Dental therapists compared with general dental practitioners for undertaking check-ups in low-risk patients: pilot RCT with realist evaluation

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Scientific summary

Dentists vs. dental therapists for low-risk check-ups

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Scientific summary

Background

The use of general dental practitioners as the 'front-line' clinician in NHS 'high-street' dental practices is costly. Over half of the 21.7 million check-ups undertaken each year result in no further treatment. Dental therapists have been shown to be equally efficacious at screening for oral diseases. What is not known is whether or not they are as effective as general dental practitioners at undertaking the check-ups for low-risk routine NHS dental patients and whether or not they could reduce the cost of service provision. This is important because the proportion of low-risk routine NHS dental patients is expected to increase further as the oral health of regular dental attenders continues to improve. In contrast, many in the population still do not regularly attend the general dental practitioner and this group tend to have the highest need.

Under current NHS regulations, dental therapists are not allowed to examine NHS patients. However, in 2013/14, regulatory changes made by the General Dental Council allowed dental therapists to see patients directly, diagnose and form treatment plans, within their competence. Dental therapists can also now undertake all of the direct routine treatments that general dental practitioners can undertake (e.g. fillings) as part of their Scope of Practice. This opens up the possibility of dental therapists being utilised to examine and treat low-risk NHS patients in the future, if they can be shown to be as effective as general dental practitioners in this regard.

Two earlier NIHR studies (NIHR/CS/010/004 and Health Services and Delivery Research 11/1025/04) investigated both the efficacy and the efficiency of dental therapists in NHS practices. The former demonstrated the efficacy (diagnostic test accuracy) and feasibility of using dental therapists for check-ups, and the latter found that dental practices using dental therapists in the NHS could be better organised to improve efficiency. The aim of this study was to inform the design for a future definitive trial by undertaking a pilot study to determine whether or not dental therapists can maintain the oral health of low-risk routine NHS patients, who form the predominant proportion of the regularly attending practice population.

Objectives

The objectives of the research were to:

- determine the most appropriate design of a definitive trial
- determine whether or not bleeding on probing is the most appropriate primary outcome measure (and, if not, determine the most appropriate measure)
- confirm the appropriateness of the non-inferiority margin of the chosen outcome measure for the definitive trial (i.e. whether or not the effect estimate lies within an appropriate margin of non-inferiority)
- further investigate recruitment, retention and fidelity rates
- confirm willingness to be randomised among study participants
- determine the potential for patient crossovers between arms (e.g. where the patient's condition is considered too complex to be managed by the dental therapist)
- undertake a process evaluation underpinned by a realist framework to understand what works, for whom, why and in what circumstances
- rehearse the health economic analysis and assess the health economic data collection tool to inform the definitive trial design
- to explore patients' preferences in a focus group setting to inform a preference elicitation exercise (e.g. discrete choice experiment) in the definitive trial.

Methods

The study was undertaken across three workstreams.

Workstream 1

Workstream 1 was an individually randomised pilot study undertaken across North West England over a 15-month period:

- population – adult asymptomatic low-risk routine dentate or partially dentate NHS patients attending high-street dental practices
- intervention – check-up and any subsequent treatment undertaken by a dental therapist
- control – check-up and subsequent treatment undertaken by a general dental practitioner (treatment as usual)
- outcome – percentage of sites with bleeding on probing.

The unit of randomisation was at the patient level and primary end points were pragmatic. Secondary outcome measures collected were based on simple adaptations of indices that are used commonly in clinical practice:

- proportion of sites that have visible plaque present (measure of oral cleanliness)
- proportion of sites with a probing depth that exceeds the Basic Periodontal Examination code 2 using the World Health Organization probe (Basic Periodontal Examination probe)
- number of new decayed and filled teeth
- number of unplanned visits between check-ups
- oral health-related quality of life (Oral Health Impact Profile score)
- patient-centred outcomes to explore behaviour change and dental anxiety through the use of validated questionnaires.

High-street NHS dental practices ($n = 8$) were recruited across North West England using the following eligibility criteria:

- The practice should employ at least one dental therapist with at least 2 years' clinical experience.
- The majority of adult service provision should be in the NHS.
- The patient should be treated under NHS regulations.
- The practice should have the support of a practice manager.

A total of 217 recruited and consented, low-risk, adult NHS dental patients had baseline and outcome measurements (15 months later) undertaken by calibrated and blinded epidemiologists. The following were the eligibility criteria for the individual patients:

- Adult (> 18 years of age) NHS patient on the recall list of the participating practice
- presented with no more than one active lesion in the last year or required no more than one dental filling owing to dental caries within the previous year
- asymptomatic at the time of the check-up
- no predisposing medical history that elevated risk status
- seen for routine check-up at least 6 months ago
- dentate or partially dentate.

New patients, adult patients presenting in pain, patients requiring root fillings or extractions and patients who were edentate or were receiving ongoing periodontal treatment were excluded. Patients with sites that had a Basic Periodontal Examination score of ≥ 3 were excluded.

Randomisation was at the individual level (patient) and performed by the North Wales Organisation for Randomised Trials in Health and Social Care Clinical Trials Unit. Treatment allocation was on a 1 : 1 basis using a sequentially randomised dynamic adaptive algorithm. This meant that each participant's allocation was recalculated and based on the overall allocation level, within stratification variables and within stratum level. This enabled the research team to maintain adequate allocation ratios while maintaining the required balance across the two groups.

Workstream 2

Workstream 2 was a theoretically driven process evaluation that ran in parallel to the pilot to understand what works, for whom, why and in what circumstances. Realist evaluation is a methodology used extensively in health services research because it recognises the complex and contingent nature that underpins the settings for new interventions and service delivery. This approach to process evaluation argues that different outcomes are influenced by underlying mechanisms that act within a given context.

Workstream 2 used purposive and convenience sampling to identify interview participants, including a chief dental officer, dental commissioners, a local dental network, general dental practitioners and dental therapists and patients. We sought to recruit across the age range for adults and ensure a culturally and ethnically diverse sample. We also undertook a 'systems-wide' approach to the evaluation because implementation and change in complex interventions are affected by macro- and meso-level factors in addition to those identified at the micro/individual level.

Workstream 3

In workstream 3 we developed and tested a health economic data collection tool and rehearsed the health economic analysis of the intervention to inform the definitive trial design. We adopted the viewpoints of both the NHS and the patient and collected resource use data, which included the costs of dental consultation by general dental practitioners and dental therapists and the use of primary and secondary NHS dental services as well as participants' out-of-pocket expenses relating to any dental problems during the trial's follow-up period. We also explored patients' preferences to inform a preference elicitation exercise for the definitive trial.

Results

Workstream 1

A total of 546 NHS patients were invited to participate in the 15-month pilot trial and 217 participants were recruited. This equated to a mean recruitment rate of 43.4 participants per month. The attrition rates for the dental therapist group and the general dental practitioner group were comparable (22.4% vs. 23.6%, respectively). There were 14 protocol deviations in the dental therapist group and none in the general dental practitioner group. A total of 13 out of the 14 protocol deviations occurred because the participant was allocated to the dental therapist group but was seen once by the general dental practitioner in error. Participants in the pilot trial were predominantly female (72.4%), non-smokers (92.2%) and white (93.1%) and were not exempt from patient charges (89.4%). The mean age was 46 years, with a standard deviation of 15.8 years and a range of 18–87 years. The proportion of missing data was < 1% for the different primary and secondary outcome measures that were collected across the two time points (baseline and follow-up).

The difference between the percentage of sites with bleeding on probing for the dental therapist group and the percentage of sites with bleeding on probing for the general dental practitioner group, based on a mixed-effect analysis of covariance model, was 0% (95% CI 0% to 0%). This did not cross the specified non-inferiority boundary of 5%. There were no discernible differences between dental therapists and general dental practitioners for the other clinical measures. The observed differences for

patient-related outcome measures were also negligible. However, there appeared to be 'floor effects' in the measurement of the different primary and secondary measures.

Workstream 2

Substantial barriers exist to the practice of role substitution in NHS dentistry. The two most dominant factors were contractual and regulatory barriers. These appeared to drive the institutional logics at the micro level, with little influence exerted at the meso level by dental commissioners. Where role substitution was successful, practice owners had found 'workarounds' to the macro factors that dominated any potential implementation.

Workstream 3

We demonstrated that we can collect the data required for an economic evaluation using costs based either on units of dental activity or on micro-costing of dental care. The economic evaluation was rehearsed and consistent results produced across the range of analyses conducted. On average, a dental therapist appeared to be less cost-effective than a general dental practitioner in terms of bleeding on probing. In terms of Oral Health Impact Profile scores, it appears that a dental therapist could be more cost-effective, based on society's willingness to pay for each point reduction in Oral Health Impact Profile score. However, the results of the economic evaluation are not a robust basis for decision-making because they are based on data from the small number of participants included in the pilot trial.

Patients' preferences proved informative and provided a list of potential attributes and levels for a future discrete choice experiment, as well as a definitive trial. These attributes and levels relate primarily to process and organisational factors about the service.

Conclusions

No differences were found in the oral health status of patients over the 15 months of the pilot trial, but this may have been influenced by floor effects in the chosen primary outcome measure in this population group (low-risk patients). This pattern was seen in the other clinical measures used, which suggests that a non-inferiority design would be more appropriate if a definitive trial was considered. However, although retention and fidelity rates were high, recruitment was challenging, suggesting that a longer recruitment period would be required in any future empirical study. These two findings may have substantial implications for a definitive trial in this population group, given the higher number of participants that would be required for a non-inferiority design and the duration of such a study. Quasi-experimental designs may offer more promise and value of information. Multiple barriers to the use of dental therapists in high-street practices were highlighted in the process evaluation, mostly relating to contractual and regulatory issues in the NHS. The economic component showed that a meaningful economic evaluation could be conducted and provided the basis of a preference elicitation tool that could extend the results of the economic evaluation.

Trial registration

This trial is registered as ISRCTN70032696.

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