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

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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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Scientific summary

The INTERVAL three-arm RCT

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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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