years	7 (9.3)	10 (14.5)	9 (12.5)	41 (10.0)	35 (8.6)
> 2 years	–	4 (5.8)	2 (2.8)	4 (1.0)	–
Patient status, *n* (%)					
NHS	53 (70.7)	48 (69.6)	54 (75.0)	328 (80.0)	330 (81.5)
Private	2 (2.7)	5 (7.2)	2 (2.8)	17 (4.1)	15 (3.7)
Combination	5 (6.7)	4 (5.8)	4 (5.6)	34 (8.3)	24 (5.9)
Type of toothbrush, *n* (%)					
Manual	39 (52.0)	47 (68.1)	44 (61.1)	238 (58.0)	244 (60.2)
Electric	22 (29.3)	13 (18.8)	20 (27.8)	151 (36.8)	136 (33.6)
Regular attender: self-report, *n* (%)	52 (69.3)	49 (71.0)	54 (75.0)	340 (82.9)	348 (85.9)
Difficulty travelling to dentist, mean (SD), *n*	6.3 (1.2), 61	6.1 (1.6), 61	6.3 (1.2), 64	6.3 (1.3), 388	6.3 (1.2),3 78

TABLE 31 Participant characteristics at baseline in Northern Ireland by randomised group

	Eligible 24-month recall			Ineligible 24-month recall	
Characteristic	**Risk-based**	**24 month**	**6 month**	**Risk based**	**6 month**
Randomised, *n* (%)	31 (100.0)	30 (100.0)	27 (100.0)	32 (100.0)	33 (100.0)
Baseline questionnaire returned, *n* (%)	17 (54.8)	16 (53.3)	15 (55.6)	28 (87.5)	30 (90.9)
Age, mean (SD), *n*	45.2 (18.3), 31	42.4 (14.5), 30	39.7 (14.6), 27	46.7 (17.8), 32	44.8 (16.6), 33
Female participants, *n* (%)	13 (41.9)	9 (30.0)	12 (44.4)	17 (53.1)	22 (66.7)
Regular smokers, *n* (%)	4 (12.9)	2 (6.7)	3 (11.1)	4 (12.5)	5 (15.2)
Time since previous visit to dentist, *n* (%)					
< 1 year	15 (48.4)	14 (46.7)	14 (51.9)	25 (78.1)	30 (90.9)
1–2 years	2 (6.5)	1 (3.3)	–	3 (9.4)	–
> 2 years	–	–	1 (3.7)	–	–
Patient status, *n* (%)					
NHS	10 (32.3)	9 (30.0)	8 (29.6)	20 (62.5)	22 (66.7)
Private	4 (12.9)	2 (6.7)	3 (11.1)	4 (12.5)	4 (12.1)
Combination	3 (9.7)	2 (6.7)	4 (14.8)	3 (9.4)	3 (9.1)
Type of toothbrush, *n* (%)					
Manual	10 (32.3)	8 (26.7)	9 (33.3)	19 (59.4)	18 (54.5)
Electric	7 (22.6)	8 (26.7)	6 (22.2)	9 (28.1)	12 (36.4)
Regular attender: self-report, *n* (%)	14 (45.2)	12 (40.0)	13 (48.1)	27 (84.4)	28 (84.8)
Difficulty travelling to dentist, mean (SD), *n*	6.0 (1.3), 17	6.9 (0.3), 16	6.5 (1.2), 15	6.2 (1.5), 28	6.4 (1.1), 30

TABLE 32 Participants' oral health-related behaviour and knowledge at baseline in Scotland by randomised group

Oral health-related behaviour or knowledge	Eligible 24-month recall			Ineligible 24-month recall	
	Risk based (*N* = 111)	24 month (*N* = 117)	6 month (*N* = 116)	Risk based (*N* = 419)	6 month (*N* = 425)
Frequency of brushing,* n *(%)					
Twice a day	66 (59.5)	75 (64.1)	76 (65.5)	272 (64.9)	270 (63.5)
More than twice a day	14 (12.6)	9 (7.7)	6 (5.2)	42 (10.0)	43 (10.1)
How often should you be brushing?* n *(%)					
Twice a day	81 (73.0)	85 (72.6)	89 (76.7)	271 (64.7)	281 (66.1)
More than twice a day	19 (17.1)	20 (17.1)	18 (15.5)	109 (26.0)	95 (22.4)
Duration of brushing,* n *(%)					
2 minutes	49 (44.1)	58 (49.6)	49 (42.2)	183 (43.7)	178 (41.9)
> 2 minutes	16 (14.4)	16 (13.7)	19 (16.4)	71 (16.9)	61 (14.4)
How long should you brush for?* n *(%)					
2 minutes	68 (61.3)	66 (56.4)	70 (60.3)	242 (57.8)	246 (57.9)
> 2 minutes	24 (21.6)	29 (24.8)	29 (25.0)	109 (26.0)	95 (22.4)
Spit not rinse after brushing, *n* (%)	51 (45.9)	44 (37.6)	47 (40.5)	140 (33.4)	126 (29.6)
Should spit not rinse after brushing, *n* (%)	59 (53.2)	59 (50.4)	57 (49.1)	161 (38.4)	154 (36.2)

TABLE 33 Participants' oral health-related behaviour and knowledge at baseline in England by randomised group

Oral health-related behaviour or knowledge	Eligible 24-month recall			Ineligible 24-month recall	
	Risk based (*N* = 75)	24 month (*N* = 69)	6 month (*N* = 72)	Risk based (*N* = 410)	6 month (*N* = 405)
Frequency of brushing,* n *(%)					
Twice a day	45 (60.0)	40 (58.0)	48 (66.7)	271 (66.1)	294 (72.6)
More than twice a day	8 (10.7)	5 (7.2)	1 (1.4)	39 (9.5)	34 (8.4)
How often should you be brushing?* n *(%)					
Twice a day	49 (65.3)	56 (81.2)	54 (75.0)	312 (76.1)	304 (75.1)
More than twice a day	11 (14.7)	5 (7.2)	7 (9.7)	65 (15.9)	66 (16.3)
Duration of brushing,* n *(%)					
2 minutes	32 (42.7)	34 (49.3)	24 (33.3)	164 (40.0)	191 (47.2)
> 2 minutes	8 (10.7)	9 (13.0)	13 (18.1)	91 (22.2)	67 (16.5)
How long should you brush for?* n *(%)					
2 minutes	42 (56.0)	42 (60.9)	45 (62.5)	222 (54.1)	226 (55.8)
> 2 minutes	14 (18.7)	12 (17.4)	13 (18.1)	114 (27.8)	99 (24.4)
Spit not rinse after brushing, *n* (%)	8 (10.7)	6 (8.7)	13 (18.1)	59 (14.4)	49 (12.1)
Should spit not rinse after brushing, *n* (%)	8 (10.7)	9 (13.0)	14 (19.4)	75 (18.3)	74 (18.3)

TABLE 34 Participants' oral health-related behaviour and knowledge at baseline in Northern Ireland by randomised group

Oral health-related behaviour or knowledge	Eligible 24-month recall			Ineligible 24-month recall	
	Risk based (*N* = 31)	24 month (*N* = 30)	6 month (*N* = 27)	Risk based (*N* = 32)	6 month (*N* = 33)
Frequency of brushing*, n *(%)					
Twice a day	12 (38.7)	13 (43.3)	8 (29.6)	17 (53.1)	23 (69.7)
More than twice a day	1 (3.2)	1 (3.3)	1 (3.7)	1 (3.1)	3 (9.1)
How often should you be brushing?* n *(%)					
Twice a day	14 (45.2)	14 (46.7)	13 (48.1)	25 (78.1)	18 (54.5)
More than twice a day	1 (3.2)	2 (6.7)	0 (0)	3 (9.4)	12 (36.4)
Duration of brushing*, n *(%)					
2 minutes	6 (19.4)	7 (23.3)	6 (22.2)	15 (46.9)	14 (42.4)
> 2 minutes	2 (6.5)	4 (13.3)	4 (14.8)	1 (3.1)	4 (12.1)
How long should you brush for?* n *(%)					
2 minutes	7 (22.6)	9 (30.0)	10 (37.0)	18 (56.3)	17 (51.5)
> 2 minutes	3 (9.7)	4 (13.3)	3 (11.1)	6 (18.8)	9 (27.3)
Spit not rinse after brushing, *n* (%)	5 (16.1)	3 (10.0)	4 (14.8)	14 (43.8)	15 (45.5)
Should spit not rinse after brushing, *n* (%)	6 (19.4)	5 (16.7)	4 (14.8)	14 (43.8)	18 (54.5)

TABLE 35 Patient-reported outcomes at baseline in Scotland by randomised group

Patient-reported outcomes	Eligible 24-month recall, mean (SD), count unless otherwise stated			Ineligible 24-month recall, mean (SD), count unless otherwise stated	
	Risk based (*n* = 111)	24 month (*n* = 117)	6 month (*n* = 116)	Risk based (*n* = 419)	6 month (*n* = 425)
Baseline questionnaire returned	102 (91.9)	109 (93.2)	108 (93.1)	391 (93.3)	387 (91.1)
Attitude	4.2 (0.8), 101	4.3 (0.9), 109	4.2 (0.7), 108	4.1 (0.9), 388	4.1 (0.9), 383
PBC	5.3 (1.3), 100	5.2 (1.4), 109	5.1 (1.4), 107	5.0 (1.5), 362	5.1 (1.4), 357
Satisfaction	5.1 (0.8), 99	5.2 (0.7), 107	5.1 (0.7), 107	5.2 (0.6), 310	5.2 (0.7), 313
Anxiety	10.0 (4.4), 98	10.4 (4.4), 109	10.4 (4.8), 107	10.1 (4.6), 387	9.9 (4.6), 384
OHIP-14	4.4 (7.4), 99	5.5 (7.0), 107	4.5 (5.5), 104	5.5 (6.4), 374	5.9 (7.3), 375

TABLE 36 Patient-reported outcomes at baseline in England by randomised group

Patient-reported outcomes	Eligible 24-month recall, mean (SD), count unless otherwise stated			Ineligible 24-month recall, mean (SD), count unless otherwise stated	
	Risk based ($n = 75$)	24 month ($n = 69$)	6 month ($n = 72$)	Risk based ($n = 410$)	6 month ($n = 405$)
Baseline questionnaire returned	62 (82.7)	61 (88.4)	64 (88.9)	391 (95.4)	386 (95.3)
Attitude	4.2 (0.8), 61	4.3 (0.8), 61	4.0 (0.7), 64	4.0 (0.8), 390	4.0 (0.9), 382
PBC	5.3 (1.3), 59	5.3 (1.4), 61	5.1 (1.5), 64	5.0 (1.5), 388	5.1 (1.5), 382
Satisfaction	5.3 (0.8), 32	5.3 (0.8), 30	5.4 (0.7), 36	5.4 (0.6), 365	5.3 (0.6), 358
Anxiety	10.8 (4.5), 62	11.4 (4.2), 61	11.0 (3.7), 64	10.1 (4.5), 386	10.2 (4.5), 384
OHIP-14	4.6 (6.0), 60	4.1 (5.9), 60	3.9 (5.1), 63	6.1 (7.5), 376	6.2 (8.1), 374

TABLE 37 Patient-reported outcomes at baseline in Northern Ireland by randomised group

Patient-reported outcomes	Eligible 24-month recall, mean (SD), count unless otherwise stated			Ineligible 24-month recall, mean (SD), count unless otherwise stated	
	Risk based ($n = 31$)	24 month ($n = 30$)	6 month ($n = 27$)	Risk based ($n = 32$)	6 month ($n = 33$)
Baseline questionnaire returned	17 (54.8)	16 (53.3)	15 (55.6)	28 (87.5)	30 (90.9)
Attitude	4.0 (0.5), 16	3.8 (0.9), 16	3.9 (0.5), 15	3.9 (0.6), 28	3.8 (0.7), 30
PBC	5.2 (1.8), 16	4.7 (1.9), 16	5.0 (1.4), 15	4.6 (1.6), 28	4.7 (1.6), 30
Satisfaction	5.4 (0.6), 16	5.1 (0.9), 16	5.2 (0.6), 15	5.4 (0.6), 28	5.4 (0.5), 30
Anxiety	11.1 (6.3), 16	9.7 (5.2), 16	9.8 (5.1), 14	11.5 (4.4), 28	11.0 (4.7), 30
OHIP-14	4.8 (8.5), 16	2.1 (2.5), 16	6.0 (11.5), 15	5.3 (6.8), 28	6.1 (6.6), 29

Description of the intervention by country

TABLE 38 Description of the intervention in Scotland: participants who attended clinical appointment

Number of check-ups, *n* (%)	Eligible for 24-month recall			Ineligible for 24-month recall	
	Risk based ($N = 78$)	24 month ($N = 76$)	6 month ($N = 75$)	Risk based ($N = 295$)	6 month ($N = 308$)
0	1 (1.3)	8 (9.8)	0 (0.0)	1 (0.3)	0 (0.0)
1	14 (17.7)	31 (37.8)	3 (3.9)	10 (3.3)	4 (1.3)
2	23 (29.1)	11 (13.4)	5 (6.5)	37 (12.3)	23 (7.3)
3 or more	40 (50.6)	26 (31.7)	67 (87.0)	247 (82.3)	281 (89.8)
Missing, *n* (%)	1 (1.3)	6 (7.3)	2 (2.6)	5 (1.7)	5 (1.6)
Number of check-ups, mean (SD), *n*	3.0 (1.8), 78	2.3 (2.1), 76	4.3 (1.5), 75	3.9 (1.5), 295	4.4 (1.5), 308

TABLE 39 Description of the intervention in England: participants who attended clinical appointment

Number of check-ups, *n* (%)	Eligible for 24-month recall			Ineligible for 24-month recall	
	Risk based (*N* = 45)	24 month (*N* = 37)	6 month (*N* = 266)	Risk based (*N* = 266)	6 month (*N* = 249)
1	1 (2.0)	11 (27.5)	3 (6.5)	4 (1.4)	3 (1.1)
2	2 (4.0)	9 (22.5)	4 (8.7)	7 (2.5)	7 (2.6)
3 or more	42 (84.0)	17 (42.5)	35 (76.1)	255 (89.8)	239 (89.5)
Missing	5 (10.0)	3 (7.5)	4 (8.7)	18 (6.3)	18 (6.7)
Number of check-ups mean (SD), *n*	4.5 (1.8), 45	3.1 (2.6), 37	6.5 (5.9), 42	6.2 (2.4), 266	6.5 (2.0), 249

TABLE 40 Description of the intervention in Northern Ireland: participants who attended clinical appointment

Number of check-ups, *n* (%)	Eligible for 24-month recall			Ineligible for 24-month recall	
	Risk based (*N* = 14)	24 month (*N* = 15)	6 month (*N* = 11)	Risk based (*N* = 21)	6 month (*N* = 21)
1	1 (2.0)	11 (27.5)	3 (6.5)	4 (1.4)	3 (1.1)
2	2 (4.0)	9 (22.5)	4 (8.7)	7 (2.5)	7 (2.6)
3 or more	42 (84.0)	17 (42.5)	35 (76.1)	255 (89.8)	239 (89.5)
Missing	5 (10.0)	3 (7.5)	4 (8.7)	18 (6.3)	18 (6.7)
Number of check-ups mean (SD), *n*	4.5 (1.8), 14	2.1 (1.5), 15	5.4 (2.2), 11	5.2 (1.5), 21	6.6 (1.2), 21

Follow-up demographic characteristics

TABLE 41 Demographic characteristics year 1

Characteristic	Eligible for 24-month recall			Ineligible for 24-month recall	
	Risk based	24 month	6 month	Risk based	6 month
Regular smokers, *n* (%)	19 (13.1)	16 (10.3)	17 (11.2)	109 (17.1)	98 (15.3)
Missing	1 (0.7)	1 (0.6)	1 (0.7)	5 (0.8)	1 (0.2)
Time since previous visit to dentist, *n* (%)					
< 1 year	122 (84.1)	97 (62.6)	143 (94.1)	600 (94.0)	629 (98.3)
1–2 years	21 (14.5)	56 (36.1)	8 (5.3)	31 (4.9)	9 (1.4)
Missing	2 (1.4)	2 (1.3)	1 (0.7)	7 (1.1)	2 (0.3)
Patient status, *n* (%)					
NHS	69 (47.6)	60 (38.7)	91 (59.9)	410 (64.3)	431 (67.3)
Private	5 (3.4)	3 (1.9)	2 (1.3)	15 (2.4)	11 (1.7)
Combination	8 (5.5)	9 (5.8)	10 (6.6)	61 (9.6)	65 (10.2)
Missing	63 (43.4)	83 (53.5)	49 (32.2)	152 (23.8)	133 (20.8)
Type of toothbrush, *n* (%)					
Manual	88 (60.7)	99 (63.9)	89 (58.6)	348 (54.5)	383 (59.8)
Electric	55 (37.9)	54 (34.8)	58 (38.2)	268 (42.0)	240 (37.5)
Toothbrush not used	–	–	1 (0.7)	–	–
Both	1 (0.7)	1 (0.6)	3 (2.0)	16 (2.5)	14 (2.2)
Missing	1 (0.7)	1 (0.6)	1 (0.7)	6 (0.9)	3 (0.5)
Regular attender: self-report, *n* (%)	132 (91.0)	131 (84.5)	142 (93.4)	601 (94.2)	615 (96.1)
Missing	1 (0.7)	2 (1.3)	1 (0.7)	5 (0.8)	1 (0.2)
Difficulty travelling to dentist, mean (SD), *n*	6.2 (1.3), 144	6.5 (1.0), 154	6.4 (1.2), 151	6.3 (1.2), 775	6.3 (1.3), 786
Replied to year 4 questionnaire, *n* (%)	145 (100.0)	155 (100.0)	152 (100.0)	638 (100.0)	640 (100.0)

TABLE 42 Demographic characteristics year 2

Characteristic	Eligible for 24-month recall			Ineligible for 24-month recall	
	Risk based	24 month	6 month	Risk based	6 month
Questionnaire returned, *n* (%)	135 (100.0)	144 (100.0)	142 (100.0)	610 (100.0)	619 (100.0)
Smoked in the last 12 months, *n* (%)	12 (8.9)	16 (11.1)	20 (14.1)	96 (15.7)	76 (12.3)
Missing	1 (0.7)	–	–	6 (1.0)	3 (0.5)
Time since previous visit to dentist, *n* (%)					
< 1 year	120 (88.9)	105 (72.9)	136 (95.8)	588 (96.4)	598 (96.6)
1–2 years	14 (10.4)	32 (22.2)	6 (4.2)	18 (3.0)	17 (2.7)
> 2 years	–	6 (4.2)	–	2 (0.3)	1 (0.2)
Missing	1 (0.7)	1 (0.7)	–	2 (0.3)	3 (0.5)
Patient status, *n* (%)					
NHS	84 (62.2)	73 (50.7)	89 (62.7)	415 (68.0)	425 (68.7)
Private	3 (2.2)	6 (4.2)	3 (2.1)	10 (1.6)	9 (1.5)
Combination	12 (8.9)	9 (6.3)	15 (10.6)	72 (11.8)	63 (10.2)
Missing	36 (26.7)	56 (38.9)	35 (24.6)	113 (18.5)	122 (19.7)
Type of toothbrush, *n* (%)					
Manual	67 (49.6)	88 (61.1)	83 (58.5)	316 (51.8)	347 (56.1)
Electric	59 (43.7)	47 (32.6)	52 (36.6)	231 (37.9)	213 (34.4)
Toothbrush not used	1 (0.7)	–	–	1 (0.2)	–
Toothbrush	7 (5.2)	8 (5.6)	7 (4.9)	57 (9.3)	56 (9.0)
Missing	1 (0.7)	1 (0.7)	–	5 (0.8)	3 (0.5)
Regular attender: self-report, *n* (%)	123 (91.1)	124 (86.1)	136 (95.8)	584 (95.7)	588 (95.0)
Missing	1 (0.7)	–	–	2 (0.3)	3 (0.5)
Difficulty travelling to dentist mean (SD), *n*	6.4 (1.2), 134	6.5 (0.9), 143	6.3 (1.2), 141	6.3 (1.2), 742	6.3 (1.2), 751

TABLE 43 Demographic characteristics year 3

	Eligible for 24-month recall			Ineligible for 24-month recall	
Characteristic	Risk based	24 month	6 month	Risk based	6 month
Questionnaire returned, *n* (%)	134 (100.0)	131 (100.0)	134 (100.0)	571 (100.0)	584 (100.0)
Smoked in the last 12 months, *n* (%)	13 (9.7)	14 (10.7)	13 (9.7)	72 (12.6)	64 (11.0)
Missing	1 (0.7)	–	1 (0.7)	4 (0.7)	2 (0.3)
Time since previous visit to dentist, *n* (%)					
< 1 year	117 (87.3)	92 (70.2)	123 (91.8)	545 (95.4)	569 (97.4)
1–2 years	14 (10.4)	36 (27.5)	8 (6.0)	21 (3.7)	14 (2.4)
> 2 years	2 (1.5)	3 (2.3)	1 (0.7)	3 (0.5)	–
Missing	1 (0.7)	–	2 (1.5)	2 (0.4)	1 (0.2)
Patient status, *n* (%)					
NHS	90 (67.2)	81 (61.8)	96 (71.6)	407 (71.3)	432 (74.0)
Private	4 (3.0)	4 (3.1)	4 (3.0)	10 (1.8)	19 (3.3)
Combination	18 (13.4)	14 (10.7)	17 (12.7)	65 (11.4)	62 (10.6)
Missing	22 (16.4)	32 (24.4)	17 (12.7)	89 (15.6)	71 (12.2)
Type of toothbrush, *n* (%)					
Manual	68 (50.7)	77 (58.8)	66 (49.3)	304 (53.2)	316 (54.1)
Electric	58 (43.3)	46 (35.1)	58 (43.3)	227 (39.8)	234 (40.1)
Toothbrush not used	1 (0.7)	–	–	–	1 (0.2)
Both	7 (5.2)	6 (4.6)	9 (6.7)	38 (6.7)	33 (5.7)
Missing	–	2 (1.5)	1 (0.7)	2 (0.4)	–
Regular attender: self-report, *n* (%)	119 (88.8)	108 (82.4)	129 (96.3)	543 (95.1)	558 (95.5)
Missing	–	1 (0.8)	1 (0.7)	3 (0.5)	3 (0.5)
Difficulty travelling to dentist mean (SD), *n*	6.4 (1.2), 134	6.6 (0.9), 131	6.3 (1.2), 133	6.4 (1.1), 703	6.3 (1.2), 715

Follow-up behaviour and knowledge related to oral health

TABLE 44 Behaviours/knowledge year 1

	Eligible for 24-month recall			Ineligible for 24-month recall	
Behaviours/knowledge	**Risk based**	**24 month**	**6 month**	**Risk based**	**6 month**
Responded	145 (100.0)	155 (100.0)	152 (100.0)	638 (100.0)	640 (100.0)
Frequency of brushing					
Once a day	20 (13.8)	32 (20.6)	36 (23.7)	112 (17.6)	100 (15.6)
Twice a day	99 (68.3)	110 (71.0)	104 (68.4)	449 (70.4)	461 (72.0)
More than twice a day	22 (15.2)	11 (7.1)	7 (4.6)	69 (10.8)	63 (9.8)
Missing	2 (1.4)	1 (0.6)	3 (2.0)	4 (0.6)	10 (1.6)
How often should you be brushing?					
Once a day	1 (0.7)	3 (1.9)	3 (2.0)	10 (1.6)	5 (0.8)
Twice a day	111 (76.6)	125 (80.6)	118 (77.6)	481 (75.4)	483 (75.5)
More than twice a day	31 (21.4)	25 (16.1)	28 (18.4)	138 (21.6)	143 (22.3)
Missing	2 (1.4)	2 (1.3)	2 (1.3)	9 (1.4)	9 (1.4)
Duration of brushing					
1–2 minutes	44 (30.3)	48 (31.0)	48 (31.6)	195 (30.6)	208 (32.5)
2 minutes	73 (50.3)	75 (48.4)	71 (46.7)	304 (47.6)	315 (49.2)
> 2 minutes	19 (13.1)	24 (15.5)	23 (15.1)	112 (17.6)	86 (13.4)
Missing	2 (1.4)	3 (1.9)	3 (2.0)	6 (0.9)	8 (1.3)
How long should you brush for?					
1–2 minutes	15 (10.3)	12 (7.7)	15 (9.9)	65 (10.2)	69 (10.8)
2 minutes	97 (66.9)	104 (67.1)	102 (67.1)	394 (61.8)	401 (62.7)
> 2 minutes	29 (20.0)	36 (23.2)	32 (21.1)	164 (25.7)	156 (24.4)
Missing	3 (2.1)	2 (1.3)	2 (1.3)	10 (1.6)	11 (1.7)
After brushing					
Rinse with water	56 (38.6)	78 (50.3)	69 (45.4)	306 (48.0)	308 (48.1)
Rinse with mouthwash	20 (13.8)	18 (11.6)	18 (11.8)	98 (15.4)	98 (15.3)
Spit not rinse	67 (46.2)	57 (36.8)	61 (40.1)	224 (35.1)	222 (34.7)
Missing	2 (1.4)	2 (1.3)	4 (2.6)	10 (1.6)	12 (1.9)
After brushing should you . . . ?					
Rinse with water	29 (20.0)	40 (25.8)	39 (25.7)	200 (31.3)	210 (32.8)
Rinse with mouthwash	33 (22.8)	35 (22.6)	30 (19.7)	145 (22.7)	157 (24.5)
Spit not rinse	79 (54.5)	76 (49.0)	79 (52.0)	276 (43.3)	261 (40.8)
Missing	4 (2.8)	4 (2.6)	4 (2.6)	17 (2.7)	12 (1.9)

continued

TABLE 44 Behaviours/knowledge year 1 (*continued*)

	Eligible for 24-month recall			Ineligible for 24-month recall	
Behaviours/knowledge	**Risk based**	**24 month**	**6 month**	**Risk based**	**6 month**
Frequency of flossing					
At least once a week	33 (22.8)	20 (12.9)	27 (17.8)	128 (20.1)	128 (20.0)
At least once a month	13 (9.0)	17 (11.0)	17 (11.2)	86 (13.5)	76 (11.9)
Never	35 (24.1)	51 (32.9)	48 (31.6)	188 (29.5)	176 (27.5)
Missing	41 (28.3)	42 (27.1)	40 (26.3)	114 (17.9)	119 (18.6)
How often should you floss?					
At least once a week	8 (5.5)	6 (3.9)	5 (3.3)	24 (3.8)	14 (2.2)
At least once a month	15 (10.3)	29 (18.7)	29 (19.1)	103 (16.1)	88 (13.8)
Never	75 (51.7)	69 (44.5)	68 (44.7)	353 (55.3)	374 (58.4)
Missing	44 (30.3)	44 (28.4)	45 (29.6)	137 (21.5)	139 (21.7)
Frequency of using interdental brushes					
At least once a week	10 (6.9)	7 (4.5)	8 (5.3)	73 (11.4)	60 (9.4)
At least once a month	4 (2.8)	8 (5.2)	14 (9.2)	49 (7.7)	43 (6.7)
Never	78 (53.8)	86 (55.5)	73 (48.0)	291 (45.6)	308 (48.1)
Missing	45 (31.0)	41 (26.5)	46 (30.3)	134 (21.0)	133 (20.8)
How often should you use interdental brushes?					
At least once a week	5 (3.4)	10 (6.5)	3 (2.0)	29 (4.5)	24 (3.8)
At least once a month	18 (12.4)	14 (9.0)	18 (11.8)	79 (12.4)	61 (9.5)
Never	19 (13.1)	17 (11.0)	17 (11.2)	95 (14.9)	101 (15.8)
Missing	98 (67.6)	104 (67.1)	106 (69.7)	401 (62.9)	411 (64.2)

TABLE 45 Behaviours/knowledge year 2

	Eligible for 24-month recall			Ineligible for 24-month recall	
Behaviours/knowledge	**Risk based**	**24 month**	**6 month**	**Risk based**	**6 month**
Responded	135 (100.0)	144 (100.0)	142 (100.0)	610 (100.0)	619 (100.0)
Frequency of brushing					
Once a day	24 (17.8)	37 (25.7)	27 (19.0)	103 (16.9)	99 (16.0)
Twice a day	95 (70.4)	96 (66.7)	105 (73.9)	443 (72.6)	443 (71.6)
More than twice a day	15 (11.1)	10 (6.9)	9 (6.3)	55 (9.0)	64 (10.3)
Missing	1 (0.7)	0 (0.0)	0 (0.0)	3 (0.5)	5 (0.8)
How often should you be brushing?					
Once a day	1 (0.7)	1 (0.7)	1 (0.7)	11 (1.8)	8 (1.3)
Twice a day	106 (78.5)	120 (83.3)	118 (83.1)	455 (74.6)	471 (76.1)
More than twice a day	27 (20.0)	22 (15.3)	23 (16.2)	137 (22.5)	130 (21.0)
Missing	1 (0.7)	1 (0.7)	0 (0.0)	7 (1.1)	9 (1.5)
Duration of brushing					
1–2 minutes	41 (30.4)	45 (31.3)	43 (30.3)	178 (29.2)	210 (33.9)
2 minutes	72 (53.3)	74 (51.4)	73 (51.4)	323 (53.0)	304 (49.1)
> 2 minutes	16 (11.9)	22 (15.3)	22 (15.5)	88 (14.4)	83 (13.4)
Missing	1 (0.7)	0 (0.0)	1 (0.7)	3 (0.5)	2 (0.3)
How long should you brush for?					
1–2 minutes	9 (6.7)	13 (9.0)	10 (7.0)	59 (9.7)	68 (11.0)
2 minutes	93 (68.9)	105 (72.9)	98 (69.0)	401 (65.7)	409 (66.1)
> 2 minutes	31 (23.0)	24 (16.7)	34 (23.9)	138 (22.6)	135 (21.8)
Missing	1 (0.7)	2 (1.4)	0 (0.0)	10 (1.6)	6 (1.0)
After brushing					
Rinse with water	49 (36.3)	64 (44.4)	46 (32.4)	264 (43.3)	275 (44.4)
Rinse with mouthwash	19 (14.1)	15 (10.4)	19 (13.4)	100 (16.4)	90 (14.5)
Spit not rinse	66 (48.9)	65 (45.1)	74 (52.1)	239 (39.2)	247 (39.9)
Missing	1 (0.7)	0 (0.0)	3 (2.1)	7 (1.1)	7 (1.1)
After brushing should you . . .?					
Rinse with water	19 (14.1)	33 (22.9)	31 (21.8)	159 (26.1)	171 (27.6)
Rinse with mouthwash	27 (20.0)	27 (18.8)	29 (20.4)	143 (23.4)	130 (21.0)
Spit not rinse	85 (63.0)	83 (57.6)	78 (54.9)	292 (47.9)	297 (48.0)
Missing	4 (3.0)	1 (0.7)	4 (2.8)	16 (2.6)	21 (3.4)

TABLE 46 Behaviours/knowledge year 3

	Eligible for 24-month recall			Ineligible for 24-month recall	
Behaviours/knowledge	Risk based	24 month	6 month	Risk based	6 month
Responded	134 (100.0)	131 (100.0)	134 (100.0)	571 (100.0)	584 (100.0)
Frequency of brushing					
Once a day	22 (16.4)	29 (22.1)	29 (21.6)	98 (17.2)	88 (15.1)
Twice a day	100 (74.6)	91 (69.5)	99 (73.9)	414 (72.5)	438 (75.0)
More than twice a day	11 (8.2)	10 (7.6)	5 (3.7)	53 (9.3)	50 (8.6)
Missing	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.4)	2 (0.3)
How often should you be brushing?					
Once a day	1 (0.7)	1 (0.8)	1 (0.7)	6 (1.1)	9 (1.5)
Twice a day	111 (82.8)	108 (82.4)	110 (82.1)	448 (78.5)	457 (78.3)
More than twice a day	22 (16.4)	22 (16.8)	22 (16.4)	112 (19.6)	115 (19.7)
Missing	0 (0.0)	0 (0.0)	1 (0.7)	5 (0.9)	2 (0.3)
Duration of brushing					
1–2 minutes	44 (32.8)	33 (25.2)	42 (31.3)	175 (30.6)	187 (32.0)
2 minutes	68 (50.7)	76 (58.0)	68 (50.7)	296 (51.8)	316 (54.1)
> 2 minutes	17 (12.7)	18 (13.7)	23 (17.2)	83 (14.5)	65 (11.1)
Missing	0 (0.0)	1 (0.8)	1 (0.7)	4 (0.7)	2 (0.3)
How long should you brush for?					
1–2 minutes	14 (10.4)	6 (4.6)	4 (3.0)	59 (10.3)	73 (12.5)
2 minutes	93 (69.4)	95 (72.5)	100 (74.6)	384 (67.3)	396 (67.8)
> 2 minutes	26 (19.4)	30 (22.9)	29 (21.6)	121 (21.2)	111 (19.0)
Missing	0 (0.0)	0 (0.0)	1 (0.7)	4 (0.7)	4 (0.7)
After brushing					
Rinse with water	38 (28.4)	59 (45.0)	44 (32.8)	236 (41.3)	263 (45.0)
Rinse with mouthwash	21 (15.7)	13 (9.9)	13 (9.7)	76 (13.3)	72 (12.3)
Spit not rinse	74 (55.2)	59 (45.0)	75 (56.0)	254 (44.5)	243 (41.6)
Rinse with both water and mouthwash	1 (0.7)	0 (0.0)	2 (1.5)	2 (0.4)	1 (0.2)
Missing	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.5)	5 (0.9)
After brushing should you . . .?					
Rinse with water	22 (16.4)	34 (26.0)	33 (24.6)	140 (24.5)	162 (27.7)
Rinse with mouthwash	26 (19.4)	21 (16.0)	20 (14.9)	112 (19.6)	121 (20.7)
Spit not rinse	84 (62.7)	76 (58.0)	81 (60.4)	309 (54.1)	289 (49.5)
Missing	2 (1.5)	0 (0.0)	0 (0.0)	10 (1.8)	12 (2.1)

TABLE 47 Behaviours/knowledge year 4

Behaviours/knowledge	Eligible for 24-month recall			Ineligible for 24-month recall	
	Risk based	24 month	6 month	Risk based	6 month
Responded	151 (100.0)	153 (100.0)	156 (100.0)	650 (100.0)	655 (100.0)
Frequency of brushing					
Once a day	27 (17.9)	31 (20.3)	32 (20.5)	112 (17.2)	94 (14.4)
Twice a day	103 (68.2)	103 (67.3)	112 (71.8)	463 (71.2)	491 (75.0)
More than twice a day	21 (13.9)	16 (10.5)	8 (5.1)	66 (10.2)	62 (9.5)
Missing	0 (0)	0 (0)	1 (0.6)	4 (0.6)	2 (0.3)
How often should you be brushing?					
Once a day	3 (2.0)	3 (2.0)	1 (0.6)	6 (0.9)	6 (0.9)
Twice a day	121 (80.1)	123 (80.4)	125 (80.1)	512 (78.8)	515 (78.6)
More than twice a day	26 (17.2)	27 (17.6)	27 (17.3)	129 (19.8)	128 (19.5)
Missing	1 (0.7)	0 (0)	2 (1.3)	3 (0.5)	4 (0.6)
Duration of brushing					
1–2 minutes	52 (34.4)	51 (33.3)	44 (28.2)	192 (29.5)	210 (32.1)
2 minutes	79 (52.3)	76 (49.7)	82 (52.6)	318 (48.9)	341 (52.1)
> 2 minutes	17 (11.3)	23 (15.0)	28 (17.9)	114 (17.5)	78 (11.9)
Missing	0 (0)	1 (0.7)	1 (0.6)	5 (0.8)	4 (0.6)
How long should you brush for?					
1–2 minutes	19 (12.6)	9 (5.9)	10 (6.4)	66 (10.2)	56 (8.5)
2 minutes	104 (68.9)	113 (73.9)	106 (67.9)	432 (66.5)	452 (69.0)
> 2 minutes	24 (15.9)	30 (19.6)	39 (25.0)	142 (21.8)	137 (20.9)
Missing	3 (2.0)	1 (0.7)	1 (0.6)	8 (1.2)	6 (0.9)
After brushing					
Rinse with water	49 (32.5)	63 (41.2)	55 (35.3)	261 (40.2)	264 (40.3)
Rinse with mouthwash	22 (14.6)	13 (8.5)	11 (7.1)	91 (14.0)	76 (11.6)
Spit not rinse	80 (53.0)	74 (48.4)	87 (55.8)	276 (42.5)	300 (45.8)
Rinse with both water and mouthwash	0 (0)	0 (0)	2 (1.3)	13 (2.0)	12 (1.8)
Missing	0 (0)	3 (2.0)	1 (0.6)	9 (1.4)	3 (0.5)
After brushing should you . . .?					
Rinse with water	30 (19.9)	29 (19.0)	31 (19.9)	158 (24.3)	166 (25.3)
Rinse with mouthwash	27 (17.9)	26 (17.0)	23 (14.7)	124 (19.1)	119 (18.2)
Spit not rinse	91 (60.3)	92 (60.1)	98 (62.8)	344 (52.9)	346 (52.8)
Rinse with both water and mouthwash	0 (0)	2 (1.3)	1 (0.6)	6 (0.9)	6 (0.9)
Missing	3 (2.0)	4 (2.6)	3 (1.9)	18 (2.8)	18 (2.7)

Clinical outcomes

The following tables and graphs present the clinical outcomes at 4 years for the overall sample.

TABLE 48 Clinical outcomes at 4 years post randomisation for the whole sample

Clinical outcome, mean (SD), *n*	Risk based	6 month
Percentage of sites bleeding	33.8 (21.6), 741	33.3 (22.0), 731
Calculus	36.7 (27.5), 746	37.9 (27.3), 733
Mean pocket depth (mm)	2.2 (0.5), 736	2.2 (0.4), 727
Number of teeth	23.9 (4.7), 749	23.5 (5.0), 737
Caries category*, n *(%)		
Sound surfaces	4 (0.5)	8 (1.1)
Initial lesions	122 (16.3)	140 (19.0)
Moderate lesions	491 (65.6)	463 (62.8)
Extensive caries or treatment needed	130 (17.4)	120 (16.3)
Missing	2 (0.3)	6 (0.8)
Maximum caries score per mouth*, n *(%)		
1	4 (0.5)	10 (1.4)
2	118 (15.8)	130 (17.6)
3	167 (22.3)	171 (23.2)
4	324 (43.3)	292 (39.6)
5	110 (14.7)	102 (13.8)
6	20 (2.7)	18 (2.4)
Missing	2 (0.3)	6 (0.8)
Root caries*, n *(%)		
Yes	146 (19.5)	154 (20.9)
No	509 (68.0)	481 (65.3)
Missing	94 (12.6)	102 (13.8)

Effect sizes adjusted for minimisation variables; linear mixed-effects model for continuous outcomes; ordinal logistic mixed-effects model for caries category (effect size is odds ratio) and logistic mixed effects for root caries (effect size is odds ratio).

Clinical outcomes by country

Scotland

TABLE 49 Clinical data at 4 years: Scotland

	Eligible for 24-month recall			Ineligible for 24-month recall	
Clinical outcome, mean (SD), *n*	**Risk based**	**24 month**	**6 month**	**Risk based**	**6 month**
Attended/randomised	79/111	82/117	77/116	300/419	313/425
Bleeding score	30.9 (18.0), 78	30.9 (19.9), 81	32.5 (20.8), 76	33.6 (22.9), 295	37.2 (22.8), 310
Calculus	40.3 (27.4), 78	45.9 (28.3), 82	43.8 (25.0), 76	32.2 (26.0), 299	36.0 (26.9), 312
Mean pocket depth (mm)	2.2 (0.5), 78	2.2 (0.4), 81	2.1 (0.4), 75	2.1 (0.4), 293	2.2 (0.4), 309
Number of teeth	23.6 (4.8), 79	22.8 (5.2), 82	24.0 (4.1), 77	23.5 (4.9), 300	22.7 (5.3), 313
Caries category*, n *(%)					
Sound surfaces	0 (0.0)	0 (0.0)	0 (0.0)	3 (1.0)	1 (0.3)
Initial lesions	12 (15.2)	14 (17.1)	13 (16.9)	53 (17.7)	49 (15.7)
Moderate lesions	57 (72.2)	53 (64.6)	56 (72.7)	186 (62.0)	199 (63.6)
Extensive caries or treatment needed	9 (11.4)	15 (18.3)	7 (9.1)	58 (19.3)	62 (19.8)
Missing	1 (1.3)	0 (0.0)	1 (1.3)	0 (0.0)	2 (0.6)
Root caries*, n *(%)					
Yes	26 (18.2)	21 (15.2)	17 (12.6)	120 (19.8)	137 (22.8)
No	96 (67.1)	100 (72.5)	96 (71.1)	413 (68.2)	385 (64.0)
Missing	21 (14.7)	17 (12.3)	22 (16.3)	73 (12.0)	80 (13.3)

England

TABLE 50 Clinical data at 4 years: England

	Eligible for 24-month recall			Ineligible for 24-month recall	
Clinical outcome, mean (SD), *n*	**Risk based**	**24 month**	**6 month**	**Risk based**	**6 month**
Attended/randomised	50/75	40/69	46/72	284/410	267/405
Percentage of sites bleeding	43.4 (18.0), 50	39.7 (19.6), 40	39.4 (22.8), 46	32.2 (21.4), 282	27.6 (20.1), 265
Calculus	26.1 (22.3), 50	25.5 (25.8), 40	27.9 (22.3), 45	42.7 (29.1), 283	40.4 (28.9), 266
Mean pocket depth (mm)	2.2 (0.4), 50	2.1 (0.2), 40	2.2 (0.5), 46	2.2 (0.5), 279	2.2 (0.5), 263
Number of teeth	25.5 (4.1), 50	25.5 (2.1), 40	25.8 (3.8), 46	24.3 (4.4), 284	23.8 (5.0), 267
Caries category*, n *(%)					
Sound surfaces	1 (2.0)	0 (0.0)	0 (0.0)	0 (0.0)	7 (2.6)
Initial lesions	9 (18.0)	11 (27.5)	15 (32.6)	43 (15.1)	51 (19.1)
Moderate lesions	29 (58.0)	24 (60.0)	27 (58.7)	191 (67.3)	165 (61.8)
Extensive caries or treatment needed	10 (20.0)	5 (12.5)	3 (6.5)	50 (17.6)	42 (15.7)
Missing	1 (2.0)	0 (0.0)	1 (2.2)	0 (0.0)	2 (0.7)
Root caries*, n *(%)					
Yes	26 (18.2)	21 (15.2)	17 (12.6)	120 (19.8)	137 (22.8)
No	96 (67.1)	100 (72.5)	96 (71.1)	413 (68.2)	385 (64.0)
Missing	21 (14.7)	17 (12.3)	22 (16.3)	73 (12.0)	80 (13.3)

Northern Ireland

TABLE 51 Clinical data at 4 years: Northern Ireland

	Eligible for 24-month recall			Ineligible for 24-month recall	
Clinical outcome, mean (SD), *n*	**Risk based**	**24 month**	**6 month**	**Risk based**	**6 month**
Attended/randomised	14/31	16/30	12/27	22/32	22/33
Percentage of sites bleeding	34.1 (21.4), 14	39.0 (19.5), 16	40.5 (21.3), 12	46.6 (18.8), 22	33.5 (21.7), 22
Calculus	27.9 (21.4), 14	30.7 (21.6), 16	32.4 (23.0), 12	37.4 (22.2), 22	37.1 (26.3), 22
Mean pocket depth (mm)	2.1 (0.7), 14	1.9 (0.2), 16	2.0 (0.2), 12	2.0 (0.2), 22	2.0 (0.3), 22
Number of teeth	22.5 (6.4), 14	26.1 (2.0), 16	26.2 (2.8), 12	23.0 (4.0), 22	24.5 (3.4), 22
Caries category*, n *(%)					
Sound surfaces	0 (0.0)	1 (6.3)	0 (0.0)	0 (0.0)	0 (0.0)
Initial lesions	1 (7.1)	3 (18.8)	5 (41.7)	4 (18.2)	7 (31.8)
Moderate lesions	12 (85.7)	10 (62.5)	4 (33.3)	16 (72.7)	12 (54.5)
Extensive caries or treatment needed	1 (7.1)	2 (12.5)	3 (25.0)	2 (9.1)	3 (13.6)
Root caries*, n *(%)					
Yes	26 (18.2)	21 (15.2)	17 (12.6)	120 (19.8)	137 (22.8)
No	96 (67.1)	100 (72.5)	96 (71.1)	413 (68.2)	385 (64.0)
Missing	21 (14.7)	17 (12.3)	22 (16.3)	73 (12.0)	80 (13.3)

Subgroup analyses

Interaction coefficients for bleeding

TABLE 52 Coefficient for interaction in subgroup for bleeding

Characteristic	Eligible for 24-month recall (24 month vs. 6 month), mean difference (99% CI); *p*-value	Overall (risk based vs. 6 month), mean difference (99% CI); *p*-value
Age		
< 45 years	3.50 (−4.59 to 11.58); 0.27	0.53 (−3.80 to 4.86); 0.75
45–64 years	−9.23 (−21.01 to 2.55); 0.04	−1.18 (−6.89 to 4.52); 0.59
≥ 65 years	−0.22 (−19.86 to 19.43); 0.98	4.47 (−3.28 to 12.23); 0.14
Country		
Scotland	−2.02 (−9.37 to 5.33); 0.48	−3.36 (−6.90 to 0.18); 0.01
England	3.47 (−9.00 to 15.94); 0.47	8.34 (3.11 to 13.57); < 0.001
Northern Ireland	1.94 (−17.16 to 21.05); 0.79	9.63 (−2.53 to 21.79); 0.04
Do you pay for treatment?		
Yes	−0.90 (−10.69 to 8.88); 0.81	−1.35 (−6.06 to 3.35); 0.46
No	0.35 (−11.69 to 12.39); 0.94	2.96 (−2.65 to 8.57); 0.17

A positive mean difference favours the 6-month-based recall group.

Interaction coefficients for caries

TABLE 53 Coefficient for interaction in subgroup for caries

Characteristic	Eligible for 24-month recall (24 month vs. 6 month), odds ratio (99% CI); *p*-value	Overall (risk based vs 6 month), odds ratio (99% CI); *p*-value
Age		
< 45 years	1.14 (0.37 to 3.53); 0.77	1.57 (0.89 to 2.79); 0.04
45–64 years	0.91 (0.16 to 5.07); 0.89	0.70 (0.32 to 1.51); 0.23
≥ 65 years	4.27 (0.20 to 88.96); 0.22	0.74 (0.24 to 2.28); 0.49
Country		
Scotland	0.96 (0.30 to 3.02); 0.92	0.88 (0.53 to 1.45); 0.51
England	1.52 (0.26 to 8.87); 0.54	1.89 (0.91 to 3.91); 0.03
Northern Ireland	2.89 (0.21 to 39.89); 0.30	3.98 (0.76 to 20.69); 0.03
Do you pay for treatment?		
Yes	1.23 (0.30 to 4.98); 0.71	1.53 (0.78 to 3.00); 0.11
No	1.04 (0.19 to 5.84); 0.95	0.77 (0.35 to 1.70); 0.39

An odds ratio > 1 favours the 6-month-based recall group.

Patient-reported outcomes

Oral Health Impact Profile-14

TABLE 54 Oral Health Impact Profile-14 over the years in the trial

	Eligible for 24-month recall, mean (SD), *n*			Ineligible for 24-month recall, mean (SD), *n*	
Time point	**Risk based**	**24 month**	**6 month**	**Risk based**	**6 month**
Baseline	4.5 (7.0), 175	4.7 (6.4), 183	4.4 (6.1), 182	5.8 (6.9), 778	6.1 (7.7), 778
Year 1	3.7 (5.4), 141	4.4 (5.6), 152	4.8 (6.4), 145	5.6 (7.6), 617	5.4 (7.4), 623
Year 2	4.4 (5.7), 128	4.6 (6.4), 143	5.2 (7.1), 137	5.6 (7.4), 585	5.1 (7.3), 599
Year 3	3.9 (5.3), 131	4.6 (5.6), 129	4.1 (5.5), 129	5.4 (6.9), 551	5.7 (8.1), 566
Year 4	4.1 (5.7), 145	4.8 (6.4), 153	4.8 (6.2), 152	5.5 (6.8), 624	5.8 (8.3), 630

Attitude and satisfaction with care

TABLE 55 Participants' views over the years in the trial

		Eligible for 24-month recall, mean (SD), *n*			Ineligible for 24-month recall, mean (SD), *n*	
Patient-reported outcome	**Time point**	**Risk based**	**24 month**	**6 month**	**Risk based**	**6 month**
Attitude	Baseline	4.2 (0.8), 178	4.3 (0.9), 186	4.1 (0.7), 187	4.1 (0.9), 806	4.0 (0.9), 795
	Year 1	4.4 (0.8), 143	4.2 (1.0), 154	4.2 (0.8), 150	4.1 (0.9), 635	4.1 (0.8), 635
	Year 2	4.2 (0.8), 134	4.2 (0.9), 144	4.2 (0.8), 142	4.1 (0.9), 608	4.1 (0.8), 616
	Year 3	4.2 (0.7), 134	4.2 (0.8), 131	4.0 (0.8), 134	4.1 (0.9), 570	4.0 (0.8), 583
	Year 4	4.3 (0.9), 151	4.3 (0.9), 153	4.1 (0.8), 155	4.1 (0.9), 647	4.1 (0.8), 654
Satisfaction with care	Baseline	5.2 (0.8), 147	5.2 (0.8), 153	5.2 (0.7), 158	5.3 (0.6), 703	5.3 (0.6), 701
	Year 1	5.1 (0.7), 143	5.0 (0.8), 153	5.1 (0.8), 150	5.1 (0.7), 620	5.2 (0.7), 623
	Year 2	5.1 (0.7), 134	4.9 (0.7), 144	5.1 (0.6), 142	5.2 (0.7), 609	5.2 (0.7), 616
	Year 3	5.0 (0.7), 134	5.0 (0.7), 131	5.1 (0.7), 134	5.2 (0.6), 570	5.2 (0.7), 583
	Year 4	5.2 (0.7), 151	5.0 (0.7), 153	5.1 (0.7), 155	5.3 (0.6), 647	5.2 (0.6), 654

Anxiety

TABLE 56 Anxiety over time by randomised group

		Eligible for 24-month recall, mean (SD), *n*			Ineligible for 24-month recall, mean (SD), *n*	
Anxiety measure	**Time point**	**Risk based**	**24 month**	**6 month**	**Risk based**	**6 month**
Overall anxiety (score from 5 to 25), mean (SD), *n*	Baseline	10.4 (5), 176	10.7 (4), 186	10.5 (4), 185	10.2 (5), 801	10.1 (5), 798
	Year 1	10.2 (4), 145	10.7 (5), 154	10.5 (4), 150	10.4 (4), 635	10.3 (4), 637
	Year 2	10.1 (4), 133	10.5 (5), 144	10.4 (4), 142	10.3 (5), 608	10.3 (4), 617
	Year 3	10.6 (5), 134	10.9 (5), 131	10.7 (4), 134	10.4 (5), 568	10.4 (5), 582
	Year 4	10.5 (5), 150	10.9 (5), 153	11.0 (5), 155	10.3 (5), 645	10.5 (5), 649
High-anxiety patients (score $\geq$ 19), *n* (%)	Baseline	12 (6.8)	12 (6.5)	13 (7.0)	53 (6.6)	53 (6.6)
	Year 1	9 (6.2)	13 (8.4)	10 (6.7)	46 (7.2)	38 (6.0)
	Year 2	7 (5.3)	12 (8.3)	10 (7.0)	42 (6.9)	40 (6.5)
	Year 3	13 (9.7)	11 (8.4)	6 (4.5)	38 (6.7)	45 (7.7)
	Year 4	9 (6.0)	12 (7.8)	11 (7.1)	40 (6.2)	46 (7.1)

Dentist belief questionnaire

TABLE 57 Dentist beliefs at baseline, follow-up and change from baseline by whether or not they deemed at least one of their patients eligible for 24-month recall

Dentist belief	Baseline, mean (SD), *n*		Follow-up, mean (SD), *n*		Change follow-up–baseline, mean (SD), *n*	
	Deemed at least one patient eligible for 24-month recall	Deemed all ineligible for 24-month recall	Deemed at least one patient eligible for 24-month recall	Deemed all ineligible for 24-month recall	Deemed at least one patient eligible for 24-month recall	Deemed all ineligible for 24-month recall
Attitude regarding a 24-month recall	3.7 (1.2), 40	4.3 (1.1), 6	4.4 (1.2), 43	4.4 (1.5), 6	0.7 (1.1), 40	0.1 (1.4), 6
Attitude regarding a 6-month recall	3.6 (1.0), 40	4.5 (0.5), 6	3.9 (1.2), 43	4.1 (0.6), 6	0.3 (0.9), 40	−0.4 (0.7), 6
General attitude	4.5 (1.1), 40	4.7 (0.7), 6	3.9 (1.1), 43	4.6 (1.0), 6	−0.6 (1.4), 40	−0.2 (1.2), 6
PBC risk	4.0 (0.9), 40	4.9 (0.6), 6	4.1 (1.1), 43	3.9 (1.1), 6	0.1 (1.1), 40	−1.0 (1.1), 6

Appendix 2 Health economics outcomes

Discrete choice experiment subgroup analyses

TABLE 58 Discrete choice experiment subgroup results

Attribute level	Base case		Female		Scotland		Smoker		Employed		Low income		Pay private		6-month check up		Decay experience	
Main effects																		
Recall (12 month)	−0.015		−0.017		0.002		−0.038		−0.017		−0.019		−0.010		−0.042		−0.016	
Recall (6 month)	0.348	***	0.351	***	0.359	***	0.373	***	0.351	***	0.335	***	0.350	***	0.282	***	0.331	***
Recall (risk based)	0.089	**	0.090	**	0.088	**	0.079	*	0.097	***	0.094	**	0.086	**	0.108	**	0.087	**
Bleed hardly ever	0.099	**	0.100	**	0.080		0.066		0.107	**	0.096	**	0.113	**	0.014		0.109	*
Bleed occasional	0.089	**	0.091	**	0.072		0.075		0.099	**	0.087	**	0.081	*	0.076		0.091	*
Bleed fairly often	−0.127	**	−0.125	**	−0.142	**	−0.149	**	−0.129	**	−0.127	**	−0.135	**	−0.213	***	−0.153	**
Bleed very often	−0.268	***	−0.277	***	−0.272	**	−0.238	**	−0.297	***	−0.257	**	−0.279	**	−0.103		−0.258	*
Early decay	0.058	*	0.059	*	0.050		0.054		0.057		0.046		0.070	*	−0.010		0.008	
Moderate decay	−0.241	***	−0.239	***	−0.245	***	−0.192	***	−0.238	***	−0.252	***	−0.270	***	−0.278	***	−0.230	***
Advanced decay	−0.382	***	−0.384	***	−0.382	***	−0.379	***	−0.400	***	−0.400	***	−0.399	***	−0.408	***	−0.295	***
Annual cost	−0.006	***	−0.006	***	−0.006	***	−0.006	***	−0.006	***	−0.006	***	−0.005	***	−0.007	***	−0.005	***
ASC	1.484	***	1.482	***	1.446	***	1.490	***	1.513	***	1.465	***	1.565	***	1.203	***	1.412	***

Attribute level	Base case	Female		Scotland		Smoker		Employed		Low income		Pay private		6-month check up		Decay experience	
Interaction terms																	
Recall (12 month)		0.075	**	0.040		−0.042		0.009		−0.036		0.005		0.036		< 0.001	
Recall (6 month)		0.010		0.025		0.043		−0.010		−0.058		0.003		0.096	*	0.043	
Recall (risk based)		−0.046		−0.008		−0.017		−0.035		0.021		−0.010		−0.021		0.010	
Bleed hardly ever		−0.045		−0.045		−0.067		−0.036		−0.030		0.044		0.121	*	−0.026	
Bleed occasional		−0.043		−0.046		−0.036		−0.063		−0.049		−0.030		0.025		−0.009	
Bleed fairly often		0.105	*	−0.030		−0.049		−0.003		−0.042		−0.018		0.109		0.033	
Bleed very often		0.053		−0.013		0.106		0.159		0.164		−0.028		−0.236	*	−0.023	
Early decay		−0.076	**	−0.010		−0.014		0.041		−0.055		0.027		0.101	**	0.091	**
Moderate decay		0.065	*	−0.003		0.085	**	−0.011		0.003		−0.111	***	0.043		−0.058	
Advanced decay		0.132	***	−0.003		−0.004		0.074		−0.098	*	−0.055		0.032		−0.173	***
Annual cost		< 0.001		> −0.001		< 0.001		0.001	***	−0.001	***	0.002	***	0.002	***	−0.001	***
ASC		−0.125		−0.111		−0.015		−0.056		−0.240	***	0.200	**	0.428	***	0.147	
LR tests																	
Log-likelihood	−3856	−3839		−3849		−3850		−3845		−3835		−3821		−3829		−3840	
AIC	7739	7730		7751		7752		7742		7722		7694		7711		7733	
BIC	7837	7926		7948		7949		7939		7919		7891		7907		7930	
LR test (chi sq)		34.92		13.61		12.12		22.05		42.59		70.14		53.91		31.80	
LR test (*p*-value)		< 0.001		0.001		0.002		< 0.001		< 0.001		< 0.001		< 0.001		< 0.001	

*$p < 0.1$, **$p < 0.05$, ***$p < 0.01$.
BIC, Bayesian information criterion; LR, likelihood ratio.
Region (1 = England; −1 = rest of UK); sex (1 = female; −1 = male); income (1 = low income < £20,800 per year; −1 = all other reported incomes); smoker (1 = current smoker; −1 = never smoked or previous smoker); 6-month recall (1 = usually attends the dentist for a check-up at least every 6 months; −1 = usually attends a check-up less than every 6 months); experience of decay (1 = any dental decay; −1 = never); pay private (1 = usually pays out of pocket or through insurance; −1 = usually obtains free or NHS-subsidised dental care).

TABLE 59 Descriptive data from multiple imputation data set

	M = 0			M = 1			M = 2			M = 3			M = 4			M = 5		
Variable	***n***	**Mean**	**SD**	***n***	**Mean**	**SD**	***n***	**Mean**	**SD**	***n***	**Mean**	**SD**	***n***	**Mean**	**SD**	***n***	**Mean**	**SD**
WTP																		
WTP (constant)	2372	£948	£0	2372	£947.51	£0.00	2372	£947.51	£0.00	2372	£947.51	£0.00	2372	£947.51	£0.00	2372	£947.51	£0.00
WTP (recall)	2209	−£48	£203	2358	−£47.84	£202.77	2358	−£50.49	£203.65	2358	−£47.18	£202.67	2358	−£49.38	£202.16	2358	−£50.22	£203.15
WTP (bleeding)	1642	£67	£55	2357	£65.78	£56.34	2357	£65.00	£57.57	2357	£66.26	£57.47	2357	£66.09	£56.82	2357	£65.62	£55.80
WTP (caries)	2063	−£144	£63	2371	−£142.97	£64.49	2371	−£143.24	£63.89	2371	−£143.07	£64.85	2371	−£142.31	£64.49	2371	−£143.41	£63.20
EQ-5D-3L utilities																		
Utility (baseline)	1606	0.905	0.198	2359	0.909	0.190	2359	0.909	0.193	2359	0.908	0.191	2359	0.905	0.202	2359	0.909	0.193
Utility (1 year)	1670	0.889	0.203	2358	0.894	0.202	2358	0.891	0.202	2358	0.889	0.204	2358	0.889	0.207	2358	0.890	0.206
Utility (2 year)	1618	0.850	0.210	2358	0.849	0.215	2358	0.848	0.213	2358	0.849	0.216	2358	0.846	0.217	2358	0.852	0.208
Utility (3 year)	1525	0.819	0.208	2358	0.821	0.209	2358	0.821	0.209	2358	0.818	0.211	2358	0.821	0.207	2358	0.822	0.206
Utility (4 year)	1735	0.784	0.210	2358	0.783	0.211	2358	0.783	0.214	2358	0.782	0.212	2358	0.780	0.215	2358	0.784	0.211
NHS costs																		
NHS dental	2209	£113.13	£173.29	2358	£112.94	£173.69	2358	£111.88	£170.19	2358	£114.03	£174.73	2358	£112.57	£172.41	2358	£112.53	£172.08
NHS GP	990	£29.94	£62.65	2357	£32.30	£64.99	2357	£32.25	£65.54	2357	£33.38	£70.81	2357	£31.24	£63.35	2357	£30.65	£65.64
NHS inpatient	1153	£8.32	£75.18	2357	£7.87	£73.19	2357	£8.60	£75.86	2357	£9.32	£79.52	2357	£9.17	£78.29	2357	£9.00	£78.08
NHS outpatient	1003	£7.29	£56.29	2357	£9.04	£66.76	2357	£9.86	£68.83	2357	£8.13	£57.22	2357	£7.28	£57.46	2357	£9.04	£63.73
NHS accident and emergency	1003	£0.90	£10.80	2357	£1.03	£11.46	2357	£1.50	£13.92	2357	£1.09	£11.84	2357	£1.32	£13.07	2357	£0.92	£10.87
Participant																		
Time and travel	2128	£92.22	£50.58	2358	£89.74	£51.55	2358	£89.40	£51.61	2358	£89.82	£51.46	2358	£89.35	£51.35	2358	£89.02	£51.25
Patient co-charges	2209	£98.88	£120.69	2358	£100.07	£122.59	2358	£98.93	£119.80	2358	£99.32	£120.35	2358	£98.89	£121.08	2358	£98.59	£119.94
Private dental	1022	£84.25	£660.22	2357	£109.04	£849.88	2357	£63.28	£499.06	2357	£84.98	£728.30	2357	£66.04	£625.52	2357	£66.34	£531.18
Manual toothbrush	747	£20.09	£9.90	2357	£19.46	£10.14	2357	£19.76	£10.07	2357	£19.68	£10.03	2357	£19.51	£9.99	2357	£19.34	£10.03
Electric toothbrush	526	£38.61	£55.08	2357	£37.02	£53.56	2357	£35.55	£50.66	2357	£35.34	£51.21	2357	£36.49	£54.15	2357	£34.06	£48.40
Replacement heads	572	£15.40	£11.09	2357	£13.88	£11.15	2357	£13.86	£11.25	2357	£13.50	£10.84	2357	£13.82	£11.12	2357	£13.85	£11.17

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